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# FORESIGHT BIAS IN PATENT LAW

Sean B. Seymore\*

## ABSTRACT

*Much of patent reform has focused on efforts to make it harder to obtain and enforce low-quality patents. The most straightforward way to achieve this goal is to raise the substantive standards of patentability. What is often ignored in discussions about raising patentability standards is that high-quality inventions can slip through the cracks. What is more troubling is that sometimes this happens because of bias. This Article draws attention to foresight bias, which occurs when a decision-maker lets over-pessimism and an oversimplified view of the future influence the patentability determination. Foresight bias leads to a patent denial regardless of the invention's technical merit. Particularly susceptible are inventions emerging from "unpredictable" fields like chemistry and biotechnology—things like chemical compounds and DNA fragments. If the invention's principal purpose is to serve as a "building block" for something else, it is unpatentable. The fear is that a patent could create a monopoly of knowledge and impede future research. Empirical studies, however, suggest that these fears have largely not materialized. More importantly, the patent denial costs the inventor, society, and the patent system.*

*This Article offers a solution to this problem. It proposes a new paradigm that gauges the patentability of building block inventions in unpredictable fields objectively without reliance on the utility requirement—the principal conduit for foresight bias. Its implementation will promote disclosure, foster more creative activity, reduce wasteful duplicative research efforts, and promote technological progress—all important objectives of the patent system. Eliminating the bias will also reconnect the patent system to many of the technical communities that it serves.*

## INTRODUCTION

Patent reform has been the subject of much scholarship and debate over the past decade.<sup>1</sup> Calls for reform have been prompted by concerns that the

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1 See JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE* (2008); DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* (2009); ADAM B. JAFFE & JOSH LERNER, *INNOVATION AND ITS DISCONTENTS* (2004).

U.S. Patent and Trademark Office (Patent Office) routinely grants poor-quality patents<sup>2</sup> and that such patents are too easy to obtain and enforce.<sup>3</sup> Congress took a step toward addressing these concerns through its recent passage of the America Invents Act.<sup>4</sup>

Much attention in the patent reform debate has focused on the substantive standards for patentability.<sup>5</sup> Many commentators have long argued that the standards are too low, thereby diminishing their gatekeeping function.<sup>6</sup> This argument deserves attention because adjusting these standards is considered the principal tool for modulating the scope, number, and quality of issued patents.<sup>7</sup> Indeed, tightening the standards of patentability has been a major goal of judicial efforts at patent reform.<sup>8</sup> Scholars and policymakers all seem to believe that raising the standards could do much to ameliorate many problems afflicting the patent system.<sup>9</sup> For instance, if the standards are sufficiently high, patents would be harder to obtain and easier to invalidate.<sup>10</sup>

There is, however, another side to the story. What is often ignored in discussions about raising patentability standards is that meritorious inven-

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2 See, e.g., Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1496 n.3 (2001) (describing the push for examiners to issue patents irrespective of quality); Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 181, 181–82 (2008) (exploring criticisms). A poor quality patent is one that is likely invalid because it fails to meet basic patentability standards or has overly broad claims. FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 5 (2003).

3 JAFFE & LERNER, *supra* note 1, at 175–76.

4 Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified in scattered sections of 28 and 35 U.S.C.). The landmark legislation seeks to “improve patent quality and limit unnecessary and counterproductive litigation costs.” H.R. REP. NO. 112-98, pt. 1, at 40 (2011).

5 The conditions for patentability are found in Title 35 of the U.S. Code. In short, the claimed invention must be useful, novel, nonobvious, and directed to patentable subject matter. 35 U.S.C. §§ 101–03 (2012). In addition, the patent 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. 35 U.S.C. § 112(a)–(b).

6 See, e.g., BESSEN & MEURER, *supra* note 1, at 162–63 (exploring the decline in patent quality and attributing the weakening of patentability standards to the Federal Circuit); JAFFE & LERNER, *supra* note 1, at 11, 201 (same).

7 See, e.g., BURK & LEMLEY, *supra* note 1, at 142 (using the biotechnology industry to demonstrate the benefits of tailored standards).

8 See, e.g., *Bilski v. Kappos*, 561 U.S. 593, 611 (2010) (holding that claims relating to a method of hedging risks are unpatentable); *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007) (rejecting the Federal Circuit’s rigid test for nonobviousness due to its inconsistency with the “expansive and flexible approach” set forth in Supreme Court precedent). Here it is worth noting that patentability standards evolve primarily through judicial rather than legislative action. See Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 53 (2010).

9 See sources cited *supra* note 1.

10 JAFFE & LERNER, *supra* note 1, at 175.

tions can slip through the cracks. A denial will deprive the inventor of a patent; however, high standards will also reduce the number of applications filed. When this happens, society is deprived of the public disclosure of technical information about the invention that occurs once a patent document publishes.<sup>11</sup> Thus, this paradigm compromises the patent system's primary goal to promote technological progress.<sup>12</sup> Any patentability standard that produces this outcome should give decision-makers considerable pause.

What is more troubling is that sometimes this occurs because of bias in the patentability determination. The type of bias most frequently discussed in patent law is hindsight bias—also known as “Monday morning quarterbacking.”<sup>13</sup> Hindsight bias is the cognitive limitation which prevents persons from disregarding their knowledge of an outcome in assessing past events.<sup>14</sup> It can creep into the patentability calculus anytime a retrospective analysis is required. The classic example is nonobviousness, the statutory requirement that prevents the patenting of inventions that are trivial advances over what is already known.<sup>15</sup> The question that must be answered is whether the invention that is now claimed would have been obvious to a person having ordinary skill in the art (PHOSITA)<sup>16</sup> at the time the patent application was filed.<sup>17</sup> Attempting to elucidate what the PHOSITA knew or could have done raises hindsight concerns because “decision-makers unconsciously let knowledge of the invention bias their conclusion concerning

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11 See discussion *infra* Section III.A (first paragraph).

12 Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CALIF. L. REV. 803, 876 (1988).

13 Jeffrey J. Rachlinski, *A Positive Psychological Theory of Judging in Hindsight*, 65 U. CHI. L. REV. 571, 571 (1998).

14 John C. Anderson et al., *Evaluations of Auditor Decisions: Hindsight Bias Effects and the Expectation Gap*, 14 J. ECON. PSYCHOL. 711, 711 (1993) (“Hindsight bias relates to individuals’ overestimation of the extent to which a realized outcome could have been anticipated.”); Baruch Fischhoff, *For Those Condemned to Study the Past: Heuristics and Biases in Hindsight*, in JUDGMENT UNDER UNCERTAINTY 335, 341 (Daniel Kahneman et al. eds., 1982); Baruch Fischhoff, *Hindsight ≠ Foresight: The Effect of Outcome Knowledge on Judgment Under Uncertainty*, 1 J. EXPERIMENTAL PSYCHOL.: HUM. PERCEPTION & PERFORMANCE 288, 292 (1975).

15 35 U.S.C. § 103(a) (2012); see also *infra* subsection II.B.2.

16 The person having ordinary skill in the art (PHOSITA) is a hypothetical construct of patent law akin to the reasonably prudent person in torts. Factors relevant to constructing the PHOSITA in a particular technical field include “(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.” *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983).

17 35 U.S.C. § 103(a). Nonobviousness is a question of law based on the following pertinent underlying facts: (1) the scope and content of the relevant prior art; (2) the differences between the prior art and the claimed invention; (3) the PHOSITA’s level of skill; and (4) secondary considerations which provide objective proof of nonobviousness, such as the invention’s commercial success. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

whether the invention was obvious in the first instance.”<sup>18</sup> As the U.S. Court of Appeals for the Federal Circuit (Federal Circuit)<sup>19</sup> has noted, “[t]hat which may be made clear and thus ‘obvious’ [today], with the invention fully diagrammed and aided . . .’ by experts in the field, ‘may have been a breakthrough of substantial dimension when first unveiled.’”<sup>20</sup> Courts are aware of the hindsight effect<sup>21</sup> and try to fight it.<sup>22</sup> Scholars have written extensively about hindsight bias in the nonobviousness realm<sup>23</sup> and in other areas of patent law.<sup>24</sup>

This Article, however, focuses on another type of bias, which has been largely overlooked in the academic literature but has important implications for patent law and policy. It is *foresight bias*, which occurs (as defined in this Article) when a decision-maker lets over-pessimism and an oversimplified view of the future bias the patentability determination.<sup>25</sup> This is related to the tendency of decision-makers to be risk averse because they overweigh the

18 Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391, 1393 (2006).

19 The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) has jurisdiction over appeals from the Patent Office and district court cases arising under the patent laws. The court was created by the Federal Courts Improvement Act of 1982. See Pub. L. No. 97-164, 96 Stat. 25 (1982) (codified as amended in scattered sections of 28 U.S.C.).

20 *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051 (Fed. Cir. 1988) (quoting *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985)).

21 See, e.g., *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (noting that factfinders should be aware of the “distortion” caused by hindsight bias); *Graham*, 383 U.S. at 36 (instructing courts to “guard against slipping into use of hindsight”) (quoting *Monroe Auto Equip. Co. v. Heckerthorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (6th Cir. 1964)); *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) (noting the importance of “casting the mind back to the time of invention” to avoid the “insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher”) (quoting *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999)).

22 See *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012) (explaining that the inventor’s objective evidence of nonobviousness can “enable the court to avert the trap of hindsight” (quoting *Crocs, Inc. v. ITC*, 598 F.3d 1294, 1310 (Fed. Cir. 2010))).

23 See, e.g., Glynn S. Lunney, Jr. & Christian T. Johnson, *Not So Obvious After All: Patent Law’s Nonobviousness Requirement, KSR, and the Fear of Hindsight Bias*, 47 GA. L. REV. 41 (2012); Mandel, *supra* note 18.

24 See, e.g., Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1199 (2002) (enablement); Tun-Jen Chiang, *Fixing Patent Boundaries*, 108 MICH. L. REV. 523, 573 (2010) (claim interpretation); Timothy R. Holbrook, *Equivalency and Patent Law’s Possession Paradox*, 23 HARV. J.L. & TECH. 1, 41–42 (2009) (enablement); Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 943 (2011) (novelty).

25 Foresight bias has a similar definition in psychology, where it is said to “result[ ] from a shallow perception of history” which “manifests itself in . . . over-confidence (and sometimes over-pessimism) and an over-simplified view of the future.” R. Bradley MacKay & Peter McKiernan, *The Role of Hindsight in Foresight: Refining Strategic Reasoning*, 36 FUTURES 161, 165 (2004). The result is “logical (and structural) path-dependencies, faulty reasoning and, ultimately, a poor understanding of the future.” *Id.*

likelihood of bad outcomes.<sup>26</sup> Foresight bias leads to a patent denial despite the invention's technical merit and ability to further the patent system's primary goals—namely to promote technological progress through the dissemination of knowledge, coordinate the future development of technology, and spur additional inventive activity. What is particularly troubling about foresight bias is that it can lead to predictions about patenting that are simply wrong.<sup>27</sup>

Foresight bias in patent law manifests itself primarily through the utility requirement.<sup>28</sup> It 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.”<sup>29</sup> A requirement for utility appeared in the original Patent Act of 1790<sup>30</sup> and has remained a part of the statutory scheme.<sup>31</sup>

26 See Daniel Kahneman & Amos Tversky, *Choices, Values, and Frames*, 39 AM. PSYCHOLOGIST 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 the phenomenon of overpessimism); cf. W. KIP VISCUSI, *FATAL TRADE-OFFS* 104 (1992) (suggesting that people overestimate low probability risks).

27 Consider *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), where the Supreme Court had to determine whether a genetically engineered bacterium constituted patent-eligible subject matter. The Patent Office and several amici argued against eligibility because patenting genetic research would lead to a “parade of horrors” 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.” *Id.* at 316. Writing for the majority, Justice Burger declined the invitation to bring fear of the unknown into the patentability calculus. *Id.* As he saw it, “[w]hether respondent’s claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.” *Id.* at 317. Needless to say, these fears were not realized; indeed, *Chakrabarty* spawned the modern biotechnology industry. See ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY* 78 (6th ed. 2013) (explaining that *Chakrabarty* was “extremely important for the then-nascent biotechnology industry because it established that the fruits of the industry’s research . . . would be eligible for patenting”); Albert Gore, Jr. & Steve Owens, *The Challenge of Biotechnology*, 3 YALE L. & POL’Y REV. 336, 339 (1985) (describing how *Chakrabarty* spurred investment in biotechnology).

28 The requirement for utility applies to *utility* patents (also known as patents for invention), which cover any new or improved “process, machine, manufacture, or composition of matter.” 35 U.S.C. § 101 (2012). Utility patents are the most common type of patent and the focus of this Article. The U.S. patent system grants two other types of patents: *design* patents, which protect any “new, original and ornamental design for an article of manufacture,” 35 U.S.C. § 171, and *plant* patents, which protect any “distinct and new variety of plant.” 35 U.S.C. § 161.

29 35 U.S.C. § 101 (emphasis added).

30 See Patent Act of 1790, ch. 7, § 1, 1 Stat. 109 (repealed 1793) (“[U]pon the petition of any person or persons . . . that he, she, or they, hath or have invented or discovered any *useful* art, manufacture, engine, machine, or device, or any improvement therein not before known or used . . . it shall and may be lawful . . . to cause letters patent to be made out.” (emphasis added)).

31 See, e.g., Patent Act of 1793, ch. 11, § 1, 1 Stat. 318, 318 (repealed 1836) (“[Applicants must allege they have] invented any new and useful art, machine, manufacture or

But what does it mean to be useful? Congress has provided no insight into its meaning.<sup>32</sup> The abstract and imprecise nature of the term invites subjective interpretations because virtually *everything* can be used by someone for something.<sup>33</sup> The *Oxford English Dictionary* defines the term simply as “beneficial”<sup>34</sup> or “fitness for some desirable purpose or valuable end.”<sup>35</sup> Until the middle of the twentieth century, the standard for utility in patent law was also *de minimis*. Some beneficial use was sufficient to establish utility unless the invention was inoperable or detrimental to the public interest.<sup>36</sup> It was believed that a low utility threshold promoted knowledge dissemination and the disclosure function of the patent system.<sup>37</sup>

But this changed in the middle of the twentieth century when utility took on an invigorated role in patent law. By this time the invention landscape had changed from primarily mechanical devices to one increasingly populated with chemical and pharmaceutical inventions.<sup>38</sup> How to adapt the utility requirement to accommodate this new landscape led to conflicts among judges on the U.S. Court of Customs and Patent Appeals (C.C.P.A.),<sup>39</sup> tension between the C.C.P.A. and the Patent Office,<sup>40</sup> and sharp ideological disagreements among Supreme Court Justices.<sup>41</sup> The end result was a ratcheted-up standard, which now requires that the inventor’s

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composition of matter, or any new and useful improvement”); Patent Act of 1836, ch. 357, § 6, 5 Stat. 117, 119 (repealed 1870) (identical language); Patent Act of 1870, ch. 230, § 24, 16 Stat. 198, 201 (repealed 1952) (same).

32 See EDWARD C. WALTERSCHEID, *THE NATURE OF THE INTELLECTUAL PROPERTY CLAUSE* 345 (2002) (noting that congressional inaction has led to the difficulty in defining the term “useful”).

33 Even a failed experiment is useful because it eliminates whatever approach was under consideration, makes way for an alternative, and always produces data from which others can learn. See NEIL BALDWIN, *EDISON: INVENTING THE CENTURY* 51 (1995) (quoting Thomas Edison’s remarks to financial supporters that “[n]o experiments are useless”); see also Sean B. Seymore, *The Null Patent*, 53 WM. & MARY L. REV. 2041 (2012) (proposing the creation of nonexclusionary patent documents known as “null patents” which would disseminate technical information harvested from failed experiments).

34 19 OXFORD ENGLISH DICTIONARY 356 (2d ed. 1989) (defining “useful”).

35 *Id.* at 368 (defining “utility”).

36 See *infra* notes 80–85 and accompanying text.

37 A low utility standard “encourage[s] inventors of new [products and] processes to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge.” *Brenner v. Manson*, 383 U.S. 519, 533 (1966).

38 See William D. Noonan, *Patenting Medical Technology*, 11 J. LEGAL MED. 263, 263–69 (1990).

39 The C.C.P.A. was a five-judge Article III court on the same level as the U.S. Courts of Appeals. It was abolished by the Federal Courts Improvement Act of 1982. See *supra* note 19.

40 See *infra* Section I.B.

41 See *infra* Section I.B.



assertions be credible<sup>42</sup> and that the invention possess “specific” and “substantial” utility.<sup>43</sup>

The crucial link between foresight bias and utility has largely escaped the attention of legal scholars. This inattention is somewhat understandable because utility—the principal conduit for foresight bias—is often assumed to be a “low bar to patentability”<sup>44</sup> or a “nonexistent” patentability requirement.<sup>45</sup> This statement is inaccurate. The utility requirement is now a powerful gatekeeper that allows the Patent Office and the courts to subjectively decide when or if something can be patented.<sup>46</sup> The lack of objective criteria for utility opens the door for all sorts of mischief in patent law.<sup>47</sup>

Foresight bias is most prominent in assessing the patentability of “building block” inventions from “unpredictable” fields like chemistry and biotechnology.<sup>48</sup> Those seeking to claim things like chemical compounds and DNA fragments can face formidable utility hurdles.<sup>49</sup> If the invention’s purpose is to serve as a building block for something else, it cannot be patented because it lacks a specific and substantial utility.<sup>50</sup> The fear is that a patent on these types of building blocks could create a monopoly of knowledge and inhibit future research.<sup>51</sup> By comparison, the utility of other types of building

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42 *In re Cortright*, 165 F.3d 1353, 1356 (Fed. Cir. 1999).

43 *See* *Brenner v. Manson*, 383 U.S. 519, 534–35 (1966) (construing “useful” in 35 U.S.C. § 101 to require “substantial” and “specific” utility); *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (defining the terms).

44 Michael Risch, *A Surprisingly Useful Requirement*, 19 GEO. MASON L. REV. 57, 58 (2011) (noting that inventions failing to meet the current standard are rare).

45 *Id.*; *see also* Lee Petherbridge, *Road Map to Revolution? Patent-Based Open Science*, 59 ME. L. REV. 339, 356 n.90 (2007) (“The utility requirement is still properly understood as very low and generally presents a low bar to patentability.”).

46 *Cf.* Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2087 (2000) (“Another possible way of understanding the utility requirement is as a timing device, helping to identify when an invention is ripe for patent protection.”).

47 *See, e.g.*, Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1491, 1514–22 (2011) (describing how bias led to decades of denials for a lack of utility for patent applications disclosing and claiming therapeutics for successfully treating baldness and cancer, despite objective evidence to the contrary, until the Patent Office and the courts became convinced that these were credible undertakings).

48 Patent law regards experimental sciences like chemistry and biotechnology as “unpredictable” because PHOSITAS in these fields often cannot predict outcomes with a reasonable expectation of success. On the other hand, inventions in applied technologies like electrical and mechanical engineering are often regarded as “predictable” arts because they are rooted in well-defined, predictable factors. *See* discussion *infra* Section I.A.

49 Here it is worth noting that DNA-related inventions can face formidable patentability hurdles aside from utility. *See* *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117 (2013) (holding that claims directed to isolated DNA sequences recite products of nature and, thus, are not patent-eligible subject matter).

50 *See infra* Section I.C.

51 *See infra* Section I.B.

blocks—things like bricks, steel beams, and software modules—is never questioned.<sup>52</sup>

To better understand the problem, consider the following hypothetical. Many pharmaceutical companies have been on a quest to invent a cholesterol-lowering blockbuster drug<sup>53</sup> to match or exceed the success of Lipitor—the best-selling drug of all time.<sup>54</sup> In 2006, scientists discovered that a compound found in dandelions lowers cholesterol in humans without side effects. But the pharmaceutical companies ran into a roadblock when they set out to make compounds that mimic this activity. The structural backbone of the dandelion compound is a molecular knot—a complex assemblage of interlocking molecular fragments—that is nearly impossible to replicate in the laboratory.<sup>55</sup> Leading organic chemists from around the world agreed that it could not be done. But in early 2013, after spending \$1.6 billion in research and development, an AcmePharma chemist invented a molecular knot (*X*) very similar in structure to the one found in the dandelion compound. Early experiments reveal that *X* is a suitable building block for larger compounds.

When AcmePharma files a patent application, the Patent Office determines that *X* and the process by which it is made are unpatentable under § 101 for a lack of utility.<sup>56</sup> The Patent Office takes the position that a patent would allow AcmePharma to create a “monopoly of knowledge”<sup>57</sup> which could “engross a vast, unknown, and perhaps unknowable area”<sup>58</sup> and potentially “block off whole areas of scientific development, without compensating benefit to the public.”<sup>59</sup> This pessimistic projection is the hallmark of foresight bias.<sup>60</sup>

Yet this view is shortsighted. What is overlooked is that while *X*'s value to society might seem small *ex ante*, the breakthrough does benefit society *immediately* by catalyzing more creative activity, spawning new areas of technology, and enriching the public storehouse of knowledge.<sup>61</sup> But rendering *X* unpatentable at this early stage delays or forecloses these possibilities. AcmePharma has every incentive to keep the technical details about *X* secret

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52 See *infra* Section I.A.

53 The pharmaceutical industry defines a blockbuster drug as one that generates at least \$1 billion in annual revenue. RONALD J. VOGEL, PHARMACEUTICAL ECONOMICS AND PUBLIC POLICY 25 (2007).

54 Lipitor had peak annual sales of \$13 billion before the patent expired in November 2011. Jonathan D. Rockoff, *Goodbye, Lipitor. Pfizer Bids a Farewell*, WALL ST. J., May 10, 2012, at B1.

55 See generally Christiane Dietrich-Buchecker et al., *Molecular Knots*, 249 TOPICS IN CURRENT CHEMISTRY 261 (2005).

56 See *supra* text accompanying note 29; *infra* Section I.C.

57 *Brenner v. Manson*, 383 U.S. 519, 534 (1966).

58 *Id.*

59 *Id.* (footnote omitted).

60 See *supra* note 25 and accompanying text.

61 See discussion *infra* Section III.A.

unless and until it develops a Lipitor replacement.<sup>62</sup> Of course, had AcmePharma known about *X*'s unpatentability *ex ante*, it might not have pursued the \$1.6 billion project in the first place.<sup>63</sup> Either outcome costs society and frustrates both the economic and innovation-related goals of the patent system.<sup>64</sup>

This Article offers a solution to this problem. It proposes that building blocks should be patentable—regardless of whether a use is disclosed. I argue that concerns about patent breadth and technical merit can be addressed through compliance with (or more rigorous enforcement of) enablement and nonobviousness—two patentability requirements that (unlike utility) are assessed through objective, fact-based inquiries. Removing utility from the patentability calculus would essentially eliminate foresight bias in unpredictable fields like chemistry and biotechnology and be a win-win-win for the patentee, society, and the patent system. The patentee could exploit the building block and recoup research and development expenditures.<sup>65</sup> Society would get the benefits that flow from the invention's disclosure, namely the addition of technical information about the invention to the public storehouse of knowledge (which, in turn, would prevent duplicative research efforts and foster more creative activity during the patent term).<sup>66</sup> The patent system would fulfill its goals of promoting technological progress, deterring secrecy, and preserving the incentives to invent and disclose.<sup>67</sup> This Article is the first to take a hard look at foresight bias in patent law. It is

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62 See *infra* Section III.A.

63 Professor Robert Merges has argued that patentability standards affect research and development (R&D) decisions involving risky research projects:

Detailed case studies show that almost every firm at least tries to evaluate the cost effectiveness of proposed research and development projects. R&D managers also consider "patentability" or "patent strength" prior to investing in R&D projects. Thus the prospect of getting a patent may enter into the *initial* project investment or selection choice. If so, the standard of patentability enters at this stage. Even for firms whose research proceeds further before making a detailed cost/benefit analysis, patentability might enter in the very rough (and sometimes implicit) economic feasibility decisions made by the R&D department at the outset of the research project.

Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 10–12 (1992) (footnotes omitted).

64 See *infra* Part III.

65 See *infra* note 376.

66 Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 541 (2009). As Judge Giles Rich once explained, "even if [the invention] does not go into the public domain during the patent term, the public gets the advantage of knowing what the invention is and how to practice it." Janice M. Mueller, *A Rich Legacy*, 14 BERKELEY TECH. L.J. 895, 900 (1999) (quoting Email from Judge Giles S. Rich, Circuit Judge of the U.S. Court of Appeals for the Federal Circuit, to Professor Janice M. Mueller, Associate Professor, The John Marshall Law School (Aug. 16, 1997)).

67 See *infra* notes 376–78 and accompanying text.

part of a larger project to bridge the disconnect between patent law and science.<sup>68</sup>

The remainder of this Article proceeds as follows. Part I describes the emergence of building block inventions from fields like chemistry and biotechnology onto the patent landscape and further explores the development and application of foresight bias. Part II begins by making the normative case for the patentability of building blocks. It then describes how concerns about patent scope and patent-worthiness should be addressed through enablement and nonobviousness rather than utility. Implementing this proposal will eliminate foresight bias in the unpredictable arts. Part III describes how the proposal promotes the policy objectives of the patent system, and responds to potential criticisms.

## I. THE BUILDING BLOCK CONUNDRUM

### A. *The Problem of Scale*

In common usage, a “building block” is something that can be used to make something bigger—like a brick used to make a wall.<sup>69</sup> Similarly in patent law, a building block invention is one that can be used to make something else.<sup>70</sup> Of course, the universe of potential building block inventions is infinite—anything from chemical compounds to gene fragments to nanotubes to bricks. The common thread shared by all building blocks—regardless of the nature of the technology—is that their principal usefulness is the structural role they perform in creating the bigger thing.

Yet, patent law treats building blocks differently depending on the nature of the underlying technology. Some are *patentably* useful and some are not. Things like bricks, steel beams, and software modules—macroscale inventions—easily satisfy § 101 because they have a “well-established” util-

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68 See generally Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127 (2008) [hereinafter Seymore, *Heightened Enablement*] (proposing a new approach for examining patent applications in unpredictable technologies which, by requiring applicants to disclose actual experimental results, resolves a striking incongruity between patent law and the experimental sciences); Seymore, *supra* note 47 (arguing that determining what constitutes credible science is the province of the scientific community, not patent law); Seymore, *supra* note 24 (arguing that current novelty doctrine can produce paradoxical outcomes for complex inventions and is seemingly incongruous with basic principles of patent law); Sean B. Seymore, *Serendipity*, 88 N.C. L. REV. 185 (2009) (arguing that although accidental discoveries pervade science, inventors who invent by accident can be unjustly deprived of patents because such discoveries do not mesh with the substantive law of invention).

69 Cf. MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 162 (11th ed. 2004) (defining building block as “a unit of construction or composition; esp[ecially]: something essential on which a larger entity is based”).

70 The “something else” can either be an invention or something that is previously known.

ity.<sup>71</sup> A “well-established” utility is one “which is well known, immediately apparent, or implied by the [applicant’s] disclosure of the properties of a material.”<sup>72</sup> For example, bricks build walls, steel beams carry loads, and software modules are put together to build software programs. These building blocks all come from the “predictable” arts—named as such because they are rooted in well-defined, predictable factors.<sup>73</sup> In the predictable arts, utility is often considered to be “so apparent as to virtually jump off the page and slap a PHOSITA in the face.”<sup>74</sup>

In contrast, *microscale* building blocks—things like chemical compounds and gene fragments—are subjected to more rigorous § 101 scrutiny. These building blocks all emerge from fields like chemistry, pharmacology, and biotechnology—referred to as the “unpredictable” arts because a PHOSITA often cannot easily predict reactivity or outcomes.<sup>75</sup> Experimentation is often required to achieve success in creating the bigger substance. This paradigm has proven to be very unsettling for patent law and opens the door for foresight bias. As the law currently stands, microscale building blocks with no specific and substantial utility at the time of filing the patent application are unpatentable.<sup>76</sup> The fear is that granting patents on these “upstream” building blocks will create problems for future research and hinder downstream innovation.<sup>77</sup> Gatekeeping is so important that the utility section of the *Manual of Patent Examining Procedure*<sup>78</sup> lists building block inventions that patent examiners should immediately reject.<sup>79</sup>

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71 See U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE, § 2107.02(II) (9th ed. 2014) [hereinafter MPEP]. The MPEP provides guidance to patent examiners and is regarded as the Patent Office’s official interpretation of statutes and regulations. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995).

72 U.S. PATENT & TRADEMARK OFFICE, REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS 7 (1999) [hereinafter INTERIM UTILITY GUIDELINES].

73 *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991).

74 *Seymore*, *supra* note 47, at 1531 (quoting *Seymore*, *Heightened Enablement*, *supra* note 68, at 156 n.151); *cf.* *Ash v. Tyson Foods, Inc.* 546 U.S. 454, 456–57 (2006) (*per curiam*) (evaluating the “jump off the page” standard in the context of an employment discrimination suit (quoting *Cooper v. S. Co.*, 390 F.3d 695, 732 (11th Cir. 2004))).

75 *Seymore*, *Heightened Enablement*, *supra* note 68, at 136–54. For example, in the chemical arts, “a slight variation in a [structure or] method can yield an unpredictable result or may not work at all.” *Cedarapids, Inc. v. Nordberg, Inc.*, No. 95-1529, 1997 WL 452801, at \*2 (Fed. Cir. Aug. 11, 1997).

76 See *infra* Section I.C.

77 See *infra* Section II.B.

78 See MPEP, *supra* note 71.

79 See, e.g., MPEP, *supra* note 71, § 2107.01(I)(B) (identifying as unpatentable basic research, chemical intermediates, and methods of making chemical intermediates where the end product does not have an identifiable utility).

### B. Why Did Foresight Bias Develop?

#### 1. A New Invention Landscape

Throughout most of the history of U.S. patent law, the threshold for utility was low. By the late nineteenth century, *some* beneficial use was sufficient to establish utility<sup>80</sup> unless the invention was inoperable (totally incapable of achieving its intended result)<sup>81</sup> or detrimental to the public interest.<sup>82</sup> The standard was truly *de minimis*, as noted in an 1883 treatise, *The Patentability of Inventions*,<sup>83</sup> which stated that “[a]s to the term ‘useful,’ the courts have construed the condition expressed by it so liberally that it almost never serves to defeat a patent.”<sup>84</sup> Importantly, the *de minimis* standard applied across the board to all inventions.<sup>85</sup>

This, however, did not last. It is important to note that patentability doctrines like utility emerged during the first century of the U.S. patent system when inventions were still primarily mechanical devices.<sup>86</sup> The invention landscape changed around the time of World War II when key breakthroughs in antibiotic, vitamin, and hormone research spawned the “therapeutic revolution”<sup>87</sup> and the advent of many first-generation wonder drugs.<sup>88</sup>

80 *Bedford v. Hunt*, 3 F. Cas. 37, 37 (C.C.D. Mass. 1817) (No. 1217) (articulating the “some beneficial use” threshold).

81 *Mitchell v. Tilghman*, 86 U.S. (19 Wall.) 287, 396 (1873) (explaining that utility is lacking “where it appears that [the invention] is not capable of being used to effect the object proposed”).

82 This negative requirement is attributed to Justice Story, who wrote that an invention’s asserted utility could not be “injurious to the morals, the health, or the good order of society.” *Bedford*, 3 F. Cas. at 37.

83 HENRY CHILDS MERWIN, *THE PATENTABILITY OF INVENTIONS* (Boston, Little, Brown & Co. 1883).

84 *Id.* at 75, *quoted in In re Nelson*, 280 F.2d 172, 179 (C.C.P.A. 1960).

85 *See, e.g., Potter v. Tone*, 36 App. D.C. 181, 184–85 (D.C. Cir. 1911) (rejecting the contention that the claimed compound must have a commercial use and holding that the description of its characteristics and properties had value for educational and research purposes and were sufficient to establish utility), *discussed in* David A. Anderson & Edward E. Dyson, Note, *Some Special Problems with the Utility Requirement in Chemical Patents*, 35 GEO. WASH. L. REV. 809, 810 (1967) (“The court felt that to require a showing of use in some commercial process . . . would amount to a holding that the inventor must make another invention which could be the subject of another patent.”); *Ex parte Watt*, 63 U.S.P.Q. 163, 165 (B.P.A.I. 1942) (determining that a chemical compound whose sole use was that of a chemical intermediate met the utility requirement).

86 *See* John Hoxie, *A Patent Attorney’s View*, 47 J. PAT. OFF. SOC’Y 630, 636 (1965) (exploring the evolution of inventions from being mostly electrical-mechanical to chemical in nature); Noonan, *supra* note 38, at 263–64 (same).

87 PHARM. PANEL COMM. ON TECH. AND INT’L ECON. AND TRADE ISSUES ET AL., *THE COMPETITIVE STATUS OF THE U.S. PHARMACEUTICAL INDUSTRY* 7–11 (1983) [hereinafter *THE COMPETITIVE STATUS*].

88 *See, e.g.,* Process for Obtaining Vitamins, U.S. Patent No. 2,049,988 (filed Sep. 27, 1932) (issued Aug. 4, 1936) (Vitamin B<sub>1</sub>; assigned to Research Corporation); Alloxazines and Isoalloxazines and Processes for Their Production, U.S. Patent No. 2,261,608 (filed Mar. 21, 1940) (issued Nov. 4, 1941) (Vitamin B<sub>2</sub>; assigned to Merck); Process of Treating

During this period, pharmaceutical companies quickly switched from a manufacturing to a research-based model and secured patents that allowed them to dominate sectors of specific therapeutic markets.<sup>89</sup> This, in turn, quickly forced the Patent Office and the courts to wrestle with fields key to drug research—like organic chemistry.<sup>90</sup> But the courts did so, at least initially, by viewing therapeutic claims with skepticism and rigidly applying mechanical-electrical patent doctrine to these unpredictable fields.<sup>91</sup> This led to nonsensical outcomes and forged a disconnect between patent law and the scientific community.

Until this point, the courts and the Patent Office agreed that chemical compounds had patentable utility despite the lack of a disclosed specific end use.<sup>92</sup> Thus, building blocks were treated no differently than other chemical compounds.<sup>93</sup> As Justice Harlan explained in *Brenner v. Manson*, “usefulness was typically regarded as inherent during a long and prolific period of chemical research and development in this country.”<sup>94</sup> But this liberal view began to deteriorate in 1950 when the C.C.P.A. issued its opinion in *In re Bremner*.<sup>95</sup> The applicant attempted to claim eight hard plastics and methods of making them,<sup>96</sup> but “said nothing whatever about use, [and] left it to the art to guess what to do with them on the basis of what he told about their properties.”<sup>97</sup> The court upheld the Patent Office’s rejection, stating that “*the law requires that there be in the application an assertion of utility and an indication of the use or uses intended*. It was never intended that a patent be granted upon a product, or a process producing a product, unless such product be useful.”<sup>98</sup> As far as *utility* is concerned, two commentators aptly observe that “there can be little doubt that the hard resins disclosed had some utility that was clear from their physical properties.”<sup>99</sup> Bremner’s problem was not so much a utility problem, but rather one of inadequate *disclosure*—a failure to comply with the enablement requirement of § 112.<sup>100</sup> As Judge Rich later explained, Brem-

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Pregnene Compounds, U.S. Patent No. 2,462,133 (filed Feb. 23, 1946) (issued Feb. 22, 1949) (synthesis of cortisone; assigned to Merck).

89 See THE COMPETITIVE STATUS, *supra* note 87, at 7–11.

90 Noonan, *supra* note 38, at 263–69.

91 See *id.*; see also Hoxie, *supra* note 86, at 636 (explaining how the judiciary tried to fit chemical inventions into the mold of mechanical-electrical inventions and contending that the judiciary’s interpretation of the patent statute did not change even as chemical inventions became more frequent).

92 See *supra* note 85 and accompanying text.

93 See *supra* note 85 and accompanying text.

94 *Brenner v. Manson*, 383 U.S. 519, 540 (1966) (Harlan, J., concurring in part and dissenting in part).

95 182 F.2d 216 (C.C.P.A. 1950).

96 *Id.* at 216.

97 *In re Nelson*, 280 F.2d 172, 185 (C.C.P.A. 1960) (distinguishing *Bremner*).

98 *In re Bremner*, 182 F.2d at 217.

99 Anderson & Dyson, *supra* note 85, at 811.

100 Enablement requires that the applicant provide a disclosure that teaches a PHOSITA both how to make and how to use the invention. See *infra* subsection II.B.1. Importantly, I argue that an applicant can satisfy the “how to use” prong of the enablement

ner “did not disclose enough as to their properties to *enable* one even to make an intelligent guess as to a use.”<sup>101</sup> But even if *Bremner* can properly be viewed as a disclosure problem, the Patent Office adopted a rigid and expansive interpretation of the above-quoted passage and relentlessly sought a higher utility standard for chemical compounds.<sup>102</sup>

## 2. The Battle over Building Blocks

A pivotal opinion addressing the patentability of building blocks is *In re Nelson*,<sup>103</sup> a 1960 case that called into question the intrinsic value of chemical compounds. The applicant sought to patent a host of microscale building blocks referred to as chemical intermediates.<sup>104</sup> The issue for the court was whether a chemical intermediate has its own utility or whether the applicant had to disclose a use for the end product in order to obtain a patent on the intermediate. Writing for the court’s majority<sup>105</sup> in an opinion that has been described as a “judicial bombshell”<sup>106</sup> and the “single most important patent ‘utility’ decision of the CCPA,”<sup>107</sup> Judge Giles Rich (the co-drafter of the 1952 Patent Act and regarded by many as “the founding father of modern

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requirement of § 112 yet still fail to satisfy the utility requirement of § 101. See discussion *infra* subsection II.B.1.c.

101 *In re Nelson*, 280 F.2d at 185 (emphasis added).

102 In 1956, a few years after *Bremner*, 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 a speech made by Robert C. Watson to an American Chemical Society meeting) (internal quotation marks omitted). By steadily ratcheting up the utility requirement since the early 1950s, Judge Giles Rich contended that the Patent Office had raised it “above anything required by the statute or by [C.C.P.A. caselaw] and develop[ed] its own brand new theories and philosophy about what the statute means by ‘useful.’” *Id.* at 952. With that said, there were C.C.P.A. judges who were sympathetic to the Patent Office’s view. See *infra* notes 105 & 142 and accompanying text.

103 *In re Nelson*, 280 F.2d at 180.

104 *Id.* at 180. For example,  $A + B$  react to make  $I$  (the intermediate). Then, a chemist can react  $I$  with  $C$  or  $D$  (or something else) to make other compounds.

105 There were dissenting views on the court. See *id.* at 190 (Worley, J., dissenting) (“[T]he net effect of granting a patent here will be to 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).

106 James F. Davis, *Judge Giles S. Rich: His Life and Legacy Revisited*, LANDSLIDE, Sept.–Oct. 2009, at 8, 11.

107 Lynn E. Eccleston & Harold C. Wegner, *The Rich-Smith Years of the U.S. Court of Customs and Patent Appeals*, 3 J. FED. CIR. HIST. SOC’Y 49, 51 (2009).



patent law")<sup>108</sup> explained that to require 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, and in a "practical" sense too. Such intermediates are "useful" under section 101. 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>109</sup>

In addition to making it clear that the *degree* of utility is irrelevant,<sup>110</sup> *Nelson* revealed that an invention's benefit to the public could be indirect.<sup>111</sup>

*Nelson* was a triumph for the research community and very important for the growth of the chemical, pharmaceutical, biotechnological, and pharmaceutical industries.<sup>112</sup> Aside from reaffirming that the standard for utility is *de minimis*,<sup>113</sup> the opinion recognized that "in the chemical industry, pure research often has an intrinsic utility despite no immediate use for the fruits of the research."<sup>114</sup> Had *Nelson* remained good law, it would have settled the building block problem and done much to bridge the gap between patent law and scientific research.

108 F. SCOTT KIEFF ET AL., *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 95. *Id.*

109 *In re Nelson*, 280 F.2d at 180–81.

110 *See id.* at 178 ("[I]t has never been a requirement for patentability that there must be any particular degree of utility."). As stated in the Curtis treatise:

[I]t follows, that every invention for which a patent is claimed must be, to a certain extent, beneficial to the community; it must be capable of use for some beneficial purpose; but, when this is the case, the degree of utility, whether larger or smaller, is not a subject for consideration in determining whether the invention will support a patent.

GEORGE TICKNOR CURTIS, *A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS IN THE UNITED STATES OF AMERICA* § 28 (Boston, Little, Brown & Co., 2d ed. 1854); *cf.* 1 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 341 (Boston, Little, Brown & Co. 1890) ("When actual utility exists, its degree is unimportant.").

111 *Cf.* 1 ROBINSON, *supra* note 110, § 341 ("Nor is it necessary that this advantage, whether great or small, should flow directly from his art or instrument, considered by itself.").

112 Davis, *supra* note 106, at 11–12.

113 *In re Nelson*, 280 F.2d at 180 ("To possess utility, a thing or a process must be capable of producing a result, and that result must be a good result." (quoting ALBERT H. WALKER, *TEXT-BOOK OF THE PATENT LAWS OF THE UNITED STATES OF AMERICA* § 77 (New York, L.K. Strouse & Co., 2d ed. 1889))). Thus, according to the court, "the concept[ ] [of utility is] simple." *Id.*

114 Salim A. Hasan, *A Call for Reconsideration of the Strict Utility Standard in Chemical Patent Practice*, 9 HIGH TECH. L.J. 245, 253–54 (1994).

The conflict between the C.C.P.A. and the Patent Office led the Supreme Court to enter the controversy in the 1966 case *Brenner v. Manson*.<sup>115</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>116</sup> The invention at issue was a new process for making a steroid (X). By the time Manson filed his patent application, the Patent Office had already issued a patent on the process to a competitor.<sup>117</sup> Although Manson could prove that he was the first to invent the process, the examiner would not declare an interference (to sort out who did) and rejected Manson's application because it failed to disclose a utility for X.<sup>118</sup>

Manson argued that X's utility could be *presumed* because other steroids of similar chemical structure were known to inhibit tumors in mice.<sup>119</sup> On appeal, the Board of Patent Appeals and Interferences affirmed the examiner's rejection because the unpredictable nature of steroid chemistry made it impossible to presume that X would have the same tumor-inhibiting properties as the other compounds.<sup>120</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" so long as "it is not, in operation or result, detrimental to the public interest."<sup>121</sup>

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115 383 U.S. 519 (1966).

116 Under the first-to-invent system, patent rights are only awarded to the first inventor. 35 U.S.C. § 102(g) (2012). 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).

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

118 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.

119 *Manson*, 383 U.S. at 521–22.

120 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)); cf. *AstraZeneca Pharm. LP v. Teva Pharm. 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.").

121 *In re Manson*, 333 F.2d 234, 236, 238 (C.C.P.A. 1964). The court's rationale was that a process (such as a method of making something) is a separate category of invention specifically recognized in the statute. *Id.* at 236; 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."); 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process . . .").

The Supreme Court reversed. Agreeing with the Patent Office, the Court held that an inventor seeking to patent a new process for making a compound could only do so if the inventor could establish utility for the compound.<sup>122</sup> Put differently, a process for making a compound like X, which is useful only as—in the words of the majority—an “object of scientific research” lacks utility and is therefore unpatentable.<sup>123</sup> In dicta,<sup>124</sup> but very importantly for present purposes, the majority stated that *the compound itself* also lacks utility if it is to serve merely as an “object” for further scientific research.<sup>125</sup>

Interestingly, the majority conceded that in contemporary chemistry, “little or nothing is wholly beyond the pale of ‘utility.’”<sup>126</sup> To be sure, even chemicals and chemical processes that are only used for research purposes would pass the three-pronged *de minimis* test.<sup>127</sup> Recall that under that test, *some* beneficial use is sufficient to establish utility unless the invention is inoperable or detrimental to the public interest.<sup>128</sup> But as applied to chemical inventions, the majority believed that the “beneficial use” and “public interest” prongs “shed [ ] little light on [the] subject” because they are overinclusive.<sup>129</sup> That the chemical or chemical process can operate to produce the intended result remains a necessary condition for utility but is insufficient on its own to warrant a patent.<sup>130</sup>

The Court then announced the heightened utility standard: “Unless and until a process is refined and developed to this point—where *specific* benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.”<sup>131</sup> Requiring less, according to the majority, could allow the patentee to create a “monopoly of knowledge”<sup>132</sup> which could “engross a vast, unknown, and perhaps unknowable area.”<sup>133</sup> The patent could become a “hunting license,”<sup>134</sup>

122 *Manson*, 383 U.S. at 531, 534–35.

123 *Id.* at 535.

124 “The term *dicta* typically refers to statements in a judicial opinion that are not necessary to support the decision reached by the court.” Michael C. Dorf, *Dicta and Article III*, 142 U. PA. L. REV. 1997, 2000 (1994). *Dicta* “is usually contrasted with a *holding*, a term used to refer to a rule or principle that decides the case.” *Id.* (footnote omitted).

125 The Court explained that the argument(s) against patenting the process “would apply equally to the patenting of the product produced by the process.” *Manson*, 383 U.S. at 535. Even if this statement could be viewed as *dicta*, the C.C.P.A. so held in subsequent cases. See discussion *infra* text accompanying notes 139–54.

126 *Manson*, 383 U.S. at 530.

127 See *supra* subsection I.B.1.

128 See *supra* subsection I.B.1.

129 *Manson*, 383 U.S. at 533.

130 See *id.* at 532.

131 *Id.* at 534–35 (emphasis added).

132 *Id.* at 534.

133 *Id.*

134 *Id.* at 536.

conferring the power to "block off whole areas of scientific development, without compensating benefit to the public."<sup>135</sup>

And so the *Manson* majority fell victim to foresight bias. Again, the fear is that granting patents on certain inventions early on will create problems for future research and hinder downstream innovation.<sup>136</sup> In doing so, the majority failed to appreciate that upstream patents promote efficiency by allowing the upstream patentee to coordinate downstream innovation, prevent duplicative research, and encourage sharing of useful information.<sup>137</sup> The majority minimized Justice Harlan's concern that a more rigorous utility standard could actually *inhibit* scientific progress by encouraging the inventor to maintain secrecy until an acceptable "use" is discovered.<sup>138</sup>

The C.C.P.A. quickly extended *Manson* to apply directly to microscale building blocks. In the companion cases *In re Kirk*<sup>139</sup> and *In re Joly*,<sup>140</sup> the court reversed *Nelson* and held that chemical intermediates are unpatentable if the end product has no known use.<sup>141</sup> Writing for the *Kirk* majority, Chief Judge Worley (Judge Rich's "nemesis")<sup>142</sup> explained:

It is not enough that the specification disclose that the intermediate exists and that it "works," reacts, or can be used to produce some intended product of no known use. Nor is it enough that the product disclosed to be obtained from the intermediate belongs to some class of compounds which now is, or in the future might be, the subject of research to determine some specific use.<sup>143</sup>

Thus, the majority adopted the Patent Office's view that a heightened utility standard should apply to chemical building block inventions.

To say that this issue fractured the court would be an understatement. *Kirk* and *Joly* each included lengthy and sharply worded dissenting opinions<sup>144</sup> from the two patent lawyers on the court: Judges Arthur Smith<sup>145</sup> and

135 *Id.* at 534 (footnote omitted).

136 *See infra* Section III.B.

137 Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 276-77 (1977).

138 *Manson*, 383 U.S. at 538-39 (1966) (Harlan, J., concurring in part and dissenting in part). For additional discussion related to Justice Harlan's concerns about secrecy, see *infra* note 323.

139 376 F.2d 936 (C.C.P.A. 1967).

140 376 F.2d 906 (C.C.P.A. 1967).

141 *In re Kirk*, 376 F.2d at 945; *In re Joly*, 376 F.2d at 908-09.

142 Eccleston & Wegner, *supra* note 107, at 50 ("In 1959, President Eisenhower bestowed upon Judge Rich both a blessing and a curse; he simultaneously nominated one of the nation's best patent attorneys to the bench, Arthur M. Smith of Michigan, while elevating his nemesis Eugene Worley to the position of Chief Judge.")

143 *In re Kirk*, 376 F.2d at 945, *quoted in In re Joly*, 376 F.2d at 908.

144 *See In re Kirk*, 376 F.2d at 947-68 (Rich, J., dissenting); *In re Joly*, 376 F.2d at 910-36 (Smith, J., dissenting).

145 Judge Smith practiced patent law in Chicago and Detroit and taught patent law at the University of Michigan Law School before joining the C.C.P.A. in 1959. GILES S. RICH, A BRIEF HISTORY OF THE UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS 142-46

Giles Rich.<sup>146</sup> They argued that the higher burden placed on those seeking chemical building block patents is irrational,<sup>147</sup> discriminatory,<sup>148</sup> improper,<sup>149</sup> overreaching,<sup>150</sup> and “changes the intent and meaning of the Patent Act.”<sup>151</sup>

An important question is whether the *Kirk* and *Joly* holdings were required by *Manson*. The dissenters in those cases and several commentators answer in the negative, suggesting that the majority relied on dicta.<sup>152</sup> Judge Rich believed that the Supreme Court did not expressly overrule *Nelson*.<sup>153</sup> As he saw it, ratcheting up the utility standard for chemical building blocks was an unwarranted extension of *Manson*.<sup>154</sup>

(1980). He was “one of the most analytically astute patent-experienced members of the judiciary.” Eccleston & Wegner, *supra* note 107, at 50.

146 For a discussion of Judge Rich and his legacy, see sources cited *supra* notes 106–07.

147 See *In re Joly*, 376 F.2d at 928 (Smith, J., dissenting) (discussing the “[i]nsupportable [r]ationale of the [m]ajority [o]pinion”).

148 See *In re Kirk*, 376 F.2d at 962 (Rich, J., dissenting) (arguing that the Patent Office’s policy applied through the chemical examining group “is something of a discrimination in legal administration”); *id.* at 967 (Smith, J., dissenting) (contending that the majority’s position is supporting evidence that “chemical inventors are being wrongfully discriminated against”); *In re Joly*, 376 F.2d at 931 (Smith, J., dissenting) (“The inventors of chemical tools should neither be *discriminated* against nor *confused* with those who devise ways and purposes to apply those tools.”).

149 See *In re Joly*, 376 F.2d at 929 (Smith, J., dissenting) (arguing that neither the Intellectual Property Clause nor the patent statute distinguishes between classes of inventors or subject matter).

150 *Id.* at 910 (“The drastic and far reaching amendment of the statute which results from the majority decision here and in *Kirk* should be the sole responsibility of Congress after due investigation and proper weighing of its effect . . .”); *cf. In re Kirk*, 376 F.2d at 950–51 (Rich, J., dissenting) (“*If usefulness was typically regarded as inherent during a long and prolific period of chemical research and development* in this country, surely this is added reason why the Court’s result should not be adopted until Congress expressly mandates it, presumably on the basis of empirical data which this Court does not possess.” (quoting *Brenner v. Manson*, 383 U.S. 519, 540 (1966) (Harlan, J., concurring in part and dissenting in part))).

151 *In re Joly*, 376 F.2d at 910 (Smith, J., dissenting); *cf. In re Kirk*, 376 F.2d at 954 (Rich, J., dissenting) (“Considering, finally, that the present statute, the Patent Act of 1952, § 101, was enacted without the slightest indication of any intent to change the law, as expressed in the cases, texts, and administrative practice, it is clear that the majority here is indulging in judicial law-making . . .”).

152 See, e.g., *In re Kirk*, 376 F.2d at 948–49 (Rich, J., dissenting) (arguing that the *Manson* majority “expressly reserved judgment with the phrase ‘we express no view’ on a group of our cases in which we held new chemical compounds to be ‘useful,’ *though having utility only in scientific investigation*”); Anderson & Dyson, *supra* note 85, at 815 (“In the first cases dealing with the area of ‘utility’ since *Manson*, the *Nelson* dissenters carried the day, giving great scope to the *Manson* dicta that was unfavorable to the *Nelson* decision.” (footnote omitted)).

153 *In re Kirk*, 376 F.2d at 949–50.

154 *Id.* at 948–49. Judge Rich noted that unlike the product at issue in *Kirk*, the issue before the *Manson* Court “was, primarily, the right of *Manson* to an interference with an

### C. *The Current Paradigm*

So what actually happens when someone applies for a chemical building block invention? In a general sense, as described by Judge Smith in his twenty-six page dissent in *Joly*,<sup>155</sup> these inventors “are improperly set apart from all inventors as a class”<sup>156</sup> and are burdened with special requirements, including the need for “more of a disclosure of utility for a chemical ‘tool,’ than what they require from inventors in the other technical areas.”<sup>157</sup> (Judge Smith’s term “tool” is, of course, synonymous with “building block.”) The ultimate question for him was: “[H]ow far can the inventor of a chemical ‘tool’ be legally required to go . . . in disclosing utility of his invention?”<sup>158</sup> The short answer is very far indeed.

To understand why, it is important to briefly describe the contours of the modern utility requirement. The current test applied in the Patent Office and sanctioned by the Federal Circuit has three prongs. The first prong, *operability* or *credible utility*, is the only one retained from the nineteenth-century test. It requires that the invention be capable of achieving its intended result.<sup>159</sup> Operability is gauged by asking if a PHOSITA would consider the inventor’s assertions believable.<sup>160</sup>

The two other prongs, “specific” and “substantial” utility, were identified but not fully defined in *Manson*.<sup>161</sup> The Federal Circuit did so nearly thirty years later in *In re Fisher*<sup>162</sup> when it essentially adopted the Patent Office’s guidelines for assessing utility.<sup>163</sup> For *substantial utility*, a PHOSITA must be

issued patent on a process claim, a subsidiary issue being the sufficiency of the affidavits.” *Id.* at 948–49 (footnote omitted).

155 *In re Joly*, 376 F.2d at 910–36 (Smith, J., dissenting).

156 *Id.* at 929.

157 *Id.*; cf. Anderson & Dyson, *supra* note 85, at 817 (“The broad reach of *Kirk* and *Joly* will work a hardship on chemical researchers, who have now been excluded from the class of people for whom compounds are ‘useful.’”).

158 *In re Joly*, 376 F.2d at 929.

159 *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999); *see also Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989) (stating that a “device lacks utility” when “it does not operate to produce what [the inventor] claims it does” (quoting *Newman v. Quigg*, 681 F. Supp. 16, 23 (D.D.C. 1988))); cf. *In re Perrigo*, 48 F.2d 965, 966 (C.C.P.A. 1931) (“It is fundamental in patent law that an alleged invention . . . must appear capable of doing the things claimed . . .”).

160 The Patent Office can establish reasonable doubt if the applicant’s disclosure “suggest[s] an inherently unbelievable undertaking or involve[s] 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)). A finding of inoperability means that the claimed invention lacks a credible utility. *Id.* at 1356; INTERIM UTILITY GUIDELINES, *supra* note 72, at 11 (“[A] utility that is inoperative is not credible.”).

161 *See Brenner v. Manson*, 383 U.S. 519, 534–35 (1966).

162 421 F.3d 1365, 1371–72 (Fed. Cir. 2005).

163 *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. 1092 (Jan. 5, 2001) [hereinafter Utility Examination Guidelines]); *see id.* at 1374 (“We

able to use the invention to provide a “significant” and “immediate” benefit to the public.<sup>164</sup> In other words, 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.”<sup>165</sup>

Finally, *specific utility* requires that an invention “provide a well-defined and particular benefit to the public.”<sup>166</sup> The purpose of this requirement is to deny patents for inventions where the asserted use is “so vague as to be meaningless.”<sup>167</sup> For example, asserted uses like “biological activity” or “useful for technical and pharmaceutical purposes” fail the requirement.<sup>168</sup>

A lack-of-utility rejection triggers an evidentiary burden-shifting process.<sup>169</sup> Once the examiner has established a *prima facie* case of unpatentability, the burden shifts to the applicant to either attack or rebut it.<sup>170</sup> An applicant can successfully attack the *prima facie* case if the examiner produces no (or insufficient) evidence to support a finding of nonutility.<sup>171</sup> Alternatively, an applicant can concede the *prima facie* case and rebut it. So, for example, if specific utility is at issue, the burden shifts to the applicant to come forward with persuasive arguments or evidence sufficient to show that the invention provides an immediate benefit to the public.<sup>172</sup> When the applicant submits rebuttal evidence, the examiner must “start over” and “consider all of the evidence anew.”<sup>173</sup> The examiner must determine patentability based on the entire record, with a preponderance of the

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agree with the Board [of Patent Appeals and Interferences] that the facts here are similar to those in *Brenner*.”). The guidelines have been incorporated into the Manual of Patent Examining Procedure. See MPEP, *supra* note 71, § 2107. The MPEP and Utility Examination Guidelines “are not binding on [the Federal Circuit], but may be given judicial notice to the extent they do not conflict with the statute.” *In re Fisher*, 421 F.3d at 1372 (quoting *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002)).

164 *In re Fisher*, 421 F.3d at 1371 (citing *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980)).

165 *Id.*

166 *Id.*

167 *Id.*

168 See, e.g., *Ex parte Aggarwal*, No. 90-3041, 1992 WL 176683, at \*6 (B.P.A.I. Jan. 14, 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.”).

169 See *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (describing the framework).

170 See *id.*

171 MPEP, *supra* note 71, § 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 § 101).

172 See *supra* note 164 and accompanying text.

173 *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984).

evidence as the standard of proof.<sup>174</sup> Whether an invention complies with the utility requirement of § 101 is a question of fact.<sup>175</sup>

## II. ELIMINATING FORESIGHT BIAS IN THE UNPREDICTABLE ARTS

Allowing foresight bias to drive patentability determinations has come at a cost. It disconnects patent law from many of the technological communities that it serves and ultimately frustrates fundamental goals of the patent system. It is now time for microscale building blocks to become patentable—even if no use is disclosed. This essentially removes utility from the patentability calculus. Here I describe how concerns about patent breadth and technical merit can be addressed through compliance with (or more rigorous enforcement of) enablement and nonobviousness—patentability requirements that (unlike utility) are rooted in objective, fact-based inquiries. This approach will essentially eliminate foresight bias in the unpredictable arts.

### A. Normative Perspectives

Patent law functions as a unitary system in that all inventions—irrespective of technological field—must satisfy the same statutory patentability criteria.<sup>176</sup> In theory, the patent system is technology-neutral, meaning that it does not differentiate across technologies or industries.<sup>177</sup> In practice, however, the courts apply the facially neutral patent statutes differently to different technologies.<sup>178</sup> Sometimes this must be done to adjust patent doctrines to accommodate new types of inventions as technology evolves.<sup>179</sup> However, courts should not craft technology-specific rules based on speculation about the potential negative consequences of granting a patent.<sup>180</sup> But this is precisely what happens when the courts fall victim to foresight bias.

Judicial partiality is no stranger to patent law, particularly when it is done for the sake of innovation. For example, in earlier times, the courts favored extraordinary technological advances by rewarding the owners of

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174 *In re Oetiker*, 977 F.2d at 1445.

175 *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956 (Fed. Cir. 1983).

176 *See supra* note 5.

177 Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1576–77 (2003). As a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization (TRIPS 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, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, arts. 70.6, 108 Stat. 4809, 869 U.N.T.S. 299, available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf).

178 Burk & Lemley, *supra* note 24, at 1156.

179 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 177, at 1576 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)).

180 Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1067 (1988).



such inventions “with exceptionally broad claim scope in exchange for their outsized technological contribution to society.”<sup>181</sup> As Professor 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>182</sup> Back then, their inventions were the ones that society cared the most about because they brought radical benefits to everyday life.<sup>183</sup>

This partiality continues to the present day. It is hard to argue that more judicial and scholarly attention focuses on biotechnology rather than masonry—genes rather than bricks. This is understandable because the field of biotechnology promises potentially limitless new possibilities and benefits for humankind.<sup>184</sup> So it is not at all surprising that much attention has been paid to microscale building blocks. An ever-present concern is if granting patents on them tends to promote innovation more than impede it.<sup>185</sup> But using a subjective patentability standard like utility is too blunt an instrument to achieve this goal. What emerges is a dubious body of judge-made law, which ultimately does more harm than good.<sup>186</sup>

One might ask why microscale building blocks raise utility concerns at the Patent Office and in the courts, but macroscale building blocks do not. There are at least two possible explanations for the disparate treatment. One possibility is that upstream patents on microscale building blocks are more likely to impede follow-on research and innovation than patents on macroscale building blocks. But Scott Kieff argues that they are not:

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181 Brian J. Love, *Interring the Pioneer Invention Doctrine*, 90 N.C. L. REV. 379, 382 (2012).

182 *Id.* (footnote omitted).

183 *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) (“[L]aypersons and technologists share the view that pioneer 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)).

184 See generally, e.g., JEREMY RIFKIN, *THE BIOTECH CENTURY* 224 (1998) (describing how biotechnology provides “near limitless possibilities to reconstruct and reinvent the body, move DNA across species boundaries, erase the genetic past, and pre-program the genetic future”); GEORGE WOLFF, *THE BIOTECH INVESTOR’S BIBLE* 326 (2001) (“With the long-term potential to cure most major diseases and to revolutionize industries as diverse as pharmaceuticals and forestry, petrochemicals and agriculture, the possibilities for biotech—and its investors—are limitless.”); Linda A. Fothergill-Gilmore & Lindsay Sawyer, *Protein Engineering*, in *BIOTECHNOLOGY* 155, 162 (Vivian Moses & Ronald E. Cape eds., 2d ed. 1999) (noting that creating new proteins with new activities gives rise to “possibilities [that] seem almost limitless, especially when one considers that a medium sized protein with 300 amino acids has 20<sup>300</sup> possible sequences”).

185 See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (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.”).

186 Scott Baker, *Can the Courts Rescue Us from the Patent Crisis?*, 88 TEX. L. REV. 593, 595 (2010) (reviewing BURK & LEMLEY, *supra* note 1).

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.<sup>187</sup>

The other possibility, related but distinct, is that microscale building blocks deserve more scrutiny because they are *qualitatively different* than macroscale building blocks. This reasoning—which relates directly to the problem of scale discussed above<sup>188</sup>—is in accord with the tendency of people to fear things that they cannot see, let alone understand.<sup>189</sup> But microscale and macroscale building blocks are *not* qualitatively different. As one commentator wisely observes, “[chemical] intermediates or building blocks are very little different from bricks which as individual pieces of ceramic [sic] material have no utility but which do have utility because they can be fabricated into a wall or other structure.”<sup>190</sup> Indeed, chemical building blocks “are no less useful to a skilled chemist than bricks to an architect or mason.”<sup>191</sup>

### B. *Allowing Patents on Building Blocks*

This Section describes how to render microscale building blocks patentable with minimal costs to society. This is achieved through enablement and nonobviousness—two patentability requirements rooted in objective, fact-intensive inquiries. Enablement constrains the scope of the patent, whereas nonobviousness excludes the patenting of inventions that lack technical merit because the claimed subject matter is too close to what is already known.

#### 1. Constraining Claim Scope Through Enablement

The basic way to limit the exclusionary right conferred by the patent grant is to constrain claim scope—the “technological territory” that the

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187 F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 720 (2001).

188 See *supra* Section I.A.

189 This can be traced to the Latin proverb “*Damnans quod non intellegunt*,” which literally means “[t]hey condemn what they do not understand.” WALDO E. SWEET, *LATIN PROVERBS* 87 (Georgia Irby-Massie & Scott Van Horn eds., 2002).

190 Edward H. Valance, *Patentability of Chemical Intermediates: The “Nelson” Case in Perspective*, 3 J. CHEM. DOCUMENTATION 33, 34 (1963) (quoting Brief for Connecticut Patent Law Association as Amicus Curiae at 10, *In re Nelson*, 280 F.2d 172 (C.C.P.A. 1960) (No. 6338)).

191 *Id.*

inventor claims is his or hers to control.<sup>192</sup> Claim scope plays a central role in patent law.<sup>193</sup> It can be defined as the “metes and bounds” of the territory conferred by the patent grant.<sup>194</sup> Specifically, a patent gives the patentee the right to exclude others from making, using, selling, offering to sell, or importing the claimed invention for any use of that invention, regardless of whether the patentee envisioned such use.<sup>195</sup> For a microscale building block like a chemical compound, this means that “[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>196</sup>

Yet this broad scope is not all bad. The ability of patentees to control future uses and downstream research that flows from the invention is a key tenet of the prospect theory of patents.<sup>197</sup> In addition, as illustrated by the AcmePharma hypothetical presented in the Introduction, generating research tools like microscale building blocks is a capital-intensive endeavor,

192 Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 844 (1990).

193 See *id.* 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.”); see also Mark A. Lemley, *The Changing Meaning of Patent Claim Terms*, 104 MICH. L. REV. 101, 101 (2005) (explaining that claims “are central to virtually every aspect of patent law”); Giles S. Rich, *Extent of Protection and Interpretation of Claims—American Perspectives*, 21 INT’L REV. INDUS. PROP. & COPYRIGHT L. 497, 499 (1990) (stating that in patent law, “the name of the game is the claim”).

194 *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) (“A claim in a patent provides 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.”).

195 *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002) (citing 35 U.S.C. § 271 (2012)); cf. *Roberts v. Ryer*, 91 U.S. 150, 157 (1875) (“The inventor of a machine is entitled to the benefit of all the uses to which it can be put, no matter whether he had conceived the idea of the use or not.”).

196 HAROLD C. WEGNER, *PATENT LAW IN BIOTECHNOLOGY, CHEMICALS & PHARMACEUTICALS* § 260, at 301 (2d ed. 1994).

197 See Kitch, *supra* note 137, at 266 (articulating the prospect theory of patents). As explained by one commentator:

One of the main concerns motivating the prospect theory in the patent context is the idea that if an inventor is not allowed to control future uses and development of the invention early on, this is likely to result in wasteful duplicative efforts among inventors. An improver might decide to take the inventor’s nascent idea and develop and commercialize it, regardless of the fact that the inventor is doing the exact same thing (perhaps in the belief that he is likely to be the first to do so). This, the prospect theory argues, results in a redundancy, or dead-weight loss, that has no social benefit.

Shyamkrishna Balganes, *Foreseeability and Copyright Incentives*, 122 HARV. L. REV. 1569, 1623 (2009).

which would provide private firms with little incentive to invent without some degree of exclusivity.<sup>198</sup>

One fear of granting patents on microscale building blocks is that they can be so expansive that they hinder follow-on inventive activity without a compensating benefit to the public.<sup>199</sup> This need not be the case because a mechanism exists in patent law that prevents this from happening. The principal tool for constraining claim scope is enablement—one of the three statutory disclosure requirements appearing in the first paragraph of § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same*, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.<sup>200</sup>

It obliges an applicant to disclose the claimed invention in sufficient detail to “enable” a PHOSITA to practice (make and use) its full scope at the time of filing<sup>201</sup> without undue experimentation.<sup>202</sup> The purpose of the requirement is to ensure that the property right granted to the inventor “is of an appropriate scope, in light of the contribution her research makes to the relevant field.”<sup>203</sup> Thus, enablement “seeks to determine whether the inventor’s claims adequately reflect her research—whether, in effect, she is claiming more than she taught [the PHOSITA].”<sup>204</sup> The scope of enablement<sup>205</sup>

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198 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) (“So if there are, for example, 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.”).

199 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, 271–72 (2008).

200 35 U.S.C. § 112(a) (emphasis added).

201 *In re Hogan*, 559 F.2d 595, 607 (C.C.P.A. 1977); see *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371–72 (Fed. Cir. 1999) (“[The] enablement determination is made *retrospectively*, *i.e.*, by looking back to the filing date of the patent application and determining whether undue experimentation *would have been* required to make and use the claimed invention at that time.”).

202 *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). While “‘undue experimentation’ does not appear in the statute, . . . it is well established that enablement requires that the specification teach [PHOSITAs] to make and use the invention without undue experimentation.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

203 *Merges*, *supra* note 63, at 18.

204 *Id.*

205 The scope of enablement is the sum of what is taught in the written description of the invention plus what is known by a PHOSITA without undue experimentation. *Nat’l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999).

sets the outer boundaries of the claim, meaning that narrow enablement will result in narrowed claim scope.<sup>206</sup>

Enablement is a standard.<sup>207</sup> Determining whether a disclosure is enabling is a legal conclusion that rests on underlying factual inquiries.<sup>208</sup> The Federal Circuit set forth several factors relevant to the enablement analysis in *In re Wands*.<sup>209</sup> 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.<sup>210</sup> While not mandatory,<sup>211</sup> the *Wands* factors are ubiquitous in evaluating enablement<sup>212</sup> because they touch on issues that are important in virtually all enablement determinations.<sup>213</sup> These include issues related to the technical scope and substance of the disclosure (factors one and two),<sup>214</sup> the nature of the technology (factors three and four),<sup>215</sup> the PHOSITA’s knowledge and skill (factor five),<sup>216</sup> and the scope of the claim sought (factor seven).<sup>217</sup> Importantly for present purposes, the *Wands* factors provide the decision-maker with a list of objective

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206 *See id.*

207 *See Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576–77 (Fed. Cir. 1984); MPEP, *supra* note 71, § 2164.01.

208 *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008).

209 858 F.2d 731, 737 (Fed. Cir. 1988).

210 *Id.*

211 *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (noting that the *Wands* factors are illustrative and not mandatory).

212 *See* 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.03 (2012) (collecting cases).

213 The factors are interrelated. For example, if the PHOSITA is really smart (factor five), an applicant need not disclose what the PHOSITA already knows or can easily figure out (factors one and two). *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987).

214 The technical substance of the disclosure lies at the heart of the enablement analysis. *See supra* note 213. The two factors are clustered together because working examples are a form of guidance. Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 641–46 (2010).

215 One way to determine the requisite amount of teaching is to ask whether the technology is “unpredictable” or “predictable.” *See supra* notes 73, 75, and accompanying text.

216 This factor has become increasingly important over the past decade as the Federal Circuit has compelled patentees to enable the full scope of the claimed invention. *See, e.g., ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 941–42 (Fed. Cir. 2010) (holding that the district court properly determined the PHOSITA’s level of skill and did not err in giving less weight to a witness who analyzed an issue using the wrong level of skill); *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (determining that where 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).

217 Enablement places an outer limit on claim scope. *See supra* note 206 and accompanying text.

criteria that do much to eliminate foresight bias and render the utility requirement unnecessary.<sup>218</sup>

a. Setting a High Disclosure Threshold

The *Wands* factors can be manipulated to set a high disclosure threshold, which can lead to a narrow patent scope. The easiest way to do this is to place a premium on actual experimental details describing work that has been performed. This type of disclosure lies at the core of technical publications because it provides the best form of teaching.<sup>219</sup> In patent law, actual experimental details or “working examples” (which correspond to the first and second *Wands* factors) provide the best evidence of enablement.<sup>220</sup> When operability is in doubt,<sup>221</sup> they can provide objective proof that the invention really works.<sup>222</sup> And, very importantly, working examples are the

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218 The operability prong of utility provides an excellent example. It *attempts* to answer the objective, technical question of whether an invention can actually achieve its intended result. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992). Unfortunately, the question is often framed in *subjective* terms, such as whether a PHOSITA would believe the truth of the inventor’s assertions. *In re Cortright*, 165 F.3d 1353, 1357 (Fed. Cir. 1999). Indeed, history reveals that gauging operability often devolves into a biased judgment about the subject matter irrespective of technical substance. Seymore, *supra* note 47, at 1511–23. To the extent that the justification for operability is to serve a gatekeeping function, it is an unnecessary requirement because a robust enablement analysis can effectively ferret out unworkable inventions. *Id.* at 1524–37.

219 See, e.g., ROBERT A. DAY & BARBARA GASTEL, *HOW TO WRITE AND PUBLISH A SCIENTIFIC PAPER* 61 (6th ed. 2006) (noting that disclosing the experimental methods is important because the scientific community must adjudge the results reproducible before attaching scientific merit to the work); ADIL E. SHAMOO & DAVID B. RESNIK, *RESPONSIBLE CONDUCT OF RESEARCH* 51 (2d ed. 2009) (“The ability of other investigators to replicate the experiments by following the method in the published report is crucial to the advancement of science.”).

220 Seymore, *supra* note 214, at 653; see also Bratislav Stankovic, *The Use of Examples in Patent Applications*, 18 INTELL. PROP. & TECH. L.J. 9, 10 (2006) (noting that in patent documents, the presence of working examples “facilitates, if not ensures, enablement of an invention”). But, as with other forms of enablement, the breadth of the teaching provided in a working example must be commensurate with the claim scope sought. See *supra* note 205. A teaching that lacks specificity or provides inadequate guidance will result in a narrow(ed) claim scope (*Wands* factor eight). BURK & LEMLEY, *supra* note 1, at 115.

221 See *supra* notes 159–60 and accompanying text.

222 For instance, working examples helped convince the Patent Office and the courts that it is possible to successfully treat cancer. Compare *In re Citron*, 325 F.2d 248, 249–53 (C.C.P.A. 1963) (explaining that applicants’ invention relating to an alleged effective treatment for cancer, which lacked specific tests, experiments, or clinical data, asserted incredible utility in the light of the knowledge of the art), with *In re Jolles*, 628 F.2d 1322, 1326–28 (C.C.P.A. 1980) (concluding that clinical tests, combined with the close structural similarity of the claimed compounds with chemotherapeutics known in the art, would allow a PHOSITA to accept the claimed utility), and *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (noting that treating cancer with chemical compounds “does not suggest an inherently unbelievable undertaking or involve implausible scientific principles” because there are “numerous successful chemotherapeutic agents”).

best way to ensure that the public gets a “[more] readable and substantively useful patent document.”<sup>223</sup> For these reasons, some have argued that there should be an across-the-board working example requirement in patent law,<sup>224</sup> except for inventions in which enablement is “so apparent as virtually to jump off the page and slap [a PHOSITA] in the face.”<sup>225</sup>

#### b. Solving the *Manson* Problem

Recall that a major challenge for the post-World War II patent system is how to assess utility for chemical and pharmaceutical inventions, particularly those that have no therapeutic or non-research-based use at the time patent protection is sought.<sup>226</sup> The *Manson* Court imposed a heightened utility threshold (the modern utility requirement) to render such compounds unpatentable.<sup>227</sup> At least from a disclosure standpoint, society loses under this regime because it fosters secrecy, delays disclosure, and conceals valuable technical information.<sup>228</sup>

The result would be very different under the proposed enablement-based paradigm. Consider the following hypothetical—loosely based on the underlying facts in *In re Joby* discussed above.<sup>229</sup> Suppose that in 2008 an inventor at a drug company sought to patent a class of chemical intermediates that can be used as building blocks for steroids that are similar in chemical structure to known drugs. The patent application includes a generic claim that, by claiming a core chemical structure with an array of five variables appended to it, encompasses thousands of compounds.<sup>230</sup> As is typical in pharmaceutical cases, the claim is incredibly broad<sup>231</sup>—here because it is possible to substitute each of the five variables appended to the core

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223 Seymore, *supra* note 214, at 642.

224 See *id.* at 641–54; see also Seymore, *Heightened Enablement*, *supra* note 68, at 156–58. Professor Cotropia also advocates an actual reduction to practice requirement. See Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 120–22 (2009) (proposing a framework wherein the Patent Office would defer examination until the applicant submits evidence of actual implementation of the invention).

225 *Ash v. Tyson Foods, Inc.*, 546 U.S. 454, 456–57 (2006) (per curiam) (quoting *Ash v. Tyson Foods, Inc.*, 129 F. App'x 529, 533 (11th Cir. 2005)); see also Seymore, *Heightened Enablement*, *supra* note 68, at 156 n.151. Invoking a working example requirement probably falls within the Patent Office's statutory authority. See Seymore, *supra* note 47, at 1506 n.82 (discussing the working model requirement of 35 U.S.C. § 114 (2012)); Seymore, *supra* note 214, at 642 n.103 (same).

226 See *supra* subsection I.B.1.

227 See *supra* subsection I.B.2.

228 See *infra* Section III.A.

229 376 F.2d 906 (C.C.P.A. 1967); see *supra* subsection I.B.2.

230 This style of claiming a class of chemical compounds in terms of structural formulas, where the substituents are recited in the claim language, is ubiquitous in the chemical and pharmaceutical arts. See *In re Harnisch*, 631 F.2d 716, 719–20 (C.C.P.A. 1980) (sanctioning the practice); *In re Driscoll*, 562 F.2d 1245, 1249 (C.C.P.A. 1977) (same).

231 Applicants have an incentive “to obtain very broad claims for which an argument can be made for patentability.” ANTHONY MIELE, *PATENT STRATEGY* 98 (2001); see also BRADLEY C. WRIGHT, *DRAFTING PATENTS FOR LITIGATION AND LICENSING* 603 (2d. ed. 2013) (advis-

structure with a variety of organic functional groups.<sup>232</sup> The patent application, however, only sets forth five compounds actually made (working examples). These five compounds are closely related to each other because the same variable (one of the five) is substituted in each.

After construing the claims, assessing the PHOSITA's level of skill, and evaluating the teaching provided in the patent application,<sup>233</sup> the examiner determines that the disclosure only teaches a PHOSITA how to make a narrower subgenus of fifty compounds, not thousands. As support for a *prima facie* case of nonenablement for the broad genus, the examiner recognizes that:

[R]eplacing a functional group on a chemical compound can often have highly unpredictable results. . . . [E]ven a change as seemingly trivial as replacing an isopropyl group with the isosteric cyclopropyl group . . . could result in either a significant improvement or reduction in the activity of the compound . . . .<sup>234</sup>

The point here is that a PHOSITA cannot extrapolate a result from a few, closely related embodiments,<sup>235</sup> across a broad genus in an unpredictable field like chemistry, with a reasonable expectation of success.<sup>236</sup>

Consequently, the examiner rejects the broad generic claim as *prima facie* nonenabled because a PHOSITA would have to engage in undue experimentation to figure out what works.<sup>237</sup> The burden then shifts to the applicant to establish by a preponderance of the evidence that the PHOSITA's knowledge, in combination with the teaching provided in the patent application, can actually enable the full scope of the generic claim.<sup>238</sup> In response, the applicant argues that a well-trained organic chemist would know where to look in the scientific literature to fill in the technical gaps.<sup>239</sup> The examiner determines that the proffered argument is insufficient to rebut the *prima*

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ing drafters of chemical patent applications to provide adequate support for claims that often covers billions of compounds).

232 A functional group is a group of atoms within a molecule with specific chemical properties that represents a potential reaction site in a compound, and thus determine a molecule's chemical reactivity. See generally RICHARD C. LAROCK, COMPREHENSIVE ORGANIC TRANSFORMATIONS (2d ed. 1999) (providing examples).

233 See *supra* notes 209–10 and accompanying text (discussing the factual inquiries underlying the enablement analysis).

234 Singh v. Brake, 317 F.3d 1334, 1344 (Fed. Cir. 2003).

235 An "embodiment" is a concrete form of an invention described in a patent application or patent. See *infra* note 365.

236 See *supra* note 75 and accompanying text.

237 See Merges & Nelson, *supra* note 192, at 848 (explaining why such a rejection is proper). There is a danger that embodiments not described either cannot be made or may require experimentation that is unduly extensive. PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996).

238 See *In re Marzocchi*, 439 F.2d 220, 223 (C.C.P.A. 1971) (articulating the burden-shifting framework).

239 Applicants often point to the much-cited statement that "a patent need not teach, and preferably omits, what is well known in the art." Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986); see *supra* note 213. However, that state-



facie case because it is not “persuasive . . . [and] supported by suitable [evidence] where necessary, that [a PHOSITA] would be able to make and use the claimed invention using the application as a guide.”<sup>240</sup>

At this point, the applicant is unable or unwilling to produce the requisite evidence. Accordingly, the applicant voluntarily cancels the broad generic claim and pursues the narrower subgenus claim covering fifty compounds. The examiner allows that claim and the applicant ultimately gets a *much narrower* patent—covering fifty compounds instead of thousands—than that which would have issued under the current regime.<sup>241</sup>

This result is a win-win for the patent system and society. Granting the narrower patent fulfills the quid pro quo because the claim scope obtained is commensurate with the disclosure provided.<sup>242</sup> This limited scope should allay concerns, à la *Manson*,<sup>243</sup> about the patentee creating “a monopoly of knowledge”<sup>244</sup> that could “block off whole areas of scientific development, without compensating benefit to the public.”<sup>245</sup> To the contrary, the public would benefit under the proposed regime because in exchange for the patent it would get very useful knowledge—actual experimental details—as opposed to less helpful forms of disclosure.<sup>246</sup>

### c. How About Enablement’s “How To Use” Requirement?

Enablement requires that the applicant provide a disclosure that teaches a PHOSITA both how to make and how to use the invention.<sup>247</sup> The “use” requirement of § 112, however, differs from the utility requirement of § 101. Whereas the latter is often a subjective value judgment,<sup>248</sup> it has been clear from the early days of the patent system that the purpose of the § 112 use requirement is simply to provide the PHOSITA with a meaningful disclosure. To make this point in *In re Nelson*,<sup>249</sup> Judge Rich quoted a nineteenth-century patent treatise explaining the enablement requirement:

[I]t is necessary . . . that the invention shall so be described in the specification, that . . . [a PHOSITA] may not only understand the invention, but be able, by following the directions given in the specification, with the assis-

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ment “is merely a rule of supplementation, not a substitute for a basic enabling disclosure.” *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

240 MPEP, *supra* note 71, § 2164.05; *see also In re Marzocchi*, 439 F.2d at 223.

241 Since (1) the current patent laws do not require any actual experimentation in order to obtain a patent and (2) the Patent Office does not have its own testing facilities, applicants in the unpredictable arts are often very successful in obtaining broad claims with dubious enablement. Seymore, *Heightened Enablement*, *supra* note 68, at 143–54; *see Seymore*, *supra* note 214, at 628–32.

242 *See supra* note 205 and accompanying text.

243 *Brenner v. Manson*, 383 U.S. 519 (1966); *see supra* subsection I.C.2.b.

244 *Manson*, 383 U.S. at 534; *see also supra* notes 57–59 and accompanying text.

245 *Manson*, 383 U.S. at 534 (footnote omitted).

246 Seymore, *supra* note 214, at 634–35.

247 *See* 35 U.S.C. § 112(a) (2012).

248 *See Eisenberg*, *supra* note 46, at 2085.

249 280 F.2d 172 (C.C.P.A. 1960).

tance of the drawings, to construct the machine or perform the process which is the subject of the patent.<sup>250</sup>

Thus, § 112 is satisfied if the inventor describes how to use the invention as broadly as it is claimed. Requiring the patent applicant to provide working examples would do just that.

But this does not mean that the how-to-use requirement of § 112(a) should be used as a proxy for the § 101 utility requirement. It is true that under the current regime, an invention that lacks utility under § 101 fails to satisfy the how-to-use prong of the enablement requirement of § 112(a) as a matter of law.<sup>251</sup> This makes sense when the § 101 problem is inoperability, because if the invention cannot operate to achieve the intended result, then it is impossible to enable a PHOSITA to use it.<sup>252</sup> But one can certainly enable an invention yet fall short of the current utility threshold. The best example is the factual scenario presented in *Manson*.<sup>253</sup> To be sure, 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>254</sup>

This last point reveals the paradoxical nature of the modern utility requirement as it relates to disclosure. An applicant can assuredly disclose an invention that enables a PHOSITA to make and use the invention (like a chemical compound), but can nevertheless fail to meet the § 101 utility threshold because the subject matter is deemed to be a “mere research proposal”<sup>255</sup> or “simply an object of research.”<sup>256</sup> Yet again, this shows that utility has little to do with the invention’s ability to provide a cognizable benefit to society.<sup>257</sup>

## 2. Ensuring Technical Merit Through Nonobviousness

A robust enablement analysis would do much to allay fears about granting patents on microscale building blocks. Since the breadth of the disclosure would tightly limit the scope of the patent, concerns about creating unjustifiable roadblocks for future innovators would diminish. But even if

250 WILLARD PHILLIPS, *THE LAW OF PATENTS FOR INVENTIONS* 233–34 (New York, Gould, Banks & Co. 1837), *quoted in In re Nelson*, 280 F.2d at 181.

251 *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*, 52 J. PAT. OFF. SOC’Y 757, 768 (1970) (providing examples).

252 *See 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) (“If a patent claim fails to meet the utility requirement because it is . . . [inoperative], then it also fails to meet the how-to-use aspect of the enablement requirement.”).

253 *See supra* subsection I.B.2.

254 *See In re Manson*, 333 F.2d 234, 239 (C.C.P.A. 1964). In evaluating Manson’s application, the Patent Office never asserted nonenablement as grounds for unpatentability.

255 *In re ‘318 Patent Infringement Litig.*, 583 F.3d 1317, 1324 (Fed. Cir. 2009).

256 *Id.*

257 *See infra* text accompanying note 277.

enablement is satisfied, a fact-intensive evaluation of the building block's *technical merit* might suggest that a patent should not issue *at all* because the potential benefit that society might derive from the invention and its disclosure does not justify the costs of granting a patent.<sup>258</sup> This is because the claimed building block does not differ substantially from what is already known. In such a situation, the proper tool to screen patentability is *nonobviousness*, not utility.

#### a. Understanding Nonobviousness

The statutory requirement for nonobviousness, embodied in § 103(a) of the Patent Act,<sup>259</sup> helps fulfill the patent system's broad policy goals of promoting technological progress,<sup>260</sup> coordinating the future development of technology,<sup>261</sup> and spurring innovation.<sup>262</sup> By reserving the quid pro quo of patent rights for inventions that represent a significant step forward in the field, the nonobviousness requirement ensures that patents are only awarded for those inventions (though novel and enabled)<sup>263</sup> whose disclosures will actually *add* to the storehouse of useful knowledge.<sup>264</sup> Among other things,

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258 Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590, 1594 (2011); see Gregory Mandel, *The Non-Obvious Problem: How the Indeterminate Nonobviousness Standard Produces Excessive Patent Grants*, 42 U.C. DAVIS L. REV. 57, 62 (2008) ("The nonobviousness requirement protects society against the social costs both of denying a deserving patent and of granting an undeserving monopoly.").

259 The statute provides in relevant part that

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a [PHOSITA] to which the claimed invention pertains.

35 U.S.C. § 103(a) (2012).

260 See Karl B. Lutz, *Patents and Science: A Clarification of the Patent Clause of the U.S. Constitution*, 18 GEO. WASH. L. REV. 50, 54 (1949) (explaining that the patent portion of the Intellectual Property Clause can be read to mean "[t]o promote the progress of technology" or "[t]o accelerate technological progress").

261 Kitch, *supra* note 137, at 266.

262 Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979).

263 See 1 CHISUM, *supra* note 212, § 3.01 (noting that nonobviousness asks if an invention is "new enough" to warrant a patent); Joseph Scott Miller, *Nonobviousness: Looking Back and Looking Ahead*, in 2 INTELLECTUAL PROPERTY AND INFORMATION WEALTH 1, 2 (Peter K. Yu ed., 2007) ("[N]onobviousness divides the patentably new from the unpatentably new . . .").

264 *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966) ("Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system . . ."); *Atl. Works v. Brady*, 107 U.S. 192, 200 (1882) ("The design of the patent laws is to reward those who make some substantial discovery or invention, which adds to our knowledge . . . It was never the object of those laws to grant a monopoly for every trifling device . . ."); Kitch, *supra* note 137, at 283 (arguing that patents should not be granted for the use and development of known technical information because "proper incentives for its acquisition and use exist without a property right").

this induces inventors to explore more challenging, socially valuable projects rather than pursuing trivial ones.<sup>265</sup> As Professor Mark Lemley puts it, non-obviousness “sets a minimum threshold social value the invention must contribute in order to make it worth the trouble of issuing and enforcing a patent.”<sup>266</sup>

Like enablement, nonobviousness is a standard. It requires a comparison of the invention with the “prior art,” which refers to preexisting knowledge and technology already available to the public.<sup>267</sup> In *Graham v. John Deere Co.*,<sup>268</sup> the Supreme Court articulated the basic framework for determining nonobviousness. It is a question of law based on the following pertinent underlying facts: (1) the scope and content of the relevant prior art, (2) the differences between the prior art and the claimed invention, (3) the PHOSITA’s level of skill, and (4) secondary considerations that provide objective proof of nonobviousness, like the fact that the invention fulfilled a long-felt but unsolved need.<sup>269</sup>

Thus, inventions that are sufficiently close to the prior art and within the PHOSITA’s technical grasp at the time of filing are unpatentable.<sup>270</sup> This essentially “creates a ‘patent-free’ zone around the state of the art,”<sup>271</sup> allowing the PHOSITA to substitute materials, streamline processes, and

265 Orin S. Kerr, *Rethinking Patent Law in the Administrative State*, 42 WM. & MARY L. REV. 127, 137 (2000); see Michael J. Meurer & Katherine J. Strandburg, *Patent Carrots and Sticks: A Model of Nonobviousness*, 12 LEWIS & CLARK L. REV. 547, 549 (2008) (“The nonobviousness threshold may be used as a ‘stick’ to induce researchers to pursue more difficult, socially preferred research projects.”).

266 Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1001 (1997); see Craig Allen Nard, *Deference, Defiance, and the Useful Arts*, 56 OHIO ST. L.J. 1415, 1437 n.81 (1995) (“The nonobviousness requirement assures that the inventor contributes something to society before she is granted a . . . right to exclude others from making, selling, or using her invention.”).

267 35 U.S.C. § 102 (2012) (defining the documents and activities that can serve as prior art); *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1453 (Fed. Cir. 1984).

268 383 U.S. 1 (1966).

269 *Id.* at 17–18. Subsequent caselaw has established that a conclusion of obviousness must be supported by clearly articulated reasoning. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (explaining that, in addition to the *Graham* factors, “[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness” (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006))); see also MPEP, *supra* note 71, § 2141(III) (listing rationales that examiners can use to support a conclusion of obviousness).

270 See 35 U.S.C. § 103(a); CRAIG ALLEN NARD, *THE LAW OF PATENTS* 305 (2d ed. 2011).

271 MARTIN J. ADELMAN ET AL., *CASES AND MATERIALS ON PATENT LAW* 288 (3d ed. 2009); see also *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) (“[T]he stringent requirements for patent protection . . . assure that ideas in the public domain remain there for the free use of the public.”).

“[make] the usual marginal improvements which occur as a technology matures.”<sup>272</sup>

b. Nonobviousness: The Proper Gatekeeper

The idea that nonobviousness is a more appropriate tool for evaluating technical merit than utility finds support in one of the Federal Circuit’s most powerful dissenting opinions. In *In re Fisher*,<sup>273</sup> the issue before the court was the utility of short DNA sequences known as expressed sequence tags (ESTs).<sup>274</sup> Though the applicant asserted seven uses for the claimed ESTs, the examiner made a § 101 rejection because: (1) the disclosed uses were applicable to all ESTs and not specific to the those claimed, and (2) there was no known use for the proteins produced from the claimed ESTs.<sup>275</sup> Citing *Manson*, the majority affirmed the rejection because the claimed ESTs were merely “research tools” that lacked specific and substantial utility.<sup>276</sup> In dissent, Judge Rader argued that ESTs—like microscopes, screening assays, and nucleotide sequencing techniques—are research tools that “provide a cognizable benefit to society.”<sup>277</sup> But what is most important for present purposes is that he argued that the utility rejection was improper:

In truth, I have some sympathy with the Patent Office’s dilemma. [It] needs some tool to reject inventions that may advance the “useful arts” but not sufficiently to warrant the valuable exclusive right of a patent. The Patent Office has seized upon this utility requirement to reject these research tools as contributing “insubstantially” to the advance of the useful arts. The utility requirement is ill suited to that task, however, because it lacks any standard for assessing the state of the prior art and the contributions of the claimed advance. *The proper tool for assessing sufficient contribution to the useful arts is the [non]obviousness requirement of 35 U.S.C. § 103. . . . [R]ather than distort the utility test, the Patent Office should seek ways to apply the correct test . . . .*<sup>278</sup>

As Professor Mark Janis recently noted, “Judge Rader’s *Fisher* dissent is a powerful reminder of our longstanding commitment to obviousness as the ultimate condition of patentability.”<sup>279</sup>

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272 ADELMAN ET AL., *supra* note 271, at 288; *cf.* Merges, *supra* note 63, at 14 (“[N]onobviousness is designed to maintain a penumbra around the stock of known devices, techniques, etc., insuring that trivial extensions from what is known will not be granted property rights.”).

273 421 F.3d 1365 (Fed. Cir. 2005).

274 *Id.* at 1367.

275 *Id.* at 1367–68.

276 *Id.* at 1369–76.

277 *Id.* at 1382 (Rader, J., dissenting).

278 *Id.* at 1381–82 (emphasis added).

279 Mark D. Janis, *Tuning the Obviousness Inquiry After KSR*, 7 WASH. J.L. TECH. & ARTS 335, 340 (2012); *cf.* Merges, *supra* note 12, at 812 (describing nonobviousness as “the final gatekeeper of the patent system”); John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771, 789 (2003) (describing nonobviousness as “[t]he fundamental gatekeeper to patenting”).

To illustrate how nonobviousness could effectively screen building block inventions, consider again the hypothetical discussed above involving a new class of chemical intermediates that can serve as building blocks for larger compounds.<sup>280</sup> Suppose the applicant has responded to the aforementioned nonenablement rejection by narrowing the scope of the claims to a subgenus of fifty compounds instead of the genus of thousands originally sought. When the examiner compares the subgenus to the prior art,<sup>281</sup> the search reveals that the claimed compounds are novel but very similar to those disclosed in a 1998 book entitled *Chemical Intermediates for Pharmaceuticals*. In fact, the claimed compounds and those described in the book are all members of the same chemical family ("homologs"),<sup>282</sup> the only difference being that a "methyl" group (one carbon) on the core structure of the prior art compounds has been replaced with an "ethyl" group (two carbons) on the core structure of the claimed compounds.<sup>283</sup> Predictably, given the minimal variation in structure, the claimed compounds are prepared by the same methods, have similar physical properties, and undergo the very same chemical reactions (albeit slightly faster) as the prior art compounds.<sup>284</sup>

After making the factual findings set forth by the Supreme Court in *Graham*,<sup>285</sup> the examiner concludes that it would have been obvious for a PHOSITA at the time of the invention to make the claimed compounds. The examiner supports this conclusion with two rationales. First, the claimed compounds are a "straightforward, one-carbon extension"<sup>286</sup> of a carbon chain—a standard structural modification in organic chemistry.<sup>287</sup> They represent "[a] [s]imple substitution of one known [chemical functionality] for another to obtain predictable results."<sup>288</sup> Accordingly, a PHOSITA would have had a reasonable expectation of success in independently arriving at the

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280 See *supra* text accompanying notes 229–41.

281 See *supra* text accompanying note 267.

282 "Homologues" refers to a family of chemical compounds, which vary from member to member by a methylene ( $-\text{CH}_2-$ ) group. *In re Wilder*, 563 F.2d 457, 458 n.7 (C.C.P.A. 1977); see also *In re Coes*, 173 F.2d 1012, 1013–14 (C.C.P.A. 1949) ("A homologous series may therefore be defined as a family of chemically related compounds, the composition of which varies from member to member by one atom of carbon and two atoms of hydrogen." (quoting JULIUS B. COHEN, *THEORETICAL ORGANIC CHEMISTRY* 51 (3d ed. 1934))).

283 A methyl group (Me or  $-\text{CH}_3$ ) is the simplest carbon-containing function group in organic chemistry. An ethyl group (Et or  $-\text{CH}_2\text{H}_3$ ) is the next simplest. THOMAS N. SORRELL, *ORGANIC CHEMISTRY* 20 (2d ed. 2006).

284 See COHEN, *supra* note 282, at 50 (noting that homologs undergo similar chemical reactions); *id.* at 51 ("[T]he advantages of [homology] will now be obvious, for it will only be necessary to describe the chemical characteristics of one member, when that of the whole series of homologues may be inferred.").

285 See *supra* text accompanying note 269.

286 K. PETER C. VOLLHARDT & NEIL E. SCHORE, *ORGANIC CHEMISTRY: STRUCTURE AND FUNCTION* 300 (4th ed. 2003) (describing a "homologation").

287 See *id.*

288 MPEP, *supra* note 71, § 2143(I); see *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) ("[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination

claimed invention.<sup>289</sup> Second and relatedly, *Chemical Intermediates for Pharmaceuticals* and knowledge in the art “would have suggested making the specific molecular modifications necessary to achieve the claimed invention”<sup>290</sup> because in this area of chemistry, ethyl derivatives are known and expected to react slightly faster than the methyl derivatives.<sup>291</sup> Thus, this is a situation where a prior art compound “suggest[s] its homolog . . . because such compounds often have similar properties[,] and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.”<sup>292</sup>

Having made a prima facie case of unpatentability, the burden of going forward shifts to the applicant.<sup>293</sup> The applicant attempts to rebut the prima facie case by arguing that the claimed compounds show an unexpected property over the prior art;<sup>294</sup> namely, that they react faster than a PHOSITA would expect.<sup>295</sup> In response, the examiner explains why the record supports the opposite conclusion: the evidence as a whole<sup>296</sup> gives rise to a presumption that homologs that are structurally very close (“adjacent homologue[s]”)<sup>297</sup> will have similar properties.<sup>298</sup> Of course, since the prior art compounds and the claimed compounds are not identical, *some differ-*

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must do more than yield a predictable result.” (citing *United States v. Adams*, 383 U.S. 39, 50–51 (1966)).

289 See *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360, 1364 (Fed. Cir. 2007) (reaffirming “reasonable expectation of success” jurisprudence post-*KSR*); *In re O’Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988) (“Obviousness does not require absolute predictability . . . [A]ll that is required is a reasonable expectation of success.”).

290 *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007) (quoting *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995)); see also *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1007 (Fed. Cir. 2009) (“[T]o establish a prima facie case of obviousness in cases involving new chemical compounds, the accused infringer must identify some reason that would have led a chemist to modify a known compound in a particular manner.”).

291 See, e.g., *SORRELL*, *supra* note 283, at 148–49 (illustrating how the variation in reactivity of homologous compounds can be attributed to “inductive effects”—the differing ability of methyl and ethyl groups to release electrons); Paul von Ragué Schleyer & Curtis W. Woodworth, *Substituents and Bridgehead Carbonium Ion Reactivities. Inductive and Steric Effects of Alkyl Groups in Saturated Systems*, 90 J. AM. CHEM. SOC’Y 6528, 6528–30 (1968) (exploring the increased rate of reactivity across a homologous series).

292 *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 995–96 (Fed. Cir. 2009) (quoting *Takeda Chem.*, 492 F.3d at 1356–57) (internal quotation marks omitted).

293 *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984).

294 To prevail, the inventor must show “that the claimed invention exhibits some superior property or advantage that [a PHOSITA] would have found surprising or unexpected.” *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995).

295 See *supra* text accompanying note 284.

296 In considering rebuttal evidence, “[t]he ultimate determination of patentability must be based on consideration of the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence.” *MPEP*, *supra* note 71, § 716.01(d).

297 *In re Wilder*, 563 F.2d 457, 458 n.7 (C.C.P.A. 1977).

298 *Id.* at 461.

ences in properties are expected to result.<sup>299</sup> That the claimed compounds react two to three times faster than the prior art compounds, however, is expected because the properties of homologs show regularities of increase (or decrease) across a series.<sup>300</sup> The totality of the evidence shows that the replacement of a methyl with an ethyl was within the capabilities of the PHOSITA, and that the slight increase in reactivity did not “produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art.”<sup>301</sup> Thus, the presumed expectation stands un rebutted. Lacking any additional evidence, the applicant decides to abandon the application.

That the patent is ultimately derailed in this scenario is good for the patent system and very much in line with the goals of the proposal. Even if the building block is new and supported by an enabling disclosure, *Graham* teaches that it “may still not be patentable if the difference between the new thing and what was known before is not considered sufficiently great to warrant a patent.”<sup>302</sup> Making a class of homologs that are virtually identical to the prior art in every respect is a routine endeavor and a mere trivial modification to what is already known. This means that the inventor could *not* provide a useful disclosure to society, because information about the homologs would add nothing to the public storehouse of knowledge.<sup>303</sup> At the time of the invention, the homologs were well within the PHOSITA’s skill and technical grasp and would have arisen through ordinary technological progress.<sup>304</sup> Indeed, organic chemists contemplate homologs all the time when constructing compounds with desired properties.<sup>305</sup>

This hypothetical reveals that nonobviousness ultimately performs three interrelated and important gatekeeping functions. First, it protects (the integrity of) the public storehouse of knowledge.<sup>306</sup> Second, it maintains a “patent-free zone” around the prior art, which allows researchers to tinker.<sup>307</sup> Third, it “weed[s] out those inventions [that] would not be disclosed or

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299 MPEP, *supra* note 71, § 716.02.

300 GEORGE FOWNES, A MANUAL OF ELEMENTARY CHEMISTRY 395 (London, John Churchill, 7th ed. 1858). See generally W.H. PERKIN & F. STANLEY KIPPING, ORGANIC CHEMISTRY 67–442 (1900) (discussing the properties of homologs).

301 *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955), quoted in *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004); see *In re Merck & Co.*, 800 F.2d 1091, 1099 (Fed. Cir. 1986) (finding *prima facie* obviousness was not overcome where the alleged difference in properties between the claimed compound and the prior art compound “is a matter of degree rather than kind”).

302 *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966) (quoting H.R. REP. NO. 82-1923, at 7 (1952)).

303 See *supra* note 264 and accompanying text.

304 Miller, *supra* note 263, at 2 (“It is socially wasteful for us to pay a patent-backed premium for an innovation that we are almost certain to receive for free and just as early.” (footnote omitted)).

305 See *supra* note 292 and accompanying text.

306 See *supra* note 264 and accompanying text.

307 See *supra* notes 271–72 and accompanying text.



devised but for the inducement of a patent.”<sup>308</sup> But unlike utility, nonobviousness is determined through an objective, fact-intensive inquiry.

### C. *Whither Utility?*

Allowing patents on microscale building blocks raises the question of what to do about utility. Since assessing utility necessarily involves foresight bias,<sup>309</sup> its role in patent law should be significantly diminished. The previous Section shows that enablement and nonobviousness can effectively constrain patent scope and evaluate technical merit without § 101. It is for these reasons that the term “useful” should once again be given a *de minimis* interpretation.<sup>310</sup> This would essentially remove utility from the patentability calculus.<sup>311</sup>

## III. POLICY IMPLICATIONS

Foresight bias arises in the microscale building block context out of the fear that the patentee could substantially impede technological progress by controlling access to the building block. Indeed, some commentators have argued that the utility standard of § 101 should be fortified to ensure that microscale building blocks remain freely accessible.<sup>312</sup> This Part responds to concerns that the proposal might impede downstream research. To the contrary, the proposal would not only represent a significant step forward in resolving the law-science disconnect but also help fulfill broader goals of patent policy.

### A. *Disclosure over Secrecy*

The *quid pro quo* rationale for patents is to incentivize the disclosure of information that the public might not otherwise get.<sup>313</sup> For the patentee, the incentive for full public disclosure of the invention is the limited period of exclusionary rights.<sup>314</sup> For the public, the exchange serves the public

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308 *Graham v. John Deere Co.*, 383 U.S. 1, 11 (1966).

309 *See supra* text accompanying notes 28–47.

310 *See supra* subsection I.B.1.

311 It is possible to make additional, independent arguments that utility should be eliminated from patent law. *See* 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”).

312 Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & CONTEMP. PROBS. 289, 299 (2003).

313 WALTERSCHEID, *supra* note 32, at 143.

314 *See* *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 142 (2001) (“The disclosure required by the Patent Act is the *quid pro quo* of the right to exclude.” (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974)) (internal quotation marks omitted)); *Kewanee*, 416 U.S. at 480–81 (describing the *quid pro quo* that supports the patent grant as a constitutional objective).

good because the disclosed information enriches the public storehouse of technical knowledge once the patent document publishes.<sup>315</sup>

The patent system goes to great lengths to promote and safeguard the disclosure function, which is regarded as “a centerpiece of patent policy.”<sup>316</sup> The inventor’s early public disclosure is the ultimate goal<sup>317</sup> because it facilitates commercialization, coordinates the development of technology, reduces wasteful duplicative efforts by competitors, and dedicates the invention to the public at an earlier time.<sup>318</sup> In fact, inventors who do not file promptly compromise their patent rights.<sup>319</sup>

If disclosure is the centerpiece of patent policy, then secrecy is its antithesis.<sup>320</sup> It would seem that any patentability requirement that fosters secrecy

315 *Kewanee*, 416 U.S. at 481 (explaining that when the information disclosed in a patent becomes publicly available it adds to the “general store of knowledge” and assumedly will stimulate ideas and promote technological development); *In re Argoudelis*, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring) (noting that the full and complete disclosure of how to make and use the claimed invention “adds a measure of worthwhile knowledge to the public storehouse”). Patent documents include issued patents and published patent applications. Note that once a patent application publishes, the information disclosed therein is considered known to the public even if it never matures into a patent. See 35 U.S.C. § 102 (2012).

316 Note, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007, 2011 (2005); see *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) (explaining that the patent system should be viewed as “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”).

317 *W.L. Gore & Assocs., Inc., v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983) (“Early public disclosure is a linchpin of the patent system.”).

318 John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 445 (2004); Kitch, *supra* note 137, at 269–77. Professor Pamela Samuelson explains:

Innovators who have a choice between trade 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 trade secret option would produce.

Pamela Samuelson, Lecture, *Enriching Discourse on Public Domains*, 55 DUKE L.J. 783, 829 (2006).

319 For example, an applicant must file a patent application within one year of disclosing the invention in a printed publication. 35 U.S.C. § 102(b)(1). A fundamental purpose of § 102(b) is to encourage prompt filing. *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).

320 See J. Jonas Anderson, *Secret Inventions*, 26 BERKELEY TECH. L.J. 917, 919 (2011) (“Patents are often conceptualized as a means of luring secret inventions out of the dark, shadowy cave of trade secrecy, and into the bright, public sunlight of the patent system.”); see also Jason Mazzone & Matthew Moore, *The Secret Life of Patents*, 48 WASHBURN L.J. 33, 35 (2008) (explaining how federal patent law “expresses a clear preference for the inventor who discloses an invention to the public and obtains a patent over the inventor who keeps the invention a secret”).

should have no place in patent law.<sup>321</sup> But the utility requirement of § 101—as it applied to microscale building block inventions—does just that! Consider the hypothetical posed earlier: an inventor at AcmePharma who invented *X*—a complex, hard-to-make, molecular knot that was useful as a building block for larger compounds—was denied a patent for a lack of utility.<sup>322</sup> Recall that AcmePharma invested \$1.6 billion in the project to find a suitable replacement for Lipitor. AcmePharma has every incentive to keep the technical details about *X* secret unless and until it develops a Lipitor replacement or some other drug.<sup>323</sup>

This outcome clearly frustrates fundamental goals of the patent system. If a patent document never publishes, knowledge about *X* never enters the public storehouse of knowledge. Since patenting induces inventors to disclose technical information about the invention in forums *outside* of the patent system (like scientific publications),<sup>324</sup> the public storehouse of knowledge is even more deprived. This increases the likelihood of wasteful duplicative efforts of competitors as they try to figure out how to make *X*.<sup>325</sup>

There is another scenario that should give the patent system considerable pause.<sup>326</sup> Suppose AcmePharma decides to disclose *X* without an identifiable end use. Currently AcmePharma cannot obtain a patent because of a lack of utility.<sup>327</sup> But suppose that a second researcher discovers a use for *X*.

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321 It is worth noting that certain provisions of the America Invents Act (AIA) might encourage secrecy. Most notably, AIA § 102(a)(1) can be interpreted to disqualify the inventor's secret commercial activities as prior art. See Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 54 (2012) (arguing that the AIA repeals the forfeiture doctrine articulated in *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 519–20 (2d Cir. 1946)). This interpretation would allow inventors to practice their inventions as trade secrets indefinitely before obtaining a patent unless and until someone else independently invents and discloses it. Paul Morgan, *The Ambiguity in Section 102(a)(1) of the Leahy-Smith America Invents Act*, 2011 PATENTLY-O PAT. L.J. 29, 31, available at <http://patentlyo.com/media/docs/2011/12/morgan.2011.aia.ambiguities.pdf>.

322 See *supra* text accompanying notes 53–60.

323 See Anderson & Dyson, *supra* note 85, 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”).

324 See Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 146 (2006) (“An 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 and not by a trade secret.”); Jason Rantanen, *Peripheral Disclosure*, 74 U. PITT. L. REV. 1, 21–37 (2012) (describing non-patent invention disclosures).

325 Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1028 (1989); 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”).

326 See MERGES & DUFFY, *supra* note 27, at 230 (describing the problem).

327 See *supra* Section I.C.

Unfortunately, the caselaw makes it crystal clear that the second researcher also cannot obtain a patent on *X* because it has entered the public domain.<sup>328</sup> At best, the second researcher will have to *settle for a much less valuable patent* on the specific use identified.<sup>329</sup> Again, this might create an incentive for one who invents a chemical to keep it secret while a use is sought.<sup>330</sup>

Even if AcmePharma cannot make a Lipitor replacement, were *X* patented and licensed, one of AcmePharma's licensees might have the creative and technical skills to do so. However, the public good is still served if that never happens. As soon as a patent document disclosing *X* publishes, there is hope that the public will use the technical details disclosed therein to improve upon *X*, to design around it, or to engage in other innovative activities.<sup>331</sup> Although AcmePharma maintains the right to exclude others from practicing *X* until the end of the patent term, "the technical information disclosed in the patent document has potential immediate value to the public, which can use the information for any purpose that does not infringe upon the claims."<sup>332</sup> Again, this supports the patent system's broader mission to promote technological progress and extend the frontiers of knowledge.<sup>333</sup>

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328 *In re Hafner*, 410 F.2d 1403, 1405 (C.C.P.A. 1969).

329 In other words, the subsequent inventor can possibly obtain a "method of use" patent for *X*. See 35 U.S.C. § 100(b) (2012) (defining a patentable "process" to "include[ ] a new use of a known . . . composition of matter, or material"); *Merck & Co. v. Teva Pharm. USA, Inc.*, 347 F.3d 1367, 1372 (Fed. Cir. 2003) (explaining that a new use for a known compound can be patented with a "method" claim). There are, however, two principal reasons why a "composition of matter claim" covering *X* is more valuable than those directed to a specific "method of making" or "method of using" *X*. First, compound claims afford the broadest protection. See *In re Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963) (discussing the "well-recognized advantages" of composition-of-matter claims); *supra* note 196 and accompanying text. Second and relatedly, method patents are difficult to enforce because the patentee "acquires only the right to preclude others from using the chemical in the exact manner he has disclosed." Paul H. Eggert, *Uses, New Uses and Chemical Patents—A Proposal*, 51 J. PAT. OFF. SOC'Y 768, 781 (1969). So the method patent might be too narrow to cover other uses for *X* that come to the fore during its term. Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 720 (2005).

330 MERGES & DUFFY, *supra* note 27, at 230; see *supra* note 323.

331 MICHAEL A. GOLLIN, DRIVING INNOVATION 15–19 (2008) (explaining that disclosure adds to the pool of accessible knowledge that other creative individuals can use and improve upon).

332 Seymore, *supra* note 214, at 624 (citing *Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd.*, [2004] UKHL 46, [2005] R.P.C. 9 at ¶ 77 (Hoffmann, L.J.)); see also Diane Leenheer Zimmerman, *Is There a Right to Have Something to Say? One View of the Public Domain*, 73 FORDHAM L. REV. 297, 303 n.23 (2004) ("A patent application must disclose the nature of the invention in detail, and although the public cannot practice the art during the period of the patent, it can use the information disclosed in a variety of other ways.").

333 This goal emanates from the Intellectual Property Clause of the Constitution: "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. I, § 8, cl. 8; see also *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966) ("Innova-

Nevertheless, concerns about secrecy are often downplayed because it is assumed that the invention will be inevitably disclosed—either in a patent or somewhere else.<sup>334</sup> This is an empirical question that is hard to answer.<sup>335</sup> Nonetheless, several points can be made. First, many nonacademic patentees choose not to disclose the technical details of their inventions outside of the patent system. Indeed, most information disclosed in a patent does not appear in another medium.<sup>336</sup> This is particularly true in industry, where scientists publish relatively little.<sup>337</sup> So, much technical information undisclosed through the patent system never enters the public storehouse of knowledge and will likely be lost.<sup>338</sup>

Second, some inventors concoct trivial uses simply to satisfy the utility requirement.<sup>339</sup> For example, AcmePharma might assert that *X* is a good lubricant, detergent, or fuel just to get the compound patented.<sup>340</sup> Judge Rich believed that having to concoct utilities to meet the legal standard is a poor expenditure of technical brainpower<sup>341</sup> and wastes time and effort

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tion, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system . . . .”); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917) (“[T]he primary purpose of our patent laws . . . is ‘to promote the progress of science and useful arts . . . .’” (quoting U.S. CONST. art. I, § 8, cl. 8)).

334 See, e.g., *Brenner v. Manson*, 383 U.S. 519, 534 (1966) (noting that concerns about the virtues of disclosure and secrecy are “easily exaggerated”).

335 It is virtually impossible to find out how many inventors forego patenting altogether because of a lack of utility.

336 Fromer, *supra* note 66, at 554; see also ESTEBAN BURRONE & GURIOBAL SINGH JAIYA, WORLD INTELLECTUAL PROP. ORG., INTELLECTUAL PROPERTY (IP) RIGHTS AND INNOVATION IN SMALL AND MEDIUM-SIZED ENTERPRISES para. 5, available at [http://www.wipo.int/export/sites/www/sme/en/documents/pdf/iprs\\_innovation.pdf](http://www.wipo.int/export/sites/www/sme/en/documents/pdf/iprs_innovation.pdf) (“It has been estimated that patent documents contain 70% of the world’s accumulated technical knowledge and that most of the information contained in patent documents is either never published elsewhere or is first disclosed through the publication of the patent application.”).

337 See generally Benoît Godin, *Research and the Practice of Publication in Industries*, 25 RES. POL’Y 587 (1996) (presenting various explanations and using bibliometrics to assess the usefulness of publication in industry). The highest priority for an industrial inventor is to generate results that show commercial promise and will ultimately find their way into a marketable product. Partha Dasgupta & Paul A. David, *Information Disclosure and the Economics of Science and Technology*, in ARROW AND THE ASCENT OF MODERN ECONOMIC THEORY 519, 522 (George R. Feiwel ed., 1987); see also Diana Hicks, *Published Papers, Tacit Competencies and Corporate Management of the Public/Private Character of Knowledge*, 4 INDUS. & CORP. CHANGE 401, 413–14 (1995) (“After all, writing papers makes no money and consumes time.”).

338 See Seymore, *supra* note 214, at 666 (discussing situations in which “the patent system is the sole medium of disclosure”).

339 See *In re Kirk*, 376 F.2d 936, 960–61 (C.C.P.A. 1967) (Rich, J., dissenting) (describing such behavior); *supra* Section II.A.

340 See Anderson & Dyson, *supra* note 85, at 817 (“[W]here patent protection is imperative, *Kirk* and *Joly* encourage the disclosure of trivial uses, developed only in an attempt to satisfy the new judicial interpretation of the statute.”).

341 *In re Kirk*, 376 F.2d at 960–61 (Rich, J., dissenting).

“which ought to be directed at a more worthy end.”<sup>342</sup> It also frustrates the disclosure function by filling the patent document (and ultimately the public storehouse of knowledge) with unhelpful information.<sup>343</sup>

Third, even if the invention is ultimately patented after a suitable use is found, the disclosure is inevitably delayed.<sup>344</sup> In other words, the technical information enters the public storehouse later rather than sooner. Of course, this conflicts directly with the patent system’s goal of promoting early disclosure.<sup>345</sup> Clearly concealment or delayed disclosure of otherwise new, nonobvious, and enabled subject matter into the public storehouse hinders innovation and frustrates basic goals of the patent system.

The approach proposed in this Article would alleviate these problems. An inventor who invents a microscale building block that does not appear to satisfy § 101 would no longer have a reason to keep the invention secret until a suitable use is found. Relatedly, there would be no need to concoct a trivial use to satisfy the statute. Rigorous enforcement of the enablement and non-obviousness requirements could ensure that the public gets a disclosure that adds robust technical information to the public storehouse of knowledge.<sup>346</sup>

### B. Addressing Fears

It is fair to say that there is widespread belief that “too many patents are granted on too many inventions.”<sup>347</sup> Thus, any proposal that potentially opens the doors of patentability goes against the grain of most academic commentary and conventional thinking about patent reform. In this Section, I respond to concerns that implementing the proposal could potentially slow, rather than promote, research and development activities.

#### 1. The Anticommons Hypothesis

The principal rationale for limiting patents on “upstream” inventions like microscale building blocks is that failing to do so would inhibit future research and hinder “downstream” innovation.<sup>348</sup> A specific concern is that

342 *Id.* at 961.

343 See Seymore, *supra* note 214, at 632 (criticizing disclosure practices which add no technical value to the patent literature).

344 *In re Joly*, 376 F.2d 906, 924 (C.C.P.A. 1967) (Smith, J., dissenting).

345 See *supra* notes 317–18 and accompanying text.

346 See *infra* Section III.B.

347 Jonathan Masur, *Patent Inflation*, 121 *YALE L.J.* 470, 480 (2011).

348 For a general theoretical discussion, see Merges & Nelson, *supra* note 192, at 842–44, 894–908 (discussing how upstream patents can retard downstream innovation); Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 *J. ECON. PERSP.* 29, 30–32 (1991) (same). Defining what constitutes “upstream” and “downstream” research can be tricky depending on the nature of the research project. But in a general sense, the terms “upstream” and “downstream” are used “to identify the proximity (temporal and conceptual) of particular research to a particular end product.” Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 *BERKELEY TECH. L.J.* 813, 816 n.9 (2001). Sometimes “upstream” is used as a

“patents on research inputs may . . . impede upstream, noncommercial research by creating 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.”<sup>349</sup> When Michael Heller and Rebecca Eisenberg articulated the anticommons hypothesis in 1998,<sup>350</sup> they posited that the phenomenon would impose significant costs in biotechnology—a field where progress depends on the accessibility of (upstream) research inputs like proteins and DNA fragments.<sup>351</sup>

If an anticommons exists in biotechnology, one should be able to look at the field for evidence of its operation. For instance, if research inputs have been over-patented, one might expect that research and development (R&D) activities would decrease because they would be more costly and difficult to undertake. The evidence, however, shows the exact opposite as R&D expenditures, venture capital investment, and the number of industry personnel have *increased* since the time the anticommons effect was posited.<sup>352</sup>

Empirical inquiries into anticommons effects in biotechnology have been unable to provide evidence that the patenting of research inputs is adversely affecting innovation. The inquiries include studies of datasets of

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synonym for “basic” research, which consists of “systematic study directed toward fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind.” OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, CIRCULAR NO. A-11: PREPARATION, SUBMISSION, AND EXECUTION OF THE BUDGET § 84, at 8 (2014).

349 John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002 (2005). A related concern is that those holding patents to research inputs “may restrict follow-on research through the exercise of exclusivity.” *Id.*; cf. Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 123 (“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 . . .”).

350 Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698–99 (1998).

351 See NAT’L INSTS. OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS 5 (1998), available at <http://biotech.law.lsu.edu/research/fed/NIH/researchtools/Report98.htm> (“The tools of the trade in biomedical research and development are crucial for all bench scientists, and access to new tools has a dramatic impact on the progress of research.”); see also Heller & Eisenberg, *supra* note 350, at 699.

352 In 2007, the Biotechnology Industry Organization (BIO)—the world’s largest biotechnology trade organization representing 1,100 members—released a whitepaper to examine the anticommons from a theoretical and empirical basis. See TED BUCKLEY, THE MYTH OF THE ANTICOMMONS (2007), available at <http://www.bio.org/sites/default/files/TheMythoftheAnticommons.pdf>. To summarize the results: the R&D expenditures of R&D companies increased by over sixty percent from 1998 through 2005, the amount of venture capital funding increased by 300% from 1995 through 2005, and the number of industry employees increased by twenty-one percent from 1998 through 2005. *Id.* at 6–9.

biotechnology patents<sup>353</sup> and surveys of intellectual property attorneys, scientists, and technology managers from academia and industry about the impact of patents on their work.<sup>354</sup> The authors of the surveys have explained that the results fail to show that the hypothesized mechanism is operating:

Studies that have examined the incidence of access or anti-commons problems find them, however, to be rare, even for industry scientists, and especially so for academic scientists. . . . [A]lthough *complaints* about access to patented technologies and findings are not rare . . . such limitations never caused the academic scientists . . . to stop a promising line of research. Finally, they find no evidence of academics being excluded from research due to patents on research 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.<sup>355</sup>

Indeed, some commentators have convincingly argued that patents can actually *promote* R&D.<sup>356</sup> Nonetheless, there are a host of reasons why an

353 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 52,000 biotechnology patents from January 1990 through December 2004, that there is “little evidence that the recent growth in biotechnology patenting is threatening innovation”).

354 See John P. Walsh et al., *Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research*, 36 RES. POL’Y 1184, 1185–86 (2007) [hereinafter Walsh et al., *Where Excludability Matters*] (reporting on a survey of 507 academic biomedical researchers); John P. Walsh et al., *supra* note 349, at 2002–03 (reporting the findings from a survey of 414 biotech researchers in academia, government, and nonprofit institutions); John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) [Walsh et al., *Research Tools Patents*] (reporting the findings from a survey of seventy respondents which included intellectual property attorneys, scientists, and managers from biotech firms, pharmaceutical firms, and university-based researchers).

355 Wesley M. Cohen & John P. Walsh, *Access—or Not—in Academic Biomedical Research*, in WORKING WITHIN THE BOUNDARIES OF INTELLECTUAL PROPERTY 1, 14–15 (Rochelle C. Dreyfuss et al. eds., 2010) (footnotes omitted). Of course, the lack of enforcement can contribute to this observation. One particular result is worth highlighting. A random sample of 381 academic researchers (including some doing drug development or other downstream work) revealed that only one percent reported having to delay or modify a project because of a patent, yet none reported having to abandon a project because of a patent. Walsh et al., *supra* note 349, at 2002.

356 See BUCKLEY, *supra* note 352, at 12 (“[B]iotechnology companies have stated not only are patents not hurting them, but on the contrary the ability to patent is a prerequisite for commercial success.”); Walsh et al., *Research Tools Patents*, *supra* note 354, at 289 (“[T]here is still ample reason—and recent scholarship—to suggest that patenting benefits biomedical innovation, especially via its considerable impact on R&D incentives or via its role in supporting an active market for technology.” (citation omitted)). Some commentators have even argued that limiting patents on research tools could actually *harm* basic science research by depriving it of the financial support that it needs. See Aaron S. Kesselheim & Jerry Avorn, *University-Based Science and Biotechnology Products: Defining the Boundaries of Intellectual Property*, 293 J. AM. MED. ASS’N 850, 852–53 (2005) (describing the decline in public funding and the rise in private funding for basic science research).



anticommons is not observed.<sup>357</sup>

One final point bears mention. The lack of evidence to support an anticommons hypothesis in biotechnology brings to light the disconnect between patent law and science.<sup>358</sup> Proponents of the hypothesis “either ignore[d] the characteristics of the scientific commons altogether or base[d] their views on questionable assumptions about it, such as the assumption that upstream patents will inevitably restrict access to essential research tools for which no alternatives exist.”<sup>359</sup> Indeed, evidence suggests that such assumptions are mistaken. A National Research Council study on patenting in biotechnology found that academic scientists abandon or delay research projects *not* because of overpatenting but for reasons that concern all academic scientists—namely “lack of funding, conflict with other priorities, a judgment that the project was not feasible, not scientifically important, or not that interesting, and the perception that the field was too crowded with competing investigators.”<sup>360</sup> All of this has led to a rethinking of the anticommons hypothesis<sup>361</sup> and its role in shaping patent policy.<sup>362</sup>

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357 First, it is widely believed that academic researchers ignore patents. See Katherine J. Strandburg, *User Innovator Community Norms: At the Boundary Between Academic and Industry Research*, 77 *FORDHAM L. REV.* 2237, 2250 (2009) (describing the “norm of ignoring patents” among scientists); Walsh et al., *Where Excludability Matters*, *supra* note 354, at 1189–90 (noting that the survey results reveal that academic scientists do not check for patents before commencing research). Industrial researchers might ignore patents because practicing an invention with knowledge of another’s valid patent could lead to a finding of willful infringement (which includes increased damages). Mark A. Lemley, *Ignoring Patents*, 2008 *MICH. ST. L. REV.* 19, 21. Second, many patent owners opt not to enforce their patents against academic researchers because of the high costs of detecting infringement, high litigation costs, and the low value of a potential lawsuit. Rebecca S. Eisenberg, *Non-compliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 *HOUS. L. REV.* 1059, 1062 (2008). Patentees 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). Third, sometimes the user takes a license. See Lori Pressman et al., *The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey*, 24 *NATURE BIOTECHNOLOGY* 31, 31–39 (2006). Fourth, researchers can “design around” the patented technology. See *infra* notes 370–71 and accompanying text. Fifth, a potential infringer may opt to challenge the patent. Wesley M. Cohen & John P. Walsh, *Real Impediments to Academic Biomedical Research*, 8 *INNOVATION POL’Y & ECON.* 1, 12 (2007).

358 For additional commentary on the disconnect, see sources cited *supra* note 68.

359 Adelman & DeAngelis, *supra* note 353, at 1686; see F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 *Nw. U. L. REV.* 691, 702–04 (2001) (arguing that, contrary to the beliefs of the patent critics, patents are essential to promoting the central norms of the basic biological research community).

360 NAT’L RESEARCH COUNCIL, *REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH* 123 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006).

361 Eisenberg, *supra* note 357, at 1061–62 (describing the empirical studies which suggest that the hypothesized anticommons effect in biotechnology has not materialized).

## 2. Controlling the Development of Technology

At this point, it is necessary to address two additional concerns related to the holder of a microscale building block patent to control the development of technology. First, it is not clear why microscale building blocks lacking a specific or substantial utility at the time of filing<sup>363</sup> would raise greater blocking concerns than those which pass the test. For example, consider an inventor who invents compound *Y*. Having determined that a patent is imperative, the inventor discloses a trivial use—that *Y* is useful as a fragrance since it has a pleasant odor—to pass muster under § 101. After the patent issues, it is discovered that *Y* is a synthetic precursor to *Z*—the first compound known to effectively regenerate human teeth.<sup>364</sup> Though the patent on *Y* will cover uses beyond those disclosed,<sup>365</sup> that the patentee can play a role in coordinating the future development of technology aligns with patent theory.<sup>366</sup> Nevertheless, the inventor's decision of how (or if) to license the patent for the emerging field of tooth regeneration has nothing to do with the utility disclosed (*Y*'s fragrant properties) to get the patent. This supports the argument that utility is a superfluous patentability requirement that does no real work.<sup>367</sup>

Second, granting a patent on a microscale building block need not—and probably will not—block off an entire field of research and create a unitary monopoly.<sup>368</sup> To begin, a patentee can exercise significant control over research progress only if there are no close substitutes for the building block

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362 See David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 1029 (2005) (observing that in biotechnology the anticommmons effect has not been confirmed by empirical studies and that the patenting of research tools “has not conformed as predicted” by theorists).

363 See discussion *supra* Section I.C.

364 See, e.g., Kazuhisa Nakao et al., *The Development of a Bioengineered Organ Germ Method*, 4 NATURE METHODS 227, 227–30 (2007) (describing a technique where researchers grew a budding tooth in a Petri dish and then transplanted it into the an empty cavity in a mouse's mouth, where it grew to full size); Zunyi Zhang et al., *Antagonistic Actions of *Msx1* and *Osr2* Pattern Mammalian Teeth into a Single Row*, 323 SCIENCE 1232, 1232–34 (2009) (reporting that deleting a specific gene in mice led them to grow extra teeth). Both groups believe that their findings will help elucidate how nature makes teeth and, eventually, lead to tooth regeneration in humans.

365 As Professor 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); see *supra* notes 195–96 and accompanying text. An “embodiment” is a concrete, physical form of an invention described in a patent application or patent. MERGES & DUFFY, *supra* note 27, at 27.

366 See Kitch, *supra* note 137, at 276–77 (discussing the prospect theory of patents); *supra* notes 197–98 and accompanying text.

367 See *supra* Section II.C.

368 Lawrence R. Velvel, *A Critique of Brenner vs. Manson*, 49 J. PAT. OFF. SOC'Y 5, 10 (1967).

and there are no close substitutes for research projects that require the building block.<sup>369</sup> In addition, other inventors can certainly design around the claimed building block and hopefully invent a better one.<sup>370</sup> This is a positive result for the patent system, which in fact encourages such behavior.<sup>371</sup> Although the patentee can exclude others from practicing the invention until the patent term expires, there is hope that the patent will foster innovation by inducing others to design around the invention and make new products and processes.<sup>372</sup> Designing around an invention lies at the heart of competition and ultimately benefits the public.<sup>373</sup>

### C. Fostering and Rewarding Invention

The Supreme Court has emphasized that two fundamental policy objectives of the patent system are to foster and reward invention and to promote the disclosure of inventions to stimulate further innovation.<sup>374</sup> The reward, of course, is the exclusionary right conferred by the patent grant.<sup>375</sup> The goals are related: the reward of a patent encourages inventors to invent<sup>376</sup> and publicly disclose<sup>377</sup> the technical details of the invention rather than keeping them as a trade secret.<sup>378</sup>

A starting point for fostering and rewarding invention is to eliminate obstacles that discourage applicants from entering the patent system in the

369 Strandburg, *supra* note 349, at 124 (citing Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 15 (2001)).

370 However, the lack of a robust experimental use defense in patent law impinges on design-around opportunities and thus the teaching function of the patent disclosure. Holbrook, *supra* note 324, at 140 ("One can read the patent but cannot make or use the invention for purposes of exploring its function or the manner in which it works.").

371 London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed. Cir. 1991).

372 *Id.*

373 State Indus., Inc. v. A.O. Smith Corp., 751 F.2d 1226, 1235–36 (Fed. Cir. 1985).

374 Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979) (citing *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974)).

375 *Atl. Works v. Brady*, 107 U.S. 192, 200 (1882). For a discussion of the "long intellectual history" of the reward theory of patent law and arguments for and against it, see Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 310–14 (1992).

376 Mark D. Janis & Timothy R. Holbrook, *Patent Law's Audience*, 97 MINN. L. REV. 72, 122 (2012) ("[T]he ex ante 'incentive to invent' theory of patent law suggests that the promise of patent protection will induce would-be innovators to engage in the inventive enterprise because they know they will be able to recoup their sunk, fixed research and development (R&D) costs over the lifetime of the patent by exploiting the patent's exclusionary power.").

377 Eisenberg, *supra* note 325, at 1028 ("The incentive to disclose argument . . . rests on the premise that in the absence of patent protection inventors would keep their inventions secret in order to prevent competitors from exploiting them.").

378 *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944); *see Abramowicz & Duffy, supra* note 258, at 1622 ("[T]rade secrecy protection can theoretically provide even more powerful incentives than patents because trade secrecy rights are potentially infinite in duration."); *supra* note 320 and accompanying text.

first place. The modern utility requirement is one such obstacle—at least for those who seek patents on chemicals, seemingly impossible inventions, paradigm-shifting inventions, and inventions emerging from nascent technologies. All inventors want to believe that they will get—and are, in fact, entitled to—a fair shot at getting a patent. But if potential applicants believe that the Patent Office and the courts are biased against granting patents for certain types of inventions (which is likely given the subjective nature of the utility requirement), they may decide not to waste their time and money pursuing a patent if a denial is inevitable. Put simply, “[i]nventors [r]espond to [h]ow the Patent Office [b]ehaves.”<sup>379</sup>

The proposal shifts this paradigm. An inventor who knows that a building block invention will receive an objective, fact-based examination might decide to seek a patent. In other words, the proposed regime’s elimination of foresight bias might *attract* inventors to the patent system who currently forego patenting because of § 101. This would be a win-win-win for the patentee, society, and the patent system.<sup>380</sup>

#### CONCLUSION

Foresight bias has no place in patent law. It is nearly impossible to predict how a patentee might behave (with regard to licensing the technology or enforcing the patent) or whether technological progress will be stalled if a patent is granted on a building block. Empirical inquiries into anticommons effects suggest that the hypothesized negative effects of upstream patents on downstream research have not materialized. This has led to a rethinking of the anticommons hypothesis and its role in shaping patent policy.

Foresight bias is an artifact of the patent system’s struggle to adjust to an evolving invention landscape. A problem of scale exists in patent law that leads decision-makers to fear things that they cannot see, let alone understand. Indeed, the *unpredictable* nature of fields like chemistry and biotechnology—the attribute that fuels research, creates new possibilities, leads to paradigm shifts, and does other things that the patent system seeks to promote—is what fuels foresight bias.<sup>381</sup> But this can be fixed. Evaluating building block inventions objectively and eviscerating the utility requirement will do just that. Implementing this proposal will promote disclosure, foster more creative activity, and reduce wasteful duplicative research efforts—all important objectives of the patent system. Finally, eliminating the bias will reconnect the patent system with many of the technical communities that it serves.

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379 JAFFE & LERNER, *supra* note 1, at 175.

380 See *supra* text accompanying notes 65–67.

381 *Diamond v. Chakrabarty*, 447 U.S. 303, 316 (1980) (“[T]he inventions most benefiting mankind are those that ‘push back the frontiers of chemistry, physics, and the like.’” (quoting *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 154 (1950) (Douglas, J., concurring))). Such inventions align with the purposes and “core concept[s]” of patent law. *Id.* at 315–16.