

# Patenting New Uses for Old Inventions

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*A bedrock principle of patent law is that old inventions cannot be patented. And a new use for an old invention does not render the old invention patentable. This is because patent law requires novelty—an invention must be new. But while a new use for an old invention does not make the old invention patentable, the new use itself might be patentable. In fact, new-use patents comprise a significant part of the patent landscape—particularly in pharmaceuticals, when drug companies obtain new-use patents to repurpose old drugs. This trend has fueled debates over follow-on innovation and patent quality. But there is a problem with new-use patents that has escaped the attention of legal scholars and commentators. The problem is when an inventor seeks a new-use patent for an old product that is, on close inspection, not new because the old product is really doing the same thing that it did before. This is a technical question that requires some understanding of the underlying science—how and why a result is achieved. But various evidentiary rules, biases, and perfunctory views of novelty preclude a true and accurate patentability assessment. Sometimes this leads to unwarranted patents; other times it derails meritorious inventions.*

*This Article corrects this problem by offering a new framework for evaluating novelty in new-use patent claims. It proposes a probing novelty inquiry that would require inventors to elucidate and disclose mechanistic information to prove that a claimed new use is truly novel. Providing mechanistic information would promote patent law's disclosure function and improve patent (examination) quality. At a broader level, this Article raises the normative and theoretical question of what it means to be identical—which is what novelty is all about. It also raises policy questions about novelty's gatekeeping function and its role in promoting broader goals of the patent system.*

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## INTRODUCTION

A bedrock principle of patent law is that an old invention cannot be patented.<sup>1</sup> And a newly discovered use for an old invention does not render the old invention patentable.<sup>2</sup> In fact, a patent *cannot* issue because it would restrict the public’s free access to something already

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1. WILLARD PHILLIPS, THE LAW OF PATENTS FOR INVENTIONS; INCLUDING THE REMEDIES AND LEGAL PROCEEDINGS IN RELATION TO PATENT RIGHTS 150 (Boston, Am. Stationers’ Co. 1837) (“It is an essential requisite that the invention shall be *new*.”).

2. JOHN PAXTON NORMAN, A TREATISE ON THE LAW AND PRACTICE RELATING TO LETTERS PATENT FOR INVENTIONS 10 (London, Butterworths 1853); accord *Howes v. Great Lakes Press Corp.*, 679 F.2d 1023, 1029 (2d Cir. 1982). As Justice Story famously explained, “A coffee mill applied for the first time to grind oats, or corn, or mustard, would not give a title to a patent for the machine.” *Bean v. Smallwood*, 2 F. Cas. 1142, 1143 (C.C.D. Mass. 1843) (No. 1,173); cf. *Phillips v. Page*, 65 U.S. (24 How.) 164, 167–68 (1861) (holding that a new use for an old saw does not render the saw patentable).

in the public domain.<sup>3</sup> Patent law requires novelty,<sup>4</sup> meaning that an invention “must be *new*, that is, bestowed for the first time upon the public by the patentee.”<sup>5</sup>

While discovering a new use for an old invention does not render an old invention patentable,<sup>6</sup> the new use itself *might* be patentable.<sup>7</sup> This gives rise to so-called new-use patents.<sup>8</sup> Consider aspirin—acetylsalicylic acid—patented by Bayer in 1900.<sup>9</sup> When the patent expired in 1917, aspirin fell into the public domain<sup>10</sup> and acetylsalicylic acid became unavailable for (re)patenting by Bayer or any other party.<sup>11</sup> But new *uses* for aspirin are patentable.<sup>12</sup>

Indeed, the quest to find new uses for old drugs like aspirin deserves special attention. Over two-thirds of the value of worldwide patents accrues to chemical and pharmaceutical firms, and more than half accrues to a small number of large pharmaceutical firms.<sup>13</sup> The cost

3. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 147–48 (1989); *Graham v. John Deere Co.*, 383 U.S. 1, 5–6 (1966).

4. Novelty is the statutory requirement that an invention be new. *See* 35 U.S.C. § 101 (2012) (“Whoever invents or discovers any *new* and useful process, machine, manufacture, or composition of matter . . . may obtain a patent . . .” (emphasis added)); *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 780 (Fed. Cir. 1985) (interpreting the novelty requirement of § 101 as a “fundamental condition[ ] for patentability”).

5. 1 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* 305 (Boston, Little, Brown & Co. 1890).

6. *See supra* note 2 and accompanying text.

7. *See* 35 U.S.C. § 100(b) (2012) (defining “process” in § 101 to “include[ ] a new use of a known process, machine, manufacture, composition of matter, or material”); 35 U.S.C. § 101 (identifying as patentable “any new and useful improvement” of a “process, machine, manufacture,” etc.); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005) (“New uses of old products or processes are indeed patentable subject matter.”); P.J. Federico, *Commentary on the New Patent Act*, 75 J. PAT. & TRADEMARK OFF. SOC’Y 161, 177 (1993) (explaining that a method claiming a new use for a known device, product, or composition of matter may be patentable if the conditions of patentability are satisfied).

8. *See infra* Part II.

9. *Acetyl Salicylic Acid*, U.S. Patent No. 644,077 (filed Aug. 1, 1898) (issued Feb. 27, 1900).

10. As the Supreme Court stated long ago, “It is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property. It is upon this condition that the patent is granted.” *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896).

11. *See Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 197 (1894) (explaining “the well-settled rule that two valid patents for the same invention cannot be granted either to the same or to a different party”). If the second patent issues, it is invalid. *Id.* at 200.

12. *See, e.g.*, *Novel Method of Administering Aspirin & Dosage Forms Containing Same*, U.S. Patent No. 4,885,287 (filed Aug. 9, 1988) (patenting a new method of administering aspirin that achieves improved delivery thereof). As Timothy Holbrook notes, “Such ‘method of use’ patents can be quite important: if an inventor finds a new use for an old drug, she can get a patent on the new method for using the drug even though she cannot get a patent on the drug itself.” Timothy R. Holbrook, *Method Patent Exceptionalism*, 102 IOWA L. REV. 1001, 1005 (2017).

13. JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE* 109 (2008). The researchers define “value” as the private value of the relevant patent, which derives from the right to exclude. *Id.* at 97. This value “is measured relative to the alternative means an innovator has for profiting

of new drug development has led these firms to pursue drug repurposing—the quest to find new uses for old drugs.<sup>14</sup> Since older drugs have already been tested in humans, much is known about their pharmacology and toxicity.<sup>15</sup> The U.S. Food and Drug Administration (“FDA”) approves drugs that have been shown to be safe and effective for the manufacturer’s intended use;<sup>16</sup> however, it also permits doctors to prescribe approved drugs for “off-label” indications.<sup>17</sup> This allows repurposed drugs to bypass much clinical testing and reach the market more cheaply, more quickly, and with less risk than new drug candidates.<sup>18</sup> Revenues generated from repurposed drugs can be substantial—eclipsing those from the drug’s original indication<sup>19</sup> and those from new drugs developed from scratch.<sup>20</sup> Repurposed drugs can also provide remarkable health outcomes for neglected diseases or for patients who otherwise have limited treatment options.<sup>21</sup>

Much of the academic commentary on drug repurposing focuses on patent evergreening—a strategy employed by drug firms to

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from her invention,” including trade secrecy and profits on complementary goods. *Id.* at 98. Unlike most other industries, the pharmaceutical industry views patents as the most effective means of profiting from inventions. See OLIVER GASSMANN ET AL., LEADING PHARMACEUTICAL INNOVATION: TRENDS AND DRIVERS FOR GROWTH IN THE PHARMACEUTICAL INDUSTRY 133–34 (2d ed. 2008) (“[Patent] protection is crucial in the pharmaceutical industry as otherwise nobody would invest in expensive and long-term drug development.”).

14. See *infra* Section II.B (examining repurposed inventions). The National Institutes of Health (“NIH”) defines “repurposing” as “discovering new uses for approved drugs to provide the quickest possible transition from bench to bedside.” *Drug Repurposing*, NAT’L CTR. FOR ADVANCING TRANSLATIONAL SCI., <https://ncats.nih.gov/preclinical/repurpose> (last updated July 25, 2019) [<https://perma.cc/D444-32ZK>].

15. Francis S. Collins, *Mining for Therapeutic Gold*, 10 NATURE REV. DRUG DISCOVERY 397, 397 (2011).

16. 21 U.S.C. § 355(a)–(d) (2012); see 21 C.F.R. § 201.57 (2019) (mandating that manufacturers must describe the intended use of a prescription drug on its label).

17. Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food Drug Administration, 37 Fed. Reg. 16503, 16503 (proposed July 30, 1972) (codified at 21 C.F.R. pt. 130); see also 21 U.S.C. § 396 (2012) (reciting that the FDA does not “limit or interfere with the authority of a health care practitioner to prescribe” approved drugs “for any condition or disease”); *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001) (recognizing that off-label prescribing “is an accepted and necessary corollary of the FDA’s mission to regulate . . . without directly interfering with the practice of medicine”).

18. See *A Higher Purpose*, ECONOMIST, Mar. 2, 2019, at 52 (describing both the opportunities and challenges of drug repurposing); *infra* Section II.B (considering repurposed inventions).

19. Ernst R. Berndt et al., *The Impact of Incremental Innovation in Biopharmaceuticals: Drug Utilisation in Original and Supplemental Indications*, 24 PHARMACOECONOMICS (SUPP. 2D) 69, 81 (2006) (finding that in some drug classes, seventy to eighty percent of total patient use could be attributed to indications developed and approved after the drug first entered the market).

20. See *infra* Section II.B (discussing repurposed inventions).

21. Curtis R. Chong & David J. Sullivan, Jr., *New Uses for Old Drugs*, 448 NATURE 645, 645–46 (2007); Sean Ekins et al., *In Silico Repositioning of Approved Drugs for Rare and Neglected Diseases*, 16 DRUG DISCOVERY TODAY 298, 299–300 (2011).

effectively extend the life of soon-to-expire product patents<sup>22</sup> by obtaining related follow-on patents for new formulations, new preparations, new delivery profiles, and new uses.<sup>23</sup> The drug firms contend that these follow-on patents are legitimate innovations; critics assert that they are trivial modifications of old drugs unworthy of patent protection.<sup>24</sup> This Article does not wade into the evergreening debate. Rather, it explores a problem with new-use patents that has escaped the attention of legal scholars and commentators. The problem is when an inventor seeks to patent a new use for an old product that is, on close inspection, not new because the old product is really doing the same thing that it did before.

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22. Dmitry Karshedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 IOWA L. REV. 1129, 1215 n.491 (2019). Drug firms tend to file patent applications very early in the research and development (“R&D”) process—often at the preclinical stage—to avoid bars to patentability arising from prior disclosures and uses. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 351–52 (2007). But early filing means that the patent term will also end early—giving drug firms less time to commercialize the product before it enters the public domain. John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 444 (2004); Eisenberg, *supra*, at 351–54. The effective patent life for small-molecule drugs is about twelve years—considerably less than the twenty-year statutory term. Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT’L J. TECH. MGMT. 98, 110 (2000); F.M. Scherer, *The Pharmaceutical Industry—Prices and Progress*, 351 NEW ENG. J. MED. 927, 927 (2004).

23. Eisenberg, *supra* note 22, at 354; Kate S. Gaudry, *Evergreening: A Common Practice to Protect New Drugs*, 29 NATURE BIOTECHNOLOGY 876 (2011); C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 327–28 (2012). Dmitry Karshedt explains the typical evergreening strategy:

After receiving approval from the [FDA], a brand pharmaceutical company typically markets a drug product exclusively, i.e., without any competition over that product from other manufacturers, thanks to patents covering the drug. As these “primary” or “pioneering” patents approach expiration, the company obtains new patents covering the drug’s modification—for example, so-called “extended-release” tablets—and secures a separate FDA approval for this version. The company then begins to advertise the new product heavily, while de-emphasizing the one that is about to go off-patent. In the more aggressive cases, the brand company might disparage the original form of the drug or even take it completely off the market, thereby forcing a switch to the modification.

Karshedt, *supra* note 22, at 1132 (footnotes omitted).

24. See, e.g., JOHN R. THOMAS, CONG. RESEARCH SERV., R40917, PATENT “EVERGREENING”: ISSUES IN INNOVATION AND COMPETITION 7–10 (2009) (exploring the debate); Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CAN. MED. ASS’N J. E385, E385–E386 (2013) (same); Janice M. Mueller & Donald S. Chisum, *Enabling Patent Law’s Inherent Anticipation Doctrine*, 45 HOUS. L. REV. 1101, 1106 n.12 (2008) (noting that drawing the line between legitimate innovation and evergreening is a “broad and difficult problem in patent law”).

To illustrate, consider a pharmaceutical firm that invents a new drug, *X*, with a stated use<sup>25</sup> as an antidepressant.<sup>26</sup> When the firm obtains a patent for *X* in the early 1960s,<sup>27</sup> its mechanism of action is unknown.<sup>28</sup> Ultimately *X* is eclipsed by a new generation of antidepressants,<sup>29</sup> but by the time the patent expires,<sup>30</sup> *X* has found new life.<sup>31</sup> It has been repurposed; off-label, new-use patents issue for *X* as a treatment for insomnia, eating disorders, incontinence, irritable bowel syndrome, migraines, fibromyalgia, and functional dyspepsia. By this time, scientists know that *X* inhibits the uptake of serotonin, a neurotransmitter.<sup>32</sup> This Article argues that if depression and the newer indications all involve serotonin uptake inhibition, then *X* is doing what it has always done (inhibit serotonin uptake) and the claimed new uses are in fact the same (old) use. In patent law nomenclature, serotonin uptake inhibition is called an *inherent* characteristic of *X*.<sup>33</sup> And the inherency case law makes clear that even if scientists in the past did not understand how or why something

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25. Contrary to popular belief, one cannot obtain a patent on something simply because it is novel. It must also be useful. 35 U.S.C. § 101 (2012) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent therefor . . .”), construed in *Brenner v. Manson*, 383 U.S. 519, 534–35 (1966) (holding that a compound that lacks a known use is unpatentable). Inventors assert a utility in the patent application; this assertion is presumptively correct. *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

26. This illustration is based on amitriptyline, sold under the brand name Elavil, launched by Merck in 1961. See R.D. Hoffsommer et al., *The Homoallylic Rearrangement in the Synthesis of Amitriptyline and Related Systems*, 27 J. ORGANIC CHEMISTRY 4134 (1962); 1 PHARMACEUTICAL MANUFACTURING ENCYCLOPEDIA 281 (3d ed. 2007).

27. See Derivatives of Dibenzo[*a,d*][1,4]cycloheptadiene and Processes for Obtaining Them, U.S. Patent No. 3,309,404 (filed Aug. 1, 1963) (assigned to Merck); Process for the Preparation of 10,11-Dihydro-5-( $\gamma$ -methyl- and dimethyl-aminopropylidene)-5H-Dibenzo[*a,d*]cycloheptene, U.S. Patent No. 3,205,264 (filed June 15, 1962) (assigned to Merck).

28. An inventor need not understand how or why an invention works in order to obtain a patent. See *infra* notes 266, 340 and accompanying text (providing case law that shows a patentee is not required to understand how their inventions work to obtain patents).

29. See generally Emil F. Coccaro & Larry J. Siever, *Second Generation Antidepressants: A Comparative Review*, 25 J. CLINICAL PHARMACOLOGY 241 (1985) (reviewing four “second generation” antidepressants in terms of their efficacy and adverse effects).

30. Under current law, a U.S. patent expires twenty years after its filing date, regardless of when the patent issues. 35 U.S.C. § 154(a)(2) (2012). For patents issuing from applications filed before June 8, 1995, the patent expires either twenty years after the its filing date or seventeen years after its issue date, whichever is later. 35 U.S.C. § 154(c)(1).

31. Oftentimes new uses come to light many years after a drug’s introduction. Annetine C. Gelijns et al., *Capturing the Unexpected Benefits of Medical Research*, 339 NEW ENG. J. MED. 693, 693–94 (1998).

32. MICHAEL J. NEAL, MEDICAL PHARMACOLOGY AT A GLANCE 133 (8th ed. 2016).

33. See *infra* Section I.C (discussing inherent characteristics and their role in patent examinations).

works, the newly gained knowledge is *not* enough to confer novelty on a claimed new use.<sup>34</sup>

The key question is whether *X* is exhibiting the same characteristic (serotonin uptake inhibition) in the claimed new use as it did in the past. As explained below, the answer turns on whether those who consumed *X* in the past *benefitted* from serotonin uptake inhibition.<sup>35</sup> At present, the Patent Office can infer, supported with evidence or scientific reasoning, that the same inherent characteristic exhibited by an old product is operating in the claimed new use, thereby establishing a *prima facie* case of unpatentability for a lack of novelty.<sup>36</sup> The burden then shifts to the applicant to rebut the inference, by a preponderance of the evidence, and establish that *X* is acting differently (or some other characteristic of *X* is operating) in the claimed new use.<sup>37</sup> This framework *should* ferret out non-novel claims; however, various evidentiary rules, biases, and perfunctory views of novelty preclude a true and accurate patentability assessment. Sometimes this leads to unwarranted patents; other times it derails meritorious inventions.

This Article corrects this problem by offering a new framework for evaluating novelty in new-use patent claims.<sup>38</sup> At its core, novelty is about *identity*; the issue in new-use cases is whether the identical inherent characteristic is responsible for the old and new use. This is a technical inquiry that often requires an understanding of *mechanism*—how or why something works. This Article proposes a probing novelty inquiry that would require inventors to elucidate and disclose mechanistic information to prove that a claimed new use is truly novel. Providing mechanistic information would promote patent law's disclosure function<sup>39</sup> and improve patent (examination) quality.<sup>40</sup>

At a broader level, this Article raises the normative and theoretical question of what it means to be *identical*—which is what novelty is all about. It also raises policy questions about novelty's

34. *In re May*, 574 F.2d 1082, 1090 (C.C.P.A. 1978); *see also* discussion *infra* note 91 and accompanying text. The U.S. Court of Customs and Patent Appeals ("C.C.P.A.") was a five-judge Article III appellate court on the same level as the U.S. Courts of Appeals. The Federal Courts Improvement Act of 1982 abolished the C.C.P.A. *See* Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.). Soon after its creation, the Federal Circuit adopted C.C.P.A. decisional law as binding precedent. *S. Corp. v. United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982) (en banc).

35. *See infra* Section I.C.

36. *See infra* Section III.B.1 (delineating the evidentiary framework and shifting burdens of proof utilized in patent examinations).

37. *See infra* Section III.B.1.

38. *See infra* Section III.C.

39. *See infra* notes 42–54 and accompanying text (explaining the reasons for patent law's disclosure requirement); *infra* Section III.D.2.

40. *See infra* Section III.D.3.

gatekeeping role in patent law. This Article is part of a larger project about novelty's role in fulfilling the patent system's goal of enhancing public welfare by promoting technological progress.<sup>41</sup>

The remainder of the Article proceeds as follows. Part I describes patent law's novelty requirement. It discusses the theory of novelty, how to assess novelty, and the inherency doctrine. Part II explores new-use patents and repurposed inventions. After briefly describing the anatomy of a new-use patent claim, it draws attention to pharmaceuticals, where invention repurposing has become a priority. Finally, Part III offers a new framework for evaluating novelty for new-use inventions. It explains how the framework would fix problems with the current examination framework, improve the quality of issued patents, and promote broader objectives of the patent system.

## I. THE NOVELTY REQUIREMENT

### A. Theoretical Basis

Fostering innovation through information dissemination is a basic goal of the patent system.<sup>42</sup> The exclusory right conferred by a patent is the inventor's reward for fully disclosing technical information about the invention.<sup>43</sup> As soon as a patent document publishes,<sup>44</sup> the invention disclosure enters the public storehouse of technical knowledge.<sup>45</sup> The public will hopefully use the disclosure to improve on

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41. See generally Sean B. Seymore, *Reinvention*, 92 NOTRE DAME L. REV. 1031 (2017) (proposing a new novelty paradigm meant to promote the patent system's goals of encouraging investment and innovation); Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919 (2011) [hereinafter Seymore, *Rethinking Novelty*] (arguing that current novelty jurisprudence mishandles the question of possession and advocating for a reframing of the inquiry).

42. Patent law "seeks to foster and reward invention" with the hope that the disclosure will "stimulate further innovation and . . . permit the public to practice the invention once the patent expires . . ." Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979); see also Brenner v. Manson, 383 U.S. 519, 533 (1966) ("It is true, of course, that one of the purposes of the patent system is to encourage dissemination of information concerning discoveries and inventions.").

43. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974) ("In return for the right of exclusion—this 'reward for inventions'—the patent laws impose upon the inventor a requirement of disclosure." (quoting *Universal Oil Co. v. Globe Co.*, 322 U.S. 471, 484 (1944))); see also *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1966) (describing a patent as "a reward, an inducement, to bring forth new knowledge").

44. The public gets detailed knowledge about the invention as soon as the patent document publishes. Patent documents include issued patents and published patent applications. Since 1999, most patent applications publish eighteen months after the earliest effective filing date. 35 U.S.C. § 122(b)(1)(A) (2012). Once a patent application publishes, the information it discloses is considered publicly known. See 35 U.S.C. § 102 (2012) (stating that a person shall not be entitled to a patent if the invention was previously described in a published application for a patent).

45. See *Kewanee Oil*, 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



the invention, design around it, or simply learn from it.<sup>46</sup> Although the patentee can exclude others from practicing the invention until the patent term expires, the invention disclosure “has potential immediate value to the public, which can use the information for any purpose that does not infringe upon the claims.”<sup>47</sup> This supports the patent system’s broader mission to promote technological progress.<sup>48</sup>

So the patent system works through a bargain—a *quid pro quo*.<sup>49</sup> Again, the inventor’s incentive for full disclosure of the invention is the limited period of exclusionary rights provided by the patent.<sup>50</sup> This regime not only discourages trade secrecy,<sup>51</sup> but also provides technical information about “non-self-disclosing” inventions like complex chemical compounds or industrial processes<sup>52</sup>—things that are hard to

(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”).

46. Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 264 (1994); Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 547–49 (2009).

47. Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 624 (2010) (footnote omitted) (citing *Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd.* [2004] UKHL 46, [2005] R.P.C. 9, ¶ 77 (appeal taken from Eng.)); see also Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets as IP Rights*, 61 STAN. L. REV. 311, 332 (2008) (“[T]he public is free to read the patent and use the invention once the patent expires twenty years after it is filed, and even before that time scientists can learn from the patent disclosure and use that information to improve on the invention or to design around it.”). But see Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 139–46 (2006) (arguing that, for a variety of reasons, the teaching function of patent documents is overstated).

48. 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 *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917) (observing that “the 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)).

49. *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*, 416 U.S. at 484)); *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) (“[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.”).

50. See *supra* note 43 and accompanying text.

51. Without the patent system, inventors would monetize their inventions through trade secrecy, thereby depriving the public of the benefit of a disclosure. J. Jonas Anderson, *Nontechnical Disclosure*, 69 VAND. L. REV. 1573, 1585 (2016). Thus, a *quid pro quo* is required to induce the inventor to publicly disclose. Katherine J. Strandburg, *The Research Exemption to Patent Infringement: The Delicate Balance Between Current and Future Technical Progress*, in 2 INTELLECTUAL PROPERTY AND INFORMATION WEALTH 107, 108 (Peter K. Yu ed., 2007).

52. A “non-self-disclosing” invention is one whose technical underpinnings cannot be ascertained by examination. Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 105–06.

replicate or reverse engineer.<sup>53</sup> Thus, the quid pro quo promotes the disclosure of information that the public might not otherwise get.<sup>54</sup>

Of course, the quid pro quo rationale only works if the public actually benefits from the invention's disclosure.<sup>55</sup> If the invention is already in the public domain, a patent should not issue because the inventor cannot give the public anything that it does not already possess.<sup>56</sup> By constitutional command, a patent can neither remove existing knowledge from the public domain nor limit free access to technology already available.<sup>57</sup> Otherwise, the public must bear the social costs of an unwarranted patent.<sup>58</sup> This is why inventions must be *new*—provided to the public for the first time by the patentee.<sup>59</sup>

### B. Assessing Novelty

Assessing novelty requires a comparison of the invention sought to be patented with the “prior art,” which refers to preexisting knowledge and technology in the public domain.<sup>60</sup> While documents such as issued patents and printed publications are common sources of prior art,<sup>61</sup> products, devices, and activities (like prior uses) can also

53. See *infra* note 346 and accompanying text.

54. EDWARD C. WALTERSCHEID, *THE NATURE OF THE INTELLECTUAL PROPERTY CLAUSE: A STUDY IN HISTORICAL PERSPECTIVE* 143 (2002).

55. 1 ROBINSON, *supra* note 5, at 305 (“If the same [knowledge] has been already made accessible to [the public] by the inventive genius . . . no benefit results to them from his inventive act and there is no consideration for his patent.”); see also Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 283 (1977) (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”).

56. *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 23 (1829); see also Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 12–13 (1992) (explaining that the “logic behind [the novelty requirement] is fairly straightforward . . . [because if] information is already in the public domain when the ‘inventor’ seeks to patent it[,] society has no need to grant a patent to get this information”).

57. *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966); see also *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 147 (1989) (explaining that awarding a patent for knowledge that is already available to the public “would not only serve no socially useful purpose, but would in fact injure the public by removing existing knowledge from public use”).

58. RONALD A. CASS & KEITH N. HYLTON, *LAWS OF CREATION: PROPERTY RIGHTS IN THE WORLD OF IDEAS* 64 (2013); see also Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2088 (2000) (“Granting patents on technologies that are not new would impose the social costs of monopolies without the countervailing benefits of promoting development and introduction of welfare-enhancing inventions.”).

59. See *supra* note 5 and accompanying text.

60. *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (citing *Graham*, 383 U.S. at 6).

61. 35 U.S.C. § 102(a) (2012).

serve as prior art.<sup>62</sup> A specific document, device, or activity asserted against the invention that the applicant seeks to patent is called a prior art reference.<sup>63</sup>

The America Invents Act of 2011 (“AIA”) converted the U.S. patent system from a first-to-invent regime to a first-inventor-to-file regime.<sup>64</sup> To qualify as novelty-defeating prior art under the AIA,<sup>65</sup> the asserted reference must satisfy three conditions. First, it must predate the applicant’s filing date.<sup>66</sup> Second, every element of the claimed invention<sup>67</sup> must be identically disclosed or described within the four corners of a single reference<sup>68</sup> (the “strict identity” requirement).<sup>69</sup> For example, if an applicant seeks to claim a paper clip made with titanium and nickel, the reference must disclose a paper clip made with titanium and nickel.<sup>70</sup> Third, the reference must be enabling,<sup>71</sup> meaning that it must disclose the invention in sufficient detail to enable a person having ordinary skill in the art (“PHOSITA”)<sup>72</sup> to make it without

62. See, e.g., *Rosaire v. Baroid Sales Div., Nat’l Lead Co.*, 218 F.2d 72, 74 (5th Cir. 1955) (holding that a patent claiming a prospecting method was invalid because a prior use of the method by another on private property, though obscure, was novelty defeating because no action was taken to conceal or exclude public viewing of the prior use).

63. HERBERT F. SCHWARTZ, PATENT LAW AND PRACTICE 18 (3d ed. 2001).

64. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(b), 125 Stat. 284, 285–87 (2011) (codified at 35 U.S.C. § 102) (amending § 102(a) and repealing § 102(g)). Congress did this to harmonize the U.S. patent system with the rest of the world. *Id.* § 3(p), 125 Stat. at 293.

65. Prior art is also used to gauge nonobviousness—the statutory requirement that bars a patent if the claimed invention is a trivial extension of what is already known. See 35 U.S.C. § 103 (2012).

66. 35 U.S.C. § 102(a)(1) (denying patentability if “the claimed invention was patented . . . before the effective filing date of the claimed invention”); 35 U.S.C. § 102(a)(2) (denying patentability if “the claimed invention was described in a patent . . . [that] names another inventor and was effectively filed before the effective filing date of the claimed invention”). The AIA provides a grace period for certain prior disclosures that came directly or indirectly from the inventor. See 35 U.S.C. § 102(b) (stating certain exceptions for disclosures that were made one year or less before the effective date of the claimed invention or that appear in patent applications).

67. A patent claim must define “the subject matter which [the applicant] . . . regards as the invention.” 35 U.S.C. § 112(b) (2012). A claim element further limits the breadth of the claim. 1 DONALD S. CHISUM, CHISUM ON PATENTS, at G1-3 (2009).

68. *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

69. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002).

70. Seymore, *Rethinking Novelty*, *supra* note 41, at 923. In this hypothetical, titanium and nickel are claim elements.

71. *In re Antor Media Corp.*, 689 F.3d 1282, 1289 (Fed. Cir. 2012). This is referred to as “anticipatory” or patent-defeating enablement because it pertains to prior art references. It is a “judicially imposed limitation” on § 102 that the description of the subject matter in the reference must be an enabling description. *In re LeGrice*, 301 F.2d 929, 939 (C.C.P.A. 1962); see also *Elan Pharms., Inc. v. Mayo Found.*, 346 F.3d 1051, 1054 (Fed. Cir. 2003) (“To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate.”). By contrast, “statutory” or patent-supporting enablement is a disclosure requirement that places an outer limit on claim scope. See *infra* note 340 and accompanying text.

72. The PHOSITA is a hypothetical construct of patent law akin to the reasonably prudent person in torts. See *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1566 (Fed. Cir. 1987)

undue experimentation.<sup>73</sup> If the asserted reference satisfies these criteria, it “anticipates” the applicant’s claim<sup>74</sup> and renders it unpatentable because the subject matter is (deemed to be) in the public domain.<sup>75</sup> Anticipation is a question of fact.<sup>76</sup>

### *C. Anticipation by Inherency*

The anticipation analysis is straightforward when the asserted prior art reference expressly or explicitly discloses each element of the claimed invention.<sup>77</sup> Returning to the paper clip example, a document that discloses with words or drawings a paper clip made from titanium and nickel or a preexisting paper clip made from titanium and nickel would each qualify as anticipatory prior art.<sup>78</sup>

However, the courts also recognize that “a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless *inherent* in it.”<sup>79</sup> Inherent anticipation occurs if the evidence makes clear that the missing characteristic (claim limitation) is “necessarily present in”<sup>80</sup> or “inevitably flows from”<sup>81</sup> the asserted prior art reference.<sup>82</sup> If the alleged

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(stating that the decisionmaker confronts a ghost who is a person having ordinary skill in the art). Factors relevant to constructing the PHOSITA in a particular technical field include the sophistication of the technology, the education level of the inventor, the education level of active workers in the field, the types of problems encountered in the art, prior art solutions to those problems, and the rapidity with which innovations are made. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983).

73. *In re Morsa*, 713 F.3d 104, 108–10 (Fed. Cir. 2013); *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008); *In re Hafner*, 410 F.2d 1403, 1405 (C.C.P.A. 1969). The enablement analysis is explained *infra* note 238.

74. *See In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009) (“A rejection for ‘anticipation’ means that the invention is not new.”).

75. *See In re Morsa*, 803 F.3d 1374, 1377–78 (Fed. Cir. 2015) (concluding that anticipation “allow[s] [the applicant] to avoid having to teach the public [the] concept”); *Impax Labs.*, 545 F.3d at 1314; *cf. In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995) (“A reference anticipates a claim if it discloses the claimed invention ‘such that a [PHOSITA] could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention.’” (quoting *LeGrice*, 301 F.2d at 936)). Thus, “anticipation is the converse of novelty: if an invention lacks novelty, it is anticipated.” Timothy R. Holbrook, *Patent Anticipation and Obviousness as Possession*, 65 EMORY L.J. 987, 993 (2016).

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

77. CRAIG ALLEN NARD, *THE LAW OF PATENTS* 272 (3d ed. 2014).

78. *See* discussion *supra* Section I.B.

79. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) (emphasis added).

80. *Cont’l Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

81. *In re Montgomery*, 677 F.3d 1375, 1381 (Fed. Cir. 2012).

82. If the feature is not inevitably present as “the natural result flowing from the operation [of the prior art] as taught,” then it is not inherent. *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981) (quoting *Hansgird v. Kemmer*, 102 F.2d 212, 214 (1939)); *see also* *Transclean Corp. v. Bridgewood*

inherent characteristic can *possibly* result from a given set of circumstances or was simply a matter of chance and not an inevitable result, there is no anticipation.<sup>83</sup> And notwithstanding the single reference rule for anticipation,<sup>84</sup> the U.S. Court of Appeals for the Federal Circuit has held that extrinsic evidence can be used to show that a characteristic in the asserted prior art reference is inherent.<sup>85</sup>

To illustrate, suppose that in 2015 an applicant seeks to patent an airtight, hollow cylinder to provide buoyancy for a pontoon boat.<sup>86</sup> The claim recites “a floatable [cylindrical] structure comprising . . . an airtight hollow interior region.”<sup>87</sup> The examiner asserts as prior art a magazine from 1965 that shows a floating cylinder. While the magazine does not explicitly state that the cylinder is hollow and airtight, it does explain that the cylinder was made using conventional blow molding techniques.<sup>88</sup> The examiner introduces a book, *Understanding Blow Molding*, as extrinsic evidence to show that the blow molding process *necessarily* would have produced an airtight, hollow cylinder.<sup>89</sup> Accordingly, the examiner can assert that the magazine inherently discloses the “airtight, hollow” claim limitation and properly reject the applicant’s claim as anticipated.

One question that arises in inherency cases is whether a PHOSITA must have known, appreciated, or recognized the inherent characteristic. While some older cases seemed to focus on recognition,<sup>90</sup>

Servs., 290 F.3d 1364, 1373 (Fed. Cir. 2002) (“[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation.”).

83. See *Tilghman v. Proctor*, 102 U.S. 707, 711–12 (1881) (finding that an accidental and incidental production of fatty acids by a steam engine did not anticipate a patented process for separating fatty bodies into fatty acids and glycerin), *discussed in* *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1378 (Fed. Cir. 2003) (“In *Tilghman*, the record did not show conclusively that the claimed process occurred in the prior art.”); see also *Mueller & Chisum*, *supra* note 24, at 1115 (“*Tilghman* is simply a case in which the evidence was insufficient to prove that the claimed process was the inevitable, certain, and necessary result of operating Perkins’s engine.”).

84. See *supra* note 68 and accompanying text.

85. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1328 (Fed. Cir. 2001); *Cont’l Can*, 948 F.2d at 1268.

86. This hypothetical is based on one described in JANICE M. MUELLER, *PATENT LAW* 233 (5th ed. 2016).

87. *Cf.* *Float and a Floatable Structure*, U.S. Patent No. 8,007,331 (filed May 3, 2006) (describing a patent for a similar type of “float”).

88. See *MUELLER*, *supra* note 86, at 233.

89. See *id.*; see also *NORMAN C. LEE*, *UNDERSTANDING BLOW MOLDING* 5 (2d ed. 2007) (likening blow molding to blowing up a balloon in that “blow[ing] air into a plastic tube that is closed on all sides except the point at which the air enters[ ] [causes] the tube [to] expand and take the shape of the mold that is around the tube”).

90. See, e.g., *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45, 66 (1923) (finding that the unintended and unappreciated results by a prior inventor “do not constitute anticipation”); *Cont’l Can*, 948 F.2d at 1268 (“[T]he missing descriptive matter [must be] necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary

newer Federal Circuit cases make clear that “inherent anticipation does not require that a [PHOSITA] . . . would have recognized the inherent disclosure.”<sup>91</sup> To illustrate, consider *MEHL/Biophile International Corp. v. Milgraum*.<sup>92</sup> The patent claimed a method of hair removal by irradiating hair follicles with a laser that destroyed the follicle, “thereby preventing hair regrowth.”<sup>93</sup> The accused infringer asserted an article that described the use of lasers to irradiate guinea pig skin, which is hairy.<sup>94</sup> The record showed that the natural result from practicing the method taught in the article requires aligning a laser with a hair follicle which, in turn, necessarily causes follicle damage.<sup>95</sup> In finding anticipation by inherency, the Federal Circuit determined that hair removal was a necessary consequence of the asserted prior art even though it was not a stated goal and the article’s authors did not appreciate the results.<sup>96</sup>

In *Titanium Metals Corp. of America v. Banner*,<sup>97</sup> the Federal Circuit made clear that the importance and usefulness of the previously unknown property do not “render the old composition patentably new to the discoverer.”<sup>98</sup> The inventors sought to patent metal alloys that had been previously disclosed in a journal article, pointing out that the article was silent as to the corrosion-resistant properties of the alloys.<sup>99</sup> The court affirmed a Patent Office decision that the claimed invention was anticipated, noting that “it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these

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skill.”) *But see In re May*, 574 F.2d 1082, 1090 (C.C.P.A. 1978) (“While appellants have discovered a hitherto unknown property . . . , such discovery does not constitute a new use.”); *In re Swinehart*, 439 F.2d 210, 212–13 (C.C.P.A. 1971) (“[I]t is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.”).

91. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003); *see also* *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005) (“[I]nherent anticipation does not require a [PHOSITA] to recognize the inherent disclosure in the prior art at the time the prior art is created.”); *Schering*, 339 F.3d at 1378 (explaining that *Tilghman* and *Eibel* do not involve recognition but an evidentiary issue as to whether the allegedly anticipatory subject matter was present in the prior art).

92. 192 F.3d 1362 (Fed. Cir. 1999).

93. *Id.* at 1364.

94. *Id.* at 1364, 1366.

95. *Id.* at 1366.

96. *See id.* at 1366–67 (noting that the “article’s [authors] failure to mention hair depilation as a goal is similarly irrelevant” and noting that “to the extent the embodiment in the patent achieves hair depilation, so does the [article’s] method”); *cf. Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1348–49 (Fed. Cir. 1999) (“Because ‘sufficient aeration’ was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention . . . . An inherent structure, composition, or function is not necessarily known.”).

97. 778 F.2d 775 (Fed. Cir. 1985).

98. *Atlas Powder*, 190 F.3d at 1347 (citing *Titanium Metals*, 778 F.2d at 782).

99. *Titanium Metals*, 778 F.2d at 776–77.

applicants discovered certain inherent properties.”<sup>100</sup> That a PHOSITA could not learn the underlying inherent characteristic from reading the journal article was “beside the point,”<sup>101</sup> and the inventors’ discovery of this knowledge was insufficient in law to permit a patent.<sup>102</sup>

That a PHOSITA need not have known, appreciated, or recognized the inherent characteristic in the prior art makes sense.<sup>103</sup> Inherency by definition involves things that the PHOSITA does not know.<sup>104</sup> If the prior art disclosure taught the PHOSITA the relevant characteristic, that would be a straightforward case of express anticipation and inherency would be unnecessary.<sup>105</sup>

This no-knowledge rule for inherency also aligns with basic novelty principles. To illustrate, consider again the hypothetical introduced earlier involving the drug *X*.<sup>106</sup> Recall that *X* was originally purposed for use as an antidepressant. But patients prescribed *X* to treat depression who also had insomnia, eating disorders, incontinence, irritable bowel syndrome, migraines, fibromyalgia, or functional dyspepsia were necessarily treated for those serotonin-related conditions as well, even if the patient or physician did not intend, know, appreciate, or recognize what was happening.<sup>107</sup> So if a subsequent inventor were issued a patent for using *X* to treat any of these conditions, it would impermissibly restrict free access to what is already in the public domain.<sup>108</sup>

100. *Id.* at 776, 782.

101. *See id.* at 780 (noting that there is “no doubt that the court was impressed by the totality of the evidence that the applicants for patent had discovered or invented and disclosed knowledge which is not to be found in the [prior art] reference”).

102. *See id.* at 782 (“Congress has not seen fit to permit the patenting of an old alloy, known to others through a printed publication, by one who has discovered its corrosion resistance or other useful properties . . .”).

103. *See NARD, supra* note 77, at 272 (describing the absence of a requirement that the PHOSITA have knowledge of the inherent disclosure at the time of invention as “logical”); *see also* Robin Feldman, *Rethinking Rights in Biospace*, 79 S. CAL. L. REV. 1, 33 (2005) (“The notion that an invention encompasses things inherent but unknown is consistent with . . . [the idea that] the footprint of the invention is defined broadly to include things beyond the state of knowledge at the time of the invention.”).

104. Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371, 374 (2005). *But see* Holbrook, *supra* note 75, at 1023–24 (arguing that for inherent anticipation, a PHOSITA should have contemporaneously appreciated the missing subject matter—otherwise there was no public notice or possession).

105. Burk & Lemley, *supra* note 104, at 374.

106. *See supra* text accompanying notes 26–32.

107. *See* David A. Kelly, *What Constitutes a “New Use” of a Known Composition and Should a Patentee’s Purported Objective Make Any Difference?*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 319, 336 (2005) (describing and analyzing a similar hypothetical, noting that “prior to Inventor 2’s discovery that compound X treats near-sightedness, near-sighted individuals taking compound X to treat their arthritis were necessarily also treating their near-sightedness, regardless of whether they intended to do so or not”).

108. *See supra* Section I.A.

Despite the no-knowledge rule, the inherency cases make clear that the public must have *benefitted* from the prior art disclosure,<sup>109</sup> even if unwitting.<sup>110</sup> Perhaps the most famous modern case is *In re Cruciferous Sprout Litigation*, where the patent at issue involved the cancer-preventative effects of eating cruciferous sprouts like broccoli and cauliflower.<sup>111</sup> The Federal Circuit affirmed the district court's finding that the claimed methods of using these sprouts to reduce the risk of developing cancer were inherently anticipated because the public was already eating the sprouts and receiving the cancer-preventative benefits despite being unaware.<sup>112</sup> Again, recent realization of a necessarily present but heretofore unknown benefit does not confer novelty.<sup>113</sup>

But prior disclosure of *one* beneficial use does not necessarily confer a public benefit of *later-discovered uses* of the same product. Consider *Rapoport v. Dement*, where the claim involved a method of using the compound buspirone to treat sleep apnea.<sup>114</sup> The asserted prior art reference disclosed a method of using buspirone to treat

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109. See Burk & Lemley, *supra* note 104, at 374 (“[T]he inherency cases are all ultimately about whether the public already gets the *benefit* of the claimed element or invention.”). The corollary is that there is no inherent anticipation if the public received no benefit from the prior disclosure. To illustrate, consider *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964), where Glenn Seaborg sought to claim “element 95,” a man-made element. The Patent Office asserted that the claim was inherently anticipated because trace amounts of element 95 were inevitably produced as a byproduct by operation of Fermi’s nuclear reactor. *Id.* at 997. The court held that Seaborg was entitled to the claim, reasoning that the public did not benefit from the Fermi reactor’s production of element 95, as it was “completely undetectable, since it would have been diluted with the 40 tons of intensely radioactive uranium fuel which made up the reactor.” See *id.* at 999 (noting that “if produced, [element 95] was produced in the most minute quantities”). If knowledge, appreciation, or recognition “were the touchstone for inherency, *Seaborg* would have come out the other way because it is clear that physicists understood that element 95 was already produced in Fermi’s nuclear reactor.” Burk & Lemley, *supra* note 104, at 383. Jeanne Fromer argues that “[t]he novelty provisions of patent law . . . accentuate how much societal possession of the benefit of a particular solution matters in patent law.” Jeanne C. Fromer, *A Psychology of Intellectual Property*, 104 NW. U. L. REV. 1441, 1487 (2010). And “unless American society actually seems to have a reasonably good chance of benefiting from a preexisting solution to a problem, it is as if the solution does not exist” for novelty purposes. *Id.*

110. “If the public already benefits from the invention, even if they don’t know why, the invention is inherent in the prior art.” Burk & Lemley, *supra* note 104, at 374.

111. 301 F.3d 1343, 1345 (Fed. Cir. 2002).

112. See *id.* at 1351–52 (“[The inventor] cannot credibly maintain that no one has heretofore grown and eaten one of the many suitable cultivars identified by its patents. It is unnecessary for purposes of anticipation for the persons sprouting these particular cultivars to have realized that they were sprouting something [with cancer-preventative effects].”).

113. See *id.* at 1346 (noting the district court’s conclusion that “broccoli sprouts . . . [cannot] be patented merely on the basis of a recent realization that the plant has always had some heretofore unknown but naturally occurring beneficial feature”).

114. 254 F.3d 1053, 1055 (Fed. Cir. 2001).



anxiety.<sup>115</sup> The Federal Circuit rejected an argument that the reference was inherently anticipated because its lack of teaching about the apnea indication (dosage amount and timing, etc.) meant that practicing the prior art method on anxiety patients also suffering from sleep apnea might *sometimes* have the effect of treating the latter.<sup>116</sup> The court reiterated that an alleged inherent characteristic must inevitably result from practicing the prior art; that it can possibly result from a given set of circumstances will not anticipate.<sup>117</sup> So the claim in *Rapoport* is novel because sleep apnea patients had not been receiving the benefit of the prior art disclosure.<sup>118</sup> Finding new uses that give the world new benefits is precisely the type of activity that the patent system seeks to encourage.<sup>119</sup>

## II. NEW-USE PATENTS

Prior to the Patent Act of 1952, new uses for old things were deemed patent-ineligible.<sup>120</sup> This prohibition was also based on novelty considerations:

115. See *id.* at 1056 (noting the prior art reference—an article titled *Buspirone: Anxiolytic Therapy with Respiratory Implications*).

116. See *id.* at 1062–63 (indicating Rapoport’s failure “to demonstrate that the proposed dosage regimen in the [prior art] would necessarily result in a therapeutically effective amount” as a basis for finding “Rapoport’s inherency argument [to be] without merit,” and for concluding that “the [prior art] does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea”); see also *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1386 (Fed. Cir. 2005) (Bryson, J., concurring in part and dissenting in part) (discussing *Rapoport*); cf. *Glaxo, Inc. v. Novopharm Ltd.*, 830 F. Supp. 871, 874 (E.D.N.C. 1993) (“In order for a claim to be inherent in the prior art it is not sufficient that a person following the disclosure sometimes obtains the result set forth in the claim, it must invariably happen.”), *aff’d*, 52 F.3d 1043 (Fed. Cir. 1995).

117. See *Rapoport*, 254 F.3d at 1063 (“Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.” (quoting *Cont’l Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991))); see also *supra* notes 80–82 and accompanying text.

118. See *Eli Lilly & Co. v. L.A. Biomedical Res. Inst.*, 849 F.3d 1073, 1076 (Fed. Cir. 2017) (holding that a prior art reference that suggests the benefits of claimed new use without a clear disclosure of the inherent characteristic cannot defeat novelty because “[t]o anticipate, a reference must do more than ‘suggest’ the claimed subject matter” (quoting *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1055 (Fed. Cir. 2010))).

119. See *Burk & Lemley*, *supra* note 104, at 407 (discussing how the inherency doctrine may perform the desired work of the products of nature doctrine, by distinguishing between products in nature based on whether people already benefit from them).

120. See *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 166 (1852) (“Applying an old machine to a new use, or to produce a new result, is not the subject of a lawful patent.”); John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609, 632–34 (2009) (providing a historical account of the prohibition). As explained by the U.S. Court of Customs and Patent Appeals, “a new use of an old thing or an old process, quite unchanged, can under no circumstances be patentable; not because it may not take as much inventiveness to discover it, . . . but because the statute allows patents only for a new ‘art, machine, manufacture or composition of matter.’” *In re Thuau*, 135 F.2d 344, 346 (C.C.P.A. 1943) (quoting 35 U.S.C. § 31 (repealed 2000)). This interpretation was widespread, as stated by Judge Learned Hand:

[T]he presence or the absence of the *patentable* quality of novelty depends in some degree on the position in which the supposed inventor stands with reference to the history of the art; for there may be in what he has done an element of novelty, and yet that novelty may consist only in the . . . new use to which he applies an old or well-known method . . . . When this is the case, the question to be determined is, whether . . . something has been discovered, or some effect produced, which . . . enters the domain of what is called invention.<sup>121</sup>

As applied to drugs, a newly discovered use was unpatentable despite the fact that “the use of the medicine would be new, and the effect of it as materially different from what is now known, as life is from death.”<sup>122</sup> This prohibition was a corollary of the judicially imposed substantial novelty standard applied under the 1793 Act.<sup>123</sup>

If [the new invention] be merely for a new employment of some “machine, manufacture or composition of matter” already known, it makes not the slightest difference how beneficial to the public the new function may be, how long a search it may end, how many may have shared that search, or how high a reach of imaginative ingenuity the solution may have demanded . . . . [I]t will not be patentable because it will not be within the terms of the statute. This is the doctrine that a “new use” can never be patentable. In this circuit we have many times applied it, and it has been recognized elsewhere.

Old Town Ribbon & Carbon Co. v. Columbia Ribbon & Carbon Mfg. Co., 159 F.2d 379, 382 (2d Cir. 1947) (footnote omitted). These cases reflect doubts (prior to the 1952 Act) as to whether methods were patent-eligible. See Holbrook, *supra* note 12, at 1005 (“Historically, there were concerns as to whether processes were categorically excluded from the patent system . . .”).

121. GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS, AS ENACTED AND ADMINISTERED IN THE UNITED STATES OF AMERICA § 53, at 44 (4th ed. 1873); see also Roberts v. Ryer, 91 U.S. 150, 157 (1875) (“It is no new invention to use an old machine for a new purpose.”). But see Blake v. City and County of San Francisco, 113 U.S. 679, 682–83 (1885):

If there is any qualification of this rule, it is that if a new and different result is obtained by a new application of an invention, such new application may be patented as an improvement on the original invention; but if the result claimed as new is the same in character as the original result, it will not be deemed a new result for this purpose.

122. See Boulton v. Bull (1795) 126 Eng. Rep. 651, 663; 2 H. BL. 463, 487 (describing a hypothetical situation in which a physician discovers that another doctor’s existing “fever powder” is a cure for a separate ailment when provided in certain dosages), cited with approval in *Tatham*, 55 U.S. (14 How.) at 166 and Joseph Story, *On the Patent Laws*, 16 U.S. app. 13, 18 (1818); cf. Morton v. N.Y. Eye Infirmary, 17 F. Cas. 879, 882–83 (C.C.S.D.N.Y. 1862) (No. 9,865) (holding that the use of ether as an anesthetic was unpatentable because it was a new use of a known compound).

123. Recall that under the 1952 Act, an invention lacks novelty if each element of the claimed invention is identically disclosed in a single prior art reference. See *supra* Section I.B. But early U.S. law required more—“substantial novelty in the alleged invention, as compared with what existed before.” CURTIS, *supra* note 121, § 32, at 25. This restrictive form of novelty “did more than merely define what was meant by ‘not before known or used’ in the patent statutes.” Edward C. Walterscheid, *Novelty & the Hotchkiss Standard*, 20 FED. CIR. B.J. 219, 228 (2010) (footnote omitted). So, the courts endeavored to “work[ ] out rules designed to prevent trivial advances from falling within the concept of patentable novelty.” Edmund W. Kitch, Graham v. John Deere Co.: *New Standards for Patents*, 1966 SUP. CT. REV. 293, 303; see also PHILLIPS, *supra* note 1, at 127 (“The sufficiency of the invention depends . . . upon its being diverse and distinguishable from what is familiar and well known, and also substantially and materially, not slightly and trivially so.”). “Under this standard . . . a patentee could show substantial novelty by indicating a different principle or by proving different results or effects, i.e., by establishing any differences in structure, operation, effect or efficiency that would tend to show that the invention was more than a ‘colorable

The 1952 Act<sup>124</sup> explicitly renders eligible the patenting of repurposed inventions.<sup>125</sup> This makes sense. It stands to reason that the original inventor did not know everything about the invention, but a subsequent inventor could discover new uses for it. As long as the claimed new use is novel, nonobvious, and adequately described, no bar to patentability should exist.<sup>126</sup>

### A. Understanding New-Use Patent Claims

Claims are central to every aspect of patent law.<sup>127</sup> They define the “technological territory” that the inventor claims is his or hers to control<sup>128</sup> and “provide[ ] the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or

variation’ of the prior art.” Kenneth J. Burchfiel, *Revising the “Original” Patent Clause: Pseudohistory in Constitutional Construction*, 2 HARV. J.L. & TECH. 155, 193–94 (1989) (footnotes omitted); cf. *Woodcock v. Parker*, 30 F. Cas. 491, 492 (C.C.D. Mass. 1813) (No. 17,971) (Story, J.) (“If he claim a patent for a whole machine, it must in substance be a new machine; that is, it must be a new mode, method, or application of mechanism, to produce some new effect, or to produce an old effect in a new way.”). So, the substantial novelty standard tried “to distinguish between the new and the really new,” Kitch, *supra*, at 304, thereby making it a “precursor to the nonobviousness requirement.” Walterscheid, *supra*, at 228; see also *Tucker v. Spalding*, 80 U.S. (13 Wall.) 453, 455–56 (1871):

But if what it actually did, is in its nature the same as sawing, and its structure and action suggested to the mind of an ordinarily skilful [sic] mechanic this double use to which it could be adapted without material change, then such adaptation to the new use, is not a new invention, and is not patentable.

(emphasis omitted).

124. The Patent Act of 1793 restricted patent-eligible subject matter to any new and useful “art, machine, manufacture, or composition of matter.” Patent Act of 1793, ch. 11, § 1, 1 Stat. 318, 319 (repealed 1836). This language “appeared to clearly restrict patentability of machines to only those that were new, and said nothing about authorizing patentability of a new use of a known machine.” Walterscheid, *supra* note 123, at 247 n.184. This language remained unchanged until the 1952 Act replaced “art” with “process” in 35 U.S.C. § 101. *Id.*

125. See *supra* note 7.

126. Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591, 610 (2008) (applying this rationale to business method patents). The patentability requirements appear in Title 35 of the United States Code. Briefly, the claimed invention must be useful, novel, nonobvious, and directed to patentable subject matter. 35 U.S.C. §§ 101–103 (2012). In addition, the application must adequately describe, enable, and set forth the best mode contemplated for carrying out the invention and conclude with claims that delineate the invention with particularity. 35 U.S.C. § 112(a)–(b) (2012).

127. Mark A. Lemley, *The Changing Meaning of Patent Claim Terms*, 104 MICH. L. REV. 101, 101 (2005); see also Giles S. Rich, *The Extent of the 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”). At the application stage, the inventor dickers with the Patent Office for broad claim scope, “and in litigation the parties try to convince the court to construe the claims in their favor.” Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 128–29 (2008).

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

selling the protected invention.”<sup>129</sup> So patentees will seek the broadest claim scope possible.<sup>130</sup>

For inventions such as drugs, patent applicants typically consider several types of claims.<sup>131</sup> These include a claim to the product,<sup>132</sup> a claim to make the product, and a claim to use the product.<sup>133</sup> Returning to the hypothetical introduced earlier involving the drug *X*, potential claims include: a product claim directed to *X*, the compound itself; method claims directed to making *X*; and method claims directed to using *X* to treat a disease.

But these claims differ in their scope of protection and potential value. A product claim covering the compound itself affords the broadest protection.<sup>134</sup> As Harold Wegner explains,

[Product claims covering the compound] have always been the premium form of patent protection in the chemical industry . . . . A claim to the compound, per se, dominates every method of making that compound and every single use of that compound, every single mixture of different components that includes that compound, and every end use composition inclusive of the compound.<sup>135</sup>

So an inventor *always* prefers a claim to *X*, the product itself.<sup>136</sup> But sometimes a product claim is unavailable. *X* might be covered by an existing patent or in the public domain.<sup>137</sup> Either way, a subsequent

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129. *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989).

130. *Merges & Nelson*, *supra* note 128, at 840; *see also* ANTHONY L. MIELE, *PATENT STRATEGY* 98 (2001) (arguing that applicants have an incentive “to obtain very broad claims for which a colorable argument can be made for patentability”).

131. U.S. CONG., OFFICE OF TECH. ASSESSMENT, *OTA-H-522, PHARMACEUTICAL R&D COSTS, RISKS, AND REWARDS* app. E, at 290–91 (1993) [hereinafter *PHARMACEUTICAL R&D*].

132. When the invention is a new chemical entity, this is also known as a “composition of matter” claim. *MUELLER*, *supra* note 86, at 456–58.

133. JEFFREY G. SHELDON, *HOW TO WRITE A PATENT APPLICATION* 6–77 (3d. ed. 2015).

134. *In re Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963) (discussing the “well-recognized advantages” of composition-of-matter claims); TONY ELLERY & NEAL HANSEN, *PHARMACEUTICAL LIFECYCLE MANAGEMENT* 93 (2012) (noting that a product patent is the “strongest” type of patent).

135. HAROLD C. WEGNER, *PATENT LAW IN BIOTECHNOLOGY, CHEMICALS, AND PHARMACEUTICALS* 177 (1992); *see also* *Merges & Nelson*, *supra* note 128, at 912 (providing examples that demonstrate the broad scope of protection). An inventor of a product must disclose a single use to satisfy patent law’s utility requirement. *See* discussion *supra* note 25. But the resulting patent covers the full scope of the product, including all uses. *In re Thuau*, 135 F.2d 344, 347 (C.C.P.A. 1943); *accord* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094–95 (Jan. 5, 2001). Also note that disclosing a single mode of using the product satisfies the statutory enablement requirement. *See* discussion *infra* note 340 and accompanying text. Thus, an inventor need not enable all uses to obtain a product claim. *Invitrogen Corp. v. Clontech Lab., Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005).

136. MARTIN A. VOET, *THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA & PHARMACEUTICAL LIFE-CYCLE MANAGEMENT* 71–74 (5th ed. 2016) (describing the “hierarchy” of patent claims and noting that product patents are the best for pharmaceuticals).

137. A famous example involves cisplatin, the most widely used anticancer drug. The drug’s biological properties were discovered through serendipity when the compound was accidentally made during a chemical experiment. *See* JIE JACK LI, *LAUGHING GAS, VIAGRA, AND LIPITOR: THE HUMAN STORIES BEHIND THE DRUGS WE USE* 10–11 (2006) (describing how the drug’s anticancer

inventor is barred from (re)patenting *X*.<sup>138</sup> But a subsequent inventor can possibly obtain a method-of-use claim for *X*.<sup>139</sup> The claim is written in the form “the [method] of applying Old Product *X* to New [Use] *Y*.”<sup>140</sup>

However, a new-use claim has two significant drawbacks. First, aside from the novelty requirement, the claimed new use may face a formidable nonobviousness hurdle.<sup>141</sup> The nonobviousness requirement<sup>142</sup> ensures that the invention is “new enough”<sup>143</sup> by denying patents for trivial extensions of what is already known<sup>144</sup> and for inventions that would have come about through ordinary technological progress.<sup>145</sup> The question that must be answered is whether the claimed new use would have been obvious to a PHOSITA

properties were first discovered). Characterization of the compound revealed that it was first made in 1845 and even contributed to the Nobel Prize for Chemistry awarded in 1913. Rebecca A. Alderden et al., *The Discovery and Development of Cisplatin*, 83 J. CHEMICAL EDUC. 728, 728 (2006). A method-of-use patent for cisplatin was issued in 1979. See Anti-Animal Tumor Method, U.S. Pat. No. 4,177,263 (filed Dec. 27, 1976) (claiming methods for treating tumors with the compound).

138. See *supra* notes 3, 10–11 and accompanying text.

139. 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”); Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 213 (1980) (recognizing the patentability of a newly discovered use over a known product); Merck & Co., Inc. 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).

140. Merges & Nelson, *supra* note 128, at 852. A method patent can provide fairly strong protection in certain situations. See, e.g., Lorie Ann Morgan & Jeffrey Tidwell, *Patents: United States Perspective*, in 4 ENCYCLOPEDIA OF PHARMACEUTICAL TECHNOLOGY 2616, 2617 (James Swarbrick ed., 3d ed. 2007) (explaining that method-of-use claims can afford important protection for pharmaceuticals because FDA approval is linked to specific therapeutic uses).

141. 35 U.S.C. § 103 (2012); see also Allegheny Drop Forge Co. v. Portec, Inc., 541 F.2d 383, 386 (3d Cir. 1976) (“A new use for an old process or product is patentable if the new use or application is itself not ‘obvious’ to [a PHOSITA].”).

142. Lack of novelty (35 U.S.C. § 102 (2012)) and lack of nonobviousness (35 U.S.C. § 103 (2012)) are substantively distinct grounds for denying patentability. Jones v. Hardy, 727 F.2d 1524, 1529 (Fed. Cir. 1984) (“[T]hough anticipation is the epitome of obviousness, [they] are separate and distinct concepts.”); see also Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1296 (Fed. Cir. 2002) (“[O]bviousness is not inherent anticipation.”). Most would agree that nonobviousness only comes into play after the novelty inquiry is complete. See *In re Bergy*, 596 F.2d 952, 960 (C.C.P.A. 1979) (explaining that an applicant must “hav[e] separate keys to open in succession the three doors of sections 101, 102, and 103”) (emphasis added), *aff’d in relevant part sub nom.* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

143. 3 CHISUM, *supra* note 67, § 3.01.

144. Graham v. John Deere Co., 383 U.S. 1, 6 (1966); see also John F. Duffy, *Inventing Invention: A Case Study of Legal Innovation*, 86 TEX. L. REV. 1, 6–7 (2007) (exploring the wisdom of denying patents for trivial inventions).

145. KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 427 (2007). If an invention lacks nonobviousness, it would have inevitably come about through routine advances; thus, the inducement of a patent (and the accompanying disclosure) are thought to be unnecessary. ALAN DEVLIN, FUNDAMENTAL PRINCIPLES OF LAW AND ECONOMICS 261 (2015); Rebecca S. Eisenberg, *Obvious to Whom? Evaluating Inventions from the Perspective of the PHOSITA*, 19 BERKELEY TECH L.J. 885, 886 (2004).

at the time the patent application was filed.<sup>146</sup> In the drug context, a new-use patent “may be difficult to obtain because the ‘new’ use may have been obvious, even if it was not obvious that the new use would be effective.”<sup>147</sup>

Second, method-of-use claims are difficult to enforce.<sup>148</sup> The patentee acquires only the right to exclude others from using the product in the *exact* manner that has been claimed.<sup>149</sup> So a new-use patent might be too narrow to cover other uses for *X* that come to the fore during the patent’s lifespan<sup>150</sup> or prevent others from using *X* for other purposes.<sup>151</sup> Also, the entity using *X* is likely to be a physician, not a competitor. Since physicians are rarely sued,<sup>152</sup> the patentee would need to pursue a deep-pocket competitor under an indirect infringement theory<sup>153</sup> (which is hard to prove).<sup>154</sup>

Assessing novelty in method claims follows the same rules described earlier, with some nuances. As a general matter, a method claim is anticipated if a single prior art reference discloses or performs all of the steps of the claimed method before the filing date.<sup>155</sup> For

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146. 35 U.S.C. § 103. 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 that provide objective proof of nonobviousness, such as unexpected results or the invention’s commercial success. *Graham*, 383 U.S. at 17–18.

147. Michael Abramowicz, *The Danger of Underdeveloped Patent Prospects*, 92 CORNELL L. REV. 1065, 1100 (2007).

148. See Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 548 n.243 (2009) (describing ways to avoid infringing a new-use patent).

149. NARD, *supra* note 77, at 522; PHARMACEUTICAL R&D, *supra* note 131, at 291.

150. Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL’Y L. & ETHICS 717, 724–25 (2005).

151. Eisenberg, *supra* note 22, at 351.

152. See *infra* note 197 and accompanying text.

153. Direct infringement occurs when a person “without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention” during the patent term. 35 U.S.C. § 271(a) (2012). Indirect infringement occurs when a defendant either: (1) “actively induces” a third party to infringe a patent; or (2) aids a third party in committing an act of direct infringement by supplying a component for use infringement. 35 U.S.C. § 271(b)–(c).

154. Proof of induced infringement requires “knowledge of the patent” and “knowledge that the induced acts constitute patent infringement.” *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 764, 766 (2011). As Dmitry Karshedt explains, “The principal difference between proving direct, as opposed to indirect, infringement is that the former is a strict liability tort, while both secondary infringement theories require a culpable state of mind.” Dmitry Karshedt, *Damages for Indirect Patent Infringement*, 91 WASH. U. L. REV. 911, 926 (2014) (footnotes omitted).

155. *Schumer v. Lab. Comput. Sys., Inc.*, 308 F.3d 1304, 1309 n.3 (Fed. Cir. 2002); see also *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1554 (Fed. Cir. 1995):

Anticipation requires identity of the claimed process and a process of the prior art; the claimed process, including each step thereof, must have been described or embodied, either expressly or inherently, in a single reference. . . . [T]he claimed invention, as

example, if the claimed method requires step A, step B, and step C, a person or thing that discloses or performs step A, step B, and step C before the filing date of the patent application anticipates the claim.<sup>156</sup>

Inherency doctrine also applies to method claims, including new-use claims. So claiming a new use for a known method is inherently anticipated if the effects of the new-use claim would have necessarily occurred as a result of practicing the known method.<sup>157</sup> To illustrate, consider the facts in *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*<sup>158</sup> The claim at issue was directed to “a method of increasing the oral bioavailability of metaxalone . . . [by] administering to the patient a therapeutically effective amount of metaxalone in a pharmaceutical composition with food.”<sup>159</sup> The asserted prior art reference disclosed taking metaxalone with food to help reduce “gastrointestinal distress,”<sup>160</sup> yet it was unknown at the time that ingesting metaxalone with food improved its absorption. Nonetheless, the Federal Circuit held that the new-use claim was inherently anticipated by the asserted prior art reference.<sup>161</sup> According to the court, taking metaxalone with food (as taught in the prior art) inherently increased the “oral bioavailability of metaxalone” because “the natural result of taking metaxalone with food is an increase in the bioavailability of the drug.”<sup>162</sup> A newly discovered benefit of a known method does not render the method patentable as a new use.<sup>163</sup>

Inherency raises another very important nuance in the law of anticipation for new-use claims. One might wonder if a *thing*, such as a product or device, can anticipate a new-use claim. The Federal Circuit faced this issue in *In re King*.<sup>164</sup> The applicant claimed a method of enhancing color effects from ambient light through a process of absorption and reflection of the light off a coated substrate.<sup>165</sup> The asserted prior art reference was a device that disclosed the coated substrate to produce architectural colors, but not the absorption and

described in appropriately construed claims, must be the same as that of the reference, in order to anticipate.

156. *Schumer*, 308 F.3d at 1309 n.3 (“[A] method claim will be anticipated by an earlier device performing all of the operative steps of the method.”); see *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993) (“[M]ethod claims . . . are infringed only when the method is practiced.”).

157. *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 633 (Fed. Cir. 1987).

158. 616 F.3d 1267, 1275–76 (Fed. Cir. 2010).

159. *Id.* at 1270.

160. *Id.* at 1272.

161. *Id.* at 1276.

162. *Id.* at 1272, 1275.

163. *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990); *Bird Provision Co. v. Owens Country Sausage, Inc.*, 568 F.2d 369, 375 (5th Cir. 1978).

164. 801 F.2d 1324 (Fed. Cir. 1986).

165. *Id.* at 1325.

reflection mechanisms of the claimed method.<sup>166</sup> But because the prior art device inherently performed the function recited in the claimed method when that device was used in normal operation, the Patent Office rejected the method claim for a lack of novelty.<sup>167</sup> Notwithstanding the applicant's argument that it was "absurd" to assert that a *device* could anticipate a *method* claim,<sup>168</sup> the Federal Circuit affirmed.<sup>169</sup> Consistent with prior precedent,<sup>170</sup> the court held that "[u]nder the principles of inherency, if a structure in the prior art necessarily functions in accordance with the limitations of a process or method claim of an application, the claim is anticipated."<sup>171</sup> The *King* court also made clear that the applicant's ability to articulate the underlying scientific phenomenon, which admittedly was unknown or undisclosed in the prior art, does not confer patentability.<sup>172</sup>

In *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*,<sup>173</sup> the Federal Circuit provided a hypothetical that illustrates how a new-use method claim can be inherently anticipated when a prior art device or method was used for a different stated purpose:

Inventor A invents a shoe polish for shining shoes (which, for the sake of example, is novel, useful, and nonobvious). Inventor A receives a patent having composition claims for shoe polish. Indeed, the preamble of these hypothetical claims recites "a composition for polishing shoes." Clearly, Inventor B could not later secure a patent with composition claims on the same composition because it would not be novel. Likewise, Inventor B could not secure claims on the method of using the composition for shining shoes because the use is not a "new use" of the composition but, rather, the same use shining shoes.

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166. *Id.* at 1326.

167. *Id.*

168. *Id.*

169. *Id.* at 1327.

170. See *Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403, 424–25 (1902) (explaining that a prior art device anticipates later process if the device carries out the process in its normal operation); *In re Ackenbach*, 45 F.2d 437, 439 (C.C.P.A. 1930) ("[I]f a previously patented device, in its normal and usual operation, will perform the function which an appellant claims in a subsequent application for process patent, then such application for process patent will be considered to have been anticipated by the former patented device.").

171. *In re King*, 801 F.2d at 1326; accord *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002) ("In order to prove that a claim is anticipated under 35 U.S.C. § 102(b), defendants must present clear and convincing evidence that a single prior art reference discloses, either expressly or inherently, each limitation of the claim.").

172. *In re King*, 801 F.2d at 1328; accord *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) ("[T]he discovery of a . . . scientific explanation for the prior art's function, does not render the old composition patentably new to the discoverer."); see *EMI Grp. N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1351 (Fed. Cir. 2001) (explaining that for anticipation, a PHOSITA need not understand the scientific mechanism of the inherent characteristic). Conversely, an applicant need not understand the underlying scientific principles or how or why an invention works in order to obtain a patent. See *infra* notes 266, 340 and accompanying text.

173. 289 F.3d 801 (Fed. Cir. 2002).



Suppose Inventor B discovers that the polish also repels water when rubbed onto shoes. Inventor B could not likely claim a method of using the polish to repel water on shoes because repelling water is inherent in the normal use of the polish to shine shoes. In other words, Inventor B has not invented a “new” use by rubbing polish on shoes to repel water.<sup>174</sup>

The bottom line is that new uses for old things and methods are unpatentable if the same underlying characteristic is operating,<sup>175</sup> regardless of whether the underlying characteristic was recognized in the past.<sup>176</sup>

### *B. Repurposed Inventions*

In theory, anything can be repurposed and the new use patented as long as the latter satisfies the statutory patentability requirements.<sup>177</sup> But repurposing has drawn the most attention in the pharmaceutical industry because drug firms recognize that developing new uses for old drugs is much cheaper than de novo drug development.<sup>178</sup> Taking a new drug from concept through FDA approval<sup>179</sup> to market can take ten to fifteen years and easily exceed one billion dollars.<sup>180</sup> Much of the time and cost can be attributed to the drug

174. *Id.* at 809–10 (citations omitted).

175. *Cf. Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005) (“[When] the inherent property corresponds to a claimed new benefit or characteristic of an invention otherwise in the prior art . . . , the new realization alone does not render the old invention patentable.”).

176. *In re Cruciferous Sprout*, 301 F.3d at 1349–50; *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001); *In re King*, 801 F.2d at 1327.

177. For the requirements, see *supra* note 126.

178. See generally John Arrowsmith & Richard Harrison, *Drug Repositioning: The Business Case and Current Strategies to Repurpose Shelved Candidates and Marketed Drugs*, in DRUG REPOSITIONING: BRINGING NEW LIFE TO SHELVED ASSETS AND EXISTING DRUGS 9 (Michael J. Barratt & Donald E. Frail eds., 2012); Richard B. Smith, *Repositioned Drugs: Integrating Intellectual Property and Regulatory Strategies*, 8 DRUG DISCOVERY TODAY 131, 131 (2011) (noting that repositioning is a major business strategy for both big and small firms); Timothy X. Witkowski, *Intellectual Property and Other Legal Aspects of Drug Repurposing*, 8 DRUG DISCOVERY TODAY 139, 139 (2011) (“Drug repurposing, particularly of previously approved drugs, is an attractive strategy because, in theory, the developer benefits from the sunk costs of prior development for a drug that has . . . additional indications . . .”). “De novo” refers to the traditional drug discovery process, which begins with identifying new chemical compounds suitable for medical use. Ted T. Ashburn & Karl B. Thor, *Drug Repositioning: Identifying and Developing New Uses for Existing Drugs*, 3 NATURE REV. DRUG DISCOVERY 673, 673–74 (2004); Mark S. Boguski et al., *Repurposing with a Difference*, 324 SCIENCE 1394, 1394 (2009).

179. New drugs typically undergo three phases of clinical testing to explore their safety and efficacy. 21 C.F.R. § 312.21 (2019). Briefly, Phase I involves limited human clinical trials to elicit basic safety data and to evaluate dosing and how a drug is metabolized; Phase II expands the testing to a larger group of subjects with the disease to test efficacy and safety; and Phase III involves an even larger group of subjects and explores long-term evaluation of the drug’s efficacy and safety. 21 C.F.R. § 312.21(a)–(c). After Phase III, the FDA determines whether the drug should be marketed.

180. JORGE MESTRE-FERRANDIZ ET AL., OFF. OF HEALTH ECON., THE R&D COST OF A NEW MEDICINE 39 (2012); Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New*

discovery and preclinical development stages.<sup>181</sup> A substantial number of de novo candidates fail,<sup>182</sup> whether due to safety, efficacy, scientific challenges, regulatory hurdles, or other reasons.<sup>183</sup> This means that de novo drug development requires pharmaceutical firms to take on substantial financial risks.<sup>184</sup> By contrast, repurposing previously approved drugs can bypass most of the de novo drug development process,<sup>185</sup> reduce the time to market to three to twelve years,<sup>186</sup> and lower the cost to only 300 million dollars on average.<sup>187</sup> There is also growing interest in repurposing failed drugs—those that have been through some clinical development but never made it to market because they did not prove effective for their intended purpose.<sup>188</sup> Finding new

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*Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 22 (2016); Steve Morgan et al., *The Cost of Drug Development: A Systematic Review*, 100 HEALTH POL'Y 4, 9 (2011).

181. Benjamin N. Roin, Solving the Problem of New Uses 4–5 (Oct. 14, 2016) (unpublished manuscript), <https://www.bu.edu/law/files/2016/10/Solving-the-Problem-of-New-Uses-Ben-n-Roin.pdf> [<https://perma.cc/DNC9-MNX3>].

182. A drug company may screen hundreds of thousands of chemical compounds as likely candidates for development, but “for every 10,000 compounds that are evaluated in animal studies, 10 will make it to human clinical trials in order to get 1 compound on the market.” RICHARD B. SILVERMAN, *THE ORGANIC CHEMISTRY OF DRUG DESIGN AND DRUG ACTION* 8 (2d ed. 2004); see also Morgan et al., *supra* note 180, at 9 (noting estimates of success rates for new drugs entering clinical trials ranging from eleven to twenty-four percent); *A Higher Purpose*, *supra* note 18, at 52 (noting that forty-five percent of new drug candidates fail clinical trials).

183. See MESTRE-FERRANDIZ ET AL., *supra* note 180, at 65–67 (exploring drivers of failure rates).

184. DiMasi et al., *supra* note 180, at 21.

185. Chong & Sullivan, *supra* note 21, at 645 (explaining that developers of repurposed drugs “can bypass almost 40% of the overall cost of bringing a drug to market by eliminating much of the toxicological and pharmacokinetic assessments”).

186. Ashburn & Thor, *supra* note 178, at 675; see also Joel T. Dudley et al., *Exploiting Drug-Disease Relationships for Computational Drug Repositioning*, 12 BRIEFINGS BIOINFORMATICS 303, 304 (2011) (“The drug development cycle for a repositioned drug can be as short as 3–12 years compared to the traditional 10–17 years required to bring a new chemical entity to market.”).

187. ALISON SAHOO, INDICATION EXPANSION: OPPORTUNITIES FOR SUCCESSFUL LIFECYCLE MANAGEMENT 28 (2007). Sometimes the cost savings is tremendous. Consider thalidomide, originally approved in the 1950s as a sedative and repurposed in 2012 to treat multiple myeloma. It is estimated that FDA approval for repurposing costs forty to eighty million dollars, compared to the average of one to two billion dollars for de novo drug development. Anna Azvolinsky, *Repurposing Existing Drugs for New Indications*, SCIENTIST (Jan. 1, 2017), <https://www.the-scientist.com/?articles.view/articleNo/47744/-title/Repurposing-Existing-Drugs-for-New-Indications/> [<https://perma.cc/49A3-8C59>] (citing J.W. Scannell et al., *Diagnosing the Decline in Pharmaceutical R&D Efficiency*, 11 NATURE REV. DRUG DISCOVERY 191, 191–200 (2012)).

188. Yoonjeong Cha et al., *Drug Repurposing from the Perspective of Pharmaceutical Companies*, 175 BRIT. J. PHARMACOLOGY 168, 175 (2018); Stephen Naylor et al., *Therapeutic Drug Repurposing, Repositioning and Rescue Part II: Business Review*, DRUG DISCOVERY WORLD 57, 62–63 (Mar. 2015), [https://www.researchgate.net/profile/Stephen\\_Naylor2/publication/282951546\\_Therapeutic\\_drug\\_repurposing\\_repositioning\\_and\\_rescue\\_Part\\_II\\_Business\\_review/inks/568c102208ae71d5cd04abdc/Therapeutic-drug-repurposing-repositioning-and-rescue-Part-II-Business-review.pdf](https://www.researchgate.net/profile/Stephen_Naylor2/publication/282951546_Therapeutic_drug_repurposing_repositioning_and_rescue_Part_II_Business_review/inks/568c102208ae71d5cd04abdc/Therapeutic-drug-repurposing-repositioning-and-rescue-Part-II-Business-review.pdf) [<https://perma.cc/K6KP-AKGE>].

uses for these “rescued” drugs is also cheaper than starting from scratch.<sup>189</sup>

But again, new-use patents have shortcomings.<sup>190</sup> Recall that new-use patent claims are narrow in scope, meaning that they are often avoided.<sup>191</sup> If the old product is still covered by a (product) patent, that patent will “dominate” the new-use patent until the (old) product patent expires.<sup>192</sup> But new-use patents for drugs face an additional challenge. Once the product patent expires, generic manufacturers can enter the market and sell cheaper versions of the drug.<sup>193</sup> Generic manufacturers can avoid a new-use patent by omitting the new indication from the drug label.<sup>194</sup> An off-patent drug can be lawfully sold, prescribed, and administered for an older, unpatented use.<sup>195</sup> Likewise, generic manufacturers can avoid infringement if the patented use is off-label.<sup>196</sup>

189. See Arti K. Rai & Grant Rice, *Use Patents Can Be Useful: The Case of Rescued Drugs*, SCI. TRANSLATIONAL MED. 1 (Aug. 6, 2014), <https://stm.sciencemag.org/content/6/248/248fs30/tab-pdf> [<https://perma.cc/9TW4-EBC4>] (explaining that the availability of use patents should “drive development of rescued drugs, which have already been derisked to some extent in early-phase clinical trials for safety”).

190. See *supra* notes 134–136 and accompanying text.

191. See *supra* notes 148–149 and accompanying text.

192. Ann M. Thayer, *Drug Repurposing*, CHEMICAL & ENG’G NEWS (Oct. 1, 2012), <https://cen.acs.org/articles/90/i40/Drug-Repurposing.html> [<https://perma.cc/9X4K-DBKC>]. This gives rise to the blocking patents paradigm, wherein the product patent is “dominant” and the new-use patent is “subservient” to it. Merges & Nelson, *supra* note 128, at 860–62. The product patent holder can prevent the new-use patent holder from practicing the new use without a license. *Id.* at 860–61. Likewise, the new-use patent holder can block the product patent holder from practicing the new-use without a license. This situation is often resolved through cross-licensing. *Id.* at 854 n.65.

193. See Levi J. Beverly & Maxwell M. Krem, *Teaching Old Drugs New Tricks: Repositioning Pharmaceuticals for Bench to Bedside Success*, 355 AM. J. MED. SCI. 205, 206 (noting that many repurposed drugs “are available as generics and are off-patent”).

194. Rai & Rice, *supra* note 189, at 1; Roin, *supra* note 181, at 35 n.249 (“FDA regulations explicitly allow for generic manufactures [sic] to exclude patented indications from their label to avoid infringing any new-use patents.” (citing 21 C.F.R. § 314.127(a)(7) (2019))).

195. Eisenberg, *supra* note 150, at 720; see also ELLERY & HANSEN, *supra* note 134, at 126 (“Even if the new indication is patented . . . there is no mechanism to stop physicians prescribing the generic or pharmacies dispensing it off-label to patients with the protected indication.”); Eisenberg, *supra* note 150, at 725 (“If the competitor merely brings the generic product to market for the old use, the fact that the product may be prescribed and used off-label for a patented new use is not enough to make the seller liable as an indirect infringer.”). But sometimes physicians are reluctant to prescribe a drug for an off-label use because of worries about legal liability if something goes wrong or concerns about whether insurance companies will pay for an unapproved use. *A Higher Purpose*, *supra* note 18, at 53.

196. To understand this point, it is necessary to briefly discuss the legal framework for generic drug approval. The Hatch-Waxman Act provides a swift route for generic manufacturers to seek FDA approval to market generic versions of previously approved brand-name drugs by establishing that the proposed generic is chemically equivalent and bioequivalent to its brand-name counterpart and that the generic will have the same labeling as the previously approved drug. 21 U.S.C. § 355(j)(2)(A)(ii)–(v) (2012). Hatch-Waxman permits generic manufacturers to apply for FDA approval before brand-name drug patents expire, 21 U.S.C. § 355(j)(2)(A)(vii), but such action *can* constitute patent infringement. 35 U.S.C. § 271(e)(2)(A) (2012). The Federal

Thus, new-use patents for drugs can be hard to enforce because drug firms rarely sue shallow-pocket individuals like patients who use the drug for the patented new use, doctors who prescribe the drug for such use, or pharmacists who fill the prescription.<sup>197</sup>

Yet these challenges have not deterred drug firms, who view repurposing as a promising strategy for increased revenue and business growth.<sup>198</sup> Repurposing offers cheaper and shorter research and development (“R&D”) timelines with a better risk-versus-reward trade-off compared with other drug development strategies.<sup>199</sup> Some repurposing successes involving well-known drugs have become legendary.<sup>200</sup> Viagra (sildenafil) was originally purposed for angina;<sup>201</sup> it has been repurposed for erectile dysfunction.<sup>202</sup> Rogaine (minoxidil) was originally purposed for hypertension;<sup>203</sup> it has been repurposed for male and female pattern baldness.<sup>204</sup> AZT (zidovudine) was originally

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Circuit has held that if the drug itself is not patented, and the use claimed in the patent at issue is off-label, the brand-name manufacturer has no infringement remedy if the generic manufacturer is not seeking FDA approval for the off-label use. *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1332 (Fed. Cir. 2003) (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1356 (Fed. Cir. 2003)). Otherwise, brand-name firms could extend their exclusivity by obtaining new-use patents and then asserting them against generic competitors seeking approval to market an off-patent drug for an approved use not covered by the patent. *Warner-Lambert*, 316 F.3d at 1359. This would bar generic manufacturers from the market, which is inconsistent with *Hatch-Waxman*. *Id.*

197. Such infringement is not only hard to detect, but enforcement against these intermediaries is inefficient and has social costs. *See Eisenberg, supra* note 150, at 724–25 (“It is more difficult to detect and prove infringing uses than it is to detect and prove infringing products, and it is less efficient to sue numerous patients and physicians than it is to sue a single manufacturer.”); *Eisenberg, supra* note 22, at 351; Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 *YALE L.J.* 1900, 1917 (2013) (describing the social norms that make monitoring of such infringement difficult).

198. *See Thayer, supra* note 192; *supra* note 178 and accompanying text.

199. *Ashburn & Thor, supra* note 178, at 673–74. Risk is reduced because older, approved drugs have been tested in humans, meaning that much is known about their pharmacology and potential toxicity. *See Arrowsmith & Harrison, supra* note 178, at 9; *Collins, supra* note 15, at 397.

200. Repositioning ideas come through various discovery methods, including targeted screening, big data analysis, and serendipity. *See Ashburn & Thor, supra* note 178, at 675, 676; *Dudley, supra* note 186, at 303–04; *Ekins et al., supra* note 21, at 300 tbl.1, 301 tbl.2.

201. *See* *Pyrazolopyrimidinone Antianginal Agents*, U.S. Patent No. 5,250,534 (filed May 14, 1992).

202. *See* *Pyrazolopyrimidinones for the Treatment of Impotence*, U.S. Patent No. 6,469,012 (filed May 13, 1994).

203. *See* *6-Amino-4-(Substituted Amino)-1,2-Dihydro-1-Hydroxy-2-Iminopyrimidines*, U.S. Patent No. 3,461,461 (filed Nov. 1, 1965).

204. *See* *6-Amino-4-(Substituted Amino)-1,2-Dihydro-1-Hydroxy-2-Iminopyrimidine, Topical Compositions and Process for Hair Growth*, U.S. Patent No. 4,139,619 (filed Aug. 19, 1977).

purposed for cancer;<sup>205</sup> it has been repurposed for HIV/AIDS.<sup>206</sup> Interest in drug repurposing will only increase as the list of successes grows and the number of candidates in the drug discovery pipeline continues to diminish.<sup>207</sup>

### III. FINDING NOVELTY IN REPURPOSED INVENTIONS

Finding new uses for old things is the type of creative activity that the patent system encourages.<sup>208</sup> But if the claimed new use is an inherent characteristic of the old thing, it is unpatentable due to a lack of novelty.<sup>209</sup> Yet there are reasons to doubt the current novelty framework's gatekeeping function. Various evidentiary rules, biases, and views of inherency preclude a true assessment of *identity*—which is what novelty is all about.<sup>210</sup> This Part offers a new framework for evaluating novelty in new-use patent applications that solves this problem.

#### A. Identifying Inherent Characteristics

The key question for any claimed new use is whether it is actually *new*.<sup>211</sup> If the old product does not explicitly disclose the claimed new use, it is nevertheless anticipated if the use is inherently disclosed.<sup>212</sup> So if the old product is doing what it has always done, the

205. The inventor sought to design a compound that would inhibit the replication of cancer cells. See Jerome P. Horwitz et al., *Nucleosides. V. The Monomesylates of 1-(2'-Deoxy-β-D-Lyxofuranosyl)thymine*, 29 J. ORGANIC CHEMISTRY 2076 (1964). The compound did not work, so the inventor shelved it and did not pursue a patent. *A Failure Led to the Drug Against AIDS*, N.Y. TIMES (Sept. 20, 1986), <https://www.nytimes.com/1986/09/20/us/a-failure-led-to-drug-against-aids.html> [https://perma.cc/MZ3L-VJN4].

206. See Treatment of Human Viral Infections, U.S. Patent No. 4,724,232 (filed Sept. 17, 1985).

207. Ashburn & Thor, *supra* note 178, at 673; Scannell et al., *supra* note 187, at 191–97. For a compilation of successes, see Ashburn & Thor, *supra* note 178, at 677–80 tbls.1–4; and Smith, *supra* note 178, at 132–33 tbl.1.

208. See Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 221 (1980) (reviewing a patent covering a new use for a known product and explaining that the “[d]evelopment of new uses for existing chemicals is . . . a major component of practical chemical research”); United States v. Adams, 383 U.S. 39, 52 (1966) (discussing the merit in “find[ing] new uses for old inventions”); Sanofi-Synthelabo v. Apotex Inc., 488 F. Supp. 2d 317, 346 (S.D.N.Y. 2006) (explaining that protecting the patentee’s blockbuster drug patent “secures the public interest in innovation by providing commercial incentive for [the patentee] to begin and continue clinical trials researching new uses for the drug”), *aff'd*, 470 F.3d 1368 (Fed. Cir. 2006).

209. *In re King*, 801 F.2d 1324, 1327 (Fed. Cir. 1986).

210. See *supra* Section I.B.

211. See *supra* Section I.B.

212. See discussion *supra* Section I.C.

claimed new use lacks novelty<sup>213</sup> regardless of whether the benefit or characteristic was known in the past.<sup>214</sup>

To illustrate, consider loratadine, an antihistamine sold under the brand name Claritin.<sup>215</sup> It was first approved as a prescription drug for treating allergies in 1993.<sup>216</sup> When consumed, loratadine *always* converts into a metabolite that inhibits the action of histamine in the body.<sup>217</sup> This makes histamine inhibition an *inherent characteristic* of loratadine because it necessarily and inevitably occurs each time the drug is consumed.<sup>218</sup>

Histamine is a biological molecule implicated in many conditions—including allergies,<sup>219</sup> gastric acid secretion,<sup>220</sup> multiple sclerosis,<sup>221</sup> schizophrenia,<sup>222</sup> and migraine headaches.<sup>223</sup> If a patient takes loratadine to treat any of these conditions, this Article contends that the use—histamine inhibition—is the same. The inherent characteristic of histamine inhibition ties everything together because loratadine is doing the same thing in each indication.<sup>224</sup> Likewise, patients prescribed loratadine for allergies but who also suffered from gastritis, multiple sclerosis, schizophrenia, or migraine headaches were necessarily treated for those histamine-related conditions as well—and benefitted from the treatment—even if the patient or physician did not so intend, know, appreciate, or recognize.<sup>225</sup> And newly discovered indications for loratadine involving histamine inhibition should be

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213. Cf. PHILLIPS, *supra* note 1, at 109 (“There is no instance in which it has been held that a mere new effect of the use of a machine already known, without any new combination, machinery, or process, is the subject of a valid patent.”).

214. Cf. Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1378 (Fed. Cir. 2005) (“[W]hen considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure.”).

215. BENJAMIN BLASS, BASIC PRINCIPLES OF DRUG DISCOVERY AND DEVELOPMENT 516 (2015).

216. ELLERY & HANSEN, *supra* note 134, at 307.

217. BLASS, *supra* note 215, at 516.

218. Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1378 (Fed. Cir. 2003).

219. See SARAH LENNARD-BROWN, ALLERGIES 9 (2004).

220. See Elisabetta Barocelli & Vigilio Ballabeni, *Histamine in the Control of Gastric Acid Secretion: A Topic Review*, 47 PHARMACOLOGICAL RES. 299 (2003).

221. See Farhad Jadidi-Niaragh & Abbas Mirshafiey, *Histamine and Histamine Receptors in Pathogenesis and Treatment of Multiple Sclerosis*, 59 NEUROPHARMACOLOGY 180 (2010).

222. See Jean-Michel Arrang, *Histamine and Schizophrenia*, 78 INT’L REV. NEUROBIOLOGY 247 (2007).

223. See Hsiangkuo Yuan & Stephen D. Silberstein, *Histamine and Migraine*, 58 HEADACHE 184 (2018).

224. Of course, this requires some understanding of the product’s mechanism of action. See *infra* Section III.B.2.

225. See *supra* notes 90–107 and accompanying text. I recognize that different doses might be an issue.

unpatentable because the same underlying inherent characteristic is operating.

### *B. Examining New-Use Patent Claims*

Patent examination is an *ex parte* proceeding between the applicant and the examiner.<sup>226</sup> The examiner's principal task<sup>227</sup> is to evaluate the patent application for compliance with the patentability requirements found in Title 35 of the United States Code,<sup>228</sup> including novelty.<sup>229</sup> Recall that gauging novelty requires the examiner to search the prior art—preexisting knowledge and technology already available to the public.<sup>230</sup>

The patent system views novelty as a rigid rule.<sup>231</sup> If the identical subject matter has been “patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention,”<sup>232</sup> it has been anticipated by the prior disclosure.<sup>233</sup>

#### 1. The Current Rubric

The examiner undertakes a three-step analysis to gauge novelty.<sup>234</sup> First, the examiner must construe the relevant claim in the

226. See ALAN L. DURHAM, PATENT LAW ESSENTIALS § 5.1 (4th ed. 2013).

227. The examiner is a quasi-judicial official with expertise in a technical field tasked with “examining patent applications and issuing patents if ‘it appears that the applicant is entitled to a patent under the law.’” *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 95–96 (2011) (quoting 35 U.S.C. § 131 (2012)) (citation omitted); cf. *Keystone Bridge Co. v. Phoenix Iron Co.*, 95 U.S. 274, 278 (1877) (explaining that examiners carry out their task by ensuring that claims are “examined, scrutinized, limited, and made to conform to what [the applicant] is entitled to”).

228. For the requirements, see discussion *supra* note 126.

229. See *supra* note 4 and accompanying text.

230. See *supra* note 60 and accompanying text.

231. Robert Merges has explained that the novelty rules protecting the public domain are so solicitous of preserving access to the prior art that they can seem almost absurd. There is no inquiry into . . . the practical accessibility of the prior art; once it is public, even marginally, and only in one obscure place or one obscure form, the game is over—no patent. Period.

ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY 143 (2011).

232. 35 U.S.C. § 102(a)(1) (2012).

233. The patent statute provides a grace period for certain prior disclosures that came directly or indirectly from the inventor. See 35 U.S.C. § 102(b).

234. Courts undertake a similar analysis in patent infringement litigation. See *Mehl/Biophile Int’l Corp. v. Milgraum*, 8 F. Supp. 2d 434, 443–44 (D.N.J. 1998) (articulating the three steps), *aff’d*, 192 F.3d 1362 (Fed. Cir. 1999). Anticipation and infringement are two sides of the same coin: that which anticipates earlier in time would infringe later in time. *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889), *superseded in part by statute* 36 U.S.C. § 102, *as recognized in* *Lewmar Marine, Inc. v. Bariant, Inc.*, 827 F.2d 744, 747 (noting the modern test is more accurately stated

patent application to determine its scope.<sup>235</sup> Second, to check for strict identity,<sup>236</sup> the examiner must compare the construed claim with the prior art reference to determine if each claim element is found in it.<sup>237</sup> Third, the examiner must determine whether the alleged prior art reference was sufficiently enabling to teach a PHOSITA how to make the invention at the time of filing without undue experimentation.<sup>238</sup>

The mechanics of *ex parte* examination are driven by an evidentiary framework that includes presumptions and shifting burdens of proof.<sup>239</sup> At the time of filing, § 102 affords the applicant a presumption of novelty because the statute recites that “a person shall be entitled to a patent *unless*” one of the statutory exclusions is shown.<sup>240</sup> Accordingly, the initial burden of proof rests with the examiner to build a *prima facie* case of anticipation.<sup>241</sup> Once made, the burden shifts to the applicant to rebut the *prima facie* case with persuasive argument or proof.<sup>242</sup> While the burden of production may shift back and forth, the ultimate burden of persuasion is on the Patent Office.<sup>243</sup>

This rubric changes when anticipation is based on inherency. Generally, an examiner who relies on inherency “must provide a basis

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as “[t]hat which would *literally* infringe if later in time anticipates if earlier than the date of invention”).

235. See *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1294 (Fed. Cir. 2002) (“[T]he anticipation inquiry first demands a proper claim construction.”). At the examination stage, the examiner must give claim terms the broadest reasonable interpretation a PHOSITA would give them while simultaneously conferring an interpretation consistent with the applicant’s written description of the invention. *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1276 (Fed. Cir. 2015), *aff’d sub nom.* *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016).

236. See *supra* note 68 and accompanying text.

237. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986) (“It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention . . .”).

238. *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008). Enablement is a standard. Determining whether a prior art reference is enabling is a legal conclusion based on factual inquiries. *Id.* The Federal Circuit has set forth several factors relevant to the enablement analysis: (1) “the amount of direction or guidance present[ed]” 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. *Id.* at 1314–15 (citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)).

239. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

240. *In re Wilder*, 429 F.2d 447, 450 (C.C.P.A. 1970) (quoting 35 U.S.C. § 102 (2012)).

241. *Oetiker*, 977 F.2d at 1445; *Wilder*, 429 F.2d at 450; see also *In re King*, 801 F.2d 1324, 1327 (Fed. Cir. 1986) (noting that the Patent Office must establish a *prima facie* case before any burden shifting occurs).

242. *Oetiker*, 977 F.2d at 1445; see also *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (explaining that when the Patent Office shows a sound basis for believing that the prior art and claimed subject matter are identical, the applicant has the burden of showing that they are not).

243. *Oetiker*, 977 F.2d at 1449 (Plager, J., concurring); *In re Warner*, 379 F.2d 1011, 1016 (C.C.P.A. 1967).



in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.”<sup>244</sup> Particularly relevant for present purposes is the scenario discussed earlier where a prior art device or product is asserted against a claimed new use.<sup>245</sup> Following inherency principles, “if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device.”<sup>246</sup> When the prior art device or product is the same as the device described in the inventor’s patent application, the *Manual of Patent Examining Procedure*<sup>247</sup> allows the examiner to presume that it will inherently perform the claimed method of use.<sup>248</sup> In this situation, a prima facie case of anticipation is established.<sup>249</sup> The burden then shifts to the applicant to “prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.”<sup>250</sup> But “before an applicant can be put to this burdensome task, the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner’s belief that the [claimed subject matter] is an inherent characteristic of the prior art.”<sup>251</sup>

The rationale for requiring the applicant to disprove inherency is fairness and expediency: the Patent Office lacks the facilities and resources to obtain products and carry out experiments.<sup>252</sup>

244. *Ex parte Levy*, 17 U.S.P.Q.2d (BNA) 1461, 1464 (B.P.A.I. 1990).

245. See *supra* notes 164–172 and accompanying text.

246. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE, § 2112.02(I) (9th ed. Rev., Jan. 2018), <https://www.uspto.gov/web/offices/pac/mpep/mpep-2100.pdf> [<https://perma.cc/5R4F-EHK6>] [hereinafter MPEP]; accord *In re King*, 801 F.2d at 1327.

247. The MPEP provides guidance to patent examiners and is entitled to judicial notice 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). The MPEP “is also made available to patent applicants and their lawyers as well as to the general public . . . [and] is used frequently by patent lawyers and agents in advising applicants and in preparing their various papers for filing in the Patent Office.” *In re Kaghan*, 387 F.2d 398, 401 (C.C.P.A. 1967).

248. MPEP, *supra* note 246, § 2112.02(I).

249. *In re King*, 801 F.2d at 1327. Thus, the examiner “[is] permitted to speculate, at least to a degree, about the function of things disclosed in the prior art, and support rejections based on the supposed functions.” Bradford J. Duft & Eric P. Mirabel, *Principles of Inherency*, 77 J. PAT. & TRADEMARK OFF. SOC’Y 539, 541 (1995).

250. *In re King*, 801 F.2d at 1327 (quoting *In re Swinehart*, 439 F.2d 210, 212–13 (C.C.P.A. 1971)); accord *In re Best*, 562 F.2d 1252, 1255 (C.C.P.A. 1977).

251. *Ex parte Skinner*, 2 U.S.P.Q.2d (BNA) 1788, 1789 (B.P.A.I. 1986); see also *supra* note 244 and accompanying text.

252. *Behr v. Talbot*, 27 U.S.P.Q.2d (BNA) 1401, 1408 (B.P.A.I. 1992); accord *In re King*, 801 F.2d at 1327 (rejecting the applicant’s contention that the Patent Office must prove inherency by experiment because the agency “is not equipped to perform such tasks”); *Best*, 562 F.2d at 1255 (explaining that “fairness” of the burden of proof “is evidenced by the [Patent Office’s] inability to manufacture products or to obtain and compare prior art products”); see also Jacob S. Sherkow,

## 2. Concerns

The preceding discussion reveals that ferreting out nonnovel claims is a formidable task because various evidentiary rules at the Patent Office favor the applicant.<sup>253</sup> An examiner seeking to challenge novelty must build a *prima facie* case of anticipation *and* carry the ultimate burden of persuasion on the issue.<sup>254</sup> The Patent Office *must* issue a patent if the examiner fails to do both.<sup>255</sup> The concern is that the current rubric has a pro-applicant bias,<sup>256</sup> which “impedes attempts ‘to weed out unwarranted patents.’”<sup>257</sup>

There are other concerns that are best explained in the drug repurposing context. One concern is indication bias. Vast differences between a drug’s old and new *indications* might lead an examiner to summarily conclude that the repurposed drug has a novel *use* even if the old and new indications in fact stem from the same underlying inherent characteristic.<sup>258</sup> Differences in the drug’s route of administration between the old and new indications could also lead the examiner astray.<sup>259</sup> For example, administering a drug as an oral liquid

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*And How: Mayo v. Prometheus and the Method of Invention*, 122 YALE L.J. ONLINE 351, 356–57 (2013) (discussing how the Patent Office is ill-equipped to handle fact-intensive inquiries).

253. Sean B. Seymore, *The Presumption of Patentability*, 97 MINN. L. REV. 990, 997–1014 (2013).

254. *See supra* Section III.B.1.

255. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (“If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.”); FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 5, at 8–9 (2003), <https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> [<https://perma.cc/C73H-ZM4J>] (explaining that the Patent Office must issue a patent unless it proves unpatentability, thereby effectively creating a presumption that every requested patent should issue).

256. *See Seymore, supra* note 253, at 1023 (“[V]arious presumptions and procedural aspects of patent examination tip the scales in favor of issuance once a patent application is filed.”). Concerns about a pro-patent(ee) bias has received considerable attention in legal scholarship. *See, e.g.*, John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 212–13 (1998) (finding that juries tend to be pro-patentee); Rochelle Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 25–26 (1989) (noting that the Federal Circuit’s monopolization of patent cases contributes to the problem); Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law’s Presumption of Validity*, 60 STAN. L. REV. 45, 69 (2007) (exploring ways to “help insulate . . . new examiners from the pro-patent mindset that has arguably infected the rest of the examining corps”).

257. Sean B. Seymore, *Patent Asymmetries*, 49 U.C. DAVIS L. REV. 963, 988 (2016) (quoting FED. TRADE COMM’N, *supra* note 255, at 31–32).

258. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 971 (Fed. Cir. 2001) (finding that a claim directed to administering a drug to block serotonin uptake in animals was anticipated by a prior patent disclosing administration of the drug to treat anxiety in humans because serotonin uptake inhibition is an inherent property of the drug upon its administration for any purpose).

259. Routes of administration include intravenous, oral, sublingual (placing the drug under the tongue without swallowing), topical, via inhalation, rectal, vaginal, and ophthalmic. ZACHARY I. HANAN & JANE M. DURGIN, DURGIN & HANAN’S PHARMACY PRACTICE FOR TECHNICIANS 478–81

for indication *A* and as an injection for indication *B* might suggest that the latter is a novel use.<sup>260</sup> These distractions can thwart a proper inherency analysis.<sup>261</sup> Returning to the earlier hypothetical,<sup>262</sup> *X*'s original indication for depression and its repurposed indication for irritable bowel syndrome could lead an examiner to conclude that the repurposed use is novel given that the bodily functions involved are vastly different. Yet in both indications, *X* works by inhibiting serotonin uptake—an inherent characteristic of *X* that *should* render the repurposed use anticipated.<sup>263</sup> This potential bias extends beyond drug repurposing and can arise whenever there are vast differences between an old and repurposed use.

Another concern is the mechanism problem. The term *mechanism* refers to how or why something works or happens.<sup>264</sup> While mechanistic information plays a substantial role in drug development,<sup>265</sup> it is typically not required in patent law<sup>266</sup> and is

(5th ed. 2015). Anticipation can hinge on the route of administration. For example, suppose the prior art teaches that oral administration of *Z* has anti-inflammatory properties. Now suppose an inventor seeks to claim a method of treating inflamed acne by topical administration of *Z* to the affected area. There are three reasons why the prior art does not anticipate the claimed new use. First, the claim explicitly requires *topical* administration of *Z*, which is not taught by the prior art. *See* *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378–79 (Fed. Cir. 2005) (reversing a district court's finding of inherent anticipation because the prior art use did not teach “topical application” required by the claimed new use). Second, since the prior art only teaches oral administration, an acne patient would have to randomly attempt to apply *Z* to the face to achieve the claimed result. An alleged inherent characteristic must necessarily and inevitably result from practicing the prior art; that it can possibly result from a given set of circumstances will not anticipate. *See supra* note 117 and accompanying text. Third and relatedly, acne patients did not benefit from the prior art disclosure of *Z*. *See supra* notes 109–113 and accompanying text.

260. This could happen even if one would expect the pharmacological effect of the same drug administered by different routes to be the same. *See* HANAN & DURGIN, *supra* note 259, at 478. I recognize that sometimes a different route of administration can involve a wholly new invention. For example, administering aspirin as a tablet to treat a headache and as a topical suspension with glycerin and alcohol to treat acne involves two different inventions because the compositions are not identical. In this type of scenario, the principal barrier to patentability is not novelty but nonobviousness. *See supra* notes 142–147 and accompanying text.

261. Even if the applicant claims a specific route of administration with the purpose of avoiding inherent anticipation, the applicant would still face a nonobviousness hurdle. *See supra* note 260.

262. *See supra* text accompanying notes 25–32.

263. *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (“Under the principles of inherency, if a structure in the prior art necessarily functions in accordance with the limitations of a process or method claim of an application, the claim is anticipated.”).

264. *Mechanism*, CAMBRIDGE ADVANCED LEARNER'S DICTIONARY 888 (3d ed. 2008).

265. *See* Editorial, *Mechanism Matters*, 16 NATURE MED. 347, 347 (2010) (explaining that while mechanistic information is not required for a drug to gain FDA approval, moving into clinical trials without this information “may set the stage for failure,” whereas obtaining it “can increase the chances for drug approval, saving money, time, and . . . the lives of patients”).

266. For example, an inventor can obtain a patent with no understanding or disclosure of how or why the invention works. *Eames v. Andrews (The Driven-Well Cases)*, 122 U.S. 40, 55–56 (1887) (“It may be that the inventor did not know what the scientific principle was . . . . That does not

seemingly irrelevant under prevailing views of inherency. For example, suppose the prior art teaches that oral administration of *Y* treats indication A and a researcher subsequently discovers that oral administration of *Y* also necessarily and inevitably treats indication B. If the researcher seeks a patent, current novelty rules would render the newly discovered use inherently anticipated regardless of why or how *Y* works in each indication—whether it be by the same or (vastly) different mechanisms.<sup>267</sup>

But ignoring the underlying science—how or why a result is achieved—precludes a robust, diligent, and probing novelty analysis. At its core, novelty is about *identity*;<sup>268</sup> the basic question in new-use cases is whether the identical inherent characteristic is responsible for the old and new use.<sup>269</sup> This is a *technical* question, which often requires some understanding of mechanism.<sup>270</sup> For example, aspirin had been used as a pain reliever, fever reducer, and blood thinner long before researchers discovered that the same mechanism of action, prostaglandin inhibition, operates in all three indications.<sup>271</sup> But researchers have learned that newly discovered uses for aspirin as an antiviral and antitumor drug stem from a *different* inherent

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vitate the patent.” (quoting *Andrews v. Cross*, 8 F. 269, 279 (C.C.N.D.N.Y. 1881)); *see also Newman v. Quigg*, 877 F.2d 1575, 1581–82 (Fed. Cir. 1989) (explaining that an invention is patentable even if “theory of operation is not correctly explained or even understood”); *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570 (Fed. Cir. 1983) (“[I]t is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests.”). This rule departs from norms in scientific publishing that require “the author-scientist to demonstrate an understanding of the underlying science.” *Seymore, supra* note 47, at 654–55. One possible explanation is that “patent law is more concerned with the ‘thing’ and less with the path to the ‘thing’ or the acumen of the person who made it.” *Id.* at 655; *cf. Radiator Specialty Co. v. Buhot*, 39 F.2d 373, 376 (3d Cir. 1930) (“It is with the inventive concept, the thing achieved, not with the manner of its achievement or the quality of the mind which gave it birth, that the patent law concerns itself.”). For criticisms of the nondisclosure rule, *see Sean B. Seymore, Patenting the Unexplained*, 96 WASH. U. L. REV. 707, 719–26 (2019).

267. *Cf. Braintree Labs., Inc. v. Breckenridge Pharm., Inc.*, 688 F. App’x 905, 909 (Fed. Cir. 2017) (holding that the mechanism by which a drug works does not count as a distinct, noninfringing use for indirect infringement purposes).

268. *See* 35 U.S.C. § 103(a) (2012) (using the term “not identically disclosed” to describe novelty in § 102); *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1554 (Fed. Cir. 1995) (“[Anticipation] requires identity of invention: the claimed invention, as described in appropriately construed claims, must be the same as that of the reference, in order to anticipate.”); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) (explaining that for anticipation, “[t]he identical invention must be shown in as complete detail as is contained in the patent claim”); *supra* Section I.B.

269. *See supra* Section III.A.

270. *Cf. MERGES, supra* note 231, at 142 (describing novelty as a “highly technical doctrine” and observing that the rule proscribing patenting of what is identically disclosed in the prior art “has a highly technical, almost scholastic, feel”).

271. DIARMUID JEFFREYS, *ASPIRIN: THE REMARKABLE STORY OF A WONDER DRUG* 231–33 (2005); *see also* John R. Vane, *Inhibition of Prostaglandin Synthesis as a Mechanism of Action for Aspirin-like Drugs*, 231 NATURE NEW BIOLOGY 232, 232–35 (1971).

characteristic: its ability to inhibit activation of the cell-signaling molecule NF- $\kappa$ B.<sup>272</sup> Clearly the absence of mechanistic information can make accurate identification and assessment of an underlying inherent characteristic difficult, if not impossible.

### C. (Dis)Proving Inherency

#### 1. Restructuring the Proof Paradigm

Here I offer a new framework for evaluating novelty in new-use patent claims that would mitigate the pro-applicant bias, eliminate indication bias, and solve the mechanism problem. This framework adopts a technical view of novelty that takes mechanism into account. If the old product is doing what it has always done, the claimed new use is inherently anticipated regardless of whether the benefit or characteristic was known in the past.<sup>273</sup> Anticipation by inherency would now depend on mechanistic differences between the old and claimed new use.<sup>274</sup> Identity of mechanism would anticipate<sup>275</sup> and raise the presumption that the prior use conferred the identical benefit to the public.<sup>276</sup> An applicant may need to elucidate the mechanism to prove that a particular inherent characteristic is not responsible for the claimed new use. To the extent that the latter would require the applicant to provide objective proof, this can be justified because the

272. See KARSTEN SCHRÖR, ACETYLSALICYLIC ACID 71 (2009); Yair Lampl, *The Brain's Neuroprotective and Proapoptotic Effects on Aspirin – A Review*, in NEW RESEARCH ON ASPIRIN IN HEALTH 1, 1–36 (Charles L. Milwood ed., 2007).

273. See *supra* notes 109–110 and accompanying text; cf. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005) (“[W]hen considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure.”).

274. “[Applying] what is known to a new purpose, without any new apparatus, means, or instruments, is not patentable.” PHILLIPS, *supra* note 1, at 106 (quoting *Woodcock v. Parker*, 30 F. Cas. 491, 492 (C.C.D. Mass. 1813) (No. 17,971) (Story, J.) (“If he claim a patent for a whole machine, it must in substance be a new machine; that is, it must be a new mode, method, or application of mechanism, to produce some new effect, or to produce an old effect in a new way.”)).

275. Returning to the aspirin hypothetical discussed in the preceding paragraph, proof that the claimed new use operates by the NF- $\kappa$ B pathway would render it patentable over the prior art uses involving prostaglandin inhibition. See *supra* text accompanying notes 271–272. Mechanism shows that the old and new uses operate by different inherent characteristics. See *supra* Section III.A.

276. See *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1351 (Fed. Cir. 2002) (affirming a finding of anticipation by inherency where the public was already receiving cancer-preventative benefits from eating certain types of cruciferous seeds); *supra* text accompanying note 35; discussion *supra* note 109.

applicant has superior information about the invention<sup>277</sup> and has the time and resources to carry out experiments.<sup>278</sup>

The proposed framework restructures the proof paradigm for evaluating novelty in new-use patent claims. First, it abandons the *prima facie* case and places the initial burden of production and the burden of persuasion on the applicant.<sup>279</sup> If the claimed new use involves an old product, the applicant must come forward with affirmative evidence or scientific reasoning to support a reasonable belief that the old and claimed new use do *not* involve the same inherent characteristic (and, consequently, that the old product's prior use did not confer the same benefit to the public).<sup>280</sup> The best evidence would be experimental data showing that the old and new uses are operating by different mechanisms.<sup>281</sup> Second, the presumption of patentability<sup>282</sup> would be replaced with a presumption of *unpatentability* because it would be presumed that the identical underlying inherent characteristic connects the old product to the claimed new use.<sup>283</sup> Insufficient proof by a preponderance of the evidence would compel a finding of anticipation.<sup>284</sup>

Adopting this framework would squarely address the three concerns outlined in the previous Section. First, it would eliminate the pro-applicant bias—rebalancing the scales of patentability to be less pro-applicant would make the issuance of a patent far from a sure

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277. Seymore, *supra* note 257, at 991–96.

278. See *Norton v. Curtiss*, 433 F.2d 779, 794–95 (C.C.P.A. 1970) (noting that the “burden” on the Patent Office arising from the agency’s lack of its own testing facilities and unlimited time to ascertain the facts necessary to evaluate the patentability of each application forces the agency to rely on applicants to disclose most of the facts on which its decisions are based), *cited in In re Loew’s Theatres, Inc.*, 769 F.2d 764, 768 (Fed. Cir. 1985) (“No more can be expected from the [Patent Office] in the way of proof . . . . The practicalities of the limited resources available to the [Patent Office] are routinely taken into account in reviewing its administrative action.”); *supra* note 252 and accompanying text.

279. Placing the burden of persuasion with the same party that carries the initial burden of production is consistent with basic evidentiary principles. See 2 KENNETH S. BROUN ET AL., MCCORMICK ON EVIDENCE § 337, at 563 (6th ed. 2006) [hereinafter MCCORMICK ON EVIDENCE] (recognizing that the two burdens generally rest with the same party); 21B CHARLES ALAN WRIGHT & KENNETH W. GRAHAM, JR., FEDERAL PRACTICE AND PROCEDURE: EVIDENCE § 5122, at 401 (2d ed. 2005) (“[T]he same party who has the burden of persuasion also starts out with the burden of producing evidence . . .”).

280. See *In re King*, 801 F.2d 1324, 1327 (Fed. Cir. 1986) (noting appellant’s failure to introduce evidence sufficient to rebut a *prima facie* case of anticipation based on inherency).

281. *Cf. In re Payne*, 606 F.2d 303, 315 (C.C.P.A. 1979) (noting that actual experimental data can be “highly probative”).

282. See *supra* note 240 and accompanying text.

283. See *supra* Section III.A.

284. 37 C.F.R. § 1.56(b)(2) (2019); see also 1 CHRISTOPHER B. MUELLER & LAIRD C. KIRKPATRICK, EVIDENCE § 3:6 (4th ed. June 2019 update) (describing the function of presumptions).

thing.<sup>285</sup> Second, requiring mechanistic information would prompt a robust, diligent, and probing novelty analysis rooted in the underlying science. This would solve the mechanism problem and allow a more accurate novelty assessment that focuses on identity—that is, if the same inherent characteristic is operating in the old and claimed new use.<sup>286</sup> Third, the presumption of unpatentability would eliminate indication bias because the examiner would presume inherency even if the old and new indications (and perhaps routes of administration)<sup>287</sup> are vastly different.

The proposed framework also aligns with the scholarly literature on evidence. How to allocate the burden of persuasion depends on a myriad of factors.<sup>288</sup> Two common factors—both of which are relevant for patent examination—are access to proof and substantive policy considerations. The burden of persuasion may be assigned to the party with superior information about an issue,<sup>289</sup> easier

285. Note that once issued, a patent is presumed valid. 35 U.S.C. § 282 (2012). This presumption “merely establishes that the accused infringer bears the burden of proving invalidity as an affirmative defense.” Timothy R. Holbrook, *Patents, Presumptions, and Public Notice*, 86 IND. L.J. 779, 816 (2011). Proof of invalidity requires clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 95 (2011). When coupled with the extant presumption of patentability, this allows the applicant to benefit from “double deference” and sets the stage for questionable patents. Seymore, *supra* note 257, at 973. The proposed framework eliminates this pro-applicant bias.

286. It is worth noting that mechanistic identity plays a major role in drug development. Indeed, drug development can “often be characterized as a race in which several firms pursue investigational drugs with similar chemical structures or with the same mechanism of action before any drug in the class obtains regulatory marketing approval.” David C. Swinney & Jason Anthony, *How Were New Medicines Discovered*, 10 NATURE REVS. DRUG DISCOVERY 507, 516 (2011) (quoting J.A. DiMasi & L.B. Fadon, *Competitiveness in Follow-on Drug R&D: A Race or Imitation?*, 10 NATURE REVS. DRUG DISCOVERY 23, 27 (2011)).

287. See *supra* notes 259–260 and accompanying text.

288. See, e.g., MCCORMICK ON EVIDENCE, *supra* note 279, § 337, at 565:

[Allocation] will depend upon the weight . . . given to any one or more of several factors, including: (1) the natural tendency to place the burdens on the party desiring change, (2) special policy considerations such as those disfavoring certain defenses, (3) convenience, (4) fairness, and (5) the judicial estimate of the probabilities;

MUELLER & KIRKPATRICK, *supra* note 284, § 3:3 (discussing five factors: custom, substantive policy, access to proof, probable truth, and proof unavailable).

289. See JOHN MACARTHUR MAGUIRE, EVIDENCE: COMMON SENSE AND COMMON LAW 179 (1947) (asserting that the burden of persuasion “is to be borne by the party having peculiar knowledge of the facts”); MCCORMICK ON EVIDENCE, *supra* note 279, § 337, at 564 (“A doctrine often repeated by the courts is that where the facts with regard to an issue lie peculiarly in the knowledge of a party, that party has the burden of proving the issue.”); see also *United States v. N.Y., New Haven & Hartford R.R. Co.*, 355 U.S. 253, 256 n.5 (1957) (applying the doctrine based on “considerations of fairness”).

access to evidence,<sup>290</sup> or greater resources.<sup>291</sup> As previously noted, at the patent examination stage the *applicant* has superior information about the invention and the time and resources to carry out experiments.<sup>292</sup> The other important factor for allocating the burden of persuasion is to serve or promote a policy objective of the underlying substantive law.<sup>293</sup> As I discuss below, the proposed framework would promote patent law's disclosure function.<sup>294</sup>

## 2. Illustrations

To illustrate the proposed framework, recall the hypothetical used earlier involving *X*, a drug invented in the 1960s for depression.<sup>295</sup> Suppose that fifty years later, a researcher discovers that *X* is useful for treating functional dyspepsia<sup>296</sup> and seeks a new-use patent for that indication. The prior art teaches that *X*'s antidepressive effects are due to serotonin uptake inhibition.<sup>297</sup> So the examiner can presume that the same characteristic that *X* exhibited in the past for use as an antidepressant—serotonin uptake inhibition—is responsible for the claimed new use to treat functional dyspepsia.<sup>298</sup> This would also raise the presumption that the prior use conferred the identical benefit (treatment of functional dyspepsia) to the public—even if previously

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290. Bruce L. Hay & Kathryn E. Spier, *Burdens of Proof in Civil Litigation: An Economic Perspective*, 26 J. LEGAL STUD. 413, 419 (1997) ("One party may have easier access to evidence . . . meaning he can assemble the appropriate evidence at lower cost . . . . Other things being equal, the lower one party's relative costs, the stronger the argument for giving him the burden of proof.").

291. Richard A. Posner, *An Economic Approach to the Law of Evidence*, 51 STAN. L. REV. 1477, 1543 (1999) (arguing that burdens of production and persuasion are economizing devices and should therefore be assigned to the party with greatest access to resources).

292. See *supra* notes 277–278 and accompanying text.

293. See MUELLER & KIRKPATRICK, *supra* note 284, § 3:3 ("First and perhaps most important, burdens are allocated to serve substantive policy . . ."); WRIGHT & GRAHAM, *supra* note 279, § 5122, at 402 ("In determining the placement of burdens of proof, courts begin with the policy of the substantive law . . ."); Fleming James, Jr., *Burdens of Proof*, 47 VA. L. REV. 51, 61 (1961) (noting that substantive policy considerations may be influential).

294. See discussion *infra* Section III.D.2.

295. See *supra* text accompanying notes 25–32.

296. Functional dyspepsia is a gastrointestinal disorder defined as stomach pain with no structural or disease-based explanation. Yaoyao Lu et al., *Antidepressants in the Treatment of Functional Dyspepsia: A Systematic and Meta-Analysis*, PLOS ONE (June 16, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4911162/> [<https://perma.cc/8WNX-7X2S>].

297. CAROL HART, SECRETS OF SEROTONIN 82 (rev. ed. 2008); NEAL, *supra* note 32, at 133–35.

298. Cf. HART, *supra* note 297, at 82 ("[A]ntidepressants are prescribed for much more than depression. They have been used to treat a wide range of eating, mood, pain, and impulse or addiction problems—basically any condition in which serotonin is known to have a role."); see also Sheng Liang Chen, *A Review of Drug Therapy for Functional Dyspepsia*, 14 J. DIGESTIVE DISEASES 623, 625 (2013) (discussing the use of older antidepressants to treat functional dyspepsia by modulating neurotransmitters like serotonin).



unknown or unappreciated.<sup>299</sup> The initial burden rests with the applicant to rebut the presumption of anticipation with argument or objective proof that some other characteristic of *X* is operating in the claimed new use. Proof could be experimental evidence that using *X* for functional dyspepsia operates by a non-serotonin-related mechanism. Production of sufficient rebuttal evidence overcomes the presumption and keeps the doors of patentability open.<sup>300</sup> Otherwise, the new-use claim is anticipated.<sup>301</sup>

Sometimes a product's mechanism is unknown. One reason is that current knowledge in the field precludes elucidation.<sup>302</sup> Unknown mechanisms are common in pharmaceuticals, even for popular drugs.<sup>303</sup> Mechanisms of action for aspirin and penicillin were developed many decades after their introduction.<sup>304</sup> A drug need only be safe and effective for FDA approval; no mechanistic information is required.<sup>305</sup> Nonetheless, the quest to make less toxic versions, reduce side effects, repurpose old drugs, and develop new drugs motivates scientists to figure out unknown mechanisms.<sup>306</sup>

Under the proposed framework, an unknown mechanism would create an insurmountable proof problem for the applicant.<sup>307</sup> To illustrate, consider acetaminophen, the popular pain reliever first used

299. See *supra* note 109 and accompanying text.

300. See *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (indicating that production of evidence of adequate weight rebuts a prima facie case); see also 9 JOHN HENRY WIGMORE, EVIDENCE IN TRIALS AT COMMON LAW § 2491, at 305 (James H. Chadbourn ed., rev. ed. 1981) (explaining that a presumption disappears when sufficient evidence is introduced to rebut it).

301. See *supra* note 284 and accompanying text.

302. See Tohru Mizushima, *Drug Discovery and Development Focusing on Existing Medicines: Drug Re-profiling Strategy*, 149 J. BIOCHEMISTRY 499, 500 (2011) (explaining that the mechanisms responsible for the clinical effects of many existing drugs have not been examined).

303. See Carolyn Y. Johnson, *One Big Myth About Medicine: We Know How Drugs Work*, WASH. POST: WONKBLOG (July 23, 2015), <https://www.washingtonpost.com/news/wonk/wp/2015/07/23/one-big-myth-about-medicine-we-know-how-drugs-work> [<https://perma.cc/25KV-AKP2>] (discussing scientific research into the largely unknown mechanisms behind popular drugs such as Tylenol and penicillin); *Mechanism Matters*, *supra* note 265, at 347 (indicating that the mechanisms of many highly prescribed drugs are not clearly known); Tanya Lewis, *Mystery Mechanisms*, SCIENTIST (July 29, 2016), <https://www.the-scientist.com/?articles.view/articleNo/46688/title/Mystery-Mechanisms/> [<https://perma.cc/2U94-6MP9>] (explaining that the exact mechanism of many drugs, from mood enhancers to pain relievers, are still unknown).

304. See Hongbaek Cho et al., *Beta-Lactam Antibiotics Induce a Lethal Malfunctioning of the Bacterial Cell Wall Synthesis Machinery*, 159 CELL 1300 (2014) (discussing the mechanisms of action of penicillin); *infra* note 359 (discussing the discovery of the mechanisms of action of aspirin).

305. See 21 U.S.C. § 355(b)(1) (2012) (requiring a new drug application to show safety and efficacy).

306. See sources cited *supra* note 303.

307. But, to be clear, an old product can inherently anticipate a new-use claim even if the underlying scientific principles or mechanism were unknown in the prior art. See *supra* note 172 and accompanying text.

clinically in 1894.<sup>308</sup> Researchers have been “guessing” at the drug’s mechanism for decades with no proposal gaining a scientific consensus.<sup>309</sup> Suppose that in 2020, an inventor files a patent application claiming a new use for acetaminophen to treat patients with anxiety and depression. The drug is now serving “double duty, easing not just the physical pains of sore joints and headaches, but also the pain of social rejection.”<sup>310</sup> Although the claimed new use is a vastly different indication, since acetaminophen is an old product, the examiner must still presume that the same underlying inherent characteristic is responsible for the old and new uses. The burden shifts to the applicant to show mechanistic distinctiveness even though the lack of scientific consensus suggests that such information might be elusive given the current state of acetaminophen research. Nonetheless, failure to rebut the presumption would render the claimed new use unpatentable.<sup>311</sup>

Claiming a new use for a failed or rescued drug might lead to a very different outcome. Recall that a failed or rescued drug never entered the market because it lacked efficacy for its original indication.<sup>312</sup> Suppose a subsequent inventor discovers that the drug is effective for a different indication and seeks a patent for the new use. Under the proposed framework, the initial burden rests with the applicant to rebut the presumption of unpatentability with argument or objective proof.<sup>313</sup> If the applicant can prove that the drug was ineffective in its original indication, then the applicant could argue that there is no anticipation by inherency because the public never *benefitted* from the prior disclosure.<sup>314</sup> This would rebut the presumption and keep the doors of patentability open.<sup>315</sup>

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308. Laurie F. Prescott, *Paracetamol: Past, Present, and Future*, 7 AM. J. THERAPEUTICS, 143, 143 (2000).

309. Carmen Drahl, *How Does Acetaminophen Work? Researchers Still Aren't Sure*, CHEMICAL & ENGINEERING NEWS (July 21, 2014), <https://cen.acs.org/articles/92/i29/Does-Acetaminophen-Work-Researchers-Still.html> [<https://perma.cc/H2EL-BYFB>].

310. *Could Acetaminophen Ease Psychological Pain?*, SCI. DAILY (Dec. 25, 2009), <http://www.sciencedaily.com/releases/2009/12/091222154742.htm> [<https://perma.cc/HR4J-FAKE>]; see also Geoffrey R.O. Durso et al., *Over-the-Counter Relief from Pains and Pleasures Alike: Acetaminophen Blunts Evaluation Sensitivity to both Negative and Positive Stimuli*, 26 PSYCHOL. SCI. 750, 750 (2015) (reporting that acetaminophen can blunt social pain in addition to physical pain).

311. See *supra* note 284 and accompanying text.

312. See *supra* notes 188–189 and accompanying text.

313. See *supra* Section III.C.1.

314. See Burk & Lemley, *supra* note 104, at 374 (“If the public doesn’t benefit from the invention, there is no inherency.”); *supra* note 109 and accompanying text.

315. See *supra* note 300 and accompanying text.

### D. Policy Considerations

Adopting a mechanism-based framework for anticipation would recalibrate novelty's gatekeeping function. Eliminating biases and focusing on the underlying science would more accurately gauge *identity*—what novelty is all about.<sup>316</sup> Nonetheless, it is important to explore the paradigm's potential impact on the public, patent law's incentive structure, and the extent to which it aligns with broader goals of the patent system.

#### 1. On "Patentable" Novelty

This Article draws attention to scenarios where a researcher discovers a use for an old product that was previously unknown or unappreciated.<sup>317</sup> If the old product is doing what it has always done, I contend that the claimed new use is inherently anticipated regardless of whether the benefit or characteristic was known in the past.<sup>318</sup> Novelty requires more.<sup>319</sup> This also aligns with the tenant in modern inherency doctrine that a PHOSITA need not have recognized the inherent characteristic in the prior art.<sup>320</sup>

One potential criticism of this paradigm is that it might discourage the search for new uses. Congress amended the patent statute to explicitly permit new-use patents.<sup>321</sup> The argument is that the novelty rules should be relaxed so that one who discovers a previously unknown or unappreciated property should be rewarded with a patent.<sup>322</sup> So "even though there may be a *technical* anticipation, the discovery of the new property and the recitation of this property in the claims 'lends patentable novelty' to the claims."<sup>323</sup>

316. See *supra* note 268 and accompanying text.

317. See *supra* text accompanying notes 26–32.

318. See *supra* Section III.A.

319. PHILLIPS, *supra* note 1, at 109 ("[T]here must be something new in the method, process, combination, or composition, in order to lay the foundation of a patent."); see *Whittemore v. Cutter*, 29 F. Cas. 1123, 1124 (C.C.D. Mass. 1813) (No. 17,601) (Story, J.):

[A] patent can, in no case, be for an *effect only*, but for an effect produced in a given manner, or by a peculiar operation . . . . [I]f new effects are produced by an old machine in its unaltered state, I apprehend that no patent can be legally supported; for it is a patent for an effect only.

320. See *supra* Section I.C.

321. See *supra* notes 124–125 and accompanying text.

322. *Cf. Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 781 (Fed. Cir. 1985) (addressing the contention that inventor's discovery of a previously unappreciated property of an old product, which a PHOSITA could not discern from the prior art, was sufficient to justify a patent grant for that contribution).

323. *In re Wilder*, 429 F.2d 447, 450 (C.C.P.A. 1970) (emphasis added), *quoted in Titanium Metals*, 778 F.2d at 782.

While I understand this view, I disagree with it. The technical contribution or public benefit of the later-discovered use is immaterial to the anticipation inquiry.<sup>324</sup> The focus should be on *identity*.<sup>325</sup> I agree with Judge Rich that “[t]he patent law imposes certain *fundamental* conditions for patentability, paramount among them being the condition that what is sought to be patented, as determined by the claims, be *new*.”<sup>326</sup> Patent law treats novelty as a rigid rule to aggressively preserve public access to the prior art.<sup>327</sup> This should be the law unless and until Congress decrees otherwise.<sup>328</sup>

## 2. Inducing Mechanistic Disclosure

Recall that the proposed framework contemplates that an applicant would need to prove mechanistic differences between an old and claimed new use to rebut a presumption of inherent anticipation.<sup>329</sup> Any experimentation required to prove mechanism would fortuitously generate technical knowledge about the invention—a core objective of patent law’s disclosure function.<sup>330</sup>

Here it is important to say more about the role of disclosure in patent law. The inventive act produces *two* things that are potentially useful to society: the invention itself, which will be defined here as the subject matter claimed in the patent (i.e., machine, product, method of use),<sup>331</sup> and the invention *disclosure*, a written description of the invention in the patent document<sup>332</sup> that furnishes technical

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324. See *Titanium Metals*, 778 F.2d at 780 (noting that the technical contribution of applicants was “beside the point” because patent law requires that what is sought to be patented be new). But the public must have benefitted from the prior art disclosure, even if unwitting, for it to anticipate by inherency. See discussion *supra* notes 109–119 and accompanying text.

325. See *supra* note 268 and accompanying text.

326. *Titanium Metals*, 778 F.2d at 780 (emphasis added); see also ROGER E. SCHECHTER & JOHN R. THOMAS, PRINCIPLES OF PATENT LAW 73 (2004) (describing novelty as “the core value of the patent system”).

327. See discussion *supra* note 231 and accompanying text.

328. See *Titanium Metals*, 778 F.2d at 782 (explaining that novelty must be considered under the laws passed by Congress); *Wilder*, 429 F.2d at 450 (indicating that until Congress decrees otherwise, patentable claims do not extend to that which is not new).

329. See *supra* Section III.C.1.

330. See *supra* Section I.A.

331. See 35 U.S.C. § 101 (2012) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor . . .”).

332. The written description is the part of the patent document that completely describes the invention. 35 U.S.C. § 112(a)–(b) (2012) (“The specification shall contain a written description . . . . The specification shall conclude with one or more claims . . .”). Although I will not discuss it in this Article, it is worth noting that the terms “written description” and “specification” are often used interchangeably (and mistakenly) in patent law. F. SCOTT KIEFF ET AL., PRINCIPLES OF PATENT LAW 155 n.4 (5th ed. 2011).

information about it (i.e., how to make it, how to use it).<sup>333</sup> Disclosure has been called the “centerpiece of patent policy”<sup>334</sup> because it supports the patent system’s broad mission to promote scientific progress through knowledge dissemination.<sup>335</sup> The invention disclosure fills the public storehouse of technical knowledge<sup>336</sup> with information that others can use.<sup>337</sup> Theory posits that others will improve on the invention, design around it, or conceive wholly new inventions—all during the patent term.<sup>338</sup>

At present, an inventor can obtain a patent without understanding (let alone disclosing) the mechanism.<sup>339</sup> If the invention disclosure is sufficiently detailed to explain to a PHOSITA how to make and use the invention, that is enough to satisfy the statutory enablement requirement.<sup>340</sup> However, this minimal disclosure threshold can produce patents that are *uninformative* from a technical standpoint, meaning that they provide little meaningful information. By contrast, patents that disclose mechanism are very informative. In the case of drugs, details about mechanism of action allow researchers to design more effective or less toxic versions.<sup>341</sup> Relatedly, it is easier

333. See Lemley, *supra* note 47, at 333 (“[I]t seems quite clear that dissemination, not just invention, of new information is one of the goals of the patent system.”).

334. Benjamin N. Roin, Note, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007, 2011 (2005); see also *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”).

335. See *supra* notes 42–48 and accompanying text.

336. For a discussion of the storehouse, see *supra* note 45 and accompanying text.

337. MICHAEL A. GOLLIN, DRIVING INNOVATION 15–19 (2008).

338. Fromer, *supra* note 46, at 548–49; see also Christopher A. Cotropia, *Physicalism and Patent Theory*, 69 VAND. L. REV. 1543, 1560 (2016) (“The reason patent law wants the invention disclosed is so that others can use that information to actually implement the invention and create other inventions.”).

339. See *supra* note 266 and accompanying text.

340. *In re Libby*, 255 F.2d 412, 415 (C.C.P.A. 1958) (“It is not necessary that a patentee should understand the scientific principles underlying his invention, so long as he makes a sufficient disclosure to enable other persons skilled in the art to practice the invention.”); see also *supra* note 71 (distinguishing “anticipatory” or patent-defeating enablement from “statutory” or patent-supporting enablement). Statutory enablement is one of the three disclosure requirements set forth in 35 U.S.C. § 112(a) (2012):

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.

(emphasis added).

341. See, e.g., Drahl, *supra* note 309 (arguing that that “the drug’s well-known danger to the liver makes understanding its mechanism more than a minor detail”).

to develop new drugs when researchers understand how old ones work.<sup>342</sup>

Of course, mechanistic disclosure is more important for some inventions than others. If a PHOSITA can look at an invention and easily elucidate mechanism, the inventor need not disclose it.<sup>343</sup> A good example is a paper clip.<sup>344</sup> But the story changes for complex inventions like drugs. Neither a (picture of a) chemical structure nor a physical product reveals the drug's mechanism of action.<sup>345</sup> And elucidating this information through reverse engineering is difficult, if not impossible (at least without considerable effort or expense).<sup>346</sup> Here, mechanistic disclosure is particularly helpful.

To illustrate, consider again *X*, a drug originally patented in the 1960s as an antidepressant.<sup>347</sup> Although the patent document explains how to make *X* and use it to treat depression, it discloses nothing about *X*'s mechanism of action. Again, such disclosure is not required to satisfy the statutory enablement requirement.<sup>348</sup> This means that a PHOSITA who wants to elucidate *X*'s mechanism must engage in experimentation—an activity that might require a license from the patentee.<sup>349</sup> The bottom line is that the omitted mechanistic

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342. See *supra* note 303.

343. Similarly, if a PHOSITA can look at an invention and figure out how to make and use it, there is no need to provide a detailed disclosure. *Lawther v. Hamilton*, 124 U.S. 1, 9 (1888) (“These several steps being well known in the art when the patent was applied for, required no particular explanation.”). This is because “patents are written by and for skilled artisans.” *Vivid Techs., Inc. v. Am. Sci. and Eng’g, Inc.*, 200 F.3d 795, 804 (Fed. Cir. 1999); *cf.* *S3 Inc. v. NVIDIA Corp.*, 259 F.3d 1364, 1371 (Fed. Cir. 2001) (“The law is clear that patent documents need not include subject matter that is known in the field of the invention and is in the prior art, for patents are written for persons experienced in the field of the invention.”).

344. What I describe is akin to—but not the same as—so-called “self-disclosing” inventions. See *Strandburg*, *supra* note 52, at 105–06. They are defined as inventions that are easy to replicate because reproduction is enabled by mere commercialization. *Id.* at 105. In other words, the “invention itself reveals its operation,” including how to make and use it. *Anderson*, *supra* note 51, at 1583. But it is important to note that a self-disclosing invention might reveal how to make and use it but *not* how and why it works.

345. This is also true for non-self-disclosing inventions. *Lemley*, *supra* note 47, at 338–39.

346. J. Jonas Anderson, *Secret Inventions*, 26 *BERKELEY TECH. L.J.* 917, 958 n.222 (2011); Pamela Samuelson & Suzanne Scotchmer, *The Law and Economics of Reverse Engineering*, 111 *YALE L.J.* 1575, 1582–91 (2002).

347. See *supra* text accompanying notes 26–32.

348. See *supra* notes 339–340 and accompanying text.

349. Practicing the claimed invention without the patentee's permission constitutes patent infringement. See 35 U.S.C. § 271(a) (2012) (“[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”). There is generally no experimental use exception that permits third parties to elucidate mechanism. *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002). In the hypothetical, an interested researcher could begin with experiments on animals to avoid infringement; however, any subsequent human experimentation would probably require a license. But it is worth noting that many patent owners do not enforce their patents against academic researchers because of the high costs of detecting

information will take time and effort to obtain. Under the current disclosure paradigm, an inventor has little incentive to elucidate an invention's mechanism before filing or, for that matter, disclose *any* information beyond that minimally required by the patent statute.<sup>350</sup>

By contrast, the proposed framework would *induce* subsequent inventors to elucidate and disclose mechanistic information. Recall that when a new-use claim involves an old product, the applicant must come forward with objective proof that an inherent characteristic is *not* responsible for the claimed new use.<sup>351</sup> Objective proof would consist of experimental results showing that the old product and claimed new use operate by different mechanisms.

To illustrate, consider again the drug loratadine, a popular antihistamine sold under the brand name Claritin.<sup>352</sup> Suppose that in 2018 an inventor files a patent application claiming a new use for loratadine to treat patients plagued with itchy hands and feet. The examiner can presume that the anti-itch indication is tied to histamine inhibition. So the initial burden rests with the applicant to rebut the presumption of anticipation with argument or objective proof that some other characteristic of loratadine is operating in the claimed new use. Given that itch is a typical allergic response<sup>353</sup> and histamine is tied to allergies,<sup>354</sup> it would be hard to argue that loratadine's known antihistaminergic effects are not responsible for the claimed new use. Accordingly, *before filing*, the inventor elucidates loratadine's mechanism of action in the itchy hands-and-feet indication. The results reveal that afflicted patients have a neurological, non-histamine-

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infringement, high litigation costs, and the low value of a potential lawsuit. Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1062 (2008); 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, 705 (2001). 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).

350. As a general matter, “under the existing regime, patentees have every incentive to disclose as little as possible.” Gideon Parchomovsky & Michael Mattioli, *Partial Patents*, 111 COLUM. L. REV. 207, 209 (2011); *see also* H. JACKSON KNIGHT, PATENT STRATEGY FOR RESEARCHERS AND RESEARCH MANAGERS 88–89 (2d ed. 2001) (describing the quantity of information an inventor should disclose). Of course, the inventor could forego patent protection altogether and opt to keep the technical information secret. *See supra* note 51.

351. *See supra* Section III.C.1.

352. *See supra* notes 215–218 and accompanying text.

353. *See* KEVIN T. PATTON & GARY A. THIBODEAU, ANATOMY AND PHYSIOLOGY 525 (9th ed. 2016).

354. *See* LENNARD-BROWN, *supra* note 219, at 9.

related itch that loratadine treats.<sup>355</sup> In other words, the mechanism of action is neurological, not allergic. This mechanistic information rebuts the presumption of inherency and ultimately publishes in the patent document.<sup>356</sup>

This *patent-induced* mechanistic disclosure fulfills broad objectives of the patent system. Mechanism provides the very best type of technical knowledge because nothing is more illuminating than details about an invention's inner workings. Even if other researchers could eventually elucidate mechanism, the proposed framework induces its *early* disclosure—an oft-stated goal of the patent system.<sup>357</sup> In theory, early disclosure of mechanism should prevent duplicative research efforts and promote the earlier flow of helpful information about the invention from the patentee to potential future innovators.<sup>358</sup> The ultimate beneficiary would be the public, which would gain quicker access to new and improved products (and uses) and other fruits of innovation.<sup>359</sup>

### 3. Patent (Examination) Quality

The Patent Office is often criticized for issuing too many low-quality patents.<sup>360</sup> Patent quality is “the capacity of a granted patent to meet (or exceed) the statutory standards of patentability—most

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355. See GIL YOSIPOVITCH & SHAWN G. KWATRA, *LIVING WITH ITCH: A PATIENT'S GUIDE* 60 (2013) (“Neuropathic itch, or nerve itch, includes a broad group of conditions in which itch is caused by damage to nerve fibers . . .”).

356. Patent applications typically publish eighteen months after filing. See *supra* note 44.

357. See *Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 558 (Fed. Cir. 1994) (rejecting an interpretation of § 112 that would “subvert the patent system’s goal of promoting the useful arts through encouraging early disclosure”); *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983) (“Early public disclosure is the linchpin of the patent system.”); Kitch, *supra* note 55, at 269–80 (arguing that early filing facilitates commercialization, coordinates the development of technology, and reduces wasteful duplicative efforts by competitors). For a discussion of the hoped-for goals of early disclosure, see *supra* notes 46–47 and accompanying text.

358. Fromer, *supra* note 46, at 599.

359. *Merges & Nelson*, *supra* note 128, at 878–79. Perhaps the best illustration is the field of drug discovery. Early disclosure of a drug’s mechanism would lead to speedier R&D of new and improved drugs which, of course, would provide an incalculable benefit to the public. Consider aspirin, the world’s most popular drug, patented by Bayer in 1900. See *supra* note 9 and accompanying text. It was used as a pain reliever for over seventy years before Sir John Vane figured out its mechanism. See *supra* note 271 and accompanying text. Vane’s Nobel Prize-winning discovery spawned an incredible amount of aspirin research, including its use to prevent heart disease and stroke. See JEFFREYS, *supra* note 271, at 235–77. To the extent that a patent-induced mechanistic disclosure could narrow the time gap between elucidating how to make and use the invention (information required to satisfy patent law’s enablement requirement) and how or why it works, the end result would be speedier follow-on innovation and earlier public benefit.

360. See generally BESSEN & MEURER, *supra* note 13; 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).



importantly, to [cover inventions that are] novel, nonobvious, and clearly and sufficiently described.”<sup>361</sup> Aside from being invalid,<sup>362</sup> low-quality patents are often worthless and burdensome on the patent system and society.<sup>363</sup>

Perhaps the biggest obstacle to robust patent examination is the examiner’s information deficit.<sup>364</sup> An examiner *should* have as much technical information as possible to accurately gauge patentability.<sup>365</sup> But, for a variety of reasons,<sup>366</sup> this often does not happen.<sup>367</sup> When it comes to assessing novelty, no one believes that the examiner’s prior art search fully captures the body of preexisting knowledge.<sup>368</sup> And notwithstanding the applicant’s duty of candor,<sup>369</sup> it is hard to believe that everything the applicant knows about the invention ends up before

361. R. Polk Wagner, *Understanding Patent-Quality Mechanisms*, 157 U. PA. L. REV. 2135, 2138 (2009); cf. Christi J. Guerrini, *Defining Patent Quality*, 82 FORDHAM L. REV. 3091, 3092–93 (2014) (defining “low-quality” or “bad” patents as those that “carve out of the public domain and deter others from practicing inventions that are in some way undeserving of patent protection”). The patentability requirements are recited *supra* note 126.

362. See FED. TRADE COMM’N, *supra* note 255, at 5 (“A poor quality or questionable patent is one that is likely invalid or contains claims that are overly broad.”).

363. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1515 (2001); see also Bronwyn H. Hall & Dietmar Harhoff, *Post-grant Reviews in the U.S. Patent System—Design Choices and Expected Impact*, 19 BERKELEY TECH. L.J. 989, 992 (2004) (explaining that the costs of low-quality patents “include entry deterrence of would-be innovators, a slower pace of innovation, and increases in patent application activity that are costly both to the firms and to society”).

364. See Seymore, *supra* note 257 at 991–96; *supra* text accompanying note 277.

365. Christopher A. Cotropia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 748 (2009) (“The assurance of a good patent quality is all about information . . .”).

366. For example, the examiner is not an active researcher and thus is hard-pressed to know what is happening at the front lines of theory and experiment in a technical field. Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1491, 1512–14 (2011). Aside from that, the inventor is generally a person of extraordinary skill who knows more about the invention and technical field than the examiner. *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985). And sometimes this leads the inventor to be strategic—sharing no more information than is absolutely necessary to satisfy the patentability criteria. See *supra* note 350 and accompanying text.

367. See Anup Malani & Jonathan S. Masur, *Raising the Stakes in Patent Cases*, 101 GEO. L.J. 637, 647 (2013) (“[T]he [Patent Office] only has the information provided by the patent applicant and whatever limited information the patent examiner is able to discover on her own.”); Beth Simone Noveck, “Peer to Patent”: *Collective Intelligence, Open Review, and Patent Reform*, 20 HARV. J.L. & TECH. 123, 124 (2006) (noting that examiners make patenting decisions based on “a limited subset of available information”).

368. See Lemley, *supra* note 363, at 1500 (“Much of the most relevant prior art isn’t easy to find—it consists of [third-party activities] that don’t show up in any searchable database and will not be found by examiners . . .”).

369. The Patent Office imposes a duty of candor on every individual substantively involved in patent procurement—including the inventor, the attorney or agent that prepares the patent application, and the assignee. 37 C.F.R. § 1.56(a), (c) (2019). These individuals must “disclose to the [Patent] Office all information known to that individual to be material to patentability.” *Id.* § 1.56(a) (emphasis added).

the examiner.<sup>370</sup> This information deficit inevitably allows questionable patents “to slip through the cracks and further contributes to the patent quality problem.”<sup>371</sup>

The information-forcing nature of the proposed framework would mitigate this problem. Procedurally, placing the initial burden of production and the burden of persuasion on the applicant, combined with the presumption of unpatentability, would compel the applicant (rather than the examiner) to furnish sufficient information to carry the burden of proof and ultimately prevail.<sup>372</sup> If the applicant could not do so, a patent would not issue—which might be the right result.<sup>373</sup> Substantively, mechanistic disclosure necessarily injects more technical information into the examination process.<sup>374</sup> This information would give the examiner a more complete picture of the invention and the surrounding technological landscape.<sup>375</sup> And sometimes the additional information could help the examiner (better) evaluate patentability requirements *other than novelty*—a spillover effect of mechanistic disclosure.<sup>376</sup> If a patent eventually issues, it will be of higher quality vis-à-vis one that would have issued under the current regime.<sup>377</sup> Thus, the proposed framework’s insistence on mechanistic disclosure for new-use claims promotes broad goals of the patent system.<sup>378</sup>

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370. See MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 579 (4th ed. 2015) (“Experience teaches . . . that applicant obligations of candor may be tempered by the great incentive they possess not to disclose information that might deleteriously impact their prospective patent rights.”).

371. Seymore, *supra* note 257, at 991–92. Mark Lemley has argued that “the [Patent Office] issues many patents that would have been rejected had the examiner possessed perfect knowledge.” Lemley, *supra* note 363, at 1500.

372. See *supra* Section III.C.1.

373. See *infra* notes 398–402 and accompanying text.

374. See *supra* Section III.D.1.

375. Such information allows the examiner to do a better job. Seymore, *supra* note 47, at 653.

376. This can cut for or against patentability. For example, a detailed, mechanistic disclosure could allow an inventor to persuasively make the case for broad claim scope—thereby bolstering compliance with the § 112(a) enablement requirement. See Seymore, *supra* note 266, at 731–36 (providing illustrations).

377. In other words, more information about the invention yields a more robust patent examination and higher-quality patents. See *supra* Section III.D.3.

378. One might ask if the proposed framework should apply to *all* inventions. Clearly the disclosure of mechanism in a patent document is ideal unless the mechanism is readily apparent. See Seymore, *supra* note 266, at 723–26 (distinguishing between inventions that are “transparent” and “opaque” with respect to mechanism). Tinkering with disclosure doctrines raises concerns about inventor behavior as well as tradeoffs between delayed filing, the rapidity of information dissemination, and ultimate societal benefit. See DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 1 (3d ed. 2004) (explaining that patent law operates as an “interdependent mix of incentives and restraints that bestow benefits and impose costs on society” and “strives to strike a balance between the promotion of technological invention and the dissemination of and access to its fruits”); *infra* text accompanying notes 397–415. For example, while mechanistic disclosure would

## 4. The Proof Paradox

The proposed paradigm contemplates that an applicant may need to perform experiments to prove that the claimed new use operates by a different mechanism than that in operation for a known use.<sup>379</sup> Herein lies a major paradox: a bedrock principle of patent law is that an inventor need not engage in any actual experimentation before obtaining a patent.<sup>380</sup> It is well settled in U.S. patent law that the mental act—conceiving of the idea—and not any physical act, is the important facet of the inventive process.<sup>381</sup> An applicant who “constructively” reduces an invention to practice by filing a patent application presumably has complied with the disclosure requirements of 35 U.S.C. § 112(a).<sup>382</sup> So it seems odd that an inventor who is not required to perform experiments to satisfy the statutory disclosure requirements would need to do so to prove novelty.

However, there are times under the existing regime when an applicant must affirmatively prove novelty. Typically, an invention enjoys a presumption of novelty, meaning that the examiner must

help the inventor satisfy the enablement and written description requirements of 35 U.S.C. § 112(a), an inventor has an incentive to disclose as little as possible to avoid creating prior art against oneself in subsequent patents. *See Seymore, supra* note 266, at 727 (“Additional disclosure can also create patent-defeating prior art against others.”). For new-use patent claims, the proposed framework is justified because there is more at stake than disclosure: novelty is a *fundamental* condition for patentability. *See supra* notes 324–328 and accompanying text.

379. *See supra* Section III.C.

380. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 60 (1998) (“[T]he word ‘invention’ in the Patent Act unquestionably refers to the inventor’s conception rather than to a physical embodiment of that idea.”). There may be occasions, however, when an actual reduction to practice is a *de facto* requirement. *See Seymore, supra* note 47, at 646–52 (discussing the historical background of an actual reduction to practice). For example, several cases suggest that an applicant must supply actual experimental data for inventions in unpredictable technologies in the early stages of development or when an applicant purports to invent something that is contrary to well-settled scientific principles. *Id.*

381. *See Pfaff*, 525 U.S. at 61 (“[A]n invention may be patented before it is reduced to practice.”). Invention requires two acts—conception and reduction to practice. *See* 1 ROBINSON, *supra* note 5, at 116 (“Every invention contains two elements: (1) An idea conceived by the inventor; (2) An application of that idea to the production of a practical result.”). Conception, often referred to as the “touchstone” of inventorship, is the “formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.” *Id.* at 532; *accord* *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1227–28 (Fed. Cir. 1994).

382. Reduction to practice occurs when the inventor either makes the invention and establishes that it works for its intended purpose or files a patent application that describes the invention in sufficient detail to satisfy the disclosure requirements of § 112(a), including the “how to make” prong of enablement. *See Kawai v. Metlesics*, 480 F.2d 880, 886 (C.C.P.A. 1973) (“[P]roof of a constructive reduction to practice would also require that the specification be sufficient to enable anyone skilled in the art to make the invention, i.e., the ‘how to make’ requirement of section 112 should also be met by the specification.”); *In re Borst*, 345 F.2d 851, 855 (C.C.P.A. 1965) (“[T]he criterion should be whether the disclosure is *sufficient to enable one skilled in the art to reduce the disclosed invention to practice.*”).

persuasively prove that the invention already exists in the prior art.<sup>383</sup> But there is a caveat best explained by illustration. Suppose the invention is a product; the examiner finds a reference that discloses a picture of an identical product but does not explain how to make it. Since an asserted prior art reference must enable a PHOSITA to make the invention,<sup>384</sup> it should not qualify as prior art.<sup>385</sup> Nonetheless, the courts have held that the examiner may *presume* that a PHOSITA could have made the product disclosed in the reference.<sup>386</sup> Put simply, *all* prior art presumptively enables a PHOSITA to make what is disclosed.<sup>387</sup> The burden of production shifts to the applicant to prove that a PHOSITA could *not* have made the product.<sup>388</sup> Actual experimental data is particularly probative in rebutting the presumption.<sup>389</sup>

The rationale for presuming that *all* prior art enables a PHOSITA to make the invention is simply to expedite patent examination.<sup>390</sup> It has nothing to do with the technical substance of the asserted reference.<sup>391</sup> This is a dubious presumption—particularly in “unpredictable” fields like chemistry, pharmaceuticals, and biotechnology<sup>392</sup> where PHOSITAs cannot easily fill in technical gaps

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383. *See In re Wilder*, 429 F.2d 447, 450 (C.C.P.A. 1970) (“If an applicant had to prove novelty before he could obtain a patent he would have an almost insurmountable burden.”).

384. *See supra* notes 71–73 and accompanying text.

385. *Cf. Gillman v. Stern*, 114 F.2d 28, 31 (2d Cir. 1940) (explaining that when considering whether a prior disclosure is anticipatory, “what ha[s] not in fact enriched the art, should not count [as prior art]”); GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS § 292, at 395 (2d ed. 1854) (noting that if the description in the allegedly anticipatory reference is nonenabling, “it cannot be said that a knowledge of that thing is in the possession of the public”).

386. *See In re Antor Media Corp.*, 689 F.3d 1282, 1287–88 (Fed. Cir. 2012) (holding that “a prior art printed publication cited by an examiner is presumptively enabling”).

387. *Id.*; *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003).

388. *See Antor Media*, 689 F.3d at 1287–88.

389. *See In re Payne*, 606 F.2d 303, 315 (C.C.P.A. 1979) (“Facts, such as test data demonstrating inoperativeness . . . or facts set forth in an affidavit . . . of an expert in the field suggesting that inoperativeness, would be highly probative.”).

390. As explained by the Federal Circuit:

[I]t is procedurally convenient to place the burden on an applicant who is in a better position to show, by experiment or argument, why the disclosure in question is not enabling . . . . It would be overly cumbersome, perhaps even impossible, to impose on the [Patent Office] the burden of showing that a cited piece of prior art is enabling. The [Patent Office] does not have laboratories for testing disclosures for enablement.

*Antor Media*, 689 F.3d at 1288; *see also In re Morsa*, 713 F.3d 104, 110 (Fed. Cir. 2013) (reaffirming the procedural basis for the presumption); *Amgen*, 314 F.3d at 1355 n.21 (further elaborating on the policy basis for the presumption).

391. *See Seymore*, *Rethinking Novelty*, *supra* note 41, at 937–46 (criticizing the rule).

392. As previously discussed, whether a prior art reference is enabling depends on the nature of the technology. *See supra* note 238. An enduring approach is to classify a technological field as either “unpredictable” or “predictable.” The courts refer to fields like chemistry and biotechnology

and typically must engage in trial and error to figure out what works and what does not.<sup>393</sup> Accordingly, placing the burden of proof on the applicant seems less defensible.

This Article's proposed framework is different *because it is all about substance*. The prior art product has been made and previously used; the inventor might be called on to prove that the claimed new use is mechanistically different from the old use.<sup>394</sup> Here placing the burden of persuasion on the applicant makes sense because the applicant knows more about the invention than the Patent Office<sup>395</sup> and is equipped to prove (by experiment) distinctiveness from the prior art.<sup>396</sup>

Nonetheless, the proposed framework would likely affect inventor filing behavior.<sup>397</sup> Faced with the possibility of having to adduce objective proof of mechanism, an inventor would have two options. The first option would be to not file at all. An inventor would have to weigh the costs of patenting (including the costs of additional experimentation) against the potential value of patent protection.<sup>398</sup> For drug repurposing, the balance might tip toward patenting given the potential financial payoff.<sup>399</sup> But a decision to forego patenting is not necessarily a bad outcome. There would be one less application to

as “unpredictable” because PHOSITAs in these fields often cannot predict whether a reaction protocol that works for one embodiment will work for others. *Cedarapids, Inc. v. Nordberg, Inc.*, No. 95-1529, 1997 WL 452801, at \*2 (Fed. Cir. Aug. 11, 1997) (explaining that in the chemical arts, “a slight variation . . . can yield an unpredictable result or may not work at all”). By contrast, applied technologies like electrical and mechanical engineering are often regarded as “predictable” because they are rooted in well-defined, predictable factors. *See In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991) (describing “mechanical or electrical element[s]” as “involving a ‘predictable’ factor”). Of course, enablement depends on the facts in a given case because, for example, a mechanical device can have unpredictable features. *See In re Bowen*, 492 F.2d 859, 861–62 (C.C.P.A. 1974) (criticizing a rigid dichotomy between “chemical” and “mechanical” cases). Relatedly, what is “unpredictable at one point in time may become predictable at a later time.” *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374 n.10 (Fed. Cir. 1999).

393. *See BURK & LEMLEY, supra* note 360, at 115 (“There is overwhelming evidence that the application of the PHOSITA standard varies by industry, leading for example to fewer, but broader, valid software patents and more, but narrower, biotechnology patents.”).

394. *See supra* Section III.C.

395. *See Seymore, supra* note 257, at 991–96 (discussing the Patent Office’s information deficit).

396. The Patent Office lacks its own testing facilities and thus has no way to prove or test inherency. *See supra* note 252 and accompanying text.

397. *See JAFFE & LERNER, supra* note 360, at 122 (“Inventors [r]espond to [h]ow the Patent Office [b]ehaves.”).

398. *See* Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 88 (2009) (discussing the balance and noting that the costs of patenting are typically low).

399. *See supra* Section II.B.

examine (and strain Patent Office resources),<sup>400</sup> one less low-quality patent,<sup>401</sup> and less clutter placed in the public domain.<sup>402</sup>

The second option would be to postpone filing until sufficient proof of mechanism can be adduced. This is seemingly at odds with early disclosure—a stated goal of the patent system.<sup>403</sup> It is true that inventors are motivated to file early to attract investors<sup>404</sup> and safeguard patent rights in the United States<sup>405</sup> and abroad.<sup>406</sup> So there might be a tradeoff between more prefiling work to produce a more robust application and the perceived need to race to the Patent Office.<sup>407</sup>

Delayed filing is not necessarily a bad outcome since early filing also has drawbacks,<sup>408</sup> including sketchy invention disclosures<sup>409</sup> and

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400. See Cotropia, *supra* note 398, at 104–05 (discussing the “overloaded patent examination system”); Michael D. Frakes & Melissa F. Wasserman, *Does the U.S. Patent and Trademark Office Grant Too Many Bad Patents?: Evidence from a Quasi-Experiment*, 67 STAN. L. REV. 613, 616 (2015) (analyzing the Patent Office’s backlog of applications).

401. See Jay P. Kesari & Andres A. Gallo, *The Political Economy of the Patent System*, 87 N.C. L. REV. 1341, 1369 (2009) (“Higher quality patents mean that fewer patents will be granted.”).

402. If the claimed new use lacks novelty, a patent would restrict the public’s free access to what was already in the public domain. See *supra* Section I.A (discussing the theoretical basis of the novelty requirement).

403. See *supra* note 357.

404. See JOHN SAMSON, INVENTIONS AND THEIR COMMERCIAL DEVELOPMENT 51 (1896) (“To have the use of capital is nearly always indispensable for the development of an invention, and, unless the inventor is of that fortunate class who have the means to work their own patents, he must appeal for support to one or more people with money.”); Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 143–44 (2000) (discussing the need for venture capital).

405. See 35 U.S.C. § 102(a) (2012) (encouraging diligence by penalizing inventors for the delayed filing of patent applications); Kitch, *supra* note 55, at 269–70 (explaining the rules in patent law that force and permit early filing). This motivation is even stronger under the first-inventor-to-file regime of the AIA. See *supra* note 64 and accompanying text.

406. Convention on the Grant of European Patents, art. 54(2), Oct. 5, 1973, 1065 U.N.T.S. 255, 272 (invoking an absolute novelty requirement that regards any prefiling disclosure, including activity by the inventor, as patent defeating).

407. A patent race “is a race among competing firms to be the first to discover and patent some new idea having commercial potential.” WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 300 (2003). While it is certainly true that the AIA’s first-inventor-to-file system raises concerns about timing, inventors have several low-cost options to secure a filing date—they can file a provisional patent application or simply make a prefiling disclosure no more than a year before filing. See 35 U.S.C. § 102(b) (prefiling disclosure); 35 U.S.C. § 111(b) (2012) (provisional application).

408. See Cotropia, *supra* note 398, at 88–119 (discussing the costs of early filing); Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. REV. 1171, 1187 (2016) (arguing that the benefits of early filing are often illusory, particularly for patent applications filed by those who have not physically made the invention); Seymore, *supra* note 47, at 659–61 (arguing that ex ante incentives that encourage early filing can thwart innovation).

409. See Wendy H. Schacht & John R. Thomas, *Patent Reform: Innovation Issues*, in PATENT TECHNOLOGY 1, 11 (Juanita M. Branes ed., 2007) (discussing the merits of the first-inventor-to-file principle).

potential patents on underdeveloped inventions or mere ideas.<sup>410</sup> Patent law contemplates that the inventor will develop the invention before filing,<sup>411</sup> which generates more information about it.<sup>412</sup> This leads to more refined inventions,<sup>413</sup> more robust patent examination,<sup>414</sup> and improved patent quality.<sup>415</sup>

## CONCLUSION

Finding new uses for old products is the type of creative activity that the patent system encourages. New-use patents are receiving considerable attention in the pharmaceutical industry because drug firms realize that it is faster and cheaper to repurpose old drugs than to develop new ones. And new-use drug patents can generate as much or more revenue than the original product patent. An important question that must be asked for repurposed inventions is if the claimed new use is *really new*. If close inspection reveals that the old product is doing what it has always done, the claimed new use lacks novelty. But various evidentiary rules and biases at the patent examination stage combined with perfunctory views of anticipation prevent a robust novelty assessment for new-use claims. Sometimes this leads to unwarranted patents; other times it derails meritorious inventions. The

410. See Jacob S. Sherkow, *Patent Law's Reproducibility Paradox*, 66 DUKE L.J. 845, 884 (2017) (discussing how “[t]he early, easy patenting of drugs encourages patent applicants to adopt several troublesome strategies at the [Patent Office]”). Such patents often provide dubious guidance to the PHOSITA, add little or nothing to the public storehouse of technical knowledge, and supply little technical fodder for subsequent researchers to build on. See Seymore, *supra* note 253, at 1022 (noting that “allowing dubiously enabled patents to issue can impede scientific and technological progress”). In addition, these patents “can create insurmountable roadblocks . . . for others with meritorious inventions.” *Id.*

411. While public use of the invention prior to filing can bar issuance of a patent under 35 U.S.C. § 102(a), a judicially created doctrine known as the experimental use exception can negate the bar by affording the inventor time to improve and perfect the invention. See *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 134–37 (1877) (discussing the experimental use exception); see also *Allen Eng'g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1353 (Fed. Cir. 2002) (listing objective factors for determining if a use is experimental). Without the experimental use exception, “inventors theoretically would have to race to the [Patent Office] to file applications on inventions that are not fully developed and not amenable to being disclosed adequately to satisfy the obligations of 35 U.S.C. § 112.” Mark D. Janis & Timothy R. Holbrook, *Patent Law's Audience*, 97 MINN. L. REV. 72, 127 n.126 (2012).

412. See Cotropia, *supra* note 398, at 123 (“An actual reduction to practice requirement would generate more technical information about the invention.”).

413. Further development and refinement “produce a better invention—whether it be safer, cheaper, more efficient, more durable, or more effective.” Seymore, *supra* note 47, at 654; see also *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 968 (Fed. Cir. 1984) (recognizing that although the patent laws encourage prompt filing, “the public interest is also deemed to be served by allowing an inventor time to perfect his invention”).

414. This would mitigate the Patent Office's information deficit. See discussion *supra* note 364 and accompanying text.

415. See *supra* Section III.C.2.

new framework proposed in this Article solves these problems by offering a more probing, robust, and diligent approach for assessing novelty in new-use claims. Forcing the inventor to elucidate and divulge more information about the claimed new use would provide more accurate novelty assessments while also promoting patent law's disclosure function. More broadly, the proposed framework recalibrates novelty's gatekeeping role and focuses the analysis on identity—what novelty is all about.