Article

Making Patents Useful

Sean B. Seymore[†]

INTRODUCTION

It is axiomatic in patent law that an invention must be useful.[1] A requirement for utility appeared in the original Patent Act of 1790[2] and has remained a part of the statutory

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† Professor of Law, Professor of Chemistry, and Enterprise Scholar, Vanderbilt University. J.D., University of Notre Dame, 2006; Ph.D. (Chemistry), University of Notre Dame, 2001; M.S.Chem., Georgia Institute of Technology, 1996; B.S., University of Tennessee, 1993. Many thanks to Michael Burstein, Christopher Cotropia, Brett Frischmann, Daniel Gervais, Timothy Holbrook, Craig Nard, Kristen Osenga, and Felix Wu for thoughtful discussions and feedback on earlier drafts of this Article. I also thank Scott Baker, Christopher Buccafusco, Kevin Collins, Jorge Contreras, Dmitry Karshtedt, and David Schwartz for incisive comments and criticisms on related earlier work. Finally, I thank Vanderbilt University Law School for a research leave and research grant to support this project and the Program in Science, Technology, and Society at the Massachusetts Institute of Technology for hosting me as a visiting professor.

1. *See* 1 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 338 (1890) ("[N]o patent can be granted for a worthless art or instrument, nor, although granted, can it be sustained after the uselessness of the invention is established."); *cf.* Brenner v. Manson, 383 U.S. 519, 534 (1966) (identifying utility as a part of the quid pro quo of the patent bargain). The requirement for utility applies to *utility* patents (also known as patents for invention), which cover any new or improved "process, machine, manufacture, or composition of matter." 35 U.S.C. § 101 (2006). Utility patents are the most common type of patent and the focus of this Article. The U.S. patent system grants two other types of patents: *design* patents, which protect any "new, original and ornamental design for an article of manufacture," *id.* § 171 (2006), *amended by* Patent Law Treaties Implementation Act of 2012, Pub. L. No. 112-211, §§ 202(a)(1), 203(a)(1), 126 Stat. 1527, 1536; and *plant* patents, which protect any "distinct and new variety of plant." *Id.* § 161 (2006).

2. *See* Patent Act of 1790, ch. 7, § 1, 1 Stat. 109, 109–10 (repealed 1793) ("[U]pon the petition of any person or persons . . . that he, she, or they, hath or have invented or discovered any *useful* art, manufacture, engine, machine, or device, or any improvement therein not before known or used . . . it shall and may be lawful . . . to cause letters patent to be made out . . . ." (emphasis added)).

scheme.[3] It is codified in § 101 of the current patent statute, which states in relevant part that "[w]hoever invents or discovers any new and *useful* process, machine, manufacture, or composition of matter . . . may obtain a patent."[4] Utility is regarded as an essential condition for patentability.[5]

But what does it mean to be useful? The *Oxford English Dictionary* defines the term simply as "beneficial"[6] or "fit[] for some desirable purpose or valuable end."[7] The abstract and imprecise nature of the term invites subjective interpretations because virtually *everything* can be used by someone for something.[8] So it seems that a thing has utility as long as it can provide *some* benefit.

But does utility have a similar de minimis meaning in patent law? Congress has never defined "useful" in the patent statute, or even specified from whose perspective utility is to be determined.[9] Perhaps this is why, throughout most of the history of U.S. patent law, utility was given short shrift. This de minimis interpretation is often attributed to Justice Story, who in the 1817 case *Bedford v. Hunt* defined a useful invention as "one as may be applied to *some* beneficial use in society, in contradistinction to an invention, which is injurious to the morals, the health, or the good order of society."[10] Until the middle of

3. *See, e.g.*, Patent Act of 1793, ch. 11, § 1, 1 Stat. 318, 318–21 (repealed 1836) (granting patent eligibility to a person who has "invented any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement"); Patent Act of 1836, ch. 357, § 6, 5 Stat. 117, 119 (repealed 1870) (identical language); Patent Act of 1870, ch. 230, § 24, 16 Stat. 198, 201 (repealed 1952) (same).

4. 35 U.S.C. § 101 (2006) (emphasis added).

5. Graham v. John Deere Co., 383 U.S. 1, 12–13 (1966) (identifying the three explicit conditions for patentability as novelty, utility, and nonobviousness); Stiftung v. Renishaw PLC, 945 F.2d 1173, 1180 (Fed. Cir. 1991) ("[Utility is] a fundamental requirement of American patent law, dating back some two-hundred years . . . .").

6. 19 OXFORD ENGLISH DICTIONARY 356 (2d ed. 1989) (defining "useful").

7. *Id.* at 368 (defining "utility").

8. Even a failed experiment has utility because it eliminates whatever approach was under consideration, makes way for an alternative, and always produces data from which others can learn. *See, e.g.*, NEIL BALDWIN, EDISON 51 (1995) (quoting Thomas Edison's remarks to financial supporters that "[n]o experiments are useless").

9. This is not uncommon in patent law. *See* John F. Duffy, *The Federal Circuit in the Shadow of the Solicitor General*, 78 GEO. WASH. L. REV. 518, 544 (2010) (explaining that patent law "has traditionally had a common law feel to it" because the courts receive little guidance from statutory sources).

10. 3 F. Cas. 37, 37 (Story, Circuit Justice, C.C.D. Mass. 1817) (No. 1217) (emphasis added).

the twentieth century, utility was easily satisfied as long as the invention could operate to achieve its intended result.[11]

A low utility threshold aligns with the broad policy goals of the patent system. The Supreme Court recognized as much in 1966 in *Brenner v. Manson*, where Justice Fortas acknowledged that a de minimis standard "encourage[s] inventors of new [products and] processes to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge."[12] Stated more succinctly, a de minimis standard promotes knowledge dissemination and the disclosure function of the patent system. Nevertheless, the *Manson* Court abandoned the de minimis standard in favor of one which substantially ratcheted up utility's gatekeeping role in patent law.[13]

So why did this happen? *Manson*, a chemical case, arose toward the end of a transformative period in patent law when the invention landscape changed from primarily mechanical devices to one populated with chemical and pharmaceutical inventions.[14] Determining how to adapt the utility requirement to accommodate this new landscape led to conflicts among judges on the U.S. Court of Customs and Patent Appeals (C.C.P.A.),[15] tension between the C.C.P.A. and the Patent Office,[16] and sharp ideological disagreements among Supreme Court Justices.[17]

Though the moral and public welfare requirements were ultimately jettisoned,[18] the modern utility requirement set forth in *Manson* and its progeny is even more subjective than the one it replaced. Not only must the disclosed utility be credible,[19] it

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11. *See infra* Part I.A.

12. 383 U.S. 519, 533 (1966).

13. *See infra* Part I.C.2.

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

15. The C.C.P.A. was a five-judge Article III court on the same level as the U.S. Courts of Appeals. *See U.S. Court of Customs and Patent Appeals (Successor to the Court of Customs Appeals), 1910–1982*, FED. JUDICIAL CTR., http://www.fjc.gov/history/home.nsf/page/courts_special_cpa.html (last visited Nov. 25, 2013). It was abolished by the 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 the C.C.P.A. decisional law as binding precedent. South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc).

16. *See infra* Part I.C.1.

17. *See infra* note 119 and accompanying text.

18. *See infra* Part I.B.2.

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

must also allow a person having ordinary skill in the art (PHOSITA)[20] to use the invention to provide a significant, immediate, and well-defined benefit to the public.[21]

This is why utility's invigorated role in patent law has come at a price. It has transformed § 101 into a powerful gatekeeper that allows the Patent Office and courts to subjectively decide when or if something can be patented.[22] One consequence has been the development of a bias against patentability for certain types of inventions. History reveals that those seeking patents on inventions in nascent technologies, fields which have a poor track record of success, and unpredictable fields like chemistry, biotechnology, and pharmaceuticals have had to fight with the Patent Office and in the courts over utility.[23] On the other hand, applicants who seek patents on toys and games have no problems establishing utility.[24] No court or commentator has been able to convincingly explain the logic behind the differing utility thresholds.

Utility has received very little attention in the academic literature—perhaps because it is assumed to be a "low bar" to patentability[25] or a "nonexistent" patentability requirement.[26]

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20. 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) (explaining that a PHOSITA "is not unlike the 'reasonable man' and other ghosts in the law"). Factors relevant to constructing the PHOSITA in a particular technical field include the sophistication of the technology, the educational level of the inventor, the educational level of active workers in the field, the types of problems encountered in the art, 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, 697 (Fed. Cir. 1983) (listing the factors).

21. *See* Brenner v. Manson, 383 U.S. 519, 534–35 (1966) (construing "useful" in 35 U.S.C. § 101 to require "substantial" and "specific" utility); *In re* Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (defining the terms); *see also infra* Part I.C.2.

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

23. *See* Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1491, 1494, 1507 (2011) [hereinafter Seymore, *Patently Impossible*].

24. *See In re* Kirk, 376 F.2d 936, 961 (C.C.P.A. 1967) (Rich, J., dissenting) ("Nor does the Patent Office worry about the utility of games, toys, and cosmetics.").

25. Lee Petherbridge, *Road Map to Revolution? Patent-Based Open Science*, 59 ME. L. REV. 339, 356 n.90 (2007) ("The utility requirement is still properly understood as very low and generally presents a low bar to patentability."); *see* Michael Risch, *A Surprisingly Useful Requirement*, 19 GEO. MA-

As this Article will show, such statements are inaccurate. It is more correct to say that the utility threshold is decidedly *biased*—a de minimis threshold for some inventions but a considerably more stringent one for others. One reason why patent denials based on a lack of utility are relatively rare might be because potential applicants with inventions falling into one of the disfavored categories logically decide not to waste time and money pursuing a patent if a denial is inevitable. Such behavior clearly hinders innovation and compromises fundamental goals of the patent system.[27]

Some have argued that the utility requirement furthers the constitutional mandate to promote technological progress by helping to ensure that the public receives a benefit from the patent grant.[28] This Article takes a radically different position. Aside from arguing that utility is *not* mandated by the Constitution,[29] this Article argues that it is a superfluous requirement because the ends it seeks can be accomplished through compliance with (or more rigorous enforcement of) other patentability requirements.[30]

For all of these reasons, this Article calls for the elimination of a stand-alone utility requirement. This is the first Article to both harshly criticize utility *and*—by seeking to eliminate it—urge a radical rethinking of what should be included in (or removed from) the patentability calculus.[31] Its goal is to inform

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SON L. REV. 57, 58 (2011) (noting that inventions which fail to meet the current standard are rare).

26. Risch, *supra* note 25, at 58.

27. *See infra* Part III.A.

28. *See, e.g.*, Brenner v. Manson, 383 U.S. 519, 534 (1966).

29. *See infra* Part III.A.1.

30. *See infra* Parts III.B–C.

31. Though several commentators have criticized utility—particularly as applied to chemical and pharmaceutical inventions—they assume that it must be retained for constitutional or statutory reasons. *See, e.g.*, Eric P. Mirabel, *"Practical Utility" Is a Useless Concept*, 36 AM. U. L. REV. 811 (1987); Lawrence R. Velvel, *A Critique of* Brenner v. Manson, 49 J. PAT. OFF. SOC'Y 5 (1967); Brent Nelson Rushforth, Comment, *The Patentability of Chemical Intermediates*, 56 CAL. L. REV. 497, 497–98 (1968). On the other hand, a few commentators have argued that utility should play a *greater* gatekeeping role in patent law. *See* Michael Risch, *Reinventing Usefulness*, 2010 BYU L. REV. 1195, 1240–41 (advocating a "commercial utility" requirement, which would be present if there were "sufficient evidence to convince a [PHOSITA] that a) there is a market for the invention, and that b) the invention can be manufactured at a cost sufficient to fulfill market demand"); Risch, *supra* note 25, at 74–100; Teresa M. Summers, Note, *The Scope of Utility in the Twenty-First Century: New Guidance for Gene-Related Patents*, 91 GEO. L.J. 475, 508–09 (2003) (advocating a heightened utility test).

the ongoing debate over patent reform and spark further discussions about the extent to which basic patent doctrines actually promote technological progress.

The Article proceeds as follows. Part I describes how utility began as a trivial patentability requirement but transformed into one which is decidedly biased—de minimis for some inventions but considerably more stringent for others. After briefly explaining how utility is currently assessed, Part II shows how the current rubric ignores an invention's inherent usefulness and often devolves into a subjective judgment about when or if something should be patentable. Such an arbitrary standard, this Part argues, frustrates fundamental goals of the patent system. To that end, Part III proposes the elimination of utility as a condition for patentability.

I. WHY IMPOSE A UTILITY REQUIREMENT?

A. TO HELP ENSURE THAT THE INVENTION BENEFITS THE PUBLIC

Until the twentieth century, patent denials for a lack of utility were rare. During this period the Patent Office and the courts agreed with Justice Story that the threshold should be low.[32] Recall that his test had two prongs: first, that the invention provided "some beneficial use" to the public;[33] and second, that the asserted utility was not "injurious to the morals, the health, or the good order of society."[34] The latter—a negative requirement—can be traced to the English Statute of Monopolies of 1623.[35] Justice Story's second prong created a forbidden class of inventions[36] that included things like "a new invention

32. *See* Bedford v. Hunt, 3 F. Cas. 37, 37 (Story, Circuit Justice, C.C.D. Mass. 1817) (No. 1217); *supra* text accompanying note 10 (discussing *Bedford*).

33. *Bedford*, 3 F. Cas. at 37.

34. *Id.*

35. It provided that patents could be granted and enforced so long as the invention "was not contrary to the law, nor mischievous to the state . . . or generally inconvenient." Statute of Monopolies, 1623, 21 Jac. 1, c. 3, § 6. For an example of the latter, Lord Edward Coke explained that even a machine which could do the work of many humans was unpatentable because "it was holden inconvenient to turn so many laboring men to idleness." EDWARD COKE, THE THIRD PART OF THE INSTITUTES OF THE LAWS OF ENGLAND 184 (4th ed. 1669).

36. Mirabel, *supra* note 31, at 813.

to poison people, or to promote debauchery, or to facilitate private assassination."[37]

The Supreme Court added a third prong in 1873 in *Mitchell v. Tilghman*.[38] Citing the legal historian George Ticknor Curtis's famous treatise on patent law,[39] the Court held that utility is lacking "where it appears that [the invention] is not capable of being used to effect the object proposed."[40] This has come to be known as the "operability" prong of the utility requirement. In theory, it, too, is de minimis because an invention is inoperable only if it is "totally incapable of achieving a useful result."[41]

In summary, by the late nineteenth century, *some* beneficial use was sufficient to establish utility unless the invention was inoperable or detrimental to the public interest.[42] The standard was truly de minimis, as noted in an 1883 treatise *The Patentability of Inventions*, which stated that "[a]s to the term 'useful', the courts have construed the condition expressed by it so liberally that it almost never serves to defeat a patent."[43]

B. TO SERVE AS A GATEKEEPER

1. The Emergence of a Double Standard

a. An Evolving Invention Landscape

The abstract and imprecise nature of the term "useful," combined with the absence of legislative guidance, has made utility the most malleable patentability requirement. Mallea-

37. Lowell v. Lewis, 15 F. Cas. 1018, 1019 (Story, Circuit Justice, C.C.D. Mass. 1817) (No. 8568).

38. 86 U.S. (19 Wall.) 287 (1873).

39. GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS, AS ENACTED AND ADMINISTERED IN THE UNITED STATES OF AMERICA (4th ed. 1873).

40. *Mitchell*, 86 U.S. (19 Wall.) at 396 (citing CURTIS, *supra* note 39, § 494).

41. Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571 (Fed. Cir. 1992); *cf. In re* Perrigo, 48 F.2d 965, 966 (C.C.P.A. 1931) ("It is fundamental in patent law that an alleged invention . . . must appear capable of doing the things claimed . . . ."). An applicant satisfies the operability prong as long as the invention accomplishes at least one stated objective. Raytheon Co. v. Roper Corp., 724 F.2d 951, 958 (Fed. Cir. 1983).

42. *See* CURTIS, *supra* note 39, § 494.

43. *In re* Nelson, 280 F.2d 172, 179 (C.C.P.A. 1960) (quoting HENRY C. MERWIN, THE PATENTABILITY OF INVENTIONS 75 (1883)), *overruled by In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967).

bility is not a foreign concept to patent law—indeed, it is expected. As the nature of the invention landscape changes to reflect advances in science and technology, patent law must respond.[44] It does so through the evolution of the common law.[45]

Of course, some changes to the invention landscape are easier to handle than others. For example, the evolution of aircraft propeller blades over the past century from wood to metal to polymer composites has been easy to accommodate because the underlying technology is easily understood.[46] In patent law, propeller blades and other mechanical devices are deemed "predictable" because they are rooted in well-defined factors such as mechanical or electrical elements.[47] By contrast, chemicals, pharmaceuticals, and biotechnology are referred to as "unpredictable" because a PHOSITA often cannot predict outcomes or extrapolate results with a reasonable expectation of success.[48]

b. Targeted Inventions

The malleability of the utility requirement has allowed the courts to create technologically specific standards for certain classes of inventions to achieve particular policy goals. The most notable classes so targeted have been chemicals and pharmaceuticals.

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

45. This is true even though all inventions—irrespective of technological field—must satisfy the same statutory patentability criteria. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1575–77 (2003); *see also* Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 53 (2010) (noting that the common law is "the dominant legal force in the development of U.S. patent law").

46. *See generally* Mike Burden et al., *Advanced Polymer Composite Propeller Blades*, *in* AEROSPACE MATERIALS 59, 60–62 (Brian Cantor et al. eds., 2001); Alvin Edward Moore, *The Screw Propeller*, 23 J. PAT. OFF. SOC'Y 896, 899–928 (1941).

47. *See In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991) (citing *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970)).

48. Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 136–54 (2008) [hereinafter Seymore, *Heightened Enablement*]. For example, in the chemical arts, "a slight variation [in a structure or method] can yield an unpredictable result or not work at all." Cedarapids, Inc. v. Nordberg, Inc., No. 95-1529, 1997 WL 452801, at *2 (Fed. Cir. Aug. 11, 1997).

Before World War II, chemical compounds were subject to the same de minimis utility standard as other inventions.[49] This changed, however, shortly after the war. By this time the invention landscape had transformed from mechanical devices to predominately chemicals and pharmaceuticals[50]—from predictable to unpredictable.[51] The Patent Office responded by making a unilateral policy decision to ratchet up the applicable utility standard.[52]

At least for chemicals and pharmaceuticals claiming therapeutic activity, the courts agreed. They specifically targeted inventions purporting to effectively treat diseases or conditions, like cancer and baldness, which the lay public long considered to be untreatable or incurable.[53] But it is doubtful that patent examiners and judges during that period could competently evaluate what was scientifically possible because they were not

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

50. *See* NAT'L ACAD. OF ENG'G, THE COMPETITIVE STATUS OF THE U.S. PHARMACEUTICAL INDUSTRY 7–11 (1983) (describing the "therapeutic revolution").

51. *See supra* notes 47–48 and accompanying text.

52. In 1956, the Commissioner of Patents squarely rejected the Patent Office's pre-war liberal view of utility in chemical cases:

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

In re Kirk, 376 F.2d 936, 952–53 (C.C.P.A. 1967) (Rich, J., dissenting) (quoting Robert C. Watson, Comm'r, U.S. Patent Office, Remarks to the Division of Medicinal Chemistry of the American Chemical Society (Sept. 19, 1956)).

53. *See* Seymore, *Patently Impossible*, *supra* note 23, at 1514–22 (discussing the judiciary's reluctance to grant patents on inventions purporting to effectively treat baldness and cancer).

active researchers and therefore were divorced from what was happening at the forefront of technology.[54]

The courts soon adopted a heightened utility standard not only for therapeutic claims, but for any claim that purported to achieve a result that seemed impossible. The Patent Office and the courts justified their skepticism as necessary for the sake of the public good.[55] As the argument goes, there was a belief (albeit an incorrect one) among the public and potential investors[56] that the government never issues patents on inoperable inventions.[57] Good public policy required the strict policing of seemingly impossible inventions to protect the public from potentially harmful products that do not work as claimed, and to protect potential investors from unscrupulous patentees.[58]

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54. *Id.* at 1512–13.

55. As stated by the Board:

> The Office is particularly bound to take notice of the question of utility, because . . . a [patent] grant is an assurance to the public of the conclusions of the Office . . . .
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> . . . Cases are not unknown where patents have been secured . . . and then used simply to impose on a public not disposed to scrutinize closely the merits of a matter upon which the Patent Office has set the seal of its approval.

Ex parte Moore, 128 U.S.P.Q. (BNA) 8, 9 (Bd. Pat. App. 1960) (quoting *Ex parte* De Bausset, 43 Off. Gaz. Pat. Office 1583, 1585 (1888)), *cited with approval in In re* Citron, 325 F.2d 248, 253 (C.C.P.A. 1963).

56. It is axiomatic in patent law that many inventors must rely on investors to cover the hefty costs of patent procurement and commercialization. *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.").

57. Daniel C. Rislove, Comment, *A Case Study of Inoperable Inventions: Why Is the USPTO Patenting Pseudoscience?*, 2006 WIS. L. REV. 1275, 1280.

58. *In re* Citron, 325 F.2d at 253; *see also* Isenstead v. Watson, 157 F. Supp. 7, 9 (D.D.C. 1957) (contending that the patent grant "gives a kind of official imprimatur to the [invention] in question on which as a moral matter some members of the public are likely to rely"). The fear is that some might view the patent grant, albeit improperly, as the government's endorsement of the technology. *See* Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J.L. & POL'Y 247, 253 n.29 (2000) (noting that issuing patents covering controversial technologies might be viewed as governmental endorsement); Timothy R. Holbrook, *The Expressive Impact of Patents*, 84 WASH. U. L. REV. 573, 599–600 (2006) [hereinafter Holbrook, *Expressive Impact*] (explaining that governments may choose to deny patents on certain inventions in order to eliminate the signal of perceived endorsement or encouragement). A patentee might also "advertise its patent to convince gullible consumers that a patent represents the government's endorsement or imprimatur that the advertised product is actually effective."

What emerged was a bias against patentability for targeted inventions.

The preferred tool for screening out therapeutics and other incredible inventions was (in)operability—the third prong of the aforementioned utility test.[59] Recall that an invention is inoperable if it cannot achieve its intended result.[60] The best example of the bias in action was the reluctance of the Patent Office and the courts to grant patents for inventions claiming to effectively treat cancer. To be sure, for most of the twentieth century they were highly skeptical of *any* invention which purported to do so.[61] Applicants claiming success faced an often insurmountable patentability hurdle because the courts allowed the Patent Office to impose a very high burden on the applicant to prove operability.[62]

The landmark opinion from this era is *In re Citron*, a 1963 C.C.P.A. case in which an applicant alleged that a serum containing hormone-like compounds extracted from cancerous tissue could inhibit the inception and growth of certain types of cancer and effectively treat the disease.[63] The applicant's disclosure described how to make the serum, provided analytical data, and contained a working example purporting to show its effectiveness in rats and humans.[64] Nevertheless, the examiner

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Christopher R. Leslie, *Patents of Damocles*, 83 IND. L.J. 133, 144 (2008) (footnote omitted). *But see In re* Hartop, 311 F.2d 249, 263 (C.C.P.A. 1962) ("[T]he issuance of a patent is not in fact an 'imprimatur' as to . . . safety and effectiveness . . . . [A patent] is no guarantee of anything . . . . The *public*, therefore, is in no way protected either by the granting or withholding of a patent.").

59. *See supra* notes 38–42 and accompanying text.

60. *See supra* note 41 and cases cited therein.

61. *See, e.g.*, *Ex parte* Moore, 128 U.S.P.Q. (BNA) 8, 9–10 (Bd. Pat. App. 1960) (determining that any suggestion that the claimed compounds could treat cancer was incredible and misleading). One exception occurred in 1959 when the Patent Office allowed a single medical use claim for a drug useful in bringing about remission in myeloid leukemia. *See Ex parte* Timmis, 123 U.S.P.Q. (BNA) 581, 583 (Bd. Pat. App. 1959). But this occurred only after two prior appeals to the Board and overwhelming evidence, which included "voluminous" clinical evidence, prior FDA approval, endorsement by the American Medical Association, patient affidavits, peer-reviewed publications, and testimony that "spontaneous remissions are rare in cases of leukemia." *Id.* at 581–83.

62. *See, e.g.*, *Timmis*, 123 U.S.P.Q. (BNA) at 581. This lies in contrast to the status quo, which places the burden on the Patent Office to prove inoperability. *See infra* Part II.B.

63. 325 F.2d 248, 251 (C.C.P.A. 1963) (quoting from the written description of the invention in the application).

64. *See id.* at 251–52. Although the disclosure did not identify the hormone-like compounds by name or structure, C.C.P.A. precedent permitted an

rejected the claim under § 101 and found that the applicant had not sustained his burden to prove operability.[65] The Board of Patent Appeals and Interferences[66] affirmed, explaining that the invention was "apparently inoperative" and, in light of contemporary knowledge in the art, could not "be accepted as operative absent clear and convincing proof thereof."[67] This heavy burden imposed upon the applicant reveals the then-existing "double standard" for therapeutic inventions.[68]

2. Does Utility Have Limits?

For a good number of therapeutic inventions, the issue was not credibility but whether the drug was safe for human use. Justice Story's public interest prong (centered around the

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applicant to claim a product by the process of making it if there was no other way to define it. *In re* McKee, 95 F.2d 264, 266 (C.C.P.A. 1938) (sanctioning product-by-process claims).

65. *Citron*, 325 F.2d at 252.

66. An applicant whose claims have been twice rejected by the examiner can appeal to an intra-office tribunal—known as the Board of Patent Appeals and Interferences at the time of *Citron*—which, among other things, reviews adverse decisions of examiners. 35 U.S.C. §§ 6(b), 134(a) (2006). The Board can affirm a rejection or reverse and remand to the examining corps. 37 C.F.R. § 1.197 (2013). Since the passage of the America Invents Act in 2011, the tribunal is now known as the Patent Trial and Appeal Board. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3, 125 Stat. 284, 285–93 (2011) (codified in scattered sections of 35 U.S.C.) (eliminating interference proceedings).

67. *Citron*, 325 F.2d at 252; *cf. In re* Ferens, 417 F.2d 1072, 1074 (C.C.P.A. 1969) ("Evidence submitted to establish usefulness must be such as would be clear and convincing to [a PHOSITA]."). Shifting the burden of proof to the applicant and ratcheting up the standard of proof were both in line with C.C.P.A. precedent. *See, e.g.*, *In re* Chilowsky, 229 F.2d 457, 462 (C.C.P.A. 1956) ("[I]f the alleged operation seems clearly to conflict with a recognized scientific principle . . . the presumption of inoperativeness is so strong that very clear evidence is required to overcome it."); Irving Marcus, *The Patent Office and Pharmaceutical Invention*, 47 J. PAT. OFF. SOC'Y 669, 673 (1965) (explaining that, from the perspective of the examining corps, heightened proof is required if human use is involved and the condition is one which is difficult to treat).

68. 1 DONALD S. CHISUM, CHISUM ON PATENTS § 4.04[2] (2013); *see also In re* Kirk, 376 F.2d 936, 958 (C.C.P.A. 1967) (Rich, J., dissenting) (observing that while utility is rarely questioned for new machines, "[a]n elaborate ritual dance is required to satisfy the Patent Office as to the disclosure of [the] utility of a drug" (quoting Joseph Gray Jackson, Address at the Institute of Patent Law of the Southwest Legal Foundation (Mar. 30, 1967))). The double standard was in reaction to the common nineteenth-century practice to emphasize a product's "patented" status, like the phrase "patent medicine," to mislead the public. 4 CHISUM, *supra*, § 4.04[2][a] (quoting EDMUND W. KITCH & HARVEY S. PERLMAN, LEGAL REGULATION OF THE COMPETITIVE PROCESS 721 (1st ed. 1972)).

"morals, the health, or the good order of society")[69] was the principal basis for denying patents under § 101 for safety-related concerns. By the early 1960s, the Patent Office had promulgated a policy which required that applicants for therapeutic patents "supply proof of safety and effectiveness of the claimed composition in man,"[70] notwithstanding any testing done on experimental animals.[71]

Realizing that the Patent Office had gone too far, the C.C.P.A. addressed the role of safety in the patentability calculus in the 1962 case *In re Hartop*.[72] The specific question for the court was whether clinical evidence or FDA approval should be a prerequisite for patenting drugs.[73] Despite the Patent Office's contention that it was "carrying out [its] statutory duty" by requiring such proof,[74] the court concluded that no such duty arises from § 101:

> [W]e observe that any statutory authority given the Patent Office [to require such proof] would have to stem from the provision of 35 U.S.C. § 101 that a patentable invention must be "useful." A comparison of this provision with the detailed provisions of the Federal Trade Commission Act and the Federal Food, Drug, and Cosmetic Act indicates to us that if Congress had intended to use its constitutional authority under the patent clause to do what it might not be able to do under the commerce clause, it would have enacted drug patent legislation in detail corresponding to those two acts.[75]

The C.C.P.A. and the Federal Circuit have reaffirmed that *no* provision in the patent statute establishes safety as a patentability criterion.[76] Imposing a safety component to § 101 should be left to Congress.[77]

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69. Bedford v. Hunt, 3 F. Cas. 37, 37 (Story, Circuit Justice, C.C.D. Mass. 1817) (No. 1217).

70. *In re* Hartop, 311 F.2d 249, 263 (C.C.P.A. 1962) (internal quotation marks omitted).

71. *Id.* at 254.

72. 311 F.2d 249.

73. *See id.* at 251.

74. *Id.* at 260 (Smith, J., concurring) (quoting the Patent Office's argument).

75. *Id.* at 259 (majority opinion) (footnotes omitted); *cf. In re* Krimmel, 292 F.2d 948, 954 (C.C.P.A. 1961) (holding that as to whether the claimed drug was safe and effective for use in humans, "[i]t is not for us or the Patent Office to legislate and if the Congress desires to give this responsibility to the Patent Office, it should do so by statute").

76. *In re* Anthony, 414 F.2d 1383, 1393–94 (C.C.P.A. 1969); *accord* Scott v. Finney, 34 F.3d 1058, 1063–64 (Fed. Cir. 1994); *cf. In re* Watson, 517 F.2d 465, 474–76 (C.C.P.A. 1975) (explaining that it is not the province of the Patent Office to determine, under § 101, whether drugs are safe).

77. *See* sources cited *supra* notes 75–76.

The moral utility doctrine has also been squarely rejected. It took a devastating blow in *Ex parte Murphy*, a 1977 case in which the Board reversed the examiner's § 101 rejection of a slot machine.[78] The final blow came nearly two decades later in *Juicy Whip, Inc. v. Orange Bang, Inc.*, where the Federal Circuit had to decide if an invention with a deceptive purpose—designed to appear to be something that it is not—could satisfy the utility requirement.[79] The court answered in the affirmative, noting that Justice Story's forbidden class of inventions is not a part of modern utility doctrine:

> [S]ince Justice Story's opinion[,] it has been stated that inventions that are "injurious to the well-being, good policy, or sound morals of society" are unpatentable. . . . [But this principle] has not been applied broadly in recent years. . . .
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> . . . .
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> . . . As the Supreme Court put the point more generally, "Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted."[80]

Just as with safety, the court explained that imposing a moral component to § 101 should be left to Congress.[81] This demise of

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78. 200 U.S.P.Q. (BNA) 801, 802 (B.P.A.I. 1977).

79. 185 F.3d 1364, 1364 (Fed. Cir. 1999).

80. *Id.* at 1366–68 (citations omitted) (quoting Webber v. Virginia, 103 U.S. 344, 347–48 (1880)).

81. *Id.* at 1368. The prospect for revival came a few years after *Juicy Whip* when the Patent Office received a patent application claiming a human-animal hybrid. *See* U.S. Patent Application No. 10/308,135 (filed Dec. 3, 2002). The applicants had not made the hybrids; their purpose in filing the application "was to provoke a debate and force Congress, the courts, or the USPTO to draw the line on patent-eligible subject matter." Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 490 (2003). The examiner rejected the claim on several grounds, including a lack of utility based on the moral utility doctrine. *See* Office Action on Patent Application No. 10/308,135 at 21–24 (Mar. 5, 2003) [hereinafter Office Action] (on file with author). Citing Justice Story's opinion in *Lowell v. Lewis*, 15 F. Cas. 1018 (Story, Circuit Justice, C.C.D. Mass. 1817) (No. 8568), the examiner concluded that "[t]he discretion to consider the well-being and good policy of society implicit in the statutory term 'useful' is properly applied when a refusal to grant a patent is necessary to avoid preempting the power of Congress to define essential questions of public policy." Office Action, *supra*, at 23. In discussing the rejection and its broader implications, Professor Timothy Holbrook argues:

> [T]he idea of denying the patent in order to allow Congress to consider the issue first is inconsistent with the Supreme Court's reasoning in *Diamond v. Chakrabarty*, where the [C]ourt allowed the patenting of a life form and noted that it is for the *courts* to decide patent eligibility in the first instance.

the judicially created moral utility requirement is in complete accord with the Supreme Court's "anything under the sun made by man" interpretation of patent-eligible subject matter set forth in *Diamond v. Chakrabarty*.[82]

C. TO ESTABLISH TECHNOLOGY-SPECIFIC PATENTABILITY STANDARDS

One might have thought that the rejection of Justice Story's public interest prong signaled a decline in utility as a patentability lever. But that is not what happened. As discussed below, the Federal Circuit's oft-quoted statement from *Juicy Whip* that "[t]he threshold for utility is not high"[83] is true for some inventions but not for others.

Recall that a key challenge for the post-World War II patent system is how to assess utility for chemical and pharmaceutical inventions.[84] For those inventions with a *known* therapeutic activity at the time of patenting, the *asserted* utility was always clear—to treat some specific ailment or disease. But what about the much broader universe of chemical compounds which have no therapeutic or other concrete, non-research-based use at the time patent protection is sought? The judicial response to this question—the essential utility question of the modern era—has shaped the current utility requirement.

1. The Growing Tension

For the first half of the twentieth century, the C.C.P.A. and the Patent Office agreed that chemical compounds had patentable utility despite the lack of a disclosed, specific end use. As Justice Harlan explained in his dissent in *Manson*, "usefulness was typically regarded as *inherent* during a long and prolific period of chemical research and development in this country."[85] But things changed; while the C.C.P.A. maintained this de minimis view through the late 1960s, by the early 1950s the Patent Office began to relentlessly seek a higher standard.[86]

Holbrook, *Expressive Impact*, *supra* note 58, at 607–08 (emphasis added); *see also* Diamond v. Chakrabarty, 447 U.S. 303, 315–18 (1980). The application was abandoned in 2005. *See* Notice of Abandonment for Patent Application No. 10/308,135 at 2 (Mar. 1, 2005) (on file with author).

82. Bagley, *supra* note 81, at 492 (quoting *Diamond*, 447 U.S. at 309).

83. *Juicy Whip*, 185 F.3d at 1366.

84. *See supra* Part I.B.1.

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

86. *See infra* notes 97–98 and accompanying text.

The best illustration of the tension is *In re Nelson*,[87] a 1960 case that called into question the intrinsic value of chemical compounds. The applicant sought to patent several compounds referred to as intermediates—compounds whose asserted utility is to serve as "building blocks" for other compounds.[88] The issue for the court was whether a chemical intermediate has its own utility or whether the applicant had to disclose a use for the end product in order to obtain a patent on the intermediate.[89] Writing for the court in an opinion that has been described as a "judicial bombshell,"[90] Judge Rich explained that to require the latter would frustrate fundamental goals of the patent system:

> We have never received a clear answer to the question "Useful to whom and for what?" Surely a new group of steroid intermediates is *useful to chemists doing research* on steroids, and in a "practical" sense too. Such intermediates are "useful" under section 101. They are often actually placed on the market before much, if anything, is known as to what they are "good" for, other than experimentation and the making of other compounds in the important field of research. Refusal to protect them at this stage would inhibit their wide dissemination, together with the knowledge of them which a patent disclosure conveys, which disclosure the potential protection encourages. This would tend to retard rather than promote progress.[91]

In addition to making it clear that the *degree* of utility is irrelevant,[92] *Nelson* revealed that an invention's benefit to the public could be indirect.[93]

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87. 280 F.2d 172, 180 (C.C.P.A. 1960), *overruled by In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967).

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

89. *Id.* at 175.

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

91. *Nelson*, 280 F.2d at 180–81.

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

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

CURTIS, *supra* note 39, § 28; *cf.* ROBINSON, *supra* note 1, § 341 ("When actual utility exists, its degree is unimportant.").

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

Nelson was a triumph for the research community and very important for the growth of the chemical, biotechnological, and pharmaceutical industries.[94] Aside from reaffirming that the standard for utility is de minimis,[95] it recognized that "in the chemical industry, pure research often has an intrinsic utility despite no immediate use for the fruits of the research."[96] Had *Nelson* remained good law, it would have done much to bridge the gap between patent law and scientific research. But instead, the Patent Office began applying a heightened utility standard for chemicals, seemingly without explanation.

What led the Patent Office to aggressively and suddenly promulgate a heightened utility threshold for chemical compounds? No one knows. As Judge Rich stated:

> [In a 1951 chemical case,] [t]he examiner had said, "Organic compounds are *inherently useful as intermediates* for preparing other compounds and this *inherent utility* satisfies the statutory requirement." That is the situation with respect to the administration of the patent law before some unidentifiable upper echelon in the Patent Office turned the thumb screws on the chemists. It did so with no mandate from Congress or the courts. It just arbitrarily decided to change the law.[97]

Judge Rich contended that by steadily ratcheting up the utility requirement since the early 1950s, the Patent Office had raised it "above anything required by the statute or by [C.C.P.A. case law] and develop[ed] its own brand new theories and philosophy about what the statute means by 'useful.'"[98] But the Patent Office was not willing to give up on the utility question so easily.

2. *Brenner v. Manson*

The conflict between the C.C.P.A. and the Patent Office led the Supreme Court to weigh in on the essential utility question in the 1966 case *Brenner v. Manson*.[99] The case was about Man-

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94. Davis, *supra* note 90, at 12.

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

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

97. *In re* Kirk, 376 F.2d 936, 952 (C.C.P.A. 1967) (Rich, J., dissenting) (quoting Avakian v. Fahrenbach, 172 Comm'r MS Decisions 425, 426 (B.P.A.I. 1951) (unpublished interference opinion)).

98. *Id.*

99. 383 U.S. 519 (1966).

son's attempt to provoke an interference—a fight between two inventors over who is entitled to a patent.[100] The invention at issue was a new process for making a steroid (*X*).[101] By the time Manson filed his patent application, the Patent Office had already issued a patent on the process to a competitor.[102] Although Manson could prove that he was the first to invent the process, the examiner would not declare an interference (to sort out who did) and rejected Manson's application because it failed to disclose a utility for *X*.[103]

Manson argued that *X*'s utility could be *presumed* because other steroids of similar chemical structure were known to inhibit tumors in mice.[104] On appeal, the Board of Patent Appeals and Interferences affirmed the examiner's rejection because the unpredictable nature of steroid chemistry made it impossible to presume that *X* would have the same tumor-inhibiting properties as the other compounds.[105] Citing *Nelson*, the C.C.P.A. re-

100. Under the first-to-invent system, patent rights are only awarded to the first inventor. *See* 35 U.S.C. § 102(g) (Supp. V 2011) (barring issuance of a patent when another inventor has made the invention before the applicant so long as the first inventor has not "abandoned, suppressed, or concealed [the invention]"). When two parties claim the same invention, the Patent Office institutes an "interference" proceeding to determine priority (i.e., which party is entitled to a patent). *See id.* (establishing the basis of "interference practice" for determining priority of invention between two parties). The party that reduced the invention to practice usually wins; however, a party that was "first to conceive the invention but last to reduce it to practice"—either actively or constructively—will win if that party "demonstrates reasonable diligence [toward] reduction to practice." Cooper v. Goldfarb, 240 F.3d 1378, 1382 (Fed. Cir. 2001).

101. *Manson*, 383 U.S. at 520–21.

102. *Id.*; *see* Process for the Prod. of 2-Methyl-Dihydrotestosterones, U.S. Patent No. 2,908,693 (filed Dec. 16, 1957) (issued Oct. 13, 1959).

103. *Manson*, 383 U.S. at 521–22. Before the passage of the America Invents Act, when a person believed that he or she was the inventor of the subject matter claimed by another in a patent application or issued patent, the remedy was to file a patent application claiming that subject matter to "provoke" an interference with the other application or issued patent. *See* 35 U.S.C. § 135(b)(1) (Supp. V 2011) (amended 2013). Today a patent applicant would file a petition to institute a "derivation proceeding" before the Patent Trial and Appeal Board. *See supra* note 66 and sources cited therein.

104. *Manson*, 383 U.S. at 521–22.

105. The Board stated, "It is our view that the statutory requirement of usefulness of a product cannot be presumed merely because it happens to be closely related to another compound which is known to be useful." *Id.* at 522. This is true because "minor changes in the structure of a steroid may produce profound changes in its biological activity." *Id.* at 532 n.19; *cf.* AstraZeneca Pharm. LP v. Teva Pharm. USA, Inc., 583 F.3d 766, 775 (Fed. Cir. 2009) (recognizing that "the properties of these structurally similar compounds [can]

versed and held that "a process which operates as disclosed to produce a known product is [itself] 'useful' within the meaning of section 101"[106] so long as "it is not, in operation or result, detrimental to the public interest."[107]

The Supreme Court reversed. Agreeing with the Patent Office, the Court held that an inventor seeking to patent a new process for making a compound could only do so if the inventor could establish utility for the compound.[108] Put differently, a process for making a compound like *X*, which is useful only as—in the words of the majority—an "object of scientific research," lacks utility and is therefore unpatentable.[109] In dicta, but perhaps most importantly, the majority stated that *the compound itself* also lacks utility if it is to serve merely as an "object" for further scientific research.[110]

Interestingly, the majority conceded that in contemporary chemistry, "little or nothing is wholly beyond the pale of 'utility.'"[111] To be sure, even chemicals and chemical processes that are only used for research purposes would pass the three-pronged de minimis test.[112] Recall that under that test, *some* beneficial use is sufficient to establish utility unless the invention is inoperable or detrimental to the public interest.[113] But as applied to chemical inventions, the majority believed that the "beneficial use" and "public interest" prongs "shed little light on [the] subject" because they were overinclusive.[114] The fact that the chemical or chemical process can operate to produce the in-

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vary significantly with minor structural changes"). For additional discussion of unpredictability, see *supra* note 48 and accompanying text.

106. *In re* Manson, 333 F.2d 234, 236 (C.C.P.A. 1964).

107. *Id.* at 238. The court's rationale was that a process (such as a method of making something) is a separate category of invention specifically recognized in the statute. *Id.* at 236; *see also* 35 U.S.C. § 100(b) (Supp. V 2011) ("The term 'process' means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."); *id.* § 101 (2006) ("Whoever invents or discovers any new and useful *process* . . . ." (emphasis added)).

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

109. *Id.* at 535.

110. *Id.* The Court explained that the argument(s) against patenting the process "would apply equally to the patenting of the product produced by the process." *Id.* And in the majority's view, "the decisions of the C.C.P.A. [were] in accord with the view that a product may not be patented absent a showing of utility greater than any adduced in the present case." *Id.*

111. *Id.* at 530.

112. *See supra* Part I.A.

113. *See supra* Part I.A.

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

tended result remains a necessary condition for utility but is insufficient on its own to warrant a patent.[115]

The Court then announced the heightened utility standard for chemical process inventions:

> The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with utility. Unless and until a process is refined and developed to this point—where *specific* benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.[116]

Requiring less, according to the majority, could allow the patentee to create a "monopoly of knowledge" which could "engross a vast, unknown, and perhaps unknowable area."[117] The patent could confer the power to "block off whole areas of scientific development, without compensating benefit to the public."[118] The majority minimized Justice Harlan's concern that a more rigorous utility standard could actually inhibit scientific progress by, *inter alia*, encouraging the inventor to maintain secrecy until an acceptable "use" is discovered.[119]

So the Patent Office won.[120] Soon after *Manson* the C.C.P.A. capitulated. In the companion cases *In re Kirk*[121] and

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115. *See id.* at 532.

116. *Id.* at 534–35 (second emphasis added).

117. *Id.* at 534.

118. *Id.* The majority's position addresses concerns that large numbers of patents on "upstream" inventions might delay or block "downstream" research and the development of commercial end products. *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, SCIENCE, May 1, 1998, at 698, 698–99. On the other hand, upstream patents promote efficiency by allowing the upstream patentee to coordinate downstream innovation, prevent duplicative research, and encourage sharing of useful information. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 276–77 (1977). In addition, there is empirical research which challenges the anticommons thesis. *See, e.g.*, John P. Walsh et al., *Working Through the Patent Problem*, SCIENCE, Feb. 14, 2003, at 1021 (finding that patents on research tools "rarely precluded the pursuit of worthwhile projects").

119. *See Manson*, 383 U.S. at 538–39 (Harlan, J., concurring in part and dissenting in part). For additional discussion related to Justice Harlan's concerns about secrecy, see *infra* Part III.A.3.

120. Perhaps not surprisingly, the Patent Office is all too eager to apply *Manson*. *See, e.g.*, *Ex parte* Aggarwal, No. 90-3041, 23 U.S.P.Q.2d (BNA) 1334, 1339 (B.P.A.I. 1992) ("There is no question that appellants have made an important discovery with regard to chemical compounds (proteins) which are the subject of serious scientific investigation but [it is nevertheless unpatentable because of its] unverified and speculative utility.").

121. 376 F.2d 936 (C.C.P.A. 1967).

In re Joly,[122] the court extended *Manson* (and reversed *Nelson*) by holding that chemical intermediates were unpatentable if the end product had no known use.[123]

The impact of *Manson*, *Kirk*, and *Joly* cannot be overstated. Utility in the chemical, pharmaceutical, and biotechnological arts now has nothing to do with the invention's inherent usefulness to a PHOSITA, ability to advance scientific knowledge, or potential to indirectly benefit the public. In these fields, the utility standard is nothing more than a subjective and arbitrary value judgment. As discussed in greater detail below, this standard is detrimental to patent law and many of the technical communities that it serves.

II. ASSESSING UTILITY

A. THE MODERN UTILITY REQUIREMENT

Like the one it replaced, the modern test for utility has three prongs. The first prong, "operability" or "credible utility," is the only one retained from the nineteenth-century test. It requires that the invention be capable of achieving the intended result.[124] *Operability* is gauged by asking if a PHOSITA would consider the inventor's assertions believable.[125]

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122. 376 F.2d 906 (C.C.P.A. 1967).

123. *Kirk*, 376 F.2d at 945; *Joly*, 376 F.2d at 908–09. In addition, the court explained:

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

Id. at 908 (quoting *Kirk*, 376 F.2d at 945).

124. *See* Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1358 (Fed. Cir. 1999); *see also* Newman v. Quigg, 877 F.2d 1575, 1581 (Fed. Cir. 1989) ("[A] device lacks utility [if] it does not operate to produce what [the inventor] claims [that] it does." (citation omitted)); *cf. In re* Perrigo, 48 F.2d 965, 966 (C.C.P.A. 1931) ("It is fundamental in patent law that an alleged invention . . . must appear capable of doing the things claimed . . . .").

125. The Patent Office can establish reasonable doubt if the applicant's disclosure "suggest[s] an inherently unbelievable undertaking or involve[s] implausible scientific principles." *In re* Cortright, 165 F.3d 1353, 1357 (Fed. Cir. 1999) (quoting *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995)). A finding of inoperability means that the claimed invention lacks a credible utility. *Id.* at 1356; U.S. PATENT & TRADEMARK OFFICE, REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS 11 (1999) [hereinafter INTERIM UTILITY GUIDELINES] ("[A] utility that is inoperative is not credible.").

The two other prongs, "substantial" and "specific" utility, were identified but not fully defined in *Manson*.[126] The Federal Circuit did so nearly forty years later in *In re Fisher*,[127] when it essentially adopted the Patent Office's guidelines for assessing utility.[128] For *substantial utility*, a PHOSITA must be able to use the invention to provide a "significant" and "immediate benefit to the public."[129] In other words, the patent application "must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research."[130]

Finally, *specific utility* requires that an invention "provide a well-defined and particular benefit to the public."[131] The purpose of this requirement is to deny patents for inventions where the asserted use is "so vague as to be meaningless."[132] For example, asserted uses like "biological activity" or "useful for technical and pharmaceutical purposes" fail the requirement.[133]

B. PROVING UTILITY

The utility analysis at the patent examination stage can take one of two paths.[134] If it is readily apparent that the invention has a "well-established" utility, § 101 is satisfied and the

126. *See* Brenner v. Manson, 383 U.S. 519, 532–35 (1966).

127. 421 F.3d 1365, 1371–72 (Fed. Cir. 2005). The facts of *Fisher* are discussed *infra* Part III.D.2.

128. "The [Patent Office's] standards for assessing whether a claimed invention has a specific and substantial utility comport with this court's interpretation . . . . We agree with the Board [of Patent Appeals and Interferences] that the facts here are similar to those in *Brenner*." *Fisher*, 421 F.3d at 1372, 1374 (citing with approval U.S. Patent and Trademark Office Utility Examination Guidelines, 66 Fed. Reg. 1092, 1097 (Jan. 5, 2001) [hereinafter Utility Examination Guidelines]). The guidelines have been incorporated into the *Manual of Patent Examining Procedure*. *See* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2107 (8th ed. Rev. 9, Aug. 2012) [hereinafter MPEP]. The MPEP provides guidance to patent examiners and is regarded as the Patent Office's official interpretation of statutes and regulations. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995). The MPEP and Utility Examination Guidelines "are not binding on [the Federal Circuit], but may be given judicial notice to the extent they do not conflict with the statute." *Fisher*, 421 F.3d at 1372.

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

130. *Id.*

131. *Id.*

132. *Id.*

133. *Id.* (quoting *In re* Kirk, 376 F.2d 936, 941 (C.C.P.A. 1967) (citation omitted)).

134. *See* MPEP, *supra* note 128, § 2107(II).

inquiry ends.[135] A "well-established" utility is one "which is well known, immediately apparent, or implied by the [applicant's] disclosure of the properties of a material, alone or taken with the knowledge of [the PHOSITA]."[136] Included in this category are most machines, mechanical devices, and other "predictable" inventions[137] where utility "is so apparent as to virtually jump off the page and slap [a PHOSITA] in the face."[138]

Alternatively, certain categories of inventions raise red flags and are subject to more rigorous scrutiny. As discussed earlier, these include inventions in nascent technologies, fields that have a poor track record of success,[139] and unpredictable fields like chemistry, biotechnology, and pharmacology.[140] To be sure, the *Manual of Patent Examining Procedure* provides examiners with lists of inventions and utilities that should be immediately rejected.[141] But this is not the end of the story. Under current law, an invention which lacks utility under § 101 also fails as a matter of law to comply with the enablement requirement of § 112(a).[142] The paradoxical nature of this dual utility-enablement rejection is addressed in detail below.

A lack-of-utility rejection triggers an evidentiary burden-shifting process. Initially, the applicant's asserted utility is presumptively correct.[143] So, for example, an examiner who questions whether the invention can achieve its intended result must establish a prima facie case of inoperability by coming

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135. *Id.*

136. INTERIM UTILITY GUIDELINES, *supra* note 125, at 7.

137. For a discussion of "predictable" technologies, see *supra* notes 46–48 and accompanying text.

138. Seymore, *Heightened Enablement*, *supra* note 48, at 156 n.15 (internal quotation marks omitted) (quoting Ash v. Tyson Foods, Inc., 546 U.S. 454, 456–57 (2006) (per curiam)); *cf. Ash*, 546 U.S. at 456–57 (evaluating the "jump off the page" standard in the context of an employment discrimination suit).

139. Here the issue is often credible utility. *See, e.g.*, *In re* Swartz, 232 F.3d 862, 864 (Fed. Cir. 2000) (per curiam) (generating energy with "cold fusion"); Newman v. Quigg, 877 F.2d 1575, 1577 (Fed. Cir. 1989) (perpetual motion machine).

140. *See supra* notes 46–48 and accompanying text.

141. *See, e.g.*, MPEP, *supra* note 128, § 2107.01(I)(B) (identifying basic research, chemical intermediates, and methods of making chemical intermediates where the end product does not have an identifiable utility); *id.* § 2107.01(II) (citing *Swartz*, 232 F.3d 862; *Newman*, 877 F.2d 1575) (identifying perpetual motion machines and cold fusion as lacking credible utility).

142. *In re* Ziegler, 992 F.2d 1197, 1200–01 (Fed. Cir. 1993).

143. *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995); *see also* MPEP, *supra* note 128, § 2107.02(III)(A) (instructing examiners not to begin the analysis by assuming that the asserted utility is false).

forward with factual evidence that shows why a PHOSITA would doubt the applicant's asserted utility.[144] Evidentiary sources can include peer-reviewed materials, non-peer-reviewed materials, anecdotal information, information from related technologies, and logic.[145] If the examiner cannot adduce the evidence, then the Patent Office must issue a patent, as long as the applicant meets the other requirements for patentability.[146]

An applicant faced with a utility rejection can either attack or rebut the examiner's prima facie case. An applicant can successfully attack it if the examiner produces no (or insufficient) evidence to support a finding of nonutility.[147] A good example is when the examiner relies on common sense or a fact asserted to be common knowledge in the field (without providing evidentiary support) as proof of noncompliance.[148] The applicant can also mount a successful attack if the examiner contends that the invention is partially operable,[149] crude,[150] or inferior to oth-

144. MPEP, *supra* note 128, § 2107(II)(C); *see also In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (explaining that the examiner bears the initial burden of presenting a prima facie case of unpatentability); Fregeau v. Mossinghoff, 776 F.2d 1034, 1038 (Fed. Cir. 1985) (applying the prima facie case to § 101).

145. *In re* Dash, 118 F. App'x 488, 491 (Fed. Cir. 2004). The nature of the source "merely go[es] to the weight of the evidence, not whether it can be relied upon at all." *Id.*

146. *Oetiker*, 977 F.2d at 1445.

147. *See* sources cited *supra* note 144.

148. The general rule is that the Patent Office "may take notice of facts beyond the record which . . . are capable of such instant and unquestionable demonstration as to defy dispute." *In re* Ahlert, 424 F.2d 1088, 1091 (C.C.P.A. 1970). But there are limits. First, as to core factual findings, the Patent Office cannot reach conclusions simply based on its own experience or assessment of what is basic knowledge or common sense. *In re* Zurko, 258 F.3d 1379, 1386 (Fed. Cir. 2001). For such facts, the Patent Office should point to concrete evidence in the record to support the rejection. *Id.* Second, if the examiner relies on common knowledge without documentary support, the rejection can survive only if it is based on sound technical reasoning and the applicant does not demand that the examiner provide authority. *See, e.g.*, *In re* Chevenard, 139 F.2d 711, 713 (C.C.P.A. 1943). Third, the applicant must have an opportunity to challenge a fact asserted to be common knowledge. *See, e.g.*, *id. But see* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418–20 (2007) (explaining that in the nonobviousness context, reliance on common sense can be appropriate).

149. *See* sources cited *supra* note 41.

150. Hildreth v. Mastoras, 257 U.S. 27, 34 (1921) ("The machine patented may be imperfect in its operation; but if it embodies the generic principle[] and works . . . though only in a crude way . . . it is enough."); Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999)

ers.[151] Reliance on any of these rationales, whether alone or in combination, is insufficient to satisfy the Patent Office's initial burden.[152]

An alternative strategy is to concede the prima facie case and rebut it. So, for example, if operability is at issue, the burden shifts to the applicant to come forward with persuasive arguments or additional evidence sufficient to convince a PHOSITA to accept the applicant's assertions.[153] When the applicant submits rebuttal evidence, the examiner must "start over" and "consider all of the evidence anew."[154] The examiner must determine patentability based on the entire record, with a preponderance of the evidence as the standard of proof.[155] Whether an invention complies with the utility requirement of § 101 is a question of fact.[156]

C. THE PERILS OF THE HEIGHTENED UTILITY STANDARD

Recall that one criticism of the pre-*Manson* test for utility was its susceptibility to subjective, value-based patentability assessments that had little to do with an invention's true usefulness to the PHOSITA.[157] This concern was certainly evident in the moral and public welfare prongs,[158] but also surfaced in the operability prong, which often devolved into a subjective judgment about the subject matter.[159]

(explaining that operability still exists even if the invention does not work perfectly under all conditions).

151. *See* Stiftung v. Renishaw PLC, 945 F.2d 1173, 1180 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result, and it need only be useful to some extent and in certain applications . . . ."); Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 960 n.12 (Fed. Cir. 1986) ("It is possible for an invention to be less effective than existing devices but nevertheless meet the statutory criteria for patentability.").

152. If the examiner does not meet this initial burden, the applicant does not need to provide any additional evidence to substantiate its assertions, which are presumptively correct. *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

153. *In re* Swartz, 232 F.3d 862, 864 (Fed. Cir. 2000) (per curiam) (citing *Brana*, 51 F.3d at 1566).

154. *In re* Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (citing *In re* Rinehart, 531 F.2d 1048, 1052 (C.C.P.A. 1976)).

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

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

157. *See supra* Part I.B.

158. *See supra* Part I.A.

159. *See* Seymore, *Patently Impossible*, *supra* note 23, at 1513–14; discussion *supra* Part I.B.

What is troubling about the modern test is that it repeats the sins of the past. While the operability prong is clearly subjective, so too is the determination of whether an invention has specific or substantial utility. By allowing the decisionmaker to arbitrarily determine when an invention is ripe for patenting, § 101 has morphed into a boundless gatekeeper in patent law.[160]

III. SUPPLANTING UTILITY

The emergence of technology-specific utility standards—de minimis for some inventions but considerably more stringent for others—has come at a cost. The bias against granting patents for certain types of inventions disconnects patent law from much of the technological community that it serves and ultimately frustrates fundamental goals of the patent system. Would the patent system be better served without a standalone utility requirement? As it turns out, scrapping the utility requirement entirely would better serve the goals of patent law.

A. WHY ELIMINATE UTILITY AS A CONDITION OF PATENTABILITY?

1. Utility Is Not Constitutionally Required

Any effort to eliminate the utility requirement must begin by asking if it is mandated by the Constitution. There is a widespread belief in patent law that utility has a constitutional basis.[161] The Federal Circuit and others who espouse this view point to the Intellectual Property Clause, which empowers Congress to authorize the granting of patents "to promote the [p]rogress of . . . *useful* [a]rts."[162] Some have argued that this

160. *See supra* note 22 and accompanying text.

161. *See, e.g.*, Brenner v. Manson, 383 U.S. 519, 534–35 (1966) ("The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility."); *In re* Bremner, 182 F.2d 216, 217 (C.C.P.A. 1950) ("[W]e feel certain that *the law requires that there be in the application an assertion of utility and an indication of the use or uses intended.* It was never intended that a patent be granted upon a product, or a process producing a product, unless such product be useful. See subsection 8 of section 8 of Article I, United States Constitution . . . .").

162. U.S. CONST. art. I, § 8, cl. 8 (emphasis added); *see* Stiftung v. Renishaw PLC, 945 F.2d 1173, 1180 (Fed. Cir. 1991) ("The utility requirement has its origin in article 1, section 8 of the Constitution, which indicates that the purpose of empowering Congress to authorize the granting of patents is 'to promote progress of . . . *useful* arts.'"); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L.

constitutional provision "must be construed in the sense that 'useful' modifies, not 'arts' but, the inventions in the arts."[163] Relatedly, given that the word "useful" also appears in § 101,[164] it is easy to assume that the word has an identical meaning in both contexts.[165]

Here, it is important to explain what is meant by "useful arts" in the Constitution. In his book *The Nature of the Intellectual Property Clause*,[166] noted legal historian Edward Walterscheid explains that when the clause's language was adopted in 1787, "useful arts" was a "unitary technical term"[167] that basically referred to "useful or helpful trades"[168] like the "industrial, mechanical, and manual arts of the 18th century."[169] As to the meaning of "useful arts" using modern language, in his article *Patents and Science: A Clarification of the Patent Clause of the U.S. Constitution*, patent scholar Karl Lutz explains that the term is best represented by the word "technology."[170] Thus, the patent portion of the Intellectual Property Clause can be read to mean "[t]o promote the progress of technology"[171] or "[t]o accelerate technological progress."[172]

REV. 77, 101 n.128 (1999) ("To the extent that the patent clause of the Constitution focuses on 'useful Arts,' the statutory utility requirement may have a constitutional dimension." (citing *Stiftung*, 945 F.2d at 1180)); *cf. Manson*, 383 U.S. at 536 (Harlan, J., concurring in part and dissenting in part) ("Certainly this reading of 'useful' in the statute is within the scope of the constitutional grant, which states only . . . '[t]o promote the Progress of Science and useful Arts' . . . .").

163. Maurice W. Levy, *Utility—The Inverted Criterion*, 30 J. PAT. OFF. SOC'Y 592, 592 (1948).

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

165. *But see* discussion *infra* note 173.

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

167. *Id.* at 349 (internal quotation marks omitted) (quoting Robert I. Coulter, *The Field of Statutory Useful Arts*, 34 J. PAT. OFF. SOC'Y 487, 496 (1952)).

168. *Id.* (citing Arthur H. Seidel, *The Constitution and a Standard of Patentability*, 48 J. PAT. OFF. SOC'Y 5, 10 (1966)).

169. *Id.* (internal quotation marks omitted) (quoting Coulter, *supra* note 167, at 496).

170. Karl B. Lutz, *Patents and Science: A Clarification of the Patent Clause of the U.S. Constitution*, 18 GEO. WASH. L. REV. 50, 54 (1949); *see also* Bilski v. Kappos, 130 S. Ct. 3218, 3244 (2010) (Stevens, J., concurring) ("Numerous scholars have suggested that the term 'useful arts' was widely understood to encompass the fields that we would now describe as relating to technology or 'technological arts.'"); *In re* Bilski, 545 F.3d 943, 1001 (Fed. Cir. 2008) (en banc) ("What the framers described as 'useful arts,' we in modern times call 'technology.'"), *aff'd sub nom.* Bilski v. Kappos, 130 S. Ct. 3218 (2010).

171. Lutz, *supra* note 170, at 54.

In this light, the next question is whether "useful" as it appears in the Intellectual Property Clause mandates an independent, constitutionally-based utility requirement. The answer appears to be no.[173] Though the *Manson* Court intimated that substantial utility might have a constitutional basis,[174] the Court conspicuously failed to cite language in the Constitution to support this conclusion.[175] In fact, Walterscheid argues that "[i]t is important to note that [the *Manson*] holding was predicated on *statutory* interpretation and not on interpretation of the constitutional meaning of 'useful' in the intellectual property clause."[176]

2. Utility Is Substantively Bankrupt

The essence of the U.S. patent system is a quid pro quo between the patentee and the public.[177] The basic idea is that in order to promote the full disclosure of information about the invention to the public, the patentee must be given something in

172. *Id.*; *see also* Paulik v. Rizkalla, 760 F.2d 1270, 1276 (Fed. Cir. 1985) (en banc) ("The exclusive right, constitutionally derived, was for the national purpose of advancing the useful arts—the process today called technological innovation.").

173. Several commentators have argued that "useful" has different meanings in the Constitution and the patent statute. *See, e.g.*, Velvel, *supra* note 31, at 13 (observing that, since the *Manson* Court chose to resolve the case on statutory rather than constitutional grounds, that "in itself is an indication that the Court regards this as basically a statutory matter"). Another commentator presents an insightful perspective:

> Most courts have assumed that the meaning of "useful" in section 101 of the Patent Act is identical to the meaning of the underlying constitutional language. A more sophisticated reading of the Constitution and the Patent Act, however, reveals a tension between the two. . . .
>
> . . . In contrast with the language of the Constitution, the focus in the Patent Act is on the individual invention. Section 101 of the Patent Act, then, presents the "micro" view of the utility requirement.

Nathan Machin, Note, *Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act*, 87 CALIF. L. REV. 421, 437–38 (1999).

174. *See supra* notes 161–62.

175. WALTERSCHEID, *supra* note 166, at 346 n.151.

176. *Id.* at 348 (emphasis added).

177. *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974); *see also* Pennock v. Dialogue, 27 U.S. (2 Pet.) 1, 23 (1829) (explaining that if the public already had possession of the invention at the time the patent was sought, "there might be sound reason for presuming, that the legislature did not intend to grant an exclusive right," given the absence of a quid pro quo).

return.[178] What the patentee gets is the limited period of exclusory rights conferred by the patent grant.[179] The public gets a full disclosure of the invention[180] as soon as the patent document publishes[181] and possession of it at the end of the patent term.[182]

Indeed, an oft-touted justification for the patent system is that society will get some benefit from the invention's disclosure.[183] In theory, the disclosure adds to the public storehouse of useful knowledge which, in turn, promotes technological progress.[184] But it is very easy for the public to get the short end of the stick in this so-called patent bargain.[185] One reason, according to Judge Rich, is because "[t]here always exists, on the part of some people, a selfish desire to obtain patent protection without making a full disclosure."[186] This is why the law strives

178. *See Kewanee*, 416 U.S. at 480–81 (discussing what the inventor receives in exchange for fully disclosing his invention).

179. *Id.* at 480 ("In return for the right of exclusion—this 'reward for inventions'—the patent laws impose upon the inventor a requirement of disclosure." (citation omitted)).

180. *See, e.g.*, J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 (2001) (noting that in order to obtain a patent on a plant, the breeder must describe the plant well enough for the public to be able to use it after the patent expires, which includes depositing publicly-available biological materials).

181. *See* Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 624 (2010) [hereinafter Seymore, *Teaching Function*] (emphasizing that "the patent document has potential *immediate* value to the public, which can use the information for any purpose that does not infringe upon the claims" (emphasis added)); *cf. Kewanee*, 416 U.S. at 481 (explaining that when the information disclosed in a patent becomes publicly available it adds to the "general store of knowledge" and assumedly will stimulate ideas and promote technological development).

182. Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 418 (1822) ("The object is to put the public in complete possession of the invention . . . so that interference with it may be avoided while the patent continues, and its benefits may be fully enjoyed by the public, after the patent expires.").

183. *See Kewanee*, 416 U.S. at 481 (explaining that the federal government "is willing to pay the high price" of exclusivity conferred by a patent for its disclosure, which, "it is assumed, will stimulate ideas and the eventual development of further significant advances in the art").

184. *See In re* Argoudelis, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring).

185. *See* Seymore, *Heightened Enablement*, *supra* note 48, at 143–54 (identifying problems with the current disclosure standard).

186. *In re* Nelson, 280 F.2d 172, 184 (C.C.P.A. 1960), *overruled by In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967); *cf.* Timothy R. Holbrook, *Patents, Presumptions, and Public Notice*, 86 IND. L.J. 779, 804 (2011) [hereinafter Holbrook, *Presumptions*] ("[Applicants] have reasons to provide just enough information to satisfy § 112 and no more so that the patentee could retain as-

to secure the public's part of the patent bargain by compelling patentees to comply with the statutory patentability requirements.[187] Put differently, the requirements work individually and collectively to ensure that the public gets a meaningful disclosure.

To illustrate, consider the basic purpose of each of the patentability requirements. Novelty ensures that the invention is "*new*, that is, bestowed for the first time upon the public by the patentee"[188] and protects knowledge that the public already possesses.[189] Nonobviousness screens for trivial extensions of extant knowledge[190] and denies patents for inventions that would have come about through ordinary technological progress.[191] The disclosure requirements[192] ensure that at the time of filing, the public can use the technical details disclosed in the patent document to improve upon the invention, to design around it, or to engage in other innovative activities during the patent term[193] and practice the invention once the patent term

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pects of the invention as a trade secret, potentially providing a competitive advantage in the market even after the patent is published or expires.").

187. *See* SHELDON W. HALPERN, SEAN B. SEYMORE & KENNETH L. PORT, FUNDAMENTALS OF UNITED STATES INTELLECTUAL PROPERTY LAW: COPYRIGHT, PATENT, AND TRADEMARK 154–55 (4th ed. 2012); *see also* Holbrook, *Presumptions*, *supra* note 186, at 804 (arguing that one can view the Federal Circuit's formalistic disclosure rules as "information-forcing default penalties" for applicants who strategically withhold information).

188. ROBINSON, *supra* note 1, § 221; *see also* 35 U.S.C. § 101 (2006) (requirement for novelty).

189. *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 147 (1989) (noting that Thomas Jefferson, the "driving force behind early federal patent policy," believed that "a grant of patent rights in an idea already disclosed to the public [i]s akin to an *ex post facto law*, 'obstruct[ing] others in the use of what they possessed before'" (alteration in original) (quoting Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), *in* 13 THE WRITINGS OF THOMAS JEFFERSON 326, 327 (Andrew A. Lipscomb & Albert Ellery Bergh eds., Library ed. 1904))); CURTIS, *supra* note 39, § 378.

190. *See* Graham v. John Deere Co., 383 U.S. 1, 11 (1966); *see also infra* Part III.D.1.

191. *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 427 (2007); *see also infra* Part III.D.1.

192. *See* 35 U.S.C. § 112(a) (Supp. V 2011).

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

expires.[194] The patentable subject matter requirement[195] ensures that the inventor makes a meaningful and genuine contribution to the public by excluding things like abstract ideas, laws of nature, mathematical formulas, and physical phenomena.[196] Together, these requirements ensure that the USPTO only awards patents for inventions that *add* to the public storehouse of knowledge[197] and support the patent system's broader mission of promoting scientific progress and extending the frontiers of knowledge.[198]

Conspicuously absent from the preceding discussion is the utility requirement. Though it has been suggested that it also helps to secure the public's part of the patent bargain,[199] one can challenge this assertion for two related reasons. First, as previously discussed, over the past half-century the utility requirement has been used, not to ensure that the public gets a meaningful disclosure, but rather to effect a subjective and arbitrary value judgment as to when or if something is patentable.[200] To be sure, plenty of patent applications denied for a lack of utility disclose copious amounts of substantive technical information that would benefit the PHOSITA and add to the pub-

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

195. *See* 35 U.S.C. § 101 (2006) (allowing patents only for a "process, machine, manufacture, or composition of matter").

196. Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010) (citing Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)); *see also* Parker v. Flook, 437 U.S. 584, 594 (1978) (noting that such things are unpatentable without some inventive concept in their applications); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (explaining that fundamental principles are "part of the storehouse of knowledge of all men[,] . . . free to all men and reserved exclusively to none"), *quoted in Bilski*, 130 S. Ct. at 3225.

197. Graham v. John Deere Co., 383 U.S. 1, 6 (1966) ("Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of . . . useful Arts.'" (alteration in original)).

198. 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* Eldred v. Ashcroft, 537 U.S. 186, 223 (2003) (Stevens, J., dissenting) (noting that the constitutional command is the patent system's "ultimate purpose"); Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502, 511 (1917) ("[T]he primary purpose of our patent laws . . . is 'to promote the progress of science and useful arts' . . . .").

199. *See supra* text accompanying note 116.

200. *See supra* Part I.C.2.

lic storehouse of knowledge.[201] A patent denial at this stage clearly has costs.[202]

Second, as discussed in the next Part, the utility requirement is superfluous because inventions can be effectively screened with other patentability requirements.[203] It is for these reasons—indifference to the technical substance of the disclosure, subjectivity, and superfluity—that the current utility requirement is substantively bankrupt.

Lacking an apparent constitutional basis for utility, what remains is the statute.[204] Since Congress has provided no insight into the meaning of the term "useful" over the past two centuries[205] and probably will not do so any time in the foreseeable future,[206] it will remain a matter of judicial interpretation.[207] As discussed below, this Article proposes a de minimis utility standard which for all practical purposes would eliminate utility as a patentability requirement.[208]

3. It Fosters Secrecy and Delayed Disclosure

Disclosure is regarded as the "centerpiece of patent policy."[209] The patent system goes to great lengths to promote and safeguard the disclosure function. Early disclosure lies at its

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201. *Cf. infra* notes 214–19 and accompanying text (discussing how much technical information is lost when inventors do not file patents because they believe their inventions cannot meet the utility requirement).

202. *See supra* text accompanying note 91 (quoting Judge Rich's views set forth in *In re* Nelson, 280 F.2d 172, 180–81 (C.C.P.A. 1960), *overruled by In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967)).

203. *See* discussion *infra* Parts III.C–D.

204. *Cf.* Velvel, *supra* note 31, at 13 (observing that Congress could overturn the holding in *Manson* through legislation because the Court treated the issue in that case "not as a [c]onstitutional one but as a statutory one").

205. *See* WALTERSCHEID, *supra* note 166, at 345 (noting that congressional inaction has led to the difficulty in defining the term "useful").

206. In 2011, Congress made the most sweeping reform to U.S. patent law since 1952. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified in scattered sections of 35 U.S.C.). Yet, even in the America Invents Act, Congress neglected to clarify the meaning of "useful." *See id.* (containing no amendments to the "useful" requirement of § 101).

207. *See* sources cited *supra* note 45.

208. *See infra* Part III.B.

209. 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").

core;[210] inventors who do not file promptly compromise their patent rights.[211] And, of course, a patent is granted only if the disclosure is fully enabling and represents a complete written description of the invention.[212]

If disclosure is the centerpiece of patent policy, then secrecy is its antithesis.[213] It would seem that any patentability requirement which fosters secrecy should have no place in patent law. But utility does just that! As Justice Harlan aptly noted in *Manson*, an inventor seeking to patent something that cannot meet the majority's new test has every incentive to make the "abstractly logical choice . . . to maintain secrecy until a product use can be discovered."[214]

Nevertheless, concerns about secrecy are often downplayed because it is assumed that the invention will be inevitably disclosed—either in a patent or somewhere else.[215] Whether this assumption is correct is an empirical question that is hard to answer.[216] But several points can be made. First, many nonacademic patentees choose not to disclose the technical details of their inventions outside of the patent system. Indeed, most information disclosed in a patent does not appear in another me-

210. 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."). For positive commentary on early filing, see John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 445 (2004) (arguing that it leads to reduced patent terms, thereby dedicating the invention to the public at an earlier time); Kitch, *supra* note 118, at 269–77 (explaining that it facilitates commercialization, coordinates the development of technology, and reduces wasteful duplicative efforts by competitors).

211. For example, an applicant must file a patent application within one year of disclosing the invention in a printed publication. 35 U.S.C. § 102(b)(1) (Supp. V 2011). A fundamental purpose of § 102(b) is to encourage prompt filing. Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1370 (Fed. Cir. 1998).

212. *See supra* notes 192–94 and accompanying text; *infra* Part III.C.1.

213. J. Jonas Anderson, *Secret Inventions*, 26 BERKELEY TECH. L.J. 917, 919 (2011); Jason Mazzone & Matthew Moore, *The Secret Life of Patents*, 48 WASHBURN L.J. 33, 35 (2008) (explaining how federal patent law "expresses a clear preference for the inventor who discloses an invention to the public and obtains a patent over the inventor who keeps the invention a secret").

214. Brenner v. Manson, 383 U.S. 519, 538 (1966) (Harlan, J., concurring in part and dissenting in part).

215. *See, e.g.*, *id.* at 534 (majority opinion) (noting that concerns about the virtues of disclosure and secrecy are "easily exaggerated").

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

dium.[217] This is particularly true in industry, where scientists publish relatively little.[218] Thus, much technical information, undisclosed through the patent system, never enters the public storehouse of knowledge and will likely be lost.[219]

Second, some inventors concoct trivial uses simply to satisfy the utility requirement.[220] For example, an inventor of a new chemical intermediate[221] (which is unpatentable as such)[222] might assert that it is a good lubricant, detergent, or fuel just to avoid raising any red flags.[223] Importantly for the inventor, once granted, the patent covers *any* use of the intermediate, including uses the patentee never envisioned.[224] Nevertheless, Judge Rich believed that having to concoct utilities to meet the

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217. Fromer, *supra* note 193, at 554; *see also* Esteban Burrone & Guriqbal Singh Jaiya, Intellectual Property (IP) Rights and Innovation in Small and Medium-Sized Enterprises 3 (n.d.) (unpublished manuscript), *available at* http://www.wipo.int/export/sites/www/sme/en/documents/pdf/iprs_innovation.pdf ("It has been estimated that patent documents contain 70% of the world's accumulated technical knowledge and that most of the information contained in patent documents is either never published elsewhere or is first disclosed through the publication of the patent application.").

218. *See generally* Benoît Godin, *Research and the Practice of Publication in Industries*, 25 RES. POL'Y 587 (1996) (presenting various explanations and using bibliometrics to assess the usefulness of publication in industry). The highest priority for an industrial inventor is to generate results that show commercial promise and will ultimately find their way into a marketable product. Partha Dasgupta & Paul A. David, *Information Disclosure and the Economics of Science and Technology*, *in* ARROW AND THE ASCENT OF MODERN ECONOMIC THEORY 519, 522 (George R. Feiwel ed., 1987); *see also* Diana Hicks, *Published Papers, Tacit Competencies and Corporate Management of the Public/Private Character of Knowledge*, 4 INDUS. & CORP. CHANGE 401, 412 (1995) ("After all, writing papers makes no money and consumes time.").

219. *See* Seymore, *Teaching Function*, *supra* note 181, at 666 (discussing situations in which "the patent system is the sole medium of disclosure").

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

221. For a definition, see *supra* note 88.

222. *See supra* Part I.C.2 (discussing *Brenner v. Manson*, *In re Kirk*, and *In re Joly*).

223. *Cf.* Anderson & Dyson, *supra* note 49, at 817 ("[W]here patent protection is imperative, *Kirk* and *Joly* encourage the disclosure of trivial uses, developed only in an attempt to satisfy the new judicial interpretation of the statute.").

224. *Cf.* Roberts v. Ryer, 91 U.S. 150, 157 (1875) ("The inventor of a machine is entitled to the benefit of all the uses to which it can be put, no matter whether he had conceived the idea of the use or not."); Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 809 (Fed. Cir. 2002) ("[A] patent grants the right to exclude others from making, using, selling, offering to sale, or importing the claimed apparatus or composition for any use of that apparatus or composition, whether or not the patentee envisioned such use.").

legal standard is a poor expenditure of technical brainpower[225] and wastes time and effort "which ought to be directed at a more worthy end."[226] It also frustrates the disclosure function by filling the patent document (and ultimately the public storehouse of knowledge) with unhelpful information.[227]

Third, to the extent that certain aspects of an invention fall into a disfavored category prone to lack-of-utility rejections (such as a nascent, paradigm-shifting, or seemingly impossible subject matter), the inventor has every incentive to conceal that feature rather than to disclose or claim it.[228] Fourth, even if the invention is ultimately patented after a use is found, the disclosure is inevitably delayed.[229] In other words, the technical information enters the public storehouse later rather than sooner. Of course, this conflicts directly with the patent system's goal of promoting early disclosure.[230] Clearly, concealment or delayed disclosure of otherwise new, nonobvious, and enabled subject matter into the public storehouse hinders innovation and frustrates basic goals of the patent system.

B. RETHINKING USEFULNESS

1. What Should It Mean to Be (Patentably) Useful?

The word "useful" in § 101 modifies the various types of inventions that can be patented—machines, manufactures, and compositions of matter.[231] But given that the term is inherently abstract and imprecise, history has shown that any attempt to set a usefulness threshold for an invention is a futile exercise. Since every invention can be used by someone (either a PHOSITA or member of the general public) for something, promulgating a technology-sensitive utility paradigm is inherently subjective and leads to nonsensical, biased, and often irrational outcomes.

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225. *Kirk*, 376 F.2d at 960–61.

226. *Id.* at 961.

227. *See* Seymore, *Teaching Function*, *supra* note 181, at 632 (criticizing disclosure practices which add no technical value to the patent literature).

228. *Cf. Kirk*, 376 F.2d at 961 ("The rule of the majority is actually an incentive, furthermore, to conceal information as to the important uses actually in contemplation by the researchers for they dare not even mention such sensitive subjects . . . .").

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

230. *See supra* note 210 and accompanying text.

231. *See* 35 U.S.C. § 101 (2006).

It is for these reasons that the term "useful" should once again be given a de minimis interpretation. A useful invention for § 101 purposes should be one that is "fit[] for some desirable purpose or valuable end" or otherwise provides "some beneficial use" to the public.[232] Such a standard is, in fact, the *first* prong of the nineteenth-century test. But the threshold advocated herein is even lower because it rejects the two other prongs of that test—public interest (which has already disappeared from modern patent law)[233] and operability.[234] This would all but erase utility from the patentability calculus.

2. A Better Theory of Usefulness

Admittedly this is a bold proposal—to essentially eviscerate "useful" from § 101 and to more or less eliminate utility as an independent patentability requirement.[235] This subsection presents a normative theory of how usefulness should be evaluated in patent law.

As an initial matter, recall that the inventive act produces *two* things that are potentially useful to the public: the *invention itself*, which will be defined here as the subject matter claimed in the patent (i.e., machine, product, process, composition of matter)[236] and the *disclosure*, which furnishes technical details about the invention (i.e., how to make it, how to use it).[237]

Though the invention is probably the first thing that comes to mind when patents are discussed, the importance of the disclosure cannot be overlooked.[238] The Court has said that "the ul-

232. *See supra* notes 7, 33 and accompanying text.

233. *See* discussion *supra* Part I.B.2.

234. Operability is superfluous because determining whether an invention can achieve its intended result can be gauged through compliance with the enablement requirement of § 112. *See infra* Part III.C.3.

235. The author is in good company because the late Judge Giles S. Rich was accused of attempting to do likewise. *See In re* Nelson, 280 F.2d 172, 190 (C.C.P.A. 1960) (Kirkpatrick, J., dissenting) ("It seems to me beyond question that the result of the court's decision and opinion is to write the requirements of the Patent Statute, that inventions must be useful, out of the law."), *overruled by In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967).

236. *See* 35 U.S.C. § 101 (2006) (defining patent-eligible subject matter).

237. *See supra* Part I.C.2.

238. Patent scholars differ in their views on the role of the disclosure. *Compare* Fromer, *supra* note 193, at 547–54 (cataloguing the beneficial uses for disclosure in patent law, including stimulating innovation, preventing duplication, gauging patentability, and signaling research-and-development strength), *and* Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 133–47 (2006) (describing the "pervasive" role of disclosure in patent

timate goal of the patent system is to bring new ideas and technologies into the public domain through disclosure."[239] And, as previously discussed, the statutory patentability requirements work collectively to safeguard the disclosure function.[240]

Why is disclosure so important? First, since the public gets many new and useful things through trade secrecy,[241] the patent system incentivizes the disclosure of information that the public might not otherwise get.[242] This is particularly important for "non-self-disclosing" inventions like chemical compounds or industrial processes which a PHOSITA cannot easy replicate or reverse engineer.[243]

Second, the disclosure conveys technical information (and becomes a part of the technical literature),[244] which "add[s] to the sum of useful knowledge"[245] *immediately*—not at the end of

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law and policy, including enriching the state of the art contemporaneously with the invention and showing evidence of possession of the invention), *with* Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. & TECH. 401, 412 (2010) (arguing that "disclosure as an objective of patent policy should be discarded in certain circumstances" because it "serves . . . an ancillary role within the larger purpose of the patent regime"), *and* Note, *supra* note 209, at 2007 ("If disclosure is an important policy goal of the patent system, then the system is in desperate need of repair.").

239. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989).

240. *See* discussion *supra* Part III.A.2.

241. Famous examples are the public's enjoyment of Coca-Cola's syrup formula and use of Google's search algorithm. *See* Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590, 1622 (2011) ("[T]rade secrecy protection can theoretically provide even more powerful incentives than patents because trade secrecy rights are potentially infinite in duration."); Anderson, *supra* note 213, at 923–27 (exploring the patent vs. trade secret distinction).

242. *See* discussion *supra* Part III.A.3. For a narrower view of disclosure, see Note, *supra* note 209, at 2014–16 (explaining that requiring disclosure is unnecessary for inventions that are easy to reverse engineer "because the invention would be disclosed to the public regardless" and also for inventions which are hard to reverse engineer because the inventor will protect them though trade secrecy).

243. Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 83; *id.* at 105–06 ("For such non-self-disclosing inventions, the disclosure of the invention in the patent [document] is valuable to society . . . because it adds something the inventor could have kept secret to the store of public technical knowledge.").

244. Giles S. Rich, *Principles of Patentability*, 28 GEO. WASH. L. REV. 393, 400 (1960). Like technical journals, for example, patent disclosures can show the state of technology, set forth what others have already achieved, and provide technical information that others can avoid repeating. Seymore, *Teaching Function*, *supra* note 181, at 623–24.

245. Graham v. John Deere Co., 383 U.S. 1, 6 (1966).

the patent term but as soon as the patent document publishes.[246] Patent theory contemplates that the early entry of useful knowledge into the public storehouse reduces research-and-development waste,[247] spurs creativity,[248] leads others "to climb onto the patentee's shoulders in seeking improvements or wholly new inventions,"[249] and, of course, extends the frontiers of science and technology.[250]

When viewed in this light, one could argue that patent law should be less concerned with useful *inventions* and more concerned with ensuring that the public gets a useful *disclosure*.[251] As discussed in the next two sections, this objective is best obtained not through the extant utility requirement, but rather through compliance with enablement and nonobviousness.

C. ENSURING USEFULNESS THROUGH ENABLEMENT

This Section argues that enablement can function in two ways to ensure usefulness. First, the disclosure standard can be raised in such a way to guarantee that the public gets a meaningful, technically robust disclosure. Second, enablement can objectively gauge whether the invention works—thereby eliminating the need for § 101's operability requirement.

1. Why Focus on Enablement?

Enablement is one of the three statutory disclosure requirements appearing in the first paragraph of § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable any person skilled in the art to which it pertains, or with which it is most nearly connected,*

246. *See supra* notes 181–82, 193–94 and accompanying text.

247. Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 267 n.79 (1994).

248. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974); *see also* MICHAEL A. GOLLIN, DRIVING INNOVATION 15–19 (2008) (explaining that disclosure adds to the pool of accessible knowledge that other creative individuals can use and improve upon).

249. Dam, *supra* note 247, at 264; *cf.* Rich, *supra* note 244, at 400 ("The literature of the art is enriched, another way of doing something is made known and even if it be inferior to the means already known, there is no telling when it may give another inventor an idea or when someone will improve on it in such a way as to surpass all that is known.").

250. *See* Rich, *supra* note 244, at 400 ("Whenever novel subject matter, unobvious to the workers of ordinary skill in an art, is published, progress in the art is promoted.").

251. It is worth repeating that most information disclosed in a patent is never published elsewhere. *See supra* note 217 and accompanying text.

> *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.[252]

Aside from policing claim scope,[253] the enablement requirement ensures that a PHOSITA can actually practice (make and use)[254] what the applicant discloses at the time of filing[255] without undue experimentation.[256]

Like utility, enablement is a standard.[257] Determining whether a disclosure is enabling is a legal conclusion that rests on underlying factual inquiries.[258] The Federal Circuit set forth several factors relevant to the enablement analysis in *In re Wands*.[259] They are: (1) the amount of direction or guidance presented in the disclosure, (2) the existence of working examples, (3) the nature of the invention, (4) the predictability or unpredictability of the art, (5) the PHOSITA's level of skill, (6) the state of the prior art, (7) the breadth of the claims, and (8) the quantity of experimentation necessary to practice the claimed

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252. 35 U.S.C. § 112(a) (Supp. V 2011) (emphasis added) (formerly § 112, ¶ 1).

253. Claim scope is the "technological territory" that the inventor claims is his or hers to control. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 844 (1990). The enablement provided serves as a constraint on claim scope. O'Reilly v. Morse, 56 U.S. (15 How.) 62, 121 (1854); *see also* Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999) (noting that enablement's purpose is to "ensure[] that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims"). The scope of enablement is the sum of what is taught in the written description of the invention plus what is known by a PHOSITA without undue experimentation. *Id.*

254. The courts often use the term "practice" when referring to the how-to-make and how-to-use prongs of the enablement requirement. *See, e.g.*, *In re* Swartz, 232 F.3d 862, 863 (Fed. Cir. 2000) (per curiam).

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

256. *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). While "undue experimentation" does not appear in the statute, "it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation." *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

257. *See* Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576–77 (Fed. Cir. 1984); MPEP, *supra* note 128, § 2164.01; Seymore, *Heightened Enablement*, *supra* note 48, at 130.

258. Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999–1000 (Fed. Cir. 2008).

259. 858 F.2d at 737.

invention.[260] While not mandatory,[261] the *Wands* factors are ubiquitous in evaluating enablement[262]—probably because they touch on issues that are important in virtually all enablement determinations.[263] These include issues related to the technical scope and substance of the disclosure (factors one and two),[264] the nature of the technology (factors three and four),[265] the PHOSITA's knowledge and skill (factor five),[266] and the scope of the claim sought (factor seven).[267]

For present purposes, the *Wands* factors are useful in three respects. First, they provide the decision maker with a list of objective criteria that help gauge the technical usefulness of the disclosure. Second, they are well suited to handle inventions that are prone to operability challenges—namely, those emerging from new, poorly understood, and paradigm-shifting technologies, as well as those from fields with a poor track record of success. Third, they can be manipulated to set a high disclosure threshold, thereby guaranteeing that the public gets a useful disclosure.

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260. *Id.* (factors reordered from original text).

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

262. *See* 3 CHISUM, *supra* note 68, § 7.03 (collecting cases).

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

264. The technical substance of the disclosure lies at the heart of the enablement analysis. *See supra* note 253 and accompanying text. The two factors are clustered together because working examples are a form of guidance. Seymore, *Teaching Function*, *supra* note 181, at 641–46.

265. One way to determine the requisite amount of teaching is to ask whether the technology is "unpredictable" or "predictable." *See supra* notes 46–48 and accompanying text.

266. This factor has become increasingly important over the past decade as the Federal Circuit has compelled patentees to enable the full scope of the claimed invention. *See, e.g.*, ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 941–42 (Fed. Cir. 2010) (holding that the district court properly determined the PHOSITA's level of skill and did not err in giving less weight to a witness who analyzed an issue using the wrong level of skill); AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (determining that where the claims covered a Type 1 or a Type 2 aluminum coating, yet the patent only described a Type 2 coating, the claims were nonenabled because a PHOSITA could not fill in the gaps without undue experimentation).

267. Enablement places an outer limit on claim scope. Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999).

2. Raising the Standard

a. The Primacy of Working Examples

Clearly, the best way to teach a technical subject is with actual experimental details.[268] Such information lies at the core of technical publications because it provides the best form of guidance and direction for replicating what is disclosed therein.[269] In patent law, actual experimental details or "working examples" (which correspond to the first and second *Wands* factors) provide the best evidence of enablement.[270] When operability is in doubt,[271] they can provide objective proof that the invention really works.[272] And, very importantly, working

268. *See, e.g.*, George Gore, *On Practical Scientific Instruction*, 7 Q.J. SCI. 215, 228 (1870) (asserting that one who teaches a technical subject must teach with examples that should be full of practical applications and familiar illustrations); Seymore, *Teaching Function*, *supra* note 181, at 641–54 (making a similar argument in the patent law context).

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

270. Seymore, *Teaching Function*, *supra* note 181, at 653; *see also* Bratislav Stanković, *The Use of Examples in Patent Applications*, 18 INTELL. PROP. & TECH. L.J. 9, 10 (2006) (noting that in patent documents, the presence of working examples "facilitates, if not ensures, enablement of an invention"). But, as with other forms of enablement, the breadth of the teaching provided in a working example must be commensurate with the claim scope sought. *See* cases cited *supra* note 253. A teaching that lacks specificity or provides inadequate guidance will result in a narrow(ed) claim scope (*Wands* factor eight). DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 115 (2009).

271. *See* Raytheon Co. v. Roper Corp., 724 F.2d 951, 956 (Fed. Cir. 1983) (stating operability is a fact question); *cf.* Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999) (explaining that operability still exists even if the invention does not work perfectly under all conditions).

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

examples are the best way to ensure that the public gets a "[more] readable and substantively useful patent document."[273] For these reasons, some have argued that there should be an across-the-board working-example requirement in patent law,[274] except for inventions in which enablement "is so apparent as to virtually jump off the page and slap [a PHOSITA] in the face."[275]

b. Solving the Manson *Problem*

Recall that the essential utility question for the post-World War II patent system is how to assess utility for chemical and pharmaceutical inventions, particularly those that have no therapeutic or non-research-based use at the time patent protection is sought.[276] In *Brenner v. Manson*, the Supreme Court imposed a heightened utility threshold (the modern utility requirement) to render such compounds unpatentable.[277] At least from a disclosure standpoint, society loses under this regime because it fosters secrecy, delays disclosure, and conceals valuable technical information.[278]

The result would be very different under the proposed enablement-based paradigm. Consider the following hypothetical example loosely based on the underlying facts in *In re Joly*[279]—a sequel to *Manson*.[280] Suppose that in 2008 an inventor at a drug company sought to patent a class of chemical intermedi-

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ical tests, combined with the close structural similarity of the claimed compounds with chemotherapeutics known in the art, would allow a PHOSITA to accept the claimed utility).

273. Seymore, *Teaching Function*, *supra* note 181, at 642.

274. Seymore, *Heightened Enablement*, *supra* note 48, at 156–58; Seymore, *Teaching Function*, *supra* note 181, at 641–54. Professor Cotropia also advocates an actual reduction to practice requirement. *See* Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 120–22 (2009) (proposing a framework wherein the Patent Office would defer examination until the applicant submits evidence of actual implementation of the invention).

275. Seymore, *Heightened Enablement*, *supra* note 48, at 156 n.151 (citing Ash v. Tyson Foods, Inc., 546 U.S. 454, 456–57 (2006) (per curiam)). Invoking a working example requirement probably falls within the Patent Office's statutory authority. *See* Seymore, *Patently Impossible*, *supra* note 23, at 1506 n.82 (discussing the working model requirement of 35 U.S.C. § 114 (2006)); Seymore, *Teaching Function*, *supra* note 181, at 642 n.103 (same).

276. *See supra* Part I.C.1.

277. *See* 383 U.S. 519, 528–36 (1966), discussed *supra* Part I.C.2.

278. *See supra* Part III.A.3.

279. 376 F.2d 906 (C.C.P.A. 1967).

280. *See supra* notes 121–23 and accompanying text.

ates which can be used as building blocks for steroids that are similar in chemical structure to known drugs. The patent application includes a generic claim that, by claiming a core chemical structure with an array of five variables appended to it, encompasses thousands of compounds.[281] As is typical in pharmaceutical cases, the claim is incredibly broad[282]—here because it is possible to substitute each of the five variables appended to the core structure with a variety of organic functional groups.[283] The patent application, however, only sets forth five compounds actually made (working examples). These five compounds are closely related to each other because the same variable (one of the five) is substituted in each.

After construing the claims, assessing the PHOSITA's level of skill, and evaluating the teaching provided in the patent application,[284] the examiner determines that the disclosure only teaches a PHOSITA how to make a narrower subgenus of fifty compounds, not thousands. As support for a prima facie case of nonenablement for the broad genus, the examiner recognizes that:

> [R]eplacing a functional group on a chemical compound can often have highly unpredictable results . . . . [E]ven a change as seemingly trivial as replacing an isopropyl group with the isosteric cyclopropyl group . . . could result in either a significant improvement or reduction in the activity of the compound against a particular biological target.[285]

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

282. Applicants have an incentive "to obtain very broad claims for which a colorable argument can be made for patentability." ANTHONY L. MIELE, PATENT STRATEGY 98 (2001); *see also* BRADLEY C. WRIGHT, DRAFTING PATENTS FOR LITIGATION AND LICENSING 457 (2008) (advising drafters of chemical patent applications to provide adequate support for claims that often cover billions of species).

283. A functional group is a group of atoms within a molecule with specific chemical properties that represents a potential reaction site in a compound, and thus determines a molecule's chemical reactivity. *See generally* RICHARD C. LAROCK, COMPREHENSIVE ORGANIC TRANSFORMATIONS: A GUIDE TO FUNCTIONAL GROUP PREPARATIONS (2d ed. 1999).

284. *See supra* notes 259–60 and accompanying text (discussing the factual inquiries underlying the enablement analysis).

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

The point here is that a PHOSITA cannot extrapolate a result from a few, closely-related embodiments,[286] across a broad genus in an unpredictable field like chemistry, with a reasonable expectation of success.[287]

Consequently, the examiner rejects the broad generic claim as prima facie nonenabled because a PHOSITA would have to engage in undue experimentation to practice its full scope.[288] At this point the burden shifts to the applicant to establish by a preponderance of the evidence that the PHOSITA's knowledge, in combination with the teaching provided in the patent application, can actually enable the full scope of the generic claim.[289] In response, the applicant argues that a well-trained organic chemist would know where to look in the scientific literature to fill in the technical gaps.[290] The examiner determines that the proffered evidence is insufficient to rebut the prima facie case because it is not a "persuasive argument[], supported by suitable [evidence] where necessary, that [a PHOSITA] would be able to make and use the claimed invention using the application as a guide."[291]

At this point, the applicant is unable or unwilling to produce the requisite evidence. Accordingly, the applicant voluntarily cancels the broad generic claim and pursues the narrower subgenus claim covering fifty compounds. The examiner allows that claim and the applicant ultimately gets a *much narrower* patent—covering fifty compounds instead of thousands—than that which would have issued under the current regime.[292]

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286. An "embodiment" is a concrete form of an invention described in a patent application or patent. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY 27 (6th ed. 2013).

287. *See supra* notes 46–48 and accompanying text.

288. *See* Merges & Nelson, *supra* note 253, at 848 (explaining why such a rejection is proper). There is a danger that embodiments not described either cannot be made or may require experimentation which is unduly extensive. PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996).

289. *See In re* Wright, 999 F.2d 1557, 1562 (Fed. Cir. 1993).

290. Applicants often point to the much-cited statement that "a patent need not teach, and preferably omits, what is well known in the art." Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986); *see also supra* note 263. However, that statement "is merely a rule of supplementation, not a substitute for a basic enabling disclosure." Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

291. MPEP, *supra* note 128, § 2164.05 (citation omitted); *see also In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971).

292. Since (1) the current patent laws do not require any actual experimen-

This result is a win-win for the patent system and society. Granting the narrower patent fulfills the quid pro quo because the claim scope obtained is commensurate with the disclosure provided.[293] This limited scope should allay concerns, à la *Manson*, about the patentee creating a "monopoly of knowledge" that could "block off whole areas of scientific development, without compensating benefit to the public."[294] To the contrary, the public would benefit under the proposed regime because in exchange for the patent it would get very useful knowledge—actual experimental details—as opposed to less helpful forms of disclosure.[295]

c. How About Enablement's "How to Use" Requirement?

Enablement requires that the applicant provide a disclosure that teaches a PHOSITA both how to make and how to use the invention.[296] The "use" requirement of § 112, however, differs from the utility requirement of § 101. Whereas the latter is often a subjective value judgment,[297] it has been clear from the early days of the patent system that the purpose of the § 112 use requirement is simply to provide the PHOSITA with a meaningful disclosure.[298] To make this point in *In re Nelson*,[299] Judge Rich quoted an eighteenth-century patent treatise explaining the enablement requirement:

> [I]t is necessary . . . that the invention shall so be described in the specification, that [a PHOSITA] may not only understand the invention, but be able, by following the directions given in the specification, with the assistance of the drawings, to construct the machine or perform the process which is the subject of the patent.[300]

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tation in order to obtain a patent, and (2) the Patent Office does not have its own testing facilities, applicants in the unpredictable arts are often very successful in obtaining broad claims with dubious enablement. *See* Seymore, *Heightened Enablement*, *supra* note 48, at 143–54; Seymore, *Teaching Function*, *supra* note 181, at 628–32.

293. *See supra* note 253 and accompanying text.

294. Brenner v. Manson, 383 U.S. 519, 534 (1966) (discussed *supra* Part I.C.2).

295. Seymore, *Teaching Function*, *supra* note 181, at 634–35.

296. *See* 35 U.S.C. § 112(a) (Supp. V 2011).

297. *See* Seymore, *Patently Impossible*, *supra* note 23, at 1514.

298. *See, e.g.*, John W. Klooster, *Historical Developments of Contemporary Scope, Impact of Section 112 upon Patent Practice*, 6 APLA Q.J. 171, 172 (1978).

299. 280 F.2d 172 (C.C.P.A. 1960), *overruled by In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967).

300. WILLARD PHILLIPS, THE LAW OF PATENTS FOR INVENTIONS 233–34 (1837), *quoted in Nelson*, 280 F.2d at 181.

Thus, § 112 is satisfied if the inventor describes how to use the invention as broadly as it is claimed. The proposed working example requirement would do just that.

But this does not mean that the how-to-use requirement of § 112(a) should be used as a proxy for the § 101 utility requirement. It is true that under the current regime, an invention which lacks utility under § 101 fails to satisfy the how-to-use prong of the enablement requirement of § 112(a) as a matter of law.[301] This makes sense when the § 101 problem is inoperability, because if the invention cannot operate to achieve the intended result, then it is impossible to enable a PHOSITA to use it.[302] On the other hand, it is possible to enable an invention yet fall short of the current utility threshold. The best example is the factual scenario presented in *Brenner v. Manson*.[303] To be sure, Manson provided an enabling disclosure, which taught a PHOSITA how to both make the compound *and* how to use it to make other compounds.[304]

This last point reveals the paradoxical nature of the modern utility requirement as it relates to disclosure. An applicant can assuredly disclose an invention which enables a PHOSITA to make and use the invention (like a chemical compound), but can nevertheless fail to meet the § 101 utility threshold because the subject matter is deemed to be a "mere research proposal" or "simply an object of research."[305] Yet again, this shows that utility has little to do with the invention's ability to provide a cognizable benefit to society.

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

302. *See In re* Swartz, 232 F.3d 862, 863 (Fed. Cir. 2000) (per curiam) (citing Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1358 (Fed. Cir. 1999) ("If a patent claim fails to meet the utility requirement because it is [inoperative], then it also fails to meet the how-to-use aspect of the enablement requirement.")).

303. *See* 383 U.S. 519, 520–22 (1965).

304. *See In re* Manson, 333 F.2d 234, 238–39 (C.C.P.A. 1964), *rev'd*, *Manson*, 383 U.S. 519.

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

3. Eliminating Operability

a. The Basic Proposition

The operability prong of the § 101 utility requirement *attempts* to answer the objective, technical question of whether an invention can actually achieve its intended result.[306] Unfortunately, the question is often framed in subjective terms, such as whether a PHOSITA would believe the truth of the inventor's assertions.[307] Indeed, history reveals that the operability inquiry often devolves into a biased judgment about the subject matter irrespective of technical substance.[308] Inventions emerging from new, poorly understood, and paradigm-shifting technologies, as well as those from fields with a poor track record of success, are the most vulnerable. For example, patents for treating cancer and baldness continued to be denied under § 101 for a lack of utility even after the scientific community recognized that these diseases could be successfully treated.[309] This outcome should be unsettling, because "the very purpose of the patent system is to encourage [the] attainment of previously unachievable results,"[310] and because it frustrates the patent system's broader mission to extend the frontiers of knowledge.[311]

To the extent that the justification for operability is to serve a gatekeeping function, it is an unnecessary requirement. The proposition is that a robust enablement analysis can effectively ferret out unworkable inventions *by itself*, with no need for, or help from, its § 101 statutory cousin. Clearly an inventor with an inoperable invention cannot furnish an enabling disclosure.[312] Enablement can perform the important gatekeeping role through an objective, technical analysis rather than through subjective credibility assessments that lie at the heart of the operability paradigm.

306. *See supra* note 41 and cases cited therein. Whether an invention is operable is a question of fact. Raytheon Co. v. Roper Corp., 724 F.2d 951, 956 (Fed. Cir. 1983).

307. *See supra* note 125 and accompanying text.

308. Seymore, *Patently Impossible*, *supra* note 23, at 1511–23.

309. *See id.* at 1514–22.

310. *In re* Ferens, 417 F.2d 1072, 1074 (C.C.P.A. 1969).

311. *See* Rich, *supra* note 244, at 400.

312. *See In re* Swartz, 232 F.3d 862, 863 (Fed. Cir. 2000) (per curiam).

b. Mechanics

To see how the proposed enablement-based approach would work, consider the following hypothetical—based on an actual patent case.[313] Suppose that an inventor files a patent application claiming a method of using heat to transform antimony into gold.[314] (This claim sounds like alchemy—the transmutation of a cheap element into a precious one in a nonradioactive process.)[315] The application discloses a working example, including the amount of starting material (antimony) used, reaction conditions and temperatures, and the amount of product (gold) isolated.[316]

An examiner with expertise in the field reads the application and checks it for compliance with the statutory patentability requirements.[317] Focusing on enablement, the patent application is presumptively enabled as filed.[318] To establish a prima facie case of nonenablement,[319] the examiner bears the initial

313. On May 7, 1897, Edward C. Brice filed a patent application claiming a process for making gold from other elements. *See* H. Carrington Bolton, *Recent Progress of Alchemy in America*, 76 CHEMICAL NEWS 61, 62–63 (1897) (describing the claimed method); Adolf G. Vogeler, *A Nineteenth Century Gold Factory*, 60 PHARMACEUTICAL J. 189, 189–91 (1898) (presenting additional experimental details).

314. Antimony is a chemical element typically obtained from complex mineral ores containing lead, tin, zinc, silver, and gold. I.J. Polmear, *Metallurgy of the Elements*, *in* CHEMISTRY OF ARSENIC, ANTIMONY AND BISMUTH 43 (N.C. Norman ed., 1998). In the actual case, the inventor chose antimony because it is found in gold ores. *Chicago Alchemist Thinks by Following in Nature's Pathway to Make Gold of Dross*, CHI. TRIB., Dec. 12, 1897, at 33.

315. *See* 1 J.W. MELLOR, A COMPREHENSIVE TREATISE ON INORGANIC AND THEORETICAL CHEMISTRY 44–55 (1922) (exploring the history of alchemy). Brice thought that heat could accomplish the task because some researchers believed "that at some long ago period . . . tremendous convulsions of subterranean gases threw up from the bowls [sic] of the earth some metallic substance which underwent a transformation into gold." *Chicago Alchemist Thinks by Following in Nature's Pathway to Make Gold of Dross*, *supra* note 314.

316. Brice built a gold-making factory in Chicago that processed over 10,000 pounds of crude ore per day. *See* Vogeler, *supra* note 313, at 189–90 (describing the daily operation of the National Metallurgical Company).

317. Recall that under the current patent statute an invention must be useful (§ 101), novel (§ 102), nonobvious (§ 103), and directed to patentable subject matter (§ 101). 35 U.S.C. §§ 101–03 (2006 & Supp. V 2011). In addition, § 112(a) requires that the application adequately disclose the invention, and § 112(b) requires that the application conclude with claims which delineate the invention with particularity. 35 U.S.C. § 112(a)–(b) (Supp. V 2011).

318. *In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971).

319. An examiner must prove unpatentability by a preponderance of the evidence. *See In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (articulating

burden of setting forth a reasonable explanation as to why the enablement provided by the applicant is not commensurate with the claim scope sought.[320] The examiner must explain any doubts as to the accuracy of any statement with evidence or reasoning rooted in fact.[321]

The examiner undertakes a *Wands* analysis by construing the claim (factor seven),[322] determining the PHOSITA's knowledge and level of skill (factor five),[323] and evaluating the teaching provided in the written description (factors one and two)[324] in light of the nature of the technology (factors three and four).[325] Almost immediately, the examiner recognizes that information pertaining to the source and purity of the antimony is conspicuously absent from the disclosure. Researchers in the field include this information as a matter of course, because impurities in starting materials can lead to irreproducible or spurious results.[326] To bolster this reasoning, the examiner consults the "antimony" entry in a chemical encyclopedia. It reveals that "[m]ost of the antimony produced in the United States is from complex antimony deposits found in Idaho, Nevada, Alaska, and Montana . . . . These deposits consist of [minerals containing] silver or *gold*."[327] Based on the totality of

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the burden-shifting framework used in patent examination).

320. *In re* Wright, 999 F.2d 1557, 1561–62 (Fed. Cir. 1993).

321. *Marzocchi*, 439 F.2d at 224; *see also In re* Brebner, 455 F.2d 1402, 1405 (C.C.P.A. 1972) (holding that the Patent Office must provide a factual basis for a lack of enablement rejection, rather than conclusory statements regarding the PHOSITA's level of skill).

322. *See* MPEP, *supra* note 128, § 2164.04 (instructing an examiner who suspects that one or more claims lack enablement to first construe them to determine their scope); *see also* AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1241 (Fed. Cir. 2003) ("Because a patent specification must enable the full scope of the claimed invention, the enablement inquiry typically begins with a construction of the claims." (citations omitted)).

323. *See supra* note 266.

324. *See supra* note 264.

325. *See supra* note 265.

326. *See* MAXINE LINTERN, LABORATORY SKILLS FOR SCIENCE AND MEDICINE 64–65 (2007) (explaining that the methods section should contain information including the commercial supplier from which materials were purchased so that a competent researcher can read the recipe and repeat exactly what was done). Laboratory chemicals vary widely in degrees of purity. *See, e.g.*, CHEMICAL TECHNICIANS' READY REFERENCE HANDBOOK 549 (Gershon J. Shugar & Jack T. Ballinger eds., 3d ed. 1990) (listing grades of purity).

327. 3 KIRK-OTHMER ENCYCLOPEDIA OF CHEMICAL TECHNOLOGY 42 (Arza Seidel ed., 5th ed. 2004) (emphasis added); *see also supra* note 314.

the evidence,[328] the examiner rejects the claim as prima facie nonenabled under § 112(a) because a PHOSITA faced with the inadequate guidance vis-à-vis the source and purity of the antimony would have to engage in undue experimentation to achieve the intended result.[329]

Next, the examiner sends the rejection to the applicant accompanied with a request for information regarding the source and purity of the antimony.[330] The applicant responds by disclosing that the antimony is technical grade (lowest purity) obtained from Acme Metals Company in Yellow Pine, Idaho.[331] Further research reveals that Yellow Pine has one of the largest gold-antimony deposits in the nation[332] and that Acme's technical grade antimony contains ten percent gold by weight. The examiner performs a calculation revealing that the amount of gold reported in the applicant's working example is less than the amount of gold known to be present in the antimony starting material. These facts lead the examiner to conclude that the applicant did not transform antimony into gold but merely recovered a fraction of the gold already present in the starting material.[333] When presented with this information, the applicant decides to abandon the application.[334]

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328. *See* MPEP, *supra* note 128, § 2164.01(a) (citing *In re* Wands, 858 F.2d 731, 740 (Fed. Cir. 1988)) (reminding examiners that "any conclusion of nonenablement must be based on the evidence as a whole").

329. *See supra* note 256 and accompanying text.

330. During the course of patent examination, the examiner may request "[t]echnical information known to [the] applicant concerning . . . the disclosure, the claimed subject matter, other factual information pertinent to patentability, or concerning the accuracy of the examiner's stated interpretation of such items." 37 C.F.R. § 1.105(a)(1)(viii) (2013).

331. Technical grade, the lowest chemical grade, "is used industrially, but is generally unsuitable for laboratory [use] because of the presence of many impurities." CHEMICAL TECHNICIANS' READY REFERENCE HANDBOOK, *supra* note 326, at 549.

332. *See, e.g.*, Junius Larsen & William C. Peters, *Idaho*, 45 INDUS. & ENG'G CHEMISTRY 2424, 2424–31 (1953) (describing the deposits).

333. The story in the actual case is quite interesting. After receiving two inoperability rejections, Brice asked the Patent Office for permission to demonstrate the claimed process. *See* Bolton, *supra* note 313, at 62. Since the Patent Office lacked laboratory facilities, the Secretary of the Treasury allowed Brice to use the spacious facilities at the U.S. Mint. *Id.* The Director of the Mint bought the requisite materials from reputable dealers and directed three experts to carry out the claimed process. *Id.* After conducting replicate experiments, the experts reported that the claimed process failed to recover the entire amount of gold known to be present in the starting material, leading them to conclude that there was "not the slightest evidence of any 'creation' or transmutation." *Id.* at 62–64 (reproducing the Report from Andrew Mason et al., U.S. Assay Office, to the Hon. R.E. Preston, Director of the Mint

The foregoing hypothetical illustrates two important points. First, it shows that a robust *Wands* analysis can ferret out a truly unworkable invention. Though alchemistic claims often conjure up notions of fraud,[335] the examiner did not need to venture down the credibility path because requesting more detail about the working example revealed the applicant's error. Second, it shows that many inoperability problems can be traced to faulty experimental technique.[336] In patent law, as in other contexts, a careful examination of the disclosure can readily reveal whether an intended result stems from sloppy research.

c. Plausibility

There is some decisional law that supports the proposition that if the case for nonenablement is very strong, that is a sufficient basis to deny patentability, notwithstanding deficiencies under § 101. In one case, *In re Speas*, the applicant sought to claim

> *any and all* devices and systems which operate in such a manner as to violate the [S]econd [L]aw of [T]hermodynamics as it is currently understood and accepted as inviolable by a majority of the worldwide scientific community, and *any and all* devices and systems which are adapted for converting thermal energy into other energy forms by contacting a heat source without the necessity of also contacting a thermal medium of lower temperature.[337]

Two things stand out. First, the "any and all" claim language immediately raises enablement concerns due to its po-

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(May 22, 1897)). As to the final disposition, Brice argued that the Patent Office rejected his application out of fear of a "monetary panic." Vogeler, *supra* note 313, at 189.

334. Of course, the applicant could try to salvage something and seek a patent claiming a method of separating gold from antimony. However, that claim would be subject to novelty, nonobviousness, and other patentability hurdles. *See supra* note 317.

335. *See* WILLIAM R. NEWMAN & LAWRENCE M. PRINCIPE, ALCHEMY TRIED IN THE FIRE 12 (2005) (discussing the divergence of chemistry and alchemy by the eighteenth century, when alchemy was repudiated as "simply fraudulent"); *see also* HERBERT S. REDGROVE, BYGONE BELIEFS 123–24 (1920) (contrasting "genuine" alchemists of ancient times with those who entered the quest in modern times).

336. Experimental researchers must work under "carefully contrived circumstances where all other potential disturbing factors are eliminated" so that "the explanation for an observed 'effect' [is] something more interesting than, say, an impure chemical reagent." JOHN ZIMAN, REAL SCIENCE 94 (2000).

337. 273 F. App'x 945, 946 (Fed. Cir. 2008) (per curiam) (emphasis added) (internal quotation marks omitted) (quoting from Speas's patent application).

tentially limitless breadth.[338] Second, any device that could continuously convert heat completely to work without any additional energy input would violate the Second Law of Thermodynamics.[339] Though not mentioned in the record or in the Federal Circuit opinion, the claimed device is a perpetual motion machine.[340] But a closer look at the applicant's description of the invention reveals that the disclosed device does *not* violate the Second Law of Thermodynamics because it actually draws in thermal energy from the surroundings.[341]

The examiner rejected the claim independently under § 112 ¶ 1 and § 101, respectively, after determining that: (1) the enablement provided was not commensurate with the claim scope sought; and (2) the invention could not achieve the intended result.[342] The Board explicitly affirmed each rejection.[343] Although the Patent Office argued both issues in its appellate brief to the Federal Circuit, it contended that the court could resolve the case *solely on enablement grounds* with no need to reach the § 101 issue.[344] This argument makes sense, because if

338. *See, e.g.*, *In re* Wright, 999 F.2d 1557, 1561–62 (Fed. Cir. 1993) (holding that the applicant failed to enable a claim covering "*any and all* live, nonpathogenic vaccines, and processes for making such vaccines").

339. The Second Law of Thermodynamics states that it is impossible to convert heat completely to work without some energy loss. R.K. RAJPUT, ENGINEERING THERMODYNAMICS 232–33 (3d ed. 2010).

340. A perpetual motion machine can run forever without any input of external power, meaning that it can do work without consuming energy. The oft-cited technical objection is that perpetual motion violates the Second Law of Thermodynamics, which holds that a machine cannot be 100 percent efficient because it can only use a fraction of the energy it receives for work and must lose a significant portion to the environment as heat, usually through friction. *See* Dimitris Tsaousis, *Perpetual Motion Machine*, 1 J. ENG'G SCI. & TECH. REV. 53, 53–57 (2008); *supra* note 339. When recognized, perpetual motion machines raise red flags at the Patent Office and in the courts. *See* MPEP, *supra* note 128, § 608.03 (permitting an examiner to request a working model when the applicant claims a perpetual motion machine).

341. *See Speas*, 273 F. App'x at 946 ("Thus, the movement of the ferrofluid imparts mechanical energy upon the wheel. Speas claims that because this ferrofluid is moved and adds energy to the paddle wheel 'without input into the system other than ambient thermal energy,' it is proof that the second law of thermodynamics is not inviolate—an object of the invention.").

342. *Id.*; *see also* Brief for Appellee Director of the U.S. Patent and Trademark Office at 7–8, *In re* Speas, 273 F. App'x 945 (Fed. Cir. 2008) (No. 2008-1076) [hereinafter Brief for Appellee].

343. Brief for Appellee, *supra* note 342, at 9–10.

344. *Id.* at 18. For support for this reasoning, see Raytheon Co. v. Roper Corp., 724 F.2d 951, 956 (Fed. Cir. 1983) ("[W]hen a claim requires a means for accomplishing an unattainable result, the claimed invention must be con-

the device did not violate the Second Law of Thermodynamics, the applicant's disclosure would not be enabling.

The Federal Circuit adopted this reasoning and affirmed on nonenablement grounds. The court held that the Board's rejection was supported by substantial evidence[345] because the applicant's "particularly broad" and "limitless" claim was not enabled by a description which was commensurately broad in its teaching.[346] The important point is that it was possible to screen out this invention solely based on (a lack of) technical merit, thereby avoiding any need to engage in a § 101 analysis.[347]

Both *Speas* and the alchemy hypothetical show that whether an invention can achieve the intended result is a yes-or-no question. If the answer is no, then enablement alone can resolve the issue, because there is no way that the applicant can provide an enabling description for something that does not work.[348] In other words, a careful examination of the proffered working example(s) will reveal the fatal flaw.[349] This enablement-based approach avoids the pitfalls of the current utility paradigm, streamlines patent examination,[350] and prevents the

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sidered inoperative as claimed and the claim must be held invalid under either § 101 *or* § 112 of 35 U.S.C." (emphasis added)).

345. For appeals from the Patent Office, the Federal Circuit reviews legal conclusions de novo and factual findings for substantial evidence. *In re* Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000). Thus, the Board's findings of fact underlying the enablement determination are reviewed for substantial evidence, while the legal conclusion of enablement is reviewed de novo. *In re* Swartz, 232 F.3d 862, 863 (Fed. Cir. 2000) (per curiam).

346. *Speas*, 273 F. App'x at 946.

347. In his commentary on *Speas*, Professor Crouch reached a similar conclusion: "Although this type of case is fun to read, it also provides an interesting lesson—that [there are] tools to reject inadequate patent applications on their merits without resorting to broad exclusions of particular subject matter." Dennis Crouch, *CAFC Rejects Patent on Invention to Overcome the Second Law of Thermodynamics*, PATENTLY-O (May 1, 2008), http://www.patentlyo.com/patent/2008/05/cafc-rejects-pa.html.

348. *Cf. Raytheon*, 724 F.2d at 956 ("[B]ecause the impossible cannot be enabled, a claim containing a limitation impossible to meet may be held invalid under § 112.").

349. *Cf.* ROBERT L. PARK, VOODOO SCIENCE 9 (2002) ("Error is a normal part of science, and uncovering flaws in scientific observations or reasoning is the everyday work of scientists."); JOHN WALLER, FABULOUS SCIENCE 40 (2004) (noting that an experimental result can be "so aberrant that error seems the most reasonable explanation").

350. This is because the examiner would no longer need to expend the time and effort formulating and building a record to support multiple rejections for a single issue. *See* discussion *supra* Part III.C.3 (explaining how when opera-

public from granting a patent in exchange for a useless disclosure.

D. THE ROLE OF NONOBVIOUSNESS

A robust enablement analysis would ensure that the public gets a useful disclosure in exchange for the patent grant. Since the breadth of the disclosure would tightly limit the scope of the patent, concerns about creating unjustifiable roadblocks for future innovators would diminish. But even if enablement is satisfied, a fact-intensive evaluation of the invention's *technical merit* might suggest that a patent should not issue at all, because the potential benefit that society might derive from the invention and its disclosure do not justify the costs of granting a patent.[351] This is because the claimed invention does not differ substantially from what is already known. In such a situation, the proper tool to screen patentability is *nonobviousness*, not utility.

1. Understanding Nonobviousness

The statutory requirement for nonobviousness, embodied in § 103 of the Patent Act,[352] helps fulfill the patent system's broad policy goals of promoting technological progress,[353] coordinating the future development of technology,[354] and spurring innovation.[355] By reserving the quid pro quo of patent rights for inventions that represent a significant step forward in the field, the nonobviousness requirement ensures that patents are only awarded for those inventions (though new and enabling)[356]

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bility and enablement are both at issue, the issue can be reduced solely to enablement).

351. Abramowicz & Duffy, *supra* note 241, at 1594; *cf.* Gregory Mandel, *The Non-Obvious Problem: How the Indeterminate Nonobviousness Standard Produces Excessive Patent Grants*, 42 U.C. DAVIS L. REV. 57, 62 (2008) ("The nonobviousness requirement protects society against the social costs both of denying a deserving patent and of granting an undeserving monopoly.").

352. The statute provides in relevant part:

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

35 U.S.C. § 103 (Supp. V 2011).

353. *See supra* note 171 and accompanying text.

354. *See* Kitch, *supra* note 118, at 266.

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

356. *See* 1 CHISUM, *supra* note 68, § 3.01 (noting that nonobviousness asks

whose disclosures will actually *add* to the storehouse of useful knowledge.[357] Among other things, this induces inventors to explore more challenging, socially preferred projects rather than pursue trivial extensions of what is already known.[358] As Professor Mark Lemley puts it, nonobviousness "sets a minimum threshold social value the invention must contribute in order to make it worth the trouble of issuing and enforcing a patent."[359]

Like enablement, nonobviousness is a standard. It requires a comparison of the invention that the applicant seeks to patent with the "prior art," which refers to preexisting knowledge and technology already available to the public.[360] In *Graham v. John Deere Co.*, the Supreme Court articulated the basic framework for determining nonobviousness.[361] It is a question of law based on the following pertinent underlying facts: (1) the scope and content of the relevant prior art, (2) the differences between the prior art and the claimed invention, (3) the PHOSITA's level of skill, and (4) secondary considerations that

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

357. Graham v. John Deere Co., 383 U.S. 1, 6 (1966) ("Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system . . . ."); Atl. Works v. Brady, 107 U.S. 192, 200 (1883) ("The design of the patent laws is to reward those who make some substantial discovery or invention, which adds to our knowledge . . . . It was never the object of those laws to grant a monopoly for every trifling device . . . ."); Kitch, *supra* note 118, at 283 (arguing that patents should not be granted for the use and development of known technical information because "proper incentives for its acquisition and use exist without a property right").

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

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

360. *See* 35 U.S.C. § 102 (Supp. V 2011) (defining the documents and activities that can serve as prior art); Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453–54 (Fed. Cir. 1984) (citing *Graham*, 383 U.S. at 6).

361. *See* 383 U.S. at 17.

provide objective proof of nonobviousness, like the fact that the invention fulfilled a long-felt but unsolved need.[362]

Thus, inventions that are sufficiently close to the prior art and within the PHOSITA's technical grasp at the time the claimed invention is made are unpatentable.[363] This essentially "creates a 'patent-free' zone around the state of the art,"[364] allowing the PHOSITA to substitute materials, streamline processes, and "[make] the usual marginal improvements which occur as a technology matures."[365]

2. Nonobviousness: The Proper Gatekeeper

The idea that nonobviousness is a more appropriate tool for evaluating technical merit than utility finds support in one of the Federal Circuit's most powerful dissenting opinions, *In re Fisher*.[366] The issue before the court was the utility of short DNA sequences known as expressed sequence tags (ESTs).[367] Though the applicant asserted seven uses for the claimed ESTs, the examiner made a § 101 rejection because: (1) the disclosed uses were applicable to all ESTs and not specific to the those claimed, and (2) there was no known use for the proteins produced from the claimed ESTs.[368] Citing *Brenner v. Manson*, the majority affirmed the rejection because the claimed ESTs were merely research tools that lacked specific and substantial utility.[369] In dissent, Judge Rader argued that ESTs—like microscopes, screening assays, and nucleotide sequencing techniques—are research tools that provide a "cognizable benefit to

362. *Id.* at 17–18. Subsequent case law has established that a conclusion of obviousness must be supported by clearly articulated reasoning. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007) (explaining that in addition to the *Graham* factors, "[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" (quoting *In re* Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006))); *see also* MPEP, *supra* note 128, § 2141(III) (listing rationales that examiners can use to support a conclusion of obviousness).

363. *See* 35 U.S.C. § 103 (Supp. V 2011); CRAIG ALLEN NARD, THE LAW OF PATENTS 305 (2d ed. 2010).

364. MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 288 (3d ed. 2009); *see also* Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1978) ("[T]he stringent requirements for patent protection . . . assure that ideas in the public domain remain there for the free use of the public.").

365. ADELMAN ET AL., *supra* note 364, at 288.

366. *In re* Fisher, 421 F.3d 1365 (Fed. Cir. 2005).

367. *Id.* at 1367, 1369.

368. *Id.* at 1367–68.

369. *Id.* at 1369–76.

society."[370] But what is most important for present purposes is that he argued that the utility rejection was improper:

> In truth, I have some sympathy with the Patent Office's dilemma. [It] needs some tool to reject inventions that may advance the "useful arts" but not sufficiently to warrant the valuable exclusive right of a patent. The Patent Office has seized upon this utility requirement to reject these research tools as contributing "insubstantially" to the advance of the useful arts. The utility requirement is ill suited to that task, however, because it lacks any standard for assessing the state of the prior art and the contributions of the claimed advance. The proper tool for assessing sufficient contribution to the useful arts is the [non]obviousness requirement of 35 U.S.C. § 103. . . . [R]ather than distort the utility test, the Patent Office should seek ways to apply the correct test, the test used world wide for such assessments (other than in the United States), namely inventive step or obviousness.[371]

As Professor Mark Janis recently noted, "Judge Rader's *Fisher* dissent is a powerful reminder of our longstanding commitment to *obviousness* as the ultimate condition of patentability."[372]

To illustrate how nonobviousness would screen inventions in the new paradigm, consider again the hypothetical discussed above involving a new class of chemical intermediates.[373] Suppose the applicant has responded to the aforementioned nonenablement rejection by narrowing the scope of the claims to a subgenus of fifty compounds instead of the genus of thousands originally sought.[374] When the examiner compares the subgenus to the prior art,[375] the search reveals that the claimed compounds are novel but very similar to those disclosed in a 1998 book entitled *Chemical Intermediates for Pharmaceuticals*. In fact, the claimed compounds and those described in the book are all members of the same chemical family ("homologs"),[376] the only difference being that a "methyl" group (one

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

371. *Id.* at 1381–82.

372. Mark D. Janis, *Tuning the Obviousness Inquiry After* KSR, 7 WASH. J.L. TECH. & ARTS 335, 340 (2012) (emphasis added); *cf.* NONOBVIOUSNESS—THE ULTIMATE CONDITION OF PATENTABILITY (John F. Witherspoon ed., 1980) (compiling papers celebrating the twenty-fifth anniversary of codification of the nonobviousness doctrine as § 103); Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CALIF. L. REV. 803, 812 (1988) (describing nonobviousness as the "final gatekeeper of the patent system"); John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771, 789 (2003) (describing nonobviousness as "[t]he fundamental gatekeeper to patenting").

373. *See supra* Part III.C.2.b.

374. *See supra* Part III.C.2.b.

375. *See supra* text accompanying note 360.

376. "Homologs" refer to a family of chemical compounds that vary from

carbon) on the core structure of the prior art compounds has been replaced with an "ethyl" group (two carbons) on the core structure of the claimed compounds.[377] Predictably, given the minimal variation in structure, the claimed compounds are prepared by the same methods, have similar physical properties, and undergo the very same chemical reactions (albeit slightly faster) as the prior art compounds.[378]

After making the factual findings set forth by the Supreme Court in *Graham*,[379] the examiner concludes that it would have been obvious for a PHOSITA at the time of the invention to make the claimed compounds. The examiner supports this conclusion with two rationales. First, the claimed compounds are a "straightforward one-carbon extension"[380] of a carbon chain—a standard structural modification in organic chemistry.[381] They represent "[a] simple substitution of one known [chemical functionality] for another to obtain predictable results."[382] Accordingly, a PHOSITA would have had a reasonable expectation of success in independently arriving at the claimed invention.[383] Second and relatedly, *Chemical Intermediates for Pharmaceuticals* and knowledge in the art "would have suggested making

member to member by a methylene (—CH_2—) group. *In re* Wilder, 563 F.2d 457, 458 n.7 (C.C.P.A. 1977); *cf. In re* Coes, 173 F.2d 1012, 1013–14 (C.C.P.A. 1949) ("A homologous series may therefore be defined as a family of chemically related compounds, the composition of which varies from member to member by one atom of carbon and two atoms of hydrogen." (quoting JULIUS B. COHEN, THEORETICAL ORGANIC CHEMISTRY 51 (3d ed. 1934))).

377. A methyl group (Me or CH_3—) is the simplest carbon-containing functional group in organic chemistry. THOMAS N. SORRELL, ORGANIC CHEMISTRY 20 (2d ed. 2006). An ethyl group (Et or CH_3—CH_2—) is the next simplest. *Id.*

378. *See* COHEN, *supra* note 376, at 50 (noting that homologs undergo similar chemical reactions); *id.* at 51 ("The advantage of [homology] will now be obvious, for it will only be necessary to describe the chemical characteristics of one member, when that of the whole series of homologues may be inferred.").

379. *See supra* text accompanying note 362.

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

381. *See id.*

382. MPEP, *supra* note 128, § 2143(B); *cf.* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 416 (2007) ("[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.").

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

the specific molecular modifications necessary to achieve the claimed invention"[384] because in this area of chemistry, ethyl derivatives are known and expected to react slightly faster than the methyl derivatives.[385] Thus, this is a situation where a prior art compound "suggest[s] its homolog . . . because such compounds often have similar properties[,] and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."[386]

Having made a prima facie case of obviousness, "the burden of going forward shifts to the applicant."[387] The applicant attempts to rebut the prima facie case by arguing that the claimed compounds show an unexpected property over the prior art;[388] namely, that they react faster than a PHOSITA would expect.[389] In response, the examiner explains why the record supports the opposite conclusion:

> The evidence as a whole[390] gives rise to a presumption that homologs that are structurally very close ("adjacent homologs")[391] will have

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

385. *See, e.g.*, SORRELL, *supra* note 377, at 148–49 (illustrating how the variation in reactivity of homologous compounds can be attributed to "inductive effects"—the differing ability of methyl and ethyl groups to release electrons); Paul von Ragué Schleyer & Curtis W. Woodworth, *Substituents and Bridgehead Carbonium Ion Reactivities. Inductive and Steric Effects of Alkyl Groups in Saturated Systems*, 90 J. AM. CHEMICAL SOC'Y 6528, 6528–30 (1968) (exploring the increased rate of reactivity across a homologous series).

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

387. *See In re* Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (interpreting *Graham* to require the Patent Office to provide a factual basis for a § 103 rejection as a part of the prima facie case).

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

389. *Cf. supra* text accompanying note 378 (pointing out that the claimed compounds would react slightly faster, although predictably so).

390. In considering rebuttal evidence, "[t]he ultimate determination of patentability must be based on consideration of the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence." MPEP, *supra* note 128, § 716.01(d) (citing *In re* Oetiker, 977 F.2d 1443 (Fed. Cir. 1992)).

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

> similar properties.[392] Of course, since the prior art compounds and the claimed compounds are not identical, *some* differences in properties are expected to result.[393] That the claimed compounds react two to three times faster than the prior art compounds, however, is expected because the properties of homologs show regularities of increase (or decrease) across a series.[394] The totality of the evidence shows that the replacement of a methyl with an ethyl was within the capabilities of the PHOSITA, and that the slight increase in reactivity did not "produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art."[395] Thus, the presumed expectation stands unrebutted.

Lacking any additional evidence, the applicant decides to abandon the application.

That the patent is ultimately derailed in this scenario is good for the patent system and very much in line with the goals of the proposal. Even if an invention is new and supported by an enabling disclosure, *Graham* teaches that it "may still not be patentable if the difference between the new thing and what was known before is not considered sufficiently great to warrant a patent."[396] Making a class of homologs that are virtually identical to the prior art in every respect is a routine endeavor and a mere trivial modification to what is already known. This means that the inventor could *not* provide a useful disclosure to society, because information about the homologs would add nothing to the public storehouse of knowledge.[397] At the time of the invention, the homologs were well within the PHOSITA's skill and technical grasp and would have arisen through ordinary technological progress. Indeed, organic chemists contemplate homologs all the time when constructing compounds with desired properties.[398]

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392. *See id.* at 460–61.

393. MPEP, *supra* note 128, § 716.02.

394. *See* GEORGE FOWNES, FOWNES' MANUAL OF CHEMISTRY 395 (Robert Bridges ed., 1857); *see also* W. H. PERKIN & F. STANLEY KIPPING, ORGANIC CHEMISTRY 67–68 (1900).

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

396. Graham v. John Deere Co., 383 U.S. 1, 14 (1966).

397. *Cf.* Miller, *supra* note 356, at 2 ("It is socially wasteful for us to pay a patent-backed premium for an innovation that we are almost certain to receive for free and just as early." (footnote omitted)).

398. *See supra* note 386 and accompanying text.

This hypothetical reveals that nonobviousness ultimately performs three interrelated gatekeeping roles in the proposed paradigm. First, it protects (the integrity of) the public storehouse of useful knowledge.[399] Second, it maintains a "patent-free zone" around the prior art which allows researchers to tinker.[400] Third, it "weed[s] out those inventions [that] would not be disclosed or devised but for the inducement of a patent."[401]

E. POLICY TRADEOFFS

1. On Patent Reform

The impetus for patent reform has been driven in large part by a belief that "too many patents are granted on too many inventions."[402] Various commentators contend that the ease with which patents can be obtained has led to the well-publicized backlog in the Patent Office[403] and the issuance of patents of questionable quality.[404] One oft-cited cause of these problems is low substantive standards of patentability.[405] This

399. *See supra* note 357 and accompanying text.

400. *See supra* notes 364–65 and accompanying text.

401. *Graham*, 383 U.S. at 11.

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

403. *See, e.g.*, Edward Wyatt, *U.S. Sets 21st-Century Goal: Building a Better Patent Office*, N.Y. TIMES, Feb. 21, 2011, at A1 (providing backlog statistics and attributing the recent surge in applications to the Internet age). One cause for the backlog is an increase in the number of patent application filings over time while the time available for examiners to review applications has remained constant. *See* John L. King, *Patent Examination Procedures and Patent Quality*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 54, 63 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (presenting an empirical study).

404. *See, e.g.*, ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS 74 (2004) (describing what can happen when the Patent Office "falls down on the job"); Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 181, 181–82 (2008) (exploring criticisms). Quality can be defined as "the capacity of a granted patent to meet (or exceed) the statutory standards of patentability—most importantly, to [cover inventions that are] novel, nonobvious, and clearly and sufficiently described." R. Polk Wagner, *Understanding Patent-Quality Mechanisms*, 157 U. PA. L. REV. 2135, 2138 (2009). From an economic perspective, a high-quality patent is "one that covers an invention that would not otherwise be made [but for the incentive of a patent] or one that ensures that a good idea is commercialized." 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, 991 (2004).

405. *See, e.g.*, JAFFE & LERNER, *supra* note 404, at 11 (noting that weak novelty and nonobviousness standards have led to patents of dubious quality); Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for*

criticism deserves attention, because adjusting these standards is considered the principal tool for modulating the scope, frequency, and quality of patents.[406] Indeed, tightening the standards of patentability has been a major goal of judicial efforts at patent reform.[407] For instance, in a series of landmark decisions, courts have trimmed the scope of patent-eligible subject matter,[408] made it harder for an applicant to satisfy the nonobviousness requirement,[409] and reinvigorated the requirement that applicants provide an adequate disclosure of the invention.[410]

The point here is that modulating the gatekeeping role of the statutory patentability requirements is a key element of patent reform.[411] This makes sense. If the standards are sufficiently high, an applicant is less likely to get a patent (or perhaps is deterred from filing an application altogether).[412] Since the extant utility requirement already does these things, any proposal to eliminate it goes against the grain of most academic commentary and conventional thinking about patent reform. But reform efforts always must be balanced against competing (and perhaps conflicting) objectives of the patent system.

Defeating Patents, 19 BERKELEY TECH. L.J. 667, 689 (2004) ("The Patent Office . . . appears to grant many patents that, when carefully scrutinized, fail to meet basic patentability standards.").

406. *See* BURK & LEMLEY, *supra* note 270, at 109, 142.

407. Patentability standards evolve primarily through judicial rather than legislative action. *See supra* note 45.

408. *See, e.g.*, Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010) (holding that claims relating to a method of hedging risks are unpatentable).

409. *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415 (2007) (rejecting the Federal Circuit's rigid test for nonobviousness due to its inconsistency with the "expansive and flexible" approach set forth in Supreme Court precedent).

410. *See, e.g.*, ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 940–41 (Fed. Cir. 2010) (reiterating that an applicant must provide a disclosure which enables a person having ordinary skill in the art to practice the full scope of the claimed invention without undue experimentation); Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351–53 (Fed. Cir. 2010) (en banc) (reaffirming well-settled law that an applicant must provide a disclosure showing possession of the full scope of the claimed subject matter).

411. *See* Sean B. Seymore, *The Presumption of Patentability*, 97 MINN. L. REV. 990, 994 (2013) ("[I]t appears that raising the substantive standards of patentability could go a long way toward solving the [patent] quality problem.").

412. "To put it crudely, if the [P]atent [O]ffice allows bad patents to issue, this encourages people with bad applications to show up." JAFFE & LERNER, *supra* note 404, at 175. On the other hand, a robust regime does the opposite because inventors "would understand that [low-quality] applications are a waste of time and money." *Id.*

2. The Need to Foster and Reward Invention

The Supreme Court has emphasized that two fundamental policy objectives of the patent system are to foster and reward invention and to promote the disclosure of inventions to stimulate further innovation.[413] The reward, of course, is the exclusory right conferred by the patent grant.[414] The goals are related: the reward of a patent encourages inventors to publicly disclose the technical details of the invention rather than keeping them as a trade secret.[415]

A starting point for fostering and rewarding invention is to eliminate obstacles that discourage applicants from entering the patent system in the first place. The modern utility requirement is one such obstacle—at least for those who seek patents on chemicals, seemingly impossible inventions, paradigm-shifting inventions, and inventions emerging from nascent technologies. All inventors want to believe that they will get—and are, in fact, entitled to—a fair shot at getting a patent. But if potential applicants believe that the Patent Office and the courts are biased against granting patents for certain types of inventions (which is likely given the subjective nature of the utility requirement), they may decide not to waste their time and money pursuing a patent if a denial is inevitable. Put simply, "inventors respond to how the Patent Office behaves."[416]

Under the regime proposed herein, an inventor claiming subject matter that currently falls into a disfavored class, and who knows that an application will receive an objective, technical examination, might decide to seek a patent. In other words, the proposed regime might attract to the patent system inventors who currently forego patenting because of the extant utility requirement. Society would benefit because the disclosure will add technical information to the public storehouse of knowledge that otherwise would likely be lost.[417]

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

414. For a discussion of the "long intellectual history" of the reward theory of patent law and arguments for and against it, see Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 310–13 (1992).

415. Universal Oil Prods. Co. v. Globe Oil & Ref. Co., 322 U.S. 471, 484 (1944); *see also supra* note 241 and accompanying text.

416. JAFFE & LERNER, *supra* note 404, at 175.

417. *See supra* notes 217–19 and accompanying text.

CONCLUSION

Utility is the most subjective standard in the entirety of patent law. Since the early days of the patent system, determining whether something has utility has largely involved a value judgment about the invention and when, or if, it should be patentable. Indeed, utility has been the patentability lever of choice for the Patent Office and the courts when there is no sound, objective, technical reason for denying a patent.

It is now time to eliminate utility as a condition of patentability. To the extent that usefulness matters at all, patent law should be less concerned with useful inventions and more concerned with ensuring that the public gets a useful disclosure. Indeed, it is the disclosure that conveys useful technical information about the invention and benefits the public by adding to the sum of useful knowledge. Importantly, the other patentability requirements can effectively ensure that the patent grant will provide the public with a useful disclosure without a standalone utility requirement.