Patently Impossible

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The difficult, the dangerous, and the impossible have always had a strange fascination for the human mind.

—John Phin[1]

INTRODUCTION

The growing backlog of patent applications in the U.S. Patent and Trademark Office ("PTO") and concerns about patent quality have led to calls for patent reform.[2] Legal commentators argue that both the backlog and quality problems stem, at least in part, from a large number of patent applications that disclose worthless inventions.[3]

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1. JOHN PHIN, THE SEVEN FOLLIES OF SCIENCE 1 (1906).

2. *See, e.g.*, Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1500 (2001) [hereinafter Lemley, *Rational Ignorance*] (arguing that inadequate examination leads the PTO to issue a large percentage of invalid patents); *see also* Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 53–56 (2007) (exploring limitations on the extent and quality of PTO review). 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). Reform efforts began when reports surfaced in the early 2000s "that documented important failings in the patent system, including laxity in the PTO examination process that let a number of bad patents issue . . . ." DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 100 (2009).

3. *See, e.g.*, Lemley, *Rational Ignorance*, *supra* note 2, at 1511 (finding that few patents are litigated or licensed and ninety-five percent of patents are never used); *see also* ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS 173 (2004) (contending that most patents are worthless). Wacky and absurd patents have received considerable attention in the

Perhaps the best solution would be to ferret out these applications at an early stage of patent examination. To some extent, this already happens. Applications disclosing perpetual motion machines;[4] cold fusion processes;[5] and other inventions that either claim seemingly unachievable results, challenge well-established scientific principles, or simply appear facially impossible, raise red flags in the PTO.[6] The oft-cited statutory basis for rejecting them is § 101 of the Patent Act, which only permits patents for "useful" inventions.[7] In patent law, an invention is not useful if it cannot operate to produce the intended result.[8] The test for operability is whether a person having ordinary skill in the art ("PHOSITA")[9] has reason to doubt the objective truth of the applicant's assertions.[10]

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popular media. *See generally* TED VANCLEAVE, TOTALLY ABSURD INVENTIONS (2001); James Gleick, *Patently Absurd*, N.Y. TIMES MAG., Mar. 12, 2000, at 44.

4. 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* discussion *infra* note 265; *see also* Dimitris Tsaousis, *Perpetual Motion Machine*, 1 J. ENGINEERING SCI. & TECH. REV. 53, 53–57 (2008).

5. *See In re* Swartz, 232 F.3d 862, 864 (Fed. Cir. 2000) (per curiam) (affirming the PTO's rejection of a cold fusion device). Cold fusion describes a nuclear fusion reaction with hydrogen that occurs at room temperature. Given that the fuel comes from water, a cold fusion apparatus could provide a limitless and nonpolluting source of energy. *See* ERIC G. SWEDIN, SCIENCE IN THE CONTEMPORARY WORLD 57–58 (2005). Critics contend that cold fusion is incompatible with nuclear physics, which holds that hydrogen fusion requires temperatures of millions of degrees Fahrenheit—as at the Sun's core. *Id.*

6. *See infra* Part II.A.

7. "Whoever invents or discovers any new and *useful* process, machine, manufacture, or composition of matter . . . may obtain a patent . . . ." 35 U.S.C. § 101 (2006) (emphasis added). Aside from utility, an invention must be novel, § 102, nonobvious, § 103, and directed to patentable subject matter, § 101. In addition, § 112 ¶ 1 requires that the application adequately disclose the invention and § 112 ¶ 2 requires that the application conclude with claims which delineate the invention with particularity.

8. *See* Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1358 (Fed. Cir. 1999) ("The utility requirement of 35 U.S.C. § 101 mandates that any patentable invention be useful and, accordingly, the subject matter of the claim must be operable."); 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 . . . ."). The U.S. Court of Customs and Patent Appeals ("C.C.P.A.") was a predecessor to the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit"). The Federal Courts Improvement Act of 1982 abolished the C.C.P.A. *See* 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. *See* South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc).

9. The PHOSITA is a hypothetical construct of patent law. *See* Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed. Cir. 1987) (explaining that a PHOSITA is "not unlike the

However, using the operability requirement of § 101 as a gatekeeper has several drawbacks. First, elucidating what a PHOSITA would believe can devolve into a subjective judgment about the subject matter. The PTO and the courts can develop a bias toward unpatentability, with inventions emerging from new, poorly understood, and paradigm-shifting technologies as well as those from fields with a poor track record of success as the most vulnerable.[11] Second and relatedly, since the PTO and the courts are probably unaware of what is happening at the cutting edge of science and technology, what happens when the impossible becomes possible? History reveals that the PTO and the courts will continue to deny patents under § 101 for a long time thereafter.[12] This time lag between technical possibility and legal recognition is unsettling since "the very purpose of the patent system is to encourage [the] attainment of previously unachievable results."[13] The current § 101 regime frustrates this purpose as well as the patent system's broader mission to extend the frontiers of knowledge.

This Article offers a new framework for gauging the patentability of seemingly impossible inventions. Briefly, it contends that a more robust enforcement of the enablement requirement of § 112 ¶ 1—which obliges a patent applicant to disclose how to make and use the invention without undue experimentation—can effectively ferret out truly impossible inventions *by itself* with no need for or help from its § 101 statutory cousin. Importantly, § 112 ¶ 1 can perform the gatekeeping role by weighing objective, technical factors rather than through subjective credibility assessments that lie at the heart of the

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'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 inventor's educational level, 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).

10. The PTO 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 inoperativeness means that the claimed invention is not supported by a credible utility. *Id.* at 1356; *see also* U.S. PATENT & TRADEMARK OFFICE, REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS 11 (1999), *available at* http://www.uspto.gov/web/offices/pac/utility/utilityguide.pdf ("[A] utility that is inoperative is not credible."); *id.* at 5 ("A credible utility is assessed from the standpoint of whether a [PHOSITA] would accept that the recited or disclosed invention is currently available for such use."). For a discussion of the other facets of the § 101 utility requirement, see discussion *infra* note 43.

11. *See infra* Part II.B.1.

12. *See infra* Part II.B.2.

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

§ 101 analysis. This enablement-based approach would eliminate the need for the § 101 operability requirement. It would also streamline patent examination, improve patent quality, yield more technically robust patents, and ultimately foster innovation.

The issue addressed in this Article—how to deal with seemingly impossible inventions—has received almost no attention in the academic literature.[14] This Article fills a gap in patent scholarship and will contribute to ongoing debates over patent reform. It is part of a larger project to resolve the disconnect between patent law and the norms of science.[15]

The remainder of the Article proceeds as follows. Part I introduces impossibility from a scientific perspective and divides seemingly impossible quests into three broad categories. Part II addresses how the patent system currently handles seemingly impossible inventions. This Part takes issue with the subjective nature of the inquiry and explores its ill-effects on innovation. It concludes that the current regime leads to credibility lags, which prevent the patent system from sitting at the cutting edge of science and technology. To solve this problem, Part III offers an enablement-based approach for handling seemingly impossible inventions. This approach replaces the currently employed, subjective credibility assessment under § 101 with an objective, fact-intensive analytical framework. This Part concludes by exploring the policy trade-offs in adopting the new framework and explains how it fulfills several broad goals of the patent system.

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14. This is the first article to comprehensively explore incredible inventions and to seriously challenge operability as a patentability requirement. Only a few articles have previously explored operability. *See generally* Robert Ederer, *On Operability as an Aspect of Patent Law*, 42 J. PAT. OFF. SOC'Y 398 (1960); Daniel C. Rislove, Comment, *A Case Study of Inoperable Inventions: Why is the USPTO Patenting Pseudoscience?*, 2006 WIS. L. REV. 1275 (2006).

15. *See generally* Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127 (2008) [hereinafter Seymore, *Heightened Enablement*] (proposing a new approach for examining patent applications in unpredictable technologies which, by requiring applicants to disclose actual experimental results, resolves a striking incongruity between patent law and the experimental sciences); Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919 (2011) [hereinafter Seymore, *Rethinking Novelty*] (arguing that current novelty doctrine can produce paradoxical outcomes for complex inventions and is seemingly incongruous with basic principles of patent law); Sean B. Seymore, *Serendipity*, 88 N.C. L. REV. 185 (2009) (arguing that although accidental discoveries pervade science, inventors who invent by accident can be unjustly deprived of patents because such discoveries do not mesh with the substantive law of invention); Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621 (2010) [hereinafter Seymore, *Teaching Function*] (proposing a disclosure regime that would allow patents to compete with other forms of technical literature as a source of substantive technical information).

I. ACHIEVING THE IMPOSSIBLE

A. Impossibility as a Driving Force

The quest to achieve the impossible is a strong driving force in scientific research.[16] Scientists who succeed in doing so are unique because they recognize nature's complexity, know what is happening at the forefront of theory and experiment, and are "capable of selecting the new tools that make it possible to achieve today what was impossible yesterday and that will be powerful but routine tomorrow."[17] But the path to success is not always smoothly paved—it is often rife with skepticism (*"It'll never work!"*) or disparagement (*"You're an idiot!"*) from the scientific community.[18] Aside from vindication,[19] success spawns new fields of inquiry,[20] illuminates old ones,[21] promotes scientific progress,[22] and extends the frontiers of knowledge.[23]

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16. "Scientists like to show that things widely held to be impossible are in fact entirely possible . . . ." JOHN D. BARROW, IMPOSSIBILITY, at vii (1998). For instance, K. C. Nicolaou—a prolific organic chemist who is the author or coauthor of over 700 scientific publications and an inventor on more than 60 patents—admits that his favorite synthetic targets are ones that "look impossible at first glance" and "provide an opportunity to discover or invent new science." *2005 ACS National Award Winners*, CHEMICAL & ENGINEERING NEWS, Feb. 14, 2005, at 60–61.

17. Gustaf Arrhenius, *Presentation of the Roebling Medal of the Mineralogical Society of America for 1976 to Carl W. Correns*, 62 AM. MINERALOGIST 603, 603 (1977).

18. This has even been the case for many Nobel Prize-winning achievements. For instance, Barbara McClintock, recipient of the 1971 National Medal of Science and the 1983 Nobel Prize in Physiology or Medicine for her pioneering work in cytogenetics, recounted that "[fellow scientists] called me crazy, absolutely mad at times." *Jumping Genes*, TIME, Nov. 30, 1981, at 106. Although McClintock published her findings in 1951, it took the scientific community over thirty years to overcome its skepticism because "the prevailing wisdom was that genetic structure was stable and immutable." *Id.*

19. Perhaps the best evidence of vindication is the numerous reports in technical journals of results long considered unachievable. A good example is K. C. Nicolaou's total synthesis of the top-selling anticancer drug Taxol. *See* K. C. Nicolaou et al., *Total Synthesis of Taxol*, 367 NATURE 630, 630–34 (1994). This achievement, "considered as the 'holy grail' of synthesis in the late 1980s and early 1990s . . . stands as the quintessential symbol of all natural products molecular complexity, and . . . [is] the single most important milestone of complex molecular construction in recent decades." Cover Legend [K. C. Nicolaou], 34 INT'L J. ONCOLOGY 299, 300 (2009).

20. The most striking example is the field of organic chemistry, which became an area of systematic study in 1828 only after Friedrich Wöhler accidentally synthesized urea from mixing two inorganic salts. *See* Friedrich Wöhler, *Ueber künstliche Bildung des Harnstoffs [On the Artificial Formation of Urea]*, 88 ANNALEN DER PHYSIK UND CHEMIE 253, 253–56 (1828); *see also* AARON J. IHDE, THE DEVELOPMENT OF MODERN CHEMISTRY 163–65 (1964) (presenting a historical account). This event, heralded as the first organic synthesis, shattered the prevailing belief that man could never make any substance extracted from living things. *See id.* at 163–64 (discussing vitalism).

21. For example, chemists long believed that it was impossible for carbon to form fewer than four bonds when it occurred in an organic compound. *See, e.g.*, AUGUST BERNTHSEN, A

B. Types of Impossibility

It is possible to divide seemingly impossible quests into three broad categories.[24] The first category, *Type I* impossibilities, encompasses quests where the hoped-for result is per se impossible because the methodology conflicts with known scientific principles or basic laws of nature. *Type I* impossibilities are easy to identify because "[t]he incontrovertible evidence that Nature is governed by reliable 'laws' allows us to separate the possible from the [truly] impossible."[25] Perhaps the best example is alchemy, which is loosely defined as the quest to transform a cheap metal like lead into gold.[26] One reason why researchers proceed down dead-end paths is because they misunderstand the underlying science. Were a *Type I* impossibility ever to become possible, "[it] would represent a fundamental shift in our understanding of [science]."[27]

TEXTBOOK OF ORGANIC CHEMISTRY 14–16 (George M'Gowan trans., 1891) (describing carbon's bonding tendencies). In 1900, a chemistry professor at the University of Michigan published a paper describing an organic molecule in which carbon only formed three bonds. *See generally* Moses Gomberg, *An Instance of Trivalent Carbon: Triphenylmethyl*, 22 J. AM. CHEMICAL SOC'Y 757 (1900). The chemistry community did not accept Gomberg's explanation for his result until decades later. *See* Aaron J. Ihde, *The History of Free Radicals and Moses Gomberg's Contributions*, 15 PURE & APPLIED CHEMISTRY 1, 9–14 (1967). Gomberg's work shed new light on chemical bonding and led scientists to realize that free radicals play a large role in natural phenomena. *See generally* BARRY HALLIWELL & JOHN M. C. GUTTERIDGE, FREE RADICALS IN BIOLOGY AND MEDICINE (3d ed. 1999).

22. Scientific progress is "the cumulative growth of a system of knowledge over time, in which useful features are retained and nonuseful features are abandoned, based on the rejection or confirmation of testable knowledge." MICHAEL SHERMER, WHY PEOPLE BELIEVE WEIRD THINGS 31 (2002).

23. As discussed below, the patent system seeks similar ends. *See infra* Part III.D.2.

24. These categories are somewhat similar to those used by others. *See, e.g.*, *In re* Chilowsky, 229 F.2d 457, 462 (C.C.P.A. 1956) (articulating three categories of inoperable inventions); MICHIO KAKU, PHYSICS OF THE IMPOSSIBLE, at xvii (First Anchor Books 2009) (dividing impossibilities into three broad categories).

25. BARROW, *supra* note 16, at vii.

26. *See* 1 J. W. MELLOR, A COMPREHENSIVE TREATISE ON INORGANIC AND THEORETICAL CHEMISTRY § 12 (1922) (exploring the history of alchemy). Alchemists believed that "just as the hardness, colour, fusibility, and other properties of certain metals can be altered, so must it be possible to change all the properties of one metal into those of another, and thus produce a veritable transmutation." *Id.* As scientists began to understand nuclear physics, they learned how to transform one element into another with radioactivity. For a description of the first artificial atomic transmutation, see BERNARD JAFFE, CRUCIBLES: THE STORY OF CHEMISTRY FROM ANCIENT ALCHEMY TO NUCLEAR FISSION 214 (4th ed. 1976) (describing Nobel Laureate Ernest Rutherford's conversion of nitrogen to oxygen in 1919).

27. KAKU, *supra* note 24, at xvii.

Type II impossibilities are pseudoscience,[28] quests that appear scientific but lack scientific foundation.[29] A good example is the claim that an electrified cage can enhance the extrasensory perception ("ESP")[30] of a human subject placed inside of it.[31] Pseudoscience's identifying characteristics include widespread skepticism,[32] the inability of others to reproduce the research claim,[33] static or randomly changing ideas,[34] the lack of connectivity with other scientific disciplines,[35] and a lack of publications in the mainstream peer-reviewed literature.[36]

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28. Alternative coinages include "junk science" and "pathological science." BRIAN STABLEFORD, SCIENCE FACT AND SCIENCE FICTION 410 (2006).

29. GILA GAT-TILMAN, SCIENCE, PSEUDOSCIENCE, AND MORAL VALUES 20 (2007); *see also* SHERMER, *supra* note 22, at 33 (defining pseudoscience as "claims presented so that they appear scientific even though they lack supporting evidence and plausibility"). Commentators differ in their views on the impact of pseudoscience on scientific progress. *Compare* JOHN GRANT, DISCARDED SCIENCE 9 (2006) (arguing that pseudoscience does not help and often impedes the advance of human knowledge), *with* RIKI G. A. DOLBY, UNCERTAIN KNOWLEDGE 207 (2002) (noting that chemistry and astronomy have pseudoscientific origins, and that Darwin's theory of evolution morphed from pseudoscience to orthodoxy).

30. Extrasensory perception, the "sixth sense," is an awareness beyond the ordinary senses of hearing, sight, smell, taste, and touch. LYNNE KELLY, THE SKEPTIC'S GUIDE TO THE PARANORMAL 125 (Thunder's Mouth Press 2004).

31. *See* ANDRIJA PUHARICH, BEYOND TELEPATHY 211–25 (1973) (describing the construction and operation of the cage and its effect on ESP); Andrija Puharich, *Electrical Field Reinforcement of ESP*, 9 INT'L J. PARAPSYCHOL. 175, 175–83 (1967) (discussing general principles). Puharich tried to patent his device. *See* Puharich v. Brenner, 415 F.2d 979, 981–83 (D.C. Cir. 1969) (affirming the PTO's rejection). Aside from doubting the results of the electrified cage experiments, most scientists remain skeptical about ESP. *See infra* note 32.

32. *See, e.g.*, BARRY H. KANTOWITZ ET AL., EXPERIMENTAL PSYCHOLOGY 15 (9th ed. 2008) ("ESP cannot be evaluated[] because only believers can be present when it is demonstrated. The scientist takes a dim view of this logic and most scientists, especially psychologists, are skeptical about ESP.").

33. *See* SCOTT O. LILIENFELD ET AL., SCIENCE AND PSEUDOSCIENCE IN CLINICAL PSYCHOLOGY 8 (2004) (contending that pseudoscientists over-rely on anecdotal evidence, which is insufficient to justify a claim and is rarely dispositive); 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.").

34. Unlike real science, where old ideas and knowledge evolve in light of new discoveries or growth in understanding, in pseudoscience ideas do not progress because there is no anchor in an established, foundational body of knowledge. GREGORY N. DERRY, WHAT SCIENCE IS AND HOW IT WORKS 159 (1999). Thus, ideas remain static because there is no reason to accept one idea over another. *Id.*

35. Given that pseudoscientists often purport to create new frameworks rather than build on existing ones, "they neglect well-established scientific principles or hard-won scientific knowledge." LILIENFELD ET AL., *supra* note 33, at 7. For this reason, mainstream science "must insist on very high standards of evidence before [accepting the claim]." *Id.* at 8.

36. Peer review refers to the screening of research results by colleagues in a particular discipline. Peter Hernon & Candy Schwartz, *Peer Review Revisited*, 28 LIBR. & INFO. SCI. RES. 1,

Finally, *Type III* impossibilities include quests that are technically impossible right now but might become possible at some point in the future.[37] A good example is a technique that would allow adults to regrow decayed, worn, or lost teeth.[38] In these quests, there is *something* that makes the impossible seem possible. This *something* could range from a promising preliminary research result to a widespread positive vibe about the discipline.[39]

These categories are important because it may be that the PTO and the courts are too quick to deem something as per se impossible (*Type I*) or pseudoscientific (*Type II*) when it is, in fact, possible now or will be at some not-too-distant point in the future (*Type III*).[40] When this miscategorization happens, it can result in delayed entry—or perhaps no entry at all—of inventions with true technical merit into the patent system.

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1 (2006). Pseudoscientists may evade peer review because they fear that the process is inherently biased against their claims (particularly if it conflicts with well-established paradigms) or if their research methodologies do not conform to the scientific method. LILIENFELD ET AL., *supra* note 33, at 6.

37. *Cf.* KAKU, *supra* note 24, at xvii (defining "Class I" impossibilities as those which are impossible today but may become possible in the future because they do not violate the laws of physics).

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

39. Nanotechnology is an excellent example. It is a field of applied science based on the fabrication, control, and manipulation of materials on the atomic or molecular scale (one billionth of a meter). CHARLES P. POOLE, JR. & FRANK J. OWENS, INTRODUCTION TO NANOTECHNOLOGY 1 (2003). In a famous speech that he delivered to the American Physical Society over five decades ago, Nobel Laureate Richard Feynman predicted that one day scientists would be able to manipulate matter on the atomic or molecular scale. *See generally* Richard Feynman, *There's Plenty of Room at the Bottom* (Dec. 29, 1959), *in* THE PLEASURE OF FINDING THINGS OUT 117 (Jeffrey Robbins ed., 2000). It now appears that nanotechnology has endless possibilities, including nanoscale drug delivery systems, nanosurgery, nanorobots, nanomachines, and nanoelectronics. *See generally* FRITZ ALLHOFF ET AL., WHAT IS NANOTECHNOLOGY AND WHY DOES IT MATTER? (2010). The federal government spent nearly $1.5 billion on nanotechnology research in 2009, which is up from $464 million in 2001. *See NNI Budget*, NAT'L NANOTECHNOLOGY INITIATIVE, http://nano.gov/about-nni/what/funding (last visited Oct. 11, 2011).

40. It is important to emphasize that the category depends on the invention, not the problem to be solved. For instance, an invention claiming a method of using milk to whiten skin might be pseudoscientific (a *Type II* impossibility; discussed *infra* notes 137–139); however, skin whitening is a problem that science can solve.

II. PATENTING THE IMPOSSIBLE

A. The Operability Requirement

The patent system and mainstream science both rely on the dissemination of technical information to promote innovation.[41] And like mainstream science, the patent system relies on credibility assessments. It seeks to derail inventions that are so speculative or esoteric in nature that operativeness appears unlikely because a PHOSITA would consider the applicant's assertions unbelievable, incredible in light of contemporary knowledge, or factually misleading.[42] Presently the patent system relies on § 101 to perform this gatekeeping function.[43] Specifically, the courts interpret the utility requirement of § 101 to mandate that an invention operate to produce the intended result.[44]

1. The Examination Rubric

The PTO undertakes a two-step analysis to gauge operability. First, the examiner construes the relevant claims to precisely define

41. *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) (explaining that the information disclosed in the patent adds to the public storehouse of knowledge); Brenner v. Manson, 383 U.S. 519, 533 (1966) ("It is true, of course, that one of the purposes of the patent system is to encourage dissemination of information concerning discoveries and inventions."); Graham v. John Deere Co., 383 U.S. 1, 9 (1966) (describing a patent as "an inducement, to bring forth new knowledge").

42. *In re* Gazave, 379 F.2d 973, 978 (C.C.P.A. 1967).

43. *See supra* note 8 and accompanying text. In addition to operability (or "credible" utility), the utility requirement of § 101 has two other parts. *See generally* U.S. Patent and Trademark Office Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001) (discussing substantial, specific, and credible utility), *cited with approval in In re* Fisher, 421 F.3d 1365, 1372 (Fed. Cir. 2005). Substantial utility requires that the invention "provide a significant and presently available benefit to the public." *Id.* at 1371. Specific utility requires that the invention provide "a well-defined and particular benefit to the public." *Id.* Together, these requirements preclude from patentability "mere ideas[,] . . . 'hypothetical possibilities, [and] objectives which the claimed [inventions] . . . *could* possibly achieve." *In re* 318 Patent Infringement Litig., 583 F.3d 1317, 1324 (Fed. Cir. 2009) (quoting *Fisher*, 421 F.2d at 1373)).

44. Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1358 (Fed. Cir. 1999). The operability requirement can be traced back to the nineteenth century. *See* Mitchell v. Tilghman, 86 U.S. (19 Wall.) 287, 396 (1873) (holding that a patentable invention must be "capable of being used to effect the object proposed"). The utility requirement itself "has its origin in [the Intellectual Property Clause of] the Constitution, which indicates that the purpose of empowering Congress to authorize the granting of patents is "to promote the progress of . . . *useful* arts." Stiftung v. Reinshaw PLC, 945 F.2d 1173, 1180 (Fed. Cir. 1991) (quoting U.S. CONST. art. I, § 8, cl. 8).

the invention to be tested for compliance with § 101.[45] Second, if it appears that the invention cannot operate to produce the intended result, the examiner assesses credibility by asking if a PHOSITA would believe what the applicant asserts in the written description of the invention.[46] If the examiner determines that a PHOSITA would reasonably doubt the applicant's assertions, then the invention is unpatentable under § 101 for lack of utility *and* under § 112 ¶ 1 for lack of enablement.[47] This dual rejection makes sense because an applicant cannot possibly enable a PHOSITA to practice[48] an invention that does not work.[49]

A rejection triggers an evidentiary burden-shifting process. Initially the applicant's disclosure enjoys a presumption of truth; the examiner must presume that the invention can operate to produce the intended result.[50] This means that the examiner must establish a

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45. Raytheon Co. v. Roper Corp., 724 F.2d 951, 956 (Fed. Cir. 1983). During examination the examiner must give claim terms their broadest reasonable interpretation as they would be understood by a PHOSITA yet consistent with the applicant's disclosure. *In re* Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

46. *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995). The *written description* is the part of the patent (or patent application) that completely describes the invention. 35 U.S.C. § 112 (2006).

47. *See* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE, § 2107.01 (8th ed. 8th rev. 2010) [hereinafter MPEP] (discussing the dual rejection). Enablement is one of the three disclosure requirements appearing in 35 U.S.C. § 112 ¶ 1:

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

35 U.S.C. § 112 (2006) ¶ 1 (emphasis added). Enablement is discussed *infra* Part III.A.

48. The courts often use the term "practice" when referring to the how-to-make and how-to-use prongs of the enablement requirement of § 112 ¶ 1. *Compare* Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1234 (Fed. Cir. 2003) ("The legal question of enablement involves an assessment of whether a patent disclosure would have enabled [a PHOSITA] at the time the application was filed to make and use the claimed invention without undue experimentation."), *with In re* Swartz, 232 F.3d 862, 863 (Fed. Cir. 2000) (per curiam) ("To satisfy the enablement requirement of § 112 ¶ 1, a patent application must adequately disclose the claimed invention so as to enable a [PHOSITA] to practice the invention at the time the application was filed without undue experimentation.").

49. *See Process Control*, 190 F.3d at 1358 ("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."); *In re* Ziegler, 992 F.2d 1197, 1200–01 (Fed. Cir. 1993) ("The how-to-use prong of § 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101. . . . If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112." (internal citations omitted)).

50. *In re* Cortright, 165 F.3d 1353, 1357 (Fed. Cir. 1999); *see also* MPEP, *supra* note 47, § 2107.02 (instructing examiners not to begin the analysis by assuming that the asserted utility is false). The underpinnings of the presumption trace back to a C.C.P.A. case:

prima facie case of unpatentability by coming forward with factual evidence of noncredibility.[51] Evidentiary sources may include peer-reviewed materials, non-peer-reviewed materials, anecdotal information, information from related technologies, and logic.[52] If the examiner cannot adduce the evidence, then the PTO must issue a patent if the applicant meets the other requirements for patentability.[53]

An applicant faced with an inoperability 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 inoperability.[54] A good example is when the examiner relies on common knowledge in the field as proof that the invention cannot work.[55] The applicant can also mount a successful attack if the examiner compels the inventor to explain precisely how or why an invention works[56] or contends that the

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> As a matter of Patent Office practice, a [written description] which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for [a PHOSITA] to question the objective truth of the statement of utility or its scope.

In re Langer, 503 F.2d 1380, 1391 (C.C.P.A. 1974) (emphasis added).

51. *In re* Gaubert, 524 F.2d 1222, 1224–25 (C.C.P.A. 1975); *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).

52. *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.*

53. *Oetiker*, 977 F.2d at 1445. The other patentability requirements appear *supra* note 7.

54. *See supra* note 51 and accompanying text; *see also* MPEP, *supra* note 47, § 2107.02 (encouraging examiners to provide documentary evidence whenever possible).

55. The general rule is that the PTO "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 PTO "cannot simply reach conclusions based on its own understanding or experience—or on its assessment of what would be basic knowledge or common sense." *In re* Zurko, 258 F.3d 1379, 1386 (Fed. Cir. 2001). For such facts, the PTO 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 for the statement. *In re* Chevenard, 139 F.2d 711, 713 (C.C.P.A. 1943). Third, the PTO must give the applicant an opportunity to challenge a fact asserted to be common knowledge. *Id. But see* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007) (explaining that in the nonobviousness context, reliance on common sense, viewed through PHOSITA's perspective, is appropriate).

56. *See* Diamond Rubber Co. v. Consol. Rubber Tire Co., 220 U.S. 428, 435–36 (1911) (explaining that an inventor need not understand the scientific principles underlying the invention); Newman v. Quigg, 877 F.2d 1575, 1581 (Fed. Cir. 1989) ("[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works . . . ."); *In re* Newman, 782 F.2d 971, 974 (Fed. Cir. 1986) (explaining that the PTO should not ask

invention is partially operable,[57] performs crudely,[58] or is inferior to others.[59] Reliance on any of these rationales, whether alone or in combination, is insufficient to establish the PTO's initial burden.[60]

An alternative strategy is to concede the prima facie case and rebut it. 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.[61] Applicants can rely on affidavits as proof of operability, although those from experts in the field that show a nexus between the intended result and the supporting evidence are the most probative.[62] When the applicant

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applicants for scientific explanations because the agency "is not a guarantor of scientific theory"); *In re* Libby, 255 F.2d 412, 415 (C.C.P.A. 1958) (explaining that enablement does not require an understanding of the underlying science).

57. "The threshold [for] utility is not high." Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366 (Fed. Cir. 1999); *see also* Testimony of Scott A. Chambers, former Assoc. Solicitor of the PTO, Federal Trade Commission Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy 95–96 (Feb. 8, 2002), *available at* http://www.ftc.gov/opp/intellect/020208intelpropertytrans.pdf (noting that the credibility standard of § 101 only requires that the invention be "plausible" to a PHOSITA). An invention is inoperable only if it is "totally incapable of achieving a useful result." Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571 (Fed. Cir. 1992). Thus, an applicant satisfies § 101 as long as the invention accomplishes at least one stated objective. Raytheon Co. v. Roper Corp., 724 F.2d 951, 958 (Fed. Cir. 1983).

58. 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."); *see also* 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).

59. *See* Stiftung v. Reinshaw 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., 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 requirements for patentability."); *In re* Ratti, 270 F.2d 810, 814 (C.C.P.A. 1959) (rejecting the PTO's contention that an invention "[must] possess some definite advantage over the prior art" in order to be patentable).

60. 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).

61. *In re* Swartz, 232 F.3d 862, 864 (Fed. Cir. 2000) (citing *Brana*, 51 F.3d at 1566); *see also In re* Ferens, 417 F.2d 1072, 1074 (C.C.P.A. 1969) (explaining that an examiner may request evidence to substantiate the applicant's assertions when they appear to be incredible in light of contemporary knowledge). *But see In re* Novak, 306 F.2d 924, 928 (C.C.P.A. 1962) (noting that rebuttal evidence is unnecessary if a PHOSITA would obviously accept the applicant's allegations as true).

62. *See In re* Payne, 606 F.2d 303, 315 (C.C.P.A. 1979) (noting that facts set forth in an affidavit from an expert in the field are highly probative); s*ee also In re* Perrigo, 48 F.2d 965, 966 (C.C.P.A. 1931) (determining that affidavits which were brief and general in character were insufficient to prove operability). Regarding the nexus, the affiant must be able to show that the intended result stems from the invention and not from some other source. *See Ferens*, 417 F.2d

submits rebuttal evidence, the examiner must "start over" and "consider all of the evidence anew."[63] The examiner must determine patentability based on the *entire* record,[64] with a preponderance of the evidence as the standard of proof.[65]

Whether an invention is operable under § 101 is a question of fact.[66] While the type and amount of proof required depends on the nature of the invention, the degree of certainty necessary for both the truth of the intended result and the ultimate fact of operativeness or inoperativeness is the same in all cases.[67] An invention rejected for inoperability under § 101 also faces rejection for lack of enablement under § 112 ¶ 1 because the applicant cannot teach a PHOSITA how to use something that does not work.[68] Whether a disclosure is enabling is a legal conclusion based on underlying factual inquiries.[69] On appeal,[70] the U.S. Court of Appeals for the Federal Circuit

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at 1075 (finding that affidavits from lay persons attesting to a cure for hair loss were unpersuasive because they evinced no understanding of the written description of the invention and could not show a nexus); *id.* (rejecting an affidavit from a doctor who, though highly skilled, was not an expert in the field and thus could not adequately set forth experimental observations about the alleged cure for hair loss).

63. *In re* Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (internal citation omitted).

64. *See* MPEP, *supra* note 47, § 2107.02 (reminding examiners that incredible utility "is a conclusion, not a starting point for analysis" under § 101).

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

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

67. *In re* Ferens, 417 F.2d 1072, 1075 (C.C.P.A. 1969); *In re* Chilowsky, 229 F.2d 457, 462 (C.C.P.A. 1956) (explaining that the patent statutes and case law lead to this rule). Regardless, one commentator suggests that the applicant may face an insurmountable burden. *See* Edward C. Walterscheid, *Insufficient Disclosure Rejections (Part II)*, 62 J. PAT. OFF. SOC'Y 229, 240–41 (1980) ("[A]n examiner has not only established a prima facie case of [inoperability] if he can show that the alleged utility is at best highly speculative and at worst incredible, but has also created an exceedingly difficult burden of proof for an applicant to overcome such a rejection.").

68. *See* cases cited *supra* notes 48–49 and accompanying text; *see also In re* Fisher, 421 F.3d 1365, 1378–79 (Fed. Cir. 2005) (holding that since the Board's § 101 rejection was supported by substantial evidence, the court would also leave the § 112 ¶ 1 rejection undisturbed because the applicant failed to satisfy the enablement requirement as a matter of law). It is worth noting that an applicant can disclose an invention which satisfies the operability requirement of § 101 but fails to satisfy the enablement requirement of § 112. *See* Mowry v. Whitney, 81 U.S. (14 Wall.) 620, 644 (1871) ("[The claimed] process may have been a highly useful invention . . . and yet he may have failed so to describe it as to teach the [PHOSITA] how to practice it.").

69. *In re* Swartz, 232 F.3d 862, 863 (Fed. Cir. 2000).

70. An applicant whose claims have been twice rejected by the examiner can appeal to an intraoffice tribunal known as the Board of Patent Appeals and Interferences 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 (2011). An applicant dissatisfied with a Board decision can appeal to the Federal Circuit or file a civil action against the Director in the U.S. District Court for the District of Columbia. 35 U.S.C. §§ 141, 145. In the latter, the parties may submit additional evidence or argue the previous evidence afresh. Gould v. Quigg, 822 F.2d 1074, 1076 (Fed. Cir. 1987).

("Federal Circuit") reviews a finding of (in)operability and the factual issues underlying enablement deferentially.[71]

2. Proof

Gauging operability is easiest when the applicant can point to actual experimental data or a working model to prove that the invention works.[72] But unlike the rules of mainstream science, which "require actual performance of every experimental detail" as a prerequisite for publication,[73] in patent law an inventor only needs to provide sufficient technical information to teach a PHOSITA how to practice the invention without undue experimentation.[74] This means that an applicant usually does not need to actually reduce an invention to practice or produce a physical embodiment[75] of it in order to obtain a patent.[76] But even if an inventor does engage in some

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71. As an initial matter, if the Board's (or trial court's) decision requires claim interpretation, it is reviewed *de novo*. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc); *see also Raytheon Co.*, 724 F.2d at 956 ("In determining utility . . . the claims must first be interpreted to define the invention to be tested for utility."). For appeals from the PTO, 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 finding of inoperability as well as the facts 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 at 863 (Fed. Cir. 2000). Where operability is at issue in a jury trial, the Federal Circuit determines if substantial evidence exists to support the verdict. Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571 (Fed. Cir. 1992). As for enablement, the Federal Circuit reviews the trial court's legal conclusion *de novo* but reviews the underlying factual findings for substantial evidence in jury trials, Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1321 (Fed. Cir. 2003), or clear error in bench trials. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1334 (Fed. Cir. 2003). While utility and enablement often involve complex scientific principles, the Federal Circuit views them not as "legal abstractions," but as issues "[which] properly devolve on the trier of fact" who, as for other kinds of evidence, "must make determinations of credibility, reliability, and weight." *Brooktree*, 977 F.2d at 1573.

72. *Cf.* Seymore, *Teaching Function*, *supra* note 15, at 652–53 (advocating a working example requirement for complex technologies which would, among other things, simplify the enablement analysis).

73. Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1377 (Fed. Cir. 2003) (Newman, J., dissenting).

74. *Id.*

75. An embodiment is a concrete form of an invention (like a chemical compound or a widget) described in a patent application or patent. ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY 27 (4th ed. 2007).

76. *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 60 (1998) (explaining that "the word 'invention' in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea"). Thus, in patent law, an invention can be actually reduced to practice by building a working model or constructively reduced to practice by filing a patent application which describes how to make and use it. Univ. of Rochester v. G. D. Searle & Co., 358 F.3d 916, 926 (Fed. Cir. 2004). A constructive reduction to practice presumptively satisfies the

prefiling experimentation, there are practical reasons why it might be de minimis.[77]

Thus, the key challenge for the PTO is gauging operability without actual proof.[78] And since the PTO lacks an experimental testing facility, it cannot easily probe the applicant's assertions.[79] A PTO official explains the problem:

> [T]o a large degree when the going gets tough, certainly the applicant is in the position to have the experts to do the testing, to submit documentary evidence to show why the examiner should allow the case. And, of course, . . . we don't have laboratories, and we don't have independent experts in that regard. So therefore, we are really compelled to accept some of that, particularly from the standpoint of the fact finding, that is presented to us.[80]

Aside from cases involving perpetual motion machines,[81] where there is a working model requirement,[82] the PTO allows applicants to

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disclosure requirements of § 112 ¶ 1. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986).

77. *See infra* Part III.D.1.

78. *See* Arthur Kantrowitz, *Proposal for an Institution for Scientific Judgment*, 156 SCIENCE 763, 764 (1967) ("It is actually very difficult to offer rigorous proof that something cannot be done . . . ."); Edward C. Walterscheid, *Insufficient Disclosure Rejections (Part I)*, 62 J. PAT. OFF. SOC'Y 217, 220 (1980) (explaining that obtaining proof can be a major problem for examiners, particularly since they must provide reasons and/or evidence to establish a prima facie case of unpatentability).

79. *See, e.g.*, Beckman Instruments, Inc. v. Chemtronics, Inc., 439 F.2d 1369, 1379 (5th Cir. 1970) (noting that in the absence of its own testing facilities, the PTO must rely on information presented to it); FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 5, at 9 (2003) [hereinafter FTC Report] ("Yet the PTO lacks testing facilities, and assertions that cannot be overcome by documentary evidence promptly identifiable by the examiner often must be accepted."). Curiously, the Patent Act of 1836, ch. 356, § 6, 5 Stat. 117 (amended 1839), required applicants to submit models at the time of filing. *See In re* Breslow, 616 F.2d 516, 522 (C.C.P.A. 1980) (recounting the history of the requirement); Kendall J. Dood, *Patent Models and the Patent Law: 1790–1880 (Part 1)*, 65 J. PAT. OFF. SOC'Y 187 (1983) (same). The Patent Act of 1870 made the submission of models discretionary. *See* Patent Act of 1870, ch. 230, §§ 28–29, 16 Stat. 198; *Breslow*, 616 F.2d at 522. The Patent Act of 1952 preserved the ancient authority in its then-existing form. *See* 35 U.S.C. § 114 (discussed *infra* note 82); *Breslow*, 616 F.2d at 522 (explaining that Congress had little interest in the statute).

80. FTC Report, *supra* note 79, ch. 5, at 9 (quoting Stephen G. Kunin, former Deputy Commissioner for Patent Examination Policy at the PTO).

81. For an explanation of perpetual motion, see *supra* note 4.

82. The patent statute permits the examiner to request a working model of an invention. *See* 35 U.S.C. § 114 ("The Director may require the applicant to furnish a model of convenient size to exhibit advantageously the several parts of his invention."). However, the PTO rarely invokes the requirement unless the invention involves perpetual motion. *See* MPEP, *supra* note 47, § 608.03 (noting the exception). The exception likely stems from Joseph Newman's fight in the PTO and the courts over the application he filed in 1979 for an "Energy Generation System Having Higher Energy Output than Input." *See* Newman v. Quigg, 681 F. Supp. 16, 16–17 (D.D.C. 1988) (presenting a chronology). After the PTO rejected the perpetual motion machine as inoperable under § 101, Newman sued the Director in district court, which ultimately remanded

choose their own way of establishing operability when the examiner questions it.[83]

B. Problems

1. The Subjective Credibility Assessment

The test for operability is whether a PHOSITA has reason to doubt the objective truth of the applicant's assertions.[84] The PTO can establish reasonable doubt if the applicant's assertions "suggest an inherently unbelievable undertaking,"[85] "involve implausible scientific principles,"[86] "run[] counter to what would be believed would happen by the [PHOSITA],"[87] or emerge from fields ridden with fraud or from which "little of a successful nature has been developed."[88] In each situation the examiner must turn to mainstream science to determine if the applicant's assertions are (in)credible in light of contemporary knowledge in the field.[89] Thus, credibility in mainstream science and operability in patent law are tightly linked. But, in light of certain idiosyncrasies in mainstream science set forth below, one might ask if this should be the case.

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the application for a new examination. *See In re* Newman, 782 F.2d 971, 972 (Fed. Cir. 1986) (summarizing the procedural history). This time the examiner ordered Newman to deliver a working model of his 9,000-pound machine to the National Bureau of Standards (NBS) for testing. *Id.* at 973–74; I. Peterson, *A Patent Pursuit: Joe Newman's "Energy Machine,"* 22 SCI. NEWS 342, 342 (1985). On appeal, the Federal Circuit held that while the NBS could not dismantle the device to elucidate *how* it works, the agency could test it to see *if* it works. *Newman*, 782 F.2d at 974; *accord In re* Aufhauser, 399 F.2d 275, 283 (C.C.P.A. 1968). The NBS determined that the device could not produce the intended result, which led the PTO to again reject the application. *See* ROBERT E. HEBNER ET AL., REPORT OF TESTS ON JOSEPH NEWMAN'S DEVICE, NBSIR 86-3405, at 24 (1986) ("[I]n no case did the device's efficiency approach 100 percent."); *see also Newman*, 681 F. Supp. at 19–23 (describing the tests). The district court agreed with the PTO, *id.* at 23–24, as did the Federal Circuit. Newman v. Quigg, 877 F.2d 1575, 1582 (Fed. Cir. 1989). Interestingly, some scientists argue that perpetual motion is not necessarily impossible; rather, it just does not fit within the present framework of thermodynamics. *See, e.g.*, DOLBY, *supra* note 29, at 75 (exploring plausible scientific theories which are consistent with perpetual motion).

83. MPEP, *supra* note 47, § 608.03.

84. *See supra* notes 10, 47 and accompanying text.

85. *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (citing *In re* Jolles, 628 F.2d 1322, 1327 (C.C.P.A. 1980) (reversing the PTO's denial of a patent for chemotherapy drugs because the applicant's assertions that they effectively put a particular type of leukemia in remission were no longer incredible)).

86. *Id.*

87. *In re* Pottier, 376 F.2d 328, 330 (C.C.P.A. 1967).

88. *In re* Gazave, 379 F.2d 973, 978 (C.C.P.A. 1967) (quoting *In re* Oberweger, 115 F.2d 826, 827 (C.C.P.A. 1940) (concluding that treating baldness is impossible)).

89. *See supra* note 52 and accompanying text.

a. Scientific Gatekeeping

In its efforts to advance scientific knowledge and maintain communal standards, mainstream science seeks to discourage *Type I* and *Type II* quests[90] while fostering those in *Type III*.[91] It does so by assessing credibility, which is the degree of belief scientists attach to a research claim and to the facts presented to support it.[92]

The process begins when a researcher formally presents a claim to the scientific community by submitting a manuscript to a journal for publication.[93] At this point, a legitimization mechanism kicks in, with the built-in "knowledge filter" known as peer review at its core[94] and with the journal editors and reviewers as the gatekeepers.[95] Their mission is "[t]o promote original ideas, valuable approaches, or new methods[,] and to reject the mediocre ones."[96]

The gatekeepers fulfill this task by engaging in "organized skepticism" to ensure that each research claim is reproducible, logical, and independent and that it satisfies other basic conditions for communal acceptability.[97] As Professor Gregory Derry explains:

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90. *See* JOHN ZIMAN, RELIABLE KNOWLEDGE 132 (1991) ("In order . . . [to] retain its reliability and credibility, each scientist . . . [must] exercise critical vigilance over his own work and the claims of his contemporaries."). This is not always an easy task. For example, consider cold fusion discussed *supra* note 5. While some scientists believe that it is impossible (first category) or pseudoscientific (second category), a growing number are optimistic and believe that it might be possible in a few decades (third category).

91. Of course, this will depend on how "incredible" the quest appears at a particular moment in time. For example, initially the scientific community may reject the quest as truly impossible (*Type I*) or pseudoscientific (*Type II*). But a promising preliminary research result will shift the quest to *Type III*. *See* discussion *supra* Part I.B (discussing *Type III* impossibilities).

92. JOHN ZIMAN, REAL SCIENCE 222 (2002).

93. DERRY, *supra* note 34, at 161; *see also* DARYL E. CHUBIN & EDWARD J. HACKETT, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY 85 (1990) (explaining that publishing in journals replaced haphazard modes of circulating science and "facilitate[s] communication, allocation of credit, and authentication of research results").

94. HENRY H. BAUER, SCIENTIFIC LITERACY AND THE MYTH OF THE SCIENTIFIC METHOD 44–48 (1992). The mechanics of peer review typically works as follows. First, the researcher submits the work to a journal. Second, the editor sends it to one or more reviewers knowledgeable about the problem to judge its merit (uniqueness, methodology, adequacy of research design, and potential contribution to the field). Third, the editor makes a final publication decision. Hernon & Schwartz, *supra* note 36, at 1.

95. FREDERICK GRINNELL, EVERYDAY PRACTICE OF SCIENCE 75 (2009) (explaining how a scientist with a new research claim must "get by the gatekeepers").

96. Juan Miguel Campanario, *Have Referees Rejected Some of the Most-Cited Articles of All Times?*, 47 J. AM. SOC'Y INFO. SCI. 302, 302 (1996).

97. ZIMAN, *supra* note 92, at 246; *see also* MARK ERICKSON, SCIENCE, CULTURE AND SOCIETY 44 (2005) (explaining that a journal's imprimatur validates the research claim and ascribes status to it). Although personal trust is very important in science, scientific communities "do not accept research claims on the mere say-so of their authors." ZIMAN, *supra* note 92, at 246.

> [A new research claim] must undergo peer review, which means that it's sent to other scientists for criticism and judgment; only work judged as worthwhile will be published. The norm in science is to subject [research results] to criticism in order to weed out bogus results. The results that survive this process become a well-established consensus, and new results that contradict this consensus are greeted by particularly severe skepticism. [But] even the consensus remains subject to criticism, and that criticism becomes severe if new and contradictory results (having survived their own skeptical scrutiny) start to accumulate. Oddly enough, skepticism keeps open the possibility of change even as it tends . . . to foster conservatism in science.[98]

Many would agree that the active, systematic exercise of skepticism through peer review facilitates open communication and the interchange of ideas, and this skepticism is largely responsible for the success of contemporary science.[99] Indeed, peer review "pervades science from beginning to end,"[100] influencing not just publishing but also what constitutes common knowledge and what scientists ultimately view as logical.[101]

b. Credibility Lags in Mainstream Science

Peer review, however, has serious drawbacks that can affect patent law.[102] Perhaps the major drawback is that the peer-review process can delay, hinder, or block the dissemination of novel ideas.[103] There are several reasons why this is so. First, quantitative studies and anecdotal sources reveal that reviewers resist change.[104] They will

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98. DERRY, *supra* note 34, at 161.

99. ELIEZER GEISLER, THE METRICS OF SCIENCE AND TECHNOLOGY 233 (2000).

100. Alister Scott, *Peer Review and the Relevance of Science*, 39 FUTURES 827, 828 (2007) (citation omitted).

101. *See* GEISLER, *supra* note 99, at 233; sources cited *supra* notes 90–94.

102. Peer review has also been the subject of considerable criticism from those within and outside of mainstream science. *See, e.g.*, Campanario, *supra* note 96, at 302 (collecting criticisms); GEISLER, *supra* note 99, at 234 (same); Rustum Roy & James R. Ashburn, *The Perils of Peer Review*, 414 NATURE 393, 393–94 (2001) (arguing that peer review hinders good science).

103. Raymond E. Spier, *Peer Review and Innovation*, 8 SCI. & ENGINEERING ETHICS 99, 102 (2002). For stories and examples of delayed recognition, see Bernard Barber, *Resistance by Scientists to Scientific Discovery*, 134 SCIENCE 596, 597–602 (1961) (providing examples dating back to the 19th century); David F. Horrobin, *The Philosophical Basis of Peer Review and the Suppression of Innovation*, 263 J. AM. MED. ASS'N 1438, 1440–1441 (1990) (eighteen examples); Moti Nissani, *The Plight of the Obscure Innovator in Science: A Few Reflections on Campanario's Note*, 25 SOC. STUD. SCI. 165, 171–76 (1995) (forty-seven examples).

104. As one scientist argues, "[It] is not permissible is to write or say something which contradicts the shared paradigm, and expect it to be tolerated . . . . because the shared paradigm, a necessary frame of reference in normal scientific communication, would be undermined." IVOR CATT, THE CATT ANOMALY 31 (2001), *available at* http://www.ivorcatt.com/28anom.htm. Often it is better for a scientist to "stop[] producing new, and perhaps unsettling, ideas" because "[r]ewriting or extending the best work of others, or one's best pieces . . . could be easier, more rewarding, and more acceptable." Graciela Chichilnisky, *Response*, *in* REJECTED: LEADING ECONOMISTS PONDER THE PUBLICATION PROCESS 67 (George B. Shepherd ed., 1995). Peer

often reject anything that clashes with then-existing ideas and generally accepted theories.[105] Second, many factors enter into a reviewer's calculus which have little or nothing to do with technical merit. These include conservatism,[106] bias,[107] conflicts of interest,[108] jealously,[109] fears of offending the scientific establishment,[110] an

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reviewers have rejected many research claims that ultimately transformed science; including those by future Nobel laureates Enrico Fermi (theory of radioactive decay), Paul Lauterbur (magnetic resonance imaging), and Hans Krebs (citric acid cycle). *See* Juan Miguel Campanario, *Rejecting and Resisting Nobel Class Discoveries: Accounts by Nobel Laureates*, 81 SCIENTOMETRICS 549, 551–58 (2009) (presenting stories from Nobel laureates rejected by scientific journals).

105. DAVID SHATZ, PEER REVIEW 10 (2004); *see also* Chichilnisky, *supra* note 104, at 57 ("In my experience, the more innovative and interesting the paper, the more likely it is to be rejected."); Stephen Lock, *Peer Review at Work*, 290 BRIT. MED. J. 1555, 1560 (1985) (disclosing an editor's admission that peer review "favor[s] unadventurous nibblings at the margin of truth rather than quantum leaps . . . ."). A recent study reveals that publishing results that do not positively align with then-existing (mainstream) ideas can have devastating reputational and pecuniary consequences. *See* Arthur M. Diamond, Jr., *The Career Consequences of a Mistaken Research Project: The Case of Polywater*, 68 AM. J. ECON. SOC. 387, 407 (2009) (concluding that researchers who wrote about polywater, either pro or con, suffered a negative impact on their future citations and a concomitant loss of financial income); Robin Hanson, OVERCOMING BIAS: POX ON BOTH HOUSES (Apr. 30, 2009, 10:00 AM), http://www.overcomingbias.com/2009/04 (opining in response to Diamond's study that "[i]f this is a typical outcome, we can conclude that academic incentives are to just ignore contrarian claims that you do not believe will become mainstream").

106. *See* CHUBIN & HACKETT, *supra* note 93, at 90 (arguing that journal peer review works against innovation and reinforces scientific dogma); DERRY, *supra* note 34, at 138 ("Very innovative ideas and unexpected results tend to get selectively filtered out, making peer review a force for conservatism in science."); THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS 64–65 (1962) (explaining that resistance to change will be strong and long-lasting when a new claim challenges well-accepted paradigms).

107. *See* SHATZ, *supra* note 105, at 45–48 (explaining bias in peer review). Potential types of bias include specialty bias, nationality bias, gender bias, age bias, and a bias toward positive results. *See* STEVE FULLER, SCIENCE 73 (1997) (articulating the operation of the "principle of cumulative advantage" where elite scientists form and maintain closed networks, which means that "the rich get richer and the poor get poorer in the knowledge production business"); Ann M. Link, *U.S. and Non-U.S. Submissions: An Analysis of Reviewer Bias*, 280 J. AM. MED. ASS'N 246, 246–47 (1998) (concluding that U.S. reviewers have a significant preference for U.S. papers); Richard Smith, *Peer Review: A Flawed Process at the Heart of Science Journals*, 99 J. ROYAL SOC'Y MED. 178, 180 (2006) (describing the bias against work which discloses negative results).

108. *See* Drummond Rennie et al., *Conflicts of Interest in the Publication of Science*, 266 J. AM. MED. ASS'N 266, 266–67 (1991) (noting that while no one expects editors to serve as "the science police," they must ensure that authors and reviewers disclose all potential conflicts).

109. One commentator argues that many reviewers are against innovation unless it is their own because "[i]nnovation from others may . . . diminish[] the importance of the scientist's own work." Horrobin, *supra* note 103, at 1441.

110. *See* FULLER, *supra* note 107, at 65 (explaining that since each scientific discipline has a few gatekeepers who pass judgment on everyone else, offending one "can be disastrous, much like failure to pay protection money to the local mafia boss").

overwhelming interest in quality control,[111] and the inability to recognize brilliance.[112] In sum, whether and when the credibility gate opens is highly subjective and idiosyncratic.

Perhaps the major downside of this credibility lag for patent law is that it can compromise patent rights. The right to obtain a patent is extremely time sensitive. To illustrate, consider an inventor who files a patent application disclosing a seemingly impossible invention at time *X*. The examiner will turn to mainstream science to determine if the applicant's assertions are (in)credible in light of contemporary knowledge in the field.[113] If the gatekeepers do not credit the finding until time *Y*, then the applicant will face an inevitable rejection. Importantly, refiling at or beyond time *Y* is often not a viable option because things have happened that probably have compromised patentability.[114]

2. What Happens When the Impossible Becomes Possible?

The history of science teaches that what was impossible yesterday might be possible today.[115] Precisely when the impossible becomes possible depends on several factors including the nature of the technology, the rate at which knowledge grows within a particular

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111. *See* Sandra Goldbeck-Wood, *Evidence on Peer Review—Scientific Quality Control or Smokescreen*, 318 BRIT. MED. J. 44, 45 (1999) (exploring difficulties with finding a bias-free metric to assess manuscript quality); Horrobin, *supra* note 103, at 1438 (arguing that "[q]uality control is one means of achieving an end, but it is not the end itself"); *id.* at 1439 (arguing that any marginal improvement gained in research quality from rejecting a manuscript is no gain at all if it's done at the expense of innovation).

112. *See* David F. Horrobin, *Peer Review: A Philosophically Faulty Concept Which Is Proving Disastrous for Science*, *in* PEER COMMENTARY ON PEER REVIEW 33, 34 (Stevan R. Harnard ed., 1982) (arguing that since brilliance is rare, a less-than-brilliant reviewer probably would not recognize it and reject the claim).

113. *See supra* text accompanying note 89 (describing the link between credibility in mainstream science and operability in patent law).

114. For example, the Patent Act contains a loss-of-right provision, § 102(b), which precludes patentability for the inventor's own conduct. Particularly relevant here is that an inventor who discloses the invention in a printed publication (including a published patent application) more than one year before filing cannot obtain a patent. 35 U.S.C. § 102(b) (2006). In the context of the hypothetical, this means that the application filed at time *X* can defeat patentability at time *Y*. *In re* Katz, 687 F.2d 450, 454 (C.C.P.A. 1982).

115. *See supra* text accompanying note 17; *see also* CEES J. HAMELINK, THE TECHNOLOGY GAMBLE, at x (1988) (arguing that since "the future cannot be seen as the linear extension of the past[,] it is essential to believe that what was impossible yesterday is tomorrow's possibility!"); H. LEE MARTIN, TECHONOMICS 89 (2006) ("[W]hat was impossible yesterday . . . becomes possible today and commonplace tomorrow.").

field, ingenuity, and serendipity.[116] But regardless of when this moment occurs, it can still take years for mainstream science to credit the claim.[117]

a. The Credibility Lag in Patent Law

The credibility lag in mainstream science has a parallel in patent law. Particularly susceptible to this lag are inventions emerging from nascent technologies; fields in rapid change, in a primitive stage of development, or in the midst of a technological renaissance; and quests which have a poor track record of success.[118] But there will always be *some* lag whenever the PTO looks to mainstream science to determine if the applicant's assertions are credible in light of contemporary knowledge because any lag that exists in mainstream science will unavoidably pass through to the patent system.

Yet, the patent system exacerbates and protracts any artifactual lag stemming from mainstream science. To begin, structural and substantive aspects of patent examination cause a technological lag. Given the technical nature of the examiner's job, one might expect this individual to know exactly what is happening at the forefront of theory and experiment in a particular discipline. However, this is not the case because the examiner is not an active researcher.[119] In addition, the current incentive structure for PTO personnel, combined with the examiner's time pressures and production goals, afford little, if any, time for professional development.[120] These realities essentially divorce examiners from the

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116. *See, e.g.*, LESLIE ALAN HORVITZ, EUREKA!: SCIENTIFIC BREAKTHROUGHS THAT CHANGED THE WORLD 1–10 (2002) (exploring various factors).

117. *See supra* Part II.B.1.

118. *See, e.g.*, *In re* Swartz, 232 F.3d 862 (Fed. Cir. 2000) (generating energy with "cold fusion"); Newman v. Quigg, 877 F.2d 1575, 1577 (Fed. Cir. 1989) (perpetual motion machine); Fregeau v. Mossinghoff, 776 F.2d 1034 (Fed. Cir. 1985) (using a magnetic field to alter the taste of food); *In re* Eltgroth, 419 F.2d 918 (C.C.P.A. 1970) (claiming a method for controlling the aging process); *In re* Ruskin, 354 F.2d 395 (C.C.P.A. 1966) (increasing the energy output of fossil fuels through exposure to a magnetic field).

119. *See supra* note 79 and accompanying text.

120. *See* Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 944–45 (2004) (discussing biased procedures at the PTO which favor hasty examiner analysis and skewed incentives); Arti K. Rai, *Growing Pains in the Administrative State: The Patent Office's Troubled Quest for Managerial Control*, 157 U. PA. L. REV. 2051, 2063–67 (2009) (describing examiner compensation and incentives). The amount of time the PTO allots for an examiner to dispose of a case depends on factors like seniority and the technology involved. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, U.S. PATENT & TRADEMARK

frontlines of science.[121] The same is true, perhaps even more so, for judges who hear patent cases.[122] Consequently, patent law inevitably lags a step or two behind the cutting edge of science and technology.

Compounding this disconnect is evidence of bias against seemingly impossible inventions. History reveals that the PTO and the courts have approached seemingly impossible claims with skepticism for the sake of the public good. As the argument goes, there is a belief (albeit an incorrect one) among the public and potential investors[123] that the government never issues patents on inventions that cannot operate to achieve the intended result.[124] Strict policing of seemingly impossible claims, therefore, should protect both the public from potentially harmful products that do not work as claimed and potential investors from patentees who might seek to defraud them.[125]

OFFICE: HIRING EFFORTS ARE NOT SUFFICIENT TO REDUCE THE PATENT APPLICATION BACKLOG 7 (2007), *available at* http://www.gao.gov/new.items/d071102.pdf (discussing production goals).

121. For thoughts on how this technology gap affects patent examination, see JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE 161 (2008) (suggesting that the examiners' unfamiliarity with new technologies and lack of knowledge may hurt patent examination quality); John R. Allison & Ronald J. Mann, *The Disputed Quality of Software Patents*, 85 WASH. U. L. REV. 297, 314 (2007) ("[P]atent examiners unfamiliar with a cutting-edge technology like software may be less capable of assessing the quality of the disclosure or of the innovation than they are in technological areas with which they are more familiar.").

122. For thoughts on the disconnect between the judicial bench and the laboratory bench and the consequences for patent law, see William D. Noonan, *Patenting Medical Technology*, 11 J. LEGAL MED. 263, 264–69 (1990) (tracing the history of the disconnect to technical and subjective factors); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1068 (2003) (highlighting the lack of technical expertise on the Federal Circuit); Seymore, *Heightened Enablement*, *supra* note 15, at 148–50 (arguing that the courts misunderstand what constitutes "undue experimentation"); Seymore, *Rethinking Novelty*, *supra* note 15, at 946–57 (exploring how the judiciary's unfamiliarity and discomfort with complex technologies has impacted the law of novelty).

123. 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."); Craig Allen Nard, *Certainty, Fence Building, and the Useful Arts*, 74 IND. L.J. 759, 759 (1999) ("The prospect of certainty in the patentee's property interest has several benefits, one of which is to create a sense of security which permits the patentee to secure risk capital from investors, which in turn facilitates the commercialization of the claimed invention." (citing Patlex Corp. v. Mossinghoff, 758 F.2d 594, 599 (Fed. Cir. 1985) ("[E]ncouragement of investment-based risk is the fundamental purpose of the patent grant . . . ."))).

124. Rislove, *supra* note 14, at 1280 (explaining that while such inventions are technically unpatentable, the PTO lets some inoperable inventions slip through the cracks).

125. *Id.* For example, there was a time when the PTO and several judges believed that clinical evidence or FDA approval should be a prerequisite for patenting drugs which appear unsafe or risky. *Compare In re* Hartop, 311 F.2d 249, 260 (C.C.P.A. 1962) (Smith, J., concurring) (criticizing the PTO's position that it was "carrying out its statutory duty, when [it] required proof of safety and effectiveness in man"), *with id.* at 263–66 (Worley, C.J., dissenting) (agreeing

Judge Giles Rich agreed, arguing that granting patents on seemingly impossible inventions violates public policy.[126] So it appears that elucidating what a PHOSITA would believe can devolve into a subjective judgment about the subject matter. Thus, for some quests, the PTO and the courts may develop a bias against patentability.

b. Example: The Legitimization of Baldness Treatment as a Credible Field

The pursuit of patents related to baldness treatments provides an excellent example of the contours of the credibility lag in patent law. The pervasiveness of hair loss,[127] its social impact,[128] and the

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with the PTO that Congress intended for it to work cooperatively with other agencies to ensure safety and effectiveness). Now it is clear that drug safety is not the PTO's responsibility. *See* Scott v. Finney, 34 F.3d 1058, 1063–64 (Fed. Cir. 1994) (explaining that § 101 and other provisions of the patent statutes do not establish safety as a patentability criterion); *In re* Anthony, 414 F.2d 1383, 1455–56 (C.C.P.A. 1969) (same); *see also In re* Sichert, 566 F.2d 1154, 1160 (C.C.P.A. 1977) (noting that a minimal level of safety will satisfy § 101).

126. *In re* Citron, 325 F.2d 248, 253 (C.C.P.A. 1963) (discussed *infra* Part II.B.2(c)); *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) (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." Christopher R. Leslie, *Patents of Damocles*, 83 IND. L.J. 133, 144 (2008) (citation omitted). *But see Hartop*, 311 F.2d at 263 ("[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.").

127. *See* Ron Shapiro & Valerie D. Callender, *Hair Transplantation*, *in* HAIR AND SCALP DISEASES 175, 175 (Amy J. McMichael & Maria K. Hordinsky eds., 2008) (noting that, in modern times, more than fifty percent of men and twenty-five percent of women suffer from some degree of hair loss).

128. Throughout history, a full head of hair has been viewed as a sign of strength and virility. Perhaps the most famous story is that of Samson and Delilah:

> So Delilah said to Samson, "Tell me the secret of your great strength . . . ." So he told her everything. "No razor has ever been used on my head," he said. . . . "If my head were shaved, my strength would leave me, and I would become as weak as any other man." . . . After putting him to sleep on her lap, she called for someone to shave off the seven braids of his hair, and so began to subdue him. And his strength left him.

Judges 16:6, 17, 19 (New International).

sensitive nature of the topic[129] may explain why reversing baldness has been an obsession since ancient times.[130] History reveals, however, that most purported baldness cures have not worked.[131] So it is not surprising that inventors seeking patents on purported cures once faced huge credibility hurdles. But it appears that several meritorious claims fell through the cracks because it took the PTO and the courts a long time to recognize that it *is* possible to treat baldness.

The legal saga began with *In re Oberweger*,[132] a 1940 case in which the applicant claimed that treating the scalp with a paste containing bone marrow, clover oil, and alcohol could regrow hair.[133] Recognizing that the prior art[134] contained "little of a successful nature,"[135] the applicant bolstered the claim with testimonials and an affidavit from a medical doctor attesting to the efficacy of the treatment.[136] Nevertheless, the PTO deemed the invention inoperable "since compositions for growing hair on the human scalp have

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129. Again, the Old Testament provides a famous example. One day the prophet Elisha, who lost most of his hair at a young age, faced mockery from a group of boys while on a journey. *See* THOMAS J. CRAUGHWELL, BAD KIDS OF THE BIBLE 225–30 (2008) (comparing the story to *The Lord of the Flies*). According to Craughwell, "[T]his mockery of his hairless head made Elisha a mite peevish." *Id.* at 228. Indeed, it led to a gruesome result:

> Elisha went up to Bethel. As he was walking along the road, some boys came out of the town and jeered at him. "Get out of here, baldy!" they said. "Get out of here, baldy!" He turned around, looked at them and called down a curse on them in the name of the Lord. Then two bears came out of the woods and mauled forty-two of the boys. And he went on to Mount Carmel . . . .

2 *Kings* 2:23–25 (New International).

130. *See generally* KERRY SEGRAVE, BALDNESS: A SOCIAL HISTORY 32–65 (1996) (exploring various quests and treatments throughout history); *id.* at 3 (discussing the first written medical record from ancient Egypt of recipes for baldness treatment).

131. For a brief historical account of the various quests, see CHRISTOPHER WANJEK, BAD MEDICINE 48–52 (2003). Contemporary treatments include topical applications, drugs, herbal remedies, massage techniques, and lifestyle changes. *See generally* D.J. VERRET, PATIENT GUIDE TO HAIR LOSS & HAIR RESTORATION (2009).

132. 115 F.2d 826 (C.C.P.A. 1940).

133. *Id.* at 827.

134. Prior art "constitutes . . . documentary sources (patents and publications from anywhere in the world) and non-documentary sources (things known, used or invented in the United States)" that may be used to determine the novelty and nonobviousness of claimed subject matter in a patent application or patent. 1 DONALD S. CHISUM, CHISUM ON PATENTS, GLOSSARY, Gl–8 (2010) [hereinafter CHISUM]; *see also* Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (defining prior art as accessible technology in the public domain).

135. *Oberweger*, 115 F.2d at 827.

136. *Id.* When an applicant submits affidavits as proof of operability, they should show a nexus between the intended result and the supporting evidence. *See supra* note 62 and accompanying text.

uniformly proven unreliable."[137] The U.S. Court of Customs and Patent Appeals ("C.C.P.A.")[138] agreed and affirmed the rejection:

> Certainly there is nothing in this record to show that appellant's composition *is any better* than the many hundreds of similar concoctions that have been advertised and sold to a *credulous public* since the beginning of recorded history. It is a *matter of common knowledge* that numerous preparations . . . have been advertised and sold for the purpose of producing hair on bald heads . . . [which are] often harmful to the human body and . . . generally understood to be a fraud upon the public.[139]

Aside from the court's improper comparison of the claimed invention to the prior art[140] and its heavy reliance on common knowledge to determine truth,[141] notably absent from the opinion was any discussion of the invention's scientific underpinnings or technical merit. Thus, it appears that the court deemed the baldness treatment a *Type II* impossibility.[142]

The C.C.P.A. had to contend with baldness again almost thirty years later in *In re Ferens*.[143] In that case, the applicant claimed that applying electric current combined with a lanolin ointment containing the extract of the jaborandi plant to the scalp could regrow hair.[144] Here too the applicant buttressed the claim with affidavits from a medical doctor and twenty-one laypersons treated with the purported cure.[145] Although the applicant admittedly could have proffered more probative evidence,[146] from a technical standpoint the applicant's assertion was not inherently unbelievable because there were numerous reports in the scientific literature that pilocarpoine, a

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137. *Oberweger*, 115 F.2d at 827. That the claimed composition comprised cheap and ordinary substances certainly raised suspicion. Indeed, the *Oberweger* court cited a case where the court invalidated a patent which claimed that a face cream made with whole milk could whiten skin. *Id.* at 828 (citing Hall v. Duart Sales Co., 28 F. Supp. 838, 839 (N.D. Ill. 1939) (invalidating Massage and Cleansing Cream and Method of Preparing the Same, U.S. Pat. No. 1,668,503 (issued May 1, 1928), for a lack of utility because the addition of milk to the cream "d[id] nothing").

138. The C.C.P.A. was a predecessor to the Federal Circuit. *See* discussion *supra* note 8.

139. *Oberweger*, 115 F.2d at 829 (emphasis added).

140. An invention need not possess some definite advantage over the prior art in order to be patentable. *See* sources cited *supra* note 59.

141. *See supra* note 55 (exploring the limits of facts asserted to be common knowledge).

142. *See supra* text accompanying note 29.

143. 417 F.2d 1072 (C.C.P.A. 1969).

144. *Id.* at 1073. Jaborandi is an herbal shrub with small reddish-purple flowers found mainly in Brazil. BEN-ERIK VAN WYK & MICHAEL WINK, MEDICINAL PLANTS OF THE WORLD 239 (2004).

145. *Ferens*, 417 F.2d at 1074.

146. The court found the affidavits unpersuasive because they did not show a nexus between the intended result and the supporting evidence (in other words, that the intended result came from the invention and not from some other source). *Id.* at 1075. The court also doubted that a neuropsychiatrist could credibly opine on hair growth. *Id.*

pharmacologically active compound found in jaborandi leaves, could stimulate hair (re)growth.[147] This did not matter because the PTO and the C.C.P.A. once again deemed the invention impossible without exploring its scientific and technical merit. Thus, baldness treatments remained pigeonholed as *Type I* or *Type II* inventions because they belonged to "a field of endeavor where little of a successful nature ha[d] been developed despite constant effort . . . ."[148]

Eventually the field emerged from the pigeonhole. One decade after *Ferens*, Upjohn obtained a patent for a method of using minoxidil (trade name Rogaine) to grow hair.[149] The PTO subsequently granted hundreds of patents for methods of treating baldness. Many of them disclose treatments using rudimentary techniques and mundane materials previously frowned upon, including jaborandi.[150] The Federal Circuit completed the legitimization process in 1999 in *In re Cortright*,[151] when it proclaimed that treating baldness is "[not] an inherently unbelievable undertaking."[152]

c. Another Example: The Recognition of Cancer as a Treatable Disease

For most of the twentieth century, the PTO and the courts were highly skeptical of any invention that purported to effectively

147. *See, e.g.*, HOBART A. HARE, A TEXTBOOK OF PRACTICAL THERAPEUTICS 322 (1897) (providing a recipe for making a hair tonic for reversing partial baldness with jaborandi extract which contains an optimal level of pilocarpine); GEORGE T. JACKSON, A PRACTICAL TREATISE ON THE DISEASES OF THE HAIR AND SCALP 135 (1898) (reporting successful cases of hair regrowth in patients whose scalps were treated with a jaborandi paste over several weeks); *Baldness and Its Treatment*, 2 LANCET 376, 376 (1892) (noting that the direct injection of either pilocarpine or an alcoholic extract of the jaborandi plant promotes hair growth but is too powerful a remedy for indiscriminate use). Pilocarpine works by increasing the blood circulation around hair follicles and opening skin pores (which has the added benefit of promoting the uptake of other compounds into the scalp). STEVEN FOSTER & REBECCA L. JOHNSON, DESK REFERENCE TO NATURE'S MEDICINE 219 (2006).

148. *Ferens*, 417 F.2d at 1074.

149. *See* 6-Amino-4-(Substituted Amino)-1,2-Dihydro-1-Hydroxy-2-Iminopyrimidine, Topical Compositions and Process for Hair Growth, U.S. Patent No. 4,139,619 (filed Aug. 19, 1977) (issued Feb. 13, 1979). Interestingly, Upjohn originally developed minoxidil in pill form to treat high blood pressure. *See* JOHN TOEDT ET AL., CHEMICAL COMPOSITION OF EVERYDAY PRODUCTS 40 (2005). However, the drug had an unexpected side effect: people who took it grew hair in an unexpected manner on their cheeks, foreheads, hands, and in other places. *See* SPENCER D. KOBREN, THE BALD TRUTH 4 (2000) (telling the minoxidil story). Researchers soon figured out that applying minoxidil directly on a balding scalp might regrow hair on it. *Id.* Minoxidil is one of two FDA-approved treatments for treating male pattern baldness. *See* VERRET, *supra* note 131, at 49.

150. *See* Composition and Method to Promote Human Hair Growth, U.S. Patent No. 7,238,375 (filed Dec. 20, 2004).

151. 165 F.3d 1353 (Fed. Cir. 1999).

152. *Id.* at 1357.

treat cancer.[153] Applicants claiming success faced a formidable—if not insurmountable—patentability hurdle because the courts allowed the PTO to impose a very high burden on the *applicant* to prove operability.[154]

The landmark opinion from this era is *In re Citron*,[155] a 1963 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.[156] 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.[157] Nevertheless, the examiner rejected the claim under § 101 and found that the applicant had not sustained his burden to prove operability.[158] The Board affirmed, explaining that the invention was "apparently inoperative"[159] and in light of contemporary knowledge in the art "[could not] be accepted as operative absent clear and convincing proof thereof."[160] Shifting the burden of proof to the applicant and ratcheting up the standard of proof required for the applicant to prevail were both in line with recent C.C.P.A. precedent.[161]

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153. *See, e.g.*, *Ex parte* Moore, 128 U.S.P.Q. 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 PTO 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. 581, 583 (Bd. Pat. App. 1959) (overturning the examiner's § 101 rejection). 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 581–82.

154. *See, e.g.*, *Timmis*, 123 U.S.P.Q. at 581 (discussed *supra* note 153). This lies in contrast to the status quo, which places the burden on the PTO to prove inoperability. *See* discussion *supra* Part II.A.1; *infra* notes 176–177 and accompanying text.

155. 325 F.2d 248 (C.C.P.A. 1963).

156. *Id.* at 251 (quoting from the written description of the invention in the application).

157. *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 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).

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

159. *Id.*

160. *Id.*; *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].").

161. In *In re Chilowsky*, 229 F.2d 457 (C.C.P.A. 1956), the court identified three types of operability cases and the requisite proof for each:

> [I]n the usual case where the mode of operation alleged can be readily understood and conforms to the known laws of physics and chemistry, operativeness is not questioned,

Writing for the court, Judge Giles Rich affirmed the Board's decision and provided several rationales for doing so:

> [W]here claimed compounds are alleged . . . to have a utility of as much public importance as is the effective treatment of cancer, which alleged utility appears to be incredible in the light of the knowledge of the art, or factually misleading, [the] applicant must establish the asserted utility by acceptable proof. . . .
>
> [W]hen an applicant bases utility for a claimed invention on allegations of the sort made by appellants here, unless [a PHOSITA] would accept those allegations as obviously valid and correct, it is proper for the examiner to ask for evidence which substantiates them. . . .
>
> [I]t is against public policy to place the oblique imprimatur of the Government via the patent grant on incredible or misleading unproven assertions in view of the possibility of exploitation of such statements in issued patents by unscrupulous persons.[162]

This heavy burden imposed upon the applicant reveals the then-existing "double standard" for therapeutic inventions.[163]

> and no further evidence is required. On the other hand, if the alleged operation seems clearly to conflict with a recognized scientific principle as, for example, where an applicant purports to have discovered a machine producing perpetual motion, the presumption of inoperativeness is so strong that very clear evidence is required to overcome it. A third type of case was involved in *In re Perrigo*, 48 F.2d 965 [C.C.P.A. 1931], wherein the device involved was of such a nature that it could not be tested by any known scientific principles. In such a case, as we there held, it is incumbent on the applicant to demonstrate the workability and utility of the device and make clear the principles on which it operates.

Id. at 462; *see also* 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 and in accord with C.C.P.A. precedent, heightened proof is required if human use is involved and the condition is one which is difficult to treat).

162. *Citron*, 325 F.2d at 253 (citation and internal quotation marks omitted). In his opinion Judge Rich cited with approval *Ex parte Moore*, 128 U.S.P.Q. 8, 9 (Bd. Pat. App. 1960). *Citron*, 325 F.2d at 253. There the Board stated the following:

> 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 . . . . 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.

Id. (quoting *Ex parte* De Bausset, 43 O.G. 1583, 1585 (1888)).

163. 4 CHISUM, *supra* note 134, § 4.04[2]; *see also* Joseph Gray Jackson, Address at the Institute of Patent Law of the Southwest Legal Foundation (Mar. 30, 1967) (observing that while utility is readily accepted without question 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"), *quoted in In re* Kirk, 376 F.2d 936, 958 (C.C.P.A. 1967) (Rich, J., dissenting). Professor Chisum has explained why the double standard existed:

> The stern view of earlier cases was in reaction to the fact that "it was common in the 19th century to emphasize in advertising the fact that an article was patented. For instance, the phrase 'patent medicine' arises from the widespread sale of patented compounds as medical remedies of various degrees of efficacy." Emphasis on the "patented" status of any product tends to be misleading to the general public because the standards of patentability focus primarily on novelty and not on comparative utility.

Particularly troubling from a technical standpoint was the absence of any discussion of the claimed invention's scientific merit or clear articulation of the type of proof required to demonstrate operability.[164]

The tide began to turn in 1980 when the C.C.P.A. explicitly stated that effectively treating cancer is not impossible. In *In re Jolles*,[165] the court reversed the PTO's rejection of a patent for a drug claiming to effectively induce remission in leukemia patients.[166] In doing so, the court announced that "the medical treatment of a specific cancer is not such an inherently unbelievable undertaking or involves such implausible scientific principles as to be considered incredible."[167] However, the double standard persisted because applicants had to substantiate their claims with heightened proof in the form of clinical data showing therapeutic efficacy in humans.[168]

The situation improved in 1995 when the Federal Circuit issued its decision in *In re Brana*.[169] There the applicant had been denied a patent for certain antitumor compounds for lack of utility because the PTO took the position that efficacy in animals with cancer was insufficient to establish a reasonable expectation of efficacy in humans.[170] The court began by unequivocally reiterating that "[t]he

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> But the problem was perceived as more severe with products closely connected with human health.

4 CHISUM, *supra*, § 4.04[2][a] (quoting EDMUND W. KITCH & HARVEY S. PERLMAN, LEGAL REGULATION OF THE COMPETITIVE PROCESS 721 (1st ed. 1972)).

164. *See* 4 CHISUM, *supra* note 134, § 4.04[2][a] (noting that the older C.C.P.A. cases "did not clearly resolve the issue of what the standard of proof of the effectiveness of a therapeutic product should be"); Marcus, *supra* note 161, at 676 (noting the challenges faced by the PTO in establishing uniform policies in therapeutic cases).

165. 628 F.2d 1322 (C.C.P.A. 1980).

166. *See id.* at 1327–28 (noting that the Board failed to give sufficient weight to animal studies because "such testing is relevant to utility in humans" and that a PHOSITA considering the entire record "would accept the [applicant's] claimed utility in humans as valid and correct").

167. *Id.* at 1327.

168. *See id.* ("When utility as a drug, medicant, and the like in human therapy is alleged, it is proper for the examiner to ask for substantiating evidence unless [a PHOSITA] would accept the allegations as obviously correct." (citing *In re* Novak, 306 F.2d 924, 928 (C.C.P.A. 1962)); *see also Ex parte* Busse, 1 U.S.P.Q.2d 1908, 1909 (B.P.A.I. 1986) (explaining that while the art of cancer treatment had advanced markedly since *Citron* to the extent that treating or curing it was no longer incredible, "unusual" asserted utilities justify the requirement for substantiating evidence); Jackson, *supra* note 163 ("If the drug is to be applied to humans, the Patent Office usually requires clinical tests, that is, tests on human patients."), *quoted in Kirk*, 376 F.2d at 958 (Rich, J., dissenting). If the applicant provided no substantiating evidence or only speculative statements, a rejection was guaranteed. *See, e.g.*, *Ex parte* Stevens, 16 U.S.P.Q.2d 1379, 1380 (B.P.A.I. 1990) (no substantiating evidence provided); *Busse*, 1 U.S.P.Q.2d at 1909 (determining that applicant's statement that the disclosed results "warrant[ed] further study" was insufficient to establish utility).

169. 51 F.3d 1560 (Fed. Cir. 1995).

170. *Id.* at 1563.

purpose of treating cancer with chemical compounds does not suggest an inherently unbelievable undertaking or involve implausible scientific principles."[171] The court had to finally decide what exactly an applicant must prove in order to establish utility for a pharmaceutical invention.[172] As to the specific facts of the case, the court held that efficacy in animals was sufficient to establish utility.[173] Thus, applicants for drug patents need not perform human testing before patent issuance.[174]

But these facts also gave the court an opportunity to confront two issues that further eroded the double standard for therapeutic inventions and shaped the contours of modern utility doctrine. First, the court adopted a uniform evidentiary framework for gauging compliance with § 101. It held that since an application as filed presumptively complies with the statutory standards for patentability,[175] both the initial and ultimate burdens of proving lack of utility rest with the PTO.[176] Hence, the same burden-shifting framework used to gauge compliance with novelty, nonobviousness, and the disclosure requirements also applies to utility.[177]

Second, the court took the position that § 101 should not be construed in such a way as to hinder research and development

171. *Id.* at 1566 (citing *In re* Jolles, 628 F.2d 1322, 1327 (C.C.P.A. 1980)).

172. *Id.* at 1564.

173. *Id.* at 1567 (citing *In re* Krimmel, 292 F.2d 948, 953 (C.C.P.A. 1961) (determining that testing with experimental animals can establish utility)) (explaining that *in vivo* and animal testing are sufficient).

174. *Id.*; *see also* Scott v. Finney, 34 F.3d 1058, 1063 (Fed. Cir. 1994) ("Title 35 does not demand that such human testing occur within the confines of [PTO] proceedings.").

175. *See In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (describing the PTO's burden to establish a prima facie case of unpatentability); *id.* at 1449 (Plager, J., concurring) (explaining that an applicant is entitled to a patent unless the PTO can prove otherwise).

176. *See In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (applying the evidentiary framework articulated for enablement in *In re Marzocchi*, 439 F.2d 220, 223 (C.C.P.A. 1971), to the utility context); *see also* MPEP, *supra* note 47, § 2107(II)(D) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided . . . ."). The C.C.P.A. laid the foundation for the presumption of utility in a case nearly thirty years earlier. *See In re* Gazave, 379 F.2d 973, 977 (C.C.P.A. 1967) (reminding the PTO that "[i]n the absence of any apparent reason why the compounds disclosed will not so function, or of any evidence showing that they actually do not, the statements in the application are generally deemed sufficient").

177. *See Brana*, 51 F.3d at 1566 ("Only after the PTO provides evidence showing that [a PHOSITA] would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

("R&D").[178] It now had to revisit the extent to which U.S. Food and Drug Administration ("FDA") Phase II clinical studies[179]—pertaining to the efficacy and safety of the drug—impact the utility determination.[180] The court explained that FDA approval is not a prerequisite for patentability:

> Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.[181]

By further removing the vestiges of the double standard, *Brana* has become a hallmark of modern utility doctrine because it explained how an overly stringent interpretation of § 101 could stifle scientific research, hinder innovation, and frustrate other goals of patent policy.[182] That may be all well and good, but it is somewhat troubling to consider the number of meritorious inventions that probably slipped through the cracks when the double standard was still the law of the land.[183]

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178. *See* Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2086 (2000) (noting that the PTO's strict interpretation of § 101 "provoked sharp rebuke" from the Federal Circuit in *Brana*).

179. Drugs typically undergo three phases of clinical testing to explore their safety and efficacy. 21 C.F.R. § 312.21 (2011). Briefly, Phase I involves limited human clinical trials to elicit basic safety data and to evaluate dosing and how a drug is metabolized; Phase II expands the testing to a larger group of subjects with the disease to test efficacy and safety; and Phase III involves an even larger group of subject and explores long-term evaluation of the drug's efficacy and safety. *Id.* § 312.21(a)–(c). After Phase III, the FDA determines whether the drug should be marketed.

180. *Brana*, 51 F.3d at 1567–68. The C.C.P.A. had dealt with this issue previously. *See* discussion *supra* note 125 and cases cited therein.

181. *Brana*, 51 F.3d at 1568.

182. *See, e.g.*, *infra* notes 285–286 and accompanying text (discussing the goal of early public disclosure). One commentator argues that if the *Brana* court had upheld the stringent utility requirement urged by the PTO, it "[ran] the risk of seriously inhibiting the incentives to compete among biotechnology companies and, therefore, jeopardize[d] the very existence of the industry." Kevin C. Hooper, *Utility and Non-Operability Standards in Biotechnology Patent Prosecution: CAFC Precedent Versus PTO Practice*, 36 IDEA 203, 250 (1996). On the other hand, a utility standard set too low "could impede scientific progress by creating a transaction-cost-heavy thicket of patents on basic research." Rai, *supra note* 122, at 1131–32.

183. For instance, as Professors Burk and Lemley have explained, "[B]y the time the developer of a new drug could show efficacy [in humans], they would likely have lost patent protection under [35 U.S.C. §] 102(b)." BURK & LEMLEY, *supra* note 2, at 111. Briefly, § 102(b) dedicates an invention to the public if the applicant does not file a patent application within one year of a public disclosure. 35 U.S.C. § 102(b) (2006) (discussed *supra* note 114 and *infra* note 283).

d. Normative Thoughts

These two examples show that technical merit and good science can ultimately triumph over skepticism and subjective bias.[184] The legitimization of baldness and cancer treatments also underscores that "[t]he mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it."[185] But with that said, examiners are still instructed to "determine if the asserted utility for the invention is *credible* based on the information disclosed in the application" and to deny patents when this is not the case.[186] This keeps the door open for the PTO and the courts to miscategorize inventions as impossible.

As a normative matter, this regime is unsettling for at least three reasons. First, science has evolved to a point where "the levels of *complexity* and *specialization* make it nearly impossible for [anyone] who is not intimately familiar with the activity[] to effectively and credibly evaluate it and its outcomes."[187] Second, given that operability is an objective question (either an invention works or it does not), an applicant who presents a meritorious claim should not face rejection because of subjective credibility assessments. Third, credibility lags prevent the patent system from sitting at the cutting edge of technology,[188] a place where patent protection is often crucial.[189]

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184. But there have been some near misses. *See* Horrobin, *supra* note 103, at 1439–41 (providing examples including the ability of lithium to act as a psychiatric drug and Krebs' citric acid cycle).

185. Gould v. Quigg, 822 F.2d 1074, 1078 (Fed. Cir. 1987) (quoting *In re* Chilowsky, 229 F.2d 457, 461 (C.C.P.A. 1956)); *cf.* MPEP, *supra* note 47, § 2107.03 ("The fact that there is no known cure for a disease . . . cannot serve as the basis for a conclusion that such an invention lacks utility.").

186. MPEP, *supra* note 47, § 2107.03 (emphasis added).

187. GEISLER, *supra* note 99, at 219.

188. *Cf.* Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CALIF. L. REV. 803, 876 (1988) (arguing that the patent system should not employ a patentability test which compromises its primary goal to promote technological progress); *see also* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150–51 (1989) (noting that the patent system seeks to incentivize inventors who in turn provide the public with new and useful advances in technology); COMM'N ON INTELLECTUAL PROP. RIGHTS IN THE KNOWLEDGE-BASED ECON., NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 41 (Stephen A. Merrill et al. eds., 2004) (explaining that accommodating new technologies is an important condition for innovation).

189. *See, e.g.*, Lemley, *Rational Ignorance*, *supra* note 2, at 1504–05 (suggesting that a firm may obtain a patent to "stake their claim" in an area of technology to signal to investors and competitors that it operates at the cutting edge); Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 647–49 (2002) (arguing that firms obtain patents to show their R&D acumen or technological capacity).

III. TOWARD OBJECTIVE GATEKEEPING

A. Theoretical Underpinnings of the Proposed Framework

The key technical question for gauging operability under § 101 is whether the invention can achieve the intended result.[190] Closely related to operability is the enablement requirement of § 112 ¶ 1.[191] Aside from policing claim scope,[192] it ensures that a PHOSITA can actually make and use what the applicant discloses.[193] Thus, operability and enablement both help to safeguard the technical integrity of issued patents by screening out inventions that cannot work.[194]

Given the close relationship between the two statutory requirements, one might ask if it is possible to merge the § 101 and § 112 ¶ 1 analyses into a single issue when operability is contested. While a merger is possible, the single focus should be enablement.[195] As explained below, a robust enablement analysis can effectively

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190. *In re* Cortright, 165 F.3d 1353, 1357 (Fed. Cir. 1999); *see also In re* Ruskin, 354 F.2d 395, 396 (C.C.P.A. 1966) ("A process is operative if it produces its intended result.").

191. *See supra* notes 47–50 and accompanying text.

192. 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); *see also* Kara Tech. Inc. v. Stamps.com Inc., 582 F.3d 1341, 1347–48 (Fed. Cir. 2009) ("It is the claims that define the metes and bounds of the patentee's invention . . . [and] define the scope of patent protection." (citing Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989)). Enablement serves as a constraint on claim scope. *See* O'Reilly v. Morse, 56 U.S. (15 How.) 62, 121 (1854) (explaining that a patentee "can lawfully claim only what he has invented and described, and if he claims more his patent is void"); Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999) (explaining that the purpose of the enablement requirement 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"); Merges & Nelson, *supra*, at 845–52. The scope of enablement is the sum of what is taught in the written description plus what is known by a PHOSITA without undue experimentation. *Nat'l Recovery Techs.*, 166 F.3d at 1196.

193. Bayer AG v. Schein Pharms., Inc., 301 F.3d 1306, 1314 (Fed. Cir. 2002) ("The enablement requirement ensures that that a specification shall disclose an invention in such a manner as will enable one skilled in the art to make and utilize it.").

194. As the Federal Circuit recently explained:

> Enablement is closely related to the requirement for utility, [which] prevents mere ideas from being patented. As we noted [previously], "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable . . . . Tossing out the mere germ of an idea does not constitute enabling disclosure."

In re '318 Patent Infringement Litig., 583 F.3d 1317, 1323–24 (Fed. Cir. 2009) (quoting Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997)).

195. In a nonprecedential opinion dealing with cold fusion, the Federal Circuit seemingly did the opposite; meaning that the court collapsed the two issues into a question of operability. *See In re* Dash, 118 F. App'x 488, 490–92 (Fed. Cir. 2004).

ferret out impossible inventions *by itself* with no need for or help from its statutory cousin.[196] Importantly, § 112 ¶ 1 can perform the gatekeeping role through an objective, technical analysis rather than through subjective credibility assessments that lie at the heart of the operability paradigm.[197] This enablement-based approach for determining whether an invention works would eliminate the need for the § 101 operability requirement.[198]

Before explaining how § 112 ¶ 1 can perform the gatekeeping role, it is important to define more precisely what it means for an invention to be enabled. Enablement exists if a PHOSITA, after reading the applicant's disclosure, can practice the full scope of the claimed invention *at the time of filing*[199] without undue experimentation.[200] Enablement is a legal conclusion that rests on underlying factual inquiries.[201]

In *In re Wands*, the Federal Circuit set forth several factors relevant to the enablement analysis.[202] They are: (1) the amount of

196. *See infra* Part III.C.

197. *See infra* notes 202–203 and accompanying text. For references to the objective nature of the enablement requirement, see Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1366 (Fed. Cir. 2010) (en banc) (Rader, J., concurring in part and dissenting in part) (noting that enablement is an objective inquiry which focuses on the four corners of the applicant's written description); *Bayer*, 301 F.3d at 1314 (explaining that "an enabling disclosure by definition turns upon the objective understanding of a [PHOSITA]"); Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1050 (Fed. Cir. 1995) ("[T]he enablement requirement . . . looks to the objective knowledge of [a PHOSITA]."); *In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971) (explaining that since § 112 ¶ 1 only requires "objective" enablement, precisely how an applicant complies with it is immaterial); 2 R. CARL MOY, MOY'S WALKER ON PATENTS § 7:45 (4th ed. 2008) (noting that enablement "address[es] whether the technological quality of the [applicant's disclosure] meets an objective, minimum standard").

198. In addition, it might be easier for an examiner to build and sustain a nonenablement rejection than one based on inoperability. Chambers, *supra* note 57, at 96.

199. *In re* Glass, 492 F.2d 1228, 1232 (C.C.P.A. 1974); *accord* Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371–72 (Fed. Cir. 1999) (explaining that in both patent examination and litigation 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."); *In re* Hogan, 559 F.2d 595, 607 (C.C.P.A. 1977) (reaffirming rule).

200. *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993); *see also* Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008) (reaffirming the standard). If the disclosure lacks sufficient detail, a PHOSITA can presumably rely on knowledge in the field to fill in the missing information. AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003). 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).

201. *Sitrick*, 516 F.3d at 999. For the applicable standards of review for enablement, see *supra* note 71.

202. 858 F.2d at 737.

direction or guidance presented in the disclosure; (2) the existence of working examples; (3) the nature of the invention; (4) the predictability or unpredictability of the art; (5) the PHOSITA's level of skill; (6) the state of the prior art; (7) the breadth of the claims; and (8) the quantity of experimentation necessary to practice the claimed invention.[203] While not mandatory,[204] the *Wands* factors are ubiquitous in evaluating enablement[205]—probably because they touch on issues that are important in virtually all enablement determinations.[206] These include issues related to the technical scope and substance of the disclosure (factors one and two),[207] the nature of the technology (factors three and four),[208] the PHOSITA's knowledge and skill (factor five),[209] and the claim scope sought (factor seven).[210]

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203. *Id.* The list of factors found its roots in the PTO. *See Ex parte* Forman, 230 U.S.P.Q. 546, 547 (B.P.A.I. 1986) (articulating eight factors for determining undue experimentation).

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

205. *See* 3 CHISUM, *supra* note 134, § 7.03 (collecting cases).

206. 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). Webster Loom Co. v. Higgins, 105 U.S. 580, 586 (1881) ("[A patentee] may begin at the point where his invention begins, and describe what he has made that is new . . . ."); Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534 (Fed. Cir. 1987) ("A patent need not teach, and preferably omits, what is well known in the art.").

207. The technical substance of the disclosure lies at the heart of the enablement analysis. *See supra* notes 192, 193, 200, and accompanying text. The two factors are clustered together because working examples are a form of guidance. Seymore, *Teaching Function*, *supra* note 15, at 641–46.

208. One way to determine the requisite amount of teaching is whether the underlying technology is "unpredictable" or "predictable." The experimental sciences are regarded as "unpredictable" because PHOSITAs often cannot predict if a reaction protocol that works for one embodiment will work for others. *See, e.g.*, Cedarapids, Inc. v. Nordberg, Inc., No. 95-1529, 1997 WL 452801 at *2 (Fed. Cir. Aug. 11, 1997) (explaining that in the chemical arts, "a slight variation . . . can yield an unpredictable result or may not work at all"). On the other hand, inventions in applied technologies like mechanical engineering are often regarded as "predictable" arts because they are rooted in well-defined, predictable factors. *In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991). For a deeper exploration of the predictable-unpredictable dichotomy, see Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 NW. J. TECH. & INTELL. PROP. 278, 282–84 (2008) [hereinafter Seymore, *Enablement Pendulum*]; Seymore, *Heightened Enablement*, *supra* note 15, at 136–54.

209. 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 Pharms., 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). For commentary on the importance of the PHOSITA in the enablement context, see Seymore,

For present purposes, the *Wands* factors are useful in two respects. First, they provide the decisionmaker with a list of objective, technical issues to consider in gauging enablement. Second, they are well suited to handle inventions emerging from new, poorly understood, and paradigm-shifting technologies, as well as those from fields with a poor track record of success. Most (if not all) seemingly impossible inventions can be so classified.[211] Thus, a decisionmaker can use the factors to readily resolve whether a seemingly impossible invention can achieve the intended result.

B. Formulating a Screen

1. The Challenge

Given that enablement is a fact-intensive inquiry,[212] it stands to reason that certain *Wands* factors can be more relevant than others in a particular case.[213] It also stands to reason that for inventions which have similar characteristics, the same subset of *Wands* factors are always highly relevant since similar inventions present similar enablement challenges.[214] In the case of seemingly impossible inventions, the most relevant subset of factors are those closely related to the PHOSITA's knowledge and abilities. To explain why, it is helpful to consider the challenges faced by a PHOSITA who wants to practice a seemingly impossible invention. Perhaps the major challenge can be referred to as the knowledge deficit. In the technologies from which seemingly impossible inventions usually emerge, there tends to be little or no helpful knowledge from which the PHOSITA can draw. The knowledge deficit can stem from a poor track record of success, the paradigm-shifting nature of the

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Enablement Pendulum, *supra* note 208, at 284–92; Seymore, *Heightened Enablement*, *supra* note 15, at 134–39.

210. 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).

211. *See supra* note 118 and accompanying text.

212. *See supra* notes 201–04 and accompanying text.

213. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991). Relatedly, a decisionmaker need not evaluate each factor before making an enablement determination. *Id.*

214. *See, e.g.*, Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004) (noting that nascent technologies "must be enabled with a 'specific and useful teaching.' " (quoting Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1367–68 (Fed. Cir. 1997)); *In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991) (noting that the requisite level of disclosure for an invention involving predictable mechanical or electrical elements is less than that required for the unpredictable arts).

technology, or other reasons.[215] This means that determining the PHOSITA's level of skill (being careful not to overestimate it)[216] and the technical scope and substance of the disclosure are very important because the PHOSITA must rely heavily, if not exclusively, on the instruction provided within the four corners of the patent document in order to practice the invention.[217]

Given the importance of the patent document, it is clear that the patentee needs to provide a disclosure of high technical quality. The best way to do this is with working examples.[218] They show with actual technical detail that the invention can really achieve the intended result.[219] As explained below, it is this technical detail that

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215. *See supra* note 211 and accompanying text.

216. Recall that enablement is always assessed retrospectively. *See supra* note 199. Overestimating the PHOSITA's level of skill typically happens for two reasons. First, the PHOSITA's knowledge and abilities can evolve over time, most notably between the time of filing and the time of the enablement analysis. As Professor Holbrook has explained, "Enablement, while conceptually simple, is legally and factually complex [because] whether a disclosure is enabling can shift over time; as the knowledge of the PHOSITA shifts, an identical disclosure may shift from not being enabled to being enabled." Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 130 (2006) (internal citation omitted) [hereinafter Holbrook, *Possession*]; Timothy R. Holbrook, *Equivalency and Patent Law's Possession Paradox*, 23 HARV. J.L. & TECH. 1, 41–43 (2009) (making a similar argument). Second, there is the problem of hindsight bias. It "will normally lead fact-finders to overestimate the level of skill in the art, since subsequent advances will suggest that the invention could not have been that difficult to do." Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1199 (2002); *cf.* Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration That the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391, 1402 (2006) ("Critical for patent law, once individuals have hindsight information, they consistently exaggerate what could have been anticipated in foresight and not only tend to view what has occurred as having been inevitable, but also as having appeared relatively inevitable beforehand."); R. Polk Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of* Festo, 151 U. PA. L. REV. 159, 205 (2002) ("[In considering] enablement, which is measured through the lens of the knowledge of the relevant field as of the filing date of the patent application[,] [a]s the filing date becomes distant, the potential for cognitive biases, such as a hindsight bias, increases.").

217. *Cf. Chiron*, 363 F.3d at 1254 (making a similar observation for inventions emerging from unpredictable technologies).

218. Seymore, *Teaching Function*, *supra* note 15, at 642.

219. Mazzari v. Rogan, 323 F.3d 1000, 1005 (Fed. Cir. 2003) (citing Cooper v. Goldfarb, 154 F.3d 1321, 1327 (Fed. Cir. 1998)). Of course, working examples vary in technical quality and helpfulness to the PHOSITA. Relevant variables include how the research was performed (and in particular, whether it was done according to the scientific method), the amount of information disclosed, lucidity, logical reasoning, and other factors. *See* HEATHER SILYN-ROBERTS, WRITING FOR SCIENCE AND ENGINEERING 39–44 (2000) (explaining how to disclose experimental results). The broader point is that the presence of working examples does not necessarily guarantee enablement. Importantly for present purposes, they must show a nexus between the claimed result and the supporting evidence. *In re* Oelrich, 666 F.2d 578, 581 (C.C.P.A. 1981) ("The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to satisfy enablement]."). The facts in the baldness case *In re* Cortright, 165 F.3d 1353, 1353 (Fed. Cir.

makes the existence of working examples the most important *Wands* factor for seemingly impossible inventions.

2. The Importance of Working Examples

It is axiomatic that the best way to teach a technical subject is with working examples.[220] They lie at the core of technical publications because they provide the best form of guidance and direction for replicating what is disclosed therein.[221] In patent documents, their presence "facilitates, if not ensures, enablement of an invention."[222]

Working examples can perform functions that extend beyond teaching. Of particular importance for present purposes is an evidentiary function. Providing a tangible method for achieving the intended result establishes credibility by signaling that the underlying research represents good science.[223] Indeed, working examples

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1999), provide a good example. One claim at issue recited a method of treating the scalp with an ointment in which the active ingredient reached the base of the hair follicle. *Id.* at 1355. The court affirmed the PTO's rejection of this claim because the written description failed to provide sufficient evidence, through actual observations or otherwise, which would allow a PHOSITA to conclude that the ingredient actually reached the base of the hair follicle. *Id.* at 1360 (explaining that the statements "*[i]t is believed*" or "applicant *surmises* that" did not constitute actual observations) (emphasis in original).

220. *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 15, at 641–54 (making a similar argument in the patent law context).

221. *See, e.g.*, BERT 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); SHAMOO & RESNIK, *supra* note 33, at 51 ("The ability of other investigators to replicate the experiments by following the method in the published report is crucial to the advancement of science.").

222. Bratislav Stankovic, *The Use of Examples in Patent Applications*, 18 INTELL. PROP. & TECH. L.J. 9, 10 (2006). 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 192. A teaching which lacks specificity or provides inadequate guidance will result in a narrow(ed) claim scope (*Wands* factor eight). BURK & LEMLEY, *supra* note 2, at 115.

223. *See* MARGARET CARGILL & PATRICK O'CONNOR, WRITING SCIENTIFIC RESEARCH ARTICLES 35 (2009) (noting that a goal for disclosing experimental procedures is to establish credibility in the work); MARTHA DAVIS, SCIENTIFIC PAPERS AND PRESENTATIONS 61 (2005) (explaining that the experimental section of a scientific paper "is the very foundation of the scientific merit and feasibility of the work"); DAY & GASTEL, *supra* note 221, at 61 (arguing that working examples are essential for showing that the potential for reproducing the result exists; otherwise the work is not good science).

distinguish good science from speculative theories by extinguishing the fires of suspicion.[224]

The facts in *In re Eltgroth* illustrate this point.[225] The applicant claimed a method for controlling aging by manipulating the concentration of isotopes of specific elements within an organism.[226] While the applicant produced scientific literature that taught how to manipulate isotope concentrations, the applicant did not explain how doing so could control aging.[227] The failure to provide a tangible method for achieving the intended result led the PTO to reject the claim under both § 112 ¶ 1 and § 101.[228] In affirming the rejection, the C.C.P.A. noted the inadequate teaching and "a conspicuous absence of proof" in the disclosure:

> Not one example is given. Not one isotope [affecting] aging is identified . . . . Moreover, appellant has . . . failed to show how knowledge available to [PHOSITAs] would enable them to make and use his invention despite the lack of specific disclosure . . . . [A]ppellant has provided no more than a speculative theory or hypothesis . . . .[229]

The applicant's inadequate teaching essentially required a PHOSITA to engage in undue experimentation to achieve the intended result.[230]

Working examples also provide the best evidence that what was impossible at one point in time is now possible (a *Type III* impossibility).[231] Similarly, the absence of working examples can

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224. *See* David S. Wainwright, *Patenting Around Nuisance Prior Art*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 221, 224 (1999) (explaining that patent applications that lack working examples can raise suspicion because "[i]t can be difficult for one outside the art to know whether a specific item is enabling or not"); *cf. In re* Lorenz, 305 F.2d 875, 878 (C.C.P.A. 1962) (stating that the strong and comprehensive language of § 112 evinces Congress's intent for applicants to "make a full and complete disclosure of their invention, leaving nothing to speculation or doubt").

225. 419 F.2d 918, 918 (C.C.P.A. 1970).

226. Isotopes are atoms of a particular element with which differ in the number of neutrons. Importantly, isotopes of a given element differ in chemical properties. *See generally* LINUS PAULING, GENERAL CHEMISTRY (3d ed. 1988).

227. *Eltgroth*, 419 F.2d at 921.

228. *Id.* at 919–20. The PTO found a statement in Supreme Court opinion particularly appropriate: "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. [A] patent system must be related to the world of commerce rather than to the realm of philosophy." Brenner v. Manson, 383 U.S. 519, 536 (1966) (quoting *In re* Ruschig, 343 F.2d 965, 970 (C.C.P.A. 1965) (Rich, J.)).

229. *Eltgroth*, 419 F.2d at 921.

230. *Id.*

231. In other words, working examples can show that the state of the art has advanced far enough to allow a PHOSITA to achieve the intended result. *See* discussion *supra* notes 37–39 and accompanying text. For instance, working examples helped convince the PTO 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

signal that a putative invention is per se impossible (*Type I*) or pseudoscientific (*Type II*). Hence, enablement matters because there is no way that an applicant claiming an invention falling into one of these two categories can provide a *working* example that achieves the intended result.[232]

In sum, working examples allow § 112 ¶ 1 to provide an objective route to elucidating whether a seemingly impossible invention can achieve the intended result. Given their central role in the enablement analysis, it has been argued that there should be an across-the-board working example requirement in patent law[233] except for inventions in which enablement "is so apparent as to virtually jump off the page and slap a PHOSITA in the face."[234]

C. Applying the Framework

The basic proposition of this Article is that the enablement requirement of § 112 ¶ 1 can effectively ferret out truly impossible inventions *by itself* with no need for or help from its § 101 statutory cousin. Part III.C.1 presents a hypothetical—based on an actual patent case[235]—illustrating the mechanics of the enablement-based framework. Part III.C.2 explores the plausibility of the proposal.

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for cancer, which lacked specific tests, experiments, or clinical data, asserted incredible utility in the light of the knowledge of the art), *with In re* Jolles, 628 F.2d 1322, 1326–28 (C.C.P.A. 1980) (concluding that clinical tests, combined with the close structural similarity of the claimed compounds with chemotherapeutics known in the art, would allow a PHOSITA to accept the claimed utility), *and In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (noting that treating cancer with chemical compounds "does not suggest an inherently unbelievable undertaking or involve implausible scientific principles" because there are "numerous successful chemotherapeutic agents").

232. *Cf.* Seymore, *Teaching Function*, *supra* note 15, at 653 (arguing that it is easiest for an examiner to gauge enablement when actual experimental results are disclosed).

233. *See* Seymore, *Heightened Enablement*, *supra* note 15, at 156–58; Seymore, *Teaching Function*, *supra* note 15, at 641–54. Professor Cotropia also advocates an actual reduction to practice requirement in patent law. *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 PTO would defer examination until the applicant submits evidence of actual implementation of the invention).

234. Seymore, *Heightened Enablement*, *supra* note 15, at 156 n.15 (internal quotation marks and brackets omitted); *cf.* Ash v. Tyson Foods, Inc. 546 U.S. 454, 456–57 (2006) (per curiam) (quoting Cooper v. Southern Co., 390 F.3d 695, 732 (11th Cir. 2004)) (evaluating the "jump off the page" standard in the context of an employment discrimination suit). Invoking a working example requirement probably falls within the PTO's statutory authority. *See supra* note 82 (discussing the working model requirement of 35 U.S.C. § 114); Seymore, *Teaching Function*, *supra* note 15, at 642 n.103 (same).

235. 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*, CHEMICAL NEWS, Aug. 6, 1897, at 61–63 (describing the claimed method); Adolf G.

1. Mechanics

Suppose that an inventor files a patent application claiming a method of using heat to transform antimony[236] into gold.[237] 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.[238]

An examiner with expertise in the field reads the application and checks it for compliance with the statutory patentability requirements.[239] Focusing on enablement, the patent application is presumptively enabled as filed.[240] To establish a prima facie case of nonenablement,[241] the examiner bears the initial burden of setting forth a reasonable explanation as to why the enablement provided by the applicant is not commensurate with the claim scope sought.[242] The examiner must explain any doubts as to the accuracy of any statement with evidence or reasoning rooted in fact.[243]

Vogeler, *A Nineteenth Century Gold Factory*, PHARM. J., Feb. 26, 1898, at 189–91 (presenting additional experimental details).

236. Antimony is a chemical element typically obtained from complex mineral ores containing lead, tin, zinc, silver, and gold. *See* NICHOLAS C. NORMAN, CHEMISTRY OF ARSENIC, ANTIMONY, AND BISMUTH 43 (1998).

237. This claim sounds like alchemy: the transmutation of one chemical element into another in a nonradioactive process. *See supra* note 26 and accompanying text.

238. In the actual case, the inventor shared his theory of transmutation with a reporter:

> [Brice] depends almost entirely upon a decomposition of the atomic properties of the antimony and a radical reconstruction as a new body [using] intense heat and the free admission of oxygen. This is nature's process, and is exemplified in the volcanic action by which most of the gold existing in a natural state was formed. [Some researchers believe] that at some long-ago period tremendous convulsions of subterraneous gas threw up from the earth's interior some metallic substance, which underwent a transmutation into gold. [Brice chose antimony as a starting material] mainly because it is found in considerable quantity [in] gold ores.

Chicago Alchemist Thinks that by Following in Nature's Pathway to Make Gold of Dross, CHI. TRIB., Dec. 12, 1897, at 33. Brice built a gold-making factory in Chicago which processed over 10,000 pounds of crude ore per day. *See* Vogeler, *supra* note 235, at 189–90 (describing the daily operation of the National Metallurgical Company).

239. *See supra* note 7 (reciting the conditions for patentability).

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

241. An examiner must prove unpatentability by a preponderance of the evidence. *See In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (articulating the burden-shifting framework used in patent examination).

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

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

The examiner undertakes a *Wands* analysis by construing the claim (factor seven),[244] determining the PHOSITA's knowledge and level of skill (factor five),[245] and evaluating the teaching provided in the written description (factors one and two)[246] in light of the nature of the technology (factors three and four).[247] 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.[248] 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 [which] consist of [minerals containing] silver or *gold*."[249] Based on the totality of the evidence,[250] the examiner rejects the claim as prima facie nonenabled under § 112 ¶ 1 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.[251]

Next, the examiner sends the rejection to the applicant accompanied with a request for information regarding the source and purity of the antimony.[252] The applicant responds by disclosing that

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244. *See* MPEP, *supra* note 47, § 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) (explaining that because a patent's written description must enable the full scope of the claimed invention, the enablement inquiry typically begins with a construction of the claims).

245. *See supra* notes 209 and 216 and accompanying text.

246. *See supra* note 207.

247. *See supra* note 208.

248. *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 571 (Gershon J. Shugar & Jack T. Ballinger eds., 4th ed. 1996) (listing grades of purity).

249. 3 KIRK-OTHMER ENCYCLOPEDIA OF CHEMICAL TECHNOLOGY 42 (Arza Seidel ed., 5th ed. 2007) (emphasis added).

250. *See* MPEP, *supra* note 47, § 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").

251. *See supra* note 203 and accompanying text.

252. 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 item." 37 C.F.R. § 1.105 (a)(1)(viii) (2009).

the antimony is technical grade (lowest purity) obtained from Acme Metals Company in Yellow Pine, Idaho.[253] Further research reveals that Yellow Pine has one of the largest gold-antimony deposits in the nation[254] 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.[255] When presented with this information, the applicant decides to abandon the application.[256]

The foregoing hypothetical illustrates two important points. First, it shows that a *Wands* analysis can ferret out a truly impossible invention by itself without a subjective credibility assessment. The claimed method in the hypothetical involves alchemy.[257] Aside from being a *Type I* impossibility,[258] modern alchemistic claims often conjure up notions of fraud.[259] Yet, the examiner did not need to venture down the credibility path because obtaining more detail about the working example revealed the applicant's error.

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253. 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 248, at 571.

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

255. The story in the actual case is quite interesting. After receiving two inoperability rejections, Brice asked the PTO for permission to demonstrate the claimed process. *See* Bolton, *supra* note 235, at 62. Since the PTO 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. 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 to the Honorable R. E. Preston, Director of the Mint, Washington, D.C. (May 22, 1897)). As to the final disposition, Brice argued that the PTO rejected his application out of fear of a "monetary panic." Vogeler, *supra* note 235, at 189.

256. 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 7.

257. *See supra* notes 26 and 237 and accompanying text.

258. *See supra* notes 25–27 and accompanying text. *But see* Vogeler, *supra* note 235, at 190 ("No one should presume to pronounce the transmutation of one element into another an impossibility, but it seems an infinite improbability.").

259. WILLIAM R. NEWMAN & LAWRENCE M. PRINCIPLE, ALCHEMY TRIED IN THE FIRE 12 (2005); *see also* HERBERT S. REDGROVE, BYGONE BELIEFS 102 (1999) (contrasting "genuine" alchemists of ancient times with those who entered the quest in modern times).

Second, it shows that many incredible claims can be traced to faulty experimental technique.[260] As the late Professor John Ziman explained in his book *Real Science*, experimental researchers must work under "carefully contrived circumstances" where "all other potential disturbing factors are eliminated" so that "the explanation for the observed [result is] something more interesting than, say, an impure chemical reagent . . . ."[261] In patent law, as in other contexts, a careful examination of the examples provided can readily reveal whether an intended result stems from sloppy research.

2. Plausibility

There is some decisional law that supports the proposition that if the case for nonenablement is very strong, then that is a sufficient base from which to deny patentability notwithstanding deficiencies under § 101. In *In re Speas*,[262] 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."[263]

Two things stand out. First, the "any and all" claim language immediately raises enablement concerns due to its potentially limitless breadth.[264] Second, any device that could continuously convert heat completely to work without any additional energy input would violate the Second Law of Thermodynamics.[265] A closer look at the applicant's description of the invention reveals, however, that the

260. ZIMAN, *supra* note 92, at 94.

261. *Id.*

262. 273 F. App'x 945 (Fed. Cir. 2008) (per curiam) (nonprecedential).

263. *Id.* at 946 (emphasis added).

264. *See 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, non-pathogenic vaccines, and processes for making these vaccines").

265. 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 (3d ed. 2010). A machine that could do so would be one hundred percent efficient. Such machines are referred to as perpetual motion machines of the second kind. *Id.* Curiously, the term "perpetual motion" does not appear either in the PTO documents or in the Federal Circuit opinion.

disclosed device does not do so because it actually draws in thermal energy from the surroundings.[266]

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.[267] The Board explicitly affirmed each rejection.[268] Although the PTO argued both issues in its appeal 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.[269] This argument makes sense because if the device did not violate the Second Law of Thermodynamics, the applicant's disclosure would be nonenabling.

The Federal Circuit adopted this reasoning and affirmed on nonenablement grounds. The court held that the Board's rejection was supported by substantial evidence because the applicant's "particularly broad" and "limitless" claim was not enabled by a description which was commensurately broad in its teaching.[270] 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 credibility assessment.[271]

Both *Speas* and the hypothetical presented above show that whether an invention can achieve the intended result is a yes-or-no question. If the answer is no, then § 112 ¶ 1 alone can resolve the issue because there is no way that the applicant can provide an enabling description for a true impossibility.[272] In other words, a

266. *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.").

267. *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).

268. Brief for Appellee, *supra* note 267, at 9–10.

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

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

271. 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.

272. *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.").

careful examination of the working example will reveal the fatal flaw.[273] Analytically, this means that the decisionmaker can use technical factors like claim breadth and the substantive content of the applicant's disclosure to achieve the same ends as the current operability regime but without the current pitfalls. This approach would also streamline patent examination because the examiner would not need to expend the time and effort formulating and building a record to support multiple rejections for a single issue.[274]

D. Policy Tradeoffs

1. Disclosure

Replacing the § 101 operability regime with an enablement-based framework elevates the role of the applicant's disclosure[275] and the PHOSITA's level of skill in resolving the workability question. The key metric for gauging enablement in the proposed framework is the working example. But the idea of ratcheting up enablement,[276] especially through a working example requirement, implicates a larger debate over the appropriate role of disclosure in patent policy.[277]

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273. *See* 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").

274. *See supra* text accompanying note 195.

275. The disclosure is the technical information provided in the patent application about the invention (including working examples). As discussed above, the disclosure must satisfy the requirements of § 112 ¶ 1, including enablement, adequate written description of the invention, and the revelation of the best mode of carrying it out. *See supra* note 47.

276. Other commentators have argued for a robust enablement requirement. *See, e.g.*, Mark D. Janis, *On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J.L. & POL'Y 55, 108 (2000) (arguing that a vigorous enablement requirement could lead to the development of more coherent patentability guidelines).

277. Patent scholars differ in their views on the role of the disclosure. *Compare* Holbrook, *Possession*, *supra* note 216, at 126, 133–47 (describing the "pervasive" role of disclosure in patent law and policy, including enriching the state of the art contemporaneously with the invention and showing evidence of possession of the invention), *and* Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 547–54 (2009) (cataloguing the beneficial uses for disclosure in patent law; including stimulating innovation, preventing duplication, gauging patentability, and signaling R&D strength), *with* Alan Devlin, *The Misunderstood Function of the 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 no more than an ancillary role within the larger purpose of the patent regime").

Clearly the enablement analysis is easiest when the applicant can point to actual experimental results as proof that the invention works. Such results are a prerequisite for communal acceptance in mainstream science.[278] Patent law, however, is not so demanding.[279] Actual experimentation is not a prerequisite for patenting.[280]

It is understandable why an inventor may choose to file a patent application with minimal teaching. First, most would agree that for simple inventions, there is no need for experimentation if the technology is so easy to understand that a PHOSITA can readily figure out the details.[281] Second, sometimes inventors must obtain patents at an early stage of R&D (well before identifying a marketable product) in order to attract investors.[282] Third, applicants must often file early in order to safeguard patent rights both in the United States[283] and abroad.[284]

Patent theory posits that early filing facilitates the entry of new technical knowledge into the public domain,[285] which in turn serves as building blocks for further innovation.[286] Filing too early,

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278. *See supra* note 221 and accompanying text.

279. *See supra* Part II.A.2.

280. *See supra* note 76 and accompanying text.

281. *See* discussion *supra* note 208 (noting that the PHOSITA needs less guidance in predictable fields). For a concrete example, see Seymore, *Teaching Function*, *supra* note 15, at 644 (contending that for a patent claiming a broom rake, a PHOSITA would not benefit from a working example because the technology is easily understood).

282. *See, e.g.*, Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 144 (2000) ("[O]ne of the reasons people are patenting at a very early stage in the process is precisely in order to attract or appease venture capital.").

283. 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) (2006). Likewise, if the invention is used in public, sold, or subject to an offer for sale in the United States, the applicant must file within one year of the event. *Id.* 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). Similarly, § 102(g) "penaliz[es] the unexcused delay or failure of a first inventor to share the benefit of the knowledge of the invention with the public after the invention has been completed." Checkpoint Sys., Inc. v. U.S. Int'l Trade Comm'n, 54 F.3d 756, 761 (Fed. Cir. 1995) (citation and internal quotation marks omitted).

284. The one-year grace period available in the United States is not available in many foreign countries. In fact, most countries have an absolute novelty requirement such that any prefiling disclosure, including activity by the inventor, is patent-defeating. *See, e.g.*, Convention on the Grant of European Patents, art. 54(2), Oct. 5, 1973, 1065 U.N.T.S. 255, 272. Accordingly, if foreign filing is a possibility, the applicant must take steps to avoid inadvertent or premature disclosure. DAVID A. BURGE, PATENT & TRADEMARK TACTICS AND PRACTICE 127–36 (3d ed. 1999).

285. *See* John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 445 (2004) (arguing that early filing leads to reduced patent terms, thereby dedicating the invention to the public at an earlier time).

286. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989); *see also* Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979) (noting that one goal of patent law is

however, can have serious consequences for the patent system.[287] Of particular importance for present purposes are two problems that arise from disclosing and patenting an underdeveloped invention. First, a feeble, nontechnically robust disclosure enters into the patent literature, which provides dubious guidance to the PHOSITA, adds little or nothing to the public storehouse of knowledge, and supplies little technical fodder for follow-on researchers to build upon.[288] Second, roadblocks are created for other inventors,[289] including the ability to dominate other technological innovations that only subsequent workers in the field can actually enable.[290] An across-the-

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"[to] promote [] disclosure of inventions to stimulate further innovation"); Transco Prods. Inc. v. Performance Contracting, Inc., 38 F.3d 551, 558 (Fed. Cir. 1994) (rejecting an interpretation of § 112 which would "subvert the patent system's goal of . . . encouraging early disclosure."); W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1550 (Fed. Cir. 1983) ("Early public disclosure the linchpin of the patent system.") (citation omitted).

287. *See, e.g.*, Cotropia, *supra* note 233, at 87–119 (presenting a comprehensive analysis of the costs of early filing on the patent system); Seymore, *Teaching Function*, *supra* note 15, at 659 (arguing that the current disclosure framework can thwart innovation).

288. In other words, the disclosure probably lacks sufficient technical detail to be helpful. Thus, it does little to advance technological progress, which is commanded by the Constitution. Graham v. John Deere Co., 383 U.S. 1, 6 (1966).

289. A good example is when an early filer strategically drafts claims which cover undeveloped technology. *See* BESSEN & MEURER, *supra* note 121, at 67 (arguing that the practice "penalizes real innovators who operate in the shadow of early, broad claims"); Michael J. Meurer & Craig Allen Nard, *Invention, Refinement and Patent Claim Scope: A New Perspective on the Doctrine of Equivalents*, 93 GEO. L.J. 1947, 1975 (2005) (exploring the practice).

290. Seymore, *Teaching Function*, *supra* note 15, at 660. Another commentator elaborates on the scope and consequences of the problem:

> The further a patent moves away from a requirement that the inventor actually have a complete and operative invention [at the time of filing], the broader the patent's scope and the greater potential that the [claims] will protect speculative ideas . . . With just a little time, money, and imagination, one may . . . without inventing anything . . . [obtain a patent with] claims that are broad enough to [encompass] technology developed for the first time years after the inventor first files an application . . . . [This can have] an undue chilling effect on the behavior of later scientists [and] researchers . . . who (sometimes many years later) through their own experimentation, hard work, and trial and error[,] succeed in [creating] a bona fide product or process that actually works.

Christopher A. Harkins, *Fending Off Paper Patents and Patent Trolls: A Novel "Cold Fusion" Defense Because Changing Times Demand It*, 17 ALB. L.J. SCI. & TECH. 407, 453 (2007). A good illustration involves *Type III* impossibilities, which were defined earlier as quests which are impossible at time *X* but might become possible at time *Y*. *See supra* Part I.B. Suppose inventor *A* obtains a patent at time *X* and inventor *B* obtains a patent for a new and nonobvious improvement at time *Y*. In order to practice the improvement, *B* must get a license from *A*. *See* Merges & Nelson, *supra* note 192, at 860–61 (explaining dominant and subservient patents). If *B* wants to avoid a license, *B* must challenge *A*'s patent in court and prove by clear and convincing evidence that *A*'s presumptively valid patent is invalid for nonenablement. ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010). Also, *B* may have a hard time getting the improvement patent because the PTO can assert the disclosure of *A*'s patent as prior art against *B*'s claim, most likely for a lack of nonobviousness. *See* 35 U.S.C. § 103. To make matters worse for *B*, the Federal Circuit has held that the examiner can *presume* that *A*'s disclosure is enabled,

board working-example requirement would ameliorate, if not eliminate, each of these problems.[291]

Although it is perhaps counterintuitive, an enablement-based approach might actually attract inventors to the patent system who would otherwise forego the patenting process under the status quo. To unpack this argument, consider that inventors claiming the impossible (or for that matter, any invention) want to believe that they will get—and are, in fact, entitled to—a fair shot at getting a patent. However, inventors who believe that the PTO and the courts are biased against granting patents for certain types of inventions (which is likely under a regime rooted in subjective credibility assessments) may decide not to waste their time and money pursuing a patent if a denial is inevitable.[292] Put simply, "inventors respond to how the Patent Office behaves."[293] Under the enablement-based approach proposed herein, an inventor with a seemingly impossible claim who knows that it will receive an objective, technical examination might decide to try getting a patent. This will give the patent system the benefit of a disclosure that it otherwise would lose.

2. Promoting Scientific and Technological Progress

With any proposed patent reform we might ask how it aligns with the patent system's overarching goal to promote scientific and technological progress.[294] As explained below, an objective,

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meaning that the examiner need not elucidate if what *A* discloses really works. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355 (Fed. Cir. 2003); *see also* Seymore, *Rethinking Novelty*, *supra* note 15, at 940–46 (criticizing this presumption). To win, *B* must rebut the presumption by a preponderance of the evidence. *In re* Sasse, 629 F.2d 675, 681 (C.C.P.A. 1980). The basic point is that in both cases *B* has to prove nonenablement for a patent that never should have issued. *Cf.* Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 765 (2002) (suggesting that concerns related to the PTO's issuance of "facially" invalid patents may stem from the examiner's inability to accurately determine the scope and content of the prior art).

291. *See* Seymore, *Teaching Function*, *supra* note 15, at 652–66.

292. This is the case for perpetual motion and cold fusion, which automatically raise red flags in the PTO. *See supra* notes 4–6, 81–82 and accompanying text. Again, a working example requirement would eliminate the need for special treatment.

293. JAFFE & LERNER, *supra* note 3, at 175.

294. 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* Bilski v. Kappos, 130 S. Ct. 3218, 3236 (2010) (Stevens, J., concurring) (explaining that Intellectual Property Clause empowered Congress "to pass a series of patent laws . . . as a means of encouraging innovation"); Eldred v. Ashcroft, 537 U.S. 186, 223 (2003) (noting that the constitutional command is the "ultimate purpose" of the patent system); Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502, 511 (1917) (observing that "the

enablement-based approach for elucidating whether an invention works is better suited for achieving this goal than the current operability regime.

Recall that at present the examiner turns to mainstream science to answer the workability question.[295] Elucidating whether an invention "borders on the incredible in light of contemporary knowledge [in the field],"[296] "suggest[s] an inherently unbelievable undertaking,"[297] "involve[s] implausible scientific principles,"[298] or "appear[s] to run counter to what would be believed would happen"[299] depends on what the scientific community views as credible at a particular moment in time. And it will not give its imprimatur to a research claim unless and until it passes through the knowledge filter. If an inventor seeks a patent before this happens, then the credibility lag will lead to a patent denial regardless of the claim's technical merit.[300] Clearly such a regime prevents patent law from sitting at the cutting edge of science and technology.[301]

This artifact of the operability regime conflicts with the fundamental goal of the patent system—that is, to encourage the rapid dissemination of technical knowledge.[302] As soon as a patent

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primary purpose of our patent laws . . . is 'to promote the progress of science and useful arts' "). Scholars have sought to clarify the meaning of the constitutional language. *See, e.g.*, EDWARD WALTERSCHEID, THE NATURE OF THE INTELLECTUAL PROPERTY CLAUSE 125–26 (2002) (explaining that in the latter part of the eighteenth century, the term "science" was synonymous with "knowledge" and "learning"); 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) (noting that the term "useful arts" is synonymous with the word "technology").

295. *See supra* Part II.B.1.

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

297. *In re* Jolles, 628 F.2d 1322, 1327 (C.C.P.A. 1980).

298. *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

299. *In re* Pottier, 376 F.2d 328, 330 (C.C.P.A. 1967).

300. *See supra* Part II.B.2.

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

302. Brenner v. Manson, 383 U.S. 519, 533 (1966) ("[O]ne of the purposes of the patent system is to encourage dissemination of information concerning discoveries and inventions."); *see also* Malla Pollack, *What is Congress Supposed to Promote? Defining "Progress" in Article 1, Section 8, Clause 8 of the United States Constitution, or Introducing the Progress Clause*, 80 NEB. L. REV. 754, 778–79 (2001) (arguing that the Intellectual Property Clause empowers Congress to create an individual right to exclude through patents only to the extent that those rights promote the dissemination of knowledge). The statutory scheme helps achieve this goal. As discussed above, a fundamental purpose of both § 102(b) and § 102(g) is to encourage prompt filing. *See supra* note 283. In addition, recent amendments to the patent statutes facilitate quicker dissemination. For instance, until recently, patent applications were kept in secret unless and until the patent issued. Now, most patent applications filed on or after November 29, 2000, publish eighteen months after the earliest effective filing date. *See* American Inventors Protection Act of 1999, 35 U.S.C. § 122(b)(1)(A) (2006).

document publishes,[303] there is hope that the public will use the technical details disclosed therein to improve upon the invention, to design around it, or to engage in other innovative activities.[304] This is where enablement enters the picture. It plays the central role in "safeguard[ing] the patent system's disclosure function by ensuring relatively swift dissemination of technical information from which others . . . can learn."[305] And the knowledge gained will reduce R&D waste,[306] spur creativity,[307] and ultimately extend the frontiers of science and technology.[308]

The preceding discussion highlights the related yet dissimilar ways that mainstream science and patent law seek to promote scientific and technological progress. Clearly both patent law and

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303. *See supra* note 302 (discussing the pregrant publication of patent applications).

304. Fromer, *supra* note 277, at 541. Importantly, the public can engage in these activities during the patent term. As the late Judge Giles S. Rich once explained:

> Another aspect of what we think of as "the patent" which should not be forgotten is that it is not only a grant of right to exclude from the government; simultaneously, it is a publication, making (in principle at least) a full public disclosure of the invention due to § 112 ¶ 1. So even if it 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. ("Literae patentes" = "open letters," in short form, "patents.") . . . .

Janice M. Mueller, *A Rich Legacy*, 14 BERKELEY TECH. L.J. 895, 900 (1999) (quoting an email from Judge Giles S. Rich, Circuit Judge of the U.S. Court of Appeals for the Federal Circuit, to Professor Janice M. Mueller (Aug. 16, 1997)). But, Professor Holbrook argues that the Federal Circuit's evisceration of the common law experimental use exception means that "[o]ne can read the patent but cannot make or use the invention for purposes of exploring its function or the manner in which it works [without risking infringement]." Holbrook, *Possession*, *supra* note 216, at 140; *see also* Ted Hagelin, *The Experimental Use Exemption to Patent Infringement: Information on Ice, Competition on Hold*, 58 FLA. L. REV. 483, 494–504 (2006) (making a similar argument).

305. FTC Report, *supra* note 79, ch. 4, at 3–4; *see also* LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1344 (Fed. Cir. 2005) (describing enablement as the essential aspect of the patent bargain); 3 CHISUM, *supra* note 134, § 7.01 (explaining that among the disclosure requirements, enablement has the deepest historical roots and "lies at the heart of the patent bargain").

306. Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 267 n.79 (1994); *see also* Anthony Murphy, *Intellectual Property*, *in* INNOVATION: HARNESSING CREATIVITY FOR BUSINESS GROWTH 87, 92 (Adam Jolly ed., 2003) (arguing that since patent applications contain a complete description of the relevant technology and are readily accessible online, "[w]hy struggle to solve a technical problem already solved by another and published in [a patent] application?"). One could argue that any delay of entry into the patent system caused by the need to make working examples could actually set the stage for duplicative research efforts. However, it is probably rare that researchers are working on the identical problem in exactly the same way at the same moment in time.

307. *See* 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).

308. *See* ROGER E. SCHECHTER & JOHN R. THOMAS, PRINCIPLES OF PATENT LAW 6 (2004) (noting that patents enrich the public domain and thus support further innovation).

science seek to foster innovative activity through the dissemination of technical knowledge.[309] But then the divergence occurs. Whereas mainstream science emphasizes legitimization of technical knowledge through peer review, patent law emphasizes its quick communication to the public. As long as the patentee provides sufficient information about the invention so that others can understand and practice it,[310] ancillary details such as the inventor's acumen[311] or how or why the invention works are irrelevant.[312]

Some may argue that patent law's indifference to the ancillary details deviates from scientific norms inasmuch as there is an inevitable trade-off between rapid dissemination and credibility. But herein lies the problem: it is not the province of patent law to determine what constitutes credible science; that task belongs

309. In particular, both mainstream science and patent law promote disclosure through publication. Once in the public domain, there is hope that others will build upon those results and engage in further research. *See* Rebecca S. Eisenberg, *Proprietary Rights and Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 184 (1987) (exploring the compatibility and conflicts between the norms of science and patent law). But Professor Eisenberg also points out that to the extent that patent protection "limit[s] the ability of other scientists to use published knowledge, intellectual property law has been perceived within the scientific research community as conflicting with the traditional norms and rewards of science." *Id.*; *see also* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1017 (1989) ("Yet the idea that exclusive rights in new knowledge will promote scientific progress is counterintuitive to many observers of research science, who believe that science advances most rapidly when the community enjoys free access to new discoveries.").

310. *See* J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 (2001) (explaining that to obtain a patent, the applicant "must describe the [invention] with sufficient specificity to enable others to 'make and use' the invention after the patent term expires" (quoting 35. U.S.C. § 112 ¶ 1)). Here it is worth noting that quests which are *per se* impossible (*Type I*) or pseudoscientific (*Type II*) can nevertheless produce knowledge which promotes scientific and technological progress. As one commentator explains:

> The pursuit of the perpetual motion machine . . . has not been fruitless from a scientific point of view. On the contrary, although inventors have never produced a perpetual motion machine, the enormous time and energy invested into building such a fabled machine has led physicists to carefully study the nature of heat engines. (In the same way, the fruitless search of alchemists for [a method to] turn lead into gold[] helped to uncover some of the basic laws of chemistry.)

KAKU, *supra* note 24, at 262–63.

311. *See* Eames v. Andrews (*The Driven-Well Cases*), 122 U.S. 40, 56 (1887) (explaining that an inventor's ignorance of the scientific principles is immaterial as long as the patent's disclosure sets forth the "thing" to be done so that it can be reproduced); Radiator Specialty Co. v. Buhot, 39 F.2d 373, 376 (3d Cir. 1930) ("It is with the inventive concept, the thing achieved, not with the manner of its achievement or the quality of the mind which gave it birth, that the patent law concerns itself."); Earle v. Sawyer, 8 F. Cas. 254, 256 (C.C.D. Mass. 1825) (No. 4,247) (Story, J.) ("It is of no consequence, whether the thing be simple or complicated; whether it be by accident, or by long, laborious thought . . . that it is first done [because the] law looks to the fact, and not to the process by which it is accomplished.").

312. *See* cases cited *supra* note 56.

primarily to the scientific community.[313] This is why the proposed enablement-based framework is better suited for fulfilling patent law's overarching goal of promoting science and technological progress than what prevails today. And, quite fortuitously, the across-the-board working example requirement advocated herein would ameliorate concerns about credibility.

CONCLUSION

Encouraging the attainment of previously unachievable results is a fundamental facet of the patent system. While success clearly benefits the public through new products and processes, the quest to achieve the impossible itself generates a body of technical knowledge that can spur creative activity, foster innovation, and extend the frontiers of science and technology. Yet, the patent system struggles to achieve these ends due to the subjective facets of the current patent examination framework. By adopting an objective approach to gauging patentability for seemingly impossible inventions based on technical merit, the proposed framework will resolve these problems, promote broader goals of patent policy, and contribute to broader debates about the intersection between patent law and science and technology.

313. *See, e.g.*, CHUBIN & HACKETT, *supra* note 93, at 4 (arguing that aside from asserting the autonomy and authority of science, peer review "makes new knowledge claims more credible to the nonscientist because [they] bear the approval of the scientific community"). *But see* Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571 (Fed. Cir. 1992) (explaining that "[w]hile utility and enablement often involve complex scientific principles, the Federal Circuit views them not as "legal abstractions," but as issues "[which] properly devolve on the trier of fact" who, as for other kinds of evidence, "must make determinations of credibility, reliability, and weight"). Despite the drawbacks in using credibility assessments for patentability purposes, they can be useful in other contexts. *See, e.g.*, Daubert v. Merrell Dow Pharms., 509 U.S. 579, 592–94 (1993) (setting forth a five-part test for U.S. judges to evaluate the credibility of scientific testimony for admissibility purposes).