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PATENT LAW'S ROLE IN PROTECTING PUBLIC HEALTH

Sean B. Seymore *

Innumerable inventions implicate public health—including drugs, vaccines, dietary supplements, and sewage treatment plants. Over the past century, the Patent Office and the courts have modulated the ability to obtain or enforce patents for these inventions—whether in response to a public health crisis or to protect the credulous public from unscrupulous inventors. While normative and policy-based arguments can justify these interventions, they've disrupted the delicate balance of two competing policy objectives in patent law—enhancing public welfare and promoting innovation. This Article offers a new approach for courts to protect public health in patent cases—by making public health an affirmative defense to infringement. If the patent owner has engaged in invention-related egregious misconduct that's jeopardized public health, the court could render the patent unenforceable by dismissing the lawsuit. Or the court could render the patent temporarily unenforceable until the misconduct ceases and its ill effects on public health dissipate. This proposal aligns with the increasing use of equitable remedies in patent disputes and raises interesting normative and policy questions about the role of public health issues in patent law.

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INTRODUCTION

The COVID-19 pandemic drew national attention to the intersection of patent law and public health.[1] The race to invent coronavirus vaccines and treatments immediately raised concerns about patenting.[2] There were efforts to suspend COVID-19-related patents or, alternatively, to encourage patent owners to make their COVID-19-related inventions freely available without the threat of litigation.[3] The goal was to prevent patents from becoming a "barrier to rapid and efficient collective action in the face of a public health emergency."[4]

The COVID-19 pandemic is just one example of a salient connection between patent law and public health. Wonder drugs like aspirin[5] and azidothymidine (AZT)[6] and medical devices like the disposable hypodermic syringe[7] and magnetic resonance imaging (MRI)[8] are inventions that changed the course of public health.[9] Nontherapeutic inventions like wastewater treatment plants did the same.[10]

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1 *See, e.g.*, Eric E. Johnson & Theodore C. Bailey, Essay, *Legal Lessons from a Very Fast Problem: COVID-19*, 73 STAN. L. REV. ONLINE 89, 94 (2020) (explaining how "siloed research" and the "winner-take-all" nature of the U.S. patent system doesn't work well during a pandemic, which "calls for something different—something more like a community barn raising, where everyone works together to accomplish a massive task in a short timeframe").

2 *See* Jorge L. Contreras, *The Open COVID Pledge: Design, Implementation and Preliminary Assessment of an Intellectual Property Commons*, 2021 UTAH L. REV. 833, 837–40; George Abi Younes et al., *COVID-19: Insights from Innovation Economists*, 47 SCI. & PUB. POL'Y 733, 738 (2020) ("The worry that patents, and other forms of IP rights, may be a barrier in the fight against COVID-19 is a legitimate concern."); Dan Diamond & Jeff Stein, *A Quarrel over Vaccine Patents*, WASH. POST, May 1, 2021, at A1; Peter Loftus, *Patents for Covid-19 Vaccines Prompt High-Stakes Disputes*, WALL ST. J., Dec. 30, 2021, at A1.

3 *See* Jorge L. Contreras, Michael Eisen, Ariel Ganz, Mark Lemley, Jenny Molloy, Diane M. Peters & Frank Tietze, *Pledging Intellectual Property for COVID-19*, 38 NATURE BIOTECH. 1146 (2020); Yuka Hayashi & Jared S. Hopkins, *U.S. Supports Patent Waivers to Produce Covid-19 Vaccines*, WALL ST. J., May 6, 2021, at A1.

4 Contreras et al., *supra* note 3, at 1148.

5 Acetyl Salicylic Acid, U.S. Patent No. 644,077 (issued Feb. 27, 1900).

6 Treatment of Hum. Viral Infections, U.S. Patent No. 4,724,232 (issued Feb. 9, 1988).

7 Hypodermic Syringe, U.S. Patent No. 2,728,341 (issued Dec. 27, 1955).

8 Apparatus & Method for Detecting Cancer in Tissue, U.S. Patent No. 3,789,832 (issued Feb. 5, 1974).

9 Interestingly, the familiar wonder drugs sulfanilamide (the first sulfa drug) and penicillin were unpatentable by the time their therapeutic properties came to light because the substances were already in the public domain (and thus lacked novelty). *See generally* Ronald Bentley, *Different Roads to Discovery; Prontosil (Hence Sulfa Drugs) and Penicillin (Hence β-Lactams)*, 36 J. INDUS. MICROBIOLOGY & BIOTECH. 775 (2009).

10 *See infra* Section II.A.

At least in a formal sense, public health–related inventions aren't unique in patent law. The patent statutes are technology neutral.[11] An inventor is entitled to a patent if the invention is useful, novel, nonobvious, and directed to eligible subject matter[12] and the patent application adequately describes, enables, and sets forth the best mode for the invention[13] and concludes with definite claims.[14] Upon issuance, the patent owner (patentee) can transfer patent rights and enforce them through litigation.[15]

But the story of public health–related inventions isn't so simple. What sets them apart are competing and perhaps irreconcilable policy conundrums.[16] For example, while some argue that strong patent protection is essential to recoup high-risk research and development expenditures for drugs,[17] others argue that the public's interest in low-cost *access* to drugs—particularly during a public health crisis—is more important.[18] Another policy conundrum is the extent to which patent

11 Yet, the technology-neutral nature of the patent statutes gives courts discretion to tailor patentability standards flexibly across technologies or industries. *See* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1156 (2002).

12 *See* Bryson Act §§ 101–103, 35 U.S.C. §§ 101–103 (2018).

13 *Id.* § 112(a).

14 *Id.* § 112(b).

15 *Id.* §§ 261, 281.

16 *See, e.g.*, JA DiMasi & HG Grabowski, *Should the Patent System for New Medicines Be Abolished?*, 82 CLINICAL PHARMACOLOGY & THERAPEUTICS 488 (2007) (exploring criticisms and policy proposals that balance the patent system's need to reward inventors for developing and commercializing new drugs with the need to guarantee low-cost access to drugs); Johnson & Bailey, *supra* note 1, at 95 (recognizing that patent law's powerful incentive structure—which "may serve to achieve a faster relative speed of research output by one group of investigators compared to others . . . may impede and slow the absolute speed of developing and rolling out key breakthroughs in COVID-19 testing, vaccination, and treatment" (emphases removed)); Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 CONN. L. REV. 57, 59 (2022) ("The COVID-19 pandemic has highlighted an uneasy balancing act between incentivizing new drug development through patent rights and preventing drug shortages.").

17 Taking a new drug from concept through U.S. Food and Drug Administration (FDA) approval to market can take ten to fifteen years and easily exceed one billion dollars. *See* JORGE MESTRE-FERRANDIZ, JON SUSSEX & ADRIAN TOWSE, OFF. OF HEALTH ECON., THE R&D COST OF A NEW MEDICINE 39 (2012); Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 22 tbl.1 (2016).

18 *See, e.g.*, Andrew Beckerman-Rodau, *Patent Law – Balancing Profit Maximization and Public Access to Technology*, 4 COLUM. SCI. & TECH. L. REV. 1, 45–47 (2002) (arguing for a compulsory licensing scheme to deliver drugs to developing nations to solve a public health crisis); Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1050 (2009) (arguing that patents are "a mere privilege granted by a nation and are inherently subject to limitations to accommodate other societal goals, such as access to medicine"); Kumar, *supra* note 16, at 59 ("[T]he exclusive rights that incentivize the development of

law should protect the public from unscrupulous inventors who jeopardize public health by making dubious claims about a therapeutic invention's safety or efficacy.[19] This Article doesn't take a position in these rich policy debates. Rather, it focuses on the role of federal courts in resolving them.

Judicial protection of public health in patent cases can be separated into two strands: modulating patentability standards and modulating patent-enforcement remedies. Under the patentability strand, courts once raised patentability standards to render unpatentable *as a matter of law* therapeutic inventions deemed unsafe or (likely) ineffective.[20] The policy goal was to protect the health of the unwitting, gullible public. Ultimately the courts abandoned this gatekeeping function after determining that assessing therapeutic safety and efficacy isn't the province of substantive patent law.[21]

Under the enforcement strand, after a finding of patent infringement, a court would deny a request for a permanent injunction if granting it would cause or exacerbate a public health crisis.[22] The goal was simple: the public benefit from infringing the patent outweighed the patentee's interest in prospective relief.[23] Yet, enforcement-strand cases are rare. And in the handful of cases where the court has objective evidence of public health concerns, the grant or denial of injunctive relief has been unpredictable.[24]

Since federal courts have abandoned their gatekeeping function for patenting public health–related inventions (patentability strand) and injunction denials in infringement suits for public health issues are rare and unpredictable (enforcement strand), it might seem that

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needed drugs simultaneously hinder the public's access to them during emergencies."). It's worth noting that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) permits member states to grant compulsory licenses for patented drugs to address a public health emergency. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31(b), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (permitting member states to use patents without the patentee's permission or authorization "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use").

19 *See* JOSEPH M. GABRIEL, MEDICAL MONOPOLY: INTELLECTUAL PROPERTY RIGHTS AND THE ORIGINS OF THE MODERN PHARMACEUTICAL INDUSTRY 27 (2014) (discussing patented "quack medicines" in the nineteenth century which threatened public health because they were "little more than an effort to dupe the public into purchasing a useless good; at worst, it was an effort to conceal the use of dangerous ingredients"); *infra* Sections I.B, III.C.

20 *See infra* Part I.

21 *See infra* Section I.D.

22 *See infra* Part II.

23 *Cf.* Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1198 (2000).

24 *See infra* Section II.C.

we should no longer expect courts to do much to protect public health in patent cases.

This Article argues, however, that there's more to the story. Consistent with the increasing use of equitable remedies in patent law,[25] I argue that a court in a patent infringement suit could act to protect public health through the affirmative defense of patent unenforceability.[26] For example, if the plaintiff-patentee engaged in invention-related egregious misconduct that jeopardized public health, the court could render the patent unenforceable by dismissing the lawsuit.[27] Alternatively, the court could render the patent temporarily unenforceable until the misconduct ceases and its ill effects on public health dissipate.[28] So public health would essentially become an affirmative defense to patent infringement.[29] This proposal raises interesting normative, theoretical, and policy questions about the role of equitable doctrines in patent law. How courts should use unenforceability to remedy patentee misconduct has been largely understudied and undertheorized in legal scholarship. This Article is part of a broader research project that attempts to fill this gap.[30]

The remainder of this Article proceeds as follows. Part I discusses how courts once modulated patentability standards to protect public health by derailing therapeutic inventions that seemed unsafe or (likely) ineffective. Part II explores how courts can (but rarely do) limit prospective relief in patent cases if the injunction would jeopardize public health. Next, Part III offers a new path for courts to protect public health in patent cases—the affirmative defense of unenforceability. Finally, Part IV addresses potential criticisms and objections to the assertion of public health as a defense to patent infringement.

I. DERAILING PATENTABILITY FOR PUBLIC HEALTH

To obtain a patent, an inventor must submit an application to the U.S. Patent and Trademark Office (Patent Office) describing the invention with the proposed claims.[31] An examiner evaluates the

25 *See infra* Section III.B.

26 *See infra* Part III.

27 *See infra* subsection III.C.1.

28 *See infra* subsection III.C.3.

29 *See infra* Part III.

30 *See generally* Sean B. Seymore, *Patent Forfeiture*, 72 DUKE L.J. 1019 (2023); Sean B. Seymore, *Unclean Patents*, 102 B.U. L. REV. 1491, 1508–14 (2022) [hereinafter Seymore, *Unclean Patents*].

31 Return Mail, Inc. v. U.S. Postal Serv., 139 S. Ct. 1853, 1859 (2019) (citing Bryson Act §§ 111, 112, 35 U.S.C. §§ 111(a)(1), 112 (2018)). Patent claims define 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). They

application to determine if the claimed invention satisfies the statutory patentability requirements.[32] An inventor is entitled to a patent unless the Patent Office can prove that one or more of the requirements hasn't been satisfied.[33] While the presumption of patentability puts an inventor in a very good position,[34] the Patent Office and the courts will apply patentability standards differentially to particular technologies to achieve specific policy goals.[35] As discussed below, this was done to therapeutic inventions for decades to protect public health.[36]

A. Heightened Scrutiny for Therapeutics

Basic patent doctrines like novelty, nonobviousness, and utility developed during the first century of the U.S. patent system when most inventions were mechanical devices.[37] The invention landscape changed around the time of World War II when major breakthroughs in antibiotic, vitamin, and hormone research spawned the so-called "therapeutic revolution."[38] This forced the Patent Office and the courts to apply patent doctrines to unfamiliar fields.[39]

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also "provide[] the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention." Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989) (citing Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950)).

32 *See supra* notes 12–14 and accompanying text.

33 *See* 35 U.S.C. § 102(a) (2018) ("A person shall be entitled to a patent *unless* . . . ." (emphasis added)); *In re* Epstein, 32 F.3d 1559, 1570 (Fed. Cir. 1994) (Plager, J., concurring) (articulating the rule that the Patent Office carries the burden of persuasion in showing why an applicant shouldn't receive a patent (first citing *Oetiker*, 977 F.2d at 1448–49 (Plager, J., concurring); then citing *In re* Warner, 379 F.2d 1011, 1016 (C.C.P.A. 1967); and then citing *In re* Caveney, 761 F.2d 671, 674 (Fed. Cir. 1985))); *In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) ("If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." (first citing *In re* Grabiak, 769 F.2d 729, 733 (Fed. Cir. 1985); and then citing *In re* Rinehart, 531 F.2d 1048, 1052 (C.C.P.A. 1976))).

34 Sean B. Seymore, *The Presumption of Patentability*, 97 MINN. L. REV. 990, 995 (2013).

35 *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1638–40 (2003); *see also supra* note 11.

36 *See infra* Section I.A.

37 *See* William D. Noonan, *Patenting Medical Technology*, 11 J. LEGAL MED. 263, 263–64 (1990).

38 NAT'L RSCH. COUNCIL, THE COMPETITIVE STATUS OF THE U.S. PHARMACEUTICAL INDUSTRY: THE INFLUENCES OF TECHNOLOGY IN DETERMINING INTERNATIONAL INDUSTRIAL COMPETITIVE ADVANTAGE 8, 7–11 (1983).

39 *See* Sean B. Seymore, *Foresight Bias in Patent Law*, 90 NOTRE DAME L. REV. 1105, 1116–23 (2015). Antibiotics provide an interesting story. Given penicillin's success and the potential for antibiotics to generate unprecedented profits, drug companies sought other antibiotics by screening potential antibiotic-producing microorganisms from nature. *See* GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS AND THE LIFE SCIENCE INDUSTRIES: PAST, PRESENT AND FUTURE 141–42 (2d ed. 2009). But "it was uncertain that the patent

Particularly noteworthy is patent law's utility requirement. It's codified in § 101 of the current patent statute, which states in relevant part that "[w]hoever invents or discovers any . . . *useful* process, machine, manufacture, or composition of matter . . . may obtain a patent."[40] Historically, it was a de minimis requirement—*some* beneficial use was sufficient to establish utility[41] unless the invention was inoperable[42] or detrimental to the public interest.[43] It was construed "so liberally that it almost never serve[d] to defeat a patent."[44] Before World War II, chemical compounds were subject to the same de minimis utility standard as other inventions.[45] This changed shortly after the war

system including the courts could deliver [the blanket patent protection] they wanted" because the compounds were essentially "gifts of nature" and thus evinced very little inventive creativity. *Id.* at 142. The pharmaceutical industry responded by pressuring Congress to amend the Patent Act. *See* William Kingston, *Removing Some Harm from the World Trade Organization*, 32 OXFORD DEV. STUD. 309, 310 (2004). The basic change was the incorporation of language in the nonobviousness provision of the 1952 Patent Act, *see* Bryson Act, Pub. L. No. 593, § 103, 66 Stat. 792, 798 (1952) (codified as amended at 35 U.S.C. § 103 (2018)) ("Patentability shall not be negatived by the manner in which the invention was made."), tailored to keep the innovation threshold rather low. DUTFIELD, *supra*, at 142.

40 35 U.S.C. § 101 (2018) (emphasis added).

41 Bedford v. Hunt, 3 F. Cas. 37, 37 (C.C.D. Mass. 1817) (No. 1217).

42 Utility is lacking "where it appears that [the invention] is not capable of being used to effect the object proposed." Mitchell v. Tilghman, 86 U.S. (19 Wall.) 287, 396 (1874) (citing GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS: AS ENACTED AND ADMINISTERED IN THE UNITED STATES OF AMERICA § 449, at 606–07 (4th ed. rev., Boston, Little, Brown, & Co. 1873)). 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) (first citing Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft m.b.H., 945 F.2d 1546, 1552–53 (Fed. Cir. 1991); then citing Moleculon Rsch. Corp. v. CBS, Inc., 793 F.2d 1261, 1268 (Fed. Cir. 1986); and then citing Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 762 (Fed. Cir. 1984)); *see also* Newman v. Quigg, 877 F.2d 1575, 1581 (Fed. Cir. 1989) ("[A] device lacks utility [if] it does not operate to produce what [the inventor] claims [that] it does." (quoting Newman v. Quigg, 681 F. Supp. 16, 23 (D.D.C. 1988)), *modified*, 886 F.2d 329 (Fed. Cir. 1989); *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 . . . ." (first citing Besser v. Merrilat Culvert Core Co., 243 F. 611 (8th Cir. 1917); and then citing Coupe v. Royer, 155 U.S. 565, 574 (1895)).

43 The asserted utility must not be "injurious to the morals, the health, or the good order of society." *Bedford*, 3 F. Cas. at 37.

44 *In re* Nelson, 280 F.2d 172, 179 (C.C.P.A. 1960), *overruled by In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967).

45 *See, e.g.*, Potter v. Tone, 36 App. D.C. 181, 184–85 (D.C. Cir. 1911) (rejecting the contention that the claimed compound must have a commercial use and holding that the description of its characteristics and properties had value for educational and research purposes and were sufficient to establish utility), *discussed in* David A. Anderson & Edward E. Dyson, Editorial Note, *Some Special Problems with the Utility Requirement in Chemical Patents*, 35 GEO. WASH. L. REV. 809, 810 (1967) ("The court felt that to require a showing of use in

when chemicals claiming therapeutic activity were viewed with skepticism.[46] Utility required proof of efficacy before a patent could issue.[47]

The Patent Office and the courts justified their skepticism as necessary for the public good.[48] The public erroneously believed that the government *never* issues patents on inventions that can't or don't work.[49] The "vagaries of human psychology"[50] and "prestige [that] a patent brings"[51] may "offer credibility by certifying that the technology met the government's (supposedly) stringent [patentability] standards."[52] So good public policy required the strict policing of seemingly impossible inventions to protect the public from potentially harmful products that don't work as described.[53]

The operability prong of the § 101 utility requirement "attempts to answer the objective, technical question of whether an invention can

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some commercial process . . . would amount to a holding that the inventor must make another invention which could be the subject of another patent.").

46 *See* Sean B. Seymore, *Making Patents Useful*, 98 MINN. L. REV. 1046, 1053–57 (2014).

47 An examiner's rejection might read: "All the claims are rejected for lack of utility. The composition is set forth as therapeutic. In the absence of clear, convincing, scientific evidence that the composition is safe and effective for the purposes set forth, no claim is allowable." *In re* Novak, 306 F.2d 924, 927 (C.C.P.A. 1962).

48 As stated by the Board of Patent Appeals and Interferences:

> The [Patent] 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.

Ex parte Moore, 128 U.S.P.Q. (BL) 8, 9 (Bd. Pat. App. 1960) (quoting *Ex parte* de Bausset, 1888 Dec. Comm'r Pat. 1583, 1585), *cited with approval in In re* Citron, 325 F.2d 248, 253 (C.C.P.A. 1963).

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

50 Stuart J.H. Graham & Ted Sichelman, *Why Do Start-Ups Patent?*, 23 BERKELEY TECH. L.J. 1063, 1082 (2008).

51 *Id.* at 1083 (quoting DAVID PRESSMAN, PATENT IT YOURSELF 8 (11th ed. 2005)).

52 *Id.*

53 *See Citron*, 325 F.2d at 253; *see also* Isenstead v. Watson, 157 F. Supp. 7, 9 (D.D.C. 1957) (contending that the patent grant "gives a kind of official imprimatur to the [invention] in question on which as a moral matter some members of the public are likely to rely"). The fear is that some might view the patent grant, albeit improperly, as the government's endorsement of the technology. *See* Timothy R. Holbrook, *The Expressive Impact of Patents*, 84 WASH. U. L. REV. 573, 599–600 (2006) (explaining that the government may choose to deny patents on certain inventions to eliminate the signal of perceived endorsement or encouragement). *But see In re* Hartop, 311 F.2d 249, 263 (C.C.P.A. 1962) ("[T]he issuance of a patent is not in fact an 'imprimatur' as to . . . safety and effectiveness . . . . [A patent] is no guarantee of anything . . . . The public, therefore, is in no way protected either by the granting or withholding of a patent.").

actually achieve its intended result."[54] Yet, the question can be framed differently, such as whether a person having ordinary skill in the art (PHOSITA)[55] would believe the truth of the inventor's assertions.[56] This alternative framing allowed the Patent Office and the courts to make policy-driven, lack-of-utility patent denials[57] irrespective of an invention's technical bona fides.[58] Specifically targeted, as discussed below, were inventions purporting to effectively treat diseases like baldness and cancer that the lay public long considered untreatable or incurable.

B. Protecting the Health of the Credulous Public

There's widespread belief that humans are, by and large, *credulous*—gullible, naïve, overly deferential to experts, and routinely swayed into costly behaviors.[59] For example, the lay public often believes that "organic" means "safe"[60] and that vitamins and nutritional supplements have been approved by the U.S. Food and Drug Administration (FDA).[61]

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54 Seymore, *supra* note 46, at 1092 (emphasis omitted); *see also supra* note 42 and accompanying text. Whether an invention is operable is a question of fact. Raytheon Co. v. Roper Corp., 724 F.2d 951, 956 (Fed. Cir. 1983).

55 The PHOSITA is a hypothetical construct of patent law. *See* Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed. Cir. 1987). Factors relevant to constructing the PHOSITA in a particular technical field include the sophistication of the technology, the educational level of the inventor, the educational level of active workers in the field, the types of problems encountered in the art, the prior art solutions to those problems, and the rapidity with which innovations are made. Env't Designs, Ltd. v. Union Oil Co. of Cal., 713 F.2d 693, 696 (Fed. Cir. 1983) (citing Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc., 707 F.2d 1376, 1381–82 (Fed. Cir. 1983), *abrogated by* Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011)).

56 The Patent Office can establish the PHOSITA's doubt by asserting that the patent application's disclosure "suggest[s] an inherently unbelievable undertaking." *In re* Cortright, 165 F.3d 1353, 1357 (Fed. Cir. 1999) (alteration in original) (quoting *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995)).

57 *See* Burk & Lemley, *supra* note 35, at 1644–45.

58 *See* Seymore, *supra* note 46, at 1053–57; Seymore, *supra* note 39, at 1125.

59 *See* HUGO MERCIER, NOT BORN YESTERDAY: THE SCIENCE OF *WHO* WE TRUST AND *WHAT* WE BELIEVE 1–14 (2020). But this belief has been challenged. *See generally id.*; Neil Vidmar & Shari Seidman Diamond, *Juries and Expert Evidence*, 66 BROOK. L. REV. 1121 (2001) ("[T]here is little evidence that [jurors] are simply impressed by jargon and awed by experts' credentials . . . . [T]hey generally make reasonable use of complex material, utilizing the expert testimony when it is presented in a form that they can use." *Id.* at 1166–67).

60 *See* CHRISTOPHER WANJEK, BAD MEDICINE: MISCONCEPTIONS AND MISUSES REVEALED, FROM DISTANCE HEALING TO VITAMIN O 144 (2003).

61 *See* Karen Russo France & Paula Fitzgerald Bone, *Policy Makers' Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels*, 39 J. CONSUMER AFFS. 27, 47

With the credulous public in mind, therapeutic patent claims that seem implausible, stray from the orthodox, or lack communal acceptance are viewed with skepticism.[62] A quintessential example is the quest for baldness treatments. The pervasiveness of hair loss,[63] its social impact,[64] and the sensitive nature of the topic[65] explain why

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(2005); Laura A.W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623, 637–38 (1999).

62 *See* JOHN ZIMAN, REAL SCIENCE: WHAT IT IS, AND WHAT IT MEANS 246 (2000) (discussing "organized skepticism" as a norm in academic science (emphasis omitted) (citation omitted)); John Lister, *Fringe Medicine—A Versatile Profession—Believers and Unbelievers*, 264 NEW ENG. J. MED. 188, 188 (1961) (discussing the credulous public and quackery). For example, successful treatment of stomach ulcers with penicillin was first reported in 1951. *See* Lyudmila Boyanova, *Historical Data*, *in* HELICOBACTER PYLORI 1, 2 (Lyudmila Boyanova ed., 2011). The scientific community initially rejected the findings because it was dogma that stomach ulcers were caused by gastric acid due to stress or diet; any notion that a pathogen was involved was "regarded as whimsical," and "the use of antibiotics or metallic ions were deemed to be quackery." Mark Kidd & Irvin M. Modlin, *A Century of* Helicobacter Pylori*: Paradigms Lost – Paradigms Regained*, 59 DIGESTION 1, 1 (1998).

63 Up to seventy percent of men and up to forty percent of women experience hair loss over the course of their lifetimes. Zenildo Santos, Pinar Avci & Michael R. Hamblin, *Drug Discovery for Alopecia: Gone Today, Hair Tomorrow*, 10 EXPERT OP. ON DRUG DISCOVERY 269, 272 (2015).

64 Hair loss "can cause emotional distress, diminish self-esteem, and make people feel less attractive." VICTORIA SHERROW, ENCYCLOPEDIA OF HAIR: A CULTURAL HISTORY 172 (2006). A full head of hair is often viewed as a sign of strength and virility. *See id.*; Santos et al., *supra* note 63, at 269. Consider the famous story 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 Version).

65 Again, the Old Testament provides a famous example. One day the prophet Elisha, who lost most of his hair at a young age, was mocked by a group of boys during his travels. *See* THOMAS J. CRAUGHWELL, BAD KIDS OF THE BIBLE: AND WHAT THEY CAN TEACH US 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. . . . 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 Version).

reversing baldness has been a human obsession since antiquity.[66] History reveals that most purported baldness treatments haven't worked.[67] This lack of success and concerns about credulity and public health led to a sixty-year patentability saga for baldness treatments.

The story begins with *In re Oberweger*,[68] 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.[69] Recognizing that preexisting knowledge in the field contained "little of a successful nature,"[70] the applicant bolstered the claim with testimonials and an affidavit from a medical doctor attesting to the treatment's efficacy.[71] Nevertheless, the Patent Office deemed the invention inoperable under § 101 "since compositions for growing hair on the human scalp have uniformly proven unreliable."[72] The U.S. Court of Customs and Patent Appeals (C.C.P.A.)[73] 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

66 *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).

67 For a brief historical account of the various quests, see WANJEK, *supra* note 60, at 48–52. 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).

68 115 F.2d 826 (C.C.P.A. 1940). The U.S. Court of Customs and Patent Appeals (C.C.P.A.) was a five-judge Article III appellate court on the same level as the U.S. Courts of Appeals. The Federal Courts Improvement Act of 1982 abolished the C.C.P.A. *See* Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.). Soon after its creation, the U.S. Court of Appeals for the Federal Circuit adopted C.C.P.A. decisional law as binding precedent. *See* S. Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc); *infra* note 90.

69 *Oberweger*, 115 F.2d at 826–27.

70 *Id.* at 827.

71 *Id.* at 827–28. Applicants can rely on affidavits as proof of operability; those from experts in the field that show a nexus between the intended result and the supporting evidence are the most probative. *Cf. In re* Payne, 606 F.2d 303, 315 (C.C.P.A. 1979); *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).

72 *Oberweger*, 115 F.2d at 827; *cf. In re* Swartz, 232 F.3d 862, 864 (Fed. Cir. 2000) (per curiam) (generating energy with "cold fusion" deemed incredible); Newman v. Quigg, 877 F.2d 1575, 1577 (Fed. Cir. 1989) (perpetual motion machine deemed incredible), *modified*, 886 F.2d 329 (Fed. Cir. 1989). 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 claiming that a face cream made with whole milk could whiten skin. *Oberweger*, 115 F.2d at 828 (citing Hall v. Duart Sales Co., 28 F. Supp. 838, 838–39 (N.D. Ill. 1939)) (invalidating Massage and Cleansing Cream and Method of Preparing the Same, U.S. Patent No. 1,668,503 (issued May 1, 1928), for a lack of utility because the addition of milk to the cream "d[id] nothing")).

73 *See supra* note 68.

> 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.*[74]

This reasoning is troubling from both a legal and technical perspective. From a legal perspective, it's bedrock patent law that an invention need not be *better* than what's already known.[75] From a technical perspective, there was no substantive consideration of the invention's scientific underpinnings or technical merit. The court's singular focus was to protect the health and welfare of the credulous public.[76]

The C.C.P.A. dealt with baldness again almost thirty years later in *In re Ferens.*[77] Here the applicant claimed that applying electric current to the scalp, followed by a jaborandi plant preparation and lanolin ointment, could regrow hair.[78] The applicant provided affidavits from a medical doctor and twenty-one laypersons treated with the purported cure.[79] The court found this evidence unpersuasive[80] and explained that the applicant must provide *clear and convincing* proof to establish utility,[81] yet it didn't "attempt to recite what evidence would be sufficient."[82] (Recall that a preponderance of the evidence is the default standard of proof with the Patent Office carrying the burden of persuasion.)[83] The court lamented that the inventor had "engaged in a field of endeavor where 'little of a successful nature has been

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

75 *See* Stiftung v. Renishaw PLC, 945 F.2d 1173, 1180 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result, and it need only be useful to some extent and in certain applications . . . ."); Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 960 n.12 (Fed. Cir. 1986) ("It is possible for an invention to be less effective than existing devices but nevertheless meet the statutory criteria for patentability."); *In re* Ratti, 270 F.2d 810, 814 (C.C.P.A. 1959) (rejecting the Patent Office's contention that an invention "[must] possess[] some definite advantage over the prior art" (emphasis omitted)).

76 *See supra* note 53 and accompanying text.

77 417 F.2d 1072 (C.C.P.A. 1969).

78 *Id.* at 1073. Jaborandi is an herbal shrub with small pinkish flowers found mainly in Brazil. BEN-ERIK VAN WYK & MICHAEL WINK, MEDICINAL PLANTS OF THE WORLD: AN ILLUSTRATED GUIDE TO IMPORTANT MEDICINAL PLANTS AND THEIR USES 261 (rev ed. 2017).

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

80 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.*

81 *Id.* at 1074 (citing *In re* Irons, 340 F.2d 974 (C.C.P.A. 1965)).

82 *Id.* at 1075.

83 *See* cases cited *supra* note 33.

developed'"[84] and adopted the view that "[t]he claims of any one that he has developed a remedy for the control or cure of baldness . . . should be viewed with the greatest skepticism."[85] So it appeared that *any* inventor in the field faced an insurmountable § 101 hurdle, regardless of technical merit. The invention's underlying science wasn't considered and was therefore irrelevant.[86] Notwithstanding concerns about public health, *Oberweger* and *Ferens* evince a subjective, policy-driven application of the utility requirement.[87]

Eventually the Patent Office and the courts abandoned the heightened utility standard for baldness treatments. One decade after *Ferens*, Upjohn obtained a patent for a method of using minoxidil (trade name Rogaine) to regrow hair.[88] The Patent Office has now granted hundreds of patents for baldness treatments—many disclosing rudimentary techniques and mundane materials previously discredited, including jaborandi plant extract.[89] The U.S. Court of Appeals for the Federal Circuit (Federal Circuit)[90] settled the issue in 1999 in *In re Cortright*,[91] when it proclaimed that treating baldness is "[not] an inherently unbelievable undertaking."[92]

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84 *Ferens*, 417 F.2d at 1074 (quoting *In re Oberweger*, 115 F.2d 826, 827 (C.C.P.A. 1940)).

85 *Id.* at 1074 n.2 (quoting *Hair and Scalp Treatments and Preparations*, 139 J. AM. MED. ASS'N 840, 844 (1949)); *see generally id.* at 1072 n.2.

86 *See id.*

87 *See supra* note 57 and accompanying text.

88 *See* 6-Amino-4-(Substituted Amino)-1,2-Dihydro-1-Hydroxy-2-Iminopyrimidine, Topical Compositions & Process for Hair Growth, U.S. Patent No. 4,139,619 (filed Aug. 19, 1977) (issued Feb. 13, 1979); *see also* Jenny Bryan, *How Minoxidil Was Transformed from an Antihypertensive to Hair-Loss Drug*, PHARM. J. (July 20, 2011), https://pharmaceutical-journal.com/article/news/how-minoxidil-was-transformed-from-an-antihypertensive-to-hair-loss-drug [https://perma.cc/UF39-4KGK]. Interestingly, Upjohn originally developed minoxidil to treat high blood pressure. *See* JOHN TOEDT, DARRELL KOZA & KATHLEEN VAN CLEEF-TOEDT, CHEMICAL COMPOSITION OF EVERYDAY PRODUCTS 40 (2005). However, it had a side effect: people who took it grew hair in an unexpected manner on their cheeks, foreheads, hands, and in other places. *See* SPENCER DAVID KOBREN, THE BALD TRUTH: THE FIRST COMPLETE GUIDE TO PREVENTING AND TREATING HAIR LOSS 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. VERRET, *supra* note 67, at 49.

89 *See, e.g.*, Composition & Method to Promote Human Hair Growth, U.S. Patent No. 7,238,375 (issued July 3, 2007). Recall that jaborandi was previously discredited in *Ferens*, 417 F.2d at 1075, discussed *supra* text accompanying notes 77–87.

90 The Federal Circuit is a twelve-judge Article III court whose jurisdiction includes appeals from the Patent Office and patent suits emerging from the U.S. district courts. *See* 28 U.S.C. §§ 44, 1295(a) (2018); *cf. supra* note 68.

91 165 F.3d 1353 (Fed. Cir. 1999).

92 *Id.* at 1357 (first citing *Ferens*, 417 F.2d at 1074; and then citing *In re Oberweger*, 115 F.2d 826, 829 (C.C.P.A. 1940)).

C. Requiring Heightened Proof for Difficult-to-Treat Diseases

The history of science teaches that what was impossible yesterday might be possible today.[93] This is the story of cancer—once widely considered a death sentence.[94] Now many cancers can be treated and even cured.[95] With that said, a cancer diagnosis often has emotional and psychological consequences.[96]

For most of the twentieth century, the Patent Office and the courts were highly skeptical of *any* invention that purported to treat cancer.[97] Applicants claiming success faced an insurmountable § 101 patentability hurdle.

A pivotal opinion is *In re Citron*,[98] a 1963 case in which an applicant claimed 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 it.[99] The patent application described how to make the serum, provided analytical data, and contained a working example purporting to show its effectiveness in rats

93 *See* CEES J. HAMELINK, THE TECHNOLOGY GAMBLE: INFORMATIC AND PUBLIC POLICY: A STUDY OF TECHNOLOGY CHOICE, 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!").

94 *See, e.g.*, JOHN EMSLEY, A HEALTHY, WEALTHY, SUSTAINABLE WORLD 70 (2010); D.J. TH. WAGENER, THE HISTORY OF ONCOLOGY 88 (2009) (noting that certain cancers were once viewed as incurable). Unfortunately, some still see a cancer diagnosis as a death sentence despite declining cancer mortality rates. *See generally* Richard P. Moser, Jamie Arndt, Tyler Jimenez, Benmei Liu & Bradford W. Hesse, *Perceptions of Cancer as a Death Sentence: Tracking Trends in Public Perceptions from 2008 to 2017*, 30 PSYCHO-ONCOLOGY 511 (2021).

95 *See, e.g.*, sources cited *supra* note 94; GLENN S. ROTHFELD & DEBORAH S. ROMAINE, THE ENCYCLOPEDIA OF MEN'S HEALTH 64 (2005).

96 *See generally* PSYCHOLOGICAL ASPECTS OF CANCER: A GUIDE TO EMOTIONAL AND PSYCHOLOGICAL CONSEQUENCES OF CANCER, THEIR CAUSES, AND THEIR MANAGEMENT (Jennifer L. Steel & Brian I. Carr eds., 2d ed. 2022); JENNIFER BARRACLOUGH, CANCER AND EMOTION: A PRACTICAL GUIDE TO PSYCHO-ONCOLOGY (3d ed. 1999).

97 *See, e.g.*, *Ex parte* Moore, 128 U.S.P.Q. (BL) 8, 9–10 (Bd. Pat. App. 1960) (determining that any suggestion that the claimed compounds could treat cancer was incredible and misleading). One exception occurred in 1959 when the Patent Office allowed a single medical use claim for a drug useful in bringing about remission in myeloid leukemia. *See Ex parte* Timmis, 123 U.S.P.Q. (BL) 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 582–83, 581.

98 325 F.2d 248 (C.C.P.A. 1963).

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

and humans.[100] The C.C.P.A. affirmed the Patent Office's § 101 rejection because the *applicant* hadn't proven operability with *clear and convincing evidence.*[101] Again, a preponderance of the evidence is the default standard of proof, with the Patent Office carrying the burden of persuasion.[102] Now heightened proof was required for drugs if the underlying condition was difficult to treat.[103]

Writing for the court, Judge Giles Rich provided a policy rationale for a heightened proof requirement:

> [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 skilled artisan in the field] would accept those allegations as obviously valid and correct, it is proper for the examiner to ask for evidence which substantiates them.
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> . . . . [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 . . . by unscrupulous persons.[104]

Despite the court's public health concerns,[105] as with baldness, there was no discussion of the invention's scientific merit or "[clear

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100 *See id.* at 251–52. Although the patent application didn't 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) (citing *In re* Grupe, 48 F.2d 936, 938 (C.C.P.A. 1931)) (approving product-by-process claims).

101 *Citron*, 325 F.2d at 252–53.

102 *See* cases cited *supra* note 33.

103 Irving Marcus, *The Patent Office and Pharmaceutical Invention*, 47 J. PAT. OFF. SOC'Y 669, 673 (1965); *see also In re* Kirk, 376 F.2d 936, 958 (C.C.P.A. 1967) (Rich, J., dissenting) (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" (quoting Joseph Gray Jackson, Address at the Institute of Patent Law of the Southwest Legal Foundation (Mar. 30, 1967))).

104 *Citron*, 325 F.2d at 253 (quoting *In re* Novak, 306 F.2d 924, 928 (C.C.P.A. 1962)).

105 Donald Chisum has explained the court's reasoning:

> 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

resolution of] what the standard of proof of the effectiveness of a therapeutic product *should* be."[106]

Momentum shifted in 1980 when the C.C.P.A. explicitly stated that effectively treating cancer *isn't* impossible. In *In re Jolles*,[107] the court reversed the Patent Office's rejection of a patent application for a drug claiming to effectively induce remission in leukemia patients.[108] It pronounced 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."[109] However, applicants had to substantiate their claims with heightened proof: clinical data showing therapeutic efficacy in humans.[110]

The road to patentability of cancer treatments dramatically improved in 1995 when the Federal Circuit issued *In re Brana*.[111] The Patent Office denied a patent for certain antitumor compounds for a

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on comparative utility. But the problem was perceived as more severe with products closely connected with human health.

2 DONALD S. CHISUM, CHISUM ON PATENTS § 4.04[2][a] (2024) (footnote omitted) (quoting EDMUND W. KITCH & HARVEY S. PERLMAN, LEGAL RESOLUTION OF THE COMPETITIVE PROCESS: CASES, MATERIALS AND NOTES ON UNFAIR BUSINESS PRACTICES, TRADEMARKS, COPYRIGHTS AND PATENTS 721 (1972)).

106 *Id.* (emphasis added). In one post-*Citron* therapeutic case, the C.C.P.A. disagreed with the Patent Office and found the applicant's evidence convincing; however, the court still failed to clearly resolve what the patentability standard should be. *See In re* Gazave, 379 F.2d 973, 977–79 (C.C.P.A. 1967) (reminding the Patent Office 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," *id.* at 977 (emphasis omitted) (quoting Bluestone v. Schmerling, 265 F.2d 948, 951 (C.C.P.A. 1959))).

107 628 F.2d 1322 (C.C.P.A. 1980).

108 *See id.* at 1327–28 (noting that the Patent Office failed to give sufficient weight to animal studies because "such testing is relevant to utility in humans," *id.* at 1327, and that a skilled artisan in the field considering the entire record "would accept [the applicant's] claimed utility in humans as valid and correct," *id.* at 1328).

109 *Id.* at 1327 (emphasis added).

110 *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 skilled artisan in the field] 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, No. 635-06, 1 U.S.P.Q.2d (BL) 1908, 1909 (B.P.A.I. Sept. 10, 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); *In re* Kirk, 376 F.2d 936, 958 (C.C.P.A. 1967) (Rich, J., dissenting) ("If the drug is to be applied to humans, the Patent Office usually requires clinical tests, that is, tests on human patients." (quoting Jackson, *supra* note 103)). If the applicant provided no substantiating evidence or only speculative statements, a rejection was guaranteed. *See, e.g.*, *Ex parte* Stevens, No. 90-0644, 16 U.S.P.Q.2d (BL) 1379, 1380 (B.P.A.I. June 29, 1990) (no substantiating evidence provided).

111 51 F.3d 1560 (Fed. Cir. 1995).

lack of utility because it believed that efficacy in *animals* with cancer was insufficient to establish a reasonable expectation of efficacy in *humans*.[112] The Federal Circuit unequivocally reiterated that "[t]he purpose of treating cancer with chemical compounds does not suggest an inherently unbelievable undertaking or involve implausible scientific principles."[113]

Now the Federal Circuit had to decide what an applicant must prove to establish utility for a therapeutic invention.[114] It held that efficacy in animals is enough.[115] So applicants for drug patents need not perform human testing before obtaining a patent.[116] *Brana* also adopted a uniform evidentiary framework for gauging compliance with § 101. Since an application as filed presumptively complies with the statute,[117] both the initial and ultimate burdens of proving lack of utility rest with the Patent Office.[118] So the same burden-shifting framework used to gauge compliance with novelty, nonobviousness, and the disclosure requirements now applies to utility.[119]

The proof questions addressed in *Brana* weren't new. They arose in the 1960s, when the Patent Office required applicants for therapeutic patents to "supply proof of 'safety and effectiveness' of the claimed composition 'in man,'"[120] notwithstanding any testing done on animals.[121] In *In re Hartop*,[122] the C.C.P.A. considered whether clinical evidence or FDA approval should be a prerequisite for patenting drugs.[123] Despite the Patent Office's argument that it was "carrying out

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112 *See id.* at 1562–64.

113 *Id.* at 1566 (citing *Jolles*, 628 F.2d at 1327).

114 *Id.* at 1564.

115 *Id.* at 1567.

116 *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 [Patent Office] proceedings.").

117 *See supra* note 33 and accompanying text.

118 *See Brana*, 51 F.3d at 1566 (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* U.S. PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE § 2107(II)(D) (9th ed. rev., Feb. 2023) [hereinafter MPEP] ("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 . . . .").

119 *See Brana*, 51 F.3d at 1566 ("Only after the [Patent Office] 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." (citing *In re* Bundy, 642 F.2d 430, 433 (C.C.P.A. 1981))).

120 *In re* Hartop, 311 F.2d 249, 263 (C.C.P.A. 1962).

121 *Id.* at 254.

122 311 F.2d 249 (C.C.P.A. 1962).

123 *See id.* at 251, 258–59.

[its] statutory duty" by requiring such proof,[124] the C.C.P.A. concluded that no such duty arises from § 101:

> [W]e observe that any statutory authority given the Patent Office [to require such proof] would have to stem from the provision of 35 U.S.C. § 101 that a patentable invention must be "useful." A comparison of this provision with the detailed provisions of the Federal Trade Commission Act and the Federal Food, Drug, and Cosmetic Act indicates to us that if Congress had intended to use its constitutional authority under the patent clause to do what it might not be able to do under the commerce clause, it would have enacted drug patent legislation in detail corresponding to those two acts.[125]

The C.C.P.A. (and subsequently the Federal Circuit) reaffirmed that no provision in the patent statute makes safety a patentability criterion.[126]

D. Takeaways

Two Federal Circuit decisions now make it hard for courts to use *patentability* as a tool for protecting public health. Both involve the utility requirement of § 101. First, as discussed above, *Brana* rejects the heightened proof standard for therapeutic inventions and (from an evidentiary standpoint) aligns utility with the other patentability requirements.[127]

The second case, *Juicy Whip, Inc. v. Orange Bang, Inc.*,[128] squarely rejects the role of morality in patentability determinations.[129] Morality entered the calculus in the 1817 case *Bedford v. Hunt*, where Justice

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

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

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

127 The modern utility requirement of § 101 has three prongs. *See generally* 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). Operability (or credible utility) requires that an invention be capable of achieving its intended result. *See* cases cited *supra* note 42. Substantial utility requires that the invention provide "a significant and presently available benefit to the public." *Fisher*, 421 F.3d at 1371. Specific utility requires that the invention provide "a well-defined and particular benefit to the public." *Id.*

128 185 F.3d 1364, 1364 (Fed. Cir. 1999).

129 *Id.* at 1366–67, 1368.

Story wrote that an invention's asserted utility couldn't be "injurious to the morals, the health, or the good order of society."[130] During the early part of the twentieth century, courts relied on Justice Story's language to craft the "moral utility" doctrine.[131] It allowed courts to exercise moral discretion to make "subjective decisions about whether inventions were good for society."[132] Inventions had to meet certain court-identified morality standards.[133]

The moral utility doctrine took a devastating blow in *Ex parte Murphy*, a 1977 case in which the Board of Patent Appeals and Interferences[134] reversed the examiner's lack-of-utility rejection for a slot machine.[135] The final blow came nearly two decades later in *Juicy Whip*, where the Federal Circuit decided that an invention with a deceptive purpose—designed to appear to be something it isn't—could satisfy utility.[136] Justice Story's forbidden class of inventions isn't a part of modern utility doctrine.[137] Now the Patent Office and the courts "apply the statutory standards without regard to the moral implications of the underlying invention."[138] The demise of moral utility aligns with the Supreme Court's "[a]nything under the sun . . . made by man"

130 3 F. Cas. 37, 37 (C.C.D. Mass. 1817) (No. 1217) (opinion of Story, J.).

131 *See* Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 489 (2003).

132 NED SNOW, INTELLECTUAL PROPERTY AND IMMORALITY: AGAINST PROTECTING HARMFUL CREATIONS OF THE MIND 141 (2022).

133 For example, in *Klein v. Russell*, 86 U.S. (19 Wall.) 433 (1874), the Supreme Court invalidated a patent that it deemed deceptive for substituting a less valuable material (sheep skin) for a more valuable one (dog skin) on an unwitting public. *See id.* at 445, 468. The Court affirmed the trial court's jury instructions that "[i]f the process patented cannot be made useful for any honest purpose, and can be used only for perpetrating a fraud upon the public, and is therefore not useful, but pernicious, the plaintiff cannot recover." *Id.* at 445.

134 An applicant whose claims have been twice rejected by the examiner can appeal to an intra-office tribunal—known as the Board of Patent Appeals and Interferences at the time of *Murphy*—which, among other things, reviewed adverse decisions of examiners. *See* 35 U.S.C. §§ 6(b), 134(a) (2006). The Board could affirm a rejection or reverse and remand to the examining corps. *See* 37 C.F.R. § 1.702(e) (2019). Since the passage of the America Invents Act in 2011, the tribunal is now known as the Patent Trial and Appeal Board. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 7, 125 Stat. 284, 313 (2011) (codified in scattered sections of 35 U.S.C.).

135 200 U.S.P.Q. (BL) 801, 802 (Bd. Pat. App. 1977).

136 *See* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999). For a discussion of the facts of this case, see *infra* text accompanying notes 377–380.

137 *See Juicy Whip*, 185 F.3d at 1366–68. The court explained that imposing a moral component to § 101 should be left to Congress. *See id.* at 1368.

138 Holbrook, *supra* note 53, at 602.

interpretation of eligible subject matter set forth in *Diamond v. Chakrabarty*.[139]

Yet, the prior stringent interpretation of § 101 has disturbing consequences. It's troubling to think about meritorious inventions that were denied patentability under the heightened standard.[140] By the time sufficient proof could be adduced, the invention was likely time-barred from patent protection.[141] Inventors also could've eschewed patenting altogether. Since inventors respond to how the Patent Office and courts behave,[142] they could logically forego pursuing a patent if a denial was inevitable.[143] This hinders patent law's disclosure function[144] and role in encouraging research in controversial technologies.[145]

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139 Bagley, *supra* note 131, at 485 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)); *see also* SNOW, *supra* note 132, at 141 ("Read together, *Chakrabarty* and *Juicy Whip* serve to negate the socially beneficial interpretation of 'useful.'").

140 *Cf.* Seymore, *supra* note 39, at 1106–07 (noting that a consequence of heightened patentability standards is that meritorious inventions "slip through the cracks," *id.* at 1107).

141 As 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)]." DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 111 (2009). Briefly, under the Patent Act of 1952, § 102(b) dedicates an invention to the public if the applicant doesn't file a patent application within one year of a public disclosure. 35 U.S.C. § 102(b) (2006).

142 *See* ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 175 (2004).

143 Seymore, *supra* note 46, at 1108; *cf.* Seymore, *supra* note 39, at 1147 n.335.

144 As explained by one commentator:

> [S]ince inventors need not seek patents . . . , they may keep their research private so the public will not scrutinize their work or benefit from its disclosure. . . . [S]uppose that the PTO revives the moral utility doctrine. A scientist knows that her purportedly immoral invention will be unpatentable and, therefore, does not even seek a patent. . . . [I]f this inventor chooses to patent this device and the PTO invalidates it on moral grounds, the public cannot benefit from disclosure of the invention and subsequently cannot scrutinize her research and its possible effects. . . . If the PTO grants a patent for the controversial invention because it meets the criteria for patentability, then the patent is disclosed to the public . . . [who] may scrutinize the work . . . .

Benjamin D. Enerson, Note, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685, 716 (2004) (footnote omitted).

145 "[I]mplementing morality standards may deter inventors from filing patents in controversial areas and initiate a chain reaction of negative effects . . . [such as] diminish[ing] the growth in a particular field of research, ultimately prohibiting inventors from creating alternative inventions . . . ." *Id.* at 715. David Taylor argues that "the best approach to dealing with the patentability of controversial technologies—technologies some may deem immoral or unethical—is to have the President and Congress determine eligible subject matter through legislation." David O. Taylor, *Immoral Patents*, 90 MISS. L.J. 271, 309 (2021).

Relatedly, the old interpretation of § 101 probably *hindered* research and development in therapeutics.[146] The *Brana* court certainly thought so:

> Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. . . . Were we to require [efficacy and safety] 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.[147]

One commentator argues that if *Brana* had upheld the stringent utility requirement urged by the Patent Office, it "[ran] the risk of seriously inhibiting the incentives to compete among biotechnology companies and, therefore, jeopardize[d] the very existence of the industry."[148] Again, by the time sufficient proof could be adduced, the invention likely would be disclosed and likely time-barred from patent protection.[149]

History shows that successful treatments for old, difficult-to-treat diseases occur with some frequency.[150] While scholars disagree about *when* a patent should issue and how descriptive it should be for such inventions,[151] there's no debate about *if* a patent should issue. A final takeaway—one that the C.C.P.A. recognized in the 1950s—is "[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."[152]

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146 *See* Seymore, *supra* note 46, at 1049–50.

147 *In re* Brana, 51 F.3d 1560, 1568 (Fed. Cir. 1995).

148 Kevin C. Hooper, *Utility and Non-operability Standards in Biotechnology Patent Prosecution: CAFC Precedent Versus PTO Practice*, 36 IDEA 203, 250 (1995).

149 *See supra* note 141 and accompanying text.

150 *See, e.g.*, IAN GLYNN & JENIFER GLYNN, THE LIFE AND DEATH OF SMALLPOX (2004); Apoorva Mandavilli, *Woman Cured of H.I.V. Using Novel Treatment: Umbilical Cord Blood*, N.Y. TIMES, Feb. 16, 2022, at A19.

151 *Compare* Christopher A. Cotropia, *Physicalism and Patent Theory*, 69 VAND. L. REV. 1543, 1561–66 (2016) (proposing that inventions should be physically made and tested—and thus further down the research and development path—before they're patentable), *and* Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 156–58 (2008) (proposing a framework that shifts the burden of proof to the applicant to establish enablement, particularly in unpredictable fields), *with* John F. Duffy, *Reviving the Paper Patent Doctrine*, 98 CORNELL L. REV. 1359, 1368–71 (2013) (exploring the history of "constructive reduction to practice," *id.* at 1368, which allows patents on inventions that can be described on paper without any physical act or proof of concept).

152 *In re* Chilowsky, 229 F.2d 457, 461 (C.C.P.A. 1956) (emphasis added), *quoted in* Gould v. Quigg, 822 F.2d 1074, 1078 (Fed. Cir. 1987).

II. LIMITING PATENT ENFORCEMENT REMEDIES FOR PUBLIC HEALTH

A patentee has the right "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States."[153] After patent issuance, the patentee can bring a suit for damages and injunctive relief against any person or entity who allegedly has infringed the patent.[154] Prior to the Supreme Court's decision in *eBay Inc. v. MercExchange, L.L.C.*,[155] a permanent injunction was the preferred form of relief[156] and would be granted "as a matter of course" if the patent was found infringed and deemed not invalid.[157]

The pre-*eBay* exception to the general rule granting prospective relief was to protect public health.[158] Based on the equities of the case,[159] a court could determine that vindicating the patentee's right to exclude[160] didn't outweigh an injunction's potentially catastrophic effect on public health.[161]

Below I explore the rare circumstances when a federal court will deny a permanent injunction in a patent case to protect public health.

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153 35 U.S.C. § 154(a)(1) (2018); *see id.* § 271(a).

154 *See id.* § 281.

155 547 U.S. 388 (2006). In *eBay*, a unanimous Court held that a district court deciding whether to grant an injunction must apply "familiar," "well-established principles of equity" without any patent-specific rules and standards. *Id.* at 391.

156 *See id.* at 395 (Roberts, C.J., concurring) ("From at least the early 19th century, courts have granted injunctive relief . . . in the vast majority of patent cases.").

157 *Id.* at 396 (Kennedy, J., concurring).

158 "[W]e have stated that a court may decline to enter an injunction when 'a patentee's failure to practice the patented invention frustrates an important public need for the invention,' such as the need to use an invention to protect public health." MercExchange, L.L.C. v. eBay, Inc., 401 F.3d 1323, 1338 (Fed. Cir. 2005) (quoting Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1547 (Fed. Cir. 1995)).

159 *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 865 (Fed. Cir. 1984) ("Whether an injunction should issue in this case, and of what form it should take, certainly depends on the equities of the case." (emphasis omitted)). While a court may grant a preliminary injunction pending trial, it can grant a permanent injunction only "after a full determination on the merits." High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc., 49 F.3d 1551, 1554 (Fed. Cir. 1995); *see also* JAMES M. FISCHER, UNDERSTANDING REMEDIES 150 (4th ed. 2021).

160 *See* Peter Lee, *The Accession Insight and Patent Infringement Remedies*, 110 MICH. L. REV. 175, 214 (2011); *see also MercExchange*, 401 F.3d at 1338 ("Because the 'right to exclude recognized in a patent is but the essence of the concept of property,' the general rule is that a permanent injunction will issue once infringement and validity have been adjudged." (quoting Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1246–47 (Fed. Cir. 1989))).

161 *Cf. Roche*, 733 F.2d at 865.

A. To Avert a Public Health Crisis

Perhaps the most storied case where an injunction was denied to protect public health is *City of Milwaukee v. Activated Sludge, Inc.*[162] At the beginning of the nineteenth century, sewage treatment was still a primitive technology.[163] Municipalities relied on crude purification methods that produced smelly, low-quality water for discharge into rivers and lakes.[164]

In the early 1910s, two English chemists discovered that treating sewage with bacteria and other microorganisms while bubbling air through it produces a clear, nonodorous discharge.[165] This "activated sludge" process made a major impact on human health and environmental protection[166] and is the most common biological sewage treatment process in the world.[167]

The City of Milwaukee consulted with a group of inventors about constructing an activated sludge treatment plant to flow directly into Lake Michigan.[168] After the plant began operation, the inventor-patentees sued the city for infringement.[169] After finding that the patents were infringed and not invalid,[170] the district court permanently enjoined the city from operating the plant.[171] This ruling had ripple effects in cities across the country—including the shutdown of existing activated sludge plants; delays in building new activated sludge plants until the patents expired; and decisions to build plants with inferior technologies.[172]

On appeal,[173] the Seventh Circuit recognized the general rule for awarding injunctive relief in patent cases.[174] But it considered the

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162 69 F.2d 577 (7th Cir. 1934).

163 *See* Glen T. Daigger, *Ardern and Lockett Remembrance*, *in* ACTIVATED SLUDGE—100 YEARS AND COUNTING 1, 3–5 (David Jenkins & Jiří Wanner eds., 2014); James E. Alleman & T.B.S. Prakasam, *Reflections on Seven Decades of Activated Sludge History*, 55 J. WATER POLLUTION CONTROL FED'N 436, 436 (1983).

164 *See* Alleman & Prakasam, *supra* note 163, at 436.

165 *See id.* at 437–38.

166 *See* Daigger, *supra* note 163, at 6.

167 H. David Stensel & Jacek Makinia, *Activated Sludge Process Development*, *in* ACTIVATED SLUDGE, *supra* note 163, at 33, 33.

168 *See* City of Milwaukee v. Activated Sludge, Inc., 69 F.2d 577, 589–90 (7th Cir. 1934).

169 Activated Sludge, Inc. sued or settled with over 100 cities for patent infringement, including Chicago, Columbus, Fort Worth, Houston, New York, and San Antonio. *See Activated Sludge, Inc.*, TIME, July 5, 1937, at 48, 48–50.

170 *See Activated Sludge*, 69 F.2d at 588–89.

171 *Id.* at 593.

172 Alleman & Prakasam, *supra* note 163, at 440.

173 In patent cases, an appellate court reviews the grant of a permanent injunction, as well as its scope, for an abuse of discretion. Joy Techs., Inc. v. Flakt, Inc., 6 F.3d 770, 772 (Fed. Cir. 1993) (citing Ortho Pharm. Corp. v. Smith, 959 F.2d 936, 945 (Fed. Cir. 1992)).

174 *See Activated Sludge*, 69 F.2d at 593.

effect of a permanent injunction on the public—whose equities "[were] even stronger than those of the parties."[175] It determined that maintaining the injunction

> would close the sewage plant, leaving the entire community without any means for the disposal of raw sewage other than running it into Lake Michigan, thereby polluting its waters and endangering the health and lives of that and other adjoining communities. . . . [T]he health and the lives of more than half a million people are involved, we think no risk should be taken . . . .[176]

So the court dissolved the injunction and held that damages were an adequate remedy for infringement.[177]

B. To Solve a National Public Health Problem

In *Vitamin Technologists, Inc. v. Wisconsin Alumni Research Foundation*, a court was unwilling to grant a permanent injunction because it'd deprive the poor of an essential vitamin needed to treat and prevent a crippling disease.[178] This is the quintessential case where academic research, patent law, public health, medicine, and scientific ethics collided.

In the early 1920s, University of Wisconsin biochemistry professor Harry Steenbock invented a process for increasing the Vitamin D content of food by irradiating it with ultraviolet light.[179] Steenbock's invention could eliminate rickets, a bone disease caused by a Vitamin D deficiency that disproportionately afflicted the poor.[180] Steenbock obtained four patents[181] to "ensure the safest, most healthful dissemination" of the technology[182]—to protect the public against "the

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175 *Id.*

176 *Id.*

177 *See id.*; *cf.* DOUGLAS LAYCOCK, THE DEATH OF THE IRREPARABLE INJURY RULE 5 (1991) (explaining that courts find damages adequate only when there's some identifiable reason to deny them in a particular case); DOUGLAS LAYCOCK & RICHARD L. HASEN, MODERN AMERICAN REMEDIES: CASES AND MATERIALS 387 (5th ed. 2019) (courts will find damages "adequate").

178 146 F.2d 941 (9th Cir. 1945).

179 *See* Rima D. Apple, *Patenting University Research: Harry Steenbock and the Wisconsin Alumni Research Foundation*, 80 ISIS 374, 375–76 (1989).

180 *See id.* at 384–85, 392; ALEXANDER ZAITCHIK, OWNING THE SUN: A PEOPLE'S HISTORY OF MONOPOLY MEDICINE FROM ASPIRIN TO COVID-19 VACCINES 50–51 (2022).

181 Peter Lee, *Patents and the University*, 63 DUKE L.J. 1, 17 (2013); *see* U.S. Patent No. 1,680,818 (filed June 30, 1924); U.S. Patent No. 1,871,135 (filed Dec. 27, 1926); U.S. Patent No. 1,871,136 (filed Dec. 27, 1926); U.S. Patent No. 2,057,399 (filed May 14, 1932).

182 Apple, *supra* note 179, at 377; *see* H. Steenbock & A. Black, *Fat-Soluble Vitamins: XXIII. The Induction of Growth-Promoting and Calcifying Properties in a Ration by Exposure to Ultra-violet Light* (pt. 17), 61 J. BIOLOGICAL CHEMISTRY 405, 405 n.* (1924) ("To protect the interest of the public in the possible commercial use of these . . . findings . . . , applications

manufacture of poor preparations,"[183] "extortionate charges,"[184] and "unscrupulous food and drug venders [*sic*]" who might market irradiated products with indefensible claims.[185]

But Steenbock's *other* reason for patenting had a very different effect on public health and went "from the altruistic to the parochial."[186] He licensed the irradiation process to companies that made Vitamin D–fortified products; including Eli Lilly, Abbott Laboratories, Anheuser Busch, Quaker Oats, and Fleischmann's.[187] Yet, there was one notable omission. Steenbock refused to license the process to margarine manufacturers in order to protect Wisconsin's dairy industry.[188] Margarine, a cheap butter substitute, challenged the dairy industry because butter was in short supply after World War I.[189] If manufacturers could fortify margarine with Vitamin D, it could be marketed and sold as a nutritional equivalent to butter.[190] Steenbock's decision had the biggest impact on poor children, whom the medical community urged should receive Vitamin D to prevent rickets and an increased risk of pneumonia.[191]

Vitamin Technologists was a patent infringement suit involving the Steenbock patents.[192] After finding that the patents were infringed and not invalid, the district court issued a permanent injunction.[193] On appeal, the accused infringer successfully asserted invalidity.[194] The

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for Letters Patent, both as to processes and products, have been filed with the United States Patent Office . . . ."); Harry Steenbock, *The Induction of Growth Promoting and Calcifying Properties in a Ration by Exposure to Light*, 60 SCIENCE 224, 225 (1924) (stating the same).

183 Apple, *supra* note 179, at 377.

184 *Id.*

185 *Id.* (alteration in original) (internal quotation omitted).

186 Lee, *supra* note 181, at 17.

187 *See* Apple, *supra* note 179, at 386–87.

188 *See id.* at 377–78.

189 *Id.* at 377.

190 *Id.* at 378.

191 *See id.* at 381 fig.1, 385.

192 *See* Vitamin Technologists, Inc. v. Wis. Alumni Rsch. Found., 146 F.2d 941 (9th Cir. 1945).

193 *Id.* at 942. The patents were owned by the Wisconsin Alumni Research Foundation (WARF)—the university's independent technology-transfer arm. Steenbock helped create WARF to manage the patents and commercialization so that faculty inventors could focus research. *See* Apple, *supra* note 179, at 383–89.

194 *See Vitamin Technologists*, 146 F.2d at 947–53. For the then-existing novelty provision, see 35 U.S.C. § 31 (1940) ("Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter . . . not known or used by others . . . before his invention or discovery thereof . . . may . . . obtain a patent therefor.") (repealed 1952).

Ninth Circuit found that the invention lacked novelty[195]: the identical process has occurred in nature whenever the sun's ultraviolet rays hit the sap of cut hay or the meat of a coconut.[196] Thus, the patents were invalidated on the merits.

But *Vitamin Technologists* is more famous for what the court said it *would've done* had the patent survived the invalidity attack. It considered "the question, not argued, whether the effect on the public health of refusing to the users of oleomargarine, the butter of the poor, the right to have such a food irradiated by the patented process is against the public interest."[197] The answer is to deny a permanent injunction.[198] The patentee's refusal to license its patent to protect the health of great numbers of the public from a preventable and treatable disease was "vastly more against the public interest" than cases where relief was denied because of the patentee's anticompetitive practices.[199]

*C. Denying Injunctions Post-*eBay *to Protect Public Health*

The public health exception notwithstanding,[200] patentees before 2006 were entitled to permanent injunctions as a matter of course if they won their infringement suits.[201] But *eBay* changed that—a district court deciding whether to grant an injunction must apply "familiar," "well-established principles of equity" without any patent-specific rules and standards.[202] This holding squarely rejects patent law

195 *See Vitamin Technologists*, 146 F.2d at 949. "Inventions, in order that they may be the proper subjects of letters-patent, must be new . . . ." Mitchell v. Tilghman, 86 U.S. (19 Wall.) 287, 396 (1874).

196 *See Vitamin Technologists*, 146 F.2d at 948.

197 *Id.* at 945.

198 *See id.* at 956.

199 *Id.* at 946 (first citing United States v. Masonite Corp., 316 U.S. 265, 278 (1942); and then citing Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661, 665 (1944)).

200 *See supra* notes 158–61 and accompanying text.

201 *See* 3 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 1220, at 653 (Boston, Little, Brown, & Co. 1890) ("A perpetual injunction issues, as a matter of course, at the conclusion of a suit in equity, whenever the plaintiff has sustained the allegations of his bill, provided the patent has not then expired."); Herbert F. Schwartz, Note, *Injunctive Relief in Patent Infringement Suits*, 112 U. PA. L. REV. 1025, 1041–42 (1964) ("By the middle of the nineteenth century, courts generally recognized that the plaintiff was entitled to . . . an injunction against future infringements for the life of the patent."). The Federal Circuit followed the "general rule that an injunction will issue when infringement has been adjudged, absent a sound reason for denying it." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1247 (Fed. Cir. 1989).

202 eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006). A recent example: the Supreme Court's rejection of the Federal Circuit's extraterritorial application of U.S. patent law and reaffirmance of the "presum[ption] that federal statutes 'apply only within the territorial jurisdiction of the United States.'" WesternGeco LLC v. ION Geophysical Corp., 138 S. Ct. 2129, 2136 (2018) (quoting Foley Bros., Inc. v. Filardo, 336 U.S. 281, 285

exceptionalism—the notion that patent law's specialized and technical nature should allow judges to deviate from recognized principles and doctrines applicable to other areas of law.[203] Other Supreme Court patent cases have chipped away at exceptionalism and seek to (re)connect patent law with other areas of law.[204]

District courts now apply a "traditional" four-factor test in each case.[205] A patent plaintiff seeking a permanent injunction must demonstrate that: (1) it suffered an irreparable injury; (2) legal remedies, like damages, inadequately compensate for that injury; (3) considering the balance of hardships between the plaintiff and defendant, an injunction is warranted; and (4) an injunction won't disserve the public interest.[206]

Public health is *the* core public interest.[207] So, a post-*eBay* court with its newfound discretion could conceivably use the public interest

(1949)). For commentary, see Timothy R. Holbrook, *Is There a New Extraterritoriality in Intellectual Property?*, 44 COLUM. J.L. & ARTS 457, 504–07 (2021).

203 *See* Paul R. Gugliuzza, *The Federal Circuit as a Federal Court*, 54 WM. & MARY L. REV. 1791, 1817–18 (2013); Tejas Narechania, *Certiorari, Universality, and a Patent Puzzle*, 116 MICH. L. REV. 1345, 1388–90 (2018) (discussing the decline of patent exceptionalism and the Supreme Court's "strong interest in universal rules," *id.* at 1390); Greg Reilly, *Decoupling Patent Law*, 97 B.U. L. REV. 551, 610 (2017); David O. Taylor, *Formalism and Antiformalism in Patent Law Adjudication: Rules and Standards*, 46 CONN. L. REV. 415, 474 (2013) (discussing Federal Circuit judges who endorse patent-specific rules given the "unique," "particular," and "special" issues that arise in patent law).

204 *See* Timothy R. Holbrook, *Explaining the Supreme Court's Interest in Patent Law*, 3 IP THEORY 62, 71–72 (2013); *see also* Peter Lee, *The Supreme Assimilation of Patent Law*, 114 MICH. L. REV. 1413, 1425–50 (2016) (discussing the Supreme Court's rejection of patent exceptionalism interest in universality and assimilation of patent law into other areas of law). For examples, see *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128–37 (2007) (rejecting the Federal Circuit's patent-specific test for declaratory judgments); and *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 550–53 (2014) (admonishing the Federal Circuit to use general equitable principles for determining "exceptional" cases for the award of attorney's fees, *id.* at 550).

205 *See eBay*, 547 U.S. at 391. It's worth noting that several remedies scholars disagree with this characterization. *See, e.g.*, LAYCOCK & HASEN, *supra* note 177, at 443 ("Certainly the grant of a permanent injunction was never automatic on a showing of liability. But there was no 'traditional' four-part test."); Doug Rendleman, *The Trial Judge's Equitable Discretion Following* eBay v. MercExchange, 27 REV. LITIG. 63, 76 n.71 (2007) ("Remedies specialists had never heard of [*eBay*'s] four-point test.").

206 *eBay*, 547 U.S. at 391.

207 This was clearly so under the Federal Circuit's pre-*eBay* rule. *See* Transcript of Oral Argument at 3–4, *eBay*, 547 U.S. 388 (No. 05-130); *supra* note 158. Some courts continue to prioritize public health in analyzing *eBay*'s public interest factor. *See, e.g.*, TiVo Inc. v. EchoStar Commc'ns Corp., 446 F. Supp. 2d 664, 670 (E.D. Tex. 2006) (granting the permanent injunction because "[t]he infringing products are not related to any issue of public health or any other equally key interest"). For criticisms, see James Boyle, *Open Source Innovation, Patent Injunctions, and the Public Interest*, 11 DUKE L. & TECH. REV. 30, 41 (2012)

factor to protect public health, which is wholly consistent with *City of Milwaukee* and *Vitamin Technologists*.[208] But in the handful of post-*eBay* public health cases where a permanent injunction has been sought, aside from requiring evidence of the alleged public health consequences,[209] no clear trends have emerged.[210] As one commentator has observed,

> one glaring conclusion is apparent: courts apply the traditional four factors unpredictably in these cases, even when devices are relatively identical. Even when important devices that help sustain life are involved (i.e., prosthetic heart valves, vascular stents, and hemodialysis machines), courts unpredictably apply the factors, with some courts granting injunctive relief despite public interest concerns and other courts denying injunctive relief due to public interest concerns.[211]

Making injunctive relief more predictable by establishing a categorical rule for public health—reestablishing a public health exception—would contradict *eBay*.[212] Regardless, public health was rarely used to deny permanent injunctions before *eBay*,[213] so there's little reason to think that it'd do much work in the public health space after *eBay*. Moreover, *eBay*'s tougher standards have led fewer patentees to seek permanent injunctions.[214]

("Courts have in some cases adopted definitions of the public interest that seemed to hearken back to the [Federal Circuit]'s old test, rejected by the Supreme Court in *eBay*.").

208 *See* Lance Wyatt, Note, *Rebuttable Presumption of Public Interest in Protecting the Public Health—The Necessity for Denying Injunctive Relief in Medically-Related Patent Infringement Cases After* eBay v. MercExchange, 13 CHI.-KENT J. INTELL. PROP. 298, 300–01 (2013).

209 *See* Acumed LLC v. Stryker Corp., 551 F.3d 1323, 1331 (Fed. Cir. 2008) (rejecting the argument that removing the infringing orthopedic device from the marketplace would have an adverse effect on public safety because of the absence in the record of "sufficient objective evidence of any public-health issue" (quoting Acumed LLC v. Stryker Corp., No. 04-CV-513, 2007 WL 4180682, at *8 (D. Or. Nov. 20, 2007))).

210 *See* Wyatt, *supra* note 208, at 309–19.

211 *Id.* at 321–22 (footnote omitted).

212 *See* WBIP, LLC v. Kohler Co., 829 F.3d 1317, 1343 (Fed. Cir. 2016) ("The district court's decision is based on its reasoning that having more manufacturers of a life-saving good in the market is better for the public interest. But this reasoning . . . would create a categorical rule denying permanent injunctions for life-saving goods, such as many patented pharmaceutical products.").

213 Bernard H. Chao, *After* eBay, Inc. v. MercExchange*: The Changing Landscape for Patent Remedies*, 9 MINN. J.L. SCI. & TECH. 543, 543 (2008) (citing Vitamin Technologists, Inc. v. Wis. Alumni Rsch. Found., 146 F.2d 941 (9th Cir. 1945)).

214 *See* Kirti Gupta & Jay P. Kesan, *Studying the Impact of* eBay *on Injunctive Relief in Patent Cases* 22–26 (Univ. of Ill. Coll. of L. Legal Stud., Research Paper No. 17-03, 2016), https://ssrn.com/abstract=2816701 [https://perma.cc/A32S-Z9HE]. This is true for patentees who manufacture the product claimed in the patent and those who don't directly compete in a product market. *See id.*

III. TOWARD PUBLIC HEALTH AS AN AFFIRMATIVE DEFENSE

Even if courts are unlikely to use patentability or injunction denials as mechanisms to protect public health, there's another possibility. This Part describes how courts can protect public health with the affirmative defense of patent unenforceability.

A. Understanding Patent Unenforceability

Much of a patent's value lies in the ability to enforce it against infringers.[215] Section 282 of the U.S. Code permits an alleged infringer to assert several affirmative defenses.[216] These include noninfringement,[217] invalidity,[218] and unenforceability.[219] The latter is an equitable defense whose application is committed to the district court's sound discretion.[220]

Some of patent law's unenforceability doctrines find their roots in unclean hands.[221] Perhaps the most storied affirmative defense in civil cases,[222] unclean hands closes the courthouse doors to a plaintiff who commits a willful act "tainted with inequitableness or bad faith"

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215 *See* 35 U.S.C. § 281 (2018) ("A patentee shall have [a] remedy by civil action for infringement of his patent."); *see also* Shaun Martin & Frank Partnoy, *Patents as Options*, *in* PERSPECTIVES ON COMMERCIALIZING INNOVATION 303, 321 (F. Scott Kieff & Troy A. Paredes eds., 2012).

216 *See* 35 U.S.C. § 282(b) (2018); *see also* SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC, 807 F.3d 1311, 1322 (Fed. Cir. 2015) (en banc) (explaining that 35 U.S.C. § 282(1) lists "categories" of defenses available in an infringement suit), *vacated in part* 137 S. Ct. 954 (2017). These defenses must be raised in the answer. § 282(b)(1).

217 *See* § 282(b)(1). Infringement is a question of fact that the patentee must prove by a preponderance of the evidence. Siemens Med. Sols. USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc., 637 F.3d 1269, 1279 (Fed. Cir. 2011) (citing Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1310 (Fed. Cir. 2005)).

218 *See* § 282(b)(2). An invalidity defense requires the accused infringer to prove by clear and convincing evidence that the patent fails to satisfy one or more of the statutory patentability requirements. *See* Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 95 (2011).

219 *See* § 282(b)(1). An unenforceable patent is essentially "useless" to the patentee. Lee Petherbridge, Jason Rantanen & R. Polk Wagner, *Unenforceability*, 70 WASH. & LEE L. REV. 1751, 1753 (2013). Note that a patent can be valid (because it satisfies the statutory patentability requirements) yet unenforceable. Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1237 (Fed. Cir. 2003) (citing PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1322 (Fed. Cir. 2000)).

220 eSpeed, Inc. v. BrokerTec USA, L.L.C., 480 F.3d 1129, 1135 (Fed. Cir. 2007) (citing Flex-Rest, L.L.C. v. Steelcase, Inc., 455 F.3d 1351, 1357 (Fed. Cir. 2006)); *see also* A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020, 1028 (Fed. Cir. 1992) (en banc), *abrogated by* SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC, 137 S. Ct. 954 (2017).

221 *See infra* text accompanying notes 222–32.

222 *See* RALPH A. NEWMAN, EQUITY AND LAW: A COMPARATIVE STUDY 250 (1961).

relative to the matter for which relief is sought.[223] It can be traced to the moral principle that "relief will be refused to one who is trying to get the court to give him relief based on a shameful act."[224] The English chancellors established the maxim that "one who invokes the aid of a court must come into it with a clear conscience and clean hands."[225] This maxim is a bedrock of equity jurisprudence.[226] In the United States, the doctrine dates back to the early Republic.[227] In patent cases, the Supreme Court has stated that the doctrine "assumes even wider and more significant proportions"[228] because of the "carefully crafted bargain"[229] or quid pro quo between the inventor and the public.[230] This bargain between the inventor and the public is the essence of the U.S. patent system.[231] Patents tainted with fraud or inequitableness prevent the public from recouping its end of the bargain.[232]

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223 Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 814 (1945).

224 NEWMAN, *supra* note 222, at 250.

225 Zechariah Chafee, Jr., *Coming into Equity with Clean Hands*, 47 MICH. L. REV. 1065, 1088 (1949) (quoting Kellog v. Kellog, 137 N.W. 249, 250 (Mich. 1912)); *cf.* 1 JOHN NORTON POMEROY & JOHN NORTON POMEROY, JR., A TREATISE ON EQUITY JURISPRUDENCE § 363, at 674 (4th ed. 1918) (listing the "maxims of equity," including "he who comes into equity must come with clean hands"); RICHARD FRANCIS, MAXIMS OF EQUITY 5 (Dublin, Henry Watts 3d ed. 1791) ("Maxim II. He that hath committed Iniquity, shall not have Equity." (footnote omitted)); Samuel L. Bray, A Student's Guide to the Meanings of "Equity" 5 (July 20, 2016) (unpublished manuscript), https://osf.io/sabev [https://perma.cc/67YG-7YSP] (describing the hallmarks of equity courts as "case-specificity, discretion, flexibility, moral reasoning, and resistance to fraud, exploitation, and the abuse of legal rights").

226 HAROLD GREVILLE HANBURY, MODERN EQUITY: BEING THE PRINCIPLES OF EQUITY 4 (1935) ("There is no clearer maxim of equity than '[h]e who comes to equity must come with clean hands.'" (quoting *id.* at 73–74)); *cf.* RONALD DWORKIN, TAKING RIGHTS SERIOUSLY 25 (1978) ("We say that our law respects the principle that no man may profit from his own wrong . . . .").

227 Zechariah Chafee, Jr., Lecture Delivered at the University of Michigan (Apr. 1949), *in* ZECHARIAH CHAFEE, JR., SOME PROBLEMS OF EQUITY: FIVE LECTURES DELIVERED AT THE UNIVERSITY OF MICHIGAN 1, 5 (Thomas M. Cooley Lectures 2d Ser., 1950). The doctrine was first recognized by the Supreme Court in *Talbot v. Jansen*, 3 U.S. (3 Dall.) 133, 158 (1795) ("[P]ersons guilty of fraud, should not gain by it. Hence the efficacy of the legal principle, that no man shall set up his own fraud or iniquity, as a ground of action or [defense]."); *see also* Cathcart v. Robinson, 30 U.S. (5 Pet.) 264, 276 (1831) (applying the "well settled" principle that "the plaintiff must come into court with clean hands," lest "a court [will] withhold its aid").

228 *Precision Instrument*, 324 U.S. at 815.

229 Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150, 150–51 (1989).

230 *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974) (explaining the wisdom of bestowing limited monopoly rights in the patent system to encourage innovation); Special Equip. Co. v. Coe, 324 U.S. 370, 378 (1945) (discussing the bestowal of exclusivity that accompanies the grant of a patent).

231 *See Kewanee Oil*, 416 U.S. at 480–81; Pennock v. Dialogue, 27 U.S. (2 Pet.) 1, 23 (1829).

232 To be sure, "it is very easy for the public to get the short end of the stick in this so-called patent bargain." Seymore, *supra* note 46, at 1074.

Federal courts recognize three affirmative defenses in patent cases derived from unclean hands—inequitable conduct, patent misuse, and unclean hands itself. Inequitable conduct is a judge-made doctrine that polices the duty of candor and good faith each patent applicant owes to the Patent Office.[233] A patent rendered unenforceable for inequitable conduct can't be asserted in future suits "because the property right [itself] is tainted *ab initio*."[234]

Patent misuse, also a judge-made doctrine,[235] withholds any infringement remedy if the patentee has engaged in postissuance practices that draw anticompetitive power from the patent right.[236] It prevents the patentee from extending the patent beyond its statutorily conferred scope.[237] The doctrine is almost exclusively applied in the context of patent licensing,[238] such as when the patentee requires a licensee to purchase unpatented goods along with the patented product or process.[239] The key question is whether, by imposing a condition upon the licensee, the patentee has "impermissibly broadened the 'physical or temporal scope' of the patent grant with anticompetitive effect."[240] If so, a court "will not lend its support to enforcement of a patent that has been misused."[241] A patent rendered unenforceable for patent misuse can become enforceable if the misuse is "purged."[242] This occurs if a court finds that "the improper practice has been abandoned and that the consequences of the misuse of the patent have

233 *See* Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc); Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995).

234 Aptix Corp. v. Quickturn Design Sys., Inc., 269 F.3d 1369, 1376 (Fed. Cir. 2001) (citing Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238, 251 (1944), *abrogated by* Standard Oil Co. of Cal. v. U.S., 429 U.S. 17 (1976) (per curiam)).

235 *See* Morton Salt Co. v. G.S. Suppiger Co., 314 U.S. 488, 492–93 (1942), *abrogated by* Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28 (2006).

236 Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 704 (Fed. Cir. 1992).

237 *See* C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998).

238 *See, e.g.*, Princo Corp. v. Int'l Trade Comm'n, 616 F.3d 1318 (Fed. Cir. 2010) (en banc) (discussing patent misuse in the licensing context and noting that "[b]ecause patent misuse is a judge-made doctrine that is in derogation of statutory patent rights against infringement, this court has not applied the doctrine of patent misuse expansively," *id.* at 1321).

239 *See* 6A CHISUM, *supra* note 105, § 19.04[3].

240 Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1001 (Fed. Cir. 1986) (quoting Blonder-Tongue Lab'ys, Inc. v. Univ. of Ill. Found., 402 U.S. 313, 343 (1971)).

241 B. Braun Med., Inc. v. Abbott Lab'ys, 124 F.3d 1419, 1427 (Fed. Cir. 1997) (citing Senza-Gel Corp. v. Seiffhart, 803 F.2d 661, 668 (Fed. Cir. 1986)).

242 *Id.*

been dissipated."[243] Importantly, the Supreme Court views the general public as the true victim of patent misuse.[244]

The third defense is unclean hands itself—a broad doctrine that polices patentee misconduct beyond (anticompetitive) misuse and dealings with the Patent Office.[245] The Supreme Court has stated that the unclean hands defense is appropriate in a patent suit when the plaintiff's alleged misconduct "has immediate and necessary relation" to the relief sought.[246] The alleged misconduct "need not necessarily have been of such a nature as to be punishable as a crime or as to justify legal proceedings of any character."[247] However, being a bad actor isn't enough[248] because the doctrine isn't applied as a generalized punishment.[249] Courts aren't "bound by formula" and have "wide . . . use of discretion in refusing to aid the unclean litigant."[250] An accused infringer asserting unclean hands must prove it with clear and convincing evidence.[251] A court's conclusion of unclean hands[252] leads to dismissal of the lawsuit.[253]

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243 Morton Salt Co. v. G.S. Suppiger Co., 314 U.S. 488, 493 (1942), *abrogated by* Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28 (2006).

244 *See id.* Mark Lemley argues that this lack-of-injury requirement rewards and encourages infringement. Mark A. Lemley, Comment, *The Economic Irrationality of the Patent Misuse Doctrine*, 78 CALIF. L. REV. 1599, 1619 (1990) ("Parties unrelated to the patentee's wrongful acts may infringe its patents with impunity, since they are protected from liability . . . . Indeed, because the bar on infringement suits continues until the wrongful consequences have been dissipated fully, a finding of misuse essentially gives a green light to infringers of that patent . . . ." (footnote omitted)).

245 *See infra* Section III.C.

246 Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240, 245 (1933).

247 Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 815 (1945).

248 *See Keystone Driller*, 290 U.S. at 245; *see also* Loughran v. Loughran, 292 U.S. 216, 229 (1934) (Brandeis, J.) ("Equity does not demand that its suitors shall have led blameless lives."); FISCHER, *supra* note 159, at 234 (noting that the unclean hands doctrine does not bar recovery for "morally repugnant persons in general").

249 *See Keystone Driller*, 290 U.S. at 245 ("They apply the maxim, not by way of punishment for extraneous transgressions . . . .").

250 *Precision Instrument*, 324 U.S. at 815 (quoting *Keystone Driller*, 290 U.S. at 245).

251 *See In re* Omeprazole Pat. Litig., 483 F.3d 1364, 1374 (Fed. Cir. 2007) (citing 6 CHISUM, *supra* note 105, § 19.03[5] (2001)); Aptix Corp. v. Quickturn Design Sys., Inc., 269 F.3d 1369, 1374 (Fed. Cir. 2001).

252 "Unclean hands is an equitable defense within the sound discretion of the district court . . . ." Hor v. Chu, 699 F.3d 1331, 1337 (Fed. Cir. 2012) (citing Princess Cruises, Inc. v. United States, 397 F.3d 1358, 1369 (Fed. Cir. 2005)).

253 *See Precision Instrument*, 324 U.S. at 819 (citing *Keystone Driller*, 290 U.S. at 245–46); *Aptix*, 269 F.3d at 1376; *see also* Gilead Scis., Inc. v. Merck & Co., 888 F.3d 1231, 1240 (Fed. Cir. 2018).

B. Protecting Public Health with Patent Unenforceability

Until 2018, the law of patent unenforceability had stagnated.[254] This changed in the 2018 case *Gilead Sciences, Inc. v. Merck & Co.*, where the Federal Circuit held that the patents-in-suit couldn't be enforced for unclean hands based on prelitigation business misconduct.[255] Before *Gilead*, most patent-related unclean hands cases dealt with litigation misconduct.[256]

To fully understand the impact of *Gilead*, it's necessary to look briefly at the facts of this complex case. Merck and Gilead began a technology collaboration in the early 2000s to explore opportunities in the field of hepatitis C.[257] Gilead offered to share sofosbuvir, its lead compound,[258] with Merck to evaluate under a nondisclosure agreement as long as Merck didn't try to discern sofosbuvir's chemical structure.[259] Gilead did agree to share sofosbuvir's structural information with Merck subject to a confidential "firewall" agreement in which the Merck chemist receiving the proprietary information wouldn't be involved with Merck's own internal hepatitis C research team.[260] But Merck didn't prevent an in-house lawyer-chemist involved in prosecuting Merck's own hepatitis C patent applications from participating in

254 For inequitable conduct, *Therasense*'s holding made materiality and intent harder to prove, *see* Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1287 (Fed. Cir. 2011), coupled with the ability of patentees under 35 U.S.C. § 257(a) to have the Patent Office "consider, reconsider, or correct information believed to be relevant to the patent" without having to admit why the missing or incorrect information was initially withheld have essentially eviscerated the defense, *see* 35 U.S.C. § 257(a) (2018). Patent misuse cases are also hard to prove. *See* Princo Corp. v. Int'l Trade Comm'n, 616 F.3d 1318, 1329 (Fed. Cir. 2010) (en banc) ("[W]e have emphasized that the defense of patent misuse is not available to a presumptive infringer simply because a patentee engages in some kind of wrongful commercial conduct, even conduct that may have anticompetitive effects." (citing C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1373 (Fed. Cir. 1998))); Tom Ewing & Robin Feldman, *The Giants Among Us*, 2012 STAN. TECH. L. REV. art. no. 1, at 28 (explaining the Federal Circuit hostility toward claims of patent misuse). Unclean hands was a dormant, seldomly asserted affirmative defense in patent cases. *See generally* Seymore, *Unclean Patents*, *supra* note 30, at 1495, 1508–14 (outlining the doctrine's evolution).

255 888 F.3d 1231 (Fed. Cir. 2018).

256 *See, e.g.*, *Aptix*, 269 F.3d 1369.

257 *See Gilead*, 888 F.3d at 1236.

258 A lead compound is a new chemical entity with sought-for bioactivity but requires further optimization to improve its bioavailability and/or minimize its side effects to become a useful drug. 108 THE IMA VOLUMES IN MATHEMATICS AND ITS APPLICATIONS: RATIONAL DRUG DESIGN, at vii (Donald G. Truhlar et al. eds., 1999).

259 *See Gilead*, 888 F.3d at 1241.

260 *See id.* A firewall "is a key method to protect a confidential compound's structural information, because it limits that confidential information to only individuals not involved with the project at hand, therefore maintaining confidentiality." Gilead Scis., Inc. v. Merck & Co., No. 13-cv-04057, 2016 WL 3143943, at *7 (N.D. Cal. June 6, 2016), *aff'd*, 888 F.3d 1231 (Fed. Cir. 2018).

a teleconference with Gilead. During this call, this attorney stated that he was a firewalled employee (which was untrue) and learned sofosbuvir's chemical structure.[261] The in-house attorney then proceeded to amend Merck's pending patent applications to focus on sofosbuvir.[262] Eventually, Merck's patents issued.[263] Meanwhile, Gilead began selling its hepatitis C drugs based on sofosbuvir.

In the ensuing litigation, Merck alleged that Gilead infringed its hepatitis C patents.[264] Gilead asserted invalidity and unenforceability due to unclean hands.[265] At trial, a jury concluded that Merck's patents weren't invalid, that Gilead infringed, and assessed damages at $200 million.[266] In a separate bench trial on the unclean hands issue, the district court found unclean hands due to litigation misconduct based on false testimony given by Merck's in-house lawyer-chemist and prelitigation business misconduct involving the teleconference and patent application amendment activities (including the in-house attorney's failure to recuse himself after breach of the firewall).[267] The court barred Merck from asserting its patents against Gilead[268] and awarded Gilead $14 million in reasonable attorney's fees.[269]

On appeal, the Federal Circuit affirmed.[270] Focusing on the business misconduct, the court held that it only needed to have the "objective potential" to "enhance[] the claimant's legal position as to either the creation or the enforcement of the legal rights at issue."[271] Here, the in-house attorney's improper acquisition of knowledge about

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261 *See Gilead*, 888 F.3d at 1241–42.

262 *Id.* at 1242.

263 *See id.* at 1237–44.

264 *See id.* at 1239.

265 Gilead raised several grounds of invalidity under the governing statutory provisions of the 1952 Patent Act, including: inadequate written description; lack of enablement; derivation of the invention from another; and prior invention by another. Gilead Sciences, Inc.'s Renewed Motion for Judgment as a Matter of Law Under Fed. R. Civ. P. 50(b) at 1, 1–10, *Gilead*, 2016 WL 3143943 (No. 13-cv-04057).

266 *Gilead*, 2016 WL 3143943, at *1.

267 *See Gilead*, 888 F.3d at 1240–47.

268 *Id.* at 1233.

269 *See id.* at 1233–34; Gilead Scis., Inc. v. Merck & Co., No. 13-cv-04057, 2017 WL 3007071, at *9–10 (N.D. Cal. July 14, 2017) (order re amount of reasonable attorneys' fees). The patent statute states that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285 (2018). Whether a plaintiff's unclean hands qualifies as an "exceptional" case falls within the sound discretion of the district court. *See* Aptix Corp. v. Quickturn Design Sys., Inc., 269 F.3d 1369, 1375 (Fed. Cir. 2001); *see also* Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 545, 554 (2014) ("[A]n 'exceptional' case is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated.").

270 *Gilead*, 888 F.3d at 1248.

271 *Id.* at 1240.

sofosbuvir and subsequent application amendments "held the potential for expediting patent issuance and for lowering certain invalidity risks" in litigation.[272] Together, these activities provided a "direct connection" to the relief sought (patent enforcement),[273] thereby satisfying the Supreme Court's "immediate and necessary relation" standard.[274]

Gilead shows that unclean hands is a potent doctrine that can now serve as a complete defense to a claim for damages (and prospective relief) and support an award of attorney's fees.[275] Importantly for present purposes, *Gilead* has reinvigorated the unenforceability defenses and paves the way for courts to use them to protect public health in patent cases.

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272 *Id.* at 1241. As the court explained:

> "[L]imiting the scope" of the claims would mean "fewer opportunities for prior art to . . . present an issue of patentability" under 35 U.S.C. §§ 102 and 103. That would be so during prosecution and also in a litigation challenge. And a narrowing amendment can reduce a patentee's risk on other invalidity issues, such as the risk that breadth can create under the requirement that the "full scope" of a claim be enabled. Such risks can be reduced even if, as here, the resulting claim still covers a large, though less large, number of compounds.

Id. at 1243–44 (citations omitted) (quoting Amgen Inc. v. Sanofi, 872 F.3d 1367, 1375 (Fed. Cir. 2017)).

273 *Id.* at 1241.

274 *Id.* at 1239, 1239–40.

275 Should unclean hands bar a patentee from asserting a legal claim for damages? *Gilead* didn't explore this question; but it's worth noting that the Federal Circuit had been reversed on the related question of whether the equitable defense of laches could be applied to claims for damages from patent infringement. *See* SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC, 137 S. Ct. 954, 959 (2017). While a full discussion of the debate is beyond the scope of this Article, views differ among scholars and judges. *Compare* DAN B. DOBBS & CAPRICE L. ROBERTS, LAW OF REMEDIES: DAMAGES—EQUITY—RESTITUTION § 2.4(2), at 67 (3d ed. 2018) ("The most orthodox view of the unclean hands doctrine makes it an equitable defense, that is, one that can be raised to defeat an equitable remedy only, but one that is unavailable to those seeking only legal relief."), Samuel L. Bray, *The System of Equitable Remedies*, 63 UCLA L. REV. 530, 549 (2016) ("[I]n the vast majority of jurisdictions [unclean hands] is an equitable defense good only against equitable claims."), *and* Brief for Samuel L. Bray as *Amicus Curiae* Supporting Petitioners at 5–10, Merck & Co. v. Gilead Scis., Inc., 139 S. Ct. 797 (2019) (No. 18-378) (arguing that the unclean hands defense shouldn't be available for legal claims), *with* Byron v. Clay, 867 F.2d 1049, 1052 (7th Cir. 1989) (Posner, J.) ("[W]ith the merger of law and equity, it is difficult to see why equitable defenses should be limited to equitable suits any more; and of course many are not so limited, and perhaps unclean hands should be one of these." (citation omitted) (citing Piper Aircraft Corp. v. Wag-Aero, Inc., 741 F.2d 925, 938–39 (7th Cir. 1984))), *and* T. LEIGH ANENSON, JUDGING EQUITY: THE FUSION OF UNCLEAN HANDS IN U.S. LAW 148 (2019) ("The defense should at least be considered in actions seeking legal relief and should not be denied solely based on premerger practices.").

C. Exemplary Scenarios

To illustrate how an accused infringer could plausibly assert patent unenforceability as an affirmative defense, consider the following scenarios. The first scenario explores how a patentee's affirmative misstatement about the therapeutic benefits of a dietary supplement could support a finding of unclean hands.[276] The second scenario explores how business misconduct involving a patented COVID-19 vaccine couldn't support a finding of unclean hands.[277] The third scenario explores how a vaccine manufacturer's anticompetitive licensing practices could support a finding of patent misuse—temporarily rendering the patent unenforceable until the anticompetitive behavior stops and its ill effects on public health cease.[278]

1. Affirmative Misstatements About Therapeutic Benefits

Americans have become more concerned over time with physical health.[279] The FDA reports that three out of four Americans—including four out of five older adults and one in three children—regularly take dietary supplements[280] to achieve their health goals.[281] Unlike prescription drugs, the FDA doesn't require that dietary supplements be proven safe and effective before marketing.[282] The burden of proving

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276 *See infra* subsection III.C.1.

277 *See infra* subsection III.C.2.

278 *See infra* subsection III.C.3.

279 *See generally, e.g.*, ANUSCHKA REES, BEYOND BEAUTIFUL: A PRACTICAL GUIDE TO BEING HAPPY, CONFIDENT, AND YOU IN A LOOKS-OBSESSED WORLD (2019) (discussing how body image and beauty narrative discussions in the media shifted toward a healthier direction).

280 The U.S. Code defines a "dietary supplement" as:

> [A] product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any [of the aforementioned ingredients].

21 U.S.C. § 321(ff)(1)(A)–(F) (2018).

281 Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on the Agency's New Efforts to Strengthen Regulation of Dietary Supplements by Modernizing and Reforming FDA's Oversight (Feb. 11, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary [https://perma.cc/YJK4-5CTQ].

282 *See* Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified in scattered sections of 21 U.S.C.). In passing the legislation, Congress found that "although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers." *Id.* § 2(13). Further, "dietary supplements are safe

that a dietary supplement doesn't do what it purports rests with the federal government.[283] And while a dietary supplement label must contain a disclaimer that statements regarding safety and efficacy "[have] not been evaluated by the Food and Drug Administration"[284] and that the product "is not intended to diagnose, treat, cure, or prevent any disease,"[285] many consumers believe otherwise.[286] That consumers *want* to believe that a dietary supplement will make them look and feel better,[287] the widely-held notion that dietary supplements are safer (or more natural) than prescription drugs,[288] and copious paid advertisements and testimonials[289] allow manufacturers to get away with making dubious claims—even if science shows that the products provide little or no health benefits.[290]

If a dietary supplement is *patented*, this can fuel dubious claims and exacerbate a consumer's confusion about safety and efficacy.[291] As previously discussed, an unscrupulous patentee can "advertise its patent to convince gullible consumers that a patent represents the government's endorsement or imprimatur that the advertised product is actually effective."[292] This is reminiscent of the nineteenth-century practice of emphasizing a product's patented status, like the phrase "patent medicine," to mislead the public.[293] At present, an unscrupulous patentee can exploit the patented status of a dietary supplement

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within a broad range of intake, and safety problems with the supplements are relatively rare." *Id.* § 2(14).

283 *See* 21 U.S.C. § 342(f)(1)(D) (2018).

284 *Id.* § 343(r)(6)(C).

285 *Id.*

286 *See* Khatcheressian, *supra* note 61, at 631; France & Bone, *supra* note 61, at 47.

287 Sapna Maheshwari, *Hard-to-Swallow Ads by Vitamin Company*, N.Y. TIMES, Sept. 3, 2018, at B3.

288 Christie Aschwanden, *The Hidden Ingredients in Dietary Supplements*, WASH. POST, June 29, 2021, at E1.

289 *See id.*

290 *See* Pieter A. Cohen, *The Supplement Paradox: Negligible Benefits, Robust Consumption*, 316 J. AM. MED. ASS'N 1453, 1453 (2016) (discussing a study showing that many supplements are no more effective than placebos); Jane E. Brody, *Studies Show Little Benefit in Supplements*, N.Y. TIMES, Nov. 15, 2016, at D5 (discussing the Cohen article and other studies); Tamar Haspel, *Most Supplements Don't Have a Milligram of Benefit*, WASH. POST, Jan. 29, 2020, at E1 (discussing interviews with National Institute of Health personnel who explain that few dietary supplements have well-established benefits).

291 This raises the interesting question of patent law's audience—specifically, do consumers *read* patents? *Cf.* Mark D. Janis & Timothy R. Holbrook, *Patent Law's Audience*, 97 MINN. L. REV. 72, 73–75 (2012).

292 Christopher R. Leslie, *Patents of Damocles*, 83 IND. L.J. 133, 144 (2008); *see also* Holbrook, *supra* note 53, at 577 ("The government imprimatur attending the patent grant can confirm the technical . . . legitimacy of a technology.").

293 2 CHISUM, *supra* note 105, § 4.04[2][a] (quoting KITCH & PERLMAN, *supra* note 105, at 721).

to bolster dubious therapeutic claims on unwitting consumers to the detriment of public health.[294]

After *Gilead*, one might ask if an accused infringer could successfully assert unclean hands to redress such misconduct. To explore this question, consider the following hypothetical: Inventor seeks to treat colorectal cancer, the third-most common cancer diagnosed in the United States.[295] The disease has made a "profound impact" on public health,[296] as more than 140,000 persons are diagnosed with it annually and over 52,000 die from it.[297] Recognizing that dietary factors are responsible for 70–90% of colorectal cancer,[298] Inventor knows that broccoli contains an enzyme, *A*, that's involved in the human body's mechanism for detoxifying potential colorectal carcinogens.[299] Inventor also recognizes that many consumers don't like broccoli's bitter

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294 *See* Ann Bartow, *Separating Marketing Innovation from Actual Invention: A Proposal for a New, Improved, Lighter, and Better-Tasting Form of Patent Protection*, 4 J. SMALL & EMERGING BUS. L. 1, 8 (2000) (discussing the use of patents as "marketing ploy[s]" to make products "seem more science-based and technologically sophisticated"). As explained by one commentator,

> [a patented] product might very well lead consumers to believe that, because the product is "endorsed" by the United States government, it is somehow better than other [unpatented] products. Indeed, anyone who has ever seen an infomercial knows that many companies try to exploit this misperception by using their patent status to sell their product. For example, one recent infomercial for a "revolutionary weight-loss" system claimed that its product is "so effective, it was submitted for a patent." Consumers are frequently inundated with such propaganda, and this might affect consumer decisionmaking regarding what products to purchase.

Richard A. Crudo, Note, *A Patently Public Concern: Using Public Nuisance Law to Fix the False Patent Marking Statute After the Leahy-Smith America Invents Act*, 80 GEO. WASH. L. REV. 568, 578–79 (2012) (footnotes omitted) (quoting *SENSA Weight Loss System: "THE Weight Loss Breakthrough of the 21st Century"* (IB Studios 2010) (transcript available in Complaint for Permanent Injunction and Other Equitable Relief pt. 2, at 4–61, FTC v. Sensa Prods., LLC, No. 14-cv-00072 (N.D. Ill. Jan. 7, 2014), ECF No. 1-1).

295 *Key Statistics for Colorectal Cancer*, AM. CANCER SOC'Y (Jan. 29, 2024), https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html [https://perma.cc/8V55-DENF].

296 Ziad F. Gellad & Dawn Provenzale, *Colorectal Cancer: National and International Perspective on the Burden of Disease and Public Health Impact*, 138 GASTROENTEROLOGY 2177, 2177 (2010).

297 *See Colorectal Cancer*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 2, 2020), https://www.cdc.gov/workplacehealthpromotion/health-strategies/colorectal-cancer/index.html [https://perma.cc/Z5ZW-MP5J].

298 Marinos Pericleous, Dalvinder Mandair & Martyn E. Caplin, *Diet and Supplements and Their Impact on Colorectal Cancer*, 4 J. GASTROINTESTINAL ONCOLOGY 409, 409 (2013).

299 *See generally* Debasish Das, Nadir Arber & Janusz A. Jankowski, *Chemoprevention of Colorectal Cancer*, 76 DIGESTION 51 (2007); Elizabeth H. Jeffery & Marcela Araya, *Physiological Effects of Broccoli Consumption*, 8 PHYTOCHEMICAL REV. 283 (2009).

taste.[300] So Inventor develops a genetically modified broccoli plant that lacks the bitter taste and contains novel enzyme *A′*, which is nearly identical in structure and function to *A*. Inventor obtains a patent that claims a method for making the genetically modified broccoli plant, a tasteless tablet of broccoli extract that contains high levels of *A′*, and a method of reducing the level of colorectal carcinogens in a human by eating the genetically modified broccoli plant or consuming the tablet.[301] Soon after patent issuance, Inventor's in-house epidemiologic studies show (1) a *weak* inverse association between broccoli consumption and colorectal cancer;[302] and (2) genetics matter: there are substantial, individualized differences in colorectal cancer risk and the preventive effect of *A*-type enzymes.[303] Inventor conceals these studies and sells the patented tablet as a dietary supplement with a product label that reads:

> Do you fear colonoscopies? The federal government has granted a patent to a group of inventors for their groundbreaking research in developing a new broccoli plant containing a novel enzyme that prevents colorectal cancer. Consuming a small, tasteless tablet once a day is a safe and effective way to prevent colorectal cancer.

Inventor markets the product by posting the label on its social media sites. Consumers quickly buy the product in large amounts, which marketing research shows is due to the label's assertions.

Inventor subsequently sues Competitor for the unlicensed use of the patented method in Competitor's cruciferous plant research. Competitor asserts the affirmative defense of unclean hands based on Inventor's alleged misstatements on the product label. Competitor argues that the labeling constitutes egregious misconduct—Inventor is

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300 *See generally* Yuchi Shen, Orla B. Kennedy & Lisa Methven, *Exploring the Effects of Genotypical and Phenotypical Variations in Bitter Taste Sensitivity on Perception, Liking and Intake of Brassica Vegetables in the UK*, 50 FOOD QUALITY & PREFERENCE 71 (2016).

301 Note that trying to patent a method for using enzyme *A*, present in regular broccoli, would be unsuccessful for a lack of novelty under 35 U.S.C. § 102(a). *See* Brassica Prot. Prods. LLC v. Sunrise Farms (*In re* Cruciferous Sprout Litig.), 301 F.3d 1343, 1351–52 (Fed. Cir. 2002). Novelty would be lacking because humans have been eating broccoli and, consequently, receiving the cancer-preventative benefits of *A* long before the scientific discoveries. *See id.* at 1346 (explaining that "broccoli sprouts . . . [cannot] be patented merely on the basis of a recent realization that the plant has always had some heretofore unknown but naturally occurring beneficial feature" (bracketed alteration in original) (quoting *In re* Cruciferous Sprout Pat. Litig., 168 F. Supp. 2d 534, 537 (D. Md. 2001), *aff'd* 301 F.3d 1343 (Fed. Cir. 2002))).

302 *See* Q.J. Wu, Y. Yang, E. Vogtmann, J. Wang, L.H. Han, H.L. Li & Y.B. Xiang, *Cruciferous Vegetables Intake and the Risk of Colorectal Cancer: A Meta-Analysis of Observational Studies*, 24 ANNALS ONCOLOGY 1079, 1081–85 (2013).

303 *See* Johanna W. Lampe & Sabrina Peterson, Brassica, *Biotransformation and Cancer Risk: Genetic Polymorphisms Alter the Preventive Effects of Cruciferous Vegetables*, 132 J. NUTRITION 2991, 2992 (2002).

using the tablet's patented status to increase sales by suggesting to an unwitting public that the product can prevent colorectal cancer and dispense with the need for colonoscopy screenings.[304] Aside from jeopardizing public health, Inventor knows from the epidemiologic studies that the asserted efficacy claims are weak.

To evaluate the affirmative defense, the court asks whether Inventor's alleged misconduct has an "immediate and necessary relation" to the relief sought.[305] There must be "direct connection" between Inventor's prelitigation business misconduct (misleading advertising and surreptitious concealment of epidemiologic studies) and the relief sought (patent enforcement).[306] *Gilead* shows that business misconduct only needs to have the "objective potential" to "enhance[] the claimant's legal position as to either the creation or the enforcement of the legal rights at issue."[307] Inventor's surreptitious concealment of the epidemiologic studies "lower[ed] certain invalidity risks" in litigation[308] because the accused infringer could assert a lack of enablement.[309]

Next, the Federal Circuit has stated that unclean hands should be reserved for *egregious* misconduct.[310] It must be an unmistakable,

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304 *See supra* note 294 and accompanying text.

305 Gilead Scis., Inc. v. Merck & Co., 888 F.3d 1231, 1239 (Fed. Cir. 2018) (quoting Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240, 245 (1933)). Trial courts have found the requisite nexus in a broad range of patent cases. For example, a court applied the doctrine to prevent a patentee who concealed a patent's existence in bankruptcy proceedings from later enforcing it in an infringement suit. Ott v. Goodpasture, Inc., 40 U.S.P.Q.2d 1831, 1836 (N.D. Tex. 1996). A court applied the doctrine to a patentee who failed to disclose a patent application and patent to an accused infringer as required by a prior settlement agreement. Hasbro, Inc. v. Amron, 419 F. Supp. 2d 678, 690–92 (E.D. Pa. 2006).

306 *See Gilead*, 888 F.3d at 1241.

307 *Id.* at 1240.

308 *See id.* at 1241, 1244.

309 A patent's claims lack enablement under 35 U.S.C. § 112(a) when, "at the effective filing date of the patent, one of ordinary skill in the art [PHOSITA] could not practice their full scope without undue experimentation." Wyeth & Cordis Corp. v. Abbott Lab'ys, 720 F.3d 1380, 1384 (Fed. Cir. 2013) (citing MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1380–81 (Fed. Cir. 2012)). Put differently, enablement is lacking when the patent's disclosure can't teach a PHOSITA "how to make and . . . use the invention as broadly as it is claimed." *In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991); *accord* Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999). Here, the accused infringer could attempt to prove by clear and convincing evidence that the epidemiologic studies show that the patented method isn't as effective as claimed. *See* Alcon Rsch. Ltd. v. Barr Lab'ys, Inc., 745 F.3d 1180, 1189–90 (Fed. Cir. 2014).

310 *See* Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc). The three Supreme Court unclean-hands patent cases all involved egregious misconduct. *See id.* at 1292–93 (first discussing *Keystone Driller*, 290 U.S. 240; then discussing Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238 (1944), *abrogated by*

"unequivocal act";[311] not "minor missteps,"[312] or behavior that's merely misleading.[313] This standard "capture[s] extraordinary circumstances."[314]

Inventor's behavior meets this standard. Both the false advertising and data concealment were unmistakable, unequivocal acts done in bad faith.[315] Inventor's activities jeopardized public health by misleading the public about the third-most common cancer in the United States.[316]

Having found an "immediate and necessary relation"[317] and egregious misconduct,[318] the court could render the patent unenforceable for unclean hands.

2. Business Misconduct During a Public Health Emergency

In 2020, AlphaPharm was selected as one of five major drug manufacturers to participate in a public-private partnership to quickly develop an effective COVID-19 vaccine.[319] AlphaPharm soon develops an effective COVID-19 vaccine, but it requires refrigeration at -80°C and two doses.[320] Competitor, who wasn't selected for the public-private partnership, has been working on its own COVID-19 vaccine. It's a highly effective single-dose vaccine that requires no refrigeration. To

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Standard Oil Co. of Cal. v. U.S., 429 U.S. 17 (1976) (per curiam); and then discussing Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806 (1945)).

311 Powell v. Home Depot U.S.A., Inc., 663 F.3d 1221, 1235 (Fed. Cir. 2011).

312 Star Sci., Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008).

313 United Food & Com. Workers Unions & Emps. Midwest Health Benefits Fund v. Novartis Pharms. Corp., 902 F.3d 1, 13 (1st Cir. 2018) (first citing Intellect Wireless, Inc. v. HTC Corp., 732 F.3d 1339, 1342 (Fed. Cir. 2013); and then citing *Therasense*, 649 F.3d at 1292).

314 *Therasense*, 649 F.3d at 1293.

315 *Cf.* Hot Wax, Inc. v. Turtle Wax, Inc., 191 F.3d 813, 826 (7th Cir. 1999) (noting in a false advertising suit brought under the Lanham Act that an "affirmative showing . . . of some willful, egregious, or unconscionable conduct or bad faith" is required to support a conclusion of unclean hands), *quoted with approval in* Radiator Specialty Co. v. Pennzoil-Quaker State Co., 207 F. App'x 361, 362 (5th Cir. 2004) ("[T]he undisputed facts did not demonstrate any 'willful, egregious, or unconscionable conduct or bad faith' . . . to constitute unclean hands.").

316 *See supra* note 295 and accompanying text.

317 Gilead Scis., Inc. v. Merck & Co., 888 F.3d 1231, 1239 (Fed. Cir. 2018) (quoting Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240, 245 (1933)).

318 *See supra* text accompanying notes 310–14.

319 *See* U.S. DEP'T OF HEALTH & HUM. SERVS., EXPLAINING OPERATION WARP SPEED (2020).

320 *See* Rebecca Robbins & David Gelles, *Vaccine Will Travel Complicated Route from Lab to Masses*, N.Y. TIMES, Nov. 13, 2020, at A7 (discussing the challenges associated with Pfizer's COVID-19 vaccine); David Gelles, *Couriers Plan for Difficulties of Shipping Vaccines at -80°C*, N.Y. TIMES, Sept. 19, 2020, at A7 (same).

speed up development of its vaccine, Competitor asks AlphaPharm for its negative know-how—knowledge about AlphaPharm's past mistakes, failed tests, and dead ends.[321] AlphaPharm won't share this information. So Competitor poaches (hires away) an AlphaPharm scientist who worked on its COVID-19 vaccine. The poached scientist inevitably uses AlphaPharm's negative know-how to help Competitor quickly gain FDA approval of its COVID-19 vaccine.[322] Competitor also obtains a patent claiming a method of making a COVID-19 vaccine that's stable at room temperature. Competitor receives quick FDA approval for its vaccine, which—based on its ease of distribution and administration—rapidly accelerates nationwide efforts to vaccinate the public. Competitor subsequently sues BetaPharm for patent infringement. During discovery, BetaPharm learns about Competitor's duplicitous poaching and acquisition of negative know-how, which Competitor doesn't deny. Although BetaPharm doesn't challenge the patent's validity,[323] BetaPharm urges the court to render the patent unenforceable based on unclean hands. Competitor argues that (1) the vaccine has vastly improved and accelerated the nation's COVID-19 response, a national public health priority,[324] which wouldn't have happened but for the poaching; and (2) even if AlphaPharm has colorable tort or contract claims, those claims have nothing to do with patent enforcement.

Recall that plaintiff's alleged misconduct must have an "immediate and necessary relation"[325] to the relief sought. So there must be

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321 *See* SI Handling Sys., Inc., v. Heisley, 753 F.2d 1244, 1262 (3d Cir. 1985) (defining "negative know-how").

322 While a full discussion is beyond the scope of this Article, the drafters of the Uniform Trade Secrets Act believed that negative know-how could be protected as intellectual property. *See* UNIF. TRADE SECRETS ACT § 1 cmt. (NAT'L CONF. OF COMM'RS ON UNIF. STATE L. 1985) (defining "trade secret" to "include[] information that has commercial value from a negative viewpoint, for example the results of lengthy and expensive research which proves that a certain process will not work could be of great value to a competitor" (emphasis omitted)).

323 This is understandable if Competitor used no (positive) data from AlphaPharm to develop its patented process.

324 The Patent Office has implemented prioritized patent examination for applications related to COVID-19. *See* COVID-19 Prioritized Examination Pilot Program, 85 Fed. Reg. 28932, 28932 (May 14, 2020) (implementing a pilot program which offers fast-track examination for applications "cover[ing] a product or process related to COVID-19 . . . [that's] subject to an applicable FDA approval for COVID-19 use").

325 Gilead Scis., Inc. v. Merck & Co., 888 F.3d 1231, 1239 (Fed. Cir. 2018) (quoting Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240, 245 (1933)). Trial courts have found the requisite nexus in a broad range of patent cases. For example, a court applied the doctrine to a patentee who concealed the existence of a patent in bankruptcy proceedings from later enforcing it in an infringement proceeding. Ott v. Goodpasture, Inc., 40 U.S.P.Q.2d 1831, 1836 (N.D. Tex. 1996). In another case, a court applied the doctrine to a patentee who failed to disclose a patent application and patent to an accused infringer as

"direct connection" between Competitor's prelitigation business misconduct (poaching to obtain negative know-how) and the relief sought (patent enforcement).[326] *Gilead* emphasized that business misconduct need only have the "objective potential" to "enhance[] the claimant's legal position as to either the creation or the enforcement of the legal rights at issue."[327] Competitor's acquisition of negative know-how did just that. Knowing what *doesn't* work certainly "held the potential for expediting patent issuance"[328] because Competitor could avoid unfruitful, time-consuming, dead-end paths. Moreover, the negative know-how allowed Competitor to write a patent application that more easily satisfied the enablement requirement.[329] This provided "fewer opportunities for . . . issue[s] of patentability" at the application stage[330] and "lower[ed] certain invalidity risks" in litigation.[331]

Next, unclean hands should be reserved for *egregious* misconduct.[332] It must be an unmistakable, "unequivocal act"[333] reserved for "captur[ing] extraordinary circumstances."[334] Competitor's behavior fails to meet this high standard. When AlphaPharm refused to share its information, Competitor obtained it by poaching an AlphaPharm scientist. Though this was done in bad faith, the law of negative know-how and its contours are unsettled.[335] There are robust theoretical arguments that question whether negative know-how even constitutes intellectual property.[336]

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required by a prior settlement agreement. Hasbro, Inc. v. Amron, 419 F. Supp. 2d 678, 690–92 (E.D. Pa. 2006).

326 *See Gilead*, 888 F.3d at 1241.

327 *Id.* at 1240.

328 *Id.* at 1241.

329 *See supra* note 309 and accompanying text.

330 *Gilead*, 888 F.3d at 1243.

331 *Id.* at 1241.

332 *See supra* note 310 and accompanying text.

333 Powell v. Home Depot U.S.A., Inc., 663 F.3d 1221, 1235 (Fed. Cir. 2011).

334 Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1293 (Fed. Cir. 2011) (en banc).

335 It has been described as a "strange[] theory of trade secret law . . . under which an employee who resigns and joins a different business can be liable for not repeating the mistakes and failures of his or her former employer." Charles Tait Graves, *The Law of Negative Knowledge: A Critique*, 15 TEX. INTELL. PROP. L.J. 387, 388 (2007).

336 *See, e.g.*, *id.* at 408. Relatedly, several scholars contend that the Defend Trade Secrets Act of 2016 (which federalizes trade secret law), Pub. L. 114-153, 130 Stat. 376 (codified in scattered sections of 18 U.S.C). doesn't cover negative know-how. *See* Sharon K. Sandeen, *The DTSA: The Litigator's Full-Employment Act*, 72 WASH. & LEE L. REV. ONLINE 308, 317 (2015) ("[The DTSA] does not apply to trade secrets that are not in use or intended for future use, such as the so-called 'negative information' . . . ."); Christopher B. Seaman, *The Case Against Federalizing Trade Secrecy*, 101 VA. L. REV. 317, 351 (2015) (explaining that misappropriation of negative know-how would be a "situation[] in which a trade secret

3. Anticompetitive Licensing Practices of Vaccines

More than 42 million Americans are currently infected with human papillomavirus (HPV) and about 13 million are infected each year.[337] HPV puts young persons at risk for developing anal, cervical, throat, penile, vaginal, and other cancers later in life.[338] HPV is estimated to cause about 32,500 cancers in men and women each year, leading the U.S. Department of Health and Human Services to deem the development of safe and effective HPV vaccines a "Public Health Priority."[339] The American Cancer Society recommends two doses of HPV vaccine beginning between ages nine and twelve for the strongest immune response.[340] Nonetheless, vaccination rates among adolescents are low—less than fifty percent.[341]

Vaxcor obtains a patent for a new HPV vaccine. Vaxcor's wholly owned subsidiary makes GentleJect, an off-patent syringe specifically designed to reduce pain or anxiety in children.[342] When Vaxcor licenses the (patented) HPV vaccine, it requires licensees to buy one (unpatented) GentleJect syringe for each dose. When Vaxcor sues Competitor for patent infringement, Competitor asserts that Vaxcor is misusing its patent rights through an impermissible tying arrangement.[343]

The district court finds patent misuse. Vaxcor attempted to expand its monopoly in its patented vaccine by requiring licensees to purchase syringes from its subsidiary; i.e., to gain a competitive advantage

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claim is potentially vulnerable to a constitutional challenge alleging that Congress exceeded its Commerce Clause power").

337 *See HPV Infection*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 10, 2023), https://www.cdc.gov/hpv/parents/about-hpv.html [https://perma.cc/PGC3-XPEH].

338 *See HPV and Cancer*, NAT'L CANCER INST. (Oct. 18, 2023), https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-and-cancer [https://perma.cc/98ZD-JW5J]; *Cancers Caused by HPV*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/hpv/parents/cancer.html [https://perma.cc/6BPN-AWSX].

339 *See Featured Priority: HPV Vaccination*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Apr. 30, 2021), https://www.hhs.gov/vaccines/featured-priorities/hpv-vaccination/index.html [https://perma.cc/Z47P-NBBA].

340 *HPV Vaccines*, AM. CANCER SOC'Y (July 21, 2020), https://www.cancer.org/healthy/cancer-causes/infectious-agents/hpv/hpv-vaccines.html [https://perma.cc/3GDT-7MX5].

341 *Featured Priority: HPV Vaccination*, *supra* note 339.

342 This hypothetical is very loosely based on the famous patent misuse case *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488 (1942), *abrogated by* Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28 (2006), which involved a patentee tying a license to the licensee's promise to purchase unpatented goods with its patented machines. *See id.* at 491–93.

343 A tying agreement is "an agreement by a party to sell one product [(the tying product)] but only on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that product from any other supplier." N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5–6 (1958).

in the sales of an unpatented product.[344] This is an impermissible tying arrangement: licensees should be free to purchase syringes other than GentleJect, if at all;[345] and healthcare providers should be free to make individualized, patient-centered syringe choices. The district court issues an order rendering the patent unenforceable. It could become enforceable again if the misuse is purged, which would require a finding that "the improper practice has been abandoned and that the [public health] consequences of the misuse of the patent have been dissipated."[346] Vaxcor's purging could include ceasing the improper licensing practices, renegotiating existing licenses, revising its standard license agreement, informing current licensees and medical professionals that they're free to buy the patented vaccine without restriction, and publishing its new sales policy in marketing materials.[347]

IV. ADDRESSING POTENTIAL OBJECTIONS

Unclean hands and patent misuse are controversial affirmative defenses.[348] Aside from vague[349] or ambiguous standards,[350] applying them allows a defendant to get away with wrongful conduct[351] and perhaps encourages patent infringement.[352] While protecting public health is a normative justification for applying these unenforceability

344 *Cf. Morton Salt*, 314 U.S. at 492–93; Carbice Corp. of Am. v. Am. Pats. Dev. Corp., 283 U.S. 27, 31 (1931) ("[Patentee] may not exact as the condition of a license that unpatented materials used in connection with the invention shall be purchased only from the licensor; and if it does so, relief against one who supplies such unpatented materials will be denied.").

345 The "essential characteristic of an invalid tying arrangement lies in the seller's exploitation of its control over the tying product to force the buyer into the purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms." *Ill. Tool Works, Inc.*, 547 U.S. at 34–35 (quoting Jefferson Par. Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 12 (1984), *abrogated by Ill. Tool Works Inc.*, 547 U.S. 28).

346 *Morton Salt*, 314 U.S. at 493.

347 *See, e.g.*, McCullough Tool Co. v. Well Survs., Inc., 343 F.2d 381, 406–08 (10th Cir. 1965) (affirming district court's finding that patent misuse had been purged); Preformed Line Prods. Co. v. Fanner Mfg. Co., 328 F.2d 265, 278–79 (6th Cir. 1964) (same).

348 *See, e.g.*, Shubha Ghosh, *Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor After* Eldred, 19 BERKELEY TECH. L.J. 1315, 1386 (2004) ("The doctrine of patent misuse has been controversial largely because it has been applied in an unpredictable manner and in situations that paralleled the improper use of antitrust laws against patent owners."); *infra* note 361 and accompanying text.

349 *See* F. Scott Kieff & Troy A. Paredes, Essay, *The Basics Matter: At the Periphery of Intellectual Property*, 73 GEO. WASH. L. REV. 174, 198 (2004) (describing the present view of patent misuse as "a broad and vaguely defined space").

350 *See* discussion *infra* subsection IV.A.1.

351 LAYCOCK & HASEN, *supra* note 177, at 990.

352 *See id.* at 993; *see also supra* note 244.

doctrines, one might ask if courts *should* apply them. Perhaps federal agencies are better suited for this task.[353] Or perhaps protecting public health would frustrate other patent policy objectives.[354] Given that patent misuse narrowly focuses on anticompetitive behavior[355] and is difficult to prove,[356] this Part addresses potential objections to applying *unclean hands* as a mechanism for protecting public health in patent cases.

A. Uncertainty

Patents are most valuable—and more desirable to obtain—if they're predictably enforceable.[357] Unclean hands is a "necessarily flexible" discretionary defense,[358] so applying it to protect public health would inevitably insert *some* uncertainty into patent law. Indeed, one criticism of unclean hands is uncertainty about how the doctrine will be applied in a particular case.[359] The Supreme Court has explained that the doctrine can be broadly applied: "Any willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the [unclean hands] maxim."[360] Of course, what a judge views as inequitable might be idiosyncratic.[361] So it's true that unclean hands has an "amorphous[] and open-ended quality."[362]

But this uncertainty isn't necessarily unjust, unbounded, or unacceptable. First, a critical part of the court's discretion in determining whether to apply the unclean hands doctrine is the ability "to *deny* the

353 *See infra* Section IV.B.

354 *See infra* Section IV.C.

355 *See supra* notes 235–44 and accompanying text.

356 *See supra* note 254.

357 Paul J. Heald, *Transaction Costs and Patent Reform*, 23 SANTA CLARA COMPUT. & HIGH TECH. L.J. 447, 458 (2007).

358 Gilead Scis., Inc. v. Merck & Co., 888 F.3d 1231, 1240 (Fed. Cir. 2018).

359 John E. Calfee & Richard Craswell, *Some Effects of Uncertainty on Compliance with Legal Standards*, 70 VA. L. REV. 965, 965–66 (1984); *see also* Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 815 (1945) (explaining that unclean hands "necessarily gives wide range to the equity court's use of discretion in refusing to aid the unclean litigant"); ANENSON, *supra* note 275, at 100 ("With any discretionary decision, there is the possibility of uncertain and inconsistent outcomes.").

360 *Precision Instrument*, 324 U.S. at 815.

361 DOUG RENDLEMAN & CAPRICE L. ROBERTS, REMEDIES: CASES & MATERIALS 429 (9th ed. 2018). This raises concerns about unfettered judicial discretion. *See* Doug Rendleman, *The Triumph of Equity Revisited: The Stages of Equitable Discretion*, 15 NEV. L.J. 1397, 1419 (2015) ("The risk of unconfined equitable discretion emerges when the judge's broad personal version of unclean doesn't coincide with positive law.").

362 RENDLEMAN & ROBERTS, *supra* note 361, at 429.

defense and *limit its application* when appropriate."[363] Requiring the accused infringer to prove that the plaintiff's alleged misconduct has an "immediate and necessary relation" to the relief sought[364] and is a sufficiently egregious, "unequivocal act"[365] are predicates that set a high bar for accused infringers asserting the defense. This high bar should also deter baseless or distracting assertions of unclean hands.[366]

Second, equity is necessarily broad, malleable, and case specific,[367] suggesting that concerns about idiosyncratic application of unclean hands might be overblown.[368]

Just as patent law is a dynamic field built on a framework that "adapt[s] flexibly to both old and new technologies,"[369] the malleable nature of unclean hands "gives it extraordinary vitality with an ability to adapt to new situations."[370] And not unlike a court applying a patentability standard, a court applying unclean hands is mindful of

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363 T. Leigh Anenson & Gideon Mark, *Inequitable Conduct in Retrospective: Understanding Unclean Hands in Patent Remedies*, 62 AM. U. L. REV. 1441, 1520 (2013) (emphasis added).

364 Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240, 245 (1933). This nexus requirement is a basic limiting principle of the defense. *Cf.* ANENSON, *supra* note 275, at 50 ("In fact, the connection component of unclean hands has been the method by which courts typically constrain the defense.").

365 Powell v. Home Depot U.S.A., Inc., 663 F.3d 1221, 1235 (Fed. Cir. 2011).

366 This possibility didn't escape the *Gilead* court:

> We are conscious, as any court presented with a defense of unclean hands must be, both of the judicial system's vital commitment to the standards of probity protected by the doctrine and, also, of the potential for misuse of this necessarily flexible doctrine by parties who would prefer to divert attention away from dry, technical, and complex merits issues toward allegations of misconduct based on relatively commonplace disputes over credibility.

Gilead Scis., Inc. v. Merck & Co., 888 F.3d 1231, 1240 (Fed. Cir. 2018).

367 *See* Swann v. Charlotte-Mecklenburg Bd. of Educ., 402 U.S. 1, 15 (1971) ("Once a right and a violation have been shown, the scope of a district court's equitable powers to remedy past wrongs is broad, for breadth and flexibility are inherent in equitable remedies."); Bray, *supra* note 225, at 5 (describing the hallmarks of equity courts as "case-specificity, discretion, flexibility, moral reasoning, and resistance to fraud, exploitation, and the abuse of legal rights").

368 *See* Grupo Mexicano de Desarrollo, S.A. v. All. Bond Fund, Inc., 527 U.S. 308, 322 (1999) (Scalia, J.) ("We do not question the proposition that equity is flexible; but in the federal system, at least, that flexibility is confined within the broad boundaries of traditional equitable relief."); John L. Garvey, *Some Aspects of the Merger of Law and Equity*, 10 CATH. U. L. REV. 59, 64 (1961) (rejecting the free-wheeling critique because equitable decisionmaking is "[n]ot a personal discretion of the individual judge, not caprice, not sympathy, but a judicial discretion . . . [that] enable[s] the court to consider a variety of factors that might be involved in the particular case and evaluate them, weighing one against the other, before coming to its conclusion" (footnote omitted)).

369 *See* Burk & Lemley, *supra* note 35, at 1576.

370 T. Leigh Anenson, *Announcing the "Clean Hands" Doctrine*, 51 U.C. DAVIS L. REV. 1827, 1832 (2018).

tradition, precedent, and policy as well as future consequences of its decision.[371]

Finally, some uncertainty can be justified to the extent that it deters misconduct and induces compliance with normative standards.[372] Somewhat shadowy rules help prevent wrongdoers from securing a road map for evading the law.[373] The challenge for courts deciding whether to protect public health through the unclean hands doctrine is sanctioning patentee misconduct without chilling desirable behavior and destabilizing other patent laws, policies, and doctrines.[374]

B. Deference

Several federal agencies regulate in areas that touch on public health matters, including the FDA[375] and—to the extent that public health intersects with consumer protection—the Federal Trade Commission (FTC).[376] So even if a court in a patent suit can redress patentee misconduct that jeopardizes public health with the unclean hands doctrine, one might ask if the court should defer the matter to the FTC (which can impose its own sanctions).[377]

To explore this issue, it's worth revisiting *Juicy Whip, Inc. v. Orange Bang, Inc.*[378] The invention was a beverage dispenser with a transparent bowl that *appeared* to mix the syrup and water; but this was just a simulation—the beverage was actually mixed outside of the customer's view

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371 *See* Anenson & Mark, *supra* note 363, at 1461 n.124.

372 *See* Anenson, *supra* note 370, at 1833 & n.23.

373 *Id.* at 1833–34; *see also* sources cited *supra* note 359.

374 *See* Anenson, *supra* note 370, at 1833; *cf.* Henry E. Smith, *Why Fiduciary Law Is Equitable*, *in* PHILOSOPHICAL FOUNDATIONS OF FIDUCIARY LAW 261, 278 (Andrew S. Gold & Paul B. Miller eds., 2014) (explaining the idea equity must be "unpredictable enough to keep the opportunists guessing but without destabilizing the law").

375 The FDA's statutory mission includes "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and "protect[ing] the public health by ensuring that[] foods are safe . . . [and] drugs are safe and effective . . . ." 21 U.S.C. § 393(b)(1)–(2)(B) (2018).

376 The FTC has the power to investigate the dissemination of "any false advertisement . . . [including an unfair or deceptive act or practice] . . . for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of food, drugs, devices, services, or cosmetics." 15 U.S.C. § 52(a), (a)(2), (b) (2018).

377 A court may deny the unclean hands defense—despite its interest in vindicating the public interest or deterring wrongful conduct—if there's another available sanction outside of the lawsuit. Anenson, *supra* note 370, at 1887 (citing Johnson v. Yellow Cab Transit Co., 321 U.S. 383, 387 (1944)). It's worth noting that courts don't defer to FDA decisions. *See* William G. Childs, *The Implementation of FDA Determinations in Litigation: Why Do We Defer to the PTO but Not to the FDA?*, 5 MINN. INTELL. PROP. REV. 155, 176–82 (2004).

378 185 F.3d 1364 (Fed. Cir. 1999); *see* discussion *supra* Section I.D.

immediately before it was dispensed.[379] The inventor's purpose was to encourage impulse buying and to avoid constant cleaning to avoid bacterial contamination.[380] Nonetheless, the district court determined that the patent was invalid for a lack of utility because its purpose was to increase sales by deception.[381]

The Federal Circuit reversed, holding that an invention with a deceptive purpose—designed to appear to be something that it isn't—could satisfy the utility requirement.[382] Importantly for present purposes, the court punted the deception issue to other federal agencies:

> The requirement of "utility" in patent law is not a directive to the Patent and Trademark Office or the courts to serve as arbiters of deceptive trade practices. Other agencies, such as the Federal Trade Commission and the Food and Drug Administration, are assigned the task of protecting consumers from fraud and deception in the sale of food products. . . .
>
> . . . [W]e find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public.[383]

This approach avoids duplication of effort[384] or the overlapping of respective jurisdictions of the Patent Office with other agencies.[385]

A few quick points bear mention. First, from a policy perspective, deception that implicates public health is much different than innocuous trade practices like those at issue in *Juicy Whip*. The former is contrary to the public interest;[386] the latter isn't.[387] Unobjectionable

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379 *Juicy Whip*, 185 F.3d at 1365.

380 *Id.*

381 *Id.* at 1366.

382 *See id.* at 1365, 1368.

383 *Id.* at 1368.

384 *See* Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1064 (1988).

385 *See* Carter-Wallace, Inc. v. Riverton Lab'ys, Inc., 433 F.2d 1034, 1039 n.7 (2d Cir. 1970).

386 *See infra* Section IV.D.

387 A good analogy is puffery—the subjective, exaggerated, unquantifiable, and overly optimistic hype about a product. *See* David A. Hoffman, *The Best Puffery Article Ever*, 91 IOWA L. REV. 1395, 1400 & n.25 (2006). Puffery appears in numerous legal spheres, oftentimes when there's an allegation of fraud—including "mail fraud, securities fraud, common-law fraud, legal ethics, common-law contracts, Uniform Commercial Code warranty cases, promissory misrepresentation, false advertising, and even law-review-publication decisions." *Id.* at 1396–97 (footnotes omitted). Yet, most puffery is deemed nonactionable when the statement is "(1) an exaggerated, blustering, and boasting statement upon which no reasonable [person] would be justified in relying; or (2) a general claim of superiority over comparable products that is so vague that it can be understood as nothing more than a mere expression of opinion." Pizza Hut, Inc. v. Papa John's Int'l, Inc., 227 F.3d 489, 497, 496–97 (5th Cir. 2000) (summarizing the views of sister circuits and leading commentators);

inventions like cubic zirconium (imitation diamond), imitation gold leaf, synthetic fibers, imitation leather, imitation grill marks on food, fake wood flooring, and imitation meat show that patent law tolerates—and should tolerate—innocuous deception.[388] When deception can have a detrimental impact on public health, it crosses the threshold into patentee misconduct—a prerequisite for unclean hands.

Second, whether the Patent Office's jurisdiction overlaps with another agency depends on the subject matter. For example, recall the illustration involving the patentee's affirmative misstatements about the therapeutic effects of a dietary supplement.[389] Unlike conventional food and drug products, the FDA has limited authority to act against allegedly misbranded or falsely marketed dietary supplements.[390] It also has the burden of proving that a dietary supplement doesn't do what it purports to do.[391]

But even if the accused infringer can seek redress with a federal agency in a public health–related case, there are several reasons why a court adjudicating patent infringement shouldn't dismiss the affirmative defense of unclean hands. First, the court has an interest in preserving its *own* integrity.[392] Court integrity is a core motivator for applying the unclean hands doctrine.[393] Judge Learned Hand explained why:

> The doctrine is confessedly derived from the unwillingness of a court, originally and still nominally one of conscience, to give its peculiar relief to a suitor who in the very controversy has so conducted himself as to shock the moral sensibilities of the judge. It has nothing to do with the rights or liabilities of the parties; indeed the defendant who invokes it need not be damaged . . . .[394]

Viewed in this way, unclean hands preserves the court's critical duty to maintain the sanctity of the legal system and process.[395] This includes

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see also Carlill v. Carbolic Smoke Ball Co. [1893] 1 QB 256 at 261(Eng. C.A.) at 261 (determining that a "mere puff" in advertising is innocuous because the statement shouldn't be taken literally).

388 *See Juicy Whip*, 185 F.3d at 1367 (citing these examples).

389 *See supra* subsection III.C.1.

390 *See Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (Feb. 21, 2024), https://www.fda.gov/food/dietary-supplements [https://perma.cc/Q7J4-ZPWX].

391 *See supra* note 283 and accompanying text.

392 *See* Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 814 (1945) (stating that the court shouldn't be "the abettor of iniquity" (quoting Bein v. Heath, 47 U.S. (6 How.) 228, 247 (1848))).

393 *See* DOBBS & ROBERTS, *supra* note 275, § 2.4(2), at 67; Anenson & Mark, *supra* note 363, at 1479.

394 Art Metal Works, Inc. v. Abraham & Straus, Inc., 70 F.2d 641, 646 (2d Cir. 1934) (Hand, J., dissenting).

395 Anenson, *supra* note 370, at 1843–44.

preventing the patentee from benefitting from misconduct that endangers public health or making the patentee answer for it in the lawsuit.[396]

C. Overdeterrence

Unclean hands can be justified for its deterrence function.[397] Potential plaintiffs who want access to the courts (perhaps to enforce a patent) will be motivated to avoid conduct that might soil their hands.[398] Of course, deterrence only works if the plaintiff is aware of the unclean hands defense and its detrimental implications.[399] For example, Inventor who's tempted to make affirmative misstatements about the therapeutic benefits of its dietary supplement might think twice if Inventor knows that any resulting patents could be rendered unenforceable for unclean hands.[400]

But applying unclean hands in patent law raises an overdeterrence problem. Patentees might take excessive precautions to avoid misconduct—especially if there's uncertainty about how the doctrine will be applied.[401] This makes intuitive sense because precautionary efforts

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396 *See Precision Instrument*, 324 U.S. at 815; Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240, 245 (1933); *see also* Aptix Corp. v. Quickturn Design Sys., Inc., 269 F.3d 1369, 1381 (Fed. Cir. 2001) (Mayer, C.J., dissenting in part) (explaining that redress through application of the unclean hands doctrine is one way to protect judicial proceedings from patentee misconduct).

397 ANENSON, *supra* note 275, at 192 ("In addition to correcting past wrongs, the deterrence of future behavior is a related substantive, albeit instrumental, aim of unclean hands.").

398 Ori J. Herstein, *A Normative Theory of the Clean Hands Defense*, 17 LEGAL THEORY 171, 203 (2011).

399 *See id.* (agreeing but recognizing that unclean hands isn't common knowledge and rarely guides conduct unless the plaintiff is sophisticated or seeks the advice of counsel).

400 *See* T. Leigh Anenson, *Beyond Chafee: A Process-Based Theory of Unclean Hands*, 47 AM. BUS. L.J. 509, 548 (2010) ("[W]ithout the bar of unclean hands, claimants would somehow benefit from their prior unclean conduct in the current action. Thus, courts invoke unclean hands to deter future misdeeds against the judicial system . . . .").

401 *See* Ralph K. Winter, *Paying Lawyers, Empowering Prosecutors, and Protecting Managers: Raising the Cost of Capital in America*, 42 DUKE L.J. 945, 962 (1993) ("[C]ourts rarely show any appreciation of the need to avoid overbroad and amorphous doctrine and to craft legal rules with bright lines . . . . Overbreadth and uncertainty deter beneficial conduct and breed costly litigation."). A jurist has made a similar point:

> As a general principle, and all other things being equal, legal rules should, if sound, also be simple and uniform. Rules that are vague or needlessly complex are inefficient—because of the uncertainty over how far they reach and what they mean, they commonly deter more behavior than they were meant to. For that reason, rules governing conduct should, generally, be simple and uniform.

United States v. McKinney, 919 F.2d 405, 426 (7th Cir. 1990) (Will, J., concurring), *abrogated by* United States v. Spears, 965 F.2d 262 (7th Cir. 1992).

might impress a court analyzing an allegation of unclean hands.[402] Maybe it's not so much about excessive precautions but just staying clean.[403]

That said, it's possible that applying unclean hands could "deter . . . [some] would-be inventors from inventing altogether."[404] It's possible to allay this fear because the clear and convincing evidence standard makes unclean hands hard to prove.[405] To be sure, allegations of the related inequitable conduct doctrine[406] dropped dramatically after the Federal Circuit raised the standard of proof to clear and convincing evidence.[407]

D. The Public Interest

A court can apply unclean hands to vindicate the public interest.[408] In patent law, the Supreme Court has noted that the public interest is "paramount."[409] The doctrine "assumes even wider and more

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402 *Cf.* Gideon Parchomovsky & Kevin A. Goldman, *Fair Use Harbors*, 93 VA. L. REV. 1483, 1486 (2007) (discussing how ambiguous standards in copyright's fair use doctrine led potential defendants to overinvest in precautions).

403 For example, deciding not to make affirmative misstatements about a product shouldn't be too burdensome. Whatever costs are involved in staying clean, "[t]hese costs . . . are minuscule compared to losing the enforceability of a valid patent, or possibly a whole family of valid patents." Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 769 (2009).

404 *Id.* at 773.

405 *See supra* note 251 and accompanying text.

406 Inequitable conduct, loosely defined as fraud on the Patent Office, renders a patent unenforceable if intentional misconduct (such as a deliberate misrepresentation or omission of material information) led the patentee to obtain an unwarranted patent claim. *See* Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc).

407 *See id.* at 1287. For commentary, see Robert D. Swanson, Comment, *The* Exergen *and* Therasense *Effects*, 66 STAN. L. REV. 695, 717–18 (2014). *But see* Eric E. Johnson, *The Case for Eliminating Patent Law's Inequitable Conduct Defense*, 117 COLUM. L. REV. ONLINE 1, 16 (2017) ("Although *Therasense* . . . make[s] the defense harder to win on the merits, . . . [t]he defense may still help many defendants achieve an off-the-merits victory, either by getting a plaintiff to accept a less favorable settlement in anticipation of swollen litigation costs or by tilting the factfinder against the plaintiff at trial by filling the air with allegations of dishonest behavior.").

408 *See, e.g.*, Morton Salt Co. v. G.S. Suppiger Co., 314 U.S. 488, 492 (1942) ("[C]ourts of equity[] may appropriately withhold their aid where the plaintiff is using the right asserted contrary to the public interest."), *abrogated by* Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28 (2006). Historically, courts applying unclean hands only considered the plaintiff and defendant and ignored any third-party harm. DOBBS & ROBERTS, *supra* note 275, § 2.4(2), at 70–71. But this view evolved to take the public interest into account. *See id.* at 70.

409 Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945).

significant proportions"[410] in patent cases because patent rights are "issues of great moment to the public."[411] The corollary is that unwarranted patent rights are contrary to the public interest.[412] As stated by Ned Snow:

> Simply put, a court may refuse to enforce patent rights in order to avoid an injury to the public. . . . [B]ecause incentivizing or rewarding unlawful conduct is detrimental to the public interest, an invention that involves unlawful conduct should be denied patent protection.[413]

Implicit in the defense is the court's discretion "to account for all the circumstances, including any mitigating factors, before deciding that unclean hands defeats a plaintiff's remedy."[414] This includes any detrimental effect of its application on the general public.[415] So the unclean hands doctrine shouldn't be applied when it'd frustrate a substantial public interest.[416]

Sometimes reaching the merits of the dispute might be in the public interest—thereby overriding an assertion of unclean hands.[417] Put differently, there are times when protecting public health warrants reaching the substantive issues of validity and infringement despite the patentee's alleged misconduct—issues which are irrelevant to the doctrine's application.[418] For example, it might serve the public interest to reach the merits of a case involving the validity of a patent covering a COVID-19 vaccine. Does the vaccine *actually work* for its intended

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410 *Id.* at 815.

411 *Id.* (quoting Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238, 246 (1944)); *see also* Christa J. Laser, *Continuing the Conversation of "The Economic Irrationality of the Patent Misuse Doctrine,"* 11 CHI.-KENT J. INTELL. PROP. 104, 112 (2012) (arguing that a patentee's unclean hands "also harms society, such as with subversion of the judicial process and negative externalities").

412 *See* J. Nicholas Bunch, Note, *Takings, Judicial Takings, and Patent Law*, 83 TEX. L. REV. 1747, 1756 n.50 (2005).

413 SNOW, *supra* note 132, at 87.

414 Anenson, *supra* note 370, at 1887.

415 *See* Byron v. Clay, 867 F.2d 1049, 1051 (7th Cir. 1989) (Posner, J.) ("The doctrine of unclean hands . . . gives recognition to the fact that equitable decrees may have effects on third parties—persons who are not parties to a lawsuit, including . . . members of the law-abiding public—and so should not be entered without consideration of those effects.").

416 *See* EEOC v. Recruit U.S.A., Inc., 939 F.2d 746, 753 (9th Cir. 1991) (citing Johnson v. Yellow Cab Transit Co., 321 U.S. 383, 387 (1944)).

417 Howard W. Brill, *The Maxims of Equity*, 1993 ARK. L. NOTES 29, 36; *see also* ANENSON, *supra* note 275, at 55–57 (explaining the importance of public policy in unclean hands cases).

418 *Cf.* Cotropia, *supra* note 403, at 740 (making a similar argument for the doctrine of inequitable conduct). Relatedly, the patentee's alleged misconduct shouldn't "cast a dark cloud" over the patent's validity or infringement. Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc).

purpose, as required by both § 101 and § 112(a) of the patent statute?[419] Such cases implicate competing policies and would inevitably require judicial balancing.[420]

CONCLUSION

There was a time when public health–related inventions received special treatment from both the Patent Office and the courts. However, the law has evolved such that outright denials of patents solely to protect public health now seem implausible. This seems right: such heavy-handedness disrupted the delicate balance of two competing policy objectives in patent law—enhancing public welfare and promoting innovation. Modulating prospective relief to protect public health is quite rare. But this doesn't mean that public health issues should be eviscerated from patent law and policy. Herein I've argued that courts could render a patent unenforceable if the patentee's misconduct has jeopardized public health. Including public health issues in the equitable calculus would align with the increased use of remedial defenses in patent disputes and help balance two competing policy objectives in patent law—enhancing public welfare and promoting innovation.

419 *See supra* notes 42 (utility) and 309 (enablement) and accompanying text.

420 *See, e.g.*, Republic Molding Corp. v. B.W. Photo Utils., 319 F.2d 347, 350 (9th Cir. 1963) (explaining that when unclean hands is raised in patent infringement suit, "[t]he relative extent of each party's wrong upon the other and upon the public should be taken into account, and an equitable balance struck").