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Prophetic Patents

Janet Freilich

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In most contexts, making up data is forbidden — considered fraudulent or even immoral. Not so in patents. Patents often contain experimental data and it is perfectly acceptable for these experiments to be entirely fictional. These so-called "prophetic examples" are not only explicitly permitted by both the Patent and Trademark Office and federal courts, but are considered almost equivalent to factual data in patent doctrine. Though prophetic examples are thought to be common, there are no studies of these experiments, no explanation for why fictional data are allowed in patents, and no evaluation of the practice.

Here, I provide the first historical, theoretical, and empirical analysis of prophetic examples. I collect and analyze a novel dataset of over 2 million U.S. patents and applications from the biological and chemical industries. I find that at least 17% of experiments in this population are fictional. Through both empirical and theoretical analyses, I assess the potential costs and benefits of prophetic examples. Prophetic examples are likely beneficial to individual patentees, but I find that on a population level, there are serious costs. Prophetic examples may hinder innovation because they prevent others from conducting their own experiments — even after the patent has expired and even if the prophetic example is incorrect. Prophetic

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examples also hopelessly confuse scientists — 99% of scientific articles that cite to prophetic examples incorrectly cite them as if they contained factual information — which means that made-up results from patents may contaminate the scientific literature.

I argue for a shift from prophesies to more clearly delimited hypotheses — roadmaps for future research, but nothing more — preserving what value there is in speculation while mitigating the clear harms of the practice. Beyond these concrete policy recommendations, my findings also have rich implications for theoretical debates about the physicality of invention, when and to whom patents should be granted, how patents transmit information, and, ultimately, how best to incentivize innovation.

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INTRODUCTION

In May of 2005, a team of scientists made headlines after the prestigious journal *Science* published a report that they had cloned human embryos.[1] Only a few months later, the team was making headlines for a different reason: the data in the paper had been faked; *Science* retracted the paper and the team's leader, Dr. Hwang Woo-Suk, was fired and spent two years in prison for violating bioethics rules.[2] Almost ten years after the retraction, Dr. Hwang received a U.S. patent on his discredited technique.[3] Other scientists were "shocked" by the

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[1] *See* Gina Kolata, *Koreans Report Ease in Cloning for Stem Cells*, N.Y. TIMES (May 20, 2005), https://www.nytimes.com/2005/05/20/science/koreans-report-ease-in-cloning-for-stem-cells.html.

[2] *See* Andrew Pollack, *Disgraced Scientist Granted U.S. Patent for Work Found to Be Fraudulent*, N.Y. TIMES (Feb. 14, 2014), https://www.nytimes.com/2014/02/15/science/disgraced-scientist-granted-us-patent-for-work-found-to-be-fraudulent.html.

[3] *See id.* The patent in question is U.S. Patent No. 8,647,872 (issued Feb. 11, 2014).

news that Dr. Hwang obtained a patent for falsified data.[4] The *New York Times* quoted Dr. Jeanne Loring, a stem cell scientist at Scripps Research Institute, saying that her first reaction was, "You can't patent something that doesn't exist."[5]

Dr. Loring's reaction is common, sensible, and intuitive — but wrong. The Patent and Trademark Office ("PTO") and the courts explicitly permit made-up experiments and fictional data in patents.[6] Far from fraudulent, fictional data are instead treated as equivalent to factual data.[7] To illustrate, the fictional experiment below was published in a recently granted patent:

> A 67-year-old male has pancreatic cancer. . . . He is provided with *A. paucinervis* pomel extract [the patented invention] for three years. This patient is examined later, and . . . [h]is tumor is reduced in mass.[8]

The supposed ability of the patented compound to cure cancer borders on miraculous — yet it is also highly improbable, as real experiments have found the compound to be extremely toxic.[9]

There is little scholarship on these fictional experiments — commonly called "prophetic examples." The articles that mentioned prophetic examples do so in passing, with no more than a few sentences dedicated to the issue.[10] These articles are almost uniformly critical of

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[4] Pollack, *supra* note 2 ("'Shocked, that's all I can say,' said Shoukhrat Mitalipov, a professor at Oregon Health and Science University who appears to have actually accomplished what Dr. Hwang claims to have done. 'I thought somebody was kidding . . . .'").

[5] *Id.*

[6] *See* Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1577 (Fed. Cir. 1984); U.S. PATENT & TRADEMARK OFFICE, MPEP § 608.01(p) (9th ed. 2015) [hereinafter MPEP].

[7] *See* DONALD S. CHISUM, CHISUM ON PATENTS § 2212 (2015).

[8] U.S. Patent No. 8,003,137 col. 27 l. 57-col. 28 l. 4 (filed May 9, 2008) (issued Aug. 23, 2011).

[9] *See* Frédéric D. Debelle, Jean-Louis Vanherweghem & Joëlle L. Nortier, *Aristolochic Acid Nephropathy: A Worldwide Problem*, 74 KIDNEY INT'L 158, 164 (2008). These experiments were conducted before the patent issued, so they did not infringe on the patent.

[10] *See* Andrew S. Baluch, Note, *Relating the Two Experimental Uses in Patent Law: Inventor's Negation and Infringer's Defense*, 87 B.U. L. REV. 213, 241 (2007) (mentioning that prophetic examples may lead to "[a]n inventor's overreach"); Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 158 (2006) (explaining that prophetic examples may chill downstream research); Dmitry Karshtedt, *Limits on Hard-to-Reproduce Inventions: Process Elements and Biotechnology's Compliance with the Enablement Requirement*, 3 HASTINGS SCI. & TECH. L.J. 109, 114 (2011) (writing about the difference between scientific norms for reporting experiments and prophetic

prophetic examples — hinting at potential problems surrounding the practice.[11] Yet despite the lack of scholarly attention, prophetic examples are common.[12] It is possible that the PTO has granted hundreds of thousands of patents based on hypothetical experiments and we know nothing about it.

In this Article, I set out to understand the history, prevalence, and impact of prophetic examples. I collected a unique data set consisting of all prophetic and non-prophetic examples from U.S. patents and applications published between 1976 and 2017.[13] To identify prophetic examples, I exploited a PTO rule that requires prophetic examples to be written in present or future tense, while non-prophetic examples are written in past tense.[14] I focused on chemistry and biology patents, as those are the industries that commonly include experimental data (real

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examples, but noting that they may disclose valuable inventions that would not otherwise come to light); Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. REV. 1171, 1179 (2016) (suggesting that prophetic examples "disadvantage inventors who actually build and test their inventions before filing a patent application"); Kristen Osenga, *Cooperative Patent Prosecution: Viewing Patents Through a Pragmatics Lens*, 85 ST. JOHN'S L. REV. 115, 157 (2011) (discussing the difference between prophetic examples and scientific writing); Lisa Larrimore Ouellette, *Pierson, Peer Review, and Patent Law*, 69 VAND. L. REV. 1825, 1830 (2016) [hereinafter *Pierson, Peer Review, and Patent Law*] (worrying that prophetic examples result in the "award of patents earlier than is socially optimal"); Lisa Larrimore Ouellette, *Who Reads Patents?*, 35 NATURE BIOTECHNOLOGY 421, 422 (2017) [hereinafter *Who Reads Patents?*] (noting that scientists who read patents may not be aware that prophetic examples are not real experiments); Sean B. Seymore, *Patenting Around Failure*, 166 U. PA. L. REV. 1139, 1149-50 (2018) (arguing that the experiments described in prophetic examples are probably not correct) [hereinafter *Patenting Around Failure*]; Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 144-45 (2008) [hereinafter *Heightened Enablement*] ("[W]hen no actual experiments are disclosed, there is a danger that the claimed invention cannot be made or is inoperative."); Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 632 (2010) [hereinafter *Teaching Function of Patents*] ("[W]hen the inventor discloses prophetic examples and no more, there is a real danger that the claimed embodiments cannot be made or that the invention will not work."); *see also* Robin Feldman, *Plain Language Patents*, 17 TEX. INTELL. PROP. L.J. 289, 292 (2009) (criticizing the code for distinguishing prophetic examples); Timothy R. Holbrook, *Equivalency and Patent Law's Possession Paradox*, 23 HARV. J.L. & TECH. 1, 9 (2009) (suggesting that prophetic examples may increase incentives to innovate).

[11] *See, e.g.*, Seymore, *Heightened Enablement*, *supra* note 10; Seymore, *Teaching Function of Patents*, *supra* note 10.

[12] Expert Report of Egon E. Berg at 41, Smith Kline & French Labs. Ltd. v. Teva Pharm. USA, Inc., No. 05-197-GMS, 2006 WL 6331923 (D. Del. 2006) ("Based on my experience as a patent attorney and patent examiner . . . prophetic examples are also common in patents.").

[13] *See infra* Part III.A.1.

[14] *See* MPEP, *supra* note 6, § 608.01(p) (9th ed. 2015).

or otherwise) in patents.[15] I analyzed 2,214,558 patents and applications in those industries, a population that contains 12,300,156 examples.[16]

To begin, I confirm that prophetic examples are indeed common; in chemistry and biology patents at least 17% of examples are prophetic and, of patents with examples, at least 24% contain some prophetic experiments.[17] This means that prophetic examples are widespread enough to seriously impact patent law — and that we need to know more about them.

At first glance, the practice of allowing prophetic examples in patents seems baffling — why would the PTO allow fictional data? The PTO has never explicitly stated its reasons, but it is possible to construct a strong theoretical case for prophetic examples.

The theoretical case for prophetic examples rests on benefit to patentees. The Patent Act requires inventors to describe how to make and use their invention.[18] Inventors often do this by writing experimental protocols and results in the patent.[19] For example, a patent on a diabetes medication might include an experiment showing how to synthesize the molecule and another showing that the molecule can be given to humans to reduce the need for insulin injections.[20] The broader the patent, the more experiments are required.[21] A patent covering one molecule might only need to include one synthesis protocol, whereas a patent covering a family of 100 molecules might need to include many more experiments.[22] It is always faster and cheaper to make up data than to conduct real experiments, so if the experiments disclosed in the patent can be fictional, inventors will be able to file broader patents more easily.[23] This should be particularly useful for small companies, who have smaller budgets and cannot afford extensive real experimentation.[24] For companies of all sizes, broader

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[15] *See infra* Part III.A.3.

[16] Because some applications become granted patents, not all of these prophetic examples are unique. See *infra* Table 1 for more information.

[17] *See infra* Table 1.

[18] *See* 35 U.S.C. § 112 (2019).

[19] *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

[20] *See, e.g.*, U.S. Patent No. 6,916,848 col. 13 ll. 23-45, col. 67 ll. 30-67 (issued July 12, 2005).

[21] *See, e.g.*, ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 942 (Fed. Cir. 2010).

[22] *See* HAROLD C. WEGNER, FIRST TO FILE PATENT DRAFTING § 8:5 (2016).

[23] *See infra* Part II.A.1.

[24] *See* Irwin M. Aisenberg, *The Past and Present of Working Examples*, 23 IDEA: J.L. & TECH. 25, 30 (1982).

patents provide a greater reward to the inventor, which might incentivize more innovation.[25]

Despite this, I find that there is little evidence that prophetic examples benefit patentees on a population level. Patents with more prophetic examples are narrower than patents with fewer prophetic examples.[26] Similarly, patents with more prophetic examples are less valuable than patents with fewer prophetic examples.[27] Finally, although small companies should benefit disproportionately from the ability to use prophetic examples, they do not. I found that small companies are significantly less likely to use prophetic examples as compared to their larger counterparts.[28]

Evidence for the benefits of prophetic examples is weak, but evidence for their *harms* is much stronger. Patents with prophetic examples are frequently abandoned, which suggests that the inventor is not commercializing their invention.[29] The problem is that, because of the patent, neither is anybody else. While in force, the patent prevents others from working in that area.[30] But even after the patent has been abandoned and no longer has legal force, a chilling effect may remain. Because patents are granted only if an invention has not been previously disclosed, it is difficult for any subsequent inventor to get a patent in an area previously described by a prophetic example.[31] This is true even if the prophetic example is incorrect and the subsequent inventor was the first to actually make a functioning prototype.[32] Essentially, instead of incentivizing innovation, prophetic examples may create an innovation dead zone.

Prophetic examples also lead to a second type of harm: they mislead scientists. In their patent, inventors must disclose a detailed description of their invention that can be used by other scientists to build further

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[25] *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989) (explaining that the purpose of patents is to incentivize innovation, and that this is done, in part, by giving inventors the exclusive right to make and use their invention).

[26] *See infra* Part III.D.2.

[27] *See infra* Part III.D.2.

[28] *See infra* Part III.D.1.a.

[29] *See infra* Part III.D.2.

[30] *See* 35 U.S.C. § 271 (2019).

[31] *See* 35 U.S.C. §§ 102-03 (2019).

[32] To anticipate a subsequent patent, the prior prophetic example must be enabled. MPEP, *supra* note 6, at § 2121.01 (8th ed. Rev. 9, 2012). However, this is not a requirement for obviousness. *See id.* Further, prophetic examples in granted patents are presumed to be enabled, so proving otherwise involves a legal battle and is sufficient to dissuade others from working in an area. *See id.*

upon the technology.[33] This disclosure function of patents has long been recognized as a crucial element of innovation — allowing downstream innovators to see further by metaphorically standing on the shoulders of giants.[34] However, the disclosure function breaks down if scientists are misled by the disclosed information.

I analyzed how prophetic examples were cited in scientific publications and found that *99%* of citations to prophetic examples incorrectly cited the example as if it represented work that had actually been done.[35] False information is infiltrating the scientific community by way of prophetic examples.

My empirical findings have implications for several core debates in patent theory, including the disclosure function of patents, theories about constructive reduction to practice, and the optimal timing of patent filing. For disclosure, the misinformation spread by prophetic examples counters a line of scholarship that argues that patent disclosure, while perhaps not ideal, is not harmful.[36] For constructive reduction to practice — a doctrine that allows inventors to obtain a patent without having physically created the invention — scholars argue that it disincentivizes physical reduction to practice.[37] However, my evidence suggests that, surprisingly, there may be more advantages to physical invention than previously realized.[38] For the optimal timing of patent filing, I show that while proponents of early filing might be expected to favor mechanisms that contribute to earlier filing, some such mechanisms — such as prophetic examples — do not fit with the traditional justifications for early filing.[39]

All of this argues for reform. Banning prophetic examples is an attractive solution, given the findings herein, but is likely too drastic an institutional change (for now). Instead, I argue that we should not think about fictional experiments as *prophecies* — a name that carries a ring of accuracy and infallibility — but rather as *hypotheses* — testable predictions that may or may not turn out to be correct.[40] The shift from prophecies to hypotheses has several practical implications. First, it

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[33] *See* 35 U.S.C. § 112 (2019).

[34] *See* Graham v. John Deere Co., 383 U.S. 1, 6 (1966) ("[T]hings which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of . . . useful Arts.'").

[35] *See infra* Part III.C.1.

[36] *See infra* Part IV.A.

[37] *See infra* Part IV.B.2.c.

[38] *See infra* Part IV.B.2.c.

[39] *See infra* Part IV.B.2.b.

[40] *See infra* Part IV.C.

would reverse the current legal presumption that prophetic examples are enabled (i.e., that they work as written), since, as I show empirically, there is simply no reason to assume accuracy. Second, we should give inventors a grace period after filing to test their hypotheses and update prophetic examples with real results. Finally, we should require prophetic examples to be clearly labeled and to include some explanation about why the inventor expects the experiment to work. These changes all reflect that the predicted results are possibilities, not inevitabilities, and the shift can preserve what value such speculation has, while mitigating the clear harms that now prevail.

The Article proceeds as follows. Part I provides background on prophetic examples, introducing the concept and related doctrine, as well as sketching their historical development. Part II makes the case for prophetic examples, and discusses costs and benefits. Part III, the heart of the Article, provides an empirical study of prophetic examples, explains the study's design and methodology, provides data, and makes the case against prophetic examples. Part IV discusses implications for patent theory and scholarship and concludes with proposals for policy reform.

I. PROPHETIC EXAMPLES

Prophetic examples are experiments that report protocols that were not actually conducted and describe results that are made up, or prophesized.[41] There is little literature on prophetic examples,[42] so this Part provides an in-depth exploration of the practice of prophesy in patents. Section A is an introduction to prophetic examples and summarizes current doctrine. Section B traces the history of prophetic examples, exploring why they were originally used and explanations for their existence.

A. Introduction to Prophetic Examples

The Patent Act requires that every patent contain a written description of the invention as well as information on how to make and use it.[43] These disclosure requirements ensure that the inventors obtain a monopoly commensurate with what they have actually invented.[44] Disclosure is also intended to promote innovation by ensuring that

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[41] *See* MPEP, *supra* note 6, § 608.01(p) (9th ed. 2015).

[42] *See* sources cited *supra* note 10.

[43] *See* 35 U.S.C. § 112 (2019).

[44] *See* Dan L. Burk, *Patent Silences*, 69 VAND. L. REV. 1603, 1620 (2016).

scientists can read and use the information in the patent and thereby build further on the technology.[45] The requirements are a *quid pro quo* to guarantee that the public receives the benefit of knowledge in exchange for granting an exclusive patent.[46] In the absence of patents, inventions that could be kept secret might never be taught to the public.[47]

The disclosure statute has two components: enablement and written description.[48] The enablement doctrine requires that the patent include sufficient detail to ensure that a person skilled in the field of the invention could make and use the invention.[49] The written description doctrine requires that the patent include sufficient detail to prove that the inventor was in possession of the invention when she filed the application.[50] Possession does not refer only to physical possession of the invention.[51] The requirement can be met if the inventor clearly describes the invention in the patent.[52]

These requirements can be satisfied in many ways, but it is common to provide examples of how the invention is made or used.[53] Examples often describe experiments and may provide instructions on how to make an invention or the effects of using said invention.[54] While examples are not required,[55] they are frequently included in patents[56] and the absence thereof is frowned upon by the courts.[57]

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[45] *See* Graham v. John Deere Co., 383 U.S. 1, 6 (1966).

[46] *See* Ouellette, *Pierson, Peer Review, and Patent Law*, *supra* note 10, at 1827.

[47] *See* Ted Sichelman & Sean O'Connor, *Patents as Promoters of Competition: The Guild Origins of Patent Law in the Venetian Republic*, 49 SAN DIEGO L. REV. 1267, 1272 (2012). In practice, some aspects of patented inventions are still kept secret. *See* W. Nicholson Price II & Arti K. Rai, *Are Trade Secrets Delaying Biosimilars?*, 348 SCI. 188, 188 (2015); W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 535 (2014).

[48] *See* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1341 (Fed. Cir. 2010).

[49] *See* 35 U.S.C. § 112 (2019); *In re* Wands, 858 F.2d 731, 735-36 (Fed. Cir. 1988).

[50] *See* § 112; *Ariad*, 598 F.3d at 1351.

[51] *See* Falkner v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. 2006).

[52] *See id.*; MPEP, *supra* note 6, § 2163.02 (9th ed. 2013) ("An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.").

[53] MPEP, *supra* note 6, § 2164.02 (9th ed. 2013).

[54] *See, e.g.*, Application of John A. Stephens, 529 F.2d 1343, 1345 (C.C.P.A. 1976).

[55] *See In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

[56] *See, e.g.*, *In re* Strahilevitz, 668 F.2d 1229, 1232 (C.C.P.A. 1982).

[57] *See, e.g.*, Wyeth v. Abbott Labs., Nos. 08-230 (JAP), 08-1021 (JAP), 2012 WL 175023, at *11-12 (D.N.J. Jan. 19, 2012), *aff'd on other grounds*, 720 F.3d 1380, 1386

There are two types of examples: (1) "working examples," which report experiments actually conducted; and (2) "prophetic examples," which report experiments that were not actually conducted.[58] The PTO defines prophetic examples as "an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved."[59] I give excerpts from prophetic and non-prophetic examples below, to give the reader their flavor. The following two examples come from U.S. Patent No. 6,869,610 which claims methods of treating pain by administration of Botox.[60] The patent contains one non-prophetic example, describing experiments conducted on rats, and several prophetic examples, describing the predicted effects of administering Botox to humans.

Non-Prophetic	Prophetic
Two experiments were carried out . . . [using] rats . . . there were 4 treatment (dose) groups: control (saline injected) rats . . . [and] 7 U BOTOX®/KG rats . . . . Limb lifting/licking by the subject animals was then recorded . . . at both 5 days and 12 days after injection, there was a significant dose dependent pain alleviation in the BOTOX® treated animals.[61]	A 46-year-old woman presents with pain localized at the deltoid region due to an arthritic condition. The muscle is not in spasm, nor does it exhibit a hypertonic condition. The patient is treated by a bolus injection of . . . intramuscular botulinum toxin type A. Within 1-7 days after neutrotoxin administration the patient's pain is substantially alleviated. The duration of significant pain alleviation is from about 2 to about 6 months.[62]

The PTO and the federal courts explicitly permit prophetic examples.[63] Both institutions have also confirmed that prophetic

(Fed. Cir. 2013); Boston Sci. Corp. v. Johnson & Johnson Inc., 679 F. Supp. 2d 539, 553, 557 (D. Del. 2010).

[58] *See* MPEP, *supra* note 6, § 608.01(p) (9th ed. 2015).

[59] *Id.* § 2164.02 (9th ed. 2013); *see also* CHISUM, *supra* note 7, § 10.05 (calling prophetic examples "specific illustrations of the invention that have not, in fact, been carried out"); *cf.* Paul R. Gugliuzza, *Early Filing and Functional Claiming*, 96 B.U. L. REV. 1223, 1226 (2016) (calling prophetic examples "basically, educated speculations").

[60] *See* U.S. Patent No. 6,869,610 (issued Mar. 22, 2005).

[61] *Id.* ex. 1.

[62] *Id.* ex. 2.

[63] *See* Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1577 n.1 (Fed. Cir. 1984); MPEP, *supra* note 6, § 2164.02 (9th ed. 2013).

examples can be used to satisfy the enablement and written description requirements in the same manner as working examples. To satisfy the enablement requirement, applicants must describe the invention sufficiently to enable another person in the field to make and use the claimed invention.[64] Prophetic examples teach strategies for making and using the invention and thus help satisfy the enablement requirement.[65] For the written description requirement, applicants must disclose the invention in sufficient detail to show that they were in possession of the invention when they filed the patent.[66] Prophetic examples help demonstrate that the patentee knew about the contours of the invention, and thus help satisfy the written description requirement.[67] Patents must also contain a statement of utility to be valid[68] and prophetic examples can be used to illustrate the utility of the invention.[69]

Though prophetic examples can serve the same function as working examples, inventors cannot pass off prophetic examples as work that has actually been done. Prophetic examples must be written in the present or future tense, while working examples are written in the past tense.[70] The Federal Circuit held that writing prophetic examples in the past tense can be inequitable conduct,[71] though district courts hearing cases on the question have produced mixed results.[72] A finding of

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[64] *See* 35 U.S.C. § 112(a) (2019).

[65] *See* Alcon Research Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1189-90 (Fed. Cir. 2014); Energy Absorption Sys., Inc. v. Roadway Safety Servs., Inc., 119 F.3d 16 (Table), 1997 WL 368379, at *5 (Fed. Cir. 1997); Cephalon, Inc. v. Watson Pharm., Inc., 769 F. Supp. 2d 729, 750 (D. Del. 2011); Boston Sci. Corp. v. Johnson & Johnson Inc., 679 F. Supp. 2d 539, 552 (D. Del. 2010) ("The burden is on one challenging validity to show, by clear and convincing evidence, that the prophetic examples, together with the other parts of the specification, are not enabling.").

[66] *See* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010).

[67] *See id.* at 1357 (confirming that prophetic examples "certainly can be sufficient to satisfy the written description requirement"); Application of Janis Robins, 429 F.2d 452, 457 (C.C.P.A. 1970).

[68] *See* 35 U.S.C. § 101 (2019).

[69] *See* Michael Risch, *Reinventing Usefulness*, 2010 BYU L. Rev. 1195, 1202 (2010). *But see* Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1, 9 (1995) (explaining that patent examiners are sometimes skeptical of prophetic examples illustrating utility).

[70] *See* MPEP, *supra* note 6, § 608.01(p) (9th ed. 2015).

[71] *See, e.g.*, Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp., 424 F.3d 1347, 1359-60 (Fed. Cir. 2005); Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1363-64 (Fed. Cir. 2003).

[72] *Compare* Presidio Components Inc. v. Am. Tech. Ceramics Corp., 723 F. Supp. 2d 1284, 1319-21 (S.D. Cal. 2010), *with* Apotex, Inc. v. UCB, Inc., 970 F. Supp. 2d

inequitable conduct, essentially fraud, can render the patent unenforceable.[73] However, prophetic examples recited in the present tense are unquestionably not inequitable conduct, a principle that has needed repeating by the Federal Circuit and district courts.[74]

B. History of Prophetic Examples

The practice of allowing fictional information in a legal document is unusual; it is not intuitive how such a practice might develop or why it might be permissible. This Section traces the development of prophetic examples.

1. Early History

Most of the earliest U.S. patents were mechanical or electrical.[75] Mechanical and electrical inventions are relatively "predictable," meaning that a skilled engineer reading a patent disclosing one model of an apparatus could predict how variations of the disclosed apparatus would perform.[76] This disclosure was often a drawing of a machine (as opposed to just text), which the skilled engineer could follow to build and use the machine.[77] Over time, this disclosure came to be considered sufficient evidence of invention — a physical model was not needed.[78] This doctrine, called "constructive reduction to practice" allowed inventors to obtain patents on anything they could describe in sufficient

1297, 1319 (S.D. Fla. 2013). Note that the Federal Circuit clarified the inequitable conduct standard in the years between *Presidio* and *Apotex*. *See* Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1287-90 (Fed. Cir. 2011).

[73] *See, e.g.*, Am. Calcar, Inc. v. Am. Honda Motor Co., 768 F.3d 1185, 1186 (Fed. Cir. 2014).

[74] *See, e.g.*, Eli Lilly & Co. v. Actavis Elizabeth LLC, 676 F. Supp. 2d 352, 363-64 (D.N.J. 2009), *rev'd on other grounds*, 435 Fed. App'x. 917 (Fed. Cir. 2011); Energy Absorption Sys., Inc. v. Roadway Safety Servs., Inc., 1997 WL 368379, at *5 (Fed. Cir. 1997).

[75] *See* Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 NW. J. TECH. & INTELL. PROP. 278, 282 (2008) [hereinafter *The Enablement Pendulum*].

[76] *Id.*

[77] Drawings are still used to satisfy patent disclosure requirements. *See* 35 U.S.C. § 113 (2019).

[78] 35 U.S.C. § 114 empowers the PTO to ask applicants for a model of their invention, but "[w]ith the exception of cases involving perpetual motion, a model is not ordinarily required by the Office . . . ." MPEP, *supra* note 6, § 608.03 (8th ed. Rev. 9, 2012).

detail to teach others to make, even if the inventor had never physically made the invention.[79]

In the early twentieth century, the field of organic chemistry burgeoned and the number of chemistry patents skyrocketed.[80] Drawings — a great aid in teaching mechanical inventions — were less helpful for chemical patents.[81] Although a drawing of a molecule shows its structure and can provide other information, it is not always clear from that structure how to synthesize the molecule or what the molecule's uses might be. To ensure that chemistry patents had adequate disclosure of how to make and use the invention, patent drafters turned to "examples" — experimental protocols that supported the chemical claim in the same way that drawings traditionally had for mechanical patents.[82] Though examples were not strictly necessary to enable a chemical invention,[83] courts often rejected chemistry patents that lacked examples[84] and patent prosecutors believed that a large number of examples would help their case.[85] Examples therefore became a standard part of chemistry patents.

Unlike the mechanical, electrical, and computer sciences, chemistry is "essentially an experimental science and results are often uncertain, unpredictable and unexpected."[86] In unpredictable fields, it is often

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[79] *See* Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986). Constructive reduction to practice is supposed to be equal to actual reduction to practice. *See* John F. Duffy, *Reviving the Paper Patent Doctrine*, 98 CORNELL L. REV. 1359, 1366 (2013) [hereinafter *Reviving*]. Underlying the doctrine is an assumption of accuracy — that the disclosed invention will function and that the inventor "has" the invention. *See* Wheeler v. Clipper Mower & Reaper Co., 29 F. Cas. 881, 888 (C.C.S.D.N.Y. 1872) (No. 17,493). If a description does not work, it is arguably not constructively reduced to practice. *See* Cooper v. Goldfarb, 154 F.3d 1321, 1328 (Fed. Cir. 1998); Conover v. Downs, 35 F.2d 59, 59-60 (C.C.P.A. 1929).

[80] The number of patents in this field grew significantly in the early twentieth century. *See* David Katz, *Proposal to Improve Patent System*, 17 J. PAT. OFF. SOC'Y 777, 780-81 (1935).

[81] *See* Eugene W. Geniesse, *Adequate Description*, 27 J. PAT. OFF. SOC'Y 784, 787-88 (1945).

[82] *See id.* at 787 ("Illustrative examples in chemical cases serve the same purposes as do drawings in mechanical cases.").

[83] *See id.*; *see also In re* Borkowski, 422 F.2d 904, 908 (C.C.P.A. 1970) ("[A]s we have stated in a number of opinions, a specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation.").

[84] *See* Harold C. Wegner, *Patent Law Simplification and the Geneva Patent Convention*, 14 AIPLA Q.J. 154, 194 (1986).

[85] *See* Joseph Rossman, *The Rejection of Broad Chemical Claims*, 14 J. PAT. OFF. SOC'Y 873, 873 (1932).

[86] Schering Corp. v. Gilbert, 153 F.2d 428, 433 (2d Cir. 1946).

impossible to predict how minor variations in the invention will affect the results.[87] The doctrine of constructive reduction to practice assumes that predictions made without physical creation will be accurate.[88] It is therefore not clear that the doctrine should be allowed in chemical patents, even if it was standard in mechanical patents. However, there are remarkably few recorded objections to constructive reduction to practice in chemical patents.[89] Instead, it quickly became clear that constructive reduction to practice was as acceptable for chemical patents as it was for mechanical patents.[90]

The need for examples in chemical patents combined with the permissibility of constructive reduction to practice led to use of constructive reduction to practice in examples: prophetic examples. If a drawing of a never-built machine could be used to enable a mechanical invention, proponents of prophetic examples argued, then why not allow a never-conducted experiment to enable a chemical invention?[91]

2. Prophetic Examples Become PTO Policy

For the first 50 years in which prophetic examples were used,[92] the PTO had no official rules concerning the practice, but had an unofficial

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[87] *See, e.g.*, Rossman, *supra* note 85, at 873-74; Seymore, *The Enablement Pendulum*, *supra* note 75, at 282.

[88] *See, e.g.*, Cooper v. Goldfarb, 154 F.3d 1321, 1328 (Fed. Cir. 1998).

[89] There are a small number of sources that point to the necessity of actual experiments in chemical patents. *See* Rossman, *supra* note 85, at 874.

[90] *See Undue Breadth — Disclosure of Single Metal as Masking Material in Welding Operation Held Insufficient Basis to Support Claim Directed Broadly to "Material,"* 29 J. PAT. OFF. SOC'Y 455, 458 (1947) ("Many patents are undoubtedly granted on structures proposed in drawings but which structures have never been actually made, and seemingly the practice does not forbid the same sort of presentation with respect to phenomena not predictable with certainty such as is found in the field of chemistry."); *see also* Geniesse, *supra* note 81, at 788 ("[A]n applicant may base a [chemical] patent application wholly on speculation . . . without doing any actual work . . . .").

[91] *See* Geniesse, *supra* note 81, at 787-88 (1945) (citing an unnamed Board of Patent Appeals and Interferences case: "We know of no authority which denies protection when applicants may not have actually produced the compounds he claims as his invention . . . but which he has visualized as the reaction product of known materials. In the mechanical field protection is given to inventions which are constructively reduced to practice . . . The description of a new compound by its formula or name in terms of standard nomenclature is analogous to the description and drawing of a machine . . . Applicants have complied with these rules by [prophetically] telling how the compounds can be made and how they can be used.").

[92] The earliest mention of prophetic examples I was able to find came from a case in 1927 where the Sixth Circuit noted that a patent's reference to "certain grades of untreated cassava" might be "perhaps merely prophetic, because the record indicates that [the inventor] had not found any raw starch which would perform properly . . . ."

practice of allowing them. In 1980, the District of Delaware sharply criticized the PTO, stating that it could

> conceive of no reason for the PTO to countenance such a practice. In effect, the PTO is permitting itself to be misled by patent applicants during the process of granting a monopoly. Moreover, the public is misled by such misrepresentations . . . .[93]

Shortly thereafter — and perhaps because of the criticism[94] — the PTO made its first official statement on prophetic examples, adding them to the Manual of Patent Examination Procedure ("MPEP") in 1981. The PTO originally inserted a provision stating that

> [a]pplicants must indicate which tests and examples are only simulated or predicted and which tests and examples have actually been carried out in order to permit the examiner to examine the same properly. Simulated or predicted tests and examples are "paper" examples and must not be confused with actual working examples. Working examples . . . must be written in the past tense . . . . Paper examples, however . . . must be written in the present or future tense.[95]
>
> . . . Clarity as to test results is essential because patent examiners have relatively little or no resources to test the veracity of representations made by applicants.[96]

Perkins Glue Co. v. Holland Furniture Co., 18 F.2d 387, 390 n.1 (6th Cir. 1927). Prophetic examples may have been used earlier.

[93] Grefco, Inc. v. Kewanee Indus., 499 F. Supp. 844, 867 n.34 (D. Del. 1980).

[94] *See* Donald G. Daus, *Chemical Names as Anticipation and Support*, 70 J. PAT. & TRADEMARK OFF. SOC'Y 377, 394 n.106 (1988) ("It is rumored . . . that the deleted changes had been responsive to criticism of the PTO in Grefco Co. v Kewanee Industries . . . .").

[95] U.S. PATENT & TRADEMARK OFFICE, MPEP § 608.01(p) (rev. Jan. 5, 1981) [hereinafter 1981 MPEP].

[96] *Id.*

This provision was inserted with no advance notice[97] or discussion.[98] The provision dismayed some attorneys, who felt it restricted patent protection.[99]

After nine months, the PTO withdrew most of the provision, leaving only the statements that prophetic examples are permitted in patent applications and that they must be described in the present tense while working examples are described in the past tense.[100] Specifically, the provision prohibiting results in prophetic examples was removed, as was the exhortation for clarity and the explanation that patent examiners cannot test the veracity of statements in patents.[101] The PTO did not clarify the reason for the changes, stating only that the original provisions "went further than was intended."[102]

Though the PTO did not specify why it chose to permit prophetic examples, the original statement in the MPEP suggests that it may have been a question of administrative necessity. The PTO may simply not have the capacity to check whether an invention had been physically made. The PTO suggested as much in its original MPEP statement noting that examiners have "little or no resources to test the veracity of representations made by applicants."[103] Scholars have suggested that the

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97 *See* Daus, *supra* note 94, at 394 ("These provisions had been inserted in the MPEP without advance notice. No 'grandfather' exceptions had been recited.").

98 *See* Aisenberg, *supra* note 24, at 26 (complaining that this "fundamental alteration in disclosure requirements should clearly require an appropriate statutory enactment rather than an insert in the M.P.E.P.").

99 *See id.* at 27-28 ("[I]t is not within the examiner's domain to limit available protection or to challenge support of claim scope by differentiating between examples which reflect concluded experiments and those which do not. It is highly questionable whether an examiner even has a right to ask which examples are merely 'paper' examples . . . . [T]he Rules still fail to provide any authority for distinguishing between examples which reflect actual reductions to practice and those which do not.").

100 *See* 1981 MPEP, *supra* note 95, § 608.01(p).

101 *See id.*

102 1146 OFFICIAL GAZETTE OF THE UNITED STATES PATENT & TRADEMARK OFFICE 206 (Jan. 5, 1993) ("The wording of the MPEP provisions prior to this amendment went further than was intended. The amended sections below spell out more clearly the Office's position from the start.").

103 *See* 1981 MPEP, *supra* note 95, § 608.01(p). Alternatively, the PTO's reluctance to question whether the application of a rule that worked for mechanical patents was appropriate for chemical patents may be a result of the insularity of the patent bar. *See* Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619, 1645 (2007) (exploring the consequences of the Federal Circuit's exclusive jurisdiction on the insularity of patent law, but noting that even before the creation of the Federal Circuit "the patent bar was a recognized specialty and a somewhat insular community").

PTO originally accepted the doctrine of constructive reduction to practice for the same reason.[104]

The law of prophetic examples has stayed substantially static since 1981. The relevant provision in the MPEP has not changed.[105] Case law has by and large simply pointed to the MPEP as a source of permission for prophetic examples. Most cases that address prophetic examples simply accept that the prophetic example supports the invention and include no discussion of the examples' value or any controversies or doctrinal points.[106]

Though it is well settled that prophetic examples can be used to satisfy the disclosure requirements, the issue still arises frequently, which suggests that litigants remain somewhat skeptical. This skepticism is not entirely unfounded. The *Wands* factors, which embody the seminal test for enablement, list the presence or absence of "working examples" as a factor in the analysis, but omit prophetic examples.[107] Furthermore, courts will often hint that prophetic examples are not quite as good as working examples by prefacing prophetic evidence with a word suggesting hesitation, such as bemoaning the lack of "working *or even* prophetic examples."[108]

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[104] *See* Duffy, *Reviving*, *supra* note 79, at 1370 (explaining that the PTO has "little or no ability to investigate the underlying physical reality of inventions"). *Moy's Walker on Patents* puts the matter more pointedly by noting that the doctrine is "an attempt to provide a theoretical basis for a problematic practice of the PTO . . . during examination the PTO does not inquire whether applicants have actually reduced their claimed inventions to practice. Thus, patents routinely issue on inventions that were not constructed as of the filing date." R. CARL MOY, MOY'S WALKER ON PATENTS § 8:93 (4th ed. 2017).

[105] *See* MPEP, *supra* note 6, § 608.01(p) (9th ed. 2015).

[106] *See, e.g.*, Phigenix, Inc. v. Genentech Inc, No. 15-CV-01238-BLF, 2016 WL 4172202, at *1 (N.D. Cal. Aug. 8, 2016) ("[The patent] describes prophetic examples that predict this phenomenon also occurs in breast cancer cells."); Regeneron Pharm., Inc. v. Merus B.V., No. 14 CIV. 1650 KBF, 2014 WL 6611510, at *18 (S.D.N.Y. Nov. 21, 2014) ("Example 3 (a prophetic example), confirms human genomic DNA."); *Ex parte* Artemis Med., Inc., No. 2010-009099, 2010 WL 4084621, at *3 (B.P.A.I. Oct. 15, 2010) ("Anderson's Prophetic Example 2 describes the preparation of a *copolymer* obtained by polymerizing lactic acid and glycolide *monomers*."); Britto v. Stampf, No. 105,624, 2008 WL 2781982, at *3 (B.P.A.I. July 16, 2008) ("Prophetic Examples 3 and 13 describe the use of PTFE-PES blend . . . ."); *Ex parte* Gwynne, No. 2000-2157, 2000 WL 33118608, at *2 (B.P.A.I. Nov. 28, 2000) ("The examiner also points to Yelton's prophetic promoter . . . which describes cloning and expression of a foreign polypeptide . . . .").

[107] *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

[108] Enzo Biochem., Inc. v. Applera Corp., No. 3:04CV929 JBA, 2013 WL 3965305, at *8 (D. Conn. Aug. 1, 2013); *see also, e.g.*, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1357-58 (Fed. Cir. 2010) (emphasis added); Takeda Pharm. Co., Ltd. v. Handa Pharm. LLC, Nos. C-11-00840 JCS, C-11-01609 JCS, C-11-01610 JCS, 2013 WL

Overall, case law on prophetic examples remains sparse.[109] An April 2017 search for cases mentioning the term "prophetic example" uncovered only fifty-two cases in Westlaw's Federal Cases database and forty-six and twelve cases from the Board of Patent Appeals and Interferences and Patent Trial and Appeal Board databases, respectively.[110] Searches for "paper example" found few relevant cases, suggesting that the dominant terminology is "prophetic" rather than "paper."

II. THE CASE FOR PROPHETIC EXAMPLES

There has never been any thorough examination of why we permit prophetic examples. Allowing fictional data in patents is, at first glance, a perplexing practice[111] — and the scholarly literature on prophetic examples, though brief, is overwhelmingly negative.[112] Nonetheless, there is a serious theoretical case to be made for the benefits of prophetic examples, and I make that case in this Part.

The purpose of patents is to incentivize innovation.[113] Inventors are motivated by the knowledge that they will receive patent exclusivity as a reward.[114] Roughly speaking, stronger, broader, and more effective

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9853725, at *72 (N.D. Cal. Oct. 17, 2013) (finding that the patent "does not contain any working examples . . . [i]nstead, all of the examples . . . are 'prophetic' . . ."); *Ex parte* Lam, No. 2007-2830, 2008 WL 503540, at *3 (B.P.A.I. Feb. 25, 2008) ("The *only* examples provided are two 'prophetic' examples.") (emphasis added); *Ex parte* Klinger, No. 2001-0407, 2006 WL 2523659, at *2 (B.P.A.I. Mar. 27, 2003). Similarly, courts have found prophetic examples based on actual experiments to be a particularly convincing flavor of prophetic example. *See, e.g.*, Warner Lambert Co. v. Teva Pharm. USA, Inc., No. CIV. A. 99-922 DRD, 2007 WL 4233015, at *11 (D.N.J. Nov. 29, 2007) ("[T]he 'prophetic' examples of the specification were based on actual experiments that were slightly modified in the patent to reflect what the inventor believed to be optimum, and hence, they would be helpful in enabling someone to make the invention.").

[109] *See* Rothschild v. Cree, Inc., 711 F. Supp. 2d 173, 209 (D. Mass. 2010) ("There are very few cases dealing with prophetic examples in patents.").

[110] The Board of Patent Appeals and Interferences ("BPAI") and the Patent Trial and Appeal Board ("PTAB") are administrative bodies within the PTO that hear appeals of patent examinations and related issues. *See* 35 U.S.C. § 6(b) (2019). The BPAI was renamed the PTAB in 2012 (at which point the BPAI ceased to exist), and Westlaw indexes decisions from the boards in separate databases.

[111] For example, one court complained that it "can conceive of no reason for the PTO to countenance such a practice." Grefco, Inc. v. Kewanee Indus., 499 F. Supp. 844, 867 n.34 (D. Del. 1980).

[112] *See* sources cited *supra* note 10.

[113] *See* Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980).

[114] *See, e.g.*, Peter S. Menell & Suzanne Scotchmer, *Intellectual Property Law*, *in* 2 HANDBOOK OF LAW AND ECONOMICS 1473, 1476-78 (A. Mitchell Polinsky & Steven Shavell eds., 2007).

patent rights increase this reward.[115] The most convincing explanation for prophetic examples is that they help patentees, thereby strengthening the exclusivity incentive for innovation. In Section A, below, I hypothesize that prophetic examples can lead to patents that are broader and filed earlier than would be possible in the absence of prophetic examples.

To make the case for prophetic examples, it is not enough that they help patentees. They must also not be harmful. In Section B, I make explicit two additional requirements that must be satisfied to justify the use of prophetic examples. First, prophetic examples should not impede innovation in the area described by the patent. Second, prophetic examples should be consistent with the underlying logic of patent law.

A. Potential Benefits

1. Earlier-Filed, Broader Patents

Patent applications with prophetic examples can be filed earlier than applications with working examples because writing a prophetic example is faster than conducting even the simplest of real experiments.[116] Moreover, real experiments might not work or may produce unexpected data, necessitating a potentially time-consuming change to protocols or development of a new procedure. Prophetic examples do not have this potential. Thus, applicants who choose prophetic examples will be able to file a patent application earlier than applicants who choose to conduct experiments, a particular advantage in competitive and fast-moving fields.[117]

Prophetic examples also help applicants obtain broader patents. Patents must teach others how to make and use their inventions, so broader patents covering more material require more explanation. To

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[115] *See generally* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990).

[116] As one guide notes: "Situations may arise when an inventor has a great idea but has no time for lengthy experimentation or time-consuming data collection . . . . In such instances, the filing of a prophetic patent application may be the solution." JOSEPH P. KENNEDY ET AL., HOW TO INVENT AND PROTECT YOUR INVENTION: A GUIDE TO PATENTS FOR SCIENTISTS AND ENGINEERS § 5.5.3 (2012).

[117] TOM BRODY, CLINICAL TRIALS 837 (2d ed. 2016) ("Prophetic examples can be [used if] . . . the inventors did not have enough time to complete, or even initiate, any of the relevant experiments before the patent application was filed."); ROBIN FELDMAN, RETHINKING PATENT LAW 160 (2012) ("A couple of times the lawyer noticed that another company had filed a patent application on the same gene and used similar prophetic embodiments a few weeks before, presumably having applied similar guesswork. Everyone is moving fast and shooting from the hip . . . .").

get a patent on a single molecule, one experimental protocol is generally enough to teach an expert how to synthesize the molecule.[118] To get a patent on many different molecules, many synthesis protocols will be needed. Thus, patent drafters will try to include more examples to support broader claims.[119] Prophetic examples are instrumental to this function as they allow applicants to seek a broad patent without conducting expensive experiments, which reduces the cost of patents.[120]

The following example illustrates how prophetic examples allow for broader, cheaper, and earlier-filed patents. Para-dichlorobenzene, the molecule historically used in scented deodorizers, was suspected to be toxic.[121] To solve this problem, a pair of inventors discovered a new, nontoxic molecule that could be combined with various scents and would slowly release those scents over time — useful for products like

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[118] *See* MPEP, *supra* note 6, § 2164.02 (9th ed. 2013) ("A single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled. However, a rejection stating that enablement is limited to a particular scope may be appropriate.").

[119] *See, e.g.*, Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1374 (Fed. Cir. 1999) (holding that the patent was not valid because "the number of working examples provided in the specifications were 'very narrow,' despite the wide breadth of the claims at issue . . .").

[120] *See, e.g.*, BRODY, *supra* note 117, at 837("[T]he inventors may have included one or more prophetic examples, in order to ensure that the combination of the working examples and the prophetic examples supported, and correspond to, the genus of compositions that is encompassed by these claims."); WILLIAM G. KONOLD ET AL., WHAT EVERY ENGINEER SHOULD KNOW ABOUT PATENTS 54 (2d ed. 1989) (describing content reasonable to include in a prophetic example); William B. Slate, *The Real Security of Continuation-in-Part Applications*, 83 J. PAT. & TRADEMARK OFF. SOC'Y 551, 554 (2001) ("[I]n many cases alternate strategies for addressing contingencies will pose greatly increased costs."); Troy Groetken & Scott McBride, *Sufficiency of Disclosure and the Great Divide Between the U.S. and Europe*, MCANDREWS (Feb. 26, 2014), https://www.mcandrews-ip.com/sufficiency-disclosure-and-the/ ("[M]any times, the actual examples provided do not provide the same level of breadth as the written word descriptive sections attempting to broaden the claimed invention. To overcome this, a number of prophetic examples are sometimes included in the specification."). For example, in *Synthes USA, LLC v. Spinal Kinetics, Inc.*, the Federal Circuit held that disclosure of one species in an unpredictable field was insufficient support for a broad genus. 734 F.3d 1332, 1334, 1344-46 (Fed. Cir. 2013). Following this case, practice guides recommended that to "avoid or minimize problems such as those in . . . Synthes . . . the applicant could have included prophetic examples . . . ." Helene C. Carlson & Gaby L. Longsworth, *Strengthening Pending and Future Application Portfolios in Advance of Potential Attack in AIA Proceedings*, 89 PAT. TRADEMARK & COPYRIGHT J. 1465 (2015).

[121] *See* U.S. Patent No. 4,842,853 col. 1 ll. 15-20 (filed Aug. 4, 1986) (issued June 27, 1989).

air fresheners.[122] If the inventors had wanted a narrow patent covering only one type of scent, including one example in the patent application might have been enough. However, the inventors sought a broader patent to cover the slow release of many different "fragrant substances."[123] Thus, it was necessary to include more examples in the patent. Perhaps lacking the time or money to conduct experiments with many different types of fragrant substances, the inventors wrote seven prophetic examples with instructions for how to make these compositions.[124] These included ingredients, amounts, and mixing instructions for making scents such as "Sea Breeze," "Lilac perfume oil," and "Lily of the valley."[125] Though these protocols were all predictions rather than tested conclusions, they were enough for the examiner to grant the broad patent.

Finding an alternative to carcinogenic deodorizers is a worthwhile innovation of the type we hope to incentivize with patents. If these inventors could only have gotten a narrow patent covering one scent, it might not have been enough of a reward to incentivize the initial invention. Prophetic examples allowed the inventor to get a broader patent. Without prophetic examples, this technology may never have been made available to the public.

2. Special Situations

Prophetic examples may also be useful in a variety of situations where the inventor is not able to conduct a real experiment. In these situations, prophetic examples create exclusivity where it would not otherwise be available, potentially incentivizing innovation. One such situation occurs when a small company cannot afford to conduct a large number of experiments (to get a broader patent) before a patent is filed. Prophetic examples may help equalize the availability of broad patents between companies with resources and those without.[126]

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[122] *See id.* at col. 1 ll. 35-40.

[123] *See id.*

[124] *See id.* at col. 3 ll. 18-65, col. 4 ll. 18-50.

[125] *Id.* at col. 3 ll. 19, 40, 65.

[126] *See* Aisenberg, *supra* note 98, at 30 (explaining that prophetic examples are important because "an individual inventor in the chemical arts is already hard put to perform or obtain testing often required to procure a reasonable scope of patent protection"). There is concern in other contexts that the patent system disadvantages small companies and individual inventors. *See, e.g.*, David S. Abrams & R. Polk Wagner, *Poisoning the Next Apple? The America Invents Act and Individual Inventors*, 65 STAN. L. REV. 517, 534 (2013) (suggesting that the Leahy-Smith America Invents Act chills

Another such situation where prophetic examples are needed for filing a patent is the catch-22 situation where a funder will not provide capital without a patent, but the experiments necessary to get the patent cannot be done without funding. Using prophetic examples to file before the experiment is conducted also helps inventors who risk losing the ability to patent if they had to obtain data before filing their patent application. This occurs because an inventor's own public disclosure about the invention can bar him from later filing for a patent on the invention.[127] What precisely constitutes a public disclosure is contextual, but it may occur if samples are sent out for testing[128] or manufacturing.[129] A particularly contentious issue is the question of clinical trials, where a drug must be distributed to doctors and patients with certain disclosures. Though appropriate confidentiality agreements can prevent clinical trials of a drug from blocking later patenting of the drug, it is a sufficiently problematic issue that the question is frequently litigated.[130]

Moreover, there may be regulatory obstacles to conducting real experiments. It is conventional in the pharmaceutical industry to file patents on treatments that show promise in *in vitro* experiments.[131] It can take years and hundreds of millions of dollars to obtain permission from the Food and Drug Administration ("FDA") for human

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individual inventors); Clark D. Asay, *Patenting Elasticities*, 91 S. CAL. L. REV. 1, 10 (2017) (arguing that the cost of patenting might dissuade innovators).

127 *See* 35 U.S.C. § 102(a)(1) (2019).

128 *See, e.g.*, Pronova Biopharma Norge AS v. Teva Pharm. USA, Inc., 549 F. App'x. 934, 939, 942 (Fed. Cir. 2013) (finding that the plaintiff's patent was invalid because the company had sent samples to a consultant for testing and promotional purposes before the patent application was filed).

129 The Federal Circuit has recently clarified that a manufacturing contract to produce a product is not a disclosure that bars later patenting assuming appropriate confidentiality requirements are met, but this has historically been an area of concern for innovators. *See* Medicines Co. v. Hospira, Inc., 827 F.3d 1363, 1373, 1377 (Fed. Cir. 2016).

130 *See* Dey, L.P. v. Sunovion Pharm., Inc., 715 F.3d 1351, 1358 (Fed. Cir. 2013) (explaining that "courts have routinely rejected the argument that such an arrangement necessarily strips the trial of confidentiality protection or renders it accessible to the public"); *see also* Bayer Schering Pharma AG v. Barr Labs., Inc., No. 05-cv-2308, 2008 WL 628592, at *11-12, *37-38 (D.N.J. Mar. 3, 2008); *In re* Omeprazole Patent Litig., 490 F. Supp. 2d 381, 507-08 (S.D.N.Y. 2007), *aff'd on other grounds*, 536 F.3d 1351 (Fed. Cir. 2008); Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., 364 F. Supp. 2d 820, 873-74 (S.D. Ind. 2005); Janssen Pharm. N.V. v. Eon Labs Mfg., Inc., 374 F. Supp. 2d 263, 276 (E.D.N.Y. 2004), *aff'd*, 134 F. App'x 425, 430 (Fed. Cir. 2005).

131 *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 348 (2007) [hereinafter *Role of the FDA*].

experiments and to conduct those experiments.[132] It is risky to make this investment without patent protection. Thus, pharmaceutical companies generally require a patent early in a drug's lifecycle and crucially, before human data can possibly be obtained.[133] Though it is not strictly necessary to include human data to obtain a patent on a drug, patents lacking human data have occasionally been invalidated and therefore pharmaceutical companies prefer to include human trials.[134]

For instance, the patent applicant in *Bone Care International, LLC v. Pentech Pharmaceuticals, Inc.* sought a patent on a method of treating osteoporosis using the molecule doxercalciferol.[135] The applicant had created a detailed plan for a clinical trial of this drug, but, probably for the reasons described above, could not wait until completion of all trials to file the patent.[136] The applicant therefore filed a patent with working examples reporting stage I and stage II clinical trials and several prophetic examples detailing a double-blind trial and its (prophetic) results[137]:

> A twelve-month double-blind placebo-controlled clinical trial is conducted with thirty-five men and women . . . Analysis of the clinical data shows that [doxercalciferol] increases . . . intestinal calcium absorption, as determined by direct measurement . . . .[138]

Because the PTO permits prophetic examples, the applicant could use the results of the clinical trial to support the patentability of the

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[132] *See* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 162 (2003).

[133] *See* Eisenberg, *Role of the FDA*, *supra* note 131, at 348.

[134] Note that patents are not invalidated solely for lacking human data, but rather for an insufficient connection between the claimed utility of the invention and the evidence in the specification. *See, e.g.*, *In re* '318 Patent Infringement Litig., 583 F.3d 1317, 1327 (Fed. Cir. 2009); Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1323-25 (Fed. Cir. 2005); *In re* Brana, 51 F.3d 1560, 1566-68 (Fed. Cir. 1995) (reversing the BPAI's rejection of the patent and explaining that "FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws").

[135] *See* Bone Care Int'l, LLC v. Pentech Pharm., Inc., 862 F. Supp. 2d 790, 800 (N.D. Ill. 2012).

[136] *See id.* at 798-99.

[137] U.S. Patent No. 5,602,116 col. 11 l. 40, col. 12 l. 5 (issued Feb. 11, 1997).

[138] *Id.* at col. 11 ll. 40-65.

compound — even before the clinical trial had been conducted.[139] Without prophetic examples, the applicant may not have felt secure enough to invest in the necessary clinical trials, thereby depriving the public of a valuable drug. With prophetic examples, Bone Care filed the patent, got FDA approval, and has sold millions of doses of the drug under the brand name Hectorol®.[140]

In situations of the types outlined above, it is simply not practical for an inventor to conduct real experiments. This means that if prophetic examples were not allowed, these inventors might not be able to get a patent. Without prophetic examples, we might see reduced innovation from small companies or those in the pharmaceutical space.

* * *

The case for prophetic examples is founded on their benefits to patentees. The Subsections above describe specific ways in which prophetic examples help patentees. Prophetic examples may allow patents to be (1) broader; (2) filed earlier; and (3) particularly useful in specific situations such as for patents filed by small entities, experiments that are expensive and cannot be done without funding, and experiments involving clinical trials.

B. Potential Costs

To be justifiable, prophetic examples must help patentees, but this alone is not enough. The underlying assumption in the case for prophetic examples is that they help patentees in a way that is not harmful to the patent system more broadly. However, prophetic examples may indeed cause harm by chilling downstream research and misleading other researchers.

1. Chilling Downstream Research

Prophetic examples might help patentees file earlier, broader patents; however, it is far from clear that these patents are actually socially

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[139] During a later trial, defendants challenged whether the prophetic example adequately enabled the relevant claim. The court found that it did and that the claim was valid. *See Bone Care*, 862 F. Supp. 2d at 804-05.

[140] *See HECTOROL - doxercalciferol injection, solution, Genzyme Corporation*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021027s015lbl.pdf (last visited Nov. 13, 2019); *Genzyme Corp. to Buy Bone Care for $719 Million*, WALL ST. J. (May 5, 2005, 12:01 AM), https://www.wsj.com/articles/SB111521906165324566 (noting Bone Care International Inc. sold the product to Genzyme).

beneficial.[141] Broad, early-filed patents are supported by adherents of the "prospect" theory of patent law[142] who argue that such patents allow patentees to coordinate technological development in that area.[143] This prevents wasteful races to invent and reduces transaction costs during downstream development.[144] These are all potential benefits of prophetic examples.

However, some scholars worry that overly broad patents reduce competition and block downstream innovation,[145] and that early-filed patents reflect less developed inventions and therefore lead to patents that are more vague, useless, or, if useful, never commercialized.[146] The problem with such patents is that they might effectively prevent others from working in the areas surrounding the patent. While the patent is in force, others cannot do their own experiments in the area covered by the patent — even if the prophetic examples do not work.[147] Even after

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[141] *See* Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 67 (2009); Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 343-44 (2010); Lemley, *supra* note 10, at 1172-73.

[142] *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 266-68 (1977).

[143] *See* A. Samuel Oddi, *Un-Unified Economic Theories of Patents — The Not-Quite-Holy Grail*, 71 NOTRE DAME L. REV. 267, 281-82 (1996).

[144] *See* Kitch, *supra* note 142, at 268-69. It also causes patents to expire earlier, a potential benefit to society. *See* John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 467 (2004).

[145] *See* Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 831 (2001) (addressing how patent law can be used to help spur biopharmaceutical innovation); *see also, e.g.*, Peter S. Menell, *The Challenges of Reforming Intellectual Property Protection for Computer Software*, 94 COLUM. L. REV. 2644, 2646 (1994) (exploring possible reforms to the legal protection of computer software).

[146] *See, e.g.*, Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521, 1540 (2005) (finding that pharmaceutical and biotechnology patents were abandoned more often than mechanical patents, and suggesting that "these industries rush to patent new compounds and genes (and their methods of manufacture) before knowing whether those compounds have great utility or commercial viability").

[147] One inoperative embodiment does not mean that the patent is invalid. *E.g.*, Application of Howard P. Angstadt, 537 F.2d 498, 502-03 (C.C.P.A. 1976) (discussing a patent application that included both operative and inoperative embodiments). It is possible that the experimental use exception would allow third parties to do research in these circumstances. However, after *Madey v. Duke University*, 307 F.3d 1351, 1361 (Fed. Cir. 2002), scholars are skeptical that the experimental use exception would cover situations where a third party tests a patented invention to see if it would work. *See, e.g.*, Tom Saunders, Comment, *Renting Space on the Shoulders of Giants:* Madey *and the Future of the Experimental Use Doctrine*, 113 YALE L.J. 261, 261-62 (2003) (discussing the impact of *Madey* for university researchers); Cristina Weschler, *The Informal Experimental Use Exception: University Research After* Madey v. Duke University, 79

the patent has expired or been abandoned, it might still chill research in that area because others cannot get a patent on an invention disclosed in or rendered obvious by a prophetic example.[148] Patents are given only for inventions that are new and nonobvious, therefore, material that is disclosed or obvious from the disclosed material is no longer patentable.[149] This is true even if the subject of the disclosure was never physically created.[150] We know that companies make strategic disclosures in their patents for the express purpose of preventing competitors from obtaining patents; prophetic examples may be one form of such disclosure.[151]

For instance, in *Ex Parte Botond Banfi*, the inventors sought to patent the use of iodide to treat microbial diseases.[152] The PTO rejected the application on the grounds that the invention was not new because it

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N.Y.U. L. REV. 1536, 1547-48 (2004) (discussing the conflict of interest issues caused requiring parties to share information). Even if the experimental use exception does cover these situations, the uncertainty around the scope of the exception is likely chilling to research.

[148] *See* 35 U.S.C. §§ 102-103 (2019).

[149] For novelty: *Ex parte Danilova*, No. 2008-1171, 2008 WL 4768088, at *4 (B.P.A.I. Oct. 31, 2008) ("As to the matter of Bower being a 'paper patent', assuming *arguendo* that this is in fact the case, the patent is nonetheless useful under §§ 102 and 103 as prior art. Note that a patent need not be commercially practical to be anticipatory."). For criticisms of this rule, see, for example, Sean B. Seymore, *Reinvention*, 92 NOTRE DAME L. REV. 1031, 1031 (2017) (arguing that the current rules of patent law may prevent many socially valuable inventions from reaching the public). However, in order to anticipate a later patent, the prophetic example must be enabled. For obviousness, see, for example, *Ex parte* Kubin, No. 2007-0819, 2007 WL 2070495, at *2-4 (B.P.A.I. May 31, 2007) (finding obviousness based on a reference, which "expressly teaches through a prophetic example how to 'isolate the cDNA clone using mAb C1.7, screening the protein expression in the cell transfected with the cDNA library and cloning a corresponding cDNA into a plasmid for sequencing'").

[150] *See Ex parte* Fisch, No. 2009-005729, 2009 WL 2760600, at *6 (B.P.A.I. Aug. 28, 2009) ("Appellant also argues that the test study designed by MacLean is a prophetic example . . . . However, anticipation does not require actual performance of suggestions in a disclosure, only that those suggestions be enabling to a skilled artisan. Therefore this argument is not persuasive . . . ."). Or, for obviousness, even if the disclosure was not enabled. *See* MPEP, *supra* note 6, § 2121.01.

[151] *See* Gideon Parchomovsky, *Publish or Perish*, 98 MICH. L. REV. 926, 926-27 (2000) (asserting "the possibility of strategic publication of research findings in order to prevent the issues of a patent to a competitor"); *see also,*, Scott Baker & Claudio Mezzetti, *Disclosure as a Strategy in the Patent Race*, 48 J.L. & ECON. 173, 174 (2005) (providing examples of "targeted" disclosures); Seymore, *Patenting Around Failure*, *supra* note 10, at 1158. *But see* Rebecca S. Eisenberg, *The Promise and Perils of Strategic Publication to Create Prior Art: A Response to Professor Parchomovsky*, 98 MICH. L. REV. 2358, 2367 (2000) (describing potential issues with disclosure).

[152] *See Ex parte* Banfi, No. 2013-000535, 2015 WL 6407275, at *1 (P.T.A.B. Oct. 19, 2015).

had been disclosed in a prior patent.[153] The prior patent had indeed disclosed the use of iodide, but in a prophetic example describing the treatment of asthma (which is not a microbial disease).[154] The prophetic example is:

> A 45 year old female with a history of severe asthma with a morning peak flow of less than 3 l/sec is treated with . . . iodide in an aerosol formulation, 2 mg three times daily continuously. After a week of treatment the peak flow improves to 6 l/sec.[155]

Although the example was prophetic and did not actually involve a microbial disease, the court reasoned that it inherently disclosed use of iodide to kill microbes.[156] If someone had used the technique, it would have incidentally resulted in the removal of microbes from the throat, even though that was not the main purpose of the treatment.[157]

Though there is no evidence that this example was included for the purpose of defensive disclosure, the example shows how use of a prophetic example can prevent patenting in a wide area around the patent. The prior patentee tried using iodide to treat asthma,[158] but the patent effectively prevented others from getting later patents on iodide to treat completely different respiratory illnesses. Innovators are scared away from research in areas near prophetic examples either because they believe that someone has already tried the technique or because they worry that they will not be able to get a patent themselves.[159] Any defense of prophetic examples must balance their benefits to patentees against this potential problem.

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153 *See id.*

154 *See id.*

155 U.S. Patent No. 6,890,920 col. 30 ll. 10-18 (issued May 10, 2005).

156 *See Ex parte Banfi*, 2015 WL 6407275, at *3.

157 *See id.* These "inherency" rejections are made when the examiner relies on "[t]he inherent teaching of a prior art reference." *In re* Napier, 55 F.3d 610, 613 (Fed. Cir. 1995). *See* MPEP, *supra* note 6, § 2112.

158 There were several articles on the use of potassium iodide to treat asthma published in the 1840s and 50s, but the technique does not appear to have caught on. *See, e.g.*, W.B. Casey M.D., *On the Use of Iodide of Potassium in Asthma*, 32 BOSTON MED. SURG. J. 40, 40-41728-29 (1845).

159 Though not in the context of prophetic examples, a scientist complained that "lazy people sit in their office and say 'we should do this' and the next minute they write a stupid invention disclosure and submit it . . . . The problem is such people rarely complete these projects . . . [and] someone who has the same idea will . . . find this patent application and assume it's been done before. I have seen personally many great ideas not being pursued because of this." Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 545, 578 (2012); *see also* Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 545 (2009).

2. Inaccurate and Misleading

The second potential cost of prophetic examples lies in their ability to satisfy the enablement and written description doctrines. As part of the patent disclosure, prophetic examples need to both teach other scientists how to make and use the invention and help inventors prove possession of the invention.[160] It is only intellectually coherent to allow prophetic examples to serve these functions if they are actually understood by scientists and are accurate predictions.

To illustrate, if prophetic examples are used to teach scientists how to make and use an invention, then they must in fact be able to do so. If prophetic examples describe protocols that are entirely incorrect, then the patent reader cannot rely on them for instruction. Similarly, if scientists are confused or misled by prophetic examples, then they do not actually teach scientists anything. Further, if prophetic examples are used to prove that the inventor had possession of the invention, they must again be accurate predictions. If the inventor's predictions are incorrect, it is doubtful that the inventor actually had possession of the invention described by those same predictions. In addition, once a patent is granted, prophetic examples are presumed to be accurate.[161] The presumption is only reasonable if prophetic examples are in fact likely to be accurate.[162]

At stake is not only whether patent doctrine is satisfied. The patent's disclosure is also supposed to promote innovation by allowing scientists to use that new technical knowledge to improve the technology or make their own inventive leaps.[163] If the information in patents is confusing to these scientists or is simply inaccurate, then it is much harder for patents to promote innovation through disclosure.

At present, we do not know if prophetic examples reflect accurate predictions. Some have suggested that prophetic examples are not accurate,[164] but the suggestion has not been discussed in depth nor has

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[160] *See* 35 U.S.C. § 112 (2019).

[161] *See, e.g.*, Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1577 ("The burden is on one challenging validity to show by clear and convincing evidence that the prophetic examples together with other parts of the specification are not enabling.").

[162] There are other reasons to have a presumption of validity, including administrative simplicity and predictability for patentees. Nonetheless, the presumption is dubious if its underlying assumption is not correct.

[163] *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) ("[The] disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art.").

[164] *See* Seymore, *Teaching Function of Patents*, *supra* note 10, at 631-32. Granted patents are presumed to be enabled and adequately described, and the challenger has

it been tested empirically. We similarly do not know if prophetic examples are understood by scientists, and again, some have suggested that they are not.[165] Ninety-one percent of industry scientists read patents.[166] If prophetic examples are inaccurate and misunderstood, it presents a major challenge to the enablement and written description requirements.

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In order to be justifiable, prophetic examples must help patentees. But they must also do more: prophetic examples must (1) avoid chilling downstream research, and (2) be both accurate and non-misleading.

III. THE EMPIRICS OF PROPHETIC EXAMPLES: A NOVEL STUDY

Given the importance of prophetic examples to several fundamental elements of the patent system, competing justifications and criticisms, and the extreme dearth of scholarship on the topic, it is important to know more about prophetic examples. This Part reports an empirical study of prophetic examples across all electronically published U.S. chemistry and biology patents and applications. The study asks two primary questions. First, how prevalent are prophetic examples? Are they sufficiently numerous to affect patents and innovation, or are they merely an unusual — but uncommon — feature of patent law? Second, can they be justified?

A. Study Design

1. Populations

Unless otherwise specified, the study patents were issued between January 1976[167] and May 2017, and the study applications were filed between 2001[168] and May 2017.[169] Although the data reported are

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the burden of proving that that they are not. *E.g.*, Impax Labs. Inc. v. Aventis Pharm. Inc., 468 F.3d 1366, 1378 (Fed. Cir. 2006) (holding that an issued patent is presumed valid, with the burden of establishing invalidity resting on the party asserting invalidity).

165 *See, e.g.*, Ouellette, *Who Reads Patents?*, *supra* note 10, at 423 (discussing how some researchers find patents "extremely difficult to understand . . .").

166 *See id.* at 421 (only 78% of academic scientists read patents).

167 The USPTO's full text database only covers 1976-onward.

168 The USPTO's application database only covers 2001-onward.

169 The patents were bulk downloaded and a variety of information was collected for each patent including the priority date (the filing date of the earliest application to

drawn from a population, not a sample, I include tests for statistical significance in the event that readers want to extrapolate from the data to similar patents such as those from other years.[170]

2. Identifying Prophetic Examples

Each patent was analyzed to determine if it contained an examples section, and, if so, the section was broken down into individual examples.[171] This strategy excluded patents with no examples or that integrated examples in the text of the patent, which is a limitation of the methodology.[172]

Prophetic examples were identified by exploiting a PTO grammar requirement: prophetic examples must be written in the present tense, while working (non-prophetic) examples should be written in the past tense.[173] Prophetic examples should be entirely in the present tense, as

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which the studied patent or application can claim benefit), the filing date (the date on which the studied application was filed), the issue date (the date on which the studied patent issued), the number of claims, number of forward and backwards citations, whether the patent is a continuation or divisional, and specification length. *See* PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299, 1306 (Fed. Cir. 2008) (priority date); 37 C.F.R. § 1.741 (2019) (filing date); MPEP, *supra* note 6, § 1309 (issue date); WORLD INTELLECTUAL PROPERTY ORGANIZATION, *IPC classifications*, *in* GUIDE TO THE INTERNATIONAL PATENT CLASSIFICATION (2017), http://www.wipo.int/export/sites/www/classifications/ipc/en/guide/guide_ipc.pdf. This information was obtained from patents downloaded from the USPTO's Patent Grant Full Text Database, hosted by Reed Tech. REED TECH, USPTO DATA SETS: PATENT GRANT RED BOOK (2017), http://patents.reedtech.com/pgrbft.php. Data on patent expiration, maintenance fees, and entity size was obtained from the USPTO. *See* UNITED STATES PATENT AND TRADEMARK OFFICE, USPTO BULK DOWNLOADS: PATENT MAINTENANCE FEES (2015), https://www.google.com/googlebooks/uspto-patents-maintenance-fees.html#1981-present. Because micro entity status has only been available as of 2013, micro entities are counted as small entities. Additionally, the USPTO maintenance fee records list entity size as of the date the maintenance fee was paid, which may be different from entity size as of the date the patent was filed. This study sought to identify entity size as of the date the patent was filed, thus, where the USPTO recorded a change from small to large entity for purposes of payment of maintenance fees, the entity was counted as a small entity.

170 I draw this strategy from John R. Allison & Lisa Larrimore Ouellette, *How Courts Adjudicate Patent Definiteness and Disclosure*, 65 DUKE L.J. 609, 629 (2016). As noted by Allison and Ouellette, because this study involves a population, coefficients may be meaningful even if they are not statistically significant – "any observed differences in a population are real ones." *Id.*

171 Full text of algorithm on file with author.

172 See *infra* Figure 1 for data on how many patents with examples were identified using this strategy.

173 *See* MPEP, *supra* note 6, § 2004 ("Paper or prophetic examples should not be described using the past tense.").

judges have warned against mixing past and present tense in an example.[174] Further, examples written in the present tense are "presumed to be prophetic."[175] Where examples consist of numbers only, and therefore have no tense, the PTO assumes that the numbers are not prophetic.[176]

Although it is impossible to verify whether patent drafters are correctly classifying experiments, the penalty for describing prophetic results in the past tense is high; therefore, there is reason to believe that the self-classification is accurate. Representing a prophetic example as if it were actually conducted may result in a finding of inequitable conduct, rendering the entire patent unenforceable.[177] There is no penalty for representing a working example as a prophetic example; however, I expect that this is uncommon. Courts assume that examples written in the present tense are prophetic,[178] which has certain disadvantages if the example is in fact working.[179] In addition, most patents with prophetic examples also contain some examples written in the past tense and it would be surprising if a patent drafter switched to the past tense for some working examples but left others in the present tense.

To validate the methodology, a patent agent manually reviewed a random sample of 100 examples and classified the examples as prophetic or non-prophetic. The patent agent identified nine errors in the algorithm's classification. Of these errors, the algorithm classified a

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[174] *See* Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1374-75 (Fed. Cir. 2003) (Newman, J., dissenting) (characterizing the majority's approach for concluding why prophetic examples in the past tense constituted inequitable conduct).

[175] *Ex parte* Sharma, No. 2010-001682, 2010 WL 2694700, at *3 (B.P.A.I. July 1, 2010). *See also Ex parte* Schwarz, No. 2008-2442, 2008 WL 2463016, at *6 (B.P.A.I. June 17, 2008) ("Since the examples were written in the present tense, they are presumed prophetic and do not represent actual evidence.").

[176] *E.g.*, *Ex parte* Fujimoto, No. 2012-000530, 2013 WL 649554, at *1 (P.T.A.B. Feb. 19, 2013) ("Applicant relies on data on page 22 of the Specification. We assume that the data is a result of actual (as opposed to prophetic) examples."); *Ex parte* Schuisky, No. 2009-011912, 2009 WL 2810323, at *3 (B.P.A.I. Sept. 2, 2009) ("The specification and drawings include data . . . . We assume the data is not based on prophetic examples.").

[177] *E.g.*, Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp., 424 F.3d 1347, 1359-63 (Fed. Cir. 2005).

[178] *E.g.*, *Ex parte* Prencipe, No. 2012-001803, 2012 WL 5387521, at *7 (P.T.A.B. Oct. 31, 2012); *Ex parte* Schwarz, 2008 WL 2463016, at *6 ("Since the examples were written in the present tense, they are presumed prophetic and do not represent actual evidence.").

[179] Most notably, the *Wands* factors. *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

working example as prophetic three times and a prophetic example as working six times.[180]

Once prophetic examples are identified, they can be counted. There are multiple equally compelling ways to count prophetic examples:

- Number of prophetic examples per patent;
- Percent of total examples in the patent that are prophetic;
- Whether the patent has some prophetic examples, as compared to patents that have no prophetic examples; or
- Whether the patent has only prophetic examples, as compared to patents that have either no prophetic examples or some prophetic examples.

For convenience, this Article generally presents results using the first of these measures. However, each analysis was also conducted using the other measures, and the results were comparable. Where results are different, these differences are noted in the text.

3. Selecting Industries

Patents are drafted differently in different industries.[181] This reflects both the varied nature of the technologies and differences in how the law is applied.[182] In particular, the bar for enablement and written description is higher in industries such as chemistry and the biology as compared to the mechanical, electrical, or computer industries.[183] Thus, there is reason to expect that examples (both prophetic and working) will be more common in chemistry and life science patents. Figure 1 validates this expectation.[184]

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[180] These errors occurred because the algorithm did not accurately capture the tense of the verbs used in these examples.

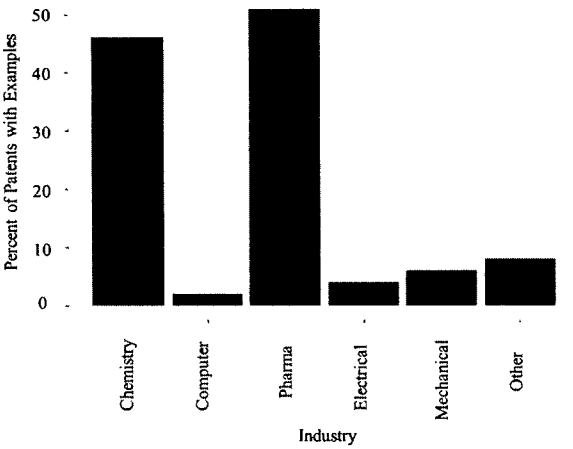
[181] *See generally* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003) (discussing the wide variation of patent law across disparate industries).

[182] *See id.* at 1577.

[183] *See* Cotropia, *supra* note 141, at 74-75.

[184] National Bureau of Economic Research ("NBER") classifications are used here because they are simpler and fewer in number than International Patent Classification ("IPC") classifications. IPC classifications are used for the remainder of the Article because NBER classifications are only current through 2015 and because NBER does not classify applications.

Figure 1. Percentage of patents issued between January 1976 and May 2017 with a separate examples section (by industry).



Note that the paucity of examples outside the chemical and biological fields is not because information conveyed through examples is not present in patents from those fields. Rather, it is attributable to drafting differences. Mechanical, electrical, and computer patents frequently contain descriptions of embodiments and these are frequently prophetic — but by convention, drafters in these industries do not put embodiments into a specific examples section. Thus, Figure 1 should be interpreted not as indicating that examples are infrequent in some industries, but instead as indicating that this Article's methodology works better for chemical and biological patents.

Because this Article's methodology works better for chemical and biological patents, the remainder of this Article studies only these industries. All experiments and graphs below represent an analysis of only chemical and biological patents. Outside of Figure 1, the population analyzed is all U.S. chemistry and biology patents and applications available electronically from the PTO.[185]

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[185] Chemistry patents are identified as those belonging to IPC classes beginning with the code "C," and biology patents are identified as those belonging to IPC classes beginning with the codes "A61" and "A62." *International Patent Classification*, WORLD INTELLECTUAL PROP. ORG. (2019), https://www.wipo.int/classifications/ipc/en.

B. The Prevalence of Prophetic Examples

Having determined that only certain industries use prophetic examples in a format easily measured by this methodology, this Section studies the prevalence of prophetic examples present in a population comprised of all chemistry and biology patents and applications. If prophetic examples are rare, perhaps we need not be concerned about their existence even if they are theoretically problematic. However, if prophetic examples are common, the task of weighing their justifications, harms, and benefits is more urgent.

As shown in Table 1, prophetic examples are indeed prevalent. Approximately half of all chemistry and biology patents contain examples. Of the patents with examples, close to a quarter contain some prophetic examples, and about 6% contain only prophetic examples. The studied population contains over 1 million prophetic examples in total.

Table 1. Prevalence of Working and Prophetic Examples

	Patents in population	Patents in population with examples	Working examples, number (percent)	Prophetic examples, number (percent)	Patents with no prophetic examples, number[186] (percent*)	Patents with some (but not all) prophetic examples, number (percent*)	Patents with all prophetic examples, number (percent*)
Chemistry and biology patents (1976-2017)[187]	1,160,471	559,406	5,063,847 (83%)	1,049,042 (17%)	391,839 (70%)	131,871 (24%)	35,696 (6%)
Chemistry and biology applications (2001-2017)[188]	1,054,087	463,743	5,222,946 (84%)	964,321 (16%)	271,820 (59%)	177,996 (38%)	13,926 (3%)

[186] Percent of the number of patents with examples.

[187] Utility patents only; design patents and plant patents were excluded.

[188] Utility applications only; design applications and plant applications were excluded.

C. The Case Against Prophetic Examples

1. Prophetic Examples Mislead Scientists

Given that prophetic examples are prevalent and that most scientists read patents, it is reasonable to assume that many scientists encounter prophetic examples. One concern, as discussed in Part II.B.2, is that scientists may be misled by prophetic examples. Here, I test whether this is the case.

To directly assess whether prophetic examples are misleading scientists, I observed how prophetic examples were cited in the scientific literature. If a document citing to a prophetic example states, either explicitly or implicitly, that the example is hypothetical, then the citing document correctly interprets the example. If the citing document refers to the prophetic example as if the example were factual, then the citing document is incorrectly interpreting the example.

I used a random sample of 100 patents that are cited by scientific articles.[189] All patents in the sample contain only prophetic examples and no working examples. I then selected the first-listed non-patent reference citing each patent on Google Scholar and determined whether it was clear from the citing document that the cited information was prophetic, or whether the citing document cited the prophetic example as if it were factual.

Strikingly, of the 100 studied patents, ninety-nine were not cited in a manner that made it clear that the cited information was prophetic. This strongly suggests that prophetic examples are misleading to scientists. The article that cited a prophetic example correctly was written by a scientist who is himself listed as an inventor on thirty-four patents and applications, suggesting that he has more experience with the patent system than most.

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[189] Randomized by associating the patents with a randomly generated number.

Table 2. Mis-citation of Prophetic Examples (%); N=100

	Prophetic Examples	Samples to illustrate categories[190]
Cited Incorrectly	99%	"Dehydration reaction in gas phase *has been* carried out over solid acid catalysts . . . ."[191] "Useful synthetic methods for imidazole derivatives *were known* to include several intermediates such as . . . 1,2-diketones."[192]
Cited Correctly	1%	"Although the microneedles concept was proposed in the 1970s [in prophetic examples], it was not demonstrated experimentally until the 1990s . . . ."[193]

The evidence above clearly demonstrates a deep misunderstanding of prophetic examples among scientists. This problem is not restricted to the citing document. Since the citing document gets cited in turn by others, prophetic examples create a chain where few readers would be aware that the underlying data are fictional. Additionally, patents are now frequently mined by databases that automatically extract information from patents.[194] These databases are in turn accessed by

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[190] Samples are all excerpts from scientific journal articles.

[191] M. Suresh et al., *Metal Organic Framework MIL-101(Cr) for Dehydration Reactions*, 126 J. CHEMICAL SCI. 527, 527 (2014) (emphasis added).

[192] Heon-Gon Kim et al., *Synthesis of Heteroaryl Substituted Imidazole Derivatives*, 21 BULL. KOREAN CHEMICAL SOC'Y. 345, 345 (2000) (emphasis added).

[193] Mark R. Prausnitz, *Microneedles for Transdermal Drug Delivery*, 56 ADVANCED DRUG DELIVERY REVIEWS 581, 582 (2004).

[194] For example, the European Bioinformatics Institute has collected 15 million chemical structures using data-mining software that automatically extracts the structures from patents. Richard Van Noorden, *Patent Database of 15 Million Chemical Structures Goes Public*, NATURE NEWS BLOG (Dec. 11, 2013, 12:01 AM), http://blogs.nature.com/news/2013/12/patent-database-of-15-million-chemical-structures-goes-public.html [https://perma.cc/3N7X-BRKA]. Prophetic examples create a problem for databases. *See, e.g.*, Ithipol Suriyawongkul et al., *The Cinderella of Biological Data Integration: Addressing Some of the Challenges of Entity and Relationship Mining from Patent Sources*, *in* DATA INTEGRATION IN THE LIFE SCIENCES 106, 107-08 (Patrick Lambrix & Graham Kemp eds., 2010) (listing disadvantages of patents as an information source for databases and including "using 'prophetic examples' never actually carried out" as a "significant disadvantage[]" of patents as compared to journal articles). Examples of databases that mine prophetic examples include Chemical Abstracts Service (*CAS Coverage of Prophetic Substances*, CHEMICAL ABSTRACTS SERVICE (last visited Oct. 18, 2019), http://www.cas.org/content/prophetics), Elsevier's MDL Patent Chemistry

scientists who may not realize that the underlying experiment is prophetic. This is yet another way that untried experiments can infiltrate the general scientific literature.

2. Prophetic Examples Are Inaccurate

Misleading scientists is only a problem if prophetic examples are inaccurate. Although I do not directly assess the accuracy of prophetic examples, I provide several pieces of evidence showing that prophetic examples most likely *are* inaccurate and therefore harmful.

a. The Unpredictable Arts

First, prophetic examples are particularly prevalent in chemistry and biology. Patent law categorizes these fields as the "unpredictable arts," in contrast to the "predictable arts," which include the computer, electrical, and mechanical sciences.[195] The very definition of "unpredictable arts" is that these fields cannot easily be predicted from prior knowledge.[196] This suggests that prophetic examples — which are predictions — are less likely to be correct.

b. High Abandonment Rates

Second, patents with prophetic examples are more likely to be abandoned by their owners before the term of the patent has run.[197] Adding one prophetic example to a patent increases the odds of abandonment four years after patent grant by 9%.[198] Adding twenty prophetic examples to a patent increases the odds of abandonment by almost 35%.[199] Higher abandonment rates for patents with more prophetic examples are consistent with prophetic examples being less accurate than working examples. Though there are many reasons why prophetic examples might be abandoned, one possibility is that the experiment was eventually tried and was found not to work.

Database (ELSEVIER, MDL PATENT CHEMISTRY DATABASE (2005), http://www.akosgmbh.de/pdf/PCD_Brochure.pdf), and SciFinder (Jeremy R. Garritano, *Evolution of SciFinder, 2011-2013: New Features, New Content*, 32 SCI. & TECH. LIBRARIES 346, 350-51 (2013)).

195 *See* Seymore, *Heightened Enablement*, *supra* note 10, at 136-37.

196 *See* MPEP, *supra* note 6, § 2164.03 ("The 'predictability or lack thereof' in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention.").

197 *See infra* Appendix 3 (providing a regression analysis to prove that prophetic examples increase the rate of abandonment).

198 *See id.*

199 *See id.*

c. The Role of the Examiner

If patent examiners police the accuracy of prophetic examples by rejecting examples that seem utterly implausible, we might have some confidence that the remaining examples are likely to be accurate. Examiners have the power to do this. They can reject a patent claim if it describes an invention that is simply too incredible to be believable[200] and can request that the applicant submit more evidence.[201] However, there is reason to doubt that examiners make such rejections: the PTO emphasizes that these rejections are "rare."[202]

To test how often patent examiners rejected patent claims because of prophetic examples or otherwise mentioned prophetic examples, I read the prosecution histories of 100 randomly selected patents that contained only prophetic examples.[203] These patents had all been rejected for lack of enablement or utility, which is where a prophetic example would most likely be mentioned. None of the prosecution histories ever discussed prophetic examples, suggesting that examiners are generally accepting of prophetic examples and do not often request corroborating data.

This result is consistent with the high grant rate for patents with prophetic examples.[204] All evidence suggests that examiners treat prophetic examples just as they do working examples. This may increase the potential for prophetic examples to harm scientists because it suggests that there is no check on the overall accuracy of prophetic examples.

d. Use of Results

As a further test of whether prophetic examples are inaccurate, I observed whether prophetic examples consisted just of protocols or whether they also included experimental results. The more results included in the example — and the more detailed the results — the less

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200 *See* MPEP, *supra* note 6, § 2107.

201 *See id.* § 2107.02. Although this rejection is allowed in the context of the utility requirement, it has the potential to allow examiners to express skepticism of prophetic examples and request corroborating data to bolster the prophecy.

202 *Id.* § 2107.01. The PTO allows examiners to make the rejection only if the assertion is "incredible in view of contemporary knowledge" and not merely where "there may be reason to believe that the assertion is not entirely accurate." *Id.* § 2107.02. Indeed, examiners reject applications for lack of credible utility mainly when the claimed invention "violated a scientific principle, such as the second law of thermodynamics." *Id.*

203 By associating the example with a randomly generated number.

204 *See infra* Appendix 4.

likely the example is to be accurate, as it is surely easier to predict a general result as compared to a specific result. Thus, if prophetic examples include results, particularly detailed results, it is an indicator of inaccuracy.

In order to test whether prophetic examples contained results, I reviewed 1,000 prophetic examples selected randomly[205] from the population of biology and chemistry patents issued from 1976 to 2017 and classified each example as containing (1) no results[206]; (2) some results[207]; or (3) detailed results.[208]

Table 3 shows the percent of prophetic examples in each of the three categories and samples to illustrate the contents of each category. A majority of prophetic examples contain at least some results, which suggests that prophetic examples may frequently be inaccurate. Further, many readers may assume that experiments with results — particularly detailed numerical results — are real, since we do not usually write results for experiments we have not conducted. Thus, the prevalence of results in prophetic examples may be one mechanism by which they mislead scientists.[209]

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205 By associating the example with a randomly generated number.

206 These examples typically described protocols or listed ingredients without any information about the outcomes or final product.

207 These examples included general information about the results of the experiment, but did not describe specific numerical results. Often these examples simply reported that the experiment worked and produced the desired result. The examples sometimes included adjectives characterizing the results in a nebulous manner.

208 These examples included some detailed description of the results — generally numeric.

209 *See, e.g.*, ROBERT D. FIER, CHEMICAL PATENT PRACTICE 44 (1975) (recommending that prophetic results and data should be "included in patent applications only where the inventor has a very high level of confidence in their operability.").

Table 3. Prophetic Examples That Include Results (%); N=1,000

	Prophetic Examples	Samples to illustrate categories[210]
No results	42%	"A solution of [several compounds] is dissolved in DMF (50 mL). The reaction mixture is stirred under nitrogen and at room temperature for 18 h. The solvents are removed in vacuo and the crude material is triturated in ethyl acetate, filtered and washed with ethyl acetate. The crude product thus obtained is dissolved in 50 mL of 50% TFA/DCM and the reaction mixture is stirred for 3 h at room temperature under nitrogen."[211]
Some results	17%	"Mice are then treated with the test article or associated vehicle by intraperitoneal injection of 0.1 ml of the indicated solution. Mice in the first group (n=24) are treated with vehicle . . . which is injected on day 0, 2, 4, 6, and 8. . . . All of the mice are sacrificed on day 18, and lungs are collected for quantitation of tumor. . . . In both groups of mice treated with zcyto24 or zcyto25, the average number of tumor foci present on lungs is significantly reduced, compared to mice treated with vehicle."[212]
Detailed results	41%	"Styrene monomer is polymerized in the presence of the rubber under dynamic conditions for controlling the rubber particle size, after phase inversion, as the polymerization proceeds. . . . The composition and properties of Example 2 are shown in Table 1 and Table 2 below. The flexural modulus of Example 2 is increased by about 10% or more (e.g., about 15% or more) compared with Example 1. The tensile modulus of Example 2 is increased by about

[210] Samples are all excerpts from prophetic examples.

[211] U.S. Patent No. 7,321,045 ex. 7 (issued Jan. 22, 2008).

[212] U.S. Patent No. 8,313,739 ex. 31 (issued Nov. 20, 2012).

		10% or more (e.g., about 15% or more) compared with example 1. Despite having a generally high concentration of monovinyl aromatic polymer and a generally low concentration of elastomeric polymer, Example 2 has improved resistance to environmental stress cracking compared with Example 1 . . . ."[213]

* * *

As demonstrated above, prophetic examples are undoubtedly misleading — a clear harm. Further, to the extent that prophetic examples are inaccurate, they are not teaching others how to make and use the invention, which is the purpose of the enablement requirement.[214] Similarly, prophetic examples are used to satisfy the written description requirement, which asks whether the inventor was in "possession" of the invention. Inaccurate prophetic examples cannot accomplish this requirement.[215] Thus, prophetic examples run contrary to the goals of the patent system and are inconsistent with the underlying logic of patent doctrine.

D. Considering Defenses of Prophetic Examples

Yet these harms may be outweighed by potential benefits of prophetic examples. Here, I consider these benefits in order to assess whether the utility of prophetic examples outweighs the disclosure harm.

1. Special Situations

Several of the potential justifications for prophetic examples are specific to certain populations. In particular, (a) small companies may be justified in using prophetic examples when they do not have the resources to conduct necessary experiments, and (b) pharmaceutical companies may use prophetic human data when the FDA prevents trials in humans. Below, I analyze the use of prophetic examples in each of these circumstances and find that they represent only a small percent of total use. This does not mean that prophetic examples cannot be justified, but it does mean that if prophetic examples are to be justified,

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213 U.S. Patent No. 9,453,125 ex. 2 (issued Sept. 27, 2016).

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

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

we must find a socially beneficial explanation for their use outside of these special circumstances.

a. Small Entities

Proponents of prophetic examples argue that they are an equalizer between large companies, who have the resources to conduct extensive experiments, and small companies, who lack extensive resources.[216] This Subsection examines how frequently prophetic examples are used by small companies.

Figure 2(a) shows that use of prophetic examples is negatively correlated with small entity status; small entities use fewer prophetic examples. Figure 2(b) shows the total number of prophetic examples in granted patents filed by small and large entities.[217] Small entities have used a total of 92,117 prophetic examples, while large entities have used a total of 611,842 prophetic examples. Thus, small entities account for only 13% of all prophetic examples. Even if prophetic examples are justifiable on the grounds that they are necessary for small companies, that explanation cannot justify 87% of prophetic examples. Further, it is unlikely that prophetic examples are necessary for most small companies as 70% of patents filed by small entities contain no prophetic examples.

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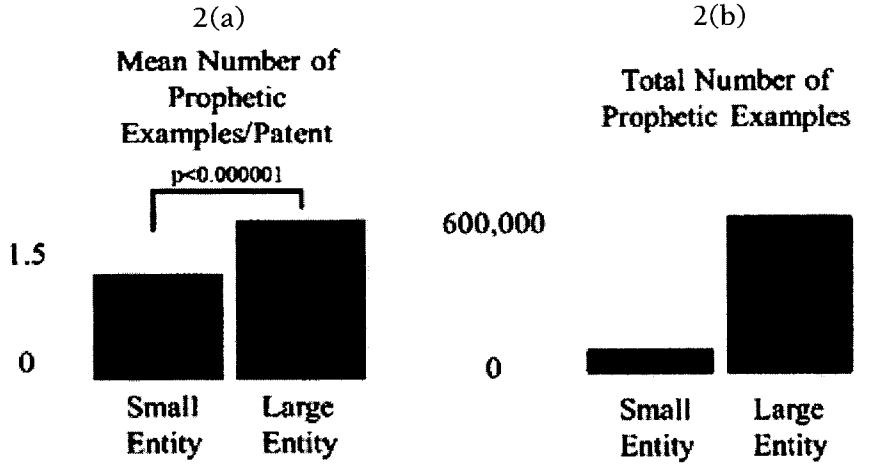
[216] *See* Aisenberg, *supra* note 24, at 30.

[217] The PTO classifies patent applications based on whether they were filed by large entities or small entities (a category that includes individuals, small business, nonprofits, and universities). *See* 37 C.F.R. § 1.27 (2015). The PTO recently introduced a new category: micro entities. Because micro entity status first became available in 2013, and therefore is not relevant to the majority of the population studied here, I classify micro entities as small entities for purposes of this study.

Figure 2. Comparing the use of prophetic examples in small and large entities (chemistry and biology patents; 1981–2016).



N=215,874 patents (small entities); 559,406 patents (large entities)

b. Human Data

Another justification for prophetic examples is that pharmaceutical companies cannot conduct real experiments because they cannot obtain data from human trials without FDA permission.[218] I reviewed 1,000 prophetic examples selected randomly[219] from the population of biology and chemistry patents issued from 1976 to 2017 to determine if the examples involved human data.

As can be seen from Table 4 below, human experiments account for only 1.9% of prophetic examples. This suggests that very few prophetic examples are used to get around the problem of filing patents before FDA approval for human studies.

Table 4. Percent of prophetic examples that describe *in vitro*, cell, animal, or human studies; N=1,000

Type of Experiment	Prophetic Examples
Human	1.9%
Animal	3.1%
Cell	3.6%
In vitro	91.4%

[218] *See supra* Part II.A.2.

[219] I did this by associating the example with a randomly generated number.

Even if human experiments are a justifiable use of prophetic examples, this specific use is rare and cannot explain the vast majority of prophetic examples.

2. Prophetic Examples and Patent Value

A further argument for prophetic examples is that they provide value to patentees and by doing so, incentivize innovation and benefit society more broadly. I study the correlation between prophetic examples and several general value indicators. As described below, I find that prophetic examples are used more in weaker patents suggesting that, to the extent prophetic examples provide any help to patentees, such help is limited. I first show the empirical data and then discuss potential mechanisms.

There is no perfect measure of patent value, but one commonly used indicator is the maintenance rate.[220] The PTO requires that patentees pay maintenance fees periodically and these fees are sufficiently substantial that many patentees do not pay them, which results in the abandonment of the patent.[221] Maintenance is a proxy for value because a patent owner who pays the maintenance fee presumably values the patent at some amount higher than the cost of the fee.

Figure 3 shows the correlation between number of examples — both prophetic and working — and payment of the required maintenance fee 11.5 years after filing.[222] For each additional prophetic example in a patent, the likelihood that the maintenance fee will be paid decreases. By contrast, the directionality of the correlation is opposite for working examples. Figure 3 does not include controls; however, the correlation remains when controlling for priority year, industry, and other factors. A regression with controls can be found in Appendix 3. Patents with more prophetic examples are less likely to pay maintenance fees, and thus may be less valuable.

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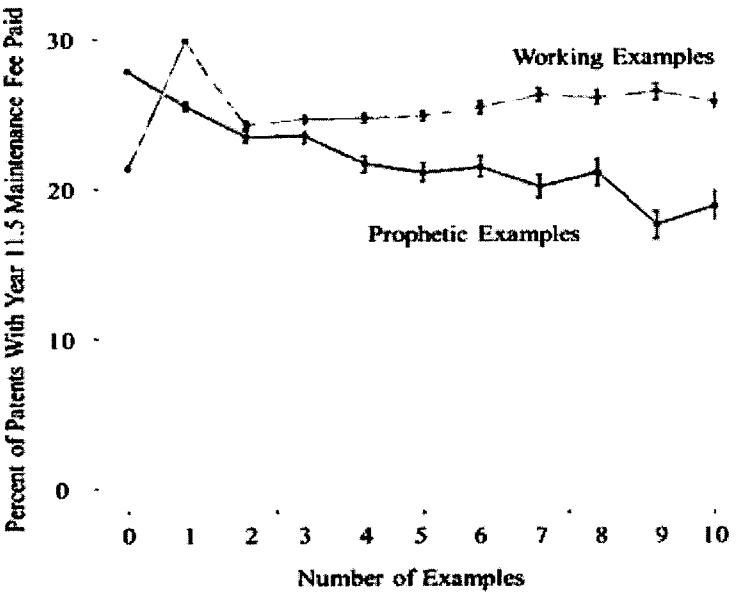
[220] *See, e.g.*, James Bessen, *The Value of U.S. Patents by Owner and Patent Characteristics*, 37 RES. POL'Y 932, 932-34 (2008); Jean O. Lanjouw et al., *How to Count Patents and Value Intellectual Property: The Uses of Patent Renewal and Application Data*, 46 J. INDUS. ECON. 405, 406-07 (1998).

[221] *See USPTO Fee Schedule*, U.S. PATENT & TRADEMARK OFFICE (Sept. 1, 2019), https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule#Patent%20Maintenance%20Fee. The fees are halved for small entities and reduced further for micro entities. *See id.*

[222] The 11.5-year fee is the last maintenance fee. *See id.* However, results for payment of other maintenance fees are similar.

Figure 3. The relationship between the number of prophetic or working examples and payment of the 11.5-year maintenance fee (for chemical and biological patents from 1981–2005. N = 305,650).



Other common proxies for patent value are number of forward citations[223] and whether a patent is litigated.[224] Appendix 3 shows correlations between these value proxies and use of prophetic examples. Both proxies are negatively correlated with use of prophetic examples meaning that, as with maintenance fees, patents with more prophetic examples appear to be less valuable.

Another proxy for value is grant rate; the likelihood that the PTO will grant a patent. Appendix 4 shows that — unlike most of the measures seen above — applications with more prophetic examples are somewhat

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[223] *See, e.g.*, Bronwyn H. Hall et al., *Market Value and Patent Citations*, 36 RAND J. ECON. 16, 16-17 (2005). If a patent covers an important technology, others will be more likely to cite it. Note that forward citations are a messy and imprecise measure of patent value. *See* C. Gay & C. Le Bas, *Uses Without Too Many Abuses of Patent Citations or the Simple Economics of Patent Citations as a Measure of Value and Flows of Knowledge*, 14 ECON. INNOVATION & NEW TECH. 333, 334 (2005).

[224] *See, e.g.*, John R. Allison et al., *Valuable Patents*, 92 GEO. L.J. 435, 439 (2004). Litigated patents are valuable enough to be worth challenging and defending in court. *See id.* at 441-42.

more likely to be granted than applications with fewer prophetic examples.[225]

A final proxy for value is the breadth of the patent claim. Broader patents — patents that cover more intellectual property — are likely more valuable. Here, I test the relationship between use of prophetic examples and a proxy for breadth: the number of words in the shortest independent claim of the patent.[226] The mechanism behind this proxy is that additional words in a claim add additional restrictions, thereby narrowing the claim (for example, the set of objects in the category "sofas" is broader than the set of objects in the category "blue sofas"). I applied this proxy to the dataset of this Article in order to determine whether use of prophetic examples correlated with increased breadth.

Figure 4 shows the correlation between the number of examples and the average number of words in independent claims. As the number of prophetic examples in a patent increases, the average number of words in the patent's independent claims also increases, meaning that the scope of the patent is *narrower*. By contrast, the number of working examples is negatively correlated with the scope proxy, meaning that as the number of working examples in a patent increases, the patent is broader. The correlation remains when controlling for priority year, industry, and other factors.[227]

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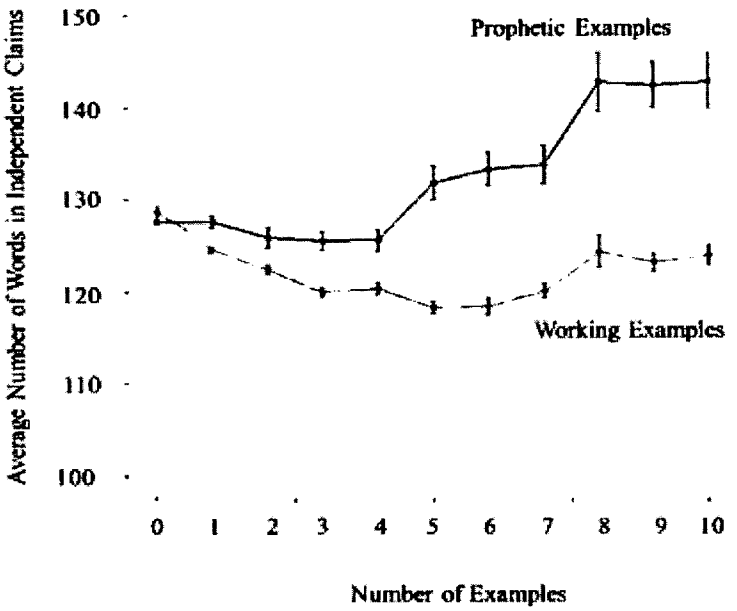
[225] This measure does not include continuations or unpublished applications. For a discussion on the challenges of measuring allowance rate, see Michael Carley et al., *What Is the Probability of Receiving a U.S. Patent?*, 17 YALE J.L. & TECH. 203, 204-05 (2015).

[226] *See* Alan C. Marco et al., *Patent Claims and Patent Scope* 7-8 (U.S. Patent & Trademark Office, Working Paper No. 2016-04, 2016), https://ssrn.com/abstract-2844964. *But see* Jeffrey M. Kuhn & Neil C. Thompson, *How to Measure and Draw Causal Inferences with Patent Scope*, 26 INT'L. J. ECON. BUS. 5, 17-18 (2019) (discussing that the trend of length to number of proxies does not hold true for biotechnology patents).

[227] *See infra* Appendix 3.

Figure 4. Correlation Between Number of Examples and Patent Breadth 1976–2016. N=559,404.



Overall, the results above demonstrate a surprisingly ambiguous — and probably negative — correlation between use of prophetic examples and patent value. This does not mean that prophetic examples *cause* patents to be weaker, merely that they are used in weaker patents. However, the prospect that prophetic examples may facilitate the process of obtaining weaker patents is particularly troubling because weaker patents hobble the patent system in numerous ways, including increasing transaction costs for other researchers[228] and chilling research in surrounding areas.[229]

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In sum, the harms of prophetic examples are clear from the empirical data: they are misleading, inaccurate, and present in low-value patents that may hinder downstream research. The benefits, conversely, while surely not entirely absent, are not apparent from the empirical analysis.

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[228] *See* Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 90 & n.59 (1994).

[229] *See* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 INNOVATION POL'Y & ECON. 119, 120 (2001).

IV. EFFECTS OF PROPHETIC EXAMPLES: IMPLICATIONS AND POLICY

In this Part, I apply the empirical findings of Part III to the costs and benefits of prophetic examples set out in Part II. Because the costs of prophetic examples are high and the benefits hard to determine, I suggest methods for reform. Throughout this Part, I emphasize that prophetic examples are no mere quirk of the patent system; rather, they carry important lessons for patent scholarship and implications for major areas of patent theory.

A. Do Prophetic Examples Harm Readers?

There is a growing literature on the disclosure function of patents — the patent system's role in creating a public repository of information that can be used to build upon patented technology and advance the progress of science.[230] However, the value of patent disclosure is vigorously debated and since empirical studies of disclosure are rare, these debates are difficult to resolve.[231] My findings provide empirical evidence of a disclosure failure, bolstering theoretical arguments for disclosure failure and countering the literature that suggest that disclosure is either useful or at least harmless.

One strand of the extensive literature on patent disclosure criticizes patents as difficult to read, insufficiently detailed, and not updated as research develops.[232] Recent policy proposals have recommended either improving or updating patent disclosures or encouraging the development of ancillary information sources.[233] However, a second strand of literature counters these proposals, arguing that disclosure is

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230 *E.g.*, Benjamin N. Roin, Note, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007, 2007 (2005).

231 *See* Heidi L. Williams, *How Do Patents Affect Research Investments?*, 9 ANN. REV. ECON. 441, 448 (2017) (finding only three empirical studies on disclosure); Bhaven N. Sampat, *A Survey of Empirical Evidence on Patents and Innovation* 13 (Nat'l Bureau of Econ. Research, Working Paper No. 25383, 2018) ("There is less empirical work on the impact of patent disclosure on innovation than on the impact of patents on innovation incentives, and most of the relevant work is survey research.").

232 *See, e.g.*, W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1043-48 (2016) ("[T]he majority view is that disclosure is often inadequate."); Seymore, *Teaching Function of Patents*, *supra* note 10, at 625-27 (2010) ("[F]or a variety of reasons, the patent literature is often overlooked or ignored.").

233 *See, e.g.*, Colleen V. Chien, *Contextualizing Patent Disclosure*, 69 VAND. L. REV. 1849, 1869-70 (2016); Jeanne C. Fromer, *Dynamic Patent Disclosure*, 69 VAND. L. REV. 1715, 1722 (2016); Jason Rantanen, *Peripheral Disclosure*, 74 U. PITT. L. REV. 1, 6-8 (2012).

good enough,[234] should not be a priority for the system,[235] or that focus on the disclosure requirements detracts from incentives for patentees to create physical embodiments of their inventions.[236]

My data on prophetic examples strengthen broader criticisms of disclosure and lend urgency to calls for reform. Prophetic examples confuse scientists and spread misinformation. By doing so, prophetic examples function in a way that is antithetical to the disclosure function of patents. Prophetic experiments are a clear example of how patent disclosure is not only not good enough, but is also actively problematic.

My findings are also consistent with a second line of disclosure scholarship. This literature focuses specifically on the criticism that conventions in patents are so different from writing conventions outside of patents that non-patent lawyers cannot understand patents.[237] Furthermore, the conventions around prophetic examples are a world away from those dictating how scientific experiments are normally written and this discrepancy is likely responsible for scientists' confusion surrounding prophetic examples. Below, I outline some of these differences and how they create confusion.

First, as they relate to prophetic examples, the rules of scientific writing are entirely opposite to the rules of patent writing. One scientist familiar with prophetic examples notes that writing a prophetic example in a scientific article would be "outright fraud"[238] while another explains that a scientific paper "should not, in fact, have any prophetic component to it whatsoever. It better not. Unless its fraud."[239]

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234 *See* Rantanen, *supra* note 233, at 16 n.6.

235 *See* Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. & TECH. 401, 402-04 (2010).

236 *E.g.*, Christopher A. Cotropia, *Physicalism and Patent Theory*, 69 VAND. L. REV. 1543, 1565 (2016); Duffy, *Reviving*, *supra* note 79, at 1361-62 (arguing that the rise of "documentary disclosure theory" was used to justify the diminishment of doctrines preferencing actual reduction to practice).

237 *See* Osenga, *supra* note 10, at 158-60.

238 ROBERT M. RYDZEWSKI, REAL WORLD DRUG DISCOVERY: A CHEMIST'S GUIDE TO BIOTECH AND PHARMACEUTICAL RESEARCH 128 (2008).

239 Expert Testimony of Samuel Danishefsky, M.D. at 203, Wyeth v. Abbott Labs., No. 08-230-JAP-TJB (D.N.J. Dec. 30, 2009), 2009 WL 8478818; *see also* Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1402 (Fed. Cir. 2003) (Newman, J., dissenting) ("[Prophetic] examples have long been accepted in patent documents, unlike their prohibition in scientific articles."); Coal. for Affordable Drugs X LLC v. Anacor Pharm., No. IPR2015-01776, at 20 (P.T.A.B. February 23, 2017) (explaining that a prior art reference containing prophetic examples "is a patent application that does not need to meet the standard of a peer-reviewed academic article"). In another case, an expert testified, "Expert: First of all, standards for reviewing manuscripts, and this is from my own work in both publishing scientific manuscripts and patent

Another scientist reacted colorfully to learning about prophetic examples, "[w]hat I call a fake experimental procedure is actually a *prophetic example*. What I call bullshit is *a modus operandi*."[240] The way that experiments are written is not only different in scientific articles as compared to patents; the practice of writing prophetic examples is actively offensive to many scientists.

If it is important to have a patent system that provides information to scientists, it is vital that scientists properly understand the information so conveyed. To the extent that prophetic examples confuse readers, they are not compatible with the disclosure goal of the patent system. Furthermore, to the extent that disclosure is a fundamental objective of the patent system, prophetic examples fail to accomplish this goal and should be reformed.

B. Do Prophetic Examples Help Patentees?

The core argument for prophetic examples is that they are valuable to patentees and that value to patentees translates into societal value.[241] However, it is far from clear that prophetic examples actually help patentees, nor that any value gains transfer to society more broadly. Most notably, the number of prophetic examples in a patent correlates negatively with most proxies for patent value: maintenance, forward citations, and litigation rates.[242] Similarly, although patenting guides recommend the use of prophetic examples to obtain a broader patent, using prophetic examples is negatively correlated with patent breadth.[243]

Nevertheless, there are a few indications that prophetic examples add value. First, patentees must believe that prophetic examples are useful

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applications, are very different. In my experience to publish in a peer reviewed journal . . . it is crucial to have definitive evidence for a new chemical entity . . . . I also understand that in patent applications the standards are different. There is an opportunity in patent applications, and I have done this with my own, to make prophetic statements. There is, as far as I am aware, no standard, no similar requirement to have to show everything that you describe as a prophetic example. Whereas, in scientific publications the idea of prophetic examples is discouraged, and in fact under most circumstances is not done. In order to get a peer reviewed article published one must have appropriate, adequate, rigorous experimental detail." Deposition of David H. Sherman, Ph.D. at 166, Enzo Biochem., Inc. v. Applera Corp., 3-04-CV-929 (JPA) (No. 236-10), 2007 WL 6475274.

240 *Patentz*, ORG PREP DAILY (June 29, 2007, 11:16 AM), https://orgprepdaily.wordpress.com/2007/06/29/patentz/, [https://perma.cc/ZVU9-W96T].

241 *See supra* Part II.A.

242 *See supra* Part III.D.2.

243 *See supra* Part III.D.2.

and increase patent value in some way; otherwise they would not use prophetic examples. This suggests that prophetic examples are valuable to patentees on an individual level, even if they do not correlate with value on a population level. Second, applications with more prophetic examples are more likely to be granted by the PTO, suggesting that prophetic examples may add value during prosecution.[244]

I begin by suggesting mechanisms driving the negative correlation between use of prophetic examples and patent value. I then argue that that this lack of value translates into broader harm to society.

1. Proposed Mechanisms

A possible mechanism to explain the results is that prophetic examples are useful mainly in low-value patents. Under this mechanism, adding a prophetic example to a patent would increase the value of that patent as compared to the value of the same patent without the prophetic example. However, patentees would only choose to add prophetic examples in situations where they were necessary, such as instances where the patentee had no working examples or where the patentee was in a hurry to file the application. These situations might be those where the patent is inherently weaker.

There are many explanations for why patentees with no or little real data might have weaker patents. A patentee might be filing a patent on a mere guess and that guess may turn out to be wrong, rendering the patent less valuable. A company might file patents with prophetic examples in areas that are not top priorities for the company and to which the company does not want to dedicate research money. Since the area was not a priority, the company may then choose not to pursue research in that direction and abandon the patent. A patentee may file a patent on a technology that she does not have funding to develop. She may then never obtain the funding and abandon the patent.

Note that the patent's weakness in these scenarios is not caused by the prophetic examples themselves; rather, situations in which prophetic examples are needed might be situations in which patents are weak.

If prophetic examples are used mainly in weaker patents, why are they positively correlated with patent application grant rates? This may be explained by the difference in the meaning of value at the examination stage and value after this stage. Since examiners appear to treat prophetic examples as equal to working examples, prophetic examples may be very valuable indeed during examination. As theorized, they

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[244] *See supra* Part III.D.2.

may help applicants obtain patents when the applicant cannot conduct real experiments.

However, the real world may not view prophetic examples as kindly as examiners. Take, for instance, a patentee who recently obtained a patent by the grace of prophetic examples. He seeks to partner with an established company to commercialize a product. The prospective partner will ask him for evidence that his invention works. He can produce only prophetic examples — which are unlikely to convince investors. Alternatively, a similar patentee may, after obtaining a patent, seek to build her product. She may discover that her prophesies are wrong and that her product does not work. The prophecies were enough for her to get a patent, but not enough to provide value past that stage.

2. Implications

a. Prophetic Examples May Encourage Weaker Patents

If prophetic examples add value to individual patents, but are generally used to enable weaker patents, they may be a net loss for society. The patent literature is replete with criticisms of weak patents.[245] Weak patents are a waste of money for both the applicant and the PTO. They increase transaction costs for other researchers.[246] Weak patents chill research in surrounding areas.[247]

If prophetic examples lead to patents that are weak and abandoned at higher rates, the patent itself may not be forcing others out of the area. However, even narrow and unenforceable patents can impede downstream research. This is both because downstream researchers may not know that the patent is narrow or unenforceable[248] and because once an invention has been disclosed in one patent, it becomes difficult

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[245] *See, e.g.*, John R. Allison, Mark A. Lemley & Joshua Walker, *Patent Quality and Settlement Among Repeat Patent Litigants*, 99 GEO. L.J. 677, 678-81 (2011); James Bessen & Michael J. Meurer, *Lessons for Patent Policy from Empirical Research on Patent Litigation*, 9 LEWIS & CLARK L. REV. 1, 16 (2005); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998); Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 1993 (2007). *But see* Mark A. Lemley, *What Ifs and Other Alternative Intellectual Property and Cyberlaw Story: Ignoring Patents*, 2008 MICH. ST. L. REV. 19, 21 (2008) (arguing that weak patents are often simply ignored).

[246] *See* Merges, *supra* note 228, at 106.

[247] *See* Shapiro, *supra* note 229, at 124.

[248] It is difficult to know if a patent is valid, so even patents that are likely invalid can have chilling effects. *See, e.g.*, Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1500-01 (2001).

for a later inventor to obtain a patent on a related invention.[249] Awarding patents based on prophetic examples may prevent the use of exclusivity incentives for inventors who actually conduct the experiments.

b. Rationales for Early Filing Do Not Fit with Prophetic Examples

There is a large body of literature on when patents should be filed and whether early filing is socially beneficial.[250] Prophetic examples have implications for this debate. Although proponents of early filing should favor prophetic examples, I argue that the use of prophetic examples as reported in this Article does not fit well with the benefits of early filing. The situations in which prophetic examples are most often used may also be those where early filing is the most problematic.

For instance, early disclosure is used to justify early filing.[251] But consider what exactly is disclosed in prophetic examples: fiction. Early disclosure of fictional data is presumably less beneficial than early disclosure of factual data. If prophetic examples were not permitted, patent applicants would file as early as possible after obtaining factual data, which would provide the earliest possible disclosure of that factual data.

Moreover, prophetic examples describe the technical inner workings of the invention, rather than a broad concept.[252] It may be beneficial for the public to obtain disclosure of a bright new idea earlier in order for others to begin working on whatever secondary innovation the idea sparks. However, the utility of speculative disclosure of the inner workings of exactly how to make that idea functional — i.e., synthesis

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[249] *See supra* Part II.B.1.

[250] *See, e.g.*, Cotropia, *supra* note 141, at 68; Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 258 (1994); George E. Frost, *The 1967 Patent Law Debate — First-to-Invent vs. First-to-File*, 1967 DUKE L.J. 923, 923 (1967); Gugliuzza, *supra* note 59, at 1225; Peter A. Jackman, *Adoption of a First-to-File Patent System: A Proposal*, 26 U. BALT. L. REV. 67, 87 (1997); Kitch, *supra* note 142, at 265; Douglas Lichtman et al., *Strategic Disclosure in the Patent System*, 53 VAND. L. REV. 2175, 2193 (2000); Brad Pedersen & Vadim Braginsky, *The Rush to a First-to-File Patent System in the United States: Is a Globally Standardized Patent Reward System Really Beneficial to Patent Quality and Administrative Efficiency?*, 7 MINN. J.L. SCI. & TECH. 757, 758-62 (2006); Andrew L. Sharp, Comment, *Misguided Patent Reform: The Questionable Constitutionality of First-to-File*, 84 U. COLO. L. REV. 1227, 1252 (2013).

[251] *See In re* Hogan, 559 F.2d 595, 606 (C.C.P.A. 1977) (discussing the importance of encouraging early disclosure of invention); Lichtman et al., *supra* note 250, at 2182 ("[E]arly filing ensures that . . . the public begins to learn from the inventor's accomplishments as soon as possible. . . .").

[252] *See* Bratislav Stankovi, *The Use of Examples in Patent Applications*, 18 INTELL. PROP. & TECH. L.J. 9, 10-13 (2006).

methods, precise doses, formulations, or dosage forms — is more dubious. First, it seems less likely to spark follow-on innovation. While the idea that compound X might be an antibiotic may lead to exciting new discoveries of related compounds with similar effects or allow a researcher to discover alternative uses for compound X, these types of secondary innovations seem less likely to result from a prophetic example stating that, for example, compound X should be administered orally in doses of 2.5 mg. Second, the speculative disclosure of the inner workings of an invention is less likely to be accurate than speculative disclosure of a broad concept. This is simply because in order for the protocol to make or use the invention to be correct, the broad concept itself also has to be correct. Moreover, a broad concept may still have useful elements even if it is wrong. For example, Jules Verne could not make a submarine,[253] but he could inspire others to pursue it. It seems less likely that a prophetic example describing, for example, a protocol for manufacturing pressure-resistant screws holding the walls of the submarine together, could be wrong and yet so widely inspiring.

Prospect theory is also used to justify early filing,[254] and again, prophetic examples do not entirely fit with this justification. An adherent of prospect theory wants the patent to be granted early, but to someone equipped to develop the prospect.[255] Prophetic examples allow patentees who have not done any experiments with a particular technology to obtain a patent over someone who has done experiments because the prophetic patentee will be able to file first. However, a patentee who has done some experimentation may be in a far better position to develop his prospect. Further, the higher abandonment rate associated with patents with more prophetic examples suggests that many users of prophetic examples are not developing their prospects.

The practical reasons for early filing — that patents are needed to obtain funding or to protect a company who must disclose the invention in order to contract with manufacturers and the like — may be valid even for prophetic examples. However, surely we can craft doctrine that addresses these practical concerns in a more targeted way that creates fewer problems.

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253 *See generally* JULES VERNE, TWENTY THOUSAND LEAGUES UNDER THE SEA (Chicago and New York, Butler Brothers 1887).

254 *See* Kitch, *supra* note 142, at 269-71.

255 *See id.*

c. Why Aren't All Examples Prophetic?

In the context of constructive reduction to practice, scholars have expressed concerns that making patents available to inventors who have not produced physical work reduces the incentive to actually create and test the patented material.[256] The same argument applies to prophetic examples: if prophetic examples are available, is there any incentive to conduct real experiments?

Apparently there is. Only 17% of examples in patents are prophetic. Given the clear advantages of prophetic examples,[257] it is surprising that more patentees do not use them. The data on prophetic examples suggest that there may actually be significant incentives to physically reduce an invention to practice. This is surprising both in the context of prophetic examples and in the larger literature on the doctrine of constructive reduction to practice, and may temper criticisms of the latter.[258]

Below, I outline motivations to explain why patentees might prefer working examples to prophetic examples and why inventors might be better off making the invention before filing a patent.

Scientific Convention: In scientific disciplines, it is conventional to wait until experiments have been run before publishing the results. Scientific conventions often carry over to some extent into patents.[259] Scientists

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256 *See, e.g.*, 2 PATENT LAW, LEGAL AND ECONOMIC PRINCIPLES § 13:31 (2d ed. 2015) ("[B]ecause writing patent applications is often less expensive and time-consuming than doing actual research, the law creates an incentive to file patent applications describing inventions before actual research involving them has been completed, and perhaps even begun. This constructive reduction to practice concept creates incentives to seek patents on purely theoretical designs and even guesses, rather than empirically tested, proven designs."); Lemley, *Ready for Patenting*, *supra* note 10, at 1178-79 (explaining that "[A]n inventor is better off filing a patent application as early as possible, before — or perhaps instead of — building a prototype or testing the invention.").

257 *See supra* Part II.A.

258 The doctrine is controversial and much debated. *See, e.g.*, Cotropia, *supra* note 141, at 120 (recommending requiring actual reduction to practice); Jeanne C. Fromer, *The Layers of Obviousness in Patent Law*, 22 HARV. J.L. & TECH. 75, 101 (2008) (arguing that the doctrine should be questioned); Ouellette, *Who Reads Patents?*, *supra* note 10, at 423 (calling the doctrine problematic); Seymore, *Heightened Enablement*, *supra* note 10, at 131 (listing constructive reduction to practice among the problems of the current enablement doctrine).

259 *See, e.g.*, FED. TRADE COMM'N, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION 84 (March 2011), https://www.ftc.gov/sites/default/files/documents/reports/evolving-ip-marketplace-aligning-patent-notice-and-

control the timing of patent filing by deciding when to contact a lawyer to begin the patenting process. It may be that, because of the strong presumption in science that one does experiments before reporting results, scientists do not think to begin the process of filing a patent before obtaining actual data.

Possibility of Error: While incorrect prophetic examples may not harm a patent application, a patent application filed on a concept that turns out not to work may be a waste of time and money. Because filing a patent application can be expensive, inventors might prefer to conduct experiments to determine if the invention is operative before sinking money into a patent. Patents based on working examples should be more valuable than those based on prophetic examples because they describe tested inventions, not guesses.[260]

Slight Enablement Advantage to Working Examples: The test for enablement is whether such a skilled artisan "could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."[261] The meaning of the phrase "undue experimentation" has been subject to much debate, but the authoritative method for determining whether experimentation is "undue" is the application of the *Wands* factors.[262] Among the eight *Wands* factors is "the presence or absence of working examples."[263] The *Wands* factors do not mention prophetic examples. Although it is clear that prophetic examples can be used to enable a claim, their omission in the *Wands* factors may lead patent drafters to prefer, all else being equal, working examples.

Use as Evidence by Opponents: Prophetic examples may paint a landscape of idealized methods for preparing a product and manners of using a product. Being prophetic, these methods and manners are not actually completed nor are they always feasible. However, if the patent results in a product and someone is injured by the product, the injured party may try to use the prophetic example as evidence in a products

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remedies-competition-report-federal-trade/110307patentreport.pdf. *See also* Janet Freilich & Jay P. Kesan, *Towards Patent Standardization*, 30 HARV. J.L. & TECH. 233, 242 (2017).

260 *See* Russ Krajec, *The First Patent: A Roadmap for a Startup's Patent Portfolio*, IP WATCHDOG (Apr. 26, 2016), http://www.ipwatchdog.com/2016/04/26/first-patent-roadmap-startups/id=68585/.

261 United States v. Telectronics, Inc., 857 F.2d 778, 785 (Fed. Cir. 1988).

262 *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

263 *Id.*

liability suit.[264] Plaintiff-oriented products liability litigation guides recommend searching patents for proposed safety features, including prophetic examples, as evidence of what the defendant knew could be done.[265]

Cost in Attorney Time: It may be cheaper to write a prophetic example than to conduct some experiments, but it is not free. A major cost of filing a patent is the drafting attorney's time and each prophetic example adds to that time. Thus, clients may be choosing to omit prophetic examples that are not absolutely essential.

Changes in Patentees and Patenting Practices: The PTO first recognized prophetic examples in 1981. This was a period of change for patent law, with the passage of the Bayh-Dole Act in 1980[266] and the creation of the Federal Circuit in 1982.[267] The Bayh-Dole Act encouraged universities to file patents, and "turned universities into major players" in the patent system.[268] Since Bayh-Dole, the number of patents filed by universities has increased considerably. The PTO reports that only 594 patents were filed by U.S. academic institutions in 1985, while 4,797 were filed in 2012.[269] Universities are less likely to use prophetic examples — university-filed patents have a mean of 1.5 prophetic examples per patent compared to 1.9 for non-university patents.[270] This may be

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[264] *See, e.g.*, Condos v. Musculoskeletal Transplant Found., 208 F. Supp. 2d 1226, 1228 (C.D. Utah 2002). In *Condos*, the plaintiff argued that the defendant negligently failed to use cleaning methods described in two patents owned by the defendant, both of which contain only prophetic examples. *Id.* The defendant explained that it is "currently attempting to implement those methods but has been unable to do so successfully." *Id.*

[265] *E.g.*, Russ M. Herman, *Sufficiency of Warnings and Labeling: When Can the Manufacturer or Others be Held Liable?, in* 2 ATLA ANNUAL CONVENTION REFERENCE MATERIALS (2000) ("[A] patent search is warranted prior to filing [a products liability] suit.").

[266] Bayh-Dole Act of 1980, H.R. 6933, 96th Cong. (1980) (codified as amended at 35 U.S.C. §§ 200-211).

[267] *See* Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 1 (1989).

[268] Arti K. Rai & Rebecca S. Eisenberg, *The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 290 (2003).

[269] *See U.S. Colleges and Universities — Utility Patent Grants 1969-2012, General Description of the Report*, U.S. PATENT & TRADEMARK OFFICE, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/univ/doc/doc_info_2012.htm (last visited Nov. 17, 2019) [https://perma.cc/256T-XBA8].

[270] University patents were identified by looking for "university" or "college" in the name of the first assignee.

because university inventors must also publish papers in scientific journals, which requires real results.

Another possibility to explain the decrease in the number of prophetic examples over time is the corresponding increase in claim fees during this period. The PTO has repeatedly increased the fees it charges for patents that include more than twenty claims.[271] Increased claim fees reduce the number of claims filed by patent applicants.[272] It may be that patentees cut out claims that covered more speculative material that was not core to their invention. These claims might be those typically enabled by prophetic examples and thus the need for prophetic examples may have decreased.

C. Reforming Prophetic Examples: From Prophecies to Hypotheses

Prophetic examples are a problem. While prophetic examples and the consequences thereof might be helpful in some instances, and perhaps desirable if used in moderation, the traditional justifications become less tenable as the proportion of patents partially or completely relying on prophetic examples grows.

I advocate for a shift away from prophecies in patents and towards hypotheses. When we think of the word prophecy in the colloquial sense, we think of accurate foreseeing; of words that should be taken as truth; of events that will inevitably occur.[273] That does not describe prophetic examples. They are conjectures about the future — hopefully educated, science-based conjectures — but conjectures nonetheless. What we currently call prophetic examples are not prophecies, they are hypotheses.

The move from prophecies to hypotheses has several overarching implications for our thinking on this topic. In a general sense, it is important to accept that prophetic examples are not infallible — a possibility that is not properly recognized by the present nomenclature or doctrine. We must treat them as predictions, not as conclusions. We should acknowledge prophetic examples as a roadmap for future work, but perhaps not as proof of past invention.

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[271] *See* Eugenio Archontopoulos et al., *When Small is Beautiful: Measuring the Evolution and Consequences of the Voluminosity of Patent Applications at the EPO*, 19 INFO. ECON. & POL'Y 103, 104 (2007).

[272] *See id.* at 111.

[273] The Merriam-Webster dictionary defines "prophecy" as (1) "an inspired utterance of a prophet"; (2) "the inspired declaration of divine will and purpose"; and (3) "a prediction of something to come." *Prophecy*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/prophecy?src=search-dict-hed (last visited Sept. 13, 2019).

Several specific policy prescriptions also follow from the shift from prophecies to hypotheses:

Reverse the Presumption of Enablement and Written Description: At present, prophetic examples are presumptively enabled and adequately described, meaning that we presume that they are accurate.[274] This is a formal presumption after the patent is granted: a challenger alleging that the patent was invalid would have to prove that the prophetic example was not enabled or properly described.[275] Before patent grant, it is an informal presumption since in practice examiners do not challenge the accuracy of prophetic examples.[276] This presumption reflects our treatment of prophetic examples as prophecies — as inspired predictions — rather than as hypotheses. There is simply no reason to assume that all prophetic examples are accurate.

It would be better to treat prophetic examples as hypotheses. They should be presumptively non-enabled, meaning that the burden would be on the patentee to prove that the prophetic example was enabled. Patents should include evidence for why a prophetic example would work — i.e., the reasoning and calculations behind the prediction. Patent examiners should determine how much credit to give prophetic examples based on that reasoning. There could also be benefits after patent grant. If prophetic examples were presumptively non-enabled, it might reduce the chilling effect and encourage others to conduct experiments in these areas.

Give Patentees a Grace Period to Update Prophetic Examples: A hypothesis is a prediction that one might someday try to verify. Right now, patentees cannot easily update a prophetic example if they later conduct the experiment.[277] This current regime reflects the view that such examples are prophecies, not hypotheses. Prophecies happen; they do not need updating. Hypotheses, by contrast, are intended to be updated and refined with experimentation. Patents are often filed as the

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[274] Or at least good enough that a person of ordinary skill in the art could make and use the patented invention without undue experimentation, which is the test for enablement. *See In re* Wands, 858 F.2d 731, 737 (1988).

[275] *See* 35 U.S.C § 282 (2019) ("A patent shall be presumed valid.").

[276] *See supra* Part III.C.2.c.

[277] Examples in patents cannot be changed (other than for clerical errors) after the patent has been granted. *See* 35 U.S.C. § 255 (2019). It is also difficult to update examples during examination and adding updated data would likely require the applicant to file a new application based on the original application and therefore lose the original filing date. Such an application is called a continuation-in-part. MPEP, *supra* note 6, § 201.08 (9th ed. 2017).

beginning of a long-term research agenda and we should explicitly acknowledge that by creating a mechanism to encourage updating hypothetical examples with real data.

A key advantage of this policy suggestion is that it would retain some of the benefits for patent applicants in situations where prophetic examples are necessary. Take, for instance, a start-up who cannot raise enough money to conduct an experiment without venture capital funding, but cannot obtain venture capital funding without filing a patent. The start-up could file a patent with a prophetic example, seek funding, and then update the example several years later.

If updates are required, it may be useful to charge a fee for prophetic examples that turn out to be completely wrong. This would disincentivize wild prophecies in fields where research is unpredictable or the inventor has little basis for the prediction, arguably the worst type of prophetic example. Such a system should have a materiality requirement in order to avoid charges for prophetic examples that were wrong in an immaterial or insignificant way.

Even if requiring or encouraging updating is not desirable, patentees and applicants should at least have the opportunity to update if they so choose. Once patentees update their prophetic examples, the examples should be presumptively enabled just like any other working example. However, this should be coupled with a prior user defense to infringement lasting from the expiration of the grace period to publication of the updated results in order to avoid "submarine examples."[278]

Although allowing updating of examples would be a major change for the U.S. patent system, other countries allow inventors to update their applications under certain circumstances, suggesting that such a proposal might be workable.[279]

Phrase examples as hypotheses, not results: There is nothing inherently wrong with including forward-looking statements in patents. Indeed, it is probably useful for patentees to disclose potential uses for their product, possible alternative methods of making the product, or

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[278] I use this term by analogy to "submarine patents" where patentees "delay the issuance of their patent precisely in order to surprise a mature industry." Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 65 (2004).

[279] For example, Australia allows inventors to add working examples to the specification as long as these examples do not encompass matter that was "not 'in substance disclosed' in the specification as filed." Shann Kerner et al., *Examples Requirements for Patentability of Inventions in U.S. and Foreign Jurisdictions*, BLOOMBERG L. REP., Sept. 4, 2009, at 4.

potential changes that could be made to the protocol to get better results. But, if these uses and methods have not been tried, it is important to phrase them as hypotheses, not results. That means that they should (1) be clearly labeled as hypotheses; (2) be written in the future tense using language that clearly indicates the predicted nature of the experiments; and (3) provide some basis for the hypothesis in the form of an explanation of what current knowledge and/or calculations leads the inventor to believe that the hypothesis will work as specified.

These changes would help scientists understand when they are reading a hypothesis as opposed to real results and would hopefully eliminate much of the confusion documented in this Article. Some of these changes would be relatively simple for the PTO to implement □ in particular a future tense requirement and a labeling requirement. The PTO already requires a tense shift for prophetic examples, so it would just be a matter of updating the requirements. The PTO also currently requires patent applicants to include certain section headings and to format some parts of the patent in standardized ways.[280] The PTO could add a requirement that, for applications that include prophetic examples, the examples should all be grouped under a heading such as "Hypothetical Examples," and perhaps also include a disclaimer such as: "The examples below describe experiments that have not actually been conducted but that the patent applicant predicts will be functional." It may be also desirable to mandate a separate heading for non-prophetic examples, perhaps "Working Examples," and an explanation indicating that these experiments have actually been conducted.

The proposals to clearly label prophetic examples and to write them in the future tense are the most feasible of the changes contemplated by this Article. It is relatively simple and easy to implement and the costs associated with compliance are minimal. Attorneys are already mindful of what information in patents is prophetic, as they must consciously switch to writing in the present or future tense. Simply adding a standardized title and disclaimer should not require significant attorney or inventor effort. Thus, these changes would have little effect on patentees.

Providing a basis for each hypothesis would be an added burden on patent applicants. However, it seems like a fair trade for allowing the applicant to include prophetic examples. Moreover, the burden is unlikely to be extreme, since presumably the patent applicant has some mental conception of why the prophetic example would work. Thus, it

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[280] *See* MPEP, *supra* note 6, § 608.01(a) (9th ed. 2015).

would just be a matter of putting it down on paper (and if the applicant does not have any understanding of why their hypothesis would work, there is probably no social benefit to allowing it to be included in the patent application). Further, this would reward applicants who make good, reliable predictions since the detailed basis for the prediction can be given more weight in the enablement and written description analyses.

Why Not Ban Prophetic Examples? Given all the problems with prophetic examples, why not just ban them? A blanket ban on prophetic examples might be too harmful to patentees and too drastic a change to the patent system — at least right now. Prophetic examples are deeply ingrained in the patent system and form an integral part of many patents. So many patentees use prophetic examples that banning them would be a major shock to the system and potentially drastically change the way patents are written and the value of patents. Moreover, to be intellectually coherent, any ban on prophetic examples would need to be accompanied by an in-depth evaluation of the role of constructive reduction to practice in the patent system and how scope correlates with the disclosed invention.[281]

Further, there are patentees who rely on prophetic examples for justifiable reasons — such as the inability to conduct a real experiment — and prophetic examples should not be removed without providing another mechanism to accommodate these patentees. There are also patentees who use prophetic examples for hypotheses of the type where we have the scientific capacity to make accurate predictions, and thus that are quite likely to be correct. These may be beneficial. Instead of banning prophetic examples entirely, it is better to require patent applicants to provide an explanation for why their hypothesis is likely to be correct and allow examiners to weigh that explanation in assessing whether the enablement and written description requirements are met. This effectively renders wild guesses valueless but still gives credit to predictions based on sound underlying principles.

I recognize that these policy suggestions would not completely remedy all ills associated with prophetic examples. Prophetic examples should be studied further — particularly in conjunction with the larger question of constructive reduction to research more generally — in order to determine if greater reform is necessary.

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[281] Doctrines of constructive reduction to practice are currently criticized as "tentative and unsystematic." Dmitry Karshtedt, *The Completeness Requirement in Patent Law*, 56 B.C. L. REV. 949, 991-92 (2015).

CONCLUSION

Through the first theoretical and empirical analysis of prophetic examples, this Article finds that at least 17% of experiments in patents from the studied industries — chemistry and biology — include made-up data. The practice arose out of early twentieth-century notions of fairness across industries as well as out of administrative necessity and has never been seriously questioned by scholars. In an era where patent scholars, the FDA, and scientists more broadly are grappling with an irreproducibility "crisis,"[282] it is time for such questioning. This Article presents evidence that damages the traditional foundations for the practice of including prophecy in patents — specifically the justification that prophetic examples help patentees. It further finds that patent readers, particularly scientists, are enormously confused about prophetic examples and that such examples lead to a plague of mis-citations and the infiltration of made up data into reputable scientific publications. Moreover, prophetic examples undermine key patent doctrines and may chill downstream research, hampering innovation. These harms, combined with the ubiquity of made-up data in chemistry and biology patents, means that we should consider measures against prophetic examples.

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[282] *See* Jacob S. Sherkow, *Patent Law's Reproducibility Paradox*, 66 DUKE L.J. 845, 846 (2017); *see also* Monya Baker, *1,500 Scientists Lift the Lid on Reproducibility*, NATURE (July 28, 2016), https://www.nature.com/news/1-500-scientists-lift-the-lid-on-reproducibility-1.19970.

APPENDIX 1. SUMMARY STATISTICS — CHEMISTRY & BIOLOGY GRANTED PATENTS

Patents are divided into ten groups based on the number of prophetic examples in the patents.

Group (Patents)	0	1	2	3	4	5	6	7	8	9
Number of prophetic examples	0	1	2	3	4	5	6-8	9-11	12-17	18-754
Number of patents	391,839	53,216	25,520	17,709	12,651	9,679	13,326	11,881	10,829	12,756
Mean priority year	1995	1994	1993	1992	1991	1991	1990	1990	1988	1988
Mean number of non-prophetic (working) examples	9	9	8	9	8	7	7	8	8	15
% of patents that are continuations	16	19	20	18	17	16	15	15	13	14
% of patents that have foreign priority	40	30	31	35	37	38	40	43	43	39
Mean length of specification (number of words)	10,168	11,123	11,376	11,118	10,874	10,868	11,560	12,620	14,535	23,551
Mean number of backwards citations	17	20	21	19	19	18	20	19	16	19
% of patents filed by small entities	17	21	21	20	18	17	15	14	12	9
% of patents paying year 4 maintenance fee	82	82	81	80	80	80	81	79	79	77
% of patents that have been litigated	0.6	0.8	0.8	0.7	0.7	0.5	0.7	0.4	0.6	0.5
Mean average number of words in independent claims	128	128	126	126	126	132	136	142	152	184
Mean number of claims	14	15	15	15	15	15	15	15	15	16

APPENDIX 2. SUMMARY STATISTICS — CHEMISTRY & BIOLOGY PATENT APPLICATIONS

Applications are divided into ten groups based on the number of prophetic examples in the applications.

Group (Patents)	0	1	2	3	4	5	6	7	8	9
Number of prophetic examples	0	1	2	3	4	5	6	7-10	11-15	16-754
Number of applications	271,820	68,250	33,577	20,893	14,585	10,292	7,939	13,965	10,115	12,307
Mean priority year	2007	2008	2007	2007	2007	2007	2007	2007	2007	2007
Mean number of non-prophetic (working) examples	10	10	11	13	13	13	13	14	18	33
% of applications that are continuations	25	27	29	28	28	29	31	29	29	36
Mean length of specification (number of words)	15,923	17,954	19,192	20,024	21,006	21,377	24,821	25,579	29,734	53,767
Mean number of claims	23	24	24	25	24	24	24	24	24	28
% of applications that are granted	44	43	43	44	44	44	43	45	45	48

APPENDIX 3. REGRESSIONS — CHEMISTRY & BIOLOGY GRANTED PATENTS

Number of Prophetic Examples and Value Measures[283]

Variable	(1) Payment of First Maintenance Fee (logit regression; odds ratios)[284]	(2) Forward Citations (Poisson regression; incident rate ratios)[285]	(3) Litigated (logit regression; odds ratios)
0 prophetic examples	Reference	Reference	Reference
1 prophetic example	0.91***	1.05***	1.06
2 prophetic examples	0.85***	1.02***	1.15
3 prophetic examples	0.83***	0.97***	0.92
4 prophetic examples	0.81***	0.97***	1.06
5 prophetic examples	0.79***	1.02***	0.90
6-8 prophetic examples	0.80***	0.97***	0.96
9-11 prophetic examples	0.75***	0.95***	0.48***
12-17 prophetic examples	0.69***	0.95***	0.94
18-754 prophetic examples	0.66***	0.92***	0.64**
Year since issuance offset		Yes	Yes
Priority year	0.99***	1.01***	0.88***
Foreign-filed	0.71***	0.66***	0.41***
Small entity	1.03***	1.13***	1.18***
Orange book listed			71.64***
Industry effect	Yes	Yes	Yes
N=	455,094	497,653	559,406

[283] Throughout the appendices, * = $p \leq 0.05$; ** = $p \leq 0.01$; and *** = $p \leq 0.001$.

[284] Only patents issued before 2013 are included in the regression, because patents issued later would not have had the opportunity to pay the maintenance fee at the time the data were analyzed.

[285] Only patents issued before 2015 are included in the regression, because forward citation data was collected from a PTO file last updated in 2014. This measure only includes forward citations by U.S. patents, not by applications, foreign patents, or non-patent literature.

Number of Prophetic Examples and Entity Size

Variable	(4) Small Entity (logit regression; odds ratios)[286]
0 prophetic examples	Reference
1 prophetic example	1.10***
2 prophetic examples	1.11***
3 prophetic examples	1.05***
4 prophetic examples	0.98
5 prophetic examples	0.97
6-8 prophetic examples	0.89***
9-11 prophetic examples	0.84***
12-17 prophetic examples	0.73***
18-754 prophetic examples	0.50***
Priority year	1.04***
Foreign-filed	0.28***
Industry effect	Yes
N=	455,094

[286] Entity size data was available only for patents issued between 1981 and 2013.

APPENDIX 4. REGRESSIONS — CHEMISTRY & BIOLOGY PATENT APPLICATIONS

Number of Prophetic Examples and Grant Rate

Variable	(1) Grant (logit regression; odds ratios)[287]
0 prophetic examples	Reference
1 prophetic example	1.02
2 prophetic examples	0.99
3 prophetic examples	1.03
4 prophetic examples	0.98
5 prophetic examples	1.00
6-8 prophetic examples	1.01
9-11 prophetic examples	1.04
12-17 prophetic examples	1.04
18-754 prophetic examples	1.15***
Years since application	0.98***
Priority year	0.98***
N=	251,755

[287] Only patents issued before 2011 are included, since applications may take several years to be granted.

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