PROPHETIC PATENTS

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In most contexts, making up data is forbidden - considered fraudulent, 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 Office and federal courts, but are considered equivalent to factual data in patent doctrine. Though prophetic examples are thought to be common, there are no in-depth studies of the practice, nor any explanation for why fictional data are allowed in patents.

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 biology and chemistry industries. I find that at least 17% of experiments in this population are fictional. Through both empirical and theoretical analyses, I weigh the potential costs and benefits of prophetic examples and find that the costs prevail. Prophetic examples could be beneficial if they help patentees; but I find little evidence that they do so, even in the specific situations in which they should be the most useful. Instead, prophetic examples likely 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 examples also hopelessly confuse scientists – a shocking 99% of scientific articles incorrectly cite prophetic examples as if they contained factual information – which means that made-up results from patents contaminate the scientific literature.

Given these harms, 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 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 is 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. The 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 have mentioned prophetic examples do so only in passing, with no more than a few sentences dedicated

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[1] Gina Kolata, *Koreans Report Ease in Cloning for Stem Cells*, N.Y. TIMES (May 20, 2005).

[2] Andrew Pollack, *Disgraced Scientist Granted U.S. Patent for Work Found to be Fraudulent*, N.Y. TIMES (Feb. 14, 2014).

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

[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] U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE [hereinafter "MPEP"] § 608 (9th ed. 2015); Atlas Powder Co. v. EI Du Pont De Nemours, 750 F.2d 1569, 1577 (Fed. Cir. 1984).

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

[8] U.S. Patent No. 8,003,137, Example 15 (issued Aug. 23, 2011).

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

to the issue.[10] These articles are almost uniformly critical of prophetic examples – hinting at potential problems surrounding the practice.[11] Despite the lack of scholarly attention, prophetic examples are common.[12] It is possible that the PTO has been granting hundreds of thousands of patents based on fake, implausible, and unreplicable 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 US 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 the present or future tense, while non-prophetic examples are written in the past tense.[14] I focused on chemistry and biology patents, as those are the only industries that commonly include experimental data (real or otherwise) in patents.[15] I analyzed 2,214,551 patents

[10] Andrew Baluch, *Relating the Two Experimental Uses in Patent Law*, 87 B.U. L. REV. 213, 241 (2007) (mentioning that prophetic examples may lead to "[a]n inventor's overreach"); Robin Feldman, *Plain Language Patents*, 17 TEX. INTELL. PROP. L.J. 289, 292 (2009) (criticizing the code for distinguishing prophetic examples); Timothy Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 158 (2006) (explaining that prophetic examples may chill downstream research); Timothy 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); Dmitry Karshtedt, *Limits on Hard-to-Reproduce Inventions*, 3 HASTINGS SCI. & TECH. L.J. 109, 114 (2011) (writing about the difference between scientific norms for reporting experiments and prophetic examples, but noting that they may disclose valuable inventions that would not otherwise come to light); Mark Lemley, *Ready for Patenting*, 96 B.U. L. REV. 1171, 1178 (2016) (suggesting that prophetic examples "disadvantage inventors who actually build and test their inventions before filing a patent application."); Lisa Larrimore Ouellette, *Pierson, Peer Review, and Patent Law*, 69 VAND. L. REV. 1825, 1827 (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) (noting that scientists who read patents may not be aware that prophetic examples are not real experiments); Kristen Osenga, *Cooperative Patent Prosecution*, 85 ST. JOHN'S L. REV. 115, 158 (2011) (discussing the difference between prophetic examples and scientific writing); Sean Seymore, *Patenting Around Failure*, 166 U. PENN. L. REV. (forthcoming 2018); Sean Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 632 (2010); Sean Seymore *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 144 (2009) (arguing in each article that the experiments described in prophetic examples are probably not correct.).

[11] *Id*.

[12] Smith Kline & French Laboratories v. Teva Pharmaceuticals USA, Inc., 2006 WL 6331923 (D.Del. 2012), Expert Report of Egon E. Berg (Sept. 22, 2006) ("Based on my experience as a patent attorney and patent examiner…prophetic examples are also common in patents").

[13] Part III.A, *infra*.

[14] MPEP § 608.

[15] Part III.B, *infra*. Note that the problem of fictional experiments is certainly present in other industries. *See* HAROLD FULLMER, PATENT PROSECUTION 277 (2017). Further, the theory and policy discussed herein also applies across industries. The empirical study focuses on chemistry and biology because the methodology is best suited to those industries. However, the implications of this Article are not so limited.

and applications in those industries, a population that contains 12,300,156 examples.[16]

I confirm that prophetic examples are indeed common: in chemistry and biology patents issued between 1976 and 2017, 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 and then test it empirically, which I do here.

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 one hundred 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 small budgets and cannot afford extensive real experimentation.[24] For companies of all sizes, broader patents provide a greater reward to the inventor, which might incentivize more innovation.[25]

I test this hypothesis empirically and find there is surprisingly little evidence that prophetic examples actually help patentees. Patents with more prophetic examples are narrower than patents with fewer prophetic examples –

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

[17] Table 1 and accompanying text, *infra*.

[18] 35 U.S.C. § 112.

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

[20] 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 Pharmaceuticals, LLC, 603 F.3d 935, 942 (Fed. Cir. 2010).

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

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

[24] Irwin Aisenberg, *The Patent and Present of Working Examples*, 23 IDEA 25, 30 (1982).

[25] *E.g.*, Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 US 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).

despite the prediction that prophetic examples help patentees get broader patents.[26] Second, there is no evidence that patents with more prophetic examples are filed earlier than those with fewer prophetic examples – again, contrary to prediction.[27] Finally, although small companies should benefit disproportionately from the ability to use prophetic examples, they do not. I find that small companies are significantly less likely to use prophetic examples as compared to their larger counterparts.[28] In sum, the case for prophetic examples does not fit with the empirical evidence.

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] Even after the patent has been abandoned and no longer has legal force, a chilling effect remains. 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 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 *ninety-nine percent* of citations to prophetic examples incorrectly cited the example as if it represented work that had actually been

[26] Part III.D.1.b, *infra*.
[27] Part III.D.1.c, *infra*.
[28] Part III.D.1.d, *infra*.
[29] Part III.D.1.a, *infra*.
[30] 35 U.S.C. § 271.
[31] 35 U.S.C. § 102-103.
[32] To anticipate a subsequent patent, the prior prophetic example must be enabled. MPEP § 2121.01. However, this is not a requirement for obviousness. *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. *Id*.
[33] 35 U.S.C. § 112.
[34] *E.g.*, Graham v. John Deere, 383 US 1, 6 (1966) ("…things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of…useful Arts.'").

done.[35] This would not necessarily be a problem if the prophetic examples were good predictions, but, as I demonstrate in this Article, many prophetic examples are probably wrong.[36] 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 adds strength to widespread accusations that disclosure functions poorly and furthers a line of the literature emphasizing the gap between scientific writing and "patentese."[37] 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.[38] However, my evidence suggests that, surprisingly, there may be more advantages to physical invention than previously realized.[39] 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.[40]

All of this strongly argues for reform. Banning fictional experiments in patents is an attractive solution, given the findings herein, but 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 of ring of accuracy and infallibility – but rather as *hypotheses* – testable predictions that may or may not turn out to be correct.[41] The shift from prophecies to hypotheses has several practical implications. First, it 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

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[35] Part III.D.2.b, *infra*.
[36] Part IV.B.1, *infra*
[37] Part III.D.2.b, *infra*
[38] Part IV.B.2, *infra*.
[39] Part IV.A.2.c, *infra*
[40] Part IV.A.2.b, *infra*.
[41] Part IV.C, *infra*.

their historical development. Part II makes the case for prophetic examples, and discusses costs and benefits. Part III, the heart of the Article, provides a novel empirical study of prophetic examples, explaining the study's design and methodology, and then providing data. Part IV then explains the study's results, examines the theoretical implications of the study for patent theory, and concludes with a proposal 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.[42] There is little literature on prophetic examples,[43] so this Section provides an in-depth exploration of the practice of prophesy in patents. Section I(a) is an introduction to prophetic examples and summarizes current doctrine. Section I(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.[44] These disclosure requirements ensure that the inventors obtain a monopoly commensurate with what they have actually invented.[45] Disclosure is also intended to promote innovation by ensuring that scientists and can read and use the information in the patent and thereby build further on the technology.[46] The requirements are a quid-pro-quo to guarantee that the public receives the benefit of knowledge in exchange for granting an exclusive patent.[47] In the absence of patents, inventions that could be kept secret might never be taught to the public.[48]

The disclosure statute has two components: enablement and written description.[49] The enablement doctrine requires that the patent include sufficient detail to ensure that a person skilled in the field of the invention

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[42] MPEP § 608.

[43] Note 10, *supra*.

[44] 35 U.S.C. § 112.

[45] Dan L. Burk, *Patent Silences*, 69 VAND. L. REV. 1603, 1606 (2016).

[46] *E.g.*, Graham v. John Deere, 383 US 1, 6 (1966).

[47] Lisa Larrimore Ouellette, *Pierson, Peer Review, and Patent Law*, 69 VAND. L. REV. 1825, 1827 (2016).

[48] Sean O'Connor & Ted Sichelman, *Patent as Promoters of Competition: The Guild Origin 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, *Making do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491 (2014); W. Nicholson Price II & Arti K. Rai, *Are Trade Secrets Delaying Biosimilars*, 10 SCIENCE 188, 188 (2015).

[49] Ariad Pharm., Inc. v. Eli Lilly and Co., 598 F. 3d 1336, 1341 (Fed. Cir. 2010).

could make and use the invention.[50] 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.[51] Possession does not refer only to physical possession of the invention.[52] The requirement can be met if the inventor clearly describes the invention in the patent.[53]

These requirements can be satisfied in many ways, but it is common to provide examples of how the invention is made or used.[54] Examples often describe experiments, and may provide instruction on how to make a composition or the effects of using said composition.[55] They are sometimes analogized to the "Materials and Methods" and "Results" sections of scientific articles.[56] While examples are not required,[57] they are frequently included in patents[58] and the absence thereof is frowned upon by courts.[59]

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 and describe content that is made up, or prophesized.[60] The Patent Office defines prophetic examples as "an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved."[61] 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.[62] 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.

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[50] 35 U.S.C. § 112; In re Wands, 858 F.2d 731, 736 (Fed. Cir. 1988).

[51] 35 U.SC. § 112; Ariad, 598 F. 3d at 1341.

[52] Falko-Gunter Falkner v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. 2006).

[53] MPEP § 2163.02 ("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.").

[54] MPEP § 2164.02.

[55] *E.g.*, Application of John A. Stephens, 529 F.2d 1343, 1345 (CCPA 1976).

[56] PRACTICING LAW INSTITUTE, HOW TO WRITE A PATENT APPLICATION, 17-26 (2016).

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

[58] In re Strahilevitz, 668 F.2d 1229, 1232 (CCPA 1982).

[59] *See, e.g.*, Wyeth v. Abbott Laboratories, 2012 WL 175023, *11 (D.N.J. 2012), *aff'd on other grounds*, 720 F.3d 1380, 1384 (Fed. Cir. 2013); Boston Scientific Corp. v. Johnson & Johnson Inc., 2010 WL 183752, *13 (D.Del. 2010).

[60] MPEP § 608.01(p).

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

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

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 recorded…at both 5 days and 12 days after injection, there was a significant dose dependent pain alleviation in the BOTOX® treated animals.[63]	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.[64]

The Patent Office and the federal courts explicitly permit prophetic examples.[65] Both institutions have also confirmed that prophetic examples can be used to satisfy the enablement and written description requirements in the same manner as working examples could be so used. 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.[66] Prophetic examples teach strategies for making and using the invention, and thus help satisfy the enablement requirement.[67] 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.[68] Prophetic examples help demonstrate that the patentee knew about the contours of the invention, and thus help satisfy the written description requirement.[69] Patents must also contain a statement of utility to be valid,[70] and prophetic examples can be used to illustrate the utility of the invention.[71]

Though prophetic examples can serve the same function as working

[63] *Id*. at Example 1.

[64] *Id*. at Example 2.

[65] Atlas Powder Co. v. EI du Pont De Nemours, 750 F.2d 1569, 1577 (Fed. Cir. 1984); MPEP § 2164.02.

[66] 35 U.S.C. § 112.

[67] Alcon Research Ltd. v. Barr Laboratories, 745 F.3d 1180, 1189 (Fed. Cir. 2014); Energy Absorption Systems, Inc. v. Roadway Safety Services, Inc., 1997 WL 368379, *5 (Fed. Cir. 1997); Boston Scientific 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 other parts of the specification are not enabling."); Cephalon, Inc. v. Watson Pharmaceuticals, Inc., 769 F.Supp.2d 729, 750 (D.Del. 2011).

[68] Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1343 (Fed. Cir. 2010).

[69] Ariad, 598 F.3d at 1357 (confirming that prophetic examples "certainly can be sufficient to satisfy the written description requirement"); Application of Robbins, 429 F.2d 452, 457 (CCPA 1970).

[70] 35 U.S.C. § 101.

[71] E.g. 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, 16 (1995) (explaining that patent examiners are sometimes skeptical of prophetic examples illustrating utility). *See also*, Michael Risch, *Reinventing Usefulness*, 2010 BYU L. Rev. 1195, 1202.

examples, inventors cannot pass off prophetic examples as work that has actually been done. Prophetic examples must be written in the present tense, while working examples are written in the past tense.[72] The Federal Circuit held that writing prophetic examples in the past tense can be inequitable conduct,[73] though district courts hearing cases on the question have produced mixed results.[74] A finding of inequitable conduct, essentially fraud, can render the patent unenforceable.[75] 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.[76]

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. The Section below traces the development of prophetic examples.

1. Early History

Most of the earliest U.S. patents were mechanical or electrical.[77] 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.[78] 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.[79] Over time, this disclosure came to be considered sufficient evidence of invention – a physical model was not needed.[80] This doctrine, called "constructive reduction to practice" allowed inventors to obtain patents on anything they could describe in sufficient detail to teach others to make, even if the inventor had

[72] MPEP § 608.

[73] Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1364 (Fed. Cir. 2003). *See also* Purdue Pharma. L.P. v. Endo Pharmaceuticals Inc., 438 F.3d 1123, 1134 (Fed. Cir. 2006); Novo Nordisk v. Bio-Tech Gen. Corp., 424 F.3d 1354, 1364, 1368 (Fed. Cir. 2005).

[74] *Compare* Presidio Components Inc. v. American Technical Ceramics Corp., 2010 WL 1462757, *28 (S.D.Cal. 2010) *with* Apotex, Inc. v. UCB, Inc., 970 F.Supp.2d 1297, 1319 (S.D.Fla. 2013). Note that the Federal Circuit clarified the inequitable conduct standard in the years between *Presidio* and *Apotex*. Therasense, Inc. v. Becton, Dickinson and Co., 649 F.3d 1276, 1279 (Fed. Cir. 2011).

[75] American Calcar v. American Honda, 768 F.3d 1185, 1186 (Fed. Cir. 2014).

[76] E.g., Energy Absorption Systems, Inc. v. Roadway Safety Services, Inc., 1997 WL 368379, at *5 (Fed. Cir. 1997); Eli Lilly and Co. v. Actavis Elizabeth LLC, 676 F.Supp.2d 352, 363 (D.N.J. 2009), *rev'd on other grounds* 435 Fed.Appx. 917 (Fed. Cir. 2011).

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

[78] *Id*.

[79] Drawings are still used to satisfy patent disclosure requirements. 35 U.S.C. § 113.

[80] 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 § 608.03.

never physically made the invention.[81]

In the early twentieth century the field of organic chemistry burgeoned and the number of chemistry patents skyrocketed.[82] Drawings – a great aid in teaching mechanical inventions – were less helpful for chemical patents.[83] Although a drawing of a molecule shows its structure, 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.[84] Though examples were not strictly necessary to enable a chemical invention,[85] courts often rejected chemistry patents that lacked examples[86] and patent prosecutors believed that a large number of examples would help their case.[87] Examples therefore became a standard part of chemistry patents.

Unlike the mechanical sciences, chemistry is "essentially an experimental science and results are often uncertain, unpredictable and unexpected."[88] In unpredictable fields, it is often not possible to predict how minor variations in the invention will affect the results.[89] The doctrine of constructive reduction to practice assumes that predictions made without physical creation will be accurate.[90] 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 records objecting to constructive reduction to practice in

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[81] 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. John Duffy, *Reviving the Paper Patent Doctrine*, 98 CORNELL. L. REV. 1359, 1366 (2013). Underlying the doctrine is an assumption of accuracy – that the disclosed invention will be function and that the inventor "has" the invention. *Wheeler v Clipper Mower and Reaper Co.*, 6 Fisher's Patent Cases 1, 16. 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, 60 (CCPA 1929).

[82] The number of patents in this field grew significantly in the early 20th century. *E.g.*, David Katz, *Proposal to Improve the Patent System*, 17 J. PAT. OFF. SOC'Y 777, 780-81 (1935).

[83] Eugene W. Geniesse, *Adequate Description*, 27 J. PAT. OFF. SOC'Y 784, 784 (1945).

[84] Geniesse, *supra* note 83, at 787 ("Illustrative examples in chemical cases serve the same purposes as do drawings in mechanical cases.").

[85] *Id*. *See also* In re Borkowski, 422 F.2d 904, 908 (CCPA 1970) ("as 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 undue experimentation.").

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

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

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

[89] Seymore, *supra* note 77, at 282; Rossman, *supra* note 87, at 873.

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

chemical patents.[91] Instead, it quickly became clear that constructive reduction to practice was as acceptable for chemical patents as it was for mechanical patents.[92]

> …an applicant may base a [chemical] patent application wholly on speculation…without doing any actual work…In layman's language this means that a patent can be secured on mere supposition without having actually invented or discovered anything.[93]

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?[94]

2. Prophetic Examples Become Patent Office Policy

For the first 50 years of prophetic examples,[95] the Patent Office had no official rules concerning the practice, but had an unofficial practice of allowing them. In 1980, the District of Delaware sharply criticized the Patent Office, stating that it

> can 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

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[91] There are a small number of sources that point to the necessity of actual experiments in chemical patents. Rossman, *supra* note 87, at 874.

[92] *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 chemistry…").

[93] Geniesse, *supra* note 83, at 788.

[94] Rossman, *supra* note 8787, at 875 (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.").

[95] The earliest mention of prophetic examples I was able to find came from a case in 1927 where the 6th 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…" Perkins Glue Co. v. Holland Furniture Co., 18 F.2d 387, 387 (6th Circ. 1927). Prophetic examples may have been used earlier.

mislead by such misrepresentations.[96]

Shortly thereafter – and perhaps because of the criticism[97] – the Patent Office made its first official statement on prophetic examples, adding them to the Manual of Patent Examination Procedure in 1981. The PTO originally inserted a provision stating that

> Applicants must indicate which tests and examples are only simulated or predicted and which tests and examples have actually been carried out to permit the examiner to examine the same properly. Simulated or predicted tests 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…[98]
>
> … 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.[99]

This provision was inserted with no advance notice[100] or discussion.[101] The provision dismayed some attorneys, who felt it restricted patent protection.[102]

After 9 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.[103] Specifically, the provision prohibiting results in

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[96] Grefco, Inc. v. Kewanee Industries, Inc., 499 F.Supp. 844, 868 (D.Del. 1980).

[97] *American Patent Law Association Midwinter Meeting – Committee Reports*, 1983 APLA 208, 209 (1983) ("Statements by the Court in *Grefco*…prompted the short lived January 1981 version of the MPEP §608.01(p) on 'Simulated or Predicted Tests or Examples.'"). *See also*, Donald G. Dau, *Chemical Names as Anticipation and Support*, 70 J. PAT. & TRADEMARK OFF. SOC'Y 377, 394 (1988) ("It is rumored…that the deleted changes had been responsive to criticism of the PTO in Grefco Co. v Kewanee Industries…").

[98] MPEP § 608.01(p), 104 (Rev. 5, Jan 1981), *available at* http://www.uspto.gov/web/offices/pac/mpep/old/E4R5_600.pdf.

[99] *Id*.

[100] Donald G .Daus, *Chemical Names as Anticipation and Support*, 70 J. PAT. & TRADEMARK OFF. SOC'Y 377, 394 (1988) ("The provisions had been inserted in the MPEP without advance notice. No 'grandfather' exceptions had been recited.").

[101] Irwin M. Aisenberg, *The Patent and Present of Working Examples*, 23 IDEA 25, 25 (1982) (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.").

[102] *Id*. at 27 (1982) ("it is not within the examiner's domain to limit available 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….The Rules still fail to provide any authority for distinguishing between examples which reflect an actual reduction to practice and those which do not.").

[103] MPEP, *supra* note 98, at § 608.01(a).

prophetic examples was removed, as was the exhortation for clarity and the explanation that patent examiners cannot test the veracity of statements in patents.[104] The PTO did not clarify the reason for the change, stating only that the original provisions "went further than was intended."[105]

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."[106] Scholars have suggested that the PTO originally accepted the doctrine of constructive reduction to practice for the same reason.[107]

3. Prophetic Examples in Recent Case Law

The law of prophetic examples has stayed substantially static since 1981. The relevant provision in the MPEP has not changed.[108] 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. [109]

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[104] *Id.*

[105] 1038 OFFICIAL GAZETTE 100 (Nov. 5, 1981) ("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.").

[106] MPEP, *supra* note 98, at § 608.01(a). 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* John Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. 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 Federal Circuit "the patent bar was a recognized specialty and a somewhat insular community.").

[107] Duffy, *supra* note 81, 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." § 8:93 Conceptual Inconsistencies – Constructive Reduction to Practice (4th ed. 2017).

[108] MPEP § 608.01(a) (9th ed. Rev. 07.2015, Nov. 2015).

[109] *See, e.g.*, Phigenix Inc. v. Genentech Inc., 2016 WL 4172202, *1 (N.D.Cal. Aug. 8 2016). ("[the patent] describes prophetic examples that predict that this phenomenon also occurs in breast cancer cells."); Regeneron Pharmacueticals v. Merus, 2014 WL 6611510, at *18 (S.D.N.Y. 2014) ("Example 3 (a prophetic example), confirms human genomic DNA."); Ex Parte Artemis Medical Inc., 2010 WL 4084621, *3 (BPAI 2010) ("Anderson's Prophetic Example 2 describes the preparation of a copolymer obtained by polymerizing lactic acid and glycolide monomers."); Ex Parte Ignatius Loy Britto, 2008 WL 2781982, *3 (BPAI 2008) ("Prophetic Examples 3 and 13 describe the use of PTFE-PES blend…"); Ex Parte David I. Gwynne et al., 2000 WL 33118608, *4 (BPAI 2000) ("The examiner points to Yelton's

Though it is well settled that prophetic examples can be used to satisfy the disclosure requirements, the issue still arises frequently, suggesting 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.[110] Furthermore decision-makers, including the Board of Patent Appeals and Interferences ("BPAI") and Patent Trial and Appeal Board ("PTAB"), 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."[111]

Overall, caselaw on prophetic examples remains sparse.[112] An April 2017 search for cases mentioning the term "prophetic example" uncovered only 52 cases in Westlaw's Federal Cases database and 46 and 12 cases from the Board of Patent Appeals and Interferences and Patent Trial and Appeal Board databases, respectively.[113] 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[114] – and the scholarly literature on prophetic examples,

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prophetic example…which describes cloning and expression of a foreign polypeptide…").

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

[111] Enzo Biochem, Inc. v. Applera Corp., 2013 WL 3965305, *8 (D.Conn. 2013). *See also*, Ariad, 598 F.3d, at 1357. *See also* Takeda v. Handa, 2013 WL 9853725, *72 (N.D.Cal. 2013) (finding that the patent "does not contain any working examples…instead, all of the examples…[are] prophetic…"); Ex Parte Robert C. Lam, 2008 WL 503540, *3 (BPAI 2005) ("The *only* examples provided are two 'prophetic' examples") (emphasis added); Ex Parte Katherine W. Klinger, 2006 WL 2523659, *2 (BPAI 2003) ("The application is devoid of working examples and/or models…*However*, as Appellants note…the Specification does include prophetic examples.") (emphasis added). Similarly, courts have found prophetic examples based on actual experiments to be a particularly convincing flavor of prophetic example. *E.g.*, Warner Lambert Co. v. Teva Pharmaceuticals USA, Inc., 2007 WL 4233015, *11 (D.N.J.) ("the '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.").

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

[113] 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. 35 U.S.C. 6(b). 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.

[114] For example, one court complained that it "can conceive of no reason for the PTO to

though brief, is overwhelmingly negative.[115] Nonetheless, there is a serious theoretical case to be made for the benefits of prophetic examples, and I make that case in this section. In doing so, I create a series of testable hypotheses that I evaluate empirically in Section III.

The purpose of patents is to incentivize innovation.[116] Inventors are motivated by the knowledge that they will receive patent exclusivity as a reward.[117] Roughly speaking, stronger, bigger, and more effective patent rights increase this reward.[118] The most convincing explanation for prophetic examples is that they help patentees, thereby strengthening the exclusivity incentive for innovation. In Part 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 Part 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.[119] Moreover, real experiments might not work or might 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

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countenance such a practice." Grefco, Inc. v. Kewanee Industries, Inc., 499 F.Supp. 844, 868 (D.Del. 1980).

[115] See all references cited in note 10, *supra*.

[116] *E.g.*, Diamond v. Chakrabarty, 447 US 303, 307 (1980).

[117] *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).

[118] *E.g.*, Robert P. Merges and Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 840 (1990).

[119] 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).

competitive and fast-moving fields.[120]

Prophetic examples also help applicants obtain broader patents. Patents must teach others how to make and use their inventions, and a broader patents covering more material require more teaching. To get a patent on one molecule, one experimental protocol is generally enough to teach how to synthesize the molecule.[121] 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.[122] Prophetic examples are instrumental to this function.[123] Prophetic examples also allow applicants to seek a broad patent without conducting expensive experiments, which reduces the cost of patents.

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.[124] To solve this problem, a pair of inventors discovered a new molecule that could be combined with various scents and would slowly releases those scents over time – useful for products like air fresheners.[125] If the inventors had wanted a

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[120] Practicing Law Institute, *How to Write a Patent Application*, 17-36 (2016). *See also* ROBIN FELDMAN, RETHINKING PATENT LAW, 160 (2012); Tom Brody, CLINICAL TRIALS, 837 (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.").

[121] MPEP § 2164 (explaining that "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.").

[122] *See, e.g.*, Enzo Biochem. Inc. v. Calgene, Inc., 188 F.3d 1362, 1374 (Fed. Cir. 199) (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…").

[123] *See, e.g.*, Brody, *supra* note 120, at 837; Troy Groetken, *IP: Sufficiency of Disclosure and the Great Divide Between U.S. and Europe*, INSIDE COUNSEL (February 26, 2014), *available at* http://www.insidecounsel.com/2014/02/26/ip-sufficiency-of-disclosure-and-the-great-divide ("[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"); WILLIAM G. KONOLD, WHAT EVERY ENGINEER SHOULD KNOW ABOUT PATENTS, 54 (1989); William B. Slate, *The Real Security of Continuation-in-Part Applications*, 83 J. PAT. & TRADEMARK SOC'Y 551, 554 (2001); PRACTICING LAW INSTITUTE, BIOTECHNOLOGY LAW: BIOTECHNOLOGY PATENTS AND BUSINESS STRATEGIES IN THE NEW MILLENNIUM, 359 (2002). For example, in *Synthes v. Spinal Kinetics*, 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 (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 and Gaby L. Longsworth, *Strengthening Pending and Future Application Portfolios in Advance of Potential Attack in AIA Proceedings*, Pharmaceutical Law & Industry Report (April 3, 2015).

[124] U.S. Patent No. 4,842,853, col. 1, ll. 15-20, 34-44 (issued June 27, 1989).

[125] *Id*.

narrow patent covering only one type of scent, including one example in the patent might have been enough. However, the inventors sought a broader patent – covering slow release of many different "fragrant substances."[126] 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 7 prophetic examples with instructions for how to make these compositions.[127] These included ingredients, amounts, and mixing instructions for making scents such as "Sea Breeze," "Lilac perfume oil," and "Lily of the valley."[128] Though these protocols were all predictions, rather than tested conclusions, but 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 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.[129]

Another such special 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 actually conducted also helps patentees who risk losing the ability to patent if they obtain data before filing a patent. This occurs because an inventor's own public disclosure about the invention can bar him from later filing for a

[126] *Id*.
[127] *Id*. at col. 3, l. 18 – col. 4, l. 53.
[128] *Id*. at col. 3, ll. 19, 40, 65.
[129] *See* Aisenberg, *supra* note 101, 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. *E.g.*, Clark Asay, *Patenting Elasticities*, 91 S. CAL. L. REV. (forthcoming 2018); Polk Wagner & David Abrams, *Poisoning the Next Apple? How the America Invents Act Harms Inventors*, 65 STAN. L. REV. 517, 534 (2013).

patent on the invention.[130] What precisely constitutes a public disclosure is contextual, but it may occur if samples are sent out for testing[131] or manufacturing.[132] A particularly contentious issue is the question of clinical trials, where a drug must be distributed to doctors and patients and certain disclosures must be made. Though appropriate confidentiality agreements can prevent clinical trials on a drug from blocking later patenting of the drug, it is a sufficiently problematic issue that the question is frequently litigated.[133]

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* – lab based – experiments.[134] It can take years, and hundreds of millions of dollars, to obtain FDA permission for human experiments and to conduct those experiments.[135] 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.[136] 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, therefore pharmaceutical companies prefer to include human trials.[137]

For instance, the patent applicant in *Bone Care International* sought a

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[130] 35 U.S.C. § 102.

[131] *E.g.*, Pronova Biopharma Norge AS v. Teva Pharmaceuticals USA, Inc., 549 Fed. Appx. 934, 939 (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).

[132] 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. The Medicines Co. v. Hospira, Inc., (Fed. Cir. July 11, 2016)

[133] *See, e.g.*, Dey, L.P., v. Sunovion Pharmaceuticals, Inc., 715 F.3d 1351, 1358 (2013) (explaining that "courts have routinely rejected the argument that such an arrangement [clinical trials] strips the trial of confidentiality protection or renders it accessible to the public."). *See also* Bayer Schering Pharma AG v. Barr Labs, Inc., 2008 WL 628592, at *11-12 (D.N.J. Mar. 3, 2008); Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., 364 F.Supp.2d 820, 273 (S.D.Ind. 2005), In re Omeprazole Patent Litig., 490 F.Supp.2d 281, 508 (S.D.N.Y. 2007), aff'd on other grounds, 536 F.3d 1351 (Fed. Cir. 2008); Janssen Pharmaceutical N.V. v. Eon Labs Mfg., Inc., 374 F.Supp.2d 263, 276 (E.D.N.Y. 2004), aff'd 134 Fed.Appx. 425, 430 (Fed. Cir. 2005).

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

[135] Joseph A. DiMasi, Ronald W. Hansen, & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 162 (2003).

[136] Eisenberg, *supra* note 134, at 348.

[137] 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* In re '318 Patent Infringement Litigation, 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.").

patent on a method of treating osteoporosis using the molecule doxercalciferol.[138] 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.[139] 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.[140]

> 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…[141]

Because the PTO permits prophetic examples, the applicant could use the results of the clinical trial to support the patentability of the compound – even before the clinical trial had been conducted.[142] Without prophetic examples, the applicant may not have felt secure enough to invest in the necessary clinical trials, 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®.[143]

In situations of the types outlined above, it is simply not practical for an inventor to conduct real experiments. This means that, were prophetic examples 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 sections above describe specific ways in which prophetic examples help patentees. From this, we can extract several testable hypotheses. Prophetic examples should allow patents to be (1) broader; (2) filed earlier; and (3) be 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.

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[138] Bone Care Intern., LLC v. Pentech Pharmaceuticals, Inc., 862 F.Supp.2d 790, 800 (N.D.Ill. 2012).

[139] *Id.* at 798.

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

[141] *Id.*

[142] 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. Bone Care, 862 F.Supp.2d at 800.

[143] Genzyme Corporation, *HECTOROL – doxercalciferol injection, solution*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021027s015lbl.pdf (Bone Care International sold the product to Genzyme).

B. Potential Costs

To be justifiable, prophetic examples must help patentees, but it is not enough for them to merely help patentees. 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. This assumption has two main components, each of which is discussed below.

1. Chilling Downstream Research

Prophetic examples might help patentees file earlier, broader patents. However, it is far from clear that these broader, earlier filed patents are actually socially beneficial.[144] Broad, early filed patents are supported by adherents of the "prospect" theory of patent law[145] who argue that such patents allows patentees to coordinate technological development in that area.[146] This prevents wasteful races to invent and reduces transaction costs during downstream development.[147] These are all potential benefits of prophetic examples.

However, some scholars worry that overly broad patents reduce competition and block downstream innovation,[148] and that early-filed patents reflect less developed inventions and therefore lead to patents that are more vague, useless, or, if useful, are never commercialized.[149] The problem with such patents is that they might effectively prevent others from working in the areas surrounding the patent. First, 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.[150] Even after the patent has expired or been abandoned, it might still chill research in that area because others cannot get a

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[144] *See* Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 67 (2009); Lemley, *supra* note 10 at 245; Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 343 (2010).

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

[146] Samuel Oddi, *Un-Unified Economic Theories of Patents – The Not-Quite-Holy Grail*, 71 NOTRE DAME L. REV. 267, 275 (1996).

[147] Kitch, *supra* note 145, at 267. It also causes patents to expire earlier, a potential benefit to society. *See* John Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 440 (2004).

[148][148] E.g., Peter Menell, *The Challenges of Reforming Intellectual Property Protection for Computer Software*, 97 COLUM. L. REV. 2644, 2646 (1994); Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry*, 16 BERKELEY TECH. L.J. 813, 831 (2001).

[149] *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.").

[150] One inoperative embodiment does not mean that the patent is invalid. E.g., *In re Angstadt*, 537 F.2d 498, 502-503 (CCPA 1976).

patent on an invention disclosed in or rendered obvious by a prophetic example.[151] Patents are given only for inventions that are new and nonobvious, therefore material that is disclosed, and everything obvious based on that disclosed material, is no longer patentable.[152] This is true even if the subject of the disclosure was never physically created.[153] We know that companies make strategic disclosures in their patents for the express purpose of preventing competitors from obtaining patents.[154] Prophetic examples may be one form of such disclosure.

For instance, in *Ex Parte Botond Banfi*, the inventors sought to patent the use of iodide to treat microbial diseases.[155] The PTO rejected the application on the grounds that the invention was not new because it had been disclosed in a prior patent.[156] The prior patent had indeed disclosed use of iodide, but in a prophetic example describing the treatment of asthma (which is not a microbial disease).[157] 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.[158]

Although the example was both prophetic and did not actually involve a microbial disease, the court reasoned that it inherently disclosed use of iodide

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[151] 35 U.S.C. §§ 102-103.

[152] For novelty: Ex Parte Natalya B. Danilova, 2008 WL 4768088, at *4 (BPAI 2008) ("As to the matter of Bower [an anticipating reference] 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 e.g., Sean B. Seymore, *Reinvention*, 92 NOTRE DAME L. REV. 1031, 1031 (2017). However, in order to anticipate a later patent, the prophetic example must be enabled. For obviousness: *Ex Parte Marek Z. Kubin and Raymond G. Goodwin*, 2007 WL 2070495, *2 (BPAI 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.'").

[153] Ex Parte Harry Fisch, 2009 WL 2760600, *6 (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. MPEP § 2121.01.

[154] E.g. Scott Baker and Claudio Mezzetti, *Disclosure as a Strategy in the Patent Race*, 48 J. L. & ECON. 173, 174 (2005); Oren Bar-Gill and Gideon Parchomovsky, *The Value of Giving Away Secrets*, 89 VA. L. REV. 1857, 1857 (2003); Rebecca Eisenberg, *The Promise and Perils of Strategic Publication to Create Prior Art: A Response to Professor Parchomovsky*, 98 MICH. L. REV. 2358, 2367 (2000); Gideon Parchomovsky, *Publish or Perish*, 98 MICH. L. REV. 926, 927 (2000); Seymore, *supra* note 10, at 1058.

[155] Ex Parte Botond Banfi, 2015 WL 6407275, *1 (Patent Tr. & App. Bd. 2015).

[156] *Id*.

[157] *Id*.

[158] U.S. Patent No. 6,890,920, Example E (Issued May 10, 2005)

to kill microbes. 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.[159]

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 never tried using iodide to treat asthma (indeed, it is not clear that the technique would work),[160] 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.[161] Any defense of prophetic examples must balance their benefits to patentees against this potential problem.

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.[162] It is only intellectually coherent to allow prophetic examples to serve these functions if they are actually understood by scientists and if they 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 on how to make the invention. 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

[159] Banfi, 2015 WL at *3. These "inherency" rejections are made when the examiner relies on "the inherent teaching of a prior art reference." In re Napier, 55 F.3d 610, 613 (Fed. Cir. 1995); MPEP § 2112.

[160] There were several articles on the use of potassium iodide to treat asthma published in the 1950s and 60s, but the technique does not appear to have caught on. *See, e.g.*, WB Casey, *On the Use of Iodide of Potassium in Asthma; Historical Document*, 12 ANN. ALLERGY 728-29 (1954).

[161] 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 the patent application and assume its been done before. I have seen personally many great ideas not being pursued because of this." Ouellette, *supra* note 10 at 564. *See also* Benjamin Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 Tex. L. Rev. 503, 545 (2009).

[162] 35 U.S.C. § 112.

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.[163] The presumption is only reasonable if prophetic examples are in fact likely to be accurate.[164]

At stake is not only whether patent doctrine is satisfied. The patent's disclosure is also supposed to promote innovation.[165] The standard explanation is that scientists get new technical information from patents and then use that knowledge to improve the technology or make their own inventive leaps.[166] 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,[167] but the suggestion has not been discussed in depth nor 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.[168] Ninety-one percent of industry scientists read patents.[169] 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

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[163] Atlas Powder, 750 F.2d at 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.").

[164] 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.

[165] Kewanee Oil Co. v. Bicron Corp., 416 US 470, 481 (1974).

[166] *Id*. ("[the] disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art.").

[167] E.g., Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 632 (2010). Granted patents are presumed to be enabled and adequately described, and the challenger has the burden of proving that that they are not. *E.g.*, Impax Labs. Inc. v. Aventis Pharm. Inc., 468 F.3d 1366, 1383 (Fed. Cir. 2006).

[168] Lisa Larrimore Ouellette, *Who Reads Patents?*, 35 NATURE BIOTECHNOLOGY 421, 423 (2017).

[169] *Id*. at 421 (only 78% of academic scientists read patents).

extreme dearth of scholarship on the topic, it is important to know more about prophetic examples. This Section describes an empirical study of prophetic examples across all electronically published U.S. 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 prophetic examples be justified?

A. Study Design

1. Populations

Unless otherwise specified, patents were issued between 1976[170] and June 2017, and applications were filed between 2001[171] and June 2017. I collected data for all granted patents and applications during this period. Although the data reported are 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, for example, those from other years.[172]

The patents were bulk downloaded and a variety of information was collected about each of these patents including the priority,[173] filing,[174] and issue dates,[175] the number of claims,[176] and the number of forward and backwards citations,[177] whether the patent is a continuation[178] or divisional,[179]

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[170] The USPTO full text database only covers 1976-onward.

[171] The USPTO's application database only covers 2001-onward.

[172] 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*.

[173] The filing date of the earliest application to which the studied patent or application can claim benefit. E.g., PowerOasis, Inc. v. T-Mobile USA, Inc., 552 F. 3d 1299, 1306 (Fed. Cir. 2008).

[174] The date on which the studied application was filed. 37 C.F.R. § 1.741.

[175] The date on which the studied patent issued. MPEP § 1309.

[176] Each patent and application concludes with one or more claims which "particularly point out and distinctly claim the invention." 35 U.S.C. § 112. Some scholars suggest that patents with more claims are broader or more important. E.g., Jean O. Lanjouw and Mark Shankerman, *Patent Quality and Research Productivity: Measuring Innovation with Multiple Indicators*, 114 THE ECONOMIC JOURNAL 441, 448 (2004).

[177] Forward citations are the number of times that the studied patent has been cited by other patents (note that this does not include citations to the application or citations by non-patent literature). This is a rough measure of the importance of the invention. *Id*. Backward citations are the number of sources that are cited by the studied patent (both those listed by the applicant and those added by the examiner). Some scholars suggest that backward citations are correlated with patent value and perhaps breadth, though any correlation would be indirect. *E.g.*, Dietmar Harhoff et al., *Citations, Family Size, Opposition and the Value of Patent Rights*, 1596 RES. POL'Y 1, 8 (2003).

[178] A continuation application has the same specification as the prior application, and uses the same priority date, but contains different claims. U.S. Water Services, Inc. v. Novozymes A/S, 843 F. 3d 1345, 1348 (Fed. Cir. 2016). Continuations can be used either to continue

IPC classifications,[180] and specification length.[181] This information was obtained from patents downloaded from the USPTO's Patent Grant Full Text Database, hosted by Reed Tech.[182] Data on patent expiration,[183] maintenance fees,[184] and entity size[185] was obtained from the USPTO.[186]

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.[187] This strategy excluded patents having no examples or integrating examples into the text of the patent, which is a limitation of the methodology.[188]

Prophetic examples were identified by exploiting a USPTO grammar requirement: prophetic examples must be written in the present tense, while working (non-prophetic) examples should be written in the past tense.[189]

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prosecution when the examiner does not grant the original application or to file several patents from the same base application, indicating that the applicant wants a portfolio of patents covering the area. Mark A. Lemley & Bhaven Sampat, *Examining Patent Examination*, 2010 STAN. TECH. L. REV. 2, 16 (2010).

[179] A divisional application, like a continuation, has the same specification and the prior application and uses the same priority date, but contains different claims. Unlike a continuation, a divisional carves pieces off of the original application after the original application was found to contain more than one invention (each patent application may cover only one invention). 37 C.F.R. § 1.142; MPEP § 201.06.

[180] International Patent Classifications (IPC) are a common classification system to group patents by the nature of the claimed technology. *Guide to the International Patent Classification* (2017), http://www.wipo.int/export/sites/www/classifications/ipc/en/guide/guide_ipc.pdf.

[181] Specification length is the number of words in the patent, excluding the abstract and the claims.

[182] Reed Tech, *USPTO Data Sets; Patent Grant Red Book* (2017), available at http://patents.reedtech.com/pgrbft.php.

[183] Patents expire either at the end of their 20-year term or earlier if maintenance fees are not paid. 37 C.F.R. § 1.362.

[184] *Id*.

[185] Inventors are classified as either "large", "small", or "micro" entities, depending on the nature of the organization and the number of employees. 37 C.F.R. § 1.27 (defining small entities); 37 C.F.R. 1.29 (defining micro entities).

[186] United States Patent and Trademark Office, *USPTO Bulk Downloads: Patent Maintenance Fees* (2015), available at 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.

[187] Full text of algorithm on file with author.

[188] See Figure 1 for data on how many patents with examples were identified using this strategy.

[189] MPEP § 2004 ("Paper or prophetic examples should not be described using the past tense.").

Prophetic examples should be entirely in the present tense, as judges have warned against mixing past and present tense in an example.[190] Further, examples written in the present tense are "presumed to be prophetic."[191] Where examples consist of numbers only, and therefore have no tense, the Patent Office assumes that the numbers are not prophetic.[192]

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.[193] There is no penalty for representing a working example as a prophetic example, in the present tense. However, I expect that this is uncommon for several reasons. First, patent drafting guides instruct that the past tense be used for working examples.[194] Second, courts assume that examples written in the present tense are prophetic,[195] and this has certain disadvantages if the example is in fact working.[196] Third, 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 9 errors in the algorithm's classification. Of these errors, the algorithm classified a working example as prophetic 3 times and a prophetic example as working 6 times.

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

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

[191] Ex Parte Vinod Sharma and Walter H. Olson, 2010 WL 2694700, *3 (BPAI 2010). *See also* Ex Parte Marlene Schwartz and Robert Richard, 2008 WL 2463016, *8 (BPAI 2008) ("Since the examples were written in the present tense, they were presumed prophetic and do not represent actual evidence.").

[192] E.g. Ex Parte Nobutaka Jujimoto and Masafumi Okamoto, 2013 WL 649554, *1 (PTAB 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 Mikael Schulsky, 2009 WL 2810323, *3 (BPAI 2009) ("The specification and drawings include data…We assume the data is not based on prophetic examples.").

[193] E.g. Novo Nordisk v Bio-Technology General, 424 F.3d 1347, 1361 (Fed. Cir. 2005).

[194] *E.g.*, SAMUEL J. SUTTON, DAVID G. CONLIN, RICHARD L. SCHWAAB, PATENT PREPARATION & PROSECUTION PRACTICE 9.16 (1976).

[195] *E.g.*, Ex Parte Michael Prencipe and Sayed Ibrahim, 2012 WL 5387521, *7 (PTAB 2012); Ex Parte Marlene Schwarz and Robert Richard, 2008 WL 2463016, *8 (BPAI 2008) ("Since the examples were written in the present tense, they are presumed prophetic and do not represent actual evidence…").

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

- 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.
- 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. [Note to editors: if you are able to host an online appendix, I will include these additional analyses in an online appendix].

3. Selecting Industries

Patents are drafted differently in different industries.[197] This reflects both the varied nature of the technologies and differences in how the law is applied.[198] In particular, the bar for enablement and written description are higher in industries such as chemistry and the life sciences as compared to the mechanical, electrical, or computer industries.[199] Thus, there is reason to expect that examples (both prophetic and working) will be more common in chemistry and life sciences patents. To test this, I obtained industry classifications from NBER.[200] As shown in Figure 1, examples are vastly more common in chemical and life sciences patents.

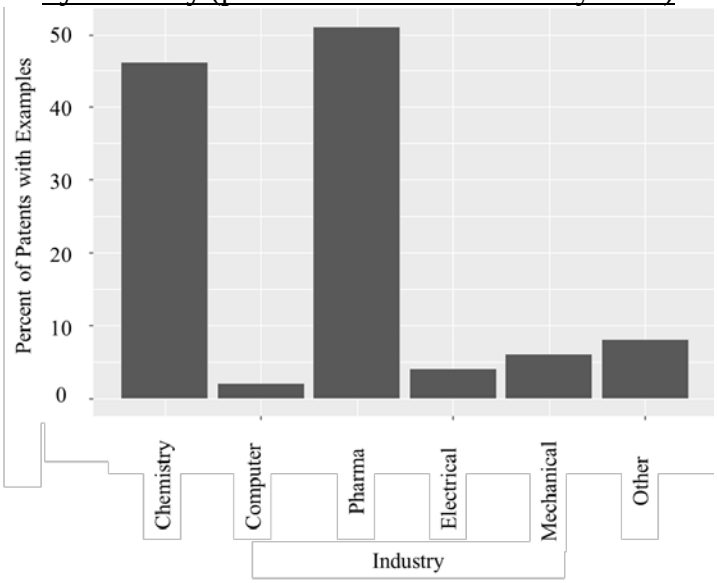
[197] *See generally*, Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, (2003).

[198] *Id*. at 1576.

[199] Christopher A. Cotropia, *The Folly of Early Filing*, 61 HASTINGS L.J. 65, 74-75 (2009).

[200] NBER classifications are used here because they are simpler and fewer in number than 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 with a Separate Examples Section, by Industry (patents issued Jan 1976-May 2017)



Note that the paucity of examples outside of the chemical and life sciences is not because information conveyed through examples are 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, the graph above 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 pharmaceutical patents.

Because this Article's methodology works better for chemical and pharmaceutical patents, the remainder of this Article studies only these industries. All experiments and graphs below represent an analysis of only chemical and pharmaceutical patents.

Outside of Figure 1, the population analyzed is all US chemistry and biology patents and applications available electronically from the USPTO. Chemistry patents are identified as those belonging to IPC classes beginning with the code "C" (a category defined as "Chemistry; Metallurgy").[201] Biology patents are identified as those belonging to IPC classes beginning with the codes A61 and A62 (categories defined as "Medical or Veterinary Science; Hygiene" and "Life-Saving; Fire-Fighting", respectively).[202]

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[201] World Intellectual Property Organization, *International Patent Classification Scheme* http://web2.wipo.int/classifications/ipc/ipcpub?notion=scheme&version=20170101&symbol=none&menulang=en&lang=en&viewmode=m&fipcpc=no&showdeleted=yes&indexes=no&headings=yes&notes=yes&direction=o2n&initial=A&cwid=none&tree=no&searchmode=smart

[202] *Id.*

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 a population comprised of all chemistry and biology patents and applications. This Section reports the prevalence of prophetic examples. If prophetic examples are rare, perhaps we need not be concerned about their existence even if they are theoretically problematic. 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. Table 1 summarizes the use of examples, both working and prophetic in patents. 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 six percent contain only prophetic examples. The studied population contains over one 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 (percent*)	Patents with some (but not all) prophetic examples, number (percent*)	Patents with all prophetic examples, number (percent*)
Chemistry and biology patents (1976-2017)[204]	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)[205]	1,054,087	463,743	5,222,946 (84%)	964,321 (16%)	271,820 (59%)	177,996 (38%)	13,926 (3%)

Although prophetic examples are prevalent, their use is decreasing over time. For patents with a priority date of 1981, when prophetic examples were first explicitly allowed by the Patent Office, 26% of examples were prophetic and 9.6% of patents contained only prophetic examples. By 2015, this had dropped to 9% and 4%. Figure 3, below, shows the average number of prophetic examples per patent in each year. This average decreases from 2.02

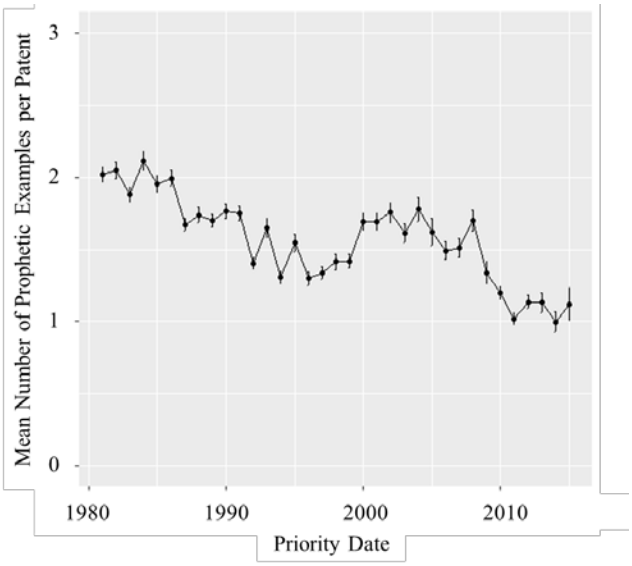
* Percent of the number of patents with examples.

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

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

in patents with a priority date in 1981 to 1.12 in patents with a priority date in 2015.

Figure 2: Number of Prophetic Examples Per Patent Over Time (Granted Biology and Chemistry Patents with Examples, N=559,406)



The reason for this decrease is not clear. It may be that as patents have become more expensive to file, there is less appetite for spending attorney time on drafting prophetic examples. It may also be that the behavior of particular patentees has not changed, but the type of entity filing patents has changed. For example, in the pharmaceutical industry, large companies have been filing fewer patents and relying more on research done – and patents filed – by small companies and universities. As discussed further in Section D(2), small companies file fewer prophetic examples so, if they make up an increasing share of pharmaceutical patentees, the average number of prophetic examples per patent will decrease. As shown in Appendix 5, the use of prophetic examples by large and small pharmaceutical patentees has stayed relatively steady over time, but small entities file a greater percentage of all pharmaceutical patents over time.

Overall, there are likely many reasons for the decrease in the number of prophetic examples over time, and the dynamics surrounding the use of prophetic examples are likely complex. Note that the percent of patents with at least one prophetic example has not changed over time.[206]

[206] Results not reported here. Results will be reported in an online appendix if possible.

C. Testing the Costs and Benefits of Prophetic Examples

1. Do Prophetic Examples Help Patentees?

At its most basic, the argument for prophetic examples is that they help patentees, and by doing so incentivize innovation and benefit society more broadly. I begin by looking at the correlation between prophetic examples and several general value indicators. These do not address any specific mechanisms by which prophetic examples may affect patent value, but provides descriptive information about the overall relationship between prophetic examples and patent value.

I then address the specific mechanisms by which prophetic examples should add value: breadth and early-filing. I also analyze use of prophetic examples in the specific situations in which prophetic examples should be especially helpful: when the inventor is a small company, when human experiments are necessary, and when the experiments are very expensive.

a. Value

There is no perfect measure of patent value,[207] but one commonly used indicator is the maintenance rate.[208] The Patent Office requires that patentees pay maintenance fees at 3.5, 7.5, and 11.5 years after grant. These fees are substantial enough ($1,600, $3,600, and $7,400, respectively) that many patentees do not pay them, which results in the abandonment of the patent.[209] Maintenance is a proxy for value because a patent owner that 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 year 11.5 maintenance fee.[210] 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

[207] It is also not possible to empirically study every known facet of patent value. For example, many patents may be valuable as signaling tools or negotiation pieces. *See, e.g.*, Michael J. Burstein, *Exchanging Information Without Intellectual Property*, 91 TEX. L. REV. 227, 241 (2012) (describing – and questioning – the premise that intellectual property is necessary for information exchange).

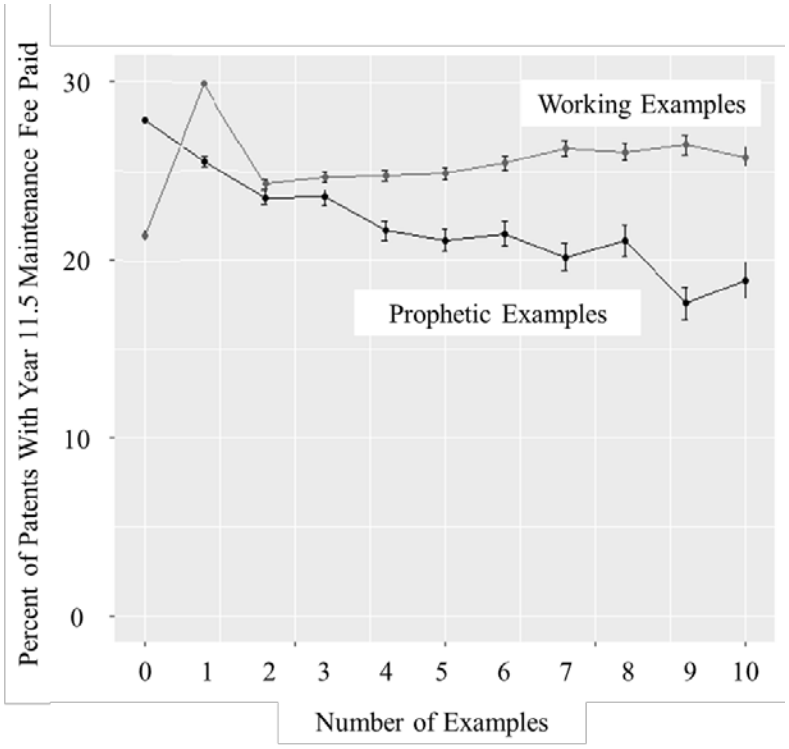
[208] E.g., James Bessen, *The Value of US Patents by Owner and Patent Characteristics*, 37 RES. POL'Y 932, 932 (2008); Jean O. Lanjouw et al., *How to Count Patents and Value Intellectual Property*, 46 J. INDUS. ECON. 405, 406 (1998).

[209] United States Patent and Trademark Office, *USPTO Fee Schedule* (Sept. 1, 2017), available at, https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule#Patent Maintenance Fee. The fees are halved for small entities and reduced further for micro entities.

[210] Figure 3 shows the correlation between examples and the last maintenance fee, however, results for payment of other maintenance fees are similar.

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.

Figure 3: Relationship Between Number of Examples and Payment of Maintenance Fees (Granted Biology and Chemistry Patents with Examples, 1981-2005, N=305,650)



A second proxy for patent value is the number of forward citations.[211] If a patent covers an important technology, others will be more likely to cite it. The correlation between the number of prophetic examples and forward citations per year (controlling for issue year) is reported in Appendix 3. As the number of prophetic examples increases, the rate of forward citations decreases. This again indicates that patents with more prophetic examples may be less valuable.

Another common method of determining if a particular characteristic correlates with patent value is to look at how frequently that characteristic

[211] Bronwyn H. Hall et al., *Market Value and Patent Citations*, 36 RAND J. ECON. 16, 17 (2005). Note that forward citations are a messy and imprecise measure of patent value. 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, 335 (2005).

appears in a specific group of patents that is known to be valuable.[212] Often this group of "valuable patents" consists of litigated patents, because litigated patents are valuable enough to be worth challenging and defending in court.[213] Appendix 3 shows the correlation between likelihood of litigation and prophetic examples. Patents with a small number of prophetic examples show little difference in litigation rates as compared to patents with no prophetic examples. However, patents with many prophetic examples are considerably less likely to be litigated.[214] As with the measures above, this suggests that patents with many prophetic examples are less valuable than patents with no prophetic examples.

In the context of biology and chemistry patents, there is a second group of "valuable patents": Orange Book-listed patents. The Orange Book is a publication maintained by the Food and Drug Administration which lists patents covering approved drug products.[215] It is expensive and time consuming to obtain approval for a drug product, so most patents listed in the Orange Book are extremely valuable.[216]

Orange Book patents are also interesting because prophetic examples are thought to be particularly useful in pharmaceutical patents more generally. This is because these are the patents that are most likely to have human examples,[217] the pharmaceutical sciences are fast moving,[218] have a high bar for enablement and written description,[219] and are often very valuable.[220] Thus, we might particularly expect to see prophetic examples adding value in pharmaceutical patents. However, Orange Book patents are not a uniform group, and more study is needed to understand the uses of prophetic examples in different types of Orange Book patents,[221] as well as to understand how

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[212] John R. Allison, Mark A. Lemley, Kimberly A. Moore, & R. Derek Trunkey, *Valuable Patents*, 92 GEO. L.J. 435 (2003).

[213] *Id*.

[214] One possibility is that the patent office has allowed invalid patents because it is not able to fully conduct the enablement and written description analysis, but patent owners do not believe that their patents would hold up in court and thus do not assert them. *See* Sean Seymore, *Patent Asymmetries*, 49 U.C. DAVIS L. REV. 963, 965 (2016).

[215] Food and Drug Administration, *Orange Book Preface* (Jan. 24, 2017), available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm. Though widely known as the "Orange Book," the publication is officially titled *Approved Drug Products with Therapeutic Equivalence Evaluations*.

[216] C.S. Hemphill & B.N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life of Pharmaceuticals*, 31 J. HEALTH ECON. 327, 330 (2012).

[217] TOM BRODY, CLINICAL TRIALS, 837 (2016).

[218] ROBIN FELDMAN, RETHINKING PATENT LAW, 160 (2012).

[219] Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific*, 17 BERKELEY TECH. L.J. 1155, 1183 (2002).

[220] Hemphill & Sampat, *supra* note 216, at 328.

[221] Patents may cover, for example, the active ingredient in the drug (drug substance), the formulation or composition of the drug (drug product), or a method of using the drug. These are often drafted at different points in the drug lifecycle, and may have very different strengths and weaknesses. *See* Janet Freilich, *The Paradox of Legal Equivalents and Scientific*

prophetic examples relate to various types of strategic behavior that has been documented in relation to Orange Book listing.[222]

Appendix 3 shows the correlation between likelihood of Orange Book listing and prophetic examples. Unlike the value measure seen before, use of prophetic examples *does* correlate with value by this measure. Orange Book listed patents are considerably more likely to include prophetic examples as compared to patents that are not Orange Book listed.

Orange Book listed patents are quite different from most patents – they cover a very specific type of technology, are filed by a small set of companies, and are often the product of extensive investment. They are also a very small group – the FDA estimates that it listed 602 unique patents in 2014.[223] Thus, Orange Book listed patents suggest that prophetic examples can be valuable in that specific group, but the results are unlikely to be applicable to the broader patent population.

Yet 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 more likely to be granted than applications with fewer prophetic examples.[224]

b. Breadth

Prophetic examples are predicted not only to add value generally, but to do so in several specific ways. One of these is that prophetic examples allow patentees to obtain broader patents than they otherwise could have done. Here, I test this claim using a proxy for patent scope: the number of words in the shortest independent claim of the patent.[225] The mechanism behind this proxy

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Equivalence, 66 S.M.U. L. REV. 59, 84-87 (2013).

[222] For example, merely listing a patent in the Orange Book is valuable for the patentee, even if the validity of the patent does not hold up in court. For an overview of such strategic behavior, see e.g., Natalie Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165 (2005).

[223] 81 Fed. Reg. 54097 (Aug. 15, 2016). For comparison, the PTO granted 326,032 patents in 2014. United States Patent and Trademark Office Patent Technology Monitoring Team, *U.S. Patent Statistics Chart Calendar Years 1963-2015*, available at https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm.

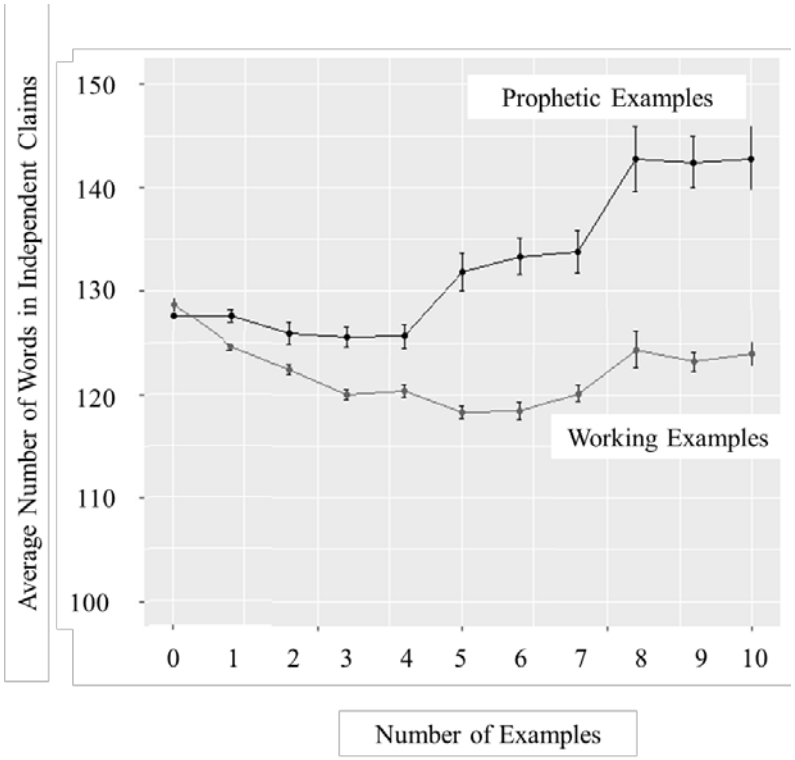
[224] This measure does not include continuations or unpublished applications. For a discussion on the challenges of measuring allowance rate see Michael Carley, Deepak Hedge, & Alan Marco, *What is the Probability of Receiving a U.S. Patent?*, 17 YALE J.L. & TECH. 203, 206 (2015).

[225] Jeffrey M. Kuhn & Neil Thompson, *The Ways We've Been Measuring Patent Scope are Wrong: How to Measure and Draw Causal Inferences with Patent Scope*, (May 2017), available at https://ssrn.com/abstract=2977273; Alan C. Marco, Joshua D. Sarnoff, & Charles deGrazia, *Patent Claims and Patent Scope*, USPTO Economic Working Paper 2016-04 (October 2016), available at https://ssrn.com/abstract-2844964.

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. Figure 4 does not include controls, however, the correlation remains when controlling for priority year, industry, and other factors.[226]

Figure 4: Correlation Between Number of Examples and Patent Breadth
(Granted Chemistry and Biology Patents with Examples, 1976-2016; N=559,404)



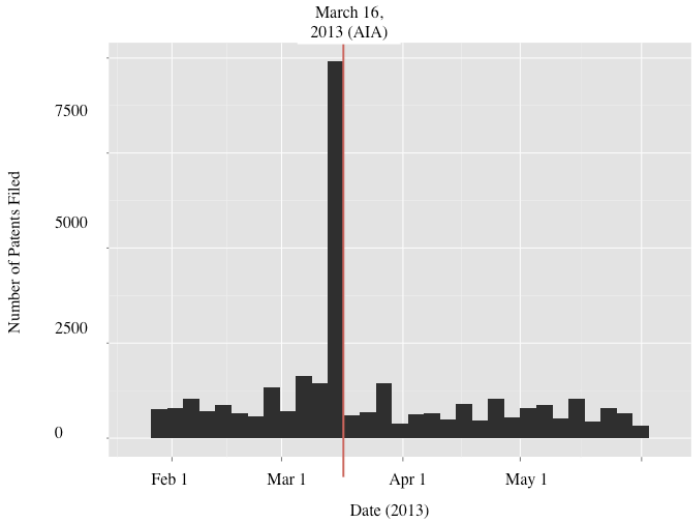
[226] *See* Appendix 3.

c. Early Filing

Prophetic examples should allow patentees to file a patent application earlier than would be possible in the absence of prophetic examples.[227] It is not possible to measure whether a patent with prophetic examples was filed earlier than it otherwise would have been, since the counterfactual is not observable. However, we can observe situations in which patentees were rushing to file applications at the patent office; situations in which they might be expected to use prophetic examples to file quickly. One such situation occurred around the effective date of the America Invents Act ("AIA").

The AIA was a major overhaul of several elements of the U.S. patent system. These changes were to some extent unfavorable to patentees, and thus patentees rushed to file applications before the effective date of these measures: March 16, 2013.[228] Patents filed before March 16, 2013 were subject to pre-AIA rules. Figure 5, below, shows the number of patent applications filed each day in the month before and after March 16, 2013. The enormous spike in applications filed in the days before the AIA came into effect is evidence of patentees' rush to the patent office. This rush is also confirmed by numerous contemporary accounts.[229]

Figure 5: Daily Patent Applications Filed Between Feb. and June 2013
(Biology and Chemistry Applications with Examples, N=24,554)



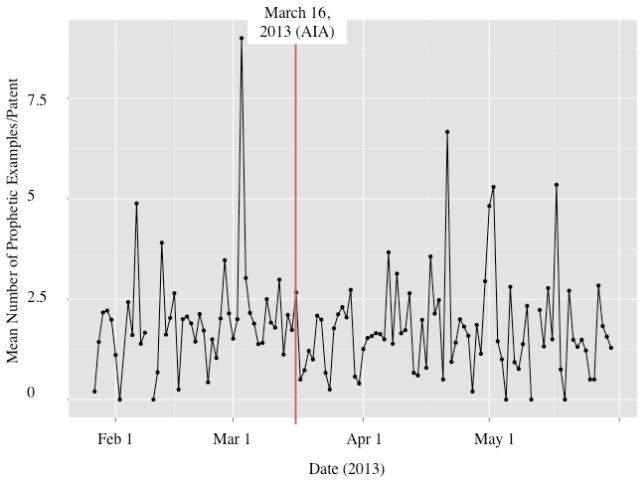
Patentees rushing to file an application with the Patent Office would have faced a choice: conduct time-consuming experiments that might not be finished by March 16, 2013, or file an application with prophetic examples. If prophetic examples are used to aid early-filing, we would expect to see an

[227] Section II.A.1, *supra*.
[228] Different provisions of the AIA had different effective dates.
[229] Dennis Crouch, *Pre-AIA Filing Number*, PATENTLY-O (March 29, 2013), available at https://patentlyo.com/patent/2013/03/pre-aia-filing-numbers.html

increase in the use of prophetic examples in the days and weeks before the effective date of the AIA, followed by a return to previous rates after the effective date of the AIA.

Surprisingly, the number of prophetic examples used in patents filed right before March 16, 2013 is essentially the same as the number of prophetic examples used in patents filed after March 16, 2013 (see Figure 6). There is no evidence that patentees were using prophetic examples to rush applications to the Patent Office.

Figure 6: Mean Daily Prophetic Examples in Patent Applications Filed Between Feb. and June 2013 (Biology and Chemistry Applications with Examples, N=24,554)



* * *

In sum, prophetic examples are negatively correlated with most value measures. Further, there is no evidence that use of prophetic examples leads to broader or earlier-filed patents. Although prophetic examples do correlate with Orange Book listings, this is unlikely to indicate a broadly applicable benefit of such examples. Mechanisms for and implications of these findings are discussed further in Section IV.

d. 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.[230] This Section tests how frequently prophetic examples are used by small companies.

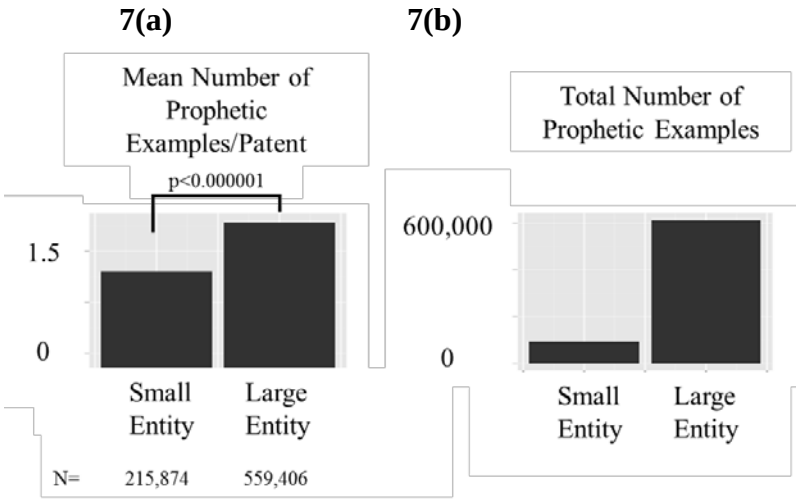
The Patent Office classifies patent applications based on whether they were

[230] *See* Aisenberg, *supra* note 101, at 30.

filed by large entities or small entities (a category that includes individuals, small business, nonprofits, and universities).[231] Figure 7(a) shows that use of prophetic examples is negatively correlated with small entity status; small entities use fewer prophetic examples.

Figure 7(b) shows the total number of prophetic examples in granted patents filed by small entities as compared to large entities. Small entities have filed a total of 92,117 prophetic examples, while large entities have filed 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. However, small entities are somewhat more likely to use small numbers (one to three) of prophetic examples as compared to large entities.[232] This suggests that prophetic examples may have some particular usefulness for small entities and is an area that merits further study.

Figure 7: Use of Prophetic Examples by Small Entities (Biology and Chemistry Granted Patents with Examples, 1981-2016, N=559,404)



e. Human Data

One justification for prophetic examples is that pharmaceutical companies cannot conduct real experiments because they cannot obtain data from human

[231] 37 C.F.R. § 1.25. The Patent Office 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.

[232] Appendix 3, *infra*.

trials without FDA permission.[233] I reviewed 1,000 prophetic examples selected randomly 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 3, 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. Note that although Orange Book listed patents are all related to drugs to treat humans, only 6% of prophetic examples in those patents describe human studies.[234] Therefore use of human studies does not explain most of the use of prophetic examples in Orange Book listed patents.

Table 3: 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%

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

f. Expensive Experiments

Another justification for prophetic examples is in instances where experiments would be extremely time-consuming or expensive. It is difficult to know whether an experiment is time-consuming or expensive. As a proxy, I reviewed the same 1,000 prophetic examples to determine if they contained experiments on animals. Animal studies are more expensive and time consuming than studies in cells which are in turn generally more expensive and time consuming than studies of molecules or chemicals in test tubes (*in vitro* studies), and thus are a rough alternative for data on the actual time and expense of experiments.

Table 3 provides at least partial evidence that many prophetic examples are based on relatively inexpensive experiments. Most prophetic examples are *in vitro* experiments. While such experiments can still be expensive, they are less expensive than *in vivo* experiments. Thus, expense of conducting real experiments may not be a full explanation for use of prophetic examples. However, I use a very rough proxy for expense here, so further study is necessary.

[233] Section II.A.2, *supra*.

[234] 6% of a sample of 100 prophetic examples selected randomly from biology and chemistry patents issued between 1976 and June 2017 and listed in the Orange Book as of August 2017.

2. Are Prophetic Examples Inaccurate or Misleading?

The prior section asked whether prophetic examples are beneficial because they help patentees and concluded that there is little evidence of such a benefit. This section asks whether prophetic examples are harmful. As set out in Part II, such harm may arise if prophetic examples are inaccurate or mislead scientists.

a. 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[235] and can request that the applicant submit more evidence.[236] However, there is reason to doubt that examiners make such rejections. The Patent Office emphasizes that these rejections are "rare," instances where such a rejection was upheld by a federal court "even rarer," and that requests for additional evidence "should be imposed rarely."[237] The Patent Office 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."[238]

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. These patents had all been rejected for lack of enablement or utility, which is where mention of a prophetic example would be most likely to occur. None of the prosecution histories ever mentioned prophetic examples. This result suggests 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.[239] All evidence suggests that examiners treat prophetic examples just as they do working examples. This may reduce the overall accuracy of prophetic examples because even those that seem incredible – such as the one cited in the introduction of this Article – pass through prosecution without objection.

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[235] MPEP § 2107.

[236] *Id*. 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.

[237] *Id*.

[238] 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*.

[239] Section III.D.1.a, *supra*.

b. How Prophetic Examples are Cited

To directly test 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 is correctly interpreting 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. All patents in the sample contain only prophetic examples and no working examples. Citations do not always indicate the specific part of the patent to which a citation refers, therefore if a patent has both prophetic and non-prophetic information, it is often impossible to know which information is cited. Patents with only prophetic examples do not have this limitation: if a document cites to such a patent, the document must be citing prophetic information.

I used Google Scholar to search for non-patent references citing each patent in the sample. I selected the first listed reference that cited the patent substantively for a specific proposition. If a patent was not cited substantively in Google Scholar, I excluded that patent and replaced it with another randomly selected patent in my sample.[240] I then 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, 99 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 34 patents and applications, suggesting that he has more experience with the patent system than most.[241]

[240] Most patents are not cited by non-patent literature. I reviewed 912 patents to obtain the sample of 100 cited patents used here.

[241] The author is Mark R. Prausnitz, a professor at the Georgia Institute of Technology. *See* Mark R. Prausnitz, *Laboratory for Drug Delivery*, http://drugdelivery.chbe.gatech.edu/.

Table 5: Miscitation of Prophetic Examples (%); N=100		
	Prophetic Examples	Samples to illustrate categories[242]
Cited Incorrectly	99%	"Dehydration reaction in gas phase *has been* carried out over solid acid catalysts…"[243] "Useful synthesis methods of imidazole derivatives *were known* to include several intermediates such as…1,2-diketones…"[244] "Hydroxyimination of aromatic ketones, followed by reduction, *was used* by Cannon et al. [in a prophetic example] to synthesize conformationally restricted derivatives of dopamine…."[245]
Cited Correctly	1%	"Although the microneedle concept was proposed in the 1970s [in prophetic examples] it was not demonstrated experimentally until the 1990s...."[246]

c. Use of Results

As a further test of whether prophetic examples are inaccurate or whether readers are likely to be misled, I observed whether prophetic examples consisted just of protocols, or whether they also included experimental results.

For instance, a prophetic example might say "formulation J [a drug compound] is be administered once daily topically to the eye of a person suffering from glaucoma" – which is simply an experimental protocol.[247] Alternatively, the prophetic example might continue with results: "[a]fter a few hours, intraocular pressure drops more and less hyperemia [eye redness] is observed than would be observed for formulation A."[248]

If prophetic examples include results, particularly detailed results, it is an indicator of both inaccuracy and the likelihood that readers will be misled. For accuracy: the more results that are included in the example – and the more detailed the results – the less likely the example is to be accurate.[249] To use the example above, it is surely easier to predict that formulation J will treat

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

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

[244] Emphasis added. Heon-Gon Kim et al., *Synthesis of Heteroaryl Substituted Imidazole Derivatives*, 21 BULL. KOREAN CHEM. SOC. 345, 345 (2000).

[245] Emphasis added. DANIEL BLANCO ANIA, PARALLEL SYNTHESIS OF POTENTIAL DRUGS BASED ON THE 2-ARYLETHYL AMINE MOIETY, 10 (2009).

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

[247] U.S. Patent No. 8,278,353, Example 5.

[248] *Id*. The results were included in the example, and the use of the prophetic example to show written description was upheld by the Federal Circuit in *Allergan, Inc. v. Sandoz, Inc.*, 796 F. 3d 1293, 1303, 1309 (Fed. Cir. 2015).

[249] Prophetic results and data should be "included in patent applications only where the inventor has a very high level of confidence in their operability." ROBERT D. FIER, CHEMICAL PATENT PRACTICE 44 (1975).

glaucoma[250] than to predict that it will work better than formulation A and that the effects will occur after just a few hours.

For likelihood of misleading readers: including results in prophetic examples– and particularly detailed numerical results – is one of the easiest ways to confuse the reader.[251] We do not usually write results for experiments that we have not conducted. Patent readers are therefore conditioned to view any results in experiments as the product of actual experimentation, rather than prophesy.

Thus, whether or not a prophetic example contains results is an indication of whether that example is both inaccurate and misleading. In order to test whether prophetic examples contained results, I reviewed 1000 prophetic examples selected randomly from the population of biology and chemistry patents issued from 1976 to 2017. I classified each example in one of the three following categories:

- No results. These examples typically described protocols or listed ingredients without any information about the outcomes or final product.
- Some results. 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 include adjectives characterizing the results in a nebulous manner.
- Detailed results. These examples included results with some detailed description of the results. This was generally numeric results.

Table 4 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 and misleading.

[250] In fact, formulation J does treat glaucoma. The patent protects the drug Lumigan®, which is approved by the FDA for treatment of glaucoma.

[251] SUTTON, *supra* note 194, at § 9.17 (explaining that may be misleading if they "conclude with a statement describing the results that were obtained…where in fact no results have actually been obtained."). Sutton cautions that "as a general rule, no results should be described unless they have actually been achieved." *Id*. Another guide recommended 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." FIER, *supra* note 249, at 44 (1975).

Table 4: Prophetic Examples That Include Results (%); N=1,000		
	Prophetic Examples	Samples to illustrate categories[252]
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."[253]
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, 5, and 8…All the mice are sacrificed on day 18, and lungs are collected for quantitation of tumor…In both groups of mice created with zctyo24 or zcyto25, the average number of tumor foci present on lungs is significantly reduced compared to mice treated with vehicle."[254]
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 10% of 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…"[255]

IV. Discussion, Implications, and Reform

In this Section, I apply the empirical findings of Section III to the costs and benefits of prophetic examples set out in Section II. I argue that the costs of prophetic examples are high and the benefits hard to determine, so I conclude with suggestions for reform.

A. Do Prophetic Examples Actually Help Patentees?

The core argument for prophetic examples is that they are valuable to patentees, and that value to patentees translates into value to society.[256] However, it is far from clear that prophetic examples actually help patentees. First, the number of prophetic examples in a patent correlates negatively with most proxies for patent value: maintenance, forward citations, and litigation

[252] Samples are all excerpts from prophetic examples.
[253] U.S. Patent No. 6,837,925, Example 8 (issued Jan. 4, 2005).
[254] U.S. Patent No. 8,313,739, Example 31 (issued Nov. 20, 2012).
[255] U.S. Patent No. 9,453,125, Example 2 (issued Sept. 27, 2016).
[256] Section II.A, *supra*.

rates.[257] Similarly, although patenting guides recommend use of prophetic examples to obtain a broader patent, use of prophetic examples is negatively correlated with patent breadth.[258] Further, there is no evidence that patentees use prophetic examples to file early.[259]

Nevertheless, there are a few indications that prophetic examples add value. First, patentees must believe that prophetic examples are useful and increase patent value in some way; otherwise they would not use prophetic examples. Second, prophetic examples appear more frequently in Orange Book listed patents, although these are a small group of atypical patents, so information drawn from these patents may not be generalizable.[260] Third, applications with more prophetic examples are more likely to be granted by the Patent Office, suggesting that prophetic examples may add value during prosecution.[261]

Overall, the results above demonstrate a surprisingly ambiguous – and probably negative – correlation between use of prophetic examples and patent value. However, the empirical analysis does not reveal the mechanism driving this correlation. I suggest such a mechanism below.

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 dollars. 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.

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[257] Section III.D.1.a, *supra*.
[258] Section III.D.1.b, *supra*.
[259] Section III.D.1.c, *supra*.
[260] Section III.D.1.a, *supra*.
[261] *Id.*

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 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 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.[262] Weak patents are a waste of money for both the applicant and the PTO. Weak patents increase transaction costs for other researchers.[263] Weak patents chill research in surrounding areas.[264]

If prophetic examples lead to patents that are weak and abandoned at

[262] *See, e.g.*, John R. Allison, Mark A. Lemley & Joshua Walker, *Patent Quality and Settlement Among Repeat Patent Litigants*, 99 GEO. L.J. 677 (2011); James Bessen & Michael J. Meurer, *Lessons for Patent Policy from Empirical Research on Patent Litigation*, 9 LEWIS & CLARK L. REV. 1, 2 (2005); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998); Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 1992 (2007); *But see* Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19, 21 (arguing that weak patents are often simply ignored).

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

[264] Carl Shapiro, *Navigating the Patent Thicket*, 1 INNOVATION POLICY & ECON. 119, 122 (2000).

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[265] and because once an invention has been disclosed in one patent it becomes difficult for a later inventor to obtain a patent on a related invention.[266] Awarding patents based on prophetic examples may prevent the use of exclusivity incentives for inventors who actually conduct the experiments.

However, any criticism on these grounds is blunted by the number of prophetic examples in high value patents. In particular, some Orange Book listed patents are exceedingly valuable and cover novel pharmaceutical products that can be enormously beneficial.[267] Outside of this small group, high value patents have fewer prophetic examples than low value patents, but high value patents nonetheless contain prophetic examples. It is very difficult to determine whether these patents could have been obtained in the absence of prophetic examples. This is because the enablement and written description standards are not bright line rules and there are many different ways to enable and adequately describe an invention. If prophetic examples encourage wastefully weak patents (and other harms, described below), is it worth permitting them if they add value to a smaller number of strong patents?

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

There is a large literature on when patents should be filed and whether early filing is socially beneficial. Prophetic examples have surprising 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 used may also be those situations in which early filing is the most problematic.

For instance, early disclosure is used to justify early filing. 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.

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[265] 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, 1503 (2010).

[266] Section II.B.1, *supra*.

[267] Though others have faced accusations of "evergreening" – a practice of filing patents on variations of the original product that extends the life of the monopoly, but is not necessarily innovating or beneficial. *See, e.g.*, Robin Feldman, *Rethinking Rights in Biospace*, 79 S. CAL. L. REV. 1, 30 (2006).

Moreover, prophetic examples describe the technical inner workings of the invention, rather than a broad concept. 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 – synthesis methods, for example, or 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 that work in similar ways, or to other uses for compound X, these types of secondary innovation 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 be wrong but may still have elements that could be useful, for example, Jules Verne could not make a submarine, 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 both wrong and yet so widely inspiring.

Prospect theory is also used to justify early filing, 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. Prophetic examples allow patentees who have not done any experiments with a particular technology to obtain a patent on that technology 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 are needed 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.

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 physically created their invention reduces the incentive to actually build and test the

invention.[268] 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,[269] it is surprising that more patentees do not use them. The data on prophetic examples suggests 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.[270]

Below, I outline motivations to explain why patentees might prefer working examples to prophetic examples; 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 actually been run before publishing the results. Scientific conventions often carry over to some extent into patents.[271] Scientists 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 is a waste of time and money.[272] Because filing a patent application can be

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[268] Mark A. Lemley, *Ready for Patenting*, 96 BU L. REV. 1171, 1178-79 (2016). (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."); PATENT LAW, LEGAL AND ECONOMIC PRINCIPLES § 13:31 (2d ed. 2015) ("…because writing patent applications is often less expensive and time-consuming than doing actual research, the law creates an incentive to file patent applications 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.").

[269] Section II.A, *supra*.

[270] The doctrine is controversial and much debated. *See, e.g.*, Christopher Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 120 (2009) (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, *supra* note 10, at 1833 (calling the doctrine problematic); Seymore, *supra* note 10, at 131 (listing constructive reduction to practice among the problems of the current enablement doctrine).

[271] E.g. FED. TRADE COMM'N, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION, 84 (2011). *See also*, Janet Freilich & Jay Kesan, *Towards Patent Standardization*, 30 HARV. J. L. & TECH. 233, 242 (2017).

[272] *E.g.*, INSTRUMENT SOCIETY OF AMERICA, ADVANCES IN INSTRUMENTATION: PROCEEDINGS OF THE INSTRUMENT SOCIETY OF AMERICA, Vol. 35, 380 (1980) ("speculation in contriving a 'paper' example often proves to be just that, unworkable except on paper.").

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.[273]

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."[274] The meaning of the phrase "undue experimentation" has been subject to much debate, but the authoritative method for determining whether experimentation is "undue" is application of the *Wands* factors.[275] Among the 8 *Wands* factors is "the existence of working examples."[276] 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 liability suit.[277] Plaintiff-oriented products liability litigation guides recommend searching patents for proposed safety features, some of which will be prophetic, as evidence of what the defendant knew could be done.[278] Defense-oriented litigation guides emphasize that lawyers should attempt to exclude prophetic examples or else offer "affirmative evidence about what was and was not done and tested."[279]

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[273] Russ Krajec, *The First Patent: A Roadmap for a Startup's Patent Portfolio*, IPWATCHDOG (April 26, 2016), http://www.ipwatchdog.com/2016/04/26/first-patent-roadmap-startups/id=68585/.

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

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

[276] *Id*.

[277] *See, e.g.*, Condos v. Musculoskeletal Transplant Foundation, 208 F.Supp.2d 1226, 1227 (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*. at 1231. The defendant explained that it is "currently attempting to implement those methods but has been unable to do so successfully." *Id*. at 1228.

[278] *See, e.g.*, ASSOCIATION OF TRIAL LAWYERS OF AMERICA, ATLA ANNUAL CONVENTION REFERENCE MATERIALS [Ann.2000 ATLA-CLE 2287] (2000) ("a patent search is warranted prior to filing [a products liability] suit.").

[279] JOSEPH EVALL, WHAT EVERY PRODUCT LIABILITY LAWYER NEEDS TO KNOW ABOUT PATENTS AND THE COMPANY'S DEFENSE OF PATENT LITIGATION, 259 (2016), http://dri.org/docs/default-source/dri-online/course-materials/2010/drug-and-medical-device/2010-drug-and-medical-device---14-what-every-product-liability-lawyer-needs-to-know-about-patents-and-the-company-s-defense-of-patent-litigation.pdf?sfvrsn=4.

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. Each prophetic example adds to that time. Clients may be choosing to omit prophetic examples that are not absolutely essential.

Changes in Patentees and Patenting Practices: The Patent Office 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[280] and the creation of the Federal Circuit in 1982.[281] The Bayh-Dole Act encouraged universities to file patents, and "turned universities into major players" in the patent system.[282] Since Bayh-Dole, the number of patents filed by universities has increased considerably. The USPTO reports that only 594 patents were filed by U.S. academic institutions in 1985, while 4,797 were filed in 2012.[283] Universities are less likely to use prophetic examples – university-filed patents have a mean of 1.5 prophetic examples compared to 1.9 for non-university patents.[284] This may be because university inventors must also publish papers in scientific journals, which require 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 USPTO has increased the fees for filing more than 20 claims several times. Increased claim fees reduce the number of claims filed by patent applicants.[285] 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.

B. Do Prophetic Examples Confuse Scientists?

Section III asked whether prophetic examples are accurate and not misleading or whether prophetic examples are plagued by inaccuracy and are causes of confusion. I discuss these findings and their implications here.

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[280] Pub. L. No. 96-517, 94 Stat. 3015, 3019-28 (1980) (codified as amended at 35 U.S.C. 200-212).

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

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

[283] United States Patent and Trademark Office, *U.S. Colleges and Universities – Utility Patent Grants 1969-2012* (Sept. 1, 2017) available at https://www.uspto.gov/web/offices/ac/ido/oeip/taf/univ/doc/doc_info_2012.htm

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

[285] E. Archontopoulos, et al., *When Small is Beautiful: Measuring the Evolution and Consequences of the Voluminosity of Patent Applications at the EPO*, 19 INFORMATION ECONOMICS & POLICY 103, 104 (2007).

1. Prophetic Examples Are Often Inaccurate

Implicit in the history and doctrine of prophetic examples is the assumption that prophetic examples are accurate.[286] This Article does not directly assess the accuracy of prophetic examples, however, it produces several results that suggest that the assumption of accuracy is probably not correct.

First, prophetic examples in unpredictable fields such as chemistry and biology are less likely to be correct than prophetic examples in predictable fields such as the mechanical sciences.[287] This Article shows that unpredictable fields have a large number of prophetic examples – 536,271 examples in chemistry patents are prophetic and 416,436 examples in biology patents are prophetic. Prophetic examples in unpredictable fields are not inevitably incorrect. However, their prevalence in the unpredictable sciences suggests that we should not accept the assumption of accuracy and predictability of inventions constructively reduced to practice without further scrutiny.

Second, the higher abandonment rate for patents with more prophetic examples is also 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.

Third, detailed results are common in prophetic examples. It is unlikely – indeed, it would be surprising – if detailed examples with hypothetical numerical data were correct in the chemical and life sciences. That is simply not how those fields work.[288] Irrespective of field, the more specific a prediction of experimental results, the less likely it is to be correct.

Finally, prophetic examples are likely to be inaccurate because there is little incentive to be accurate. Though patentees would prefer not to be entirely incorrect, since that might result in a valueless patent, being merely somewhat wrong will often not be harmful.[289] Moreover, there is some advantage to being vaguely incorrect. First, it does not give away all the cards to a competitor.[290] Second, a vague prophetic example may enable a broader claim than a more specific prophetic example.

The following example illustrates the advantages of vague and somewhat

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[286] Section I.B.1, *supra*.

[287] Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 144 (2009).

[288] *Id*. *See also* Jacob S. Sherkow, *Patent Law's Reproducibility Paradox*, 66 DUKE L.J. 845, 846 (2017). *See also* John P.A. Ioannidis, *Why Most Published Research Findings Are False*, 2 PLOS MED. 124, 124 (2005).

[289] And inoperative embodiments are not invalidating generally. MPEP § 2164.08(b).

[290] Note that being *deliberately* wrong or misleading is not permitted. *See* 37 C.F.R. § 1.56.

incorrect prophetic examples. Allergan Plc makes the widely-marketed product Latisse®, a prescription mascara that increases eyelash growth and thickness.[291] One of the patents covering Latisse® is directed to use of prostaglandin F analogs to "arrest hair loss, reverse hair loss, and promote hair growth."[292] While much of the patent's discussion relates to scalp hair loss, the patent includes the following prophetic example:

> A mascara composition is prepared. The composition comprises: [the example then lists 26 ingredients, including prostaglandin F]…A human female subject applies the composition each day. Specifically, for 6 weeks, the above composition is administered topically to the subject to darken and thicken eyelashes.[293]

The prophetic example is partially right: there is a prostaglandin F analog that darkens and thickens eyelashes, and this became the commercially available Latisse® product. However, there are many details of the prophetic examples that do not reflect the final product. Most notably, the specific prostaglandin F analogs used in the prophetic example are not the same prostaglandin F analogs used in Latisse®. In addition, the concentration of the active ingredient is different in the prophetic example and the commercial product, as are the inactive ingredients and the period of administration. However, the differences between the prophetic example and Latisse® are inconsequential as a matter of patent law. The prophetic example enabled a broad claim to "a method of growing hair" using a broad range of thousands of different prostaglandin F analogs. The example was somewhat incorrect, but it was nonetheless useful for the patentee and to society, if society values eyelash thickeners.[294]

The likely inaccuracy of prophetic examples is troubling. Prophetic examples are used to satisfy the enablement and written description requirements, but both of those requirements have an underlying assumption that prophetic examples are accurate.[295] Since they are in many cases not accurate, it is illogical to allow patentees to use false prophecies to fulfill the disclosure requirements. This is a serious flaw in a fundamental aspect of the patent system.

2. Prophetic Examples Mislead Scientists

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[291] LATISSE Highlights of Prescribing Information (2013), https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022369s007lbl.pdf.

[292] U.S. Patent No. 8,906,962, abstract (issued Dec. 9, 2014).

[293] *Id*. at Example 6.

[294] This issue is related to discussions about the failure of the enablement requirement to force full disclosure of all relevant details of the patented invention. *See, e.g.*, Brian J. Love & Christopher B. Seaman, *Best Mode Trade Secrets*, 15 YALE J. L. & TECH. 1, 7-8 (2013); Nicholson Price *Expired Patents, Trade Secrets, and Stymied Competition*, NOTRE DAME L. REV. 4 (forthcoming 2018), available at https://ssrn.com/abstract=2888988.

[295] Section II.B, *supra*.

Along with an assumption of accuracy, prophetic examples also rely on the assumption that they are not misleading.[296] Above, I present direct evidence that prophetic examples are misleading – 99% of scientific papers cite prophetic examples as if the experiment had actually been conducted.[297] This clearly demonstrates a deep misunderstanding of prophetic examples among scientists. And the problem is not restricted to the citing document. The citing document gets cited in turn by others, creating a chain where few readers would be aware that the underlying data is fictional. Additionally, patents are now frequently mined by databases that automatically extract information from patents.[298] This is yet another way that untried experiments can infiltrate the general scientific literature.

The findings presented in this Article impact the already-existing literature on problems with patent disclosure. This literature predominantly criticizes disclosures as difficult to read, insufficiently detailed, and not updated as research develops.[299] Recent policy proposals have recommended either improving or updating patent disclosures or encouraging the development of ancillary information sources.[300] However, some scholars criticize these proposals, arguing that disclosure is good enough,[301] should not be a priority for the system,[302] or that focus on the disclosure requirements detracts from

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[296] *Id*.

[297] Section III.D.2.b, *supra*.

[298] 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), *available at* http://blogs.nature.com/news/2013/12/patent-database-of-15-million-chemical-structures-goes-public.html. Prophetic examples create a problem for databases. *See, e.g.*, Ithipol Suriyawongkul, Christopher Southan, & Sorel Muresan, *The Cinderella of Biological Data Integration: Addressing the Challenges of Entity Relationship Mining from Patent Sources*, 2010 SPRINGER LECTURE NOTES IN BIOINFORMATICS 1, 2 (2010) (Listing disadvantages of patents as an information source for databases and including "using 'prophetic examples' not carried out" as a "significant disadvantage[]" of patents as compared to journal articles.). Examples of databases that mine prophetic examples include Chemical Abstracts Services (Chemical Abstracts Services, *CAS Coverage of Prophetic Substances* (2017), http://www.cas.org/content/prophetics), Elsevier's MDL Patent Chemistry 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, 355 (2013)).

[299] *See, e.g.*, W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1042-1048 (2016); Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 627 (2010).

[300] Colleen Chien, *Contextualizing Disclosure*, 69 VAND. L. REV. 1849, 1869-72 (2016); Jeanne Fromer, *Dynamic Patent Disclosure*, 69 VAND. L. REV. 1715, 1722 (2016); Jason Rantanen, *Peripheral Disclosure*, 74 U. PITT. L. REV. 1, 18 (2012).

[301] E.g. J. Jonas Anderson, *Secret Inventions*, 23 BERKELEY TECH. L.J. 917, 940 (2011); Rantanen, *supra* note 300, at 16.

[302] Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. & TECH. 401, 402 (2010).

incentives for patentees to create physical embodiments of their inventions.[303]

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 problematic.

Prophetic examples 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.[304] 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"[305] while another explains that a scientific paper "should not, in fact, have any prophetic component to it whatsoever. It better not. Unless its fraud."[306] One scientist reacted colorfully to learning about

[303] E.g. John Duffy, *Reviving the Paper Patent Doctrine*, 98 CORNELL. L. REV. 1359, 1361 (2013) (arguing that the rise of "documentary disclosure theory" was used to justify the diminishment of doctrines preferencing actual reduction to practice). *See also* Christopher Cotropia, *Physicalism and Patent Theory*, 69 VAND. L. Rev. 1543, 1565 (2016).

[304] Kristen Osenga, *Cooperative Patent Prosecution: Viewing Patents Through a Pragmatics Lens*, 85 ST. JOHN'S L. REV. 115, 158 (2011).

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

[306] Wyeth v. Abbott Laboratories, 2009 WL 8478818 (D.N.J. Dec. 30, 2009) (Expert Testimony of Samuel Danishefsky, M.D.). (Document 103-18). *See also* Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354 (Fed. Cir. 2003) (Judge Newman, dissenting) ("[prophetic] examples have long been accepted in patent documents, unlike their prohibition in scientific articles."). *See also* Coalition for Affordable Drugs X LLC v. Anacor Pharmaceuticals, IPR2015-01776, 20 (PTAB 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 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 data." Enzo Biochem, Inc. v. Applera Corp., 2007 WL 6475274 (D. Conn. June 20, 2007) (Expert Testimony of David H. Sherman, Ph.D.)

prophetic examples, "[w]hat I call a fake experimental procedure is actually a *prophetic example*. What I call bullshit is *a modus operandi*."[307] 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.

Prophetic examples not only deviate from scientific norms, they also deviate from the norms of everyday speech. In everyday conversation, the speaker is discouraged from making hypothetical statements unless these are expressed as opinions, hopes, or otherwise clearly marked as statements without evidentiary support.[308] Prophetic examples do not follow these conventions.

To the extent that prophetic examples confuse scientists, they are arguably unconstitutional. The Constitution authorizes patents to "*promote* the Progress of Science."[309] The Supreme Court has explained that "[i]nnovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system" governed by that constitutional command.[310] There has been little discussion of the meaning of "progress"[311] and courts have recently declined to find intellectual property provisions unconstitutional.[312] However, there is at least a plausible argument that if prophetic examples mislead and hamper scientists they are regressing "the Progress of Science."

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.

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Prophetic examples are justified on the grounds that they add value to patentees, which in turn incentivizes innovation that benefits society, that they are useful in certain special circumstances, and that they are likely to be accurate and not misleading. While prophetic examples likely add value to individual patents, they appear to be present predominantly in lower value

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(Document 236-10).

[307] (emphasis in original). ORG PREP DAILY (June 29, 2007), https://orgprepdaily.wordpress.com/author/milkshake/page/18/.

[308] Kristen Osenga, *Cooperative Patent Prosecution: Viewing Patents Through a Pragmatics Lens*, 85 ST. JOHN'S L. REV. 115, 158 (2011).

[309] U.S. CONST. art. I, § 8, cl. 8.

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

[311] Dotal Oliar, *Making Sense of the Intellectual Property Clause: Promotion of Progress as a Limitation on Congress's Intellectual Property Power*, 94 Geo. L.J. 1771, 1844 (2006).

[312] *E.g.*, Eldred v. Ashcroft, 537 U.S. 186, 188 (2003). Other cases are summarized in Oliar, *supra* note 311, at 1833.

patents, which may have some cost to society. Further, mechanisms by which prophetic examples were predicted to add value – increasing breadth, early filing – are not apparent from the empirical evidence. In addition, even if prophetic examples are necessary in special circumstances, the vast majority of prophetic examples are not used in these special circumstances, and therefore cannot be justified on these grounds. Finally, there is evidence that prophetic examples are both inaccurate and misleading. In their present form, prophetic examples are a problem.

C. Reform: From Prophecies to Hypotheses

Prophetic examples are a problem. Justifications for prophetic examples are shaky, and their harms potentially extensive. 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.

Yet 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.[313]

Thus, banning prophetic examples entirely might therefore be too harmful to patentees and too drastic a change to the patent system – at least right now. 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. In addition, there is nothing inherently wrong with making predictions about how a technology will progress in the future – in fact, such predictions could be valuable. I propose softer measures to mitigate the harms of prophetic examples with a less drastic shock to the patent system.

1. Clearly Label Prophetic Examples

To address the problems of prophetic examples without banning them, certain aspects of prophetic examples should be reformed. First, it should be

[313] 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)) and the Patent Office's guidelines "are no more helpful." Ouellette, *supra* note **Error! Bookmark not defined.** at 7.

easier for scientists and engineers reading patents to understand that, even though prophetic examples contain experimental data, it is not real data. The present grammatical tense shift is insufficient for this purpose. It is unreasonable to expect non-lawyers to be aware of the meaning of the tense shift and even for lawyers who are aware the distinction is difficult to grasp.[314]

The Patent Office currently requires patent applications to include certain section headings and to format some parts of the patent in standardized ways.[315] The Patent Office should add a requirement that, for applications that include prophetic examples, the examples should all be grouped under a heading such as "Prophetic Examples." However, only a heading is not sufficient because not all patent readers will understand the meaning of 'prophetic'. Immediately underneath the heading, the PTO should require a disclaimer, perhaps in bold or italics, explaining the meaning of prophetic examples. This may be a phrase such as "The examples below describe experiments that have not actually been conducted but that the patent applicant predicts will be functional." The beginning and end of the prophetic examples section should be clearly delineated. It may be desirable to mandate a separate heading for non-prophetic examples, perhaps "Working Examples" and an explanation there indicating that these examples have actually been conducted. These headings and explanations would make patents more user friendly and would prevent accidental interpretation of the data in prophetic examples are real data.

Labeling would not only help scientists, it would also prevent translation errors. Many companies seek patent protection in more than one country. Generally, they will file an international patent application that will go through preliminary examination and then be examined in more detail in individual countries when the application enters the national stage. The international application is usually filed in the inventor's native language and then, when it enters the national stage, is translated into the languages of countries where patent protection is sought.

The translation process creates an opportunity for error. Verb tense, which currently distinguishes between prophetic and working examples, may be mistranslated. Some patent translating guides caution that "when translating the examples, it is important that the translation properly reflect the nature of the example (working or prophetic)."[316] This is no simple exercise as "in some languages there is no easy way to distinguish between the tenses."[317]

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[314] Feldman, *supra* note 10 at 292 (explaining that use of the present tense is "unlikely to mean much to the uninitiated").

[315] MPEP § 608.

[316] T. Dave Reed, *International Patenting and the Translator: An Essential Partnership*, THE ATA CHRONICLE 18 (June 2008), *available at* http://www.atanet.org/chronicle-online/wp-content/uploads/3706_16_dave_reed.pdf.

[317] *Id*.

Disturbingly, most patent translation guides do not mention prophetic examples or tenses at all, suggesting that errors may arise from ignorance. Some firms caution, "one cannot assume that the foreign associates will translate the application correctly."[318] Moreover, there is greater potential for confusion in jurisdictions that do not accept prophetic examples.[319]

The proposal to clearly label prophetic examples is 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 tense, so simply adding a standardized title and disclaimer should not require significant attorney or inventor effort. Further, patent attorneys may favor the policy proposal because heightened separation of prophetic and working examples during the prosecution process may prevent accidental inclusion of prophetic information in the past tense, which is inequitable conduct.

Additionally, it would be helpful to ban results in prophetic examples. Results are probably the most misleading part of prophetic examples and the greatest deviation from scientific norms. Not all prophetic examples include results, but clearly many do. Removing results from prophetic examples would prevent some of the confusion surrounding prophetic examples.

Further, banning results would have a minimal effect on patentees. Patent applicants often need to include examples for enablement or written description purposes, but nothing in patent doctrine requires these examples to have results or interprets the example as more valuable to patent validity if it has a result. There are some doctrines, such as utility, where the ultimate use of the invention would still have to be stated in the patent, but there is no reason that would have to be done in the context of a prophetic example. Thus, banning results in prophetic examples would benefit the reader with little harm to the patentee.

2. Give Patentees a Grace Period to Update Prophetic Examples

In some cases, patent applicants fully intend to conduct the experiments recounted in prophetic examples. These applicants file prophetic examples because they are not able to conduct the experiments before the application needs to be filed. This can occur for many reasons such as temporary lapses in funding, needing the patent before funding can be obtained, or long approval processes for human trials. These may be legitimate uses for prophetic

[318]Fish & Tsang Intellectual Property Law, *Chapter 10 – PCT and Foreign Patent Practice & Procedure*, http://www.fishiplaw.com/chapter-10-pct-and-foreign-patent-practice-a-procedure.

[319] *Id*. ("In Japan, for example, practitioners are not generally used to prophetic examples [because they are not permitted] and may well translate a prophetic example in the past tense."

examples.

If patentees plan to conduct the described experiments, they should be allowed to file a patent with prophetic examples as a placeholder with the requirement that they update the patent within a period of time with the results of the experiment. Experiments that do not work should be left in, but updated with an explanation that they did not work. This would help combat underreporting of negative results, a major problem in the research world.[320]

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.

As present, it is not possible to update prophetic examples. Examples in patents cannot be changed (other than for clerical errors) after the patent is granted.[321] 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.[322] These rules should be loosened to allow patentees and applicants to update prophetic examples. Even if requiring or encouraging updating is not desirable, patentees and applicants should at least have the opportunity to update if they so choose. Although this would be a major change for the US patent system, other countries allow inventors to update their applications under certain circumstances, suggesting that such a proposal might be workable.[323]

3. Remove Presumption of Enablement

If patentees had a grace period to update prophetic examples, examples that were not updated at the end of the period should be presumptively non-enabled. An example is enabled if a person of ordinary skill in the art could make and use the invention based on the disclosed information.[324] This means that the example must both disclose a functional invention and disclose it in

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[320] *E.g.*, Paul Hsieh, *The Positive Value of Negative Drug Trials*, FORBES (August 30, 2015), available at http://www.forbes.com/sites/paulhsieh/2015/08/30/the-positive-value-of-negative-drug-trials/#490b0952413a.

[321] 35 U.S.C. § 255.

[322] MPEP 201.08.

[323] 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, Andrej Barbic, & Kyle Robertson, *Examples Requirement for Patentability of Inventions in US and Foreign Jurisdictions*, 3 Bloomberg Law Reports, 8, 14 (2009).

[324] 35 USC § 112.

sufficient detail that it could be replicated without undue experimentation. At present, examples in granted patents are presumptively enabled,[325] meaning that a challenger alleging that the patent was invalid would have to prove that the prophetic example was not enabled. If prophetic examples were presumptively non-enabled, the burden would shift and the patentee would have to prove that the prophetic example was enabled. If such a policy were implemented, the patentee should be able to update the example at any point and shift to presumptive enablement. 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."[326]

This would not only have an effect in litigation, it would also have an effect on downstream research in the area. If a prior patent has disclosed an invention, a later patent cannot claim it, because the invention is novel.[327] However, earlier disclosure is only a bar to novelty if the earlier invention is enabled. Since granted patents are presumptively enabled, it is risky to seek a patent on an invention disclosed in a granted patent – even if the invention is likely not enabled – because the later patentee must show non-enablement. Thus, fewer inventors will conduct research in that area. If non-updated prophetic examples were presumptively non-enabled, it might reduce the chilling effect and encourage others to conduct experiments in these areas.

4. Evaluate Prophetic Examples Based on Underlying Evidence

When evaluating a patent for enablement, examiners should not simply accept prophetic examples. Instead, examiners should review the example with an eye towards determining if it would really work. Patent applicants should include an explanation of why they believe the prophetic example would work, including any calculations or reasoning necessary to understand the prediction. A patent examiner could then give greater weight to well-reasoned prophetic examples in areas where the science is predictable, and less weight to wild predictions. Greater explanation of the reasoning behind prophetic examples would both help examiners and help patent readers determine if the prediction is useful.

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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

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

[326] 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, 35 (2004).

[327] 35 U.S.C. § 102.

reduction to research more generally – in order to determine if greater reform is necessary.

CONCLUSION

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. In an era where patent scholars, the FDA, and scientists more broadly are grappling with an irreproducibility "crisis,"[328] it is time to re-think the justifications for prophetic examples. This Article presents evidence that questions the traditional foundations for the practice of including prophecy in patents. 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. Prophetic examples are undoubtedly useful for some patentees, but they also have clear harms. These competing effects, combined with the ubiquity of made up data in chemistry and biology patents means that patent scholars, practitioners, and policy makers must be more aware of prophetic examples.

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[328] *See* Sherkow, *supra* note 288. *See also* Monya Baker, *Is There a Reproducibility Crisis?*, 533 NATURE 452 (2016).

APPENDIX 1: SUMMARY STATISTICS – CHEMISTRY & BIOLOGY GRANTED PATENTS
Patents are divided into ten groups based on the number of prophetic examples in the patent

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 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

Correlation Between Number of Prophetic Examples and Value Measures

Variable	(1) Payment of First Maintenance Fee (logit regression; odds ratios)[329]	(2) Forward Citations (poisson regression; incident rate ratios)[330]	(3) Litigated (logit regression; odds ratios)	(4) Orange Book Listed (logit regression; odds ratios)
0 prophetic examples	Reference	Reference	Reference	Reference
1 prophetic example	0.91***	1.05***	1.06	1.17
2 prophetic examples	0.85***	1.02***	1.15	1.55***
3 prophetic examples	0.83***	0.97***	0.92	1.35*
4 prophetic examples	0.81***	0.97***	1.06	1.21
5 prophetic examples	0.79***	1.02***	0.90	0.99
6-8 prophetic examples	0.80***	0.97***	0.96	1.67***
9-11 prophetic examples	0.75***	0.95***	0.48***	1.90***
12-17 prophetic examples	0.69***	0.95***	0.94	1.70**
18-754 prophetic examples	0.66***	0.92***	0.64**	1.28
Year since issuance offset		Yes	Yes	
Priority year	0.99***	1.01***	0.88***	1.02*
Foreign-filed	0.71***	0.66***	0.41***	0.89
Small entity	1.03***	1.13***	1.18***	0.41***
Orange book listed			71.64***	
Industry effect	Yes	Yes	Yes	Yes
N=	455,094	497,653	559,406	559,406

[329] Only patents issued before 2013 are included in the regression, because patents issued later will not have had the opportunity to pay the maintenance fee.

[330] 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 US patents, not by applications, foreign patents, or non-patent literature.

Correlation Between Number of Prophetic Examples and Entity Size

Variable	(5) Small Entity (logit regression; odds ratios)[331]
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	

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

APPENDIX 4: REGRESSIONS - CHEMISTRY & BIOLOGY APPLICATIONS

Figure 4: Correlation Between Number of Prophetic Examples and Grant Rate

Variable	(1) Grant (logit regression; odds ratios)[332]
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	

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

APPENDIX 5: EFFECT OF ENTITY SIZE TRENDS ON NUMBER OF PROPHETIC EXAMPLES IN PHARMACEUTICAL PATENTS

The number of prophetic examples has been decreasing over time. For pharmaceutical patents (defined using NBER's industry classification), this may be due to an increase in patenting by small companies. Clockwise from top left: 5(a) shows the decrease in prophetic examples per patent over all pharmaceutical patents (N=233,823). 5(b) shows the increasing percent of pharmaceutical patents filed by small entities (N=142,481); 5(c) shows that the use of number of prophetic examples per patent filed by *small entities* has stayed relatively steady over time (N=41,681). 5(d) shows the same, but for *large entities* (N=110,800).