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Science Fiction: Fictitious Experiments in Patents

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Prophetic examples may unnecessarily distort understanding

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Although it may surprise scientists, one can receive a patent in many jurisdictions without implementing an invention in practice and demonstrating that it works as expected. Instead, inventors applying for patents are allowed to include predicted experimental methods and results, known as prophetic examples, as long as the examples are not written in the past tense (*1*–*3*). Allowing untested inventions to be patented may encourage earlier disclosures about new ideas and provide earlier certainty regarding legal rights—which may help small firms acquire financing to bring their ideas to market. Yet granting patents too early may also discourage researchers from doing the work to bring ideas to fruition (*4*, *5*). Even if allowing untested inventions to be patented is desirable, we think prophetic examples deserve closer scrutiny, and clearer labeling, because of the likelihood that they are unnecessarily confusing—particularly to scientists, many of whom read patents but are unlikely to appreciate that not all the claims are based on actual data.

The U.S. Patent and Trademark Office (USPTO) formally recognized prophetic examples in 1981, but the practice is considerably older. A patent application need only contain sufficient information that a skilled researcher in the field would recognize as credibly demonstrating how to make and use the invention (*6*). Prophetic examples are one way to help satisfy this legal standard for inventions that have not yet been demonstrated to work (*2*). Although prophetic examples that are close variations on actual experiments are preferable, many prophetic examples appear to be entirely hypothetical predictions. Preliminary research suggests that these examples are particularly prevalent in chemistry and biology; an estimated 17% of examples in U.S. patents in these fields are prophetic, and almost one-quarter of U.S. patents in these fields have at least one prophetic example—making prophetic examples a commonplace feature (for examples, see the box) (*7*).

Because of concerns about awarding patents to unproven inventions, prophetic examples are viewed with greater skepticism in Europe (*8*), Canada (*9*), Japan (*10*), and China (*11*). However, because patents with the same contents are often filed in multiple regions, prophetic examples originating in U.S. applications will often be present in applications filed in other jurisdictions. Further, because patent offices and examiners in those countries commonly read and cite patents from other jurisdictions, countries skeptical of prophetic examples still feel their effects.

PROPHETIC EXAMPLES MAY BE CONFUSING

Contrary to the assertions of some patent scholars that scientists never read patents, survey evidence shows that many researchers do look to the patent literature for general research, to browse information about cutting-edge technologies, and to learn how other researchers solved particular problems (*12*). Training on how to search patents is even provided in some undergraduate science classes (*12*). But the usefulness of patents as a source of technical information is diminished if scientific readers are unable to distinguish actual data from predicted results.

Although scientists read patents—and therefore also read prophetic examples—the verb tense rule that distinguishes these predicted results from actual data is unlikely to be familiar to the average scientist. Most patent drafters do not seek to intentionally mislead readers, but they are writing for a legal audience and using conventions that may be unclear to nonlegal readers. Prophetic examples are confusing because they mimic real experiments, particularly by including excessive detail—for example, age of the hypothetical patient ("a 46-year-old woman…")—and specific, numerical results ("blood pressure is reduced within 3 hours…"). Some preliminary work suggests that of 100 randomly selected patents with only prophetic examples—that is, no actual data—that were cited in a scientific article or book for a specific proposition, 99 were not cited in a way that made clear that the cited information was prophetic (*7*). To the contrary, these prophetic patents were cited with phrases such as "[d]ehydration reaction in gas phase has been carried out over solid acid catalysts" (*7*), suggesting that prophetic examples mislead scientist readers.

Prophetic examples may also be confusing to other readers who are unfamiliar with the tense rule, such as investors seeking to accurately evaluate complex technologies. Causing further misunderstanding, the subtlety of prophetic examples may literally be lost in translation for patent applications that must be translated into different languages because they are filed in international jurisdictions. To be sure, quantifying the cost of this confusion would be challenging, especially because most confused scientists, investors, and patent examiners are likely unaware of the problem. But given the lack of a corresponding benefit, there seems to be no reason to perpetuate the practice. Nothing in patent law requires early-stage ideas to be described in a way that might confuse these different audiences by mimicking factual experiments; prophetic examples could be signaled more clearly or avoided altogether.

WHY USE PROPHETIC EXPERIMENTS?

To explore whether benefits for patentees from prophetic examples can be obtained through less confusing patent-drafting methods, we interviewed professional patent prosecutors who write U.S. patents. As described in the supplementary materials, we identified prophetic examples as those written in the present or future tense. We then contacted a randomly selected sample of patent prosecutors in the fields of chemistry and biology who, in patent applications filed between 2011 and 2013, either never used prophetic examples or used prophetic examples in more than half of applications filed. We conducted 26 interviews, with a yield rate of 67%.

Prosecutors who use prophetic examples consistently explained that such examples make clear how an inventor expects an idea to work in scenarios for which there is not time or money to test before the desired patent filing deadline. Because patents can cover all variations of an invention described in enough detail for others to make and use without undue experimentation, prophetic examples with predicted

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results can extend the patent's legal protection. For example, if an inventor has made a particular protein in her laboratory but also believes that the protein will work similarly if certain amino acids are switched, a prosecutor can draft prophetic examples with the alternate sequences and a prediction of the expected outcome. These examples help the inventor obtain patent coverage beyond the specifics of what has been done in the laboratory, including to block competitors from working on similar technologies.

Interviewed prosecutors generally acknowledged the possibility that scientists reading prophetic examples might be unable to correctly interpret the verb tense rule, although they emphasized the legality of the practice and their duty to obtain the strongest possible patent for their clients. They also agreed, however, that an equally strong patent could be obtained with prophetic examples that were explicitly labeled as predictions that had not been carried out. Interviewees who do not use prophetic examples argued that there is no legal reason to present these predictions in the form of fictitious experiments with specific results rather than in more general terms; to the contrary, prophetic examples carry some legal risk, such as if the example turns out to be inoperative. Prosecutors were particularly wary of using prophetic examples in patent applications that would be filed internationally, given the greater skepticism of these examples in certain countries.

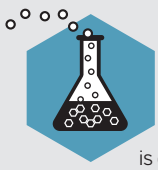
The only benefit to patentees that would be reduced by requiring greater clarity seems to be the benefit that comes from confusion. For example, several prosecutors suggested that prophetic examples could illustrate a technology's promise to potential investors, who might not be able to distinguish between prophetic examples and experiments actually conducted. This potential confusion was considered a benefit to patentees, but this benefit does not seem worth preserving.

MORE CLARITY, LESS CONFUSION

The benefits flowing from prophetic examples exist because some patent systems recognize and allow the use of hypothetical experiments and data. Within these legal systems, prosecutors, patent examiners, and courts can already identify prophetic examples through the tense rule, so requiring a more explicit distinction between prophetic and nonprophetic examples would have no legal impact; prophetic examples would continue to be recognized and rewarded as such, just with lower risk of confusion.

Patently Prophetic

The present tense used in patents for a chemical synthesis, a medical procedure, and a medical device suggests that the procedures likely had not actually been conducted at the time of filing a patent application.



U.S. Patent No. 3,931,205

2.5 g of 2-(5H-[1]benzopyrano[2,3-b]pyridin-7-yl)acrylic acid is dissolved in 20 ml of 0.5 N aqueous sodium hydroxide solution, and 1 g of Raney nickel is added. The solution is stirred in a hydrogen stream at ordinary pressure and temperature until absorption of 230 ml of hydrogen is attained. The Raney nickel is removed by filtration, and the filtrate is neutralized with hydrochloric acid. The resulting crystalline precipitate is filtered off, washed with water, and recrystallized from aqueous dioxane to give 1.8 g of 2-(5H-[1]benzopyrano[2,3-b]pyridin-7-yl) propionic acid melting at 183°–184°C.

U.S. Patent No. 6,869,610

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 between about 50 units and 200 units of intramuscular botulinum toxin type A. Within 1 to 7 days after neurotoxin administration the patient's pain is substantially alleviated. The duration of significant pain alleviation is from about 2 to about 6 months.

U.S. Patent No. 7,291,497

Each patch [for drawing and sampling 0.1 ml of blood for vancomycin] consists of two parts. ... Micro-needles automatically draw small quantities of blood painlessly. A mechanical actuator inserts and withdraws the needle ... mak[ing] several measurements after the patch is applied. ... Needles are produced photolithographically in molds at [the Stanford Nanofabrication Facility]. ... Blood flows through the micro-needles into the blood reservoir. ...

The impact of clarifying prophetic examples would also be felt outside the legal systems that allow the practice. Scientists previously unable to distinguish or unaware of the distinction between prophetic and real experiments would gain more information and clarity. Investors using patents as a source of information about new technologies would find such information clearer and more useful. And international patent offices wrongly interpreting prophetic examples when tenses are lost in translation would be able to avoid such errors.

What should be done? A simple and effective solution is to require that prophetic examples in new patent applications be clearly labeled, perhaps with a heading such as "hypothetical experiment" or an introductory phrase such as "it is expected that these experiments would provide these results." In the United States, for example, this change could be implemented by the USPTO along with its other rules for patent formatting. The USPTO already requires that prophetic examples be labeled (by avoiding the past tense), so our proposal does not add a labeling requirement; it merely makes an existing requirement more effective. Further, patent drafters should be encouraged to be mindful of clarity and avoid potentially confusing phrases and details.

Just because some patents are not based on actual results does not mean they need to be confusing. Scientists regularly write grant applications in a way that makes clear what preliminary data they have already acquired and what the expected goal of the proposed project is. Perhaps this is an area in which the patent system could learn from the scientific community. ■

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SUPPLEMENTARY MATERIALS

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