



## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

[Docket No.: PTO-P-2021-0020]

### Properly Presenting Prophetic and Working Examples in a Patent Application

**AGENCY:** United States Patent and Trademark Office, Department of Commerce.

**ACTION:** Notice.

**SUMMARY:** The United States Patent and Trademark Office (USPTO) is reminding applicants that patent applications must properly present examples in a manner that clearly distinguishes between prophetic examples that describe predicted experimental results and working examples that report actual experimental results. The distinction must be clear to satisfy the written description and enablement requirements and comply with the applicant's duty of disclosure.

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**SUPPLEMENTARY INFORMATION:** The USPTO is reminding patent applicants of their duty to ensure that patent applications are written in a manner that clearly distinguishes prophetic examples with predicted experimental results from working examples with actual experimental results.

### *Prophetic Versus Working Examples*

Prophetic examples, also called paper examples, are typically used in a patent application to describe reasonably expected future or anticipated results. Prophetic examples describe experiments that have not in fact been performed. Rather, they are presented in a manner that forecasts simulated or predicted results. In contrast, working examples correspond to work performed or experiments conducted that yielded actual results. The Manual of Patent Examining Procedure (MPEP) states that prophetic examples should not be described using the past tense. MPEP 608.01(p), subsection II. Prophetic examples may be written in future or present tense. This drafting technique assists readers in differentiating between actual working examples and prophetic examples.

### *Written Description and Enablement Requirements*

To be complete, the contents of a patent application must include a specification containing a written description of the invention that enables any person skilled in the art or science to which the invention pertains to make and use the invention as of its filing date. *See* 35 U.S.C. 112(a). At least one specific operative embodiment or example of the invention must be set forth. The example(s) and description should be sufficient to justify the scope of the claims. MPEP 608.01(p). The specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). *See* MPEP 2164.02.

The courts have sanctioned the use of prophetic examples to meet the written description and enablement requirements for a patent application. *See, e.g., Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1310 (Fed. Cir. 2015) (“efficacy data are generally not required in a patent application” and “a patentee is not required to provide actual working examples”). A patent application does not need to provide a guarantee that a prophetic example actually works. *Id.* at 1310. “Only a sufficient description enabling a person of ordinary skill in the art to carry out an invention is needed.” *Id.* The courts have further cautioned that the presence of prophetic examples alone should not be the basis for asserting that a specification is not enabling; rather, a lack of operative embodiments and undue experimentation should be determinative. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984).

Disclosed results of tests and examples, whether working or prophetic examples, in a patent application are not normally questioned unless there is a reasonable basis for doing so. However, when prophetic examples are described in a manner that is ambiguous or that implies that the results are actual, the adequacy and accuracy of the disclosure may come into question. If the characterization of the results, when taken in light of the disclosure as a whole, reasonably raises any questions as to whether the results from the examples are actual, the examiner will determine whether to reject the appropriate claims based on an insufficient disclosure under the enablement and/or written description requirements of 35 U.S.C. 112(a) following the guidance in MPEP 2164 and 2163, respectively. When such a rejection(s) is made, the applicant may reply with the results of an actual test or example that has been conducted, or by providing relevant arguments and/or declaration evidence that there is strong reason to believe that the result would be as predicted, being careful not to introduce new matter into the application. MPEP 707.07(l) and 2161-2164.08(c).

*Applicant’s Duty of Disclosure*

Care should be taken to see that inaccurate or misleading statements, inaccurate evidence, or inaccurate experiments are not introduced into the record. MPEP 2004 sets forth best practices to avoid duty of disclosure problems (*see*, in particular, MPEP 2004, item 8). As noted above, prophetic examples should not be described using the past tense. *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367 (Fed. Cir. 2003) (improperly identifying a prophetic example in the past tense validly raises an inequitable conduct issue based on the intent of the inventors in drafting the example in the past tense, when the example, in fact, is prophetic). Knowingly asserting in a patent application that a certain result “was run” or an experiment “was conducted” when, in fact, the experiment was not conducted or the result was not obtained is fraud. *Apotex Inc. v. UCB, Inc.*, 763 F.3d 1354, 1362 (Fed. Cir. 2014) (the inventor “admitted that he never performed the experiments described in the ... patent, and yet he drafted the examples in the specification entirely in past-tense language.”). No results should be represented as actual results unless they have actually been achieved. Distinguishing prophetic examples from working examples in a clear manner will avoid raising issues relating to the applicant’s duty of disclosure.

### *Best Practices*

When drafting a patent application, care must be taken to ensure the proper tense is employed to describe experiments and test results so readers can readily distinguish between actual results and predicted results. Any ambiguities should be resolved so a person having ordinary skill in the art reading the disclosure, including those who may not have the level of skill of the inventor, can rely on the disclosure as an accurate description of experiments that support the patent claim coverage. It is a best practice to label examples as prophetic or otherwise separate them from working examples to avoid ambiguities. Such presentation will help a reader easily distinguish

prophetic examples from working examples with actual experimental results and will enhance the public's ability to rely on the patent disclosure.

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