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Jurisdictional Briefing, US: working examples in patent applications: how much detail to include?

Asaf Batelman, Counsel at Cantor Colburn LLP, provides guidance for preparing working examples.

A common topic of discussion between inventors and a patent practitioner drafting a patent application is how much detail to include in actual performed experimental examples, also known as working examples. While industry inventors may prefer limiting disclosure, such preference for limited disclosure may present significant risks.

Under US law, examples are not required in United States patent applications. See United States Patent and Trademark Office (USPTO) Manual of Patent Examining Procedure (MPEP) § 2164.02 ("Compliance with the enablement requirement … does not turn on whether an example is disclosed."). However, inclusion of examples is often advisable, as examples may help satisfy statutory requirements for patent applications, such as the written description and enablement requirements of 35 U.S.C. § 112(a). On the other hand, in a 2021 Federal Register Notice, the USPTO advised to distinguish between working examples and prophetic examples that describe predicted experimental results. See USPTO Notice "Properly Presenting Prophetic and Working Examples in a Patent Application," 86 FR 35074 (July 1, 2021). Details of a working example are nevertheless helpful and can establish that a skilled artisan could reasonably conclude that the inventor(s) had possession of the claimed invention, thereby satisfying the written description requirement, as well as establish that experimentation needed to practice the claimed invention is not undue or unreasonable, thereby satisfying the enablement requirement.

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Therefore, detailing working examples may provide concise disclosure supporting written description and enablement requirements that are difficult to refute. On the contrary, working examples that are not particularly detailed may not clearly satisfy written description and enablement requirements for the patent application.

Accordingly, from a patent application drafting point of view, a description of the ideal level of detail to be disclosed in working examples often provided to inventors is as much detail as possible and certainly enough detail such that one of ordinary skill in the art could reproduce the working examples. The ability to reproduce working examples can help establish that the inventor(s) had possession of the claimed invention and that experimentation needed to practice the claimed invention is not undue or unreasonable, noting that a patent application must provide adequate guidance to make and use the full scope of the claimed invention.

As the Supreme Court explained in *Amgen Inc. v. Sanofi*, 598 US 594 (2023), a specification may call for a reasonable amount of experimentation to make and use a claimed invention, though what is reasonable will depend upon the nature of the invention. The opinion of the Court held that claims covering potentially millions of antibodies – the science of which remains unpredictable – "sweep much broader" than the

26 working examples of the application and affirmed a ruling that the enablement requirement had not been satisfied.

The amount of guidance or direction needed to enable an invention is often inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. If little is known about the nature of the invention and the art is unpredictable, the specification generally requires more detail as to how to make and use the invention in order to be enabling. On the other hand, the more that is known about the nature of the invention and how to make and use it, the less information needs to be explicitly stated in the specification. See MPEP § 2164.03.

Moreover, applicants often rely on working examples in a patent application to establish nonobviousness of a claimed invention. Arguments directed to nonobviousness based on working examples can be more convincing when the working examples include sufficient detail that one of ordinary skill in the art could reproduce the working examples.

In particular, arguments directed to nonobviousness based on working examples contained in a patent application can hinge on convincing an Examiner that the working examples are commensurate in scope with the claims. This can be significantly more difficult when the level of detail provided in the working examples does not allow for establishment of a clear nexus between the evidence of nonobviousness and the claimed invention. Conversely, if the working examples include sufficient details such that a skilled artisan could reproduce them, stronger arguments can often be constructed to establish a clear nexus between the evidence of nonobviousness and the claimed invention. For example, additional working example details may prevent an Examiner from arguing that non-disclosed details of the working examples preclude a proper comparison to support patentability.

However, other factors, for example, applicant commercial considerations, may influence the level of detail to be disclosed in working examples. Educating applicants about the benefits and drawbacks associated with the level of detail to be disclosed in working examples should help facilitate a mutual understanding with regard to the most appropriate level of detail to address applicant needs, which may vary between applications and applicants.

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Résumé

Asaf Batelman's practice focuses on preparing and prosecuting patent applications. His current areas of focus include engineered materials, polymer synthesis and processing, and display technologies, and he also has experience in a wide range of technical areas, including semiconductor packaging and fabrication, petrochemicals, chemical and gas processing, and battery technologies. Asaf previously served as an in-house patent attorney at a privately held company in the greater Washington, D.C. area, where his work was focused on patent portfolio strategy and licensing relating to carbon nanotube technology, including conductive polymer-carbon nanotube composites.