

# THE DAILY RECORD

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## IPFRONTIERS

# The importance of describing, enabling your invention

A patent is a contract between an individual inventor and the government. Both parties derive benefit — or at least that was the thinking of the framers of the U.S. constitution.

The inventor gets to use the police power of the state to prevent others from making, using or selling her invention for the next 20 years; in return, society learns of her invention thoroughly enough that the public can use the invention freely after the 20 years has elapsed. For this bargain to work to both parties' advantage, the disclosure of the invention must be commensurate in scope with the claims, which are the inventor's deed to the intellectual property.

A patent application must meet several legal requirements developed over the past 219 years to ensure that the bargain is fair. Two intertwined requirements concern providing an effective description of what it is that the inventor has invented. These are commonly called the Enablement requirement and the Written Description requirement.

In exchange for granting inventors a limited monopoly, one legal requirement for a patent claim to be valid is that it be "enabled" — the public is taught how to make and use the invention. Understandably, at the outset of preparing the patent application, inventors and their patent counsel attempt to claim an invention as broadly as the prior art will allow.

However, if the claim is too broad, it risks failing the enablement test and being held invalid. The Court of Appeals for the Federal Circuit has explained that the Enablement requirement is met "when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation."

The case of *Automotive Technologies International, Inc. v. BMW of North America, Inc.* 501 F.3d 1274 (Fed. Cir. 2007), is illustrative. There, the plaintiff's patent covered side-impact sensors used in automotive airbags.

The claim was broad enough to cover both mechanical and

electronic sensors. The patent's specification, on the other hand, described mechanical sensors in detail, however, the electronic sensor was described in broad terms and illustrated in one conceptual figure. The Court of Appeals ruled that the claim was invalid on the grounds that the full scope of the claims covered electronic sensors as well as mechanical sensors, but the specification did not teach a person skilled in the art how to make and use the invention with an electronic sensor (i.e. the claim was not enabled).

As well as meeting the Enablement requirement, every claim in an issued patent must also meet the separate Written Description requirement. To satisfy the Written Description requirement, the patent application needs to be sufficiently detailed, such that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention as of the filing date of the application.

The case of *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 918 (Fed. Cir. 2004), is illustrative. There, plaintiff sued Pfizer based on the fact that Pfizer's multi-billion dollar drug Celebrex was a selective COX-2 inhibitor, and plaintiff had just obtained a patent that covered a method for selectively inhibiting the activity of the protein COX-2 by administering a COX-2 inhibitor. However, the patent application failed to disclose any compounds that could be used to inhibit the activity of the protein. The Court of Appeals held the inventors did not have possession of the claimed invention and that the claims were invalid for failure to satisfy the Written Description requirement.

Although Written Description is a factual inquiry, the requirement focuses on the patent specification itself. Enablement, on the other hand, is a legal inquiry and relates to what the specification teaches a person of ordinary skill. For reasons beyond the scope of this article, some attorneys on the bar had long advocated that the Enablement and Written Description should not be separate legal requirements.

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A recent case, *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.* addressed this issue. The case involved whether Eli Lilly's popular Evista and Xigris drugs infringed Ariad's patent.

Ariad's patent claims recited methods of suppressing NF-kB activity. NF-kB is an important regulator of gene transcription and Ariad's claims were broadly drawn to cover any method, known or unknown, for suppressing NF-kB activity in cells, while providing minimal disclosure for achieving this inhibition. Unlike the University of Rochester case, however (see above), Ariad's patent did identify three classes of molecules potentially capable of suppressing NF-kB activity, albeit the patent specification failed to describe specific molecules capable of accomplishing the inhibition.

In the highly anticipated recent decision *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1341 (Fed. Cir. 2010) (*en banc*), the court upheld its earlier panel decision that Ariad's patent claims were invalid for failure to satisfy the written description requirement, holding that the law contains both a Written Description requirement and an Enablement requirement.

The court had little sympathy for academic researchers, for whom the Written Description requirement is often the most difficult to satisfy, stating that "patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others."

Thus, the Written Description and Enablement requirements demand that the person drafting the patent application describe the invention sufficiently so that someone with ordinary skill in that technology would understand that the inventor possessed the subject matter claimed and, separately, the specification must teach one of ordinary skill in the art how to make and use the invention.

As the law is today, the Written Description requirement places major hurdles for inventors, companies, universities and their counsel in their pursuit of patents covering basic inventions in new technologies. For example, when drafting a broad claim, there remains some ambiguity as to how many examples are required to satisfy the Written Description requirement.

In the Life Sciences, in particular, a patent application requires potentially extensive disclosure to define as many embodiments as possible prior to filing. These hurdles are especially felt by smaller companies and academic institutions because such entities have limited resources, which they cannot devote to the pursuit of multiple similar embodiments, and they face other practical pressures of publishing and commercializing. It remains to be seen whether future legislative action will provide a remedy.

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