

The Patentability Black Hole

ANTONIA L. SEQUEIRA

Fenwick
FENWICK & WEST LLP

An inventor faces a number of significant hurdles and pitfalls in patenting his invention. Having a patent specification providing proper and sufficiently thorough disclosure of the invention being claimed by the patentee can, by itself, be a large hurdle, especially in the biosciences where experimental data is essential. Section 112, first paragraph, of Title 35 of the United States Code sets forth the disclosure requirements that all patentees must meet. This section is commonly interpreted as requiring that a patent specification contain a full written description showing that the inventor was in possession of the claimed invention at the time the patent application was filed (the “written description” requirement) and that a patent specification enable a person of ordinary skill in the relevant field to make and use the invention based on the specification (the “enablement” requirement). See *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Company*, 598 F.3d 1336, 1340 (2010).

While patentees in all fields must meet both of these requirements, the bioscience fields and other “unpredictable arts” are effectively held to a heightened standard of disclosure that can be a challenge to meet. Courts have repeatedly held that “actual” reduction to practice (i.e., experimental data) is not required for patentability. Nonetheless, inventors in the unpredictable arts are routinely required to provide experimental data showing that a compound or method does have the effect claimed (known as a “working example”) in order to satisfy the disclosure requirement for their inventions. *Ariad*, 598 F.3d at 1352. In the race to get a patent application filed as early as possible, however, an inventor may only have time to acquire a limited amount of experimental confirmation of his invention. Commonly, the inventor only possesses in vitro experimental data or possibly in vivo data from animal model experiments, as testing in a human population can take years and millions of

dollars. Yet, with only in vitro experimental data, the USPTO will often reject a claim to an invention that is broad enough to cover in vivo methods. Furthermore, even in vivo animal-model data may not support a claim that encompasses methods involving humans. See USPTO Training Materials for Examining Patent Applications with Respect to 35 U.S.C. Section 112, First Paragraph-Enablement Of Chemical/Biotechnical Applications, Sections III.A.1, III.A.2.c.ii, III.C. Thus, the inventor may only have enough data to provide working examples supporting a narrow, less desirable claim to his invention.

One possible solution to this dilemma is for an inventor to wait to file his patent application until he generates sufficient experimental data to broadly demonstrate working examples of his invention that are sufficient to meet the written description and enablement requirements for the unpredictable arts. The problem is that the inventor will then face issues meeting other patent law requirements, including that his invention be novel and nonobvious. The nonobviousness requirement, in particular, can be a difficult, sometimes insurmountable, hurdle for inventors. Section 103 of Title 35 of the U.S. Code governs the nonobviousness requirement and states that a patent cannot be obtained if, in view of the prior art, the invention would have been obvious at the time of filing to a person having ordinary skill in the art. This hurdle increased with a 2007 U.S. Supreme Court case, *KSR v. Teleflex*, which held that an invention combining familiar elements in a predictable way is likely to be obvious. See *KSR International Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1739 (2007). Yet, in reality, nearly every invention is basically a combination of elements that are known or familiar in some manner. If the various elements of the invention claimed are found across multiple pieces of prior art, those prior art references can be used in combination to invalidate a claimed invention.

Between the disclosure requirements and the nonobviousness requirements, the inventor can thus get stuck in a patent law Catch-22. If the inventor gets his application to the USPTO too early, his patent application may fail because he does not have the data he needs to fully describe his invention so that he can meet written description and enablement. Yet, if he waits for the essential data and so gets to the USPTO any later, his patent application may fail because his invention may be held obvious in view of the ever-expanding prior art, which may grow to contain all of the elements of his invention. So, where is the disconnect between the requirements for an inventor to disclose an invention versus the prior art to render an invention unpatentable? What has created this patentability black hole between proper disclosure and obviousness into which inventors so inevitably fall?

The black hole seems due, at least in part, to the fact that the prior art cited against a patent application is not held to the same disclosure requirements as is the application itself. The prior art need only provide a description disclosing the invention, but does not need to provide experimental evidence or working examples. Moreover, although the prior art is supposed to be enabling, the enablement requirement is lessened and the burden is on the inventor to prove the prior art is not enabled. *Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir.2005). In addition, there is no section 112 written description requirement for prior art references. Thus, while a patent application can be found to lack sufficient written description or enablement of the invention, a prior art reference disclosing even less can be used to show the invention to be not novel or obvious.

Consider, for example, an inventor working in a new biosciences field who files patent claims on a method for inhibiting gene expression using a biological mechanism that the inventor has just discovered in vitro. If the USPTO can find a reference suggesting that this new field is unpredictable, and so in vitro data does not necessarily correlate with results in vivo

(e.g., in humans), the claimed invention would likely be found not enabled or properly described for in vivo uses. Yet, a prior art reference describing the same method, but providing no experimental data, would likely be cited by a Patent Examiner as rendering this same claim obvious. Not only will this inventor in this new field be unable to patent in vivo treatment of humans, but also inventors in later years following—those who do provide actual human clinical data—will likely be unable to patent in vivo treatment of humans. Even though the prior art itself provides no in vivo human data, it still describes that invention. This effectively results in no inventors, even pioneers in a new field, being able to claim the broader method.

Similarly, a claim to a particular type of genetic sequences from 10 to 20 nucleotides in length, filed with a patent specification that only provides experimental data for one 15-nucleotide genetic sequence, might not have sufficient written description or enablement to cover the full scope of that claim. The Patent Examiner will likely require limitation of the claim to only sequences of 15 nucleotides in length or possibly to only the single particular sequence disclosed. Yet, a prior art reference mentioning that sequences of this type can be 1 to 50 nucleotides in length, without actually providing experimental examples, would still likely be cited by the Examiner as rendering this same claim obvious.

How can this patent law paradox for the unpredictable arts be solved? One solution to the black hole problem would be to require the prior art to meet the same standard of enablement and written description as is required of an inventor under section 112. In the predictable arts, for example, a patentability hole also exists between obviousness and disclosure requirements, but in practice it seems to be a much smaller pothole in the patent road, partly because the predictable arts are held to a lower disclosure standard—one closer to the standard applied to the prior art. If the prior art were held to the same disclosure standard as a patent application, the prior art would only render obvious an invention if the

prior art itself also fully enabled and described that invention.

In the meantime, inventors in the unpredictable arts still have to deal with this unfortunate paradox. To help mitigate the patentability black hole, patent practitioners in the unpredictable arts should file patent applications as early as possible and should disclose the invention in as much detail as they can, with an eye towards aggressively including as much experimental data as they can. Filing the application first as a provisional application provides the additional benefit of buying a year of time for gathering more experimental data. As new data are acquired, additional “rolling” provisional applications can be filed to secure additional early priority dates, and all of these applications can be consolidated into a single nonprovisional one year from the first provisional’s filing date. While this approach cannot actually solve the patentability black hole problem, accumulating experimental data that supports the patent claims as thoroughly and as broadly as possible will help to at least limit its consequences.

Antonia L. Sequeira is a senior associate in the Intellectual Property Group of Fenwick & West in Mountain View. Her practice includes analysis, counseling, prosecution, litigation and transactions involving patents and other intellectual property.

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