

Ruling Tightens Requirements to Secure Early-Stage Patents

If your research is aimed at commercializing an innovation, your success likely depends in part on securing a patent fairly early in the discovery process. For decades, principal investigators simply submitted manuscripts as patent applications — and patents often were granted for what amounted to little more than theories.

That has changed with a recent court ruling that patent applications must contain a written description of the invention — meaning you must actually have invented what you’re claiming to have invented. You can’t simply know that it will exist eventually.

“In the past 10 years, many PIs were just filing their manuscripts before speaking at a conference or online publication of their papers,” explains **Sara D. Vinarov**, PhD, JD, a patent attorney in the Chicago office of Quarles & Brady LLP.

“Usually, they had exemplified one or two target compounds that were not representative of a genus that they later wanted to claim in a patent.” Now, though, “PIs will either have to wait until they have an adequate written description before filing an application or they will need to reasonably ‘predict’ what other compounds, peptides or genes could be representative of the genus they want to lay claim to,” says Vinarov.

The good news: That’s not impossible to do.

The case is *Ariad Pharmaceuticals Inc. v. Eli Lilly and Co.*, No. 2008-1248 (Fed. Cir. 2010). In it, the court confirmed that patents must meet both written description and enablement requirements under Title 35 of the United States Code (patent law) §112 (1975), reports the law firm Bracewell & Giuliani LLP on its Web site.

“The inventors discovered a transcription factor called NF-kB [that] assists cells in surviving exposure to harmful extracellular elements,” the law firm notes. “An excess of NF-kB, however, can harm a cell. The inventors concluded that NF-kB could be artificially inhibited; [al]though the patent specification did not include any specific details, the patent was issued with broad claims reciting the step of ‘reducing NF-kB activity.’”

In 2007, a jury found that two of Lilly’s products infringed on that patent, but then an appellate court struck it down “for failure to meet the written description requirement.” On subsequent appeal, the court had to decide if “the patent statute contain[s] a written description requirement separate from an enablement requirement; and if there is a separate written description requirement, what its scope and purpose [are].”

The court, Bracewell & Giuliani note, “rejected the argument that the written description requirement is only for purposes of identifying what is to be enabled.” As far as scope, “the court stated that ‘the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.’ The court refused to issue any bright-line rules.”

Says attorney **Lindsay S. Adams**, with New York firm Day Pitney LLP: “Stated otherwise, PIs need to show they actually invented what they claim is the invention. Wishful thinking won’t cut it. The problem for PIs is they want to publish results as soon as possible; however, the vast majority of the time, the invention has not been flushed out.”

Is there a way to meet the mandates of technology commercialization under the *Ariad* ruling?

“According to the court,” Vinarov points out, “patents ‘should not be awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others,’ but rather to those

who ‘conceive of the complete and final invention.’ Going forward, PIs will need to be cognizant that the written-description requirement remains in force, and that it will remain important to substantiate claims with a representative number of working and/or prophetic examples sufficient to demonstrate that the inventor actually invented the claimed invention.”

Such a determination of possession, she adds, should include:

- a reduction to practice;
- disclosure of drawings or structural chemical formulas;
- sufficient relevant identifying characteristics, such as complete structure, partial structure (functional domains), physical and/or chemical properties or functional characteristics when coupled with a known or disclosed correlation between function and structure;
- method of making the claimed invention;
- level of skill and knowledge in the art; and
- predictability in the art.

Vinarov offers these additional practice points for PIs to consider in response to the *Ariad* ruling:

- There should be claims of varying scope, including at least one “picture claim” directed to each explicitly disclosed embodiment. If broader generic claims are desired, disclose as many multiple detailed specific embodiments as possible. Clearly depict the claimed invention in drawings and/or sequence listings and/or descriptions of method steps and step components. If biological matter is claimed, make a deposit of said matter.
- Establish a checklist against which claims are compared for at least description, but preferably description and examples of all claimed elements, method steps and step components not known in the art.
- Consider filing provisional applications on initial findings and follow up with additional provisional applications with broader claims supported by additional disclosure so as to form an overlapping application “portfolio” that serves as the basis for non-provisional applications (rather than attempting to describe and claim everything in one application).