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Legal News

Case poised to reshape patent law

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Boston attorney Lee C. Bromberg's $65 million patent verdict in Ariad Pharmaceuticals Inc. v. Eli Lilly and Co. has had a wild ride since his 2006 victory.

This spring, the verdict was overturned by the Federal Circuit. But in August, in response to a petition from Ariad's appellate lawyers, the court granted a rare en banc rehearing of its decision.

Now the case has become the focal point for a much-litigated issue in patent law: whether or not patents must include a "written description" of an invention in order to be valid.

"Written description is a prominent issue, so it's not a surprise for it to be hotly contested." said Bromberg. "But for it to emerge where the whole Federal Circuit is going to address it — that's pretty remarkable."

Historically, complicated patents, particularly in the field of biotech, have been required to contain written descriptions of the product and its underlying technology. But now the Federal Circuit is considering whether such a requirement really exists.

According to patent lawyers watching from the sidelines, the stakes are high.

Milwaukee patent attorney Timothy E. Newholm likened the case to a "David vs. Goliath" match-up. He suggested that big companies like Eli Lilly prefer enforcement of the written description rule to avoid giving rivals a broader spectrum of potential claims.

"The concern is that companies can see what's coming out on the market and couch language on their application to cover what other companies are doing, despite the fact that it is not clear at the time the inventor has possession of what was claimed," he said.

If the written description requirement were eliminated, smaller biotech companies and universities could succeed with broader claims, said Foley & Lardner patent attorney J.P. Meara.

But if the court rules against Ariad, Meara said smaller companies and universities will "continue to be at a disadvantage compared to larger companies."

Strengthening the requirement could create an onerous burden for inventors, agreed Michael J. Meurer, an IP professor at Boston University School of Law.

But eliminating the requirement could allow inventors to patent products they don't actually know how to make, he cautioned.

To Meurer, the debate is really about determining when an inventor's work is done.

"What's at stake in the business world is, 'How far do we need to get [in development] before we can get our patent?'" he said.

History of case

In 2002, the day it received its patent for methods of inhibiting the activity of a specific kind of molecule in cells, Ariad sued Eli Lilly, a fellow pharmaceutical company, in U.S. District Court in Massachusetts.

Ariad alleged that several of Lilly's drugs inhibited the same molecule's activity, and therefore infringed its patent.

After a 14-day trial in April 2006, a jury found that two of Lilly's drugs infringed on Ariad's patent and awarded Ariad $65 million.

Lilly moved for judgment as a matter of law, arguing, among other claims, that there was a lack of written description in Ariad's patent.

After a bench trial, U.S. District Court Judge Rya W. Zobel denied the motion. Lilly appealed, and in April 2009, the Federal Circuit overturned Zobel's decision, finding that "the jury lacked substantial evidence for its verdict that the asserted claims were supported by adequate written description."

Ariad filed a petition for rehearing en banc, arguing that the court's interpretation of "written description" was in error. On Aug. 21, the full court ruled that Ariad's argument warranted reconsideration. It granted the en banc petition and vacated its own opinion. It then ordered both parties to prepare arguments about whether 35 U.S.C. §112 contains a written description requirement, and, if so, what the "scope and purpose" of that requirement is.

The decision to rehear the case attracted attention from around the country, including over a dozen amicus briefs. On Dec. 7, the issue was argued before the full panel. A ruling is expected in 2010.

Simple products not affected

In his brief, Eli Lilly's attorney, Howard W. Levine of Finnegan, Henderson, Farabow, Garrett & Dunner in Washington D.C., argued that Ariad had audaciously claimed all methods of inhibiting a certain kind of molecule's activity in a cell, even though it had not actually invented any means of doing so.

The written description requirement prevents "preemption of great swaths of fertile research ground by those whose ideas have not yet advanced to the point of a full and complete conception," he wrote.

The argument that it is impossible to see whether the inventors of a patent are really in possession of the invention unless they accompany it with a detailed explanation is a favorite of those who support the written description requirement, Bromberg said.

But Meurer said the argument is problematic, because while courts apply the written description requirement to biotech and chemical patents, patents for simpler products, such as electronic appliances, can be submitted before the product is completed.

"If I invented a new DVR, no one would have ever expected me to have actually made the DVR by the time I filed my application," he said. "That's another reason why the biotech patent people really hate [the written description requirement]. They feel like they're being picked on, like they're being singled out."

Despite this, Newholm, of Boyle Fredrickson SC, (http://www.boylefred.com/) does not ultimately expect the Federal Circuit to eliminate the written description requirement.

"This issue is very well entrenched in case law," he noted, "and from a public policy standpoint, there is a lot to be said for some level of notice."