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Fed. Circ. Written Description Scrutiny Has Lessons For Attys

By **Ryan Davis**

Law360 (December 20, 2021, 11:12 AM EST) -- Two recent Federal Circuit decisions finding drug patents invalid for not adequately describing the claimed invention highlight how important it is to review patent applications during research and development to ensure they cover what ends up being the key invention, attorneys say.

In decisions in late November, the appeals court found patents for Indivior's **opioid addiction treatment** Suboxone and Biogen's **multiple sclerosis drug** Tecfidera invalid for not meeting the requirement that patents have a written description showing the inventor possessed the invention as of the filing date.

The court said that while the patent claims identified a dosage or a numerical range of a chemical that would be effective, those were not supported by the written description of the invention in the patent application. In the Indivior case, the Federal Circuit said the law requires "a statement of an invention, not an invitation to go on a hunting expedition."

The decisions illustrate the problems that can arise when research performed after an application is filed brings more certainty about what is effective than is conveyed by broader statements in the application, said Bryan Wheelock of Harness IP.

"It's not a matter of staking out a claim and going prospecting: I figured out that someplace in here, there's something good, and I'm going to go find it," he said. "What they're looking for is more like a treasure map, where X marks the spot."

As research and development progresses following a patent application, inventors and attorneys always have to keep in mind whether the new direction being pursued is covered by the initial filing, and if not, take steps to address it, possibly by filing a new application, said Jeffrey McIntyre of Oblon McClelland Maier & Neustadt LLP.

"For me, it reinforces something that should be in people's minds generally anyway, which is making sure that your current R&D is covered by your application," he said. "If you're not pretty sure that your previous application covers it, you need to consider filing something new, particularly in view of these new written description cases. That's the most cautionary note."

In the Indivior case, the patent claims described the invention as a film, about 40% to 60% of which is a water-soluble polymeric matrix. The Federal Circuit said that specific range was not found in the original application, since it instead used phrases like "at least 25%," which the court found did not convey that the inventor knew the 40% to 60% range would be effective.

In the Biogen case, the patent claims describe treating MS with 480 mg of a specific drug, but the Federal Circuit said that dose was not adequately described. While a "single passing reference" to that number was included in the written description, it was a part of a wide range of doses that didn't indicate that 480 mg was the effective dose, the court found.

Written description cases turn on highly fact-specific details like that, but the takeaway for attorneys and inventors is that the Federal Circuit is paying very close attention to ensuring that the patent discloses that the inventor knew at the time of the application what the working invention was.

"Attorneys can't just take what the client says. We have to investigate it, prod them into being more specific and keep a fire lit under them: 'Look, this is a broad range. You need to get your work done really fast to actually have an invention here,'" Wheelock said.

Patent applications need to be filed quickly, but "until you have that treasure map where it actually works, neither the inventor's nor the attorney's work is done," he said.

Nika Aldrich of Schwabe Williamson & Wyatt PC said that the Biogen ruling, in particular, stood out for him because the 480 mg figure was in fact mentioned in the written description, yet the Federal Circuit still ruled that the patent was invalid because it was just one of several other dosages that were mentioned.

"Even though the number was expressly stated, the court agreed that it wasn't enough here. I've never seen that happen before, though I'm not saying it hasn't," he said, describing the decision as "the outer boundary of finding a patent invalid based on a lack of written description."

The court's stringent application of the written description requirement "is vulnerable to some sort of further review, and I would expect that there will be a petition for rehearing," Aldrich said.

McIntyre said it wasn't clear to him that the Biogen decision was anomalous, since the Federal Circuit was reviewing a lower court decision under a standard that substantially defers to the findings of fact below. He also noted that Biogen added an inventor to the patent later in the process, suggesting that it may not have possessed the invention at the time of the original filing.

"Facts can be interpreted in different ways, which is another reason why there can't be any 100% rules to follow when making sure to satisfy the written description requirement," other than to make sure the patent claims and the written description cover what really works, he said.

McIntyre said that the most effective formulation may not become apparent until years later, which is when the applicant has to take a clear-eyed look at whether the original application has adequate support. Filing a new application may be necessary to avoid the risk of being issued a patent rendered invalid for lacking an adequate written description.

While both decisions applied what the Patent Act says is needed to comply with the written description requirement, Wheelock said he questioned the premise that a patent with an inadequate written description should be rendered entirely invalid, since it does describe something.

"It ought to be that your claim can only cover what you have a written description of," he said. "If you described something, shouldn't you get it? We shouldn't let a drafting mistake completely wipe out the real invention just because you didn't meet this technicality. I don't know what to do about that. We'd have to revise the statute because this is the way it's been interpreted for a long time."

The cases are Indivior UK Ltd. v. Dr. Reddy's Laboratories SA, case number 20-2073, and Biogen International GmbH v. Mylan Pharmaceuticals Inc., case number 20-1933, both in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Brian Baresch and Alyssa Miller.
