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The Balance Between Obviousness and Written Description — Lessons Learned from Recent Decisions

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KEY POINTS

- Summarizes the Federal Circuit case of *Nuvo Pharms. v. Dr. Reddy's Labs*., in which the Federal Circuit invalidated Nuvo Pharmaceuticals' patent, holding that Nuvo's disclosure of the drug's effectiveness was necessary for a written description requirement but was not met by the specification.
- Summarizes the Northern District of West Virginia case of *Biogen Intn'l GMBH et al. v. Mylan Pharms. Inc*., in which the district court invalidated Biogen's patent for lack of written description, citing *inter alia* the *Nuvo* decision and giving insight into how district courts will apply the written description requirement.
- Both cases suggest that if the core functionality of a claimed invention would not be expected by a person of ordinary skill in the art (POSA), and if the specification does not provide sufficient information to alter the expectation, then the claims are at risk of failing the written description requirement.

"The written description requirement of 35 U.S.C. § 112, ¶ 1 provides, in pertinent part, that '[t]he specification shall contain a written description of the invention.' That requirement is satisfied only if the inventor 'convey[s] with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and demonstrate[s] that by disclosure in the specification of the patent.' 'The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention.'" *Nuvo Pharms. v. Dr. Reddy's Labs*., 923 F.3d 1368, 1376-77 (Fed. Cir. 2019).

In *Nuvo*, the claims required that a portion of the tablet comprising uncoated proton pump inhibitor (PPI) had to be effective in raising gastric pH to at least 3.5. To avoid an obviousness challenge, Nuvo insisted that a person of ordinary skill in the art (POSA) would not have expected uncoated PPIs to be effective. Indeed, that was explicitly stated in the specification itself. Nuvo argued, though, that it still met the written description because every limitation of the asserted claims was found in the specification. The Federal Circuit held that such *ipsis verbis* disclosure was, in these circumstances, sufficient to demonstrate possession of the invention. *Id*. at 1380. The court recognized that experimental data demonstrating effectiveness is not always required. *Id*. It further recognized that written description does not require theory or explanation of how, or why, a claimed composition will be effective. Yet, the Federal Circuit still invalidated the patent.

Analytically, it first found that a POSA at the time would not have believed, based on the prior art, that an uncoated PPI would be effective in controlling gastric pH. *Id*. at 1380. Then, it considered whether the specification evidenced possession of that unexpected result. It found that "In light of the fact that the specification provides nothing more than the mere claim that uncoated PPI might work, even though persons of ordinary skill in the art would not have thought it would work, the specification is fatally flawed. It does not demonstrate that the inventor possessed more than a mere wish or hope that uncoated PPI would work, and thus it does not demonstrate that [the inventor] actually invented what he claimed." *Id*. at 1381. In so finding, it considered the testimony of the inventor. In a difficult application of the written description requirement for patentees, it held that while inventor testimony cannot establish written description support where none exists in the four corners of the specification, it can illuminate the absence of critical description. *Id*.

In *Nuvo*, the court distinguished previous cases where adequate written description was found. Nuvo had cited *Alcon Research Ltd. v. Barr Labs., Inc.*, that it was enough that the patent teach making and using the claimed combination. However, the Federal Circuit highlighted the data in *Alcon* and the corresponding lack of any data in the specification at issue to distinguish this case. *Id*. at 1382. Nuvo also argued that the specification's disclosure of the formulation itself inherently met the written description requirement under *Allergan, Inc. v. Sandoz Inc*. 796 F.3d 1293, 1308 (Fed. Cir. 2015). However, the Federal Circuit noted that in *Allergan* the specification referenced experimental results for similar drug formulations demonstrating a trend toward effectiveness, and that the parties in *Allergan* did not dispute that the specification's disclosed formulation inherently possessed the claimed properties. Id. It thus distinguished the instant case, where the parties hotly disputed whether the disclosed composition was in fact effective.

In the wake of *Nuvo*, it was unclear whether the decision was a one-off based on the specific facts of the case, or the beginning of a trend. In *Biogen v. Mylan*, the district court's decision showed that *Nuvo* has teeth. *Biogen Intn'l GMBH et al. v. Mylan Pharms. Inc*., 1:17-cv-116 (N.D. W. Va. Jun. 18, 2020). The *Mylan* court applied reasoning akin to that of *Nuvo* to invalidate Biogen's key '514 patent covering its multi-billion dollar Tecfidera product.

In *Mylan*, the patent at issue similarly had an efficacy component — 480 mg/day of dimethyl fumarate (DMF) for the therapeutically effective treatment of multiple sclerosis (MS). During prosecution of the patent in response to an obviousness rejection, Biogen asserted that 480 mg/day had unexpected efficacy. This position was reasserted by Biogen in multiple different forums in defending against obviousness attacks to the patent — in multiple *inter* partes review (IPR) proceedings, in district court litigation against other generic drug manufacturers in Delaware, and in the Mylan action. Specifically, Biogen asserted that a prior art reference summarizing a Phase II clinical trial demonstrated that 720 mg/day was effective, but that lower doses of 120 mg/day and 360 mg/day were not. *Id*. As a result, a POSA would not expect that 480 mg/day would be effective.

Mylan asserted the '514 patent failed to meet § 112's written description requirement. In determining the issue, the district court focused on whether the disclosure allows a person of skill in the art to recognize that the patentee invented what is claimed. *Mylan*, at § IIIA. That recognition must be demonstrated by the specification; actual possession or reduction to practice outside the specification is not sufficient. *Id*. (citing *Ariad Pharm., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1351 (Fed. Cir. 2010)) (*en banc*). The district court essentially reasoned that coming into the '514 specification, based on the Phase II clinical trial data, a POSA would expect 720 mg/day to have efficacy but would not expect lower doses. The court then focused on the disclosures in the specification to determine if there was a showing that 480 mg/day would be effective for treating MS. It found that the disclosures in the specification regarding dosing were not sufficiently related to MS to allow a POSA to conclude that the inventors possessed an effective 480 mg/day dose. The court further found that the examples with data in the patent were not sufficient to establish efficacy of DMF at a specific dose. In so doing, like the Federal Circuit in *Nuvo*, the court credited inventor Dr. Lukashev's testimony that the disclosure in the patent did not speak to clinical efficacy. And the testimony of another inventor, Dr. Oneil, was not sufficient because his possession of the invention was not evidenced in the

patent specification but instead was based, at least in part, on his knowledge of confidential information from a partner that was not disclosed in the specification.

Together, these cases suggest a significant application of the written description requirement: if the core functionality of the claimed invention would not be expected by a POSA, and the specification does not provide sufficient information to alter that expectation, then the claims are at risk of failing the written description requirement.

In practice, this requirement creates a tricky proposition for patentees. Often, the patentee is forced to establish the first element of the written description defense — that the core functionality of the invention would not be expected by a POSA — to defeat an obviousness challenge. *See*, *e.g.*, *Mylan*, at § IIID3 ("At every stage of this case and the related IPR proceeding, Biogen defended against Mylan's obviousness challenge by insisting that a POSA would not have expected a 480mg/day dose of DMF to be efficacious in treating MS."). Now, under the rubric of *Nuvo* and *Mylan*, a patentee arguing an unexpected result must be prepared to identify support in the specification demonstrating the unexpected result. *See Nuvo* at 1379 ("[T]he specification would still need to provide support for the notion that uncoated PPI is effective").

For more information, please contact Katten's Intellectual Property practice or any of the following attorneys:

Chris B. Ferenc
+1.202.625.3647
chris.ferenc@katten.com

Deepro Mukerjee
+1.212.940.8552
deepro.mukerjee@katten.com

Lance A. Soderstrom
+1.212.940.6330
lance.soderstrom@katten.com

Brian Sodikoff
+1.312.902.5462
brian.sodikoff@katten.com

Jillian M. Schurr
+1.312.902.5468
jillian.schurr@katten.com