GT GreenbergTraurig

Written Description After 'Biogen': Make Sure You Show Possession

Be mindful of this decision when drafting patent applications. Merely mentioning a claim element once may be an insufficient written description if it is not clear that the inventor was in "possession" of the claimed subject matter.

By James J. DeCarlo and Jose R. Vento| April 29, 2022 | New Jersey Law Journal

In yet another appellate case with spirited dissents, the Court of Appeals for the Federal Circuit (CAFC) continues to reveal differences of opinion among members of the court in how precedent and the use of extrinsic evidence should guide current decisions. In the recent case of *Biogen International GmbH v. Mylan Pharmaceuticals*, which dealt with the adequacy of a patent's written description under 35 USC §112, there were strong dissents in the panel decision and in the court's denial of requests for a panel rehearing and rehearing en banc.

By way of background, Mylan filed an Abbreviated New Drug Application (ANDA) with the FDA under the Hatch-Waxman Act (the Act) to manufacture, use, and market a generic dimethyl fumarate (DMF) drug for the treatment of multiple sclerosis (MS). Biogen owned U.S. Patent 8,399,514 directed to a method of treating MS using a DMF-based drug. Biogen filed suit for patent infringement against Mylan under the Act, asserting several patents including the '514 Patent. Mylan counterclaimed seeking a declaratory judgment of invalidity.

At trial, Mylan asserted that the '514 Patent was invalid for lack of written description because (1) a person skilled in the art (POSA) "would not have expected the claimed invention—a 480mg/day dose of DMF—to effectively treat MS," and (2) that "selectively-plucked disclosures in the specification of the '514 Patent fails to sufficiently describe the claimed invention." Biogen argued, inter alia, that Mylan mistakenly relied on irrelevant evidence of obviousness, and maintained that the specification provided adequate written description for the claim elements.

Representative claim 1 recited a method "of treating a subject in need of treatment for multiple sclerosis comprising … (a) a therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof … wherein the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof is about 480 mg per day." The Specification of the '514 Patent apparently only mentioned a therapeutically effective amount of about 480 mg per day once. Paragraph 177 recited, in relevant part:

For example, an effective dose of DMF or MM[F] to be administered to a subject orally can be from about 0.1 g to 1 g per pay, 200 mg to about 800 mg per day (e.g., from about 240 mg to about 720 mg per day; *or from about 480 mg* to about 720 mg per day; or about 720 mg per day). For example, the 720 mg per day may be administered in separate administrations of 2, 3, 4, or 6 equal doses (emphasis added).

The district court found Mylan's arguments persuasive and held that Mylan had established by clear and convincing evidence that the asserted claims of the '514 Patent were invalid for lack of written description under 35 U.S.C. §112. Specifically, the district court found that "the specification did not reasonably convey to a POSA that the '514 Patent inventors had 'actually invented' a method of treating MS with a therapeutically effective dose of DMF480."

On appeal the CAFC affirmed, finding that "a skilled artisan would not have recognized, based on the single passing reference to a DMF480 dose in the disclosure that DMF480 would have been efficacious in the treatment of MS, particularly because the specification's only reference to DMF480 was part of a wide DMF-dosage range and not listed as an independent therapeutically efficacious dose." The panel majority focused on the fact that at the time of filing, Biogen did not have the benefit of the results of a Phase III clinical trial of the DMF480 dose and, therefore, "Biogen did not possess an invention directed to the specific use of a therapeutically effective DMF480 dose for the treatment of MS as of 2007." The CAFC emphasized that the single reference to DMF480 weighed against Biogen in light of the repeated mentions of other doses. The CAFC was unreceptive to Biogen's argument that an artisan "would be drawn to the DMF480 dose because it was 'anchored' to the effective DMF720 dose."

Now former Judge O'Malley dissented, arguing, inter alia, that the "district court's failure to distinguish therapeutic effects and clinical efficacy also led it to conflate concepts of obviousness and written description." Her dissent noted that "the district court's refusal to acknowledge the difference between therapeutic and clinical effects evinces a fundamental misunderstanding of what is claimed—and, thus, what requires written description support." The conflation of therapeutic and clinical efficacy, Judge O'Malley argued, caused the district court to erroneously apply the "blaze marks" precedent (referring to prior cases that require a patent's specification to contain markers or a roadmap to the patented invention) by finding that "the '514 patent does not contain enough 'blaze marks' to direct a POSA toward MS treatment" as MS was only one disease "among a slew of competing possibilities." Her dissent further argued that the "blaze marks" precedent did not "apply to the claimed DMF480 dose because [the specification] does not provide a laundry list disclosure of therapeutically effective doses. Despite providing a varying degree of ranges, [the specification] begins one such range with the *exact* DMF480 dose that is claimed."

Biogen sought a panel rehearing and rehearing en banc, but the CAFC denied the petition. In a spirited dissent, Judge Lourie, joined by Chief Judge Moore and Judge Newman, argued that, in upholding the circuit court's determination of invalidity, the panel "imports extraneous considerations into the written description analysis and blurs the boundaries between the written description requirement and the other statutory requirements for patentability." The dissent outlined four main points of error by the panel majority: (1) an emphasis on unclaimed disclosures in the specification, (2) imposing a heightened burden on the patentee to show that the specification proves efficacy, (3) importing legal factors from other patentability requirements, and (4) considering irrelevant extrinsic evidence.

To the first point, the dissent argued that: (i) the panel majority had engaged in irrelevant comparisons between the amount of disclosure of the claimed subject matter versus the unclaimed subject matter; (ii) that this implied that a patent fails the written description requirement of 35 U.S.C. §112 when it contains too much disclosure beyond the claimed invention, which is incorrect; and (iii) that a patentee must disclose the claimed subject matter more than once, which is also incorrect, so that "a court may arbitrarily count the number of times the claimed subject matter is disclosed in the specification relative to the number of times unclaimed subject matter is disclosed, which is incorrect."

On the second point, the dissent argued that the panel majority's decision erroneously imposed "a burden of proof on the patentee to show that the specification proves the efficacy of the claimed pharmaceutical composition" contrary to the court's precedent. On this point the court has held that "it is unnecessary to prove that a claimed pharmaceutical compound actually achieves a certain result." The district court found, and the panel majority affirmed, that the '524 patent failed the written description requirement because "nothing in [the specification] teaches a [person of ordinary skill in the art] that a 480 mg/day dose of DMF [] is therapeutically effective for treating MS." Yet, the dissent argued, "[t]he claims specify precisely the amount that they claim would be 'therapeutically effective,' namely, '480 mg per day' … [a]nd the patent specification leaves nothing for the skilled artisan to deduce; it expressly states that 480 mg per day is an effective amount."

On the third and fourth points, the dissent took issue with the district court's importation of extraneous legal considerations into the written description analysis and what it viewed as erroneous considerations of extrinsic evidence, stating that while "extrinsic evidence regarding how a person of ordinary skill would understand what is disclosed in the patent specification can, at times, be relevant … extrinsic evidence should be used only as part of an objective inquiry into what is meant by the disclosure in the patent specification." Further, "where the disclosure in a patent's specification plainly corresponds to what is claimed, extrinsic evidence should not be used to cast doubt on the meaning of what is disclosed." In the dissent's opinion the description of the disputed claim element was not in question, "the '514 patent contains a disclosure that corresponds to what is claimed—treatment of multiple sclerosis with 480 mg per day of DMF."

While spirited dissents might make good reading (and possibly provide fuel for later arguments), the fact is the panel majority's decision stands—merely mentioning a claim element once can be found an insufficient written description if it is not clear from the rest of the specification that the inventor was in "possession" of the claimed subject matter. As the panel majority noted, to establish possession "[a] precise definition of the invention is pivotal." Practitioners should be mindful of this decision when drafting their patent applications.

About the Authors:

James J. DeCarlo is a shareholder in Greenberg Traurig's Intellectual Property and Technology Practice. **Jose R. Vento** is an associate at Greenberg Traurig and a member of the Intellectual Property & Technology Practice.