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Fed. Circ. Clarifies Law For Functional Antibody Claims

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On Oct. 5, the Federal Circuit issued a decision in Amgen Inc. v. Sanofi (No. 2017-1480), a closely watched case involving functional antibody claims, claims that define antibodies not by their sequence or structure but by their function, such as the ability to bind a biological target. The Federal Circuit held that although written description and enablement of such claims are assessed at the priority date, post-priority-date evidence is relevant to determining the breadth of the functional claims and whether antibodies representative of the claimed genus have been disclosed. The court also held that the disclosure of a new therapeutic target does not provide a written description of the antibodies that may bind and inhibit that target, even if it is routine to make such antibodies.[1] These holdings have important ramifications for the biotech industry.

Post-Priority-Date Evidence

On appeal, Sanofi and Regeneron and their amici argued that post-priority-date evidence, such as the antibody they developed as well as third party antibodies, provide real world evidence as to the breadth of the functional antibody claims asserted by Amgen as well as whether the antibodies disclosed in the patent were representative of antibodies covered by the functional claims. The evidence showed that Sanofi's and Regeneron's antibody as well as those of third parties were highly different from the antibodies disclosed by Amgen. The district court excluded the post-priority evidence since it "did not illuminate the state of the art at the time of filing."[2] Sanofi and Regeneron argued on appeal that without such evidence, including their own commercial antibody with its unique sequence and structure, their written description and enablement challenge was effectively gutted: it was Hamlet without the prince.

The Federal Circuit agreed with Sanofi and Regeneron. The court held that the district court erred as a matter of law in excluding evidence that postdated the priority date. Judge Sharon Prost, writing for the court, explained that evidence showing that species disclosed in a patent are not representative of a claimed genus is in fact likely to postdate the priority date:

Evidence showing that a claimed genus does not disclose a representative number of species may include evidence of species that fall within the claimed genus but are not disclosed by the patent, and

evidence of such species is likely to postdate the priority date. If such evidence predated the priority date, it might well anticipate the claimed genus.[3]

The Federal Circuit noted that Sanofi's and Regeneron's evidence was not intended to "illuminate the state of the art on the priority date but to show that the patent purportedly did not disclose a representative number of species."[4] The court stated that as a "logical matter" the excluded evidence is relevant to the representativeness question and is admissible as it can "reasonably bear on whether a patents 'fails to disclose a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus.'"[5]

The court elaborated that "the common-sense logic of admissibility" was supported by its prior decision in AbbVie Deutschland GmbH & Co. v. Janssen Biotech Inc., 759 F.3d 1285 (Fed. Cir. 2014). In that case, Centocor stipulated to infringement of a functional antibody claim and relied on the accused product, its own antibody, to show that the antibodies disclosed in the patents were not representative of the claimed genus. The sequence and structure of Centocor's antibody differed considerably from that of the antibodies in the patents. Both the district court and the Federal Circuit "relied heavily" on Centocor's antibody in upholding the invalidity verdict without regard to whether the antibody postdated the priority date of the patents.[6]

The court also pointed out that the district court erred in relying on In re Hogan, 559 F.2d 595 (CCPA 1977) to prohibit the use of post-priority-date evidence to assess the representativeness of the disclosed antibodies. The court explained that In re Hogan does not address that question; instead, it prohibits the use of post-priority-date evidence to show that a claimed genus is not enabled due to a change in the state of the art.[7] The court stressed that "the use of post-priority-date evidence to show that a patent does not disclose a representative number of species of the claimed genus is proper" and that it was legal error for the district court to exclude Sanofi's and Regeneron's evidence, both their own antibody — the accused product in the case — as well as the other post-priority-date antibodies.[8] The court ordered a new trial on written description on that basis.

The court also ordered a new trial on enablement so that Sanofi's and Regeneron's post-filing-date evidence could be considered. Sanofi and Regeneron sought to introduce evidence to show that Amgen experienced difficulties after the priority date in making antibodies within the scope of the claims. The court held that "[s]uch evidence could have been relevant to determining if the claims were enabled as of the priority date and should not have been excluded simply because it post-dated the claims' priority date."[9]

Newly Characterized Antigen Test

The Federal Circuit also addressed the so-called "newly characterized antigen test" for functional antibody claims. The test is set forth in the instruction that the district court provided to the jury:

In the case of a claim to antibodies, the correlation between structure and function may also be satisfied by the disclosure of a newly characterized antigen by its structure, formula, chemical name or physical properties if you find that the level of skill and knowledge in the art of antibodies at the time of filing was such that the production of antibodies against such an antigen was conventional or routine.[10]

According to the instruction, written description for antibodies is satisfied by disclosure of a newly characterized antigen (a target that the antibody binds) combined with the ability to make antibodies.

The court held that "the district court's instruction is not legally sound and is not based on any binding precedent."[11]

The court explained that the instruction traces its way back to the U.S. Patent and Trademark Office's guidance, which the court first discussed in Enzo Biochem Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002):

[T]he PTO would find compliance with 112, [¶] 1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of the well-defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature.[12]

However, the court explained that Enzo did not involve antibodies and that its discussion of the PTO's guidance for antibodies is dicta. The court noted that its discussion of the PTO's guidance in Noelle v. Lederman, 355 F.3d 1343 (Fed. Cir. 2004) also was dicta since the patent at issue in Noelle did not disclose the structure of the antibody or the antigen.[13]

The court explained that it revisited Enzo, Noelle and the PTO's guidance in Centocor Ortho Biotech Inc. v. Abbott Labs., 636 F.3d 1341 (Fed. Cir. 2011), the only prior case where the court considered the newly characterized antigen test in detail. In Centocor, the Federal Circuit held that the antibody claims at issue were invalid for lack of written description even though the patent disclosed the antigen. Judge Prost, who also wrote for the court in Centocor, explained that in that case the court questioned "the propriety of the 'newly characterized antigen' test and concluded that instead of analogizing the antibody-antigen relationship to a 'key in a lock,'" it was more apt to analogize it to a lock and a "ring with a million keys on it."[14]

The Federal Circuit then held that the fundamental problem with the district court's jury instruction is that it dispensed with the requirement for a written description of the invention, instead relying on a separate requirement, enablement. The court explained that "[a] jury would naturally understand the instruction to permit it to deem any antibody within the claim adequately described merely because the antibody could easily be 'produc[ed]' (and, implicitly, used as an antibody)."[15] By conflating written description with enablement, the district court's instruction was improper and contrary to precedent.

The court stressed that an adequate written description must contain enough information about "the actual makeup of the claimed products," not merely how to make and use the claimed products.[16] It also explained that the "'newly characterized antigen' test flouts basic legal principles of the written description requirement" since it "allows patentees to claim antibodies by describing something that is not the invention, i.e., the antigen."[17] According to the court, in doing so, the test "contradicts the statutory 'quid pro quo' of the patent system where 'one describes an invention, and if the law's other requirements are met, one obtains a patent.'" [18] In casting yet a further stone at the discredited test, the court stated that it eschews exceptions to the written description requirement based on the particular subject matter of the claims and that Congress also has not created a special written description requirement for antibodies.

Conclusion

The court's decision undoubtedly will have significant impact on how written description and enablement are litigated for genus claims in general and for functional antibody claims in particular. The decision provides clarity on the proper use of post-priority-date evidence for such claims. Post-priority-

date evidence will figure more prominently in challenges to written description and enablement of genus claims. The decision also makes clear that the disclosure of a target of interest, an antigen, combined with the ability to produce antibodies is not sufficient to satisfy the written description requirement. Antibodies that bind the target and are representative of the scope of the claims must be disclosed. The representativeness of the disclosed antibodies is key to providing a description of the claims. Disclosing a large number of highly similar antibodies may not suffice.[19]

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[1] The court also decided important questions concerning the reach of Dynamic Drinkware LLC v. Nat'l Graphics, Inc., 800 F.3d 1375 (Fed. Cir. 2015) to published patent applications and the proper application of the standard for injunctive relief. These holdings, of interest in their own right, are not addressed in this article.

[2] Amgen, slip op. at 7.

[3] Amgen, slip op. at 8-9.

[4] Id. at 9.

[5] Id. (quoting Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc)).

[6] Id.

[7] Id. at 11.

[8] Id.

[9] Id. at 11-12.

[10] Id. at 12.

[11] Id. at 13.

[12] Id. at 13-14 (quoting Enzo, 323 F.3d at 960).

[13] Id. at 14.

[14] Id. at 15 (quoting Centocor, 636 F.3d at 1352).

[15] Id.

[16] Id. at 17.

[17] Id. at 18.

[18] Id. (quoting Ariad, 598 F.3d at 1345).

[19] See AbbVie, 759 F.3d at 1300 (antibody claims invalid for lack of written description since the disclosed antibodies were large in number but similar to each other).