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Following a jury trial, the District Court in *Amgen Inc. v. Sanofi*[1] entered a final judgment finding Amgen's[2] U.S. Patent Nos. 8,829,165 and 8,859,741 not invalid[3] and permanently enjoining sales of Sanofi's Praluent® alirocumab product. On October 5, 2017, the Federal Circuit[4] reversed and remanded for a new trial on written description and enablement, finding that the District Court wrongly excluded Sanofi's evidence of written description and enablement that postdated the priority date of the patents in suit, and that the District Court's jury instruction concerning written description was improper. The Federal Circuit also: (1) affirmed the District Court's denial of Sanofi's motion for a judgment as a matter of law (JMOL) of lack of written description and enablement; (2) affirmed the District Court's decision granting Amgen JMOL of non-obviousness; and (3) vacated and remanded the District Court's grant of a permanent injunction.

The Patents in Suit

The patents in suit share the same specification, share a priority date of January 9, 2008, and claim a genus of antibodies that reduce LDL (low-density lipoprotein, i.e., bad) cholesterol. These antibodies bind to specific amino acid residues on PCSK9,[5] a protein that occurs naturally in the body and binds to — and ultimately destroys — liver cell receptors responsible for removing LDL cholesterol. By binding to PCSK9, the claimed antibodies prevent PCSK9 from binding to and destroying liver cell receptors. The liver cell receptors can, therefore, continue removing LDL cholesterol from the body.

Sanofi's Post-Priority Date Evidence Concerning Written Description and Enablement was Admissible

Written Description

The Federal Circuit explained that to satisfy the written description requirement of 35 U.S.C. § 112, a patent specification must demonstrate that the inventor was in possession of the invention as of the patent's filing date. Demonstrating possession requires a "precise definition" of the invention.[6] When the claimed invention is a genus, to provide a "precise definition" of the invention, the patentee must 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 ordinary skill in the art can 'visualize or recognize' the members of the genus."[7]

Sanofi proffered evidence that the patents in suit failed to meet the written description requirement because their specifications did not disclose a representative number of species within the claimed genus. The proffered evidence postdated the priority date of the patents in suit.

Amgen argued, and the District Court agreed, that post-priority date evidence is only relevant to a written description analysis if the evidence concerns the state of the art as of the filing date. However, the Federal Circuit disagreed, and held that post-priority date evidence can be used to show that a patent does not disclose a representative number of species of a claimed genus.[8]

Enablement

With respect to enablement, the Federal Circuit explained that a patent's specification must teach ordinarily skilled artisans how to make and use the full scope of the claimed invention without undue experimentation.

Sanofi sought to introduce post-priority date evidence allegedly showing that Amgen engaged in

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lengthy and undue experimentation after the priority date of the patents in suit and that it was not until the conclusion of that experimentation that the full scope of the claimed inventions was enabled. The District Court excluded Sanofi's post-priority date evidence for the same reason it excluded Sanofi's proffered post-priority date written description evidence, i.e., the District Court reasoned that enablement is determined as of the priority date, and evidence postdating a patent's priority date is not relevant to the issue of whether a patent satisfies the enablement requirement. Again, the Federal Circuit disagreed, finding that such post-priority date evidence was relevant to the enablement issue.

Because the Federal Circuit reversed the District Court's decision to exclude post-priority date evidence concerning written description and enablement, it remanded for a new trial of those issues.

The District Court Improperly Instructed the Jury on the Written Description Requirement

After correctly instructing the jury that a patentee may satisfy the written description requirement by disclosing either: (1) a representative number of species within a claimed genus or (2) structural features common to the members of the genus such that an ordinarily skilled artisan can visualize or recognize the members of the claimed genus, the District Court also instructed the jury that:

> 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 production of antibodies against such an antigen was conventional or routine.

The Federal Circuit faulted the District Court's above-quoted instruction because it improperly allowed a description of how to make and use the invention (i.e., an enabling disclosure) to satisfy the written description requirement. As the Federal Circuit explained in *Ariad Pharm., Inc. v. Eli Lilly & Co.*,[9] the written description and enablement requirements are separate; both requirements must be met to satisfy 35 U.S.C. § 112.

The Federal Circuit also explained that "[b]ecause the scientific premise behind the 'newly characterized antigen' test stated in the [District Court's jury instruction] was neither 'generally known' nor 'accurately and readily' ascertainable, we cannot take judicial notice of the premise and displace the required fact finding with what amounts to a rule of law."[10]

Accordingly, the Federal Circuit instructed the District Court on remand to correct its jury instruction concerning written description.

The District Court Correctly Denied Sanofi's Motion for JMOL of No Written Description and No Enablement

Sanofi argued that it was entitled to a judgment as a matter of law: (1) on the issue of written description because the patents in suit teach only where an antibody binds to an antigen, but say nothing about the structure of the antibodies; and (2) on the issue of enablement because an ordinarily skilled artisan would have to unduly experiment to enable the full scope of the claimed genus. The Federal Circuit affirmed the District Court's denial of Sanofi's JMOL motion because the record before the Federal Circuit was incomplete. The Federal Circuit concluded that on the record before it, it could not determine whether the jury had a sufficient evidentiary basis to determine whether the patents in suit met the written description and enablement requirements.

The District Court Correctly Granted Amgen's Motion for JMOL of Non-Obviousness

Relying on the pre-America Invents Act version of 35 U.S.C. § 102(e), Sanofi attempted to prove obviousness in the District Court by relying on two published PCT publications. The PCT applications claimed priority to provisional applications that were filed before the priority date of the patents in suit, but the PCT applications themselves were published after the priority date. The Federal Circuit explained that for a non-provisional application to claim priority to a provisional application for prior art purposes, the specification of the provisional application must: (1) enable an ordinarily skilled artisan to practice the invention claimed in the non-provisional application; and (2) demonstrate that the inventor was in possession of the inventions claimed in the non-provisional application. Because Sanofi failed to make those showings, the Federal Circuit affirmed the District Court's decision granting Amgen JMOL of non-obviousness.

The District Court's Entry of a Permanent Injunction was Improper

Because the Federal Circuit vacated the District Court's judgment concerning written description and enablement and remanded for a new trial on those issues, the Federal Circuit vacated the permanent injunction entered by the District Court. But the Federal Circuit admonished the District Court for improperly entering a permanent injunction in the first place. According to the Federal Circuit, the District Court made two errors when it enjoined Sanofi's accused product from the market.

First, the District Court erred by entering a permanent injunction despite its finding that an injunction would disserve the public interest. As the Federal Circuit explained, in the Supreme Court's decision in *eBay, Inc. v. MercExchange, L.L.C.*,[11] the Court determined that a plaintiff must make four showings, one of which is "that the public interest would not be disserved by a permanent injunction."[12] The District Court could not, therefore, find that the public interest would be disserved **and** enter a permanent injunction.

Second, the District Court's reasoning for determining that an injunction would disserve the public interest was itself erroneous. In making its determination, the District Court opined that eliminating a choice of drugs would disserve the public interest. The Federal Circuit observed, however, that eliminating a choice of drugs is, without more, an insufficient basis for finding that the public interest would be disserved. Otherwise, a patentee would never be able to obtain a permanent injunction for a pharmaceutical patent as the public interest would always be disserved by removing a helpful product from the market.