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Federal Circuit Patent Bulletin: *Amgen Inc. v. Sanofi*

October 30, 2017

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.

On October 5, 2017, in *Amgen Inc. v. Sanofi*, the U.S. Court of Appeals for the Federal Circuit (Prost,* Taranto, Hughes) reversed-in-part, affirmed-in-part, vacated-in-part and remanded the district court's judgment that U.S. Patents No. 8,829,165 and No. 8,859,741, which related to antibodies that help reduce low-density lipoprotein cholesterol (LDLC) or "bad cholesterol," were not invalid, as well as the permanent injunction enjoining sales of Praluent® alirocumab. The Federal Circuit stated:

Section 112 states that "[t]he specification shall contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same . . . ." This requirement ensures "that the inventor actually invented the invention claimed." To show invention, a patentee must convey in its disclosure that it "had possession of the claimed subject matter as of the filing date." Demonstrating possession "requires a precise definition" of the invention. To provide this "precise definition" for a claim to a genus, a 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 skill in the art can 'visualize or recognize' the members of the genus."

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Here, the parties dispute whether a court may rely on post-priority-date evidence to determine if a patent discloses "a representative number of species." [W]ritten description is judged based on the state of the art as of the priority date. Accordingly, evidence illuminating the state of the art subsequent to the priority date is not relevant to written description. Appellants, however, are also correct that a patent claiming a genus 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 skill in the art can 'visualize or recognize' the members of the genus." 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.

Here, Appellants sought to introduce evidence not 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. As a logical matter, such evidence is relevant to the representativeness question. Simply, post-priority-date evidence of a particular species can reasonably bear on whether a patent "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." . . . [Here,] Appellants were not offering post-priority-date evidence to show that Appellees' claimed genus is not enabled because of a change in the state of the art. Instead, Appellants offered Praluent and other post-priority-date antibodies to argue that the claimed genus fails to disclose a representative number of species. As explained above, the use of post-priority-date evidence to show that a patent does not disclose a representative number of species of a claimed genus is proper. It was thus legal error for the district court to categorically preclude all of Appellants' post-priority-date evidence of Praluent and other antibodies. Accordingly, we reverse the district court's decision and remand for a new trial on written description.

For many of the same reasons, the district court's improper exclusion of post-priority-date evidence requires a new trial on enablement as well. Under the enablement requirement, "the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." Appellants purportedly sought to introduce post-priority-date evidence showing that Appellees engaged in lengthy and potentially undue experimentation to enable the full scope of the claims. Such 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. Accordingly, we reverse the district court's decision excluding Appellants' post-priority-date evidence of enablement and remand for a new trial on enablement. . . .

An adequate written description must contain enough information about the actual makeup of the claimed products—"a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials," which may be present in "functional" terminology "when the art has established a correlation between structure and function." But both in this case and in our previous cases, it has been, at the least, hotly disputed that knowledge of the chemical structure of an antigen gives the required kind of structure-identifying information

about the corresponding antibodies. A court may take judicial notice of a fact only when it is either "generally known" or "accurately and readily[discernible] from sources whose accuracy cannot reasonably be questioned." Because the scientific premise behind the "newly characterized antigen" test stated in the instruction in this case 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. . . .

Further, the "newly characterized antigen" test flouts basic legal principles of the written description requirement. Section 112 requires a "written description of the invention." But this test allows patentees to claim antibodies by describing something that is not the invention, i.e., the antigen. The test thus 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."