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Federal Circuit Patent Bulletin: *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*

July 1, 2014

"Functionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support, especially in technology fields that are highly unpredictable, where it is difficult to establish a correlation between structure and function for the whole genus or to predict what would be covered by the functionally claimed genus."

On July 1, 2014, in *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Lourie,* O'Malley, Chen) affirmed the district court's judgment that certain claims of U.S. Patents No. 6,914,128 and No. 7,504,485, which related to fully human antibodies that bind to and neutralize the activity of human interleukin 12 (IL-12), were invalid for inadequate written description under 35 U.S.C. § 112. The Federal Circuit stated:

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. We have explained that "requiring a written description of the invention plays a vital role in curtailing claims . . . that have not been invented, and thus cannot be described." "[T]he purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.'" We have held that the written description requirement with respect to

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particularly claimed subject matter is met if the specification shows that the stated inventor has in fact invented what is claimed, that he had possession of it. We have stated that possession is shown by disclosure in the patent.

One particular question regarding the written description requirement has been raised when a genus is claimed but the specification only describes a part of that genus that is insufficient to constitute a description of the genus. . . . Whether the written description requirement for a genus is met by a particular disclosure depends upon the facts. . . . "For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including 'the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.'" When a patent claims a genus using functional language to define a desired result, "the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus." We have held that "a sufficient description of a genus . . . requires the disclosure of either 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, the claimed invention is a class of fully human antibodies that are defined by their high affinity and neutralizing activity to human IL-12, a known antigen. AbbVie's expert conceded that the '128 and '485 patents do not disclose structural features common to the members of the claimed genus. The question therefore is whether the patents sufficiently otherwise describe representative species to support the entire genus. One factor in considering the question is how large a genus is involved and what species of the genus are described in the patent. If the genus is not large or, even if it is, the specification discloses species representing the genus throughout its scope, the requirement may be met. On the other hand, analogizing the genus to a plot of land, if the disclosed species only abide in a corner of the genus, one has not described the genus sufficiently to show that the inventor invented, or had possession of, the genus. He only described a portion of it. That is the case here.

It is important not to take the analogy of a plot of land too far in thinking of written description issues because, even if one builds a house only in one corner of the plot, one may still own the whole plot. One describes a plot of land by its furthest coordinates, in effect drawing a perimeter fence around it. That may be akin to the function of patent claims to particularly point out and distinctly circumscribe the outer boundaries of a claimed invention. With the written description of a genus, however, merely drawing a fence around a perceived genus is not a description of the genus. One needs to show that one has truly invented the genus, i. e., that one has conceived and described sufficient representative species encompassing the breadth of the

genus. Otherwise, one has only a research plan, leaving it to others to explore the unknown contours of the claimed genus.

Here, the jury heard ample evidence that AbbVie's patents only describe one type of structurally similar antibodies and that those antibodies are not representative of the full variety or scope of the genus. All of the antibodies described in AbbVie's patents were derived from Joe-9 and have V_H3 type heavy chains and

Lambda type light chains. Although the described antibodies have different amino acid sequences at the CDRs, they share 90% or more sequence similarity in the variable regions and over 200 of those antibodies differ from Y61 by only one amino acid. The patents describe that other V_H3/Lambda antibodies maybe modified to attain IL-12 binding affinity. However, the patents do not describe any example, or even the possibility, of fully human IL-12 antibodies having heavy and light chains other than the VH3 and Lambda types.

Because each of the asserted claims encompasses both the Joe-9 antibodies and the allegedly infringing [Centacor product] Stelara, the claimed genus covers structurally diverse antibodies. The '128 and '485 patents, however, only describe species of structurally similar antibodies that were derived from Joe-9. Although the number of the described species appears high quantitatively, the described species are all of the similar type and do not qualitatively represent other types of antibodies encompassed by the genus. . . . It is true that AbbVie's patents need not describe the allegedly infringing Stelara in exact terms. However, the patents must at least describe some species representative of antibodies that are structurally similar to Stelara. On review of the record, there is no evidence to show any described antibody to be structurally similar to, and thus representative of, Stelara. There is also no evidence to show whether one of skill in the art could make predictable changes to the described antibodies to arrive at other types of antibodies such as Stelara.

Instead, AbbVie argues that structural differences are legally irrelevant and inappositely attempts to rely on the k_{off} rates to show representativeness. The k_{off} rate is merely a desired result, rather than the actual means for achieving that result. The asserted claims are directed to new compositions, i.e., fully human antibodies having desired IL-12 binding characteristics. It is undisputed that the structure of the antibody determines its antigen binding characteristic. In order to demonstrate that it has invented what is claimed, AbbVie's patents must adequately describe representative antibodies to reflect the structural diversity of the claimed genus.

Functionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support, especially in technology fields that are highly unpredictable, where it is difficult to establish a correlation between structure and function for the whole genus or to predict what would be covered by the functionally claimed genus. It is true that functionally defined claims can meet the written description requirement if a reasonable structure-function correlation is established, whether by the inventor as described in the specification or known in the art at the time of the filing date. However, the record here does not indicate such an established correlation. Instead, AbbVie used a trial and error approach to modify individual amino acids in order to improve the IL12 binding affinity. Moreover, the '128 and '485 patents do not describe any common structural features of the claimed antibodies. The asserted claims attempt to claim every fully human IL-12 antibody that would achieve a desired result, i.e., high binding affinity and neutralizing activity, and cover an antibody as different as Stelara, whereas the patents do not describe representative examples to support the full scope of the claims. We therefore conclude that substantial evidence supports the jury verdict of invalidity for lack of an adequate written description of the claimed genus and affirm the district court's denial of JMOL on that issue.