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For Statutory Equivalents, Even One Means May Be Enough

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A US Patent & Trademark Office (PTO) appeals review panel decided that a means-plus-function (M+F) claim element supported by the disclosure of only a single species is not invalid for indefiniteness or lack of written description, even if the specification lacks other disclosed statutory corresponding equivalents. *Ex parte Chamberlain*, Appeal No. 22-001944 (App. Review Panel, May 21, 2024) (Vidal, Dir.; Udupa, Boalick, APJs) (*per curiam*).

The independent claims of the patent application at issue involved methods of treating patients with "anti-C5 antibod[ies]" that include amino acid substitutions devised to increase the *in vivo* half-life of the antibody. Each claim involved similar preambles: "A method of treating a patient by administering an anti-C5 antibody comprising . . . ." One of the independent claims was in Jepson form, whereas the other included a M+F limitation.

Following rejections by the examiner and the applicant's appeal to the Patent Trial & Appeal Board, the Board entered new grounds of rejection finding both claims invalid under 35 U.S.C. § 112, ¶1 (written description) and affirmed the examiner's rejection of the claims for obviousness-type double patenting. The Board also entered a new ground of rejection finding the claim including the M+F claim element indefinite under 35 U.S.C. § 112, ¶2. Following the applicant's appeal to the Federal Circuit, the PTO took the unusual step of petitioning the Federal Circuit to "administratively remand [the case] to the Office in order to convene an Appeals Review Panel to clarify the Office's position on the proper analysis of '*Jepson*-format and means-plus-function claims in the field of biotechnology, and particularly in the antibody art' and 'to issue a revised decision.'"

On remand, the panel affirmed the Board's determinations that written description was lacking but overturned the Board's finding of indefiniteness for the claim including the M+F element. In doing so, the panel offered useful commentary on the invalidity standard for M+F claim elements as well as the implications that a limiting preamble may have on invalidity.

The panel found the "treating a patient" preamble recitation limiting in both claims.
For the *Jepson* claim, the preamble was per se limiting. However, the panel went on to find that, even independent of the *Jepson* claim format, the "treating a patient" phrase would be limiting.
Outside the *Jepson* context, the panel characterized the inquiry of determining whether a preamble limits the body of the claim as a highly contextual one. According to the panel, the "treating a patient" term did not merely provide "circumstances in which the method may be useful" but instead constituted "the *raison d'être* of the claimed method itself." The "treating a patient" language was

necessary to “give life, meaning, and vitality” to limitations in the body of the claim involving increasing the *in vivo* half-life of the antibodies and administering the antibodies.

Having determined that the “treating a patient” recitation was limiting, the panel found that the limitation was overbroad compared to the scope of the patent’s disclosure, and thus the *Jepson* format claim lacked adequate written description. Read in light of the specification, the recitation “treating a patient” was not limited to any condition or disease or even treatment of human patients. The specification only mentioned three general categories of diseases that might be treated by anti-C5 antibodies. For the same reasons (the “treating a patient” preamble limitation), the panel found the other independent claim invalid for lack of written description.

Similarly, the panel found the recitation “an anti-C5 antibody” to be limiting in both claims but drew different conclusions about the invalidity of these claims in light of that term. Preamble terms in both claims were construed to claim all anti-C5 antibodies, but the specification only mentioned one example of an anti-C5 antibody: the 5G1.1 antibody. The panel construed the non-*Jepson* format claim to include a M+F limitation with the corresponding disclosed structure being the 5G1.1 antibody. As a matter of law, the panel found that such disclosure of corresponding structure was sufficient to satisfy statutory written description and definiteness requirements, even without the disclosure of statutory “equivalents” of such a structure.

In reaching this conclusion, the panel interpreted pre-AIA 35 U.S.C. § 112, ¶6, explaining that M+F “claim[s] shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” The panel noted that the statute distinguishes between the “structure, material, or acts” required in the specification to inform the construction of an M+F claim element and “equivalents,” which by implication need not appear in the specification. By contrast, in interpreting a similar preamble in the context of a non-M+F claim, the panel found the *Jepson* format claim invalid for lack of adequate written description for claiming a broad genus (all antibodies binding to C5) while disclosing only the 5G1.1 antibody.

Practice Note: Applicants should ensure that preamble claim language is sufficiently circumscribed so that its breadth is commensurate in scope with the written description. For method of treatment preamble language, best practice consistent with *Ex parte Chamberlain* is to reference particular diseases (or class of diseases) rather than a broad genus including all potential conditions.

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