Keywords: Interference; Interference-in-Fact; Priority; Genus; Species; Two-Way Test

General: In evaluating claims to determine whether an interference-in-fact exists, only the subject matter of the claims is to be evaluated, not otherwise disclosed but unclaimed subject matter.

Noelle v. Lederman
69 U.S.P.Q.2d 1508 (Fed. Cir.)
January 20, 2004

I. Facts

On November 1, 1996, Noelle filed U.S. Patent Application Serial No. 08/742,480 (the '480 application) claiming antibodies for the CD40CR antigen, which is involved in cell-to-cell signaling in immunological reactions. In particular, claim 42 of the '480 application claimed a mouse form of the antibody, claim 52 claimed a human form of the antibody, and claim 51 was directed to a genus form of the antibody. The '480 application claimed priority to application Serial No. 07/835,799 (the '799 application) filed on February 14, 1992.

On September 3, 1999 an interference was declared between the '480 application and U.S.P.N. 5,474,771 (the '771 patent), which was effectively filed on November 15, 1991 by Lederman et al. (collectively "Lederman"). The interference included only one count, which was directed to the antibody of claims 42 and 51 of the '480 application and to the human form of the antibody recited in claim 1 of the '771 patent.

On June 28, 2001, the Board held a hearing to dispose of preliminary motions of the parties. In the hearing the Board denied the motion of Lederman for judgment against claim 42 (the mouse claim) of the '480 application for lack of written description as of the November 1, 1996 filing date. The Board did, however, determine that claim 51 and 52 (the genus and human claims) of the '480 application failed to comply with the written description requirement as of February 14, 1992 due to the failure of the earlier application to describe any features of the human or genus antibodies or antigens. As a result, claims 51 and 52 of the '480 application constituted new matter and were denied the benefit of the filing date of the '799 application. In view of the ineligibility of claims 51 and 52 to February 14, 1992 filing date of the '799 application, the Board found that claims 51 and 52 were anticipated by the '771 patent (as well as by a second reference) under 35 U.S.C. §102(b).

On October 19, 2001, the Board ruled on the remaining motions, essentially requesting a decision as to the existence or absence of an interference-in-fact between the remaining claims, i.e., claim 1 of the '771 patent directed to the human form of the antibody and claim 42 of the '480 application directed to the mouse form of the antibody. The Board concluded that no interference-in-fact existed, finding that one skilled in the art would not have had a reasonable expectation of success in isolating the human form of the antibody using the mouse antigen. Noelle timely appealed.

II. Issues

A. Was Noelle entitled to the priority date of the '799 application for claims 51 and 52 of the '480 application?

B. Was there an interference-in fact between the mouse form of the antibody recited in claim 42 of the '480 application and the human form of the antibody recited in claim 1 of the '771 patent?

III. Discussion

A. No. The test to determine whether an application is entitled to receive the priority benefit of an earlier filed application is whether one of ordinary skill in the art would recognize that the applicant was in possession of the subsequently claimed subject matter as of the filing date of the earlier application. In the case of genetic material, an earlier statement of function or result may be insufficient to meet the written description requirement of later claimed subject matter. In the case of antibodies, as long as the applicant has disclosed a fully characterized antigen (characterized by structure, formula, chemical name, physical properties, or deposit) the applicant can claim an antibody based on its binding affinity to the characterized antigen. Here, however, Noelle failed to disclose the structural elements of human antibody or antigen in the earlier '799 application and, therefore, cannot claim the priority benefit of the '799 application with regard to the human form of the antibody.

Furthermore, Noelle is ineligible to the priority benefit for the genus form of the antibody based solely on a description of the mouse antigen. Noelle's arguments with regard to the genus form of the antibody rely on the case of *Staehelin v. Secher* decided by the Board of Patent Appeals and Interferences on September 28, 1992. In *Staehelin*, the Board held that it was not necessary to describe the exact details for preparing every species within a genus to claim the genus. The present Panel found Noelle's reliance on *Staehelin* to be misplaced, noting that the case is not binding precedent and that decisions subsequent to *Staehelin* had subsequently held that a patentee of biotechnological inventions cannot necessarily claim a genus after describing only a limited number of species due to the unpredictability in the art. The Panel, therefore, limited the applicability of *Staehelin* to the extent that it conflicts with the *Enzo Biochem v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002) and *Regents of the Univ. of Cal. v. Eli. Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). In view of Noelle's reliance on the *Staehelin*, *Staehelin*'s lack of precedential value, and the limitations read onto *Staehelin* by the Panel, Noelle was ineligible to claim the genus form of the antibody based solely on the characterized mouse antigen and was therefore unable to claim the priority benefit of the '799 application with regard to the genus form of the antibody.

B. No. The Board properly applied the two-way test promulgated by the P.T.O. and approved by the Federal Circuit in *Eli Lilly v. Bd. of Regents of the Univ. of Wash.*, 334 F.3d 1264 (Fed. Cir. 2003). In view of this two-way test, *each* invention must anticipate or render obvious the other for an interference-in-fact to exist. The parties agreed that the claims did not anticipate one another but disagreed as to obviousness. In particular, the parties disagreed as to whether the prior art would provide a reasonable likelihood of success for one skilled in the art to obtain the human antibody if in possession of the mouse antibody. Noelle argued that, in this analysis, the Board improperly ignored the techniques set forth in the detailed description of the '799 patent application, which would have provided a reasonable likelihood of success in this endeavor, because the techniques were not set forth in the claims.

The Panel, however, affirmed the Board's decision to not consider the methods set forth in specification because they were neither part of the invention nor part of the prior art. An interference-in-fact exists when both parties claim the same patentable invention, which is only found in the claims (absent reliance on 35 U.S.C. § 112, paragraph 6). Comparison of two inventions to determine whether an interference-in-fact exists, therefore, involves only a comparison of the parties claims, absent ambiguity in the claim language. Since Noelle did

not claim an isolation method, but the antibody itself, Noelle may not rely on an otherwise disclosed method of isolating the human antigen to prove obviousness between the inventions.

IV. Conclusion

In the biotechnological arts, a single species is generally insufficient to support a claim to a genus.

In determining whether an interference-in-fact exists, only the claimed subject matter may be relied on, not subject matter which is otherwise disclosed but unclaimed.