

*NOELLE V. LEDERMAN**355 F.3d 1343 (Fed. Cir. 2004)*

The Federal Circuit held that in order for a priority filing date to apply to a subsequent claim for an antibody, the previous patent had to sufficiently describe the antigen to which the antibody has binding affinity. The court further held that no interference-in-fact exists where the inventions fail to satisfy both prongs of the “two-way” test, which the Board of Patent Appeals and Interferences (“Board”) in the instant case described as the “one-way distinctiveness” test.

Lederman, Chess, and Yellin (collectively “Lederman”) described and claimed the human form of CD40CR monoclonal antibody and the hybridomal cell line that produced the antibody in Patent No. 5,474,771 (“the ’771 patent”). The ’771 patent had an effective filing date of November 15, 1991. Noelle claimed the same antibody and hybridomal cell line, along with the genus, mouse, chimeric (“hybrid”), and humanized form of the antibody, in application Serial No. 08/742,480 (“the ’480 application”), which was filed on November 1, 1996 and was the second continuation of the application Serial No. 07/835,799 (“the ’799 application”) filed on February 14, 1992.

The Patent Office declared an interference in 1999. Lederman sought to have Noelle’s claims rejected with regard to its mouse, genus, and human forms of the CD40CR antibody. The Board determined that Noelle satisfied the written requirement of 35 U.S.C. § 112 as of the date the ’480 application was filed with respect to the mouse form but not with respect to the human and genus forms. Since the parent ’799 application did not describe the human or genus antigens or antibodies, the Board found that the human and genus claims covered new matter, and therefore, the ’480 application did not warrant the earlier priority date of the ’799 application with respect to those claims. The Board further found that Lederman’s ’771 patent and another patent anticipated Noelle’s genus and human forms as prior art. Thus, the Board rejected the ’480 application claims relating to the genus and human forms of the antibodies. Lastly, the Board found no interference-in-fact because one skilled in the art would not have had a “reasonable expectation of success” of isolating the human CD40CR antibodies from the mouse antigen. Noelle appealed.

The Federal Circuit held that the disclosure of a “‘fully characterized antigen,’ either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public repository” would enable an applicant to then claim an antibody by its binding affinity to the described antigen. The court then found that Noelle did not sufficiently describe the human form of the CD40CR antigen in its earlier application and therefore could not claim the human antibody in its later application. The Federal Circuit also held that Noelle could not claim the genus form of the antibody by simply describing the mouse form; therefore, Noelle was not entitled to a priority filing date based on the previous application. Finally, the court affirmed the Board’s finding that prior art patents anticipated Noelle’s human and genus claims.

In reviewing the Board’s decision that there was no interference-in-fact, the Federal Circuit noted that it had previously approved of the two-way test, which requires invention A to anticipate or make obvious invention B and vice versa, and that the Board had applied this test under the name of the “one-way descriptiveness test.” The court affirmed

the Board's finding of no interference-in-fact as proper and supported by substantial evidence.