

In re Alonso

No. 08-1079, Fed. Cir. (Michel, Mayer, Stearns*)

[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated.

On October 30, 2008, the Federal Circuit affirmed the USPTO Board of Patent Appeals and Interferences decision upholding the examiner's rejection under 35 U.S.C. § 112 for lack of enablement and written description of U.S. patent application Serial No. 08/469,749, which related to treating neurofibrosarcoma, a rare cancer of the sheath of a peripheral nerve, using human monoclonal antibodies targeted at a patient's tumor. The Federal Circuit stated:

The written description requirement of 35 U.S.C. § ' 112, ¶ 1 [requires that] the specification must describe the invention in sufficient detail so "that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." The requirement "serves a teaching function, as a 'quid pro quo' in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'"

The Board framed the issue raised by the '749 Application as follows. [W]hether the single monoclonal antibody described in the Specification is representative of the genus of monoclonal antibodies required to practice the claimed treatment method. That, in turn, depends on whether or not the antibodies (and the antigens they bind) would have been expected to vary substantially within the genus. The greater the variation in the genus, the less representative any particular antibody would be. The Board properly characterized the relevant genus as the "genus of antibodies specific to neurofibrosarcoma cells." A genus can be described by disclosing: (1) a representative number of species in that genus; or (2) its "relevant identifying characteristics," such as "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

Relying principally on two scientific articles, including one authored by Alonso himself, the Board determined that [t]here is ample evidence of record that the specificities of antibodies falling within the scope of the genus (and the structures of the antigens they bind) would be expected to vary substantially. For example, Osband provides evidence of a recognition in the art that considerable antigenic "heterogeneity of tumors both between patients and metastatic sites within a single patient" is to be expected. In addition, an article authored by [Alonso] acknowledges that "[t]he efficacy of antibody therapy is thought to be related to tumor burden as well as to idiotypic change in the original tumor." This acknowledged heterogeneity is reflected in the goal of the claimed method - to raise customized antibodies to possibly unique antigens on a particular patient's

tumor. [Finally,] for purposes of satisfying the written description requirement, it is not enough merely to disclose a method of making and identifying compounds capable of being used to practice the claimed invention. That is, it is not enough to describe[] the procedure for making a human-human hybridoma from neurofibrosarcoma, and teach how to determine whether a given antibody, specific to a patient's neurofibrosarcoma, will function in the claimed method. We find that the single antibody described in the Specification is insufficiently representative to provide adequate written descriptive support for the genus of antibodies required to practice the claimed invention.

The Board's conclusion is supported by substantial evidence. The articles relied upon by the Board confirm the hypothesis that the antibodies required to perform Alonso's claimed method vary substantially in their composition. We have previously held in a similar context that "a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated." . . .

Alonso argues that the Board's findings as to sufficiency of description and enablement are at odds with one another. It is true that the written description and enablement requirements "usually rise and fall together. That is, a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention, and vice versa." However, we have been clear that "[a]lthough the legal criteria of enablement and written description are related and are often met by the same disclosure, they serve discrete legal requirements." "[A]n invention may be enabled even though it has not been described." . . .

The specification of the '749 Application does not characterize the antigens to which the monoclonal antibodies must bind; it discloses only the molecular weight of the one antigen identified in Example 2. This is clearly insufficient. The specification teaches nothing about the structure, epitope characterization, binding affinity, specificity, or pharmacological properties common to the large family of antibodies implicated by the method. While Alonso's claim is written as a method, the antibodies themselves are described in purely structural language – "a monoclonal antibody idiotypic to the neurofibrosarcoma of said human." This sparse description of antibody structure in the claim stands in stark contrast to the detailed method of making the antibodies found in the specification. . . .

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