

NOVEMBER 20, 2006

Impax Labs., Inc. v. Aventis Pharms., Inc.

No. 05-1313, Federal Circuit (Rader, Schall, Prost)

[P]roof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation. That is, a section 102 prior art reference does not have to be “effective” to be enabling and thus anticipating. [T]he effectiveness of the prior art is not relevant.

On November 20, 2006, the Federal Circuit vacated and remanded the district court’s judgment that U.S. Patent No. 5,527,814, which related to the use of riluzole to treat amyotrophic lateral sclerosis (ALS or Lou Gehrig’s disease), was not invalid as anticipated under 35 U.S.C. § 102(b). Impax had sought a declaratory judgment that its filing of an Abbreviated New Drug Application for approval of generic Rilutek® did not infringe the ‘814 patent under 35 U.S.C. § 271(e)(2) because the ‘814 patent was invalid and unenforceable. The Federal Circuit affirmed the district court’s judgment that the ‘814 patent was not unenforceable. Regarding invalidity, the Federal Circuit stated:

An invention is anticipated if it “was . . . described in a printed publication in this . . . country . . . more than one year prior to the date of application for patent in the United States.” A patent claim is invalid as anticipated if every limitation in a claim is found in a single prior art reference, either explicitly or inherently. [T]o be anticipating, a prior art reference must be enabling so that the claimed subject matter may be made or used by one skilled in the art. Prior art is not enabling so as to be anticipating if it does not enable a person of ordinary skill in the art to carry out the invention.

The enablement requirement for prior art to anticipate under section 102 does not require utility, unlike the enablement requirement for patents under section 112. [W]e have stated that ‘anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art.’”

“Whether a prior art reference is enabling is a question of law based upon underlying factual findings.” [When] an accused infringer asserts that either claimed or unclaimed material in a



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prior art patent anticipates patent claims asserted against it, the infringer is entitled to a presumption that the allegedly anticipating material is enabled. However, “[i]f a patentee presents evidence of nonenablement that a court finds persuasive, the trial court must then exclude the particular prior art patent in any anticipation inquiry, for then the presumption has been overcome.” In this case, the issue is whether the prior art enables the treatment of a specific disease with a specific compound.

We turn first to the question of whether the ‘940 patent is an enabling prior art reference. Riluzole is a compound of formula I in the ‘940 patent.... While the ‘940 patent includes riluzole as a formula I compound, suggests that formula I compounds may be used to treat ALS, and provides some dosage information, the district court found that the ‘940 patent did not anticipate the ‘814 patent because the disclosure of the ‘940 patent was not enabling at least in part because there was no evidence that it would be “effective.” [However,] proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation. That is, a section 102 prior art reference does not have to be “effective” to be enabling and thus anticipating. [T]he effectiveness of the prior art is not relevant.

Rather, the proper issue is whether the ‘940 patent is enabling in the sense that it describes the claimed invention sufficiently to enable a person of ordinary skill in the art to carry out the invention. [H]owever, the district court focused only on the former question. Thus, we remand to allow the district court to make the proper factual determinations and then reach its own legal conclusion as to whether the ‘940 patent is enabled....

What the district court must determine on remand is whether the disclosure of formula I in the ‘940 patent enables a person of ordinary skill in the art to carry out the invention claimed in claims 1-5 of the ‘814 patent. Specifically, the district court must determine whether the ‘940 patent enables a person of ordinary skill in the art to treat ALS with riluzole. Effectiveness in treating ALS does not have to be established. If the district court determines that what is disclosed in formula I of the ‘940 patent is enabling in that a person of ordinary skill in the art can carry out the invention, then it will be for the district court to determine whether that disclosure anticipates claims 1-5 of the ‘814 patent. If, however, the district court determines that what is disclosed in formula I of the ‘940 patent is not enabling in that a person of ordinary skill in the art could not carry out the invention, then the district court should again hold that claims 1-5 of the ‘814 patent are not anticipated by the disclosure of the ‘940 patent and that therefore claims 1-5 are not invalid.

For more information on these issues or other intellectual property law matters, please contact **Lawrence M. Sung, Ph.D.** at lsung@nixonpeabody.com or 202-585-8221.

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