Keywords: enablement, utility, test results, treatment methods, therapeutic use

General: The Federal Circuit finds that a stated hypothesis and proposed testing for a treatment method is not enough to establish utility.

In re '318 Patent Infringement Litigation
Nos. 2008-1594, 2009-1070, 2009-1088 (Fed. Cir. 2009)
Decided September 25, 2009

I. Facts

Janssen Pharmaceutica N.V. (hereinafter "Janssen"), a licensee of U.S. Patent No. 4,663,318 ("the '318 patent"), brought patent infringement actions against several generic drug companies for infringement of the '318 patent. The '318 patent is directed to a method of treating Alzheimer's disease using galanthamine. The '318 patent contains one independent claim, which claims, "A method for treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof."

The specification, which was just over one page in length, briefly summarized six scientific papers describing the use of galanthamine in humans and animals. The first two papers described how galanthamine raised levels of human hormones controlled by the central nervous system. The remaining four papers described how administering galanthamine to animals could improve memory and treat amnesia. However, the specification failed to provide information linking the scientific papers to galanthamine's potential to treat Alzheimer's disease. Further, the specification did not suggest that the amnesia studied in animals was similar to Alzheimer's disease.

During prosecution, the Examiner rejected the claims as obvious based on the scientific papers cited in the specification that described using galanthamine to treat amnesia in animals. In response, the inventor submitted arguments that the brains of the animals studied did not have the "physiological changes" that corresponded to Alzheimer's disease. The inventor stated that because the studies were conducted under "circumstances having no relevance to Alzheimer's disease" it would be "baseless" to predict from these studies that galanthamine would be useful to treat Alzheimer's disease. The inventor also commented that animal testing was underway. However, these tests were not completed until after the '318 patent had issued. Several years after issuance, the '318 patent was licensed to Janssen who brought an infringement action against the generic drug companies. In defense, the generic drug companies asserted invalidity based on anticipation, obviousness, and nonenablement.

In the infringement case, the district court found that the '318 patent was not anticipated or obvious. However, the district court held that the '318 patent was invalid for lack of enablement. Specifically, the district court held that the patent did not demonstrate utility because the testing was not finished prior to allowance of the patent. Janssen subsequently appealed to the United States Court of Appeals for the Federal Circuit.

II. Issue

Did the district court err in concluding that the '318 patent was not enabled?

III. Discussion

No. The court found that because the specification merely stated a hypothesis and proposed testing, there was no utility.

Enablement is determined as of the effective filing date and requires the specification to "contain a written description of the invention . . . as to enable any person skilled in the art . . . to make and use the same . . . ." 35 U.S.C. § 112, first paragraph. Enablement is closely related to the utility requirement, which states that a person may obtain a patent for "any new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. "If a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement." *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999).

The court focused on the policy behind the utility requirement, which prevents mere ideas from being patented. The court stated, "A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner v. Manson*, 383 U.S. 519, 536 (1966). The court stressed that by allowing research proposals to be patented, scientific development could be blocked off without compensating the public.

In reviewing the district court's enablement findings, the court first affirmed the district court's holding that the subsequent test results could not be used to establish enablement because these results were not available at the time of filing. The court also concluded that the animal testing summarized in the specification did not establish utility. During prosecution and in testimony at trial, the inventor and Jansen's witnesses recognized that the utility of the invention could not be inferred from the summarized animal testing.

Janssen asserted that utility could be established based on analytical reasoning and provided a series of logical inferences that one skilled in the art could have made to understand the utility of the invention. However, none of these inferences were described in the specification. Further, the court reasoned that even if these inferences could substitute for "an explicit description of utility," there was no evidence that someone skilled in the art would make these inferences. The court cited the inventor's own testimony at trial, which was particularly damaging. In particular, the inventor stated, "When I submitted this patent, I certainly wasn't sure, and a lot of other people weren't sure that [galantamine] would ever work." In summary, the court found that the specification only described an unproven hypothesis, which was not enough to establish utility.

The court also provided guidance on the level of testing that may be needed to establish utility for methods of treatment. The court noted that human testing was not required, due in part to the large cost of conducting human trials. Instead, animal tests or in vitro experiments could be used. Further, the court recognized that although patent applications claiming treatment methods typically include test results, testing does not have to be conducted by the inventor. The court cited the Manual of Patent Examining Procedure, which has recognized that reasoning may be used to establish therapeutic utility. M.P.E.P. § 2107.03. (The court recognized that guidelines were not binding but could be given judicial notice if there was no conflict with the relevant statute.) In particular, "statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or a combination thereof" may be used to establish therapeutic use. *Id.* By these statements, the

court seems to imply that previous studies could be used to show utility. However, the court recognized that it was not aware of any cases where only analytical reasoning was used to show utility. In previous cases, at least in vitro testing was performed.

IV. Dissent

Justice Gajarsa would vacate the judgment and remand the case to the district court to determine whether at the time of filing, the written description conveyed to one skilled in the art galanthamine's utility for treatment of Alzheimer's disease. Justice Gajarsa thought the district court should have determined how one skilled in the art would have understood the cited scientific papers. Based on Justice Gajarsa's dissent, it appears that the district court only evaluated one of the cited papers in full.

V. Conclusion

To be enabled, therapeutic treatment methods should include an explicit description of utility in the specification. To be safe, utility should be shown by test results, which may include human trials, animal tests, or in vitro experiments. It may be possible to establish utility through analytical reasoning; however, the logical inferences and connections should be described in the specification.