

SENJU PHARMACEUTICAL CO., LTD. V. LUPIN LTD., Appeal No. 2013-1630 (Fed. Cir. March 20, 2015). Before Plager, Newman, and Moore. Appealed from D. Del. (Judge Robinson).

Background:

Senju owns a patent directed to an eye drop formulation that is a mixture of gatifloxacin and ethylenediaminetetraacetic acid (EDTA). This is the fourth time that Senju's patent has been asserted in a lawsuit before Judge Robinson, including a prior finding that the claims were invalid as obvious over seven prior art references in a lawsuit against Apotex. Following that original obviousness decision, Senju filed a request for *ex parte* reexamination by the U.S. Patent and Trademark Office (PTO) on the basis of the seven prior art documents cited in the original obviousness decision. During reexamination, the PTO issued a reexamination certificate for the claims once amended to recite specific concentrations of the ingredients (*e.g.*, "about 0.3 to about 0.8 w/v%" of gatifloxacin and "about 0.01 w/v%" of EDTA).

Following reexamination, Senju was barred from asserting the reexamined claims against the same party (Apotex) who won the first obviousness decision on the grounds of claim preclusion. However, Senju was allowed to assert the reexamined claims against new parties, Lupin and Hi-Tech. Lupin counterclaimed asserting that the claims were invalid for obviousness based on the same seven prior art references that were asserted in the original lawsuit against Apotex and applied in the reexamination proceeding. The district court found that the reexamined claims were infringed, but were invalid for obviousness based on that same prior art.

Issue/Holding:

Did the district court err in determining that the reexamined claims were invalid for obviousness? No, affirmed.

Discussion:

In a 2-1 decision, the Federal Circuit rejected Senju's arguments that the district court improperly presumed that the reexamined claims were invalid based on its original obviousness decision in the Apotex case and handpicked limitations in the reexamined claims to analyze. The Federal Circuit concluded that the district court properly applied a presumption of validity to the reexamined claims and considered the claims as a whole, including the amendments to the claims to recite specific concentrations of the ingredients. Additionally, the Federal Circuit stated that even though the seven references were previously considered by the PTO during reexamination, the burden of proof is the same, and the district court did not err in finding that Lupin set forth clear and convincing evidence of invalidity.

The Federal Circuit further stated that the case revolved around a battle of experts and, absent a compelling reason otherwise, the Federal Circuit generally defers to such credibility determinations by the district court. In this case, the district court's finding of obviousness was based chiefly on a determination that Lupin's experts were more credible than Senju's experts. The Federal Circuit held that such a determination by the district court is well within the broad discretion the court has to assess expert credibility.

Judge Newman dissented, asserting that the district court failed to give proper deference to the PTO's decision of validity of the reexamined claims and improperly invalidated the amended claims on the same basis that the original claims were found obvious. Judge Newman further opined that the majority repeated the mistakes of the district court in failing to consider the scope of the reexamined claims, the teaching away of the prior art, and the unexpected results.