

<u>ANTARES PHARMA, INC. v. MEDAC PHARMA INC.</u>, Appeal No. 2014-1648 (Fed. Cir. November 17, 2014). Before <u>Dyk</u>, Reyna and Taranto. Appealed from D. Del. (Judge Robinson).

Background:

Antares held a patent directed to automatic injection devices to self-administer pharmaceuticals. Antares was subsequently granted a broadening reissue patent that included original claims (reciting features relating to "jet injection") plus additional claims (reciting additional safety features but omitting the "jet injection" feature).

Antares sued Medac for infringement of some of the additional claims added in the reissue. In response, Medac counterclaimed for invalidity and noninfringement. Medac argued that the asserted reissue claims were invalid for violating the recapture rule and also for failing to satisfy the 35 U.S.C. §251 "original patent" requirement. The District Court denied a preliminary injunction against Medac, finding that the asserted reissue claims are likely invalid under the recapture rule. Antares appealed.

Issue/Holding:

Did the court err in denying a preliminary injunction because the claims are likely invalid? No, affirmed.

Discussion:

While the District Court denied the preliminary injunction based on the likely invalidity of the asserted reissue claims for recapture, the Federal Circuit did not address that issue. Instead, the court found that the asserted reissue claims are invalid for violating the 35 U.S.C. §251 "original patent" requirement, and affirmed the District Court's denial of a preliminary injunction on that basis.

The Federal Circuit discussed the history of the original patent requirement in the case law, finding that this aspect of 35 U.S.C. §251 requires reissue claims to be directed to aspects of the invention that are explicitly disclosed in the specification, for example as a separate invention, and not just merely suggested in the specification.

In this case, the asserted reissue claims were directed to safety features for an injection device, but did not require jet injectors. The Federal Circuit found the specification to be clear that the invention was directed to jet injectors (citing to the title, abstract and statements regarding "the present invention" in the specification). Although the specification described the safety features claimed, it did so as incidental aspects of the jet injection invention. Thus, the specification did not explicitly and unequivocally describe the claimed safety features separate from the jet injection invention.

Thus, the Federal Circuit held that the asserted claims are invalid for failure to satisfy the original patent requirement of 35 U.S.C. §251, and affirmed denial of the preliminary injunction.

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