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## Federal Circuit Patent Bulletin: *Antares Pharma, Inc. v. Medac Pharma, Inc.*

November 17, 2014

*"[T]he essential inquiry under the 'original patent' clause of § 251 . . . is whether one skilled in the art, reading the specification, would identify the subject matter of the new claims as invented and disclosed by the patentees."*

On November 17, 2014, in *Antares Pharma, Inc. v. Medac Pharma, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Dyk,\* Reyna, Taranto) affirmed the district court's denial of Antares' motion for a preliminary injunction seeking to enjoin Medac from infringing U.S. Patent No. RE44,846 (a reissue of U.S. Patent No. 7,776,015), which related to automatic injection devices used to self-administer pharmaceuticals, because Antares failed to show likelihood of success on the merits with respect to these claims. The Federal Circuit stated:

Section 251 allows a patent holder to correct an existing, issued patent by broadening or narrowing the originally issued claims. If the claims sought on reissue are broader than the original claims, the patentee must apply for the reissue within two years of the patent issuing. Here, the applicants complied with the two-year requirement. . . .

The filing of continuations and divisionals is limited by the co-dependency requirement of § 120: a continuing application cannot be filed after the original parent application issues. In such circumstances, an applicant can only seek to add claims by filing a

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reissue application. The delay in seeking to broaden the claims is not without cost. By waiting until after the patent is issued, the applicant becomes subject to two additional requirements relevant here: first, the claims must not violate the recapture rule; second, the claims must satisfy the statutory original patent requirement of 35 U.S.C. § 251. . . .

“[T]he essential inquiry under the ‘original patent’ clause of § 251 . . . is whether one skilled in the art, reading the specification, would identify the subject matter of the new claims as invented and disclosed by the patentees.” . . . [F]or § 251, “it is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification.” Rather, the specification must clearly and unequivocally disclose the newly claimed invention as a separate invention.

[A]sserted reissue claims 31, 34, 35, and 37 are invalid. The original claims are significantly different in scope and coverage than the asserted claims. Claims 1-22 are focused on jet injectors, and every one of those claims contains the “jet injection” limitation. The asserted claims are focused on particular safety features and do not contain the jet injection limitation. Indeed, appellants themselves argue that the asserted reissue claims cover a different invention than that originally claimed. To be sure, the original patent requirement focuses on the original specification rather than the original claims. While the claims may be used to determine whether the written description requirement has been satisfied outside of the reissue context, by definition in reissue the original claims do not disclose the invention claimed on reissue. Thus, we must look to the specification. The original specification here does not adequately disclose the later-claimed safety features . . . . The specification discussed only one invention: a particular class of jet injectors. . . .

Although safety features were mentioned in the specification, they were never described separately from the jet injector, nor were the particular combinations of safety features claimed on reissue ever disclosed in the specification. Rather, the safety features were serially mentioned as part of the broader conversation: how to build the patented jet injection device. . . . Nowhere does the specification disclose, in an explicit and unequivocal manner, the particular combinations of safety features claimed on reissue, separate from the jet injection invention. This does not meet the original patent requirement under § 251.