Federal Circuit Reinvigorates "Original Patent" Requirement of 35 U.S.C. § 251 For Reissue Patents

On November 17, 2014, the Court of Appeals for the Federal Circuit, in *Antares Pharma, Inc. v. medac Pharma Inc. and medac GmbH*, ruled in favor of Ropes & Gray client Medac and breathed new life into the "original patent" requirement of 35 U.S.C. § 251 for reissue claims. Citing to Supreme Court cases dating back more than 150 years, the Federal Circuit clarified the standard for meeting the original patent requirement, finding that hints, suggestions and indications in the original patent's specification are insufficient. Rather, the original patent's "specification must clearly and unequivocally disclose the newly claimed invention as a separate invention." The decision is likely to have a significant impact on the prosecution and litigation of reissue claims.

In April 2014, Antares Pharma, Inc. ("Antares") filed a motion for preliminary injunction against medac Pharma Inc. and medac GmbH (collectively, "Medac") in the District of Delaware, including under Reissue Patent RE 44,846 ("the RE '846 patent"). Antares's original patent (U.S. Patent 7,776,015) claimed jet injection devices. On reissue, Antares broadened its claims to cover any "injection device." Medac's opposition raised two independent invalidity challenges under § 251: (1) the reissue claims violate the "original patent" requirement; and (2) the reissue claims violate the recapture rule. On July 10, 2014, the district court denied Antares's motion for preliminary injunction, finding that the RE '846 patent likely violates the recapture rule. In reaching its conclusion under the recapture rule, the district court cited to the "original patent" requirement but did not invalidate the patent on that basis.

Antares appealed to the Federal Circuit, arguing that the recapture rule should not apply in view of the alleged "overlooked aspects" of safety features for a non-jet injection device that were the subject of the reissue claims. Medac argued that the recapture rule was properly applied by the district court, and also raised an alternative ground for affirmance – the non-jet reissue claims are invalid for failing the "original patent" requirement.

On November 17, 2014, the Federal Circuit affirmed the district court's denial of Antares's preliminary injunction and found that "the reissue claims are invalid for failure to comply with the 'original patent' requirement of 35 U.S.C. § 251." Having found the claims invalid under the "original patent" requirement, the Court did not need to reach the question of whether they also violated the recapture rule. Writing for the Court, Judge Dyk provided the history of the "original patent" requirement, stating that it is "well-established, being recognized in the reissue statute and longstanding Supreme Court jurisprudence." In discussing the definitive Supreme Court case, *U.S. Industrial Chemicals, Inc. v. Carbon Chemicals Corp.*, 315 U.S. 668 (1942), the Federal Circuit said:

> "'[I]t is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification' . . . [when] it was nonetheless clear that the invention disclosed in the original patent required the presence [of the element omitted in the reissue claims]."

The Federal Circuit found the "original patent" requirement to be "analogous" to the written description requirement of 35 U.S.C. § 112, but for reissue claims, § 251 requires something more -- a clear and unequivocal disclosure of the newly claimed invention as a separate invention. The Court explicitly distinguished reissue patents under § 251 from continuing applications under § 120, in which new claims need only satisfy the written description section of § 112.

> "By waiting until after the patent is issued, the applicant becomes subject to two additional requirements: 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."

This decision sheds light on the more stringent standard for the patentability of reissue claims, which will impact the prosecution and litigation of broadening reissue claims.

To find out how the Federal Circuit's decision in *Antares Pharma v. medac Pharma* affect your interests, please contact your usual Ropes & Gray attorney or one of the Ropes & Gray attorneys representing Medac listed below.

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