PATTON BOGGS LLP

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Federal Circuit Affirms Inequitable Conduct Judgment for Non-disclosure of Material References

Intellectual Property Client Alert

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The Court of Appeals for the Federal Circuit recently affirmed a District Court's judgment of inequitable conduct based on the patent applicant's failure to disclose to the U.S. Patent and Trademark Office (USPTO) references that rendered two patents invalid for obviousness under 35 U.S.C. § 103. The decision in *Aventis Pharma S.A., et al. v. Hospira, Inc.*, No. 11-1018 (Fed. Cir. Apr. 9, 2012) (available here), reaffirms the holding in *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1511 (Fed. Cir. May 25, 2011) (here) and provides additional guidance for conduct from which it may infer an intent to deceive the USPTO.

Aventis Pharma and Sanofi-Aventis U.S. (Sanofi) owns U.S. Patent Nos. 5,750,561 ("'561 Patent") and 5,714,512 ("'512 Patent") and is the New Drug Application holder for Taxotere. The '561 and '512 patents are pharmaceutical patents related to the administration of the chemotherapy cancer drug docetaxel, which is marketed under the brand-name Taxotere. Taxotere belongs to the class of compounds known as taxanes, which are administered intravenously by slowly delivering the drug in a diluted aqueous solution called a perfusion. Taxanes have low solubility in water and tend to precipitate. Surfactants and ethanol are added to Taxanes to stabilize the perfusion and delay the amount of time before precipitation occurs. In the prior art, the surfactant Cremophor was used with taxanes to form the stock solution, but it was known to trigger serious allergic reactions, including anaphylactic shock.

Apotex Inc and Apotex Corp. applied for Federal Drug Administration approval to market generic versions of Taxotere. Sanofi filed suit against them in U.S. District Court for the District of Delaware under 35 U.S.C. § 271(e) for infringement of the '561 and '512 patents. After a bench trial, Chief Judge Sleet found that two claims of the patents were invalid as obvious under § 103 and that both patents were unenforceable for inequitable conduct.

On appeal, the Federal Circuit agreed with the District Court's invalidity determination. Sanofi argued that the Federal Circuit should reverse the District Court's inequitable conduct judgment because one of the named-inventors provided an explanation why he did not disclose two prior artreferences to the USPTO. Additionally, the inventor explained why these references were not material to patentability of the '561 and '512 patents because they were duplicative of references that were before the USPTO. Thus, according to Sanofi, there was no intent to deceive the USPTO and no inequitable conduct. Apotex responded that the District Court's intent findings were supported by the evidence and the court's credibility determinations. It maintained that the District Court properly applied the but-for materiality analysis in concluding that the references were material to patentability. Relying on its decision in *Therasense*, the Federal Circuit agreed with Apotext.

In *Therasense*, the Federal Circuit rejected the "sliding scale" approach for proving inequitable conduct in favor of a standard, which established both the materiality of the withheld reference and the applicant's intent to deceive the USPTO. Here, the Federal Circuit affirmation of the District Court's holding that the '561 and '512 patents were invalid under § 103 based on the withheld prior art references, indicates that these references were necessarily material to patentability, and the materiality requirement was established.

To satisfy the *Therasense* intent requirement, “the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” This specific intent to deceive must be the “the single most reasonable inference able to be drawn from the evidence.” Here, the District Court expressly rejected the inventor’s explanation that he and his co-inventors did not disclose a reference to the USPTO because he believed that experiments based on this reference were failures. His credibility was also weakened because the submissions to the USPTO cited a reference that identified the “problem” the inventors were trying to solve– certain anaphylactic reactions – but did not cite the reference, which revealed the “solution.” As to the second reference, the District Court also rejected the inventor’s explanation, noting that he affirmatively took steps to list the reference in a clinical brochure for Taxotere, but left the reference out of his submissions to the PTO. On these facts, the Federal Circuit affirmed the finding of inequitable conduct.

The best way to avoid inequitable conduct is for clients to provide their patent counsel with all documents that appear to be material to patentability of an invention, as the omission of a single reference known to the applicant, but not provided to the USPTO may result in a court later finding there was an intent to deceive the USPTO, rendering the patent unenforceable.