

REPORT

**U.S. DUTY OF DISCLOSURE IS CLARIFIED REGARDING
MATERIALITY OF PATENT PROSECUTION STATEMENTS**

February 2, 2010

Our October 9, 2009 Special Report addressed the U.S. duty of disclosure in connection with U.S. and foreign Office Actions in related patent applications.¹ In that Special Report, we noted that the U.S. Court of Appeals for the Federal Circuit ("the Federal Circuit") has held that interpretations of references appearing in Office Actions in related U.S. patent applications must be disclosed to the U.S. Patent and Trademark Office ("USPTO") if those interpretations conflict with or are inconsistent with positions the applicant takes in prosecuting a U.S. patent application. We also pointed out that the same reasoning may also be applied in the future to Office Actions issued in related foreign patent applications.

In a January 25 decision,² the Federal Circuit has now held that the U.S. duty of disclosure also extends to inconsistent or contradictory statements submitted by applicants in prosecution of foreign patent applications. In particular, the Federal Circuit held that a patentee engaged in inequitable conduct that rendered the patent-in-suit unenforceable by not disclosing attorney arguments that had been filed in the European Patent Office ("EPO") in a prior revocation proceeding against a European patent. The subject European patent was a counterpart of a prior art U.S. patent that was distinguished by attorney argument and a declaration in prosecution of the U.S. patent-in-suit.

¹ See our Special Report entitled "The U.S. Duty of Disclosure as Applied to U.S. and Foreign Office Actions," October 9, 2009.

² *Therasense, Inc. v. Beckton, Dickson and Company et al.*, Appeals Nos. 2008-1511-1514 and -1595 (Fed. Cir. January 25, 2010).

I. The *Therasense* Decision**A. The District Court Action**

In *Therasense, Inc. v. Beckton, Dickinson and Company*, Therasense's successor, Abbott Laboratories ("Abbott"), alleged in the District Court that Beckton, Dickinson ("BD") infringes Abbott's 551 patent. BD asserted that the Abbott 551 patent is unenforceable due to inequitable conduct in the USPTO because Abbott intentionally failed to disclose material information to the USPTO during prosecution of the Abbott 551 patent.³ In particular, BD pointed out that Abbott presented attorney arguments and an expert opinion declaration to the USPTO, both of which stated that certain language in an applied prior art reference, Abbott's US 382 patent, should not be interpreted literally, but should instead be interpreted in the context of patent drafting to mean something different from its literal interpretation. BD further pointed out that, in proceedings involving the European counterpart of the prior art 382 patent, Abbott had argued to the EPO that the same language was "unequivocally clear."⁴ BD argued that Abbott's failure to disclose to the USPTO the existence of this prior contradictory argument constituted inequitable conduct in the USPTO. The District Court agreed, and held the 551 patent unenforceable.

³ A number of other issues were also involved, but are not addressed in this Special Report.

⁴ This argument was made to the EPO to distinguish other prior art that had been applied against the European counterpart to the 382 patent in a revocation proceeding.

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B. The Federal Circuit Decision

On appeal, the Federal Circuit affirmed the District Court's holding that the 551 patent is unenforceable for inequitable conduct in the USPTO. In a three-judge panel decision, with one judge dissenting, the Federal Circuit held that the existence of prior, contradictory representations to the EPO concerning the proper interpretation of the subject language was "highly material" information that should have been disclosed to the USPTO. The Federal Circuit further held that intent to deceive the USPTO could be inferred in view of the facts that (i) the interpretation of the subject language was critical to allowance, (ii) the EPO statements contradicted the representations made to the USPTO, (iii) both the attorney and the declarant knew of the EPO statements and consciously withheld them from the PTO, (iv) neither the attorney nor the declarant provided a credible explanation for failing to submit the EPO arguments to the USPTO, and (v) the attorney's and declarant's explanations for withholding the EPO documents were not credible.

The Federal Circuit decision was emphatic in finding that the attorney arguments that had been filed in the EPO were "highly material" to the USPTO. The Federal Circuit opened its discussion by acknowledging that "the penalty for inequitable conduct is severe, as an entire patent is rendered unenforceable. Therefore it is important that courts maintain a high standard." The Federal Circuit further acknowledged that, in reviewing a District Court's factual determinations of materiality and intent, its role is only to determine whether the District Court's determinations were "clearly erroneous." The Federal Circuit nevertheless stated that the District Court's holding regarding materiality of the statements to the EPO "is not clearly erroneous, and indeed is clearly correct."

The Federal Circuit specifically disagreed with Abbott's contentions that mere attorney argument about prior art is not material to patentability, "and that since both the EPO and the PTO representations were merely argument, any inconsistency between the two could not be material." The Federal Circuit stated that none of the cases relied on by Abbott to support this contention "involved a situation in which contradictory arguments made in another forum were withheld from the PTO. They [the cases] do not speak to the applicant's obligation to advise the PTO of contrary representations made in another forum. ... An applicant's earlier statements about prior art, especially one's own prior art, are material to the PTO when those statements directly contradict the applicant's position

regarding that prior art in the PTO."⁵ The Federal Circuit also noted that the statements in the declaration were not merely attorney argument, but were instead "factual assertions as to the views of those skilled in the art, provided in affidavit form."

Regarding intent, the Federal Circuit noted the well-established concept that, because direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence. Based on the facts discussed above, the Federal Circuit inferred that both the U.S. attorney and the declarant intended to deceive the USPTO by withholding from the USPTO the contradictory representations that had been made to the EPO in connection with the European counterpart of the prior art 382 patent. The Federal Circuit stated that this was not even a "close case," but emphasized that "when a question of materiality is close, a patent applicant should err on the side of disclosure."

Focusing on the declaration, the Federal Circuit stated that "cases involving affidavits or declarations are held to a higher standard." The Federal Circuit held that the declarant did not satisfy his duty of disclosure to the USPTO merely by providing the EPO documents to the U.S. attorney for Abbott. Instead, the Federal Circuit held that the declarant had a special duty to avoid deception in the declaration itself, and that merely disclosing the information to the U.S. attorney did not obviate that duty.

C. The Dissenting Opinion

As noted above, one judge dissented from the Court's holding on the inequitable conduct issue. However, it is important to note that the dissent did not disagree with the concept that contradictory arguments made to a foreign patent office in prosecution of a counterpart of a prior art reference could be material to patentability, and thus invoke the duty of disclosure, in U.S. patent prosecution. To the contrary, the dissent merely argued that the respective arguments in question could be construed as not being contradictory.

⁵ As discussed in a similar context in our October 9 Special Report, such reasoning might also be applied to conflicting comments appearing in an Office Action in a foreign patent application, as well as to conflicting arguments or factual assertions made by the applicant in another U.S. patent application.

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The dissent argued that both the U.S. and the EPO arguments were capable of multiple interpretations, some of which would be contradictory, and some of which would not be contradictory. Because of this ambiguity, and because the U.S. attorney and the declarant both testified that they did not consider the subject arguments to have been contradictory, the dissent contended that the Court should not have found that the level of materiality and intent were high enough to support a holding of inequitable conduct. Implicitly, however, the dissent agreed that if the arguments to the EPO had indisputably contradicted the arguments to the USPTO, the EPO arguments would have been highly material, and the inference of intent to deceive would have been appropriate.

II. Recommendations

In view of the *Therasense* decision, we recommend the following:

- (1) The handling of related patent applications worldwide should be coordinated to avoid generating contradictory arguments or assertions of fact.
- (2) Worldwide patent prosecution should be carried out with an awareness that all Office Actions and arguments from the worldwide prosecution can, and almost certainly will, be uncovered in the discovery process in litigated cases.
- (3) Office Actions and arguments made in any given country may or may not be relevant to scope or enforceability of the patent in that country, but should be expected to be considered in connection with the enforceability of a U.S. patent.
- (4) If an argument is to be made in U.S. prosecution that contradicts arguments or factual assertions that have been made in the United States or any other country, the prior contradictory arguments should be disclosed to the USPTO. Apparent contradictions are better resolved on the record so that they will not appear to have been concealed from the USPTO.
- (5) In close cases, where the prior arguments or factual assertions might be argued to be contradictory, but might not necessarily be contradictory, the prior arguments or factual assertions should be disclosed, and addressed as necessary, to avoid the risk of adverse inferences arising from their nondisclosure.
- (6) Statements made in declarations or affidavits submitted to the USPTO should be especially carefully scrutinized for any potential conflict with arguments or factual assertions made elsewhere.

Please do not hesitate to contact us with any questions or comments concerning these important matters.

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