

# THE DAILY RECORD

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## IP FRONTIERS

### Disclose prior art, material information

The Court of Appeals for the Federal Circuit, the federal appeals court established to hear cases involving patent law, has scheduled a Nov. 9 oral argument for *Therasense Inc. v. Becton, Dickinson & Co.*, which may have profound — and, one might hope, favorable — consequences for patent owners.

Through the course of the last 10 years, a series of disparate court decisions has left patentees vulnerable to invalidation of their patents by resourceful and creative infringers, who have been successful in convincing the court to steadily expand the “duty of disclosure.” The duty requires certain individuals to disclose material information to the U.S. Patent and Trademark Office during patent prosecution. Failure to properly discharge the duty — called “inequitable conduct” — can result in total invalidation of the resultant patent.

The successful procurement of intellectual property rights requires a firm understanding of what constitutes “prior art” and “material” information that must be disclosed to the USPTO. Despite the significant differences associated with the two, the failure to recognize prior art in a timely manner and to disclose material information may result in irretrievable loss of patent rights.

#### Prior art

Those who regularly work toward the procurement of patent rights already have a good understanding of what constitutes “prior art.”

Due to the stringent obligations the law places on the individuals involved in developing patentable technology, it is good practice to educate product development teams and others on what “prior art” is, and what issues are important on the topic.

“Prior art” is rather complex. The Federal Circuit demonstrated that fact last month in *Orion v. Hyundai*, which invalidated a patent as anticipated by a promotional publication. Interestingly, in finding the publication to be an anticipatory reference, the court looked beyond what actually was disclosed in the printed publication, and relied on expert testimony relating to how the system described actually was used.

Despite the complexities involving the prior art discussion, conveying the basics is relatively straightforward. Prior art is information that can be cited against a patent application to reject claims as obvious or lacking novelty. Although other prior art categories certainly exist, the following covers some of the most commonly-encountered prior art: An inventor will not be

entitled to a patent if, before he or she invented it, the invention was known or used by others in the U.S., or was patented or described in a printed publication anywhere in the world. If an invention is patented or described in a printed publication anywhere in the world, or is in public use or on sale in the United States, even if such activity is by the inventor, an applicant must apply for a patent within one year of such activity, or lose the right to apply for protection. If an article is published that discloses an invention, for example, or if an individual offers to sell an invention, the inventor has only one year from such activity to file a patent application.

Courts have found that the following all constitute prior art printed publications — government grant proposal, which was found to be sufficiently publicly accessible; a thesis filed and indexed in a university library; a paper delivered orally at a conference, where at least six copies were distributed, and a poster displayed for three days at a conference and at a university. As those examples demonstrate, there is a wide

array of activities that could trigger a statutory bar for applying for a patent, and individuals may be partaking in such potentially adverse activities without even knowing it.

#### Material information and inequitable conduct

Understanding what is “material information” is critical for those involved in the procurement of patents — and apparently even for those involved tangentially involved — because the failure to disclose such information can result in a patent being held invalid and unenforceable.

37 C.F.R. §1.56 (“Rule 56”) places a duty of candor and good faith on certain individuals, including a duty to disclose information material to patentability during patent prosecution. Individuals bound by the Rule 56 duty of disclosure include each named inventor on a patent application; each attorney or agent who prepares or prosecutes the application and every other person substantively involved in the preparation or prosecution of the application and associated with the inventor, the assignee, or anyone to whom there is an obligation to assign the application.

The Federal Circuit has held that Rule 56 materiality “is not limited to prior art but embraces any information that a reasonable examiner would be substantially likely to consider impor-

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tant in deciding whether to allow an application to issue as a patent." So, in addition to prior art, as I discussed earlier, "material" information also includes, *inter alia*, information relating to enablement, possible prior uses, sales, offers to sell, derived knowledge, prior invention by another, inventorship conflicts and any information that is inconsistent with a position applicant takes in arguing in favor of patentability.

The rules are directly relevant to the materiality component of inequitable conduct because if a misstatement or omission is material under the Rule 56 standard, it is material for purposes of inequitable conduct. It should be noted, however, that in the context of an inequitable conduct determination, materiality and intent to deceive are considered together. As the Federal Circuit articulated in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer*, "when balanced against high materiality, the showing of intent can be proportionally less," and vice versa. The stakes are high because a party needs to show only inequitable conduct with respect to one claim in order to render the entire patent unenforceable.

For example, in *Bristol-Myers*, the Federal Circuit held a reissued patent to be invalid due to inequitable conduct based on a failure to disclose a non-prior art article written by the inventors during prosecution of the original patent. In that case, the article suggested, as claimed, that the invention was not fully enabled. The French agent who drafted the foreign priority application knew of the article (published after the patent's priority date), but did not disclose it to U.S. counsel. The article was not cited during prosecution of the original patent, but was cited to, and considered by the USPTO during prosecution of the reissued patent. Notwithstanding its disclosure during reissue prosecution, the Federal Circuit found the reissued patent invalid based on inequitable conduct, holding that the article was material, and inferring that the French patent agent intended to deceive the office.

In a more recent case decided last month, *Avid Identification Systems Inc. v. Crystal Import Corp.*, the Federal Circuit affirmed the invalidity of a patent based on inequitable conduct, when the

company's president had demonstrated "some technology" at a livestock trade show more than one year before filing a patent application. Even though the demonstration did not contain all of the elements of the claimed invention, the court held it still was material art, reasoning that even if the art does not invalidate a patent, a reasonable examiner still may consider it important to patentability. The Federal Circuit held that Avid's president was substantively involved in the preparation and prosecution of the application based on the nature and scope of his position as president and founder, therefore the duty of disclosure applied to him. *Avid* demonstrates the infectiousness of the current inequitable conduct doctrine, and makes it unquestionably clear that everyone involved in the prosecution of patent applications — even others — must be conscious of the doctrine and its requirements.

In yet another case decided in January, *Therasense Inc. v. Becton, Dickinson & Co.*, the Federal Circuit affirmed the unenforceability of a patent based on inequitable conduct for failure to disclose statements made to the European Patent Office in a corresponding application. In that case, after the withheld statements were found to be material, intent to deceive was inferred based merely on the importance of the withheld statements and the applicants' knowledge of them. The Federal Circuit granted an *en banc* rehearing of its panel decision in April, however. Issues to be considered during *en banc* review include the proper standard for materiality, whether it is proper to infer intent from materiality and whether the materiality-intent-balancing framework for inequitable conduct should be modified, replaced or abandoned. Parties' briefs on the issues were due June 10.

There is hope that the *Therasense* rehearing will provide some relief from the impending inequitable conduct plague. Unless and until it does, it is imperative for organizations to understand what constitutes material information, and to be exceptionally cautious in ensuring such information is provided to the USPTO during patent prosecution.

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