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Decisions Keep Inequitable Conduct a Strong Defense to Patent Infringement

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Special to the Legal

The Northern District of California made a finding that a patent of Therasense Inc. was unenforceable for inequitable conduct in *Therasense Inc., et al. v. Becton, Dickinson and Company and Consolidated Cases*. This case is consistent with decisions in past years on inequitable conduct before the U.S. Patent and Trademark Office where inequitable conduct continues to be a strong defense against infringement.

The duty to disclose material information to the PTO arises from the patent rules and case law of the U.S. Court of Appeals for the Federal Circuit. Rule 56 provides that those involved with filing and prosecuting patent applications have a “duty of candor and good faith” when dealing with the PTO. This “includes a duty to disclose ... all information known to that individual to be material to patentability.” What is “material” is also defined in Rule 56 as information that is not “cumulative”; and information that alone, or in combination, establishes prima facie unpatentability; or refutes, or is inconsistent with, a position the applicant takes in arguing for a patent. The rule does not say “references,” which are traditionally considered as “prior art” but invokes “information” generally.

Virtually all accused infringers attempt a defense of inequitable conduct. While the defense requires a high burden of proof — clear and convincing evidence of knowing omission of material information coupled



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with a specific intent to deceive the PTO — the pay-off is significant as it can render all of the claims of a patent unenforceable. When challenging patent claims on statutory invalidity grounds, a similar high evidentiary showing is required, but that showing must be made on a claim-by-claim basis.

Proving “intent to deceive” is and should be the highest challenge in this defense. However, the Federal Circuit case law supports a balancing test that tends to cut against this challenge. The higher the materiality of the omitted prior art information, the lower the intent showing required. The underlying premise for the balancing is that if something is highly material, it is harder to believe the applicant’s motives were innocent in omitting the information. In applying the balancing, it is easier to sustain allegations of inequitable conduct that incur the draconian outcomes of loss of all enforceable rights and damage to reputations of legal professionals, scientists and companies. While there are many times when such punishment is clearly deserved, at times the facts are not as clear. In such cases, proof of

intent is the pivotal factor. The legal standard pushes practitioners and applicants to err on the side of disclosure of information to the PTO, even where it is not clear that information is material or noncumulative, as the potential harm of omission is great.

Up until about 2006, the Federal Circuit appeared to be returning to its position in the late 1980s of pulling back on upholding findings of inequitable conduct. Many speculated it was due to patent reform movements in Congress and attempts to change the disclosure rules at the PTO coupled with the Supreme Court taking the Federal Circuit to task on its patentee favorable legal positions. However, case law points in the opposite direction.

In *Therasense*, one of the applicant’s own prior patents was cited as a basis for rejecting a new patent application. Arguments were made based on the prior patent to overcome the rejections. These arguments were specifically contradictory to statements made by the same company regarding the meaning of the exact language at issue in the prior art patent, which statements were made in obtaining the European version of the same prior patent. To find intent, the court relied on the highly material nature of the omitted information as well as a lack of a credible explanation why the contradictory arguments were not cited. The in-house attorney and a scientific expert that worked for the applicant knew of the contradictory statements and consciously withheld the information from the PTO.

Noting that this alone does not establish intent to deceive, the court evaluated the

attorney's rationale for not citing the prior art and disagreed with it, finding the attorney an unconvincing trial witness with "no plausible reason for consciously withholding" and taking into account his witness demeanor. The facts do seem to support a finding of inequitable conduct, but the district court seems to rely on inferred intent, and the accused infringer does not appear to affirmatively prove intent by clear and convincing evidence. The accused are called on to establish a lack of culpability. The right outcome may be reached, but the burden is on the accused.

Similar cases can be seen over the last year or two. In *Synthon IP v. Pfizer Inc.* inequitable conduct was tried first and so other substantive merits issues were not reached. The Federal Circuit upheld the district court's findings that Synthon withheld information showing that the process it sought to patent was already described by Pfizer.

In *Aventis Pharma S.A., et al. v. Teva Pharmaceuticals USA Inc.*, several submissions in the form of technical sworn declarations and arguments were made concerning mixtures of multiple molecular weight components in a formulation for sulfated heparinic polysaccharides. In providing data from various tests, the scientist making the declarations did not specifically point out that some of the data were evaluated using different dosages in comparison with that of the cited prior art. He later corrected this, and included the tests, just without pointing out the dosage differences. Initially, intent was found to be lacking, and the case remanded to determine why the scientist did not disclose the differing dosages. The district court then reconsidered the proffered reasoning and again found inequitable conduct. On appeal, the Federal Circuit noted, "[g]iven that direct evidence is often unavailable, intent is generally inferred from surrounding facts and circumstances. The district court, upon finding materiality and intent, shall 'balance the equities to determine whether the patentee has committed inequitable conduct that warrants holding the patent unenforceable.'" The court examined each of the district court findings noting that there was no clear abuse of discretion.

Notable in *Aventis* is Judge Randall Rader's dissent. He points out that he did not see a

showing of clear and convincing evidence of intent to deceive. He states the "threat of inequitable conduct, with its 'atomic bomb' remedy of unenforceability, ensures [] candor and truthfulness." Rader regrets that inequitable conduct, which was supposed to facilitate examination, has "taken on a new life as a litigation tactic." He harkened back to earlier admonishments of the court that inequitable conduct was a plague on patent litigation, citing cases from the late 1980s, *Burlington Industries v. Dayco Corp.* and *Kingsdown Med. Consultants Ltd. v. Hollister Inc.*, in which the court attempted to reduce instances of inequitable conduct, and noted that the defense was not supposed to be a remedy for every mistake in patent prosecution, but designed only to punish clearly culpable conduct with an intent to deceive. He pointed to more recent cases, such as *Nilssen v. Osram Sylvania Inc.*, which was denied certiorari to the Supreme Court, where inequitable conduct was largely founded on varied claims of misuse of small entity status. While he noted that there is a high standard of review of a district court finding of inequitable conduct, he noted that the standard "is not insurmountable."

Rader also noted that "without question" the scientist in *Aventis* should have disclosed the dosage information, but that his omissions, while most likely negligent or careless, did not appear to meet the culpability required by the court in *Kingsdown* and that on the record, the district court was likely wrong on materiality and intent findings.

In *Monsanto Co. v. Bayer Bioscience N.V.*, the patent application was rejected based on an abstract of a scientific paper given at a poster presentation. The abstract itself was disclosed to the PTO by the applicant, however, Bayer did not disclose handwritten notes of one of its employees who had personally attended the conference. That employee explained the notes in detail at deposition, and it was established that the notes were widely circulated within Bayer. However, the attorney of record noted that when he asked the employee about the notes during prosecution, she was unable to remember anything. The district court found the attorney's and employee's testimonies to be contradictory, and the notes made on the

poster inconsistent with arguments made to the PTO. The notes were held "material," and the court noted materiality may be found in "any information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent." The court held that "absent a credible reason for withholding the information, '[i]ntent may be inferred where the patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application.'"

In a post-*KSR v. Teleflex* world, applicants are relying more on technical data, other secondary considerations and sworn declarations to overcome hypertechnical prima facie obviousness rejections at the PTO. Applicants need to pay attention to use of data in the specification or a declaration in view of what other data they may have internally or know of through other scientific endeavors. Care must be taken to disclose the background and relationship of declarants and applicants/owners of patent applications, as well as to avoid hyperbole in describing data and results.

Other avenues for avoiding later findings of inequitable conduct include being mindful of use of small entity status under the current standards, and watching arguments made in counterpart filings in other countries and in co-pending applications at the PTO. Applicants should be aware that not only traditional prior art is at issue — but all "information" (notes, tables, internal documents and other data) that refutes or is inconsistent with arguments. This is not always easy for applicants to understand. It is a good reason for avoiding spreading too many co-pending related applications, or applications in the same technological area, around at too many law firms without open and clear communication for all or a strong central attorney contact person, since the opportunities for inadvertent disclosure that can be transformed later in litigation to an inequitable conduct defense are higher in such circumstances. Hopefully, either the Federal Circuit will demand a greater showing to establish intent as Rader's dissent in *Aventis* calls for, or patent reform lessening the draconian standard will prevail. •