The duty of disclosure in the post-*Therasense* landscape

Mary Anne Armstrong*

In Greek mythology the Hydra was a multi-headed creature, with the singular attribute that if one head was cut off two heads would grow. Today a hydra is "a persistent or multifaceted problem that cannot be eradicated by a single effort" [101].

Section 37 C.F.R. §1.56 states, in part, that the duty of disclosure "includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section" [1]. Inequitable conduct may be found, and a patent held unenforceable, when information material to patentability is intentionally withheld from the USPTO. Beginning around 10 years ago, US courts created a hydra through several decisions regarding the duty of disclosure [2–5]. With these cases, the courts developed a sliding scale test, in which materiality of the information was balanced against 'intent' [4]. Using the sliding scale, if the information was found to be highly material, intent could be inferred. Because of this test, applicants would submit hundreds of documents, which were of little to no relevance to the patentability of the claims under examination, in an effort to comply with the heightened duty of disclosure. Compliance with the duty of disclosure in the USA became a hydra where no matter how much information the applicant submitted to the USPTO, there seemed to always be more prior art or information that could be submitted. Concomitant with this was the effect on litigations where it has been estimated that up to 80% of patent litigations included an affirmative defense of inequitable conduct for failing to comply with the duty of disclosure [6].

Recognizing the nearly impossible compliance standard that was created, in particular by the sliding scale test, the Court of Appeals for the Federal Circuit (CAFC) revisited the duty of disclosure in the *en banc* decision of *Therasense Inc. v. Becton Dickinson and Co.* [7]. The invention in *Therasense* involved a single-use disposable electrode strip. The element at issue was the feature that the electrode was configured to be exposed to a blood sample ‘without an intervening membrane’ [7]. The applicant distinguished the invention from a prior art reference by arguing that, in the reference, the membrane was considered to be an essential feature. However, in Europe, the applicant characterized the membrane in the European equivalent of the US reference as preferred, but not necessary. The applicant did not submit the statements made before the EPO to the USPTO.

In the *en banc* decision, the court first newly defined materiality as being a ‘but-for’ materiality. Under this standard, ‘but-for’ materiality is met if the USPTO "would not have allowed a claim had it been aware of the undisclosed prior art" [7].

**Keywords:** but-for materiality • duty of disclosure • inequitable conduct • intent • *Therasense*
Regarding the required ‘intent’, the CAFC held that a knowing and deliberate decision to deceive the PTO is required to establish deceptive intent [7]. Importantly, the court overruled the sliding scale and stated that:

“Intent and materiality are separate requirements … A district court should not use a ‘sliding scale,’ where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa. Moreover, a district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality. Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive” [7].

In addition, clear and convincing evidence is required to show a specific intent to deceive is “the single most reasonable inference able to be drawn from the evidence” [7].

Following Therasense, there have been a number of decisions, which considered inequitable conduct in view of the revised duty of disclosure test set forth by the CAFC. In the remand of Therasense, the district court found that there was inequitable conduct. The district court held in Therasense Inc. v. Becton, Dickinson and Co. [8] that the USPTO would not have allowed the claims had the EPO submission been considered. Thus, the district court found that the ‘but-for’ test for materiality had been met. The court further found by clear and convincing evidence that the patent owner and attorney involved with the prosecution of the application knew that if they had given the USPTO the EPO submission, the claims would have been rejected. The district court also found that there was intent, stating that:

“The single most reasonable inference to be drawn from the trial record, including witness demeanor, and particularly the witness demeanor of Dr Sanghera and Attorney Pope, is that they did believe that the omission was necessary to win an allowance and that they did deliberately elect to withhold the EPO briefs” [8].

In Santarus Inc. v. Par Pharm., Inc. [9], the CAFC upheld a decision by the US District Court of Delaware that an intent to deceive had not been shown by clear and convincing evidence. At issue were experimental tests and a declaration by the inventor. The inventor testified that he was unaware that he was required to submit information regarding the experiments to the USPTO and the attorney who prosecuted the application testified that he was unaware of the experiments until the examination of a continuing application, at which time the information was submitted to the USPTO. The district court found that there was some

materiality regarding the experiments and the declaration and that the inventor’s explanation for failing to disclose the experiments to the USPTO ‘strained credibility’. However, despite finding that the explanation of the inventor ‘strained credibility’, it was held that “the evidence presented is not sufficient to establish by clear and convincing evidence” that there was an affirmative intent to deceive [9].

Conversely, in Aventis Pharma S.A. v. Hospira Inc. [10], the CAFC affirmed a decision from the US District Court of Delaware finding inequitable conduct by the patent owner. At question in Aventis, were two prior art references, which had been not submitted to the USPTO, but of which the inventor was aware. The court found that the references met the ‘but-for’ materiality standard, despite the argument from Aventis that the references were duplicative. Regarding intent, the inventor testified that he had repeated the experiments in the ‘Vidal reference’ and “believed that these experiments were failures and that he therefore did not need to disclose the Vidal reference to the PTO” [10]. The court chose to give more weight to other testimony by the inventor regarding the Vidal reference and development of the invention. The district court considered the inventor’s explanation for withholding the Vidal reference and found, in part, that the explanation lacked credibility. Similarly, regarding the second reference (‘GV reference’) “the district court found that … [the inventor’s] testimony was not credible and relied on the other evidence presented during the trial in finding that Fabre [the inventor] withheld the reference with the specific intent to deceive the PTO” [10].

Upon reviewing the decisions by the CAFC following the Therasense en banc decision, it can be seen that the CAFC has set a more reasonable standard for determining whether inequitable conduct because of an intentional failure to comply with the duty of disclosure has taken place. Importantly, the CAFC has more clearly defined a higher threshold for materiality with the ‘but-for’ standard. In addition, the court has eliminated the sliding scale, which allowed a lower showing for intent to be inferred if the information was found highly material. However, there is still a subjective element involved, particularly with regard to intent, which causes an element of uncertainty to remain. In Therasense the district court, in part, based their finding of intent on the ‘witness demeanor’. In Santarus, the court found that although the explanation of the
inventor ‘strained credibility’ there was no finding of intent. On the other hand, in Aventis, the court found that the testimony of the inventor lacked credibility and therefore found the requisite intent for inequitable conduct. Because of this level of uncertainty and subjectivity, applicants should still err on the side of caution and submit any information, which is may be later asserted during a litigation as being material under the ‘but-for’ materiality test, to the USPTO for consideration.

Financial & competing interests disclosure
The author has no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

References
1 37 C.F.R. §1.56.

Website
www.thefreedictionary.com/hydra