

*Therasense, Inc.
v. Becton Dickinson & Co.*



99 U.S.P.Q. 2d 1065
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- I. Inequitable conduct in obtaining a patent in the U.S. Patent and Trademark Office
 - a) A Judge made defense to enforceability of a patent.
 - b) Gradually changing standard; modified in the U.S.P.T.O. Rule 56.
 - c) Standard changed by Federal Circuit in *Therasense* case en banc, by a 6-5 majority.
- II. The Problem
 - a) Defense of inequitable conduct has been asserted too often. No legal drawback or harm to asserting it.
 - b) The inequitable conduct defense had been called the “atomic bomb” of patent law in that upon inequitable conduct having been found, it affects enforceability of not only a single claim directly involved in the conduct, but the entire patent becomes unenforceable.
 - c) To avoid finding of inequitable conduct, attorneys prosecuting patent applications have been citing too many prior art documents.
 - a) Burdens Examiners to study cited art.
 - b) May bury most relevant art.



III. New standards in courts under *Therasense*

- A) Prior Art, not other actions must be cited.
- B) Changed Standard of Materiality of Information.
 - a) But for the information in the prior art reference the claim would (not) have been allowed.
 - b) If claim would have been allowed over a reference, if it had been cited, reference is not material.
 - c) Previous Rule 56 standard of materiality is no longer applicable.
 - d) Clear and convincing evidence standard for patent invalidity.
 - e) However, preponderance of the evidence is the standard for Materiality for a finding of inequitable conduct.



C) Intent

1) Materiality of information.

- a) Require knowledge of reference, knowledge of its materiality and deliberate intention to conceal reference.
- b) Standard: clear and convincing evidence of the intent (preponderance for materiality).
- c) Negligence and Gross negligence is insufficient.
- d) Massive numbers of documents need not be filed.
- e) Can rely on direct, indirect and circumstantial evidence.
- f) Intent is the single most reasonable conclusion from the evidence.
- g) Good faith explanation not required until a threshold level of evidence of intent to deceive is presented.
- h) any persons involved in the prosecution of claims, inventor, patent owner assignee, U.S. or foreign patent attorney, expert witness.

D) Materiality and Intent are determined independently.

- 1) No sliding scale with greater presence of one requiring correspondingly lesser presence of other.



E) Egregious Misconduct not involving withholding prior art.

- 1) Under *Therasense*, material information is divided into two types, patents and publications, which must be disclosed, and other activities not consisting of patents and publications.
- 2) Includes false statements and omissions.
- 3) No materiality standard for such misconduct.

F) Equitable Remedy

- 1) Court will apply equity so remedy of unenforceability is not necessarily imposed for inequitable conduct, especially if it was immaterial to issuance of patent.
- 2) The Courts now have the discretion through relief in equity as to how and how much of the patent may be held unenforceable if inequitable conduct is found.



G) New PTO standard follows *Therasense* opinion definition of materiality.

H) The recently enacted America Invents Act provides for Supplemental Examination which may be requested by the Patentee to correct possible inequitable conduct during the prosecution of the Patentee's application.

This Examination may be requested upon discovery by the patentee or perhaps by another party of the possible inequitable conduct to be cured.

I) If the facts rise to a level that a party defending against an infringement claim believes will be sufficient to find inequitable conduct by clear and convincing evidence, the defense should be asserted. The bars to be exceeded for both materiality and intent have been raised.



Subsequent Federal Circuit Cases

No changes to *Therasense* opinion requirements

American Calcar, Inc. v. American Honda Motor Co., Inc.

99 U.S.P.Q. 2d 1137 (Fed. Cir. 6/27/11)

Federal Circuit reiterated the *Therasense* standards of materiality and intent. It vacated a finding of inequitable conduct and remanded for further proceedings.

Delano Farms Co. v. The California Table Grape Commission

2011 U.S. App. Lexis 17685 (Fed. Cir. 8/24/11)

Repeats the requirement of *Therasense*, makes no decision.

August Tech. Corp. v. Camtek, Inc.

2011 U.S. App. Lexis 17451 (Fed. Cir. 8/22/11)

Court found no “but-for” materiality.



History of *Therasense* Case

The *Therasense* case concerned the United States patent attorney of the Patentee and an expert he retained concerning interpretation of a clause in the specification of the a prior art reference in the United States Patent and Trademark Office to avoid that prior art and not disclosed to United States Examiner assertion a contrary interpretation of the same clause of the prior art reference to obtain a patent within the European Community Patent Office. Inequitable misconduct was found.

The statement in the prior art patent is: “optionally, but preferably when being used on live blood, a protective membrane surrounds ...”.

To overcome that prior art passage, the Patentee’s United States attorney asserted that the claims in the United States application were novel by interpreting the passage in the prior art as disclosing a sensor for use in whole blood, that is without a protective membrane. The attorney argued, with the support of the expert’s Declaration, that a person skilled in the art would construe the disclosure of the prior art that a membrane is required, not that it is optional or merely preferred.

Years earlier, in contesting an Opposition against the corresponding European application, the Patentee’s attorney avoided the European equivalent of the same prior art by arguing that in the prior art patent, the protective membrane is optional, but preferred, so that the membrane was not required.



The asserted interpretations were that the membrane is required in the interpretation in the United States and not required in the interpretation in the European Patent Office. The attorney's expert declared in the U.S. that the phrase "optionally, but preferably" is not a technical teaching, but mere patent phraseology.

The District Court invalidated the U.S. patent claim over the prior art.

The U.S. District Court also held the patent unenforceable for inequitable conduct because the U.S. Patentee did not disclose to the Examiner its argument briefs to the European Patent Office, which stated the contrary of what was stated to the U.S. Examiner.

The initial three Judge panel of the CAFC found inequitable conduct.

The CAFC granted en banc review, by a 6-5-majority opinion set a new standard for materiality of information, and particularly prior art and remanded the case to the District Court.

