New Standards for the Ethical Duty to Disclose and Proving Inequitable Conduct

Implications of the Federal Circuit's En Banc decision in Therasense v. Becton

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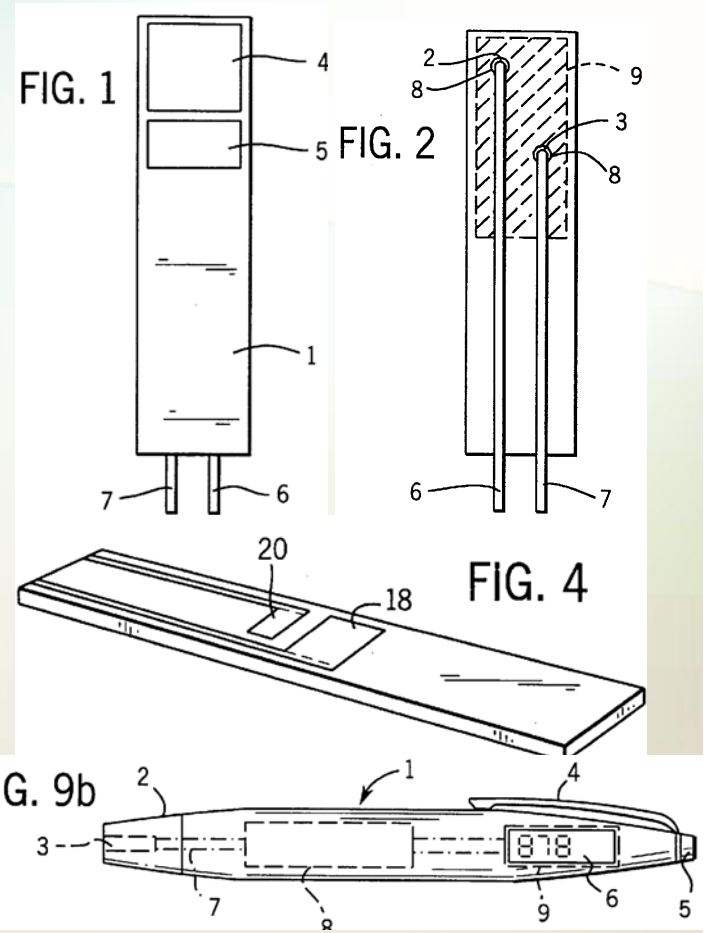
Outline

- Underlying Facts in Therasense
- New Materiality Standard;
- New Intent Standard;
- Additional Clarifications on Proving Intent;
- Litigation Implications;
- Prosecution Implications;
- Recent Events – Possible Supreme Court review may further change standards.

Relevant Facts in Therasense

- Abbott (formerly Therasense) asserted U.S. Patent No. 5,820,551 (the '551 patent).
- The '551 patent involves disposable blood glucose test strips for diabetes management.



Relevant Facts in Therasense

- The U.S. prosecution of the ‘551 patent commenced in 1984.
- During its 14 years of prosecution, the ‘551 received 12 sets of rejections, 11 of the rejections relied on Abbott’s own prior art ‘382 patent, or its European counterpart.
- The prior art ‘382 patent was related by subject matter, but was from a different patent family.

Relevant Facts in Therasense

- In 1996, with prosecution of the '551 patent pending, Abbott purchased the owner of the application, and its in-house attorney, Lawrence Pope, took control of prosecution.
- Pope brainstormed with R&D Director Gordon Sanghera, and decided to pursue claims for a test strip with an electro-chemical sensor for testing whole blood without a membrane over its electrode.

Relevant Facts in Therasense (cont.)

- Problem: The prior art '382 patent specification discussed protective membranes in the following terms:

  "Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules."

Relevant Facts in Therasense (cont.)

- Abbott's Solution: Assert that in 1983, persons of ordinary skill would not have taken the statement in the prior art '382 patent literally, and instead would believe a membrane was essential.

Relevant Facts in Therasense (cont.)

- When presented with Abbott's solution during an interview in 1997, the PTO Examiner stated an affidavit would be necessary to overcome the teaching of the '382 patent.

Relevant Facts in Therasense (cont.)

- Abbott's R&D Director Dr. Sanghera submitted a declaration to the PTO stating:

  > [H]e is sure that one skilled in the art would not read [the 'optionally but preferably' language of the '382 patent] to teach that the use of a protective membrane with a whole blood sample is optionally or merely preferred.

Relevant Facts in Therasense (cont.)

- Attorney Pope submitted remarks, citing to the Dr. Sanghera's declaration stating:

  One skilled in the art would not have read the disclosure of [the '382 patent] as teaching that the use of a protective membrane with whole blood samples was optional. He would not, especially in view of the working examples, have read the optionally, but preferably language at line 63 of column 6 as a technical teaching but rather **mere patent phraseology**

  ....

  There is no teaching or suggestion of unprotected active electrodes for use with whole blood specimens in this patent or the other prior art of record in this application.

Relevant Facts in Therasense (cont.)

- In response to Dr. Sanghera's declaration and Attorney Pope's remarks, the examiner allowed the claims and the '551 patent issued.

- However, in 1994 and 1995, during opposition proceedings to its European equivalent of the prior art '382 patent, Abbott's predecessor arguably made inconsistent or contrary statements that the equivalent prior art '382 patent did not require certain membranes.

Relevant Facts in Therasense (cont.)

- **Abbott's European Counsel in opposition proceedings stated:**

  "Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules."

  It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood …. For this very reason the sensor electrode as claimed does not have (and must not have) a semipermeable membrane in the sense of D1.

Relevant Facts in Therasense (cont.)

In PTO:

Argued that the prior art '382 patent required a sensor with a membrane. (It was not optional.)

In EPO:

Argued that the European equivalent to the '382 patent, which contained an identical specification, did not require a sensor with a membrane. (It was optional.)

Relevant Facts in Therasense (cont.)

- Additional problems for Abbott:
  - Abbott's R&D Director Dr. Sanghera, who provided the declaration to the US PTO, had helped prepare the arguments in the EPO proceedings that were inconsistent with the PTO declaration;
  - Dr. Sanghera provided the documents and arguments from the EPO proceedings to Abbott's prosecution Attorney Pope; and
  - Attorney Pope and Dr. Sanghera admitted they were both fully aware of the EPO statements, and they intentionally decided not to submit them to the USPTO.

Trial Court Decision

- The trial court found various claims of the '551 patent obviousness over the prior art '382 patent.
- The trial court also held the '551 patent unenforceable, because Abbott did not disclose its briefs submitted to the European Patent Office that contained arguably contradictory statements regarding the prior art '382 patent.

Federal Circuit Redefined the Elements of Inequitable Conduct

- Although the Federal Circuit redefined certain elements of inequitable conduct, the most basic components of the defense remain unchanged.
- An accused infringer still has the burden to prove by clear and convincing evidence:

  (1) that an applicant

  (a) affirmatively misrepresented a material fact,

  (b) submitted false/misleading material information, or

  (c) failed to disclose material information;

  AND

  (2) The applicant committed the above acts or omissions with intent to deceive the USPTO

Federal Circuit Redefined the Elements of Inequitable Conduct (cont.)

- However, the Federal Circuit has now:
  - Redefined and significantly narrowed what constitutes "material" information; and
  - Redefined and made it more difficult to prove intent to deceive the USPTO.

Federal Circuit's New Standard for Materiality

Prior Definitions of Materiality:

- USPTO Rule 56 (1992):
  - prima facie case of unpatentability of a claim, or
  - refutes or inconsistent with position applicant took regarding patentability

Federal Circuit's New Standard for Materiality

Prior Definitions of Materiality:

- Reasonable Examiner: substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent

Federal Circuit's New "But-For" Standard for Materiality

- New Definition: Information is material only "if the PTO would not have allowed a claim had it been aware of the undisclosed prior art."

Application of New "But-For" Standard for Materiality

- To determine materiality, courts now must:
  - use the broadest reasonable interpretation of the claims, and
  - apply a preponderance of the evidence standard in determining whether the PTO would not have allowed the claim had it been aware of the reference.

Application of New "But-For" Standard for Materiality

- Courts may therefore employ different standards when determining invalidity and unenforceability:
  - For invalidity, the trial court will use (a) a claim interpretation determined by the court after considering arguments from the parties, and (b) the "clear and convincing" evidence standard; and
  - for unenforceability the court will use (a) the broadest reasonable interpretation of the claims, and (b) the preponderance of the evidence standard.

Application of New "But-For" Standard for Materiality

- If a claim is properly invalidated in district court based on a deliberately withheld reference, then that reference is necessarily material because a finding of invalidity in a district court requires a higher evidentiary burden than that used during prosecution before the PTO.

Application of New "But-For" Standard for Materiality

- If a district court does not invalidate a claim based on a deliberately withheld reference, the reference may still be material if it would have blocked patent issuance under the PTO's different evidentiary standards [i.e., broadest reasonable claim interpretation and preponderance of the evidence standard].

Exception to "But-For" Standard for Materiality

- Information can be material even if it would not have affected the allowance of a claim, where an applicant actively attempted in an extreme manner to mislead the PTO, such as the filing of an unmistakably false affidavit.

Exception to "But-For" Standard for Materiality

- The majority decision expressly excludes non-disclosure of information from the above exception – it must be an affirmative act of misconduct.
- However, the minority argues it can be difficult to accurately define which acts are affirmative, and which involve non-disclosure of information.

Federal Circuit's Rejection of USPTO's Rule 56 Standard for Materiality

- The Fed. Cir. explicitly rejected arguments by the USPTO, the minority decision, and the accused infringers to adopt the PTO's Rule 56 standard to define materiality
- Court found that tying the materiality standard to the USPTO's Rule 56, which changes "from time to time, has led to uncertainty and inconsistency in the development of the inequitable conduct doctrine."
- Court found Rule 56's definition of materiality too broad, and would not change the current incentives for applicants to submit excess information to the PTO having marginal relevance to patentability, and patent litigators to continue to charge inequitable conduct in nearly every case.

New Standard for Proving Intent to Deceive

- As to the intent prong, the Fed. Cir. clarified that in the case of withheld information, an accused infringer must prove by clear and convincing evidence that the applicant:
  - knew of the information;
  - knew that it was material; and
  - made a deliberate decision to withhold it.

New Standard for Proving Intent to Deceive

- This new standard clarifies and makes it more difficult to prove intent, primarily due to the "knew that it was material" prong.
- It rejects contrary precedent which previously found it sufficient that the applicant "knew or should have known" the information was material; and

New Standard for Proving Intent to Deceive (cont.)

- The new definition for "materiality" is now incorporated into the intent standard.
- Therefore, one must now prove an applicant knew the USPTO would not have allowed a claim had it been aware of the withheld information.

Limitations on Inferring Intent to Deceive

- Direct evidence of intent to deceive the PTO is rarely, if ever available.
- The Federal Circuit acknowledged that intent to deceive can be shown indirectly from the facts, i.e., inferred or presumed.

Limitations on Inferring Intent to Deceive (cont.)

- However, to prove intent to deceive by clear and convincing evidence, any inference of intent to deceive:
  - must be "the single most reasonable inference able to be drawn from the evidence,"
  - The evidence "must be sufficient to require a finding of deceitful intent in the light of all the circumstances," and
  - If a reasonable inference can be drawn that does not involve an intent to deceive, then no intent to deceive can be found.

Further Clarifications on Intent to Deceive

- The Federal Circuit also adopted holdings from former Chief Judge Michel's *Star* Scientific case to emphasize:
  - the elements of materiality and intent to deceive must each be separately proven by clear and convincing evidence;
  - 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;
  - the patentee need not offer any good faith explanation unless the accused infringer first proves a threshold level of intent to deceive by clear and convincing evidence; and
  - absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.

Sliding Scale vs. Balancing

- The Prohibited "sliding scale"
  - applied by trial courts traditionally using a strong showing of materiality to offset a weak showing of intent;
  - Without first ensuring that both intent to deceive and materiality were separately established by clear and convincing evidence.

Sliding Scale vs. Balancing

- Required "Balancing"
  - Occurs after materiality and intent to deceive are separately proven by clear and convincing evidence;
  - Trial court must weigh the equities to determine whether the applicant's conduct before the PTO warrants rendering the entire patent unenforceable.

Recent Events

- Becton-Dickinson filed a motion (which was denied) to stay the mandate of the Federal Circuit pending a request to the U.S. Supreme Court to review this case.
  - Supreme Court review is quite possible given:
    - the number of dissenting judges and the disagreement whether "but-for" test is consistent with Supreme Court precedent;
    - The clear policy disagreement on whether applicants under the new materiality standard have sufficient incentives to submit all relevant information to the USPTO.

Recent Events

- USPTO is currently studying Therasense decision to assess impacts on agency practice and procedures; expects to issue further guidance to applicants shortly.

Recent Events

- Congress is considering enactment of a "Supplemental Examination" procedure, within the present round of patent reform legislation.
- This would allow patent owners to voluntarily and proactively cure perceived defects in their patents prior to enforcement and preclude an inequitable conduct defense. See S. 23, 112th Cong. § 10 (2011) and H.R. 1249, 112th Cong. § 11 (2011).
- Presently, inequitable conduct cannot be cured through reissue or re-examination.

Litigation Implications

- Therasense decision, if not reversed or amended by Supreme Court, makes it much more difficult to prove inequitable conduct in litigations.
  - Substantially higher "but-for" standard for materiality
  - Substantially higher standard for intent
- These higher standards for proving inequitable conduct are consistent with other recent Fed. Cir. decisions raising standards for alleging inequitable conduct. (Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312 (Fed. Cir. 2009)

Litigation Implications

- Decision leaves open possible gray areas for accused infringers to exploit:
  - Dissent and concurring opinions argue it is still possible to rely upon highly material information to support inferring an intent to deceive, as long as the intent element is proven by clear and convincing evidence.
  - The exception to the "but-for" standard for affirmative egregious misconduct will be tested and expanded.
  - One can still use a pattern of multiple nondisclosures and/or misrepresentations as a basis to infer that the single most reasonable inference to be drawn from such conduct is a deliberate intent to deceive the USPTO.
  - Accused infringers might assert "unclean hands" more often as a defense, since the court acknowledged it remains a viable defense distinct from inequitable conduct and does not require "materiality."

Litigation Implications

- Given the large number of dissenting judges, a majority of a Fed. Cir. panel could be dissenters from the Therasense decision
  - Such a panel may interpret Therasense narrowly, and ultimately dilute the impact of Therasense
  - This occurred to some degree after the en banc decision in *Kingsdown* regarding the "intent to deceive" prong of inequitable conduct.

Prosecution Implications and Recommendations:

IDS and related case statement filing procedures should NOT be changed at this time.

- Despite the court's rejection of Rule 56 materiality, with regard to patent prosecution all USPTO rules still must be followed (including disclosing material information from domestic and foreign prosecution that is related by family or subject matter, as well as related litigation).
- U.S. Supreme Court may still alter the standard.
- Still awaiting USPTO guidance and possible legislative action.

Prosecution Implications and Recommendations: (cont.)

- In the Microsoft vs. i4i case, the Supreme Court on June 9, 2011, determined that patents continue to be
  - presumed valid and
  - must be proven invalid by clear and convincing evidence, even with respect to prior art that was not before the examiner during prosecution.

Prosecution Implications and Recommendations: (cont.)

- However, the Supreme Court acknowledged that "if the PTO did not have all material facts before it, its considered judgment may lose significant force," and "a jury may be instructed to evaluate whether the evidence before it is materially new, and if so, to consider that fact when determining whether an invalidity defense has been proved by clear and convincing evidence."

Prosecution Implications and Recommendations: (cont.)

- This Supreme Court decision confirms that IDS submissions should not be reduced in view of *Therasense*, because submitting all relevant prior art minimizes the chance that any unsubmitted prior art is "materially new" for purposes of invalidity.

Additional Ethical Obligations under VA Rules of Professional Conduct (follows ABA Model Rules)

- Rule 3.3 Candor Toward the Tribunal
  - (a) A lawyer shall not knowingly:
    - (1) make a false statement of fact or law to a tribunal;
    - (2) fail to disclose a fact to a tribunal when disclosure is necessary to avoid assisting a criminal or fraudulent act by the client, subject to Rule 1.6;
    - (3) fail to disclose to the tribunal controlling legal authority in the subject jurisdiction known to the lawyer to be adverse to the position of the client and not disclosed by opposing counsel; or
    - (4) offer evidence that the lawyer knows to be false. If a lawyer has offered material evidence and comes to know of its falsity, the lawyer shall take reasonable remedial measures.
  - (b) A lawyer may refuse to offer evidence that the lawyer reasonably believes is false.
  - (c) In an ex parte proceeding, a lawyer shall inform the tribunal of all material facts known to the lawyer which will enable the tribunal to make an informed decision, whether or not the facts are adverse.
  - (d) A lawyer who receives information clearly establishing that a person other than a client has perpetrated a fraud upon a tribunal shall promptly reveal the fraud to the tribunal.

Additional Ethical Obligations under 37 CFR § 11.18(b)(1) and MPEP § 410)

- Equivalent to Rule 11 of Federal Rules

(b) By presenting to the Office (whether by signing, filing, submitting, or later advocating) any paper, the party presenting such paper, whether a practitioner or non-practitioner, is certifying that—

(1) All statements made therein of the party's own knowledge are true, all statements made therein on information and belief are believed to be true, and all statements made therein are made with the knowledge that whoever, in any matter within the jurisdiction of the Patent and Trademark Office, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be subject to the penalties set forth under 18 U.S.C. 1001, and that violations of this paragraph may jeopardize the validity of the application or document, or the validity or enforceability of any patent, trademark registration, or certificate resulting therefrom.

37 CFR § 11.18(b)(1)

- Thank You
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