DLA PIPER

EVERYTHING MATTERS

Citation of Prior Art & the America Invents Act

Dale Lazar

McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897 (Fed. Cir. 2007)

The invention was a patient identification system for relating items with patients using bar codes associated with the items and patients and bar code readers in communication with a base station.

The conduct in issue was disclosure of a copending application with similar claims, BUT nondisclosure to the USPTO of Examiner cited prior art, rejections, and notice of allowance in the copending application.

McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897 (Fed. Cir. 2007)

District Court:

Patent was unenforceable because of inequitable conduct. Prior art and prosecution history of patent with similar claims was material under the "reasonable examiner" standard. Intent to deceive was found based on a pattern of nondisclosure of material information and a balancing of evidence for and against intent.

Reasonable Examiner standard:

Any information that a reasonable examiner would substantially likely consider important in deciding whether to allow a patent to issue is material information.

McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897 (Fed. Cir. 2007)

CAFC affirmed.

A reasonable examiner would have considered the copending application information material to the present application, and the failure to disclose this information to the USPTO constituted inequitable conduct. The Court balanced levels of materiality and intent to determine that the conduct was inequitable.

McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897 (Fed. Cir. 2007)

Regarding *materiality*, CAFC said: Any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent is material.

1) The existence of other, better, more relevant references does not remove the duty to disclose a reference.
2) Prior art need not be substantially similar to the subject matter of the application to be material.
3) Subject matter of a copending application also does not have to be substantially similar to subject matter of the application to be material.
4) Information that is "merely cumulative" to that information already considered by the examiner is not material.

McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897 (Fed. Cir. 2007)

Regarding *intent*, CAFC said: The intent required for a finding of inequitable conduct is intent to deceive. This is proven by inferences drawn from facts.

1) The rejection in the copending application contradicted an argument for patentability made by applicants in this application.
2) Testimony by applicant's patent attorney established that he was typically "over inclusive" with citing prior art.
3) Applicants failed to provide a credible explanation for failing to submit the copending application documents to the USPTO.
4) Some evidence of a lack of intent to deceive (disclosure of the existence of the copending application) did not overcome the inferences established by the other facts.

Dissent by Judge Newman – inferences were not "clear and convincing"

Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1289 (Fed. Cir. 2010)

The invention was a test strip with an electromechanical sensor for testing whole blood without any membrane over the electrode.

The conduct in issue was nondisclosure to the USPTO of contradictory statements made to the EPO concerning the teachings of prior art during prosecution of the EPO counterpart.

District Court:

Patent was unenforceable because of inequitable conduct. Applicants' statements made to the EPO contradicted statements made to USPTO. Intent to deceive was found based on the absence of a good faith explanation for failing to disclose the EPO statements.

CAFC initially affirmed.

Statements made to the EPO concerning prior art patent were inconsistent with statements made to the USPTO regarding the same patent. The statements made to the EPO were material, and the failure to disclose those statements to the USPTO constituted inequitable conduct.

Regarding **materiality**, CAFC initially said: An applicant's earlier statements about prior art, especially one's own prior art, are material to the USPTO when those statements directly contradict the applicant's position regarding that prior art in the USPTO.

Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1289 (Fed. Cir. 2010)

Regarding **intent**, CAFC initially said: There was ample support in the record for the district court's findings:

1) The statements made to the USPTO concerning the prior art were absolutely critical in overcoming the examiner's earlier rejections.
2) The EPO statements would have been very important to an examiner because they contradicted the representation made to the USPTO.
3) Applicants knew of the EPO statements and consciously withheld them from the USPTO.
4) Applicants failed to provide a credible explanation for failing to submit the EPO documents to the USPTO.
5) Applicant's explanations for withholding the EPO documents were so incredible that they suggested intent to deceive.

Strong dissent by Judge Linn.

Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1289 (Fed. Cir. 2010)

Therasense was decided on January. 25, 2010.

On April 26, 2010, the CAFC granted the petition for rehearing en banc and vacated the initial CAFC decision of January 25, 2010.

The En Banc Decision
Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1289 (Fed. Cir. 2010)

The two analytical prongs used to test for inequitable conduct have been and remain **materiality and intent**. However, the proof for establishing each prong has been heightened.

"This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public."

The En Banc Decision
Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1289 (Fed. Cir. 2010)

To satisfy the materiality prong for inequitable conduct, the court held that **"but-for"** materiality must be established. In other words, the information must be so material that **"but-for"** the withholding or false submission, the patent should not have issued.

The court recognized an exception to the **"but-for"** materiality standard in cases of *"affirmative acts of egregious misconduct."*

The En Banc Decision
Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1289 (Fed. Cir. 2010)

To satisfy the "**intent**" prong for inequitable conduct, intent must be proven by clear and convincing evidence.

"[T]he accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it."

The CAFC vacated the District Court's finding of inequitable conduct and remanded it for further proceedings consistent with this opinion.

The day after the *Therasense* decision, the USPTO issued a press release stating that it was studying *Therasense* to assess impacts on USPTO practice and procedures and the prior art and information applicants must disclose.

Current Rule 56 (37 CFR § 1.56)

Patent practitioners have a duty to disclose all information known to be material to patentability. The duty to disclose exists with respect to each pending claim until the claim is cancelled or withdrawn or the application becomes abandoned.

A patent will not issue if fraud is practiced or attempted or the duty of disclosure is violated through bad faith or intentional misconduct.

Examples of information that may be material include:

1) Prior art cited in search reports of a foreign patent office in a counterpart application.
2) Information that is known to be similar to what is defined by any pending claims.

Current Rule 56 (37 CFR § 1.56)

Information may be material if:

1) It establishes, by itself or in combination with other information, that a claim is unpatentable if given its broadest reasonable construction consistent with the specification and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.
2) It is inconsistent with an argument asserting patentability or opposing an Examiner's argument of unpatentability presented to the Patent Office.

Information that is merely cumulative to information already of record in the application may not be material information.

Proposed Rule 56

On July 21, 2011, the USPTO published a Notice of Proposed Rulemaking to revise the standard for materiality. (Federal Register, Vol. 76, No. 140 / Thursday, July 21, 2011).

The proposal is to change 37 C.F.R. § 1.56 Duty to Disclose Information Material to Patentability as follows:

b) Information is material to patentability if it is material under the standard set forth in *Therasense*, and that information is material to patentability under *Therasense* if:

(1) The Office would not allow a claim if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or

(2) The applicant engages in affirmative egregious misconduct before the Office as to the information.

Proposed Rule 56

Perhaps out of concern that applicants would reduce their submissions, the PTO added:

"The Office recognizes the tension inherent in a disclosure standard based on unpatentability, but appreciates and expects that patent applicants are inclined to be forthcoming and submit information beyond that required by proposed Rule 56, in an effort to assist examiners in performing their duties. The Office wishes to facilitate and encourage such efforts by applicants."

In the meantime, current Rule 56 (37 C.F.R. § 1.56) remains in force and all applicants should continue to comply with current Rule 56.

H.R. 1249 – The America Invents Act
Section 12 – Supplemental Examination

Provisions take effect on September 16, 2012.

A patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent.

If a substantial new question of patentability is raised by information in the request, the Director shall order reexamination of the patent.

A patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent.

H.R. 1249 – The America Invents Act
Section 12 – Supplemental Examination

After a patent issues, failures to disclose or mistakes in disclosure of material information can be corrected. The information can be submitted with a request for supplemental examination.

Not applicable for:

1) Supplemental examination must be requested before unenforceability is raised in civil actions.
2) Supplemental examination must be requested before allegations of unenforceability are set forth in abbreviated new drug applications.
3) Defenses raised in actions brought in ITC action (unless the supplemental examination and any subsequent reexamination are concluded before the action is brought)
4) Material fraud (note that practitioners can still be sanctioned for misconduct)

H.R. 1249 – The America Invents Act
Preissuance Citation of Prior Art

Provisions take effect on September 16, 2012.

Patents and printed publications may be submitted by any 3rd Party for consideration and inclusion in the record of any patent or application.

Third party submissions must be made in writing before the earlier of

- the date a notice of allowance is mailed in the application for patent; or
- the later of 6 months after the date on which the application for patent is first published, or the date of the first rejection.

H.R. 1249 – The America Invents Act
Preissuance Citation of Prior Art

Any third party submission must include:

- a concise description of the asserted relevance of each submitted document
- any required fee, and
- a statement by the person making such submission affirming that the submission was made in compliance with this section.

H.R. 1249 – The America Invents Act
Citation of Prior Art in Issued Patents

Information that can be submitted by a third party includes:

- Prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent; or
- Statements of the patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of a particular patent.

Submitted statements of the patent owner are only used by the Patent Office to determine the proper meaning of a patent claim in an inter partes or post-grant review proceeding.

Written Statements are Placed in the Official File

Identity of the submitting person may be kept confidential upon request.

Tips for Avoiding Inequitable Conduct Problems

1) Cite all prior art known to you and the applicants.

   Under the America Invents Act, mistakes can be corrected, but it remains fraud to intentionally fail to cite known prior art. Practitioners can be sanctioned/referred to the Justice Department.

2) Inform inventors and others involved with the application of their duties to disclose.

3) Practitioners may be able to be less aggressive in determining that applications have related subject matter.

   Proposed rule 56, when adopted, will raise the materiality standard to a “but-for” standard. Information will be material if the Office would not allow a claim if it were aware of the information.

   Therasense establishes that material reference was intentionally withheld if clear and convincing evidence establishes that the applicant knew of the reference, knew it was material, and made a deliberate decision to withhold it.

Tips for Avoiding Inequitable Conduct Problems

4) Concise explanation for non-English references.

- Prepared abstract or English version of ISR sufficient ONLY IF the abstract or ISR discloses all material portions of prior art, provided you can understand the prior art.
- No requirement to prepare translation, but if you can understand the prior art, you have a duty to ensure that the relevant portions are disclosed.
- Machine translations are generally acceptable.

Tips for Avoiding Inequitable Conduct Problems

5) Provide inventors – and those substantively involved in preparation or prosecution of the application – with a copy of 37 CFR. § 1.56 – and discuss duty in "plain Japanese".

   Consider: IP Managers, Lab Supervisors, Lab Technicians, Marketing Staff

6) Discuss/explore inventorship, e.g., listed inventors different from authors of a publication disclosing the invention? Any disputes to inventorship? Inquire into contributions to the invention made by:

   Marketing/Sales Staff, Corporate Officers, Lab Managers, Lab Technicians, Consultants, Suppliers, Attorneys, etc.

Tips for Avoiding Inequitable Conduct Problems

7) Review 35 U.S.C. § 102 – especially 102(b) and (f)

102(b): the invention was patented or described in a printed publication in the U.S. or a foreign country or in public use or sale in the U.S. more than one year prior to the application date

102(f): the applicant did not himself invent the subject matter sought to be patented

Tips for Avoiding Inequitable Conduct Problems

8) Discuss oath/declaration with inventors prior to signing. Provide translation if inventor does not understand English.

9) Emphasize possible consequences of breach.

10) To facilitate cooperation and disclosure, emphasize that prompt and full disclosure of material information will:

- Reduce application drafting and prosecution costs
- Minimize arguments, amendments, and possible estoppels
- Reduce pendency in USPTO, thus increasing patent term
- Increase the likelihood that if the patent is challenged it will be held valid and enforceable

Tips for Avoiding Inequitable Conduct Problems

11) Ask if disclosed tests/results were actually done or are merely expected results of future tests

12) If declarations/affidavits are submitted, provide full disclosure of present and past relationships between the declarant and applicant

13) Disclose related litigations or decisions by USPTO Board of Appeals.

Tips for Avoiding Inequitable Conduct Problems

14) Different standards based on important applications?

- Citing prior art from corresponding applications in other countries or providing translations – no difference based on importance
- Deciding other U.S. applications are related – maybe less aggressive for less important applications

ありがとうございました

ご質問等ございましたら、下記までお気軽に
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