WEST MICHIGAN CORPORATE IP ROUNDTABLE

Disclosure Strategies for Avoiding Inequitable Conduct Claims

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The Duty of Candor

37 CFR 1.56 (“Rule 56”) imposes a duty of candor and good faith in dealing with the USPTO.

Each individual associated with the filing and prosecution of an application must disclose all known information that is “material to patentability.”

Overview of Inequitable Conduct

- Failure to disclose *material* information

or

- Submission of *materially false* info.

coupled with

- *Intent* to mislead or deceive the patent examiner

equals

INEQUITABLE CONDUCT

Overview of Inequitable Conduct

The Early Years – *Much Ado About Nothing*

- **Routinely asserted, but generally disfavored.**
- **CAFC routinely referred to inequitable conduct charges as "an absolute plague."**
- **Intent to deceive was extremely hard to prove.**

The Winds of Change - Inequitable Conduct Claims Rebound and the List of What Should Be Disclosed Grows

- *McKesson Information Solutions, Inc. v. Bridge Medical, Inc. (2007)*
- *Monsanto v. Bayer Bioscience (2008)*
- *Larson v. Aluminart (2009)*
- *Therasense, Inc. v. Becton, Dickinson and Co. (2010)*

McKesson

Inequitable conduct found from the failure to disclose three items of information:

- A prior art patent cited in one pending application (not disclosed in other pending application);
- Grounds of rejection of substantially similar claims in co-pending applications (pending before different examiners)
- Notice of allowance in co-pending application (pending before the same examiner)

Monsanto

- Inequitable conduct found from the failure to disclose notes taken by Applicant's employee during a scientific conference, though a poster representing the presenter's finding was disclosed
- Applicant's representative admitted that the notes would have been important to an Examiner if the notes contained reliable notes.
- The notes directly contradicted arguments made to the PTO in support of patentability.

Monsanto (Con’t)

- “Excuse” for not disclosing notes: not decipherable standing alone and the note-taker supposedly could not remember anything about the notes
- However, the note-taker was miraculously was able to provide detailed testimony about the notes years later.

Larson

Materiality of Withheld Information: Yes

Intent: Probably Not

- Two pending applications, subject patent in Reexamination after stay of litigation, same attorney prosecuting
- Disclosed materials from litigation, second Office Action (OA) from co-pending application, three prior art references from co-pending application

Larson (con't)

Materiality of Withheld Information: Yes

Intent: Probably Not

- Did not disclose 3rd and 4th OAs from co-pending application in Reexamination.
- Did not disclose German patent cited in the 4th OA in the Reexamination.
- Did not disclose two other pieces of prior art (product and marketing materials of other companies).

Larson (con't)

Materiality of Withheld Information: Yes

Intent: Probably Not

- CAFC found that the two OAs were material.
- CAFC found that the withheld prior art patent and marketing materials were cumulative of other art already submitted.
- CAFC remanded because the D.C. intent finding was based on both the OAs and the withheld prior art.

Therasense

- After years of failed prosecution, the patent applicant came up a new theory of patentability – a sensor for use in whole blood *without* any protective membrane.
- However, a prior art patent appeared to disclose membraneless sensors:

> "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."

Therasense (Con't)

- To overcome the prior art, the applicant submitted a declaration that stated in 1983 skilled artisans would have believed that a membrane was essential even in the face of the prior art disclosure. i.e, one of ordinary skill in the art would not have taken the "optionally, but preferably" language literally.
- The patent attorney referred to the "optionally, but preferably" language as "mere patent phraseology" rather than a "technical teaching."

Therasense

• However, at the time the "phraseology" argument was made, both the attorney and the declarant were aware of previous contradictory statements made during prosecution of a European patent that corresponded to the cited *prior art* patent:

- EPO argument: the "optionally, but preferably" sentence demonstrated that the invention did *not* need a membrane.

CAFC’s take:

“An applicant's earlier statements about prior art, especially one's own prior art, are material to the PTO when those statements directly contradict the applicant's position regarding that prior art in the PTO.”

What Do These Cases Tell Us?

- Everyone involved in the application process must understand their disclosure obligations.
  - Invest in training on disclosure obligations, including giving examples of potentially material information
  - Remind your clients *continually* through prosecution about the duty to disclose

What Do These Cases Tell Us?

- Implement a Strategy to Identify “Related” Applications and Cross-File Material Information in Those Cases
  - Invest in a savvy docketing system that can link “related” cases
  - Create a master IDS for known art for “related” cases
  - Cross-file OAs, prior art, responses, NOAs in “related” cases as a matter of course

What Do These Cases Tell Us?

- Build Prosecution Teams for Related Subject Matter (i.e., consolidate cases for same subject area) to make it easier to identify "related cases."
- If it is decided *not* to disclose something, document the reasons for the decision (and place in file).
- Upon issuance, check to make sure that all IDS were considered by the Examiner, and verify that all information from "related cases" were submitted.

Case Study for Dealing *McKesson* issues

Owens Corning's Current Practice

• Manage all patent/application files in electronic database

- CPA (Memotech)

• Relate all cases

- Look at product/process
- If related technology, relate cases

Case Study for Dealing *McKesson* issues

Owens Corning's Current Practice

- Develop master IDS
  - All related case references
  - Searches, prosecution, corporate files
  - Ensure all references cited for all related cases unless not relevant to examiner

Case Study for Dealing *McKesson* issues

Owens Corning's Current Practice

- IDS for prosecution – all related cases
  - Office Action
  - Notice of Allowance
  - Response
  - US & Foreign
- Manually created
- Pull case from issue for IDS if not completed
- Added staff to support (contract)

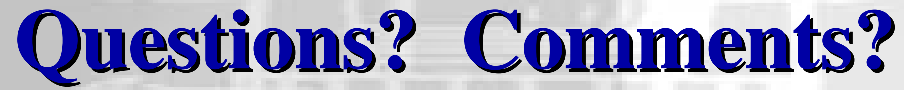
Case Study for Dealing *McKesson* issues

Owens Corning's Future Plans

- CPA (Memotech) – Automated

- Each reference = record
  - Assigned to case
  - Creates an "event" in each related case
  -"Automatic" IDS for each related case

- Prosecution = record (OA, NOA, Resp)
  - Creates an "event" in each related case
  - "Automatic" IDS for each related case



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