Duty to Disclose


- Federal Circuit en banc established new standards for establishing both 10 materiality and 2) intent for a showing of inequitable conduct

Materiality:
- Federal Circuit en banc established a “but-for” materiality standard
- In addition to “but-for” test as a general rule, also cases where patentee has engaged in “cases of affirmative egregious misconduct” such as the filing of unmistakably false affidavit, the misconduct is material
- Federal Circuit rejected PTO’s current standard for materiality under 37 CFR 1.56
- Question whether “sliding scale” of materiality/intent still proper analysis
Duty to Disclose


**Intent:**
- Federal Circuit en banc also articulated “knowing and deliberate” standard for intent to deceive

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Duty to Disclose

- Federal Circuit’s “But for” test for materiality:
  When an applicant fails to disclose prior art to the PTO, the prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art
  Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction …
  Often the patentability of a claim will be congruent with the validity determination – if a claim is properly invalidated in district court based on deliberately withheld reference, then that reference is necessarily material because a finding of invalidity in a district court requires a clear and convincing evidence, a higher evidentiary standard than that used in prosecution at the PTO.
  However, even if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked the patent issuance under the PTO’s different evidentiary standard.
Duty to Disclose

*Therasense v. Becton Dickinson & Co.* – continued

- Federal Circuit’s “knowing and deliberate” standard for intent to deceive
  The district court found intent to deceive based on the absence of a good faith explanation for failing to disclose the EPO briefs.
  However, a “patentee need not offer any good faith explanation unless the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence.” Star, 537 F.3d at 1368. The district court also relied upon the “should have known” negligence standard in reaching its finding of intent. See Trial Opinion at 1113 (“Attorney Pope knew or should have known that the withheld information would have been highly material to the examiner”).
  Because the district court did not find intent to deceive under the knowing and deliberate standard set forth in this opinion, this court vacates the district court’s findings of intent. Id. at 1113-16. On remand, the district court should determine whether there is clear and convincing evidence demonstrating that Sanghera or Pope knew of the EPO briefs, knew of their materiality, and made the conscious decision not to disclose them in order to deceive the PTO.

On May 27, 2011, USPTO issued press release:

“We are now studying the potential impact of Therasense v. Becton Dickinson on Office practice, and we expect to soon issue guidance to applicants regarding the materials they must submit to the Office under their duty of disclosure.”
Duty to Disclose

♦ Ensures that PTO has the information it needs to effectively examine the patent application
♦ Without this duty, a patent might issue to undeserving applicants and inventions, which would unfairly exclude public from making, using and selling claimed invention
♦ VIOLATION OF DUTY - INEQUITABLE CONDUCT
  ♦ U.S. PTO does not investigate inequitable conduct violations
  ♦ This issue is decided in U.S. courts when a person challenging the validity of a patent asserts that the patentee has engaged in inequitable conduct

Duty to Disclose

♦ If inequitable conduct is found, the entire patent is unenforceable, even if the inequitable conduct relates to only one claim (see MPEP § 2016)
  ♦ Examples: Submitting misleading information (e.g., false test data) in order to intentionally mislead the PTO
  ♦ Intentional concealment of a relevant prior art reference
  ♦ Other patents which are related to unenforceable patent (e.g., continuation patents) may also be held unenforceable if fraudulent conduct affects the other patent (e.g., failure to submit a relevant reference in parent application which is also relevant in a continuation application)
Duty to Disclose

- **WHO HAS DUTY**
  - Each individual associated with the filing or prosecution of the patent application (see 37 C.F.R. § 1.56(c))
  - Each inventor named in the application
  - Each U.S. attorney or agent, who prepares or prosecutes the application
  - Every other person who is substantially involved in the preparation or prosecution of the application and who is associated with the inventor, the assignee, or with anyone to whom there is an obligation to assign the application

- **Members of the Company Patent Section who work on the application**
- **Non-U.S. attorney who work on the application**
  - Non-U.S. patent attorneys have a duty to disclose material information cited in foreign applications (see MPEP § 2004 and Molins PLC v. Textron, Inc., 33 USPQ2d 1823 (Fed. Cir. 1995) - British patent attorney violated the duty to disclose by his failure to submit a reference cited in a foreign patent office)
  - Individuals other than the U.S. attorney, agent, or inventor can satisfy the duty by disclosing information to the U.S. attorney, agent, or inventor (see 37 C.F.R. § 1.56(d) and MPEP § 2002.01)
Duty to Disclose

♦ Duty only applies to individuals, not to organizations, companies, etc.
♦ WHAT IS MATERIAL
  ♦ Current Rule 56(b) - effective March 16, 1992
    ♦ Information which is not cumulative to information of record in the application, and
    ♦ It (i) helps establish a prima facie case of unpatentability, or (ii) is inconsistent with arguments made by the applicant to the PTO regarding patentability
  ♦ Information is not material if it is less relevant than, or cumulative to, prior art which was considered by the PTO

Duty to Disclose

♦ Information is not material if it is not prior art under at least one section if 35 U.S.C. § 102 (e.g., a publication which is published after the U.S. filing date)
♦ Non-material information does not have to be submitted to the PTO
♦ Examples of Material Info. (see MPEP § 2001.04)
  ♦ U.S. patents and published patent applications
  ♦ Other pending U.S. and non-U.S. patent applications including cited prior art, search reports, and office actions (see 37 C.F.R. 1.56(a)(1), MPEP § 2001.06(a), and Dayco Products v. TCI, 329 F.3d 1358 (Fed. Cir. 2003))
Duty to Disclose

Issued / published patent applications from all countries
Public uses, sales, and offers to sell of any product which contains some or all of the elements of the claimed invention
Technical publications
Information related to inventorship disputes
There is no duty to disclose information which is favorable to patentability (e.g., evidence of commercial success), and information related to the level of skill in the art (see MPEP § 2001.04)

WHAT TO SUBMIT
Related U.S. applications
Submit the existence of the related application cited prior art, and rejections (see MPEP § 2001.06(b))
Even if the examiner in the other application(s) is the same, do not assume that he will remember the other application and references cited in the other application
Dayco Products v. TCI (see above) held that rejections of “substantially similar” claim is “material” information ⇒ submit office actions and search reports!
See also Larson Mfg. Co. v. Aluminart Products Ltd. (Fed. Cir. 2009) (held inequitable conduct based on failure to submit rejection in co-pending case)
Duty to Disclose

- Related Non-U.S. Applications
- Prior art search reports and rejections in related foreign applications (see 37 C.F.R. 1.56(a)(1), MPEP § 2001.06(a), and Dayco v. TCI)
- Conflicting arguments made to other (non-U.S.) Patent Offices

Duty to Disclose

- Related litigations
- Information from litigation related to subject matter of patent application (see MPEP § 2001.06(c))
- The existence of the litigation
- Evidence of prior public use or sales
- Questions of inventorship
- Prior art relied on in an assertion of invalidity
- Allegations of fraud, inequitable conduct, or violation of duty to disclose
- This information can be disclosed by filing a copy of the court papers related to this information
Duty to Disclose

♦ Other information to submit
  ♦ Marketing and sales information
  ♦ Information from conventions / trade shows
  ♦ Submissions to other government agencies (e.g., FDA – see Bruno Independent Living Aids Inc. v. Alcorn Mobility Services, 394 F.3d. 1348 (Fed. Cir. 2005))
  ♦ HOW TO SATISFY THE DUTY
    ♦ Submit all information known to be material to the patentability of the application in an Information Disclosure Statement in time to be considered by Examiner (see Part II)

Duty to Disclose

♦ There is no duty to perform search, only need to disclose information that is known
♦ RECOMMENDATIONS
  ♦ If materiality is unclear, submit reference and let PTO decide
  ♦ If you are not sure reference is prior art, submit reference and let PTO or U.S. attorney decide
  ♦ Forward all references cited in counterpart and related non-U.S. applications to U.S. patent attorney ASAP
  ♦ This is especially important after the mailing date of a final Office Action or Notice of Allowance
Duty to Disclose

- Submit prior art which is material to broadest claim, not just information which is only material to the focus of the invention
- Patents are strengthened by submitting a lot of references
- Submission of references avoids later questions of materiality and intent to deceive (which can be very expensive to defend in litigation) accurately, do not mischaracterize (report failures too)
- Reporting experimental results

Avoid filing very long lists of prior art references. Filing large numbers of less relevant references along with a smaller number of more relevant references can be considered to be an attempt to hide the more relevant references. If a long list of references is filed, indicate the ones which are more relevant.

When filing CIP applications, don't forget to submit references which may not be prior art in the parent application, but may be prior art for the new matter.

Duty to Disclose

♦ If prior art references are considered by Company Patent Engineer / Non U.S. Agent, but not submitted because it is believed that they are not material, record this fact in file
♦ A copy of U.S. patent references do not have to be supplied
♦ References not in English
  ♦ A concise English explanation of relevant portions is required

Duty to Disclose

♦ Submission of English Abstract is not recommended unless

Abstract describes all relevant portions of reference
♦ English translation must be filed if it is readily available (already in existence) to anyone associated with the prosecution of the application (see 37 C.F.R. § 1.98(c)) – Machine translations are arguably “already in existence”
♦ English Search Report that cites reference can be used
Duty to Disclose

INFORMATION DISCLOSURE STATEMENT - IDS

WHEN TO FILE

- Within 3 months of filing date or before 1st Office Action on the merits (whichever occurs last) (37 C.F.R. § 1.97(b))
  - No fee or certification required, IDS is always considered by Examiner
  - Restriction Requirement and Election of Species Requirement are not office actions on the merits

Before mailing date of final office action or notice of allowance (37 C.F.R. § 1.97(c))

- Must file a certification, OR pay a fee to have IDS considered by Examiner
- Certification must state (see 37 C.F.R. § 1.97(e)):
  - i) That each item in the IDS was cited in communication from another patent office in a counterpart application not more than 3 months from filing of the IDS, or
Duty to Disclose

♦ ii) No item in the IDS was known to anyone associated with the application (see 37 C.F.R. § 1.57(c)) more than 3 months before filing the IDS
♦ RECOMMENDATION
  ♦ If part (i) cannot be certified it is better to just pay the fee since it is difficult to positively certify part (ii)
  ♦ After mailing date of final office action or notice of allowance, but before payment of issue fee (37 C.F.R. § 1.97(d))
  ♦ Must file a certification under 37 C.F.R. § 1.97(e) (see III.A.2.b. above) AND pay a fee to have IDS considered

Duty to Disclose

♦ After mailing date of final office action or notice of allowance, but before issue date if CANNOT file under (37 C.F.R. § 1.97(d)) (i.e. after pay issue fee or cannot certify)
  ♦ IDS will be place in file wrapper, but will NOT be considered by Examiner
  ♦ Duty to disclose is satisfied
  ♦ Must file a continuation application / Petition to Withdraw from Issue + RCE in order to have IDS considered by the Examiner (see 37 C.F.R. § 1.313(b)(5))
Duty to Disclose

♦ After Issue Date
  ♦ Patentee or any third person can make any patent or printed publication of record in a patent file by filing a prior art statement under 37 C.F.R. § 1.501 at any time during the term of the patent
  ♦ Statement filed by patentee can include a statement which explains how the claims are different than the prior art reference
  ♦ There is **NO** duty to submit any information after issue date
  ♦ If prior art is very relevant, can submit in Reexam

♦ RECOMMENDATION
  ♦ Submit IDS within 3 months of U.S. filing date in order to be sure that references always will be considered by Examiner
  ♦ WHAT TO INCLUDE IN IDS - 37 C.F.R. § 1.98
  ♦ A list of all patents, publications, etc. which are being submitted for consideration by the PTO (PTO Form 1449)
    ♦ U.S. patents should be identified by inventor, patent number, and issue date
    ♦ Non-U.S. patents and published patent applications should be identified by country, document number, and publication date
Duty to Disclose

♦ Publications should be identified by author, title, relevant pages, and date and place of publication (see 37 C.F.R. § 1.98(b))
♦ A copy of each reference - U.S. patent applications do not have to be supplied (37 C.F.R. § 1.98(a)(2)(iii))
♦ References not in English
  ♦ A concise explanation of the relevance of each ref.
  ♦ Concise explanation can be included in the patent specification
  ♦ English Search Report that cites reference

Duty to Disclose

♦ English translation must be filed if it is readily available (already in existence) to anyone associated with the prosecution of the application (see 37 C.F.R. § 1.98(c))
♦ Copy of reference is not required if it was cited by, or submitted to, the PTO in a prior U.S. application which is being relied on for domestic priority under 35 U.S.C. § 120 (e.g., a continuation application, see 37 C.F.R. § 1.98(d))
♦ If any references are cumulative, copies of only one of the cumulative references can be filed (see 37 C.F.R. § 1.98(c))
Duty to Disclose

♦ VIOLATION OF DUTY
♦ HOW TO PROVE
  ♦ Patent challenger must prove by clear and convincing evidence\(^3\) that
    ♦ The applicant withheld **material** (relevant) information from, or made a **material** misrepresentation to the PTOs.
    ♦ The applicant **knew** of the undisclosed information or misrepresentation and its materiality, and
    ♦ The applicant **intended** to mislead the PTO

\(^3\) Evidence which establishes that the truth of the facts asserted is highly probable.

Duty to Disclose

♦ Materiality and intent must **always**, be shown
♦ Good faith (honest) failure to submit a reference, good faith misrepresentation to the PTO (e.g., false statement in oath), or good faith mistake (e.g., failure of inventor to understand a declaration) does **NOT** constitute inequitable conduct
♦ **BALANCING INTENT AND MATERIALITY**\(^4\) - SEE CHART I
  ♦ First, the court decides whether the materiality of the withheld information exceeds a threshold level \(\alpha\) (see Point A)

Duty to Disclose

- If the threshold level of materiality is exceeded, the court decides whether the applicant's conduct exceeds a threshold level of intent (see Point B)
- If the threshold levels of materiality and intent are exceeded, the court then balances the materiality and intent
- If the withheld information or misrepresentation is less material, a greater degree of intent must be proven (see Point C)
- If withheld information is more material, a lesser degree of intent is required (see Point D)

Duty to Disclose

- MATERIALITY
  - As defined above in Therasense (and presumably 37 C.F.R. § 1.56 as will be revised)
- INTENT
  - Intent does not have to be proven with direct evidence e.g., a statement by the applicant that he intended to mislead the PTO is not required
  - Usually, intent is proven by showing that the applicant should have known of the materiality of the withheld reference or misrepresentation (see Bruno v. Acorn above)

Duty to Disclose

- Failure to submit to the PTO a reference that was cited in another patent office may create an inference that the failure to submit the reference was intentional (see Molins, above)
- If withheld information or misrepresentation is highly material, then intent to deceive may be inferred (see Jack Frost Laboratories, Inc. v. Physicians & Nurses Mfg. Corp., 901 F. Supp. 718 (S.D.N.Y. 1995))
- Once intent is inferred, patentee must present evidence that they did not intend to deceive the PTO, a mere denial of intent to deceive will not defeat a finding of inequitable conduct
Duty to Disclose - Appendix

♦ Post-Therasense Cases
  ♦ American Calcar, Inc. v. American Honda Motor Co., Inc. (Fed. Cir. 2011)
  ♦ August Tech. Corp. v. Camtek, Ltd. (Fed. Cir. 2011)
  ♦ Cordis Corp. v. Boston Sci. Corp. (Fed. Cir. 2011)
  ♦ Aventis Pharma S.A. v. Hospira, Inc. (Fed. Cir. 2012)

♦ AIA: Supplemental Examination
  ♦ Patent shall not be found unenforceable based on information considered in supplemental examination
  ♦ It is, however, inapplicable to cure existing allegations
  ♦ It will take effect on 9/16/2012

Duty to Disclose - Appendix

♦ Therasense standard

  ♦ Materiality and intent are separate requirements. (No more sliding scale approach).

  ♦ To satisfy the materiality requirement, it must be proved that if the PTO had been aware of an undisclosed prior art reference, the PTO would not have allowed a claim unless there is affirmative egregious misconduct such as filing of an unmistakably false affidavit. (but-for standard)

  ♦ To satisfy the intent requirement, it must be proved that the patent applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it. (specific intent standard)
American Calcar, Inc. v. American Honda Motor Co., Inc.

- During prosecution of a patent application, American Calcar, Inc. (ACI) did not disclose a document.

- During litigation, ACI alleged that it did not disclose because the document is cumulative, but the court found that it is not cumulative and found that it is critically important document for patentability determination.

- Honda argued that ACI intended to deceive USPTO because the undisclosed document is critically important in patentability determination.


- Powell presented a prototype to Home Depot.

- Powell filed a patent application. During prosecution, he filed a Petition to Make Special on the ground that he was obligated to manufacture and supply devices embodying the claims sought.

- Negotiation between Powell and Home Depot failed and Home Depot contacted another company to build an alternative.

- Powell did not inform the PTO that he no longer qualified to get the Special designation.

- But-for material?
August Tech. Corp. v. Camtek, Ltd.

- During prosecution of an August Tech's patent, the inventors did not submit to the PTO information about August Tech’s NSX-80 wafer inspection device.

- During litigation, Camtek argued that August Tech’s patent claims are invalid on the ground that (i) August Tech's NSX-80 wafer inspection device is a 102(b) prior art, (ii) the NSX-80 device in combination with other prior art references would have made the patent claims obvious. Camtek also argued that the patent claims should be found unenforceable because the NSX-80 information was not submitted.

- But-for material?

Aventis Pharma S.A. v. Hospira, Inc.

- During prosecution of a patent, the inventors did not submit two prior art references.

- During litigation, the court found the patent invalid over the two references. The inventors testified that he did not submit the references because they described only "failed experiments."

- But-for material?

- Specific intent?

During prosecution of a EP counterpart patent application, the inventors received a EP Search Report (ESR). In the ESR, a reference A was identified as category "X" and a reference B was identified category "Y." ESR was accompanied by their attorney's letter stating that the only reference particularly relevant is A.

During prosecution of a U.S. patent application, the inventors submitted A to the PTO, but did not submit B.

During prosecution of a U.S. continuation application, the inventors submitted A and B to the PTO.

Specific intent?