



Therasense and Duty of Candor

Biotechnology/Chemical/
Pharmaceutical Customer Partnership
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Hans Sauer,
Biotechnology Industry Organization

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“Lying, Cheating, and Stealing”

- The inequitable conduct defense evolved from Supreme Court “unclean hands” cases involving truly egregious behavior
- Bribed “prior user” to suppress evidence and file false affidavit favoring patentee - *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933).
- Paid an expert to sign an attorney-written article praising invention, arranged for publication, and submitted the fabricated rebuttal evidence to PTO - *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944).
- Patentee discovered and suppressed evidence of perjury and used it to blackmail the inventor into a favorable settlement of interference - *Precision Instruments Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 606 (1945).

“... where applicants 'lied, cheated, and stole' to obtain a patent...”

Chief Judge Rader, *Always at the Margin: Inequitable Conduct In Flux*
59 Am. U. L. Rev. 777, 780 (2010)

Materiality

- **Rule 56 (1949):** “Any application fraudulently filed or in connection with which any fraud is practiced or attempted on the Patent Office may be stricken from the files.”
- **Rule 56 (1977):** information is material when “there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.”
- **Rule 56 (1992):** Information is material when it is not cumulative of information of record and:
 - (1) It establishes, by itself or in combination with other information, a *prima facie case* of unpatentability of a claim; or
 - (2) It refutes or is inconsistent with, a position an applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.

What happened in Therasense?

- Abbott's application leading to 5,820,551 faced repeated rejections over '382 patent. Eventually, Abbott presented new claims to a test strip for whole blood glucose measurement without a membrane.
- Prior art patent 4,545,382 , also owned by Abbott, teaches:
“Optionally, but preferably when being used on live blood, a protective membrane surrounds [the glucose test strip]”
- Examiner requested affidavit showing that prior art required a membrane
- Abbott's expert affidavit and argument stated that a skilled person would not have viewed a protective membrane as merely optional; a membrane was believed to be necessary in the art; “optionally, but preferably” is mere patent phraseology.

What happened in Therasense?

- Some years earlier, while prosecuting the EP counterpart to the prior art '382 patent, Abbott faced a prior art rejection over a German reference requiring a membrane.
- To the EPO, Abbott explained that the protective membrane of its invention serves a different purpose and it is “unambiguously clear” that is “optional,” albeit preferred when used with live blood.
- Question: does the prior art '382 patent teach that the membrane is optional (as Abbott argued in the EPO in 1994/95) or that it is not optional (as Abbott argued in the USPTO in 1998)?
- CAFC affirmed materiality under Rule 56 standard (Abbott's EPO arguments “contradicted” its position in the USPTO) *37 CFR §1.56(b)(2)* - not “reasonable examiner” standard.

Therasense

- April 16, 2010: Fed. Cir. vacates panel decision, orders *en banc* rehearing
- May 15, 2011, Fed. Cir. issues *en banc* opinion authored by Chief Judge Rader, vacating and remanding on the issue of unenforceability (invalidity was undisturbed)
- Court addresses its past “low standards for intent,” “broad views on materiality,” and the “sliding scale” approach that “conflated, and diluted” these “reduced standards.”

“While honesty at the PTO is essential, low standards for intent and materiality have inadvertently led to many unintended consequences, among them, increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality. 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.”

Therasense

- Sliding scale is rejected: “A 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.”
- “Specific intent” to deceive the PTO must be proved separately by clear & convincing evidence; it may be inferred, but it must be the single most reasonable inference from the evidence, sufficient to require a finding of deceitful intent.
- Proving an applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive.

Therasense

- Rejects current Rule 56 as judicial materiality standard
- “Prima facie” standard is overly broad because information is considered material even if it would be rendered irrelevant in light of patentee’s rebuttal evidence or argument.
- “Refutes or is inconsistent with” standard is too broad because it “encompasses anything that could be considered marginally relevant to patentability.”
- Reliance on this standard has resulted in the very problems this court sought to address by taking this case en banc.
- Establishes “but for” materiality standard: “prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. (using the preponderance of the evidence standard and broadest reasonable construction)

Therasense

- Short-cut to materiality: “if a claim is properly invalidated in district court based on the deliberately withheld reference, then that reference is necessarily material because a finding of invalidity in a district court requires clear and convincing evidence, a higher evidentiary burden than that used in prosecution at the PTO “
- If the withheld information does not invalidate the claim in litigation, it may still be “but-for” material if it would have blocked the issuance of the patent under the PTO’s preponderance/broadest reasonable construction standard.
- For instances other than nondisclosure: When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material.

Whither, Therasense? Wither, Therasense?

- **No materiality:** *Powell v. Home Depot*, 2011 WL 5519820 (Fed. Cir. 2011)
- Small inventor designed prototype rotary saw hand guards for installation at Home Depot locations;
- Prosecuted his patent application under a Petition to Make Special because he expected to get the contract (obligation to manufacture)
- Home Depot arranged to have the invention copied by a cheaper fabricator
- Inventor failed to update the petition after it became clear he wouldn't get the contract
- Fed. Cir: failure to update the petition does not meet “but for” materiality standard. Also, failure to inform PTO that conditions to make special no longer exist is not “affirmative, egregious misconduct” like filing a false affidavit.

Cordis v. Boston Scientific

- **No intent:** *Cordis v. Boston Scientific*, 658 F.3d 1347 (Fed. Cir. 2011)
- Inventor prosecuted U.S. case pro se, and used outside counsel to coordinate foreign prosecution. An EPO search identified one “X” and several “Y” references
- Parent application issued without Y reference being disclosed;
- Y reference was later pointed out to inventor by business partner in continuation application; was disclosed with 70 other references
- Continuation application issued, and patent was found valid and infringed in subsequent litigation
- Fed Cir.: Specific intent to deceive the PTO was not the “single most reasonable inference.” The inventor relied on foreign prosecution counsel directing attention to “X” reference as the most important; once alerted to “Y” reference, it was promptly disclosed

Apotex v. Cephalon

- **Inequitable conduct found:** *Apotex v. Cephalon*, 2011 WL 5172909 (E.D.Pa.)
- Cephalon patent claims composition of modafinil drug particles of certain size
- Drug material meeting claim limitations had been provided by Lafon (French partner) under development and supply agreement. Lafon also provided particle product specs.
- District court found on-sale bar under 102(b) and derivation under 102(f) – Invalidity establishes **materiality**.
- Lafon's role as manufacturer, supplier, and provider of technical data was not disclosed to PTO. Internal Cephalon memo: *“application is unusual ... we did not want to include any Lafon data so as to avoid disclosing their confidential information; thus, the task of disclosure of the invention was unique.”*
- District court: **Intent to deceive** is only reasonable inference

Schering v. Mylan

- **Summary judgment of no inequitable conduct denied:** *Schering v. Mylan*, 2011 WL 3736503 (D.N.J.)
- Schering did not disclose to the PTO that several of the claimed compounds were metabolites of one of its own prior art compounds.
- Schering argued that Mylan cannot show the patents wouldn't have issued "but for" its failure to disclose, because prosecution occurred before the Fed. Cir. 2003 decision in *Schering v. Geneva* 339 F.3d. 1373 (Fed. Cir. 2003) established that such information must be disclosed
- District court unconvinced; *Geneva* was not so great a shift in the law on inherent anticipation of metabolites that disclosure of the parent compound couldn't have blocked issuance of the metabolite claim
- SJ would be inappropriate, Mylan need only prove by preponderance of the evidence that PTO would have denied Schering's claims had it been aware of the undisclosed parent compound.

Schering v. Mylan (cont.)

- Schering also argued that there was insufficient evidence to support the heightened intent standard under *Therasense*; No showing that Schering knew of the materiality of the information and deliberately withheld it from the PTO.
- Schering in-house counsel testimony: believed metabolites to be patentable at the time.
- Mylan: Schering's counsel could not recall the basis for her belief, could not recall ever reading the *Geneva* opinion, and prior caselaw on inherency generally stated that a feature in the prior art was not patentable even if it was previously unrecognized.
- Court: Evidence is sufficient from which reasonable fact-finder could draw an inference of deliberate withholding and knowledge of materiality.

PTO Response to *Therasense*

- 76 Fed. Reg. (July 21, 2011)
- Rule 1.56 is amended by revising paragraph (b) to read as follows:
- “Information is material to patentability if it is material under the standard set forth in *Therasense*.
- Information is material to patentability under *Therasense* if:
 - (1) the Office would not allow a claim if it were aware of the information, applying a 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.”

Observations on NPRM

- Based on feedback and commentary received from BIO member companies
- BIO comments submitted Oct. 19, 2011, available at:
<http://www.bio.org/advocacy/letters/revision-materiality-patentability-standard-duty-disclose>

Legal Stability?

- BIO members believe that the proposed revisions to Rule 56 are unlikely to contribute to greater stability in the law
- PTO proposes a direct importation of judicial materiality standard (“information is material under Rule 56 if it is material under *Therasense*”)
- *Therasense* standard is likely to evolve, drift, and erode in the course of judicial interpretation.
- PTO’s self-adjusting materiality standard would give the force of regulation to shifts in future court decisions interpreting *Therasense*
- Creep and uncertainty in the operation of Rule 56 would follow
- PTO does not have to let the evolution of its own disclosure standard be driven by self-interested private litigants

Legal Certainty?

- BIO members believe that the proposed revisions to Rule 56 do not create significantly greater certainty about art that must be submitted
- Under current standard, art must be submitted if sufficient for a *prima facie* case.
- Under the proposed standard, art must be submitted if it is “but for” material – i.e. sufficient to maintain a rejection + make final
- The delta between the two is unclear, probably small from an *ex ante* perspective
- In most instances, applicants won't be able to predict the sufficiency of a reference for a final rejection with any greater certainty than they can predict the sufficiency of that reference for a *prima facie* case.
- The proposed standard is not significantly more helpful than the current standard in deciding what to submit.

Effectiveness?

- BIO members believe that the proposed revisions to Rule 56 may accomplish less than the PTO hopes
- Even under the proposed rule, applicants may not feel comfortable disclosing significantly less art to the PTO
- Not clear how many of the references that are disclosed today wouldn't need to be disclosed under the proposed new standard
- Making a decision to withhold, even under *Therasense*, continues to create a risk under the “intent” prong – relative to the significant risk reduction caused by disclosing information. (“no downside to disclosing more rather than less”)

Necessary?

- Numerous BIO members have asked why the PTO continues to need Rule 56 at all
- If the PTO wants only the *Therasense* standard, then why have a rule at all – *Therasense* is already the law
- If fraud, perjury, falsification etc. is the concern, federal statutes such as 18 USC 1001 are available
- Rule 56 is practically enforceable only against registered practitioners, who are bound by the Canons and professional conduct standards and could surely be sanctioned even if no Rule 56 existed.
- Moreover, the AIA expands PTO authority to sanction practitioner misconduct

AIA will change the picture?

- AIA contains new post-grant and inter partes review proceedings
- Expands Director's reexamination authority
- Provides more opportunities for third party submissions of prior art and patentee representations about claim scope
- Provides for supplemental examination
- Most applications are published and available on public PAIR
- These mechanisms provide checks on instances of nondisclosure and misrepresentation. Such checks did not exist when Rule 56 was last revised in 1992

Alternative approaches?

- BIO believes that *Therasense* arguably creates greater relief from later being accused of misrepresentation than from being accused of concealment
- Affirmative representations about prior art are likely to be material only if they qualify as “affirmative, egregious misconduct” (such as falsifications)
- Accordingly, *Therasense* may create an opening for PTO incentives for applicants to identify, discuss and explain art they view as most relevant

How to decrease submissions?

- BIO believes that applicants will need to submit whatever the evolving court standards require;
- Additionally, under the AIA applicants will have to consider new prior art, such as foreign public uses or sales or information “otherwise available to the public.”
- For the time being, there may not be a big drop-off in prior art disclosures, and BIO encourages PTO to be permissive and patient (recall 2006 IDS Rules)
- However, BIO members have made a variety of proposals that may over time relieve the perceived disclosure pressure

How to decrease submissions? (2)

- Whole categories of information are at least as available to the PTO as they are to applicants – e.g. patents and applications
- Arguably, in most situations the applicant's help is not “needed” to identify relevant prior art
- Empirical studies suggest that examiners rarely rely on IDS submissions to make art-based rejections
- Some BIO members proposed to impose a disclosure obligation only for non-public material information. Because the AIA establishes public availability as a basic criterion for all prior art, there should be no obligation to disclose prior art.

How to decrease submissions? (3)

- Other BIO members believe that disclosure obligations should extend only to obscure information (but including prior art) that would reasonably be expected to be outside PTO's reach
- E.g. foreign public uses or offers for sale, obscure foreign language documents, limited distribution pamphlets, sales brochures etc.
- Mainstream publications, standard journals, patents, and applications which today constitute the bulk of unnecessary submissions should not be included.
- Other BIO members propose to replace the legal “patentability” standard with a technical “closest art” standard: applicants would not be required to make an ex ante legal judgment about a reference's effect on patentability. Instead, applicants would identify references they deem technically “close.”

Safe harbors, incentives, assurances

- Many BIO members propose disclosure “safe harbors” – e.g. Applicant’s disclosure obligation should be discharged by providing information to registered practitioner
- PTO should incentivize voluntary submissions alongside disclosed prior art, describing, prioritizing the references and explaining their relation to the claimed invention
- In doing so, PTO should make explicit that it will consult but not rely on such applicant submissions – this will provide some assurance that the applicant cannot later be accused of having misled the examiner or induced the PTO’s reliance.
- BIO members widely agree that all participants in PTO proceedings should be under a duty to not compromise the integrity of the PTO’s processes, including reexam requesters, post grant and inter partes review petitioners, and their declarants.

Thank you!

Hans Sauer
Deputy General Counsel, BIO
1201 Maryland Avenue, S.W.
Washington, D.C. 20024
U.S.A.

Tel. (x1)-202-962-6695
Fax. (x1)-202-488-0650
hsauer@bio.org


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