



Your Evolving Ethical Obligations - Therasense and Avid

Seattle, June 16, 2010

Washington State Patent Law Assoc.

Prof. Hawley, ©Franklin Pierce Law
Center

Scope

- Significant CAFC Cases
 - “substantially involved”
 - Avid v. Crystal Import
 - Inequitable Conduct
 - Therasense en banc order

Scope

- Other Cases
 - Intent Standard
 - Purdue Pharma Products L.P. v. Par Pharmaceutical, Inc. (June 3)
 - Leviton Mfg. v. Universal Security (May 28)
 - Best Mode
 - Ajinomoto v. ITC (March 8)

Professional Responsibility

Rule 3.3

(a) A lawyer shall not knowingly:

(1) make a false statement of fact or law to a tribunal or fail to correct a false statement of **material** fact or law previously made to the tribunal by the lawyer;

37 C.F.R. 1.56

Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be **material** to patentability as defined in this section.

Material?

- (b)** Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
- (1)** It **establishes**, by itself or in combination with other information, **a *prima facie* case of unpatentability** of a claim; or

Material?

- (2)** It refutes, or is inconsistent with, a position the applicant takes in:
 - (i)** Opposing an argument of unpatentability relied on by the Office, or
 - (ii)** Asserting an argument of patentability.

1992 Amendment – Previous standard:

Important to a reasonable examiner (1977-1992)

Material?

A *prima facie* case of unpatentability is established when the information **compels a conclusion that a claim is unpatentable** under the preponderance of evidence, burden-of-proof standard, giving each term in the claim 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.

Professional Responsibility

Rule 3.3

(a)(3) offer evidence that the lawyer knows to be false.

(d) In an ex parte proceeding, a lawyer shall inform the tribunal of all material facts **known to the lawyer** that will enable the tribunal to make an informed decision, whether or not the facts are adverse.

37 C.F.R. 1.56

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) inventors, (2) attorneys or agents
- (3) **Every other person who is substantively involved**

Washington ver. 3.3

[14] Ordinarily, an advocate has the limited responsibility of presenting one side of the matters that a tribunal should consider in reaching a decision; the conflicting position is expected to be presented by the opposing party. However, in any ex parte proceeding, such as an application for a temporary restraining order, there is no balance of presentation by opposing advocates.

Washington ver. 3.3

The object of an ex parte proceeding is nevertheless to yield a substantially just result. The judge has an affirmative responsibility to accord the absent party just consideration. The lawyer for the represented party has the correlative duty to make **disclosures of material facts** known to the lawyer and that the lawyer reasonably believes **are necessary to an informed decision**.

3.3 v 1.56 v IC

What is a prosecuting patent attorney to do?:

Are the standards under rules 3.3 and 1.56 the same?

If you satisfy 3.3 *AND* 1.56, can the patent still be held unenforceable for inequitable conduct?

35 USC 282

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

- (1) Noninfringement, absence of liability for infringement or **unenforceability**,

Does not say “inequitable conduct”; does not require materiality or intent; does not require a standard of proof; no balancing

Unenforceability

- Equitable concepts of laches, estoppel or unclean hands
- Prosecution laches (Symbol v. Lemelson)
- Patent misuse, for example “tying”
- “Clear and convincing” rather than “preponderance of the evidence”
- Intent – “single most reasonable inference”

Avid v. Crystal Import

- CAFC April 27 2010 Judge Prost
- a multi-mode radio-frequency identification system
- which individuals are “substantively involved” in the preparation or prosecution of a patent application?? and thus owe a duty of candor and good faith to the Patent and Trademark Office under 37 C.F.R. § 1.56.

Avid v. Crystal Import

- A party may show inequitable conduct by producing clear and convincing evidence of (1) material prior art, (2) knowledge chargeable to the patent applicant of prior art and its materiality, and (3) the applicant's failure to disclose the prior art to the PTO with intent to mislead.

Avid v. Crystal Import

- To have a duty to disclose information to the PTO, an individual must (1) be associated with the filing and prosecution of a patent application such that he owes a duty of candor to the PTO, and (2) know that the information in question is material. §1.56(a).
- “every other person who is substantively involved in the preparation” of the application

Avid v. Crystal Import

- Dr Stoddard was not an inventor nor an agent or attorney involved with the application: was he “substantially involved”??
- We read “substantively involved” to mean that the involvement relates to the **content** of the application or **decisions** related thereto, and that the involvement is not wholly administrative or secretarial in nature.

Avid v. Crystal Import

- The district court's fact findings related to Dr. Stoddard include: the nature of his position as president and founder of Avid, that Avid is a closely held company, and that Stoddard hired the inventors to reduce his encrypted chip concept to practice.
- the district court found that Dr. Stoddard was "involved in all aspects of the company's operation, from marketing and sales to research and development."

Avid v. Crystal Import

- Additionally, the district court determined that Dr. Stoddard's testimony at trial was **not credible**, his memory of facts was suspiciously selective, and he refused to acknowledge certain incontrovertible events.
- Under the terms of Rule 56, the PTO does not assign a duty of candor to persons not associated with a patent application, or to those involved only in a **ministerial** capacity.

Avid v. Crystal Import

- Such persons would not be in a position to appreciate that their conduct or knowledge might be relevant to the PTO.

Avid v. Crystal Import

- Intent?? Admitted?
- Materiality: reasonable examiner standard (filed prior to 1992)
- Jury found that the patent was valid even after informed of the withheld information:
 - Clearly not a “but for” standard

So What Do you Do?

“the involvement relates to the **content** of the application or **decisions** related thereto”

“Thereto” relates to “content” “decisions” or both?

What about the inventor’s supervisor? CTO?

Duty of inquiry? Rule 3.3? Rule 1.56?

Editorial: I agree with the Linn dissent

Therasense v. Becton Dickinson

- CAFC Jan 2010 Judge Dyk
- Disposable blood glucose test strips
- '551 Claims 1-4 obvious; entire patent unenforceable: affirmed
- The claims of the '551 patent describe a test strip with an electrochemical sensor for testing whole blood **without any membrane over the electrode.**

Therasense v. Becton Dickinson

- Prior art test strips employed membranes to;
 - Control diffusion
 - Prevent Fouling
- The central question with respect to obviousness is whether the prior art disclosed a glucose sensor without a membrane for use in whole blood.

Therasense v. Becton Dickinson

- Abbott asserts that the conventional wisdom of those skilled in the art was that a membrane was necessary when testing with blood.
- The district court plainly found the Abbott testimony **not credible** and credited the Bayer testimony...
- Claims 1-4 obvious

Therasense v. Becton Dickinson

- Following the bench trial, the district court also held the '551 patent unenforceable for inequitable conduct based on a **failure to disclose statements made to the European Patent Office** (“EPO”) during a revocation proceeding of the European counterpart to the '382 patent.

Therasense v. Becton Dickinson

- Rule 1.56 (What would 3.3 Require?)

The Office **encourages** applicants to carefully examine:

- (1) Prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) The closest **information** over which individuals ... believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

Therasense v. Becton Dickinson

- During prosecution of '551, the '382 patent was characterized:
 - “one skilled in the art would have felt that an active electrode comprising an enzyme and a mediator would **require** a protective membrane if it were to be used with a whole blood sample. Therefore, he is sure that one skilled in the art would **not** read ..'382 to teach that the use of a protective membrane with a whole blood sample is **optionally** or merely preferred”

Therasense v. Becton Dickinson

- First, the district court found that by describing the “[o]ptionally, but preferably” language as “unequivocally clear,” Abbott’s EPO representations contradicted Abbott’s representations to the PTO that a person having ordinary skill in the art would have understood the phrase as mere “patent phraseology” that did not convey a clear meaning.

Therasense v. Becton Dickinson

- The district court correctly found that Abbott also argued before the EPO that the protective membrane of the '636 patent [Abbott's patent sought to be revoked] was optional. The optional nature of the membrane was not irrelevant to the distinction of the D1 reference's semipermeable membrane because the optional nature of the membrane proved that it was **not the type of membrane required by the D1 reference**, as Abbott appears to recognize.

Therasense v. Becton Dickinson

- Pope in his testimony **agreed that the plain English reading of what Abbott told the EPO was contrary to what Abbott told the PTO.** To deprive an examiner of the EPO statements—statements directly contrary to Abbott’s representations to the PTO—on the grounds that they were not material would be to eviscerate the duty of disclosure.

Therasense v. Becton Dickinson

- “[The cited cases] do not speak to the applicant’s obligation to advise the PTO of contrary representations made in another forum.”
- What is a forum?
 - EPO or other patent office, yes,
 - IRS? It is a federal agency.
 - FDA? Patent attorney review all NDA data?
 - Customs?
 - Customers – promotional literature?

Therasense v. Becton Dickinson

- Linn Dissent:
 - Detailed reasons were provided for why they subjectively believed that the information was immaterial.
 - Such an explanation will defeat a charge of inequitable conduct if it is “plausible”.
 - This belongs under the subjective intent prong.

Therasense v. Becton Dickinson

- CAFC En Banc Order April 26 2010
- Inequitable Conduct
- Six Questions

Therasense v. Becton Dickinson

1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?
2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? If so, what is the appropriate standard for fraud or unclean hands?

Therasense v. Becton Dickinson

3. What is the proper standard for materiality? What role should the United States Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?
4. Under what circumstances is it proper to infer intent from materiality?

Therasense v. Becton Dickinson

5. Should the balancing inquiry (balancing materiality and intent) be abandoned?
6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.

Purdue Pharma Products L.P. v. Par Pharmaceutical, Inc

- CAFC June 2010 Judge Lourie
- Non-precedential
- Patent obvious and **not** unenforceable
- Controlled-release tramadol formations
- “any differences in incorporating tramadol as the active ingredient in a once-a-day formulation would have involved only routine experimentation”: obvious

Purdue Pharma Products L.P. v. Par Pharmaceutical, Inc

- Allegedly:
 - Withheld material experimental data
 - Submitted a misleading declaration by Ms. Malkowska
- But
 - Declaration was prepared for EPO proceeding
 - Latter Napp declaration had more pertinent (and potentially more damaging) data: resurrection?

Leviton v Universal Security

- CAFC May 2010 Judge Michel
- Attorneys fees and costs awarded based on IC (\$1M): CAFC vacates and remands
- The '766 patent and the Germain application have no common inventors, and neither claims priority to the other. The '766 patent's claimed 1999 priority date is three and a half years before Germain's claimed 2003 priority date. The '766 patent and Germain have many claims that are nearly identical.

Leviton v Universal Security

- Under our **scattered precedents**, information may be considered material if 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.”
- Note: pre-1992 Rule 56 standard for a post 1992 application
- Information “material”; intent?

Leviton v Universal Security

- “ Leviton argues that Narcisse offered a reasonable explanation for why he did not inform the PTO of the Germain application: he did not believe that Germain was prior art because the priority date of the '766 patent was at least three years before Leviton filed the Germain application.” – issue of fact
- But: inventorship; double-patenting?

Leviton v Universal Security

- “Further, the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be **the single most reasonable inference able to be drawn from the evidence** to meet the clear and convincing standard.”
- “we cannot agree that Narcisse’s explanation of his thoughts at the time were unreasonable as a matter of law” - remand

Leviton v Universal Security

- What do you think???
- “Single most reasonable inference”??
- “And so the Germain was not prior art to the '766, and therefore the Germain application didn't come into the picture at all.”
- Dissent: Deceptive intent is not the single most reasonable inference, it is the **only** reasonable inference

Ajinomoto v. ITC

- CAFC March 8 2010 Judge Lourie
- E. coli over-expression of lysine
- Best Mode and Inequitable Conduct
- In contrast to the disclosure in the specification, it is undisputed that the actual strain used by the inventors had two additional genetic alterations made to it before the addition of mutant ldc.

Ajinomoto v. ITC

- The ALJ concluded that the inventors had violated the best mode requirement by
 - (1) concealing their **preferred and only host strain**, WC80-196S, via a misrepresentation of the steps actually performed to create a mutant Idc host strain;
 - (2) concealing **sucrose as their preferred carbon source**, which materially affects achieving the claimed invention; and
 - (3) submitting data associated with **fictitious host strains** in support of the best mode

Ajinomoto v. ITC

- Yet, before filing the Japanese application from which the '160 patent claims priority, the inventors characterized a different strain, AE-70, as their best lysine producer.
- The disclosure requirement, however, is limited to “the invention defined by the claims.”

Ajinomoto v. ITC

- First, the court must determine whether, at the time the patent application was filed, the inventor possessed a best mode of practicing the claimed invention..This prong is highly subjective; it focuses on the inventor's own personal preferences as of the application's filing date.... Second, if the inventor has a subjective preference for one mode over all others, the court must then determine whether the inventor "concealed" the preferred mode from the public. ...In other words, the second prong asks whether the inventor's disclosure is adequate to enable one of ordinary skill in the art to practice the best mode of the invention.

Ajinomoto v. ITC

- while not every preference constitutes a best mode for purposes of §112, the preferred embodiment of the invention must be disclosed.
- It is not limited, as Ajinomoto asserts, to vague “innovative aspects” or “inventive features”
- IC issues waived.

So What Do you Do?

You don't tug on Superman's cape

You don't spit into the wind

You don't pull the mask off of that old Lone
Ranger

And you don't mess around with Jim

Jim Croce

Many Thanks !!

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