Therasense

Will it impact a practitioner's duty of candor in prosecution?

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Disclaimers

- The presentation does not represent the opinion of Drinker Biddle, its clients, my colleagues, AIPLA, or standard industry practice

Topics

- A follow-on to Julie Burke's June 2010 IDS talk
- IDS timing requirements & issues
- 37 C.F.R. §1.97(e) certifications
- Translations
- Prosecutorial reality – how do you get an issued patent today?
- Proposed Supplemental Examination – 35 U.S.C. § 257

Therasense

- "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."

- "Because the district court's findings that the EPO submissions were **highly material to the prosecution** of the '551 patent and that Pope and Dr. Sanghera intended to deceive the PTO by withholding those submissions were not clearly erroneous, the district court did not abuse its discretion in holding the '551 patent unenforceable due to inequitable conduct."

The CAFC's 6 Questions

Therasense, Inc. v. Becton, Dickinson & Co., 2010 WL 1655391 (Fed. Cir. April 26, 2010) (granting petition for rehearing en banc and vacating previous decision)

- **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?
- **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?
- 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.

Some *Therasense* Amicus Filers

- ABA
- AIPLA
- BIO
- Dolby Laboratories
- Verizon
- University of Kentucky IP Law Association
- Professor David Hricik
- IPO
- Acacia and 1st Media
- Apotex
- Aventis and Microsoft
- IP Law Professors
- Nilssen and Geo Foundation
- Washington State Patent Law Association
- Verizon
- Becton Dickenson and Nova Biomedical
- Boston Patent Law Association
- Chicago IP Law Association
- Conejo Valley Patent Law Association
- Ecore Int'l
- Eisai
- Intel
- Int'l Intellectual Property Institute
- Eli Lilly
- Federal Circuit Bar Association
- Houston IP Law Association
- Johnson & Johnson and Proctor & Gamble
- PhRma
- San Diego IP Law Association
- SAP
- Teva, Cisco & Generic Pharmaceutical Assoc.
- USPTO
- Abbott

Many in support of neither party

AIPLA's Amicus Brief

- AIPLA supported neither party and argued to the en banc Federal Circuit that the basis for a finding of inequitable conduct should be fraud on the PTO, provable only with specific intent to deceive. In addition, the brief maintains that materiality should be found only where at least **one claim would not have issued "but for" the alleged misconduct**, and that limits on inequitable conduct are justified by the severe penalty of unenforceability.

Therasense Prosecution Implications

- Does an applicant have a duty to submit to the USPTO ***all*** arguments in replies made to a foreign patent office

- ***OR*** only those directly ***contradictory*** to arguments made before the USPTO?

- **WAYS TO DISTINGUISH *THERASENSE*?**
  - Can the applicant distinguish the case over the facts of *Therasense*?
  - Can the practitioner track his prosecution arguments worldwide?
    - Does one only track ***contradictory*** arguments?
    - When is an argument abroad ***contradictory*** to an argument before the USPTO?
  - What does the applicant ***really*** have to submit from foreign applications?
    - *e.g.*, references, search reports, declarations, and replies?

The *Therasense* Crystal Ball

- The CAFC heard *Therasense* en banc November 9, 2010
- Decision expected – Spring 2011
- The Court may "likely" alter the test for determining inequitable conduct
- However, the factual scenarios of *Dayco*, *McKesson*, *Larson*, and *Therasense* will remain as will the implications of the reporting requirements they raise

Looking Back

What are the implications of *Dayco*, *McKesson* & *Larson*?

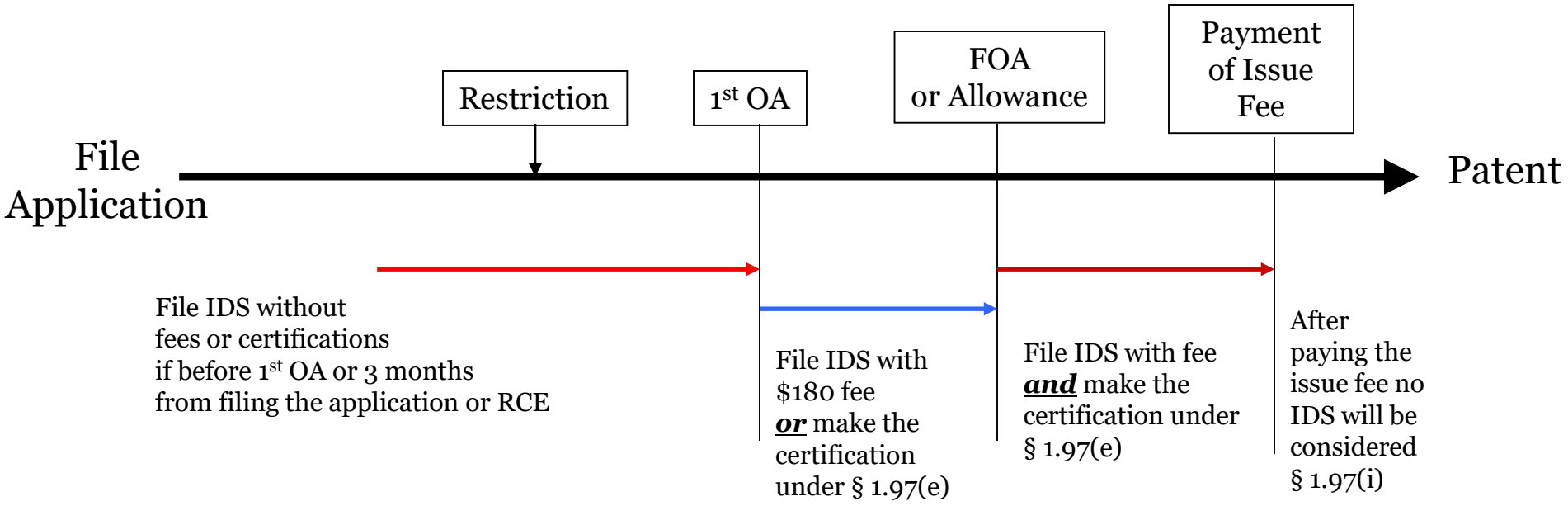
The *Other* Horsemen of the Duty of Candor Apocalypse

- *Dayco Prods. Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed Cir. 2003)
  - Report references from applications having ***substantially similar claims ("SSCs")*** but not in the same family
- *McKesson Info. Solutions v. Bridge Medical, Inc.*, 487 F.3d 897 (Fed. Cir. 2007)
  - Report Office Actions and references in same family even with the same examiner, if it's not a progeny application
  - SSCs identified only by obviousness type double patenting (ODP) rejections?
- *Larson Mfg. Co. v. Aluminart Prods. Ltd.*, 559 F.3d 1317 (Fed. Cir. 2009)
  - Report ***all*** Office Actions (not just some) from a progeny application to a parent application
  - Report all applicant responses in a progeny application to its parent, ***OR*** only if there are contradictory arguments????

Implications in Prosecution

Can the Applicant Get an Issued Patent?

"When" to report?



- Duty of candor ends with patent issuance. 37 CFR §§ 1.56 & 1.99
- Can still submit under 37 C.F.R. § 1.501 after issuance
  - See *Molins PLC v. Textron Inc.*, 48 F.3d 1172 (Fed. Cir. 1995)

37 CFR § 1.97(e)(1)

- (e) A statement under this section must state either:

(1) That each item of information contained in the information disclosure statement was ***first*** cited in ***any*** communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement;

A Reality of § 1.97(e)(1)

- Unless the practitioner is the international coordinating counsel, he may not know about ***all*** the related foreign applications and their prosecution when filing foreign origin applications

- The cost of assessing whether a reference "was ***first*** cited" in "***any***" communication is higher than the $180 fee given the potential of inequitable conduct for making the certification

- **THOUGHTS:**
  - Pay fee ***OR***
  - Request statement from coordinating counsel that § 1.97(e)(1) requirement has been met

37 CFR § 1.97(e)(2)

- (e) A statement under this section must state either:

(2) That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the ***knowledge of the person signing*** the certification after making ***reasonable inquiry***, no item of information contained in the information disclosure statement ***was known to any individual designated*** in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

A Reality with § 1.97(e)(2)

- **WHEN USED:**
  - § 1.97(e)(2) can be used for reporting USPTO Office Actions & Applicant responses
- **WHO CERTIFIES:**
  - The practitioner makes the certification, **BUT** the practitioner may not know all the cases with substantially similar claims (SSCs) in order to make the certification
  - The practitioner has to certify for ***everyone*** subject to the duty of candor [next slide]
- **THOUGHTS:**
  - Have the coordinating counsel indicate that the (e)(2) certification can be made, ***OR***
  - Pay the fee, because the $180 fee is cheaper than **(1)** determining whether all cases with substantially similar claims, and **(2)** all people subject with a duty of candor **(3)** who may be in other countries have met their duty
    - **AND** the $180 fee is much cheaper than the potential of finding inequitable conduct
    - **AND** what does "reasonable inquiry" mean?

37 C.F.R. § 1.56(c) – The Who

- (c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:
  - (1) **Each inventor** named in the application;
  - (2) **Each attorney** or **agent** who prepares or prosecutes the application; and
  - (3) **Every other person who is substantively involved** in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

Remember, timing is everything!

- If filed after final rejection / NOA and certification is to be avoided, then an RCE must be filed
- If the issue fee is paid, then an RCE must be filed

- **NOTE:** An RCE can impact patent term adjustment (PTA) & application pendency

Potential of RCE Churn

- U.S. prosecution frequently goes first
- EPO and other jurisdictions start afterwards, with search reports arriving at ***any*** time

- COMPLAINT HEARD:

"I can't get a patent to issue because I have to file an RCE in order to get the foreign Office Action and references submitted or because of prosecution going on in an US application with SSCs."

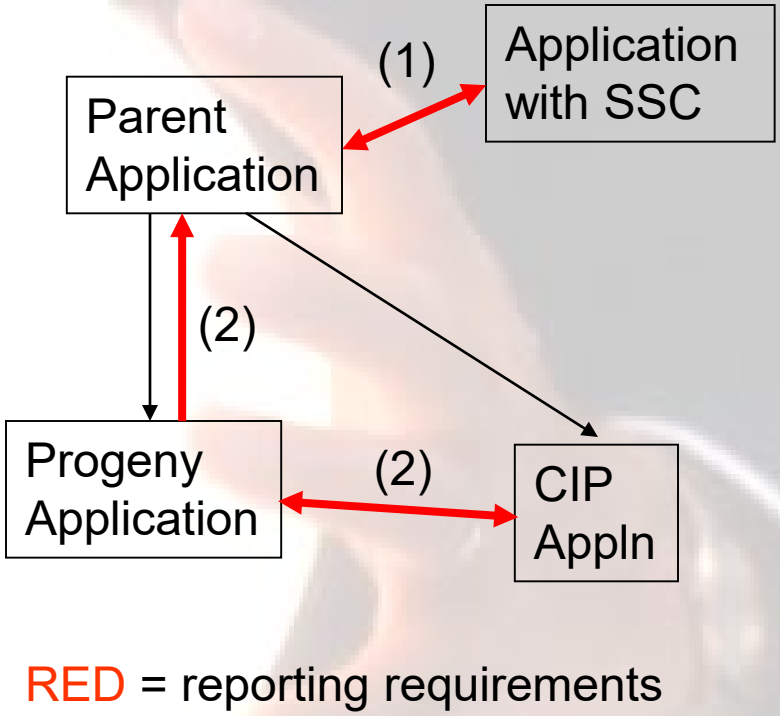
"How" to report?

- Limited guidance on "***how***" Applicants report certain non-patent items in order to meet the duty of candor
  - US Office Actions & Replies from related or SSC applications
    - Do we just cite the related application / patent?
    - Do we also have to provide copies of all Office Actions?
    - Do we have to provide copies of all Replies?
  - Manner of citing non-reference materials from related foreign applications (*e.g.*, search reports, declarations, Applicant replies with contradictory arguments, etc.)
    - Do we have to cite or just provide the ISRs? Foreign Office Actions?
    - Or, can we just provide the cited references?

- **RESULT:** Lots of different ways practitioners are submitting materials and lots of different materials being submitted

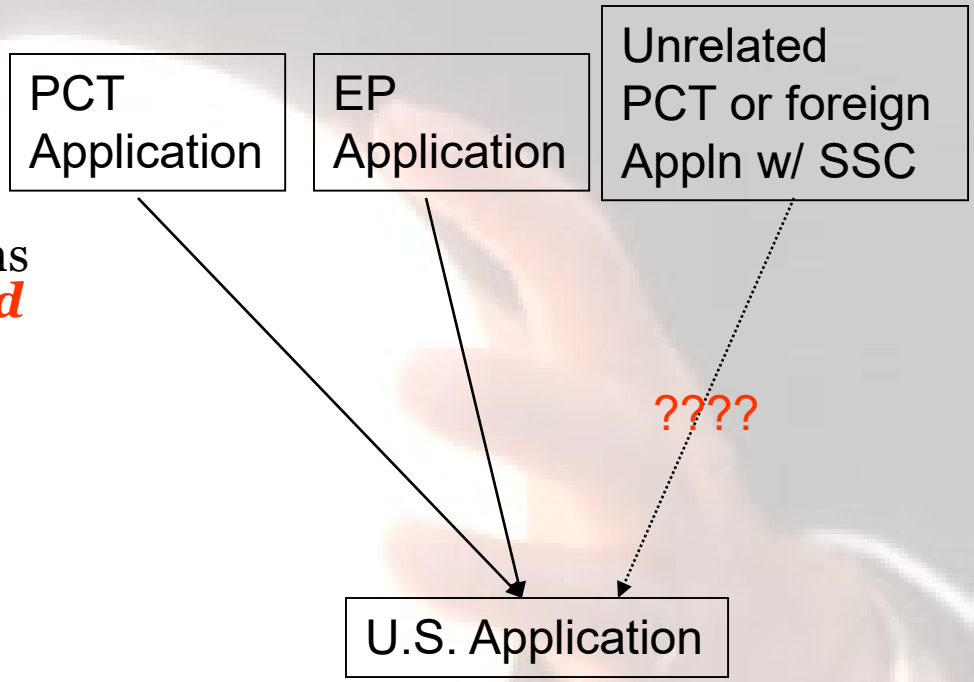
"What" to report?

- References and materials from applications with substantially similar claims (SSCs) (*Dayco*) (1)
  - Do applicants submit only applications with obviousness type double patenting (ODP) rejections?
  - ***OR*** also applications which *may* have SSCs but no ODP?
  - What if the ODP is withdrawn?
- References and Office Actions from applications that are not immediate progeny (*McKesson* & *Larson*) (2)



"What" to report? (2)

- Does one submit only references from ***related*** foreign applications?
  - MPEP §2001.06(a)
  - 37 CFR § 1.97-1.98
- Does one submit all Office Actions and Search Reports from ***related*** foreign applications?
- Does one only have to submit contradictory arguments from ***related*** foreign applications?
  - *Therasense*
- What constitutes a contradictory argument?
  - Oppositions
- What about ***unrelated*** foreign applications with potential SSCs?



What do the rules say?

- **1.56(a): ....**The duty to disclose ***all*** information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by **§§ 1.97**(b)-(d) and **1.98**....

- **1.98(a):** Any information disclosure statement filed under § **1.97** shall include the items listed in paragraphs (a)(1), (a)(2) and (a)(3) of this section.
  - (1) A list of all patents, publications, applications, or other information submitted for consideration by the Office. U.S. patents and U.S. patent application publications must be listed in a section separately from citations of other documents....
  - (2) A legible copy of:
    - (i) **Each foreign patent**;
    - (ii) **Each publication** or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office;
    - (iii) For each cited pending **unpublished U.S. application**, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion; and
    - (iv) **All other information** or that portion which caused it to be listed.
  - (3) [slides on translations]

Potential "Other" Information*

Potential supplemental examination submission list

- Pre-critical date sales & public uses
- Inventorship information
- **Unpublished notes**
- False declarations
- Materials relevant to enablement
- Litigation papers & proceedings
- Facts pertinent to the interest and relationships of affiants
- Statements made in petitions to make special
- Small entity status of applicants

*List from Lisa Dolak's presentation for AIPLA December 1, 2010 entitled *Ethics: Supplemental Examinations to Consider, Reconsider or Correct Patent Related Information*
Not an exhaustive list!

But, look at § 1.98(c)(5)

- Given the prior list, ***how*** would an applicant comply?
  - 1.98(c)(5): Each ***publication*** listed in an information disclosure statement must be identified by **publisher**, author (if any), title, **relevant pages** of the publication, **date**, and **place** of publication.
  - For Office Actions (US or foreign), Search Reports, Applicant Replies, Declarations, when they are submitted they become publications
    - Redundant information on overburdened USPTO servers
  - But, what about the other "stuff"? (e.g., unpublished notes)
    - *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229 (Fed. Cir. 2008) where IC was found based on handwritten notes from one of the scientists regarding an abstract which made clear that the abstract was in fact enabled

Translations and § 1.98(a)(3)

- **Non-English References**
  - A concise explanation, if not in English, that can be in the specification or separate; or
    - CAUTION: The explanation may need to be later updated if relevance differs in the progeny application. MPEP 609.04(a) and 1.98(a)(3)(i)
    - If in the specification, how do we cite the specification given references discussed in the specification generally are not considered?
  - An English language equivalent (1.98(d)); or
  - An English language abstract of a reference may fulfill the concise explanation requirement; or
  - Explanation of relevance from a foreign patent office search report

Translations (2)

- **Full and Partial Translations**
  - No obligation to provide an English translation if you do not have one, § 1.98(a)(3)(ii)
    - Failure to submit a translation if in possession can lead to an unenforceable patent
      - *See Poly-America, Inc. v. GSE Lining Technology, Inc.*, 1998 WL 355477 at *4 (N.D. Tex. 1998)
    - BUT, failure to disclose a translation in applicant's possession is not sufficient to infer intent
      - *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991 (Fed. Cir. 2006)
  - Translations do not need to be verified
  - Partial Translation
    - Providing a partial translation with a concise explanation of the full reference is also not a safe harbor – the problem of mischaracterization of the document *as a whole* remains.
      - *See* MPEP § 609 & *Semiconductor Energy Lab. Co. v. Samsung Elec Col. Ltd.*, 204 F.3d 1368, 1376 (Fed. Cir. 2000)
  - **NOTE:** Under *Ex parte Bonfils,* if the PTO relies on a foreign language document, it must provide a translation at latest before forwarding to the Board
    - *Ex parte Bonfils*, 64 USPQ2d 1456 (Bd. Pat. App. & Int. 2002) (unpublished)

What is a probable result of all this case law, lack of guidance, and rampant IC usage in litigation?

The problem of "burying"

- Burying a reference is insufficient alone to find inequitable conduct
  - BUT, burying a reference and mischaracterizing it may make a finding of inequitable conduct more likely at least under the current test for inequitable conduct

    • *Molins PLC v. Textron Inc.*, 48 F.3d 1172 (Fed. Cir. 1995) for listing a lot of references and "burying" important references

    • *Golden Valley Microwave Foods Inc. v. Weaver Popcorn Co., Inc.*, 837 F. Supp. 1444 (N.D. Ind. 1992), where the attorney listed the reference but only discussed less relevant aspects of it

Does *Therasense* ***really*** change anything? NO?

- MPEP § 2001.06(a) cites to *Gemveto Jewelry Company Inc. v. Lambert Bros., Inc.* (SDNY 1982):
  - "Foreign patent attorneys representing applicants for U.S. patents through local correspondent firms surely must be held to the same standards of conduct which apply to their American counterparts; a double standard of accountability would allow foreign attorneys and their clients to escape responsibility for fraud or inequitable conduct merely by withholding from the local correspondent information unfavorable to patentability and claiming ignorance of United States disclosure requirements."

Does *Therasense* ***really*** change anything? YES?

- *In re Harita*, 6 USPQ2d 1930 (Fed. Cir. 1988):
  - Japanese patent agent's failure, in 1975, to communicate knowledge of new prior art to U.S. attorney prosecuting patent application does **not** constitute evidence of intent to mislead Patent and Trademark Office, in view of lack of any evidence of actual misstatements in prosecution, in view of lack of any evidence of deliberate scheming, and **in view of agent's action, after coming to comprehend USPTO practice**, in filing re-issue application for dual purpose of cancelling anticipated claims and advising PTO of newly-found prior art, and evidence of any intent to mislead may not be inferred from agent's asserted "gross negligence."

IC Currently

- "Inequitable Conduct" leads to patent unenforceability in the courts
- A finding of IC requires:
  1. Misrepresentation or omission of material information,
  2. Intent to deceive, and
  3. Balancing of materiality and intent
- Burden of proof = Clear and convincing evidence
- Result:
  - Unenforceability of all claims in the patent, and
  - Possible unenforceability of some, or all, related patents
- Note:
  - 4 tests for materiality and 2 tests for intent
    - *AstraZeneca Pharmaceuticals LP v. Teva Pharmaceuticals USA Inc.*, 583 F.3d 766 (Fed. Cir. 2009) for discussion of materiality
    - *Exergen Corp. v. Wal-Mart Stores Inc.*, 575 F.3d 1312 (Fed. Cir. 2009) for discussion of intent

Federal Circuit Since the En Banc Order to Rehear *Therasense*

- Since the April 26, 2010 *en banc* Order, the Federal Circuit has rendered several decisions on IC:
  - *Optium Corp. v. Emcore Corp.* – May 5, 2010
  - *Taltech v. Esquel*—May 12, 2010, affirmed finding of IC, after an earlier remand; Garjarsa dissented
  - *Orion IP LLC v. Hyundai Motor America* – May 17, 2010
  - *Aspex Eyewear Inc. v. Clariti Eyewear Inc.* – May 24, 2010
  - *Leviton v. Universal Security Instrument*—May 28, 2010, remanded a district court's SJ ruling of IC; Prost dissented
  - *Purdue Pharma v. Napp Pharma*—June 3, 2010, affirmed the denial of IC after a bench trial
  - *Advanced Magnetic Closures v. Rome Fastner*—June 11, 2010, affirmed IC after trial; Rader concurred
  - *Avid Identification v. Crystal Import*—July 16, 2010, denied a request for rehearing; Newman dissented
  - *Ring Plus v. Cingular Wireless*—August 6, 2010, reversed an IC finding, even though the district court had made findings of intent based on lack of credibility
  - *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*—August 9, 2010, remanded IC to the district court on intent; Newman dissented
  - *Cancer Research Technology Ltd. v. Barr Laboratories Inc.* – November 9, 2010, Newman and Lourie overturning an IC holding; Prost dissented

Federal Circuit Since the *En Banc* Order to Rehear *Therasense*

- *Taltech v. Esquel*—May 12, 2010, affirmed finding of IC, after an earlier remand; Garjarsa dissented
  - "[t]his case exemplifies the **ongoing pandemic of baseless inequitable conduct charges** that pervade our patent system."
  - "the majority's opinion affirms a district court judgment that contains no supportable finding of intent, limited materiality findings, and wholly ignores evidence of good faith. In doing so, the majority reverses the road upon which this court's inequitable conduct precedent is presently travelling. As we recently explained, '[t]he need to strictly enforce . . . [an] elevated standard of proof . . . is paramount because the penalty for inequitable conduct is so severe, the loss of the entire patent . . . . This penalty was originally applied only in cases of fraud on the Patent Office." Id. (internal quotation marks omitted). The district court's finding of deceptive intent is not supported by clear and convincing evidence and the inequitable conduct finding should be reversed." *Id.* (citations omitted).

Federal Circuit Since the *En Banc* Order to Rehear *Therasense*

- *Leviton v. Universal Security Instrument*—May 28, 2010, remanded a district court's SJ ruling of IC; Judge Prost dissented
  - In a strongly-worded dissent, Judge Prost disagreed with the majority decision, saying that the district court "properly found inequitable conduct on summary judgment." She also noted, "I disagree with the majority's refusal to uphold the district court's inference of intent to deceive." She criticized the majority opinion for a number of reasons, including for "suggesting legal standards for which I believe there is no basis in our precedent." She also accused the majority of sidestepping the fact that the district court had concluded that the withheld reference was "**highly material**."

Federal Circuit Since the *En Banc* Order to Rehear *Therasense*

- *Advanced Magnetic v. Rome Fastner*—June 11, 2010, affirmed IC after trial; Rader concurrence
  - "I write separately to express my view that, absent extreme facts such as those found in the present case, **this court should refrain from resolving inequitable conduct cases until it addresses the issue en banc**. … In Therasense this court has been asked to address the transformation of inequitable conduct from the rare exceptional cases of egregious fraud that results in the grant of a patent that would not otherwise issue to a rather automatic assertion in every infringement case. The exception has become the rule. Generally, I would hold inequitable conduct cases until after this court reexamines whether to put the doctrine back into the exception category."

Federal Circuit Since the *En Banc* Order to Rehear *Therasense*

- *Avid Identification v. Crystal Import*—July 16, 2010, denied a request for rehearing *en banc* on IC; Newman dissented
  - **"I would grant this stay [to wait to decide this motion until after the *Therasense* en banc case is decided].** The law as applied in *Avid* is subject to conflicting precedent, a conflict whose resolution is reasonably likely to alter the result. Thus it is prudent, and just, to hold Avid's petition while the law is clarified. The court today has declined to do so, rendering the subject patent permanently unenforceable, although the patent was found valid on the same prior art that is the basis for its unenforceability."

Federal Circuit Since the *En Banc* Order to Rehear *Therasense*

- *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*—August 9, 2010, remanded IC to the district court on intent; Newman dissented
  - "As for materiality, I do not share the conclusion that the undated … brochure, obtained at a trade show … a few weeks after this patent application was filed, and found not to be invalidating prior art, was so clearly and convincingly "material to patentability" that failure to provide a copy of the brochure while quoting its front page, invalidates the patent that was found valid over the entire content of the brochure. **The record does not show that the brochure was published before the Golden Hour patent application was filed.** The defendants provided no documentary evidence of any publication date, and the district court did not find the brochure to be prior art; their only evidence was the "uh-huh's" of the brochure's author, quoted at footnote 1 of the majority opinion."
  - "The record showed that when the brochure came into Golden Hour's possession at the trade show, it was given to Golden Hour's patent attorney, who referred to it in the Invention Disclosure Statement filed with the PTO, including quotation of the cover page but not the inner page. At the trial, the full brochure was in evidence, and stressed by the defendants, and the jury found that it was not invalidating. In view of the majority's ruling that deceptive intent was not established in the district court, and the jury's verdict of validity despite the brochure, the charge of inequitable conduct should be laid to rest."

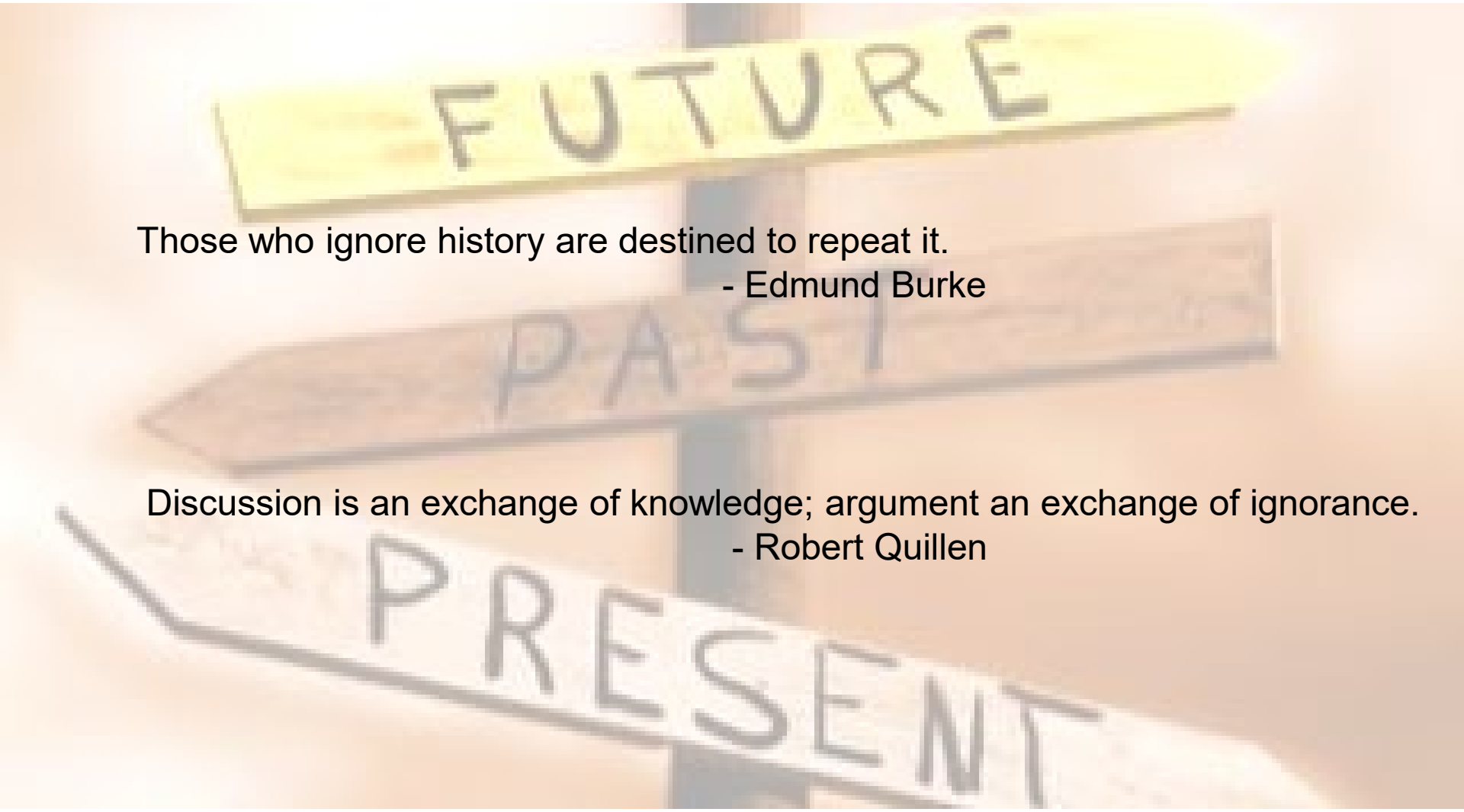
Proposed Legislation on Supplemental Examination

Giving the Patent Owner an Ability to Clean-up the Prosecution History

Supplemental Examination

- Proposed 35 U.S.C. § 257 would provide patent owners the opportunity to preempt inequitable conduct charges
  - § 257(c)(1): "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."

- Check out Lisa Dolak's presentation for AIPLA December 1, 2010 entitled *Ethics: Supplemental Examinations to Consider, Reconsider or Correct Patent Related Information*
    - (email her at: LADolak@law.syr.edu)



Those who ignore history are destined to repeat it.

- Edmund Burke

Discussion is an exchange of knowledge; argument an exchange of ignorance.

- Robert Quillen

MORE QUESTIONS & *DISCUSSION*

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