What Chemists Should Know about U.S. Patent Litigation and the Duty of Candor

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Enforcing Patent Rights


Infringer

- **Infringement** (35 U.S.C. § 271).
  - [W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports … any patented invention … infringes the patent.
- **Damages/Attorney Fees** (35 U.S.C. § 284-285)
  - [D]amages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs.
  - Court may increase the damages **up to three times** the amount found.
  - In exceptional cases may award reasonable attorney fees to the prevailing party.
- **Defenses** (35 U.S.C. § 282)
  - Non-infringement.
  - Unenforceability.
  - Invalidity (35 U.S.C. §§ 101-103, 112, 251).
  - Invalid term extension.

Challenging Patent Validity

- **Declaratory Judgment**
  - Court proceeding to challenge validity of a patent.
  - Plaintiff must establish an actual controversy over the validity of the patent.
- ***Ex Parte* Reexamination**
  - Request USPTO examination of an already-granted patent based on patents and printed publications requester party brings to the USPTO's attention.
  - Requester must establish that the submitted prior art establishes a substantial and new question of patentability.
  - Requester does not participate in the proceedings.
  - No estoppel against requester, but unsuccessful reexamination may make it harder to challenge validity based on the prior art.

Challenging Patent Validity

- ***Post-Grant* Review (PGR)**
  - Challenge must be filed within nine months of a patent's issuance establishing that at least one challenged claim is more likely than not to be found unpatentable.
  - On any grounds that can be used to challenge the validity of a patent claim.
- ***Inter-Partes* Review (IPR)**
  - Challenge must be filed after 9 month window for PGR, establishing that at least one challenged claim is more likely than not to be found unpatentable.
  - Challenge based on patents and printed publications.
- **For Both Types of Review**
  - Adversarial proceeding before the Patent Trial and Appeal Board.
  - Estoppel – if review is instituted and patentability of claims is confirmed, challenger cannot challenge validity of the patent in litigation on any grounds that could have been raised in the PGR or IPR.

USPTO Proceedings *versus* Litigation

- USPTO Examination and Post-Grant Proceedings:
  - No presumption of validity / patentability.
  - Preponderance of evidence standard.
  - Broadest reasonable construction of the terms in the claims.
- Litigation:
  - Patent claims are presumed valid.
  - Invalidity must be proved by clear and convincing evidence.
  - Claims are construed based on intrinsic and extrinsic evidence to determine how person skilled in the art would understand the claims.

Patent Litigation

- Filed in U.S. District Court.
- Adversarial process:
  - Plaintiff and Defendant each Work to Persuade Judge/Jury of Merits of its Case and Discredit Opponent's Case.
- Stages of litigation can include:
  - Pleadings (e.g. Complaint/Answer, Counter-claims).
    - Allege infringement of patent or seek declaratory judgment of non-infringement or invalidity.
  - **Discovery.**
  - Pre-trial Proceedings.
  - Trial.
  - Post-trial Proceedings.
  - Appeal.

Discovery

- Exchange of Information between Parties to Litigation.
- Scope (FRCP Rule 26(b)(1):
  - Parties may obtain discovery regarding **any nonprivileged matter that is relevant to any party's claim or defense**—including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter. For good cause, the court may order discovery of **any matter relevant to the subject matter involved in the action**. Relevant information need not be admissible at the trial if the discovery appears **reasonably calculated to lead to the discovery of admissible evidence**.
- Can include:
  - Production of documents.
  - Deposition of witnesses.

Document Production

- Party can Request production of:
  - Any designated documents or electronically stored information—including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations—stored in any medium from which information can be obtained.
- Even (especially) confidential company information.
- Examples:
  - E-mails; computer files (can include meta-data); presentations (internal and public); meeting minutes; laboratory notebooks and other experimental records; prior art references in possession of inventor.
- Goal: discover evidence to support party's case, *e.g.*:
  - Patent is invalid (*e.g.*, obvious, not enabled).
  - Evidence of infringement or copying / unsuccessful design-around attempts (*i.e.*, evidence invention not obvious).
  - Witness is not credible.
- Assume anything you write (or have written) will be available to litigation opponent.

In re Google (Fed. Cir. 2011)

- Oracle alleged that Google's Android system infringed Oracle's patents and copyright covering Java.
- E-mail (and auto-save versions) produced during discovery:

  What we've actually been asked to do (by Larry and Sergei) is to investigate what technical alternatives exist to Java for Android and Chrome. We've been over a bunch of these and think they all suck. We conclude that we need to negotiate a license for Java under the terms we need.

  … We think there is a value in the negotiation to put forward our most credible alternative, the goal being to get better terms and prices for Java.

  It looks to us that Obj-C provides the most credible alternative in this context, which should not be confused with us thinking we should make the change.

- E-mail was not privileged or attorney work product.

Trial

- Each side presents its evidence (witnesses, exhibits) to a fact-finder.
  - Jury (most cases).
  - Judge (if parties consent; ANDA cases).
- Witnesses subject to cross-examination.
- Discovery limits opportunities for surprises (e.g. experts reports produced before trial).
- Verdict.

Allergan v. Barr Labs. (D. Del. 2011)

- Plantiffs challenged credibility of defendants' expert witness:
  - "M[]'s credibility was eviscerated on cross-examination. Allergan's counsel established that M[] had incorrectly drawn the bimatoprost molecule during his deposition and utilized slides in his trial presentation that incorrectly represented the bond at the C5-C6 position. Counsel also impeached M[] with statements made in a 2008 declaration submitted in a prior litigation ... in Canada."
  - "The court found M[]'s credibility flawed on a fundamental level. The court simply can assign no weight to M[]'s testimony .... Because they are entirely not credible, the court need not further dissect M[]'s opinions nor render judgment regarding the additional flaws in his reasoning asserted by Allergan."
- The court's findings limited defendants' ability to challenge validity of the patent claims as obvious over the prior art.

Damages

- **Damages** (35 U.S.C. § 284)
  - [D]amages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs.
  - Court may increase the damages **up to three times** the amount found for willful infringement.
- **Reasonable Royalty**
  - The royalty a willing licensor and a willing licenssee would have agreed at the time the infringement began.
  - Numerous factors considered (*Georgia-Pacific Corp. v. United States Plywood Corp*., 318 F. Supp. 1116 (S.D.N.Y. 1970).
- **Lost Profits**
  - Plaintiff can be awarded lost profits on the infringing sales if it can show it would have made the sale but for the infrringement.

Injunction

- Court order that defendant from continuing infringement.
- Takes infringer off the market.
- Not automatic – court has discretion.
- Four-factor test requires a plaintiff to demonstrate:
  - (1) that it has suffered an irreparable injury;
  - (2) that remedies available at law are inadequate to compensate for that injury;
  - (3) that considering the balanceof hardships between the plaintiff and defendant, a remedy in equity is warranted; and
  - (4) that the public interest would not be disserved by a permanent injunction.

  eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).

Inequitable Conduct: What it is

- Equitable **affirmative defense** to a charge of patent infringement (*i.e.*, court will award no damages even if patent is otherwise valid and infringed).
- "Fraud on the Patent Office": breach of duty to prosecute the patent application with candor, good faith and honesty.
  - "Inequitable conduct … is a lesser offense than common law fraud, and includes types of conduct less serious than 'knowing and willful' fraud." *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069 (Fed. Cir. 1998).
- Formerly alleged in "almost every" patent infringement law suit.
  - "[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague." *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

Inequitable Conduct: Consequences

- Entire patent unenforceable
  - Precludes any future enforcement of the patent.
  - All claims unenforceable, even if no claims are invalid.
  - Contrast: invalidity only affects particular claim(s) found invalid.
  - Other asserted patents may also be held unenforceable. *Monsanto Co. v. Bayer Bioscience N.V.,* Nos. 2007-1109, 2008 WL 200027 (Fed. Cir. Jan. 25, 2008)
  - Infectious unenforceability – related patents may be held unenforceable. *Consol. Aluminum Corp. v. Foseco Int'l Ltd.,* 910 F.2d 804 (Fed. Cir. 1990).
- Attorneys fees.
- Antitrust claims.
- ***Therasense v. Becton Dickinson,* 649 F.3d 1276 (Fed. Cir. 2011) (en banc) raised standard for finding patent unenforceable due to inequitable conduct.**

Inequitable Conduct: Basic Elements

- Concerns information provided to (or withheld from) the Patent Office:
  - **Failure to disclose** material information.
  - **Submitting false** material information or **misrepresenting** a material fact.
- Inequitable conduct under *Therasense* requires:
  1. **Materiality**:
     - Failure to disclose material prior art (patent office **would not have issued patent had it been aware of undisclosed prior art**); or
     - Patentee has engaged in affirmative acts of egregious misconduct, e.g. filing an unmistakably false affidavit.
  2. **Intent:**
     - Specific intent to deceive the PTO must be the single most reasonable inference sufficient to require a finding of deceitful intent.
  - **Both be established by clear and convincing evidence, but:**
    - Evidence presented by adversaries in the litigation.
    - Hindsight review focusing on the information in question.

Inequitable Conduct: Who?

- Inequitable conduct concerns:
  - Inventors.
  - Patent attorneys/agents.
    - Foreign practitioners held to same standard as U.S. practitioners.
  - Anyone else substantively involved in preparing or prosecuting the patent application
- Under 37 C.F.R. § 1.56 these people have:
  - [D]uty of candor and good faith … includes a duty to disclose to the Office all information known to that individual to be material to patentability …

What is Material Information?

- **Duty to Disclose to USPTO** (37 C.F.R. § 1.56(b)): Information is material if:

  (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 the applicant take*s* in:

  (i) Opposing an argument of unpatentability relied on by the Office, or

  (ii) Asserting an argument of patentability.

- **Standard for Finding Inequitable Conduct in Litigation:** ***Therasense*** **"but for" standard**: prior art is material **if the PTO** would not have allowed **one claim** had it been aware of the undisclosed information (applying preponderance of evidence / broadest reasonable construction) or the patentee engages in affirmative act of egregious misconduct as to the information.

Failure to Disclose Prior Art

- Materiality standard: patent office would not have issued patent had it been aware of undisclosed prior art.
  - If a claim is invalidated based on a deliberately withheld reference, the reference is material (clear and convincing evidence required for invalidity)
  - Withheld information that does not invalidate a claim in litigation, may still be "but-for" material if it would have blocked the issuance of the patent (USPTO preponderance/broadest reasonable construction standard for rejecting claims).
- Specific information – Rule 56(a) "encourages applicants to carefully examine":
  - Prior art cited in foreign counterpart application.
  - Closest prior art over which it is believed pending claim patentably defines.
- Presumption of validity is "much diminished" when material information was not disclosed to PTO. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007).

Failure to Disclose Prior Art – Examples

- *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995).
  - Prior art cited in foreign counterpart withheld.
  - Submitted during reexamination – claims not rejected.
  - Patent unenforceable: "References were not cited when they should have been."
  - Possible different result under *Therasense* standard.
- *Semiconductor Energy Lab Co. v. Samsung Electronics Co.*, 204 F.3d 1368 (Fed. Cir. 2000).
  - Partial translation of Japanese reference omitted most material portions.
  - Inequitable conduct.

Failure to Disclose Prior Sales/Public Use

- *Dippin Dots, Inc. v. Mosey*, 476 F.3d 1337 (Fed. Cir. 2007).
  - Declaration submitted disclosing sales of claimed invention to show commercial success omitted all sales that were arguably § 102(b) prior art.
  - Inequitable conduct found: reasonable examiner would consider prior sales important in deciding whether to allow patent.
  - Failure to disclose prior sales is "*particularly egregious*" because examiner has no way of securing information on his own.
- Should disclose possible prior sales or public use.
- Experimental use may not be prior art – however, disclose and argue the use is experimental:
  - Clinical trials may be prior art. *See Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals, Inc.*, 471 F.3d 1369, 1373 (Fed Cir. 2006).

Inventor Publications

- Information Need Not be "Prior" Art to be Material.
- *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rover*, 326 F.3d 1226 (Fed. Cir. 2003).
  - Patent directed to a process for the semi-synthesis of paclitaxel.
  - Application was prepared based on draft of an article which eventually published in *JACS* and showed that the synthesis could be successfully achieved only with specific protecting groups and under unique reaction conditions, but the claims were not limited to the specific protecting groups.
  - *JACS* article was not disclosed to the Patent Office.
  - Patent held unenforceable because withheld article was **material to enablement**.

Failure to Disclose Proper Inventors

- *Perceptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315 (Fed. Cir. 2000).
  - Affirmed finding of inequitable conduct when patentee intentionally failed to identify the proper inventors.
  - Inventors made intentional misrepresentations regarding inventorship and failed to disclose extensive collaboration with unnamed inventors.
  - Good faith disagreement over joint inventorship does not result in inequitable conduct.
- Situations where opponent may argue motive to falsify inventorship (supporting "intent to deceive"):
  - Prior art issues ("inventive entity").
  - Omitted possible inventor not obliged to assign to same entity.

Inequitable Conduct Found Post-*Therasense*

- *Apotex v. Cephalon*, 2011 WL 5172909 (E.D.Pa.)
- Patent claimed composition of modafinil drug particles of particular size.
- Drug material meeting claim limitations and particle product specifications had been provided by Lafon under development and supply agreement.
- Lafon's role was not disclosed to PTO.
- Materiality:
  - Claims invalid due to on-sale bar (§ 102(b)) and derivation (§ 102(f)).
- Intent to deceive was only reasonable inference:
  - Complete failure to disclose Lafon's involvement..
  - 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."

Inaccurate/Incomplete Experimental Results

- Failure to disclose inoperative examples.
  - *Novo Nordisk Pharmaceuticals Inc. v. Biotechnology General Corp.*, 424 F.3d 1347 (Fed. Cir. 2005) found inequitable conduct when example was relied upon to establish priority over intervening reference without disclosing the example was inoperative.
- Failure to disclose examples were prophetic.
  - *Hoffmann-La Roche Inc. v. Promega Corp.*, 323 F.3d 1354 (Fed. Cir. 2003). Referring to example in the specification (written in past tense) without disclosing the experiment had never been performed as written could be sufficient to amount to inequitable conduct, but trial court finding of inequitable conduct was vacated in this case.
- Experimentals for patent applications should be written up as performed or using present tense for prophetic examples.

Misconduct Relating to Declarations Filed with USPTO

- Failure to Disclose Relationship btw. Declarant and Patent Owner.
  - *Ferring B.V. v. Barr Laboratories, Inc.*, 437 F.3d 1181 (Fed. Cir. 2006).
    - Examiner requested evidence from non-inventor to evaluate prior art.
    - Expert declarations failed to disclose that declarants were former employees and/or recipients of research funds from patentee.
    - Finding of inequitable conduct was affirmed.
- False Statements
  - *Cargill, Inc. v. Canbra Foods, Ltd*., 476 F.3d 1359 (Fed. Cir. 2007).
    - Applicant argued that data in two applications show that claimed invention and prior art had "strikingly different oxidative stability values" but withheld data and internal report showing properties were similar, and, in certain instances prior art was superior.
    - Inequitable conduct: withheld data dealt with a critical issue.
- Misleading Comparisons
  - *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d 1334 (Fed. Cir. 2008).
    - Declaration comparing claimed compound to prior art did not disclose that the data compared were generated at different dosages. Data generated at same dosages not submitted and showed no significant difference.
    - Federal Circuit affirmed holding of inequitable conduct.

What Do Chemists Need to Know?

- Discovery:
  - Assume that all written documents, e.g. lab. notebooks, inventor records, emails will be available to opponent in patent litigation.
  - Telephone and face-to face meetings are not recorded.
  - Written records can also be useful documentation, e.g. inventorship.
  - Speak with company patent attorney for best practice.
- Information provided to USPTO may be asserted to be false:
  - May be used to impeach your credibility as an inventor witness.
  - Could be used as basis for charge of inequitable conduct.
- Patent application.
  - No discrepancies btw. examples, notebooks – describe experiments as performed.
  - Prophetic examples – use present (or future) tense, never past tense; if a similar real experiment did not work it must be disclosed.
  - Beware of implying that predicted result is supported by experimental data.
  - Beware of undisclosed potentially relevant data.
  - Identify all potential inventors to the patent attorney.
  - Best mode must be disclosed (need not be identified, might be prophetic).

What Do Chemists Need to Know?

- Prior art.
  - Disclose all potentially relevant references to patent attorney.
  - Use consistent criteria for determining what is relevant.
  - Prior disclosures / offers for sale / use of the invention.
  - Beware of inventor publications contradicting argument for patentability (even if not “prior” art).
- Inventorship must be determined carefully and correctly: make sure attorney is aware of all the facts.
- Disclose co-pending applications with related subject matter.
  - Disclose the applications and prior art cited in their prosecution
  - Disclose office actions rejecting related claims
- Declarations (evidence to overcome rejections)
  - Relationship between inventor/assignee and expert declarant must be disclosed.
  - Comparisons made to support patentability must be fully disclosed: disclose **all** relevant data and point out differences in protocols for comparator experiments.

Thank you!

Questions?

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