

Experimental Testing in Patent Litigation

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Parties in patent infringement lawsuits often conduct experimental testing. For example, plaintiffs may need to test the accused product or process to determine whether it meets the patent's limitations. Indeed, as the patent holder bears the burden of proof on infringement, failure to test the accused product may be fatal.¹ Defendants also may find testing important in establishing noninfringement, proving inherency of a limitation in a prior art reference for an anticipation defense, or supporting nonenablement arguments.² This article discusses "dos and don'ts" of testing for patent litigation.

How to Conduct the Testing

Under Federal Rule of Evidence 702 and *Daubert*, testing evidence will be admissible in a patent case only if it is both relevant and reliable.³ Many reliability and relevance challenges revolve around how the testing was conducted.

Although the specific test chosen is fact-dependent on the patents and products at issue, there are a few helpful guidelines applicable to testing generally. It is preferable to use a test that has been generally accepted by the relevant scientific community.⁴ For example, in a patent case involving generic versions of Prilosec, the defendants challenged the plaintiff's infringement testing.⁵ The court denied the defendant's motion to strike the experts' testimony, noting that the pH testing used by the expert was a "standard" technique to determine alkalinity.⁶ In another case, the Federal Circuit rejected a *Daubert* challenge to expert testimony on patent infringement that was premised on the expert's computational fluid dynamics (CFD) analysis, in part because "CFD analysis has been recognized as reliable by at least one circuit."⁷ If there is more than one generally accepted test, try to determine which technique is the "gold standard." Another option is to use the type of testing that the opposing party uses in its ordinary course of business.⁸

Any test mentioned in the patents-in-suit should be considered.⁹ Moreover, if the claims themselves define a limitation in terms of a particular test, using the same test may be essential. For example, in *Zenith Lab. v. Bristol-Myers Squibb Co.*,¹⁰ the patent covered a crystalline compound with certain "x-ray diffraction" properties. In reversing a finding of infringement, the Federal Circuit disregarded two tests assessing crystallinity that were not mentioned in the patent's

claim, criticizing them as "only inferentially relevant given that the claim is drafted in terms of x-ray diffraction lines."¹¹

Another factor to consider when choosing which test to perform is whether it has been subject to peer review and publication.¹² Further, a high error rate can result in exclusion.¹³ If the error rate for the most applicable test is high, consider doing multiple types of tests, especially if the testing concerns an issue on which your client bears the burden of proof.¹⁴

Most importantly, the results of the test chosen must actually support the expert's conclusions.¹⁵ Courts may reject expert testimony where "there is simply too great an analytical gap between the data and the opinion proffered."¹⁶ Such gaps can be especially critical when attempting to establish patent infringement because insufficient evidence as to even one claim limitation will doom the patentee's cases. In other words, certain tests may be indicative of a related fact but not go the distance needed. For example, in a patent case involving diapers, the court excluded a test measuring whether a drop of water was absorbed because the test was "not probative" of a claim limitation requiring that the diaper material provide "an additional absorbent barrier against leakage."¹⁷

The precise experimental protocol used with the chosen test is also important.¹⁸ First, the provenance of samples tested should be documented, and samples should be stored and handled with care to prevent allegations regarding contamination or spurious results.¹⁹ Blinded testing can heighten credibility of the expert's opinion about the results.²⁰ It is generally wise to follow a standard operating procedure for the test if one exists. Moreover, although not *per se* requirements, "[f]ailure to test for alternative causes or to use control experiments may provide a basis for exclusion."²¹ Experts should apply the same scientific rigor in litigation testing as they do in their regular professional work.²² Good record keeping while conducting the experiments is also important.²³ Complete records ensure that a test can be reproduced (a hallmark of good science), can be used to refresh a witness's recollection on the stand, and can enhance credibility.²⁴

Who Should Conduct the Testing

Another important consideration in patent litigation is who should conduct the testing. Of course, the person or company conducting the test must be qualified to do so.²⁵ Among the qualified, there are several options: the work can be conducted in-house, by an outside expert, or by a commercial testing laboratory. Keep in mind that anyone involved with the testing may possibly be deposed.

Conducting the work in-house, although usually cheaper and easier, carries several drawbacks. Allegations of bias will almost assuredly arise,²⁶ and it may not be possible to protect the results as work product if you choose not to use the results at trial. Moreover, as discussed below, if the employee testifies about the results at trial and the court views the employee as a

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testifying expert, privilege over communications with counsel will be waived.

Testing by an outside expert is the most common choice. A consulting expert can conduct experiments under the protection of the work product immunity doctrine. A party can later choose to disclose the tests during expert discovery and turn the consulting expert into a testifying expert for trial, or have a testifying expert rely on those test results. The third option is to hire an independent laboratory, which can be advantageous if your needs lend themselves to standardized testing. An outside company usually specializes in the type of test conducted, follows standard operating procedures, and appears neutral before a jury. The outside company's work can generally also be shielded by work product immunity, as long as its results are kept confidential by counsel. Some parties also choose to have an expert design and supervise experiments, while having an independent laboratory carry out the work.²⁷

Disclosure and Waiver Considerations

Under Federal Rule of Civil Procedure 26, parties must disclose the experts that they expect to use at trial. Designating an expert as a trial witness waives work product protection over his or her opinions, as well as over communications and materials (including testing) considered in forming those opinions.²⁸ Significantly, this disclosure requirement includes information that may be harmful to the party's position.²⁹ There is also a duty to preserve information considered, including testing.³⁰

Conversely, parties need not disclose experts acting solely as consultants; their identity, reports, and any testing conducted will only be discoverable under "exceptional circumstances."³¹ While a person can be both a testifying expert as to one subject matter and a consulting expert on a different subject matter, such "two hatted" experts can be dangerous.³² Only "documents having no relation to the expert's role as an expert need not be produced."³³ The party resisting disclosure bears the burden of showing that an expert did not consider certain documents in forming his opinion, which "can be a difficult task because the roles can often be blurred."³⁴ The burden cannot be met by an expert's representations alone, and "any uncertainty about 'the role played by the expert'" is resolved in favor of the party seeking disclosure.³⁵ Having an expert wear both hats will likely involve costly motion practice and may, in the worst-case scenario, result in a broad waiver. The safest course is to choose your experts carefully and analyze their opinions and tests, as well as the material and communications they have considered, prior to designation.

Another factor to consider with respect to testing done in connection with patent infringement lawsuits is whether it imposes a duty to disclose the test results to the U.S. Patent and Trademark Office. There would be such a duty if the test results are material to examination of a party's pending patent application and the results are known by the inventor, the prosecuting attorney, or others associated with the filing and prosecution of the patent application.³⁶ This scenario could arise, for example, where testing is done by a patentee to rebut charges of invalidity by an accused infringer and

there are pending patent applications that are continuations or continuations-in-part of the patent-in-suit.

Use of Testing at Trial

Careful planning will make it more likely that your testing will be admissible at trial. A common reason why courts exclude test results is untimely disclosure.³⁷ For example, in a patent case involving "sippy" cups for children, the court excluded certain tests that the defendants conducted on prior art cups because the expert failed to disclose them in his initial report.³⁸ Late production of improperly withheld test results also can lead to other sanctions, such as an adverse inference regarding the results of testing.³⁹ Given that experiments can often take more time than expected, work should begin as soon as possible to ensure that complete results and documentation are available before expert reports are due.

An incomplete expert report also can cause exclusion of testing evidence. Under Federal Rules of Civil Procedure 26, an expert report must contain a "complete statement" of all the expert's opinions, the bases for each opinion, as well as the data or other information considered in forming the opinion.⁴⁰ Parties are also under a duty to supplement expert reports if they learn that the report is incomplete or incorrect in some material respect.⁴¹ It is important that an expert disclose all testing documentation when submitting his or her report to avoid any problems with "incompleteness."

Another common admissibility challenge is reliability. Evidence, including test results, must be sponsored by a witness to be heard by the fact finder. Typically, this requires an expert's testimony, which is subject to attack under *Daubert* and Rule 702. The party offering the expert's testimony must establish by a preponderance of the evidence that the testimony is admissible.⁴² Rule 702 provides: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."⁴³ *Daubert* recognizes, however, that "[v]igorous cross examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."⁴⁴ We discuss above how to improve your chances of withstanding a reliability attack.

Less common, but still important, are challenges based on admissibility of the testing data. Challenges for lack of foundation or hearsay can arise when an expert's opinions rely on someone else's testing data. If the test results are inadmissible, a litigant may still try to introduce an expert's ultimate conclusion under Federal Rule of Evidence 703. Rule 703 provides that "[i]f of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted."⁴⁵

Prudent selection of your testing methodology can ensure that your experimental test data will meet the requirements

of Rule 703.⁴⁶ For example, in *Monsanto Co. v. David*, the Federal Circuit found that an expert's opinion testimony would have been admissible under Rule 703, regardless of the admissibility of the seed reports on which that testimony was based.⁴⁷ An expert's ultimate opinion may be unpersuasive, however, if the expert is not permitted to describe the testing on which the opinion is based. Under Rule 703, an expert may not disclose such inadmissible test data to the jury unless the court determines that the "probative value in assisting the jury to evaluate the expert's opinion substantially outweighs [sic] [their] prejudicial effect."^{48, 49} If the evidence is admitted under this balancing test, the trial judge must give a limiting instruction upon request, informing the jury that the underlying information must not be used for substantive purposes.⁵⁰

As a final note, the admissibility battle is almost always won or lost at the trial court level. A district court judge has "considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable."⁵¹ Moreover, the Federal Circuit reviews decisions regarding admissibility under regional circuit law,⁵² and the regional circuits generally use the stringent abuse of discretion standard.⁵³ Consequently, the Federal Circuit rarely reverses district court admissibility rulings with respect to testing. The most prudent practice is to plan ahead: expect challenges and bolster testing evidence while it is being conducted by ensuring that the expert is conducting rigorous scientific work designed to answer the relevant technical questions.

Conclusion

Reliable experimental data based on sound scientific methodology are important in many patent cases. The following are important practice pointers regarding testing.

- Begin early—it will take longer than you expect.
- Consider hiring an independent testing laboratory to conduct a "blind" test.
- Choose a type of test that is generally accepted, has a low error rate, and goes the needed distance of establishing the fact at issue.
- Use control experiments, follow a standard operating procedure if applicable, and ensure that whoever is involved in the testing keeps detailed records.
- Carefully preserve walls between testifying and consulting experts.
- Timely disclose testing evidence and related expert opinions.
- Plan ahead for direct admissibility of the testing evidence, and consider using Rule 703 if the testing is deemed inadmissible. ■

Endnotes

1. *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1353 (Fed. Cir. 2008) (affirming finding of no direct infringement where plaintiff's expert failed to test defendant's products); *see also Warner-Lambert Co. v. Purepac Pharm. Co. (In re Gabapentin Patent Litig.)*, 503 F.3d 1254 (Fed. Cir. 2007) (reversing summary judgment of noninfringement where plaintiff produced test results sufficient to create an issue of material fact).

2. *See, e.g., Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, Case Nos. 3:05-cv-135-J-32TEM, 3:06-cv-301-J-32TEM, 2008 U.S. Dist. LEXIS 97816, at *38–39 (M.D. Fla. Dec. 3, 2008) (although expert

did conduct certain testing on contact lens recreated from prior art patent, evidence was insufficient to show inherency of claim limitation); *see also Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 296 (Fed. Cir. 1985) (reversing judgment of invalidity where defendant did not produce any "objective evidence" that the prior art process necessarily resulted in the phenolic resin claimed by the plaintiff's patent).

3. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993); *FED. R. EVID.* 702.

4. *Daubert*, 509 U.S. at 590–91.

5. *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp. 2d 423, 490 (S.D.N.Y. 2002).

6. *Id.*

7. *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1221 (Fed. Cir. 2006) (affirming denial of motion for judgment as a matter of law of noninfringement that challenged admissibility of expert testimony regarding expert's use of CFD analysis to establish infringement).

8. *Ecolab, Inc. v. Amerikem Lab., Inc.*, 98 F. Supp. 2d 569, 582 (D.N.J. 2000) (dismissing complaints about testing where complaining party itself recommended use of the techniques prior to the litigation), *aff'd in part and vacated in part on other grounds*, 264 F.3d 1358 (Fed. Cir. 2001).

9. *See, e.g., Boston Sci. Scimed, Inc. v. Cordis Corp.*, 483 F. Supp. 2d 390, 394–95 (D. Del. 2007) (expert used specific test mentioned in the patent); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, No. A-01-CA-167-SS, 2004 U.S. Dist. LEXIS 28975, at *30–31 (W.D. Tex. Feb. 12, 2004) (same), *aff'd in part and reversed in part on other grounds*, 424 F.3d 1374 (Fed. Cir. 2005). If the patent's recited test is outdated, however, it may be impugned at trial.

10. 19 F.3d 1418, 1420 (Fed. Cir. 1994).

11. *Id.* at 1423.

12. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590–91 (1993); *compare Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp. 2d 423, 489–90 (S.D.N.Y. 2002) (admitting expert's acetone-washing tests despite lack of peer review and publication), *with Carnegie Mellon Univ. v. Hoffmann-LaRoche, Inc.*, 55 F. Supp. 2d 1024, 1030–41 (N.D. Cal. 1999) (excluding plaintiff's expert's testimony where his opinion was contrary to published literature and not subjected to peer review).

13. *Compare U.S. v. White Horse*, 177 F. Supp. 2d 973, 975 (D.S.D. 2001) (in nonpatent case, excluding test having 24% error rate), *with Astra Aktiebolag*, 222 F. Supp. 2d at 493–94 (admitting expert's water content tests despite "very high standard deviation").

14. *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1035 (N.D. Ill. 2003) ("multiple testing is *de rigueur*"), *aff'd*, 365 F.3d 1306 (Fed. Cir. 2004), *vacated on other grounds*, 403 F.3d 1328 (Fed. Cir. 2005).

15. *GE v. Joiner*, 522 U.S. 136, 146 (1997).

16. *Id.*

17. *Arquest, Inc. v. Tracy*, No. 02 C 1649, 2002 U.S. Dist. LEXIS 23412, at *9–13 (N.D. Ill. Dec. 4, 2002); *see also MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, Nos. 2006-1305, 2006-1326, 2007 U.S. App. LEXIS 22434, at *7–9 (Fed. Cir. Sept. 20, 2007) (unpublished) (affirming exclusion of expert testimony regarding infringement where test results could not prove that all claim limitations were met).

18. *Rosco, Inc. v. Mirror Lite Co.*, 506 F. Supp. 2d 137, 148 (E.D.N.Y. 2007) (striking expert's template test due to unreliable methodology).

19. *Compare Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp. 2d 423, 491 (S.D.N.Y. 2002) (rejecting arguments that test samples were mishandled), *with SmithKline*, 247 F. Supp. 2d at 1040–41 (criticizing spectroscopy expert for not taking known precautions with sample handling).

20. *See SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1039 (N.D. Ill. 2003) (criticizing expert for not conducting "blindfold" tests of samples).

21. *AstraZeneca AB v. Mylan Labs., Inc. (In re Omeprazole Patent Litig.)*, 490 F. Supp. 2d 381, 402 (S.D.N.Y. 2007); *see also SmithKline*, 247 F. Supp. 2d at 1035 (criticizing expert for lack of controlled experiments).

22. *SmithKline*, 247 F. Supp. 2d at 1041–42.

23. *Astra Aktiebolag*, 222 F. Supp. 2d at 492 (noting with approval expert's detailed record keeping of experimental conditions and results).

24. *Despoir, Inc. v. Nike USA, Inc.*, No. 03 C 8817, 2005 U.S. Dist. LEXIS 10845, at *22 (N.D. Ill. Feb. 9, 2005) (admitting expert's testimony where underlying experiments were "empirically testable and 'intellectually rigorous'").

25. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993); compare *Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157, 1170 (Fed. Cir. 2008) (dismissing challenge to expert's credentials where expert had doctoral degree and extensive experience), with *Rosco, Inc. v. Mirror Lite Co.*, 506 F. Supp. 2d 137, 147 (E.D.N.Y. 2007) (excluding tests and expert's testimony where expert had no prior experience).

26. *But see SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1040–41 (N.D. Ill. 2003) (criticizing party for hiring "nominal" outside expert where "real expert" was employee, and noting that both employees and experts have potential bias as "expert witnesses are not known for biting the hand that feeds them").

27. There is no requirement that an expert personally conduct or supervise the tests on which he bases his opinions. *Monsanto Co. v. David*, 516 F.3d 1009, 1015 (Fed. Cir. 2008) (rejecting challenge to expert's infringement testimony based on testing done by someone else because "an expert need not have obtained the basis for his opinion from personal perception"); see also *Ecolab, Inc. v. Amerikem Lab., Inc.*, 98 F. Supp. 2d 569, 574 (D.N.J. 2000); *Daubert*, 509 U.S. at 592. Of course, personal involvement may heighten reliability and make the expert's testimony more credible.

28. FED. R. CIV. P. 26(a)(2); *In re Pioneer Hi-Bred Int'l, Inc.*, 238 F.3d 1370, 1375 (Fed. Cir. 2001).

29. FED. R. CIV. P. 26(a)(2), Adv. Comm. Notes to 1993 Amendments; *Schwab v. Philip Morris USA, Inc.*, No. 04-CV-1945 (JBW), 2006 U.S. Dist. LEXIS 11047, at *13 (E.D.N.Y. Mar. 20, 2006) ("Adverse material reviewed and rejected by an expert bears on his credibility, the soundness of his techniques, and the weight to be given his conclusions.").

30. FED. R. CIV. P. 26(a)(2), Adv. Comm. Notes to 1993 Amendments.

31. FED. R. CIV. P. 26(b)(4)(B)(ii).

32. See *Schwab*, 2006 U.S. Dist. LEXIS 11047, at *12–15 (mandating disclosure of survey allegedly conducted in testifying expert's consulting capacity).

33. *B.C.F. Oil Ref. Inc. v. Consol. Edison Co.*, 171 F.R.D. 57, 62 (S.D.N.Y. 1997).

34. *Emcore Corp. v. Optium Corp.*, No. 06-1202, 2007 U.S. Dist. LEXIS 91009, at *4–5 (W.D. Pa. Dec. 11, 2007).

35. See *Schwab v. Philip Morris USA, Inc.*, No. 04-CV-1945 (JBW), 2006 U.S. Dist. LEXIS 11047, at *11–12 (E.D.N.Y. Mar. 20, 2006).

36. 37 C.F.R. § 1.56; *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1364–68 (Fed. Cir. 2007) (affirming unenforceability due to inequitable

conduct where applicants failed to disclose adverse testing data).

37. FED. R. CIV. P. 37(c)(1); *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1375–76 (Fed. Cir. 2008) ("[E]venth hour disclosures . . . violate both the rules and principles of discovery, and the obligations lawyers have to the court. Exclusion and forfeiture are appropriate consequences . . ."); *Contech Stormwater Solutions, Inc. v. Baysaver Techs., Inc.*, 534 F. Supp. 2d 616, 623 (D. Md. 2008) (excluding expert's tests that were disclosed after the close of discovery).

38. *First Years, Inc. v. Munchkin, Inc.*, 575 F. Supp. 2d 1002, 1009 (W.D. Wis. 2008).

39. FED. R. CIV. P. 37(c)(1).

40. FED. R. CIV. P. 26(a)(2)(B).

41. FED. R. CIV. P. 26.

42. See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993).

43. FED. R. EVID. 702.

44. *Daubert*, 509 U.S. at 596.

45. FED. R. EVID. 703.

46. *But see AstraZeneca AB v. Mylan Labs., Inc. (In re Omeprazole Patent Litig.)*, 490 F. Supp. 2d 381, 532 (S.D.N.Y. 2007) (noting that "chemists do not typically rely on reports created for the purpose of patent litigation in performing their regular tasks and duties").

47. 516 F.3d 1009, 1015–16 (Fed. Cir. 2008).

48. The opposing party may "open the door" on cross-examination to testimony about the inadmissible underlying data. FED. R. EVID. 705.

49. FED. R. EVID. 703; compare *Forest Labs., Inc. v. Ivex Pharms., Inc.*, 237 F.R.D. 106, 112 (D. Del. 2006) (admitting studies relied upon by accused infringer's expert under Rule 703), with *Turner v. Burlington N. Santa Fe R.R. Co.*, 338 F.3d 1058, 1061–62 (9th Cir. 2003) (denying admission under Rule 703 where prejudicial effect of lab report outweighed probative value). Note that Rule 703 was amended in 2000 to presume inadmissibility.

50. FED. R. EVID. 703; *Pineda v. Ford Motor Co.*, No. 07-1191, 2008 U.S. App. LEXIS 6091, at *23 n.14 (3d Cir. Mar. 24, 2008).

51. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

52. *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1219 (Fed. Cir. 2006).

53. See generally *GE v. Joiner*, 522 U.S. 136, 146 (1997); 1 JACK B. WEINSTEIN & MARGARET BERGER, WEINSTEIN'S FEDERAL EVIDENCE §1-103.40[1] (2d ed. 2008).