

**DRAFTING PATENT VALIDITY &
INFRINGEMENT OPINIONS
YOU CAN DEFEND**

SPEAKERS:

Samuel C. Miller, III

Bruce T. Wieder

Crystal City, Virginia

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OUTLINE FOR PRESENTATION FOR SPRING CLE PROGRAM

PRESENTORS: Samuel C. Miller, III & Bruce T. Wieder¹

I. Introduction — Uses For Opinions of Counsel

A. Defensive Uses — Advice of Counsel Defense to Charges of Willful Infringement

1. Nature of the Willful Infringement Charge

- Under 35 U.S.C. § 284, the court may enhance damages for infringement up to three times the actual amount found or assessed. This may be done if the infringement is found to be "willful," *i.e.*, that the infringer acted in wanton disregard of the patentee's patent rights. *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826 (Fed. Cir. 1992).
- Liability for willfulness of infringement turns on the intent, state of mind, and culpability of the infringer. *National Presto Industries, Inc. v. West Bend Co.*, 76 F.3d 1185, 1192 (Fed. Cir. 1996).
- Factors that have been considered in determining whether infringement is willful include:
 - a. Whether the infringer deliberately copied the ideas or design of another;
 - b. Whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good faith belief that it was invalid or that it was not infringed;
 - c. The infringer's behavior as a party to the litigation;
 - d. The infringer's size and financial condition;
 - e. The closeness of the case;

¹ Partners, Burns, Doane, Swecker & Mathis, L.L.P., Alexandria, Va. Mr. Miller is an Adjunct Professor (Patent, Trademark & Trade Secret Law) and Mr. Wieder is an Adjunct Professor (Advanced Patent Law Seminar), both at Georgetown University. The presentors would like to acknowledge the assistance of Harold R. Brown, Susan M. Dadio and Matthew P. Blischak in the preparation of this paper. The views expressed are those of the authors and should not be attributed to Georgetown University, Burns, Doane, Swecker & Mathis, L.L.P., or any of its clients.

- f. The duration of the infringer's misconduct;
- g. Remedial action taken by the infringer, for example, where the infringer ceases manufacture of the infringing article during litigation;
- h. The infringer's motivation for harm; and
- i. Whether the infringer attempted to conceal its misconduct. *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826-27 (Fed. Cir. 1992).

- "Willful infringement is . . . a measure of reasonable commercial behavior in the context of the tort of patent infringement." *Hoechst Celanese Corp. v. B.P. Chemicals Ltd.*, 78 F.3d 1575, 1583 (Fed. Cir. 1996).
- Willfulness is determined based on the "totality of the surrounding circumstances." *Ortho Pharmaceutical Corp. v. Smith*, 959 F.2d 936, 944 (Fed. Cir. 1992). There are no "hard and fast per se" rules. *State Indus., Inc. v. Mor-Flo Indus., Inc.* 883 F.2d 1573, 1581 (Fed. Cir. 1989).
- Willfulness is a matter of degree. *Rite-Hite Corp. v. Kelley Corp.*, 819 F.2d 1120, 1125-26 (Fed. Cir. 1987). The degree of willfulness can be reflected in the Judge's determination of what multiplier to use in damage enhancement, e.g., double or treble damages.

2. Opinions of Counsel as a Defense to Willful Infringement

- "It is well settled that a potential infringer having actual notice of another's patent rights has an affirmative duty of due care. That affirmative duty will normally entail the obtaining of competent legal advice before engaging in any potentially infringing activity or continuing such activity." *Spindelfabrik Suessen-Schurr v. Schubert & Salzer*, 829 F.2d 1075, 1084 (Fed. Cir. 1987).
- "[W]e have held that when an infringer refuses to produce an exculpatory opinion of counsel in response to a charge of willful infringement, an inference may be drawn that either no opinion was obtained or, if an opinion was obtained, it was unfavorable." *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1056 (Fed. Cir. 1994).

B. Other Litigation Uses of Attorney's Patent Opinions

- An attorney's opinion may be used to deflect an allegation of a Rule 11 violation or sham litigation. See *Judin v. U.S.*, 110 F.3d 780, 783 (Fed. Cir. 1997) and *Nobelpharma AB v. Implant Innovations*, 129 F.3d 1463 (Fed. Cir. 1997). See generally, Beem, R., "Recovering Attorney Fees & Damages When Defending Against Bad Faith Patent Litigation," 80 JPTOS 81 (1998).
- Antitrust liability may flow from a patentee's attempted enforcement of a patent known to be invalid, not infringed, or unenforceable. *Argus Chemical Corp. v. Fibre Glass-Evercoat Corp.*, 812 F.2d 1381, 1385-86 (Fed. Cir. 1987); *Handgards, Inc. v. Ethicon, Inc.*, 743 F.2d 1282, 1295-97 (9th Cir. 1984), *cert. denied*, 469 U.S. 1190, 105 S. Ct. 963 (1985).
- An attorney's failure to perform an independent analysis of infringement may result in Rule 11 sanctions. *S. Bravo Systems, Inc. v. Containment Technologies Corp.*, 96 F.3d 1372, 1374-76 (Fed. Cir. 1996) (suggesting that an attorney should compare the accused device with the patent claims before an infringement action is filed).
- An attorney's opinion can be significant in the award of damages. However, *Warner-Jenkerson Corp. v. Hilton Davis Chem. Co.*, 117 S. Ct. 1040 (1997) has broadly affirmed that direct infringement -- even where the doctrine of equivalents is involved -- has no intent requirement. The effect, if any, of an attorney's opinion to deflect a charge of inducement of infringement has not been fully clarified. Compare *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544 (Fed. Cir. 1990) with *CVI/Beta Ventures, Inc. v. Tura LP*, 905 F. Supp. 1171, 1195-96 (E.D.N.Y. 1995).

II. Disclosure and Reliance On Attorney's Opinions May Effect a Subject Matter Waiver of Attorney-Client Privilege and Work Product Exemption

A. What causes the waiver?

- Deliberate injection of the advice of counsel into a case, for example, in defense of a willfulness charge waives the attorney-client privilege. *Handgards Inc. v. Johnson & Johnson*, 413 F. Supp. 926, 929 (N.D. Cal. 1976).

- Work product immunity is waived by the injection of attorney advice into the case. *Mushroom Assocs. v Monterey Mushrooms Inc.*, 24 U.S.P.Q.2d, 1767, 1770-71 (N.D. Cal. 1992)
- There is a split of authority as to when a commercial, non-litigation disclosure of a patent opinion constitutes a waiver of privilege. Compare *Hewlett-Packard v. Bausch & Lomb Inc.*, 115 F.R.D. 308 (N.D. Cal. 1987), with *Union Carbide v. Dow Chem.*, 619 F. Supp. 1036, 1050 (D. Del. 1985).
- “Trial courts should give serious consideration to a separate trial on willfulness” where revelation of opinion risks prejudice on the liability issue. *Quantum Corp. v. Tandon Corp.*, 940 F.2d 642, 643 (Fed. Cir. 1991).

B. Scope of the waiver

- The waiver is a subject matter waiver, driven by considerations of fairness.
- “A party should not be allowed to rely on self-serving documents in its defense while withholding potentially damaging information under the guise of the attorney-client privilege.” *Mushroom Assocs. v Monterey Mushrooms Inc.*, 24 U.S.P.Q.2d, 1767, 1770-71 (N.D. Cal. 1992). When a party asserts an intention to rely upon an advice-of-counsel defense to a willful infringement charge, the party cannot pick and choose among opinions or portions of opinions upon which it intends to rely. E.g., *Abbott Laboratories v. Baxter Travenol Laboratories, Inc.*, 676 F. Supp. 831, 832-33 (N.D.Ill. 1987). Otherwise, a “party claiming good faith reliance upon legal advice could produce three opinions of counsel approving the conduct at issue in a law suit and withhold a dozen more expressing grave reservations over its legality.” *Id.* at 832.
- The patent owner must have a complete opportunity to assess the reasonableness of the alleged infringer's reliance, which would include the client's assessment or understanding of the competence and completeness of the opinions. See, e.g., *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 829 (Fed. Cir. 1992).
- To evaluate the infringer's intent, a patentee must be able to conduct an examination of the circumstances and communications surrounding the infringer's state of mind. See *Frazier Indus. Co. v. Advance Storage Prods.*, 33 U.S.P.Q.2d 1702, 1703 (C.D. Calif. 1994).

- Such circumstances and communications surrounding the infringer's state of mind may include not only the opinion of counsel but also "communications between attorney and client concerning the subject matter, all documents referring to counsel's opinion, and all documents in the possession of [the infringer] bearing upon its state of mind." *Steelcase Inc. v. Haworth Inc.*, 954 F. Supp. 1195, 1199 (W.D. Mich. 1997).

- A representative opinion discussing the scope of a waiver provides:

There is no question that Plaintiff waived its attorney/client privilege when it produced the Barker [patent] opinion letter to Defendant. Thus, Plaintiff is ordered to produce for Defendant documents or other materials used by or prepared by Plaintiff or Plaintiff's counsel which refer to the Barker opinion. Additionally, any other opinions which support, contradict or weaken the Barker opinion, or other evidence which would go to Plaintiff's good faith reliance on the Barker opinion must also be produced by Plaintiff.

Kelsey-Hayes Co. v. Motor Wheel Corp., 155 F.R.D. 170, 172 (W.D. Mich. 1991).

- There is some authority for the proposition that the waiver extends to communications with patent counsel occurring after the opinion that cast doubt on the bases of an earlier opinion, and whether the party or its patent counsel "came into possession of information which contradicted a premise of the earlier opinion." *Micron Separations, Inc. v. Pall Corp.*, 159 F.R.D. 361, 363 (D. Mass. 1995).
- Typically, a party cannot properly produce only a redacted version of its opinion on the grounds the redacted material is irrelevant. *Steelcase*, 954 F. Supp. at 1198. Therefore, an opinion should be drafted as a freestanding unit and should not digress into other privileged issues.
- *See Micron Separations, Inc. v. Pall Corp.*, 159 F.R.D. 361, 365-66 (D. Mass. 1995) (subject matter waiver for all privileged and work product protected communications before and after opinion rendered by counsel, except that accused infringer could decline to produce opinion work product of present trial counsel which is solely consistent with the opinion letter relied on. *Board of Trustees of Leland Stanford Jr. Univ.*

v. Coulter Corp., 4 U.S.P.Q.2d 1652, 1653-54 (S.D. Fla. 1987)(all documents which constitute, refer, relate or form the basis of any opinion concerning validity or infringement of the patent to be produced, except that defendant could excise those portions necessary to protect against disclosure of mental impressions, conclusions, opinion, or legal theories as directed by the last sentence of Fed. R. Civ. P. 26(b)(3)).

III. Timing Of Defensive Opinions Of Invalidity Or Noninfringement

A. What Triggers The Duty To Investigate A Potential Infringement?

- A key issue: When did awareness of the patent and awareness of the accused product come to a responsible agent for the infringer who could recognize the problem? *See Stryker Corp. v. Osteonics Corp.*, 96 F.3d 1409, 1415-16 (Fed. Cir. 1996); Rooklidge & Bolan, "The Official Gazette and Willful Patent Infringement," 79 JPTOS 605 (1997).
- Recent example of triggering: an in-house engineer writing, "I believe we're probably infringing." *SRI Int'l v. Advanced Tech. Labs. Inc.*, 127 F.3d 1462, 1465 (Fed. Cir. 1997).
- What knowledge of the patent within a corporate client is enough to trigger? Huge volumes of patent copies flow through patent and research departments either on paper or electronically. Discovery of patents through the infringer's own diligence is a factor suggesting reasonableness, not willfulness. *Braun Inc. v. Dynamics Corp. of Am.*, 975 F.2d 815, 823 (Fed. Cir. 1992).
- The problem of activities that evolve into an infringement: "Significant design changes, in most instances, would require a new opinion of counsel." *Critikon Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.2d 1253, 1259 (Fed. Cir. 1997).
- Notice of a pending patent application may give rise to a duty to investigate. *Avia Group Intern., Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1566 (Fed. Cir. 1988).

B. Actual Notice of the Patent

- Actual notice of the patent can come formally by a cease and desist letter or by informal verbal notice. *See, e.g., Great Northern Corp. v. Davis Core & Pad Co., Inc.*, 782 F.2d 159, 166-67 (Fed. Cir. 1986).

C. How Quickly Must An Opinion Be Obtained?

- The opinion should be in place before proceeding with potentially infringing activity, if possible. “Prudent behavior generally requires that competent legal advice was obtained before the commencement of infringing activity . . . [but] we need not decide whether willful infringement can ever be purged by subsequent legal advice. . . .” *SRI Int’l v. Advanced Tech. Labs. Inc.*, 127 F.3d 1462, 1468 (Fed. Cir. 1997).
- There is no rule that an infringer “must be allowed a certain amount of time to ‘develop’ willfulness.” *Ralston Purina Corp. v. Far-Mar-Co.*, 772 F.2d 1570, 1577 (Fed. Cir. 1985).
- Some of an infringer’s activity can be more willful during some time periods than during others. “On-going consultation with a patent lawyer is highly probative evidence of good faith.” *Braun Inc. v. Dynamics Corp. of Am.*, 975 F.2d 815, 822 (Fed. Cir. 1992).
- Patent infringement is a continuing tort, and the filing of a lawsuit does not stop the clock insofar as culpability may arise from continuing disregard of the legal rights of the patentee. *Pall Corp. v. Micron Separations*, 66 F.3d 1211, 1221 (Fed. Cir. 1995). Infringement may, for example, be found not to be willful when begun, but may become willful as circumstances change. *Id.* at 1222.

1. Some Timing Examples

- 7 years later, opinion was “too little, too late.” *SRI Int’l v. Advanced Tech. Labs. Inc.*, 127 F.3d 1462, 1467 (Fed. Cir. 1997).
- Opinion 20 months after infringement began was too late. *American Med. Sys. Inc. v. Medical Eng’g Corp.*, 6 F.3d 1523, 1531 (Fed. Cir. 1993).
- Willfulness was found where no opinion was obtained until 11 months after the essentially simultaneous issuance of the patent and the filing of suit. *National Presto Indus. Inc. v. The West Bend Corp.*, 76 F.3d 1185, 1193 (Fed. Cir. 1996).

- A double damages award was affirmed in a context including a delay of five months in consulting an attorney after the first of three intervening notices of infringement. *DelMar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1328-29 (Fed. Cir. 1987).
- No liability for willful infringement was found in spite of delay in procuring an opinion for eight months after receiving written notice of infringement, and continuing infringement after the patent was confirmed on reexamination where patent expired four months after reexamination completed. *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1571 (Fed. Cir. 1996).
- Pre-issuance conduct cannot, by itself, give rise to liability for infringement, much less willful infringement. *See Gustafson Inc. v. Intersystems Industrial Prods. Inc.*, 897 F.2d 508, 510 (Fed. Cir. 1990). However, prepatent conduct can be used to support a finding of willfulness in later infringement, as, for example, where the infringer is warned that a patent is about to issue and has misappropriated trade secrets relating to the invention. *Minnesota Mining & Manufacturing Corp. v. Johnson & Johnson*, 976 F.2d 1581 (Fed. Cir. 1992).

IV. The Opinion Document as Evidence/The Author As Witness

A. Who Should Author The Opinion?

- No rule excludes reliance on in-house counsel opinions. *SRI Int'l v. Advanced Tech. Labs. Inc.*, 127 F.3d 1462, 1467 (Fed. Cir. 1997); *Studiengesellschaft Kohle Dart Indus.*, 862 F.2d 1564, 1576 (Fed. Cir. 1988). However, opinions by in-house counsel seem to be viewed with greater skepticism, as are opinions of foreign patent counsel. *See Minnesota Min. & Mfg. v. Johnson & Johnson*, 976 F.2d 1559, 1580-81 (Fed. Cir. 1992); *Spindelfabrik Suessen-Schurr v. Schubert & Salzer*, 829 F.2d 1075, 1084 (Fed. Cir. 1987); *Bott v. Four Star Corp.*, 807 F.2d 1567, 1572 (Fed. Cir. 1986).
- A “case analysis” by outside litigation counsel found by Master to be “inherently suspect.” *Minnesota Mining & Manufacturing*, 976 F.2d 1559, 1582 n. 13 (Fed. Cir. 1992).

- Memos of in-house executives and engineers to the effect that the instant subject matter is unpatentable, may not be given much weight. *Rosemount Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1548 (Fed. Cir. 1984).
- The fact that the attorney consulted was a general attorney, not a patent attorney was a factor in finding willfulness. *Acoustical Design Inc. v. Control Electronics Corp. Inc.*, 932 F.2d 939 (Fed. Cir. 1991); *Underwater Devices Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1390 (Fed. Cir. 1983).

B. What Kinds Of Attacks May Be Mounted Against the Opinion and Author?

- Because it is the state of mind of the accused infringer at issue, provided that the accused infringer asserts reliance upon a competent written opinion that properly sets out the basis for the conclusions reached, there should ordinarily be no need to make inquiries into the state of mind of the attorney who prepared the opinion. *Liqui-Box Corp. v. Reid Valve Co.*, 16 U.S.P.Q.2d 1074, 1075 (W.D.Pa. 1989); *Automotive Prods. v. Tilton Eng'g Inc.*, 1993 U.S. Dist. LEXIS 3752, 32 (C.D. Cal. 1993); *Ristvedt-Johnson, Inc. v. Cummins-Allison Corp.*, 1990 U.S. Dist. LEXIS 9297, 7-10 (N.D. Ill. 1990).
- There is, however, authority for questioning of the attorney who prepared the opinion alleged to have been relied upon by an accused infringer as to the basis for his opinion. *Amsted Indus. Inc. v. National Castings, Inc.*, 16 U.S.P.Q.2d 1737, 1741 (N.D. Ill. 1990) (permitting inquiry into the question of whether the accused infringer withheld information from the attorney in procuring his opinion). See Bajefsky & Manspeizer, *Can the Attorney Who Prepares a Validity/Infringement Opinion Act as Trial Counsel in a Later Case?*, IP Litigator 8 (November/December 1997) (criticizing *Amsted* on grounds including that the willfulness analysis must focus on the content of the written opinion itself; analysis of the written opinion could have determined whether the opinion contained the allegedly withheld information and, if it did not, the court could then determine whether it was reasonable for the recipient to rely on an opinion that did not consider the information; technical and patent law experts, rather than the opinion's author, could testify as to whether the missing information was material).
- The opinion may be attacked on the grounds that the attorney, in testimony, has tried to rely on other arguments not made in the opinion, though this was not dispositive of the willfulness question. *Kohle*, 862

F.2d at 1577-78 (The changed arguments do not mean that the attorney's initial reasoning was irrelevant as opposed to simply wrong).

C. Opinion and Author Benefitting the Infringer's Defense

- Generally, the opinion author's experience, background and thoroughness is objective evidence of the reasonableness of the client's reliance on the opinion.
- Even though reliance on advice of counsel typically involves consideration of the reasonableness of the accused infringer's belief based upon the contents expressed in the attorney's opinion, attorney testimony at trial can provide evidence of non-willfulness. *See generally Windsurfing Intern., Inc. v. Fred Ostermann GmbH* 668 F. Supp. 812, 814-17 (S.D.N.Y. 1987), *aff'd, Bic Leisure Products, Inc. v. Windsurfing Intern, Inc.*, 1 F.3d 1214 (Fed. Cir. 1993); *Smith Corona Corp. v. Pelikan, Inc.*, 784 F. Supp. 452, 480-81 (M.D.Tenn. 1992).
- Supporting a finding of no willfulness, a U.S. patent attorney involved in proceedings before the U.S.P.T.O. concerning the patent-in-suit and testifying as to his belief in the invalidity of the patent "impress[ed] the court as both competent and experienced in patent matters." *Windsurfing Intern*, 668 F. Supp. at 815.
- An outside U.S. patent attorney's testimony concerning his opinion of invalidity supported a finding of no willfulness where the central issue involved disputed interpretations of law, and the attorney's opinion relied on a viable, though controverted, interpretation of the law. *Smith Corona Corp. v. Pelikan, Inc.*, 784 F. Supp. at 480-81 (legal issue as to whether preamble limited the claims).
- The testimony of non-U.S. patent counsel may also be persuasive. Non-U.S. patent counsel may testify concerning parallels between U.S. and foreign patent laws, and reasonableness of expectations concerning patent proceedings in U.S. in view of preceding legal proceedings concerning corresponding non-U.S. patents. *Windsurfing Intern*, 668 F. Supp. at 816-17.

V. Correctness, Competence and Certitude

A. Correctness vs. Obvious Incompetence

- “While an opinion of counsel letter is an important factor in determining the willfulness of infringement, its importance does not depend on its legal correctness. Indeed, the question arises only where counsel was wrong. Rather, counsel’s opinion must be thorough enough, as combined with other factors, to instill a belief in the infringer that a court might reasonably hold the patent is invalid, not infringed, or unenforceable.” *Ortho Pharmaceutical Corp. v. Smith*, 959 F.2d 936, 944 (Fed. Cir. 1992).
- A written opinion which is incompetent on its face will not suffice to defeat a charge of willfulness. See *Read v. Portec, Inc.*, 970 F.2d 816, 829 (Fed. Cir. 1992) and cases cited there. “That an opinion is ‘incompetent’ must be shown by objective evidence.” *Id.*

B. Instances Where Information is Often Inadequate to Render an Opinion

- Unenforceability for inequitable conduct. Evidence of intent to deceive the PTO is difficult to find, particularly without discovery. Though a “smoking gun” is not required -- typically such evidence comes only through discovery, if it exists.
 - “[D]ifference of opinion is a slender heed on which to hang a very serious allegation.” *SRI Int’l v. Advanced Tech. Labs. Inc.*, 127 F.3d 1462, 1466 (Fed. Cir. 1997)
- Establishing when an invention was made for an invalidity case under 102(a), (e) or (g) often requires access to your opponent’s priority proofs and documents (*e.g.* lab notebooks).
- Dealing with invalidity of potential divisional applications. See *Ortho Pharmaceutical Corp. v. Smith*, 959 F.2d 936, 944 (Fed. Cir. 1992) (involving such an opinion letter, which was not criticized on this ground; follow-up letter also issued).

C. What Is The Appropriate Degree Of Certitude?

1. What is the intent standard for the client?

- “To serve as exculpatory legal advice the opinion of counsel is viewed objectively, to determine . . . [inter alia] . . . whether the opinion warranted a reasonable degree of certainty that the infringer had the legal right to conduct the infringing activity.” *SRI Int’l v. Advanced Tech. Labs. Inc.*, 127 F.3d 1462, 1467 (Fed. Cir. 1997) (emphasis added).

2. What are appropriate verbal formulations for the opinion?

- *Westvaco Corp. v. Int’l Paper Corp.*, 991 F.2d 735, 744 (Fed. Cir. 1993) (no willfulness found in instance involving an opinion letter stating “it was more likely than not” that claims would be held invalid.)
- “An honest opinion is more likely to speak of probabilities than certainties.” *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 829 n.9 (Fed. Cir. 1992).
- “A party is not guilty of ignoring patent rights because it resolves a close question of infringement in its favor.” *Ortho Pharmaceutical Corp. v. Smith*, 959 F.2d 936, 945 (Fed. Cir. 1992).
- It is acceptable for an attorney to draft an opinion in terms of his “belief” that there is no infringement. *Studiengesellschaft Kohle Dart Indus.*, 862 F.2d 1564, 1576-77 (Fed. Cir. 1988)
- Willfulness may be found where the infringer had “no reason to be confident that a court would hold” the patent invalid or not infringed. *Minnesota Mining & Manufacturing*, 976 F.2d 1559, 1580 (Fed. Cir. 1992).
- Attorney’s opinion that there was a “reasonably good chance that patent might be held invalid” over art of record in the PTO did not “by itself raise an inference of good faith substantial enough to convince us that the trial court’s determination of willful infringement was clearly erroneous.” *Central Soya Comp., Inc.*

v. Geo. A. Hormel & Comp., 723 F.2d 1573, 1576-77 (Fed. Cir. 1983).

- An attorney's pronouncement concerning noninfringement which "nowhere draw[s] a clear line for the client, as to what would be right and what would be wrong" does not support reversal of a determination of willfulness. *Central Soya*, 723 F.2d at 1581-82 (concurrency).

VI. Content of the Opinion Letter²

A. Background - why you are writing this letter

1. who asked for the letter
2. what was asked for in the letter
 - validity/invalidity opinion
 - infringement/noninfringement opinion
 - enforceability/unenforceability opinion
3. brief review of what was investigated
 - what products/processes were examined
 - what patents were examined
 - what other information was examined (persons interviewed, prior art documents reviewed, etc.)

B. Summary - state the ultimate conclusion(s) (some readers may stop reading at this point)

² The authors do not intend to imply that all of the topics/inquiries listed below are necessary or appropriate in all cases.

C. Investigations Undertaken

1. the subject product or process
 - what information was provided to or obtained by the author about the subject product or process (identify product by model and serial number, identify process by process designation, if possible, identify when subject activities began/ended, identify where the subject activities took place {inside/outside the United States})
 - when was the information obtained (consider that products/processes may change, when was the product purchased)
 - how was this information obtained, *i.e.*, who provided the information or how did the author otherwise obtain the information (who purchased the product or who provided the information about the product/process -- this must establish the reliability, correctness and completeness of the relevant information, but consider that all persons named may later be deposed, consider also that conducting only a cursory investigation before filing a complaint may raise Fed. R. Civ. P. 11 problems, *Judin v. United States*, 110 F.3d 780, 784-85 (Fed. Cir. 1997)).
2. the patent's procedural posture
 - have maintenance fees been paid (37 C.F.R. § 1.378)
 - has patent expired (no longer a simple question)
 - have terms of terminal disclaimer been violated (37 C.F.R. § 1.321(c)(3))
 - ownership/rights in the patent (who has the right to license/sublicense, is the subject party licensed?) *Ethicon Inc. v. United States Surgical Corp.*, 45 U.S.P.Q.2d 1545, 1552-53 (Fed. Cir. 1998); consider also federal government rights under 35 U.S.C. §§ 200-210
 - have any foreign filings complied with 35 U.S.C. § 184 or is patent barred under 35 U.S.C. § 185

- any pending reexam or reissue proceedings
 - any prior or ongoing litigation involving the patent (what was at issue, what results {if a court has already examined prior art that you want to rely on, need to explain why court was wrong/right})
3. the patent's enforceability/validity
- evidence of unenforceability of patent (failure to disclose to PTO known, relevant, non-cumulative information such as prior art documents)
 - false statements made during prosecution, *General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1407-12 (Fed. Cir. 1994)
 - evidence of on-sale bar
4. prior art search
5. level of ordinary skill in the art
- educational level of inventor
 - prior art approaches to the problem
 - problems encountered in the art
 - rapidity with which innovations are made in the art
 - sophistication of the technology
 - educational level of those working in the field, *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1382 (Fed. Cir. 1983)
6. secondary considerations relating to obviousness
- commercial success of claimed product/process
 - long-felt but unsolved needs met by claimed product/process
 - failure of others

- praise of the invention by others
 - departure from expert-accepted principles
 - wide recognition of the significance of the invention, *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546 (Fed. Cir. 1984)
7. when did the accused party first learn of the patent
8. how was the subject product/process developed (evidence of independent development, copying, designing around)
9. legal research - the applicable legal standards
- infringement
 - infringement entails a two step analysis, first, a determination of the meaning and scope of the claims, and second, comparing the properly construed claims to the accused product/process, *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995)
 - literal infringement exists only if the subject product/process embodies each and every limitation recited in the claim, *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934-35 (Fed. Cir. 1987)
 - infringement under the doctrine of equivalents ("Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention? ... [The inquiry is] whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element." *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 117 S. Ct. 1041, 1054 (1997))
 - equivalency, *i.e.*, "knowledge of interchangeability between elements" is evaluated "at the time of infringement, not at the time the patent was issued." *Hilton-Davis*, 117 S. Ct. at 1053

- burden of proof is a preponderance of the evidence, *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758 (Fed. Cir. 1984)
- invalidity due to anticipation
 - requires that “every element of the claimed invention must be identically shown in a single [prior art] reference,” *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990)
 - burden of proof is clear and convincing evidence, *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677 (Fed. Cir. 1988)
- invalidity due to obviousness
 - requires determining: (1) scope and content of prior art; (2) differences between claims and prior art; (3) level of ordinary skill in the art; and (4) any secondary considerations of non-obviousness (commercial success, long-felt but unsolved needs, failure of others, etc.), *Uniroyal, Inc. v. Rudkin- Wiley Corp.*, 837 F.2d 1044, 1050 (Fed. Cir. 1988)
 - burden of proof is clear and convincing evidence, *Diversitech Corp.*, 850 F.2d at 679
- unenforceability due to inequitable conduct
 - requires showing: “[1] affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, [2] coupled with an intent to deceive,” *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995)
 - burden of proof is clear and convincing evidence, *Molins PLC*, 48 F.3d at 1178

- D. Explain the product/process set forth in the written description portion of the specification, *Amsted Industries v. Buckeye Steel Casings Co.*, 24 F.3d 178, 183 (Fed. Cir. 1994) (it should be clear from the opinion that you understand the patented invention)
- E. Review the relevant portions of the file history (discuss any amendments to the originally filed claims and explain the bases, if discernable, for any amendments to the claims) *Hilton-Davis*, 117 S. Ct. at 1054 (recall that where the patentholder is unable to establish that an amendment made during prosecution had a purpose unrelated to patentability, "a court should presume that the purpose behind the required amendment is such that prosecution history estoppel would apply")
- F. Describe the subject product/process in appropriate detail (a factual recitation based on the investigation)
- G. Claim interpretation (examine each claim of interest)
1. intrinsic evidence
 - review the patent (claims and written description part of the specification)
 - review the file history including prior art of record
 2. extrinsic evidence (if "analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term . . . it is improper to rely on extrinsic evidence." *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996); "[e]xtrinsic evidence is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." *Markman*, 52 F.3d at 981)
 - dictionaries
 - prior art not of record
 - information from technical people (either from within or outside company) who can explain what particular terms would have meant to one of ordinary skill at the time, *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1584-85 (Fed. Cir. 1996)
 3. interpretation of means-plus-function limitations requires citation to the specification. ("the accused device must employ means identical to or

the equivalent of the structures, material, or acts described in the patent specification. The accused device must also perform the identical function as specified in the claims." *Valmont Indus. v. Reinke Mfg. Co.*, 983 F.2d 1039, 1042 (Fed. Cir. 1993)).

4. claim interpretation is the same for purposes of both validity and infringement, *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1279 (Fed. Cir. 1988)

H. Infringement/non-infringement opinion (examine for each claim of interest)

1. direct infringement
2. contributory infringement
3. inducement of infringement
4. literal infringement
 - apply properly interpreted claim to the subject product/process
 - analyze claim element-by-element, *Read*, 970 F.2d at 821-22
5. infringement under the doctrine of equivalents
 - no equitable threshold of intent necessary for the application of the doctrine of equivalents, *Hilton-Davis*, 117 S. Ct. at 1052 ("intent plays no role in the application of the doctrine of equivalents")
 - where claims are amended during prosecution, burden is on patentholder to establish reason for amendment, where no explanation is established, "court should presume that the PTO had a substantial reason related to patentability for including the limiting element added by amendment. In those circumstances, prosecution history estoppel would bar the application of the doctrine of equivalents as to that element." *Hilton-Davis*, 117 S. Ct. at 1051
 - analyze claim element-by-element, looking for elements in accused device/process identical or equivalent to each claimed element, *Hilton-Davis*, 117 S. Ct. at 1049 & 1054

- evaluate equivalency (including any knowledge of interchangeability) at time of infringement, *Hilton-Davis*, 117 S. Ct. at 1053
 - consider evidence of independent development ("[i]ndependent experimentation by the alleged infringer would not always reflect upon the objective question whether a person skilled in the art would have known of the interchangeability between two elements, but in many cases it would likely be probative of such knowledge." *Hilton-Davis*, 117 S. Ct. at 1052), evidence of copying versus designing around has less value. *Id.*
 - to determine whether substitutes for claimed elements can be used "without fear of infringement, a competitor would look to the claim language, the specification, and the patent's prosecution history." *Tanabe Seiyaku Co. v. United States Int'l Trade Comm.*, 109 F.3d 726, 732 (Fed. Cir. 1997)
 - evaluate equivalency by examining traditional function/way/result test AND whether any differences between the claimed elements and the corresponding elements in the accused product/process are insubstantial, *Hilton-Davis*, 117 S. Ct. at 1054
 - "[t]he test is objective, with proof of the substantiality of the differences resting on objective evidence rather than unexplained subjective conclusions, whether offered by an expert witness or otherwise," *Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1519 (Fed. Cir. 1995)
6. explain why claim limitations are/are not met by the subject device/process (conclusory statements alone are insufficient, *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 829 (Fed. Cir. 1992))
 7. does evidence meet burden of proof (preponderance of the evidence)
 8. consider where particular activities occurred for purposes of 35 U.S.C. 271, *i.e.*, did the activities occur inside or outside the United States

9. consider if activities constitute permissible repair or impermissible reconstruction, *Sandvik Aktiebolag v. E.J. Co.*, 121 F.3d 669 (Fed. Cir. 1997), *petition for cert. filed Jan. 13, 1998* (No. 97-1177)
10. if patent issued within prior two (2) years, consider effect of broadening reissue 35 U.S.C. § 251

I. Validity/invalidity and enforceability/unenforceability opinion (examine each claim of interest)

1. discuss factors relating to the patent's procedural posture (listed above)
2. discuss evidence of unenforceability of patent (failure to disclose to PTO known, relevant, non-cumulative information; false representations made to the PTO; evidence of intent to mislead), *General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405 (Fed. Cir. 1994); *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1988); *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553 (Fed. Cir. 1984)
3. discuss evidence of on-sale bar
4. discuss relevant prior art (regardless of whether or not cited during prosecution)
 - anticipation
 - examine each claim element, if each claim element is found, either expressly or inherently, in a single prior art reference, the reference anticipates, *Tyler Refrigeration v. Kysor Industrial Corp.*, 777 F.2d 687, 689 (Fed. Cir. 1985)
 - does evidence meet burden of proof
 - obviousness
 - examine scope and content of prior art (regardless of whether or not cited during prosecution)
 - examine differences between the claims and the prior art
 - discuss the level of ordinary skill in the art

- discuss secondary considerations
 - commercial success of claimed product/process
 - long-felt but unsolved needs met by claimed product/process
 - failure of others
 - praise of the invention by others
 - departure from expert-accepted principles
 - wide recognition of the significance of the invention, *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546 (Fed. Cir. 1984)
- discuss how prior art provides (or fails to provide) "some teaching, suggestion or incentive supporting the combination" *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 140 (Fed. Cir. 1986) ("When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself." *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985))
- does evidence meet burden of proof
- enforceability/unenforceability
 - discuss any evidence of potential unenforceability due to inequitable conduct, which has included failure to inform the PTO of litigation involving a patent involved in reissue proceedings, *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1258-59 (Fed. Cir. 1997)
 - does evidence meet burden of proof?

J. Conclusion

1. short re-recitation of ultimate conclusion of validity/invalidity, infringement/noninfringement, enforceability/unenforceability

2. opinion is limited to the product/process described, if the product/process is changed, re-evaluation of the infringement/noninfringement opinion may be appropriate *Critikon*, 120 F.3d at 1259
3. if client becomes aware of any additional information that may affect the bases for the opinion, that information should be brought to the author's attention
4. remind client that should litigation develop, opinion letter could remain protected by the attorney-client privilege, so distribution of the opinion should be limited to those employees or officers of the client who need to see it, and they should be cautioned to treat the opinion as privileged and confidential.