Strategies for Drafting Opinions of Counsel: What Will *Knorr-Bremse* change?

by Michael R. Dzwonczyk[1]
Sughrue Mion LLP

Opinions of counsel take many forms and are prepared for a variety of different purposes. Most common are opinions relating to patentability (and scope of protection during prosecution), freedom to operate, validity/invalidity and infringement or noninfringement. Each of these opinion forms has, as its basic purpose, to provide the client with a practitioner's analysis of the scope of rights and limitations on those rights accorded both existing patents and pending applications.

This paper focuses solely on validity and non-infringement opinions and their uses in license negotiations and in litigation.

I. Why are Non-Infringement/Invalidity Opinions Prepared?

Non-infringement/invalidity opinions can be prepared for a variety of reasons, including *e.g.*, as a prelude to negotiation of a license, as a measure of diligence before acquisition of a business entity, or as a possible exculpatory defense to allegations of willful infringement.[2]

Before a decision is made to out-license or in-license patented technology, either party to the transaction may seek an opinion to assess the scope of rights being conferred by the license. A licensor may seek an advice of counsel with respect to the strength and scope of patents in a portfolio to be licensed. Additionally, weaknesses or potential invalidating defenses may also be explored. Perspective licensees may also seek the advice of counsel to determine the validity of a patent or patents in a portfolio under consideration for license. A licensee may also request an analysis of the claim scope of one or more patents in a portfolio relative to other patents in the portfolio or as compared to prior art. Certainly, potential licensees should evaluate whether current manufacturing, sales or other activity may constitute an infringement of the technology considered for licensing or even whether future activity by the licensee may be considered as such. Opinions of counsel provide guidance to parties engaged in all phases of technology transfer.

Parties acquiring businesses or patent estates will frequently seek the advice of counsel in determining the strength of the business or patent estate. Potential weaknesses, such as bases for invalidity or unenforceability, are considered. Opinions of counsel may

---

[1] Mr. Dzwonczyk is partner at Sughrue Mion LLC in Washington, D.C. This paper reflects the views of the author alone, and should not be attributed to Sughrue Mion LLC or any of its members or past or present clients. © 2004 M.R. Dzwonczyk.

[2] *See* Sec. II.B. *infra* regarding *Knorr-Bremse*.

also be sought to identify infringement or non-infringement issues attendant to any prospective sale.

Finally, opinions of counsel have frequently been procured by parties as exculpatory defenses to allegations of willful infringement. In some circumstances, opinions prepared in contemplation of a license or in the acquisition of a business or patent estate are produced in response to charges of willful infringement as a measure to avoid an award of damage enhancement. It is for this reason that all non-infringement/invalidity opinions are, in a sense, "pre-litigation opinions" and should be prepared with the expectation that they may ultimately be used as a defense to charges of willful infringement and will be produced during discovery.

II. The Standard of Conduct for Potential Infringers

The federal circuit has stated that a potential infringer having actual knowledge of another's patent rights has an affirmative duty to exercise due care in determining whether or not there exists potential infringement.[3] The duty has included the procurement of competent legal advice from counsel from the initiation of any possible infringing activity.[4] However, it is equally clear since the federal circuit's decision in *Underwater Devices* that willful infringement is based on a totality of the circumstances. That is, the absence or presence of an exculpatory opinion of counsel is not *per se* dispositive as to whether an infringer's activity was willful.

For example, deliberate copying of a patented invention and a party's conduct to litigation have also been considered in determining the willfulness of an infringer's conduct. Notwithstanding, the absence of an opinion of counsel (or the refusal to produce one where obtained) has -- by itself -- paved the way for findings of willful infringement; in some instances through adverse inferences or presumptions based on the refusal to produce the opinion. For this reason, the opinion of counsel has taken on unique significance among the factors considered probative of willful infringement.

A. The “requirement” of an opinion of counsel

The *dictum* in *Underwater Devices* stating that the “affirmative duty includes . . . the duty to seek and obtain competent legal advice from counsel *before* the initiation of any possible infringing activity” has elevated the opinion of counsel to a virtual *per se* requirement of compliance with the standard of conduct. Of course, it is not.

The federal circuit has now revisited the question of whether an infringer’s refusal to waive privilege over the advice and conclusions of counsel in an opinion should give rise to an adverse inference or a jury instruction presuming the opinion was negative.

In September, 2003, the federal circuit *sua sponte* undertook to hear *en banc Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp*., 133 F. Supp.2d 833

[3] *Underwater Devices, Inc. v. Morrison-Knudsen Co.,* 717 F.2d 1380, 1389-1390 (Fed. Cir. 1983).

[4] *Id.*

(E.D. Va. 2001) (and related orders) to reconsider its own precedent concerning the drawing of adverse inferences with respect to willful patent infringement, based on the actions of the party charged with infringement in obtaining legal advice.

In *Knorr-Bremse*, the defendants argued that the district court drew an adverse inference *solely* from their failure to obtain or produce an opinion of counsel with respect to their Mark II brake devices accused of infringement.[5] (Defendants maintained that a business strategy not to commercialize the Mark II brakes drove the decision not to obtain an opinion of counsel, and that their business strategy did not fairly suggest a negative opinion.[6]). Knorr-Bremse disagreed, urging that the inference was based on *multiple* factors. Accepting the case *en banc sua sponte*, the federal circuit certified four questions for briefing and invited the participation of *amici* on three of those:

- whether it is appropriate to draw an adverse inference with respect to willful infringement when the attorney-client privilege and/or work product privilege is invoked;
- whether it is appropriate to draw an adverse inference with respect to willful infringement when the defendant has not obtained legal advice; and
- whether the existence of a substantial defense to infringement is sufficient to defeat liability for willful infringement even if no legal advice has been secured.

In a virtually unprecedented response, 24 amicus briefs were submitted. The 22 *amici* who responded to question 1 unanimously said "no" to the propriety of drawing an adverse inference based on the invocation of privilege or work-product. Eighteen of twenty *amici* who responded to question 2 said "no", and 12 of 19 *amici* responding said "yes" to question 4. The federal circuit has not yet issued its decision, but the strong message from the bar is a signaled retreat from the practice of making opinions of counsel a minimum "requirement" for defending against allegations of willfulness.

B. The Effect of *Knorr-Bremse* on the Decision to Procure an Opinion

Assuming the court adopts the views of the bar and removes the adverse inferences attendant to nondisclosure or nonprocurement of counsel's opinion, what effect -- if any -- will this have on the decision of *whether* or not to even obtain an opinion of counsel? The answer is complex and may depend on factors such as[7]:

1. The quality of other factors used to defend against willfulness;

[5] The parties, in their briefs to the federal circuit, dispute whether there was no opinion of counsel or whether there was an opinion that was not produced.

[6] *Opening Brief Of Defendants-Appellants*, July 16, 2001 at 13.

[7] Strategies of *whether* or not to obtain an opinion of counsel will doubtless involve a more fact-based inquiry, but are premature in view of the pendency of the *Knorr-Bremse* appeal.

2. Whether or not the fact of an undisclosed or unprocured opinion is admissible, or whether a jury instruction to that effect is permitted;

3. the basis for the noninfringement position and the closeness of the case;

4. the size and nature of the business conducting the infringing activity.

For the large majority of companies/clients, the prudent course of action will still be to seek the advice of counsel before engaging in any potentially infringing activity. There are several reasons for this. First, even in a "totality of the circumstances" analysis of the factors relied upon to defend against a charge of willfulness, the opinion of counsel has achieved a measure of historical importance. The unavailability of an express adverse inference for failure to obtain an opinion of counsel may do little to convince a trier of fact that a sophisticated infringer with a "pure heart and an empty head" was not at least negligent or even reckless for failing to obtain an opinion.

Second, a defense of noninfringement based on a claim interpretation requires legal analysis, and is appropriately the subject of counsel's advice -- preferably in the form of an opinion. It is important to remember that the *dictum* in *Underwater Devices* now being revisited by the federal circuit in *Knorr-Bremse* predated *Markman* by over a decade. Procedurally, claim construction in patent disputes since *Markman* has taken on a heightened significance (relative to pre-*Markman* litigation), resulting in a higher percentage of the federal circuit's patent appeals based on claim construction disputes after summary judgment grants. Since claim interpretation is a matter of law, parties whose noninfringement defenses are based on particular interpretations of the claims are prudently advised to seek counsel's assistance.

Third and perhaps most significantly, it is unclear how the nonproduction or nonprocurement of counsel's opinion will be treated from an evidentiary perspective by the trier of fact. Is the fact of nonproduction or nonprocurement too prejudicial under Rule 403 to be given to the trier of fact? Infringers will doubtless argue "yes," with the silent expectation that a jury will regard such conduct with opprobrium even absent an instruction to draw an adverse inference. In stark contrast, patentees will argue that an infringer's conduct is relevant under a totality of the circumstances analysis and that any decision to not obtain (or not produce) an opinion is probative of an infringer's state of mind. Both arguments have merit and illustrate the difficulty of applying any change in the law *Knorr-Bremse* may bring if it does not also provide practical guidance.

Until and unless there is either guidance (*dicta*) or law protecting infringers from the consequences of failing to produce or procure counsel's opinion, including a jury's impression of that failure *even absent an instruction*, obtaining an opinion may still be the safest and most conservative course of action for would-be infringers.

C. The Contents of an Opinion of Counsel

An opinion of counsel must be competent in order to provide a potential infringer with a basis to form a good faith belief in its contents and conclusions.[8] Counsel preparing the opinion should be well-versed and current in an understanding of claim interpretation principles, a doctrine of equivalents analysis, prosecution history review, PTO practice, and, more broadly, all current developments related to patentability under 35 U.S.C. §§ 101, 102, 103 and 112. In general, the opinion of an outside counsel has been accorded more weight than an in-house attorney; however, courts have accepted the opinion of in-house counsel where it is thorough and reasonable. Nor is it problematic that the author of the opinion is a general practitioner rather than a patent attorney; however, in any "totality of the circumstances" analysis, the qualifications of the author as counsel will be considered in addressing the strength and deficiencies of the opinion, and thus, the nature of any good faith reliance thereupon. It is preferable that the opinion be written as opposed to oral, and essential that the potential infringer rely on the advices contained in the opinion.[9]

A competent opinion will also reflect consideration of all materials necessary to reach a conclusion. This includes the patent and prosecution history, usually the prior art cited therein, and sometimes, foreign counterpart patents or published applications as well.

Non-infringement opinions will additionally include a thorough description and evaluation of the product or process being considered as well as a claim chart or its equivalent comparing features of the claims with features of the product or process under consideration. Invalidity opinions will define the bases for invalidity and set forth the appropriate legal standards. In the case of prior art defenses, a thorough discussion of the invalidating references in the context of Sections 102 or 103 will also be presented.

III. Writing the Opinion

There is no single correct way to write a competent opinion. The style and form should take into account the needs of the client, the preferences of the author and the ultimate audience. The content must provide an adequate basis to support the conclusions in order to be considered competent under federal circuit standards.

When should an opinion be written? Ideally, an opinion should be prepared before a client engages in activity that might be considered an infringement of an issued patent.[10] When activity has commenced before a patent issues, it is advisable to seek an opinion as soon as possible after the potential infringer has notice of the patent.

---

[8] For a brief summary of willful infringement and the elements of a competent opinion of counsel, *see* Racine, R. and Bosch, M., *Will Infringement: A Real Concern,* 3 Fed. Cir. Bar J., No. 4, p. 409 (Winter 1993).

[9] *SRI International , Inc. v. Advanced Technology Laboratories, Inc.* 127 F.3d 1462, 1465 (Fed. Cir. 1997)

[10] *Ryco, inc. v. Ag-Bag Corp.,* 857 F.2d 1418, 1428 (Fed. Cir. 1988) ("The duty of care normally requires that a potential infringer obtain competent legal advice before infringing or continuing to infringe.").

IV. Getting Started

When obtaining a copy of the prosecution history, check to see that maintenance fees have been paid and are current. This applies to patents that have been issued for some time, but which may have only come to the attention of your client recently. Also, if your client did not receive notice of the patent directly from the patent owner, it is always advisable to determine the proper assignee of record. The real party in interest is the owner or exclusive licensee, who may not always be listed on the face of the patent.

Write opinions in plain English. Avoid legalese. Remember that while the client may be patent counsel, a patent savvy business director or a scientist, the ultimate arbiter of the opinion's competence is a judge or jury. As lay persons, judges and juries are persuaded more by what they understand than by what they do not.

Opinions presented in letter form with attachments, bullet points (summary form), or in the form of a legal memorandum may all be appropriate in certain circumstances. However, where summaries or conclusions are presented in a short letter or memo form, it is strongly urged to present an application of relevant law to the facts in the text of the opinion. It is more important that opinions are well-reasoned (although ultimately incorrect in conclusion) than merely conclusory in nature.[11]

V. Interpreting the Claims; Summarizing the Disclosure and Prosecution History

The claims of a patent being studied must always be presented either literally, in summary form or in some combination of both. The claims of a patent delineate the scope of the property right and it is the patent claims that are infringed, held invalid or are unenforceable. Claims must be interpreted in accordance with the relevant standards for claim construction, discussed *infra*.

The patent's disclosure should be summarized, emphasizing those points relevant to the opinion's purpose and conclusions. This is important for several reasons:

- The `Background of the Invention' section usually provides valuable insight into the scope and content of the prior art. This section may also contain a statement of the `problem to be solved' addressed by the inventor, also relevant to a *Graham* analysis.

- The patent disclosure provides the basis for Section 112 defenses - especially important in early biotechnology patents, where the enablement and written restriction requirements were most often

[11] *Ortho Pharmaceutical Corp. v. Smith,* 959 F.2d 936, 944-945 (Fed. Cir. 1992) ("While an opinion of counsel letter is an important factor in determining willfulness of infringement, its importance does not depend on its legal correctness. Indeed the question arises only where counsel was wrong.").

used as a basis of rejection during examination.

- The disclosure is necessary for patent claim interpretation. *Vitronics* at 1582. Because claims are construed the same way for validity as for infringement purposes, a discussion of the specification and how it aids in the claim interpretation is an integral part of a competent, well reasoned opinion.

Finally, the competent opinion will include a discussion of the prosecution history.[12] The prosecution history is a necessary tool in claim interpretation, and a necessary component assessing infringement under the doctrine of equivalents.[13]

The Supreme Court has held that any narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel.[14] A presumption exists that a narrowing amendment made for a reason of patentability surrenders the entire territory between the original claim limitation and the amended claim limitation, which presumption may be overcome by showing that "at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent."[15] Thus, a summary of the prosecution history should be focused, and highlight those portions necessary to the purposes of the opinion.

Careful review of the prosecution history may also be invaluable for developing new invalidity defenses. For example, many *pre-Pfaff* patents were obtained after satisfying an Examiner that a claimed invention (rejected as "on sale" under §102) was subject to ongoing experimental development. Since *Pfaff,* it is appropriate to apply the "ready for patenting" standard to patents where the on-sale bar was at issue during prosecution. Many *pre-Pfaff* patents may have evidence in their prosecution histories that now satisfies the ‘ready for patenting’ standard of the on-sale bar.

VI. Describe in detail the product/process considered for infringement purposes

For noninfringement opinions, it is important to describe in precise terms the product or process being evaluated. This description should generally be agreed upon between counsel and client before the opinion is completed. The competence of the noninfringement opinion will rest strongly on the conclusion that a claimed element is absent-both literally and under the doctrine of equivalents - in the subject product or process. Of course the patent owner's own commercial embodiment is not relevant - it is the claims of the patent that define the scope of protection.

The importance of this exercise should not be understated. The opinion is a

---

[12] *See Underwater Devices, Inc. v. Morrison-Knudsen Co., Inc.,* 717 F.2d 1380, 1390 (Fed. Cir. 1983), describing consideration of file histories a "normal and necessary preliminary to a validity or infringement opinion."

[13] *Festo Corporation v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.,* 234 F.3d 558 (Fed. Cir. 2001).

[14] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 535 U.S. 722, 736 (2002).

[15] *Id*. at 741.

snapshot in time of a product or process compared with a patent claim in view of the law as it exists at the time of drafting. The opinion is not generally scrutinized by a judge or jury until years later after infringement is proven. Not infrequently, both the law and the accused product or process will have changed in the interim. A detailed description of the product or process clearly establishes its parameters, and provides a sound basis for the conclusions of noninfringement.[16]

VII. Interpretation of Claims

A determination of whether or not a patent is infringed involves a two-step process.[17] The first step is claim construction which involves ascertaining the scope and meaning of the claims at issue, while the second step involves determining whether the claims as construed read on the accused device.[18] The first step is determined by a court as a matter of law, while the second step of comparing the claim as construed to the accused product or process is a question of fact, and can be subject to a jury trial determination.[19]

Using the patent, its prosecution history, and any dictionaries or technical references necessary, it is first necessary to interpret the claims. Since *Markman,* claim interpretation is a necessary predicate for invalidity and noninfringement determinations, and the competent opinion must discuss claim interpretation.

First, focus on the claim terms themselves.[20] There is a "heavy presumption" that the claim terms mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art.[21] Dictionaries, encyclopedias and treatises are particularly useful resources to assist in determining the ordinary and customary meanings of claim terms.[22] Because words often have multiple dictionary definitions, some having no relation to the claimed invention, the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor.[23] If more than one dictionary definition is consistent with the use of the words

---

[16] Willful infringement has been found where an opinion of counsel contained incorrect technical information about the composition of the infringing product and was otherwise considered "conclusory and woefully incomplete." *SRI International, Inc. Y. Advanced Technology Laboratories, Inc.,* 127 F.3d 1462, 1466 (Fed. Cir. 1997).

[17] *Markman v. Westview Instruments, Inc.,* 52 F.3d 967 (Fed. Cir. 1995), *of 'd* 517 U.S. 370 (1996).

[18] *Steamfeeder, LLC v. Sure-Feed Sys., Inc.,* 175 F.3d 974, 981 (Fed. Cir. 1999). *See also, Bai v. L&L Wings, Inc.,* 160 F.3d 1350, 1353 (Fed. Cir. 1998).

[19] *Cyber Corp. v. AS Etches.,* 138 F.3d 1448, 1456 (Fed. Cir. 1998) (in banc).

[20] The primary tools for determining the meaning and scope of a claim are the words of the claims themselves, the patent specification, and the prosecution history of the patent. *Vitronics Corp. v. Conceptronic, Inc.,* 90 F.3d 1576, 1582 (Fed. Cir. 1996); *Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 979 (Fed. Cir. 1995) *(en banc), aff'd,* 517 U.S. 37 0 (1996).

[21] *Texas Digital Sys. v. Telegenix, Inc*., 308 F.3d 1193, 1201-02 (Fed. Cir. 2002); *CCS Fitness, Inc. v. Brunswick Corp.,,* 288 F.3d 1359, 1366 (Fed. Cir. 2002).

[22] *Id.*

[23] *Id*. at 2003, citing *Dow Chem Co. v. Sumitomo Chem Co*., 257 F.3d 1364, 1372-73 (Fed Cir. 2001); *Multiform Dessicants, Inc. v. Medzam, Ltd*., 133 F.3d 1473, 1478 (Fed. Cir. 1998).

in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings.[24] The objective and contemporaneous record provided by the intrinsic evidence is the most reliable guide to help determine which of the possible meanings of the terms in question was intended by the inventor to particularly point out and distinctly claim the invention.

Next, examine the intrinsic record to determine whether the presumption of ordinary and customary meaning has been rebutted. Indeed, the intrinsic record may show that the specification uses the words in a manner clearly inconsistent with the ordinary meaning reflected, for example, in a dictionary definition. In such a case, the inconsistent dictionary definition must be rejected.[25]

Third, review the prosecution history to determine whether, and to what extent, statements made or positions taken by the applicant limit the scope of a term's definition. This step is important both for purposes of literal infringement (claim scope) as well as infringement under the doctrine of equivalents (estoppels). These are distinct purposes, and the federal circuit has stated that although prosecution history estoppel does not apply to the determination of literal claim scope, a particular interpretation of a claim term may have been disclaimed by the inventor during prosecution.[26] A thorough analysis of a claim term's scope will reflect any limitations imposed by the prosecution history.

While the foregoing rules are easily articulated, they have not been applied with uniformity. There has been a trend in recent months toward panel-dependent outcomes in claim construction disputes considered by the federal circuit. For the purposes of opinion preparation, therefore, it appears that adherence to the rules of claim construction is more important than arriving at the "correct" conclusion.

---

[24] *Id*.

[25] In any event, analysis of the intrinsic record is undertaken after construing the claims in accordance with the "ordinary" meaning. *Texas Digital Sys. v. Telegenix, Inc*., 308 F.3d 1193, 1204 (Fed. Cir. 2002) ("Consulting the written description and prosecution history as a threshold step in the claim construction process, before any effort is made to discern the ordinary and customary meanings attributed to the words themselves, invites a violation of our precedent counseling against importing limitations into the claims."). See *Housey Pharmaceuticals, Inc. v. Astrazeneca UK, Ltd.,et al*., Nos. 03-1193, -1210 (Fed. Cir. May 7, 2004), *citing Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (requiring "words or expressions of manifest exclusion or restriction" before broad terms in a claim will be read narrowly in *light* of a narrow specification (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2000)).

[26] *Ballard Med. Prods. v. Allegiance Healthcare Corp*., 268 F.3d 1352, 1358-59 (Fed. Cir. 2001), citing *Biodex Corp. v. Loredan Biomedical, Inc*., 946 F.2d 850 (Fed. Cir. 1991). *See also McGill, Inc. v. John Zink Co*., 736 F.2d 666, 673 (Fed. Cir. 1984) ("Prosecution history may be used not only in an estoppel context but also as a claim construction tool.").

VIII. A Determination of Noninfringement

In discussing noninfringement, it is strongly recommended to consider both literal infringement and infringement under the doctrine of equivalents.[27] Literal infringement requires that the product under study contains each and every limitation of the claims.[28] Thus, a literal noninfringement analysis need contain little more than a comparison of claim elements with corresponding elements of the accused product or process. Claim charts may be extremely helpful for some claims. Highlight elements that are plainly missing and cite to proper legal authority for your conclusions.[29]

IX. Infringement under the Doctrine of Equivalents

Where literal infringement is not found, it is appropriate to consider infringement under the doctrine of equivalents. An equivalents analysis should be well-reasoned in view of the facts and acknowledged relevant law. Clearly, the focus is on claims not literally infringed by the accused product or process, and particularly, on the specific elements of those claims that are absent.

A. Tests for equivalence

Both the "function-way-result" test and the "insubstantial differences" tests have been used to assess the question of equivalence between a claimed feature and an accused element. The Supreme Court has declined to articulate a preference for one test or the other,[30] noting that the function-way-result test might be well suited to analyzing mechanical devices but poorly suited to analyze other products or processes.[31] At the outset, therefore, select a legal framework that is readily adaptable to the claims and the technology at issue. Define the controlling legal standards. Infringement under the doctrine of equivalents is found where:

- there is an insubstantial difference between the limitations of the claim

[27] While a doctrine of equivalents analysis is not *per se* necessary, failure to consider infringement under the doctrine will be evaluated in conjunction with other aspects of the opinion's competence, *i.e*., a totality of the circumstances analysis. *Westvaco Corp. v. Int'l Paper Co.,* 991 F.2d 735 (Fed. Cir. 1993); *Datascope Corp. v. SMEC, Inc.,* 879 F.2d 820 (Fed. Cir. 1989), *cert. denied, 493* U.S. 1024 (1990).

[28] *See, e.g., North Am. Vaccine, Inc. v. Am. Cyanamid Co., 7* F.3d 1571, 1574 (Fed. Cir. 1993).

[29] A wrinkle arises in chemical *and pharmaceutical* cases with respect to terms that are definitionally elastic. What are the literal metes and bounds of terms like "about", "approximately" and "effective amount?" Suffice it to say that a good deal has been written about the meaning of these terms, and they will not be discussed further here. When confronted with interpretation of such terms, apply rules of claim construction (e.g., *Markman, Vitronics, Teleflex*).

[30] In *Warner-Jenkinson Co. v. Hilton Davis Chem. Co*., 520 U.S. 17, 40 (1997) , the court stated:

> In our view, the particular linguistic framework used is less important than whether the test is probative of the essential inquiry: Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention? Different linguistic frameworks may be more suitable to different cases, depending on their particular facts.

[31] Id.

and the accused product,[32] or

- the accused device performs substantially the same function, in substantially same way, to achieve the same result as the claimed invention.[33]

Factors to be considered in assessing the substantiality of the differences include: (1) whether persons skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was; (2) evidence of copying; *(3)* efforts to design around the claims of a patent; and (4) evidence of independent development.[34] If there is specific information with respect to copying, design around or independent development, include it in your discussion.

Frequently, however, the interchangeability prong of *Warner-Jenkinson* and the function way result test of *Graver Tank* may be the most relevant for analysis. Look to relevant literature, articles, etc. to determine whether an unclaimed element would be interchangeable with a claimed element. Interchangeability and function-way-result analyses may also include discussions with scientists or others skilled in the art about the state of knowledge of substitution or operation of the claimed element. Seek help from your client. Also, consider the patent specification for guidance with the interchangeability analysis. There is usually a discussion of equivalents or alternatives for claim elements, or a description of embodiments that do not work or give less than desirable results. Sometimes, these may be found in the characterization of the prior art.

A patent's disclosure that an alternative (1) does not work; (2) may work, but yields less than desirable results; or (3) is in the prior art that led to the development of the invention is an invitation to consider the "alternative" as not interchangeable with the claimed element. Certainly, “alternatives” in the specification that are not claimed are unavailable through recapture under the doctrine of equivalents.[35]

For these reasons, it is perfectly appropriate to rely on the patent's teachings in concluding whether "alternatives" would or would not be interchangeable under *Warner Jenkinson.*

Finally, a function-way-result analysis is an appropriate framework for determining infringement by equivalents and its application will require an understanding of the function, way, and results of the claimed element as well of the accused product or process. The former can usually be obtained by careful study of the patent and file history; the latter is usually obtainable from the inventor, assignee or client providing a complete description of the technology.

---

[32] *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 29, 39-41 (1997).

[33] *Graver Tank & Mfg. Co. v. Linde Air Products Co,* 339 U.S. 605 (1950).

[34] *Id.* at *1874.*

[35] *Johnson & Johnston Associates, Inc. v. R.E. Service Co., Inc.,* 285 F.3d 1046 (Fed. Cir. 2002).

B. Limitations on equivalents: the rule of *Festo*

The Supreme Court's ruling in *Festo* acts as a limitation on the doctrine of equivalents. Where no reason for a narrowing amendment was given during prosecution, it is presumed such amendment was made for reasons of patentability and will give rise to an estoppel if unrebutted by the patentee. This is because the patentee, as the author of the claim language, is expected to draft claims encompassing readily known equivalents. There are some cases, however, where claim amendment cannot reasonably be viewed as surrendering a particular equivalent:

- the equivalent may have been unforeseeable at the time of the application;
- the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or
- there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.

The Supreme Court has stated that in such cases the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence.

As a matter of practical analysis, look for estoppels as presumptive bars to equivalence. If a claim element being considered for purposes of equivalence was added or amended during prosecution -- and no explanation is given for the amendment -- it is presumed to have been made for reasons of patentability. The burden then shifts to the patentee to rebut the presumption. In preparing a *noninfringement* opinion, look for any evidence in the patent or prosecution history that the accused equivalent element or structure was "foreseeable" at the time the patent was drafted; that a claim could have been drafted to encompass it literally; and that the failure to do so forecloses a scope of equivalence that encompasses the accused device.

In preparing an *infringement* opinion look for any evidence in the prosecution history that the amendment was not made for purposes of patentability; that no claim could have been drafted encompassing the accused equivalent structure (*i.e.*, it was unforeseeable); or that the rationale underlying the amendment bore no more than a tangential relation to the equivalent in question. Evidence tending to support these factors may rebut the presumption that the claim amendment in question was made for purposes of patentability, and defeat any resulting estoppel that precludes the use of the doctrine.

"Argument based estoppel" is also an appropriate limitation on the scope of equivalents.[36] Independent of claim amendment, the positions an applicant takes with respect to prior art, claim scope, the disclosure, or a general characterization of the

[36] *Abbott Labs. v. Dey,* 287 F.3d 1097, 1103 (Fed. Cir. 2002); *Elkay Mfg. Co. v. Ebco Mfg. Co.,* 192 F.3d 973, 979 (Fed. Cir. 1999).

invention, etc., all bear on the scope of equivalents. Even inaction by an applicant can create an estoppel. The federal circuit stated recently:

> Prosecution history estoppel, however, is not limited to the applicant's own words, but may embrace as well the applicant's responses to the examiner's actions. If the patentee does not rebut an examiner's comment or acquiesces to an examiner's request, *the patentee's unambiguous acts or omissions can create an estoppel.*[37]

Leave no stone unturned. In *Ekchian v. Home Depot, Inc., 104* F.3d *524* (Fed. Cir. 1997), the federal circuit held that statements made in an IDS can create an estoppel and thus preclude a finding of infringement under the doctrine of equivalents.

The patent disclosure also provides a basis for limitations on the scope of equivalents. In *Johnson & Johnston Associates, Inc. v. R.E. Service Co., Inc.,* 285 F.3d 1046 (Fed. Cir. 2002), the federal circuit held that disclosed but unclaimed subject matter cannot be recaptured through the doctrine of equivalents. Overruling its earlier decision in *YBM Magnex , Inc. v. U.S. Int'l Trade Comm., 145* F.3d *1317* (Fed. Cir. *1998),* the court stated "when a patent drafter discloses but declines to claim subject matter, as in this case, this action dedicates that unclaimed subject matter to the public. Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would conflict with the primacy of the claims in defining the scope of the patentee's exclusive right."'[38]

Thus, to the extent the element missing in the accused product/process is found in the patent disclosure, *Johnson* precludes a scope of equivalents that includes the disclosed but unclaimed feature.

X. Invalidity as a Defense

If you have developed a well-reasoned noninfringement position on all claims, should you include an invalidity analysis? Perhaps not.

First, it is not always necessary. In order to defend against a finding of willfulness based on advice of counsel, an infringer must reasonably rely on a competent opinion of counsel. That opinion need only provide a good faith basis for reliance that the would-be infringer does not infringe. The opinion will have been shown to be incorrect in its conclusions at the time willfulness arises. As long as the opinion is competent and the infringer relied in good faith upon its advices, a claim of willfulness may be overcome. An opinion does not have to additionally opine on the invalidity of a patent in order for infringer to defend against a finding of willfulness.

Second, there is more to defend against when an invalidity analysis is added to a noninfringement opinion. When the opinion's author is ultimately deposed, every

[37] Glaxo *Wellcome, Inc. v. Impax Laboratories, Inc.,* 356 F.3d 1348, 1357 (Fed. Cir. 2004) (emphasis added).

[38] *Id*. at 1054.

additional defense provides another target for attacking the competence of the opinion. A single, well-reasoned defense is all that is required for an opinion to be considered competent. Less is more.

Third, litigation counsel may not ultimately pursue the invalidity defense articulated in the opinion - for reasons that may have nothing to do with the quality of the opinion's analysis. This, of course, raises questions as to the viability of an invalidity defense and places the client in the awkward position of explaining how it relied on the opinion's invalidity advice before continuing to infringe, but chose not to rely on that defense at trial.

If an invalidity defense is strong as to all claims but a noninfringement defense is strong only with respect to some of the claims, it may be more prudent to simply prepare a single invalidity opinion.

If an invalidity opinion is to be prepared, evaluate the best defenses. Is the best defense under § 102, § 103 or § 112? Is there an inventorship issue? Is there solid, factual support for defenses of inequitable conduct, misuse or unenforceability? It is generally a sound idea to pick the single best defense and base the invalidity opinion on that defense. It is generally less sound to base an invalidity opinion solely on defenses that are highly fact specific or that require a subjective component, *i.e*., inequitable conduct, best mode, patent misuse, etc. (Frequently the opinion drafter will not have access to all of the facts necessary to reasonably conclude the defense is meritorious.)

Sometimes, it may be necessary to discuss a collateral defense that is related to the principal defense relied upon. Avoid resort to a litany of defenses that are at best mediocre. Remember - the opinion doesn't have to win the case. It must be considered competent so that an infringer may reasonably rely upon its contents. A discussion of too many defenses: (1) tends to weaken the strength of the best defense; (2) becomes fodder for deposition during litigation when not all defenses are pursued by litigation counsel; and (3) can be confusing.

XI. Anticipation Under Section 102

Under 35 U.S.C. §102, patent claims may be anticipated and found invalid as lacking novelty if each and every limitation of the claim is disclosed in a single prior art reference.[39] For this reason, anticipation has been termed a "technical defense." While other references may be used to interpret an allegedly anticipating reference, anticipation must be found in a single reference.[40]

A well-grounded § 102 defense is amenable to easy analysis by simple comparison

[39] *See Rockwell Int'l Corp. v. U.S.,* 147 F.3d 1358, 1363 (Fed. Cir. 1998); *Hazani v. U.S. Int'l Trade Comm'n,* 126 F.3d 1473, 1477 (Fed. Cir. 1997).

[40] *See Shearing v. lolab Corp.,* 975 F.2d 1541, 1544-45 (Fed. Cir. 1992); *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236 (Fed. Cir. 1989).

of the patent claim to a single piece of prior art.[41] It may be convenient to summarize the analysis in chart form, showing where each claim element is found in the prior art reference. The prior art reference must contain each and every element of the claimed invention. However, the reference may anticipate by inherency where the missing material is inherently present in the product, process or method disclosed in the reference.[42] Recently, the federal circuit has stated that "a limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art."[43]

XII. Obviousness Under Section 103

Under 35 U.S.C. §103(a), a claim is invalid as obvious over the prior art "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. §103 (2001).

Obviousness determinations must be made on a case-by-case basis after the proper factual inquiries have been made under *Graham v. John Deere Co.,* 383 U.S. 1, 17-18 (1966), including:

(1) the scope and content of the prior art;

(2) the differences between the prior art and the claimed invention;

(3) the level of ordinary skill in the art; and

(4) any objective indicia of nonobviousness.[44]

Invalidity opinions based on Section 103 must engage in a *Graham* - type obviousness analysis. The use of a "combination of references" type approach (akin to an examiner's *prima facie* rejection of obviousness during prosecution) that focuses solely on the "differences" prong of the *Graham* analysis, may improperly ignore the other three relevant portions of the *Graham* inquiry. Such an approach also ignores the presumption of validity under 35 U.S.C. §282. The burden of establishing invalidity rests on the party challenging the patent's validity, and can only be overcome by a showing of clear and

---

[41] Depending on the reference's publication or filing dates, it may be necessary to demonstrate how the reference qualifies as prior art and under what subsection(s) of § 102 it would be considered as such. For example, a foreign patent published prior to the date of U.S. invention of the patent-in-suit qualifies as prior art under 35 U.S.C. § 102(a) but not § 102(e).

[42] *See Continental Can Co. USA Inc. v. Monsanto Co.,* 948 F.2d 1264, 1268 (Fed. Cir. 1991).

[43] *Schering Corp. v. Geneva* Pharmaceuticals*., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003), citing *Eli Lilly & Co. v. Barr Labs., Inc.,* 251 F.3d 955, 970 (Fed. Cir. 2001); *see also In re Kratz,* 592 F.2d 1169, 1174 (CCPA 1979) (suggesting inherent anticipation of a compound even though the compound's existence was not known).

[44] *Graham,* 383 U.S. at 17-18; *accord Uniroyal, Inc. v. Rudkin- Wiley Corp., 837* F.2d 1044, 1050 (Fed. Cir.), *cert. denied,* 488 U.S. 825 (1988).

convincing evidence.[45] Under Section 103, the proper framework is mandated by the Supreme Court's decision in *Graham.*

A. The Scope and Content of the Prior Art

The scope and content of the prior art can usually be determined from the prosecution history as well as the patent specification itself. The PTO's classification of the invention and the art related thereto provides some indication of the framework under which the application was examined. Statements in the patent itself are frequently helpful in describing the field of the invention, the need in the art for the invention, and the purported solution of the invention.

B. The Differences Between the Prior Art and the Claimed Invention

A discussion of differences between the prior art and the claimed invention is the essence of an obviousness analysis. Focus on your analysis and use of selected prior art references. What does each disclose? Was the art cited during prosecution?[46] Are the references properly combinable?[47] What other sources of prior art are there? In certain circumstances, prior art under Section 102 is available under Section 103 for obviousness purposes.[48] Thus, embodiments on sale, commercial products, prior invention by others, etc. may all be sources of prior art for use under Section 103. Identify, in one or at most two references, the elements of the claimed invention, and explain how the suggestion to combine those references is/is not found in the references themselves. If an element is missing in a primary reference or a commercial embodiment, etc., explain how its inclusion in the prior art would/would not have rendered obvious the claimed invention to one skilled in the art at the time the claimed invention was made.

---

[45] *See, e.g., Glaverbel* Societe *Anonyme v. Marketing & Supply Inc., 45* F.3d 1550, 1553 (Fed. Cir. 1995); *Jones v. Hardy,* 727 F.2d 1524, 1528 (Fed. Cir. 1984). *See also* 35 U.S.C. §282 (2000).

[46] 22 As a practical matter, The clear and convincing evidence standard is more easily met in the case of prior art that was not considered by the examiner, where the non-considered prior art is more pertinent than prior art considered during examination of the application. *See, e.g., Uniroyal, Inc. v. Rudkin-Wiley Corp.,* 837 F.2d 1044, 1050 (Fed. Cir.), *cert. denied,* 488 U.S. 825 (1988).

[47] Where separate prior art references *each* disclose separate elements of a claim, there must be some teaching or suggestion in the prior art to one of ordinary skill in the art to combine the references to make the claimed invention. *See In re Rouffet,* 149 F.3d at 1355; *Smithkline Diagnostics, Inc. v. Helena Lab. Corp.,* 859 F.2d 878, 886-87 (Fed. Cir. 1988). The "suggestion" to combine the prior art references may be found in the references themselves, in the knowledge of those skilled in the art that certain references are known to be of special interest or importance in a particular field, or even in the nature of the problem solved by the inventors particularly, where the nature of the problem would lead one skilled in the art to look to the prior art references for the solution. *See Micro Chemical Inc. v. Great Plains Chemical Co.,* 103 F.3d 1538, 1546 (Fed. Cir. 1997) (citing *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75* F.3d 1568, 1573 (Fed. Cir. 1996)).

[48] *Baker Oil Tools, Inc. v. Geo Mann,* Inc., 828 F.2d 1558 (Fed. Cir. 1987) ("If a device was in public use or on sale before the critical date then that device becomes a reference under section 103 against the claimed invention"); *Pfaff v. Wells Electronics, Inc.,* 124 F.3d 1429 (Fed. Cir. 1997), *affd,* 525 U.S. 55 (1998) ("In effect, what was offered for sale before the critical date becomes a [prior art] reference under section 103 against the claimed invention."). *But see, e.g.,* MPEP §706.02(l) (2001) (for applications filed prior to AIPA, subject matter developed by another that qualifies as prior art under §§ 102(f) or 102(g) could not be considered as a basis for rejection under §103 if it was commonly owned at the time of the invention.).

C. The level of ordinary skill in the art

The level of skill in the art is a fact-specific inquiry determined on a case-by-case basis. *See Graham v. John Deere Co.,* 383 U.S. 1, 17-18 (1966). Relevant factors in determining the level of skill include, "type of problems encountered in art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field."[49]

An assessment of the level of skill in the art is relevant to how the art is viewed by those of *ordinary skill*. Overstating the level of skill in the art results in the trivialization of the differences between the prior art and the claimed invention. Yet, if the level of skill is overstated, the basis for the opinion is easily challenged and reasonable reliance upon its conclusions may be considered suspect. It is therefore a better practice to fairly assess the level of skill in the art and perhaps, err on the side of understatement. A patentee will be in a difficult position challenging a conclusion that the claimed invention would have been obvious to one of ordinary *(or even less than ordinary)* skill in the art.

D. Objective indicia of nonobviousness

Objective indicia of non-obviousness include: (1) evidence of unexpected results of the claimed invention; (2) commercial success; (3) a long felt but unsolved need for the solution of the invention; (4) the failure of others to solve the problem; (5) copying of the claimed invention; (6) industry acquiescence in the patent (i.e. licensing); and (7) skepticism expressed by skilled workers in the field as to a solution to the problem presented before the invention was made.[50]

It is important to remember that these so-called "secondary considerations" are not ancillary to the first three *Graham* factors, but are a necessary consideration in each case. Endeavor to determine what information - if any - exists with respect to this factor. Consult your client; to the extent there is information related to secondary considerations, it is advisable to include it within the opinion. If you are not aware of any information, state as much. In the latter case, the reader may challenge your conclusion due to an absence of information about a *Graham* factor, but will not be able to challenge your methodology or the competence of the opinion based on the applicable law. You, as counsel, will have done your job.

XIII. Technical Requirements Under Section 112

35 U.S.C. § 112 contains the technical requirements for the patent's disclosure. Included are the enablement, written description and best mode requirements.[51] The best

---

[49] *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.,* 807 F.2d 955, 962 (Fed. Cir. 1986).

[50] *See In re Rouffet,* 149 F.3d 1350, 1355 (Fed. Cir. 1998) (citations omitted). Moreover, a clear unmistakable *nexus* with the attributes of the invention must also be shown. *See e.g., Gambro Lundia AB v. Baxter Healthcare Corp.,* 110 F.3d 1573, 1579 (Fed. Cir. 1997); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851* F.2d 1387, 1394 (Fed. Cir. 1988).

[51] "Means plus Function" language is included in paragraph 6 but will not be discussed further here.

mode requirement has as a component the subjective knowledge of the inventor.[52] As the potential infringer will rarely - if ever - have information sufficient to conclude the best mode requirement has not been satisfied, that defense will not be discussed further here.

The written description and enablement requirements are legally distinct requirements under Section 112.[53] Section 112 requires a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains,...to make and use the same...". Courts have interpreted this to mean that the description must be enabling such that the invention can be practiced without undue experimentation.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.[54] An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.[55] Possession may be also be shown by an actual reduction to practice, or that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.[56] Thus, description requires possession -- possession requires description.

Written description challenges are rare, and arise most frequently in chemical or biotech cases where, *e.g.,* (1) the claimed technology was non-existent at the time of filing,[57] (2) *ipsis verbis* support for the composition of matter claims in the specification was unaccompanied by description of other than biological activity,[58] or (3) no compounds were disclosed in a patent whose method claims required the use of certain compounds.[59]

Enablement under Section 112 requires that "the prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue

---

[52] *Chemcast Corp. v. Arco Industries Corp.,* 913 F.2d 923 (Fed. Cir. 1990) (establishing the necessity of determining whether, at the time of filing, the inventor knew of a mode of practicing his claimed invention considered to be better than any other method known. This part of the inquiry is wholly subjective, and resolves the question of whether the inventor must disclose any facts in addition to those sufficient for enablement. If the inventor in fact contemplated such a preferred mode, the second part of the analysis compares what the inventor knew with what was disclosed.).

[53] *In re Curtis*, *et al*., 354 F.3d 1347 (Fed. Cir. 2004), citing *Amgen Inc. v. Hoechst Marion Roussel, Inc.,* 314 F.3d 1313, 1330 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar,* 935 F.2d 1555 (Fed. Cir. 1991).

[54] MPEP § 2163; *see*, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563

[55] *Id*., citing *Lockwood v. American Airlines, Inc*., 107 F.3d 1565, 1572 (Fed. Cir. 1997).

[56] *Id.,* citing*, Pfaff v. Wells Electronics, Inc*., 525 U.S. 55, 68 (1998); *Eli Lilly*, 119 F.3d at 1568.

[57] *Chiron Corp. v. Genentech, Inc.,* Nos. 03-1158,-1159 (Fed. Cir. March 30, 2004)

[58] *Enzo Biochem, Inc. v. Gen-Probe, Inc. et al.,* 323 F.3d 956 (Fed. Cir. 2002).

[59] *University of Rochester v. G.D. Searle & Co., Inc. et al*., 358 F.3d 916, ___ (Fed. Cir. 2004)

experimentation."[60] Failure to comply with the enablement requirement must be proven by clear and convincing evidence, and in evaluating the enablement of the claimed invention, it is important to consider whether the full scope of the claimed invention has been enabled by the disclosure.

Look for claimed ranges. Does the specification teach how to practice the full scope of the claimed range[61]? Does the specification supply the novel aspects of the invention[62]? Do the claims require the use of certain features or elements that are not disclosed? Does the practice of the claims require undue experimentation? The federal circuit has outlined several factors to be considered in determining whether undue experimentation is necessary.[63]

In evaluating enablement, consider not only the prosecution history but any related applications as well. Disclosure necessary to practice the claimed invention that was added after the application was filed, or which is present only in a related application may serve as a basis for an enablement defense.

XIV. Inequitable Conduct and Unenforceability

Inequitable conduct is the failure to disclose material information, or the submission of false material information, with an intent to deceive.[64] Materiality and intent are separate elements; "[m]ateriality does not presume intent, which is a separate and essential component of inequitable conduct...". The withholding of information must meet the thresholds of both materiality and intent,...and absent intent to withhold it is not controlling whether the reference is found to anticipate or otherwise be material."[65] After threshold levels of both materiality and intent are shown, the court must balance them and determine as a matter of law whether the scales tilt to a conclusion that inequitable conduct occurred.[66]

As an initial matter, intent to mislead the PTO usually can only be found as a matter of inference from circumstantial evidence. That evidence must support a finding

---

[60] *Elan Pharmaceuticals, Inc. et al. v. Mayo Foundation*, 346 F.3d 1051, 1054 (Fed Cir.2003), citing *Minnesota Mining and Manufacturing Co. v. Chemque, Inc.,* 303 F.3d 1294 (Fed. Cir. 2002*)*; *Enzo Biochem, Inc. v. Calgene, Inc.,* 188 F.3d 1362, 1369 (Fed. Cir. 1999)

[61] A patent specification must enable the full scope of a claimed invention. *AK Steel Corp. v. Sollac et al*., 344 F.3d 1234, 1241 (Fed. Cir. 2003), citing *In re Wright,* 999 F.2d 1557, 1561 (Fed. Cir. 1993).

[62] A specification need not disclose what is well known in the art. *Genentech, Inc., 108 F.3d at 1366* (citation omitted). However, knowledge in the art can merely supplement, but not be a substitute for, a basic enabling disclosure.

[63] *See e.g., In re Wands,* 858 F.2d 731 (Fed. Cir. 1988). In *In re Wands,* the Federal Circuit outlined eight factors to be considered in determining whether disclosure would require undue experimentation. They include (1) the quantity of the experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of claims. *Id.* at 737.

[64] *Kingsdown Medical Consultants v. Hollister, Inc*., 863 F.2d 867 (Fed. Cir. *1988).*

[65] *Allen Organ Co. v. Kimball International,* 839 F.2d 1556.1567-68 (Fed. Cir. 1988).

[66] *J.P. Stevens & Co., Inc. v. Lex Tex Ltd. Inc.,* 747 F.2d 1553, 1560 (Fed. Cir, 1984), *cert. denied, 474* U.S. 822 (1985).

of actual intent, not merely negligence.[67] However, gross negligence or recklessness on the part of the applicant or his agents may be sufficient to find inequitable conduct depending on other factors.[68]

Beyond that, a misrepresentation must be material in order to constitute fraud or inequitable conduct. The Federal Circuit has referred to the PTO standard for determining materiality, *J.P. Stevens at* 1559, which in turn is premised on 37 C.F.R. § 1.56 and states:

> information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56 (2001).[69]

Under this legal framework, it is difficult on the record alone to conclude the existence of inequitable conduct in the procurement of the patent, or that a finding of unenforceability would eventually result. The subjective component of the defense requires consideration of factors not generally in the possession of counsel drafting the opinion. Notwithstanding, it is appropriate to comment on the materiality of the uncited reference based purely on Rule 1.56 standards. It may also be appropriate to comment on the evidentiary deficiencies based on the record alone and what further facts may need to be developed to substantiate the defense.

Unenforceability can, of course, result from conduct other than "inequitable conduct," *e.g.,* patent misuse. However this is a highly fact-specific defense to enforcement of the patent, and counsel preparing the opinion is not usually possessed of the requisite facts sufficient to support this defense. Furthermore, unenforceability from misuse can be purged. Therefore, a patent that is unenforceable today might well be enforceable tomorrow. Thus, an opinion based on unenforceability for misuse should be periodically reviewed for any change in circumstances.

---

[67] *Orthopedic Equip Co. v. All Orthopedic Appliances, Inc.,* 707 F.2d 1376, 1383 (Fed. Cir. 1983) ("mere evidence of simple negligence, oversight, or an erroneous judgment made in good faith ... is not sufficient to render a patent unenforceable"); *accord, Litton Indus. Prods. Inc. v. Solid State Systems Corp.,* 755 F.2d 158, 166 (Fed. Cir. 1985)("Wholly inadvertent errors or honest mistakes, which are caused by neither fraudulent intent nor by the patentee's gross negligence, do not constitute the requisite level of intent.").

[68] The federal circuit in *Hewlett-Packard* stated, "grossly negligent conduct may or may not compel an inference of an intent to mislead. Such an inference depends on the totality of the circumstances, including the nature and level of culpability of the conduct and the absence or presence of good faith." *Id.* at 1562. (emphasis added).

[69] The duty of disclosure extends to "each individual associated with the filing and prosecution of a patent application" and "includes a duty to disclose to the Office all information known to that individual to be material to patentability." *Id.* The duty "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." *Id.*

XV. Conclusion

Noninfringement is a factual conclusion. Invalidity is a legal conclusion based on the absence or proof of certain facts. It is therefore appropriate to couch your ultimate conclusions in terms of what a reasonable trier of fact would conclude. It is equally appropriate to opine as to the legal conclusions a court may reach. "An opinion is competent if it is 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."[70] Acknowledge uncertainty where appropriate. An opinion of counsel [ ] need not unequivocally state that the client will not be held liable for infringement. An honest opinion is more likely to speak of probabilities than certainties.[71]

---

[70] Johns Hopkins University v. Cellpro, Inc., 152 F.3d 1342 (Fed. Cir. 1997), citing Ortho Pharm. Corp. v. Smith (Fed. Cir. 1992).

[71] *Read Corp. v. Portec, Inc., 970* F.2d 816 (Fed. Cir. 1992).

Summary of Opinion Drafting Strategies

1. Set forth the scope of work undertaken, including a detailed list of materials considered and those actually relied upon. Describe also relevant materials not considered or steps not undertaken in formation of the opinion.

2. Summarize the patent disclosure and patent prosecution history with a particular focus on the points needed to support the conclusions reached in the opinion.

3. Describe in detail the product or process actually being evaluated for infringement or noninfringement purposes. Use model nos., formulation designations, compound descriptions, names of genetic material, etc. Agree upon the description with the client in advance of finalizing the opinion.

4. Determine the assignee-of-record of the patent being studied and additionally whether maintenance fees are current.

5 Construe the claims according to *Markman, Vitronics,* and *Teleflex* using the patent specification, prosecution history, related applications and dictionaries as appropriate.

6. In a doctrine of equivalents analysis, determine which test most appropriately lends itself to the technology being considered. Determine from your client what evidence exists relating to independent development of design-around efforts. (The Supreme Court has said these are appropriately considered as probative of non-equivalence).

7. Look for evidence of interchangeability or the lack thereof. Consult literature references, individuals skilled in the art, and the patent specification.

8. Evaluate the prosecution history for claim amendments that presumptively act to foreclose any equivalents of a claimed element. Consider what evidence exists to rebut that presumption (tangentiality, unforseeability), and why a claim could or could not have been drafted to encompass the asserted equivalent.

9. Look for other limitations on equivalents, such as argument-based estoppel and disclosed but unclaimed subject matter - now considered dedicated to the public.

10. If a well-reasoned basis exists for noninfringement, question the need to opine on invalidity.

11. When opining on invalidity, present the single best defense (or two) and provide ample support for that defense. Avoid the temptation to present a list of less substantial defenses.

12. Use the *Graham* factors when opining under Section 103, not the *prima facie*

standards used by examiners.

13. If the opinion is drafted for the potential infringer; err on the side of understating the level of ordinary skill in the art.

14. Scrutinize carefully compliance with the written description requirement of Section 112 since *Enzo.*

15. Comment on the status of the record with respect to inequitable conduct and unenforceability defenses. Describe evidentiary deficiencies. Finally, it is acceptable to speak in terms of probabilities in rendering opinions rather than absolute certainties.