

Texas Intellectual Property Law Journal
Fall 1999

UNDERSTANDING WILLFULNESS IN PATENT INFRINGEMENT: AN ANALYSIS OF THE “ADVICE OF COUNSEL” DEFENSE

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Table of Contents

I.	Introduction	40
II.	Willfulness and Enhancement of Damages	41
	A. Policy and Statutory Basis for Enhancement	41
	B. The Requirement of Culpable Conduct	43
III.	Non-Infringement Opinions	45
	A. Attorney-Client Privilege	45
	1. Discovery of Non-Infringement Opinions	46
	2. Disclosure of Non-Infringement Opinions and the Ethical Dilemma	48
	B. The Existence of an Opinion Is Not Dispositive	49
IV.	Guidelines for Drafting Non-Infringement Opinions	50
	A. Factors to Consider Regarding the Competency of the Opinion	50
	B. The Nature of the Author’s Status: In-House, Outside Counsel, Patent Agents	51
	C. Sufficiency of the Opinion	54
	D. Compiling Necessary Background Materials and Related Patent Files	54
	E. Claim Interpretation - Claim Construction	56
	F. Literal Infringement	59
	G. Doctrine of Equivalents Infringement	61
V.	Patent Invalidity - General Considerations	63

A. Invalidity Predicated on Section 102 - Novelty and Loss of Rights	64
1. Invalidity Predicated on the Public Use Bar	65
2. Invalidity Predicated on the On-Sale Bar	66
B. Invalidity Predicated on Section 103 - Obviousness	68
C. Invalidity Predicated on Fraud or Inequitable Conduct	69
VI. Conclusion	69

***40 I. Introduction**

A patent infringement case is expensive. The damages incurred can be very costly, often with millions of dollars at stake. If the case is prolonged, then prejudgment and post-judgment interest can add to the base damages amount.¹ A large damages award can often bankrupt a company.² Imagine now that the court enhances the damages, possibly by trebling the base damages amount because of willful infringement.³ Obviously, the infringer's motivation to expunge or vitiate a claim of willful infringement becomes of paramount concern.⁴ One method of doing so is to rely on the "advice of counsel" defense, which usually manifests as a non-infringement opinion or an opinion of patent invalidity.⁵ A defendant may escape liability either because it can prove that it is not infringing, or because the patent is invalid. In the latter case, the advice of counsel may opine that the defendant is not liable because the asserted patent is invalid.

In the practical context, the issue of a non-infringement opinion plays out as follows. The infringer is accused of willful patent infringement because the infringer failed to obtain clearance of its product.⁶ To obtain this clearance, the infringer should investigate whether its product infringes. An infringer will normally do this by requesting an attorney to render a non-infringement opinion. Accordingly, the infringer will parade the non-infringement opinion to the jury as a defense to treble damages even though it may be liable for infringement. The infringer will claim that it is not willfully liable since it abided by the attorney's advice that the product did not infringe. In essence, the ***41** infringer defends itself on the grounds that it acted on the "advice of counsel." However, since the infringer is parading this non-infringement opinion to the jury, the patentee will seek to criticize the sufficiency and competency of the opinion to undermine the credibility of the opinion.

This article examines the entire legal regime surrounding willful infringement and the "advice of counsel" defense. Part II. A discusses the statutory scheme and the background to finding willfulness for the purposes of treble damages. Part III discusses non-infringement opinions written by counsel and the attorney-client privilege shielding such opinions from discovery. Part IV generally examines the nature of the non-infringement opinions. In particular, it provides a detailed legal analysis of two overriding themes: (a) the competency of the opinion; and (b) the legal sufficiency of the opinion. Furthermore, Part IV examines the general infringement scheme and correlates each phase of infringement litigation with the sufficiency of the opinion. The sufficiency of an opinion with respect to claim construction, literal infringement, and equivalency infringement is examined. Part V of the paper discusses patent invalidity opinions and the various grounds on which a patent can be invalidated. The article also examines case law discussing the sufficiency of opinions, and thus provides guidance to U.S. district court judges who adjudicate these issues, or to patent practitioners in drafting a judicially defensible opinion. It is crucial for the author who prepares a non-infringement or invalidity opinion to examine every way in which the opinion can be criticized. In the end, the opinion that addresses all of the considerations addressed herein, where appropriate, will likely survive attack and exorcise the specter of treble damages.

II. Willfulness and Enhancement of Damages

A. Policy and Statutory Basis for Enhancement

The enhancement of damages for willful infringement serves three major policies. First, damages enhancement recognizes that infringement resides on a spectrum ranging from accidental or unknowing, to deliberate, or even reckless.⁷ Thus, damages enhancement considers the relative culpability of the infringer and punishes infringers who engage in grossly

culpable conduct. Second, enhancement acts as an economic deterrent to the infringer, thus discouraging the infringer from engaging in such behavior *42 again.⁸ Finally, enhancement provides some sort of compensation or amelioration to the patentee in an attempt to make the patentee whole again.⁹

As an added bonus to the patentee, a finding of willfulness includes a determination of whether the case is “exceptional” and warrants an award of attorney fees.¹⁰ Thus, a finding of willfulness may lead to treble damages to fulfill the policies above and to an award of attorney fees to the patentee, thereby holding an infringer liable for a series of additional damages.

35 U.S.C. § 284 requires a court to award damages adequate to compensate for infringement.¹¹ The same section also gives the court discretion to award treble damages.¹² Since the statute gives no guidance regarding enhancement of treble damages, the Federal Circuit has adopted a two-part test to analyze the criteria for the enhancement of damages.¹³ The first step determines whether the infringer’s conduct warrants an increase in damages. General factors to consider include, but are not limited to:

- (a) whether the infringer intentionally copied the patented invention;
- (b) whether the infringer investigated the likelihood of infringement after learning of the patent;
- (c) whether the infringer believed, in good faith, that the patent was not infringed or was invalid; or
- (d) the infringer’s behavior during litigation.¹⁴

The second step requires the district court to use its sound discretion in determining the amount of enhancement.¹⁵ The factors and amount of enhancement are balanced on a totality of the circumstances.¹⁶

***43 B. The Requirement of Culpable Conduct**

In determining particular types of conduct likely to increase damages, the Federal Circuit stated that an increase of damages is punitive in nature and thus requires some form of culpable conduct to impose such a sanction.¹⁷ Hence, the imposition of increased damages requires some form of willful infringement or bad faith.¹⁸ Willful infringement satisfies the “culpable conduct” requirement and is sufficient to meet the first requirement for trebling compensatory damages.¹⁹

As part of the “culpable conduct” predicate, bad faith also justifies enhancing compensatory damages.²⁰ This justification begs the question of the meaning of bad faith. In patent law, bad faith is used in many contexts, for example, in reference to misconduct during prosecution of the patent (inequitable conduct before the PTO), or misconduct during litigation (vexatious, unjustifiable suits, or unnecessary prolongation of suits).²¹ Note though, prosecutorial or litigation misconduct has nothing to do with the underlying infringement, nor do they relate to the degree of culpability. Therefore, by themselves, they do not justify enhancement of damages.²² Since the ultimate fact in proving enhanced damages relates to the degree of culpable conduct, bad faith in prosecution or litigation is just one of several factors to consider in the totality of the circumstances test, and do not constitute independent bases for the enhancement of damages.²³ Thus, the willfulness determination evaluates bad faith in relation to the degree of culpable conduct.

In the context of culpable conduct, bad faith generally relates to the infringer’s failure to affirmatively exercise his duty of due care in avoiding infringement. This affirmative duty generally triggers the duty to obtain competent legal advice.²⁴ In this regard, an infringer exercises good faith in discharging this duty if the infringer determines:

- (a) that the patent is invalid;
- *44 (b) that despite the validity of the patent, there is no infringement; or**
- (c) that his conduct is covered under licensing agreements.²⁵

If good faith exists, the infringer will not suffer enhanced damages even though the infringer is later found liable for infringement.²⁶ Thus, liability for infringement does not transform prior good faith into bad faith for the purposes of awarding enhanced damages.

In contrast, an infringer may have acted in bad faith if the infringer has not investigated his potentially infringing conduct, fails to cease from infringing, or does not possess reasonable defenses to infringement.²⁷ This may occur when the infringer blatantly copies the patented embodiment, obtains incompetent opinions of counsel, or obtains opinions late in the day to use as a shield against the trebling of compensatory damages.²⁸

The jury determines whether the first criteria for trebling damages has been met by weighing all of the culpable conduct factors and then deciding whether the infringement was willful.²⁹ If the jury finds willful infringement, then the judge determines the amount of the enhancement in the second step.³⁰ The judge considers several non-exclusive factors in determining the extent of enhancement, including:

- (a) whether the infringer deliberately copied the patented invention;
- (b) whether the infringer knew of the patent and possessed good faith defenses;
- (c) the infringer's behavior in the litigation;
- (d) the infringer's size and financial condition; and
- (e) the closeness of the willfulness issue.³¹

If a jury finding of willful infringement exists, this does not *ipso facto* necessitate a treble damages award. The decision to enhance damages rests squarely within the discretion *45 of the court, and a judge can refuse to enhance damages.³² However, if the jury determines that the infringement was willful, the judge must provide detailed reasoning for not awarding enhanced damages or attorney fees.³³

The primary focus of willful infringement is on the accused infringer's intent and reasonable beliefs.³⁴ The infringer may not know it was infringing since the law only imposes an affirmative duty to investigate infringement after the infringer becomes aware of the asserted patent.³⁵ Once the infringer becomes aware of the patent at issue, it has an affirmative duty to diligently ascertain whether it is infringing the patent.³⁶ One of the most important factors to consider in determining willfulness is whether the infringer sought out competent legal opinions prior to starting the infringing activity or prior to the time the infringer was on notice of the asserted patent.³⁷

In summary, the simplest embodiment of willfulness requires, at a minimum, (a) knowledge of the patent; and (b) the infringer's culpable conduct in believing that it had the right to practice the claimed invention.³⁸

III. Non-Infringement Opinions

A. Attorney-Client Privilege

Once the infringer obtains a non-infringement opinion, all is well until the patentee sues the infringer. The patentee will likely allege willful infringement and the infringer will likely defend itself with its non-infringement opinion. This defense permits a jury instruction that even if the defendant is found liable for infringement, the jury can determine that the infringement was not willful if the infringer reasonably relied on the non-infringement opinion drafted by counsel. However, this causes an interesting legal issue to surface that is steeped in the history of common law: attorney-client privilege. Every attorney understands and recognizes the doctrine of attorney-client privilege. Generally, it protects the confidential communications between attorney and client. The *46 purpose of the doctrine is to promote a full and frank discussion between the attorney and client.³⁹

The ultimate goal for an infringer facing a charge of willful infringement is to parade the non-infringement opinion to the jury to vitiate the willfulness claim. However, in order to accomplish this, certain preliminary procedural rules need to be discussed. The first issue is whether the non-infringement opinions of counsel are discoverable.

1. Discovery of Non-Infringement Opinions

Rule 26(b)(1) of the Federal Rules of Civil Procedure states that privileged documents are not within the proper bounds of discovery. As stated in *United States v. United Shoe Machinery Corp.*,⁴⁰ the district court outlined the factors to be considered in determining if the attorney-client privilege exists, namely:

- (a) whether the asserted holder of the privilege is or sought to become a client;
- (b) whether the person to whom the communication was made is a member of the bar (or his subordinate) and was acting as a lawyer;
- (c) whether the communication relates to a fact of which the attorney was informed by his client, in confidence, and was made for the purpose of securing primarily either an opinion of law, legal services, or assistance in some legal proceeding, and not for the purpose of committing a crime or tort; and,
- (d) whether the privilege has been claimed and not waived.⁴¹

It is safe to assume that most non-infringement opinions fall squarely within the attorney-client privilege, since these opinions are prepared when a client hires an attorney to opine on the legal issue of infringement.

In addition, the doctrine of attorney work product provides an independent source of immunity from discovery because it protects certain documents or writings prepared in anticipation of litigation or trial by or for a party or its representatives.⁴² This issue is relevant since an infringer often obtains the opinion of counsel after suit is filed. Any claim of privilege must adequately identify the documents for which the privilege *47 protection is sought.⁴³ A failure to adequately identify privileged documents may be construed as a waiver.⁴⁴ In addition, inadvertent disclosure of the opinion may result in a waiver.⁴⁵ Due to the sheer volume of discovery, privileged documents are often inadvertently disclosed. Case decisions addressing the waiver issue have followed three distinct schools of thought:

- (i) accidental disclosure can never constitute a waiver since there was no intentional relinquishment of the waiver right;⁴⁶
- (ii) accidental disclosure is always a waiver since “a card laid is a card played” and one cannot make secret again that which is now known;⁴⁷ and
- (iii) a middle ground where the rights are balanced by burdening the producing party to show that the production was inadvertent and that there was no waiver intended.⁴⁸

Factors to examine include, *inter alia*, the reasonableness of the precautions taken to prevent disclosure, the time taken to rectify the inadvertent disclosure, the scope of discovery, the extent of the disclosure, and the interests of justice.

One reason for adopting a more flexible approach to inadvertent disclosures is that a strict waiver standard belies the reality of modern patent litigation.⁴⁹ Due to the sheer volume of discovery, human error is bound to occur. The strict waiver standard also fails to consider the trend towards professionalism and courtesy in the legal system.⁵⁰ As such, a strict standard is Draconian. In contrast, the loose standard that an inadvertent disclosure is never a waiver, behooves sloppy lawyering, promotes inattention to document disclosure, and promotes conflict between lawyers in their efforts to get back inadvertently disclosed documents.⁵¹

***48** A key predicate among the schools of thought involves the intent of the disclosing party. When a party intentionally discloses a document, it waives any privilege.⁵² One exception to this waiver occurs when a party discloses the document to other co-parties (e.g., where one co-defendant discloses to another co-defendant) under the “community of interest” doctrine.⁵³ In summary, even though an opinion may be covered by the attorney-client privilege, the opinion may become discoverable through inadvertent or intentional disclosure.

Along the same lines as the community of interest doctrine, intentional disclosure of privileged information to expert witnesses may or may not act as a waiver. Rule 26(b)(4)(B) as amended, distinguishes between testifying and non-testifying experts. The information held by non-testifying experts is generally non-discoverable. However, information used by testifying experts to form their opinions is no longer privileged.⁵⁴ Therefore, the materials used by experts in formulating their opinions, including materials discussed with counsel or the client, may be discoverable.⁵⁵

Often times, an infringer will not obtain an opinion until after suit is filed. Since the infringer contracts with the attorney during the pendency of litigation, the opinion is drafted in anticipation of litigation or during the pendency of litigation and thus qualifies as attorney work product. Information used by experts in formulating expert testimony is often imported into the attorney's non-infringement opinion. Accordingly, expert testimony used in the formulation of non-infringement opinions may also be discoverable.

2. Disclosure of Non-Infringement Opinions and the Ethical Dilemma

If the infringer wishes to parade the non-infringement opinion to the jury, it is faced with a dilemma, namely: (a) whether to disclose the opinion to the opponents, to vitiate a claim of willfulness, thereby waiving any attorney-client privilege; or (b) whether to invoke the attorney-client privilege, thereby abandoning the "advice of counsel" defense, since the patentee will have no opportunity to attack the sufficiency of the opinion.⁵⁶ The rationale for the latter theory is to prevent the infringer from shielding the entire opinion from opponents under the assertion of privilege, while at the same time selecting *49 favorable portions of the opinion to stave off the charge of willfulness.⁵⁷ Generally, asserting the "advice of counsel" defense waives privilege to all subject matters pertaining to that opinion.⁵⁸ In this regard, all underlying information is discoverable, including any consultations with experts.

One consequence of the decision not to disclose the opinion is the negative inference drawn against the infringer. If the infringer invokes the privilege to protect the opinion, the district court judge will likely instruct the jury that they may infer either that the defendant did not procure a non-infringement opinion, or that the infringer did procure one, but it was unfavorable. The jury may negatively infer either situation to the infringer's detriment.⁵⁹

One way to circumvent inadvertent waiver of privileged material is to separate issues in different opinions. For example, a non-infringement opinion could include a section discussing non-infringement as well as a section discussing invalidity. However, if the defendant wishes to shield expert testimony that speaks to patent invalidity (as discussed below), an opinion on that issue should be written in a separate document. It may be prudent to have multiple opinion letters that discuss discrete aspects of non-infringement or invalidity. By having these separate opinions, the issue of accidental waiver of the attorney-client privilege can be obviated.

Therefore, with all the attention given to the opinions of non-infringement, and the degree of scrutiny these opinions must withstand, guidelines in drafting opinions are needed. These guidelines are discussed below. Obviously, not all of the guidelines discussed are relevant in every situation.

B. The Existence of an Opinion Is Not Dispositive

To reiterate, an underlying issue is whether the infringer obtained competent legal advice of non-infringement to vitiate a charge of willful infringement.⁶⁰ However, the mere existence of a non-infringement opinion does not "always and alone" dictate a finding that the infringement was not willful,⁶¹ although the decision to obtain a non-infringement opinion is relevant to determining willful infringement.⁶² Similarly, the lack *50 of a non-infringement opinion does not *ipso facto* give rise to a conclusion of willfulness.⁶³ The existence of a non-infringement opinion is only a single factor in the totality of circumstances that give rise to a finding of willfulness.⁶⁴

Finally, whether an opinion is written or oral is not dispositive. However, oral opinions are disfavored because they can be created *ab initio*, or can be bolstered during the pendency of litigation.⁶⁵

IV. Guidelines for Drafting Non-Infringement Opinions

A. Factors to Consider Regarding the Competency of the Opinion

An important predicate to any non-infringement opinion is that the author fully understands the patented invention. In fact, an opinion is suspect if the client knows that the author did not fully comprehend all of the facts.⁶⁶ Case law precedent clearly indicates that an opinion which concludes (even if ultimately incorrect) that an infringer will not be liable for infringement will insulate an infringer from a charge of willful infringement if the opinion is competent.⁶⁷ 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 invalid, not infringed, or unenforceable.”⁶⁸ Cases where willful infringement has been found despite the existence of an opinion of counsel involve situations where the opinion of counsel was either ignored or found to be incompetent.⁶⁹

In addition, even if the non-infringement opinion is equivocal in its ultimate conclusion of infringement, it may be sufficient to thwart the allegation of willfulness.⁷⁰ First, patent laws are in a state of flux and hence it would be unfair to penalize an infringer whose attorney opines in a manner consistent with the existing law. Second, *51 since many legal issues addressed in an opinion are questions of law, a definitive unequivocal opinion is not possible since ultimately a trial judge or appellate court must decide the issue. Therefore, it would be unfair to penalize the infringer if the facts and circumstances were too close for the attorney to opine non-infringement. In summary, if all other considerations of willfulness point to an equivocal opinion of non-infringement, then the attorney’s judgment should not be penalized since it likely does not rise to the level of culpable conduct or bad faith.

B. The Nature of the Author’s Status: In-House, Outside Counsel, Patent Agents

The general rule of law is that competent authors must draft the non-infringement opinion. This inquiry delves into whether the author has some vested interest or inherent bias. Using in-house counsel to draft non-infringement opinions does not necessarily disqualify the opinion.⁷¹ Just as the overall determination of willfulness is dependent on the totality of the circumstances, so too is the infringer’s decision to use a particular counsel.⁷² However, in-house counsel non-infringement opinions are suspect because of the inherent bias or interest of the counsel in the outcome of litigation. In-house counsel could unreasonably opine that the company was not infringing, to reduce the exposure to a potential treble damages award. This potential bias is especially troublesome if a treble damages award could bankrupt the company and force the in-house attorney into unemployment. Thus, there is an issue of whether the in-house patent attorney can be impartial enough to render a “competent” opinion.

In *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc.*,⁷³ the court stated that competency can be equated to objectivity. The court stated that the in-house counsel’s opinion was suspect since it was doubtful whether the attorney could have the requisite impartiality to objectively evaluate the patents in issue.⁷⁴ However, in *Studiengesellschaft Kohle v. Dart Industries, Inc.*,⁷⁵ the Federal Circuit overturned the Master’s findings that reliance on in-house counsel was misplaced. The Federal Circuit held instead that the management’s reliance on its in-house counsel was reasonable since the attorney was qualified and had monitored the field for three years.⁷⁶

*52 One measure of independence is whether the attorney has a stake in the outcome of the opinion. In *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc.*,⁷⁷ the court criticized the sufficiency of the legal opinion.⁷⁸ Although the attorney was “outside” counsel, the attorney had a stake in the outcome, since the attorney stood to receive 50% of the gross marginal profit of the product. In addition, if any litigation occurred, the attorney’s firm would handle the litigation, thereby generating fees. Therefore, the attorney’s personal stake in the non-infringement opinion called into question the independence of the opinion.⁷⁹

Another measure of independence concerns the input of the infringer. If the infringer attempts to “sway” or persuade the attorney to find non-infringement or patent invalidity, the opinion is tainted. In *Westvaco Corp. v. International Paper Co.*,⁸⁰ the court noted favorably the involvement of the infringer during the draft stages of the opinion.⁸¹ However, in *Comark Communications, Inc. v. Harris Corp.*,⁸² the Federal Circuit stated that less than full honesty by the infringer to the patent counsel may result in a finding of willful infringement. In this case, the court found that the infringer deliberately withheld from the attorney relevant and material information regarding the accused device. Accordingly, the attorney did not have available to it all of the objective evidence and thus opined incorrectly regarding the non-infringement of the accused device. In its opinion, the Federal Circuit reiterated the general policy reasons behind the advice of counsel defense:

The reason a potential defendant obtains an opinion from counsel is to ensure that it acts with due diligence in avoiding activities which infringe the patent rights of others. Obtaining an objective opinion letter from counsel also provides the basis for a defense against willful infringement. In order to provide such a prophylactic defense, however, counsel’s opinion must be premised upon the best information known to the defendant. Otherwise, the opinion is likely to be inaccurate and will be ineffective to indicate the defendant’s good faith intent. Whenever material information is intentionally withheld, or the best information is intentionally not made available to counsel during the preparation of the opinion, the opinion can no longer serve its prophylactic purpose of negating a finding of willful infringement.⁸³

Therefore, an attorney should not shy away from soliciting input by the infringer. However, the attorney should also maintain a level of decorum and distance from the infringer so as not to solicit judgment from the infringer. In this regard, the attorney can *53 acquire a sophisticated understanding of the product without being compromised by the infringer's input.

Another factor to consider when evaluating the competency of a non-infringement opinion is whether the opinion was obtained from a qualified patent attorney⁸⁴ or a non-patent attorney.⁸⁵ *BIC Leisure Products Inc. v. Windsurfing International, Inc.*⁸⁶ held that a competent and experienced patent attorney should render a legal opinion.⁸⁷ In general, non-patent attorneys do not possess the required skills in patent prosecution or patent office procedure to render competent opinions. As mentioned above, competency also includes the content of the opinion.⁸⁸

Similarly, often times the author of the opinion is also the patent prosecuting attorney or trial counsel for the client. However, the competency of the opinion may be affected if the opinion is inherently suspect because a single attorney is playing multiple roles.⁸⁹

Yet another aspect of a competent non-infringement opinion is that an attorney author it. Since many patent agents are employed as in-house patent prosecutors, it is tempting for a company to have its patent agents opine on the issue of non-infringement of a competitor's patent. Under *Sperry v. Florida*,⁹⁰ the only legal services (or opinions) patent agents are authorized to render are those "necessary and incident" to patent prosecution (e.g., patentability opinions).⁹¹ Since the issue of patent infringement is not incident to prosecution, a patent agent cannot render such an opinion.

However, a situation where a patent agent could conceivably render an infringement opinion, as incident to prosecution, is where the agent files a Petition To Make Special.⁹² This petition is available when the patent applicant is aware of a potential infringer but does not yet have an issued patent. The petition is used to expedite prosecution so that the application will issue into an enforceable patent more quickly. *54 Under this section, the agent must, *inter alia*, make a rigid comparison between the pending claims in the application and the accused device, which may require an inquiry into the claim construction and an infringement analysis. But it must be very clear, a patent agent cannot opine whether a product infringes an issued patent.

C. Sufficiency of the Opinion

After the author's status has been examined, the opinion must meet the test of sufficiency. To meet this best, the author must have examined and evaluated the file wrapper, claim construction, estoppel, literal infringement, and equivalency infringement. An opinion must not be terse or merely conclusory.⁹³ In addition, the opinion must be authoritative and objective.⁹⁴ It should not contain mere assurances of non-infringement or superficial analyses. As such, the opinion author should thoroughly review the cited prior art, the prosecution history, and the patent itself.⁹⁵

In *In re Hayes Microcomputer Products, Inc. Patent Litigation*,⁹⁶ the court upheld the willfulness determination because the opinion in the case treated the claims superficially, failed to set out a standard for one of ordinary skill in the art, failed to consider secondary considerations in determining obviousness, mischaracterized the prior art, failed to perform a proper best mode analysis, discussed only invalidity, and failed to discuss infringement.⁹⁷ The import is that the Federal Circuit encourages detailed explanations in opinions of patent invalidity, non-infringement, or both, such that those opinions include an analysis of the file wrapper, pertinent prior art, as well as a review of certain tests, experiments, and studies.⁹⁸ A prudent author may also search for additional prior art not cited in the prosecution history to bolster an opinion of invalidity.⁹⁹

D. Compiling Necessary Background Materials and Related Patent Files

Next, the opinion author must obtain the allegedly infringing product and determine how the product was developed. Likewise, the author must assemble all documentation *55 relating to the product, including any patents on the product or technical literature. This demonstrates that the author had all of the necessary materials for understanding the function and structure of the product. The author should also ensure that there are written conference notes of any oral discussion with the product developers to determine concretely how the product was developed. If the developer knew of a patent and attempted to design around it (albeit unsuccessfully), this may vitiate willfulness.¹⁰⁰ It is equally important to determine if the developer copied the product because copying gives rise to an inference of willfulness.¹⁰¹ If a prior non-infringement opinion was

rendered, the author should query the developer to determine whether significant design changes occurred after the first opinion. Significant design changes, under most circumstances, require a new opinion of counsel.¹⁰²

Since the crux of preparing a non-infringement opinion is to compare the patented invention against the infringer's product, the author must examine the patent that is allegedly being infringed. In addition, a competent opinion must examine the file wrapper and associated file wrappers of patents in the same family.¹⁰³ Examining file wrappers in the family may reveal sources of estoppel or disclaimers.¹⁰⁴ Arguments made in parallel files shed light on the meaning of the asserted patent, especially when the parallel files contain amendments and responses to Office Actions that are substantive, *i.e.*, the arguments that resulted in the allowance of a claim.¹⁰⁵ In this regard, the prosecution history in parallel files may estop the patentee from asserting a theory inconsistent with prior statements made during prosecution. The touchstone of prosecution history estoppel is that a patentee is unable to reclaim subject matter surrendered or disclaimed during prosecution.¹⁰⁶ To determine the scope of estoppel, the author should examine objectively whether a competitor would reasonably conclude that a patentee's prosecution conduct surrendered the subject matter in question.¹⁰⁷ As such, the opinion should clearly identify the sources of prosecution history in parallel files.

***56 E. Claim Interpretation - Claim Construction**

Once the author assembles the documentation and the allegedly infringing products, the next step is to analyze whether infringement exists. The Supreme Court's decision in *Markman v. Westview Instruments*¹⁰⁸ caused some morphing of the traditional infringement analysis, which included two steps: (a) determination of the scope of the claims (claim construction or claim interpretation); and (b) application of the claim construction to the accused device. The Supreme Court in *Markman* altered this traditional analysis by holding that step (a) claim construction is a question of law.¹⁰⁹ Subsequently, the Federal Circuit ruled that even the underlying factual predicates were questions of law.¹¹⁰

Furthermore, patent claims must be construed through the eyes of a person of ordinary skill in the art and not by what a layperson understands the claims to mean.¹¹¹ The six non-exclusive factors to consider in determining the level of ordinary skill in the art include: (i) the educational level of the inventor; (ii) the type of problems encountered in the art; (iii) prior art solutions; (iv) rapidity of the innovation; (v) sophistication of the technology; and (vi) the educational level of active workers in the field.¹¹² Therefore, a non-infringement opinion should state and justify who the ordinary artisan is, since claim construction may be dispositive of the infringement issue.

Since each claim in a patent must be supported by the specification, the next step is to determine if each claim is adequately supported by the written description.¹¹³ In interpreting the scope of a claim, it is also necessary to determine the scope of the specification, since a claim cannot be broader than the scope of the specification.¹¹⁴ Thus, it follows that the scope of the claim is restricted by the scope of the enablement.¹¹⁵ To satisfy the written disclosure requirement, the patentee must show that he was in possession of the invention by describing the invention with claim limitations, words, structures, figures, drawings, tables, formulae, etc.¹¹⁶ Therefore, the opinion author may *57 safely opine that a product does not infringe because the scope of the claims, as interpreted using the specification, do not read on the accused product.

Another issue in claim interpretation is the use of "intrinsic" versus "extrinsic" evidence. In *Vitronics Corp. v. Conceptronic, Inc.*,¹¹⁷ the Federal Circuit stated that a district court judge, when construing a claim, should resort to intrinsic evidence first, which includes the patent itself, the claim language, and the prosecution history.¹¹⁸ If the claim language is clear and unambiguous, then any use of extrinsic evidence is improper.¹¹⁹ The author of a non-infringement opinion may look at extrinsic evidence to educate himself about the invention and the relevant technology, but the author should not use extrinsic evidence to arrive at a claim construction that is at odds with the construction mandated by the intrinsic evidence.¹²⁰ Therefore, the author should explicitly state in the opinion whether the author regards the claim to be ambiguous, any sources of extrinsic evidence used, and whether the extrinsic evidence was used merely for self-education or for actual claim interpretation. It is wise for a non-infringement opinion to outline various claim construction scenarios to avoid a situation where a judge strikes the one and only scenario.

Special attention must be paid to judicially narrow claims such as means plus function claims. In means plus function claims,¹²¹ the analytical construct determines: (a) the function identified in the claims; (b) whether the identical function is performed by the accused device;¹²² (c) the structures described in the patent specification that perform that stated function; (d) whether there is a proper link or nexus stated in the patent specification between the stated structures and the stated function; and (e) whether the structures found in the accused device are identical or equivalent structures (not structural

equivalents) to those recited in the patent specification.¹²³ Therefore, claims in means plus function form should be carefully analyzed and interpreted.

A claim may also be judicially narrowed because of ambiguity in the claim.¹²⁴ For example, if there are multiple interpretations of a claim and the specification clearly *58 supports a narrow interpretation, then the court may construe the claim according to the narrower scope. In *Athletic Alternatives, Inc. v. Prince Manufacturing, Inc.*,¹²⁵ the court stated:

Were we to allow AAI successfully to assert the broader of the two senses of “between” against Prince, we would undermine the fair notice function of the requirement that the patentee distinctly claim the subject matter disclosed in the patent from which he can exclude others temporarily. Where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning.¹²⁶

Therefore, the author of the opinion should carefully examine whether the claim is ambiguously narrow or broad.

Unbeknownst to the infringer, the infringer may be practicing prior art and thus may not be an infringer after all. The patent may also have dedicated some embodiments to the public during prosecution. The Federal Circuit held in *Maxwell v. Baker*,¹²⁷ that subject matter in a canceled claim could be construed as dedicating that matter to the public.¹²⁸ Similarly, subject matter or embodiments found in the specification, but not claimed in the issuing patent, are also dedicated to the public. Therefore, anyone is free to practice unclaimed subject matter so long as it does not infringe another’s patent claims.

Finally, the opinion author should note that claims in an issued patent are presumptively valid.¹²⁹ Accordingly, if the author determines that the claim is susceptible to two separate interpretations, where one interpretation reads on the infringing device while the other interpretation does not, then the author should strongly characterize why the product does not fall under the first claim interpretation. However, if there are two claim interpretations, one of which is invalid while the other is valid, then the author should argue that there is no infringement under the valid interpretation. If the only basis for infringement is concededly under the valid interpretation, then a court may strive to find a basis for upholding the validity and hence finding infringement. This is because the court is faced with two interpretations, one of which would lead to an invalid claim, and the court will favor adopting the valid interpretation.¹³⁰

*59 In summary, the opinion must contain a section dedicated to claim construction. This section should state all assumptions, characterizations, bases for estoppel, and the like. Ideally, this section should include a separate discussion of each claim variation scenario.

F. Literal Infringement

After determining the scope of the claims, each claim construction scenario must be applied to the accused product to determine if there is literal infringement of the claims. Literal infringement occurs when each element of a claim is present in the accused device.¹³¹ Since literal infringement requires the accused device to contain each limitation of the claim exactly, any deviation from the claim precludes a finding of literal infringement. Therefore, finding an element in the claim that does not exist in the accused product will negate literal infringement. Accordingly, the non-infringement opinion should identify the absence of a stated claim limitation.

The simplest way to establish non-literal infringement of a means plus function claim is to show that the accused device does not have the identical or equivalent structure required by the claim. In addition, the infringer avoids infringement if the function performed by the accused device is not identically performed by the claimed structure.¹³² However, a non-infringement opinion should never end with the argument that infringement does not exist because the accused product is not “equivalent” to the product shown in the asserted patent. In response the patentee may argue that the structures need not be equivalent under a reading of 35 U.S.C. § 112, ¶ 6.¹³³

The plain text of the statute states that the claim should cover the following six permutations: (i) a structure, (ii) an equivalent structure, (iii) a material, (iv) an equivalent material, (v) an act, or (vi) an equivalent act. However, according to the Federal Circuit, the claim only covers: (i) a structure, (ii) an act, (iii) a material, or (iv) an equivalent structure,¹³⁴ because the phrase “equivalents thereof” only modifies the first phrase, “structure.” Nevertheless, a patentee will argue that the means plus

function claim ought *60 to cover any listed structures, acts, materials, and equivalent structures, equivalent acts, or equivalent materials, based on the plain reading of the statute.

The inapplicability of the Federal Circuit's statutory construction is evident when applied to section 101, which states, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”¹³⁵ Application of the Federal Circuit's analytical construction to this section would suggest that the phrase “or any new and useful improvement” only modifies the first phrase “process.” Therefore the category of patentable subject matter would become: (i) a process, (ii) any new and useful improvement to a process, (iii) a machine, (iv) a manufacture, or (v) a composition of matter. This belies the reality that millions of improvement patents exist on machines, manufactures, and compositions of matter.

Another interesting issue is raised in means plus function claims when the accused means element is well established in the prior art and the accused device uses this well-known means. If the patent specification does not specify this old means and the old means is not an equivalent structure, there is no means plus function infringement. For example, assume a claim calls for two pieces of wood and a means for connecting the pieces of wood. The specification discloses a nail as the means for connecting the pieces but omits a recitation of other well-known means such as screws, bolts, or adhesives. If the accused device uses a screw, bolt, or adhesive (assuming it is not an equivalent structure), then the infringer may escape liability. The rationale for this new *Palsgraf*¹³⁶ patent rule, enumerated in *Chiuminatta Concrete Concepts Inc. v. Cardinal Industries Inc.*,¹³⁷ is that if it was reasonably foreseeable for the patentee to include these well-known means in the specification at the time the patent application was filed, then unless the means of the accused device is an equivalent structure, there is no infringement.¹³⁸

Of course, the opinion author may hedge and state that a patent applicant need not describe each and every possible embodiment in the specification that is well known in the art. In *Hybritech v. Monoclonal Antibodies*,¹³⁹ the court stated that the specification should not become a catalog of existing technology since the specification need not teach, and preferably omits, that which is well known in the art.¹⁴⁰ Since the more recent dicta of *Chiuminatta* seems to directly contradict the past dicta of *Hybritech*, an author should *61 be careful in opining that there is no infringement because the patentee failed to include a catalog of past, well known means. Therefore, in the above example, it may not suffice to opine non-infringement because the patentee failed to include screws, bolts, and adhesives in the specification.

In non-infringement opinions, an excellent tool for identifying elements present and absent in the accused device is a claim chart. A claim chart directly compares the element of a claim and the parallel element of the accused device.¹⁴¹

The author should give special attention to the existence of the infringer's product in the patent specification. A reference in the specification to an embodiment similar to the accused product would ordinarily serve as a powerful indication that the claims should be construed broadly enough to include the described embodiment, and thus to read on the accused product.¹⁴²

In summary, since a literal infringement analysis requires an element by element comparison of each element to the infringer's device, the author should provide a clear explication of the elements missing from the accused device.

G. Doctrine of Equivalents Infringement

The Doctrine of Equivalents (“DOE”) is a method of adjudicating infringement in the absence of literal infringement. While the DOE is subject to increasing scrutiny and hostility by the Federal Circuit, the Supreme Court recently upheld its applicability as an independent source of infringement.¹⁴³ Under the DOE, “a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is ‘equivalence’ between the elements of the accused product or process and the claimed elements of the patented invention.”¹⁴⁴ Infringement may be found under the DOE if every limitation of the asserted claim or its “equivalent” is found in the accused subject matter, and the difference between the equivalent and the claimed limitation is insubstantial. Whether a component in the accused subject matter performs substantially the same *function* as the claimed limitation in substantially the same *way* to achieve substantially the same *result* (the “function-way-result” test) may be relevant to this determination.¹⁴⁵ Therefore, any discussion of the DOE must necessarily include an *62 element by element analysis of each claimed and accused element, along with the “insubstantial change” test or the function-way-result test.

In addition, a later issued patent covering the accused device may be probative evidence of non-equivocality because it implies that the Examiner considered the product non-equivalent or a non-obvious variation of the earlier patent-in-suit.¹⁴⁶ Since the test for infringement under the DOE includes an insubstantial change test, the Examiner's conclusion that the accused device patent is not obvious indicates that there is a substantial difference between the two devices.

The prosecution history of each patent and patent family at issue must be examined to determine if there was any prosecution history estoppel. The Supreme Court has stated that any amendment made to the claims during prosecution is presumed to have been added to overcome prior art and thus presumptively creates estoppel, unless another reason is provided for the amendment.¹⁴⁷ Therefore, a simple amendment to correct a technical defect could be considered estoppel unless the applicant states that the amendment is for technical correction, and not predicated on patentability.¹⁴⁸ Examining the prosecution history may demonstrate that a particular element in an accused device does not fall under the DOE if it was surrendered during prosecution. In summary, if the patentee stated during patent prosecution that certain subject matter was not covered under the scope of the claims in order to get the claims allowed, then the patentee will not recover this subject matter for the purposes of equivalency infringement.

In drafting the non-infringement opinion, each claim construction scenario must be evaluated under the DOE. The non-infringement opinion must account for all possible claim constructions to vitiate a charge of willfulness. This will minimize the risk of a holding of willful infringement, in the event the court does not adopt the primary claim interpretation presented by the opinion.

One identifiable trend with means plus function claims is that a finding of no literal infringement necessarily precludes infringement under the DOE. The Federal Circuit reasoned that in literal infringement the accused element must be an identical or equivalent structure to that claimed in the patent. If it is not, then there is no literal infringement. Thus, that same element cannot be "equivalent" under the DOE since it would have already been equivalent under literal infringement.¹⁴⁹

***63** *Warner-Jenkinson* further held that there is no DOE infringement as a matter of law, if a theory of equivalence would vitiate an expressed claim limitation.¹⁵⁰ Similarly, *Maxwell v. Baker* suggests that any unclaimed subject matter dedicated to the public cannot be recaptured under the DOE.¹⁵¹ However, in *YBM Magnex v. International Trade Commission*,¹⁵² the Federal Circuit distinguished *Maxwell v. Baker* by holding that even though unclaimed matter exists, it does not necessarily preclude the application of the DOE.¹⁵³ Therefore, claim limitations, prosecution history estoppel, and equivalency require special attention in a non-infringement opinion.¹⁵⁴

V. Patent Invalidity - General Considerations

Another potential argument available to the infringer is that its product may not infringe because the patent is invalid. Invalidity predicated on lack of enablement must carefully determine the scope of the specification plus the scope of what is known to the ordinary artisan without undue experimentation.¹⁵⁵ More often, patent invalidity is asserted when prior art surfaces that challenges the validity of the patent on the grounds of novelty or obviousness.¹⁵⁶ The alleged infringer should consider having its attorney prepare an invalidity opinion separate from the non-infringement opinion.

Since a patent is presumptively valid, any assertion of invalidity must be demonstrated by clear and convincing evidence.¹⁵⁷ Therefore, the opinion should not be so brief as to only satisfy the lower standard of preponderance of the evidence. However, when the author opines that relevant prior art was not considered by the Examiner during patent prosecution, the infringer's burden is more readily discharged.¹⁵⁸ This is because the Examiner never had the opportunity to consider the newly surfaced art and thus the presumption of patent validity is suspect. However, since each claim stands alone as its ***64** own definition of the invention, and a presumption of validity attaches to each claim, prior art relevant to one claim may not be relevant to another claim.¹⁵⁹

The opinion author must be cognizant of the deference given by district courts to the PTO Examiner. If the author opines invalidity predicated solely on prior art that was presented to the Examiner during prosecution, the competency of the opinion may be suspect. A district court judge may be hesitant to evaluate complex and technical subject matter, and accordingly give deference to the PTO Examiner's conclusion that the patent is valid over the prior art.¹⁶⁰ In contrast, a district court is not required to give any deference to the PTO Examiner's conclusion of patent validity if the Examiner did not consider the prior art cited by the infringer.¹⁶¹ Therefore, an opinion predicated on prior art not cited to the PTO Examiner is stronger and may be considered more competent.

Furthermore, when patent invalidity is asserted, a clear nexus is required between the prior art cited and the claim elements. For example, each element of the claim must be linked to some aspect of the prior art disclosure. If the prior art does not disclose the claimed element either inherently, expressly, or obviously, then no nexus can be made and the claim survives.¹⁶² The opinion must clearly express the reasons for invalidity. A claim chart that visually aids the drafter, the judge, and the jury in determining which elements of the claims are found in the prior art or are obvious modifications thereof, is extremely helpful towards this end.

A. Invalidity Predicated on Section 102 - Novelty and Loss of Rights

If the basis for invalidity is predicated on the novelty-destroying or loss of rights provisions of section 102, the best illustration of invalidity is a claim chart.¹⁶³ An assertion of invalidity due to anticipation requires that a single prior art reference disclose all elements of the claimed invention.¹⁶⁴ Charting the asserted patent's claimed elements with a corresponding notation to the exact disclosure in the prior art clearly establishes that each element of the asserted patent is disclosed.

***65** A single prior art reference does not have to be a written document, although it is often the best evidence to prove invalidity, particularly when in the form of either a printed publication or a published patent.¹⁶⁵ A reference may include anticipation via the “public use” or the “on-sale” bars.¹⁶⁶ The general policy reasons for including the public use or on-sale bars are threefold: (i) it facilitates the widespread disclosure of new inventions to the public via issued patents as quickly as possible by encouraging inventors to file patent applications or otherwise risk being barred from applying;¹⁶⁷ (ii) the bars discourage inventors from engaging in commercial activity and then later applying for a patent to artificially extend the de facto exclusivity period;¹⁶⁸ and (iii) to discourage inventors from removing technology from the public domain after the public has earned the right to practice that technology because of the public’s use of the invention.¹⁶⁹ Therefore, non-documentary activity may anticipate the asserted patent if that activity occurred more than one year before the patent was filed in the U.S.

1. Invalidity Predicated on the Public Use Bar

Under the public use bar, the Federal Circuit has defined “public use” as including “any use of [the claimed] invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor.”¹⁷⁰ The question of public use is evaluated by asking “how the totality of the circumstances of the case comports with the policies underlying the public use bar.”¹⁷¹ An assertion of patent invalidity should not be based solely on oral testimony of the defendant, because courts have long held that invalidity predicated on prior use should be corroborated.¹⁷² Issued patents enjoy a presumption of validity and must be invalidated by clear and convincing evidence.¹⁷³

***66** A public use bar may occur even when only one product is used in public. As the Supreme Court held in *Egbert v. Lippmann*,¹⁷⁴ a public use of an innovative undergarment need not be open and notorious in order to be “public.”¹⁷⁵ Because Egbert himself put the invention into use eleven years before filing for patent protection, the corset insert worn by Egbert’s intimate friend, though not in plain view, was abandoned to the public. Therefore, the opinion author should examine whether any public use has ever occurred, no matter the frequency, and whether that public use can be corroborated.

2. Invalidity Predicated on the On-Sale Bar

As with the public use bar, the on-sale bar will invalidate an asserted issued patent if anticipatory activity has occurred more than one year prior to the asserted patent’s filing date.¹⁷⁶ Recently, the Supreme Court in *Pfaff v. Wells Electronics*¹⁷⁷ changed the test for determining whether an invention is “on-sale” under section 102(b). Under the new test, the Court held that an invention is on-sale when two conditions occur before the critical date: (1) the product must be subject to a commercial sale or offer for sale; and (2) the invention must be ready for patenting. The latter condition may be satisfied in at least two ways: (a) by proof of a reduction to practice before the critical date; or (b) by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that would enable a person of ordinary skill in the art to practice the invention.¹⁷⁸

The Supreme Court in *Pfaff* abandoned a Federal Circuit test, which had previously examined the “totality of the

circumstances" when evaluating the public use bar.¹⁷⁹ However, there are several facial problems with this new Supreme Court test. The first prong of the test speaks to a "product" subject to a commercial offer for sale. A patentee may defend the validity of its patent by stating that the patent covers a process and thus is not subject to the new test. Accordingly, the patentee may assert that any allegation of invalidity should be predicated on the "old" totality of the circumstances test, not the current Supreme Court test. In addition a court could still use the totality of the circumstances test in evaluating each prong of the Supreme Court test. For example, since the first prong concerns a commercial offer for sale, the determination of when this occurs could be evaluated on a totality of the circumstances. Similarly, the second prong *67 concerns whether the invention is ready to be patented. Again, whether an invention has been reduced to practice or whether a drawing sufficiently describes the details of the invention could be evaluated on the totality of the circumstances.

This situation occurred in *Weatherchem v. J.L. Clark*,¹⁸⁰ when the Federal Circuit re-evaluated trial evidence to determine if the inventive condiment lid was on sale. The Court noted that the record demonstrated three distinct commercial activities prior to the critical date.¹⁸¹ Rather than vacating and remanding the case to the trial court for a reevaluation of an on sale bar in light of *Pfaff v. Wells*, the Federal Circuit reviewed the trial court transcripts for evidence of an invention ready for patenting. The Federal Circuit reevaluated the second prong under the totality of the circumstances, and determined that the invention was ready for patenting because it was sufficiently described in many drawings.¹⁸²

Just as with a public use bar, all on-sale activity must be corroborated. Since time fades memories and destroys documents, an allegation of on-sale activity may require many depositions. One difficulty with promoting an on-sale defense predicated on witness memory is that Rule 30(a)(2) limits the number of depositions a party can take.¹⁸³ Accordingly, a defendant must carefully plan how to prove on-sale activity or risk running out of deposition permits prior to obtaining the necessary proof to adequately corroborate on-sale activity.

Therefore, an opinion author must be aware of several considerations in opining invalidity based on the on-sale bar. First the author should assert patent invalidity using the best test set forth by the Supreme Court, clearly addressing the first and second prongs. Second, the author should note that if the asserted patent covers an inventive process, the new Supreme Court test may not necessarily apply; rather the "old" totality of the circumstances test may apply. Third, the author should state that a reduction to practice is not necessary to invoke the on sale bar. The discovery of detailed drawings showing the invention may be enough to invalidate a patent. As *Pfaff* and *Weatherchem* indicate, these drawings may be in the form of either production orders or orders for commercial sales. Finally, the opinion author should consider whether the sale or offer for sale of the invention fell within the experimental use exception.¹⁸⁴

***68 B. Invalidity Predicated on Section 103 - Obviousness**

Patent invalidity based on obviousness should discuss both the primary and the secondary indicia of non-obviousness, or otherwise state that no such information currently exists.¹⁸⁵ Obviousness under section 103 requires the author to examine: (a) the scope and content of the prior art; (b) the differences between the prior art and the claimed invention; (c) the level of ordinary skill in the art; and (d) the objective secondary indicia of obviousness.¹⁸⁶ The objective secondary indicia of obviousness include: (i) evidence of copying; (ii) long felt but unsolved needs; (iii) failure of others;¹⁸⁷ (iv) commercial success;¹⁸⁸ (v) unexpected successful results of the claimed invention; (vi) unexpected properties of the claimed invention;¹⁸⁹ (vii) licenses showing industry respect for the claimed invention;¹⁹⁰ and (viii) skepticism of skilled artisans prior to the invention.¹⁹¹ One factor not considered under an obviousness inquiry is the ease with which the invention was made.

When the author asserts that the patent was obvious based on a combination of references, the author must point out the motivation, suggestion, or teaching in the prior art to combine the cited references.¹⁹² The author must explain whether the motivation, suggestion, or teaching flows from the nature of the problem to be solved,¹⁹³ the teachings of the references themselves,¹⁹⁴ or the knowledge of those skilled in the art that certain references have special importance in a particular field.¹⁹⁵ The author must faithfully apply these criteria to prevent the appearance of impermissible hindsight in combining the references. An author may not use the claimed invention as a blueprint for finding references to subsequently invalidate the claims.¹⁹⁶

***69 C. Invalidity Predicated on Fraud or Inequitable Conduct**

An opinion that asserts invalidity due to fraud or inequitable conduct should present specific facts.¹⁹⁷ Fraud and inequitable

conduct must be proved by clear, unequivocal, and convincing evidence with a heavy burden of persuasion on the infringer.¹⁹⁸ It is difficult to reasonably allege fraud solely on an examination of the patent prosecution history, because the patentee's state of mind is an element of fraud. However, examining the prosecution history could reveal whether the patentee's attorney complied with the required duties of candor and good faith.¹⁹⁹ Obtaining the prosecution history of related files would demonstrate whether prior art cited in related applications was cited in the prosecution of the patent-in-suit.²⁰⁰ For example, if the asserted patent was filed in a foreign country, prior art cited to foreign patent offices may not have been found by, or cited to, the U.S. examiner. This is especially likely when the asserted patent is filed as a co-pending P.C.T. (Patent Cooperation Treaty) application in which the patentee designates the European Patent Organization (EPO) as the International Search Authority.²⁰¹ EPO examiners search for prior art in multiple languages and issue an International Search Report (ISR) about sixteen months after the priority date of the P.C.T. application.²⁰² Patent attorneys often forget to submit the ISR and cited art to the U.S. Examiner during the pendency of the parallel U.S. patent application.²⁰³ Depending on the nature, relevance, and materiality of the prior art found in the ISR, the patent may be invalid for failing to disclose this art to the PTO.

In summary, an invalidity opinion must outline the factual bases for any claim of patent invalidity. A lengthy and detailed explanation will greatly assist the infringer in either invalidating a patent or vitiating a claim for willful infringement.

VI. Conclusion

As shown herein, while an allegation of willful infringement is fraught with problems for the infringer, there are several tools the infringer may use to vitiate this allegation to stave off treble damages. In contracting with an attorney to prepare a non-infringement or invalidity opinion, it is crucial for the attorney to examine all the ways *70 in which the opinion will be criticized. In the end, the opinion that encompasses all the considerations addressed herein, where appropriate, will likely survive attack and exorcise the specter of treble damages.

Footnotes

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¹ See *General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 655-56, 217 U.S.P.Q. (BNA) 1185, 1188-89 (1983). *See also* 35 U.S.C. § 284 (1994).

² See e.g., *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1575, 35 U.S.P.Q.2d (BNA) 1065, 1094 (Fed. Cir. 1995) (“The consequence of expansion of legal injury in this case is that the patentee’s major competitor, an innocent infringer, has been forced into bankruptcy by the lost profits award on unprotected goods.”) (Nies, J., dissenting).

³ See e.g., *Johns Hopkins Univ. v. CellPro, Inc.*, 978 F. Supp. 184, 196 (D. Del. 1997), *aff’d by* 152 F.3d 1342, 47 U.S.P.Q.2d (BNA) 1705 (Fed. Cir. 1998).

⁴ While a party is not truly an “infringer” until a court so decides, the term “infringer” is used in this article to denote a party that may ultimately be liable for infringement.

⁵ In patent parlance, the legal opinion is also referred to as a non-infringement opinion (the infringer’s product or process does not infringe), a right to use opinion (the infringer has the right to use his own product or process), or a freedom to use opinion (the infringer is free to use the patented product or process). A non-infringement opinion is recognized to generally encompass the belief that the alleged infringer’s product does not infringe. On the other hand, an invalidity opinion focuses primarily on the issue of a patent’s validity, or lack thereof.

⁶ Patents may be obtained for products, methods of performing processes, products made by certain processes, designs, and certain plants. *See* 35 U.S.C. § 101 (1994).

⁷ See *Comark Communications Inc. v. Harris Corp.*, 156 F.3d 1182, 1190, 48 U.S.P.Q.2d (BNA) 1001, 1008 (Fed. Cir. 1998) (“In determining whether willfulness has been shown, we look to the totality of the circumstances, understanding that willfulness, ‘as in life, is not an all-or-nothing trait, but one of degree. It recognizes that infringement may range from unknowing, or accidental, to deliberate, or reckless, disregard of the patentee’s legal rights.’”).

⁸ See *Rite-Hite Corp. v. Kelley Co.*, 819 F.2d 1120, 1126, 2 U.S.P.Q.2d (BNA) 1915, 1919 (Fed. Cir. 1987).

⁹ See *id.*

¹⁰ See 35 U.S.C. § 285 (1994); *Modine Mfg. Co. v. Allen Group, Inc.*, 917 F.2d 538, 543, 16 U.S.P.Q.2d (BNA) 1622, 1626 (Fed. Cir. 1990).

¹¹ See *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1569, 38 U.S.P.Q.2d (BNA) 1397, 1399 (Fed. Cir. 1996).

¹² See *id.* at 1570; 38 U.S.P.Q.2d at 1399.

¹³ See *id.*

¹⁴ See *In re Hayes Microcomputer Prod. Inc. Patent Litig.*, 982 F.2d 1527, 1543, 25 U.S.P.Q.2d (BNA) 1241, 1253 (Fed. Cir. 1992).

¹⁵ See *Jurgens*, 80 F.3d at 1570, 38 U.S.P.Q.2d at 1399.

¹⁶ See *id.*

¹⁷ See *id.*

¹⁸ See *Beatrice Foods Co. v. New England Printing & Lithography Co.*, 923 F.2d 1576, 1578, 17 U.S.P.Q.2d (BNA) 1553, 1555 (Fed. Cir. 1991).

¹⁹ See *Jurgens*, 80 F.3d at 1570, 38 U.S.P.Q.2d at 1400.

²⁰ See *id.*

²¹ See *id.*

²² See *id.*

²³ See *id.* at 1571, 38 U.S.P.Q.2d at 1400.

²⁴ See *Comark Communications Inc. v. Harris Corp.*, 156 F.3d 1182, 1191, 48 U.S.P.Q.2d (BNA) 1001, 1009 (Fed. Cir. 1998) (“The reason a potential defendant obtains an opinion from counsel is to ensure that it acts with due diligence in avoiding activities which

infringe the patent rights of others. Obtaining an objective opinion letter from counsel also provides the basis for a defense against willful infringement.”).

²⁵ See *Jurgens*, 80 F.3d at 1571, 38 U.S.P.Q.2d at 1400-01.

²⁶ See *id.*, 38 U.S.P.Q.2d at 1401.

²⁷ See *id.*

²⁸ See *id.*

²⁹ See *id.*

³⁰ See *id.* at 1571-72, 38 U.S.P.Q.2d at 1401.

³¹ See *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826-27, 23 U.S.P.Q.2d (BNA) 1426, 1435 (Fed. Cir. 1992), *abrogated on other grounds by* *Markman v. Westview Instruments, Inc.*, 52 F.3d. 967, 975, 34 U.S.P.Q.2d (BNA) 1321, 1326 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996).

³² See *Odetics Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1274, 51 U.S.P.Q.2d (BNA) 1225, 1235 (Fed. Cir. 1999).

³³ See *Jurgens*, 80 F.3d at 1572, 38 U.S.P.Q.2d at 1401.

³⁴ See *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 944, 22 U.S.P.Q.2d (BNA) 1119, 1125-26 (Fed. Cir. 1992).

³⁵ See *id.*

³⁶ See *Belmont Textile Mach. Co. v. Superba, S.A.*, 48 F. Supp. 2d 521, 522, 51 U.S.P.Q.2d (BNA) 1050, 1051 (W.D.N.C. 1999).

³⁷ See *id.* at 522-23, 51 U.S.P.Q.2d at 1051-52.

³⁸ See *Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 181, 30 U.S.P.Q.2d (BNA) 1462, 1464 (Fed. Cir. 1994).

³⁹ See *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1546, 24 U.S.P.Q.2d (BNA) 1133, 1138 (Fed. Cir. 1992).

⁴⁰ 89 F. Supp. 357 (D. Mass. 1950), *rev’d on other grounds by*, *American Standard Inc. v. Pfizer Inc.*, 828 F.2d 734, 745-46, 3 U.S.P.Q.2d (BNA) 1817, 1825 (Fed. Cir. 1987).

⁴¹ See *id.* at 358-59.

⁴² See FED. R. CIV. P. 26(b)(3) (codifying the rule of *Hickman v. Taylor*, 329 U.S. 495 (1947)).

⁴³ *See* Willemijn Houdstermaatschaapij BV v. Apollo Computer Inc., 707 F. Supp. 1429, 1443, 13 U.S.P.Q.2d (BNA) 1001, 1011 (D. Del. 1989).

⁴⁴ *See id.*

⁴⁵ *See* Interlego A.G. v. F.A.O. Schwarz, Inc., 196 U.S.P.Q. (BNA) 8, 11 (N.D. Ga. 1977).

⁴⁶ *See* Dyson v. Amway Corp., 17 U.S.P.Q.2d (BNA) 1965, 1966 (W.D. Mich. 1990).

⁴⁷ *Id.* at 1966-67.

⁴⁸ *See id.* at 1967.

⁴⁹ *See id.*

⁵⁰ *See id.*

⁵¹ *See id.*

⁵² *See* Smith v. Alyeska Pipeline Service Co., 538 F. Supp. 977, 981-82, 218 U.S.P.Q. (BNA) 468, 470-71 (D. Del. 1982), *aff'd*, 758 F.2d 668 (Fed. Cir. 1984).

⁵³ *See* Union Carbide Corp. v. Dow Chemical Co., 619 F. Supp. 1036, 1047, 229 U.S.P.Q. (BNA) 401, 407 (D. Del. 1985).

⁵⁴ *See* FED. R. CIV. P. 26(a)(1)(B).

⁵⁵ *See* Intermedics, Inc., v. Ventritex, Inc., 139 F.R.D. 384, 397, 22 U.S.P.Q.2d (BNA) 1481, 1491 (N.D. Cal. 1991). This view has been rejected by other district courts that have considered the issue.

⁵⁶ *See* Belmont Textile Mach. Co. v. Superba, S.A., 48 F. Supp. 2d 521, 523, 51 U.S.P.Q.2d (BNA) 1050, 1052 (W.D.N.C 1999).

⁵⁷ *See id.*

⁵⁸ *See* Johns Hopkins Univ. v. CellPro, Inc. 160 F.R.D. 30, 34, 34 U.S.P.Q.2d (BNA) 1276, 1279 (D. Del. 1995).

⁵⁹ *See Belmont*, 48 F. Supp 2d at 523, 51 U.S.P.Q.2d at 1052.

⁶⁰ *See* Ortho Pharm. Corp. v. Smith, 959 F.2d 936, 944, 22 U.S.P.Q.2d (BNA) 1119, 1125-26 (Fed. Cir. 1992).

⁶¹ Kori Corp. v. Wilco Marsh Buggies & Draglines, Inc., 761 F.2d 649, 656-57, 225 U.S.P.Q. (BNA) 985, 989-90 (Fed. Cir. 1985).

62 See *Studiengesellschaft Kohle v. Dart Indus., Inc.*, 862 F.2d 1564, 1573-76, 9 U.S.P.Q.2d (BNA) 1273, 1282-84 (Fed. Cir. 1988).

63 See *Belmont*, 48 F. Supp. 2d at 523, 51 U.S.P.Q.2d at 1052.

64 See *id.*

65 See *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1580, 24 U.S.P.Q.2d (BNA) 1321, 1339 (Fed. Cir. 1992).

66 See *Amsted Indus. Inc v. Buckeye Steel Castings Co.*, 24 F.3d 178, 182-83, 30 U.S.P.Q.2d (BNA) 1462, 1466 (Fed. Cir. 1994).

67 See *Underwater Devices Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1390, 219 U.S.P.Q. 569, 576-77 (Fed. Cir. 1983).

68 *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 944, 22 U.S.P.Q.2d (BNA) 1119, 1126 (Fed. Cir. 1992).

69 See *Read Corp. v. Portec*, 970 F.2d 816, 828-29, 23 U.S.P.Q.2d (BNA) 1426, 1437 (Fed. Cir. 1992), *abrogated on other grounds by* *Markman v. Westview Instruments, Inc.*, 52 F.3d. 967, 975, 34 U.S.P.Q.2d (BNA) 1321, 1326 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996).

70 See *id.* at 829 n.9, 23 U.S.P.Q.2d at 1437 n.9.

71 See *Studiengesellschaft Kohle v. Dart Indus., Inc.*, 862 F.2d 1564, 1573-76, 9 U.S.P.Q.2d (BNA) 1273, 1282-83 (Fed. Cir. 1988).

72 See *Underwater Devices Inc.*, 717 F.2d at 1390, 219 U.S.P.Q. at 576.

73 976 F.2d 1559, 24 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 1992).

74 See *id.* at 1582, 24 U.S.P.Q.2d at 1340.

75 862 F.2d 1564, 9 U.S.P.Q.2d 1273 (Fed. Cir. 1988).

76 See *id.* at 1579, 9 U.S.P.Q.2d at 1284-85.

77 2 F. Supp. 2d 366, 48 U.S.P.Q.2d (BNA) 1741 (S.D.N.Y. 1998).

78 See *id.* at 377, 48 U.S.P.Q.2d at 1750-51.

79 See *id.*

80 991 F.2d 735, 26 U.S.P.Q.2d (BNA) 1353 (Fed. Cir. 1993).

81 *See id.* at 744-45, 26 U.S.P.Q.2d at 1361.

82 156 F.3d 1182, 48 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 1998).

83 *Id.* at 1191, 48 U.S.P.Q.2d at 1009 (Fed. Cir. 1998).

84 A patent attorney is an attorney who has passed the U.S. Patent Office Bar Examination. This designation qualifies an attorney to represent clients in the preparation and prosecution of patent applications before the U.S. Patent Office. *See generally* 37 C.F.R. §§ 10.5-10.20 (1999).

85 *See* Underwater Devices Inc. v. Morrison-Knudsen Co., 717 F.2d 1380, 1390, 219 U.S.P.Q. (BNA) 569, 576 (Fed. Cir. 1983).

86 1 F.3d 1214, 27 U.S.P.Q.2d (BNA) 1671 (Fed. Cir. 1993).

87 *See id.* at 1222-23, 27 U.S.P.Q.2d at 1678.

88 *See* Jurgens v. CBK, Ltd., 80 F.3d 1566, 1572, 38 U.S.P.Q.2d (BNA) 1397, 1402 (Fed. Cir. 1996).

89 *See* Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1582 n.13, 24 U.S.P.Q.2d (BNA) 1321, 1340-41 n.13 (Fed. Cir. 1992).

90 373 U.S. 379, 137 U.S.P.Q. (BNA) 578 (1963).

91 *See id.* at 386, 137 U.S.P.Q. at 581.

92 *See* Manual of Patent Examining Procedure § 708.02 (7th ed. 1998).

93 *See Jurgens*, 80 F.3d at 1572, 38 U.S.P.Q.2d at 1402.

94 *See Minnesota Mining & Mfg. Co.*, 976 F.2d at 1580, 24 U.S.P.Q.2d at 1339.

95 Underwater Devices Inc. v. Morrison-Knudsen Co., 717 F.2d 1380, 1389-90, 219 U.S.P.Q. (BNA) 569, 576-77 (Fed. Cir. 1983).

96 982 F.2d 1527, 25 U.S.P.Q.2d (BNA) 1241 (Fed. Cir. 1992).

97 *See id.* at 1543-44, 25 U.S.P.Q.2d at 1253-54.

98 *See* Uniroyal, Inc. v. Rudkin Wiley Corp., 939 F.2d 1540, 1546-47, 19 U.S.P.Q.2d (BNA) 1433, 1438 (Fed. Cir. 1991).

99 *See* Central Soya Co. v. Hormel & Co., 723 F.2d 1573, 1577, 220 U.S.P.Q. (BNA) 490, 492 (Fed. Cir. 1983).

¹⁰⁰ See *Yarway Corp. v. Eur-Control USA, Inc.*, 775 F.2d 268, 277, 227 U.S.P.Q. (BNA) 352, 358 (Fed. Cir. 1985).

¹⁰¹ See *Therma-Tru Corp. v. Peachtree Doors, Inc.*, 44 F.3d 988, 997, 33 U.S.P.Q.2d (BNA) 1274, 1280 (Fed. Cir. 1995).

¹⁰² See *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1259, 43 U.S.P.Q.2d (BNA) 1666, 1672 (Fed. Cir. 1997).

¹⁰³ A patent can be in the same family as the asserted patent if it is a Continuation Patent under 35 U.S.C. § 120 (1994), a Divisional Patent under 35 U.S.C. § 121 (1994), 37 C.F.R. § 1.53(b)(1) (1999), or a Continuation-In-Part (CIP) Patent under 37 C.F.R. § 1.53(b)(2) (1999). Accordingly, since the subject matter disclosed in each of these patents or applications may relate to the asserted patent, they are relevant to determining the scope of the asserted patent.

¹⁰⁴ See *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 30, 41 U.S.P.Q.2d (BNA) 1865, 1872 (1997).

¹⁰⁵ See *id.* at 30-31, 41 U.S.P.Q.2d at 1871-72.

¹⁰⁶ See *id.* at 30, 41 U.S.P.Q.2d at 1871.

¹⁰⁷ See *Cybor Corp. v. FAS Tech., Inc.*, 138 F.3d 1448, 1457, 46 U.S.P.Q.2d (BNA) 1169, 1175.

¹⁰⁸ 517 U.S. 370, 38 U.S.P.Q.2d (BNA) 1461 (1996).

¹⁰⁹ See *id.* at 372, 38 U.S.P.Q.2d at 1462.

¹¹⁰ See *Cybor*, 138 F.3d at 1456, 46 U.S.P.Q.2d at 1174-75 (Fed. Cir. 1998).

¹¹¹ See *Multiform Dessicants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477, 45 U.S.P.Q.2d (BNA) 1429, 1432 (Fed. Cir. 1998).

¹¹² See *Environmental Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 696, 218 U.S.P.Q. (BNA) 865, 868 (Fed. Cir. 1983).

¹¹³ See *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1480, 45 U.S.P.Q.2d (BNA) 1498, 1503-04 (Fed. Cir. 1998).

¹¹⁴ See *id.*

¹¹⁵ See 35 U.S.C. §112, ¶ 1 (1994).

¹¹⁶ See *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d (BNA) 1961, 1966 (Fed. Cir. 1997).

¹¹⁷ 90 F.3d 1576, 39 U.S.P.Q.2d (BNA) 1573 (Fed. Cir. 1996).

¹¹⁸ See *id.* at 1582, 39 U.S.P.Q.2d at 1576.

¹¹⁹ See *Bell & Howell Document Management Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706, 45 U.S.P.Q.2d (BNA) 1033, 1038 (Fed. Cir. 1997).

¹²⁰ See *Key Pharm., Inc. v. Hercon Lab. Corp.*, 161 F.3d 709, 716, 48 U.S.P.Q.2d (BNA) 1911, 1917 (Fed. Cir. 1998).

¹²¹ See 35 U.S.C. § 112, ¶ 6 (1994) (permitting claims drafted in means plus function format to cover a step or means in a combination claim to cover structures, materials and acts described in the specification and equivalents thereof).

¹²² See *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 936, 4 U.S.P.Q.2d (BNA) 1737, 1739 (Fed. Cir. 1987).

¹²³ See *Valmont Indus., Inc. v. Reinke Mfg. Co.*, 983 F.2d 1039, 1042, 25 U.S.P.Q.2d (BNA) 1451, 1453-54 (Fed. Cir. 1993).

¹²⁴ Cf. *In re Vickers*, 141 F.2d 522, 525, 61 U.S.P.Q. (BNA) 122, 125 (C.C.P.A. 1944).

¹²⁵ 73 F.3d 1573, 37 U.S.P.Q.2d (BNA) 1365 (Fed. Cir. 1996).

¹²⁶ *Id.* at 1581, 37 U.S.P.Q.2d at 1372.

¹²⁷ 86 F.3d 1098, 39 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 1996).

¹²⁸ See *id.* at 1106, 39 U.S.P.Q.2d at 1006.

¹²⁹ See 35 U.S.C. § 282 (1994 & Supp. III 1997).

¹³⁰ See *Whittaker Corp. v. UNR Indus., Inc.*, 911 F.2d 709, 712, 15 U.S.P.Q.2d 1742, 1744 (Fed. Cir. 1990).

¹³¹ See *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1580, 12 U.S.P.Q.2d (BNA) 1382, 1386 (Fed. Cir. 1989).

¹³² See *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 936, 4 U.S.P.Q.2d (BNA) 1737, 1739 (Fed. Cir. 1987).

¹³³ Section 112, paragraph 6 states that:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

¹³⁴ See *Valmont Indus., Inc. v. Reinke Mfg. Co.*, 983 F.2d 1039, 1041-42, 25 U.S.P.Q.2d (BNA) 1451, 1454 (Fed. Cir. 1993).

¹³⁵ 35 U.S.C. § 101 (1994).

¹³⁶ *Palsgraf v. Long Island Ry. Co.*, 162 N.E. 99 (N.Y. 1928).

¹³⁷ 145 F.3d 1303, 46 U.S.P.Q.2d (BNA) 1752 (Fed. Cir. 1998).

¹³⁸ *See id.* at 1311, 46 U.S.P.Q.2d at 1758.

¹³⁹ 802 F.2d 1367, 231 U.S.P.Q. (BNA) 81 (Fed. Cir. 1983).

¹⁴⁰ *See id.* at 1384, 231 U.S.P.Q. at 94.

¹⁴¹ *See Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1390, 219 U.S.P.Q. (BNA) 569, 577 (Fed. Cir. 1983).

¹⁴² *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583, 39 U.S.P.Q.2d (BNA) 1573, 1577-78 (Fed. Cir. 1996).

¹⁴³ *See Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 40-41, 41 U.S.P.Q.2d (BNA) 1865, 1876 (1997).

¹⁴⁴ *Id.* at 17, 41 U.S.P.Q.2d at 1866.

¹⁴⁵ *See id.* at 38, 41 U.S.P.Q.2d at 1875.

¹⁴⁶ *See Zygo Corp. v. Wyko Corp.*, 76 F.3d 1563, 1570, 38 U.S.P.Q.2d (BNA) 1281, 1286 (Fed. Cir. 1996).

¹⁴⁷ *See Warner-Jenkinson*, 520 U.S. at 33-34, 41 U.S.P.Q.2d at 1873.

¹⁴⁸ *See Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1326, 50 U.S.P.Q.2d 1865, 1873 (Fed. Cir. 1999).

¹⁴⁹ *See Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1310, 46 U.S.P.Q.2d (BNA) 1752, 1758 (Fed. Cir. 1998).

¹⁵⁰ *See Warner-Jenkinson*, 520 U.S. at 39 n.8, 41 U.S.P.Q.2d at 1875 n.8 (1997).

¹⁵¹ *See Maxwell v. Baker*, 86 F.3d 1098, 1106, 39 U.S.P.Q.2d (BNA) 1001, 1006 (Fed. Cir. 1996).

¹⁵² 145 F.3d 1317, 46 U.S.P.Q.2d (BNA) 1843 (Fed. Cir. 1998).

¹⁵³ *See id.* at 1322, 46 U.S.P.Q.2d (BNA) 1843, 1847 (Fed. Cir. 1998).

¹⁵⁴ *See Datascope Corp. v. SMEC Inc.*, 879 F.2d 820, 828, 11 U.S.P.Q.2d (BNA) 1321, 1327 (Fed. Cir. 1998).

¹⁵⁵ *See National Recovery Tech., Inc. v. Magnetic Separations Sys., Inc.*, 166 F.3d 1190, 49 U.S.P.Q.2d (BNA) 1671, 1675-76 (Fed. Cir. 1999).

¹⁵⁶ It goes without saying that any lack of compliance with the requirements of 35 U.S.C. § 101 *et seq.* is grounds for patent invalidity.

¹⁵⁷ See 35 U.S.C. § 282 (1994 & Supp. III 1997); *Trans-World Mfg. Corp. v. A1 Nyman & Sons, Inc.*, 750 F.2d 1552, 1560, 224 U.S.P.Q. 259, 263 (Fed. Cir. 1984).

¹⁵⁸ See *Aktiebolaget Karlstads Mekaniska Werkstad v. United States Int'l Trade Comm'n*, 705 F.2d 1565, 1577, 217 U.S.P.Q. (BNA) 865, 873-74 (Fed. Cir. 1983).

¹⁵⁹ See *Preemption Devices, Inc. v. Minnesota Mining & Mfg. Co.*, 732 F.2d 903, 907, 221 U.S.P.Q. (BNA) 841, 843 (Fed. Cir. 1984).

¹⁶⁰ See *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-60, 220 U.S.P.Q. (BNA) 763, 770-71 (Fed. Cir. 1984).

¹⁶¹ See *id.*

¹⁶² See *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1364, 47 U.S.P.Q.2d (BNA) 1705, 1721-22 (Fed. Cir. 1998).

¹⁶³ See *Underwater Devices Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1390, 219 U.S.P.Q. (BNA) 569, 577 (Fed. Cir. 1983).

¹⁶⁴ See *Standard Havens Prod., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1369, 21 U.S.P.Q.2d 1321, 1328 (Fed. Cir. 1991).

¹⁶⁵ See 35 U.S.C. § 102(a), (b) (1994).

¹⁶⁶ See 35 U.S.C. § 102(b) (1994).

¹⁶⁷ See *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1062, 12 U.S.P.Q.2d (BNA) 1449, 1454 (Fed. Cir. 1989).

¹⁶⁸ See *id.*

¹⁶⁹ See *Tone Bros., Inc. v. Sysco Corp.*, 28 F.3d 1192, 1198, 31 U.S.P.Q.2d (BNA) 1321, 1324-25 (Fed. Cir. 1994).

¹⁷⁰ *In re Smith*, 714 F.2d 1127, 1134, 218 U.S.P.Q. (BNA) 976, 983 (Fed. Cir. 1983) (citing *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881)).

¹⁷¹ *Tone Bros., Inc.*, 28 F.3d at 1198, 31 U.S.P.Q.2d at 1324.

¹⁷² See *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d. 1368, 1371, 47 U.S.P.Q.2d (BNA) 1363, 1366 (Fed. Cir. 1998).

¹⁷³ See 35 U.S.C. § 282 (1994 & Supp. III 1997).

¹⁷⁴ 104 U.S. 333 (1881).

¹⁷⁵ See *id.* at 336.

¹⁷⁶ See 35 U.S.C. § 102(b) (1994).

¹⁷⁷ 525 U.S. 55, 48 U.S.P.Q.2d (BNA) 1641 (1998).

¹⁷⁸ See *id.* at 311-12, 48 U.S.P.Q.2d at 1646-47.

¹⁷⁹ See *Envirotech Corp. v. Westech Engineering, Inc.*, 904 F.2d 1571, 1574, 15 U.S.P.Q.2d (BNA) 1230, 1232 (Fed. Cir. 1990).

¹⁸⁰ 163 F.3d 1326, 49 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 1998).

¹⁸¹ See *id.* at 1333, 49 U.S.P.Q.2d at 1007.

¹⁸² See *id.* at 1333-34, 49 U.S.P.Q.2d at 1007.

¹⁸³ FED. R. CIV. P. 30(a)(2).

¹⁸⁴ See generally *LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1071, 22 U.S.P.Q.2d 1025, 1028 (Fed. Cir. 1992).

¹⁸⁵ See *Sensonics, Inc. v. Aerasonic Corp.*, 81 F.3d 1566, 1571, 38 U.S.P.Q.2d (BNA) 1551, 1555 (Fed. Cir. 1996).

¹⁸⁶ See *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881, 45 U.S.P.Q.2d (BNA) 1977, 1981 (Fed. Cir. 1998).

¹⁸⁷ See *Graham v. John Deere*, 383 U.S. 1, 17-18, 148 U.S.P.Q. (BNA) 459, 467 (1966).

¹⁸⁸ See *In re Huang*, 100 F.3d 135, 139-40, 40 U.S.P.Q.2d (BNA) 1685, 1689-90 (Fed. Cir. 1996).

¹⁸⁹ See *In re Mayne*, 104 F.3d 1339, 1342, 41 U.S.P.Q.2d (BNA) 1451, 1454 (Fed. Cir. 1997).

¹⁹⁰ See *Arkie Lures Inc. v. Gene Larew Tackle Inc.*, 119 F.3d 953, 957, 43 U.S.P.Q.2d (BNA) 1294, 1297 (Fed. Cir. 1997).

¹⁹¹ See *In re Dow Chemical*, 837 F.2d 469, 473, 5 U.S.P.Q.2d (BNA) 1529, 1532 (Fed. Cir. 1988).

¹⁹² See *In re Geiger*, 815 F.2d 686, 688, 2 U.S.P.Q.2d (BNA) 1276, 1278 (Fed. Cir. 1987).

¹⁹³ See *Pro-Mold & Tool Co. Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 U.S.P.Q.2d (BNA) 1626, 1630 (Fed. Cir. 1996).

¹⁹⁴ See *In re Sernaker*, 702 F.3d 989, 994, 217 U.S.P.Q. (BNA) 1, 5 (Fed. Cir. 1983).

¹⁹⁵ See *Pro-Mold & Tool Co. Inc.*, 75 F.3d at 1573, 37 U.S.P.Q.2d at 1630.

196 *See* Sensonics, Inc. v. Aerosonic Corp., 81 F.3d 1566, 1570, 38 U.S.P.Q.2d (BNA) 1551, 1554 (Fed. Cir. 1996).

197 *See* FED. R. CIV. P. 9(b).

198 *See* FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415, 5 U.S.P.Q.2d (BNA) 1112, 1115 (Fed. Cir. 1987).

199 *See* Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co., 324 U.S. 806, 818, 65 U.S.P.Q. (BNA) 133, 139 (1945).

200 *See* Molins PLC v. Textron Inc., 48 F.3d 1172, 1180, 33 U.S.P.Q.2d (BNA) 1823, 1828 (Fed. Cir. 1995).

201 *See* Patent Cooperation Treaty, June 19, 1970, art. 16, 28 U.S.T. 7645, 1160 U.N.T.S. 231.

202 *See id.* at art. 15-16, 18.

203 *See* ATD Corp. v. Lydall, Inc., 159 F.3d 534, 547, 48 U.S.P.Q.2d (BNA) 1321, 1330-31 (Fed. Cir. 1998).