

The Next Generation of Freedom-to-Operate

Gregory W. Smock
Schwegman Lundberg & Woessner, P.A.
Minneapolis

Suneel Arora
Schwegman Lundberg & Woessner, P.A.
Minneapolis

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Introduction

In a crowded patent landscape, does performing a comprehensive freedom-to-operate (“FTO”) or clearance investigation become cost prohibitive for companies, such as start-up technology companies with limited funding? Can venture capitalists or acquiring companies perform more efficient and effective FTO investigations when undertaking due diligence on a company of interest? Can investment in FTO investigations be reused or leveraged for other strategic purposes, such as offensive assertion analysis, invalidity indexing, or false marking review?

This paper addresses the fundamentals of an FTO investigation and how such an investigation can be fundamentally reshaped to maximize its value. In particular, FTO clearance investigations, willful infringement, opinions, privileges, and techniques for more efficient and cost effective FTO are discussed.

Fundamentals of a Freedom-to-Operate Investigation

Freedom-to-Operate 101

Despite the common misconception suggesting otherwise, a patent by itself does not provide a company with the right to commercialize its protected technology, but rather, only the right to exclude all others from commercializing it. FTO, or the right to commercialize the protected technology without fear of litigation, requires the absence of non-licensed third-party patents that would block otherwise infringing activities, such as making, using, selling or offering to sell a patented product or process.ⁱ

An FTO investigation is intended to proactively identify potential barriers to a company’s product or process launch in a specific market. Each specific market includes an associated patent landscape, which can be conceptualized

as a tract of land divided into parcels by boundaries. For example, some patents (or parcels) may be owned by your company or your client’s company, some patents (or parcels) may be owned by a third-party, and some patent space (or parcels) may currently be unclaimed.

A good FTO investigation enables a company to clearly assess patents having desirable patent claim coverage (or desirable parcels of land). In this way, the company can identify infringement risks (or parcels of land that may be trespassed on) and aid in the design of a country-by-countryⁱⁱ strategy for the research, development and commercialization of its product or process. It should, however, be noted that there is an inherent uncertainty in any FTO investigation as the patent landscape of interest can never be completely up to date due to an 18-month time lag between patent filing and publication.ⁱⁱⁱ For this reason, it is recommended that any FTO investigation be updated periodically to identify any relevant, newly published patent applications.

In short, an FTO investigation is an informed, reasoned, and calculated best estimate of potential for infringement liability, in a given jurisdiction, at a given period of time.

Two Flavors of Patent Infringement

Determining whether a patent is infringed is a two-step process. First, the asserted claim or claims of the patent are construed (i.e., interpreted) to establish their meaning and scope. Second, the claims as construed are compared to the product or process accused of infringement. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454, (Fed. Cir. 1998) (*en banc*).

Patent infringement comes in two flavors—“literal infringement” and infringement under the “doctrine of equivalents.” “Literal infringement” means that a company’s proposed product or process literally infringes a

third-party's patent claim. See *Eklay Mfg. Co. v. EBCO Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999). This is in comparison to infringement under the "doctrine of equivalents," a judicially created doctrine, which can attach infringement liability in the absence of literal infringement. Thus, even if a company's product or process does not fall within the literal scope of a third-party patent claim, but is nevertheless equivalent to the claimed combination, infringement liability can attach. To infringe a claim under the "doctrine of equivalence," an accused product or process must include an equivalent for each claim limitation that is not literally present. *Dawn Equip. Co. v. Kentucky Farms*, 140 F.3d 1009, 1015 (Fed. Cir. 1998).

If each element of at least one claim is either identically or equivalently^{iv} met by the accused device or process, the patent is infringed.

Pros and Cons of an FTO Investigation

A company that timely undertakes an FTO investigation can beneficially:

1. Acquire at least some peace of mind regarding infringement risks when moving forward with a new product or process;
2. Learn of possible impediments before making a significant investment in a new product or process;^v
3. Proactively develop a forward-looking strategy for identified problematic patents, such as seeking out a license when some flexibility and leverage exists, design around a patent before it is asserted, prepare an opinion, or use judicial or administrative means to "kill" a patent;
4. Reduce exposure to a willful infringement finding (see, e.g., mechanisms listed in no. 3, *supra*); and
5. Potentially save on prosecution costs by leveraging FTO investigation findings for patentability studies.

Typical company drawbacks to an FTO investigation include:

1. High costs—up to \$50,000 to \$100,000+ for a comprehensive FTO search in a crowded field, review of search results, and preparation of one or more opinions for patents having a high likelihood of an infringement charge;^{vi} and
2. Consuming personnel time (e.g., engineers, managers, etc.)

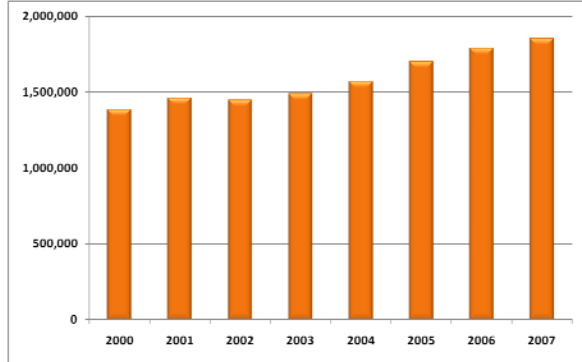
Patent Law in the New Millennium

In today's intellectual property (IP) environment, establishing FTO is becoming more difficult due to a heightened awareness around IP rights and the increased number of patent application filings and issued patents it has generated.

Looking back to the 1960s, less than 250,000 patents were in force. If an FTO investigation was undertaken during the 1960s, it was a comparatively easy review and the odds of infringing a patent "by accident" were low. For these or other reasons, companies often skipped FTO investigations to save money. By 1990, approximately 1,000,000 patents were in force and court enforcement of patents started becoming more common. By the end of the 1990s, it was rare for there to be no patent issues for a company to resolve when performing an FTO investigation on a new product or process.

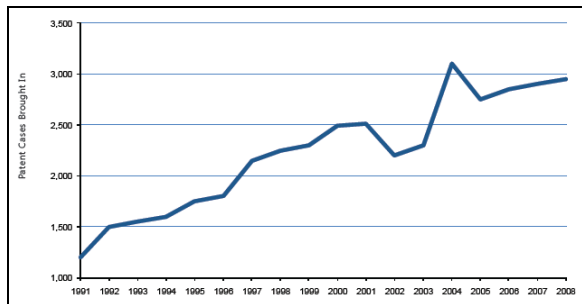
Today, near 2,000,000 patents are in force and patent litigation is at or near its all-time peak. (See Figures 1 and 2.) In 2008, almost 3,000 patent infringement actions were filed in U.S. Federal Courts compared to less than 1,000 actions filed in the early 1990s. It is, therefore, increasingly important for companies to establish FTO to reduce the risk of patent infringement before sinking resources into a new product or process.

Figure 1: U.S. Patents in Force.



Source: WIPO Statistics Database, June 2009

Figure 2: Patent Cases Brought in U.S. Federal Courts Since 1991.



Sources: U.S. Patent and Trademark Office: Performance and Accountability; Report and U.S. Courts: Judicial Facts and Figures (years are based on September year-end)

FTO Investigation Process

How can a company learn about a patent landscape associated with the technology area of its product or process? This involves conducting a product or process clearance investigation to proactively identify patents in the technology area of interest.

The costs of not doing a clearance investigation can be significant. For example, a third-party patent owner may be able to get an injunction, thereby blocking your company or your client's company from making, using, selling or offering to sell its product or process. Other ramifications can include a finding of willful patent infringement resulting in increased damages (discussed below), or paying a significant royalty to the third-party patent holder.

1. Define Target Product or Process

It is most efficient to fully understand the scope of a target product or process before performing an FTO investigation, particularly before performing a comprehensive patent landscape clearance search. To this end, it is important to interview a company's technical experts to better understand the target landscape scope and the product or process of interest.

2. Search

In general, an FTO investigation can never guarantee that a company has a clear path to market its product or process. It is necessarily limited by the effectiveness of the product or process clearance search, and accordingly, the conclusions of any FTO investigation should reflect this lack of complete certainty.

An effective clearance search includes multiple search strategies and possibly multiple searchers, databases,^{vii} or searching facilities to get a good view of the patent landscape of interest. All aspects of the product or process should be considered and searched, if practicable. This includes meticulously dissecting the product or process into its fundamental components and then scrutinizing each component for any third-party patent rights. If previous clearance searches have been carried out on earlier versions of the product or process, it may be possible to focus the clearance search on those aspects of the product or process that are considered new over the previous product or process.



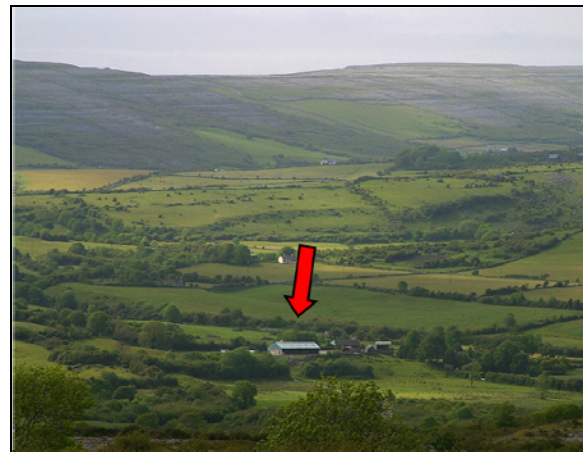
The early preparations for an FTO investigation are crucial because they will influence all that follows and, accordingly, determine the quality of the resulting FTO work product. Different searching strategies can identify and use applicable keyword algorithms, known prolific inventors, known competitor assignees, forward and backward citation searches of particularly interesting references, and/or U.S. Patent & Trademark Office (“USPTO”) or international patent classifications. Although the competitive patent landscape will be determined by issued patents and published patent applications of others, the clearance search should still consider non-patent literature as well as a company’s own issued patents and published patent applications. This will help to put the patent rights of others in the appropriate context, as well as to help identify company-owned bargaining chips for licensing negotiations. Visual patent claim charting, as discussed below, may also help the company understand where it can and cannot go.

3. Identify

Following the FTO patent landscape search, an attorney and technical expert undertake the time consuming and expensive process of pouring through the search hits to identify the set of patents requiring an in-depth analysis. At this stage of an FTO investigation, the attorney and technical expert should be looking for any patent documents that do not have any outward reason to eliminate from consideration in light of a company’s target product or

process. That is, do any of the patent landscape claims literally cover, or could they, under the “doctrine of equivalents,” cover the product or process technology used or contemplated? If the answer is yes, then further detailed analysis is required to study the boundaries of the problematic patent claims. If the answer is no, then one or more grounds for non-infringement of each patent document can be recorded.

The FTO patent landscape may be littered with potential problematic patents. It is important to proactively identify and deal with these potentially problematic patents (or property) owned by a third-party.



As third-party rights of patents and the legal landscape changes and evolves, the dynamics of the results of an FTO patent landscape may also change. For example, some of these “problematic” patents may issue, expire, or be invalidated; licenses may be granted or terminated; or patents may be assigned and then reassigned. The patent term may be shortened by a terminal disclaimer of another patent.

The expired patents may represent a “safe harbor” opportunity, for example, if a claim of the expired patent fully covers the company’s product or process. Since the subject matter claimed in a patent becomes dedicated to the public upon its expiration, such an expired patent may provide a “safe harbor” in which the

company can operate without risking patent infringement. Care should be exercised, however, to ensure that the company does not need access to any still-patented improvements on the expired patent. Similarly, safe harbor may lie in a patent that is still in force but which has disclosed but failed to claim the desirable subject matter. See *Johnson & Johnston Assocs. Inc. v. R.E. Service*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). This holds true if such a patent has no children patent applications still pending, which could provide an opportunity for obtaining broader or otherwise problematic claims. Further, such a patent should have issued beyond the two-year window for obtaining a reissue patent application with broader claims. See 35 USC § 251.

4. Analyze and Assess

A good FTO investigation strategy requires careful business and legal considerations when dealing with potentially problematic patents, including a balance between possible risks and anticipated benefits. The strategy should analyze the claims of those patent matters identified as requiring an in-depth review to determine their boundaries, consider all options, and then decide on the approach that best fits the goals of your company or your client's company and its tolerance to risk.



Dealing with Potentially Problematic Patents

Factors that can help determine the best approach for your company or your client's company to deal with a potentially problematic patent includes, among others, the nature of the technology, the company's goals, available licensing opportunities, validity position of the patent, design around opportunities and jurisdiction.

It can be best to have a step-wise approach to arrive at an optimum solution to deal with a given patent situation. This may include waiting until the patent expires or, alternatively, steering research, or making changes^{viii} to the product or process in order to avoid infringement risks. If redesigning to clearly avoid infringement is not a viable option, other alternatives such as licensing or cross-licensing^{ix} for the blocking patent, obtaining a non-infringement, invalidity or unenforceability opinion, or seeking to invalidate the patent through a Patent Office opposition or reexamination proceeding, or a declaratory judgment suit may be considered.

When to Perform a Freedom-to-Operate Investigation

Various situations can trigger the need to start thinking about an FTO investigation including:

1. Clearing prospective licensed or acquired technology (product or process);
 2. Evolving research and development on a product or process;
 3. Upcoming launching of a product or process in a marketplace; and/or
 4. Lapse in time since last FTO investigation.
- New patents are being issued on a weekly basis by patent offices throughout the world.

When to best conduct the actual FTO investigation is a frequently raised issue that depends on a company's particular circumstances at hand. If the FTO clearance search is conducted too early, such as during an

early research phase, the final product or process may evolve in unexpected ways and much of the search may turn out to be inapplicable. On the other hand, waiting too long to conduct the clearance search can also be problematic, as it usually means that the product is too far along to change.

Cost-sensitive companies may choose to defer an FTO investigation until after research and development of a product or process with the goal of minimizing costs. The underlying thought is that if features of a product or process have been defined, the applicable FTO patent landscape will be smaller than would be the case with a less well-defined product or process. However, it is important to note that a substantial redesign may be needed if one or more blocking patents are found during a late-conducted FTO investigation. If a substantial redesign is needed, release of the company's product will likely be delayed, manufacturing retooling may be needed, and bad PR for the company can result.

It can be a better approach to perform an FTO investigation before and during the research and development phase of the product or process. This allows one or more features of the product or process to adapt if and when any problematic blocking patent is found. While this approach is typically the most expensive and time consuming because it requires an iterative review of design permutations and applicable patent documents, interactive claim charts (discussed below) can help keep costs and time consumption to a minimum.

The Evolving Role of Notice and Duty of Care

Until the recent decision of *In re Seagate* ("Seagate") (discussed below), there was particular concern regarding the effect of being put on "notice" of potential infringement problems and the affirmative duty of due care that such notice triggers. See *In re Seagate Techn., LLC*, 497 F.3d 1360 (Fed. Cir. 2007). Before *Seagate*, when a company received an

actual notice of another's patent(s), it had an affirmative duty to exercise due care to investigate whether the patent(s) were valid and infringed upon. See *Underwater Devices, Inc. v. Morrison-Knudsen Co., et al.*, 717 F.2d 1380, 1389 (Fed. Cir. 1983).

Notice triggering the affirmative duty of due care focused on a potential infringer's knowledge of another's patent rights. For example, getting sued, of course, constitutes knowledge of the patent rights triggering the affirmative duty of due care. See *Crystal Semiconductor v. Tritech Microelec. Int'l, Inc.*, 246 F.3d 1336 (Fed. Cir. 2001). Receiving a "Cease and Desist" letter also constitutes such knowledge of the patent rights triggering the affirmative duty of due care. See *Mentor HIS, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365, 1379 (Fed. Cir. 2001). Getting a written or verbal offer of license similarly amounts to knowledge of the patent rights sufficient to trigger the affirmative duty of due care. See *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1577 (Fed. Cir. 1985) (written license offer); see also *Power Lift, Inc. v. Lang Tools, Inc.*, 774 F.2d 478,482 (Fed. Cir. 1985) (telephone license offer). Requesting or becoming a party to an interference proceeding also can constitute knowledge of the patent rights triggering the duty of due care. See *E.J. DuPont De Nemours and Co. v. Monsanto Co.*, 903 F.Supp. 680, 741 (D. Del. 1995).^x Additionally, an infringer may also obtain notice independently through his/her own patent search. See *Studiengesellschaft Kohle, mbH v. Dart Indus., Inc.*, 862 F.2d 1564, 1576 n.4, 9 USPQ2d 1273, 1284 n.4 (Fed. Cir. 1988).

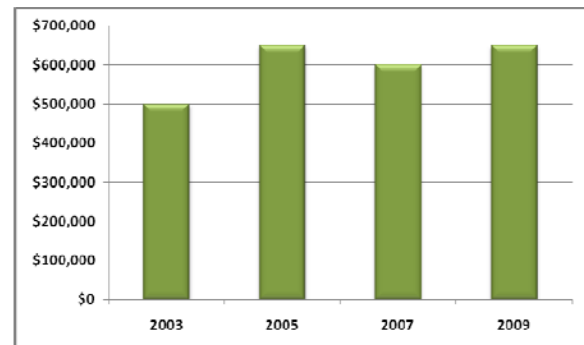
In summary, before *Seagate's* abandonment of the duty of due care, it is clear that such duty could arise well before receiving actual notice of infringement from a patentee. Knowledge of the infringement was not required; instead, it was knowledge of the patent rights that created the duty of due care.

Willfulness

Understanding the law surrounding willful patent infringement is helpful to preparing, evaluating, or opting not to execute a non-infringement or invalidity opinion letter. In a patent infringement suit, a finding of patent infringement may lead to an award of enhanced damages. A judicial doctrine of “willfulness” has risen over the patent statute’s provision for a trebling of damages. See 35 USC § 284.^{xi} Due to the monetary incentive of treble damages, willfulness is frequently alleged. One study in 2004 showed that willfulness was alleged in over 90% of infringement cases. Kimberly A. Moore, *Empirical Statistics on Willful Patent Infringement*, 14 Fed. Cir. B.J. 227, 232 (2004) (detailing a study conducted by Professor Moore, now a Federal Circuit judge, on cases from 1999-2000). Thus, it is important for companies and its attorneys dealing with patented technology to be aware of ways to defend against and avoid charges of willfulness.

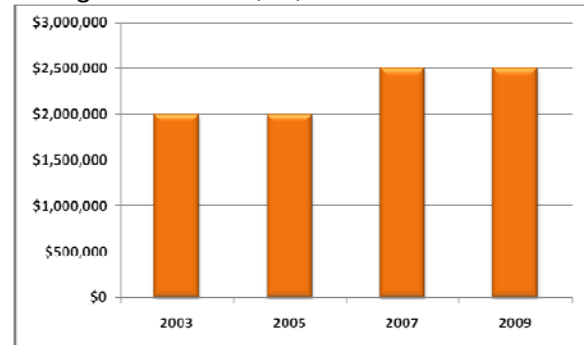
Moreover, a court “may in exceptional cases award reasonable attorney fees to the prevailing party.” See 35 USC § 285. Whether a case is exceptional is linked to, but not necessarily coextensive with, willful infringement. The American Intellectual Property Law Association (“AIPLA”) reports median litigation costs (per side) for patent litigation cases reaching trial. See Figures 3-5. In 2009, a company could expect to pay about \$650,000 for a litigation matter when less than \$1 million was at stake, \$2.5 million for a litigation matter when between \$1-\$25 million was at stake, and \$5.5 million for a litigation matter when more than \$25 million was at stake. Therefore, a significant dollar value may attach to attorney fees for exceptional cases potentially creating a separate risk even in cases where actual damages would be small.

Figure 3: Median Litigation Costs for Patent Infringement When Less Than \$1 Million is at Risk.



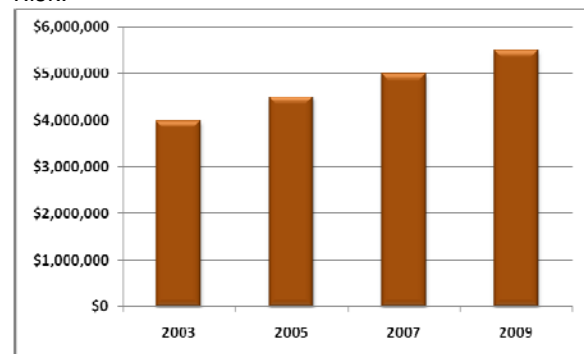
Source: AIPLA Report of Economic Survey 2009

Figure 4: Median Litigation Costs for Patent Infringement When \$1-\$25 Million is at Risk.



Source: AIPLA Report of Economic Survey 2009

Figure 5: Median Litigation Costs for Patent Infringement When More Than \$25 Million is at Risk.



Source: AIPLA Report of Economic Survey 2009

Because the patent code, particularly 35 USC § 284, does not define the conditions or circumstances justifying enhanced damages, courts have been left to decide on their own

what justifies the imposition of enhanced damages. Various factors have been considered. A good-faith belief that the patent is invalid or not infringed will usually justify denial of enhanced damages. Enhanced damages are likely if the infringing activity is shown to have been undertaken deliberately. “Willfulness” is the catch-all word often used to characterize the justification for enhanced damages. While there are no hard and fast rules, a finding of no willfulness has typically been supported by reliance on an opinion of counsel while willfulness has been based on a deliberate disregard of warning signs, deceptive conduct, etc. Most often these factors play out in varying degrees within the context of all of the facts of a case.

For more than 20 years, U.S. case law held that a potential patent infringer had to “exercise due care to determine whether or not he is infringing” and that such duty includes, among other things, “the duty to seek and obtain competent legal advice.” *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1389-90 (Fed. Cir. 1983). Although courts considered the “totality of the circumstances” in assessing willfulness,^{xii} in practice, the analysis usually focused on whether the defendant acquired a competent opinion of counsel. *See, e.g., Electro Med. Sys., S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048, 1056 (Fed. Cir. 1994) (“possession of a favorable opinion of counsel is not essential to avoid a willfulness determination; it is only one factor to be considered, albeit an important one.”) Thus, when a company received a demand letter from a third-party accusing them of infringement, the receiving company would generally attempt to satisfy its affirmative duty to investigate that charge by obtaining an opinion of counsel. U.S. law further held that a defendant’s failure to produce an opinion in litigation warranted an “adverse inference” that any opinion would have been unfavorable to the alleged infringer. *Fromson v. W. Litho Plate & Supply Co.*, 853 F.2d 1568, 1572-73 (Fed. Cir. 1988).

In 2004, the Court of Appeals for the Federal Circuit (Federal Circuit) redefined the consequences of obtaining or not obtaining an opinion. As a result, an adverse inference regarding willful infringement can no longer be made if an opinion is not produced during trial.^{xiii} *See Knorr-Bremse Systeme Fuer Nutzarzeuge GMBH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004). Yet, the *Knorr-Bremse* decision further held that opinions are still relevant to determining willful infringement, enhanced damages, and an award of attorneys’ fee to the winning party.

In *Seagate*, the Federal Circuit held that proof of willful infringement requires an objective showing of recklessness. *In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007). To the extent that the previous affirmative duty of care invoked a mere negligence standard, *Seagate* raised the bar for finding willful infringement. In theory, it should now be more difficult for a patentee to prevail on a claim for willful infringement. *Seagate* established a two-step test for determining objective recklessness:

1. The patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions infringed a valid patent. In making this threshold determination, the infringer’s subjective state of mind is irrelevant; and
2. If the patentee can meet this threshold requirement, then the patentee must demonstrate that the objectively high risk was either known or should have been known to the infringer. *See id.*

In addition, the *Seagate* court noted that because it is abandoning the affirmative duty of care, “there is no affirmative obligation to obtain opinion of counsel,” effectively restoring the status of a competent legal opinion to one consideration in the long-standing “totality of circumstances test.” *See id.* at 1369-1371. Previously, many accused infringers felt compelled to obtain a formal non-infringement or invalidity opinion from an attorney whenever

they were confronted with the threat of a patent infringement suit.

While *Seagate* cut against the necessity of having to obtain a formal opinion of counsel to convincingly defend against allegations of willful infringement, it can still be advantageous to have an opinion in place. It could, for example, be one of the best pieces of evidence in your client's willfulness defense.

Unanswered Questions after Seagate

The Federal Circuit's decision in *Seagate*, like many court decisions, left some unanswered questions, including:

1. Now that the importance of opinions for willfulness purposes is diminished, under what circumstances is it helpful for a potential infringer to obtain an opinion of counsel?
2. What types of evidence can be used to prove or disprove objective recklessness?
3. What is a patentee's evidentiary burden with regard to proving that a potential infringer knew or should have known of an objectively high risk of infringement?

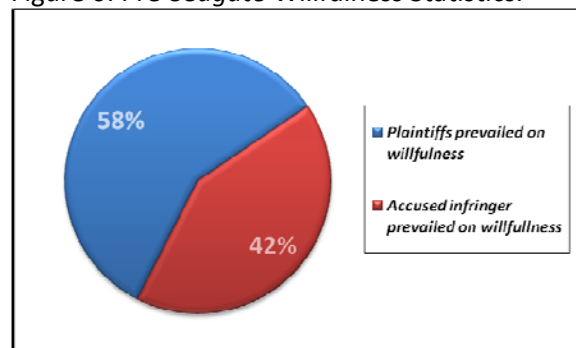
In answer to question no. 1, one commentator^{xiv} has suggested at least three situations in which an opinion is still valuable post-*Seagate*^{xv}:

1. Situations where an accused infringer believes that it is at risk of being named as a defendant in a patent infringement suit. By way of an opinion, the accused infringer can document a reasonable belief that its actions did not amount to infringement of a valid patent;
2. Due diligence situations, which include a "freedom-to-operate" opinion, to minimize infringement risks and reassure investors, lenders, and possible acquirers; and
3. Pre-litigation preparation by patent holders, to ensure that they have a reasonable basis for filing a patent suit against a believed infringer.

Post-Seagate World

Statistical analysis of recent court decisions can make it easier to interpret *Seagate*'s practical impact. Before *Seagate*, plaintiffs were more likely than accused infringers to prevail on a charge of willfulness. In a study of 148 cases between 2000 and August 2007 (before *Seagate* was decided) in which courts made a finding regarding willful infringement, Plaintiffs prevailed on willfulness 58% of the time.

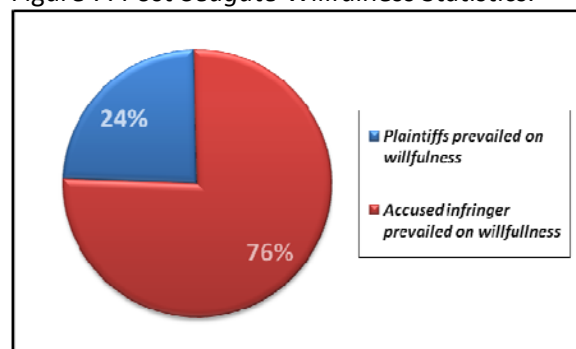
Figure 6: Pre-*Seagate* Willfulness Statistics.



Source: Erin Coe, *Courts Get Tough on Willfulness after Seagate*, Law360, March 2, 2009 (citing statistics from the University of Texas Law Center)

However, in a post-*Seagate* study of 29^{xvi} decisions published after August 2007, Plaintiffs prevailed on willfulness a mere 24% of the time.

Figure 7: Post-*Seagate* Willfulness Statistics.



Source: Erin Coe, *Courts Get Tough on Willfulness after Seagate*, Law360, March 2, 2009 (citing statistics from the University of Texas Law Center)

Based on this initial data, *Seagate* appears to have significantly narrowed the range of situations in which a patent holder can now

credibly assert willful infringement. Where the damages model depends at least in part on a finding of willfulness, the *Seagate* decision may motivate some patent holders to reconsider bringing costly patent infringement cases (see Figures 3-5, *supra*) and instead encourage them to negotiate less costly settlements, seek licensing arrangements, or take no action at all. If the patent holder is less likely to obtain lucrative treble damages, the potential return may not justify the overall investment necessary to reach that return.

In the context of FTO investigations, the *Seagate* decision may have tempered the threat of a future charge of willfulness as a reason to avoid a patent clearance search. Before *Seagate*, the mere knowledge of an existing patent might be enough to trigger an affirmative duty of care and obtaining an expensive opinion of counsel. In today's post-*Seagate* world, however, it seems more likely that conducting a competent clearance search may instead help weigh against a finding of willfulness under the current objective recklessness standard.

Some Additional Post-Seagate Statistics

Seagate held that obtaining a competent opinion of counsel is not an absolute requirement. However, it may still help foreclose the possibility of a successful charge of willfulness. Interesting statistical data was compiled and presented by Kurt Rogers, now chief legal officer and secretary of Vonage Holdings Corp., in March 2009. In his presentation, "*Willful Patent Infringement: Post-Seagate Trends*," Mr. Rogers analyzed post-*Seagate* statistics from Federal Circuit and District Court decisions. (<http://www.cipla.net/calendar/rogers.pdf>, visited on August 18, 2010). Mr. Rogers found that, among other things:

1. The presence or absence of a legal opinion was addressed by courts in 14 of the 29 post-*Seagate* cases. In 3 of the 14 cases, the

accused infringer did not have an opinion but still avoided a finding of willfulness. Conversely, other cases demonstrated that relying upon an invalidity argument that was previously rejected by the USPTO, such as during normal patent examination, can lead to a finding of willful infringement.^{xvii} Thus, patentees and accused infringers should carefully consider prior USPTO decisions when developing an invalidity position;

2. All 4 post-*Seagate* cases that included a bench trial resulted in a finding of no willful infringement; and

3. All 8 post-*Seagate* cases involving a defendant's motion for summary judgment resulted in a finding of no willful infringement.

While circumstances may vary for individual cases, these statistics may be useful in helping evaluate some different bases for prevailing on the decision of willfulness

From the patentee's point of view, although *Seagate* has made establishing willfulness more difficult, chances for such a finding of willfulness may be improved by preparing a detailed Cease-and-Desist demand letter to an accused infringer making subsequent behavior by the accused infringer more likely to meet the two-prong test for objective recklessness (set forth by *Seagate*). This is particularly true if the patentee can predict and discredit any defenses that an alleged infringer might raise.

Opinions

Many FTO investigations conclude with one or more non-infringement, invalidity, or unenforceability opinions for patents having a high likelihood of an infringement charge. The opinion of counsel need not address both invalidity and infringement. In *Finisar Corp. v. DirectTV Group, Inc.*, the Federal Circuit stated that "a competent opinion of counsel" directed to non-infringement or invalidity "would provide a sufficient basis . . . to proceed without engaging in objectively reckless behavior." See

Finisar Corp., v. DirectTV Group, Inc., 523 F.3d 1323 (Fed. Cir. 2008).

A patent opinion letter is a document drafted by a registered patent attorney to an inventor or company who plans to make, use, sell or offer to sell a product or process. The patent opinion states: (1) that the inventor's or company's product or process does not infringe an existing subject patent (a "non-infringement opinion"); (2) the existing patent is invalid and therefore is incapable of being infringed (an "invalidity opinion"); or (3) the existing patent is unenforceable due to a failure to pay maintenance fees or the relevant claims were "disclaimed" in the Official Gazette,^{xviii} for example.

The audience for an opinion may be a client, a non-client, such as a third-party suitor or investor, or other third parties such as suppliers, distributors, customers, joint ventures, or stockholders. The audience may include both patent counsel and business people. Since an opinion may be relied upon and produced in a patent infringement trial, the audience may include a judge or jury. Therefore, it is of utmost importance that opinion letters not assume any familiarity with patent law or the applicable technology, and be clearly written and logically organized to aid in the judge's and jury's decision-making process.

As with the multiple audiences, opinions may include different purposes. Does it provide objective and balanced advice? Does it advocate for a tenable position? Does it aim to provide an "insurance policy" serving as a mitigating factor against willfulness? Does it serve as a pre-suit investigation by a patentee? Is its goal to remediate a discoverable previous poor conclusion by another? Does it validate a design-around effort? Regardless of its purpose, an opinion needs to provide sound, competent legal advice. The elements of a competent opinion typically include a qualified author, delivery, well-reasoned content, and timeliness.

Non-Infringement Opinions

A non-infringement opinion distinguishes a product or process from close patent claims by first construing the claims within the analytical framework set forth by judicial precedent, and then reading the claims upon the product or process to establish no infringement, both literally, and under the "doctrine of equivalents." The non-infringement opinion can serve to avoid known problems, for example, to validate that the product or process has properly been "designed-around" problematic patent claims of others. More typically, the non-infringement opinion serves to avoid enhanced damages from willfulness should the product or process ultimately be found to infringe such problematic patent claims.

Many factors will affect whether a non-infringement opinion is deemed competent. For example, the opinion should have been timely sought and obtained, either before initiating the potentially infringing activity or upon acquiring knowledge of the patent rights in question. See *Underwater Devices*, 717 F.2d at 1390. In *Dickey-John Corp. v. International Tapetronics Corp.*, the Seventh Circuit of Appeals found that a patent opinion obtained just two days before the infringing product's first day of sale was not sufficient to overcome a claim of willful infringement. 710 F.2d 329, 332-33, 348, 219 USPQ 402, 405, 418 (7th Cir. 1983). Since preparing a competent written non-infringement opinion necessarily takes time (for example, to obtain and analyze the prosecution history and the prior art), it may be worth considering whether an initial oral opinion should be first given and memorialized-provided that the oral opinion can be well-founded in both its legal analysis and its technical accuracy regarding the accused product.^{xix} Although oral opinions are not favored (see *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559 (Fed. Cir. 1992)), such oral opinions do carry weight in the willfulness determination

(see *Radio Steel & Mfg. v. MTD Prods., Inc.*, 788 F.2d 1554 (Fed. Cir. 1986)).

A non-infringement opinion addressing a U.S. patent should be authored by a qualified U.S. patent attorney.^{xx} Using outside counsel may bolster the objectivity of the legal opinion, however, there is no *per se* rule against using in-house counsel to provide an exculpatory opinion. See Mark J. Thronson et al., *Intellectual Property Legal Opinions* § 6.04[A][2] (2004 Supp.). Some precaution should be taken when using the same attorney as both opinion and trial counsel because of waiver concerns (discussed below). The non-infringement opinion should include an accurate technical description of the accused product or process. Incorporating pictures or diagrams may be particularly helpful, such as for a reviewing judge or jury. Any technical expert providing such technical description of the accused product or process should be well qualified to do so. The technical expert should separately review the technical description for accuracy and completeness, preferably before the remainder of the opinion is drafted.

In crafting a competent non-infringement opinion, the prosecution file history and prior art of record should be obtained and analyzed. See, e.g., *Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820 (Fed. Cir. 1989). Since there is considerable likelihood that the attorney-client privilege will be waived and the opinion produced at trial, the non-infringement opinion represents a useful opportunity for advocacy against willfulness. Therefore, the opinion should be substantially unequivocal to provide such advocacy but should, of course, incorporate objectivity. In practice, this typically involves anticipating and analyzing any counterarguments by setting up such counterarguments as “straw men” and disposing of them appropriately.

The opinion should provide a separate non-infringement analysis for each independent claim in the patent. If non-infringement is

established for an independent claim, its dependent claims may, but need not, be separately analyzed. Moreover, in using the analytical framework of the Federal Circuit, the non-infringement analysis of each claim should be separated into its constituent components: (1) claim construction; and (2) reading each construed claim onto the accused product. It is sometimes tempting to conflate these two steps of the non-infringement analysis, particularly when the claim is to be interpreted in accordance with the plain and ordinary meaning of its claim terms.

Even when this is the case, however, the two steps in the analysis can be kept distinct by stating that nothing in the patent specification or file history would lead one of ordinary skill in the art to believe that any special meaning for a claim term has been created such that the claim term will be interpreted according to its plain and ordinary meaning. This will help lead the judge or jury through the proper analysis, and will also memorialize for any future appellate court that the opinion was carried out using the proper two-step framework for non-infringement analysis. Moreover, before carrying out the claim construction analysis, a litigation search should also be performed to determine whether the claims have already been construed by a court during previous litigation. If a court has already construed the claims, the court’s claim construction can serve to either bolster the claim construction used in the opinion or, if different, the court’s claim construction must be reconciled with the opinion’s claim construction.

The non-infringement analysis should be complete in that it should perform an element-by-element analysis for both literal non-infringement and for non-infringement under the judicially-created “doctrine of equivalents.” Indirect infringement, such as contributory infringement and induced infringement, should also be considered where appropriate.

Invalidity and Unenforceability Opinions

An invalidity opinion serves to neutralize patent claims that cannot be avoided if it can be determined that such patent claims are invalid. Invalidity analysis typically involves first construing the claims, then reading the claims on the prior art to determine whether the claims are valid. Like the non-infringement opinion, the invalidity opinion serves to avoid known problems and to avoid enhanced damages from willfulness.

Sometimes the questions of non-infringement and invalidity are inextricably intertwined. For example, sometimes a patent claim can be reasonably interpreted two different ways: a first (e.g., broad) interpretation that would render the claim invalid as failing to distinguish over the prior art; and a second (e.g., narrow) interpretation that preserves the claim's validity but fails to read on the accused product. In such cases it may be appropriate to include such non-infringement and invalidity analysis in the same opinion.

Exculpatory opinions based on invalidity or unenforceability are often reserved for situations in which non-infringement cannot be established for at least one of the independent claims in a patent. Perhaps this is because of the perceived or actual difficulties with invalidity opinions. For example, each claim is presumed to be valid independent of the validity of the other claims in the patent. See 35 USC § 282. Therefore, unlike non-infringement, which need only be established for each independent claim in the patent, invalidity must be established for each and every claim in the patent except for any non-infringing independent claims and their dependent claims. Moreover, invalidity must be established by clear and convincing evidence to overcome the presumption of validity. See *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206 (Fed. Cir. 1998).

Examples of potential bases for establishing invalidity or unenforceability include: (1) anticipation (see 35 USC § 102); (2) obviousness (see 35 USC § 103); (3) double patenting; (4) lack of enablement (see 35 USC § 112); (5) lack of Written Description (see 35 USC § 112); (6) failure to describe best mode (see 35 USC § 112); (7) indefiniteness (see 35 USC § 112); (8) improper inventorship (see 35 USC § 102(f) and § 256); (9) failure to obtain a foreign filing license (see *In re Gardner*, 604 F.2d 1348 (CCPA 1979)); (10) inequitable conduct (e.g., failure to cite known relevant prior art; (11) patentee mischaracterized reference(s) during prosecution and “but for” the mischaracterization, no allowance; and (12) patentee submitted data and/or statements in an FDA filing, which are contrary to remarks and/or data in the patent record, and “but for” the discrepancies, no allowance. Not all of these bases are equally solid grounds for an invalidity opinion. For example, invalidity based on improper inventorship and failure to obtain a foreign filing license may be correctable by the patentee and, therefore, are of somewhat limited value in forming an invalidity opinion. Similarly, an invalidity opinion based on anticipation (e.g., all claim elements present in a single prior art reference) is likely more solid than an invalidity opinion that is based on obviousness (e.g., all claim elements are present in a combination of prior art references).

Of course, some of these bases of invalidity are more difficult to establish in a pre-litigation exculpatory opinion than in litigation, which allows discovery of additional information. For example, it may be difficult to determine whether a patentee failed to disclose the best mode of practicing the invention or whether a patent failed to properly name the inventors without obtaining some discovery. Moreover, certain of these bases of invalidity may need to meet certain additional judicially imposed legal requirements in order to properly invalidate a patent claim. For example, an opinion of invalidity for anticipation that is based on a

claim of prior inventorship must meet a corroboration requirement—a heightened evidentiary standard unique to patent law. See *Price v. Symsek*, 988 F.2d 1187, 1194 (Fed. Cir. 1993).

In particular, forming an invalidity opinion based on obviousness may be challenging. Such an invalidity opinion should follow the *Graham v. Deere* analytical framework for determining obviousness, which includes consideration of: (1) the scope and content of the prior art; (2) any differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art; (4) secondary considerations (e.g., unexpected results, commercial success, long-felt but unsolved need, failure of others, copying by others, etc.). Even though such secondary considerations may be more difficult to establish in the pre-litigation opinion-drafting context than during litigation, the Federal Circuit has indicated that they must nonetheless be addressed in an invalidity opinion based on obviousness. See *Kegel Co. v. AMF Bowling, Inc.*, 127 F.3d 1420, 1430 (Fed. Cir. 1997); *Akamai Techs., Inc. v. Cable & Wireless Internet Services, Inc.*, 344 F.3d 1186, 1196-97 (Fed. Cir. 2003). Similarly, the above element of establishing the level of ordinary skill in the art may be somewhat involved. Relevant factors include the educational level of the inventor, the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of workers active in the field.

Since an obviousness assertion is typically based upon multiple prior art references, the prior art references should come from the same field (or an analogous field) of endeavor. However, in light of the Supreme Court's decision in *KSR Int'l Co. v. Teleflex, Inc.*, 550 US 398 (2007), such prior art references need no longer provide one of ordinary skill in the art with an explicit teaching, suggestion or motivation to combine the references. Prior art not previously considered by the USPTO will generally be more

effective at overcoming the presumption of validity than prior art that was cited and considered by the patent examiner at the USPTO. Like the non-infringement analysis, an invalidity opinion should separate its analysis into two distinct components which are: construing the claims; and reading the prior art references upon the claims.

Like an invalidity opinion that is based on obviousness instead of anticipation, an invalidity opinion based on 35 USC § 112 (e.g., indefiniteness, lack of enablement and/or written description, or failure to describe best mode) is sometimes viewed as somewhat risky. However, such an opinion may be worth considering, particularly if the patent has a glaring error rather than a mere hyper technical defect. A patent may be found invalid for lack of enablement if it would require “undue experimentation” to practice the claimed invention. Factors considered in this determining whether practicing the invention would require undue experimentation include: quantity of experimentation necessary; amount of direction or guidance presented in the patent: presence or absence of working examples in the patent; nature of the invention; state of the prior art; relative skill of those in the art; predictability or unpredictability of the art; and breadth of the claims. See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Even if a patent is infringed and valid, there remains the possibility that the patent is unenforceable, such as for inequitable conduct, patent misuse, intervening rights, laches, or equitable estoppel. Inequitable conduct requires clear and convincing evidence of an intentional material misrepresentation to deceive the USPTO. See, e.g., *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995). While it is sometimes difficult to establish such intent in a pre-litigation exculpatory opinion, it is not impossible. In strong enough circumstances, it may be possible to infer such intent from the prosecution file history or other public documents. In determining whether an

opinion can be based on inequitable conduct, the drafter should first look at any factual representations to USPTO in the patent as well as in any declarations, affidavits, and statements made during prosecution. Inequitable conduct can also be established based on a breach of the Rule 56 “duty of candor and good faith” to the USPTO. *See* 37 C.F.R. § 1.56. This typically involves a failure to disclose to the UPSTO known material prior art. However, it can sometimes be based on a failure to disclose material information that is not even prior art. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239 (Fed. Cir. 2003). Investigating inequitable conduct should also include determining whether the patentee failed to disclose material similar patent applications being prosecuted, particularly if such patent applications were assigned to different patent examiners. *See McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897, 926 (Fed. Cir. 2007); *see also, Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003). Laches or equitable estoppel may also create a basis for unenforceability. Laches refers to an unreasonable and inexcusable delay of asserting a known claim resulting in prejudice or injury. Laches will preclude damages for pre-suit infringement. *See A.C. Aukerman Co. V. RL Chaides Construction Co.*, 960 F.2d 1020 (Fed. Cir. 1992). Equitable estoppel exists where the patentee leads the accused infringer to believe that patent will not be enforced against the accused infringer resulting in reliance and material prejudice from enforcing the patent. Equitable estoppel will preclude any damages against that accused infringer. *See id.*

Invalidity Defense Statistics

Interesting statistical data was presented by Jeanne M. Gills, “Crafting An Effective Patent Invalidity Opinion-Is It The Last Bastion of Defense?” (http://www.foley.com/files/tbl_s3_1_Publications/File_Upload_1_3711527/Gillsfinal.pdf, visited on May 1, 2005). In a study (using data derived from

<http://www.patstats.org>), Ms. Gills analyzed data derived from John R. Allison and Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Quarterly J. at 185-275), which ranked the effectiveness of various invalidity defenses as follows: double patenting (about 72%); anticipation by other than prior art references (about 60%); anticipation by prior art references (about 40%); obviousness (about 37%); lack of enablement or lack of written description (about 37%); claim indefiniteness (about 35%); failure to disclose the best mode (about 35%); and improper inventorship (about 10%). While circumstances may vary for individual cases (indeed these statistics vary even between the different studies), these statistics may be useful in helping evaluate different bases for an invalidity defense.

Use of Opinions

Even the most competent legal opinion cannot add value to a willfulness determination if the opinion is not reviewed and followed. *See In re Hayes Microcomputer Patent Litig.*, 982 F.2d 1527 (Fed. Cir. 1992) (the opinion should be the genuine basis for decision making about proceeding with the potentially infringing activity). Simply obtaining a patent opinion on a product or process is not enough to avoid charges of willful infringement. *See mach. Corp. of Am. v. Gullfiber, A.B.*, 774 F.2d 467, 472, 227 USPQ 368, 370 (Fed. Cir. 1985). Therefore, an opinion drafter should docket and document a follow-up discussion with the receiving client to make sure that the opinion was read, understood, and followed. *See Central Soya Co., Inc. v. Geo. A. Hormel & Co.*, 723 F.2d 1573 (Fed. Cir. 1983) (finding willfulness in spite of competent opinion where advice was not timely followed). In particular, this follow-up inquiry should determine if the client is aware of any facts or circumstances that would undermine the basis of the opinion. *See SRI International*, 127 F.3d at 1465-66 (improper reliance on an opinion containing incorrect technical information about the infringing product).

Ultimately, an opinion must be reviewed and relied upon in the business context of deciding to proceed with the allegedly infringing conduct. Thus, if the opinion was delivered to the client's in-house patent counsel, the opinion drafter should also verify that the client's in-house patent counsel discussed the opinion and the resulting course of action with management. Any such follow-up discussions with the client can also be used as an opportunity to remind the client of the importance of maintaining the attorney-client privilege protecting the document and avoid generating any independent notes about the opinion, which might be discoverable.

Updating Opinions

Once generated, a written opinion is static. However, business circumstances typically are not. If things change in a way that affects any analysis in the opinion, the opinion may need to be updated to reflect the new reality. For example, the product design or process may change in a way that makes it unreasonable to rely on the analysis set forth in an earlier opinion. Similarly, the law may evolve through statutory changes or the common law process thereby impacting the earlier opinion's analysis. Moreover, new patents may issue and new patent applications may be published. A business transaction may itself affect the analysis of an earlier opinion, either by its consummation or failure. Even more generally, a client's business strategy may change thereby affecting the analysis of an earlier opinion. If circumstances change in a way that materially affects the opinion's analysis, a new or supplementary opinion may be warranted.

Attorney-Client and Work Product Privileges

As discussed above, *Knorr-Bremse* precludes drawing an adverse inference when the attorney-client privilege is invoked with respect to an opinion of counsel. However, an alleged infringer who relies on an opinion at trial waives

attorney-client privilege for the opinion and communications relating to the opinion. *In re EchoStar Communications Corp.*, 448 F.3d 1294, 1304 (Fed. Cir. 2006).

In *Seagate*, the Federal Circuit limited the scope of the privilege waiver. Particularly, the court held that, in general, asserting an advice-of-counsel defense in response to a charge of willful infringement and disclosing opinions of counsel does not result in a waiver of the attorney-client privilege for communications with trial counsel. *See In re Seagate Techn., LLC*, 497 F.3d 1360 (Fed. Cir. 2007). Similarly, on the attorney work product front, the Federal Circuit held that relying on patent opinion counsel's work product in asserting an advice-of-counsel defense will generally not waive work product immunity with regard to trial counsel, and the waiver "does not extend to work product that was not communicated to the alleged infringer." *See id.* at 1370. To ensure a clear separation between the opinions and trial counsel thereby preventing the spread of waiver, it is recommended that an alleged infringer not use the same attorney for both opinion drafting and trial counsel.

It may be possible to compartmentalize the opinion by providing separate opinions thereby further limiting the scope of a privilege waiver. For example, a freedom-to-operate opinion can generally be separated from a non-infringement opinion. In some circumstances, a non-infringement opinion can be separated from an invalidity opinion. Individual patents can be considered in separate opinions. Similarly, individual products can be considered in separate opinions. In sum, while it may not be possible to selectively waive different opinions on the same subject, it may still be possible to separate different subjects into different opinions thereby preserving the possibility of selective waiver that is limited only to relevant subjects.

Techniques for More Efficient and Cost Effective Freedom-to-Operate

We live in a world in which companies are feeling downward price pressures and a general slowdown in economic activity persists. There is a silver lining, however. According to the *Kauffman Index of Entrepreneurial Activity*, the number of new businesses (“start-ups”) created during the 2007-2009 recession years had increased steadily year-after-year. In 2009, business start-ups reached their highest level in 14 years, even exceeding the number of start-ups during the 1999-2000 technology boom. (<http://www.kauffman.org/newsroom/despite-recession-us-entrepreneurial-activity-rate-rises-in-2009.aspx>, visited on August 18, 2010). Start-ups, by nature, have limited investment of capital and labor—two resources needed to complete a traditional FTO investigation, yet have a keen interest in obtaining IP and steering clear of others IP.^{xxi}

Without question, FTO investigations and associated opinions are expensive, particularly in a crowded patent landscape, but can be valuable, as discussed above. Thankfully for start-ups and other clients with limited financial capital, lengthy formal opinions are not viewed as being quite as necessary as they once were before the Federal Circuit’s decision in *Seagate*. Do other means exist to further reduce the cost of an FTO investigation while also providing an FTO output that can be reused or leveraged for other strategic purposes or adapted to changed circumstances?

New technology allows the use of software-assisted FTO claim charts that are updatable, reusable, and interactive. This can allow concurrent, comprehensive, easily updated, and accurate screening of claim coverage across hundreds of patents for infringement or protection concerns against an unlimited number of a company’s target products or processes. For example, Lucid Patent, LLC^{xxii} administers, markets, and manages a web-based software tool (“ClaimBot® software”)

that produces FTO claim charts that can provide for more efficient and cost-effective FTO investigations, as now discussed.

Following an FTO patent landscape search, numerous patent numbers can be input into ClaimBot’s® user-interface. The software can automatically import patent data from the U.S. Patent Office’s database, for example, including title information, assignee information, filing data information, images of each figure, and the text of the specification and claims. During the import process, ClaimBot® software automatically parses independent and dependent patent claims, as well as chronologically organizes each patent matter included in the landscape.

Figure 8: Representative Patent Data and Information Retrieved, Aggregated, Filtered, Stored and Displayed by ClaimBot’s® Interactive Claim Chart.

Patent Data Types	Patent No. 1	Patent No. 2	Patent No. 3
Title	Expandable spinal implant and surgical method	Middle expandable intervertebral disk implants	Artificial vertebral body
Patent #	5,099,199	5,171,278	5,291,312
Assignee Name	Spine-Tech, Inc. (Minneapolis, MN)	Petrotech Corp. (Brownsville, TX)	Alphatec (Palm Desert, CA)
Filing Date	Apr 13, 1990	Feb 22, 1991	Sep 03, 1991
Total Claims	29	8	15
Claim # (Independent)	1 10 11 12 14 15 21 22 24 25 28	1 4 6 7	1 10 15

1. A spinal implant for insertion into a bore formed between opposing vertebrae of a spine, said implant comprising: a plurality of deformable ribs; said ribs deformable in response to a deforming force to change from a first shape to a second shape; said ribs in said first shape presenting exterior surfaces cooperating to define a first exterior dimension sized to be received within a bore formed between adjacent vertebrae of a spine; and ribs in said second shape presenting exterior surfaces cooperating to define a second exterior dimension greater than said first exterior dimension and sized to urge said adjacent vertebrae apart; applying means for applying said deforming force to said ribs.	1. A method of implanting an intervertebral disk unit between two vertebrae after removal of a diseased or damaged intervertebral disk from therebetween, the disk unit being cylindrical in shape and comprising a member capable of adapting to the shape of an anatomical region of said disk space and means for variably expanding said member to substantially conform the shape of said member to the shape of a portion of said disk space, comprising the steps of: (a) inserting said disk unit into said disk space; (b) expanding the middle of said disk unit without changing the diameter of the diametrical ends thereof; (c) introducing cancellous bone particles into said disk space and allowing said particles to fuse.	1. An implantable artificial vertebrae which is biocompatible and sized for replacing a vertebrae, comprising: a first hollow component having an abutting end for abutting a vertebrae of a living being and an anchoring window formed in said abutting end, an open first side establishing an access window, and an open end formed opposite said abutting end; a second hollow component having a vertebrae of a living being and a second anchoring window formed in said second abutting end, an open first side establishing a second access window, and a second open end formed opposite said second abutting end, the second component being slidably receivable through the open end of said first component; and motion preventing means engageable with both of said components for substantially preventing relative motion between said components.
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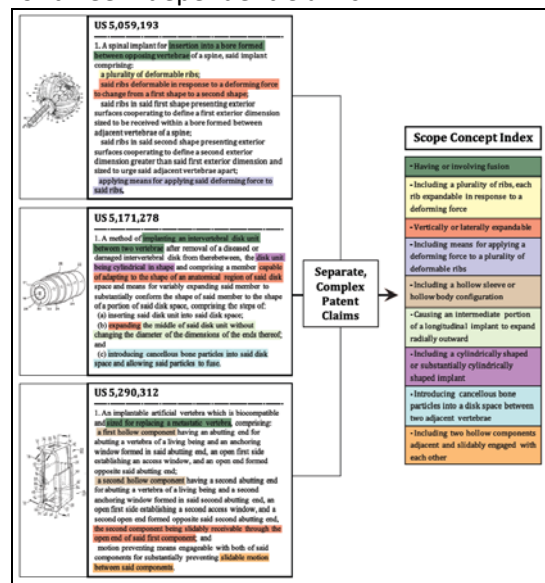
Once the independent claims of the patents of interest are scraped into the ClaimBot® software, a patent attorney can efficiently parse various limitations from the independent claims and, where appropriate, combine like claim limitations into simplified “scope concepts.” Conceptually, scope concepts can be thought of as useful abstractions of claim limitations (e.g., similar to “headnotes” in a summary of a published court decision). Scope concepts can,

and often do, have varying levels of abstraction and can apply across claims or even across patents.

This method of claim charting recognizes that many sets of patent claims (such as the 3 independent claims of patents '193, '278, and '312 in Figure 8), can be reduced to a set of constituent scope concepts that can serve to represent the limitations recited in the claims. These scope concepts can provide a powerful categorization, filtering, and searching mechanism for quickly and accurately analyzing large numbers of patent claims concurrently. As the number of claims in the patents of interest increases, the efficiency of using ClaimBot® software increases over the traditional FTO process.

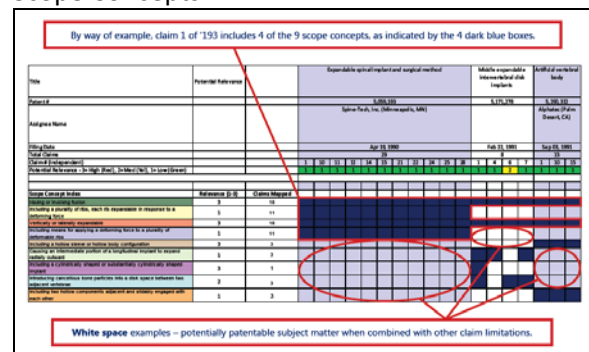
The coverage of a particular claim can be represented by a combination of scope concepts derived from the set of patent claims. As an example, similar colors across the independent claims recited in the example of Figure 9 are intended to represent similar limitations. For each of these limitations a broader, easier to understand scope concept can be drafted to represent the claim limitation.

Figure 9: Representative Scope Concept Index for three Independent Claims.



In a similar manner, hundreds of independent patent claims with thousands of constituent claim limitations can be reduced to a relevant, greatly-reduced number of scope concepts. In Figure 9, for example, the 3 independent claims of patents '193, '278, and '312 can be simplified into 9 scope concepts. Each dark blue box shown in Figure 10 represents an inclusion of a scope concept within a particular claim.

Figure 10: Representative Portion of a ClaimBot® Software-Produced Claim Chart Illustrating the Association of Patent Claims and Scope Concepts.



Using ClaimBot® software-produced claim charts, one can very quickly screen large numbers of patents for determining claim coverage. As an example, in a recent case study directed at a spinal medical device patent landscape, 171 patents including 729 independent claims were consolidated into approximately 400 scope concepts. Each of these 729 independent claims was “charted” to at least three scope concepts. Accordingly, by answering approximately 400 simplified scope concept questions, 729 independent claims were concurrently reviewed for infringement analysis purposes.

ClaimBot® software can automatically generate an interactive claim chart. The claim chart serves as an exclusionary tool allowing simple, accurate, real-time coverage analysis of a group of claims to a target product or process. Using this interactive feature, a user with domain expertise (e.g., a company’s engineers, scientists, or management) can help evaluate

whether or not each scope concept is applicable to a target product or process and enter these findings into the interactive claim chart (e.g., as a “1,” “2,” or “3”—see designation below). For each scope concept that is not applicable to the product or process, all claims with that scope concept can be excluded as not covering the target product or process.

Scope concepts can be analyzed and deemed either:

“1” - not relevant to target product or process;

“2” - not relevant to target product or process, but possibly worth considering for future technology or design around opportunities; or

“3” - worth further consideration in light of the known features of the target product or process.

Based on the “all elements” literal infringement rule, a claim inherits the lowest rating of any scope concept indexed to it. For example, if a particular claim requires two scope concepts—one of current interest (3), and one of no interest (1), then that particular claim is deemed to be of no interest (1). Similarly, if a particular claim requires two scope concepts—one of current interest (3), and one of future interest (2), then that particular claim is deemed to be of only future interest (2). Provided that the scope concepts are appropriately drafted broader than any of the claim elements charted to them and, thus, represent the outer limits of claim coverage, “doctrine of equivalence” concerns can be diminished.

When all scope concepts in the chart have been evaluated in light of the target product or process, the completed interactive claim chart flags the claims excluded from coverage and the reasons for their exclusion (see, e.g., Figure 10). Further, the completed interactive claim chart also flags claims that may require more detailed review to achieve FTO. The interactive feature of the spreadsheet can be modified such that if

particular scope concepts come into play or fall away as the plans for the current design or future design change, then by merely re-evaluating the scope concepts, claim applicability designations are automatically updated in the claim chart. This capability provides a company’s engineers, scientists, and management with the ability to determine various possible design options for FTO scenarios, in real time, earlier in the design process than previously possible using traditional FTO methods, and with minimal incremental cost.

ClaimBot’s® software-produced claim charts are easily updatable. For example, if other potentially relevant patents issue or later become known, they can easily be added to the previous claim chart and addressed.

Similar concepts to those discussed can also be leveraged for, among other things, due diligence, offensive assertion analysis, coverage review (such as for resource allocation or false marking review), invalidity indexing (prior art can be “indexed” to the claim chart to aid with invalidity investigations), licensing potentials (recognize license and/or acquisition potentials), unclaimed subject matter (specifications can be mapped against the claims to reveal interesting, but unclaimed subject matter), and categorization (patents in the FTO landscape can be grouped into one or more technology categories that can be integrated into ClaimBot’s® claim charts).

Systematically evaluating a company’s FTO position before launching a new target product before its design freeze, or even as early as concept review, can help minimize the risk of infringing valid patent rights of others and can also improve the company’s chances of finding business partners and attracting investors to support its business development plans. With help from software-assisted claim charts, a company can evaluate its FTO position on various target product or process designs using an economical, methodical and easy-to-use

process instead of the time consuming and expensive process of manually looking through a patent landscape to identify those needing in-depth analysis.

Conclusion

Whatever manner is chosen to limit the chances of facing potentially risky and expensive patent litigation, companies are well advised to perform an FTO investigation early on in the research, development and commercialization stages of a new product or process. In some cases, minor product or process adaptations or payment of a licensing fee to a patent owner may be sufficient to avoid future disputes. By systematically evaluating FTO prior to launching a new product, such as via interactive software-assisted claim charts, a company can minimize, although not eliminate, the risk its product or process is infringing patents owned by others. FTO investigations can also improve a company's chances of finding business partners and attracting inventors to support business development plans.

Legal budget limits prohibit companies from seeking an opinion of counsel for all patents surfaced in an FTO investigation. After *Seagate*, it is difficult to justify continuing extensive formal opinion practice when legal resources could arguably be more efficiently and cost effectively used to establish a clearance position to avoid objective recklessness with respect to willful infringement. Patent practitioners can use interactive software-assisted claim charts or other similar techniques that can help business decision makers efficiently and effectively understand a patent landscape of interest and make informed decisions, including where to expend precious resources on obtaining formal opinions.

Although U.S. case law recognizes that there is no *per se* requirement that an accused infringer must always obtain an opinion of counsel before initiating or continuing potentially infringing activity, such formal legal opinions

can still play an important role to avoid a willfulness finding, particularly for patents that have a high likelihood of an infringement charge. In addition, opinions of counsel can be an important mechanism to assure potential investors, business partners, and customers that patent due diligence was conducted.

Endnotes

ⁱ The 35 USC § 271 states that, “[e]xcept as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”

ⁱⁱ Patent rights, and thus FTO investigations, are territorial. A product or process might possess FTO in one jurisdiction (or country), but not in another jurisdiction (or country). Reasons why FTO may exist in some countries, but not others, include: patents may not have been applied for in certain countries; patents may not have been granted in some of the countries where applications were made; laws about what is patentable vary between countries; each country's patent office may apply different prior art references during the patent examination process leading to broader or narrower claim coverage; and some countries have exemptions for certain types of claims.

ⁱⁱⁱ Since U.S. patent applications enjoy at least an 18-month period of secret pendency at the U.S. Patent & Trademark Office (*see* 35 USC § 122), no FTO investigation search can be 100% accurate since it may not uncover prior art that, at the time the

search is conducted, is pending in secret at the U.S. Patent & Trademark Office.

^{iv} If a patent applicant's amendment narrows the claim(s) during prosecution for any reason relating to a statutory requirement of patentability, the applicant will be estopped from later invoking the "doctrine of equivalents" for the amended claim element. *Festo v. Shoketsu Kuzoku Kogyo kabushki Co.*, 234 F.3d 558, 566 (Fed. Cir. 2000) (*en banc*), *cert. granted*, 121 S. Ct. 2519 (2001). Prior art disclosures also limit the reach of the "doctrine of equivalence."

^v In a survey carried out by Derwent in Europe, over 70% of the companies surveyed admitted that they had spent money on research and development on a new product or process only to find out that the product or process was already protected by a third-party competitor's patent. (<http://www.priorartsearch.com/infringement.htm>, visited August 18, 2010).

^{vi} Typical costs for an FTO investigation can vary greatly due to (1) area of technology; (2) the number of pending, applicable patent documents in the technology landscape; and/or (3) how many and which countries are of interest to a company.

^{vii} Free patent databases include, but are not limited to, the U.S. Patent & Trademark Office database (<http://www.uspto.gov/>) and the European Patent Office database (<http://ep.espacenet.com/>). Commercial databases include, but are not limited to, Lexis-Nexis® database, Westlaw® database, Delphion® database, Innography® database, and MicroPat® database.

^{viii} A deliberate attempt to avoid infringement is strong evidence that a party did not willfully infringe on an existing patent. *See Read Corp. v. Portec, Inc.*, 970 F.2d 816, 828, 23 U.S.P.Q.2d (BNA) 1426, 1436 (Fed. Cir. 1992).

^{ix} A strategy used by medical device companies, for example, is to patent in the third-party "space," with an eye toward developing intellectual property bargaining chips if a problematic patent becomes an issue.

^x Since requesting an interference proceeding can constitute knowledge of patent rights, any request for an interference should be accompanied by careful consideration of whether an exculpatory opinion of counsel is needed.

^{xi} 35 USC § 284 authorizes the award of damages for patent infringement. In addition to compensatory damages, including interest and costs, § 284 states, "... the court may increase the damages up to three times the amount found or assessed." This permits a court to assess what are often referred to as "enhanced damages."

^{xii} The factors weighed in the "totality of the circumstances" willfulness test can include: whether the infringer received a competent opinion (*see Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 1428, 8 USPQ2d 1323, 1332 (Fed. Cir. 1988)); whether there was a good faith belief on the part of the infringer that the patent was invalid or not infringed (*see Radio Steel & Mfg. Co. v. MTD Prods.*, 788 F.2d 1554, 1558-59, 229 USPQ 431, 434 (Fed. Cir. 1986)); whether the infringer had actual knowledge of an existing patent (*see Power Lift, Inc. v. Lang Tools*, 774 F.2d 478, 482, 227 USPQ 435, 438 (Fed. Cir. 1985)); whether the infringer made a good faith attempt to design around the patent (*see Amstar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 1546-47, 3 USPQ2d 1412, 1418-19 (Fed. Cir. 1987)); and/or whether the infringer's behavior and tactics at trial were consistent with an overall finding of good faith (*see Bott v. Four Star Corp.*, 807 F.2d 1567, 1572, 1 USPQ2d 1210, 1213 (Fed. Cir. 1986) (holding willfulness was present where the defendant had a long history of ignoring and thereby infringing, the plaintiff's patents). The significance of each factor depends on the facts of the particular case. *See Studiengesellschaft Kohle, mbH v. Dart Indus.*, 862 F.2d 1564, 1574-75, 9 USPQ2d 1273, 1283 (Fed. Cir. 1988). *See also, Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826-27 (Fed. Cir. 1992) (stating that the factors can include: "(1) whether the infringer deliberately copied the ideas or design of another; (2) whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed; . . . (3) the infringer's behavior as a party to the litigation;" (4) "defendant's size and financial condition;" (5) "closeness of the case;" (6) "duration of defendant's misconduct;" (7) "remedial

action by the defendant;” (8) “defendant’s motivation for harm;” and (9) “whether defendant attempted to conceal its misconduct.”).

^{xiii} Because waiving the privilege, which may extend to attorney work product as well as covering attorney-client communications, is no longer required to avoid drawing an adverse inference. *Knorr-Bremse* has made it even more important to carefully conduct business transactions and other acts in a manner that preserves the attorney-client and work product privileges.

^{xiv} James M. Singer of Pepper Hamilton LLP

^{xv} (<http://ipspotlight.com/2007/08/27/are-patent-opinions-still-valuable-after-in-re-seagate/>, visited on August 18, 2010.)

^{xvi} The 29 post-*Seagate* decisions break down into 5 decisions from the Federal Circuit and 24 decisions from 17 district courts.

^{xvii} See *Church & Dwight Co. Inc. v. Abbott Labs.*, 2008 WL 2565349 (D.N.J. Jun. 24, 2008). In *Church & Dwight Co.*, the court upheld the jury’s finding of willful infringement where the defendant’s “invalidity defenses were not very strong and . . . previously rejected by the USPTO.” See also, *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 2008 WL 2958968 (D. Ariz. Jul. 29, 2008). In *Bard Peripheral Vascular, Inc.*, the court upheld the jury’s finding of willful infringement given the defendant’s “reli[ance] on the same references . . . to support its invalidity defense that the PTO previously found not to invalidate [the] invention.”

^{xviii} <http://www.uspto.gov/go/og/index.html>

^{xix} The court has been clear that the date an opinion is received by a client is given more weight than the date the opinion is requested in determining state of mind for willfulness. See *In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1544, 25 USPQ2d 1241, 1254 (Fed. Cir. 1992); and *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1259, 43 USPQ2d 1666, 1671 (Fed. Cir. 1997).

^{xx} Unlike U.S. patent attorneys, U.S. patent agents can opine only on invalidity and not on infringement. Furthermore, the Federal Circuit has stated that the

strongest weight will be given to an opinion from outside counsel who is a registered U.S. patent attorney. See *Underwater Devices*, 717 F.2d at 1390.

^{xxi} The news magazine, *The Economist*, estimates that up to 75% of the value of U.S. public companies is based on their intellectual property. See “A Market for Ideas,” *ECONOMIST*, Oct. 22, 2005, at 3, 3 (special insert). Often, even a greater percentage of a start-up company’s value is based on its intellectual property.

^{xxii} <http://www.lucidpatent.com/>