The Key Issues in Promoting IP Culture in Litigious Industries:
In-House Counsel Perspective

by

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1 The views and opinions expressed in this paper are solely those of the authors in their private capacity, and do not in any way represent those of their respective employers.

2 This material has been prepared for informational purposes only, and is not intended to provide, and should not be relied on for legal advice. Further, note that Dr. Sebor is not an attorney-at-law.
I. Introduction

Promoting a culture of intellectual property (IP) protection is becoming more and more critical to all organizations and corporations. When IP litigation is possible, probable, or even imminent, the securing of IP throughout the organization can be highly consequential. This paper will explore various issues and best practices concerning company culture and communications to strengthen a company’s position in view of potential or eminent litigation including in the areas of preservation of privilege, attorney work product, opinion counsel and waivers, consultants, protective orders, confidential documents, intra-company communications, document retention, and memorializing and tracking innovation. Whether working in a litigious or non-litigious environment, the goal of this paper is to provide the reader with a basis for strengthening their organization’s IP positioning by establishing best practices throughout.

II. Thorny Issues in Maintaining Privilege and Attorney Work Product

A. Attorney-Client Privilege and Attorney Work Product Overview

Maintaining attorney-client privilege is a bedrock issue for building and maintaining a strong and healthy legal culture. Attorney-client privilege is an evidentiary principle which prevents the disclosure of communications between an attorney and her client. A few general principles regarding attorney-client privilege governing the discussion infra include:

- Generally, only documents between the client, the lawyer, and agents of the client or lawyer are eligible for privilege protection. *U.S. v. Bernard*, 877 F.2d 1463 (10th Cir. 1989).
- Attorney-client privilege is separate and apart from an attorney’s duty of confidentiality to her client, as articulated for instance in ABA Model Rule 1.6 which provides that “[a] lawyer shall not reveal information relating to the representation of a client unless the client gives informed consent, the disclosure is impliedly authorized in order to carry out the representation or the disclosure is [otherwise] permitted by [a recognized exception].”
- Attorney-client privilege extends to potential clients even if the potential client never actually retains the attorney. *Barton v. U.S. Dist. Court*, 410 F.3d 1104, 1111 (9th Cir. 2005); *In re Auclair*, 961 F.2d 65 (5th Cir. 1992).
- Privilege can also extend to third parties sharing a common interest. The “common interest” doctrine applies where: (i) a privilege serves as the basis of the claim; (ii) the communication was made while the parties shared a legal, factual, or strategic common interest; (iii) the parties shared the information in furtherance of that common interest; and (iv) the parties did not otherwise waive the privilege. *Haines v. Liggett Grp. Inc.*, 975 F.2d 81, 94 (3d Cir. 1992).

The application of attorney-client privilege is absolute. Once established, a court cannot compel production of privileged material. Attorney work product, in contrast, is not so absolute. Federal Rule of Civil Procedure 26(a)(3) provides that “[o]rdinarily, a party may not discover documents and tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative.” Even attorney work product may be discoverable, however, if another party “shows that it has substantial need for the materials to prepare for its case and

Factual information not calling for legal opinions, advice, or analysis are not subject to privilege. Weil Ceramics & Glass Inc. v. Work, 110 F.R.D. 500, 504 (E.D.N.Y. 1986). “Where the principal purpose is securing legal advice, the privilege will be upheld despite the inclusion of technical data in the communication.” Cuno v. Pall Corp., 121 F.R.D. 198, 201 (E.D.N.Y. 1988).

B. Outside Counsel vs. In-House Counsel Relationship and Differences

Corporations are not people, and by not being people courts historically strained to determine whether all employees, including low level employees, enjoyed an attorney-client relationship with counsel. Some courts developed a “control group” test whereby only upper-level management were considered the “client” for purposes of protecting communications as privileged. See e.g. Radian Burners, Inc. v. Am. Gas Ass’n, 320 F.2d 314, 323-324 (7th Cir. 1963). Another test developed was the “subject matter” test, which held that privilege attaches to communications that met a series of factors to determine if the subject matter of the communication as appropriately protectable as privileged.

The United States Supreme Court did away with bright line rules, such as the “control group” test, in Upjohn Co. v. United States, 449 U.S. 383 (1981). Instead, the Supreme Court established adopted a modified “subject matter” test and identified a series of factors to determine whether attorney-client privilege applies to lower-level employees, including whether:

- the information is necessary to supply the basis for legal advice to the corporation or was ordered to be communicated by superior officers;
- the information was not available from “control group” management;
- the communications concerned matters within the scope of the employees’ duties;
- the employees were aware that they were being questioned in order for the corporation to secure legal advice; and
- the communications were considered confidential when made and kept confidential. Upjohn, 449 U.S. at 394-395.

While determining who with within a corporation is subject to privilege protection, equally confounding is determining who within a corporation can waive attorney-client privilege, and it what instances. Generally, “[t]he power to waive the corporate attorney-client privilege rests with the corporation’s management and is normally exercised by its officers and directors.” CFTC v. Weintraub, 471 U.S. 343, 348 (1985).

Privilege will usually be maintained with former employees regarding the scope of their employment, but after the employee has left future conversations, such as those held during the course of a litigation, are unlikely to be privileged. See e.g. Peralta v. Cendant Corp., 190 F.R.D. 38 (D.Conn. 1999) (finding circumstances related to employees termination to be privileged, but conversations related to facts developed during litigation were not privileged).
C. Patent Infringement, Damages and Opinions of Counsel

Opinions of counsel are particularly relevant in patent infringement cases because they can provide evidence that an alleged infringer had a good faith belief that it did not infringe or that the patent at issue is invalid, and therefore is not liable for enhanced damages otherwise imposed for willful infringement.

In recent years, the legal standard of proof for finding willfulness shifted from a comparative rigid objective standard to a more fluid subjective standard. Accordingly, the Opinions of Counsel and depending on their contents, the privilege attached to them, is now more important than ever.

Section 284 of the Patent Act states that, where infringement occurs, courts "may increase the damages up to three times the amount found or assessed." Such treble damages have generally been reserved for cases of "willful or bad-faith infringement." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 505, n. 20 (1964).

Historically, courts have used a two-part test for willful infringement set out by the Federal Circuit in the *Seagate* case. *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007). There, the Court held that willful infringement requires that the patentee prove by clear and convincing evidence that:

1. The defendant acted despite "an objectively high likelihood that its actions constituted infringement of a valid patent" (also called the "objective recklessness" prong) and
2. The objectively high likelihood was "either known or so obvious that it should have been known" to the defendant (also called the "subjective recklessness" prong).

Post-*Seagate*, willful infringement became extremely hard to prove, leading to a decrease in enhanced damages awards and thereby reducing the need for potential infringers to obtain formal opinions of counsel. "The renewed importance of Opinions of Counsel in Patent Infringement" Proskauer Client Alert (August 11, 2016).

The Supreme Court's ruling in *Halo Electronics, Inc. v. Pulse Electronics, Inc.* *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, et al., 579 U.S. __, No. 14-1513, dramatically altered the landscape for proving and obtaining enhanced damages in patent infringement cases. Under *Halo*, district courts have discretion to impose enhanced damages more freely. In *Halo*, the Court held that "[t]he subjective recklessness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless." In addition, under the Halo decision, willful infringement no longer must be proven by clear and convincing evidence but rather by a preponderance of the evidence. "The renewed importance of Opinions of Counsel in Patent Infringement" Proskauer Client Alert (August 11, 2016).

In view of *Halo*, the threat of enhanced damages looms larger. Because an infringer's subjective belief is a factual issue, it appears that juries will play a larger role in determining whether willful infringement exists. Therefore, obtaining a well-reasoned opinion of counsel for instances of possible infringement is crucial to reduce the risk of enhanced damages being imposed at trial.
Note that under Halo and other prior cases, opinions obtained after litigation begins are given less weight than those obtained prior, presumably because they are viewed to be more self-serving defensive maneuvers. For this reason, it is best to retain opinion counsel as soon as a “threat of litigation” arises if not sooner. Strategically, however, from the perspective of attorney client privilege (as opposed to work product) there is a natural tension between early planning and risk-mitigation (as, for example, design around and avoidance of infringement and freedom to operate concerns) and actual “threat of litigation” (whether via receipt of a complaint, demand letter or other communication from a patentee) sufficient for attorney-client privilege to attach.

As a practical matter, Opinions (and associated effort, cost and legal position) may take different forms depending on the level of infringement risk, the stage of product development, the potential for design around and even future business strategy. For example, in the pharmaceutical industry, where many clinical stage development activities are covered by statutory “safe harbor” from infringement (35 U.S.C. § 271(e)(1)) counsel may nevertheless be considering defenses for potential infringement claims which could arise many years in future, if at all – raising the question whether there is a “current” threat of litigation.

For the development of an early defensive (if not also offensive) strategy, a simple claim chart of elements and comparisons may be sufficient. If and when litigation draws near, a more formal, written, signed and acknowledged Opinion may be warranted. Note, however, that in highly “volatile” industries with significant merger and acquisition activity and shifting product focus, potential defendants contemplating cross-licenses or straight out purchases of third party litigants should exercise caution with respect to formal Opinions. The same Opinions which provide a strong defense could undermine the value of the license or patent ownership later obtained and the ability, to assert the same claims against yet another third party infringer.

D. Experts, Consultants and Privilege

Rule 702 of the Federal Rules of Evidence sets forth the basic criteria for qualification of an expert witness:

“A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.”
“The Federal Rules also differentiate between testifying experts and consulting experts. Consulting experts may help lawyers with preparation and conduct of the litigation. They may also assist in evaluating the other side’s expert reports and deposition. But, consulting experts do not testify at trial or even by deposition. The work product of consulting experts can be kept confidential. On the other hand, a testifying expert will prepare a report that is shared with the other side, will be deposed by the other side, and ultimately will testify at trial and be cross examined by the other side. The materials, reports and work product of the testifying expert all must be shared with the opposition.” “Call in the experts! Finding and using expert witnesses in tech IP litigation,” Melvin C. Garner (June 5, 2015)

In general, communications between a non-testifying expert, attorney, and client are protected from disclosure by attorney-client privilege. Although a consulting expert is technically a third party, if the consultants communications made are on behalf of the client to obtain legal advice, attorney-client privilege applies. See, e.g. U.S. v. Kovel, 296 F.2d 918, 922 (2nd Cir. 1961). This legal rule is based upon the fact that attorney-client privilege is understood to extend to agents of the client or the client’s attorney, and non-testifying experts are therefore considered agents of the client and/or the client’s attorney. See, e.g., Golden Trade v. Lee Anrael Co., 143 F.R.D. 514, 518 (S.D.N.Y. 1992). If a consulting expert is hired by an attorney to assist in dispensing legal advice, those communications are protected by attorney-client privilege.

As discussed more fully below, there are instances in which a non-testifying expert’s opinion may not be protected under the doctrine of attorney-client privilege. For instance, if a consulting expert discloses their opinion to a third party who lacks a common legal interest, attorney-client privilege is waived. Attorneys must also be careful on their part not to disclose any information that an expert imparted to them for the client’s benefit to a third party, as this may also bring into question whether the privilege still applies. Finally, the client must not share the information given by a consulting expert because such an action would ordinarily waive attorney-client privilege. “Do Non-Testifying Expert Witnesses have Attorney-Client Privilege?” Forensis Group, Kat S. Hatziavramidis (Nov. 17, 2014)

However, it has been held that in cases where the client made a disclosure to a third party who is assisting the client’s attorney in obtaining legal advice, the client has not waived the protections of the attorney-client doctrine. See Kovel, supra at 922.

The question of whether a non-testifying expert’s work product is protected by attorney-client privilege turns on the issue of what purpose the information is intended for. Consultants’ communications, where the consultant is acting as an “arm” or extension of an attorney, typically fall under the umbrella of a protected communication under the doctrine of attorney-client privilege. In contrast, where a consultant is retained to determine the cause of a particular event, the communication is not typically a privileged one, and the information imparted by the consultant may be discoverable. See, e.g. Federal Rule of Civil Procedure 26(b)(4)(B).

Fact fathering not calling for legal opinions, advice, or analysis are not subject to privilege. Weil Ceramics & Glass Inc. v. Work, 110 F.R.D. 500, 504 (E.D.N.Y. 1986). “Where the principal purpose is securing legal advice, the privilege will be upheld despite the inclusion of technical data in the communication.” Cuno v. Pall Corp., 121 F.R.D. 198, 201 (E.D.N.Y. 1988).
The distinction between fact gathering and counsel based on facts is made clear by the analysis of the Court in *U.S. Postal Service v. Phelps Dodge Refining Corp.*, 825 F. Supp. 156 (E.D.N.Y. 1994). The *Phelps* court stated that an expert’s opinion may not be protected by attorney-client privilege where the expert’s “function was not to put information gained from defendants into usable form for their attorneys to render legal advice, but rather, to collect information not obtainable directly from defendants.” *Id.* The court clarified that where an expert’s opinion or guidance is based on factual and scientific data that he or she collected, rather than on client confidences, the former communication is not protected by attorney-client privilege. *Id.* The underlying rationale in *Phelps* was that where an expert is hired to collect information that is typically factual and is obtained from sources other than the client, that expert is no longer acting as an agent of the client or the client’s attorney.

**Summary Recap: Distinguish Consulting from Testifying Experts**

Consulting experts:

- can assist counsel with learning and understanding the technology of the asserted patents;
- can provide background information or analysis to testifying experts;
- can provide counsel with guidance in the expert's specialty area when conducting discovery or making strategic case decisions; and
- Typically do not have to be disclosed to opposing counsel unless they need to receive the opposing party's confidential information.

Testifying experts:

- typically submit a written opinion in the form of an expert report;
- are typically deposed concerning their expert report; and
- May provide testimony at trial.

**E. Waiver of Privilege**

An opinion of counsel is useful, if not necessary, to rebut an allegation of willfulness but reliance on an opinion means the opinion must be disclosed and placed into evidence which waives the attorney client privilege with respect to the subject matter of the opinion. Furthermore, the scope of the waiver can extend not only to outside counsel that prepared the opinion but all in house counsel, executives and senior management involved in its review and preparation.

Care should also be taken when selecting opinion counsel if you are already involved in litigation, as some cases suggest the waiver of attorney-client privilege could extend to trial counsel if they are also involved in the opinion work. If feasible, your opinion counsel should be at a different firm than your trial counsel. At the very least, opinion counsel should comprise different lawyers than your trial team. The same principle applies to in-house counsel: clients should monitor the role of inside lawyers overseeing the opinion to ensure that they are not too closely involved in the litigation. See, “Three’s a Crowd: Third-Party Attorney-Client Privilege Waivers,” Tamar S. Wise et. al (Sept 14, 2015).
Determination of who within a corporation is subject to privilege protection, but it can also be a challenge to determine who within a corporation can waive attorney-client privilege, and under what circumstances. Generally, “[t]he power to waive the corporate attorney-client privilege rests with the corporation’s management and is normally exercised by its officers and directors.” *CFTC v. Weintraub*, 471 U.S. 343, 348 (1985).

The attorney-client privilege is designed to protect communications between attorneys and their clients. Sharing privileged information with entities or individuals beyond the attorney-client relationship is considered a waiver of the privilege, and such information would be required to be disclosed. However, courts recognize several narrow exceptions to the rule of third-party waiver. Practitioners should be wary of the extent of these limited exceptions to ensure that attorney-client communications revealed to third parties remain protected from disclosure in litigation. See, “Three’s a Crowd: Third-Party Attorney-Client Privilege Waivers,” Tamar S. Wise et. al (Sept 14, 2015).

Two of these exceptions, the *Kovel* line of cases and the “common interest doctrine,” are discussed below.

1. **The Kovel Doctrine**

   In 1961, the U.S. Court of Appeals for the Second Circuit decided *United States v. Kovel*, which considered whether communications to an accountant waived attorney-client privilege. *Kovel* held that where the accountant was necessary to “interpret” a client’s “complicated tax story to the lawyer” to enable the lawyer to represent the client, that accountant did not destroy the privilege between the lawyer and his client. The *Kovel* court made clear that the doctrine should be fluid to adapt to the changing realities of modern legal practice.

   In the fifty years since *Kovel* was decided, courts have been wary of extending the doctrine beyond its very narrow parameters. Courts have allowed third-party professionals other than accountants to remain within the attorney-client umbrella, but have imposed strict guidelines. The party asserting the privilege must demonstrate that the communications with the third party were intended to (and did) remain confidential and that the third party was necessary to assist the lawyer in communicating with the client. Indeed, the third party cannot simply be useful or convenient in preparing for litigation or implementing legal strategy; courts have been clear that they need to be “indispensable” or serve a “specialized purpose” that the lawyer cannot fulfill without them.

   Care should be taken, however, to distinguish between a third party acting as an agent of the lawyer (which would fall under *Kovel*) and the third party as an agent of the client (where protections are more limited). For example, in *In re Myers* (Bkrtcy. N.D. Ohio 2013), an Ohio federal bankruptcy court considered whether a client’s personal accountant destroyed privilege. It was conceded that the accountant was not hired by the attorney for purposes of translating financial documents and information between the lawyer and client. As such, *Kovel* was not deemed to apply and the presence of the accountant in meetings or on emails destroyed attorney-client privilege. However, to the extent that the accountant, as agent for the client, provided information to the attorneys, these documents were held subject to the attorney-client privilege.

   Practitioners should not be discouraged from seeking to employ third parties for assistance in legal strategy or fact-finding, but should be careful that the third parties offer a skill
set not held by the attorneys, work at the direction and agency of the attorney, and provide a necessary—rather than useful—addition to the legal team.

2. **Common Interest Doctrine**

Another avenue for protecting communications with third parties is the “common interest doctrine.” Under this doctrine, where parties share a common legal interest, communications between them in the course of formulating a common legal strategy are protected from disclosure. The common interest doctrine is similarly limited in nature. It does not protect a common commercial interest between parties, a shared goal or mere shared concerns about potential litigation.” The legal interests between the parties must be identical, rather than merely similar, and the parties must enter into an agreement (even if informal) establishing a common enterprise toward an “identical legal strategy.”

The parameters for the common interest doctrine allow parties to a litigation (or to a potential litigation) to share strategy, information and support without the risk of disclosure. Parties seeking to employ the doctrine should be mindful of its strict requirements – identical legal interest and an overt agreement to engage in a joint legal strategy.

3. **Recent Waiver Case in Patent Law Context**

The District Court for the Eastern District of North Carolina recently issued an opinion (post-Halo) on the issue of attorney-client privilege and work product privilege with respect to the waiver in a patent infringement case in which the defendant relied on opinion of counsel. See, *Krausz Industries Ltd. v. Smith-Blair Inc. & Sensus USA Inc.* (E.D.N.C. Dec. 13, 2016).

Specifically, the court addressed multiple streams of attorney communication including: (1) communications between Opinion Counsel and Trial Counsel; (2) communications between Trial Counsel and Defendants; Communications between In-House Counsel and Defendants; and Communication between In-House Counsel and Trial Counsel. In addition to the parties involved in the communications, the court also addressed waiver from multiple perspectives including subject matter of the communication and the timing of the communication. The alleged infringer argued that the waiver should only apply to pre-litigation matters and materials but the District Court concluded that the waiver also extended to post-litigation matters – including a waiver of privilege otherwise covering communications between the opinion counsel and trial counsel. *Krausz Industries Ltd. v. Smith-Blair Inc. & Sensus USA Inc.* (E.D.N.C. Dec. 13, 2016). See also, “Advice of Counsel Defense in Patent Litigation: Protecting Attorney-Client Privilege,” Michael E. McCabe et. al. (webinar presentation and materials) (March 16, 2017).

**Best Document and Communication Practices for Expert Consultants**

1. **Testifying Expert Activities**

Many aspects of a testifying expert's activities are protected from disclosure under the work product doctrine, including:

- Drafts of any reports or disclosures required by FRCP 26(a)(2), regardless of the form in which it is recorded.
• Communications between counsel and testifying experts, except communications:
  o relating to the expert's compensation;
  o identifying facts or data that counsel provided and that the expert considered in forming her opinions; or

• Identifying assumptions that counsel provided and that the expert relied on in forming her opinions. (FRCP 26(b)(4).)

Work performed by a consulting expert is typically protected from disclosure under both the attorney-client privilege and work product doctrines. A consulting expert's work may not be protected if either:

• A testifying expert relies on the consulting expert's work to form her opinion.
• There is substantial collaboration between the testifying and consulting expert.3


To minimize the risk that an expert's work is subject to disclosure, counsel should:

• Consider including provisions regarding the scope of expert discovery in the parties' proposed discovery plan under FRCP 26(f), including protection for:
  o experts' notes;
  o draft expert disclosures or reports; and
  o Email correspondence between counsel and the experts.

• Limit the interactions between consulting and testifying experts.
• Limit the interactions between experts and the client's technical employees.

3. Confidentiality Considerations for Experts

Counsel should consider which documents each expert may need to form her opinions. Common documents used by patent litigation experts include:

• technical documents relating to the design, development, features and functionality of the accused products;
• documents reflecting sales, profits and marketing of the commercial embodiments and accused products;
• documents relating to the design, development, conception and reduction to practice of the claimed invention;
• prosecution history files of the asserted patents; and
• Licensing agreements related to the asserted patents, commercial embodiments and accused products.

Before sending any documents to consulting or testifying experts, counsel should:

- review the terms of the governing Protective Order or Discovery Confidentiality Order
- ensure that the protective order includes sufficient protections for its own confidential documents;
- determine which experts will need access to the opposing party's confidential information;
- determine the confidentiality designations of the documents counsel wishes to send to its experts; and
- Comply with the protective order's requirements for providing notice to opposing counsel.

Counsel should collect and be prepared to disclose the following information about each expert that will receive confidential information:

- the expert's current address;
- the expert's current employer;
- the expert's most recent curriculum vitae;
- the entities for which the expert has provided services in her area of expertise within the last four, five or ten years; and
- The litigations for which the expert has provided expert testimony in the last four, five or ten years.

To minimize the risk that confidential information is misused by an expert, counsel should:

- provide each expert with a copy of the confidentiality agreement;
- review the key terms of the confidentiality agreement with each expert;
- disclose each expert to the other parties as early as possible so that counsel has enough time to resolve any objections before sharing confidential information;
- designate expert reports and deposition transcripts with the appropriate confidentiality notice; and
- Promptly collect all confidential information from each expert at the end of the case.

4. **Suggestions in light of Krausz Opinion**

Post-Halo, motivation to seek formal legal opinions on issues of non-infringement and invalidity as a preemptive defense against a willfulness claim will increase. Opinion Counsel likely has excellent experience, subject matter knowledge and institutional memory but is not prudent to make them part of the trial team. Engage a different firm from than consulting or advisory counsel as well from trial counsel to serve as formal Opinion Counsel. Do not use prosecution counsel or post-grant proceedings counsel; use separate Opinion Counsel and treat
them like an expert witness. Courts will find waiver for trial counsel communications, even if opinion counsel is not on the communications. Waiver of privilege for in-house counsel and his own client/employer has huge ramification. For important communication, limit the number of recipients and use the phone!

II. Corporate Document and Communication Practices Before, During and After Litigation

A. Best Practices for Keeping Secret Documents Secret

An organization’s differentiation and competitive advantage relies on innovative ideas to develop best-in-class new products and services for its customers. These invaluable ideas must be carefully protected, especially when they need to be disclosed to others. In today’s open, collaborative, information-sharing environments, each employee must understand their responsibility for protecting this vital intellectual property. If Information Assets are not safeguarded, new product designs, for example, can reach the market prematurely or end up in the hands of competitors, damaging profitability and success and/or leading to costly litigation.

Intellectual property theft is a significant and growing concern. Confidential invention information can be stolen, for example, by an unauthorized user accessing an organization’s computer systems, by an organization insider stealing confidential information, or by an employee inadvertently disclosing confidential information. Therefore, within a corporate environment, it is important to establish policies around confidential agreements and documents, policies around trade secrets, and good anti-intellectual property theft policies and actions including, for example, employee education, ensuring all intellectual property security procedures are up-to-date and relevant especially with regards to server environments, tightening and refining procedures for intellectual property confidentiality among employees currently employed, and those that exit the organization.

Every organization should undertake substantial precautions to ensure that its highly confidential information is not misused, including by restricting it to only its trusted employees having a need for such access. For example, companies should require employees not only to execute confidentiality agreements upon commencement of their employment, but also to confirm their understanding of their obligations at the time of their departure, and affirmatively represent to the organization upon their termination that they had not retained any confidential information. As another example, organizations should employ robust technical protections in its systems to detect and thwart unauthorized downloads and access to its confidential and sensitive information. These types of precautions can be helpful to prove intentional and deliberate illegal acts thereafter.

Trade secrets are a valuable and relatively inexpensive, yet effective, tool in protecting sensitive information relevant to the company’s business and the company’s competitive edge. Information kept as a trade secret, which can include formulas, processes and other types of information that is not readily known without disclosure, is not shared outside the organization, and is kept as a secret, providing legal protection without any time limits. Examples of

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information that may be of value to retain as a trade secret include: algorithms, chemical formulas, computer programs, business plans, manufacturing methodologies, design techniques, policy manuals, and customer/supplier lists.

Trade secret laws give broad protection to confidential inside knowledge and generally do not require a substantial financial investment, but they must be managed with a clear and careful policy. For example, to qualify as a trade secret, the information should be clearly marked, employees must have an obligation to keep the information secret, and disclosure within the company of the information should be limited to a “need to know” basis. However, unlike the situation with a patent, the company will have no rights under trade secret laws to prevent others from using its innovation if it was discovered independently by a third party (i.e., without using the trade secret information obtained directly from the company). Trade secrets are only as good as the ability of the company to keep the information a secret, and they are more valuable if it is difficult for competitors to come up with the same information on their own.

In 2016, the Defend Trade Secrets Act became effective, providing a federal trade secret protection that sets forth a uniform definition of trade secrets, a standard for misappropriation of trade secrets, and a process to enforce trade secrets at the federal level, while still preserving trade secret protections under the states. According to the act, “An owner of a trade secret that is misappropriated may bring a civil action under this subsection if the trade secret is related to a product or service used in, or intended for use in, interstate or foreign commerce.” 18 U.S.C. § 1836(b)(1). The enactment of the Defend Trade Secrets Act makes it more important than ever for companies to manage their trade secret portfolio through careful documentation, tracking, and controlling the trade secrets so that at the necessary time, the company can provide the correct and sufficient evidence to enforce this valuable type of intellectual property.

Company culture and education around communications, when the goal is to maintain secrecy or confidentiality, is important to the success of any trade secret or agreement policy. Examples of confidential information that should be included in an employee training process, so that employees learn to recognize and treat as potentially confidential include:

- company information on development products
- unpublished data
- unpublished manufacturing processes
- information on company business development activities
- company financial information
- third party information subject to a confidentiality agreement
- invention disclosures and unpublished patent applications

Employees should be trained to have a basic understanding of what is a confidentiality agreement, how to determine if they need one, how to determine if one is already in place, and the timing and process for establishing confidentiality with a third party. Employees should also be aware of how to report loss or unauthorized use of confidential information such as reporting a theft or loss of any device containing intellectual property and/or confidential information, and reporting an unauthorized disclosure or attempt to gain unauthorized access to such information.

Company policies should be implemented and well communicated to all employees for the managing of such important information including, for example: sharing information only with those who have a specific business need to know and appropriately labeling and classifying
all information. Further, if disclosing to a third party, policies should ensure all information is labeled confidential and “do not redistribute” and that a written agreement containing confidentiality provisions is required. Company policies should further require employees to lock desks and cabinets at end of the workday, keep documents, laptops, portable electronic devices and storage media in their control or locked up. Employees should also be coached that when accessing confidential information in public places, they should ensure that it cannot be seen by others.

B. Best Practices for Company Communications

Ideally, IP protection should become a common business practice throughout the organization. Protect against “IP Leakage” as an unexpected result of any and all activities. Collaboration with the information security team, the commercial legal team, the company communications team, and others can be invaluable in achieving “IP Lockdown” throughout the organization. Provide a common thread in all company communications using repetitive themes and repetitive phrasing. Use a catchy phrase such as “Pause to Protect IP” as a way non-legal employees can readily remember and understand. When making IP protection a common business practice, re-evaluate all agreement templates, all company procedures, document marking, and the like to be consistent and clear in all activities.

Employees who are not part of the legal department are frequently under immense pressure to meet deadlines and do their part to advance company goals and products. As such, they can be quite unaware that their communications may be consequential in litigation until it is too late. The challenge to the legal department is developing a process for educating employees on how to recognize what can be discovered in litigation and its potential impact, and most importantly, to understand and accept their role in maintaining the appropriate mindset as they forge ahead on company projects. Understanding the corporate culture and the pressures to which employees are exposed will enable a more productive education method, which can be tailored to different groups within the company.

First, employees should be educated on a basic (high-level) understanding of confidentiality, privilege, and what can be obtained during a discovery process in litigation. For example, many employees are surprised to learn that documents subject to discovery can include not only reports and lab notebooks, but what is in their emails, what is written on their white board, what is in meeting minutes, and even what is scribbled on scrap paper and inadvertently tossed in a drawer.

Second, company employees should be educated on how to create the necessary supporting proof that may establish that their communications are privileged and/or confidential. Helpful tips include:

- Make it simple to identify the attached privilege
- Mark documents with the appropriate legend (e.g., Confidential, Attorney-Client Privilege, Work Product Doctrine Applies, etc.)
- Don’t use abbreviations, slang or acronyms in privileged communications
- Don’t communicate with third parties regarding a patent or other intellectual property (unless under a confidentiality agreement)
- Develop a controlled process for both marking and sequestering documents that are specifically subject to attorney-client privilege separately from day-to-day
documentation (e.g., notes from a meeting with the legal department regarding a possible non-infringement strategy in view of a competitor’s product)

- Don’t use your notebook or any document that is not a direct communication with the legal department (for the purpose of rendering legal advice) to opine on the validity of a competitor’s patent, or whether your idea is obvious, or whether your current project infringes another patent

- Seek legal advice from the legal department when your question involves a patent or other form of intellectual property

Managing communications becomes especially difficult in this digital age where the norm is to communicate via email, text messaging, hangouts and the like. Employees must be educated to prioritize phone calls and in person discussions over electronic communications when litigation may be implicated thereafter.

Tips for employees on how to communicate appropriately electronically include:

- Limit messaging streams to one topic (e.g., one product, one idea, one question, etc.)
- Practice the “WSJ” rule (e.g., imagine your email will be on the front page of the Wall Street Journal tomorrow)
- Do not make legally conclusive statements (unless it is a privileged communication directly with legal counsel)
- Limit distribution of confidential messages to a controlled group
- Mark confidential and/or privileged messages as such

C. Best Practices for Managing and Memorializing Innovation, Innovation Ownership, and for Avoiding Conflicts Created by Non-IP Company Disclosures

1. Managing and Memorializing Innovation and Invention Disclosures

Development of a corporate innovation strategy could be thought of as building an intellectual property “fence”. The fence draws a boundary around the intellectual property of the company and the ultimate formation of the fence (e.g., memorialization of the innovation) may take many forms: (a) offensive intellectual property positions (intellectual property, including patents, trademarks, and copyrights, that attracts investors and partners, maintains a competitive advantage by protecting core business technology, and creates exit options); (b) defensive intellectual property positions (intellectual property that provides a defense from competition, blocks alternative technologies, and builds value through incremental improvements to core technology); (c) documented trade secrets; and (d) defensive, or strategic, publications. A well-crafted innovation strategy can be used to protect innovations directly related to lead or core projects and future programs, and also to protect platform, or disruptive, technologies that may place a company as a major force within the competitive landscape.

Part of a corporate innovation strategy is developing best practices for managing innovation from its inception (ideation) to final implementation or disposition, and for memorializing the innovation in a form (e.g., a patent application, a trade secret, a trademark, a copyright, a defensive publication, or simply a confirmation that no further action is to be taken) that brings the company the maximum value.
Keeping a developing innovation private for a period of time has the advantage of allowing the company to evaluate the innovation at legal, business and management levels, to conduct experiments, to undertake development work, and to advance design concepts. In addition, keeping innovation private for a time may be especially strategic in fields such as the pharmaceutical field, where careful positioning of patent application filings against the timing of regulatory submissions can leverage patent term extension (PTE) and thus greatly enhance the value of the patent to the company through life cycle management. In addition, keeping an innovation secret until proof-of-concept is established or other business goals are met allows a company to strategically make competitors aware of advances and the direction the company is planning to take.

While the timing of public disclosures has always been a key to preserving intellectual property rights for patents and defensive publications, as of March 16, 2013, the last provisions of the America Invents Act (AIA)\(^5\) came into effect, causing patent law in the U.S. to transition from a “first to invent” to a “first inventor to file” system. Under the new system, while a one-year grace period still exists for public disclosures, the public disclosure is limited to those made by the inventor, and is quite limited in scope as interpreted by the USPTO\(^6\), such that the applicant may still fall prey to an intervening disclosure. In addition, there are prior art penalties for the unwary related to any public disclosures by a third party, including printed publications, public use, on sale, or any disclosure “otherwise available to the public”\(^7\).

Therefore, the corporate practitioner is pressured to carefully manage innovation and to pursue appropriate protection in a timely and strategic manner. However, innovation management and memorialization efforts within a company are often subject to a variety of other internal and external forces that can disrupt the best planning, including budget issues, lack of time for employees to devote to innovation, lack of time and resources required to develop the innovation, shifting business priorities and competitive strategies, and changes in management support for innovation. Therefore, company-wide education about innovation, intellectual property strategy, and how inventions are vetted, pursued, and enforced, and development of a clear process for memorializing innovation within a company will benefit the IP strategy at all levels of the company.

How should innovation be memorialized and tracked? Many companies employ a method of innovation reporting which captures ideas in the form of an invention disclosure or innovation disclosure. Whether this disclosure is provided on paper or in electronic format, a first objective should be to ensure that the completion of the document and the actual communication of the document from the inventor is in the form of a confidential communication from the inventor directly to the corporation’s legal department, or directly to a patent practitioner (patent attorney or patent agent) working for the corporation (in-house or outside counsel), with the express intent to obtain legal advice regarding the invention. This process establishes a privileged communication between the innovator and his legal department regarding the innovation.

Invention disclosures, being prepared by employees who are likely not patent practitioners or lawyers, and who may have little experience with the patent process, may contain

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\(^6\) Examination Guidelines, 78 Fed. Reg. at 11,067
\(^7\) 35 USC §102, post-AIA
statements and opinions regarding the prior art, opinions about the features of the invention, opinions about the shortcomings of the invention, and comments on a “design-around” of a competitor’s product (which might be patented), as examples. While such statements are relatively harmless and may be quite informative during the innovation evaluation and memorialization process when taken in the context of an invention disclosure, a litigator would likely find such statements to be a treasure trove of problems for the inventor’s employer during litigation. Accordingly, the invention disclosure should always be treated as a confidential and privileged document throughout the management process.

Invention disclosures in litigation have been the subject of some notable court decisions. For example, in the case of In re Spalding Sports Worldwide, Inc. the Federal Circuit reviewed the issue of whether the attorney-client privilege applies to an invention record (i.e., invention disclosure) for a patent in litigation, where the invention record was asserted by the plaintiff to be subject to the privilege. The court granted Spalding’s petition for a writ of mandamus and reversed the denial of privilege by the district court. In this case, the court confirmed that communication to a patent attorney is privileged “as long as it is provided to the attorney ‘for the purposes of securing primarily legal opinion, or legal services, or assistance in a legal proceeding’”.

In another case, E.I. du Pont de Nemours & Co. v. MacDermid, Inc., the court examined whether communications involving an in-house, registered, non-attorney patent agent, should be protected by attorney-client privilege. The court found that communications about an invention between the patent agent and non-attorney personnel (e.g., inventors) were not protected by attorney-client privilege, although in this case, the decision relied on the fact that the patent agent in question did not directly report to the in-house patent attorney, but was instead assigned to the business side of the company, and only worked “with him, as opposed to for him or under his authority”. While the specific question of whether there is a patent agent-client privilege has since been affirmed by the Federal Circuit, the focus on the separation of business and legal units when privilege is applied to communications about inventions should be noted.

An invention disclosure can be documented and maintained in paper form, but an electronic form is better for purposes of clearly memorializing the disclosure in a form that can be preserved and accessed by relevant parties within the corporation. Having a database or document management system that records and tracks the receipt of the invention disclosure is an additional best practice. If possible, such a system should also be able to: (a) route the disclosure to an Innovation Review Committee (a committee who will review and recommend or decide on further actions), (b) calendar dates for further action (to keep innovations on track for a final decision on whether and how to protect the innovation and to avoid abandonment of ideas), and (c) document and track the ultimate disposition of the disclosure (patent application, trade secret, etc.). The invention disclosure should be signed by at least the submitting party, preferably with a non-inventor witness, and also by any possible inventors, if identified. Finally,

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8 In Re Spalding Sports Worldwide, Inc. 203 F.3d 800 (Fed. Cir. 2000).
9 Id., quoting Knogo Corp. v. United States, 213 USPQ 936, 940 (Ct. Cl. Trial Div. 1980) and Sperry v. Florida at 379.
11 Id. at p. 11.
12 In re Queen’s University at Kingston, Parteq Research and Development Innovations, 2015-145, F.3d (Fed. Cir. March 7, 2016)
while many forms of inventions disclosures exist, an invention disclosure including the following elements are particularly useful:

- Describes the invention in as complete a manner as possible
- Includes working examples, drawings, pictures and other illustrations of the invention, when possible
- Describes the inventor’s knowledge of the prior art in an objective manner, preferably without excessive opining on the prior art
- Describes the advantages of the invention over the prior art
- Describes and highlights any unexpected or surprising results
- Provides full contact information for the inventor (for use later in the preparation of Declarations and Assignments, in the case of patent protection)
- Provides a business justification for the innovation, i.e., relationship to core technology or lead product development
- Provides any information regarding real or possible disclosures of the innovation to a third party, even if under CDA
- Identifies any potential inventors, including those that may be consultants, collaborators, or other business partners of the company

As discussed above, the results of ideation sessions or general innovation efforts within a company should be tracked, and the successes touted, to promote future ideation and support of the innovation management process by product development teams and management. The invention disclosure process should preferably document the outcome of any decision to (a) pursue a patent or trademark filing; (b) hold the innovation as a trade secret, (c) publish the innovation either as a defensive publication or a benefit to innovators whose ideas did not merit options (a) or (b); or (d) take no further action with respect to the innovation. Such documentation is important so that the correct follow-on procedures are initiated for the various decision points, and so that there is no lack of clarity with inventors, with management, or with consultants or collaborators, if involved, as to the intended use of (or decision to abandon or release) the innovations. For decision (a) when the invention may be patentable, the elements of timing for patent filings as discussed generally above will come into play, and a process should be established for moving toward a filing of the invention to avoid inadvertent abandonment of the innovation or other loss of rights. Documentation of decision (b) for trade secrets is discussed in earlier sections of this paper. Decision (c) may require additional strategic planning relative to the timing of the publication, if defensive. With respect to (d), some companies offer the invention to the inventor(s) to pursue on their own. In this case, the transfer of ownership, and the boundaries of that transfer (e.g., coverage of the invention as disclosed versus improvements) should be carefully documented and clearly understood by the company and by the inventor(s).

By carefully managing and memorializing innovation, a company can (a) protect its innovations in the most appropriate manner without unintentionally losing or jeopardizing rights; (b) quantify the impact of the resulting intellectual property for management by establishing key performance indicators; (c) engage and incentivize company innovators and reward them for that innovation; and (d) advance critical projects by providing actively managed and strategic intellectual property initiatives. These efforts validate the continued investment by the company in intellectual property and encourage the innovation process to repeat and advance.

2. Ownership and Assignments
Issues regarding ownership of intellectual property can plague a company, if not managed properly. Deals have been jeopardized and presumed patent rights found to be missing when it was learned that the company did not have clear title to the intellectual property it thought it owned. Ownership of intellectual property can be protected, and lost, in many different ways. A patent is a personal property and as such, the determination of ownership of a patent is based in property law. Under U.S. laws, patents, applications for patents, or any interest therein, are “assignable in law by an instrument in writing.” The America Invents Act (AIA) brought changes the presumption of ownership when an application for patent is filed. For applications filed prior to September 16, 2012, the named inventor(s) are presumed to be the owner of the application for patent, unless there is an assignment. However, for applications filed on or after September 16, 2012, the original applicant is presumed to be the owner of an application for an original patent, unless there is an assignment. The distinction is important because a “juristic entity” (e.g., a corporation) may now file a patent application with the presumption of ownership and then take limited actions in the prosecution of the application (e.g., sign terminal disclaimers, statements under 37 CFR 3.73(c), powers of attorney, and a substitute statement).

Execution and recordation of a proper assignment of the patent, application or other patent interest to the employer or assignee is also critical to ensure that the rights are transferred to the employer, and that the employer can then further transfer ownership with clear title or engage in other corporate transactions, or take certain actions in the patent (e.g., enforcement, collection of damages, etc.). Accordingly, to ensure that the corporation qualifies as a “juristic entity” that can act as applicant under the patent rules and rightfully record assignment of an invention, it is a best practice (if not essential) to utilize a proper employment agreement with employees at hire (e.g., proprietary information and invention agreements, or the like). A proper agreement will include clear provisions regarding what proprietary information is owned by the company, as well an active assignment to the employer of any inventions made by the employee within the scope of her employment. Implementation of well-drafted employment agreements will prevent and resolve situations, such as the now infamous dispute over invention ownership between Leland Stanford Junior University and Roche Molecular Systems, Inc.

For a company that is involved in litigation, or in frequent transactional agreements involving patent properties, timely recordation of the Assignment after execution, preferably within three months of its date of execution, or in any event, no later than upon payment of the issue fee in an application, should also be considered a best practice. For example, paragraph 4 of 35 USC 261 reads:

13 35 U.S.C. §261
15 37 CFR 3.73(a) pre-AIA; and Beech Aircraft Corp. v. EDO Corp., 990 F.2d 1237, 1248, 26 USPQ2d 1572, 1582 (Fed. Cir. 1993)
16 37 CFR 3.73(a)
17 37 CFR § 1.42
18 Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., et al., slip.op. 563 U.S. (2011). The Supreme Court held that the Bayh-Dole Act did not automatically vest title to an invention in Stanford, because the faculty member inventor had only signed an acknowledgment of a duty to assign future inventions with Stanford, but affirmatively assigned his rights in the same invention to Cetus (later owned by Roche).
“An assignment, grant or conveyance shall be void as against any subsequent purchaser or mortgagee for a valid consideration, without notice, unless it is recorded in the Patent and Trademark Office within three months of its date or prior to the date of such subsequent purchase or mortgage.”

Other intellectual property ownership scenarios may create complications for a company. For example, ownership of intellectual property may be unclear when the inventor is a company founder, an employee who has a relationship or contractual arrangement with another entity such as an academic or not-for-profit institution, or a newer employee who has a prior employment contract and obligations with a previous employer. Further complications can arise when improvements to a technology are made that are subject to government rights or under agreements with collaborators, particularly when the collaborator is a university or other government entity. In all of these situations, best practices often point to first having a process whereby the corporation comes to clearly understand all prior obligations that may attach to a particular employee before an invention is made at the company, and second, if possible, drafting agreements that are clear and maximize the ability and opportunities to obtain clear title, or at least an appropriate license, to the invention.

Corporations should also be mindful of ownership of intellectual property created by consultants. Consultants who may or will be involved in innovation and therefore may be expected to convey rights in the invention or other intellectual property should, prior to beginning any work for the company, first execute an agreement that clearly states what proprietary information is owned by the company, and includes an active assignment to the employer of any inventions made by the consultant within the scope of the engagement. As the following examples shows, it is also a best practice to understand what prior work and inventions a consultant might have made prior to the agreement, and understand and review issues of inventorship and ownership related to any such work.

In the recent case of TriReme Med., LLC v. AngioScore, Inc.19, AngioScore engaged a consultant to help with the development of a medical device, although prior to the execution of the consultant agreement, the consultant had already started work. Importantly, certain advice by the consultant provided in connection with the work prior to execution of the consulting agreement later resulted in patents directed to the medical device filed by AngioScore. Also importantly, in the consulting agreement, when asked to provide a list of any prior inventions, the consultant provided no list. The consultant eventually completed work with AngioScore. Fast-forward some years, when AngioScore’s competitor, TriReme executed an agreement with the same consultant in order to obtain ownership of any inventive rights of the consultant that were created prior to the execution of his agreement with AngioScore. TriReme then sued AngioScore and argued ownership of the consultant’s rights in the invention. While the District Court ruled in favor of AngioScore because their consulting agreement contained an active assignment of inventions and did not list any prior inventions, the Federal Circuit reversed the decision on the basis that in the absence of specific, limiting language, the absence of a listing of the prior inventions did not prevent the assignment of such inventions to TriReme. Best practices learned from this case: (1) always have consultants execute the consulting agreement prior to beginning any work for the company; and (2) clearly define how and under what

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circumstances, rights from prior work are to be assigned to the company, as well as rights from work performed during and even after the agreement expires or is terminated.

3. Avoiding Conflicts Created by Non-IP Company Disclosures

As a company advances an intellectual property strategy, and particularly, a patent strategy, or as a company develops a position with respect to a competitor’s patent position, care must be taken to avoid conflicts that can arise by creating contradictions in other documents, such as filings to the government (Food and Drug Administration (FDA), Securities and Exchange Commission (SEC), etc.), in internal presentations or project meeting notes, or in an innovator’s lab notebooks and development documentation. A patent practitioner may take great care to ensure that filings and statements made during the preparation and prosecution of a patent application, both in the U.S. and abroad, are consistent, meet disclosure requirements where applicable, and attempt to limit negative exposure during litigation. Similarly, a patent attorney or litigator evaluating freedom to operate based on non-infringement or invalidity may take great care in ensuring that the documentation of such positions and opinions is confidential and privileged, and that the position advanced during litigation is consistent with those positions and opinions. However, while much attention is given to these areas, a trap for the unwary corporate practitioner may be found in other corporate documentation that takes a position or makes a statement that unknowingly and/or inadvertently contradicts the position taken in the patent filing or litigation strategy. Such problems are often the result of the simple distribution of responsibilities within the organization, and can also result from a lack of coordination or communication and/or review of documentation filed among different business units of a corporation, as well as a lack of understanding of the patent and litigation processes within departments other than the legal department.

Failing to understand the consequences of statements made in such other documentation can result in the provision of a roadmap for: (a) a competitor to allege infringement or a competitor to avoid a charge of infringement, (b) the ruination of an invalidity position; (c) the loss of patent rights during prosecution or after patent issue; or (d) charges of inequitable conduct.

During prosecution of a patent application, each individual associated with the filing and prosecution of a patent application has a “duty to disclose to the Office all information known to that individual to be material to patentability” (as defined in 37 CFR 1.56)\textsuperscript{20}. While the standard for inequitable conduct has been in flux both through the courts\textsuperscript{21} and the USPTO’s proposed rule-making\textsuperscript{22}, the general legal analysis considers whether the applicant was aware of the prior art, whether there was an intent to deceive the USPTO by withholding the art, and whether the prior art was material.

Companies who must comply with regulatory laws under the FDA are particularly susceptible to conflicting disclosures. Patent strategies may be developed in isolation, or perhaps lack understanding, of a corresponding regulatory strategy, which may create issues with respect to the duty of disclosure and defense of patents during litigation. In the case of medical device manufacturers, this conflict has created an issue when representations regarding §510(k) devices

\textsuperscript{20}See 37 CFR 1.56 and MPEP 2000
\textsuperscript{22}Federal Register Vol. 81, No. 209, 74987, October 28, 2016
made to the FDA conflict with statements made during patent prosecution or patent litigation. Specifically, under one type of §510(k) approval for medical devices, an applicant may rely on a "predicate device" and establish that their new medical device is "substantially equivalent" to the approved and legally marketed predicate device. The document averring this position will ultimately become publicly available. This may create issues with a corresponding patent claiming the device because (1) an assertion of equivalence with respect to safety and efficacy may negatively impact the assessment of novelty and non-obviousness under patent laws; and (2) an assertion of equivalence may allow one competitor to allege infringement of its patents by the device or another competitor to avoid infringement using the applicant’s own admissions.

While courts have trended toward recognizing the problems of conflating substantial equivalence statements with admissions of unpatentability, a corporation must still be very cognizant of the potential conflicts. In Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd., Bruno argued that its statements of substantial equivalence to the FDA for a stairlift in a 510(k) filing was “relevant only for the purpose of securing FDA approval,” and that the failure to disclose the prior art (predicate) device to the USPTO during prosecution of its patent was not material. The Federal Circuit disagreed and confirmed that Bruno committed inequitable conduct.

In contrast, in Pfizer Inc. v. Ranbaxy Laboratories Ltd. and Abbott Laboratories v. Sandoz, Inc. where data submitted to the FDA that was not also submitted to the USPTO, and data submitted to the FDA that indicated a lack of support for product-related patent claims, respectively, were not deemed to constitute inequitable conduct. The particular details of these cases are of course informative, and beyond the scope of this paper, but should be reviewed as relevant to the ultimate decisions.

An article by Arora et al. eloquently summarizes the issues that a company can encounter when patent litigation crosses paths with non-patent corporate documentation. While this commentary is specific to the medical device industry and regulatory submissions, the message could be generally applied to other to industries in which regulatory law and litigation are common (pharmaceuticals, biotechnology). Indeed, regardless of which industry a given company occupies, the lessons conveyed here are still very much worth noting.

“For medical devices, the patent and FDA regulatory processes have considerable interplay. Simply put, commercializing a medical device is unlike developing other products. As explained above, it can involve significant clinical research, a clinical trial to demonstrate safety and effectiveness, and regulatory approval from the FDA. How a company handles these tasks will impact its patent portfolio. The people focused on these tasks are likely oblivious to patent consequences—they are simply diligently working toward other goals and have other business needs. Medical device patent attorneys should beware: you may live and breathe patents, but you likely lead a solitary existence. Most

23 21 CFR 807.93
25 394 F.3d 1348, 1350–51 (Fed. Cir. 2005)
26 457 F.3d 1284 (Fed. Cir. 2006)
27 544 F.3d 1341, 1343 (Fed. Cir. 2008)
28 Arora et al., supra
people in your company are probably blissfully unaware of how their everyday activities can impact your company’s patent portfolio. You may never know the consequences of what they are doing until uncovered much later during patent litigation, which is common in the medical device industry. Infusing knowledge of the interplay between the patent and FDA processes can help ensure coordination between regulatory and intellectual property personnel, increase opportunities, and avoid pitfalls with the patent portfolio and accompanying business strategy.”

D. Dealing with Protective Orders in Discovery

Even the youngest attorneys recognize that discovery is an arduous process through which thousands, and often tens or hundreds of thousands, of documents are exchanged, hours of depositions are taken, and dozens if not hundreds of discovery requests are served. The Federal Rules of Civil Procedure, often in conjunction with a court’s local rules, govern the process for taking discovery. The rules broadly permit discovery to extend into “any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case” and “[i]nformation within this scope of discovery need to be admissible in evidence to be discoverable.” Fed. R. Civ. P. 26(b)(1). Thus, with the exception of privileged information and attorney work product, most anything remotely relevant to the case will be discoverable.

The scope of discovery extends to extremely confidential and sensitive material, especially in the context of intellectual property litigation. This includes carefully protected trade secrets, business and financial information, and other categories of information a party would not want accessible to either the public or another party. The desire to keep these documents out of the public record is natural and understandable. After working tirelessly to develop competitive edges and to protect confidential documents, as discussed supra, granting the public or a competitor access to these documents would ruin their benefit.

Keeping confidential documents out of the public domain and away from competitors must be balanced, however, with the public policy of keeping court’s open and accessible to the public.29 This balance is often struck by the court entering a protective order at the outset of discovery. Federal Rule of Civil Procedure 26(c) provides a mechanism for obtaining a protective order. “Any party or any person from who discovery is sought may move for a protective order in the court where the action is pending” and “[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, or undue burden or expense[.]” Fed. R. Civ. P. 26(c)(1).30 Rule 26(c) lists several possible remedies for moving parties, including: “forbidding the disclosure or discovery;” “specifying terms, including the time and place or the allocation of expenses, for the disclosure or discovery;” and “prescribing a

29 Also being balanced is a party’s first amendment right to freely disseminate information gained in discovery. Jepson, Inc. v. Makita Elec. Works, Ltd., 30 F.3d 854, 858 (7th Cir. 1994); In re Harkin, 598 F.2d. 176, 188 (D.C. Cir. 1979).

30 Protective orders, even if they are applied for jointly, are not automatically granted and failure to demonstrate “good cause” can be a tripping point. See Foltz v. State Farm Mut. Auto. Ins. Co., 331 F.3d 1122, 1130 (9th Cir. 2003) (“A party asserting good cause bears the burden, for each particular document it seeks to protect, of showing that specific prejudice or harm will result if not protective order is granted.”)
discovery method other than the one selected by the party seeking discovery.” Fed. R. Civ. P. 26(c)(1)(A)-(C).

At the outset of discovery, and lieu of moving for a protective order on a document by document basis, the parties will often jointly move for an overarching protective order pursuant to Rule 26(c) to generally govern the discovery of documents and other information which should be restricted from the public, other parties, or both. See e.g. In re Alexander Grant & Co. Litig., 820 F.2d 352, 357 (11th Cir. 1987) (“We conclude that in complex litigation where document-by-document review of discovery materials would be unpracticable, and when the parties consent to an umbrella order restricting access to sensitive information in order to encourage maximum participation in the discovery process, conserve judicial resources and prevent the abuses of annoyance, oppression and embarrassment, a district court may find good cause and issue a protective order pursuant to Rule 26(c).”). These joint, or consented, protective orders have become extremely common place in federal court litigation. In these protective orders, discovery material such as produced documents and deposition testimony will typically be given confidentially designation prescribed by the protective order. For instance, confidential information that should not be disclosed to the public but does not rise to the level of a trade secret or highly sensitive financial document could be labelled “CONFIDENTIAL” while trade secrets and other documents whose disclosure could destroy a critical business advantage might be labelled “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY.” The later designation would be for discovery material that only attorneys, and not the parties themselves, could view and be granted access. While parties may still feel uncomfortable producing highly sensitive documents to opposing counsel, these designation tiers at least provide a framework to allow discovery to progress while providing safeguards to prevent opposing party’s access to a company’s closely guarded secrets.

As in-house counsel, one notable area of tension is the ability for in-house counsel to view and access highly sensitive documents. On the one hand, in-house counsel are themselves attorneys tasked with managing, and sometimes actively participating in, the underlying litigation and it may be critical to the success of the litigation that in-house counsel be granted access to the opposing party’s highly confidential material. On the other hand, in-house counsel are strictly employed and compensated by the party, and that compensation often includes stock options, and in-house counsel may be actively involved in the party’s business decisions. Thus, compartmentalizing what in-house counsel may learn about another party’s highly confidential documents during litigation may not be realistic. As a practical scenario, in-house general counsel learning a competitor’s pricing structure or its royalty rates with third parties for an asserted patent cannot be reasonably expected to ignore this information as counsel is sitting at the negotiating table with competitors extraneous to the litigation. Accordingly, counsel should carefully consider the need for in-house counsel to be able to participate in the discovery process as its negotiating how the most sensitive information is handled pursuant to a protective order.

Protective orders can have a costly, and perhaps chilling, effect if the designation privileges are abused. Public documents erroneously designated “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL-ATTORNEYS EYES ONLY” may inhibit litigation in several ways. Confidential documents will be subject to under-seal filing restrictions, which in some
jurisdictions are onerous and can increase litigation costs. Documents may also be given a confidential designation for no purpose other than to inhibit opposing parties from viewing information in an effort to stymie their litigation efforts. If a critical document is given a highly confidential label, outside counsel may be unable to share this document with their client pursuant to the protective order, which may affect their ability to explain litigation or settlement strategy. Protective orders should provide a challenge mechanism in order to resolve designation disputes. For instance, a protective order might provide for a meet and confer process before a party can move the court for de-designation pursuant to an entered protective order. Counsel should carefully review any such process before agreeing to the terms of the protective order. An overly laborious meet and confer requirement for de-designation might still have the practical effect of slowing down litigation even though the information may eventually be de-designated.

Once the litigation has concluded, protective orders often will require confidential material to be destroyed. This may include a certification provided by the receiving party with a certain a time frame. Counsel should consider whether the destruction requirements are overly restrictive in agreeing to protective order terms with respect to what happens with the confidential material exchanged.

III. Conclusion

The critical role of the intellectual property practitioner in the development of a company culture that understands, respects, and applies best practices in communications cannot be underemphasized, whether the company is routinely or rarely involved in litigation. A careful review of corporate-wide policies, attention to education of employees at all levels of the company, and an understanding that some employees may be unaware of how their everyday activities can impact your company’s intellectual property portfolio are all essential elements in the development of a company culture designed to reduce negative issues faced in the litigation environment.

31 It is not uncommon for courts to require parties to publicly file a notice of filing under seal. See e.g. Local Rule 5.3(a), E.D. Mich; Local Civil Rule 5(B), E.D. Va. Other courts require the filing party to move for leave to file any document under seal. See e.g. Local Rule 5.2, N.D. Ohio; Local Civil Rule 5.3(C), E.D. Va; Local Rule 1.09, M.D. Fla; General Local Rule 79(d), E.D. Wis. Under seal filings may also require redacted copies to be filed publically. Whether it is a notice or motion, the more documents filed under seal the greater the increase in motion practice for the parties.

32 Paraphrased from Aroro et al., supra.