

Complex IP Issues and the C-Suite: How to Explain Them to the Boss

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Avoiding Problems While Collaborating in the Medical Textile Industry

December 19, 2019

Medical Product Outsourcing

By Mareesa A. Frederick; Courtney A. Bolin

In the textile industry, medical textiles represent one of the fastest growing segments of the market. Driven by a demand for new innovative products, the medical textile industry is constantly evolving and looking for ways to improve the efficacy and wearability of medical products. However, as with many textiles, commercializing a medical textile can be prohibitively expensive—the manufacturing equipment is costly, research budgets can balloon, and the timeline to reach the market is frequently unpredictable. In addition to the costs of developing a medical textile, companies also must obtain U.S. Food and Drug Administration approval before selling their products in the domestic market; this process can take years.

Companies may seek to overcome these barriers by outsourcing parts of the manufacturing process to partner companies or universities—this kind of arrangement is often referred to as a horizontal supply chain. A horizontal supply chain can be beneficial because it fosters a more collaborative environment that helps get a finished product to market faster. For example, when companies work together, there is more specialized expertise and varied approaches to problem solving—which can reduce upfront costs, lead to an improved finished product, and allow for more competitive pricing later on. However, from a legal standpoint, working collaboratively can also create problems.

In this article, we highlight how collaboration can affect patent rights, and provide suggestions that may help companies avoid problems arising out of improperly including or excluding an inventor from a patent application.

The Legal Implications of Working Collaboratively on Inventorship

In the United States, patents grant the right to exclude others from making, using, selling, offering for sell, or importing the patented invention. Essentially, obtaining patent rights provides the patent holder an opportunity to enter the market exclusively and profit from the invention before his or her competitors. Another benefit of obtaining patent protection is that patents can be sold or licensed to others, which means that a company can profit from their patented invention even if they do not manufacture it themselves. In order to obtain a patent, the invention must meet the legal requirements of patentability. In this article, we focus on the legal requirement that the true inventor(s) must be named in the patent application.

Conception of any idea begins with an inventor—an individual who had a light-bulb moment, offered a solution to a problem, or had a spark of creativity. However, identifying the inventor (or joint inventors) is not always a straightforward task. This is especially true in the medical textile industry where scientists at different companies often collaborate.

There are several requirements to keep in mind when determining whether one is a joint inventor. Each of these requirements must be satisfied:

• **Collaboration**: Joint inventorship can only arise if some form of collaboration or common effort exists between one or more individuals. For example, scientists who work in groups and share ideas would be considered

1

collaborators regardless of whether they are in the same physical location.

- Contribution: Each inventor must contribute to the idea that ultimately becomes the patented invention. This requires more than just providing general research tips or an overall goal, rather to be an inventor one must have a specific idea in mind and a particular means of achieving that result. As an example, if two scientists jointly agreed to develop an improved hernia mesh, and Scientist 1 suggests a specific fabrication and Scientist 2 suggests a specific finishing, both would be considered joint inventors.
- Considerable Contribution: Finally, the contribution that each inventor makes must be significant. In other words, the contribution must be one that is new and not just a concept well-known by others in the medical textile field. For example, if the fabrication proposed by Scientist 1 was already known to improve hernia meshes, he would not be considered an inventor, because he did not contribute anything new. As another example, if Scientist 1 came up with the idea to use both the fabrication and finishing to make the hernia mesh and Scientist 2 merely used well-known techniques to manufacture Scientist 1's invention, Scientist 2 would not be an inventor.

Establishing collaboration, contribution, and the significance of that contribution is highly fact-specific and requires a close look at the work of each individual participating in the collaboration. Thus, collaborating companies must have measures in place to track individuals' contributions to product development and ensure that each company understands their right to any resulting patents from the collaboration.

Avoiding Legal Issues Caused by Incorrect Inventorship

In view of the legal requirements required to be a joint inventor, good record-keeping is important to collaboration. Good record-keeping may take different forms for certain companies; however, there are some general guidelines that we suggest for recording and tracking the product development process:

- Have a System for Recording Information: No matter what form it takes, a company should have a permanent, complete, and continuous method of recording where ideas originated and the work conducted to carry out those ideas. These records may be in the form of bound or digital laboratory notebooks where the details of meetings, experiments, and data are kept.
- Track Who Enters Information: Further, it's just as important to know who recorded information as it is to record the information itself. Make sure that all record keeping entries are dated and signed (preferably by two people; more preferably, at least one person from each collaborating company). This will allow companies to track the source of information and follow up with questions if needed later on.
- Have a Contract in Place that Discusses Intellectual Property Rights: Collaborating companies should ensure that contracts are in place that address the intellectual property rights of each party. Joint development agreements typically state that patents on inventions jointly made by employees of both contracting parties will be jointly owned. However, parties should also carefully consider all provisions relating to ownership rights, in particular, the rights and obligations of the parties with respect to jointly owned patents. Patents are property rights and may be owned by one or more parties. This means that, if there is a dispute between the parties and no writing exists regarding ownership, the outcome may be unpredictable. When considering ownership provisions, it is important for companies to talk to each other and determine how patent rights will be owned. For example, Company 1 may fund the research and development of Company 2's product, and in return Company 1 may own any resulting patent rights and grant Company 2 a nonexclusive license.

By taking measures to maintain good records and clear contracts, collaborating companies are better equipped to file patent applications naming the proper inventors and reduce the likelihood of future disputes. Although the initial undertaking of putting record keeping systems and contracts in place between the parties can be daunting, these measures are essential to collaborating on product development and maintaining healthy long-term business relationships.

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Mareesa A. Frederick Partner Washington, D.C. +1 202 408 4383 Email



Courtney A. Bolin Associate Washington, D.C. +1 202 408 4203 Email

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ARTICLE

Clean Your Room: Protecting Against Trade Secret Misappropriation Claims

May 8, 2019
Westlaw
By Mareesa A. Frederick; Nate S. Ngerebara

The constant movement of talent between competitors exposes would-be employers to potential liability for trade secret misappropriation.

If proper precautions are not in place, a key lateral hire may place a company at risk. A newly launched product tainted by a competitor's trade secrets results not only in costly litigation but also in negative press in the industry.

How does a company protect itself from being on the wrong end of trade secret misappropriation litigation? The best tool may be to create an effective "clean room."

Crown Jewels

A company can keep its crown jewels in perpetual confidence and reap the commercial benefits they provide. Properly maintained, trade secrets can offer benefits not otherwise available through patent protection.

While patents are inherently valuable, the public disclosure requirement coupled with their term limits make them, in some cases, less appealing than trade secrets.

Additionally, patent litigation can be expensive and carries a risk that the patents could be invalidated in the enforcement process.

Moreover, infringement can be difficult to prove, especially for patent claims covering methods of manufacturing.

For that reason, chemical manufacturers and ancillary industries often rely on trade secrets to protect their confidential manufacturing processes.

However, these industries may face allegations of trade secret misappropriation and theft, resulting in multimillion-dollar liability claims. 1

Trade secrets can also result in criminal liability. The U.S. government has secured several convictions for trade secret misappropriation with penalties that included significant restitution awards. Many of the reported thefts occur at the hands of current or former employees.²

Trade secret misappropriation claims can arise whenever there is an exchange of confidential information between a company and a third party.

The following are typical scenarios that often lead to such claims:

- **Joint ventures**: Companies engaging in joint ventures with suppliers or other companies to develop products and processes, which require the disclosure of sensitive Though a research and development strategic alliance can be useful for combining the resources and sensitive assets of multiple entities to facilitate technical development, unwitting or unscrupulous participants might usurp the sensitive information provided by other parties for their own commercial gain. Alternatively, a company may inadvertently use another's confidential information exchanged during the joint venture because adequate protection or security measures were not in place.
- Consulting relationships: Companies hiring consultants and contractors, giving them access to otherwise sensitive information, or permitting the contractors' sharing of sensitive business information about the competitors' business practices.
- Acquiring or licensing technology: Companies assessing new technology under a non-disclosure agreement
 for the purpose of acquiring or licensing the technology and subsequently implementing, disclosing or
 appropriating those technologies without
- **Recruitment**: Companies hiring employees from competitors without proper procedures to prevent contamination of their own processes resulting from the use of the competitor's confidential information.³
- **Supplier relationships**: Companies evaluating new raw materials provided by a supplier and using the supplier's confidential information to develop and seek patent protection of formulations and products incorporating the new raw material.

What is a trade secret?

A trade secret can be any confidential business information that gives a company a competitive edge (i.e., has economic value to the user), if it is not generally known or readily ascertainable by "proper means," such as reverse engineering, and for which the company has established reasonable measures to safeguard its secrecy.

Just as they can do for companies in other industries, trade secrets can cover technical and business information of chemical companies:

Technical information	Business information
Processes and formulas for the manufacture of drugs, foods, chemicals or other materials (e.g., the formula for Coca-Cola ⁴)	Financial information prior to public release
Manufacturing methods and techniques (know-how) ⁵	Cost and pricing information
Engineering notebooks	Internal market analysis and forecasts
Negative information, e.g., failed designs (information that has commercial value from a negative viewpoint, like the results of lengthy and expensive research proving that a certain process will not work)	Client lists
Plans, designs and patterns, such as those for specialized equipment (e.g. machine for manufacturing synthetic diamonds ⁶)	Non-public business relationships being negotiated

Unlike owners of other forms of intellectual property, a trade secret owner does not have to file an application or seek registration identifying or describing its trade secrets.

Instead, protection attaches automatically and perpetually as long as the sensitive information is kept secret by the owner.

Keeping sensitive information secret requires recognizing and identifying the protectable information or processes and establishing proper policies and practices to protect the information.

"The nature and character of the vigilance required of the owner to protect secrecy varies, depending upon a variety of factors," according to IP treatise author Roger M. Milgrim. "Among things to be considered are the size and character of the enterprise (generally, large, sophisticated enterprises are held to a higher 'secrecy effort' standard), the location of the enterprise (elaborate steps that may be required in an 'industrially dense' area may not be required in, say a rural area) and the nature and character of the enterprise's staff."

Reasonable measures can include advising employees with access to trade secret information of the information's status as a trade secret and educating them on how to protect the information; establishing physical and data security measures to keep secret documents secure; limiting access to the information to a "need to know" group; and requiring people who have access to the information to sign confidentiality and non-disclosure agreements.

What is trade secret misappropriation?

A company commits trade secret misappropriation if it acquires a trade secret through improper means, such as by breaching a contractual obligation or committing fraud or theft.

Misappropriation can also occur if a company uses another's trade secret with knowledge that the person who gave it the

information acquired it through improper means or under circumstances giving rise to a duty to maintain its secrecy or limit its use.

Importantly, independent discovery or reverse engineering of commercially available products or processes does not constitute misappropriation.⁸

As such, companies accused of misappropriation often claim independent discovery, even when the companies were exposed to the confidential information of their competitors — either through a former employee, joint venture or licensing negotiations.

In those instances, the accused company needs to show that its development process was not contaminated by another's improperly acquired confidential information.

One way to show independent discovery is through the establishment and implementation of "clean room" procedures.

'Clean Room' Procedures

Clean-room procedures attempt to safeguard the development of products and production processes, guarding against any claims that the new work uses another's proprietary/trade secret information.

Companies can also apply these procedures during the development of competing products within a company, such as when a product is being jointly developed with another company while a similar product is also being simultaneously developed internally.

Clean-room procedures have been successfully implemented in the software industry despite the industry's high risk of misappropriation claims.

In software development, liability for trade secret misappropriation does not require proving actual copying of a competitor's software.

Instead, as is true with respect to copyright claims, it is sufficient to show that the accused party had access to the competitor's source code and that the accused party's software is substantially similar.

Exposure to competitive or substantially similar code could create legal risks, especially if a company is developing software with similar functionality.

Under a clean-room scheme for software development, three separate teams of employees collaborate to develop the products and processes:

- Specification team: This group is typically familiar with the competitor's products and processes, and might
 include individuals who have been exposed to the competitor's confidential information (e.g., the competitor's
 former employees). The goal of this team is to analyze the competitor's products and create a list of
 functionality specifications for developing a competing product. The specifications must not include any
 reference to the competitor's trade secrets or other confidential information.
- Coordination (or "gatekeeper") team: This team serves as the screeners of information provided to the development team. The coordination team evaluates the specifications to keep out protected information that flows in and out of the clean room, and it ensures that all procedures are followed and properly This team often comprises engineers or scientists (to assess the technical information) and individuals trained in trade secret law.⁹
- **Development/design team**: This team is often physically and electronically isolated in the clean room. The team is allowed access only to the specifications and information reviewed and approved by the coordination It executes the actual development of the products or processes. The team's members must be screened to ensure that they have no access to alleged trade secrets. As such, former employees of competitors and other employees who might have had access to a competitor's confidential information are excluded from this team.

Similar procedures can be implemented for the research and development in chemical companies.

For example, when a new engineer, having knowledge of a competitor's confidential information, joins a company to work on a competitive formulation or process, that engineer may be assigned to the specification team to analyze the competitor's formulation or processes and to create a list of specifications needed to develop a competing formulation.

However, the employee is walled off from working with or sharing any information related to the competitor's formulation or process with the development team, and any information received from that employee is screened by a coordination team comprised of other engineers and lawyers.

Limitations and Best Practices

Despite their obvious benefits, clean rooms also pose risks that companies must be aware of and take appropriate measures to account for.

Cost of Establishing Clean-room Procedures

Establishing clean-room procedures is expensive. Having multiple teams involved in developing products and processes that otherwise require one team is undoubtedly costly.

Further, maintaining development records and constantly educating employees about the company's procedures will create additional financial obligations.

Deficient Clean Rooms

Suppose, for example, that a research and development team realizes that a competitor's trade secrets were used in the development of the company's top pipeline product.

The team can remove the trade secret information and begin development from scratch with a team that has no knowledge of the trade secret information.

Alternatively, the team can remove the trade secret information and continue to develop the product.

In the latter scenario, it is likely that the final product would still be contaminated by knowledge obtained from the competitor's trade secret information. ¹⁰

However, as a practical matter, most companies (given cost concerns and business deadlines) would likely not start the development process from scratch with an entirely new team.

Moreover, despite a company's efforts to establish proper clean-room procedures, there is always the risk that contaminated information will still seep through the screens.

A company's good-faith efforts will not absolve it of liability if its processes and products still contain tainted material, or if people on development team are found to have used or maintained competitors' trade secret information.

Best Practices When Establishing Clean-room Procedures

In establishing clean-room policies and procedures, companies should ensure that comprehensive rules are in place to regulate the flow of information between clean-room teams — and make sure that the rules are followed.

The following additional considerations can also help minimize the risk of misappropriation.

First, companies should conduct regular trade secret audits to be aware of their confidential and trade secret information and take reasonable steps, as discussed above, to protect confidential information.

Second, companies should educate new hires, current employees, contract employees, temporary employees, consultants and retirees about the consequences of nondisclosure agreements signed as part of the employment contracts, supplier agreements or a company joint venture as well as the risks associated with contaminating company processes and products using confidential information from competitors.

In particular, companies should ensure that their onboarding processes include agreements preventing new employees from bringing or using any proprietary information from former employers, and new employees should be briefed on the companies' trade secret policies and procedures and safeguards against misappropriation.

Further, when hiring an employee from a competitor, companies should consider placing that employee in a completely different role for a few years.

Third, the clean-room coordination teams should ensure that all work is thoroughly, properly and methodically documented.

The documentation should include as much detail as possible about the personnel involved, the products and processes developed and all sources of information, as well as when and where the products and processes were developed.

This information could come from a variety of sources. These sources include internal development documents (e.g., patent applications, lab notebooks, witnessed invention disclosures, etc.), acquired or licensed-in technologies, and publicly available sources (such as dated articles, books, etc.).

The development records should be maintained in the regular course of business and not only when a company suspects it might be particularly susceptible to misappropriation claims.

Good documentation lays the foundation for substantiating an independent development defense if the company is later accused of trade secret misappropriation.

Finally, companies should make sure to collect and preserve all confidential information from a departing employee before the last day of employment.

Too many companies discover a former employee has left with substantial amounts of confidential information only after that employee has already started working for a competitor.

The risks and costs associated with claims of misappropriation claims are high.

While not guaranteed to protect against all inadvertent receipt of trade secrets, proper clean-room procedures can be a useful tool to guard against claims of trade secret misappropriation for chemical companies to mitigate these risks.

Endnotes

- ¹ See, e.g., E.I. du Pont de Nemours & Co. v. Kolon Indus. Inc., 564 F. App'x 710 (4th Cir. 2014) (jury verdict for \$919.9 million in damages and 20-year worldwide injunction, later vacated for new trial); CardiAQ Valve Techs. Inc. v. Neovasc Inc., 708 F. App'x. 654 (Fed. Cir. 2017) (affirming reasonable royalty award of \$70 million, which was enhanced to \$91 million, against Neovasc Inc. for misappropriation of three trade secrets).
- ² See, e.g., United States Xu, No. 17-cr-63 (D. Del. 2017) (former employee of Chemours Co. and DuPont pleaded guilty to conspiracy to theft of trade secrets related to the development and marketing of sodium cyanide); United States v. Shi, No. 17-cr-110 (D.D.C. 2017) (former employees of Trelleborg indicted for conspiring to steal trade secrets relating to syntactic foam, a buoyant material filled with tiny spheres that has commercial and military uses); United States v. You, No. 19-cr-14 (E.D. Tenn.) (former employee of companies working for Coca-Cola indicted of conspiracy to steal trade secrets related to bisphenol-A-free coatings).
- ³ The vast majority of cases about trade secret theft involve an employee or business See *David S. Ameling, A Statistical Analysis of Trade Secret Litigation in State Courts*, Gonz. L. Rev., Vol. 46:1 at 66 (2011).
- ⁴ See, g., Thomas v. Soft Sheen Prod. Co., 500 N.Y.S.2d 108 (App. Div. 1986) (formula for hair conditioner); West v. Alberto Culver Co., 486 F.2d 459 (10th Cir. 1973); Coca-Cola Bottling Co. of Shreveport Inc. v. Coca-Cola Co., 107 F.R.D. 288 (D. Del. 1985).
- ⁵ Minnesota Mining & Mfg. Co. Pribyl, 259 F.3d 587 (7th Cir. 2001) (know-how like operating procedures, training manuals and process standards for using equipment in making adhesive resin sheeting).
- ⁶ Elec. Co. v. Sung, 843 F. Supp. 776 (D. Mass. 1994).
- ⁷ Roger Milgrim, 1 MILGRIM ON TRADE SECRETS § 1.04. 8 See, e.g., Bonito Boats Inc. v. Thunder Craft Boats Inc., 489 U.S. 141 (1989).
- ⁸ See, e.g., NEC Corp. Intel Corp., No. 84-cv-20799, 1989 WL 67434 (N.D. Cal. Feb. 6, 1989); Bridgetree Inc. v. Red F Mktg. LLC, No. 10-cv- 228, 2013 WL 443698 (W.D.N.C. Feb. 5, 2013) (outlining the clean-room process to be used by enjoined parties wishing to offer or sell the product at issue: designating a physical location within a specific geographic area, limiting employees who may be present in the clean room, requiring a third party "gatekeeper" to review materials going into and work product coming out of the clean room to ensure they are free of trade secrets).

⁹See, e.g., Patriot Homes Inc. Forest River Hous. Inc., No. 05-cv-471, 2007 WL 2782272 (N.D. Ind. Sept. 20, 2007) (finding a clean room ineffective where months after its creation, "the 'clean room' was still tainted").

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Mareesa A. Frederick Partner Washington, D.C. +1 202 408 4383 Email



Nate S. Ngerebara Associate Palo Alto, CA +1 650 849 6763 Email

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ARTICLE

Don't Ignore Trademark Basics

March 2019 FMCG CEO By Clare A. Cornell

Do I need to invest in intellectual property? Is there value in this right that requires the involvement of lawyers, part of my budget which could be used on product and packaging development or marketing campaigns? This is a question that businesses ask, and the answer is indeed complex. But bear in mind that, even if you are not thinking about protecting your IP, it is certainly on the minds of your competitors who are looking for ways to have a slice of your hard-earned cake.

So, what rights are available and how do they fit into my business?

Trademark registrations protect your name, or logo, or in some cases the shape of your product. They are cost effective and easy to register. Your trademark is there not only to attract customers to try your products but importantly to allow repeat purchases knowing that they can rely on the name to identify products of a certain quality coming from you, not your competitors. Registering your brand name as a trademark can be a powerful tool to block copycats in today's ruthlessly competitive market. A registered trademark can not only help you to stop somebody from using an identical mark, but also a similar mark on products which compete with yours and are similar enough to confuse customers. A trademark registration can also be a useful tool in takedown procedures on social media, recovering a domain name, and preventing import of counterfeit products.

Choosing a trademark is a not an easy exercise but making the right choice can avoid difficulties when launching a new product and enforcing your rights in the future. Importantly, your mark should not be descriptive of your products, or similar to your competitor's marks. A trademark which directly describes your product, or its characteristics will not be registrable. For example, FRESH 'N' JUICY is a bad choice for your fruit products. Invented words or those with no connection to your product are distinctive; a great example being the name of a fruit being used on electronic goods.

Although it may be tempting from a marketing perspective, adopting a mark similar to the market leader is a risky practice. Trademark searches can assess whether somebody else is using the mark you are interested in and instructing a clearance search prior to filing a trademark application or launching your product can save the expense of an opposition or infringement action.

Once you have chosen your new trademark, securing registration is relatively easy and inexpensive. At a cost of as little as £1,500 including attorney charges, a registration is money well spent for a legal right which prevents other people from trespassing on your brand and lasts for 10 years and is renewable indefinitely.

Registered designs also provide a valuable weapon in your arsenal when protecting visually new and unusually-shaped products or their packaging. Novel designs can be registered for only a few hundred pounds and last up to 25 years.

Although notoriously more expensive, patents also have a place in an IP portfolio. If you have designed new product packaging which has an innovative function, solved a technical problem, or devised a new manufacturing process, this could be protected by patents. A patent could give you the competitive edge to manufacture your product more efficiently while putting your competitors at a disadvantage. You could even license this technology to them for additional income.

In addition to registered rights, there are also unregistered rights which protect your IP. In the UK, if your product has a distinctive and well know appearance you may be able to prevent copycat products if your customers would believe that the copy originates from your business. Unregistered design rights also protect the shape and configuration of objects and provide protection from copying for 10 years after first sale. Copyright which enables you to prevent copying of your artistic and written material also arises automatically. So, if there is something new in your portfolio which needs protecting, why not register it?

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Clare A. Cornell
Partner
London
+ 44 (0)20 7864 2815
Email

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ARTICLE

Don't Let Intellectual Property Accidents Crash Your Social Media Marketing

August 14, 2018

The Social Media Monthly

By B. Brett Heavner; Margaret A. Esquenet

Immediate and inexpensive, social media drives advertising directly to your target consumer. Facebook, Instagram, Twitter, dedicated blogs, and self-hosted chat forums are important business marketing platforms. Unfortunately, the ease and speed of posting often leads to thoughtless intellectual property fouls because advertisers often don't review posts as thoroughly as "real advertising." Worse, social media's swift distribution and user-amplification can substantially increase both the risk of exposure and the scope of damage an infringement may cause. Moreover, violations can stem from a business' own marketing posts as well as posts by paid influencers and others. However, by complying with the following four rules of the road, advertisers can avoid these intellectual property accidents.

First, identify all intellectual property within each post, particularly copyright, trademark, right of privacy, and right of publicity. Copyright protects an author's exclusive right to control his or her creative works, including visual art, music, and text. Trademark protects the names, logos, and slogans businesses use to identify their products and services. Right of privacy protects a person from public exposure of private information. Right of publicity protects an individual's ability monetize her own name or likeness. If the post contains any graphical elements, photographs, music, competitor comparisons, images of people, or endorsements, it will almost certainly include at least one of these types of intellectual property.

Second, confirm that you have the right to use the intellectual property that you have identified. Many advertisers mistakenly believe that if they find graphics, art, photography, or music posted on the internet it is free to use in their own postings. This assumption is wrong and can be costly. While some web sources indicate that the materials on their site are free to use, most do not grant such universal permission. Before incorporating any internet-sourced materials into your marketing post, you must obtain permission from the owners of those materials. If you cannot identify the owner, it is best not to use the materials. Similarly, if any photograph or art you wish to use contains a depiction of a person who can be identified—whether or not they are famous—you must obtain permission from that person. The safest course to avoid copyright, right of privacy, and right of publicity infringement is to stick with art that your employees have created for your business or licensed, and to only depict people who have specifically consented to appear in the post.

Third, make certain that your post is accurate and not misleading. For example, while it is considered "fair use" to reference a competitor's trademark to make a comparison to your goods or services, that comparison must be completely accurate to avoid false advertising and trademark infringement allegations by the competitor, consumers, government regulators, or the platform itself. Similarly, do not use the trademarks of other businesses to falsely suggest that they endorse your products or services. Stick to the exact facts of your relationship with the trademark owner (i.e., "we are experienced in repairing brand X products" and not an exaggeration like "we are the preferred repair shop for brand X products"). When commenting on public institutions or public figures, do not use their names or images in a way that could be construed as a testimonial or endorsement. If you do pay influencers to market your business (either in money or goods/services) you need to disclose that relationship. For example, a

grocery chain was sued by a famous athlete for a post congratulating him on his induction into the hall of fame. However, the post included photos of his jersey and a coupon for one of his "favorite" products. A court found that the post falsely suggested that the athlete endorsed the store.

Fourth, for websites, blogs, and social media pages that you host, make certain that you have an effective method of removing user comments if a copyright owner objects to the post. The Digital Millennium Copyright Act (DMCA) provides hosts with a "safe harbor" to avoid copyright infringement liability for problem user posts if the hosts meet certain requirements. To take advantage of the DMCA, the host must designate an agent to receive complaints about copyright infringement and remove any objected-to posts within a reasonable time. The designated agent must also be registered with the U.S. Copyright Office. Although there is no statutory safe harbor for trademark infringement and right of privacy/publicity complaints, hosts would be well advised to identify a similar agent to receive those complaints to avoid liability as a "contributory infringer."

By following these four rules, social media advertisers can reduce their risk of intellectual property "accidents" while still engaging with their customers using these rapid and economical marketing platforms.

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B. Brett Heavner Partner Washington, D.C. +1 202 408 4073 Email



Margaret A. Esquenet Partner Washington, D.C. +1 202 408 4007 Email

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ARTICLE

ITC Basics: What Makes the ITC a Unique and Desirable Forum

September/October 2019

IP Litigator

By Daniel C. Cooley; Mareesa A. Frederick; Jonathan J. Fagan

By some estimates, as much as \$118 billion worth of foreign infringing products entered the United States in a single year. While the current news cycle focuses on tariffs, the International Trade Commission (ITC) offers patentowners a powerful weapon to combat infringement: a Section 337 action to block the importation of infringing products at U.S. ports of entry. While this powerful remedy can make the ITC an ideal forum for certain cases, the ITC differs from standard district court litigation in important ways. This article provides a general overview of some of the unique aspects of an ITC investigation.

I. Filing a Complaint and the Burden of Proof

Like a district court action, a party must file a complaint seeking a remedy under Section 337.² The ITC complaint must allege that products are being imported into the United States that "infringe a valid and enforceable United States patent" and that there is "domestic industry"—i.e., "an industry in the United States, relating to the articles protected by the patent . . . [that] exists or is in the process of being established."3

To satisfy the domestic industry requirement, a complainant must demonstrate significant domestic investments in, for example, labor, capital, facilities, or research and development that support "articles protected by the patent" (i.e., domestic industry products). Therefore, the complainant must show that patent claims cover both the respondent's product (accused product) and the complainant's own product (domestic industry product).

After the complainant files the complaint, the ITC decides whether to institute an investigation.⁵ The ITC typically decides institution within 30 days.⁶ The ITC will publish its decision to institute in the Federal Register.⁷ When this notice is published, the investigation is officially instituted.⁸ If there are pending district court proceedings involving the same issues between the same parties, those cases will be stayed (upon motion) after the ITC institutes its investigation.⁹

II. The Judge and Staff

An instituted investigation is assigned to an Administrative Law Judge (ALJ). ¹⁰ The ALJ is the primary factfinder during the investigation, presiding over hearings and deciding motions. ¹¹ The Commission can review the ALJ's decisions. ¹² The "Staff" is another unique feature of the ITC. The Staff is an attorney, appointed from the Office of Unfair Import Investigations (OUII), who acts as an independent party during the investigation. OUII does not appoint an attorney for every investigation. ¹³ When present, however, Staff may fully engage in the investigation, filing its own discovery requests, conducting its own depositions, and taking positions on motions. ¹⁴

III. Schedules and Ground Rules

The ITC must complete an instituted investigation "at the earliest practicable time." Within 45 days after the ITC institutes an investigation, the ITC determines a "target date" for the final decision (i.e., the "final determination"). ¹⁶ The ALJ's initial target date can be within 16 months from the investigation's institution. ¹⁷ The ALJ also issues an order establishing a procedural schedule with deadlines regarding, for example, discovery, claim construction, motion practice, and hearings. ¹⁸ The ALJs follow certain statutory procedural rules but also have their own ground rules that govern the nuts and bolts of the investigation. ¹⁹

IV. Fact Discovery and Protective Orders

After an investigation's institution, the parties may begin the discovery process according to the procedural schedule. A party may obtain discovery regarding any nonprivileged matter that is relevant to:

- the claim or defense of the party seeking discovery or to the claim or defense of any other party, including the existence, description, nature, custody, condition, and location of any books, documents, or other tangible things;
- the identity and location of persons having knowledge of any discoverable matter;
- the appropriate remedy for a violation of section 337 of the Tariff Act of 1930; or
- the appropriate bond for the respondents, under section 337(j)(3) of the Tariff Act. ²⁰

At the ITC, parties may seek relevant, discoverable information using interrogatories, requests for production, requests for admissions, subpoenas, and depositions. ²¹ One departure from district court procedure is that the ALJs' Ground Rules allow only 10 days to respond to discovery requests. ²² Additionally, discovery in the ITC is often completed in a matter of months, rather than a year or more, as in district court. ²³ To protect information obtained during discovery, each ALJ will issue a protective order requiring attorneys to sign a protective order subscription. ²⁴ The protective order prevents disclosure of confidential business information (CBI). ²⁵ Typically, only the outside-counsel attorneys from each side, experts (and, of course, the Staff, ALJ, and Commission) may view information designated as CBI. ²⁶

V. Hearings

Hearings at the ITC differ from district court trials in several significant ways. First, because the ALJ serves as the factfinder, an ITC hearing is never held before a jury. A second major difference is that many ALJs require the parties to submit their direct testimony through written witness statements, rather than obtaining that testimony live in court.²⁷ A witness statement consists of a series of questions and answers that simulate live testimony. The opposing party may then conduct live cross-examination of the witness at the hearing.²⁸

VI. Initial and Final Determinations and Remedies

After the hearing and any posthearing briefing, the ALJ will issue the initial determination (ID).²⁹ While the ID may contain the ALJ's findings on certain evidentiary issues, the most important finding is whether the ALJ found that the complainant established a violation of Section 337 by proving importation of an infringing product and the existence of a domestic industry. The ALJ's findings on infringement include a claim-by-claim analysis, so the ID may find a violation with respect to some claims of the patent and no violation with respect to other claims.

After the ITC's determination becomes final, the complainant may obtain the benefit of the remedy in the FD, assuming a violation was found. The ITC, generally, issues two sorts of remedies: (1) exclusion orders; and (2) cease and desist orders.³⁰

An exclusion order is a tool whereby the ITC directs U.S. Customs and Border Protection to block infringing products at the ports of entry. The ITC may issue one of the two types of exclusion order: (1) a general exclusion order or (2) a limited exclusion order. A general exclusion order blocks importation of all infringing products, regardless of the identity of the importer or manufacturer. The complainant must meet a higher

standard to obtain a general exclusion order.³⁴ A limited exclusion order blocks importation of infringing products from the manufacturers or importers identified in the investigation.³⁵ An exclusion order is typically directed to the claims of the relevant patent, rather than the specific names of products identified in the investigation.³⁶ This may help prevent respondents from circumventing the order by renaming their products.

In addition to exclusion orders, the ITC may issue a cease and desist order.³⁷ These orders can help prevent a respondent from stockpiling infringing goods in the United States before an exclusion order goes into effect and then selling those goods. The cease and desist order will prevent the respondent from selling their inventory of infringing products in the United States.³⁸

The parties may petition the Commission to review all or part of the ID.³⁹ The Commission will then determine whether to review the ID in whole, in part, or not at all. If the Commission takes review, it will issue a notice indicating which issues it intends to review.⁴⁰ The Commission will then issue a written opinion—a final determination (FD)—affirming or altering the ID.⁴¹ Any issue that the Commission chooses not to review becomes part of the FD.⁴²

VII. Presidential Review and Appeals

Because the ITC is a government agency deriving power from the executive branch of the U.S. Constitution, ⁴³ if a violation is found, the exclusion order is subject to final review by the President of the United States. ⁴⁴ This means that for 60 days after the ITC issues its FD, the current president may indicate disapproval of the exclusion order. ⁴⁵ If a 60-day period elapses without presidential action, the ITC's determination becomes final. ⁴⁶ After the presidential review period expires, either party may appeal the ITC's decision to the United States Court of Appeals for the Federal Circuit. ⁴⁷ The General Counsel's office may participate in the appeals.

VIII. Conclusion

The ITC differs from district court litigation in many procedures and requirements and understanding those differences can make the difference between winning and losing. But for the right cases, the ITC offers patentowners strong remedies to combat infringement.

Endnotes

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<sup>1</sup> The Commission on the Theft of American Intellectual Property, Update to the IP Commission Report at 9 (2017) (available at http://ipcommission.org/report/IP_Commission_Report_Update_2017.pdf).
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<sup>2</sup> 19 U.S.C. § 1337(b)(1).
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⁶ Id.

⁷ 19 C.F.R. § 210.10(a).

⁸ 19 C.F.R. § 210.10(b).

³ 19 U.S.C. § 1337(a)(1)(B) and (a)(2).

⁴ 19 U.S.C. § 1337(a)(3).

⁵ 19 C.F.R. § 210.10(a).

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<sup>9</sup> 28 U.S.C. § 1659(a).
<sup>10</sup> 19 C.F.R. § 210.3.
11 Id
<sup>12</sup> See 19 C.F.R. § 210.42.
<sup>13</sup> See 19 C.F.R. § 210.3; ITCTLA, FAOs; What Is the Role of the Commission Investigative Attorney in a Section 337
Investigation?, http://www.itctla.org/resources/fags#role.
<sup>14</sup> Id.
<sup>15</sup> 19 U.S.C. § 1337(b)(1).
16 Id
<sup>17</sup> See USITC, "Answers to Frequently Asked Ouestions," at 20 n.16 (available at
https://www.usitc.gov/intellectual property/documents/337 fags.pdf).
<sup>18</sup> See, e.g., Certain Intraoral Scanners and Related Hardware and Software, USITC Inv. No. 337-TA-1090, Order
No. 6 (an example of ALJ Lord's procedural schedule); Certain Hybrid Electric Vehicles and Components Thereof,
USITC Inv. No. 337-TA-998, Order No. 3 (an example of ALJ Pender's procedural schedule).
<sup>19</sup> See 19 C.F.R. § 210.5(e).
<sup>20</sup> 19 C.F.R. § 210,27(b)(1).
<sup>21</sup> 19 C.F.R. §§ 210.28-32.
<sup>22</sup> See. e.g., Certain Protective Cases for Elec. Devices and Components Thereof, USITC Inv. No. 337-TA-955,
Order No. 2, 8 (Apr. 30, 2015) (an example of Chief ALJ Bullock's Ground Rules): Certain Elec, Devices, Including
Wireless Communication Devices, Computers, Tablet Computers, Digital Media Players, and Cameras, USITC Inv.
No. 337-TA-952 Order No. 2, 1 (Apr. 1, 2015) (an example of ALJ Shaw's Ground Rules).
<sup>23</sup> See, e.g., Certain Intraoral Scanners and Related Hardware and Software, USITC Inv. No. 337-TA-1090, Order
No. 6 (setting the close of fact discovery to less than five months from the issuance of the procedural schedule):
Certain Hybrid Electric Vehicles and Components Thereof, USITC Inv. No. 337-TA-998, Order No. 3 (same).
<sup>24</sup> See 19 C.F.R. § 210.5.
25 <sub>Id</sub>
<sup>26</sup> Id.
<sup>27</sup> See, e.g., Certain Elec. Devices, Including Wireless Communication Devices, Computers, Tablet Computers,
Digital Media Players, and Cameras, USITC Inv. No. 337-TA-952 Order No. 2, 9 ("Unless ordered otherwise, all
witness testimony . . . shall be made by witness statements in lieu of live testimony.").
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<sup>28</sup> Id. ("Witnesses shall be available for cross-examination on the witness stand unless waived.").
<sup>29</sup> See 19 C.F.R. § 210.42.
<sup>30</sup> See 19 C.F.R. § 210.75.
31 ld.
32 See 19 C.F.R. § 210.12(a)(11).
<sup>33</sup> See 19 U.S.C. § 1337(d); VastFame Camera, Ltd. v. ITC, 386 F.3d 1108, 1114 (Fed. Cir. 2004).
<sup>34</sup> Id.
<sup>35</sup> Id.
<sup>36</sup> See 19 U.S.C. § 1337(d)(2).
<sup>39</sup> 19 U.S.C. § 1337(f).
<sup>40</sup> Id.
<sup>41</sup> 19 C.F.R. § 210.43.
<sup>42</sup> 19 C.F.R. § 210.43(d).
<sup>43</sup> 19 C.F.R. § 210.44(c).
<sup>44</sup> 19 C.F.R. § 210.42(h)(6).
<sup>45</sup> USITC, About the USITC, https://www.usitc.gov/press_room/about_usitc.htm ("We provide high-quality, leading-
edge analysis of international trade issues to the President and the Congress.").
<sup>46</sup> 19 U.S.C. § 1337(j).
^{47} Id.
<sup>48</sup> Id.
<sup>48</sup> 28 U.S.C. § 1295(a)(6).
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Patent Litigation ITC Section 337

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Daniel C. Cooley Partner Reston, VA +1 571 203 2778 Email



Mareesa A. Frederick Partner Washington, D.C. +1 202 408 4383 Email

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ARTICLE

Patent Quality Makes a Difference

March 27, 2018 Haaretz Cyber Magazine By Patrick J. Coyne

Intellectual Property is the global currency of innovation. Whether you are a start-up, development stage, or mature company, intellectual property is likely among your most valuable assets.

Intellectual property is intangible. This makes it hard to value. Patents are complex. They are one of the few exceptions to competition laws worldwide. And, they can be extremely powerful, both as an offensive weapon and defensive shield against competitors. But how do you know you are getting good value?

Patents are complicated for two reasons. First, the market for legal services is very competitive. Vigorous competition benefits inventors through greater choice and lower prices. The price of patent preparation and prosecution (the process of getting a patent) services has been relative constant for decades. But competition has also introduced wide variability in the quality of legal services.

At the same time, Patent Offices and Courts are tightening the requirements to get broad patents. International harmonization has increased predictability but also "raised the bar." Courts, particularly in the United States, are imposing more stringent requirements on patents. Patents must have an adequate written description. They must adequately support the full scope of the claims. And, they must distinguish the invention from prior inventors' work.

At the same time, information is becoming more readily available. Information about prior inventors' work that in the past could not be found through even an exhaustive search can now be located with the touch of a button. Electronic translations are readily available. Patent Offices are cooperating much more effectively. All of this makes it harder to get broad patents. But as with most things in life, you get what you pay for. Patents written without careful thought and on a shoestring budget likely aren't worth the paper they are printed on.

What is patent quality? This question is particularly relevant to the business community having suffered more than a decade of litigation involving questionable internet and telecom patents. Two years ago, the author attended several of the U.S. Patent and Trademark Office's Quality Initiative Public Hearings. In a private discussion with the then-Director, we discussed patent quality. The author's answer as a trial lawyer is simple: A patent must survive the challenges that await it. There are essentially five points in the life of a patent when it will be challenged.

- 1. **Investment:** Startups are constantly seeking investment. Investors increasingly look for whether you have patented your inventions. Depending on the type and level of investment, the level of scrutiny may vary. It may be modest. But substantial investors will want assurances that your patents will survive and effectively protect your business.
- 2. Acquisition: As the company grows and develops you may attempt to sell the business. And when you do, your patents are also on the block. The buyer will conduct diligence to ensure they are well-written, protect your business, and will survive if challenged. Does the disclosure adequately support the claims? Do the claims adequately protect the business? Are they commercially valuable? Do they adequately cover the company's current and developmental products? Will they prevent competitors from designing around? Unless

- all these issues have been thought through and addressed carefully in the original filing, it will likely be too late to do anything about it by the time that you were discussing these issues with investors.
- 3. Licensing: Your patents will be stress-tested if you try to license them. Nobody pays top dollar unless they are getting what they are paying for. Your licensee is likely going to conduct prior art searches and test the patents to see whether the claims are patentable. Do they preclude obvious design arounds? Will designing around will cost more than paying royalties under a license?
- 4. Post Grant Challenge: Europe has had post-grant challenges for decades. In 2012, the United States established a post-grant procedure. The United States and the European Union are formidable markets. Will your patents survive post-grant challenges in them? If they were prepared poorly on a shoestring budget, not likely.
- 5. Assertion: Ultimately, you may be forced to sue to enforce your rights. And when you do, the defendant will likely deny infringement and assert invalidity. Will your patent survive these challenges? Is the disclosure written clearly? Is it broad enough to support the full scope of the claims? Have you thought through how your invention is different from prior inventions, and not just from the art you were aware of when you filed? Once you sue, the defendant will be strongly incentivized to look a lot harder than you did when you filed the application. Will your patent survive? Or will it fail at the time when you need it most?

Quality boils down to your patent's ability to survive all these challenges. Invest the resources appropriate to the significance of your invention to your business. Draft the application carefully. Adequately describe your invention. Differentiate it from prior inventions. Anticipate how others will design around it. A patent that survives these challenges is truly a high-quality patent.

Tags

startup

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Patrick J. Coyne Partner Washington, D.C. +1 202 408 4470 Email

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ARTICLE

Successful Companies Don't Just Patent Everything—They Make and Follow a Strategy

October 8, 2018
Globes Magazine
By Elliot C. Cook; Jeffrey A. Berkowitz

Sophisticated companies know that patents are indispensable in the modern economy. Patents are barriers against competitors practicing a particular technology. Without patents, companies gamble with their future by being defenseless against competitors copying their technology. But some companies go too far. Some companies—or their overzealous engineers or software developers—want to patent every potentially novel detail of their technologies. This type of unfocused, shotgun approach to patenting can be just as much a gamble as the "patent nothing" approach. Both approaches suffer from the same defect—a lack of strategy. Both lead to high costs and wasted opportunities to generate real value.

A brief illustration of both types of problems highlights their common flaw:

First, imagine a company that develops a new software-based technology or mechanical device yet decides not to patent anything. We call this a "patent nothing" strategy. And like most companies, there are no inherent barriers to entry (e.g., government regulations, massive R&D costs, an immovable customer base, etc.) protecting this "patent nothing" company. But the product they developed is innovative and customers really like it. As the company's product begins to finally generate a profit, after years of investment and research, a competitor discovers the product on the market and decides to make a copy—for lower cost or with add-on features that customers also like. Lacking any patents to protect the product and their business, the company sees its profit erode and eventually disappear, powerless to stop this market phenomenon called "competition." This company saved some money in the short-run by neglecting patents but loses its competitive advantage and thus fails in the long-run.

Second, consider a "patent everything" company that lets its engineers or software developers patent every new feature they consider cool and different. After spending a lot of money on patents, the company has a few dozen highly specific patents on a smattering of different features. Some of the features matter to the company's long-term business plan, but many do not. Some of the patents are arcane or simply incomprehensible. All of the patents are easy to design around by competitors, if they are infringed at all, since they are so narrowly focused. This company also fails to realize the value of patents.

In both of the above illustrations, the companies failed to develop and implement a patent strategy. Emerging companies should concentrate on building a patent monopoly covering the most commercially important aspects of their new technologies while making efficient use of their patent dollars and the precious time of their key inventors. In short, when companies formulate their business strategy, patents should play an integral role. Patenting too sparingly or recklessly is not strategic and is not a way to generate company value.

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Elliot C. Cook Partner Reston, VA +1 571 203 2738 Email



Jeffrey A. Berkowitz Partner Reston, VA +1 571 203 2710 Email

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ARTICLE

The Key to Powerful Patents for Cyber (and All) Companies

March 25, 2020

Calcalist

By Gerson S. Panitch

Why do some companies have reputations for developing powerful patents, while others don't? Why can some companies command millions of dollars in royalties from their patents, while for other companies, patents are merely an expense line on their balance sheet? And why is it that the patents of some companies scare competitors away, while patents of other companies do not even make competitors flinch?

The answer is that all patents are not created equal. To understand why, and to understand how you, as a corporate executive, can turn your patent program into a valuation builder, let's consider a hypothetical cybertech company named Cyber-sode. Cyber-sode solves the problem of viruses and worms entering through unapproved ports. Avishai, the CTO, is brilliant, and came up with an elegant solution to this problem: maintain an approved list of ports, and determine the presence of suspicious activity by examining dataflow through ports not on the approved list. Knowing that sophisticated investors always ask about patents, Guy, the CEO, told Avishai to meet with Moti, the company's patent attorney. So Avishai obliged and spoke to Moti, a very bright patent attorney who was able to stand toe-to-toe with Avishai. Moti wrote a fantastically detailed patent. Just as Avishai described, Moti defined the invention in terms of a series of switches, routers, hubs and bridges. Two years later, the patent issued, and the company threw a party celebrating Avishai's achievement. But no one recognized that the patent is horrible. Why? Because there are many ways to get to the same solution without the arrangement of switches, routers, hubs and bridges required by the patent. A competitor who likes Cyber-sode's solution, will say, "Great idea! I can get to the same result with another arrangement of components. And when I do, I will not have to worry about Cyber-sode's patent."

What did Cyber-sode do wrong? It pursued a technical patent rather than a conceptual patent. By focusing on Avishai's particular technical solution, Moti left open the possibility that a competitor could get to the same result without using that particular technical solution. It's really not Moti's fault. He did what Avishai told him to do. The problem is that Avishai thinks like an engineer, and therefore he guided Moti to prepare a technical patent that ended up protecting one narrow technical solution.

What should Cyber-sode have done differently? It should have engaged in strategic patent planning to figure out how to block competitors from stealing a revenue stream as opposed to blocking competitors from stealing a particular technical solution. Guy, the CEO, or someone else with a strong business head should have been involved, along with a representative of Marketing. Had Cyber-sode adopted a business, rather than technical approach to its patenting, it would have realized that instead of patenting an arrangement of switches, routers, hubs and bridges, it should have more generally patented a system that uses an approved port list to check for suspicious activity on unapproved ports. Such a patent would have blocked everyone from using the conceptual solution, regardless of the technical arrangement of components.

If you are thinking to yourself, "that's silly," no one can get a patent that broad, think again. That's just the patent Hewlett Packard received. Check it out: U.S. Patent No. 9,521,154.

Unfortunately, according to many analysts, Cyber-sode's mistake is repeated more than 90% of the time across all companies, regardless of technology. Business strategy run by business people, goes in one direction; and patenting, led by techies, goes in another. Then, when it comes time to use the patents to stope competitors, the patents don't work. To be successful with patents, companies must adopt a business approach to patenting. Before beginning to write patents, companies should first identify the business goals that the patents need to accomplish. Then, the strategy for each prospective patent should be tested to determine the likelihood that such a patent will block competitors. Business people need to be involved in this process together with a patent strategist. If a strategy is likely to achieve the business goal, the patent should be pursued. If it is not likely to achieve the goal—no matter how clever the invention—the patent should not be pursued. With global patent costs in the neighborhood of \$200,000 per patent family over the family's life, companies need to be more cautious in their approach to patenting. Otherwise, as we often see, companies have huge patent expenses with not much to show for it. As one Israeli CEO recently said, "it's taken me a long time to come to this realization, but when it comes to patents, either do it right, or don't do it at all."

Tags

Cybertech

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Gerson S. Panitch Partner Washington, D.C. +1 202 408 4080 Email

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ARTICLE

Trade Secrets: Protecting Clean Energy Technology

March/April 2018 North American Clean Energy By Maximilienne Giannelli, Ph.D.; Kenneth O. Aruda, Ph.D.

In today's competitive marketplace, it is vital that you have a comprehensive plan in place to protect your intellectual property. While most companies include patents and trademarks as key components of their plan, many overlook the existence, role, and/or value of trade secrets. That mistake can prove costly.

Trade secrets are prevalent in the clean energy sector. In the solar industry alone, the United States has secured convictions of several individuals for economic espionage, e.g., trade secret misappropriation benefiting a foreign government, instrumentality, or agent, with penalties resulting in imprisonment and multi-million dollar restitution awards. Importantly, the vast majority of reported trade secret theft occurs at the hands of current or former employees. And, while a subset of these employees intend to profit from the theft of company secrets, some employees may claim they were unaware of the scope of what they could permissibly disclose. At least with respect to this latter category, some simple steps may help you prevent trade secret misappropriation.

You may wonder whether your company actually possesses enforceable trade secrets. In general, any confidential information that gives your company a competitive edge may qualify as a trade secret, as long as it is not generally known or readily ascertainable by proper means (such as reverse engineering), and provided that you safeguard such information using reasonable measures to maintain secrecy.

Technological trade secrets can develop along two paths. First, you may rationally decide at the outset that trade secret protection would provide greater value than patent protection. This may be the case if a patent would not carve out a meaningful space in the marketplace, if your secret information might provide a competitive advantage for more than a 20-year patent term, if you expect that you can maintain the secrecy of your information, and if you doubt that others could reverse engineer or independently develop your secret. Cost may also be a consideration, as trade secret protection has no upfront costs. However, particularly during early stages of commercialization, it may be difficult to predict when trade secrets will provide greater value than patents.

The second path by which trade secrets develop may be referred to as hindsight recognition. Such trade secrets develop over time, often hand-in-hand with manufacturing experience and the development of technical know-how. These trade secrets may, at times, include combinations of features previously disclosed in patents, provided that the overall trade secret remains valuable, secret, not generally known, and not readily ascertainable through proper means. Particularly if your company engages in commercial manufacture, you may well have trade secrets but not realize they exist. Technological trade secrets often relate to production processes, including chemical reagents, recipes, specialized equipment, process parameters, and/or combinations thereof.

Taking active steps to evaluate and protect your confidential information may help prevent costly misappropriation. First, know your trade secrets. Knowing which information provides you with a competitive advantage will help you devise reasonable steps to protect that information. This may involve a company-wide trade secret audit, resulting in a list of the type of information that may qualify as trade secrets. Importantly, you should balance how broadly you categorize your secrets. Labeling everything "secret" or "confidential" may confuse employees, and devalue the protection of legitimately confidential or secret information. On the other hand, it is important to categorize your secret information broadly enough to ensure that no valuable confidential information falls through the cracks.

Second, once you have a general sense of what type of information needs to be protected, devise a plan for securing that information. Limit disclosure appropriately. For example, limit access to those with a need to know. For facilities where confidential activities like manufacturing occur, restrict access, prohibit photography, and conceal the identities of key components or reagents by using code names. For electronic information, use passwords, encryption, and other appropriate measures. For hardcopy materials, require that employees with access check out materials, and sign and date whenever such information is accessed.

Third, ensure your employees know their responsibilities. This should occur at all stages of employment. Upon hiring, have appropriate terms and conditions spelling out confidentiality obligations; clearly state that the confidentiality of your company secrets never expires. Consider using an employee handbook detailing permissible activities, including whether and/or when employees may work from home, copy company data to personal laptops, or use external emails or memory devices. For anyone with access to confidential information, implement appropriate levels of training and repeat that training periodically. Importantly, for any departing employees, conduct exit interviews where you explain all ongoing obligations, including at least the obligation not to disclose any company secrets. These issues often confuse employees, so invite discussion, and ask departing employees to contact the company if they are confused about what information they may permissibly tell others. Where an employee has had access to highly valuable information, ask them to formally sign an acknowledgement of their confidentiality obligations prior to their departure. At all times, ensure that employees know what information your company considers confidential, and what steps they need to take to ensure that secrecy is maintained.

Finally, evaluate your agreements with third parties, including vendors, collaborators, purchasers, and any others. When appropriate, ensure that your agreements have robust non-disclosure provisions. If the identity of equipment, chemicals, or other items gives your company a competitive edge, consider including a provision that prevents vendors from telling others about the existence of your business relationship and/or what was sold; discuss these restrictions with the vendors' sales representatives to ensure that they understand their confidentiality obligations. While it may not be possible to prevent all acts of calculated trade secret theft, these measures may help prevent inadvertent disclosures and thereby help maintain the competitive edge provided by your trade secrets.

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Maximilienne Giannelli, Ph.D. Of Counsel Reston, VA +1 571 203 2432 Email

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ARTICLE

Virtual Marking: A Flexible Option for **Pharmaceuticals**

July 1, 2020 Life Science Leader By Laura P. Masurovsky; Mark J. Feldstein, Ph.D.; Olivia C. Martzahn

Physically marking a product, or in some cases its associated packaging, with the "patent" or "pat." and the numbers of any patents covering the product provides constructive notice to the public that the product is covered by the identified patents. Marking can be important for obtaining damages for infringing products sold prior to the date when you sue an infringer. A 2011 change in the law provides a new option for marking: "virtual marking."

While physically marking remains an option, virtual marking allows a patent owner to mark the product with "patent" or "pat." along with an internet address. The corresponding webpage, in turn, identifies the patents covering the product. Like traditional physical marking, virtual marking can provide constructive notice that a product is patent protected. Also like traditional physical marking, virtual marking can preserve your right to recover pre-suit damages for patent infringement.

Read the full article here.

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1



Laura P. Masurovsky Partner Washington, D.C. +1 202 408 4043 Email



Mark J. Feldstein, Ph.D. Partner Washington, D.C. +1 202 408 4092 Email



Olivia C. Martzahn Associate Washington, D.C. +1 202 408 4371 Email

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ARTICLE

What Makes Some Patents More Powerful Than Others? Finnegan's Two Secret Ingredients

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By Gerson S. Panitch

Technology companies who lack strategic patents are at a serious disadvantage. Simply having patents is not enough. Patents are only valuable if they block critical paths that competitors will need to compete. It's fairly easy to get a patent. It's much more difficult to obtain a patent that blocks competitors.

When it comes to patent protection, the U.S. is the most critical stop for global companies. This is because the U.S. represents almost a quarter of the global market and has a very strong patent system that discourages infringement. The U.S. also has some of the most complex patent rules in the world. So, if a patent is properly designed to survive challenges in the U.S., it is likely to survive challenges in other countries as well. For this reason, global companies tend make the U.S. the centerpiece of their patent focus.

U.S.-based Finnegan, one of the largest IP firms in the world with 10 global offices, represents over 160 of Israel's leading companies and hottest startups. Finnegan strategically develops patents for its Israeli clients, enforces those patents in court, and defends Israeli companies accused of infringement in the U.S.

Finnegan's Israeli clients, like their successful counterparts around the world, understand that there are two secret ingredients in building strong patent portfolios. First, companies need to realize that patents are business tools that must be designed to achieve business goals. The patenting process should be driven from a business perspective, with support from the technical side. Too often, the technical side drives corporate patenting decisions, with insufficient or no business input. As a result, companies end up with a pile of technically nuanced patents that can be easily circumvented. Patents should block competitors from offering features that are critical to competition, not necessarily what engineers and scientists find interesting from their academic perspectives. So the first secret to building a powerful patent portfolio is to work with a patent strategist who designs patents from a business perspective to achieve business goals.

As a leader in the U.S. IP market for more than fifty years, and with a strategic patent planning group focused on business-driven patents, Finnegan strives to help its Israeli clients super-power their patent portfolios with IP assets that directly impact the bottom line.

The second secret to building powerful patents is that they must be carefully designed to withstand court challenges. Patents are vulnerable instruments. One wrong choice of words or failing to follow one subtle rule pronounced by a court, can mean the difference between a multimillion dollar patent and a patent worth nothing. When U.S. patents are developed by patent attorneys who never stepped foot in a U.S. courtroom and who therefore are not focused on the many ways patents are attacked in the U.S., the resulting patents tend to be highly vulnerable. For this reason, companies serious about patenting involve U.S. courtroom lawyers in the patenting process.

Recognizing that these critical skills were lacking in Israel, ten year ago, the University of Haifa Law School invited lawyers from Finnegan to teach a masters degree course on strategic patenting. To educate Israeli executives, the University of Haifa co-sponsored an annual lecture series on strategic patenting, taught by U.S. courtroom litigators from Finnegan. That lecture series alone reached nearly 4,000 Israeli executives over five years. Since that time, the Coller School of Business at Tel Aviv University added a patent strategy course to its MBA program, inviting Finnegan to teach that course as well. Now, as the result of years of education, many Israeli executives understand how important it is to not only adopt a business approach to patenting, but to ensure that U.S. courtroom litigators participate in the patenting process.

With sophisticated international investors regularly scouring Israel for companies having valuable, proprietary technology, and at a time when insufficiently protected innovations are quickly copied, Israeli companies cannot afford to have second-rate patent portfolios. Simply having patents is not enough. Patents must be designed to block competitors and withstand courtroom challenges. Otherwise, patents are virtually worthless.

Related Practices

Patent Portfolio Management, Monetization, and Transactions

Related Professionals



Gerson S. Panitch Partner Washington, D.C. +1 202 408 4080 Email

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ARTICLE

Why Medical Device Companies Should Make More Use of the ITC

June 15, 2020 Intellectual Asset Management By Anthony D. Del Monaco; Zachery D. Olah; Alissa E. Green

Intellectual property litigators understand that the International Trade Commission (ITC) is a unique forum. Companies with United States domestic industries, however, often overlook the benefits of enforcing their intellectual property there. From its strong remedies, to its quick timeline, the ITC offers litigation benefits for all IP owners, including medical devices companies, that other forums - like district court - do not.

Unlike other litigation forums, the ITC does not award money damages to a winning complainant/IP owner. Instead, after an IP owner files a complaint, the ITC has the authority to stop the accused entities from importing infringing products into the United States if it finds a violation. This is a powerful way to retain US market share.

Additionally, the ITC offers complainants the benefit of an expedited timeline to a final decision. Unlike district court cases that can take years to reach a conclusion, the ITC's schedule is significantly shorter. At the ITC, a hearing is conducted before an ALJ as soon as nine months after the Commission institutes the investigation, while a final decision from the commission is provided as soon as 15 months.

Despite these benefits, the medical device industry has underused this forum. In fact, in the last 10 years, only 40 of the over 500 complaints filed at the ITC involved medical device products.

To analyse how medical device companies have performed at the ITC we looked at every investigation filed from January 2010 through February 2020. If the accused product(s) in an investigation involved medical devices and/or medical equipment, it was identified as a relevant investigation. We did not include ITC investigations relating to pharmaceutical companies or products.

To calculate the win rate, we defined an IP owner win as those cases where the IP owner was able to secure a settlement agreement, a consent order, a limited exclusion order, a general exclusion order and/or a cease and desist order against at least one of the of the accused products. The study does not include cases where a complaint was withdrawn.

Of the 40 complaints filed at the ITC since January 2010 by medical device companies, six had not yet concluded at the time of writing. Additionally, six complaints were withdrawn, leaving 28 cases involving medical device products where the investigation reached a conclusion.

Of these 28, the IP owner won 23, translating to an 82%-win rate. Breaking this down further, 12 of the "wins" involved a settlement, four involved a consent order and the remaining eight concluded with either a limited exclusion order, a general exclusion order, a cease and desist order or a combination thereof.

On the other hand, only five of the cases resulted in "losses" for the complainant, translating to a loss rate of 18%. In each of these cases, the respondent did not settle and the ITC found that it did not violate Section 337.

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The 82%-win rate is even more encouraging when compared to the success rate of similar companies in district courts across the country. For example, according to statistics compiled by LegalMetric, at the district court level, medical device companies filing patent infringement lawsuits were only successful 40.7% of the time from January 2010 to December 2019. Similar to the ITC investigations analysed, LegalMetric defined medical device companies as any company whose primary business involves medical devices and/or medical equipment.

The discrepancy between win rates at the ITC versus district court should encourage more medical device IP owners to consider enforcing their IP rights at the ITC.

Digging deeper into the numbers, we determined that the average time to resolution on all medical device investigations at the ITC was just under 14 months. The 23 cases we analysed where the IP owner won were resolved within an average of 12 months.

One example of an ITC investigation that ended quickly with a settlement agreement is *Certain Obstructive Sleep Apnea Treatment Mask Systems and Components Thereof*, USITC Inv No 337-TA-1136. This case only took seven months to reach its conclusion. In considering an investigation on the longer side of the spectrum, in *Certain Sleep-Disorder Breathing Treatment Systems and Components Thereof*, USITC Inv No 337-TA-890, a commission opinion finding a violation of Section 337 took only 17 months to issue.

LegalMetric also compiled nationwide statistics for the length of medical device cases. These statistics included cases where the plaintiff won and lost. According to LegalMetric, in district court, medical device litigations over the same time period averaged 19 months to resolution. This statistic includes multiple types of terminations that were not considered for this article; for example, termination because cases were consolidated or transferred intra-district (an ITC case cannot be transferred to another jurisdiction). These district court cases had a very short average pendency of 2.4 months and 2.3 months respectively. Therefore, the average time to resolution in district court cases is slightly skewed and the length of cases with results most like those analysed at the ITC are much longer.

For example: district court cases resulting in a consent judgment averaged 26 months; grant of summary judgment averaged about 32 months; and jury verdict averaged about 37 months. Furthermore, it took parties an average of 16 months to reach a settlement in district court cases involving medical devices.

These figures not only highlight how quickly a medical device company can complete an ITC investigation compared to similar district court proceedings, but also emphasises that favourable decisions can come from the ITC in these shortened timelines.

Medical device companies can also effectively utilise the ITC by filing one complaint against multiple alleged infringers at the same time and in the same forum, so saving time and money for the complainant. This approach became beneficial after the AIA compelled parties enforcing their intellectual property to file different litigations against different defendants despite asserting the same intellectual property.

Additionally, unlike lawsuits filed in a district court, ITC investigations are not subject to the venue requirements of 28 USC \S 1400(b). After the Supreme Court rejected the broad interpretation of \S 1400(b) in TC Heartland LLC v Kraft Foods Group Brands LLC, some patent owners began looking to the ITC because of its unique governing statute, which includes its own jurisdictional requirements. Section 337 jurisdiction is based solely on the importation of products into the United States regardless of where the person or corporation making or importing the accused product resides. As such, when patent owners file their actions in the ITC against multiple defendants, there is no risk that the case may be transferred to a different jurisdiction due to lack of personal jurisdiction.

For example, in *Certain Electric Skin Care Devices, Brushes and Chargers Thereof, and Kits Containing the Same*, USITC Inv No 337-TA-959, complainant Pacific Bioscience Laboratories Inc filed a single complaint against 18 different respondents. They included companies from the United States, China, Korea, the United Kingdom, Canada and Israel. With one complaint in one jurisdiction, Pacific was able to get various positive outcomes against many of the respondents, including consent orders, exclusion orders, and settlement agreements.

For at least this efficiency, medical device IP owners considering asserting their rights against multiple infringers that import accused products should consider the ITC as a potential forum.

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The ITC is a strong forum to litigate medical device intellectual property. With a recent success rate of 82%, expedited timeline to resolution and ability to address multiple infringers in one investigation in one forum, medical device companies should seriously consider enforcing their intellectual property at the ITC.

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Patent Litigation ITC Section 337

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Anthony D. Del Monaco Partner Washington, D.C. +1 202 408 4023 Email



Zachery D. Olah Associate Washington, D.C. +1 202 408 4390 Email



Alissa E. Green Associate Washington, D.C. +1 202 408 4305 Email

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