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Intellectual Property Law Update

NEWSLETTER

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The holidays: a winter wonderland of business opportunities such as:

- new offensive and defensive patent strategies;
- tips for dealing with foreign trade secret theft;
- tips on most profitable use of trademarks in franchising situations;
- steps you MUST take now to meet your GDPR obligations; and
- need for online re-designation of website copyright agents;

Patently Obvious!

Timing Your Patent Filing: The Pros and Cons of Filing Early and Quickly

The decision as to when to complete your patent filing can have a significant effect on the success of your application and enforceability of the patent that will issue from it. In fact, the implementation of the "first-to-file" patent system under the America Invents Act (AIA) significantly altered the application process by stipulating that an applicant who files first, regardless of the date of invention, is entitled to the patent rights and protections afforded by the USPTO.

The first-to-file patent system supplanted the U.S. first-to-invent patent system for applications filed on or after March 16, 2013. The most obvious benefit of this system is that the applicant can prevent others from obtaining a patent for a particular invention by quickly putting their application on file with the USPTO. A prompt filing effectively means that your application would preempt a potential competitor's filing and avoid any ambiguity as to which party is entitled to the patent for an invention. As a result, inventors and potential investors can proceed confidently with the knowledge that the rights to the patented invention are definite and secure. Those who wait to file are faced with uncertainty as to the status of their patent rights. In addition, any public disclosures by others made prior to the application filing date can be deemed prior art and may be used to oppose an applicant's patent claims.

While a prompt and early filing is clearly advantageous for these reasons, there are a number of factors that an applicant must evaluate before filing their application. Applicants may erroneously focus solely on filing their applications quickly to secure their rights without adequately assessing the strength and thoroughness of the disclosure of the invention that is provided in the application. If the application process is not managed and executed correctly, then the applicant's rights can be significantly impaired in the future. In the race to file, what should potential applicants consider before initiating the filing process?

Inadequate disclosures. An inventor should adequately develop an idea and/or document the implementation of an invention before applying for a patent. In general, an applicant should strive to submit narrowly tailored, distinct claims that emanate from practical applications of the invention to ensure the best possibility for success, in addition to broader claims that may provide blocking value against competitors or easy design arounds. An idea that is only partially or insufficiently developed may be deemed overbroad and fail to qualify for patent rights. Moreover, elaborations that are submitted at a later date run the risk of exclusion from the initial application that bears the priority date.

Incomplete descriptions of the invention. The actual application must include a complete description of the invention, optionally with an accompanying illustration and/or working examples if applicable, and enough information for someone else to make and use the invention without "undue experimentation." The absence of these elements may result in a lack of adequate support for future claims related to the idea or invention. Because the priority date applies only to the invention described in the application, an applicant should ideally wait until the initial key stages of development, such as testing and research, are at a stage at which data may be included in the patent application. Filing before there is adequate technical information may be detrimental to the prospect of securing protection for the invention, and in a broader context, may incur cost and devote resources to applications for inventions for which there are no commercially viable uses.

Subsequent filings. An inventor who has failed to adequately develop the invention or has not described the idea thoroughly in the patent application typically must file subsequent applications, but the actual priority date may be deemed to be the date on which full information about the invention is provided. As more information becomes available, the applicant may need to file new applications to describe variations or improvements to the original invention or to explain newly discovered applications of use for the idea.

Ultimately, a well-developed, researched invention accompanied by a thorough patent application is a good candidate for early and prompt filing. A provisional patent application provides the filer a 12 month period before they are required to submit a formal patent application. After filing, the provisional application provides confidence that a public disclosure may be made, while the underlying invention is protected. Further, the filing of a provisional application establishes the patent priority date, thereby allowing the applicant to access the benefits of the first to file system. Most importantly, the time lapse provides applicants with the opportunity to perfect the idea and assess the viability of the invention in the public sector before incurring the expense of a nonprovisional application one year later.

<u>Chemical Patenting: What are Fatal Flaws Justifying a Validity Challenge?</u>

Generally, a party wishing to invalidate a patent will attack the process by which the patent was obtained rather than the substance of the discovery. This is because in most cases a third party wishes to practice the discovery and is blocked from doing so by an issued U.S. Patent. One common method of attacking validity is an attack on the data present in the patent. For example, when experiments disclosed in the original Application are repeated by others and the original teachings are found to be inoperable.

For chemical, especially pharmaceutical, applications, this requirement mandates that for new compositions of matter there be confirming analytical data that suggests the desired compound was in possession of the inventors and that an adequate process for preparing the compound be disclosed. For example, an application that merely provides a generic or specific chemical structure without some form of evidence, *inter alia*, ^{1}H NMR, ^{13}C NMR, mass spectrum and the like, would not be deemed "enabled" under the Patent Act.

In addition to verification of the structure, the Applicant must disclose a "use" for the molecule and one or more examples of that usage. For example, a method of treating cancer assertion together with *in vitro* or even *in vivo* supporting data. There are instances wherein a chemical compound or composition is discovered and patented and it is not until science advances that a new use of the compound is found. This article discusses one possible fatal flaw when contemporary patent Applications rely on decades old initial discoveries and the written description contained in the original patent Application. The question is: how does one prove that one actually has possession of the invention when there is a significant error in the original disclosure? What constitutes a fatal flaw in the patent's disclosure? Is the misidentification of a chemical formula a fatal flaw that can invalidate a U.S. Patent?

In 1973 the German pharmaceutical company, Boehringer Ingleheim, obtained a German patent which disclosed a number of antiseizure medications. The patent disclosed the complete synthesis of an analog TIC10. Subsequently the National Cancer Institute (NCI) incorporated this compound into one of its databases.

In 2013 a researcher at Penn State, Wafik S. El-Deiry, reported that TIC10 demonstrated potential anticancer activity. The Penn State researchers used Boerhinger Ingleheim's disclosed procedure for making this analog and confirmed the structure using mass spectrum analysis. The compound was then patented in 2014 (U.S. 8,673,932 B2) for use as a method for treating cancer. Penn State licensed the patent to Oncoceutics a drug development company founded by El-Deiry.

Upon learning of TIC10's anti-cancer activity, a group led by Dr. Kim Janda at Scripps Institute decided to investigate this drug. They developed a shorter and higher yield synthesis of the compound having the formula published in El-Deiry's patent. When the compound they prepared was tested it was found to be inactive. Janda secured a sample of TIC10 from the NCI data base and analyzed it using techniques not available to Boehringer Ingleheim 40 years earlier. It was found that the originally assigned structure was incorrect. Is Oncoceutic's patent potentially invalid because of this error?

We believe the answers to the above questions can be found in *Cubist Pharmaceuticals, Inc. v. Hospira Inc*. (Fed. Cir. 2015). The District Court held that a patent was not invalid because of an incorrect chemical formula and that the error was correctible after the patent was issued. In upholding the District Court's judgment, the Federal Circuit discussed the relationship between what is actually obtained and what is believed to be possessed. Supporting Pennsylvania State University in the patents under discussion, the court held that after detailed analysis of the state of knowledge at relevant times, there was a reasonable scientific explanation for the original erroneous disclosure which explanation allowed it to uphold the patents.

The court has reaffirmed by this decision that it is not a chemical formula that places possession of a discovery into patentee's hands, but the ability to make the molecule by a recognized reproducible process. Prior to modern spectroscopy techniques, many patentees relied only on a reproducible process to show possession.

An important lesson from all of this for patent applicants and those contemplating a patent validity challenge is that an attack on a patent for misleading or incorrect disclosures during its prosecution must be considered in the context of the then-prevailing scientific environment in order to determine if there was a reasonable explanation for the error.

ITC Becomes Appealing Venue for Patent Suits in Light of Supreme Court Decision

In its landmark decision in *TC Heartland*, which we discussed in our June 2017 issue, the U.S. Supreme Court placed limits on where a company may be sued for patent infringement. *In light of this ruling,* entities must carefully determine where to bring their patent suits.

One potential venue that may be appealing to patent holders is the U.S. International Trade Commission ("ITC" or the "Commission"). Pursuant to Section 337 of Tariff Act of 1930, as amended ("Section 337"), parties can file complaints with the ITC relating to unfair trade practices that have been used in the importation of goods into the United States. Various kinds of unfair trade practices can serve as the basis for a Section 337 complaint, including the infringement of statutory IP rights (*e.g.*, patents and federally registered copyrights and trademarks). Other kinds of actionable unfair trade practices include, among other things, trade secret misappropriation, common-law trademark infringement, passing off, false designation of origin of goods, and violations of certain U.S. trade laws.

In terms of remedies, the ITC can grant any one or more of the three following kinds of relief following the finding of a violation of Section 337: a limited exclusion order ("LEO"); a general exclusion order ("GEO"); and/or a cease and desist order ("CDO"). The actual remedies that are granted will depend on the specific relief requested and whether all of the requirements for granting such relief are satisfied.

In Section 337, cases relating to patent infringement, which can involve multiple parties and multiple patents, a complainant must show: (1) the importation into the U.S., the sale for importation, or the sale within the U.S. after importation by the owner, importer, or consignee of the articles; (2) infringement by the articles of one or more claims of a valid patent; and (3) an industry in the U.S. relating to the articles protected by the patent exists or is in the process of being established (the "Domestic Industry Requirement"). Of these three elements, the Domestic Industry Requirement, which has an economic prong and a technical prong in patent infringement cases, often proves to be the most challenging one to satisfy for complainants.

Our international trade-related IP partners have considerable experience in Section 337 matters and are pleased to work with clients to develop strategies for succeeding at the ITC.

Combatting Trade Secret Theft by Foreign Entities

The Commission on the Theft of American Intellectual Property issued a report earlier this year that detailed the massive scope and cost of IP theft to U.S. companies, including that relating to misappropriation of U.S. trade secrets by foreign entities (the "IP Commission Report"). *See* http://ipcommission.org/report/IP_Commission_Report_Update_2017.pdf. This article discusses ways in which such trade secret misappropriation can be addressed.

Following the issuance of the IP Commission Report, in August 2017, the Office of the U.S. Trade Representative ("USTR") initiated a Section 301 investigation concerning China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation (the "Section 301 Investigation"). In response to the notice of initiation relating to the Section 301 investigation, a number of entities submitted comments to the USTR, including the American Bar Association's Section of Intellectual Property Law ("ABA-IPL"). In its comments, which were prepared by a Task Force led by Geoffrey Goodale (a

Partner at FisherBroyles and Vice-Chair of the ABA-IPL's IP Practices Division), the ABA-IPL expressed deep concerns regarding ways in which U.S. companies have been forced to transfer technology and/or had their trade secrets misappropriated by Chinese entities with little recourse available to them in China. The ABA-IPL's comments can be accessed at https://www.regulations.gov/document?D=USTR-2017-0016-0012.

It likely will take several months before the USTR announces what actions, if any, the U.S. Government may take to address the deficiencies that exist with respect to Chinese enforcement of IP rights. Fortunately, though, there are actions that U.S. companies can take on their own if their trade secrets are being misappropriated by Chinese or other foreign entities.

For example, in instances where products are being sold or offered for sale in the U.S. that are manufactured abroad utilizing trade secrets that have been misappropriated from a U.S. company, that company could bring a Section 337 action before the U.S. International Trade Commission ("ITC"). Key aspects of Section 337 actions, including potential remedies and required elements that must be satisfied, are discussed in a separate article in this newsletter. Significantly, the ITC has ruled in favor of complainants in the vast majority of trade secret-related cases, and U.S. courts have routinely affirmed such ITC decisions.

Companies also can bring actions relating to trade secret misappropriation taking place outside of the U.S. in federal court under the Defend Trade Secrets Act (DTSA). The ways in which companies can do so under the DTSA are discussed in detail in an article written by a Partner at this Firm, that appeared in a recent issue of the ABA Section of Antitrust Law's *Competition Torts News* that can be accessed at https://www.fisherbroyles.com/wp-content/uploads/2017/09/Halligan-Competition-Torts-News.pdf.

Many of our IP partners have considerable experience in cases before the ITC and before federal and state courts and are always happy to assist clients on trade secret and other IP matters.

Trademark Licensing: Consistency is the Cornerstone of Franchising

Trademarks are an integral part of any franchise. They represent and protect the brand and create brand strength through their continued use. Brand strength is viewed in terms of customer perception; not what the franchisor believes it to be. This distinction can get lost. The focus is always on what the customers perceives the brand to be.

Trademark protection is about consistency, the hallmark of a solid franchise chain. Franchisors should take care to send exact messages to their customers. The mark must be spelled exactly as it appears on the registration. No additional periods. No deviations in color shading. No shifty words around. All of those are considered different trademarks and their continued use will weaken a franchisor's registered trademarks.

Consistency is important on the franchisee level as well. Care should be taken to monitor the franchisees' use of the trademarks beyond a simple contractual obligation. Train franchisees on the importance of trademark consistency. Make monitoring franchisee use of the trademarks a priority. Incorporate into the franchise operations a system of checks and checklists to ensure that the franchisor's trademarks are used in a manner consistent with registration.

Be alert for changes in the brand through the eyes of a consumer, especially for trademarks that do not incorporate a logo or design. Such brand identification may not be what it was at the beginning of the franchise chain. How do the customers refer

to the brand? Maybe a franchisor registered the words, High Society Burger Crossing. That may, indeed, be what the franchisor perceives the brand to be. But the customers? Are they likely to say "Let's go to High Society Burger Crossing for lunch?" Likely not. It's likely the customer associates the brand with the words "High Society" or "High Society Burgers". If so, that is one of the chain's trademarks. Register it, preferably at the federal level.

Creating a culture of trademark consistency is imperative to a franchisor or other trademark licensor. This ensures that the franchisor's trademarks remain strong and economically valuable in the eyes of its customers.

Privacy and Information Security

Ready or Not: Here the GDPR Comes!

No matter where you are in the world, the EU's General Data Protection Regulation (GDPR) applies to you if you are collecting or processing personal information (PI) of any EU individual. Of special significance are **transfers** of such information from the EU to the US or elsewhere. The law goes into effect in May 2018, and the following is an outline of some initial steps. Compliance must be viewed as a **business necessity** in that penalties may be as much as 4% of annual revenue (turnover). Senior management and directors may face personal liability for non-compliance under certain circumstances.

Get familiar with GDPR vocabulary. Processing means "any operation" involving PI, including collecting, storing, transmitting, disseminating, recording, organizing, and altering. The "controller" determines the purposes and means of PI processing. The "processor" processes the PI on behalf of the controller.

Designate responsible persons. The GDPR requires "appropriate technical and organizational measures" to ensure compliance. This means documented (for example in meeting agendas and minutes), ongoing oversight and deliberation by an organization's board of directors or other supervisory body. Deference to technical staff will not suffice. A data protection officer (DPO) may be required depending on the scope and nature of data collection (e.g., large scale or involving sensitive data). Board of Directors' oversight is essential considering, among other things, the onerous penalties for non-compliance. While there remains some ambiguity regarding formal requirements, many companies may mitigate their exposure by designating a representative physically situated in the EU to receive pertinent notices.

Map your data. Chart your data flows, both incoming and outgoing. For each data category, ask and record: Why and how is it collected? Is collection/retention in identifiable form necessary, and if so, for how long? Who is accountable? Where is it stored – i.e. server location? Could it be more prudent to store on servers located in the EU in order to avoid any transfer? Who has access to it? With/to whom is it shared/disclosed? Consider affiliates, suppliers, vendors and IT providers. For each incoming and outgoing flow, a permissible mechanism must be in place such as affirmative data subject consent, Standard Contractual Clauses (SCCs), Binding Corporate Rules (BCRs), a qualifying derogation, or adherence to an approved certification (Privacy Shield).

Update your contracts. Controllers must ensure that data subjects provide affirmative, knowing and "unbundled" consent that can be withdrawn. Contracts with suppliers may need updating to reflect an approved transfer method (e.g., Privacy Shield, SCCs, BCRs). If you are a processor, be prepared to negotiate and update your controller-facing contracts (and your

data practices as needed) to address the GDPR's requirements (such as with SCCs) and/or consider certifying to the Privacy Shield.

Update your privacy policy. A GDPR-compliant privacy policy given to consumers in hard copy or posted on a website must set out additional items, such as: how long data is held; a data subject's right to access, correct and request deletion of data and to lodge a complaint; the legitimate interests for data processing; and whether the data will be transferred out of the EU and if so the corresponding transfer mechanisms. Ensure that all statements remain true, as the making of inaccurate policy statements is also a deceptive trade practice prohibited under US law.

Update your incident response plan. Like the US, the GDPR contains requirements to report data breaches to authorities and data subjects in certain circumstances, usually within 72 hours. Your incident response plan will need to incorporate required notifications and time frames.

The foregoing is not a complete path to compliance, but taking these steps will in the least demonstrate good faith efforts to comply with the GDPR. There remain some grey areas with the GDPR (such as EU member state implementing legislation, GDPR-specific SCCs, etc.), so compliance will be an ongoing exercise for a period of time.

Our Privacy Partners are happy to provide guidance and assistance.

Copyright Compliance – Website Administration

Those with website accepting public submissions or who function as an internet service provider in any manner need to comply with the 2017 year end deadline for re-designation of copyright agents to receive notice of infringement. Compliance with this step and other steps prescribed by the Digital Millennium Copyright Act are needed to reduce your exposure to claims from copyright holders of infringement resulting from someone else's use of your site and/or infrastructure. Even if you previously did a paper filing with the Copyright Office, a new online filing is required.
Our IP Partners can assist.

BREAKING NEWS: As this went to press, the Federal Circuit determined that the provision of the trademark statute which prohibits registration of trademarks which are deemed "scandalous" is unconstitutional. More to come ….