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The FDA's New Proposed Regulations Affecting the Medical Device Approval Process

By Tiffany DeGruy

On August 4, 2010, the U.S. Food and Drug Administration's Center for Devices and Radiological Health ("FDA") released a preliminary report which proposes several changes to the medical device approval process nationwide.

According to the FDA, the recommendations in the newly-released report are intended to enhance the predictability of the approval process for new medical devices while at the same time improving patient safety and expanding medical device innovation. It is the FDA's position that adopting these new regulations will increase the predictability of the regulatory pathways, and thus stimulate new medical technology while increasing the global market position of medical devices from the United States. In a press release on this issue, the newly appointed Director for the Center for Devices and Radiological Health, Jeffrey Shuren, has declared that "these preliminary reports show a smarter FDA – an agency that recognizes both sides of our mission to protect and promote public health." Further, Shuren stated that his "agency is ready to make necessary improvements to support device innovation while assuring patients receive safe and effective devices."

Details of the proposed regulations include plans to streamline the medical device approval process for lower-risk novel devices which ordinarily cannot be cleared under the current guidelines due, at times, to the lack of a predicate device currently on the market, however do not warrant more rigorous premarket approval. According to the FDA, this regulation is an attempt to ease the burden on device manufacturers and shorten the timeline of the approval process of novel medical devices. This new regulation would allow a medical device developer to have a better understanding of the requirements set forth by the FDA and data required to get a new medical device approved.

Further, the new regulations would also create a new class of devices which would require clinical evidence establishing efficacy and safety be submitted before the product could be approved. The regulations would also provide greater communication to applicants on the front-end regarding the requirements for gaining approval of a medical device, thus avoiding unnecessary surprise and delays which are said to exist in the current system. The agency has declared that this regulation is intended to allow the medical device manufacturer to obtain predictability in what is expected of them in order to get their medical device approved.

Additionally, the agency seeks to increase the use of scientific experts outside of the agency, specifically by the use of web-based social medical technology, to create "Notice to the Industry" letters to more quickly communicate regulatory changes to those in the industry. It also intends to form a Center Science Council to oversee science-based decisions in order to support consistency in decision making within the agency. Also, the proposed regulations would attempt to foster

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information sharing with the public by creating a searchable online public database to provide information with regard to medical devices. This website would include summaries of agency review decisions, photographs and design schematics of approved devices, and up-to-date information about device labeling.

The proposed FDA regulations are not yet effective; in fact, the agency is currently seeking public comments on its proposals by inviting interested individuals to submit comments on the report. It is anticipated the public comment period will close within the next few months. After the public comment period has been completed, the agency will announce which regulations it intends to implement and will decide on the timeline for the implementation of these new regulations.

An Ounce of Prevention: IP Considerations to Strengthen Litigation Positions

Reprinted from the DRI's The Business Suit, Volume 13 Issue 5.

By Stephen Hall

We have all been faced with commercial and intellectual property litigation where we would give almost anything to change a few key facts. One area where some proactive steps can greatly strengthen a client's later litigation position is in the area of intellectual property. Advising our clients to follow a few internal procedures, and assisting our clients in policing certain activities, can ensure a client litigates from a position of strength, rather than having to face many of the unfortunate, and often inadvertent, problems that may arise in litigation.

Intellectual property litigation often involves claims of patent, trademark, or copyright infringement, as well as trade secret misappropriation. A client that implements the following basic policies and procedures related to its patents, trademarks, copyrights, and trade secrets can greatly strengthen its infringement/misappropriation claims, and often avoid having its claims thrown out on summary judgment.

PATENTS

- Designate one person to be in charge of the patent process, so that at least one person is aware of all patent activities.
- Ensure that all appropriate employees have executed an employment agreement containing an intellectual property assignment transferring all intellectual property rights, including all patent rights, to the company. Generally, it is the "inventor", and not the employer, that is entitled to a patent. Thus, absent such an assignment, while an employer may obtain certain "shop rights" to the invention, the inventor will likely retain ownership rights to the invention.
- Instruct employees to submit invention disclosure forms to the patent coordinator, **before** any public disclosure, sale, or offer for sale. This not only helps establish an early "invention" date, but it also ensures that any potential patent applications can be evaluated prior to the client's own activities triggering a time bar under Section 102.
- Instruct research and development personnel to maintain dated research log books or internal notebooks, and have the books signed each day, preferably by someone else as well as the original author. The log books or notebooks should be kept in chronological order where possible. These notebooks can be critical to establishing the earliest possible dates of conception and reduction to practice of the invention, as well as establishing the appropriate "inventors" of an invention.
- Ensure that the company has invention rights agreement with any third parties or outside contractors that are utilized in the development, testing, or manufacture of the invention. Often, a third party contributes to improvements or modifications to the invention, and may inadvertently become a co-inventor if the contribution involves "conception of the invention" and is included in one or more claims of the patent. This can cause significant problems because if deemed a co-inventor, such third party may commercialize the invention without the company's consent and without any accounting for its profits.
- Prepare and file patent applications for those inventions for which international patent protection may be sought, prior to any public disclosure, sale, or offer for sale of the invention. Unlike the United States which allows a one-year grace period for patent filings, many countries are considered "absolute novelty" countries, which require some type of patent application (or an application from which priority can be claimed) be filed before any such disclosure.
- Mark products associated with pending applications as "patent pending", and mark products covered by existing issued patents with the applicable patent number. Where the product cannot be marked directly, the packaging for the product should be marked. Properly and consistently marking patented products allows potential patent damages to accrue even if an alleged infringer is not aware of the patent.
- Track expiration dates of existing patents to ensure that patent markings are modified when the patents expire. This is all the more important in light of all the recent false patent

marking cases that are clogging the federal court dockets.

- Evaluate new products before they are introduced to the market to verify that no existing patents would be infringed by the new products, i.e., a freedom to operate analysis.
- Track various domestic and international patent maintenance fees to ensure that existing patents are not inadvertently allowed to lapse.
- Conduct a thorough and diligent pre-filing investigation before any patent litigation is commenced. This obviously begins with a reasonable claim construction of the company's own patent, see Q-Phama, Inc. v. Andrew Jergens Co., 360 F.3d 1295, 1200-1201 (Fed. Cir. 2004), along with an analysis of the allegedly infringing device or method that establishes a reasonable suspicion that the accused device or method meets each limitation in the claim. See id. at 1302; Judin v. United States, 110 F.3d 780, 784 (Fed. Cir. 1997). Absent a thorough pre-filing investigation, a patent infringement litigant faces the risk of Rule 11 sanctions and/or a malicious prosecution claim by a defendant.

TRADEMARKS

- When new marks are being considered for adoption, a company should understand the distinctiveness "spectrum", and preference should be given to fanciful, arbitrary, or suggestive marks. Companies should be advised of the potential limitations associated with marks that are deemed to be "descriptive." Choosing a fanciful, arbitrary, or suggestive mark will not only make federal trademark protection more likely, it will also decrease the likelihood that the mark will infringe another third party's mark.
- New trademarks being considered for adoption should be screened and searched before being adopted, particularly for marks that will be used nationally. It is always better to know what potentially conflicting marks already exist in the marketplace so that appropriate steps can be taken before considerable investment in time and expenses are incurred in promoting the new mark.
- Trademarks used in interstate commerce should be evaluated for potential registration with the United States Patent and Trademark Office. Federal registration provides significant advantages to trademark owners, and access to federal court.
- Trademarks should be properly marked with the ® for registered marks, or with the ™ or ℠ symbol for marks which are not registered.
- Consider implementing a watching service for its existing trademarks to monitor and evaluate other marks which may cause a likelihood of confusion with its registrations. If proactive steps are not taken to eliminate potentially conflicting marks, the distinctiveness and protectability of a mark can be lost.
- Strive to use trademarks properly, namely as an adjective, and not a noun or verb. Otherwise, companies run the risk of its marks becoming generic and not enforceable. For example, aspirin, escalator, and thermos were all trademarks at one time, but have become "generic", and thus, unprotectable terms.
- Where possible, the distinctiveness of the trademark should be highlighted, for example by using larger or different font for marks, and/or setting the mark apart from any general descriptions of the product.
- Domain names for new trademarks, products and company names should be reserved. It is often advisable to reserve domain names prior to promotion of the new mark to avoid cybersquatters acquiring the domain name. Consideration should also be given to reserving domain names that may contain common misspellings or alternative spellings. While cybersquatters can often be forced to give up rights to various domains names, such proceedings can be expensive and time consuming.

COPYRIGHTS

- Consideration should be given to registration of original works of authorship, particularly those that are likely to be accessible to others, and/or have independent commercial value if copied. Copyright protection is often advisable for computer software code, particularly if it is distributed to customers. Copyright registration is inexpensive, and easy to do. Having a copyright registration prior to the first act of infringement is essential to recovery of statutory damages and/or the potential to recover attorney's fees. Moreover, a copyright registration (or in some jurisdictions, the filing of a copyright application) is a jurisdictional prerequisite to filing a copyright infringement action.
- For any works of authorship that may be created by third parties, ensure that the contracts with such third parties are clear, that the works are "works made for hire," **and** that such works of authorship are assigned to your client. Absent such an agreement, and/or assignment, the original author of the work will normally maintain the copyright ownership of the work. It is also noteworthy that simply referring to a work as a "work made for hire" is often insufficient, because a "work made for hire" under the Copyright Act is limited to a relatively narrow list of specific types of works. Thus, the express copyright assignment is often necessary to transfer the ownership rights.
- Properly use the copyright designation along with the copyright owner, and the date that the work was created. The copyright designation provides notice that the copyrights are reserved to the author/owner, and often avoids a claim of "innocent infringement" by a defendant.

- Identify any open source software that may be used in a particular copyrightable software product, and what "license" applies to the use of the open source software. It is becoming increasingly common for software developers to include certain open source software within new software code. However, many developers fail to recognize that such use may inadvertently cause such software code to be made available to third parties at no charge under the various licenses that govern use of such code. Open source is normally available at no charge, but is still governed by license restrictions.

TRADE SECRETS

- Implement a written trade secret policy, and preferably include the policy in its employee handbook. New employees should read and sign the trade secret policy when hired, and preferably acknowledge the policy in any exit interview.
- Although each state has its own trade secret laws, almost invariably, one requirement of a trade secret is that a company must take reasonable steps to maintain its confidentiality. There are no "hard and fast" rules for what steps are sufficient, and each case will depend on its particular set of facts. Generally, the more valuable a trade secret, the more steps a company may need to take to keep it confidential. As a good rule of thumb, companies should at least (a) limit disclosure of its trade secrets to those employees with a "need to know," (b) mark trade secret documentation accordingly, i.e. designated as "confidential" or "proprietary", and (c) require employees to sign confidentiality agreements acknowledging the confidential nature of inventions, customer lists, pricing, manufacturing apparatus, procedures, etc.
- Carefully review and evaluate any "standard" non-disclosure agreements that are presented by third parties. These agreements are often seen as "boilerplate", and companies sometimes don't see the need to involve outside counsel. However, many of these "standard" non-disclosure agreements have a short time limit on the non-disclosure obligations. For example, the agreement may require confidentiality for only two years after disclosure. If valuable trade secrets will be disclosed, two years may not offer the necessary protection. For example, what if Coca-Cola had entered into a non-disclosure agreement with one of its bottlers, and only required confidentiality of its secret formula for two years? Thus, carefully consider what protection is offered for trade secrets before blindly entering into a non-disclosure agreement.

Implementing some or all the foregoing recommendations will strengthen your position when faced with intellectual property litigation matters. While these proactive steps do not address all of the "best practices" to be followed, if clients can utilize some of these steps, they will likely find themselves in a much stronger position in the event of litigation involving their intellectual property.

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Preemption Lives On Through Rejected Warnings

By Lindsey Boney

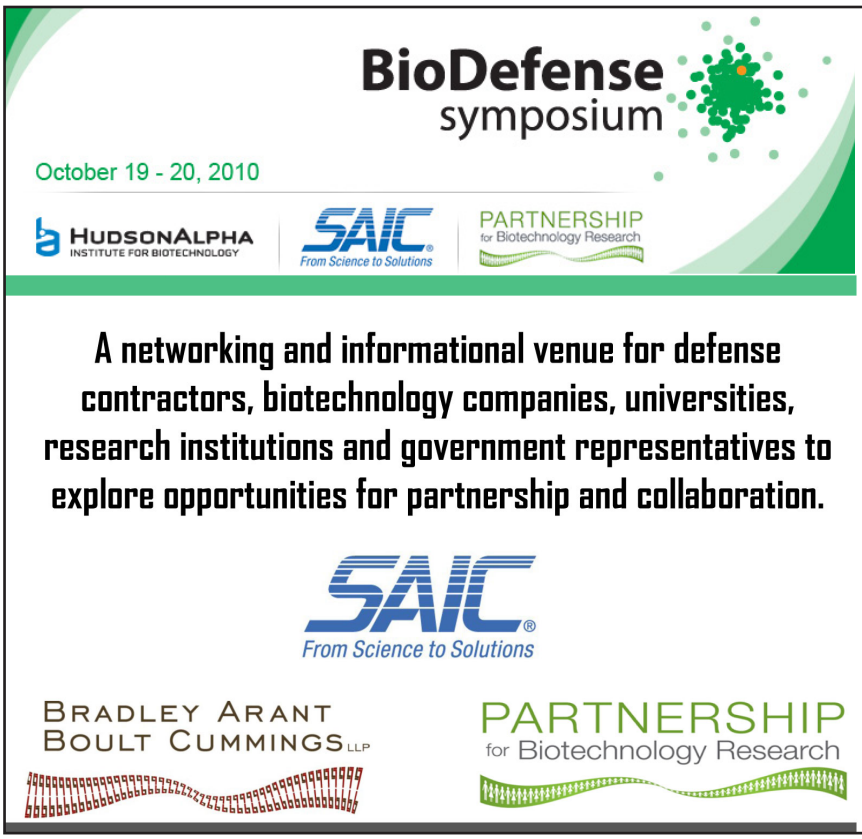
The United States Court of Appeals for the Seventh Circuit recently clarified, in its decision in *Robinson v. McNeil Consumer Healthcare*, 2010 WL 3156548, No. 09-4011 (7th Cir. Aug. 11, 2010), a defense left open by the Supreme Court of the United States last year in *Wyeth v. Levine*—implied preemption of state law when the FDA has expressly rejected a proposed warning. The Supreme Court suggested in *Levine* that a drug manufacturer can establish that it is impossible to comply with inconsistent federal and state regulations if it proves by clear evidence that the FDA would not have approved the change to the warning that a plaintiff suggests would have prevented her injury. *Robinson* clarifies that defense.

Levine involved a failure-to-warn claim in which a Vermont jury had awarded a $7.4 million verdict to the plaintiff. The Supreme Court affirmed, holding that neither FDA approval of a drug's label, specifically, nor the labeling regime created by the Food, Drug, and Cosmetic Act, generally, preempted a state-law claim of failure to warn. 129 S. Ct. 1187, 1191 (2009). The Court also stated that a drug manufacturer cannot prove impossibility of compliance with both state and federal regulation "absent clear evidence that the FDA would not have approved a change to [the drug]'s label."

Robinson is an important decision because it clarifies that rejection by the FDA of a proposed change to a drug label is "clear evidence" that compliance with inconsistent federal and state regulations is impossible. The case involved a failure-to-warn claim about Children's Motrin in which the plaintiff alleged that she experienced an allergic reaction to the ibuprofen in the drug and developed toxic epidermal necrolysis (TEN), "a rare but life-threatening disease that causes severe blistering and consequent sloughing off of skin over much of the body," and Stevens-Johnson syndrome (SJS). The plaintiff argued at trial that the drug label, which warned that the drug could cause "a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock," should have included "rash" as a possible allergic reaction and warned of SJS/TEN.

The Seventh Circuit affirmed a defense verdict. Most importantly, the court rejected the argument of the plaintiff that the failure to warn of SJS/TEN was an implied warranty that the drug would not cause SJS/TEN. Not only did the drug manufacturer not have a duty to "guarantee against every conceivable adverse consequence of taking the drug," but also the manufacturer proved that it had no duty to warn against SJS/TEN because the FDA explicitly rejected a proposed warning about SJS/TEN. The court, citing *Levine*, stated that "a court cannot order a drug company to place on a label a warning if there is 'clear evidence' that the FDA would not approve it." The clear evidence that the drug manufacturer presented was "the agency's refusal to require a reference to SJS/TEN on the label of over-the-counter drugs containing ibuprofen, when it had been asked to do so in the submission to which the agency was responding."

Drug manufacturers should keep *Robinson* in their toolbox when litigating failure-to-warn cases. If the FDA has expressly refused to require the very warning that a plaintiff argues would have made the drug safer, implied preemption is a viable defense.



The Huntsville BioDefense Symposium will be held October 19-20, 2010, at the Jackson Center adjacent to the HudsonAlpha Institute CRP Biotechnology Campus in Huntsville, Alabama. Biotechnology, intelligence and defense experts from around the country will be giving presentations and participating in panel discussions over the course of the two day event. This symposium will facilitate greater understanding of commercial opportunities in biodefense while bringing together compatible communities to leverage resources. Renowned biodefense expert Dr. Jerry Jax will present the keynote address on October 19. Bradley Arant Boult Cummings is proud to be a sponsor of this exciting event. For more information and registration details, see http://www.cvent.com/EVENTS/Info/Summary.aspx?e=19a9849b-7bce-4416-b042-d360f1fc8b8c