MEDICAL DEVICES

Legal News℠

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THE PULSE IS NOW LEGAL NEWS: MEDICAL DEVICES ... A MODERN APPROACH TO DELIVERING THE SAME CUTTING-EDGE THOUGHT LEADERSHIP YOU'VE COME TO EXPECT FROM FOLEY.

Legal News is part of our ongoing commitment to providing up-to-the minute information about pressing concerns or industry issues affecting our medical device clients and colleagues. If you have any questions about this issue or would like to discuss these topics further, please contact your Foley attorney or the following individuals:

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FDA Issues Draft Guidance on "Off-Label" Use Information

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The U.S. Food and Drug Administration (FDA) is seeking public comments on recently issued draft guidance titled, "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices" (Draft Reprint Guidance). The Draft Reprint Guidance was issued in the face of strong congressional criticism (as being too permissive), and can be expected to draw a wide spectrum of public comments. It replaces previous policy and regulations based on a now-expired statutory provision.

The Food, Drug, and Cosmetic Act (Act) broadly prohibits the marketing or promotion of new drugs, biologics, or medical devices that the FDA has not approved or cleared as safe and effective under the Act and related FDA regulations. FDA approval/clearance is limited to the specific uses (indications) identified in the product labeling. While medical professionals are free to prescribe or use approved products for unapproved or "off-label" uses based on their professional judgment, manufacturers who actively promote their products for such uses are subject to FDA enforcement action under the Act.

The Draft Reprint Guidance clarifies the conditions under which the FDA will, or will not, treat the dissemination of journal articles or scientific references (reprints) as independent evidence of unlawful off-label promotion, taking into account the competing values of statutory enforcement and free scientific exchange and commercial speech under the First Amendment. Key recommendations include:

- **Acceptable Types of Scientific/Medical Publications:** Peer-reviewed publications employing independent experts subject to editorial policies that ensure full disclosure of any conflict or interest or biases for all associated authors, contributors, or editors.
- **Excluded Publications:** Reprints of materials written, edited, excerpted, specifically published by or for a manufacturer, or edited or significantly influenced by a manufacturer or anyone having a significant financial relationship with a manufacturer.
- **Acceptable Types of Information:** Acceptable reprints should discuss adequate and well-controlled clinical investigations that are considered scientifically sound by experts with scientific training and expertise to evaluate safety and effectiveness of the drug/device.

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- **Excluded Information:** Letters to the editor, abstracts, reports of phase one trials in healthy subjects, or reference publications lacking substantive discussion of the relevant investigation or data. More broadly, false or misleading off-label information (e.g., information inconsistent with the weight of credible scientific evidence, or information disclaimed or called into question by the publisher, an author, or the FDA), or information that could pose a significant public health risk.
- **Dissemination Methods:** Reprints must be unabridged and not marked, highlighted, summarized, or characterized by the manufacturer in any way. Reprints must be distributed separately from any promotional information or materials and in a non-promotional setting. The information must be accompanied by the following: approved product labeling; a comprehensive bibliography of previously published studies/scientific information; (if relevant) a representative publication that reaches contrary or different conclusions about the off-label use; a prominent and permanently affixed statement that the use discussed is not FDA approved; specified financial disclosures; and any known significant safety risks not discussed in the reprint.

Preliminary responses to the Draft Reprint Guidance have been mixed. Even before it was released, a leaked copy was obtained by Representative Henry Waxman, Chairman of the House Committee on Oversight and Government Reform, who condemned it as an "ill-advised" and likely to "allow drug and device companies to short-circuit FDA review and approval" by conducting and circulating deliberately biased trials, thus "put[ting] the public at risk for ineffective and dangerous uses." At the other end of the spectrum, the Washington Legal Foundation, which had successfully challenged key aspects of prior off-label use restrictions on First Amendment grounds, has hinted that further litigation may be in store unless the FDA further clarifies its standard for "adequate and well controlled studies" in this context. Other preliminary reactions have been more moderate, pointing out that the FDA's basic policy with respect to off-label reprints is not changed significantly, although the details of the new draft guidance are both more and less restrictive in certain respects.

As a practical matter, drug and device manufacturers who wish to distribute reprints on off-label uses in future would be well advised to carefully review their practices against the draft guidance (and any future final version). While many standard practices may not change, more aggressive manufacturers may need to modify their procedures, particularly with respect to the limitation on types of acceptable publications (e.g., no abstracts or sponsored publications), the information and materials expected to accompany a reprint, and the separation of promotional versus medical functions and personnel.

A full copy of the guidance may be obtained online at http://www.fda.gov/oc/op/goodreprint.html. The deadline for submitting public comments to the FDA is April 21, 2008.

Plenty of Reasons Why You Should Bother Getting U.S. Patents

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Companies expend considerable time, human resources, and company finances to develop new products for the biomedical industry. Without patent protection, much of that effort will in effect be wasted by competitors' copying of the fruits of the innovative company. Consequently, great concerns have been developing about the value of patents based on recent court decisions and pending legislation in Congress. While some court decisions have altered the playing field somewhat, the strength of the U.S. patent and legal systems remains quite strong. A closer look at important U.S. court decisions themselves bears this out.

A Patent Applicant Can Seek Patent Protection for a "Combination of Old Elements"

Even after the *KSR International Corporation v. Teleflex, Inc. (KSR)* U.S. Supreme Court decision, a patent applicant can seek patent protection for a combination of old elements, as long as that combination is suitably non-obvious.

In *KSR*, the Supreme Court noted that:

> [c]ommon sense teaches … that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.

Thus, based on the *KSR* holding, an obvious combination of old elements is not patentable, but a non-obvious combination of old elements is patentable.

KSR may have made it more difficult to overcome a combination rejection. Nonetheless, any perceived raising of the "patent hurdle" should not cause any potential patent applicant not to file a patent application or to abandon an existing patent application. *KSR* places greater emphasis on the quality of the patent application and prosecution before the United States Patent and Trademark Office (USPTO). Consequently, more care should be used to prepare and prosecute patents, but the *KSR* decision in effect makes a newly issued patent more difficult to overcome if you are an infringer.

Recent USPTO Rules Restricting Continuation Practice

The USPTO recently tried to enact rules that would limit certain aspects of patent prosecution, whereby the imposition of those rules has been at least temporarily enjoined by a federal court in *Triantafyllos Tafas v. Jon W. Dudas and the U.S. PTO*, case number 1:07cv846, a lawsuit filed in the Eastern District of Virginia, until a final decision can be made. Should the federal court rule against the USPTO, those rules will never be enacted. Furthermore, there is current legislation before Congress that may affect the USPTO's rulemaking authority.

There Is Current Assurance of Reliable Patent Licensing

In *MedImmune, Inc. v. Genentech, Inc., (MedImmune)* the U.S. Supreme Court held that the Federal Circuit's standard for declaratory judgment jurisdiction was too strict with respect to cases involving disputes between a licensee and a patent holder. The U.S. Supreme Court held that the licensee need not break or terminate its license agreement before seeking a declaratory judgment that the underlying patent is invalid, unenforceable, or not infringed.

While *MedImmune* opens up a category of situations where licensees might chose to challenge patent validity, patent owners may employ various contractual mechanisms to extract the value of the license and mitigate the likelihood that a licensee will seek to challenge the validity of the patent at will. Seen in that light, *MedImmune* does not affect the reliability of patent licensing, since a carefully drafted patent license by a competent patent attorney can provide great rewards to a patent owner who seeks to license a patent.

Increased Damages Can Still Be Obtained After *Seagate*

In *Seagate Technology v. Convolve, Inc., (Seagate)* the Court of Appeals for the Federal Circuit (CAFC) set forth a two-part test that must be met in order for a patent owner to obtain increased damages. First, the patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. Second, the patentee must demonstrate that this objectively defined risk was either known or so obvious that it should have been known to the accused infringer.

While some might consider it less necessary to obtain formal opinions of counsel under *Seagate*, such opinions remain the best evidence to defend against a willfulness claim. *Seagate* does not permit companies to ignore patent rights of others. Anyone accused of patent infringement should not assume that, based on *Seagate*, there is little if any possibility that enhanced damages will be assessed against them.

Patent Owners Who Do Not Manufacture the Patented Subject Matter Can Still Obtain an Injunction, Even After *eBay*

In eBay, Inc. v. MercExchange, LLC (eBay), the Supreme Court imposed the traditional four-factor test for injunction relief, reversing the lower-standard "methodology" test set out by the CAFC, which has imposed a rule of presumptively granting injunction relief for patent infringement.

In particular, the U.S. Supreme Court held that:

> A plaintiff … must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

The U.S. Supreme Court made clear that denying injunctive relief in broad categories of cases is not acceptable. The U.S. Supreme Court further reasoned that:

> [S]ome patent holders, such as university researchers or self-made inventors, might reasonably prefer to license their patents, rather than undertake efforts to secure the financing necessary to bring their works to market themselves. Such patent holders may be able to satisfy the traditional four-factor test, and we see no basis for categorically denying them the opportunity to do so.

The U.S. Supreme Court also cited with approval a prior case where injunctive relief was awarded to a patentee who did not choose to exploit the invention. From that, one can conclude that for universities and individual inventors who do not practice their inventions but instead exploit them through licensing, the U.S. Supreme Court decision will allow such patent owners to obtain injunctive relief as long as they meet the four-factor test.

Creating an Effective China Strategy by a U.S. Medical Device Company

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With a large population and a skilled and inexpensive labor force, China can be both a promising market and a good place for sourcing products for many U.S. medical device companies. However, in order to be successful in China, a company needs to create an effective China strategy and carefully select experts to assist in the process to avoid many problems which can arise.

Creating an Appropriate Business Strategy

Sourcing products from China may make sense for some medical device companies. When doing so, a U.S. medical device company should carefully choose the contract manufacturer and continuously monitor the production process to assure product quality and protect its intellectual property (IP) rights.

In regard to Chinese markets, growth of China's medical device market will likely be fueled by the central government's plan to invest billions of RMB in establishing health services and system in rural areas in the next few years. It has been estimated that 30 percent of this funding is to be spent on increasing or upgrading medical devices used in such areas. Before selling in China, however, a U.S. medical device company should be very familiar with China's registration and certification requirements for medical device products and the pricing controls for certain large high-end medical devices.

Choosing the Right Investment Vehicle

A U.S. company may expand its business to China by entering into a contractual arrangement with a Chinese party (such as a contract manufacturer or distributor), forming a joint venture with a Chinese partner, or creating a wholly foreign owned enterprise (WFOE).

It is relatively easy to establish a contractual relationship with a Chinese partner. Generally an agreement between a U.S. company and a Chinese company regarding selling or buying products in China (with the exception of a separate technology license agreement) does not require governmental approval. The cost of setting up such an arrangement is low, significant parts of which are in the form of due diligence on, and monitoring of, the Chinese business partner. The downside of having a contract manufacturing arrangement is that a U.S. company has limited control over a Chinese partner and relies on the Chinese partner for supply chain management and quality control. With respect to using a Chinese distributor, one important concern is that the U.S. company has to rely on the Chinese partner for after-sale services. In China's medical device industry, after-sale services are especially important because the person in charge of purchasing the products may be concerned about corruption or bribery problems and the inability to correct problems with the products.

A joint venture may work for some businesses; however, the partners' different business objectives, management styles, and work ethics can frequently create conflicts. As a result, many U.S. businesses prefer to establish a WFOE wherever practical.

IP Protection

While China has made significant progress in enacting laws to recognize and protect IP rights, meaningful enforcement of such rights is still lacking. Before starting to buy or sell in China, a U.S. company should conduct a thorough inventory of its IP portfolio and identify the IP that should or should not be transferred to China. Additional measures should be taken to protect the IP that will be transferred to China. Thus, it is important to establish effective trade-secret

protections and put in place employment contracts that are strong and enforceable under Chinese labor laws.

Obtaining Registered Protection

China uses a first-to-file system, so it is important to obtain registered protection (such as patents and trademarks, which should generally include the English name, Chinese name, and domain registration) before entering the Chinese market.

Controlling the Manufacturing Process

When sourcing products from China, a U.S. company should control the ownership of tooling, so that tooling can be repossessed if unauthorized use is detected. In addition, it may make sense to hire different contract manufacturers to produce different parts of a product so that no one contract manufacturer has access to the complete product. However, such splitting-the-parts approach should be balanced with the potential increase in production cost due to increased transportation costs.

On-the-Ground Monitoring and Action

It is important to have people on the ground in China to monitor potential infringement or misappropriation of a company's IP rights and react quickly to violations.

Technology Transfer to China

The transfer of U.S. technology to China must comply with both U.S. export control regulations and the import and export control regulations of China. Under the applicable Chinese regulations, one must first determine whether a technology can be transferred into or out of China. In addition, one should pay special attention to the Chinese law, which mandates that during the term of a technology license contract, ownership of improvements to transferred technology belongs to the improving party. Thus, if a Chinese licensee makes improvements to the technology licensed by a foreign licensor, the improvements belong to the Chinese licensee. The foreign licensor needs to think creatively about ways to deal with the improvement issue before signing a technology license agreement.

The U.S. Supreme Court Finds New Immunity Defense for Medical Device Manufacturers

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A recent U.S. Supreme Court case will have a direct impact on plaintiffs' ability to sue medical device manufacturers for alleged product failures. The FDA operates and administers a number of programs, including the Food, Drug, and Cosmetic Act as well as certain amendments that are specific to medical devices. One of these amendments, the Medical Device Amendments of 1976 (MDA), created a process known as "premarket approval" for medical devices. Given the highly regulated nature of medical products and devices, medical device manufacturers have long argued that federal law should preempt state laws that impose inconsistent and often increased levels of liability for their products, particularly under state common law.

Questions regarding the scope of state common law preemption were answered recently by the Supreme Court in *Riegel v. Medtronic, Inc. (Riegel)*, 552 U.S. — (2008). In *Riegel*, a patient and his wife brought a claim against Medtronic, based upon common law theories, alleging that a medical device it manufactured had injured the patient, leading to severe injuries, including a companion loss of consortium claim by the patient's spouse. Medtronic had submitted the device at issue to the FDA for premarket approval under the MDA, which includes a "rigorous" review process by the FDA, including review of the proposed labeling of the device as well as continuing reporting requirements.[1] Under the MDA provisions, unless the FDA grants permission for changes, those manufacturers that have obtained premarket approvals from the FDA are prohibited from making changes in the design specifications, manufacturing processes, labeling, or other similar changes, if they would impact safety or effectiveness. This prohibition appeared to be important to the Supreme Court's analysis of the review process.[2]

Medtronic argued that the MDA preempted the plaintiffs' claims in the case because the device in question was submitted to the FDA for premarket approval and was approved by the FDA. The MDA expressly preempts certain state laws and, in order to begin its analysis, the Supreme Court examined a prior decision regarding the scope of preemption under the MDA (also involving Medtronic)

and stated that the touchstone of preemption under the MDA was whether "… the Food and Drug Administration has established specific requirements applicable to a particular device …"[3] In this case, the Supreme Court examined the extensive process that products must go through in order to obtain premarket approval, and concluded that liability under state law, even common law, was preempted by the MDA if it imposed restrictions that are "different from, or in addition to" federal requirements. The Supreme Court concluded that the plaintiffs' claims could not proceed because they were preempted, and it affirmed the District Court's ruling dismissing that the plaintiffs' common law claims.

Thus, under this new decision, traditional strict product liability theories against medical device manufacturers that obtain premarket approval are preempted, unless the claim is based upon one that is a "parallel" FDA requirement that is one based on the federal regulations.[4] While this offers a narrow exception to the court's ruling, it likely will not permit many plaintiffs to assert a viable theory; if a medical device manufacturer complies with the applicable standards, then there would appear to be no claim by plaintiffs that would not be preempted by the MDA. While this case offers some certainty to the medical device manufacturers regarding their liability, it also may indicate a broader trend that could permit companies in other highly regulated industries to successfully argue that federal law, not state law, determines the scope of their liability.

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[1] *Riegel v. Medtronic, Inc.*, 552 U.S. – (2008).

[2] *Riegel v. Medtronic, Inc.*, 552 U.S. – (2008).

[3] *Riegel v. Medtronic, Inc.*, 552 U.S. – (2008); citing Lohr, 518 U.S. at 495; 21 C.F.R. § 808.1(d).

[4] *Riegel v. Medtronic, Inc.*, 552 U.S. – (2008)("Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.") citing *Lohr*, 518 U.S., at 495.

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