



Currents

ISSUES AND TRENDS IN INTELLECTUAL PROPERTY AND E-COMMERCE LAW

Under the microscope:

FDA's 510(k) Plan of Action

By Nancy Brigner Waite

On Jan. 19, 2011, the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) released its Plan of Action to improve the 510(k) clearance process for medical devices. The Plan outlines 25 steps CDRH intends to take in 2011 to foster medical device innovation, enhance regulatory predictability and improve patient safety. The medical device industry was relieved that the Plan defers action on the most controversial, burdensome recommendations proposed by two CDRH working groups charged with evaluating the current 510(k) program.

QUICK LOOK **INSIDE**

SPRING 2011

- The great software protection debate - to patent or copyright?
- Intellectual property in contract terms and conditions
- Web-specific jurisdiction standard adopted for copyright infringement
- Speeches and publications

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Background

The 510(k) program is the most commonly used pathway to market for medical devices, and CDRH utilizes the 510(k) program to clear approximately 3,000 new medical devices annually. In order to obtain 510(k) clearance to market a device, a 510(k) submitter must demonstrate that its device is "substantially equivalent" to a legally marketed predicate device.

The 510(k) program's public health goals are to assure devices available to consumers are safe and effective and to foster innovation in the medical device sector. However, in recent years, the FDA has been criticized for failing to optimally achieve either goal. The medical device industry alleges the 510(k) process stifles innovation, because it is unpredictable, inconsistent and opaque. At the same time consumers and health care professionals criticize the 510(k) process for being too lax to protect the public from unsafe medical devices. Finally, FDA's own doctors and scientists acknowledge that the 510(k) program is not well-suited to handle the increasingly complex devices under review.

To address these concerns, CDRH convened two internal working groups to review the 510(k) program. In August 2010, these groups released 55 recommendations to improve the 510(k) program. After soliciting and reviewing public comments on the recommendations, in January 2011, CDRH released its Plan describing the 25 actions it intends to take in 2011 to "implement or reach a major implementation milestone" for the 40

recommendations that received strong support or “support with a caveat or modification” from the public comments. In response to the stakeholders’ significant concerns regarding the remaining 15 recommendations, CDRH deferred action on them or intends to implement them only on a case-by-case basis through device-specific guidance.

Highlights of CDRH’s Plan of Action

CDRH focused its efforts on implementing those actions that will have the greatest impact on improving and streamlining the 510(k) process. Industry representatives praised the Plan as a good first step to address the major problems without placing significant, unnecessary burdens on industry.

To facilitate innovation in medical devices, CDRH will:

- Streamline the de novo classification process by issuing draft guidance by Sept. 30, 2011. A new device that has yet to be classified is automatically designated as a class III device. The de novo classification process permits classification of devices that cannot be cleared through the 510(k) process, because they lack a predicate but whose risks may not warrant the premarket approval approach. After a de novo review, the device may be classified into class I or II. Currently, CDRH conducts a full 510(k) review prior to initiating the de novo process. This combination of a 510(k) review and a de novo review can create a lengthy path to market. CDRH’s guidance is expected to streamline the de novo classification process and to clarify its evidentiary expectations for de novo requests. CDRH hopes the de novo process can become a more viable pathway to market for lower-risk devices that lack a predicate.
- Clarify when clinical data should be submitted in support of a 510(k) filing by issuing draft guidance by Sept. 30, 2011. FDA regulations broadly describe the evidence that should be included in a 510(k) submission; however, CDRH’s new guidance will provide greater clarity regarding the circumstances in which it will request clinical data in support

of a 510(k) application and what type and level of clinical data are adequate to support clearance.

- Clarify when a modification to a device requires a new 510(k) submission and which modifications are eligible for a Special 510(k). Draft guidance is expected by June 15, 2011.
- Establish a new Center Science Council of senior FDA experts within CDRH to assure more timely and consistent science-based decision-making. The Council will serve as an oversight body to facilitate knowledge-sharing across review branches, divisions and offices, consistent with CDRH’s ongoing efforts to improve internal communication and integration. As of March 31, 2011, the Council’s Charter was posted to the FDA’s web site at www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm249248.htm and the Council will post initial results of its 510(k) audit to the FDA website by June 15, 2011.

To bolster safety of medical devices, CDRH will:

- Improve collection and analysis of postmarket information to develop better data sources and methods/tools for collecting and analyzing meaningful postmarket information. By June 30, 2011, the FDA will determine system requirements and select the platform for a new adverse event database.
- Implement a Unique Device Identification System to permit the rapid and accurate identification of devices, to facilitate and improve adverse event reporting and identification of device-specific problems. FDA will issue proposed regulations by June 30, 2011.
- Clarify submission of labeling requirements. By Dec. 31, 2011, FDA will issue proposed regulations regarding submission of labeling.
- Track transfers of 510(k) ownership. By Dec. 31, 2011, FDA will issue proposed regulations regarding reporting transfer of 510(k) ownership. Current law and regulations do not

Editor’s Notes

The statistics are impressive: Since 2000, Ohio bioscience employers have added 10,222 jobs, representing a 19.5 percent increase in bioscience employment in contrast to a 8.6 percent decline in the state’s total employment. In all, Ohio’s bioscience industry directly employs more than 62,500 workers. We have created a dedicated column in each *Currents* issue to topics of interest to bioscience companies. Look for **Under the Microscope** in this issue and future issues.

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Susan Rector, Editor

expressly require the initial 510(k) holder to notify FDA when a transfer of ownership occurs. Lack of up-to-date ownership information creates a number of challenges for the FDA and for 510(k) holders and submitters.

To enhance regulatory predictability, CDRH will:

- Develop and implement training on core competencies for CDRH staff and industry by Aug. 31, 2011, to help ensure that key terms are consistently interpreted during 510(k) reviews and to foster submission of appropriate 510(k) device information.
- Establish Notice to Industry Letters as a standard practice to clarify and more quickly inform stakeholders when CDRH has changed its regulatory expectations on the basis of new scientific information. A Standard Operating Procedure related to Notice to Industry Letters will be posted to the FDA web site by June 15, 2011.

Deferring action on controversial recommendations

The CDRH's Plan includes an ambitious schedule to implement many of the recommendations set forth in the committees' reports. However, in light of substantial industry opposition and other concerns raised by public comments, CDRH recognized that implementation of some of the recommendations may be problematic. Therefore, CDRH provided the Institute of Medicine (IOM) an opportunity to provide feedback as part of its independent review of the 510(k) program before CDRH decides whether to implement seven of the most contentious recommendations. The IOM report is expected during the summer of 2011.

In addition, four recommendations that raised significant concern will be limited to higher-risk or novel technologies and only implemented through device-specific guidance. CDRH also intends to seek additional public comment on recommendations to create an online labeling repository and a public database of photographs of cleared devices. Finally, CDRH limited its assurance case recommendation to an infusion pump pilot program.

Impact of the Action Plan

The medical device industry expressed cautious optimism toward the FDA's approach to improving the 510(k) pathway, because the FDA scaled back or deferred action on the most burdensome and contentious recommendations. While all the stakeholders hope that the Plan's implementation will improve the 510(k) pathway, the FDA must continue to address the inherent tension between the desire to give patients quicker access to the latest medical device technology while assuring the cleared devices are safe and effective.

Industry representatives as well as patient advocates and health care providers should monitor CDRH's implementation efforts. The Plan's recommendations are draft guidance and the proposed regulations' comment periods will provide interested stakeholders with an opportunity to comment before draft regulations are finalized.

The Plan of Action and any updates on the status of the Action Plan items are posted on the CDRH's web site at: www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports. ■

Sidebar

Recommendations CDRH referred to IOM:

1. Consider defining the scope and grounds for the exercise of CDRH's authority to fully or partially rescind a 510(k) clearance.
2. Seek greater authorities to require postmarket surveillance studies as a condition of clearance for certain devices.
3. Develop guidance defining class IIb devices for which clinical information, manufacturing information or, potentially, additional evaluation in the postmarket setting would typically be necessary to support a substantial equivalence determination.
4. Clarify when a device should no longer be available for use as a predicate.
5. Consolidate the phrase "indication for use" and "intended use" into a single phrase, "intended use."
6. Consider the possibility of requiring each 510(k) submitter to keep at least one unit of the device under review available for CDRH to access upon request.
7. Explore the possibility of pursuing a statutory amendment that would provide CDRH with the express authority to consider an off-label use when determining the "intended use" of a device. ■

The great software protection debate - *to patent or copyright?*

By Amy Tulk

A common decision that many software developers face when creating new software programs is whether to pursue patent protection, copyright protection or both. Often, the answer lies in the nature of the software, including the function, novelty and obviousness in light of other inventions, and the needs and resources of the author or inventor.

In general, a copyright protects original works of authorship and can protect both the source code and screen displays of a software program. A copyright protects the manner in which an idea, concept or method of operation is expressed, not the idea or methodology itself. However, copyright may still protect software from being copied.

A patent, on the other hand, can protect a wide variety of inventions and, in the context of software programs, may protect computer-directed machines and computer-performed processes, including the way a certain computer function is performed.

General copyright principles

In general, copyright protects “original works of authorship,” such as software source code and screen displays from being copied without authorization. Subject to some exclusions, the Copyright Act specifically gives an owner of a copyright the exclusive right to reproduce the work, prepare derivative works based on the work, distribute copies of the work and perform or display the work publicly. Ordinarily, copyright protection lasts for the life of the author, plus an additional 70 years after the author’s death. For a “work made for hire,” for example, a work created by an employee for his or her employer, the term is 95 years from publication or 120 years from creation, whichever is shorter.

To obtain a registration, there is no requirement that a given work be inventive, it need only be originally authored. However, one of the shortcomings of copyright protection is that copying of the work must be proven as part of a case of infringement, while independent creation is an absolute defense.

Copyright applied to software

Copyright protection, as it applies to software or computer programs, extends to all the copyrightable expression embodied in the software program. Copyright protection is not available for ideas, program logic, algorithms, systems, methods, concepts or layouts. The rights attached to a copyright that most often come into play with software programs are the rights to reproduce, prepare derivative works and distribute copies of the program. Because copyright protection extends to all forms of expression in the program, both the expression of the source code and expression of the screen displays associated with the program are protected.

General patent principles

Patent protection is often desirable over copyright protection because of the strength of protection afforded to patents. Patents provide a patent owner the “right to exclude others from making, using or selling the [patented] invention throughout the United States.” This gives the patent owner the exclusive right to make, use and sell the invention, regardless of whether another party copies the computer program or independently creates the very same invention. As a result, others may only make, use or sell with authorization, usually in the form of a license or assignment, from the patent owner. Further, in contrast to the lengthy protection afforded by copyright law, patents typically expire 20 years after the date on which the application is filed.

United States patent laws only extend protection to certain subject matter. Section 101 of the Patent Act states that anyone who “invents or discovers any new and useful process, machine, manufacture, or composition of matter, or

any new and useful improvement thereof, may obtain a patent." Although the statute does not specifically include software programs, software and other inventions not explicitly listed in the statute have been determined to be patentable subject matter by U.S. courts. However, courts have limited patentable subject matter by excluding laws of nature, natural phenomenon and abstract ideas.

In addition to being novel and useful, a patentable invention must be nonobvious over the prior art (essentially all previous inventions in the same field). If an invention is simply an improvement over a previous invention that would have been obvious to one with ordinary skill in the field, it is "obvious" and therefore not patentable.

Software patentability

The state of the law regarding software patents has greatly fluctuated over the past several years. Although the end was considered by some to be near for business method and software patents, the Supreme Court's decision last year in *Bilski v. Kappos* appears to have confirmed the continued life of most business method and software patents for the time being (for a full discussion of this decision, see *CURRENTS* Fall 2010 "Business Methods Dodge Bullet in *Bilski*").

The main advantage of a software patent over a software copyright is the strength of the patent protection and the ability to prevent others from utilizing, in some cases, certain algorithms or functions in the context of a computer program. In contrast to copyright protection, this ability to exclude others can apply to a software program regardless of the genesis of the specific underlying source code.

Pursuing both avenues

If a software program appears to meet the requirements of patentability, there are several reasons why both patent and copyright protection should be pursued concurrently. First, the current pendency rate for software patents in the 2009 fiscal year was reported to be an average 29.4 months until a first office action from the United States Patent and Trademark Office and an average 40.7 months until final disposition (such as abandonment, final rejection or issuance). Copyright registrations, on the other hand, can be completed in a manner of months (about three if filed online). Although patent protection can offer broader protection to the inventor, copyright registration can provide a cheaper and faster means of protection while the patent application is pending.

Additionally, inventors should keep in mind that the two forms of protection differ in scope. Although patent protection is generally considered broader and stronger, it does not protect the creative expression and content of the software. In other words, in many cases creative aspects such as the user

interface or graphics contained within the program can only be protected by a copyright and not a patent. Copyright protection can be best and of most immediate value where the computer program cannot be protected from copying (either by members of the public, or by independent contractors or employees who may be tempted to copy it for competitive advantage).

Several factors make obtaining patent protection for software programs inherently more difficult than obtaining copyright protection, such as the novelty and nonobvious requirements and the prohibition against the patenting of abstract ideas, which falls outside the scope of "patentable subject matter." Further, the cost of obtaining and subsequently enforcing a patent can be considerably greater than the cost of obtaining and enforcing a copyright. When deciding which avenue to pursue, an author or inventor of a software program, preferably with the help of a knowledgeable intellectual property attorney, should look at the totality of the relevant factors to make the most appropriate determination. ■

Intellectual property in contract terms and conditions

By Roger Gilcrest

The terms and conditions in most contracts deal with the standard nuts-and-bolts aspects of production, schedules, delivery and payment, as well as general warranties and representations. Intellectual property issues concerning the ownership, control, sharing and enforcement of patents, trademarks, copyrights and trade secrets are rarely completely covered.

In a business environment where interests may be shifting toward new markets with technologies and customers (and their competitors) unfamiliar to the manufacturer, care should be taken to be sure that the company's business interests are protected. Protection takes the form of the ability to produce a product and/or practice a technology as well as gaining and holding valuable rights against competitors.

Forms of IP protection

Intellectual property law covers a relatively complex patchwork of largely invisible, intangible property rights that vary in what they cover, and how each may be created, owned, maintained (or lost), licensed and enforced. Utility patents may cover any useful machine, process, material composition or manufactured article, and U.S. patent rights are owned initially by the inventor(s) until assigned. The same is true of design patents that cover the aesthetic appearance of any useful article.

Trade secrets can protect any valuable information kept in confidence, whether or not of a technical nature, and may include everything from technical know-how, designs and data, to best practices, pricing, business plans and the identities of customers or suppliers. These rights have value simply by acquiring the information and keeping it secret.

Copyrights protect works of original art or authorship from being copied, distributed or incorporated into a new version. These rights arise as soon as the work of art or authorship is put in some tangible form. Copyright registration, though not required to preserve rights, gives many legal advantages and should be sought as soon as practicable.

Trademarks are symbols of a company's goodwill, whether words, symbols or other device such as color combinations. These rights start once, and to the extent, the mark is used. Federal and/or state trademark registrations enhance and extend these rights.

These often interwoven rights sometimes can make a simple contract for manufacturing product into fertile ground for legal conflict. Suppose a manufacturer successfully responds to a request for proposal (RFP) by a sensor company to produce components for a medical sensor to be sold by its customer, a downstream medical device company. The parts to be produced are for a medical sensing device that has a housing and specially arrayed vapor openings and associated controls. The housing is to be produced by a specialized molding process that allows portions of the housing walls to be molded to a specific attenuation to make it permeable to gas. The technique is to be disclosed to the successful bidder, and a proprietary patented resin is to be specified and is to be blended by the manufacturer.

The RFP also provides that a logo is to be embossed upon one of the housing parts: an archer with a drawn bow and arrow; a new logo designed by an independent artist for the sensor company. The new logo bears some resemblance to a depiction of the Sagittarius Centaur (the half man, half horse mythical creature), also drawing a bow and arrow, that is a

registered trademark of the medical device company's competitor.

The manufacturer wins the contract and the customer provides the manufacturer with the necessary CAD files and confidential information needed to prepare the components. While working with the mold set, one of the manufacturer's engineers develops an improved method for extracting the attenuated-walled component from the mold, leading to 20 percent less waste.

Unknown to, or unforeseen by, the manufacturer:

1. The sensor has been copied by the customer who in turn sells it in competition with its own competitor that owns trade secrets relating to the molding process that were given to the customer by a competitor's former employee.
2. The specified resin is covered by a patent owned by a large chemical company who exclusively licensed the technology to the competitor.
3. The medical device company's competitor also sells an array of medical devices and supplies, that are used in the same clinical setting as the manufactured medical device, in association with the Sagittarius Centaur logo.
4. The artist was never paid for designing the archer artwork. He demands that the customer not use his copyrighted artwork - the same artwork that is now embossed on 4,000 sensor housings.
5. The customer claims ownership in the invention made by the manufacturer's engineers, because it paid for the work.

Under this nightmare scenario, the manufacturer might face legal action by the competitor for trade secret misappropriation, the chemical company for patent infringement, the medical device company's competitor for trademark infringement and the artist for copyright infringement.

From a defensive standpoint, terms and conditions should address situations that might place the manufacturer in the legal cross-hairs of intellectual property infringement, typically by providing representations, warranties and agreements relating to the defense and settlement of legal challenges. The manufacturer may also wish to check its own insurance policy for coverage and limits for these types of injuries and claims.

In this scenario, it turns out that the manufacturer's own engineer may have created a patentable invention and/or

valuable confidential information which should be claimed and secured for the manufacturer's benefit. There often are misunderstandings regarding the ownership of intellectual property rights, and contract terms should also allocate ownership of rights that may arise as work proceeds. While typically one party may be in a position simply to demand ownership (and the other party is willing to comply in the interest of preserving the business relationship), it is best to spell out ownership in the contract to be sure the rights to exploit inventions and confidential information are preserved.

Contract terms should therefore provide for obligations of assignment and cooperation, as well as reciprocal confidentiality provisions to protect know-how that may remain confidential. It is also beneficial to secure obligations of future cooperation to mature patent and copyright rights through the required filings.

Responses to proposals and negotiations, especially between previously unfamiliar parties, should go hand-in-hand with diligent investigation of the nature of the technology to be applied, its source and the third parties involved or that might become involved. In some manufacturing scenarios, it may be advisable to provide contractual obligations that parties keep each other apprised under confidence of on-going development efforts, so that they might cooperate to secure, apportion and license intellectual property rights to plan for their future exploitation.

Understanding the nature of all forms of intellectual property – what they protect and how they are created and secured – allows a company to provide contractual terms and conditions to prevent accidental or intentional loss of rights, avoidance and/or defense of infringement of third parties' rights (and pursuit infringement by third parties), as well as to preserve the relationship between the parties before unanticipated developments forestall development of profitable ventures.

Early due diligence, alertness to possible scenarios where important intellectual property may be created or infringed and timely involvement of counsel are keys to the development of both standard terms and conditions, as well as more detailed contractual language tailored to specific situations of greater complexity that arise or are anticipated. ■

Web-specific jurisdiction standard adopted for copyright infringement

By Susan Rector

The New York Court of Appeals held on March 24 in *Penguin Group USA Inc. v. American Buddha*, 2011 WL 1044581 (N.Y. March 24, 2011) that when determining long-arm jurisdiction, a different analysis applies to online copyright infringement than other forms of copyright infringement. The long-arm statute allows jurisdiction over persons who commit tortious acts outside the state that result in injuries within New York if the other grounds for jurisdiction are found.

The suit arose when New York publisher Penguin Group brought suit against American Buddha, an Oregon nonprofit that published complete copies of five Penguin Group works on two separate web sites. The suit was brought in New York and appealed to the U.S. Court of Appeals for the Second Circuit. Recognizing a split of authority in New York district courts regarding the application of the long-arm jurisdiction statute in two copyright infringement cases against out-of-state defendants, the Second Circuit certified a question concerning the statute to the New York Supreme Court. The long-arm statute allows jurisdiction over persons who commit tortious acts outside the state that result in injuries within New York if the other grounds for jurisdiction are found.

The certified question was: In copyright infringement cases *involving the upload of a copyright printed literary work onto the Internet*, is the situs of the injury for purposes of determining long-arm jurisdiction ... the location of the infringing action or the residence or location of the principal place of business of the copyright holder? The court found the location of the copyright holder determines that a tortious act occurred in New York.

The convergence of two factors persuaded the New York court that an in-state injury has occurred when a copyright owner's printed literary work is uploaded without permission onto the Internet for public access. First, the digital environment poses a unique threat to the rights of copyright owners, because digital technology enables pirates to reproduce and distribute perfect copies at virtually no cost at all to the pirate. An intended consequence of those activities creates an instantaneous availability of those copyrighted works on American Buddha's web sites for everyone, in New York or elsewhere, with an Internet connection to read and download the books free of charge. Despite the fact that the electronic copying and uploading of the work was apparently undertaken in Oregon or Arizona, where American Buddha servers were located, the harm was spread across the country.

In the case of online infringement, identifying the situs of the injury is not as simple as looking to the place where the plaintiff lost business. Here, the place of uploading is inconsequential, and it is difficult, if not impossible, to correlate lost sales to a particular geographical area.

Secondly, the situs of the injury derives from the unique bundle of rights granted to copyright owners. The five exclusive rights of copyright embody an overarching right to exclude others from using a copyright holder's property. An owner whose copyright is infringed suffers more than an indirect financial loss; it diminishes the publisher's incentive to publish and the harm is often characterized as irreparable in light of possible consumer confusion.

The court was quick to point out that its decision does not open up Pandora's box allowing any party accused of digital copyright infringement to be haled into a New York court when the plaintiff is a New York copyright owner of a printed literary work. Rather, the long-arm statute requires a plaintiff to show that the copyright owner both expects or should reasonably expect the act to have consequences in the state and derive substantial revenue from interstate or international commerce. There also must be proof that the out-of-state defendant has requisite minimum contacts with the forum state and that the prospect of defending a suit there comports with traditional notice of fair play and substantial justice.

The New York Supreme Court in a reasoned analysis extended existing case law to hold that the diffused nature of the harms associated with online copyright infringement warrants a different analysis under the state's long-arm jurisdiction statute than is required for offline copyright infringement. This reasoned decision is likely to be adopted by additional courts in deciding whether a state's long-arm statute should apply to infringement that occurs by use of the Internet. This holding will make it easier for copyright owners to pursue infringers in their home court, and viewed from the infringer's standpoint, infringement on the Internet subjects the infringer to suit in the copyright owner's backyard. ■

Sidebar

The New York long-arm jurisdiction statute requires a showing that (1) a defendant committed a tortious act outside of New York, (2) the cause of action arose from that act, (3) the tortious act caused an injury to a person or property in New York, (4) the defendant expected or should reasonably have expected the act to have consequences in New York, and (5) a defendant derived substantial revenue from interstate or international commerce. At issue in this case was solely the third factor -- whether an out-of-state act of copyright infringement caused injury in New York. ■

Speeches and publications

On Feb. 6, 2011, **Earl LeVere** presented "Launching Your New Products" at the V-Twin Expo held in Cincinnati, Ohio.

In March 2011, **Roger Gilcrest** and his client **Robert Vincent**, professor at Bowling Green State University, were selected to receive the Ohio Patent Impact Award for 2011 from The Ohio Academy of Science and the Intellectual Property Law Section of the Ohio State Bar Association. The patent award was based on several criteria that included a patent which has significantly impacted the state of Ohio through positive changes measured by economic, social change, health benefits, growth of new industries, jobs or other possible criteria.

On April 12, 2011, **Susan Rector** was a panelist at TechColumbus's **Women in Technology & Science** event: **Angel and Venture Funding** held in Columbus, Ohio.

In April 2011, **Earl LeVere** and **Amy Tulk** published an article entitled, "Targeted Medical Marketing--A Lamp in the Darkness or a Hospital Gown You Can't Close?" in the American Health Lawyers Association's *Life Sciences* newsletter.

WEB EXTRAS

The cases, statutes and regulations referenced in this newsletter can be accessed from the online version of this *Currents* issue accessible from the SZD homepage at szd.com. Click *Resources*, *SZD Publications*, then *Currents*. SZD newsletters are posted with live links (when applicable).

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