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Life Sciences

2013 Legal Developments You Need to Know About

Welcome

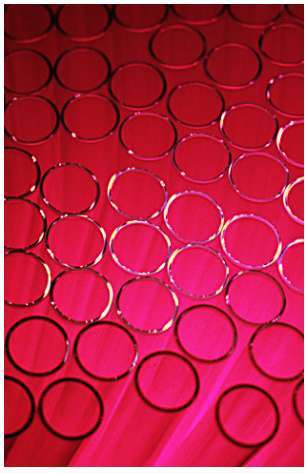
This is a short guide outlining some of the key legal developments in the life sciences sector in 2013.

The developments include a proposed modification to the HSR Form that would impact reporting requirements, AIA's First-Inventor-to-File provisions, Federal Circuit cases to watch, Reverse-Payment legislation, proposed State legislation concerning the substitution of biosimilar products, the US Federal Excise Tax on medical devices sales and the FDA's draft guidance for the evaluation and labeling of abuse-deterrent opioids.

For further information or advice, please contact your usual contact at Mayer Brown or any of the contributing attorneys whose details can be found at the end of this guide.

Proposed Modification to the HSR Form that Would Impact the Pharmaceutical Industry's Reporting Requirements

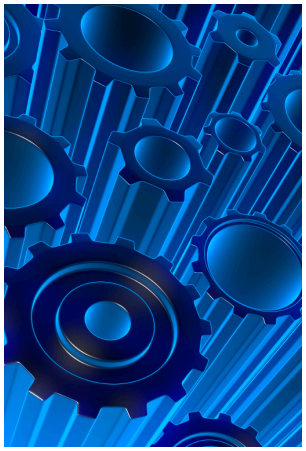
Under the Hart-Scott-Rodino (HSR) Act, when an acquisition meets certain monetary thresholds, the parties must submit a premerger notification form to the US Federal Trade Commission (FTC) and the Department of Justice (DOJ) and observe a waiting period—usually 30 days—before the deal can be consummated. On August 20, 2012, the FTC, in conjunction with the Antitrust Division of the DOJ, published an announcement in the Federal Register seeking public comments in response to a proposed modification to the HSR form. The proposed change, which only impacts companies in the pharmaceutical industry, would require the parties to report any acquisitions of exclusive patent rights. According to the announcement, the purpose of the change is to "provide a framework for determining when a transaction involving the transfer of rights to a patent in the pharmaceutical, including biologics, and medicine manufacturing industry (North American Industry Classification System Industry Group 3254) ("pharmaceutical industry") is reportable under the [HSR Act]." Several individuals and companies, such as Pharmaceutical Research and Manufacturers of America, have submitted comments in response to the proposed change. The FTC and DOJ anticipate that a final rule will be issued in early 2013.



FDA Issues Draft Industry Guidance for the Evaluation and Labeling of Abuse-Deterrent Opioids.

Prescription opioid analgesics are an important component of pain management. Nevertheless, the FDA views the abuse and misuse of these products as a serious and growing health concern. Accordingly, the development of opioid formulations that deter abuse is a potentially important step toward creating safer opioid analgesics. To help the development of abuse-deterrent opioids, the FDA recently issued draft guidance for evaluating and labeling of such abuse-deterrent opioids.

The guidance describes the FDA's views about "the studies that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how those studies will be evaluated, and what labeling claims may be approved based on the results of those studies." The FDA is currently seeking public comment on the draft guidance and is encouraging additional scientific and clinical research to advance the development and assessment of abuse-deterrent technologies.



First-Inventor-to-File Provisions of the AIA Take Effect March 16, 2013

The Leahy-Smith America Invents Act (AIA), signed into law on September 16, 2011, embodies the most significant changes to the United States patent system in decades. One of the major changes is transitioning the United States from a "first-to-invent" system to a "first-inventor-to-file" system. In general, under the new system, if two inventors independently file patent applications on the same invention, the patent will be awarded to the inventor who first filed the patent application. This is in stark contrast to the current first-to-invent system, in which the patent is awarded to the inventor who first conceived of the invention and reduced it to practice.

The new system, which is set forth in Section 3 of the AIA, takes effect on March 16, 2013. Whether a given US patent application will be subject to the new first-inventor-to-file system or to the current first-to-invent system depends on the effective date of the patent application. Section 2(a) of the AIA defines the "effective filing date" either as the actual filing date of the invention or "the filing date of the earliest application for which the patent or application is entitled." Generally, under the AIA, a single patent claim to subject matter that has an effective filing date of March 16, 2013 subjects the entire application—and applications claiming priority to it—to the first-inventor-to-file system. For example, a non-provisional application filed on or after March 16, 2013 that claims priority to a provisional application filed before March 16, 2013, may be subject to the first-inventor-to-file provisions if the non-provisional application ever contains a patent claim that is not entitled to the filing date of the provisional application.

In addition, the first-inventor-to-file provisions specifically amend 35 U.S.C. § 102 by expanding the scope of what is considered prior art. Under the new system, both public uses and sales outside of the United States are considered prior art.

Federal Circuit Cases to Watch: The Effect of Filing a Request for Continued Examination on Patent Term Adjustment

In November 2012, two district courts issued decisions that could drastically impact the patent term adjustments granted to applications that have been pending before the US Patent and Trademark Office (USPTO) for more than three years. Under these rulings, a Request for Continued Examination (RCE) filed after an application has been pending for three years would have no effect on the patent term adjustment granted, while requests

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made within three years of initial filing would continue to cut off the applicant's ability to receive an extension for this delay. However, both of these cases have been appealed and another case, decided in late January 2013, reached the opposite conclusion.

Under 35 U.S.C. § 154(b)(1)(B), patent applicants are guaranteed that an application will not be pending for more than three years due to the USPTO's action. Thus, an applicant is entitled to a patent term adjustment for any USPTO action (or inaction) that delays issuance until after that three-year time period—known as "B delay." However, according to its terms, "any time consumed by continued examination of the application requested by the applicant" is excluded from this extension. Previously, the USPTO interpreted this statute to mean that after an applicant files a Request for Continued Examination, no further extensions may be granted for B delays, regardless of when the RCE is filed. This frequently resulted in cutting months, if not years, off of a patent term where a patent applicant files an RCE.

Judge Ellis of the US District Court for the Eastern District of Virginia disagreed with the USPTO's blanket approach to the effect of RCEs, regardless of when filed. In Exelixis, Inc. v. Kappos, No. 1:12-cv-96, 2012 WL 5398876 (E.D. Va. Nov. 6, 2012) ("Exelixis I"), the court ruled that "RCE's operate to toll the three year guarantee deadline if, and only if, they are filed within three years of the application filing date." If an RCE is filed after an application has been pending for more than three years, it has no effect on the PTA.

The district court for the District of Columbia concurred, adopting the rationale of Exelixis in Novartis v. Kappos, No. 1:10-cv-1138, 2012 WL 5564736 (D.D.C. Nov. 15, 2012). However, in Novartis, the district court refused to hear a number of challenges to PTA on the grounds that they were not timely under 35 U.S.C. § 154(b)(4)(A), which provides that an applicant dissatisfied with the Director's decision may bring a civil action within 180 days of the grant of the patent. Novartis argued that this provision was inapplicable because the USPTO had made no pre-issuance PTA determination, but the court rejected that argument.

On January 28, Judge Brinkema of the Eastern District of Virginia reached the opposite conclusion in another challenge by Exelixis. Exelixis, Inc. v. Kappos, No. 1:12-cv-574, 2013 WL 314754 (E.D. Va. Jan. 28, 2013) ("Exelixis II"). In Exelixis II, the court called the treatment of an RCE filed before three years different from one filed after three years an "absurd result." Accordingly, the court determined that the USPTO's regulation that disallowed PTA for any time an RCE was under consideration—regardless of when it was filed—was reasonable.

The USPTO has appealed both Exelixis I and Novartis, and Novartis has appealed the district court's dismissal of its remaining claims as untimely. No briefing schedule has been set. In light of the conflicting decisions, the USPTO will likely continue to deny PTA based on RCEs filed at any time, and the Federal Circuit's review will be necessary to resolve the issue.

If affirmed, the Exelixis I and Novartis decisions could significantly impact patent applicants. For example, the timing of the RCE is now critical, as an RCE filed before the three-year period will foreclose the possibility of obtaining a PTA for B-delay, while an RCE filed after the three-year period will have no impact. Thus, mere days or weeks could result in decreasing the PTA by months or years.

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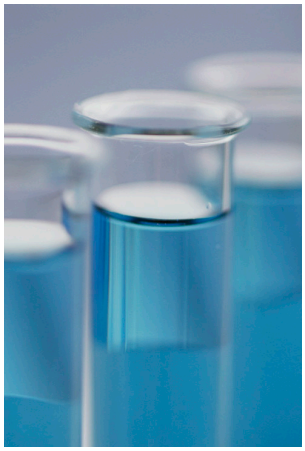
Further, the Novartis decision underscores the importance of carefully monitoring PTA decisions upon patent issuance. If any basis for challenging the PTA calculations exists, a patentee should first file a request for reconsideration of the patent term calculation within two months of issue under 37 CFR 1.704(d). Should that request be denied, a prompt lawsuit filed within 180 days of issue presents the best chance of receiving relief from an improper PTA calculation under Novartis.

The US Supreme Court to Consider Reverse-Payment Settlements of Patent Infringement Litigation

The US Supreme Court has granted certiorari in FTC v. Watson Pharmaceuticals, No. 12-416, to resolve a circuit split over whether an agreement to settle a Hatch-Waxman patent lawsuit is presumptively unlawful under the federal antitrust statutes if a branded drug company agrees to pay a defendant generic-drug manufacturer to delay the launch of a generic version of a drug. Such agreements—known as reverse-payment or "pay-for-delay" settlements—have been one of the FTC's primary concerns for years.

In this case, the district court for the Northern District of Georgia dismissed the FTC's complaint for failure to state a claim. Following its own precedent, the Eleventh Circuit affirmed, holding that, "absent sham litigation or fraud in obtaining the patent," reverse-payment settlement agreements are lawful as long as their "anticompetitive effects fall within the scope of the exclusionary potential of the patent." However, the Eleventh Circuit's rule, which has also been adopted by the Second and Federal Circuits, conflicts with the Third Circuit's holding in In re K-Dur Antitrust Litigation, 686 F.3d 197, 218 (3d Cir. 2012), that a reverse-payment agreement is "prima facie evidence of an unreasonable restraint of trade."

This case carries enormous weight for the pharmaceutical industry. Both branded and generic drug manufacturers will monitor this case closely since the Court's ruling will affect their ability to settle claims in Hatch-Waxman suits



Reverse-Payment Legislation To Be Reintroduced

While the US Supreme Court considers the issue of reverse-payment settlement agreements, two US senators are pushing for a legislative solution. Senators Amy Klobuchar, D-Minn., and Chuck Grassley, R-Iowa, have reintroduced legislation that would make reverse-payment settlements presumptively illegal. Former Wisconsin Senator Herb Kohl sponsored the Preserve Access to Affordable Generics Act several times in the past, but the bill never passed the Senate. Klobuchar, who has taken over for Kohl as chair of the antitrust subcommittee, says the FTC's 2012 report on reverse-payment settlements was the impetus for reviving the bill.

In that report, the FTC observed a gradual increase in the number of such settlements since the Commission started tracking them in 2003. However, the report showed an increase from 28 reverse-payment settlements in 2011 to 40 in 2012. According to Klobuchar, that growth highlights the need for legislation. The bill was reintroduced on February 5 as S. 214. The bill mirrors the language of those formerly introduce by Kohl, incorporating updated facts and figures from the FTC's study of pay-for-delay settlements. The new bill also removes the effective date provision that appeared in previous versions of the bill.

Is the FDA's Use of Confidential Information in BLAs a Taking?

In order to receive approval for a biological product, a pharmaceutical company must submit to the US Food and Drug Administration (FDA) a biologics license application (BLA), which includes extensive information regarding safety and efficacy of the proposed drug product. Pharmaceutical companies typically designate much of this information as trade secrets, and the FDA keeps any such information in confidence.

On March 23, 2010, President Obama signed the Biologics Price Competition and Innovation Act (the Act), which permits the FDA to approve biological products that are similar to licensed biological products, i.e., "biosimilars." The Act provides that the FDA may approve these biosimilars on the grounds that the referenced licensed product has been deemed safe, pure and potent.

On April 2, 2012, Abbott Laboratories submitted a citizen petition to the FDA, arguing that the biosimilar approval process involves a misappropriation of trade secrets under state law and an unconstitutional taking of Abbott's property in violation of Article V of the Constitution.

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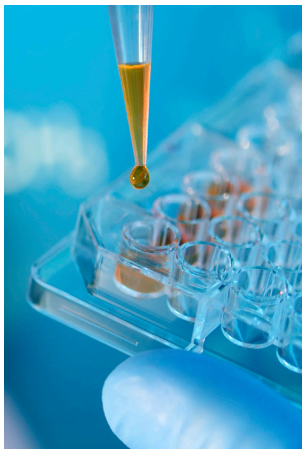
In arguing that the FDA is misappropriating Abbott's trade secrets, the citizen petition noted that any FDA approval of a biosimilar application necessarily uses trade secrets that were submitted in support of the referenced BLA. Abbott argued that this causes an injury to the trade secret owner under established trade secret law, and that a use of a trade secret occurs when a subsequent company is relieved from the obligation to submit its own information. Finally, Abbott noted that the finding that a reference product is safe and effective cannot be separated from the underlying trade secret information provided.

Abbott went on to argue that this use constitutes an unconstitutional taking under Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984). According to Abbott, when it submitted its BLA in 2002, it had a reasonable expectation, based on the law as well as FDA regulations and practice at the time, that the trade secrets in its application would not be used as a basis for approval of any other product. The FDA's purported violation of that reasonable expectation had an economic impact on Abbott that it claims constituted a taking.

The FDA has not yet acted on Abbott's citizen petition, but it previously denied a citizen petition from Genentech asking that the FDA refrain from publishing draft guidance document setting forth the similarity requirements of biosimilar products. Genentech's petition argued that the FDA could not develop or publish such draft guidance without relying on trade secret and confidential information provided by innovators. The FDA determined that Genentech's complaints lacked merit, and that its guidances did not rely either directly or indirectly on confidential information.

It remains to be seen how the FDA will respond to this citizen petition, and whether Abbott or others will pursue other action in the courts should the FDA refuse to act. This is an important issue to monitor, as it could impact the FDA's treatment of biosimilar applications based on BLAs submitted before March, 2010.



States Propose Legislation Concerning the Substitution of Biosimilar Products for the Brand-Name Reference Product

While no US state has enacted legislation concerning the substitution of biosimilar products, some are already considering the issue. For example, legislation has been introduced in Illinois and Virginia that, if enacted, would permit the substitution of biosimilar products for the brand-name reference product, provided certain conditions are met. Although there are differences in the legislation introduced in Illinois and Virginia, both generally require: (i) an FDA determination that the biosimilar product is interchangeable with the brand-name reference product; (ii) that

the prescribing physician does not indicate that substitution is prohibited; (iii) patient consent to the substitution; (iv) that the prescribing physician is notified of the substitution; and (v) that a record of the biosimilar product substitution be maintained for a statutorily determined period of time.

As applications for biosimilar products are filed with the FDA, state legislative developments concerning the substitution of biosimilar products will likely increase and affect the ability of pharmacists to substitute biosimilar products for the brand-name reference product.

US Federal Excise Tax of 2.3 Percent Takes Effect on Sales of Medical Devices

On January 1, 2013, the newest of many longstanding manufacturers excise taxes, the medical device excise tax (MDET) came into effect. The MDET is a 2.3 percent excise tax imposed on the gross sales price of a taxable medical device by a medical device manufacturer, producer or importer. The term "taxable medical device" is generally defined as any device listed with the FDA that is not otherwise exempted. Throughout the medical device industry there is uncertainty regarding application of the tax, primarily because existing law addresses issues particular to long-time excise taxes on automobiles, tires and fuel. The medical device industry has found that, in many instances, the manufacturers excise tax framework does not adequately address high-tech medical devices or the industry's varied supply chains, contracting practices and pricing methods (e.g., equipment leases, long-term contracts and/or software licensing).

Medical device manufacturers, suppliers and health care providers are primarily concerned with (i) whether products are subject to the MDET or are exempt from tax either through various safe harbors or the retail exemption, (ii) the price on which the tax applies as certain costs are allowed to be excluded and (iii) how software licenses, kits and combination products that contain both a device and a biologic should be taxed. The US Treasury (Treasury) and Internal Revenue Service (IRS) jointly issued final regulations to address these concerns in December 2012, and they are in the process of finalizing interim guidance on application of the MDET on certain issues related to price, supply chains, convenience kits and software licenses. Comments to Treasury and the IRS are requested by March 29, 2013

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