Morgan Lewis

LIFE SCIENCES INTERNATIONAL REVIEW

Welcome to the Q3 2019 issue of our ***Life Sciences International Review***. This issue covers new developments within Europe, Asia, and the United States in intellectual property, regulatory, pricing, and international trade, among others. Content for the newsletter was generated by Morgan Lewis lawyers. Many of these subjects will be updated in future issues as we will stay current with the continuous happenings and trends within the life sciences industry.

Read the latest issue of *Life Sciences International Review* >

ASIA

Japanese IP High Court Ruling May Increase Future Patent Damages Awards

A grand panel of the Japanese Intellectual Property High Court recently clarified the criteria for calculating damages awards in Japanese patent infringement cases in a manner that is favorable to plaintiff patentees. This ruling indicates that the court may be moving in a direction that is consistent with the recent revisions to the Japanese Patent Act, which intends to increase potential damages awards and thus strengthen the patent litigation system in Japan.

The May 2019 revisions to the Japanese Patent Act (JPA) aim to make the Japanese system more patentee friendly. Shortly after the revisions were approved by the Japanese Diet, a grand panel of the Japanese Intellectual Property High Court issued an important decision with respect to methodologies for damages calculations under the JPA on June 7. This ruling is generally favorable to plaintiff patentees and is expected to have an impact on further increasing damages awards in future patent infringement litigation cases in Japan.

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New Regulation on Management of Human Genetic Resources

China recently issued a new Regulation on the Management of Human Genetic Resources (the Regulation). We expect that this regulation would have significant impact on foreign pharmaceutical companies and CROs because these companies inevitably would involve collection, storage, using and/or export of Human Genetic Resources (HGRs) during their R&D activities in China. We include a quick summary of key takeaways of the Regulation below:

- This new Regulation highlights national security as a critical consideration for regulating HGR-related activity in China, including the collection, storage, using and sharing of HGRs.
- Chinese HGRs can only be collected and stored by Chinese entities with a prior approval from the HGR regulator. When a Chinese partner provides a foreign-owned partner with access to Chinese HGRs, it must provide duplicate copies of the HGRs to the HGR regulator for a record.
- Under the Regulation, Chinese partners should have the right to be substantially involved in the entire collaboration projects that involve HGRs. Chinese partners should have full access to and obtain a duplicate copy of all the data generated from the coloration projects.
- Any patents derived from scientific research collaborations must be co-owned by the Chinese and foreign-controlled partners.
- It expressly prohibits any entities owned or actually controlled by foreign investors from seeking access to Chinese HGRs, unless they collaborate with Chinese partners. This new restriction appears to put a direct ban on the nominee shareholders structure (sometimes also referred to as variable interest entity or VIE structure), which is designed to get around the direct legal restrictions on foreign invested companies.
- The Regulation grants more power and authority to the HGR regulator, such as conducting onsite inspection of HGR-related activities, interviewing individuals from R&D institutions, reviewing and duplicating documents, and seizing HGR samples or HGR-related data that they believe relevant to the investigations.
- It also significantly increases penalties for a variety of violations. For example, a foreign-owned entity that violates the Regulation could be subject to a confiscation of illegal gains and monetary fines up to RMB 10 million ($1.41 million), or five to 10 times any illegal gains that exceed RMB 1 million ($140,0000).
- The Regulation also imposes personal liability on responsible corporate officers of the entities that violate the Regulation. The personal liability may be monetary fines up to RMB 500,000 ($70,500); and in serious cases, the person may be temporarily (e.g. one to five years) or permanently barred from any further HGR projects in China.

EUROPE

Understanding Privacy Rights Under the GDPR

Protection of the fundamental right to privacy has been the central focus and raison d'etre of European data privacy regulation since the mid-20th century and is the central purpose of the General Data Protection Regulation (GDPR). Navigating the GDPR should thus begin with a clear understanding of the specific privacy rights the regulation aims to protect. Chapter 3 of the GDPR enumerates those rights, which range from the well-known "right to be forgotten" in Article 17 to the less well-known right to have incorrect information corrected.

Read more.

INTERNATIONAL TRADE

Highlights from CFIUS's New Proposed Regulations Implementing FIRRMA

The Committee on Foreign Investment in the United States (CFIUS) on September 17 released its long-awaited proposed regulations implementing many aspects of the Foreign Investment Risk Review and Modernization Act of 2018 (FIRRMA), issuing both general proposed regulations and a new set of detailed proposed regulations focused specifically on real estate transactions. While the proposed regulations provide guidance on new mandatory filings and clarify the scope and types of transactions, data, and technology that will come within CFIUS's jurisdiction, several important areas remain unaddressed and are therefore not yet clear until the US Department of the Treasury publishes future regulations or guidance.

Key Takeaways – Major Items in the Proposed Regulations that Provide Guidance or Clarify FIRRMA's Language:

- The proposed regulation articulates requirements for cross-border investments where foreign parties maintain a non-controlling interest in the US business.
- The proposed regulation identifies three types of non-controlling investments, termed "TID Businesses," that would fall within CFIUS's jurisdiction: investments involving certain critical technologies; investments involving certain critical infrastructure; or investments where a US business collects or stores "sensitive personal data" for a certain number of customers and for particular purposes.
- The proposed regulation establishes a risk-based framework for assessing the national security implications of a covered cross-border investment. This framework applied prior to FIRRMA but has now been proposed for inclusion directly in the CFIUS regulations. The elements of this analysis focus on "threats", "vulnerabilities", and "consequences to national security" and are briefly defined.

- The proposed regulations provide additional guidance regarding investment fund transactions that fall within CFIUS's jurisdiction.
- Mandatory filings for foreign-government-controlled investors in certain circumstances would be required.
- The proposed regulations clarify when CFIUS jurisdiction exists over investment funds making certain non-controlling minority "covered investments," as they are newly termed.
- The proposed regulations include definitions of the scope and type of "sensitive personal data" that the US business may collect or store and when those activities subject the investment to CFIUS jurisdiction.
- The regulations propose to grant CFIUS jurisdiction over the creation of foreign joint ventures, when they involve a contribution of a US business.
- The proposed regulations include definitions of "material non-public technical information" and "substantive decision-making" capability for purposes of making covered investment determinations.
- The proposed regulations related to real estate transactions now include a list of US military bases/installations and refer to lists of other facilities such as air/maritime ports where nearby investments may result in CFIUS scrutiny.

Read more.

Drugs and Other FDA-Regulated Products Among Latest Proposed Tariffs

The Trump administration has issued a fourth set of proposed tariffs on an additional $300 billion of goods related to China, this time adding a range of commercial goods across industries. This round affects medical devices and their components, certain chemicals and precursors that are in pharmaceuticals and dietary supplements, and other FDA-regulated products. The administration continues to try to use tariffs as a means of balancing the trade deficit with China and to bring the Chinese government to the negotiating table on a longstanding set of issues related to IP, cyber, and technology transfer.

Read more.

INTELLECTUAL PROPERTY

Proposed Patent Eligibility Reforms Impacting Medical Device Innovation

Proposed reforms to patent subject matter eligibility in the United States are once again making headlines. With advancements in medical device technologies and the increasing integration of software, patent eligibility considerations implicate a growing realm of medical devices. In a recent LawFlash, we address a draft bill in the US Congress that could broaden the range of patent eligible subject matter with implications for stronger commercialization of medical device technologies in the United States. We also discuss two recent letters to the US Senate that crystalize the growing debate over expanding patent eligibility with possible effects on medical device innovation, affordability, and availability.

The former chief judges of the US Court of Appeals for the Federal Circuit (CAFC), and former heads of the US Patent and Trademark Office (USPTO) sent a letter to the US Senate Judiciary Committee's Intellectual Property Subcommittee (IP Subcommittee) in support of recently proposed legislation that would change the way patent subject matter eligibility is determined.

The Patent Lawyers Letter stands in opposition to a letter from the American Civil Liberties Union (ACLU) and other medical, health, and civil rights organizations arguing against the proposed legislation. The two letters make clear that the debate on patent eligibility is far from over, and could lead to additional revisions of the bill.

Read more.

Federal Circuit Provides Guidance for What Constitutes Delay for Determination of Patent Term Adjustment

The Court of Appeals for the Federal Circuit recently affirmed a decision by the US District Court for the Eastern District of Virginia related to a determination of Patent Term Adjustment (PTA) for US Patent No. 8,648,077. The District Court had previously affirmed the grant of summary judgment in favor of the US Patent and Trademark Office (USPTO) because the determination of applicant delay was based on a permissible interpretation of the applicable statute and proper reading of the regulations.

As background, during prosecution of the '077 patent, the USPTO issued a final office action where no claims were allowed on the basis of the same rejections from the previous nonfinal Ooffice action. The applicant responded to the final office action on the three-month due date with the same arguments that were previously found unpersuasive by the eExaminer. The eExaminer then issued an advisory office action indicating that the after-final response failed to overcome the rejections. In the advisory office action, however, the examiner suggested amending certain claims to overcome the outstanding rejections. The applicant then filed a second response 21 days after the previous office action response. The examiner subsequently issued a notice of allowance, and the patent was granted.

The USPTO determined that the 21 days after the three-month due date for responding to the final office action that applicant required to file the second response constituted applicant delay. The office determined that the first response to the final office action did not constitute a proper

response under applicable regulations. The applicant filed a complaint in the US District Court for the Eastern District of Virginia seeking judicial review of the PTA determination. The office prevailed via summary judgement in the district court, which determined that nothing in the plain language of the applicable statute indicates that reasonable efforts to conclude prosecution should be read to include response that fails to place the application in condition for allowance. The applicant subsequently appealed the decision to the Federal Circuit.

The Federal Circuit affirmed the district court ruling that an applicant shall be deemed to have failed to engage in reasonable efforts to conclude examination for the cumulative total of any periods of time in excess of three months that are taken to reply to any office action on the merits. The Federal Circuit focused its analysis on what constitutes a proper office action response for determining applicant delay. The issue specifically addressed by the Federal Circuit is whether a response to a final office action that argues the merits of the rejection constitutes a failure to engage in reasonable efforts to conclude prosecution such that applicant delay would accrue.

The Federal Circuit found that it is permissible to interpret an after-final response that merely continues to argue the merits of a final rejection as a failure to engage in reasonable efforts to conclude prosecution, and as such, it would not stop the accrual of applicant delay. The Federal Circuit further found that the applicable regulation does not explicitly define a "reply" (i.e., office action response), but that does not mean any response by the applicant, no matter how superficial, may qualify as a "reply" for purposes of ceasing accrual of applicant delay.

In view of this decision, applicants are advised to respond to final office actions well before the three month due date so as to obtain allowance before passing the three month due date.

Read more about the case, *Intra-Cellular Therapies v. Iancu* (Fed. Cir. 2019).

Updates on Diagnostic Method Patent Eligibility

New and developing efforts by Congress may change the way patent subject matter eligibility is determined for years to come, changing the landscape for medical diagnostic methods. This congressional action comes following intense pleas from some Federal Circuit judges and has the potential to unravel decades of US Supreme Court precedent relating to the current patent eligibility test.

In recent years, US courts have increasingly scrutinized the eligibility of patents covering methods of diagnosing medical conditions. New diagnostic methods require intense and costly research to develop and are vital to the medical industry. Some have argued that they are among the most meritorious candidates for patent protection. But diagnostic methods often rely on scientific concepts that are ineligible for patenting, such as naturally occurring phenomena in the human body.

Read more.

REGULATORY

Patent Opportunities in FDA Bispecific Antibody Guidance, *Law360*

Morgan Lewis partners Christopher Betti and Kathleen Sanzo and associates Richard Martin and Maria Doukas authored an article for Law360 on draft guidance issued by the US Food and Drug Administration (FDA) in April 2019 on bispecific antibody development programs. In the article, they discuss key issues identified by the FDA that companies should consider when structuring their patent strategy.

Read the full *Law360* article.

FDA Clarifies Premarket Path for Ecigarette Products

The FDA on June 11 issued the final guidance, "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems" (the ENDS Guidance), which is intended to assist persons submitting premarket tobacco product applications (PMTAs) for electronic nicotine delivery systems (ENDS) pursuant to 21 USC Section 387j. This final ENDS Guidance is substantially similar to the draft guidance that was issued in May 2016.

The main takeaways from this ENDS Guidance are:

- The final ENDS Guidance is essentially unchanged from the draft; companies that have taken measures consistent with the draft guidance will generally be in compliance with the final ENDS Guidance.
- ENDS on the US market as of August 8, 2016, must submit a PMTA or an application to obtain an FDA substantial equivalence order by August 2022 to stay on market.

The ENDS Guidance explains:

- the types of products that are subject to FDA regulation;
- when a PMTA must be submitted and what information must be included in the application;
- FDA's general procedures for review of an ENDS PMTA; and
- the type of information that should be submitted in an ENDS PMTA to show that permitting the proposed ENDS to be marketed would be appropriate for the protection of the public health.

Read more.

OTHER NEWS AND NOTES

Patent Opportunities in FDA Bispecific Antibody Guidance, Law360

The Morgan Lewis *Pharma Review* summarizes key recent cases from the Federal Circuit and district courts that impact the pharma space, including Federal Circuit and district court decisions in Hatch-Waxman litigations, Federal Circuit reviews of IPR challenges to Orange book–listed patents, and appellate and district court decisions in pharma-related antitrust litigations.

We hope *Pharma Review* can serve as a one-stop source for your patent and antitrust pharma-related legal developments.

Read the second issue of *Pharma Review*.

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