Morgan Lewis

LIFE SCIENCES
INTERNATIONAL REVIEW

AUGUST 2020

Welcome to the August 2020 issue of our ***Life Sciences International Review***. This issue covers new developments within Asia, Europe, 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.

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ASIA

Cross-Border Transactions Caught at the Crossraods: Navigating the Global COVID-19 Crisis Through Force Majeure Provisions

The coronavirus (COVID-19) pandemic has had sweeping effects around the world, and in this era of globalization, business transactions that span multiple jurisdictions and markets have fallen prey to new and unexpected risks presented by the pandemic. In this highly uncertain business climate, how should multinational companies be negotiating new commercial agreements and addressing these risks through force majeure provisions?

This White Paper explores some key issues for international businesses to keep in mind as they tread uncharted waters during the COVID-19 pandemic, focusing on force majeure provisions that may forgive contractual performance. The phrase "force majeure" comes from the French language and means "superior force" that can be neither anticipated nor controlled. A force majeure provision is used for "allocating the risk of loss if performance becomes impossible or impracticable, especially as a result of an event or effect that the parties could not have anticipated or controlled."

Read more.

Unveiling and Preventing Common Expense Fraud Schemes in China

In this LawFlash, we outline the expense fraud scheme reported in a 2019 case involving the crime of illegal sale of "fapiaos," examine some typical expense fraud schemes in China, and provide our practical takeaways with regard to preventing expense fraud.

Expense fraud, in which employees submit fictitious expense reports to get reimbursement from their employers, has become a major compliance concern for almost all businesses around the globe, regardless of size or industry. In China, particularly in the pharmaceutical sector, employers often see expense fraud when employees funnel improper payments to healthcare providers in order to influence the providers' prescription decisions.

Read more.

EUROPE

EU Looks to Ensure 'Safe and Affordable' Medicines Post-COVID-19

The coronavirus (COVID-19) pandemic has persuaded the European Commission of the need to future-proof the EU approach to the life cycle of medicines, from R&D and patient access. As a consequence, it launched a "Pharmaceutical Strategy" with the broad aims of ensuring the supply of safe and affordable medicines in the European Union and the continued world-leading status of the EU pharmaceutical industry.

The new pharmaceutical strategy is likely to lead to a review of the existing regulatory framework and policy, and legislative actions could include a targeted evaluation and subsequent review of the basic pharmaceutical legislation (for instance, Directive 2001/83/EC and Regulation (EC) 726/2004).

The commission expresses concerns over shortages of essential medicines in the European Union, exacerbated by COVID-19 pandemic, issues around the reliability and security of supply chains, EU dependence on imported active pharmaceutical ingredients and medicines from third countries.

In June 2020, the commission launched an open consultation in questionnaire form on the strategy seeking views on four main topics: (i) autonomy for API manufacture, (ii) accessibility and affordability of medicines, (iii) R&D and product authorisation, and (iv) environmental factors in manufacture, disposal, etc.

Notable priorities include encouraging and incentivising the production of essential medicines within the European Union, avoiding shortages, including the possible imposition of obligations on manufacturers and others in the supply chain to ensure medicine availability. Responses are required by 15.

The strategy could well result in substantial policy and legislative changes and pharmaceutical companies involved in the EU market are encouraged to follow and engage in the consultation process.

See the strategy document.

EU Court Extends Patent Term

On 9 July 2020, the Court of Justice of the European Union (CJEU) reached its decision in the *Santen* case (C-673/18), effectively settling the issue as to whether supplementary protection certificates (SPCs) should be available for new therapeutic applications of previously approved active ingredients under Regulation (EC) No 469/2009 concerning the SPC for medicinal products (SPC Regulation).

SPCs were introduced to compensate for the development time needed to obtain regulatory approval of medicinal and certain other products and apply after the patent expires with a maximum protection of five years, subject to a six-month extension where a Paediatric Investigation Plan (PIP) has been submitted (under Regulation (EC) No 1901/2006).

Specifically, the CJEU considered whether the definition of "product" in Article 1(b) of the SPC Regulation is restricted to the therapeutic application of the active ingredient, and whether a new therapeutic application of a previously authorised active ingredient can be considered a separate "product", with the consequence that a marketing authorisation (MA) covering that new therapeutic application would constitute the "first authorisation" under Article 3(d) of the SPC Regulation.

Article 3(d) states that an SPC cannot be granted if there has been an earlier MA for the same "product" (i.e., the active ingredient or active ingredients of the medicinal product under Article 1(b) of the SPC Regulation).

The issue has been long running, with the CJEU deciding in two earlier cases against granting SPC protection for second medical use but, in its decision in Neurim (C-130/11) it indicated that SPCs would be available for such subsequent uses. With the CJEU acting as a "Grand Chamber" of 13 judges reflecting the perceived importance of the issue, the uncertainty seems now to have been definitively settled. The CJEU effectively reversed the Neurim concluding that an MA for a new therapeutic application of a known active ingredient (or combination of active ingredients) which has already been the subject matter of an MA for another therapeutic application, cannot be considered as the first MA within the meaning of Article 3(d).

This is obviously a blow for pharmaceutical companies researching new uses for existing products hoping for SPC protection on that later MA.

Read the decision.

Medical Device Regulation Is Postponed

The EU Regulation on Medical Devices 2017/745 (the MDR) replacing the Medical Device Directive 93/42/EEC (MDD), had been due to become fully applicable on 26 May 2020. However, its implementation has been delayed by the European Union until 26 May 2021.

The MDR was introduced in the wake of the the PIP breast implant scandal and metal-on-metal hips litigation. It was widely acknowledged that the existing regulatory regime was no longer fit for purpose in light of technological and other advances since the 1990s.

It had already been running into delays before the disruption of COVID-19 finally justifying its delay. In particular, the slow pace of qualification of Notified Bodies under the Regulation, the lack of Medical Device Coordination Group (MDCG) guidance for industry in many critical areas (in particular clinical investigation and evaluation requirements) and the two-year delay in the EUDAMED medical device database, had led industry bodies and other stakeholders to call for a postponement. However, the European Commission had insisted on sticking with the original timescale until the pandemic struck.

New rules under the MDR will include:

- Stricter premarket control of high-risk devices at an EU level
- The inclusion of certain aesthetic products
- A new risk classification system for diagnostic medical devices
- Improved transparency through the EU database of medical devices (Eudamed)
- Device traceability through the supply chain "economic operators"
- A requirement for an "implant card" for patients with implanted medical devices
- Stricter rules on clinical data and clinical studies on devices
- Manufacturers to collect data about the real-life use of their devices
- Improved coordination between EU member states

The delay has bought regulators, the industry, and the supply chain further time but with the ongoing disruption there is plenty to resolve, including addressing gaps in guidance and ensuring that Notified Bodies are capable in dealing with the flow of CE-marks currently granted under the MDD, which will need to be reapproved under the stricter requirements of the MDR.

It is anticipated that the United Kingdom is expected to transpose the key elements of the MDR into UK legislation but detailed arrangements for Brexit are uncertain.

Read more.

Court Rules on Samples of Prescription-Only and Over-the-Counter Products

In June 2020, the CJEU delivered its judgement in case *C-786/18 GmbH v. Novartis Consumer Health GmbH* on whether free samples of medicinal products can be given to pharmacists.

The legal dispute which led to the decision of the CJEU was an unfair competition lawsuit between two pharmaceutical companies selling non-prescription pain gel. One of the companies had supplied free samples to pharmacists "for demonstration purposes." The other company considered this to be in violation of German and EU medicines law.

The decision centred on the interpretation of Article 96(1) of the Community Code (2001/83/EC) which provides that free drug samples be offered "only to persons qualified to prescribe them" on an exceptional basis.

The court ruled that even though pharmaceutical companies are authorised to distribute free samples of these medicinal products to pharmacists under certain restrictive conditions, the Community Code does not authorise pharmaceutical companies to distribute to pharmacists free samples of medicinal products available only on prescription. However, it does not prohibit the distribution to pharmacists of free samples of medicinal products of over-the-counter (OTC) medicines.

Read the decision.

Germany Further Tightens Its National Foreign Direct Investment Screening Regime

The updated German Foreign Trade and Payments Act enters into effect on July 17 and is the second of three major steps planned for 2020 to reform Germany's foreign direct investment regime.

The updated German Foreign Trade and Payments Act (Außenwirtschaftsgesetz (AWG)) includes the necessary changes for alignment with the EU FDI Screening Regulation, which sets the stage for a more coherent foreign direct investment (FDI) regime across the European Union. Further, and of high practical relevance, the updated AWG extends the notification obligations for foreign investors investing in companies domiciled in Germany and introduces sanction mechanisms in case of noncompliance.

Read more.

EU Moves Toward New Framework for Foreign Subsidies Control

The European Commission has published a White Paper proposing to grant the Commission new enforcement powers to address competition distortions caused by companies operating in, or entering into, the European Union's Internal Market, which benefit from subsidies from third-country governments.

A proposal by the European Commission (EC or Commission) is the latest in a series of measures demonstrating that the European Union (EU) has become increasingly sensitive with regard to the economic and financial influence of third-country governments on its Internal Market. These fears have increased during the coronavirus (COVID-19) pandemic, which has left many companies vulnerable.

Read more.

UNITED STATES

US Supreme Court to Review FTC's Right to Seek Equitable Monetary Relief

For decades, the Federal Trade Commission (FTC) has invoked Section 13(b) of the Federal Trade Commission Act to file suit in federal court in pursuit of both injunctive relief and equitable monetary relief. On July 9, the US Supreme Court granted certiorari and consolidated two cases—*AMG Capital Management, v. Federal Trade Commission* and *Federal Trade Commission v. Credit Bureau Center*—that call into question the Commission's authority to seek equitable monetary relief in Section 13(b) cases.

The Supreme Court's resolution of these cases during the 2020–2021 term is likely to have profound implications for the Federal Trade Commission and the companies and industries that it oversees.

Read more.

Federal Circuit Emphasize Role of Common Sense in Obviousness Analysis

In *B/E Aerospace v. C&D Zodiac*, published June 26, the US Court of Appeals for the Federal Circuit affirmed a fin al written decision of the US Patent and Trademark Office's Patent Trial and Appeal Board (PTAB), holding that the PTAB's reliance on common sense when invalidating claims for obviousness was proper because it was accompanied by reasoned analysis and evidentiary support.

B/E Aerospace owned two patents, US Patent No. 9,073,641[1] (the '641 patent) and US Patent No. 9,440,742[2] (the '742 patent), both directed to space-saving modifications to aircraft walls enclosing lavatories, closets, and galleys. Claim 1 of the '641 patent, which is representative of the challenged claims, discloses a "first recess" to accommodate the seat back of a passenger seat and a "second recess" to receive the aft-extending seat support. C&D Zodiac Inc. challenged B/E Aerospace's claims as obvious in a petition requesting inter partes review.

Read more.

The Prep Act: Critical Liability Immunity for Critical Products

As the coronavirus (COVID-19) pandemic resurges, PREP Act liability immunity continues to be critical for manufacturers and users of COVID-19 medical products.

At the start of the COVID-19 pandemic, the US Food and Drug Administration (FDA) rushed to issue multiple emergency use authorizations (EUAs) for a variety of drug and device products intended to diagnose, treat, or prevent COVID-19, including SARS-CoV-2 diagnostic tests, ventilators, face masks and other personal protective equipment, remote patient monitoring devices, and various drugs, such as remdesivir. As the pandemic wears on and case numbers rise, companies that are developing, manufacturing, distributing, and/or using such medical products will continue to face significant product liability risks from increased hospitalizations, deaths, and long-term adverse health effects. Additionally, FDA has withdrawn, modified, or limited EUAs for certain COVID-19 devices and drugs based on postmarket developments concerning their safety or effectiveness.

Read more.

FDA Regulation of COVID-19 Apps, Digital Therapeutics, and Other Digital Health Technologies

With the coronavirus (COVID-19) pandemic showing no signs of abating, many digital health developers have refocused their technical expertise to develop products for use in the pandemic, including software apps for COVID-19 screening and risk assessments, digital therapeutics, and remote patient monitoring systems. The Food and Drug Administration (FDA) also has focused on the use of digital health technologies to address pandemic-related issues by issuing several new guidance documents on various types of digital health devices. In addition, FDA has approved multiple Emergency Use Authorizations (EUAs) for software intended for use in screening COVID-19 patients, remote monitoring systems, and wearable device technologies.

Companies developing digital health technologies for use in the COVID-19 pandemic should be mindful of FDA's quickly evolving policies and guidance and should consider what, if any, FDA requirements may be applicable to their products.

Read more.

Morgan Lewis

CONTACTS AND AUTHORS

ASIA

Todd Liao
Shanghai | +86.21.8022.8799
todd.liao@morganlewis.com

Nancy Yamaguchi
San Francisco | +1.415.442.1242
nancy.yamaguchi@morganlewis.com

EUROPE

Michael Masling
Frankfurt | +49.69.714.00.753
michael.masling@morganlewis.com

Paul Ranson
London | +44.20.3201.5660
paul.ranson@morganlewis.com

Christina Renner
Brussels | +32.2.507.7524
christina.renner@morganlewis.com

UNITED STATES

Dion M. Bregman
Silicon Valley | +1.650.843.7519
dion.bregman@morganlewis.com

Michele L. Buenafe
Washington, DC | +1.202.739.6326
michele.buenafe@morganlewis.com

Dennis C. Gucciardo
Washington, DC | +1.202.739.5278
dennis.gucciardo@morganlewis.com

John P. Lavelle, Jr.
Philadelphia | +1.215.963.4824
john.lavelle@morganlewis.com

Stephen Paul Mahinka
Washington, DC | +1.202.739.5205
stephen.mahinka@morganlewis.com

Steven A. Reed
Philadelphia | +1.215.963.5603
steven.reed@morganlewis.com

Stephen E. Ruscus
Washington, DC | +1.202.739.5870
stephen.ruscus@morganlewis.com

CONTACTS

Michael J. Abernathy
Chicago | +1.312.324.1447
mike.abernathy@morganlewis.com

Alan B. Leeds
Princeton | +1.609.919.6677
alan.leeds@morganlewis.com

Jeffry S. Mann, Ph.D.
San Francisco | +1.415.442.1119
jeffry.mann@morganlewis.com

Kathleen M. Sanzo
Washington, DC | +1.202.739.5209
kathleen.sanzo@morganlewis.com

Connect with us

www.morganlewis.com

081120_201772