Morgan Lewis

# LIFE SCIENCES

# INTERNATIONAL REVIEW

Welcome to the Q2 2018 issue of our *Life Sciences International Review*.

The most-significant recent development is the entry into force on 25 May of the EU General Data Protection Regulation. This new legislation will have a substantial impact on the processing of data both within the EU and internationally with revised grounds on which personal data can be processed, enhanced data subject rights, greater international remit, obligations to report breaches, and far higher potential fines. For more information please see our LawFlash **here**. The new regulation can be found **here**.

Other major news includes a proposal to bring a degree of harmonisation to the widely differing national methods of health technology assessment, a General Court decision on the European Medicines Agency's transparency regime, a potential for international trade tensions over the US biotechnology sector, and recent developments in the ongoing Brexit saga.

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# INTELLECTUAL PROPERTY

### Patent Settlements

As part of the continuing pharmaceutical sector inquiry initiated in 2009, the European Commission published its eighth report on pharmaceutical patent settlements. The inquiry has long determined that settlement agreements that limit entry of generic medicines onto the market on the basis of 'pay for delay' are potentially anticompetitive in that they reduce the choice of medicines at lower prices. The new report confirms that patent settlements still continue to be used in the European pharmaceutical sector but most pose little need for competition law scrutiny.

The latest report can be found **here**.

### Supplementary Protection Certificate (SPC) Dates

In the 2015 *Seattle Genetics* decision, the Court of Justice of the European Union (CJEU) decided that the correct date for determining the duration of the SPC should be the date on which the Marketing Authorisation (MA) holder was notified of the grant, commonly some days after the formal Commission decision.

In *Incyte* (C-492/16), the CJEU has recently ruled that an SPC holder can seek to correct the MA date to bring it in line with *Seattle Genetics* at any time before expiry of the SPC, even if the period for appealing the decision under national legislation has passed.

See the case report **here**.

### UPC

On 26 April 2018 the UK ratified the Unified Patent Court (UPC) Agreement by depositing its instrument of ratification with the European Council.

The UPC Agreement establishes a new UPC and unitary patent system for participating EU countries and will come into force once France, Germany, and the UK have ratified. It only remains for Germany to do so but it is facing a challenge in the Federal Constitutional Court on which there will be a procedural decision this year. If Germany goes ahead and the UPC comes into operation before Brexit the current Brexit transition period (29 March 2019 to 31 December 2020) would seem to permit the United Kingdom's continued involvement in the new system at least until the end of 2020 when it is hoped a more permanent arrangement will have been concluded.

The UK Intellectual Property Office's press release is available **here**.

### Biotechnology as a US 'National Security Concern'

On 22 March the biotechnology industry was designated by the White House Office of the United States Trade Representative (USTR) along with six other technology- and innovation-related areas as of special national security concern to the protection of the US industrial and scientific base.

The USTR's primary concern in its investigation was with acquisitions and investments related to technology transfer, intellectual property (IP), and innovation in these seven industry sectors that are specifically identified as being of significant national security concern. Such transactions are highlighted for increased scrutiny, through expanded reviews of certain types of deals by the Committee on Foreign Investment in the United States (CFIUS).

While the USTR report focused on Chinese acquisitions and investments, other foreign acquisitions and investments may be subject to deeper review by the CFIUS.

Meanwhile, the Pharmaceutical Research and Manufacturers of America (PhRMA) and BIO have both requested that the EU be added to the US Trade Representative 'Special 301' watch list over review of IP-related incentives.

This relates to the complaint of the ongoing European Commission review of IP incentives such as SPCs, including the proposed SPC manufacturing waiver. See the report **here** and the European Parliament response **here**.

For more information, see Morgan Lewis alerts **here** and **here**.

# EXCLUSIVITY

### Orphan Designation

The EU General Court recently ruled in a case involving Shire Pharmaceuticals' appeal against a decision by the European Medicines Agency (EMA) to reject an application for orphan designation under Regulation No 141/2000 (Orphan Product Regulation or OPR) for Idursulfase for intrathecal administration (Idursulfase-IT) for cognitive disorders arising with Hunter Syndrome. Idursulfase itself was designated an orphan medicinal product for the treatment of Hunter Syndrome in 2001 and was marketed as 'Elaprase' in 2007.

Shire argued that Idursulfase-IT should have its own orphan status as it considered that cognitive disorders arising with Hunter Syndrome constitute a distinct disease from Hunter Syndrome itself. The EMA disagreed, and considered that it was only a severe form of Hunter Syndrome, an indication which had already been granted an MA.

The court in deciding in favour of Shire considered that the objective of the OPR was to encourage the development and marketing of medications for rare diseases and nothing in the regulation prevented an application for another orphan medicinal product with the same active substance as another authorised product provided the other requirements under the OPR were met. The case report is **here**.

### The Role of Concerned Member States Under the Decentralised Procedure

The CJEU has confirmed that the competent authority of a concerned member state (CMS) within the decentralised procedure (DCP), when asked to grant an MA to a generic of a reference medicinal product (RMP), cannot itself determine the starting point of the regulatory data protection (RDP) period of the reference medicinal product after the close of the coordinated procedure. A CMS court can, however, review the determination of the RDP period verified under the DCP but has no jurisdiction to review the initial MA for the RMP where the MA was granted by another member state.

The decision can be found **here**.

## REGULATORY

### EMA's Approach to Transparency for Authorised Medicines

In response to challenges by pharmaceutical companies against the EMA's decision to release the concerned documents in accordance with the Transparency Regulation and EMA's 2010 policy on access to documents (Policy 0043), the EU General Court recently delivered rulings upholding the EMA's decisions to release documents requested in accordance with Regulation (EC) No 1049/2001, the so-called "Transparency Regulation," to the effect that information in documents held by EMA cannot be considered commercially confidential in its entirety.

See a sample decision **here**.

### French Medicinal Product Names

The French National Agency for Medicines and Health Products Safety (ANSM) recently issued recommendations for applicants and marketing authorisation holders on the choice of the name of medicines under the national procedure, a European mutual recognition and decentralised procedure. These would obviously be inapplicable to centrally approved procedures, where the EMA requirements would apply.

The ANSM recently faced misuse of medicines that it attributed to confusions created by umbrella brands.

To be acceptable to ANSM the name must be either invented or a common or scientific name merged with a brand name or the name of the marketing authorisation holder or the operator. An invented name must not cause confusion with other medicines and must not be misleading with respect to the medicine's quality or characteristics. In response to recent criticism, the ANSM has specifically decided not to prohibit the use of umbrella brands for certain products.

See the recommendations **here**.

### FDA Finalises ICH Guidance on Good Clinical Practices

On 28 February 2018, more than a year after being adopted by ICH, the FDA finalised its version of the ICH addendum on good clinical practices. According to the FDA, the amendments to the guidance are aimed at encouraging "implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording, and reporting while continuing to ensure human subject protection and reliability of trial results." The changes in the addendum primarily address investigator, clinical trial site, and sponsor responsibilities for the oversight and monitoring of third parties involved in clinical trial programs, and steps to ensure the integrity of electronically stored information. The addendum further states that sponsors should implement a system to manage quality throughout all stages of the clinical trial process, focusing on trial activities essential to ensuring human subject protection and the reliability of trial results. Overall, this addendum requires that both sponsors and investigators take direct responsibility for the actions of third parties that they may engage and for the quality and integrity of clinical trial records. The FDA addendum can be viewed **here**.

### Impact of Chinese Government Restructuring on Life Science Industry

On 17 March 2018, China's National People's Congress (NPC) approved a general plan proposed by China's State Council to restructure Chinese governmental agencies (Chinese Government Restructuring). This restructuring plan affects a wide range of Chinese governmental institutions as well as life science companies, including the medical and food sectors, replacing the previous relevant bodies, including the China Food and Drug Administration and pricing and antimonopoly bodies with the State Administration for Market Regulation (SAMR) with effect 10 April 2018.

The SAMR will become a super-regulatory agency under China's State Council. It will be responsible for a broad range of regulatory matters, including (i) market supervision and management, market entity registration, and the maintenance of market order; (ii) the supervision of the safety of industrial products, equipment, and foods; and (iii) the management of issues related to the examination of products and their testing, certification, and accreditation. See more details from the Morgan Lewis China team **here**.

## PRICING AND REIMBURSEMENT

### European Commission on Health Technology Assessment (HTA)

The European Commission has published its proposal for a regulation on HTA. The proposal stresses the differences between the medicinal product and medical device sectors

although it is envisaged that the regulation will cover both.

The proposal is largely based on the assumption that Member States jointly produce relative efficacy assessments (REAs) (i.e., reports on the relative effectiveness in terms of clinical/medical benefits of the technology), available to all through a shared repository, with measures for the uptake of the joint work at national level. The cooperation is intended to be confined to REAs with the assessment of nonclinical factors to remain under the responsibility of Member States.

The proposal intends a phased approach for the future cooperation on HTA:

- Following the entry into force, a three-year period before the date of application is proposed which will allow for the development and adoption of all implementing and delegated acts as well as the preparatory steps necessary for the joint work.
- Following the date of application, a further three-year transitional period is envisaged to allow for a phased-in approach in terms of the work undertaken and to allow Member States to fully adapt to the new system. During this transitional period, Member States would have the option to delay their participation in the joint work on joint clinical assessments and joint scientific consultations.

The proposal limits the joint clinical assessments to centrally authorised medicinal products or existing products for which the MA is extended to a new indication with the exception of generic and well-established use applications.

As far as medical devices are concerned, certain medical devices classified as class IIb and III and certain in-vitro diagnostic medical devices classified as class D will also be subject to joint medical assessments.

The proposal also anticipates regular monitoring and reporting on the implementation of the regulation as soon as the first year after its date of application, as well as the implementation of the provisions on the scope of the joint clinical assessments and on the functioning of the support framework within two years after the end of the transitional period. Finally, the European Commission is also obliged by the proposed regulation to carry out an evaluation of this regulation, and report on its conclusions no later than five years after publication.

See the proposal **here**.

### Department of Health and Human Services Releases Plan to Lower US Drug Costs

On 11 May 2018, President Donald Trump and the US Department of Health and Human Services (HHS) released a plan to lower drug costs in the United States, which is being referred to as the American Patients First Blueprint (the Blueprint). The Blueprint includes actions that may be taken immediately and actions that HHS is considering. The actions fall into four categories: increasing drug competition; improving drug price negotiation; incentives to encourage the lowering of list drug prices; and lowering out-of-pocket costs. Some of the more interesting immediate potential actions from an FDA regulatory perspective include:

- FDA issuance of a guidance addressing what HHS describes as "ways in which manufacturers may seek to use shared systems [Risk Evaluation and Mitigation Strategies (REMS) to delay or block competition from generic products entering the market."
- FDA issuance of policies "to improve the availability, competitiveness, and adoption of biosimilars as affordable alternatives to branded biologics."
- FDA evaluation of "the inclusion of list prices in direct-to-consumer advertising."

Additionally, HHS is seeking comments on other FDA regulatory areas to potentially lower drug prices, such as ideas for:

- Increasing competitor access to drug product samples for generic product development;
- Facilitating the development of and decreasing development costs for biosimilar and interchangeable biologics;
- Improvements to the FDA's listing of licensed biologics, referred to as the Purple Book;
- Provider and patient education concerning biosimilar and interchangeable products and the role of state pharmacy practice acts in increasing biosimilar utilisation; and
- Improvements to biosimilar interchangeability

From a drug pricing perspective, the Blueprint is fairly aspirational with few specific recommendations and no immediate changes to any government programs nor any recommendation to directly address the cost of federal healthcare programs by extending mandatory discounts, euphemistically referred to as government price negotiation, to Medicare.

See further details in the American Patients First Blueprint **here**.

## BREXIT NEWS

Brexit negotiations have resumed and this third phase will cover issues outstanding from the last phases—the Irish border in particular—and the framework for future EU-UK relations.

Specifically, in relation to life sciences, in light of Brexit the United Kingdom and European Union have each been stating their positions once the United Kingdom leaves. The UK government has identified life sciences as an area where it most wants to have closely cooperative regulatory

systems with Prime Minister Theresa May advocating 'Associate' membership of the EMA. The UK Parliament's Health and Social Care Committee report on the second phase of its inquiry into the impact of Brexit on life sciences and healthcare have similarly focussed on issues relating to medicines, medical devices, and substances of human origin. The key message from the inquiry and the report is that in order to minimise the risks to all stages of the development and timely supply of medicines and devices, the UK government should seek the closest possible regulatory alignment with the EU.

The United Kingdom had envisaged continuing to play its part within the EMA during the transitional phase (March 2019 to the end of 2020). The European Union however, based on the assumption of a 'hard' Brexit has announced that it has already put in place measures to reallocate the United Kingdom's rapporteur and other roles between the competent authorities of the other 27 member states and push back on the less essential projects while the EMA readjusts to the potential loss of the MHRA. The MHRA is currently responsible for some 30% of the work involved in the EMA's approvals and other assessments). The EMA position can be seen **here**.

Guidance to industry on necessary changes, largely predicated on the outcome of a hard Brexit, are found **here** and the EMA Brexit resources page **here**.

A notice to stakeholders in the field of industrial products including medical devices **here** also assumes a hard Brexit in warning that a manufacturer placing devices on the European market can only do so if such firm is based in the European Union, or by using an authorised representative (AR). If the United Kingdom leaves the European Union, British manufacturers will need an EU-based AR.

It is evident that there is a degree of EU Commission 'war gaming' around a 'cliff-edge' departure with a view to encouraging the United Kingdom to compromise.

Morgan Lewis

## CONTACTS AND AUTHORS

### UNITED STATES

**Kathy Sanzo**
Washington, DC
+1.202.739.5209
kathleen.sanzo@morganlewis.com

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

**Randy Sunberg**
Princeton
+1.609.919.6606
randall.sunberg@morganlewis.com

**Donna Yesner**
Washington, DC
+1.202.739.5887
donna.yesner@morganlewis.com

**Steve Mahinka**
Washington, DC
+1.202.739.5205
stephen.mahinka@morganlewis.com

**Jacqueline R. Berman**
Washington, DC
+1.202.739.5057
jacqueline.berman@morganlewis.com

### EUROPE

**Tom Cartwright**
London
+44.20.3201.5671
tom.cartwright@morganlewis.com

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

### ASIA

**Todd Liao**
Beijing | Shanghai
+86.10.5876.3500 | +86.21.8022.8799
todd.liao@morganlewis.com

**Jeff Mann**
Singapore
+65.6389.3023
jeffry.mann@morganlewis.com

**www.morganlewis.com**