Morgan Lewis

LIFE SCIENCES
INTERNATIONAL REVIEW

Welcome to the Q4 2018 issue of our *Life Sciences International Review*.

This issue covers life sciences developments in the areas of intellectual property, regulatory, pricing and reimbursement, international trade, litigation, and competition that are of particular importance across Europe, Asia, and the United States. It also provides some of the latest information on Brexit.

Some of the subjects from this quarter include new China rules on cybersecurity, FDA guidance on food recalls, rulings on diagnostic claims, pricing investigations, and registration of medicines in Russia to name a few. As you will find, many of the subjects covered in this issue are ongoing and we will continue to keep you updated on developments. The *Life Sciences International Review* team continues to monitor developments and will include updates in future issues to keep our readers current with the latest events and trends in the life sciences industry.

Q4 | 2018

TABLE OF CONTENTS

INTELLECTUAL PROPERTY

SPCs for Combination Medical Devices

The Court of Justice of the European Union (CJEU) decided in Boston Scientific (C-527/17) that Supplementary Protection Certificates (SPCs) did not extend to medical devices that incorporate a medicinal product for medicinal products.

SPCs afford extended protection, beyond patent expiry, for medicinal or plant protection products which compensate patentees for the time spent in obtaining a market authorisation under Directive 2001/83/EC prior to market entry. Medical devices per se are approved under Directive 93/42/EC or the Medical Devices Regulation 2017/745 and are hence not eligible for SPC protection.

Medical devices that incorporate a medicinal product must be categorised as either a medical device or a medicinal product depending on whether the device may be used exclusively with that medicinal product (in which case the combination product is treated as a medicinal product) or whether the action of medicinal product is ancillary to that of the medical device itself (rendering the product a medical device).

The case concerned a stent into which paclitaxel was incorporated marketed under Directive 93/42/EC but involving consideration of the issues under 2001/83/EC in relation to the incorporated medicinal product.

The court considered that the authorisation processes for the two types of products are not cross-applicable and that the assessment of quality, safety and usefulness for component medicinal products under Directive 93/42/EC or Regulation 2017/745 could not be considered equivalent to that under Directive 2001/83/EC.

The European Commission recently issued a public consultation on SPCs seeking views on whether they should be extended beyond medicinal or plant protection products and a degree of support was received for extension to medical devices.

See the decision **here**.

Oligonucleotide Primers Held to be Patent Ineligible Subject Matter

In *Roche Molecular Systems v. Cepheid*, No. 2017-1690 (Fed. Cir. Oct. 9, 2018), the Federal Circuit again affirmed the invalidity of diagnostic claims under 35 U.S.C. §101. The patent in question, U.S. Patent No. 5,643,723 (the '723 patent) has claims directed to oligonucleotide primers and detection of specific *Mycobacterium tuberculosis* (MT) bacterium DNA using the oligonucleotide primers. Infection with MT bacterium results in tuberculosis and detection of MT bacterium prior to the '723 patent could take as much as 3-8 weeks. The '723 patent discloses a rapid test to confirm a tuberculosis diagnosis and indicate whether it is a drug-resistant strain. More specifically, the claims of the '723 patent are directed to oligonucleotide primers and detecting MT bacterium comprising amplifying MT bacterium DNA encoding the rpoB gene by polymerase chain reaction (PCR) amplification using the oligonucleotide primers of the claims, and determining the presence or absence of any of eleven position-specific MT bacterium nucleotides.

As to the detection claims, the Court affirmed the district court holding finding the claims invalid because it is undisputed that PCR is a routine and conventional technique and the recited nucleotide sequences in the claims are indistinguishable from their corresponding naturally occurring segments on DNA. This finding seems contrary to some of the exam guidance currently be provided by the U.S. Patent Office. Specifically, Example No. 29 in Life sciences examples 28-33 (issued May 4, 2016 by the U.S. Patent Office) appears to indicate that methods of detection are patent eligible subject matter (see **here**).

With respect to the oligonucleotide primer claims, the Court held that these claims were directed to ineligible subject matter as well because they had genetic sequences identical to those found in nature. Roche argued that the oligonucleotide primers in the claims were patent-eligible because they had a 3-prime hydroxyl group, which is not present in naturally-occurring DNA but the Court disagreed as this issue had already been decided in *University of Utah Research Foundation v. Ambry Genetics*, No. 2014-1361 (Fed. Cir. Dec. 17, 2014). In that case, the Court rejected structure based arguments that the primers were patent eligible because they were (a) synthetically replicated and (b) single stranded, both of which do not occur in the human body. The Court found that the primers were structurally indistinguishable from the isolated DNA found to be patent ineligible because they contained the same sequence. The Court further noted that the primers were structurally distinguishable from cDNA found to be patent eligible by the Supreme Court in *Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013).

In the present case, however, the Court did recognize that the identifying nucleotides in the DNA from the MT bacterium rpoB gene as a valuable contribution to diagnostics, providing faster detection of MT bacterium in a biological sample. The Court held that these specific nucleotides were found in nature and were accordingly not patent eligible. In a concurring opinion, Judge O'Malley indicated that the Court may want to revisit its prior holding in *University of Utah Research Foundation v. Ambry Genetics*, No. 2014-1361 (Fed. Cir. Dec. 17, 2014) with regard to oligonucleotide primer claims as the holding was based on an underdeveloped record in that case. Judge O'Malley cited additional facts in this case that were not developed in *University of Utah Research Foundation v. Ambry Genetics*, No. 2014-1361 (Fed. Cir. Dec. 17, 2014) including: (i) the claimed primers are single-stranded while naturally occurring primers are not; (ii) the claimed primers are comprised of DNA while naturally

occurring primers are comprised of RNA; (iii) the claimed primers are at least 14 nucleotides while naturally occurring primers are only 3-10 nucleotides long; and (iv) the claimed primers have a 3-prime end with 3-prime hydroxyl group while naturally occurring primers lack a 3-prime end with a 3-prime hydroxyl group.

To view, click **here**.

PRICING AND REIMBURSEMENT

Health Technology Assessment (HTA) in the EU

HTA is a process to value a health technology compared with other technologies for the indication purpose and is widely used in Europe but with considerable variations between member states The European Parliament recently adopted its Report on the Commission Proposal for a HTA Regulation for new medicinal products and certain medical devices.

The aim is to encourage member state cooperation in identifying emerging health technologies, joint clinical and scientific assessments and other aspects of HTA so that methodologies and procedures applied are more predictable across the EU and that joint clinical assessments are not repeated at national level with a view to avoiding higher costs for industry, delays in access to technologies and a negative effect on innovation. It is welcomed by industry but some member states are concerned that the initiative might restrict their freedom to decide on prices (considered a national competence). However, the proposal does provide for member states to conduct their own "complementary assessment".

See the Parliament's position on the Proposal **here**.

Italian Reimbursement of Products for Off-label Use

The Court of Justice of the European Union (CJEU) recently decided, in one of a series of cases concerning Avastin and Lucentis, that an Italian law that allows the national payers to reimburse a medicinal product for a use not covered by its marketing authorisation (even where there is a licensed alternative) in order to save money does not infringe Directive 2001/83/EC.

Under Directive 2001/83/EC, a medicinal product may only be marketed in a Member State if it has marketing authorisation. However, national laws may, under certain conditions, permit the use of a medicinal product for a therapeutic indication outside its marketing authorisation, e.g. where there is no other treatment available. Moreover, there is no EU restriction on off-label use and repackaging for such use provided it complies with Directive 2001/83/EC.

Lucentis is indicated for eye diseases and Avastin is authorised for cancer treatment, although it is frequently used off-label to treat wet, age-related macular degeneration (AMD). When Lucentis was authorised for the treatment of eye diseases in 2012, Avastin was excluded from the Italian list of authorised, reimbursable off-label products but in 2014 Avastin was subsequently reinserted (if repackaged by pharmacies) for its off-label treatment of AMD.

A challenge in the Italian courts was eventually referred to the CJEU which decided that Directive 2001/83/EC does not prohibit off off-label use nor the repackaging of medical products for off-label use provided that it complies with the Directive. Even though the Advocate General took the view that such off-label use should only be permitted for therapeutic reasons rather than the solely cost-saving purposes, the CJEU did not expressly address this question.

It has been suggested that this decision we will lead to an increase in off-label use generally.

See the case **here**.

OECD Pricing Investigation

On November 28, 2018, the Competition Committee of the Organization for Economic Cooperation and Development (OECD) held a discussion on excessive pricing by pharmaceutical companies. The briefing paper provides an overview of recent competition law enforcement against excessive pricing in the pharma market.

The European Commission and national regulators, including Italy, Netherlands, UK and Denmark have already taken action and more enforcement proceedings seem likely.

The paper notes that each of the recent cases in Europe relates to established, off-patent medicines where there had been no R&D investment justifications for sudden and significant price hikes, which are essential to patients and without an early prospect of alternatives.

Despite legal difficulties in determining whether a price is excessive, the UK Competition and Markets Authority (which itself was found to have misapplied CJEU principles in a recent case involving an epilepsy drug) continues to argue that "ensuring consumers are not exploited by unfairly high prices is at the heart of antitrust enforcement". There have also been more radical suggestions with the Netherlands' authorities proposing compulsory licences when a medicine is above a "socially acceptable price".

See the OECD briefing paper **here**.

UK Voluntary and Statutory Pricing Schemes

The PPRS is a voluntary scheme, last negotiated in 2014 and renegotiated every five years between the UK trade association (the ABPI) and the UK Government. Its aim is to limit the growth of branded medicines. PPRS repayments are triggered if the growth in NHS spending on branded medicines increases more than the agreed level. The PPRS repayment percentage for 2018 was 7.80%. The Government has recently published the renamed 2019 Voluntary Scheme for Branded Medicines Pricing and Access **here** .

The overall rate of allowed growth has been capped at 2% for each of the five years of the scheme. The repayment rate for 2019 has been set at 9.6%, with the payment rate for future years will be determined based on actual sales growth.

There will also be "more and faster NICE appraisals" with the intention that all new active substances be appraised by NICE with baseline cost effectiveness threshold to be maintained at between £20,000 and £30,000 for the duration of the scheme.

For those branded medicines companies that do not join the voluntary scheme, the alternative is the statutory scheme and the Government has recently published its response to the consultation on this. The response outlines several minor changes to the proposals set out in the consultation,. This scheme similarly provides for repayment of growth with the overall allowed growth rate for medicines covered by the scheme set at 1.1% with the prepayment percentages for 2019, 2020 and 2021 set at 9.9%, 14.7% and 20.5%. The Government has committed to carrying out an annual review of the scheme no later than April 2019 to consider whether the scheme is meeting its objectives.

See the consultation response **here**.

REGULATORY

New California Law Will Ban Sale of Cosmetics Tested on Animals, Bloomberg BNA

Morgan Lewis partners Collie James and Kathleen Sanzo and associate Amaru Sanchez have authored an article for Bloomberg BNA summarizing the progression of the California laws that will ban the sale of cosmetic products that use animal testing starting in 2020. They examine how the law may have potential conflicts with FDA requirements and create product liability risks, as well as provide practical considerations for compliance.

Read the LawFlash **here**.

Medical Devices – New Regulation Transition Plan

The European Commission has released an "implementing measures rolling plan" in relation to the Medical Devices Regulation 2017/745 and the In Vitro Devices Regulation 2017/746, which are scheduled to apply from 26 May 2020 and 26 May 2022 respectively. The new Regulations replace

Directives dating back to the 1990s creating new quality and transparency requirements for medical device companies in the European Union. The document will be revised by the European Commission on a quarterly basis.

The Commission provides information on the main changes introduced by the Regulations, guidance concerning the essential implementing acts and actions that need to be introduced, suggestions as to how to respond to the changes including step-by-step implementation model documents and "frequently asked questions". It also reports that 33 applications have been received from notified bodies to be designated under the Regulations covering all the devices under the Regulations and that the Commission anticipates that a EU medical devices database (EUDAMED) will be operational by March 2020.

New guidance documents concerning the UDI system are also available on the European Commission website.

See the plan **here**. It is worth noting that many in the industry and other commentators consider much of this timing over-optimistic and are calling for a longer transition period. See for example **here** or **here**.

Recently, the International Consortium of Investigative Journalists (ICIJ) published a series of reports on implantable medical devices in 36 different countries and established the 'International Medical Devices Database'(IMDD) which includes data on recalls, safety alerts and field safety notices across 11 countries and is searchable by device name, manufacturer or country. See the IMDD **here**.

Falsified Medicines – A Final Reminder

A reminder that the Falsified Medicines Directive (Directive 2011/62/EC) introducing a verification system against falsification and protection of the legal supply chain of prescription medicines in EU and EEA countries comes into force on 9 February 2019. Commission Delegated Regulation 2016/161/EU sets up a system which requires the use of safety features and a establishing a repository which stores information on each individual pack.

Marketing authorisation holders (MAHs): are required to upload their product data in the national system and wholesalers, pharmacies and hospitals must also connect their systems to this verification repository (NMVO). All relevant stakeholders, i.e. marketing authorisation holders, manufacturers, importers and wholesalers (including parallel distributors), and persons authorised or entitled to supply medicines to the public must comply with these new rules.

Non-compliance with these obligations by February 9, 2018 will constitute a violation of EU law and entail sanctions according to national legislation of the EU Member States.

See further **here**.

Orphan and Paediatric Medicines

The European Commission has recently conducted a public consultation on the Orphan and Paediatric Regulations. This evaluation will assess whether "the EU legislation is efficient and effective" and "whether it is fit for purpose" and considers in particular the "impact of the incentives introduced for research, development and marketing" of medicines for special populations. The Commission is also carrying out a survey on those involved in the development and marketing of medicines for rare diseases assessing the

"efficiency, effectiveness, relevance and EU added value of the EU Orphan Regulation as well as its coherence with other regulations.". The study is expected to be completed by the middle of 2019 and the report will be publically available. See further **here**.

Meanwhile, the European Medicines Agency has published a reflection paper on the use of extrapolation when developing medicinal products for paediatric use. From the starting point that children should only participate in clinical trials when there are no alternatives, the paper highlights the possibilities and advantages of extrapolation to ensure that children only participate in clinical trials with specific objectives that further the scientific understanding of a medicinal product for use in children and address the requirements for regulatory decisionmaking.

The paper seeks to promote the use of available evidence and objective criteria to support extrapolation. See **here**.

BREXIT – "NO DEAL" PLANNING

While the UK government has concluded a departure deal with the European Union, it is still far from sure that the UK parliament will accept it. Acknowledging that the United Kingdom must prepare for a no deal scenario for 29 March, the government published a series of 106 Technical Notices setting out information to allow businesses and citizens to understand what they would need to do in a no-deal scenario so they can make informed plans and preparations. These included dealing with medicines, medical devices and clinical trials.

Following a consultation on the relevant notices, the Medicines and Healthcare Products Regulatory Agency has recently issued updated guidance.

For medicines, the proposals include

- automatically converting Community Marketing Authorisations to UK Marketing Authorisations, a process known as "grandfathering";
- targeted assessment of new applications for products containing new active substances or biosimilars which have been submitted to the EMA and received a Committee for Medicinal Products for Human Use (CHMP) positive opinion;
- a fully accelerated assessment for new active substances;
- free scientific advice, including for orphan medicines, for UK-based small and medium-sized enterprises;
- a period until the end of 2021 to amend packaging and leaflets for a product already on the market;
- allowing the parallel import of medicinal products that hold a marketing authorization from an EU or EEA country; and
- continuing to recognize prescriptions issued in EU or EEA countries.

For medical devices, the key arrangements include

- for a time-limited period, devices that have a CE mark from a notified body based in the UK or an EU country will continue to be recognized by UK law and allowed to be placed on the UK market; and
- the expansion of the MHRA's registration system to all classes of medical device (currently only class 1 is covered).

For clinical trials, the plans include

- continuing to recognize existing approvals so there will be no need to re-apply;
- requiring the sponsor or legal representative of a clinical trial to be in the United Kingdom or country on an approved country list that would initially include EU or EEA countries; and
- aligning, where possible, with the EU Clinical Trials Regulation when it applies.

These proposals are still subject to parliamentary approval of the relevant statutory instruments that are required to bring these proposals into law.

See the press release **here**.

China Creates 'Special Channel' for Fast-Track Approval of Some Foreign Drugs

Expanding on recent reforms allowing innovative pharmaceutical drugs to be approved on the basis of overseas clinical trial data, China's National Medical Products Administration (NMPA) has created special channels for the approval of new pharmaceuticals subject to "urgent" clinical needs. On the heels of its July 10 Technical Guidelines for the Acceptance of Overseas Clinical Trial Data for Drugs, the NMPA (formerly known as the China Food and Drug Administration, or CFDA) has created a "special channel" for the fast-track approval of urgently needed pharmaceutical drugs developed overseas through its Review and Approval Procedures for Urgently-Needed Pharmaceutical Drugs Developed Overseas, published on October 30, 2018 (the Procedures). This reform is the latest step in the regulator's push to remove obstacles to bringing pharmaceuticals developed overseas to the Chinese market. The July 10 guidelines described rules by which pharmaceuticals may gain approval for sale in the China market on the basis of overseas clinical trial data, reducing the delays and costs for Chinese consumers. The special channel will further accelerate the process for select drugs.

Read the LawFlash **here**.

China to Promulgate More Rules to Expedite Approvals for Genetic Resources Administration

The right to privacy in China is generally recognized in the Constitution of the People's Republic of China and Tort Liability Law. Over the past years, the Chinese government has continued to actively legislate into law a myriad of

new regulations related to data privacy. With China's Cybersecurity Law (CSL) and General Principles of Civil Law taking effect in 2017—which stipulate more stringent requirements for data governance and a private right of action against infringement of privacy, among others—the Chinese government has also made top-level policy statements to reaffirm its commitment to strengthening cybersecurity and the protection of data privacy. These policy directives are driven by increasing prevalence of data breach incidents as well as mounting economic value of "big data" analytics derived from population health information, genetic and clinical research data, biometrics, and other sensitive personal information. In recent months, several headline cases have further propelled the Chinese government's legislative and enforcement priorities in this area to the forefront of the public discourse.

In addition, the Chinese government's renewed focus and reinforced regulations on genetic resources have caused the life sciences community to question whether increased regulations could create hurdles and delays in scientific exchanges and international collaborations on the R&D of new drugs. The Chinese government has avowed its support for international collaboration on biomedical research in State Council's 2015 Action Outline for Promoting Big Data and is addressing these concerns by implementing other measures to expedite the related approval processes.

Read the LawFlash **here**.

To Recall or Not to Recall? FDA Issues Q&A Guidance on Food Recalls

On November 6, the US Food and Drug Administration (FDA) announced that its final guidance on Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff (Mandatory Recall Guidance) is now available. The Mandatory Recall Guidance provides information on the implementation of the mandatory food recall provisions of the Food Safety Modernization Act (FSMA). The Mandatory Recall Guidance comes in the form of a Q&A on common topics about the FSMA's mandatory recall provision.

In the wake of a number of large-scale food contamination outbreaks and recalls, Congress enacted FSMA on January 4, 2011. Section 206 of FSMA (Federal Food, Drug, and Cosmetic Act (FD&C Act) Section 423) significantly expanded FDA's enforcement powers over potentially dangerous foods. Under Section 423(a) of the FD&C Act, FDA has the authority to order the mandatory recall of foods for which there is a "reasonable probability" that the articles are "adulterated . . . or misbranded . . . and the use of or exposure to such article[s] will cause serious adverse health consequences or death to humans or animals." Prior to the enactment of the FSMA, FDA generally had to rely upon manufacturers' voluntary recall efforts or obtain a court order to remove contaminated or misbranded foods, other than infant formula, from the food supply.

Read the LawFlash **here**.

FDA and USDA 'Raise the Steaks': Agencies Plan to Jointly Oversee Production of Cell-Based Food Products

The US Food and Drug Administration (FDA) and US Department of Agriculture (USDA) issued a joint statement on November 16 indicating that both FDA and USDA will jointly oversee the production of cell-based food products derived from livestock and poultry. The proposed regulatory framework generally involves the FDA overseeing cell collection, cell banks, and cell growth/differentiation, and USDA overseeing the production and labeling of the food products following cell harvest. While it is encouraging to see the agencies working together to resolve this threshold question, it simply sets the stage for further evaluation of any number of challenging questions.

From the Morgan Lewis Blog, *Well Done*.

To view, click **here**.

USDA Finalizes Rule Establishing National Bioengineered Food Disclosure Standard

The US Department of Agriculture (USDA), through its Agricultural Marketing Service (AMS) published its final rule (NBFDS Final Rule) on December 21 establishing a nationwide labeling disclosure requirement for foods containing bioengineered (BE) ingredients, defined as foods or substances that contain genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or be found in nature. While a more thorough analysis is still being conducted, here we provide a summary of the major topics addressed in the NBFDS Final Rule.

To view, click **here**.

Marketing Authorizations for Medicines in Russia

Russian Ministry of Health suggested amendments to the rules on the registration of medicines in Russia. Russia considers changing the procedures of obtaining marketing authorizations for medicines, in order to ensure better protection of originators' IP rights.

The Ministry of Health, the local authority responsible for state registration of medicines, has recently proposed amendments to Article 18 of Federal Law No. 61-FZ "On Circulation of Medicines" dated April 12, 2010 (the "Law on Medicines").

According to the proposed amendments, an applicant will need to confirm its rights to use intellectual property embedded in a medicine when applying to the Ministry of Health for the marketing authorization. In particular, the applicant will need:

(i) to confirm if the medicine enjoys trademark and/or patent protection in Russia, and to provide the documents confirming such protection (in particular, the applicant will need to provide copies of trademark and patent certificate(s), or, alternatively, the copy of the trademark/patent license

with the owners of the respective IP rights, duly registered with the Russian Patent and Trademark Office); and

(ii) to submit a written guarantee to the Ministry of Health confirming that:

- registration of the respective medicine and issuance of the marketing authorization will not infringe any third party IP rights and is specifically allowed under the respective trademark/patent license agreement with the originator (if applicable); and
- all information in the registration dossier is accurate, have been obtained in a legitimate manner and also does not infringe any third party IP rights.

The new procedure will be applicable not only to the applicants for the new marketing authorizations to be granted by the Ministry of Health, but will also apply to the owners of the currently effective marketing authorizations. The owners of the effective marketing authorizations will need to submit the documents/guarantees to the Ministry of Health no later than by January 1, 2020.

According to the currently effective law, the Ministry of Health is under no obligation to check whether the medicine encompasses any third party IP rights or if the applicant for the marketing authorization has legal grounds to use intellectual property embedded in the medicine. This approach has been supported by the Russian courts in a number of cases, where the court ruled that the mere fact of obtaining marketing authorization to generics does not infringe originators' IP rights.

The proposed amendments (if adopted in their current form) will bring the national legislation in line with the Unified Principles and Rules of Circulation of Medicines within the Eurasian Economic Union adopted by Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia in 2014.

PRIVACY

China Issues New Rules Strengthening Local Authorities' Power to Enforce Cybersecurity and Data Privacy Laws

The Chinese Ministry of Public Security on September 15, 2018, released the Provisions for the Supervision and Inspection of Network Security by Public Security Agencies, also known as "Circular 151." This new regulation provides a legal basis and framework for wide-ranging authority for local law enforcement agencies (Public Security Bureau, or PSB) in China to enforce China's cybersecurity and data privacy laws by conducting onsite or remote inspections of internet service providers, as well as any entities that use networks for their operations. Circular 151 will officially come into effect on November 1. Businesses operating in China should prepare for this new development and take note of the Chinese government's enforcement priorities.

Read the LawFlash **here**.

MORGAN LEWIS NEWS

Announcing Our Newest Blog – *As Prescribed*

In today's fast-paced world, there is little time to keep up with the many legal and regulatory developments in the pharmaceutical and biotechnology sectors. Let *As Prescribed* be your go-to resource to quickly understand the critical issues facing companies in this space.

We are pleased to announce the launch of *As Prescribed*, Morgan Lewis's newest blog that will provide our clients and friends with analysis of the latest legal and regulatory developments that shape the pharma and biotech sectors. From regulatory decisions and rulings to important litigation, transactions, and policy trends, *As Prescribed* provides the insight you need, when you need it.

Read the blog >

Life Sciences Growth Series

The Morgan Lewis Life Sciences Growth Series is an online series of tailored webinars led by a cross-practice team of Morgan Lewis life sciences lawyers. The program is designed to provide startup and early-stage companies with a comprehensive overview of a variety of topics affecting the life sciences industry.

The program provides a user-friendly way to learn about the latest life sciences issues and developments and is geared toward addressing legal issues in the life sciences industry faced by startup and early-stage companies.

Each session is self-contained, and participants can pick topics of particular interest or relevance or attend the whole series. The webinars are structured for learning in an efficient and convenient format.

Previous Sessions

Top 10 Mistakes that Life Sciences Entrepreneurs Make

Understanding University Licensing

Key Commercial Agreements for Early-Stage Life Sciences Companies

Upcoming Sessions

January 15, 2019 | **Preparing for a Series A Investment and Due Diligence**

February 12, 2019 | **FDA and IP Primer for Early-Stage Life Sciences Companies**

Morgan Lewis

CONTACTS AND AUTHORS

UNITED STATES

Michael Abernathy
Chicago
+1.312.324.1447
michael.abernathy@morganlewis.com

Suzanne Bassett
Washington, DC
+1.202.739.5656
suzanne.bassett@morganlewis.com

Ann Begley
Washington, DC
+1.202.739.5613
ann.begley@morganlewis.com

Rebecca Dandeker
Washington, DC
+1.202.739.5614
rebecca.dandeker@morganlewis.com

Robert Hibbert
Washington, DC
+1.202.739.5611
robert.hibbert@morganlewis.com

Amaru Sanchez
Washington, DC
+1.202.739.5655
amaru.sanchez@morganlewis.com

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

Robert Smyth
Washington, DC
+1.202.739.5139
robert.smyth@morganlewis.com

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

EUROPE

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

Tim Corbett
London
+44.20.3201.5690
timothy.corbett@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

Dora Wang
Shanghai
+86.21.8022.8576
dora.wang@morganlewis.com

www.morganlewis.com