













UK Life Sciences and Healthcare Newsletter

January 2021

Legal Updates: Hot Topics



Counterfeit Medicines: A Growing Threat to Consumers and Pharmaceutical Companies

Paul Kavanagh and Nathan Smith share an update in relation to the recently published report by the European Union Intellectual Property Office and Organisation for Economic Co-Operation and Development on counterfeit pharmaceuticals based on global customs seizure data from 2014 to 2016.

Read more »



UK Government Launches Consultation into Potential Reform to Employee Non-compete Clauses

Charles Wynn-Evans, Emma Byford, Rose Limaye and Heidi Fitchett share an update on the UK government's recent launch of a consultation into potential reforms to post-termination non-compete clauses in employment contracts.

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Dechert Panel: How Does the Investment Landscape Look Post COVID-19? 12th Annual Healthcare Investor Conference

The 12th Annual Investor Healthcare Conference by Optimum Strategic Communications in partnership with Dechert LLP was recently held in virtual format. Robert Darwin, a corporate partner based in Dechert's London office chaired the closing panel "How Does the Investment Landscape Look Post COVID-19?". The panel discussion video can be accessed below.

Watch the panel »

Guest Contributor

This month's guest contributor is Linden Thomson. Linden leads investment in the AXA IM Framlington Biotech Fund and supports the wider team in her role as Co-Head Global Equities at AXA IM Framlington.

She has nearly two decades of buy-side and sell-side experience as one of the early specialists in the biotechnology sector. Her formative career was spent with Goldman Sachs in the Global Investment Research team covering healthcare/biotechnology. Subsequently she joined a healthcare hedge fund at start-up stage, as a key member of the team that built and launched the fund. She has been at AXA IM Framlington since 2011. She holds a BSc in Biology (Medical Microbiology Hons) from the University of Edinburgh and is a CFA Charterholder.



All Eyes Were on Biotech in 2020: Some Investor Observations

Linden Thomson considers the biotechnology capital markets in 2020. Read more »

Notwithstanding the impact of the COVID-19 pandemic, Dechert has recently been involved in advising on a number of significant life sciences transactions, including advising:

- Bpifrance, Sofinnova Partners, Novo Holdings, Seventure, Ysios Capital and Financière Arbevel, on the Series C financing of CorWave for a total amount of €35 million.
- Elsan and Kohlberg Kravis Roberts & Co. (KKR), on the acquisition of the C2S group of generalist clinics from Eurazeo Patrimoine.
- Kurma Partners, Bpifrance Investissement, BNP Paribas Développement, Aquiti Gestion and IRDI Soridec Gestion, on a €5.5 million seed financing round for Lucine, a French start-up specialised in Digital Therapeutics (DTx).
- Resolve Biosciences, a German molecular cartography firm, in its US\$24 million Series A financing round.

Team News:

 Dechert LLP recently announced that Howard Levine and Jennifer Swan have joined the firm in Washington, D.C. and Silicon Valley, respectively, as partners in the intellectual property group, further expanding Dechert's global life sciences capabilities. Click here for details.

Knowledge:

- Life Sciences: What's new in France?: A legal update on recent developments in the life sciences sector in France produced by Dechert's Paris life sciences team.
- Life Sciences Cos. Increasingly Turn To Arbitration: Law360 article featuring Dechert's international
 arbitration lawyer, Erica Stein. The article dicusses how life sciences companies' lawyers are
 increasingly embracing international arbitration to resolve disputes with their clients' international
 partners.

Events:

- FT Digital Dialogue | Innovative Clinical Research Strategies, 3 February: This FT Digital Dialogue on Innovative Clinical Research Strategies, organised in partnership with ICON plc, will discuss how to design and run more resilient trials in an uncertain world, where the need to decentralise is driving investment in new technology solutions and changing the pharma R&D landscape.
- European Private Markets Virtual Series Private Equity: Healthcare Sector Focus, 4
 February: Join this live event to hear expert speakers discuss the short-term impacts of COVID-19 on different healthcare subsectors as well as the longer-term effect on traditional healthcare infrastructure and the maturation of the digital health and health-tech sector.
- Pharma & Biotech Patent Litigation in Europe, 23 25 February: The 13th Annual Forum where the
 "Who's Who" of the European Life Sciences Patent Bar gather each year to shape patent litigation
 policies and procedures.

Regulatory Updates:

MHRA updates post-transition guidance

Since 31 December 2020, the Medicines and Healthcare products Regulatory Agency (MHRA) has been updating various aspects of the regulatory regime for medicines and medical devices following the end of the Brexit transition period such as:

- MHRA's 150-day objective for assessing applications for marketing authorisations (MAs);
- o The rolling review process for MA applications (rather than a consolidated full dossier submission);
- The process by which, for a two-year period from 1 January 2021, MHRA may rely on a decision taken by the European Commission (EC) on the approval of a new MA in the centralised procedure when determining an application for a Great Britain (GB) MA.
- MHRA's decentralised or mutual recognition procedures which would enable MAs approved in EU member states (or Iceland, Liechtenstein, Norway) to be granted in the UK or GB;
- The 'Unfettered Access Procedure' which would enable MA holders in Northern Ireland to seek recognition in GB.

In addition, the MHRA has updated its post-transition guidance on, among other matters: (i) importing medicines into GB, (ii) pharmacovigilance procedures (in particular on the use of country codes and worldwide case IDs when submitting Individual Case Safety Reports (ICSRs)) and (iii) its intended approach for medicinal products approved or pending in the decentralised procedure (DCP) or mutual recognition procedure (MRP).

UK-Canada interim agreement on Good Manufacturing Practice (GMP)
On 5 January 2021, the MHRA and Veterinary Medicines Directorate (VMD) announced that they had entered into an interim agreement with the Regulatory Operations and Enforcement Branch of Health

Market News:

Recent notable industry transactions.

- Royal Philips announced that it has agreed to acquire Capsule Technologies, Inc., a provider of medical device integration and data technologies for hospitals and healthcare organisations, for US\$635 million.
- Sanofi and Biond Biologics entered into an exclusive global licence agreement for Biond Biologics' ILT2-targeting immune checkpoint inhibitor BND-22, which is under development for the treatment of solid tumours. Biond will receive US\$125 million in an upfront cash payment and is eligible to receive more than US\$1 billion in potential milestone payments.
- Sanofi has agreed to acquire Kymab for an upfront payment of approximately US\$1.1 billion and up to US\$350 million upon achievement of certain milestones. The transaction will result in Sanofi having full global rights to KY1005, a fully human monoclonal antibody that has a novel mechanism of action.
- PerkinElmer announced that it has agreed to acquire Oxford Immunotec at a deal value of approximately US\$591 million, subject to customary closing conditions.
- Ribometrix announced a strategic collaboration with Genentech, a member of the Roche Group, to
 discover and develop novel RNA-targeted small molecule therapeutics against several targets, with
 Ribometrix receiving a US\$25 million upfront payment and potential milestone payments exceeding \$1
 billion
- Centene Corporation and Magellan Health entered into a merger agreement for a value of US\$2.2 billion and will establish a leading behavioural health platform.
- AstraZeneca has agreed to sell the commercial rights to Atacand and Atacand Plus in around 70 countries to Cheplapharm for US\$400m.
- Angelini Pharma and Arvelle Therapeutics, a Swiss-based biopharmaceutical, concluded a merger agreement under which Angelini will acquire Arvelle for a total value of up to US\$960 million.
- Myovant Sciences entered a collaboration with Pfizer to develop and commercialise relugolix, a oncedaily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist. Myovant will be eligible to receive up to US\$4.2 billion.
- Lilly had agreed to acquire Prevail Therapeutics for a total value of approximately US\$1.04 billion.
- Boehringer Ingelheim has agreed to acquire NBE-Therapeutics, a clinical-stage Swiss biotech company working on antibody-drug conjugates (ADC) and cancer therapies for a transaction value of US\$1.44
- Takeda Pharmaceuticals sold its primary care businesses in the Asia Pacific region to Celltrion for US\$278.3 million and separately has agreed to divest a portfolio of non-core prescription pharmaceutical products sold in China to Hasten Biopharmaceu for US\$322 million. Takeda also completed its sale of select prescription products to Cheplapharm for a total value of US\$562 million.
- AstraZeneca has sold rights to Crestor (rosuvastatin, for the treatment of dyslipidaemia and hypercholesterolaemia) and associated medicines in certain European markets to Grünenthal for at least US\$320m.
- Biogen and Sage Therapeutics have executed a collaboration and licence agreement to develop and commercialise zuranolone (SAGE-217) for major depressive disorder, postpartum depression and other psychiatric disorders, and SAGE-324 for essential tremor and other neurological disorders. Sage will receive US\$1.525 billion in cash, comprising an upfront payment and an equity investment in Sage, in addition to potential milestone payments.

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