Biotecnología

Las cuestiones jurídicas a que se enfrentan nuestros clientes de biotecnología son tan diversas como las habilidades que ponemos a su disposición. Nuestro equipo de biotecnología cuenta con abogados con conocimientos jurídicos, científicos y médicos que entienden la complejidad del negocio y del entorno reglamentario en el que operan nuestros clientes.

Los retos a los que se enfrentan hoy día las empresas biofarmacéuticas y de dispositivos médicos son mayores que nunca. Para que las empresas puedan llevar terapias prometedoras desde el laboratorio al mercado deben protegerlas de los riesgos de propiedad intelectual, reglamentarios y reputacionales. Además, en los últimos años hemos sido testigos de una presión cada vez mayor desde varios frentes, como son la demanda de más rentabilidad para los accionistas, la pérdida de fuentes de ingresos claves debido a la expiración de patentes u otros retos generales, la competencia feroz en áreas terapéuticas fundamentales, las presiones en los precios por parte de los financiadores del gasto sanitario , nueva regulación gubernamental que trasciende las cuestiones básicas de seguridad, el incremento de los costes de I+D, las dificultades para maximizar la rentabilidad en los mercados emergentes y la aplicación rigurosa de la normativa por parte de las autoridades.

Nuestro equipo del área de biotecnología es uno de los mayores y más activos en el mercado legal. Trabajamos como un único equipo, que cubre más de treinta países, combinando la experiencia en nuestra área de especialización con un amplio conocimiento del sector, incluyendo los entornos científico, médico, reglamentario, comercial y de cumplimiento a los que se enfrentan nuestros clientes de biofarmacia, dispositivos médicos y de sistemas de diagnóstico.

Nuestro equipo cuenta con abogados galardonados por su trayectoria en procesal, cumplimiento normativo e investigaciones, estrategia y tutela de propiedad intelectual, fusiones y adquisiciones, licencias y distribución, asesoramiento en ensayos clínicos, privacidad, externalización, derecho societario y defensa de la competencia. También asesoramos a nuestros clientes en todas las demás áreas necesarias para abordar cualquier riesgo con éxito, incluyendo las relaciones con la administración, legislación medioambiental, importaciones / exportaciones, fiscalidad, Derecho inmobiliario y laboral. Muchos de nuestros abogados son antiguos profesionales del sector, otros muchos tienen doctorados en medicina u otros diplomas de posgrado en el campo de la biotecnología, y

Marco de Morpurgo
Socio
Roma
T: +39 06 68 880 1
marco.demorpurgo@dlapiper.c

Andrew P. Gilbert
Socio
New Jersey (Short Hills)
T: +1 973 520 2553
andrew.gilbert@dlapiper.com

Matt Holian
Socio
Boston
T: +1 617 406 6009
matt.holian@dlapiper.com

- Antitrust and Competition
- Corporate
- Laboral
- FDA
- Intellectual Property and Technology
- International Tax Counsel
- Litigation, Arbitration and Investigations
- Real Estate
- Tax

otros han ejercido previamente como funcionarios o fiscales.

- Digital Health

Sabemos que las necesidades de nuestros clientes varían, por ello nuestros equipos se organizan y adaptan inmediatamente para ofrecer el mejor servicio al cliente, ya se trate de una gran empresa farmacéutica, una pyme de dispositivos médicos o una empresa biotecnológica en fase de desarrollo. Estos equipos están integrados por profesionales internacionales y locales para dar una respuesta eficiente a las demandas del mercado, tanto si se trata de una operación internacional, una investigación, la resolución de un conflicto o un proyecto transfronterizo.

Nuestros sistemas para determinar los abogados a cargo de cada proyecto, de elaboración de presupuestos y de facturación, creados específicamente para ayudar a los clientes globales de biotecnología, son de última generación y aseguran que nuestros equipos aportan el máximo valor añadido, además de conseguir óptimos resultados.

Nuestro equipo de biotecnología ayuda a los clientes a enfrentarse a sus retos cotidianos. Como ejemplos de nuestra experiencia cabe destacar:

- Realización de una delicada investigación en China.
- Negociación de un acuerdo complejo de distribución que incluía a varios países de Latinoamérica.
- Actuación como abogados a escala nacional en una acción colectiva por negligencia punible en EE. UU.
- Ayuda en la venta o adquisición de un gran activo empresarial.
- Asesoramiento en la implantación de legislación de transparencia o sobre el impacto de nueva legislación.
- Diseño de un plan de reducción de riesgos para un producto clave.
- Negociación de un importante contrato con una ONG global respecto a una vacuna.
- Asesoramiento en un ensayo clínico multijurisdiccional.
- Asesoramiento en reducción de plantillas en Europa.
- Apoyo a los responsables de conducta empresarial y cumplimiento normativo globales
- Externalización de funciones clave de I+D+I o TI.
- Diseño de una estrategia de propiedad intelectual para una nueva y prometedora terapia
- Negociación de un contrato de licencia y colaboración a escala mundial.
- Protección de un medicamento superventas en un litigio de patentes

NOVEDADES

Publicaciones

The rise of global telehealth

30 June 2022
AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Partners Kristi Kung and Greg Bodulovic discuss the rise of telehealth amid the COVID-19 pandemic, as well as advancements in technology aiming to address disparate access to healthcare globally.

Coming soon: a national security screening mechanism for outbound investments

28 June 2022
The US would not be alone in regulating outbound investment.

FDA Regulatory News and Trends

28 June 2022
Guidance coming to supplements industry on new dietary ingredients; approval rescinded for a cancer drug; program will seek new ways to sterilize devices.

Former BIO CEO Jim Greenwood: 1 million dead, $16 trillion in losses is our wake-up call on pandemic preparedness

7 June 2022

While biological events may be inevitable, their level of impact on our country is not.

Food and Beverage News and Trends

20 May 2022
FOOD AND BEVERAGE NEWS AND TRENDS

FDA warns about consumption of copycat products that contain THC; Canada tackles food fraud; Kansas enacts meat analog labeling law.

FDA continues CBD enforcement and ramps up delta-8 THC enforcement; agency focuses on youth-appealing products

19 May 2022

FDA has adopted a more aggressive enforcement strategy toward delta-8 THC than it has for CBD, and it is actively moving against products that carry significant risk of youth appeal.

FDA premarket approval and the use of “FDA Approved” claims

17 May 2022
When do products, facilities, labels, and claims require Formal Premarket Approval, and when do they not?

Global M&A Intelligence Report 2022

Updated: 29 June 2022
Our annual Global M&A Intelligence Report is based on an analysis of key deal terms in almost 5,000 private M&A transactions on which we have advised since 2015.

Israel Group News April 2022

28 April 2022
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

Colombia is using AI to improve insolvency proceedings

22 April 2022
PANORAMA

Artificial intelligence creates a completely new experience for the interaction of the user with the insolvency system.

Advising the advisor: Tips for navigating the life sciences and regulatory environment

19 April 2022
AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Emilio Ragosa is joined by Kevin Sheridan, Joint Global Head of Healthcare Investment Banking at Jefferies LLC, to discuss the importance of advisors having an understanding of the life sciences industry.

What is a SPAC? The basics, when you are contemplating going public in 2022

6 April 2022
PANORAMA

Key developments and implications for Latin American companies.

The moral imperative: Balancing innovation, regulation and prescription drug availability

21 March 2022
AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Jim Greenwood and Geoff Levitt are joined by Peter Kolchinsky to discuss the importance of – and complications in - balancing biopharmaceutical innovation, industry regulations and prescription drug availability.

Incentivizing diverse representation in clinical trials

2 March 2022
AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Kirsten Axelsen and Sarah Schick are joined by Shazia Ahmad, Senior Director and Head of Patient and Physician Services at UBC, to discuss the importance of regulatory incentives to drive racial and ethnic diversity in clinical trials.

The beginning of the end: FDA details roadmap to terminating COVID-19 EUAs and enforcement policies for medical devices, PPE

2 March 2022
The webinar sought to prepare stakeholders for the upcoming transition back to normal operations by describing its expectations for the industry over the 180-day transition period.

US escalates its sanctions regime against Russia, targeting its financial system

28 February 2022
GLOBAL SANCTIONS ALERT

And additional measures are expected to be announced by the US and its allies in the coming days

Aiscension: an AI tool to ensure effective risk management by detecting anti-competitive practice

24 February 2022

Anti-competitive activity has been rife in companies for centuries and there are many who like to take the ostrich approach and bury their head in the sand. However, it is known that this approach to risk management is ineffective should the regulators come looking, and with fines of up to 10% of global turnover, it is a big risk to take.

New US sanctions in response to Russia's actions against Ukraine

23 February 2022
GLOBAL SANCTIONS ALERT

Additional sanctions are expected that will target Russia's financial, technology, and defense sectors.

Medicare audit? CMS expands ability to revoke for non-compliant billing

14 February 2022
These broad revisions provide CMS with greater revocation authority.

Telehealth's impact on low-income communities

24 January 2022
AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Shared from our Beyond the Curve podcast series

Ray Williams and Kirsten Axelsen are joined by Dr. Benson Hsu of the University of South Dakota Sanford School of Medicine for a frank discussion on disparities to engaging with telehealth and ways to better serve low income communities. Originally recorded on March 3, 2021.

Israel Group News January 2022

24 January 2022
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

US Department of Homeland Security seeks comments on implementation of Uyghur Forced Labor Prevention Act

24 January 2022
Considerations for US importers and entities with supply chains that may involve China.

2022 – a busy year for privacy legislation has already started

12 January 2022

Biometric privacy, cybersecurity standards and consumer protection are among the subjects of the bills.

A legal overview

4 January 2022

UNDERSTANDING THE UK NATIONAL SECURITY & INVESTMENT REGIME PODCAST

In episode 2 of our podcast series we discuss the legal context of the regime: how it will operate and the implications for businesses. In particular, the legislation - which comes into force today, 4 January - has wide reaching implications for M&A involving businesses or assets connected with the UK.

Supporting the health of your health system: 2022

3 January 2022

Helping you tend to healthcare system wellness throughout the business life cycle.

The crossroad of science and law

16 December 2021

AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Lucas Przymusinski and Raymond Williams are joined by Michael King, Vice President and Associate General Counsel at Jazz Pharmaceuticals, to discuss the benefits of medical and science backgrounds when litigating matters for pharmaceutical and medical device companies.

The Glasgow Climate Pact: What does it mean for Business?

23 November 2021

In this article, members of our Sustainability and ESG Steering Committee share their thoughts on eight key themes emerging from COP26 and what they mean for business.

Social media's impact on the life sciences industry

8 November 2021

AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Chris Campbell and Jody Rhodes are joined by Sarah Heineman, Senior Assistant General Counsel at Bayer, to discuss how social media affects the public's view of medicine and science.

Israel Group News October 2021

25 October 2021

ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

An interview with Aldersgate Funding

11 October 2021

In this podcast, DLA Piper partner Henry Quinlan interviews Jim Holding and Matthew Lo at Aldersgate Funding Limited, who shed some light on the advantages of litigation and arbitration funding; the types of claims eligible for funding; the process of funding a case; and the jurisdictional constraints on this type of financing.

DLA Piper · Aldersgate Funding on how litigation funding can help your business

---

Understanding AI and its use in drug discovery

6 October 2021

AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

DLA Piper partners Ellen Scordino and Susan Krumplitsch are joined by Duane Valz, General Counsel of Insitro, to discuss how machine learning is being used to generate and leverage data for the development of better medicines.

FTC's Policy Statement on breach notifications in mobile health apps: a new, broad approach that may face legal challenge

27 September 2021

The Policy Statement highlights the FTC's intention to step up enforcement consistent with these broad new interpretations.

Can an AI system be named the inventor? In wake of EDVA decision, questions remain

23 September 2021

AI OUTLOOK

Artificial intelligence is notable among the new technologies posing fundamental questions about the viability of the inventor's oath.

The Hidden Cost of Price Control Policies with Kirsten Axelsen

15 September 2021

An interview with Kirsten Axelsen about what would change in biopharma if price controls were implemented.

President Biden announces new vaccination requirements – what private employers and federal contractors need to know

14 September 2021

Employers already struggling with a puzzling array of compliance challenges aimed at combating COVID-19 now face additional vaccination and testing requirements.

The Pharmaceutical Corner

September 2021

Teva v. Amicus is the first lawsuit to test the reach of the CREATES Act. Expect more.

New workplace sexual harassment laws passed – (some) Respect@Work recommendations become law

8 September 2021

After months of anticipation, the Australian Federal Government's Sex Discrimination and Fair Work (Respect at Work) Amendment Act 2021 has now passed both houses of Parliament. The amendment contains important reforms to address workplace sexual harassment.

---

mRNA Technology: A New Approach to Therapeutics

8 September 2021

AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Dr. Lisa Haile talks with Dr. Kathy Fernando about the study of mRNA and how COVID-19 catalyzed its advancement.

Electronic disclosures on mobile devices: CFPB to study

30 August 2021

As mobile devices have become the platform of choice for many consumers, the effective delivery of disclosures on those devices has become a key consideration for financial service providers.

Israel Group News August 2021

16 August 2021

ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

The state of HealthTech and future opportunities

03 August 2021

TECHLAW PODCAST

Podcast 41 of our TechLaw podcast series sees David Bell, Director at Hampleton Partners, leading M&A and corporate finance consultancy for companies with technology at their core, and DLA Piper Partner, Mark O'Conor, engage in an exciting conversation on the current innovations in HealthTech, as well as a futuristic outlook on the industry. Key highlights include the benefits of software as a medical device, macro factors influencing innovation and investment opportunities. Join David and Mark at our fifth European Technology Summit on the 5th October 2021 where they will be resuming this conversation. Register at our fifth European Technology Summit on the 5th October 2021.

DLA Piper TechLaw Podcast Series · The state of HealthTech and future opportunities

---

Patent eligibility of diagnostic methods in Australia confirmed: *Ariosa Diagnostics, Inc v Sequenom, Inc* [2021] FCAFC 101

29 June 2021

For many years, the following question awaited judicial determination under Australian law: is a DNA-based diagnostic method patent eligible subject matter? The Full Court of the Federal Court of Australia has confirmed that diagnostic methods involving the practical application of "natural phenomena" can be patentable inventions in Australia.

The Pharmaceutical Corner

June 2021
We look at the underlying decision in *Immunex v. Sandoz* and the potential implications on pharma patent licensing strategies.

United States v. Arthrex: Where does the Supreme Court's decision leave the PTAB?

23 June 2021
If the APJs' appointment is unconstitutional, what is the appropriate remedy?

Global M&A Intelligence Report 2021

23 June 2021
Our annual Global M&A Intelligence Report is based on an analysis of key deal terms in over 3,200 private M&A transactions on which we advised since 2015.

Global corporate benchmarking group seeks inputs on corporate human rights standards

22 June 2021
Comments are requested by June 25, 2021.

Food and Beverage News and Trends

11 June 2021
FOOD AND BEVERAGE NEWS AND TRENDS

Supreme Court declines to act on vaping regulations, FDA proposes "common sense reform" for dietary supplements industry, USDA and CDC investigate Salmonella linked to chicken parts.

FDA solicits public comment on adding list of device materials to certain medical device labels

26 May 2021
The proposed change would apply to all medical devices that may be in contact with a patient long term.

Multi-jurisdiction guide for screening foreign investments

26 May 2021
The aim of this guide is not to substitute proper due diligence and specialized advice when conducting business, it will hopefully help the reader navigate the different FDI regimes. Particularly in this complex context and in view of the proliferation of new regimes, by explaining the key aspects of regimes including main issues to consider, thresholds and proceedings to take into consideration when investing in our globalized world.

Why I Lawyer: Q&A with Lisa Haile

18 May 2021
WHY I LAWYER

Having so many years in the industry has given me a deep understanding of the business of biopharma and provides me with a different perspective when I advise clients on the value of a particular technology or the likelihood of success in the market relative to competitors.

Israel Group News May 2021

1 May 2021
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

S 415, narrowing the scope of new chemical entities, is now law: Implications for innovator companies

29 April 2021
The new law, signed by the President on April 23, narrows the scope of drug compounds that qualify as an NCE.

FDA warning letters: More warnings and closer scrutiny of COVID-19 and vaping products

26 April 2021
A large percentage of warning letters concern adulterated, unapproved or misbranded products related to COVID-19, and e-cigarette companies continue to be in the agency's crosshairs for selling unapproved products.

Preliminary injunction granted in Cal Chamber lawsuit concerning acrylamide Prop 65 warning

1 April 2021

California's Eastern District federal court found that Prop 65's acrylamide warning requirement was likely unconstitutional and preliminarily enjoined new lawsuits alleging failure to warn for acrylamide exposure in food and beverages.

Patent eligibility in bioinformatics: Federal Circuit affirms rejection of computerized haplotype phasing claims

31 March 2021
Yet another hurdle for inventors in the growing field of bioinformatics and computational biology.

The Pharmaceutical Corner

30 March 2021
The opinion may render functional claiming more difficult, but functional claims that follow its guidance may still have an important role to play in pharmaceutical patents.

Understanding the USPTO guidance on patenting AI technologies

30 March 2021
The USPTO guidance opens the door for applicants to obtain patent protection for their AI technologies.

United States imposes significant new export controls and sanctions on Russia and China

23 March 2021

Reflecting a further hardening of US foreign policy and national security policy positions with those two countries.

California Prop 65: OEHHA proposes changing popular short-form warning

3 February 2021
Businesses selling products in California that utilize short-form Proposition 65 warnings may have to be re-label yet again or risk enforcement actions.

Expectations for white collar enforcement under the Biden Administration

18 February 2021
Six key areas where the Biden Administration may focus its enforcement efforts.

Corruption Perceptions Index 2020 - a regional perspective

11 February 2021

Last week Transparency International launched the 2020 edition of its Corruption Perceptions Index (CPI), which ranks 180 countries and territories by their perceived levels of public sector corruption, according to experts and business people, using a scale of zero to 100 (100 being very clean and zero being highly corrupt).

The Qualified Maquiladora Approach Agreement has been renewed: Implications for multinationals' transfer pricing

26 January 2021
US-based multinationals using the maquiladora structure to manufacture goods in Mexico are taking note.

Israel Group News January 2021

19 January 2021
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

No Surprises Act creates new model for commercial payors and providers

7 January 2021
The act contains consumer protection and transparency requirements that may fundamentally change health payor and provider operations.

Supporting the health of your health system

4 January 2021
Helping you tend to healthcare system wellness throughout the business life cycle.

Boardroom Brexit: What the deal means for business

31 December 2020
BOARDROOM BREXIT

Welcome to this last edition of Boardroom Brexit, marking the end of the negotiations and the agreement of a new trade deal, the UK-EU Trade and Cooperation Agreement (TCA). In this edition, we summarise the impact of the deal on all aspects of business operations in one place – please use the hyperlinks below to help you navigate the report.

Boardroom Brexit: What the deal means for trade in goods

31 December 2020
BOARDROOM BREXIT

What will the Trade and Cooperation Agreement mean for tariffs and quotas, rules of origin, technical barriers to trade, customs and product standards

Boardroom Brexit: What the deal means for trade in services

31 December 2020
BOARDROOM BREXIT

The TCA has substantial sectoral coverage, including professional and business services (e.g. legal, auditing, architectural services), delivery and telecommunication services, computer-related and digital services, financial services, research and development services, most transport services and environmental services.

The EEOC breaks its silence on the COVID-19 vaccine

22 December 2020
Some of the most important questions answered by the EEOC's guidance.

The Pharmaceutical Corner

22 December 2020
A precedential decision with potentially far-reaching impacts for future Hatch-Waxman litigation and generic-product launches.

Landmark artificial intelligence legislation advances toward becoming law

16 December 2020
AI OUTLOOK

An overview of the key AI initiatives and funding set out in the defense bill.

Navigating risk and compliance in government contracts M&A

14 December 2020
Webinar now available: government contracts and pre-closing diligence.

Silver linings for FCA defendants in new HHS Working Group

11 December 2020
The US Department of Health and Human Services is launching the Working Group to better protect taxpayer funds and deter "would-be fraudsters."

FDA seeks feedback on industry best practices for medical device cybersecurity communications

9 December 2020
The agency emphasizes the evolving responsibility of medical device manufacturers to promptly, clearly communicate cybersecurity issues to patients and healthcare providers.

CMS, OIG finalize Stark and AKS overhaul – paving the way for value-based care

25 November 2020
We highlight some of the most important ways in which HHS followed through on its ideas from 2019, as well as the instances where they pivoted in reaction to public comments.

HHS-OIG issues alert warning pharmaceutical and device manufacturers about the kickback risks of speaker programs

24 November 2020
Key details and takeaways.

The US Hemp Production Handbook

4 November 2020
A concise, high-level overview for businesses that are currently or are considering operating in this growing market.

Vaping and COVID-19: Plausibility and causality

26 October 2020
In a courtroom, assertions must be analyzed in the context of tort law.

China signs off on PRC Biosecurity Law: What this means for industry players in China

21 October 2020
The Biosecurity Law establishes a comprehensive framework replacing the current somewhat piecemeal legislation.

Germany’s New Foreign Direct Investments (FDI) Act took effect on 11 October 2020

19 October 2020
In addition to the intended amendments to the Foreign Trade and Payments Act Germany’s Federal Government on 20 May 2020 has decided on a bill that broadens the scope and the scrutiny with regard to foreign investments.

China Enforces Tax Collection on Employees Working for Chinese-invested Enterprises Overseas

16 October 2020
With the recent IIT reform in 2019, and the introduction of a number of implementation rules (particularly the tax policy on overseas income), it appears the China tax authorities are taking a harder stance on how overseas income derived by China tax residents will be taxed in China, starting with Chinese expatriates working for Chinese state-owned enterprises.

COVID-19 – Galvanising your business against supply chain and customer insolvency risk

7 October 2020
The risk of unforeseen counterparty customer or supplier financial distress and failure amidst the on-going challenges for businesses from COVID-19 means that pre-emptive legal and operational protections against the risk of heavy financial loss or business disruption from customer/supplier failure are more valuable than ever.

Israel Group News October 2020

7 October 2020
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

Mass layoffs and collective redundancies guide

6 October 2020
As COVID-19 continues to impact the global economy in unprecedented ways, companies that have had to scale back or shut down operations are bracing for what the next few months will bring, and what this means for their workforces. In this guide, we examine key considerations for employers looking to make permanent reductions in force across APAC.

Coronavirus Resource Center: Our global repository of insights and events

30 September 2020
A central repository for our reports and commentary on the legal and regulatory concerns arising from the pandemic.

New CFIUS regulations change mandatory filing requirements and increase the importance of US export controls

30 September 2020
The new rule modifies the criteria that trigger a mandatory filing with CFIUS, potentially subjecting more transactions to mandatory CFIUS review.

Philadelphia grows privacy capabilities with a new arrival

30 September 2020
Ronald Plesco, an internationally known information security and privacy lawyer, has joined our Philadelphia office.

The Pharmaceutical Corner

30 September 2020
In this inaugural column, we look at the implications of IPR and PGR proceedings in Hatch Waxman litigation.

California on the verge of instituting new deidentification requirements, broader research exemptions for health data

23 September 2020
AB 713 has an emergency clause that means it will go into immediate effect once the governor signs it.

Four years later, federal court upholds convictions but harshly criticizes off-label prosecutions

23 September 2020
The decision will likely draw attention both in the First Circuit and beyond.

Digital Therapeutics - evolution and entry into mainstream healthcare

18 September 2020
Research undertaken by DLA Piper's Life Sciences sector in conjunction with The Lawyer seeks to understand the current developments in the field of digital therapeutics, looking at key questions that need to be addressed if these products are to become mainstream components of health systems across the world.

PREP Act immunity: federal courts weigh in

4 September 2020
The decisions suggest PREP Act immunity may apply broadly to manufacturers but may be more limited for hospitals, nursing homes, healthcare providers and others.

Details of the second tranche of Hong Kong's Employment Support Scheme released

24 August 2020
On 18 August 2020 the Hong Kong government announced details surrounding the second tranche of the Employment Support Scheme. While the majority of the rules surrounding the second tranche remain largely the same as the first tranche, there are new penalties for employers who have fallen foul of a number of nebulous terms.

Release of exposure draft legislation for major reforms to Australia's Foreign Investment Framework

10 August 2020

Many governments around the world have been strengthening their laws relating to foreign investment. Australia is no exception to this development and has just released proposed sweeping reforms to its foreign investment regime. In this article, we provide a high level overview of the key proposed amendments and our thoughts on how some of those proposals are likely to affect foreign investment into Australia.

For the healthcare industry, seeking to incentivize restocking of elective surgery supplies may lead to civil and criminal risk

6 August 2020
Discounts and incentives may have unforeseen consequences under certain federal anti-bribery laws.

New Executive Order forecasts permanent telehealth funding changes

5 August 2020
The Order implies a possible mechanism for making telehealth changes in spite of statutory confines and signals to Congress to take further action to permanently expand telehealth access in the Medicare program.

Vlog series: How to raise equity capital during the Coronavirus pandemic (UK)

4 August 2020
The first half of 2020 has seen an unprecedented volume of activity by companies raising capital through follow-on equity offerings on the London Stock Exchange in response to the Coronavirus pandemic. There have been over 140 equity issues on the London Stock Exchange's main market or AIM since 20 March 2020 raising more than GBP14 billion.

HHS extends COVID-19 public health emergency declaration, preserving major Medicare changes (for now)

27 July 2020
The PHE declaration is an important prerequisite for certain major emergency measures the government has deployed to help address the pandemic.

Momentum builds for permanent expansions in federal telehealth policy

21 July 2020
Recent legislative proposals and administrative initiatives suggest that the federal government may be moving to make permanent certain emergency fixes to the telehealth regulatory landscape.

Hong Kong Government increases statutory entitlement for maternity leave

16 July 2020

On 10 October 2018, the Chief Executive stated in her policy address that the government proposed to increase the statutory maternity leave entitlement from ten to 14 weeks.

Israel Group News July 2020

8 July 2020

ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

The legal challenges facing the vaping industry in the EU/UK and the US: An overview and a look ahead

7 July 2020
Notes as the industry matures.

CMS proposed rule aims to encourage value based purchasing for drugs, now open for comment

6 July 2020
The rule is intended to spur the development of contractual arrangements between insurers and biopharma companies that rely on the observed value from medicines in exchange for payment.

PFAS: in California, regulators put cleanup levels on hold, but announce major data hunt

7 MAR 2019
This data hunt will affect thousands of facilities, drinking water systems and private drinking water well owners.

California Proposition 65 lists two chemicals, PFOA and PFOS, found in a number of consumer products

12 DEC 2018

Given Prop 65's active and litigious enforcers, companies doing business in California that suspect their products may cause an exposure to PFOA/PFOS should consider compliance options now.

California court's narrow Prop 65 coffee ruling should not be misinterpreted

9 APR 2018

A careful understanding of the narrow basis of the ruling is important for coffee consumers and for all manner of product-based companies doing business in California.

New glyphosate decision forces Prop 65 to reckon with federally accepted science

7 MAR 2018
This outcome will likely put wind in the sails of industry groups and individual companies challenging the science behind other Prop 65 listings.

Precarious steps: patent eligibility for healthcare IT

26 SEP 2016

Three recent Federal Circuit decisions, along with new updates from the USPTO, offer guidance on which steps to take in patenting

healthcare IT-related inventions.

Stop them in their tracks: key points in seeking a preliminary injunction against medical device infringers

22 SEP 2016

Three considerations to bear in mind when bringing or defending a preliminary injunction motion in a medical device infringement case.

Is your cybersecurity upgrade FDA reportable?

28 SEP 2016

Draft guidance lends insight into the way the FDA may apply existing postmarket regulatory requirements to evolving cybersecurity-related technological issues.

Supreme Court Corner: Q1 2016

29 MAR 2016
Two cases to watch.

Are IPRs impacting the pharmaceutical industry?

9 JUN 2015
Choosing between IPRs and district court litigation

Supreme Court Corner - Q1 2015

24 MAR 2015

Recent decisions and cases to watch

Intellectual Property and Technology News (United States), Issue 23, Q3 2014

10 SEP 2014

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS

Our Intellectual Property and Technology News reports on worldwide developments in IP and technology law, offering perspectives, analysis and visionary ideas.

Substitution allowed? State biosimilars laws are evolving

10 SEP 2014
Biosimilar products have not yet reached the US market, but debates on the laws and regulations that will govern them have been raging for some time

---

Supreme Court Corner - Q3 2014

10 SEP 2014
A review of cases relevant to IPT decided or argued before the Court during Q3

DOJ dismisses last of the drug trafficking charges against FedEx: two key takeaways

5 JUL 2016
A sudden about-face from the DOJ.

Ten tips for generating a life sciences brand name

19 NOV 2015

The proliferation of brands, combined with the PR and financial consequences of a potential rebrand in the event of infringement, has made selecting a trademark trickier than ever. Christina Martini and Virginia Wolk Marino report.

Distributing patent rights between affiliates: guidelines to support enforcement rights around the world

16 NOV 2015

Considering a few issues at the outset when rights are distributed between Parent and Affiliate (or between multiple affiliates) may avoid difficulties in the future when a company wants to enforce patent rights.

Wellness innovators take note: FDA reveals risk-based approaches to the regulation of health IT and mobile medical apps

2 FEB 2015

With these draft guidance documents, FDA indicates it will not take enforcement action in connection with low-risk general wellness products and establishes a new risk-based approach to medical device accessories

Revenue pressure climbs for skilled nursing facilities − what does this mean for healthcare REITs?

3 JUN 2015
Healthcare REITs must be mindful of the challenges they may face due to changes in the healthcare environment

SEC begins Dodd-Frank rulemaking with new open process

28 Jul 2010

EVENTOS

Reciente

FDLI Annual Conference

15 June 2022
Washington

Using AI to monitor your compliance risks

31 March 2022
Webinar

GSK v. Teva: Induced Infringement Liability the Fate of Section VIII Carve-Outs

9 November 2021 | 9:30 am - 10:30 am ET
New York

Food and Drug Law Journal 2021 Symposium

4 November 2021
Webinar

False Claims and *Qui Tam* Summit for Life Sciences and Healthcare

24 September 2021
Webinar

Embracing Digital Evolution

15 September 2021
Webinar

IP strategies and litigation for life sciences companies

25 May 2021 | 12:00 - 1:00 ET
Webinar

The current state of life sciences financing

2 March 2021 | 3:00 - 4:00 EST
Webinar

Communication and information sharing in support of healthcare for vulnerable populations

22 February 2021
Webinar

EDPB recommendations for safeguarding data transfers after Schrems II

19 November 2020
Webinar

Planning for an Uncertain World

16 November 2020
TECHLAW EVENT SERIES

Webinar

Women in Science and Technology Conference

29 October 2020 | 5:30 - 7:30 p.m. AST
Webinar

2020 BioHealth Capital Region Virtual Forum

19 October 2020 | 4:30 - 5:00 EDT
Webinar

Considerations for drug pricing and demonstrating value in a post-pandemic environment

5 August 2020 | 12:00 – 1:00 ET
Webinar

TechLaw

31 July 2020
TECHLAW EVENT SERIES

Webinar

NOTICIAS

DLA Piper partner Jessica Wilson named a *Law360* Life Sciences Rising Star

14 June 2022

DLA Piper is pleased to announce that partner Jessica Wilson has been named a 2022 *Law360* Life Sciences Rising Star.

DLA Piper advises CONMED Corporation in its US$145 million acquisition of In2Bones Global, Inc.

24 May 2022

DLA Piper advised CONMED Corporation (NYSE: CNMD) in its agreement to acquire privately-held In2Bones Global, Inc. (In2Bones), on a cash-free, debt-free basis, for cash consideration of US$145 million at closing. The deal also includes an additional US$110 million in growth-based earnout payments over a four-year period.

DLA Piper advises Aspen Neuroscience in its US$147.5 million Series B financing

18 May 2022

DLA Piper advised Aspen Neuroscience, a private biotechnology company developing autologous cell therapies, in the closing of its US$147.5 million Series B funding, which would go towards the clinical trials of company's first iPSC-derived autologous neuron replacement treatment for Parkinson's disease.

DLA Piper advises Philip Morris International Inc. on USD16 billion recommended cash offer for Swedish Match

12 May 2022
DLA Piper, as International Counsel, is advising Philip Morris Holland Holdings B.V., an Affiliate of Philip Morris International Inc. (PMI), on its USD16 billion recommended public offer to the shareholders of Swedish Match AB (Swedish Match), a public limited company with shares listed on Nasdaq Stockholm.

DLA Piper continues expansion of its Regulatory and Government Affairs practice with David Kopans in Washington, DC

6 May 2022

DLA Piper has added nationally regarded healthcare regulatory partner David Kopans in its Washington, DC office.

DLA Piper represents Intercept Pharmaceuticals, Inc. in US$450 million deal to sell Ocaliva to Advanz Pharma outside the US

6 May 2022

DLA Piper is representing Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT) – a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases – in its deal to sublicense to Advanz Pharma the rights to commercialize Ocaliva® (obeticholic acid) outside of the US, and sell certain foreign subsidiaries and rights regarding Intercept's international operations.

DLA Piper expands its Intellectual Property & Technology practice with the addition of Melissa Harwood, Ph.D. in Seattle

4 May 2022

DLA Piper is expanding its Intellectual Property & Technology practice with the arrival of Melissa Harwood as partner in the firm's Seattle office. Harwood will be part of the Intellectual Property & Technology practice's Patent Prosecution subgroup.

Bethany Hills joins DLA Piper's FDA Regulatory practice in New York

3 May 2022

DLA Piper continues the growth of its FDA Regulatory group with the arrival of Bethany Hills as a partner in the firm's New York office. Hills will join as vice chair of the FDA practice, working with co-chairs Geoff Levitt and Stefanie Fogel to support their rapid expansion of DLA Piper's FDA regulatory capabilities.

DLA Piper partner Jayme Long named to Los Angeles Business Journals 2022 Women of Influence

18 April 2022

DLA Piper is pleased to announce that Jayme Long, a partner in the firm's Litigation practice, has been named to the *Los Angeles Business Journal*s 2022 Women of Influence: Attorneys list.

DLA Piper advises Axsome Therapeutics in its acquisition of Sunosi from Jazz Pharmaceuticals

13 April 2022
DLA Piper represented Axsome Therapeutics in connection with its acquisition of Sunosi from Jazz Pharmaceuticals.

DLA Piper advises Linus Health on its acquisition of Kinesis Health Technologies

6 April 2022

DLA Piper has advised Boston-based digital health company Linus Health on its acquisition of Kinesis Health Technologies, a Dublin-based leader in physical function assessment for older adults.

DLA Piper advises Knopp Biosciences in the sale of its subsidiary, Channel Biosciences, to Biohaven

21 March 2022

DLA Piper represented Knopp Biosciences LLC as IP counsel in the sale of Knopp's subsidiary, Channel Biosciences LLC, and its Kv7 channel targeting platform for the treatment of epilepsy and other neurologic disorders, to Biohaven Pharmaceutical Holding Company Ltd. (NYSE: BHVN).

Leading IP strategists and renowned patent lawyers Raymond Miller, Nicole Endejann and Joseph Helmsen join DLA Piper's award-winning Intellectual Property and Technology practice and Life Sciences sector

24 January 2022
DLA Piper announced today that Raymond Miller, Nicole Endejann and Joseph Helmsen have joined the firm's industry-renowned Intellectual Property and Technology (IPT) practice and Life Sciences sector as partners. The team has worked together for nearly 20 years and has been recognized in the industry as among the 300 World Leading IP Strategists and among the World's 1000 best patent practitioners by IAM Media, the definitive resource that identifies world-class, private practice patent expertise.

DLA Piper announces new office and regional leadership

19 January 2022
DLA Piper is pleased to announce changes to its office leadership in Atlanta, Boston, New York, Northern Virginia, Philadelphia, San Francisco, San Juan, Seattle and Short Hills, as well as a change to its regional leadership in Northern California.

Christopher Halliday joins DLA Piper's Patent Prosecution practice and Life Sciences sector in Philadelphia

18 January 2022

DLA Piper announced today that Christopher Halliday has joined the firm's Patent Prosecution practice and Life Sciences sector as a partner in Philadelphia.

Campos Mello Advogados announces four new partners

8 December 2021
DLA Piper announced today the addition of four new partners at Campos Mello Advogados (CMA), which has a cooperation agreement with DLA Piper.

DLA Piper partners Jeff Baglio and Erin Gibson named to *San Diego Business Journal*'s 2021 Leaders in Law list

15 November 2021
DLA Piper is pleased to announce that partners Jeff Baglio and Erin Gibson have been named to the *San Diego Business Journal*s 2021 Leaders in Law list.

William Mulholland joins DLA Piper's Patent Prosecution practice in Phoenix

15 November 2021
DLA Piper announced today that William Mulholland has joined the firm's Patent Prosecution practice and Life Sciences sector as a partner in Phoenix.

DLA Piper advises underwriters in MDxHealth SA's IPO of American depository shares

5 November 2021
DLA Piper represented Piper Sandler & Co. and Oppenheimer & Co. as lead book-running managers in the US$45 million initial public offering of MDxHealth SA (Nasdaq and Euronext Brussels: MDXH) in the United States. The offering consisted of 37,500,000 ordinary shares of MDxHealth in the form of 3,750,000 American depository shares (ADSs) at a price of US$12.00 per ADS.

DLA Piper advises Agena Biosciences in its sale to Mesa Labs

27 October 2021
DLA Piper represented Agena Biosciences, Inc. in its sale to Mesa Labs (NASDAQ:MLAB), a global leader in the design and manufacturing of critical quality control solutions for the pharmaceutical, healthcare and medical device industries.

DLA Piper lawyers, practices and sectors ranked in latest edition of *The Legal 500 Latin America*

25 October 2021

DLA Piper today announced that the firm received 46 individual lawyer rankings and 68 firm rankings in The Legal 500 Latin America 2022 guide.

DLA Piper vice chair Loren Brown named to New York Law Journals 2021 Distinguished Leaders list

7 October 2021
DLA Piper is pleased to announce that Loren Brown, DLA Piper's US vice chair and chair of the US Disputes practice, has been named to the *New York Law Journal's* 2021 Distinguished Leaders list recognizing lawyers in leadership roles who achieved impressive results over the past year and "had great performances while demonstrating clear leadership skills leading to positive outcomes."

Ardith Bronson, Isabel De Obaldia and Rebecca Jones McKnight named to The American Lawyer's list of 2021 South Trailblazers

4 October 2021
DLA Piper is pleased to announce that Ardith Bronson, Irma Isabel De Obaldia and Rebecca Jones McKnight have been named to *The American Lawyer's* inaugural list of South Trailblazers. The list recognizes professionals in the South "who have moved the needle in the legal industry."

DLA Piper advises Kadmon Holdings in its acquisition by Sanofi

14 September 2021

DLA Piper is representing Kadmon Holdings, Inc. (NASDAQ: KDMN) in its pending acquisition by global biopharmaceutical company Sanofi S.A. (NASDAQ: SNY) for approximately US$1.9 billion.

DLA Piper partner Jeff Baglio named a 2021 BTI M&A Client Service All-Star

9 September 2021
DLA Piper is pleased to announce that BTI Consulting Group has recognized partner Jeff Baglio for providing superior service to clients in its 2021 BTI M&A Client Service All-Star report.

DLA Piper partner Lisa Haile named to *San Diego Business Journal*'s 2021 Women of Influence in Life Sciences list

30 August 2021
DLA Piper is pleased to announce that partner Dr. Lisa Haile has been named to the *San Diego Business Journal*'s 2021 Women of Influence in Life Sciences list.

DLA Piper advises Hinduja Global Solutions on USD1.2 billion sale of its healthcare business

11 August 2021
DLA Piper is advising Hinduja Global Solutions Limited (HGS) on the sale of its healthcare solutions business to Baring Private Equity Asia, in a transaction valued at USD1.2 billion subject to closing adjustments.

DLA Piper advises underwriters of MaxCyte's upsized US IPO

30 July 2021
DLA Piper represented Cowen and Company, LLC, Stifel, Nicolaus & Company, Incorporated and William Blair & Company, L.L.C., as underwriters in the initial US public offering of 13,500,000 shares of common stock of MaxCyte, Inc. (Nasdaq: MXCT) (LSE: MXCT, MXCN), a leading provider of cell-engineering platform technologies, at an initial offering price of US$13.00 per share.

DLA Piper advises 4G Clinical in US$230 million growth equity investment from Goldman Sachs Asset Management

19 July 2021
DLA Piper represented 4G Clinical in a growth equity investment of over US$230 million from Goldman Sachs Asset Management.

DLA Piper advises Cowen and Company, William Blair & Company, BTIG and Stephens Inc. as underwriters of Alpha Teknova IPO

12 July 2021
DLA Piper represented Cowen and Company, LLC, William Blair & Company, L.L.C., BTIG, LLC and Stephens Inc. as underwriters in the US$110.4 million initial public offering of Alpha Teknova, Inc.

DLA Piper advising PMI on its GBP1 billion competitive offer for Vectura Group plc

9 July 2021
DLA Piper is advising Philip Morris International (PMI) on its recommended public offer for Vectura Group plc, a public limited company whose shares are listed on the Official List of the London Stock Exchange (Vela). PMI's bid values Vectura at approximately GBP1 billion.

DLA Piper advises HUTCHMED on its Hong Kong IPO

8 July 2021
DLA Piper is advising global biopharmaceutical company HUTCHMED on its Hong Kong public offering. This will be the third listing for the company, following its first on London's AIM exchange and then NASDAQ in the US.

DLA Piper lawyers and practices ranked in latest edition of *The Legal 500*

17 June 2021
DLA Piper announced today that the firm received 42 individual lawyer rankings and 49 firm rankings in *The Legal 500 United States* 2021 guide.

DLA Piper partner Raymond Williams named a Distinguished Leader by the *Legal Intelligencer*

22 June 2021
DLA Piper is pleased to announce that Raymond Williams has been named to the *Legal Intelligencer*'s 2021 list of Distinguished Leaders.

Lauren Murdza named a 2021 Unsung Hero by the *Legal Intelligencer*

21 June 2021
DLA Piper is pleased to announce that Lauren Murdza, a partner in the Philadelphia office, was named a 2021 Unsung Hero by the *Legal Intelligencer* for her outstanding work counseling prominent life science clients related to COVID-19.

DLA Piper partners and firm COO named to *Law360* 2021 Editorial Advisory Boards

10 May 2021
DLA Piper is pleased to announce that 11 of its lawyers, as well as firm COO Bob Bratt, have been named to *Law360*s 2021 Editorial Advisory Boards.

DLA Piper advises SeaSpine Holdings Corporation in its US$101 million public offering

5 May 2021
DLA Piper represented SeaSpine Holdings Corporation in its recent public offering of 5,175,000 shares of its common stock at a price of $19.50 per share.

DLA Piper shortlisted for five *Mergermarket* North America M&A Awards

4 May 2021
DLA Piper is pleased to announce that it has been shortlisted for five *Mergermarket* North America M&A Awards.

DLA Piper advises Akoya Biosciences in its US$151 million initial public offering

3 May 2021
DLA Piper represented Akoya Biosciences, Inc. (Nasdaq: AKYA) in its recent initial public offering of 7,567,000 shares of its common stock at a price of $20 per share, including the exercise of the underwriters' option to purchase 987,000 shares of common stock, less underwriting discounts and commissions.

Leading trial lawyer Lyn Pruitt joins DLA Piper, along with Adria Conklin and Mary Catherine Way

25 March 2021
DLA Piper announced today that nationally recognized trial lawyer Lyn Pruitt has joined the firm's Litigation and Regulatory practice, along with Adria Conklin and Mary Catherine Way.

Geoffrey Levitt joins DLA Piper's Litigation and Regulatory practice as co-chair of Life Sciences Policy and Regulatory group

22 March 2021
DLA Piper announced today that Geoffrey Levitt has joined the firm's Litigation and Regulatory practice as co-chair of the Life Sciences Policy and Regulatory group.

DLA Piper advises Piper Sandler & Co. as placement agent in US$175 million PIPE for Alpha Healthcare Acquisition Corp.

2 March 2021
DLA Piper represented Piper Sandler & Co. as placement agent in a US$175 million private investment in public equity (PIPE) transaction for Alpha Healthcare Acquisition Corp.

DLA Piper advises Piper Sandler & Co. as sole book-running manager in connection with US$92 million common stock offering by Infinity Pharmaceuticals

2 March 2021
DLA Piper represented Piper Sandler & Co. as sole book-running manager in connection with the US$92 million public offering of common stock of Infinity Pharmaceuticals, a clinical-stage biotechnology company.

DLA Piper advises NuVasive in its acquisition of Simplify Medical

1 March 2021
DLA Piper represented NuVasive, Inc., in its recent acquisition of Simplify Medical, a privately held company and developer of the Simplify Cervical Artificial Disc for cervical total disc replacement (cTDR).

DLA Piper advises Haemonetics in its acquisition of Cardiva Medical

21 January 2021
DLA Piper represented Haemonetics Corporation (NYSE: HAE), a global medical technology company focused on delivering innovative medical solutions to drive better patient outcomes, in its acquisition of Cardiva Medical, Inc., an industry-leading manufacturer of vascular closure systems based in Santa Clara, California, for US$475 million at closing and up to an additional US$35 million in contingent consideration based on sales growth.

DLA Piper advises Histogen in its US$14 million upsized public offering

6 January 2021
DLA Piper advised Histogen, Inc., in its public offering of 11,600,000 shares of common stock, pre-funded warrants to purchase up to 2,400,000 shares of common stock and warrants to purchase up to an aggregate of 14,000,000 shares of common stock at a price of US$1.00 per share.

DLA Piper advises Arlington Capital Partners in majority investment in Everest Clinical Research Corporation

21 December 2020
DLA Piper represented Washington, DC-based private equity firm Arlington Capital Partners in its investment in Everest Clinical Research Corporation, a leading contract research organization providing a comprehensive suite of mission-critical clinical research services to the worldwide pharmaceutical, biotechnology and medical device industries across Phase I-IV trials.

DLA Piper advises Locanabio in its US$100 million Series B financing

15 December 2020
DLA Piper represented Locanabio, an RNA-targeting gene therapy company focused on developing life-changing therapies for patients with severe neurodegenerative, neuromuscular and retinal diseases, in its recent US$100 million Series B financing led by Vida Ventures.

DLA Piper advises Otsuka America Pharmaceutical in its purchase of the assets of Proteus Digital Health

26 August 2020
DLA Piper represented Otsuka America Pharmaceutical, Inc. in connection with its stalking horse bid to purchase substantially all of the assets of Proteus Digital Health, Inc., including its ingestible and wearable sensor technology.

Former Congressman Jim Greenwood joins DLA Piper as senior policy advisor, adding significant strength to growing life sciences policy and regulatory group

4 August 2020
DLA Piper announced today that former US Representative Jim Greenwood has joined the firm's Litigation and Regulatory practice as a senior policy advisor based in Washington, DC.

DLA Piper advises Liquidia in its acquisition of RareGen and its US$75 million follow-on offering

6 July 2020
DLA Piper represented Liquidia Technologies, Inc. in its acquisition of RareGen, LLC.

Sustainability and ESG

Sustainability and resilience are core business issues in the life sciences sector, given the sector's central role in addressing systemic global challenges including pandemics, access to medicine, and fundamental human rights. Although the specific factors from a sustainability, environmental, social and governance (SESG) perspective in the life science industry differ from those of other industries, creating new and sustainable value in the life science space will depend upon how companies address relevant SESG risks. Boards must actively identify such SESG risks and ensure that they are efficiently mitigated in order for their companies to avoid pitfalls and ensure compliance with evolving regulation around the globe – and also to maintain their competitive position and profitability.

On the basis of our experience in the sector, we believe the following sustainability-related themes to be the core SESG issues that will continue to affect life science businesses:

- **Access and affordability:** Addressing unmet healthcare needs, increasing access to affordable essential medicines and strengthening health systems around the world are all fundamental to social and economic progress. The coronavirus disease 2019 (COVID-19) has further highlighted the importance of the life sciences sector in addressing these challenges. Against this background, international life science business will need to engage in discussions about and develop strategies addressing these issues across the world, particularly with regard to improving the situation in lesser developed countries.
- **Supply chain compliance:** Many governments and regulators around the world are implementing tighter rules on supply chain compliance. To retain their license to operate, life sciences companies must adhere to an evolving set of global laws and regulations. Furthermore, transparency requirements, as well as responsibility and liability for global suppliers are increasing. This ongoing regulatory shift, and the increased likelihood of litigation which goes with it, will have a significant impact on the global life sciences industry. This is because supply chains are often particularly lengthy and complex and influenced by many different internal and external factors that are hard to monitor and control.
- **Product safety and quality:** Fake or substandard medicines lead to hundreds of thousands of deaths each year. Drug safety, along with protecting health consumers from counterfeit medicines and drug diversion, are integral to ensuring public health and maintaining trust and confidence in the life sciences sector. Consequently, life science companies will need to put increasing focus on ensuring product safety as well as maintaining secure distribution channels to patients.
- **Business ethics:** There is increasing stakeholder attention, including from regulators and policymakers and also from providers of capital, on transparency and ethics in business dealings with healthcare providers and medical practitioners for the sale and use of products, as well as in relation to lobbying and advocacy activities. The way in which businesses respond to these expectations can have a direct impact upon their reputation, their cost of capital and ultimately upon their license to operate.
- **Transparency and access in clinical trials:** Stakeholders increasingly expect transparency in clinical trials and wider access to trial data for scientific exchange and research. There is a bright spotlight on participant safety and privacy. Businesses are demanding more effective information sharing to enable informed decision-making and consent, along with post-trial access to results. Technology and collaborative partnerships with patient and health worker groups enable wider representative demographic populations to participate in clinical trials.

- **Sustainable sourcing, product lifecycles and a circular economy:** Markets demand greater visibility across product lifecycles, businesses make commitments to net-zero decarbonisation and business model innovation is driven by circular economy concepts. Underpinned by an increasingly complex transnational regulatory landscape, these developments are changing the way raw materials are sourced; how products are designed, manufactured, packaged, sold, reused or recycled; how waste and hazardous material is treated; and how wider environmental and social impacts relating to issues like emissions, plastics, water use, biodiversity loss, labour conditions and community impacts are managed.
- **Net-zero decarbonisation and optimisation of processes:** In striving to decarbonise the economy, businesses are implementing commitments to Science Based Targets, increasing energy efficiency and reducing carbon output, decreasing dependency on fossil fuels and increasing the use of renewables. The implementation of these initiatives is creating operational efficiencies, optimising the drug manufacturing, packaging and distribution process and reducing costs across the sector.

To discuss the implications of these issues for your business, please contact our ESG leaders.

DLA PIPER

Biotecnología

Las cuestiones jurídicas a que se enfrentan nuestros clientes de biotecnología son tan diversas como las habilidades que ponemos a su disposición. Nuestro equipo de biotecnología cuenta con abogados con conocimientos jurídicos, científicos y médicos que entienden la complejidad del negocio y del entorno reglamentario en el que operan nuestros clientes.

Los retos a los que se enfrentan hoy día las empresas biofarmacéuticas y de dispositivos médicos son mayores que nunca. Para que las empresas puedan llevar terapias prometedoras desde el laboratorio al mercado deben protegerlas de los riesgos de propiedad intelectual, reglamentarios y reputacionales. Además, en los últimos años hemos sido testigos de una presión cada vez mayor desde varios frentes, como son la demanda de más rentabilidad para los accionistas, la pérdida de fuentes de ingresos claves debido a la expiración de patentes u otros retos generales, la competencia feroz en áreas terapéuticas fundamentales, las presiones en los precios por parte de los financiadores del gasto sanitario , nueva regulación gubernamental que trasciende las cuestiones básicas de seguridad, el incremento de los costes de I+D, las dificultades para maximizar la rentabilidad en los mercados emergentes y la aplicación rigurosa de la normativa por parte de las autoridades.

Nuestro equipo del área de biotecnología es uno de los mayores y más activos en el mercado legal. Trabajamos como un único equipo, que cubre más de treinta países, combinando la experiencia en nuestra área de especialización con un amplio conocimiento del sector, incluyendo los entornos científico, médico, reglamentario, comercial y de cumplimiento a los que se enfrentan nuestros clientes de biofarmacia, dispositivos médicos y de sistemas de diagnóstico.

Nuestro equipo cuenta con abogados galardonados por su trayectoria en procesal, cumplimiento normativo e investigaciones, estrategia y tutela de propiedad intelectual, fusiones y adquisiciones, licencias y distribución, asesoramiento en ensayos clínicos, privacidad, externalización, derecho societario y defensa de la competencia. También asesoramos a nuestros clientes en todas las demás áreas necesarias para abordar cualquier riesgo con éxito, incluyendo las relaciones con la

administración, legislación medioambiental, importaciones / exportaciones, fiscalidad, Derecho inmobiliario y laboral. Muchos de nuestros abogados son antiguos profesionales del sector, otros muchos tienen doctorados en medicina u otros diplomas de posgrado en el campo de la biotecnología, y otros han ejercido previamente como funcionarios o fiscales.

Sabemos que las necesidades de nuestros clientes varían, por ello nuestros equipos se organizan y adaptan inmediatamente para ofrecer el mejor servicio al cliente, ya se trate de una gran empresa farmacéutica, una pyme de dispositivos médicos o una empresa biotecnológica en fase de desarrollo. Estos equipos están integrados por profesionales internacionales y locales para dar una respuesta eficiente a las demandas del mercado, tanto si se trata de una operación internacional, una investigación, la resolución de un conflicto o un proyecto transfronterizo.

Nuestros sistemas para determinar los abogados a cargo de cada proyecto, de elaboración de presupuestos y de facturación, creados específicamente para ayudar a los clientes globales de biotecnología, son de última generación y aseguran que nuestros equipos aportan el máximo valor añadido, además de conseguir óptimos resultados.

Nuestro equipo de biotecnología ayuda a los clientes a enfrentarse a sus retos cotidianos. Como ejemplos de nuestra experiencia cabe destacar:

- Realización de una delicada investigación en China.
- Negociación de un acuerdo complejo de distribución que incluía a varios países de Latinoamérica.
- Actuación como abogados a escala nacional en una acción colectiva por negligencia punible en EE. UU.
- Ayuda en la venta o adquisición de un gran activo empresarial.
- Asesoramiento en la implantación de legislación de transparencia o sobre el impacto de nueva legislación.
- Diseño de un plan de reducción de riesgos para un producto clave.
- Negociación de un importante contrato con una ONG global respecto a una vacuna.
- Asesoramiento en un ensayo clínico multijurisdiccional.
- Asesoramiento en reducción de plantillas en Europa.
- Apoyo a los responsables de conducta empresarial y cumplimiento normativo globales
- Externalización de funciones clave de I+D+I o TI.
- Diseño de una estrategia de propiedad intelectual para una nueva y prometedora terapia
- Negociación de un contrato de licencia y colaboración a escala mundial.
- Protección de un medicamento superventas en un litigio de patentes

NOVEDADES

Publicaciones

The rise of global telehealth

30 June 2022
AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Partners Kristi Kung and Greg Bodulovic discuss the rise of telehealth amid the COVID-19 pandemic, as well as advancements in technology aiming to address disparate access to healthcare globally.

Coming soon: a national security screening mechanism for outbound investments

28 June 2022
The US would not be alone in regulating outbound investment.

FDA Regulatory News and Trends

28 June 2022

Guidance coming to supplements industry on new dietary ingredients; approval rescinded for a cancer drug; program will seek new ways to sterilize devices.

Former BIO CEO Jim Greenwood: 1 million dead, $16 trillion in losses is our wake-up call on pandemic preparedness

7 June 2022

While biological events may be inevitable, their level of impact on our country is not.

Food and Beverage News and Trends

20 May 2022

FOOD AND BEVERAGE NEWS AND TRENDS

FDA warns about consumption of copycat products that contain THC; Canada tackles food fraud; Kansas enacts meat analog labeling law.

FDA continues CBD enforcement and ramps up delta-8 THC enforcement; agency focuses on youth-appealing products

19 May 2022

FDA has adopted a more aggressive enforcement strategy toward delta-8 THC than it has for CBD, and it is actively moving against products that carry significant risk of youth appeal.

FDA premarket approval and the use of “FDA Approved” claims

17 May 2022
When do products, facilities, labels, and claims require Formal Premarket Approval, and when do they not?

Global M&A Intelligence Report 2022

Updated: 29 June 2022
Our annual Global M&A Intelligence Report is based on an analysis of key deal terms in almost 5,000 private M&A transactions on which we have advised since 2015.

Israel Group News April 2022

28 April 2022

ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

Colombia is using AI to improve insolvency proceedings

22 April 2022

PANORAMA

Artificial intelligence creates a completely new experience for the interaction of the user with the insolvency system.

Advising the advisor: Tips for navigating the life sciences and regulatory environment

19 April 2022
AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Emilio Ragosa is joined by Kevin Sheridan, Joint Global Head of Healthcare Investment Banking at Jefferies LLC, to discuss the importance of advisors having an understanding of the life sciences industry.

What is a SPAC? The basics, when you are contemplating going public in 2022

6 April 2022
PANORAMA

Key developments and implications for Latin American companies.

The moral imperative: Balancing innovation, regulation and prescription drug availability

21 March 2022
AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Jim Greenwood and Geoff Levitt are joined by Peter Kolchinsky to discuss the importance of – and complications in - balancing biopharmaceutical innovation, industry regulations and prescription drug availability.

Incentivizing diverse representation in clinical trials

2 March 2022
AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Kirsten Axelsen and Sarah Schick are joined by Shazia Ahmad, Senior Director and Head of Patient and Physician Services at UBC, to discuss the importance of regulatory incentives to drive racial and ethnic diversity in clinical trials.

The beginning of the end: FDA details roadmap to terminating COVID-19 EUAs and enforcement policies for medical devices, PPE

2 March 2022
The webinar sought to prepare stakeholders for the upcoming transition back to normal operations by describing its expectations for the industry over the 180-day transition period.

US escalates its sanctions regime against Russia, targeting its financial system

28 February 2022
GLOBAL SANCTIONS ALERT

And additional measures are expected to be announced by the US and its allies in the coming days

---

Aiscension: an AI tool to ensure effective risk management by detecting anti-competitive practice

24 February 2022

Anti-competitive activity has been rife in companies for centuries and there are many who like to take the ostrich approach and bury their head in the sand. However, it is known that this approach to risk management is ineffective should the regulators come looking, and with fines of up to 10% of global turnover, it is a big risk to take.

New US sanctions in response to Russia's actions against Ukraine

23 February 2022
GLOBAL SANCTIONS ALERT

Additional sanctions are expected that will target Russia's financial, technology, and defense sectors.

Medicare audit? CMS expands ability to revoke for non-compliant billing

14 February 2022
These broad revisions provide CMS with greater revocation authority.

Telehealth's impact on low-income communities

24 January 2022
AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Shared from our Beyond the Curve podcast series

Ray Williams and Kirsten Axelsen are joined by Dr. Benson Hsu of the University of South Dakota Sanford School of Medicine for a frank discussion on disparities to engaging with telehealth and ways to better serve low income communities. Originally recorded on March 3, 2021.

Israel Group News January 2022

24 January 2022
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

US Department of Homeland Security seeks comments on implementation of Uyghur Forced Labor Prevention Act

24 January 2022
Considerations for US importers and entities with supply chains that may involve China.

2022 – a busy year for privacy legislation has already started

12 January 2022
Biometric privacy, cybersecurity standards and consumer protection are among the subjects of the bills.

A legal overview

4 January 2022

UNDERSTANDING THE UK NATIONAL SECURITY & INVESTMENT REGIME PODCAST

In episode 2 of our podcast series we discuss the legal context of the regime: how it will operate and the implications for businesses. In particular, the legislation - which comes into force today, 4 January - has wide reaching implications for M&A involving businesses or assets connected with the UK.

Supporting the health of your health system: 2022

3 January 2022

Helping you tend to healthcare system wellness throughout the business life cycle.

The crossroad of science and law

16 December 2021

AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Lucas Przymusinski and Raymond Williams are joined by Michael King, Vice President and Associate General Counsel at Jazz Pharmaceuticals, to discuss the benefits of medical and science backgrounds when litigating matters for pharmaceutical and medical device companies.

The Glasgow Climate Pact: What does it mean for Business?

23 November 2021

In this article, members of our Sustainability and ESG Steering Committee share their thoughts on eight key themes emerging from COP26 and what they mean for business.

Social media's impact on the life sciences industry

8 November 2021

AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Chris Campbell and Jody Rhodes are joined by Sarah Heineman, Senior Assistant General Counsel at Bayer, to discuss how social media affects the public's view of medicine and science.

Israel Group News October 2021

25 October 2021

ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

An interview with Aldersgate Funding

11 October 2021

In this podcast, DLA Piper partner Henry Quinlan interviews Jim Holding and Matthew Lo at Aldersgate Funding Limited, who shed some

light on the advantages of litigation and arbitration funding; the types of claims eligible for funding; the process of funding a case; and the jurisdictional constraints on this type of financing.

DLA Piper · Aldersgate Funding on how litigation funding can help your business

---

Understanding AI and its use in drug discovery

6 October 2021
AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

DLA Piper partners Ellen Scordino and Susan Krumplitsch are joined by Duane Valz, General Counsel of Insitro, to discuss how machine learning is being used to generate and leverage data for the development of better medicines.

FTC's Policy Statement on breach notifications in mobile health apps: a new, broad approach that may face legal challenge

27 September 2021
The Policy Statement highlights the FTC's intention to step up enforcement consistent with these broad new interpretations.

Can an AI system be named the inventor? In wake of EDVA decision, questions remain

23 September 2021
AI OUTLOOK

Artificial intelligence is notable among the new technologies posing fundamental questions about the viability of the inventor's oath.

The Hidden Cost of Price Control Policies with Kirsten Axelsen

15 September 2021

An interview with Kirsten Axelsen about what would change in biopharma if price controls were implemented.

President Biden announces new vaccination requirements – what private employers and federal contractors need to know

14 September 2021
Employers already struggling with a puzzling array of compliance challenges aimed at combating COVID-19 now face additional vaccination and testing requirements.

The Pharmaceutical Corner

September 2021
Teva v. Amicus is the first lawsuit to test the reach of the CREATES Act. Expect more.

New workplace sexual harassment laws passed – (some) Respect@Work recommendations become law

8 September 2021

After months of anticipation, the Australian Federal Government's Sex Discrimination and Fair Work (Respect at Work) Amendment Act 2021 has now passed both houses of Parliament. The amendment contains important reforms to address workplace sexual harassment.

---

mRNA Technology: A New Approach to Therapeutics

8 September 2021
AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Dr. Lisa Haile talks with Dr. Kathy Fernando about the study of mRNA and how COVID-19 catalyzed its advancement.

Electronic disclosures on mobile devices: CFPB to study

30 August 2021
As mobile devices have become the platform of choice for many consumers, the effective delivery of disclosures on those devices has become a key consideration for financial service providers.

Israel Group News August 2021

16 August 2021
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

The state of HealthTech and future opportunities

03 August 2021
TECHLAW PODCAST

Podcast 41 of our TechLaw podcast series sees David Bell, Director at Hampleton Partners, leading M&A and corporate finance consultancy for companies with technology at their core, and DLA Piper Partner, Mark O'Conor, engage in an exciting conversation on the current innovations in HealthTech, as well as a futuristic outlook on the industry. Key highlights include the benefits of software as a medical device, macro factors influencing innovation and investment opportunities. Join David and Mark at our fifth European Technology Summit on the 5th October 2021 where they will be resuming this conversation. Register at our fifth European Technology Summit on the 5th October 2021.

DLA Piper TechLaw Podcast Series · The state of HealthTech and future opportunities

---

Patent eligibility of diagnostic methods in Australia confirmed: *Ariosa Diagnostics, Inc v Sequenom, Inc* [2021] FCAFC 101

29 June 2021
For many years, the following question awaited judicial determination under Australian law: is a DNA-based diagnostic method patent eligible subject matter? The Full Court of the Federal Court of Australia has confirmed that diagnostic methods involving the practical application of "natural phenomena" can be patentable inventions in Australia.

The Pharmaceutical Corner

June 2021
We look at the underlying decision in *Immunex v. Sandoz* and the potential implications on pharma patent licensing strategies.

United States v. Arthrex: Where does the Supreme Court's decision leave the PTAB?

23 June 2021
If the APJs' appointment is unconstitutional, what is the appropriate remedy?

Global M&A Intelligence Report 2021

23 June 2021
Our annual Global M&A Intelligence Report is based on an analysis of key deal terms in over 3,200 private M&A transactions on which we advised since 2015.

Global corporate benchmarking group seeks inputs on corporate human rights standards

22 June 2021
Comments are requested by June 25, 2021.

Food and Beverage News and Trends

11 June 2021
FOOD AND BEVERAGE NEWS AND TRENDS

Supreme Court declines to act on vaping regulations, FDA proposes "common sense reform" for dietary supplements industry, USDA and CDC investigate Salmonella linked to chicken parts.

FDA solicits public comment on adding list of device materials to certain medical device labels

26 May 2021
The proposed change would apply to all medical devices that may be in contact with a patient long term.

Multi-jurisdiction guide for screening foreign investments

26 May 2021
The aim of this guide is not to substitute proper due diligence and specialized advice when conducting business, it will hopefully help the reader navigate the different FDI regimes. Particularly in this complex context and in view of the proliferation of new regimes, by explaining the key aspects of regimes including main issues to consider, thresholds and proceedings to take into consideration when investing in our globalized world.

Why I Lawyer: Q&A with Lisa Haile

18 May 2021
WHY I LAWYER

Having so many years in the industry has given me a deep understanding of the business of biopharma and provides me with a different perspective when I advise clients on the value of a particular technology or the likelihood of success in the market relative to competitors.

Israel Group News May 2021

1 May 2021

ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

S 415, narrowing the scope of new chemical entities, is now law: Implications for innovator companies

29 April 2021

The new law, signed by the President on April 23, narrows the scope of drug compounds that qualify as an NCE.

FDA warning letters: More warnings and closer scrutiny of COVID-19 and vaping products

26 April 2021

A large percentage of warning letters concern adulterated, unapproved or misbranded products related to COVID-19, and e-cigarette companies continue to be in the agency's crosshairs for selling unapproved products.

Preliminary injunction granted in Cal Chamber lawsuit concerning acrylamide Prop 65 warning

1 April 2021

California's Eastern District federal court found that Prop 65's acrylamide warning requirement was likely unconstitutional and preliminarily enjoined new lawsuits alleging failure to warn for acrylamide exposure in food and beverages.

Patent eligibility in bioinformatics: Federal Circuit affirms rejection of computerized haplotype phasing claims

31 March 2021

Yet another hurdle for inventors in the growing field of bioinformatics and computational biology.

The Pharmaceutical Corner

30 March 2021

The opinion may render functional claiming more difficult, but functional claims that follow its guidance may still have an important role to play in pharmaceutical patents.

Understanding the USPTO guidance on patenting AI technologies

30 March 2021

The USPTO guidance opens the door for applicants to obtain patent protection for their AI technologies.

United States imposes significant new export controls and sanctions on Russia and China

23 March 2021

Reflecting a further hardening of US foreign policy and national security policy positions with those two countries.

California Prop 65: OEHHA proposes changing popular short-form warning

3 February 2021
Businesses selling products in California that utilize short-form Proposition 65 warnings may have to be re-label yet again or risk enforcement actions.

Expectations for white collar enforcement under the Biden Administration

18 February 2021
Six key areas where the Biden Administration may focus its enforcement efforts.

Corruption Perceptions Index 2020 - a regional perspective

11 February 2021

Last week Transparency International launched the 2020 edition of its Corruption Perceptions Index (CPI), which ranks 180 countries and territories by their perceived levels of public sector corruption, according to experts and business people, using a scale of zero to 100 (100 being very clean and zero being highly corrupt).

The Qualified Maquiladora Approach Agreement has been renewed: Implications for multinationals' transfer pricing

26 January 2021
US-based multinationals using the maquiladora structure to manufacture goods in Mexico are taking note.

Israel Group News January 2021

19 January 2021
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

No Surprises Act creates new model for commercial payors and providers

7 January 2021
The act contains consumer protection and transparency requirements that may fundamentally change health payor and provider operations.

Supporting the health of your health system

4 January 2021
Helping you tend to healthcare system wellness throughout the business life cycle.

Boardroom Brexit: What the deal means for business

31 December 2020
BOARDROOM BREXIT

Welcome to this last edition of Boardroom Brexit, marking the end of the negotiations and the agreement of a new trade deal, the UK-EU Trade and Cooperation Agreement (TCA). In this edition, we summarise the impact of the deal on all aspects of business operations in one place – please use the hyperlinks below to help you navigate the report.

Boardroom Brexit: What the deal means for trade in goods

31 December 2020
BOARDROOM BREXIT

What will the Trade and Cooperation Agreement mean for tariffs and quotas, rules of origin, technical barriers to trade, customs and product standards

---

Boardroom Brexit: What the deal means for trade in services

31 December 2020
BOARDROOM BREXIT

The TCA has substantial sectoral coverage, including professional and business services (e.g. legal, auditing, architectural services), delivery and telecommunication services, computer-related and digital services, financial services, research and development services, most transport services and environmental services.

The EEOC breaks its silence on the COVID-19 vaccine

22 December 2020
Some of the most important questions answered by the EEOC's guidance.

The Pharmaceutical Corner

22 December 2020
A precedential decision with potentially far-reaching impacts for future Hatch-Waxman litigation and generic-product launches.

Landmark artificial intelligence legislation advances toward becoming law

16 December 2020
AI OUTLOOK

An overview of the key AI initiatives and funding set out in the defense bill.

Navigating risk and compliance in government contracts M&A

14 December 2020
Webinar now available: government contracts and pre-closing diligence.

Silver linings for FCA defendants in new HHS Working Group

11 December 2020
The US Department of Health and Human Services is launching the Working Group to better protect taxpayer funds and deter "would-be fraudsters."

FDA seeks feedback on industry best practices for medical device cybersecurity communications

9 December 2020
The agency emphasizes the evolving responsibility of medical device manufacturers to promptly, clearly communicate cybersecurity issues to patients and healthcare providers.

CMS, OIG finalize Stark and AKS overhaul – paving the way for value-based care

25 November 2020
We highlight some of the most important ways in which HHS followed through on its ideas from 2019, as well as the instances where they pivoted in reaction to public comments.

HHS-OIG issues alert warning pharmaceutical and device manufacturers about the kickback risks of speaker programs

24 November 2020
Key details and takeaways.

The US Hemp Production Handbook

4 November 2020
A concise, high-level overview for businesses that are currently or are considering operating in this growing market.

Vaping and COVID-19: Plausibility and causality

26 October 2020
In a courtroom, assertions must be analyzed in the context of tort law.

China signs off on PRC Biosecurity Law: What this means for industry players in China

21 October 2020
The Biosecurity Law establishes a comprehensive framework replacing the current somewhat piecemeal legislation.

Germany’s New Foreign Direct Investments (FDI) Act took effect on 11 October 2020

19 October 2020
In addition to the intended amendments to the Foreign Trade and Payments Act Germany’s Federal Government on 20 May 2020 has decided on a bill that broadens the scope and the scrutiny with regard to foreign investments.

China Enforces Tax Collection on Employees Working for Chinese-invested Enterprises Overseas

16 October 2020
With the recent IIT reform in 2019, and the introduction of a number of implementation rules (particularly the tax policy on overseas income), it appears the China tax authorities are taking a harder stance on how overseas income derived by China tax residents will be taxed in China, starting with Chinese expatriates working for Chinese state-owned enterprises.

COVID-19 – Galvanising your business against supply chain and customer insolvency risk

7 October 2020
The risk of unforeseen counterparty customer or supplier financial distress and failure amidst the on-going challenges for businesses from COVID-19 means that pre-emptive legal and operational protections against the risk of heavy financial loss or business disruption from customer/supplier failure are more valuable than ever.

Israel Group News October 2020

7 October 2020
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

Mass layoffs and collective redundancies guide

6 October 2020
As COVID-19 continues to impact the global economy in unprecedented ways, companies that have had to scale back or shut down operations are bracing for what the next few months will bring, and what this means for their workforces. In this guide, we examine key considerations for employers looking to make permanent reductions in force across APAC.

Coronavirus Resource Center: Our global repository of insights and events

30 September 2020
A central repository for our reports and commentary on the legal and regulatory concerns arising from the pandemic.

New CFIUS regulations change mandatory filing requirements and increase the importance of US export controls

30 September 2020
The new rule modifies the criteria that trigger a mandatory filing with CFIUS, potentially subjecting more transactions to mandatory CFIUS review.

Philadelphia grows privacy capabilities with a new arrival

30 September 2020
Ronald Plesco, an internationally known information security and privacy lawyer, has joined our Philadelphia office.

The Pharmaceutical Corner

30 September 2020
In this inaugural column, we look at the implications of IPR and PGR proceedings in Hatch Waxman litigation.

California on the verge of instituting new deidentification requirements, broader research exemptions for health data

23 September 2020
AB 713 has an emergency clause that means it will go into immediate effect once the governor signs it.

Four years later, federal court upholds convictions but harshly criticizes off-label prosecutions

23 September 2020
The decision will likely draw attention both in the First Circuit and beyond.

Digital Therapeutics - evolution and entry into mainstream healthcare

18 September 2020
Research undertaken by DLA Piper's Life Sciences sector in conjunction with The Lawyer seeks to understand the current developments in the field of digital therapeutics, looking at key questions that need to be addressed if these products are to become mainstream components of health systems across the world.

PREP Act immunity: federal courts weigh in

4 September 2020
The decisions suggest PREP Act immunity may apply broadly to manufacturers but may be more limited for hospitals, nursing homes, healthcare providers and others.

Details of the second tranche of Hong Kong’s Employment Support Scheme released

24 August 2020
On 18 August 2020 the Hong Kong government announced details surrounding the second tranche of the Employment Support Scheme. While the majority of the rules surrounding the second tranche remain largely the same as the first tranche, there are new penalties for employers who have fallen foul of a number of nebulous terms.

Release of exposure draft legislation for major reforms to Australia’s Foreign Investment Framework

10 August 2020

Many governments around the world have been strengthening their laws relating to foreign investment. Australia is no exception to this development and has just released proposed sweeping reforms to its foreign investment regime. In this article, we provide a high level overview of the key proposed amendments and our thoughts on how some of those proposals are likely to affect foreign investment into Australia.

For the healthcare industry, seeking to incentivize restocking of elective surgery supplies may lead to civil and criminal risk

6 August 2020
Discounts and incentives may have unforeseen consequences under certain federal anti-bribery laws.

New Executive Order forecasts permanent telehealth funding changes

5 August 2020
The Order implies a possible mechanism for making telehealth changes in spite of statutory confines and signals to Congress to take further action to permanently expand telehealth access in the Medicare program.

Vlog series: How to raise equity capital during the Coronavirus pandemic (UK)

4 August 2020
The first half of 2020 has seen an unprecedented volume of activity by companies raising capital through follow-on equity offerings on the London Stock Exchange in response to the Coronavirus pandemic. There have been over 140 equity issues on the London Stock Exchange's main market or AIM since 20 March 2020 raising more than GBP14 billion.

HHS extends COVID-19 public health emergency declaration, preserving major Medicare changes (for now)

27 July 2020
The PHE declaration is an important prerequisite for certain major emergency measures the government has deployed to help address the pandemic.

Momentum builds for permanent expansions in federal telehealth policy

21 July 2020
Recent legislative proposals and administrative initiatives suggest that the federal government may be moving to make permanent certain emergency fixes to the telehealth regulatory landscape.

Hong Kong Government increases statutory entitlement for maternity leave

16 July 2020

On 10 October 2018, the Chief Executive stated in her policy address that the government proposed to increase the statutory maternity leave entitlement from ten to 14 weeks.

Israel Group News July 2020

8 July 2020
ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, recent events and more.

The legal challenges facing the vaping industry in the EU/UK and the US: An overview and a look ahead

7 July 2020
Notes as the industry matures.

CMS proposed rule aims to encourage value based purchasing for drugs, now open for comment

6 July 2020
The rule is intended to spur the development of contractual arrangements between insurers and biopharma companies that rely on the observed value from medicines in exchange for payment.

PFAS: in California, regulators put cleanup levels on hold, but announce major data hunt

7 MAR 2019
This data hunt will affect thousands of facilities, drinking water systems and private drinking water well owners.

California Proposition 65 lists two chemicals, PFOA and PFOS, found in a number of consumer products

12 DEC 2018

Given Prop 65's active and litigious enforcers, companies doing business in California that suspect their products may cause an exposure to PFOA/PFOS should consider compliance options now.

California court's narrow Prop 65 coffee ruling should not be misinterpreted

9 APR 2018

A careful understanding of the narrow basis of the ruling is important for coffee consumers and for all manner of product-based companies doing business in California.

New glyphosate decision forces Prop 65 to reckon with federally accepted science

7 MAR 2018
This outcome will likely put wind in the sails of industry groups and individual companies challenging the science behind other Prop 65 listings.

Precarious steps: patent eligibility for healthcare IT

26 SEP 2016

Three recent Federal Circuit decisions, along with new updates from the USPTO, offer guidance on which steps to take in patenting healthcare IT-related inventions.

Stop them in their tracks: key points in seeking a preliminary injunction against medical device infringers

22 SEP 2016

Three considerations to bear in mind when bringing or defending a preliminary injunction motion in a medical device infringement case.

Is your cybersecurity upgrade FDA reportable?

28 SEP 2016

Draft guidance lends insight into the way the FDA may apply existing postmarket regulatory requirements to evolving cybersecurity-related technological issues.

Supreme Court Corner: Q1 2016

29 MAR 2016
Two cases to watch.

Are IPRs impacting the pharmaceutical industry?

9 JUN 2015
Choosing between IPRs and district court litigation

Supreme Court Corner - Q1 2015

24 MAR 2015

Recent decisions and cases to watch

Intellectual Property and Technology News (United States), Issue 23, Q3 2014

10 SEP 2014

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS

Our Intellectual Property and Technology News reports on worldwide developments in IP and technology law, offering perspectives, analysis and visionary ideas.

Substitution allowed? State biosimilars laws are evolving

10 SEP 2014
Biosimilar products have not yet reached the US market, but debates on the laws and regulations that will govern them have been raging for some time

---

Supreme Court Corner - Q3 2014

10 SEP 2014
A review of cases relevant to IPT decided or argued before the Court during Q3

DOJ dismisses last of the drug trafficking charges against FedEx: two key takeaways

5 JUL 2016
A sudden about-face from the DOJ.

Ten tips for generating a life sciences brand name

19 NOV 2015

The proliferation of brands, combined with the PR and financial consequences of a potential rebrand in the event of infringement, has made selecting a trademark trickier than ever. Christina Martini and Virginia Wolk Marino report.

Distributing patent rights between affiliates: guidelines to support enforcement rights around the world

16 NOV 2015

Considering a few issues at the outset when rights are distributed between Parent and Affiliate (or between multiple affiliates) may avoid difficulties in the future when a company wants to enforce patent rights.

Wellness innovators take note: FDA reveals risk-based approaches to the regulation of health IT and mobile medical apps

2 FEB 2015

With these draft guidance documents, FDA indicates it will not take enforcement action in connection with low-risk general wellness products and establishes a new risk-based approach to medical device accessories

---

Revenue pressure climbs for skilled nursing facilities − what does this mean for healthcare REITs?

3 JUN 2015
Healthcare REITs must be mindful of the challenges they may face due to changes in the healthcare environment

---

SEC begins Dodd-Frank rulemaking with new open process

28 Jul 2010

EVENTOS

Reciente

FDLI Annual Conference

15 June 2022
Washington

Using AI to monitor your compliance risks

31 March 2022
Webinar

GSK v. Teva: Induced Infringement Liability the Fate of Section VIII Carve-Outs

9 November 2021 | 9:30 am - 10:30 am ET
New York

***Food and Drug Law Journal* 2021 Symposium**

4 November 2021
Webinar

False Claims and *Qui Tam* Summit for Life Sciences and Healthcare

24 September 2021
Webinar

Embracing Digital Evolution

15 September 2021
Webinar

IP strategies and litigation for life sciences companies

25 May 2021 | 12:00 - 1:00 ET
Webinar

The current state of life sciences financing

2 March 2021 | 3:00 - 4:00 EST
Webinar

Communication and information sharing in support of healthcare for vulnerable populations

22 February 2021
Webinar

EDPB recommendations for safeguarding data transfers after Schrems II

19 November 2020
Webinar

Planning for an Uncertain World

16 November 2020
TECHLAW EVENT SERIES

Webinar

Women in Science and Technology Conference

29 October 2020 | 5:30 - 7:30 p.m. AST
Webinar

2020 BioHealth Capital Region Virtual Forum

19 October 2020 | 4:30 - 5:00 EDT
Webinar

Considerations for drug pricing and demonstrating value in a post-pandemic environment

5 August 2020 | 12:00 – 1:00 ET
Webinar

TechLaw

31 July 2020
TECHLAW EVENT SERIES

Webinar

NOTICIAS

DLA Piper partner Jessica Wilson named a *Law360* Life Sciences Rising Star

14 June 2022

DLA Piper is pleased to announce that partner Jessica Wilson has been named a 2022 *Law360* Life Sciences Rising Star.

DLA Piper advises CONMED Corporation in its US$145 million acquisition of In2Bones Global, Inc.

24 May 2022

DLA Piper advised CONMED Corporation (NYSE: CNMD) in its agreement to acquire privately-held In2Bones Global, Inc. (In2Bones), on a cash-free, debt-free basis, for cash consideration of US$145 million at closing. The deal also includes an additional US$110 million in growth-based earnout payments over a four-year period.

DLA Piper advises Aspen Neuroscience in its US$147.5 million Series B financing

18 May 2022

DLA Piper advised Aspen Neuroscience, a private biotechnology company developing autologous cell therapies, in the closing of its US$147.5 million Series B funding, which would go towards the clinical trials of company's first iPSC-derived autologous neuron replacement treatment for Parkinson's disease.

DLA Piper advises Philip Morris International Inc. on USD16 billion recommended cash offer for Swedish Match

12 May 2022
DLA Piper, as International Counsel, is advising Philip Morris Holland Holdings B.V., an Affiliate of Philip Morris International Inc. (PMI), on its USD16 billion recommended public offer to the shareholders of Swedish Match AB (Swedish Match), a public limited company with shares listed on Nasdaq Stockholm.

DLA Piper continues expansion of its Regulatory and Government Affairs practice with David Kopans in Washington, DC

6 May 2022

DLA Piper has added nationally regarded healthcare regulatory partner David Kopans in its Washington, DC office.

DLA Piper represents Intercept Pharmaceuticals, Inc. in US$450 million deal to sell Ocaliva to Advanz Pharma outside the US

6 May 2022

DLA Piper is representing Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT) – a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases – in its deal to sublicense to Advanz Pharma the rights to commercialize Ocaliva® (obeticholic acid) outside of the US, and sell certain foreign subsidiaries and rights regarding Intercept's international operations.

DLA Piper expands its Intellectual Property & Technology practice with the addition of Melissa Harwood, Ph.D. in Seattle

4 May 2022

DLA Piper is expanding its Intellectual Property & Technology practice with the arrival of Melissa Harwood as partner in the firm's Seattle office. Harwood will be part of the Intellectual Property & Technology practice's Patent Prosecution subgroup.

Bethany Hills joins DLA Piper's FDA Regulatory practice in New York

3 May 2022

DLA Piper continues the growth of its FDA Regulatory group with the arrival of Bethany Hills as a partner in the firm's New York office. Hills

will join as vice chair of the FDA practice, working with co-chairs Geoff Levitt and Stefanie Fogel to support their rapid expansion of DLA Piper's FDA regulatory capabilities.

DLA Piper partner Jayme Long named to Los Angeles Business Journals 2022 Women of Influence

18 April 2022

DLA Piper is pleased to announce that Jayme Long, a partner in the firm's Litigation practice, has been named to the *Los Angeles Business Journal*s 2022 Women of Influence: Attorneys list.

DLA Piper advises Axsome Therapeutics in its acquisition of Sunosi from Jazz Pharmaceuticals

13 April 2022
DLA Piper represented Axsome Therapeutics in connection with its acquisition of Sunosi from Jazz Pharmaceuticals.

DLA Piper advises Linus Health on its acquisition of Kinesis Health Technologies

6 April 2022

DLA Piper has advised Boston-based digital health company Linus Health on its acquisition of Kinesis Health Technologies, a Dublin-based leader in physical function assessment for older adults.

DLA Piper advises Knopp Biosciences in the sale of its subsidiary, Channel Biosciences, to Biohaven

21 March 2022

DLA Piper represented Knopp Biosciences LLC as IP counsel in the sale of Knopp's subsidiary, Channel Biosciences LLC, and its Kv7 channel targeting platform for the treatment of epilepsy and other neurologic disorders, to Biohaven Pharmaceutical Holding Company Ltd. (NYSE: BHVN).

Leading IP strategists and renowned patent lawyers Raymond Miller, Nicole Endejann and Joseph Helmsen join DLA Piper's award-winning Intellectual Property and Technology practice and Life Sciences sector

24 January 2022
DLA Piper announced today that Raymond Miller, Nicole Endejann and Joseph Helmsen have joined the firm's industry-renowned Intellectual Property and Technology (IPT) practice and Life Sciences sector as partners. The team has worked together for nearly 20 years and has been recognized in the industry as among the 300 World Leading IP Strategists and among the World's 1000 best patent practitioners by IAM Media, the definitive resource that identifies world-class, private practice patent expertise.

DLA Piper announces new office and regional leadership

19 January 2022
DLA Piper is pleased to announce changes to its office leadership in Atlanta, Boston, New York, Northern Virginia, Philadelphia, San Francisco, San Juan, Seattle and Short Hills, as well as a change to its regional leadership in Northern California.

Christopher Halliday joins DLA Piper's Patent Prosecution practice and Life Sciences sector in Philadelphia

18 January 2022

DLA Piper announced today that Christopher Halliday has joined the firm's Patent Prosecution practice and Life Sciences sector as a partner in Philadelphia.

Campos Mello Advogados announces four new partners

8 December 2021
DLA Piper announced today the addition of four new partners at Campos Mello Advogados (CMA), which has a cooperation agreement with DLA Piper.

DLA Piper partners Jeff Baglio and Erin Gibson named to *San Diego Business Journal*'s 2021 Leaders in Law list

15 November 2021
DLA Piper is pleased to announce that partners Jeff Baglio and Erin Gibson have been named to the *San Diego Business Journal*s 2021 Leaders in Law list.

William Mulholland joins DLA Piper's Patent Prosecution practice in Phoenix

15 November 2021
DLA Piper announced today that William Mulholland has joined the firm's Patent Prosecution practice and Life Sciences sector as a partner in Phoenix.

DLA Piper advises underwriters in MDxHealth SA's IPO of American depository shares

5 November 2021
DLA Piper represented Piper Sandler & Co. and Oppenheimer & Co. as lead book-running managers in the US$45 million initial public offering of MDxHealth SA (Nasdaq and Euronext Brussels: MDXH) in the United States. The offering consisted of 37,500,000 ordinary shares of MDxHealth in the form of 3,750,000 American depository shares (ADSs) at a price of US$12.00 per ADS.

DLA Piper advises Agena Biosciences in its sale to Mesa Labs

27 October 2021
DLA Piper represented Agena Biosciences, Inc. in its sale to Mesa Labs (NASDAQ:MLAB), a global leader in the design and manufacturing of critical quality control solutions for the pharmaceutical, healthcare and medical device industries.

DLA Piper lawyers, practices and sectors ranked in latest edition of *The Legal 500 Latin America*

25 October 2021
DLA Piper today announced that the firm received 46 individual lawyer rankings and 68 firm rankings in The Legal 500 Latin America 2022 guide.

DLA Piper vice chair Loren Brown named to New York Law Journals 2021 Distinguished Leaders list

7 October 2021
DLA Piper is pleased to announce that Loren Brown, DLA Piper's US vice chair and chair of the US Disputes practice, has been named to the *New York Law Journal's* 2021 Distinguished Leaders list recognizing lawyers in leadership roles who achieved impressive results over the past year and "had great performances while demonstrating clear leadership skills leading to positive outcomes."

Ardith Bronson, Isabel De Obaldia and Rebecca Jones McKnight named to The American Lawyer's list of 2021 South Trailblazers

4 October 2021
DLA Piper is pleased to announce that Ardith Bronson, Irma Isabel De Obaldia and Rebecca Jones McKnight have been named to *The American Lawyer's* inaugural list of South Trailblazers. The list recognizes professionals in the South "who have moved the needle in the legal industry."

DLA Piper advises Kadmon Holdings in its acquisition by Sanofi

14 September 2021

DLA Piper is representing Kadmon Holdings, Inc. (NASDAQ: KDMN) in its pending acquisition by global biopharmaceutical company Sanofi S.A. (NASDAQ: SNY) for approximately US$1.9 billion.

DLA Piper partner Jeff Baglio named a 2021 BTI M&A Client Service All-Star

9 September 2021
DLA Piper is pleased to announce that BTI Consulting Group has recognized partner Jeff Baglio for providing superior service to clients in its 2021 BTI M&A Client Service All-Star report.

DLA Piper partner Lisa Haile named to *San Diego Business Journal*'s 2021 Women of Influence in Life Sciences list

30 August 2021
DLA Piper is pleased to announce that partner Dr. Lisa Haile has been named to the *San Diego Business Journal*'s 2021 Women of Influence in Life Sciences list.

DLA Piper advises Hinduja Global Solutions on USD1.2 billion sale of its healthcare business

11 August 2021
DLA Piper is advising Hinduja Global Solutions Limited (HGS) on the sale of its healthcare solutions business to Baring Private Equity Asia, in a transaction valued at USD1.2 billion subject to closing adjustments.

DLA Piper advises underwriters of MaxCyte's upsized US IPO

30 July 2021
DLA Piper represented Cowen and Company, LLC, Stifel, Nicolaus & Company, Incorporated and William Blair & Company, L.L.C., as underwriters in the initial US public offering of 13,500,000 shares of common stock of MaxCyte, Inc. (Nasdaq: MXCT) (LSE: MXCT, MXCN), a leading provider of cell-engineering platform technologies, at an initial offering price of US$13.00 per share.

DLA Piper advises 4G Clinical in US$230 million growth equity investment from Goldman Sachs Asset Management

19 July 2021
DLA Piper represented 4G Clinical in a growth equity investment of over US$230 million from Goldman Sachs Asset Management.

DLA Piper advises Cowen and Company, William Blair & Company, BTIG and Stephens Inc. as underwriters of Alpha Teknova IPO

12 July 2021
DLA Piper represented Cowen and Company, LLC, William Blair & Company, L.L.C., BTIG, LLC and Stephens Inc. as underwriters in the US$110.4 million initial public offering of Alpha Teknova, Inc.

DLA Piper advising PMI on its GBP1 billion competitive offer for Vectura Group plc

9 July 2021
DLA Piper is advising Philip Morris International (PMI) on its recommended public offer for Vectura Group plc, a public limited company whose shares are listed on the Official List of the London Stock Exchange (Vela). PMI's bid values Vectura at approximately GBP1 billion.

DLA Piper advises HUTCHMED on its Hong Kong IPO

8 July 2021
DLA Piper is advising global biopharmaceutical company HUTCHMED on its Hong Kong public offering. This will be the third listing for the company, following its first on London's AIM exchange and then NASDAQ in the US.

DLA Piper lawyers and practices ranked in latest edition of *The Legal 500*

17 June 2021
DLA Piper announced today that the firm received 42 individual lawyer rankings and 49 firm rankings in *The Legal 500 United States* 2021 guide.

DLA Piper partner Raymond Williams named a Distinguished Leader by the *Legal Intelligencer*

22 June 2021
DLA Piper is pleased to announce that Raymond Williams has been named to the *Legal Intelligencer*'s 2021 list of Distinguished Leaders.

Lauren Murdza named a 2021 Unsung Hero by the *Legal Intelligencer*

21 June 2021
DLA Piper is pleased to announce that Lauren Murdza, a partner in the Philadelphia office, was named a 2021 Unsung Hero by the *Legal Intelligencer* for her outstanding work counseling prominent life science clients related to COVID-19.

DLA Piper partners and firm COO named to *Law360* 2021 Editorial Advisory Boards

10 May 2021
DLA Piper is pleased to announce that 11 of its lawyers, as well as firm COO Bob Bratt, have been named to *Law360*s 2021 Editorial Advisory Boards.

DLA Piper advises SeaSpine Holdings Corporation in its US$101 million public offering

5 May 2021
DLA Piper represented SeaSpine Holdings Corporation in its recent public offering of 5,175,000 shares of its common stock at a price of $19.50 per share.

DLA Piper shortlisted for five *Mergermarket* North America M&A Awards

4 May 2021
DLA Piper is pleased to announce that it has been shortlisted for five *Mergermarket* North America M&A Awards.

DLA Piper advises Akoya Biosciences in its US$151 million initial public offering

3 May 2021
DLA Piper represented Akoya Biosciences, Inc. (Nasdaq: AKYA) in its recent initial public offering of 7,567,000 shares of its common stock at a price of $20 per share, including the exercise of the underwriters' option to purchase 987,000 shares of common stock, less underwriting discounts and commissions.

Leading trial lawyer Lyn Pruitt joins DLA Piper, along with Adria Conklin and Mary Catherine Way

25 March 2021
DLA Piper announced today that nationally recognized trial lawyer Lyn Pruitt has joined the firm's Litigation and Regulatory practice, along with Adria Conklin and Mary Catherine Way.

Geoffrey Levitt joins DLA Piper's Litigation and Regulatory practice as co-chair of Life Sciences Policy and Regulatory group

22 March 2021
DLA Piper announced today that Geoffrey Levitt has joined the firm's Litigation and Regulatory practice as co-chair of the Life Sciences Policy and Regulatory group.

DLA Piper advises Piper Sandler & Co. as placement agent in US$175 million PIPE for Alpha Healthcare Acquisition Corp.

2 March 2021
DLA Piper represented Piper Sandler & Co. as placement agent in a US$175 million private investment in public equity (PIPE) transaction for Alpha Healthcare Acquisition Corp.

DLA Piper advises Piper Sandler & Co. as sole book-running manager in connection with US$92 million common stock offering by Infinity Pharmaceuticals

2 March 2021
DLA Piper represented Piper Sandler & Co. as sole book-running manager in connection with the US$92 million public offering of common stock of Infinity Pharmaceuticals, a clinical-stage biotechnology company.

DLA Piper advises NuVasive in its acquisition of Simplify Medical

1 March 2021
DLA Piper represented NuVasive, Inc., in its recent acquisition of Simplify Medical, a privately held company and developer of the Simplify Cervical Artificial Disc for cervical total disc replacement (cTDR).

DLA Piper advises Haemonetics in its acquisition of Cardiva Medical

21 January 2021
DLA Piper represented Haemonetics Corporation (NYSE: HAE), a global medical technology company focused on delivering innovative medical solutions to drive better patient outcomes, in its acquisition of Cardiva Medical, Inc., an industry-leading manufacturer of vascular closure systems based in Santa Clara, California, for US$475 million at closing and up to an additional US$35 million in contingent consideration based on sales growth.

DLA Piper advises Histogen in its US$14 million upsized public offering

6 January 2021
DLA Piper advised Histogen, Inc., in its public offering of 11,600,000 shares of common stock, pre-funded warrants to purchase up to 2,400,000 shares of common stock and warrants to purchase up to an aggregate of 14,000,000 shares of common stock at a price of US$1.00 per share.

DLA Piper advises Arlington Capital Partners in majority investment in Everest Clinical Research Corporation

21 December 2020
DLA Piper represented Washington, DC-based private equity firm Arlington Capital Partners in its investment in Everest Clinical Research Corporation, a leading contract research organization providing a comprehensive suite of mission-critical clinical research services to the worldwide pharmaceutical, biotechnology and medical device industries across Phase I-IV trials.

DLA Piper advises Locanabio in its US$100 million Series B financing

15 December 2020
DLA Piper represented Locanabio, an RNA-targeting gene therapy company focused on developing life-changing therapies for patients with severe neurodegenerative, neuromuscular and retinal diseases, in its recent US$100 million Series B financing led by Vida Ventures.

DLA Piper advises Otsuka America Pharmaceutical in its purchase of the assets of Proteus Digital Health

26 August 2020
DLA Piper represented Otsuka America Pharmaceutical, Inc. in connection with its stalking horse bid to purchase substantially all of the assets of Proteus Digital Health, Inc., including its ingestible and wearable sensor technology.

Former Congressman Jim Greenwood joins DLA Piper as senior policy advisor, adding significant strength to growing life sciences policy and regulatory group

4 August 2020
DLA Piper announced today that former US Representative Jim Greenwood has joined the firm's Litigation and Regulatory practice as a senior policy advisor based in Washington, DC.

DLA Piper advises Liquidia in its acquisition of RareGen and its US$75 million follow-on offering

6 July 2020
DLA Piper represented Liquidia Technologies, Inc. in its acquisition of RareGen, LLC.

Sustainability and ESG

Sustainability and resilience are core business issues in the life sciences sector, given the sector's central role in addressing systemic global challenges including pandemics, access to medicine, and fundamental human rights. Although the specific factors from a sustainability, environmental, social and governance (SESG) perspective in the life science industry differ from those of other industries, creating new and sustainable value in the life science space will depend upon how companies address relevant SESG risks. Boards must actively identify such SESG risks and ensure that they are efficiently mitigated in order for their companies to avoid pitfalls and ensure compliance with evolving regulation around the globe – and also to maintain their competitive position and profitability.

On the basis of our experience in the sector, we believe the following sustainability-related themes to be the core SESG issues that will continue to affect life science businesses:

- **Access and affordability:** Addressing unmet healthcare needs, increasing access to affordable essential medicines and strengthening health systems around the world are all fundamental to social and economic progress. The coronavirus disease 2019 (COVID-19) has further highlighted the importance of the life sciences sector in addressing these challenges. Against this background, international life science business will need to engage in discussions about and develop strategies addressing these issues across the world, particularly with regard to improving the situation in lesser developed countries.
- **Supply chain compliance:** Many governments and regulators around the world are implementing tighter rules on supply chain compliance. To retain their license to operate, life sciences companies must adhere to an evolving set of global laws and regulations. Furthermore, transparency requirements, as well as responsibility and liability for global suppliers are increasing. This ongoing regulatory shift, and the increased likelihood of litigation which goes with it, will have a significant impact on the global life sciences industry. This is because supply chains are often particularly lengthy and complex and influenced by many different internal and external factors that are hard to monitor and control.
- **Product safety and quality:** Fake or substandard medicines lead to hundreds of thousands of deaths each year. Drug safety, along with protecting health consumers from counterfeit medicines and drug diversion, are integral to ensuring public health and maintaining trust and confidence in the life sciences sector. Consequently, life science companies will need to put increasing focus on ensuring product safety as well as maintaining secure distribution channels to patients.
- **Business ethics:** There is increasing stakeholder attention, including from regulators and policymakers and also from providers of capital, on transparency and ethics in business dealings with healthcare providers and medical practitioners for the sale and use of products, as well as in relation to lobbying and advocacy activities. The way in which businesses respond to these expectations can have a direct impact upon their reputation, their cost of capital and ultimately upon their license to operate.
- **Transparency and access in clinical trials:** Stakeholders increasingly expect transparency in clinical trials and wider access to trial data for scientific exchange and research. There is a bright spotlight on participant safety and privacy. Businesses are demanding more effective information sharing to enable informed decision-making and consent, along with post-trial access to results. Technology and collaborative partnerships with patient and health worker groups enable wider representative demographic populations to participate in clinical trials.
- **Sustainable sourcing, product lifecycles and a circular economy:** Markets demand greater visibility across product lifecycles, businesses make commitments to net-zero decarbonisation and business model innovation is driven by circular economy concepts. Underpinned by an increasingly complex transnational regulatory landscape, these developments are changing the way raw materials are sourced; how products are designed, manufactured, packaged, sold, reused or recycled; how waste and hazardous material is treated; and how wider environmental and social impacts relating to issues like emissions, plastics, water use, biodiversity loss, labour

conditions and community impacts are managed.

- **Net-zero decarbonisation and optimisation of processes:** In striving to decarbonise the economy, businesses are implementing commitments to Science Based Targets, increasing energy efficiency and reducing carbon output, decreasing dependency on fossil fuels and increasing the use of renewables. The implementation of these initiatives is creating operational efficiencies, optimising the drug manufacturing, packaging and distribution process and reducing costs across the sector.

To discuss the implications of these issues for your business, please contact our ESG leaders.