# 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.


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

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

### European Commission’s Proposals for reform of AIFMD, UCITS Directive and the ELTIF regime

26 November 2021

Following its review of the scope and functioning of the Alternative Investment Funds Manager Directive[1] (AIFMD), the European Commission (the Commission) has concluded that the AIFMD’s standards for ensuring high levels of investor protection are mostly effective, but that amendments are required which are intended to be targeted in scope, but may have far-reaching effects.

The Commission has now published new legislative amendments to AIFMD, the UCITS Directive[2] (UCITSD) and the ELTIF Regulation[3] (ELTIF Regulation) (the Commission Proposal). The proposed amendments set out in the Commission Proposal will be introduced by way of an omnibus directive amending the AIFMD, UCITSD and the ELTIF Regulation.[4]

### 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.

### Israel Group News October 2021

25 October 2021
ISRAEL GROUP NEWS

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

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### 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

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### 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.

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### The Pharmaceutical Corner

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

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### 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.

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### Israel Group News August 2021

16 August 2021
ISRAEL GROUP NEWS

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

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### 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

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### 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.

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### The Pharmaceutical Corner

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

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### 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.

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### 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.

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### Global COVID-19 Vaccine Guide for Employers

24 May 2021

In our newly launched global guide we set out some of the key considerations with regard to requiring or encouraging employees to be vaccinated and highlight some of the differences in risk around the world.

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### Israel Group News May 2021

1 May 2021
## ISRAEL GROUP NEWS

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

### 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.

### 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.

### 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 Pharmaceutical Corner

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

### 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.

### 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.

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### 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.

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### 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.

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### 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.

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### The Pharmaceutical Corner

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

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### 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.

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### 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.

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### 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.

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### 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.

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### 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.

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### Israel Group News July 2020

8 July 2020
ISRAEL GROUP NEWS

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

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### Clinical trials during the COVID-19 pandemic: A global guide

2 July 2020
The consequences of the COVID-19 pandemic continue to develop dynamically. Some countries are beginning to ease lockdown measures, whilst other retain or even impose new restrictions. The situation continues to impact the ability to conduct clinical trials on a global scale. Pharmaceutical companies need to address even more challenges to ensure the continuity of trials on human medicines.

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### A go-to firm for defending patent cases

30 June 2020
Recognition from *Law360*

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### Atlanta expands privacy capabilities

30 June 2020
Lael Bellamy's arrival bolsters our data protection, privacy and security capabilities throughout the firm.

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### Changes to Hong Kong anti-discrimination legislation

30 June 2020
Anti-discrimination laws in Hong Kong have undergone a series of changes over the past few years.

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### Hatch-Waxman Litigation 101: The Orange Book and the Paragraph IV Notice Letter

30 June 2020
A few of the key issues that must be addressed before a Hatch-Waxman suit is filed.

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### Intellectual property rights are a renewed focus as the world looks beyond a global viral outbreak

30 June 2020
A few key IP-related considerations for companies, whether they are seeking to expand into new markets or looking to preserve their place in an existing market.

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### Northern California bolsters telecom and regulatory practice

30 June 2020
Regulatory and telecom attorney Kristin Jacobson has joined our Northern California office in Sacramento.

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### Washington, DC grows technology capabilities with two new arrivals

30 June 2020
Marius Domokos and Justin Ilhwan Park have joined our Washington, DC practice.

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### First emerging technologies identified and controlled for export in the EAR

26 June 2020
The designation also makes these a "critical technology," giving CFIUS jurisdiction over foreign investments in US businesses that engage with these items.

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### Therapies for COVID-19: Two major developments

25 June 2020
The developments, one negative and one positive, involve widely available medications.

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### CFIUS encourages public to provide tips and referrals

24 June 2020
The new webpage encourages tips and referrals about non-notified deals, violations of CFIUS mitigation measures, and other matters that raise national security risk.

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### Australia tightens rules on foreign investment

17 June 2020

In this article we summarise the tax-related developments from early June 2020, as Australia takes a more stringent approach towards compliance procedures involving foreign investments.

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### Preparing for global class actions arising from COVID-19

28 May 2020
The risk to companies of global and cross-border class action and collective redress proceedings is rising.

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### Chinese and other emerging market companies listed in the US face increased scrutiny from Congress and Nasdaq

27 May 2020
Within a span of two days, the US Senate, House and Nasdaq each took steps to safeguard investors in the US capital markets.

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### Helping patients during the pandemic

14 May 2020
Some important considerations for biopharma manufacturers.

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### [UPDATED] Therapies for COVID-19: What is in the pipeline?

11 May 2020
As of May 8, 2020, there are over 1,300 clinical trials investigating potential therapies for COVID-19, of which nearly 800 are interventional trials.

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### US takes action to abate tariffs and duties in wake of COVID-19

8 May 2020
US importers may consider navigating the various tariff exemptions and deferrals in several ways.

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### Coronavirus: Changes to rules governing meetings and the execution of company documents (Australia)

7 May 2020

Certain requirements in the *Corporations Act 2001* (Cth) (**Corporations Act**) relating to shareholders meetings, and document signatures, are not compatible with public health requirements for social distancing during the coronavirus pandemic. In order to facilitate these important corporate functions during this period, on May 6, 2020 the Australian Federal Government introduced the Corporations (Coronavirus Economic Response) Determination (No. 1) 2020.

This determination modifies the legislative requirements regarding meetings and execution of company documents. These changes come into force on 6 May 2020, and will expire after six months, on 5 November 2020.

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### Latest round of CMS COVID-19 waivers includes telehealth expansion and other billing flexibilities

7 May 2020
Congress is permitting dramatic expansion of telehealth coverage for the duration of the public health emergency. These are the latest developments.

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### Life Sciences Top of Mind: COVID-19 sector insights

7 May 2020
Top COVID-19 considerations for the life sciences sector.

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### COVID-19: New York and Other Northeast Council states take phased approach to reopening economy

6 May 2020
These developments raise a number of immediate questions and considerations for businesses operating in the region.

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### Coronavirus: Directors' duties and making decisions in a crisis (Australia)

4 May 2020

Directors need to carefully consider the risks of the COVID-19 outbreak within their business, given its impact on the global economy. As many now face significant, and increasing, cash flow pressure, directors should carefully consider their actions in the context of the legal framework.

In this new guide we have set out the practical steps directors should be taking to protect their company and its business going forwards.

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### Israel Group News May 2020

4 May 2020
ISRAEL GROUP NEWS

Providing access to valuable business resources in real time.

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### Post-COVID-19: What to expect in the "next normal"

30 April 2020
Issues that are front of mind, based on an informal survey of some of the largest companies and most influential global business leaders.

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### HHS clarifies PREP Act immunity for COVID-19-related activities

28 April 2020
These immunity provisions may provide significant protection to manufacturers, distributors, and others engaged in COVID-19-related efforts.

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### US telehealth update: New federal guidance to state Medicaid agencies suggests more coverage is coming

27 April 2020

A powerful signal that CMS is ready to support targeted interventions in favor of telehealth.

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### Connected care funding for healthcare providers from the CARES Act

24 April 2020
New funding to promote and support telehealth.

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### Coronavirus: State Attorneys General take action against alleged price gouging in personal protection equipment sales

21 April 2020
State Attorneys General coast to coast are taking aggressive action.

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### Opening Up America Again Guidelines signal relaxation in elective surgery restrictions

20 April 2020
For healthcare providers as they evaluate how the Opening Up America Again Guidelines pertain to their respective practices.

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### Clinical trials during the COVID-19 pandemic: A global guide

17 April 2020
The unprecedent situation resulting from the COVID-19 pandemic impacts the ability to conduct clinical trials on a global scale. Pharmaceutical companies need to address multiple challenges to ensure the continuity of trials on human medicines.

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### CMS regulatory waivers relax supervision and other requirements in an effort to address staff shortages caused by rising COVID-19 cases

16 April 2020
These changes are effective immediately.

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### Immediate COVID-19 relief to Medicare providers arrives… with conditions

16 April 2020

For eligible Medicare providers who continue to suffer economic losses stemming from the pandemic, this program is welcome, but it comes with detailed conditions.

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### Paradigm Change in Germany's Foreign Direct Investments (FDI) Law

14 April 2020
Germany's FDI rules so far had a reputation of not being very strong. In the past few years, only three transactions have been prohibited. This is set to change under a new bill.

### COVID-19: New York State provides new guidance on essential businesses

13 April 2020
The Guidelines raise a number of immediate questions and considerations for New York businesses.

### Coronavirus: Overview of healthcare funding stimulus and policy provisions in the CARES Act (United States)

10 April 2020
Among numerous health policy provisions in the CARES Act is one allowing BARDA to partner with private sector companies on R&D.

### EU Antitrust Framework for the coordination of essential coronavirus COVID-19 products and services

10 April 2020
ANTITRUST AND COMPETITION: NOVEL ISSUES IN A POST-CORONAVIRUS WORLD

On 8 April 2020 the Commission published a Temporary Framework for the antitrust assessment of increased business cooperation between competitors in response to coronavirus COVID-19. The aim is to reduce shortages for essential products and services.

### Families First Coronavirus Response Act – Health emergency leave and exempted health care providers

10 April 2020
The temporary health emergency leave measures include a key carveout for "Health Care Providers" and "Emergency Responders."

### US $2T stimulus COVID-19 package includes significant R&D funding

10 April 2020

A summary of R&D funding in the CARES Act broken out by federal departments and agencies.

### UK government to provide additional financial support measures for mid-market business impacted by COVID-19

9 April 2020
On 3 April 2020 the Chancellor announced a new scheme for larger companies, with the creation of the new Coronavirus Large Business Interruption Loan Scheme (CLBILS) to ensure that more firms are able to benefit from government-backed support during this difficult time.

### COVID-19: Tort immunity for vaccines and antivirals – lessons from the swine flu of 1976

8 April 2020

While the common goal is to quickly develop countermeasures to combat COVID-19, it is important to consider the potential legal and reputational risks.

### European Commission proposes one-year postponement of MDR application date

8 April 2020
Following an informal heads-up on 25 March 2020, today the European Commission adopted a proposed regulation to postpone by one year the date of application of the Medical Devices Regulation (Regulation (EU) 2017/745, “MDR”). If enacted, the Medical Device Directive (Directive 93/42/EEC) and implementing legislation of the EU member states will continue to apply as far as they have not yet been amended.

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### Contract analysis in a crisis: flowcharts

7 April 2020
Flowcharts providing considerations for analyzing commercial contracts in the context of the COVID-19 pandemic through a logical process flow that can serve as a practical checklist.

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### Coronavirus - Mitigating supply chain and customer insolvency risk (Canada)

7 APR 2020
The on-going impact of the COVID-19 outbreak could have a significant impact on your global supply and customer chains.

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### Cost-cutting considerations in the time of COVID-19 (Part 3 – employment issues outside the US)

7 April 2020

A deeper dive into various cost-saving measures and their viability for employers outside the US.

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### FCA publishes guidance on UK mortgage “payment holidays” relating to COVID-19

7 April 2020
Following an announcement by the UK government on 17 March 2020, the Financial Conduct Authority (FCA) has published guidance for participants in the residential mortgages sector, setting out their expectations in respect of payment holidays that are to be offered to customers experiencing financial difficulties arising from the COVID-19 outbreak.

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### HHS issues notification of enforcement discretion under HIPAA for certain uses and disclosures by business associates

7 April 2020

This announcement permits business associates to share personal health information with public health authorities and agencies in accordance with HIPAA exceptions as part of COVID-19 relief efforts.

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### A balance between the government, the private sector and the needs of the people: Invocation of rarely used provisions to ensure public safety during the COVID-19 pandemic

6 April 2020

The Defense Production Act, compulsory licensing and march-in rights are means for authorizing the government to step in and assert rights against private companies.

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### COVID-19 and the "essential business" designation: Practical guidance for businesses that fall in the gray area between "essential" and "non-essential"

6 April 2020

Certain frequently asked questions as well as practical guidance.

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### COVID-19 emergency declaration allows Centers for Medicare & Medicaid Services to issue 1135 waivers, 1915(c) waivers and changes to survey and audit processes

6 April 2020

Issued in a public health emergency, the waivers help ensure healthcare items and services are available for individuals enrolled in Social Security Act programs.

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### Coronavirus: Supplier due diligence for vetting Chinese medical suppliers for quality, safety, fair pricing and anti-corruption compliance

6 April 2020

Some key risks, and potential solutions to reduce cross-border operational risks.

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### Coronavirus: The Defense Production Act's authorities and limitations in the fight against COVID-19

6 April 2020

The DPA has significant implications for companies receiving a direct order from the President and for the subcontractors and suppliers behind them; meanwhile, recent legislation has created procurement opportunities under the DPA.

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### [UPDATED] As device industry veterans and newcomers step up to the line, FDA swiftly adjusts regulatory hurdles for personal protective equipment during the COVID-19 pandemic

6 April 2020
A high level overview of the FDA's tiered, risk-based approach to masks, face shields and respirators based on developments to date.

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### CARES Act may offer relief for medical practices, but raises questions for private equity-backed practice management companies

3 April 2020
Medical practices and practice management companies are urged to consider options under the CARES Act.

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### CARES Act waivers from CMS provide additional flexibility for telehealth services and relief from certain Stark Law liabilities (United States)

3 April 2020
This latest relief further expands healthcare practitioners' ability to reach patients through telehealth, an important tool for addressing patient needs while reducing in-person contact.

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### Beyond social distancing: What employers need to know to keep their workplaces safe and manage privacy obligations in the face of COVID-19

2 April 2020
Guidance from OSHA, EEO and CDC to help employers seeking to protect the health, safety and privacy of their on-site employees.

### Coronavirus: Cybersecurity considerations for your newly remote workforce (United States)

31 March 2020

Cyber risk management involves balancing the productivity of a workforce with ensuring confidentiality, integrity and availability of the company's own systems and data, as well as that of their supply chain.

### Importing critical healthcare supplies during the COVID-19 pandemic: Recent US developments

31 March 2020

Practical guidance is critical to help importers of medical products efficiently navigate legal and regulatory hurdles so that admissible products with the potential to safeguard patients' health and well-being may be granted entry into US markets as expeditiously as possible.

### Are you ready for CCPA class action litigation?

30 March 2020
Many businesses may not have fully contemplated the major data breach class action litigation risk created by the California Consumer Privacy Act.

### Top franchise developments of 2019

30 March 2020

Two top franchise developments in 2019 stand out from the rest.

### Coronavirus: DHS Response to COVID-19 - What US Employers Need to Know

29 March 2020
Key questions and answers related to the new DHS guidance.

### COVID-19 prompts CMS to give new flexibility to participants in Medicare Quality Programs

25 March 2020
In light of COVID-19, participants in the Medicare Quality Payment Program will have extra time to report some quality metrics and can temporarily suspend other tracking and reporting activities altogether.

### Coronavirus: Cyber hygiene practices

25 March 2020
While the world is responding to the coronavirus disease 2019 (COVID-19), and individuals are increasingly focused on personal hygiene and social distancing, augmenting cyber hygiene efforts at home and at work are increasing in importance too.

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### Coronavirus: Employee furloughs, reductions-in-force and similar temporary cost-saving measures (Part 2 – Employment issues outside the US)

25 March 2020
A general overview of key employment issues to consider outside of the US in light of COVID-19.

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### Coronavirus: Employee furloughs, reductions-in-force and similar temporary cost-saving measures in the US - Part 1

25 March 2020
Key employment-related issues for US-based employers in relation to cost-saving measures due to COVID-19.

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### Hotels and hospitals may find new partnerships to solve for bed capacity issues and vacancies

25 March 2020
The impacts of COVID-19 upon the hospitality sector as well as hospital systems and the healthcare industry have been sudden and dramatic.

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### CMS Emergency Preparedness Rule: Planning during COVID-19 (United States)

24 March 2020

As healthcare providers continue to face a variety of challenges during the coronavirus disease 2019 (COVID-19) pandemic, healthcare providers and suppliers should be aware of the Centers for Medicare and Medicaid Services Emergency Preparedness Rule and its resources.

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### Coronavirus: Several state and local governments issue “shelter in place” orders (United States)

23 March 2020
Between March 17 and 22, state and local governments have promulgated at least a dozen “Stay-at-Home” / “Shelter-at-Home”-type Orders. This alert provides details on a number of state and local government orders.

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### 90-day deferral for US federal income tax payments

20 March 2020
Those who decide to defer their federal tax payments will be able to do so on a penalty-free and interest-free basis, with penalties and interest beginning to accrue for payments submitted after July 15, 2020.

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### Potential paths forward amidst the challenges to COVID-19 therapeutic and vaccine development; collaboration and communication among clinical trial stakeholders takes on heightened importance (United States)

20 March 2020

In a March 19, 2020, briefing and press release, the US Food and Drug Administration outlined ways that existing regulatory options may make it possible to expedite access to therapeutics and vaccines with the potential to treat or prevent coronavirus disease 2019 (COVID-19).

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### COVID-19: The benefits of US chapter 11 relief in a time of economic crisis

19 March 2020
Highlighting some of the most significant benefits of US chapter 11 for companies facing severe challenges under the current circumstances.

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### Coronavirus: business resilience and continuity planning

19 March 2020
Prudent companies understand that their response to the COVID-19 pandemic should be consistent with their business resilience plans.

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### Telehealth update: COVID-19 prompts emergency Medicare coverage and other seismic shifts (United States)

18 March 2020
Multiple federal agencies have issued regulatory waivers and released additional funding to loosen the constraints on telehealth services and encourage widespread adoption.

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### Coronavirus: Congress expected to pass expanded paid leave (United States)

16 March 2020
The paid leave requirements in the current version of the Families First Coronavirus Response Act.

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### Coronavirus: federal and state tax relief (United States)

16 March 2020
Congress and state legislatures and administrative agencies are working hard to provide necessary tax relief for those affected by the coronavirus disease (COVID-19) pandemic.

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### Coronavirus (COVID-19): ten practical steps for global employers, right now (Global)

13 March 2020
These steps are not based on laws of any one jurisdiction but rather are designed to provide a global employer with themes to consider, understanding that what may be suitable for each employer may vary greatly depending on the employer's unique circumstances.

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### Defending your supply chain against coronavirus COVID-19 (United States)

9 March 2020

An action plan that companies can implement to make strategic decisions related to potential supply chain disruptions.

### Europe initiates regulations on artificial intelligence; industry presented with opportunity to provide inputs

5 March 2020
AI OUTLOOK

The White Paper on AI initiates a process that could potentially establish the world's first far-reaching regulatory framework for AI.

### An update on the impact of the coronavirus on business in Singapore

12 February 2020

Due to the evolving 2019- nCoV acute respiratory disease (the COVID-19) situation, the Ministry of Health (the MOH) and the Ministry of Manpower (the MOM) have, since January 2020, issued advisories which employers will need to be aware of. In particular, the MOH and MOM have, since our last update on February 12 2020, updated and issued new advisories due to the increased risk of importation of COVID-19 into Singapore.

### DLA Piper's Dylan Kennett joins panel debate at the Cannabis Investor Summit in Odense, Denmark

11 February 2020
On January 28, Dylan Kennett, Senior Associate in DLA Piper's corporate team and co-lead of our Global Cannabis practice, joined a panel debate at the Cannabis Investor Summit in Odense, Denmark. DLA Piper is proud to be a partner on this summit hosted by Invest in Odense, Invest in Denmark and Novo Nordisk Engineering (NNE).

### Hong Kong Government introduces mandatory quarantine measures

11 February 2020

On 9 February 2020, the number of deaths due to the rapidly spreading coronavirus in Mainland China officially surpassed the figure seen during the 2002/2003 SARS epidemic.

Numerous governments have been implementing restrictions barring entry to those with recent travel history through Mainland China, including Singapore, Japan, Australia and the United States. Following pressure from public health workers, the Hong Kong Government has now followed suit and has begun a mandatory two-week quarantine for anyone arriving from Mainland China.

### How to resume business amid the coronavirus outbreak (China)

11 February 2020

As reported in our previous article, China has extended its Chinese New Year holiday and work suspension period as a result of the novel coronavirus outbreak which has now infected more than 40,000 people around the world.

This is a summary of the Back to Work Day and compensation for working before Back to Work Day in key cities and provinces across China.

### Israel Group News February 2020

10 February 2020

# ISRAEL GROUP NEWS

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

## APAC employment issues arising out of the Coronavirus (AsiaPac)

31 January 2020

On 29 January 2020, the number of confirmed cases of the rapidly spreading coronavirus in Mainland China officially surpassed the figure seen during the 2002/2003 SARS epidemic.

Multinationals with local operations around the APAC region have been significantly affected. As staff return to the office following the Chinese New Year holiday period, businesses are now considering what they can do to minimise any risk to health and safety and support staff through this challenging period where anxiety and uncertainty is rife, whilst at the same time complying with their employment obligations and maintaining business continuity. Putting in place detailed business and contingency plans and ensuring careful communications with staff to address key topics and concerns is key, as is keeping such plans and communications under frequent review given the fluidity of the current situation.

This alert considers some of the key issues that HR and business leaders should be considering across the APAC region.

## Harsher penalties on discriminatory employment practices in Singapore

29 January 2020
The Fair Consideration Framework was updated in January 2020 to impose harsher penalties on employers found to be engaging in discriminatory practices such as by favouring the hiring of foreigners over Singaporeans.

## China extends holidays for workers amid coronavirus outbreak (China)

28 January 2020
Learn about how the widely publicised corona virus outbreak affects business in Greater China.

## EU MDCG issues new guidance on Cybersecurity for medical devices

27 January 2020
On 7 January 2020, the EU Medical Device Coordination Group published new guidance to help manufacturers fulfil all relevant cybersecurity requirements in Annex I to the new Medical Device Regulations (Regulations 2017/745 on medical devices and 2017/746 on in vitro diagnostic medical devices).

## New regulations reinforce CFIUS's expanded role with respect to foreign investments in the United States

16 January 2020
The new CFIUS regulations become effective on February 13, 2020.

## Top of Mind: Life Sciences

16 January 2020
Eight big topics that life sciences businesses have been thinking about and how DLA Piper has been covering those stories.

### The almost free US-Japan Trade Agreement is now in effect

9 January 2020
This trade agreement reduces or eliminates US customs duties on numerous goods.

### CCPA Rescue Kit arrives amid new privacy law change

19 December 2019
A series of integrated compliance offerings to help businesses begin the journey of compliance with this important new privacy bill.

### Street art raises novel copyright issues – or does it?

19 December 2019

Is street art less entitled to copyright protection than are traditional art forms?

### EU launches preparatory work for a global sanctions regime for human rights violations

17 December 2019
On 9 December 2019, High Representative/Vice-President of the European Union Josep Borrell announced that the Foreign Affairs Council has agreed with strong consensus to start the preparatory work for a global sanctions regime to address serious human rights violations.

### 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.

### 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.

### 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.

## EVENTOS

### Reciente

**Embracing Digital Evolution**

15 September 2021
Webinar

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**EDPB recommendations for safeguarding data transfers after Schrems II**

19 November 2020
Webinar

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**Women in Science and Technology Conference**

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

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## NOTICIAS

**DLA Piper advises Genomma Lab in the issuance of MX$1.25 billion in short-term debt securities**

13 August 2020
DLA Piper represented Genomma Lab Internacional S.A.B. de C.V. in its issuance of MX$1.25 billion in short-term debt securities in the form of Certificados Bursátiles.

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**DLA Piper announces partnership promotions for 2020**

30 April 2020

DLA Piper is proud to announce that 67 lawyers have been promoted to its partnership. The promotions are effective as of April 1, 2020 in the United States and May 1, 2020 for EMEA and Asia Pacific. The promotions have been made across many of the firm's practice areas in 35 different offices throughout 13 countries.

Across the firm's practices globally, Corporate saw the largest intake of new partners with 19 promotions, followed by Litigation and Regulatory with 15. Intellectual Property and Technology and Finance and Projects had ten and eight promotions respectively, while there were six in Real Estate. Tax and Employment both had four, and there was one in Restructuring.

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**DLA Piper lawyers named Acritas Stars**

10 March 2020

Acritas has named over 200 DLA Piper lawyers as 2020 Acritas Stars. Now in its fourth year, Acritas Stars highlights the stand-out lawyers in private practice as nominated by clients around the world. More than 3,000 senior in-house counsel feed into the nomination process to give a comprehensive view of highly recommended lawyers across the globe.

# Sustainability and ESG

Sustainability is a core business issue in the life sciences sector, given its central role in addressing systemic global challenges including pandemics, access to medicine, and climate change. Creating new and sustainable value depends upon connecting stakeholder experiences with business outcomes – from patients to health workers, as well as wider health sector players. Boards must focus on more personalized healthcare and specialized services, leveraging technology in product development and patient care, and fostering trust on key issues like transparency of clinical trials, use of health and patient data, product quality and safety, and the environmental and social impacts across product life-cycles.

A number of sustainability-related themes affect businesses operating in the life sciences sector:

- **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.
- **Digital transformation:** The use of AI, machine learning, automation and other digital technologies is transforming the global life sciences landscape. The application of AI, robotics and cloud services has paved the way to innovative, effective and cost-efficient therapy discoveries and the development of preventative and wellness-focused consumer wearables, personalized telemedicine services and remote patient monitoring. This digital transformation is expected to continue as more than 50 percent of health consumers support the use of AI and robotics to improve health outcomes.
- **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.
- **Trust and ethical use of data:** Vast amounts of valuable health data are generated through health and wellness apps, digital or automated diagnostics, cloud-based patient records and other medical devices. There is also a growing number of stakeholders with access to this data, including healthcare providers, health workers, insurers, governments and app developers. A key expectation within the life sciences sector is that data to improve health outcomes will continue along the path of increased accessibility while also ensuring its ethical use and the protection of individuals' privacy.
- **Patient-centered services and more personalized healthcare:** The changing priorities of health consumers and professionals are leading to a greater focus on the patient experience, from prevention and wellness to diagnosis and management of disease. Technology gives health consumers greater control over prevention and management of disease and provides health professionals access to better data to track and monitor their patients.
- **Net-zero decarbonization:** In striving to decarbonize 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, optimizing processes and reducing costs across the sector.
- **Sustainable sourcing, product life-cycles and a circular economy:** Stakeholders demand greater transparency across product life-cycles, businesses make commitments to net-zero decarbonization 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, labor conditions and community impacts are managed.
- **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.
- **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 and ultimately upon their license to operate.

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

# 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

#### European Commission’s Proposals for reform of AIFMD, UCITS Directive and the ELTIF regime

26 November 2021

Following its review of the scope and functioning of the Alternative Investment Funds Manager Directive[1] (AIFMD), the European Commission (the Commission) has concluded that the AIFMD’s standards for ensuring high levels of investor protection are mostly effective, but that amendments are required which are intended to be targeted in scope, but may have far-reaching effects.

The Commission has now published new legislative amendments to AIFMD, the UCITS Directive[2] (UCITSD) and the ELTIF Regulation[3] (ELTIF Regulation) (the Commission Proposal). The proposed amendments set out in the Commission Proposal will be introduced by way of an omnibus directive amending the AIFMD, UCITSD and the ELTIF Regulation.[4]

#### 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.

#### 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

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### 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.

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### The Pharmaceutical Corner

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

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### 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.

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### Israel Group News August 2021

16 August 2021
ISRAEL GROUP NEWS

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

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### 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

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### 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.

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### The Pharmaceutical Corner

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

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### 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.

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### 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.

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### Global COVID-19 Vaccine Guide for Employers

24 May 2021

In our newly launched global guide we set out some of the key considerations with regard to requiring or encouraging employees to be vaccinated and highlight some of the differences in risk around the world.

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### Israel Group News May 2021

1 May 2021
## ISRAEL GROUP NEWS

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

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### 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.

### 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.

### 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.

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### The Pharmaceutical Corner

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

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### 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.

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### 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.

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### 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.

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### Israel Group News October 2020

7 October 2020
ISRAEL GROUP NEWS

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

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### 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.

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### 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.

### 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.

### 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.

### 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.

### 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.

### Clinical trials during the COVID-19 pandemic: A global guide

2 July 2020

The consequences of the COVID-19 pandemic continue to develop dynamically. Some countries are beginning to ease lockdown measures, whilst other retain or even impose new restrictions. The situation continues to impact the ability to conduct clinical trials on a global scale. Pharmaceutical companies need to address even more challenges to ensure the continuity of trials on human medicines.

### A go-to firm for defending patent cases

30 June 2020

Recognition from *Law360*

### Atlanta expands privacy capabilities

30 June 2020

Lael Bellamy's arrival bolsters our data protection, privacy and security capabilities throughout the firm.

### Changes to Hong Kong anti-discrimination legislation

30 June 2020

Anti-discrimination laws in Hong Kong have undergone a series of changes over the past few years.

### Hatch-Waxman Litigation 101: The Orange Book and the Paragraph IV Notice Letter

30 June 2020

A few of the key issues that must be addressed before a Hatch-Waxman suit is filed.

### Intellectual property rights are a renewed focus as the world looks beyond a global viral outbreak

30 June 2020

A few key IP-related considerations for companies, whether they are seeking to expand into new markets or looking to preserve their place in an existing market.

### Northern California bolsters telecom and regulatory practice

30 June 2020
Regulatory and telecom attorney Kristin Jacobson has joined our Northern California office in Sacramento.

### Washington, DC grows technology capabilities with two new arrivals

30 June 2020
Marius Domokos and Justin Ilhwan Park have joined our Washington, DC practice.

### First emerging technologies identified and controlled for export in the EAR

26 June 2020
The designation also makes these a "critical technology," giving CFIUS jurisdiction over foreign investments in US businesses that engage with these items.

### Therapies for COVID-19: Two major developments

25 June 2020
The developments, one negative and one positive, involve widely available medications.

### CFIUS encourages public to provide tips and referrals

24 June 2020
The new webpage encourages tips and referrals about non-notified deals, violations of CFIUS mitigation measures, and other matters that raise national security risk.

### Australia tightens rules on foreign investment

17 June 2020
In this article we summarise the tax-related developments from early June 2020, as Australia takes a more stringent approach towards compliance procedures involving foreign investments.

### Preparing for global class actions arising from COVID-19

28 May 2020
The risk to companies of global and cross-border class action and collective redress proceedings is rising.

### Chinese and other emerging market companies listed in the US face increased scrutiny from Congress and Nasdaq

27 May 2020

Within a span of two days, the US Senate, House and Nasdaq each took steps to safeguard investors in the US capital markets.

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### Helping patients during the pandemic

14 May 2020
Some important considerations for biopharma manufacturers.

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### [UPDATED] Therapies for COVID-19: What is in the pipeline?

11 May 2020
As of May 8, 2020, there are over 1,300 clinical trials investigating potential therapies for COVID-19, of which nearly 800 are interventional trials.

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### US takes action to abate tariffs and duties in wake of COVID-19

8 May 2020
US importers may consider navigating the various tariff exemptions and deferrals in several ways.

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### Coronavirus: Changes to rules governing meetings and the execution of company documents (Australia)

7 May 2020

Certain requirements in the *Corporations Act 2001* (Cth) (**Corporations Act**) relating to shareholders meetings, and document signatures, are not compatible with public health requirements for social distancing during the coronavirus pandemic. In order to facilitate these important corporate functions during this period, on May 6, 2020 the Australian Federal Government introduced the Corporations (Coronavirus Economic Response) Determination (No. 1) 2020.

This determination modifies the legislative requirements regarding meetings and execution of company documents. These changes come into force on 6 May 2020, and will expire after six months, on 5 November 2020.

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### Latest round of CMS COVID-19 waivers includes telehealth expansion and other billing flexibilities

7 May 2020
Congress is permitting dramatic expansion of telehealth coverage for the duration of the public health emergency. These are the latest developments.

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### Life Sciences Top of Mind: COVID-19 sector insights

7 May 2020
Top COVID-19 considerations for the life sciences sector.

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### COVID-19: New York and Other Northeast Council states take phased approach to reopening economy

6 May 2020
These developments raise a number of immediate questions and considerations for businesses operating in the region.

### Coronavirus: Directors' duties and making decisions in a crisis (Australia)

4 May 2020

Directors need to carefully consider the risks of the COVID-19 outbreak within their business, given its impact on the global economy. As many now face significant, and increasing, cash flow pressure, directors should carefully consider their actions in the context of the legal framework.

In this new guide we have set out the practical steps directors should be taking to protect their company and its business going forwards.

### Israel Group News May 2020

4 May 2020

ISRAEL GROUP NEWS

Providing access to valuable business resources in real time.

### Post-COVID-19: What to expect in the "next normal"

30 April 2020

Issues that are front of mind, based on an informal survey of some of the largest companies and most influential global business leaders.

### HHS clarifies PREP Act immunity for COVID-19-related activities

28 April 2020

These immunity provisions may provide significant protection to manufacturers, distributors, and others engaged in COVID-19-related efforts.

### US telehealth update: New federal guidance to state Medicaid agencies suggests more coverage is coming

27 April 2020

A powerful signal that CMS is ready to support targeted interventions in favor of telehealth.

### Connected care funding for healthcare providers from the CARES Act

24 April 2020

New funding to promote and support telehealth.

### Coronavirus: State Attorneys General take action against alleged price gouging in personal protection equipment sales

21 April 2020

State Attorneys General coast to coast are taking aggressive action.

### Opening Up America Again Guidelines signal relaxation in elective surgery restrictions

20 April 2020
For healthcare providers as they evaluate how the Opening Up America Again Guidelines pertain to their respective practices.

### Clinical trials during the COVID-19 pandemic: A global guide

17 April 2020
The unprecedent situation resulting from the COVID-19 pandemic impacts the ability to conduct clinical trials on a global scale. Pharmaceutical companies need to address multiple challenges to ensure the continuity of trials on human medicines.

### CMS regulatory waivers relax supervision and other requirements in an effort to address staff shortages caused by rising COVID-19 cases

16 April 2020
These changes are effective immediately.

### Immediate COVID-19 relief to Medicare providers arrives… with conditions

16 April 2020

For eligible Medicare providers who continue to suffer economic losses stemming from the pandemic, this program is welcome, but it comes with detailed conditions.

### Paradigm Change in Germany's Foreign Direct Investments (FDI) Law

14 April 2020
Germany's FDI rules so far had a reputation of not being very strong. In the past few years, only three transactions have been prohibited. This is set to change under a new bill.

### COVID-19: New York State provides new guidance on essential businesses

13 April 2020
The Guidelines raise a number of immediate questions and considerations for New York businesses.

### Coronavirus: Overview of healthcare funding stimulus and policy provisions in the CARES Act (United States)

10 April 2020
Among numerous health policy provisions in the CARES Act is one allowing BARDA to partner with private sector companies on R&D.

### EU Antitrust Framework for the coordination of essential coronavirus COVID-19 products and services

10 April 2020
## ANTITRUST AND COMPETITION: NOVEL ISSUES IN A POST-CORONAVIRUS WORLD

On 8 April 2020 the Commission published a Temporary Framework for the antitrust assessment of increased business cooperation between competitors in response to coronavirus COVID-19. The aim is to reduce shortages for essential products and services.

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### Families First Coronavirus Response Act – Health emergency leave and exempted health care providers

10 April 2020
The temporary health emergency leave measures include a key carveout for "Health Care Providers" and "Emergency Responders."

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### US $2T stimulus COVID-19 package includes significant R&D funding

10 April 2020

A summary of R&D funding in the CARES Act broken out by federal departments and agencies.

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### UK government to provide additional financial support measures for mid-market business impacted by COVID-19

9 April 2020
On 3 April 2020 the Chancellor announced a new scheme for larger companies, with the creation of the new Coronavirus Large Business Interruption Loan Scheme (CLBILS) to ensure that more firms are able to benefit from government-backed support during this difficult time.

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### COVID-19: Tort immunity for vaccines and antivirals – lessons from the swine flu of 1976

8 April 2020

While the common goal is to quickly develop countermeasures to combat COVID-19, it is important to consider the potential legal and reputational risks.

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### European Commission proposes one-year postponement of MDR application date

8 April 2020
Following an informal heads-up on 25 March 2020, today the European Commission adopted a proposed regulation to postpone by one year the date of application of the Medical Devices Regulation (Regulation (EU) 2017/745, “MDR”). If enacted, the Medical Device Directive (Directive 93/42/EEC) and implementing legislation of the EU member states will continue to apply as far as they have not yet been amended.

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### Contract analysis in a crisis: flowcharts

7 April 2020
Flowcharts providing considerations for analyzing commercial contracts in the context of the COVID-19 pandemic through a logical process flow that can serve as a practical checklist.

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### Coronavirus - Mitigating supply chain and customer insolvency risk (Canada)

7 APR 2020
The on-going impact of the COVID-19 outbreak could have a significant impact on your global supply and customer chains.

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### Cost-cutting considerations in the time of COVID-19 (Part 3 – employment issues outside the US)

7 April 2020

A deeper dive into various cost-saving measures and their viability for employers outside the US.

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### FCA publishes guidance on UK mortgage “payment holidays” relating to COVID-19

7 April 2020
Following an announcement by the UK government on 17 March 2020, the Financial Conduct Authority (FCA) has published guidance for participants in the residential mortgages sector, setting out their expectations in respect of payment holidays that are to be offered to customers experiencing financial difficulties arising from the COVID-19 outbreak.

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### HHS issues notification of enforcement discretion under HIPAA for certain uses and disclosures by business associates

7 April 2020

This announcement permits business associates to share personal health information with public health authorities and agencies in accordance with HIPAA exceptions as part of COVID-19 relief efforts.

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### A balance between the government, the private sector and the needs of the people: Invocation of rarely used provisions to ensure public safety during the COVID-19 pandemic

6 April 2020

The Defense Production Act, compulsory licensing and march-in rights are means for authorizing the government to step in and assert rights against private companies.

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### COVID-19 and the "essential business" designation: Practical guidance for businesses that fall in the gray area between "essential" and "non-essential"

6 April 2020

Certain frequently asked questions as well as practical guidance.

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### COVID-19 emergency declaration allows Centers for Medicare & Medicaid Services to issue 1135 waivers, 1915(c) waivers and changes to survey and audit processes

6 April 2020

Issued in a public health emergency, the waivers help ensure healthcare items and services are available for individuals enrolled in Social

Security Act programs.

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### Coronavirus: Supplier due diligence for vetting Chinese medical suppliers for quality, safety, fair pricing and anti-corruption compliance

6 April 2020

Some key risks, and potential solutions to reduce cross-border operational risks.

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### Coronavirus: The Defense Production Act's authorities and limitations in the fight against COVID-19

6 April 2020

The DPA has significant implications for companies receiving a direct order from the President and for the subcontractors and suppliers behind them; meanwhile, recent legislation has created procurement opportunities under the DPA.

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### [UPDATED] As device industry veterans and newcomers step up to the line, FDA swiftly adjusts regulatory hurdles for personal protective equipment during the COVID-19 pandemic

6 April 2020
A high level overview of the FDA's tiered, risk-based approach to masks, face shields and respirators based on developments to date.

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### CARES Act may offer relief for medical practices, but raises questions for private equity-backed practice management companies

3 April 2020
Medical practices and practice management companies are urged to consider options under the CARES Act.

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### CARES Act waivers from CMS provide additional flexibility for telehealth services and relief from certain Stark Law liabilities (United States)

3 April 2020
This latest relief further expands healthcare practitioners' ability to reach patients through telehealth, an important tool for addressing patient needs while reducing in-person contact.

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### Beyond social distancing: What employers need to know to keep their workplaces safe and manage privacy obligations in the face of COVID-19

2 April 2020
Guidance from OSHA, EEO and CDC to help employers seeking to protect the health, safety and privacy of their on-site employees.

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### Coronavirus: Cybersecurity considerations for your newly remote workforce (United States)

31 March 2020

Cyber risk management involves balancing the productivity of a workforce with ensuring confidentiality, integrity and availability of the

company’s own systems and data, as well as that of their supply chain.

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### Importing critical healthcare supplies during the COVID-19 pandemic: Recent US developments

31 March 2020

Practical guidance is critical to help importers of medical products efficiently navigate legal and regulatory hurdles so that admissible products with the potential to safeguard patients' health and well-being may be granted entry into US markets as expeditiously as possible.

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### Are you ready for CCPA class action litigation?

30 March 2020
Many businesses may not have fully contemplated the major data breach class action litigation risk created by the California Consumer Privacy Act.

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### Top franchise developments of 2019

30 March 2020

Two top franchise developments in 2019 stand out from the rest.

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### Coronavirus: DHS Response to COVID-19 - What US Employers Need to Know

29 March 2020
Key questions and answers related to the new DHS guidance.

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### COVID-19 prompts CMS to give new flexibility to participants in Medicare Quality Programs

25 March 2020
In light of COVID-19, participants in the Medicare Quality Payment Program will have extra time to report some quality metrics and can temporarily suspend other tracking and reporting activities altogether.

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### Coronavirus: Cyber hygiene practices

25 March 2020
While the world is responding to the coronavirus disease 2019 (COVID-19), and individuals are increasingly focused on personal hygiene and social distancing, augmenting cyber hygiene efforts at home and at work are increasing in importance too.

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### Coronavirus: Employee furloughs, reductions-in-force and similar temporary cost-saving measures (Part 2 – Employment issues outside the US)

25 March 2020
A general overview of key employment issues to consider outside of the US in light of COVID-19.

### Coronavirus: Employee furloughs, reductions-in-force and similar temporary cost-saving measures in the US - Part 1

25 March 2020
Key employment-related issues for US-based employers in relation to cost-saving measures due to COVID-19.

### Hotels and hospitals may find new partnerships to solve for bed capacity issues and vacancies

25 March 2020
The impacts of COVID-19 upon the hospitality sector as well as hospital systems and the healthcare industry have been sudden and dramatic.

### CMS Emergency Preparedness Rule: Planning during COVID-19 (United States)

24 March 2020

As healthcare providers continue to face a variety of challenges during the coronavirus disease 2019 (COVID-19) pandemic, healthcare providers and suppliers should be aware of the Centers for Medicare and Medicaid Services Emergency Preparedness Rule and its resources.

### Coronavirus: Several state and local governments issue “shelter in place” orders (United States)

23 March 2020
Between March 17 and 22, state and local governments have promulgated at least a dozen “Stay-at-Home” / “Shelter-at-Home”-type Orders. This alert provides details on a number of state and local government orders.

### 90-day deferral for US federal income tax payments

20 March 2020
Those who decide to defer their federal tax payments will be able to do so on a penalty-free and interest-free basis, with penalties and interest beginning to accrue for payments submitted after July 15, 2020.

### Potential paths forward amidst the challenges to COVID-19 therapeutic and vaccine development; collaboration and communication among clinical trial stakeholders takes on heightened importance (United States)

20 March 2020

In a March 19, 2020, briefing and press release, the US Food and Drug Administration outlined ways that existing regulatory options may make it possible to expedite access to therapeutics and vaccines with the potential to treat or prevent coronavirus disease 2019 (COVID-19).

### COVID-19: The benefits of US chapter 11 relief in a time of economic crisis

19 March 2020
Highlighting some of the most significant benefits of US chapter 11 for companies facing severe challenges under the current circumstances.

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### Coronavirus: business resilience and continuity planning

19 March 2020
Prudent companies understand that their response to the COVID-19 pandemic should be consistent with their business resilience plans.

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### Telehealth update: COVID-19 prompts emergency Medicare coverage and other seismic shifts (United States)

18 March 2020
Multiple federal agencies have issued regulatory waivers and released additional funding to loosen the constraints on telehealth services and encourage widespread adoption.

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### Coronavirus: Congress expected to pass expanded paid leave (United States)

16 March 2020
The paid leave requirements in the current version of the Families First Coronavirus Response Act.

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### Coronavirus: federal and state tax relief (United States)

16 March 2020
Congress and state legislatures and administrative agencies are working hard to provide necessary tax relief for those affected by the coronavirus disease (COVID-19) pandemic.

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### Coronavirus (COVID-19): ten practical steps for global employers, right now (Global)

13 March 2020
These steps are not based on laws of any one jurisdiction but rather are designed to provide a global employer with themes to consider, understanding that what may be suitable for each employer may vary greatly depending on the employer's unique circumstances.

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### Defending your supply chain against coronavirus COVID-19 (United States)

9 March 2020

An action plan that companies can implement to make strategic decisions related to potential supply chain disruptions.

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### Europe initiates regulations on artificial intelligence; industry presented with opportunity to provide inputs

5 March 2020
AI OUTLOOK

The White Paper on AI initiates a process that could potentially establish the world's first far-reaching regulatory framework for AI.

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### An update on the impact of the coronavirus on business in Singapore

12 February 2020

Due to the evolving 2019- nCoV acute respiratory disease (the COVID-19) situation, the Ministry of Health (the MOH) and the Ministry of Manpower (the MOM) have, since January 2020, issued advisories which employers will need to be aware of. In particular, the MOH and MOM have, since our last update on February 12 2020, updated and issued new advisories due to the increased risk of importation of COVID-19 into Singapore.

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### DLA Piper's Dylan Kennett joins panel debate at the Cannabis Investor Summit in Odense, Denmark

11 February 2020
On January 28, Dylan Kennett, Senior Associate in DLA Piper’s corporate team and co-lead of our Global Cannabis practice, joined a panel debate at the Cannabis Investor Summit in Odense, Denmark. DLA Piper is proud to be a partner on this summit hosted by Invest in Odense, Invest in Denmark and Novo Nordisk Engineering (NNE).

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### Hong Kong Government introduces mandatory quarantine measures

11 February 2020

On 9 February 2020, the number of deaths due to the rapidly spreading coronavirus in Mainland China officially surpassed the figure seen during the 2002/2003 SARS epidemic.

Numerous governments have been implementing restrictions barring entry to those with recent travel history through Mainland China, including Singapore, Japan, Australia and the United States. Following pressure from public health workers, the Hong Kong Government has now followed suit and has begun a mandatory two-week quarantine for anyone arriving from Mainland China.

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### How to resume business amid the coronavirus outbreak (China)

11 February 2020

As reported in our previous article, China has extended its Chinese New Year holiday and work suspension period as a result of the novel coronavirus outbreak which has now infected more than 40,000 people around the world.

This is a summary of the Back to Work Day and compensation for working before Back to Work Day in key cities and provinces across China.

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### Israel Group News February 2020

10 February 2020
ISRAEL GROUP NEWS

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

### APAC employment issues arising out of the Coronavirus (AsiaPac)

31 January 2020

On 29 January 2020, the number of confirmed cases of the rapidly spreading coronavirus in Mainland China officially surpassed the figure seen during the 2002/2003 SARS epidemic.

Multinationals with local operations around the APAC region have been significantly affected. As staff return to the office following the Chinese New Year holiday period, businesses are now considering what they can do to minimise any risk to health and safety and support staff through this challenging period where anxiety and uncertainty is rife, whilst at the same time complying with their employment obligations and maintaining business continuity. Putting in place detailed business and contingency plans and ensuring careful communications with staff to address key topics and concerns is key, as is keeping such plans and communications under frequent review given the fluidity of the current situation.

This alert considers some of the key issues that HR and business leaders should be considering across the APAC region.

### Harsher penalties on discriminatory employment practices in Singapore

29 January 2020
The Fair Consideration Framework was updated in January 2020 to impose harsher penalties on employers found to be engaging in discriminatory practices such as by favouring the hiring of foreigners over Singaporeans.

### China extends holidays for workers amid coronavirus outbreak (China)

28 January 2020
Learn about how the widely publicised corona virus outbreak affects business in Greater China.

### EU MDCG issues new guidance on Cybersecurity for medical devices

27 January 2020
On 7 January 2020, the EU Medical Device Coordination Group published new guidance to help manufacturers fulfil all relevant cybersecurity requirements in Annex I to the new Medical Device Regulations (Regulations 2017/745 on medical devices and 2017/746 on in vitro diagnostic medical devices).

### New regulations reinforce CFIUS's expanded role with respect to foreign investments in the United States

16 January 2020
The new CFIUS regulations become effective on February 13, 2020.

### Top of Mind: Life Sciences

16 January 2020
Eight big topics that life sciences businesses have been thinking about and how DLA Piper has been covering those stories.

### The almost free US-Japan Trade Agreement is now in effect

9 January 2020
This trade agreement reduces or eliminates US customs duties on numerous goods.

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### CCPA Rescue Kit arrives amid new privacy law change

19 December 2019
A series of integrated compliance offerings to help businesses begin the journey of compliance with this important new privacy bill.

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### Street art raises novel copyright issues – or does it?

19 December 2019

Is street art less entitled to copyright protection than are traditional art forms?

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### EU launches preparatory work for a global sanctions regime for human rights violations

17 December 2019
On 9 December 2019, High Representative/Vice-President of the European Union Josep Borrell announced that the Foreign Affairs Council has agreed with strong consensus to start the preparatory work for a global sanctions regime to address serious human rights violations.

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### 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.

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### 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.

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### 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.

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## EVENTOS

## Reciente

### Embracing Digital Evolution

15 September 2021
Webinar

### EDPB recommendations for safeguarding data transfers after Schrems II

19 November 2020
Webinar

### Women in Science and Technology Conference

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

## NOTICIAS

### DLA Piper advises Genomma Lab in the issuance of MX$1.25 billion in short-term debt securities

13 August 2020
DLA Piper represented Genomma Lab Internacional S.A.B. de C.V. in its issuance of MX$1.25 billion in short-term debt securities in the form of Certificados Bursátiles.

### DLA Piper announces partnership promotions for 2020

30 April 2020

DLA Piper is proud to announce that 67 lawyers have been promoted to its partnership. The promotions are effective as of April 1, 2020 in the United States and May 1, 2020 for EMEA and Asia Pacific. The promotions have been made across many of the firm's practice areas in 35 different offices throughout 13 countries.

Across the firm's practices globally, Corporate saw the largest intake of new partners with 19 promotions, followed by Litigation and Regulatory with 15. Intellectual Property and Technology and Finance and Projects had ten and eight promotions respectively, while there were six in Real Estate. Tax and Employment both had four, and there was one in Restructuring.

### DLA Piper lawyers named Acritas Stars

10 March 2020

Acritas has named over 200 DLA Piper lawyers as 2020 Acritas Stars. Now in its fourth year, Acritas Stars highlights the stand-out lawyers in private practice as nominated by clients around the world. More than 3,000 senior in-house counsel feed into the nomination process to give a comprehensive view of highly recommended lawyers across the globe.

# Sustainability and ESG

Sustainability is a core business issue in the life sciences sector, given its central role in addressing systemic global challenges including pandemics, access to medicine, and climate change. Creating new and sustainable value depends upon connecting stakeholder experiences with business outcomes – from patients to health workers, as well as wider health sector players. Boards must focus on more personalized healthcare and specialized services, leveraging technology in product development and patient care, and fostering trust on key issues like transparency of clinical trials, use of health and patient data, product quality and safety, and the environmental and social impacts across product life-cycles.

A number of sustainability-related themes affect businesses operating in the life sciences sector:

- **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.
- **Digital transformation:** The use of AI, machine learning, automation and other digital technologies is transforming the global life sciences landscape. The application of AI, robotics and cloud services has paved the way to innovative, effective and cost-efficient therapy discoveries and the development of preventative and wellness-focused consumer wearables, personalized telemedicine services and remote patient monitoring. This digital transformation is expected to continue as more than 50 percent of health consumers support the use of AI and robotics to improve health outcomes.
- **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.
- **Trust and ethical use of data:** Vast amounts of valuable health data are generated through health and wellness apps, digital or automated diagnostics, cloud-based patient records and other medical devices. There is also a growing number of stakeholders with access to this data, including healthcare providers, health workers, insurers, governments and app developers. A key expectation within the life sciences sector is that data to improve health outcomes will continue along the path of increased accessibility while also ensuring its ethical use and the protection of individuals' privacy.
- **Patient-centered services and more personalized healthcare:** The changing priorities of health consumers and professionals are leading to a greater focus on the patient experience, from prevention and wellness to diagnosis and management of disease. Technology gives health consumers greater control over prevention and management of disease and provides health professionals access to better data to track and monitor their patients.
- **Net-zero decarbonization:** In striving to decarbonize 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, optimizing processes and reducing costs across the sector.
- **Sustainable sourcing, product life-cycles and a circular economy:** Stakeholders demand greater transparency across product life-cycles, businesses make commitments to net-zero decarbonization 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, labor conditions and community impacts are managed.
- **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.
- **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 and ultimately upon their license to operate.

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