



Life Sciences

As the legal matters confronting our life science clients are varied, so are the skill sets we employ. DLA Piper's life sciences team comprises lawyers with legal, scientific and medical knowledge who understand the complexity of the business and regulatory environments in which our clients operate.

The challenges facing today's biotechnology and medical device companies are greater than ever. For companies to take promising therapies from the laboratory to the market, they must protect those therapies from IP, regulatory and reputational risks. Furthermore, the last few years have seen increasing pressure from many sides: demand for greater shareholder return, loss of key revenue streams due to patent expiration or generic challenges, fierce competition in key therapeutic areas, pricing pressures from health care payors, increased government regulation beyond core safety issues, rising costs of R&D, challenges in maximizing return in emerging markets and aggressive government enforcement action.

Our life sciences sector team is one of the largest and most active of any law firm. Operating as one team across more than 30 jurisdictions, we combine subject matter experience with considerable knowledge of the sector, including the scientific, medical, regulatory, commercial and enforcement environments facing our biopharmaceutical, medical device, research and diagnostics clients.

DLA Piper's team includes award-winning lawyers practicing litigation, compliance and investigations, IP strategy and enforcement, M&A, licensing and distribution and clinical trial advice. They also support clients across all other areas needed to address risk, including government affairs, environmental law, import/export, tax, real estate and employment law. Many of our lawyers are former sector professionals, many have PhDs or other advanced degrees in the life sciences field and others are former government officials or prosecutors.

Recognizing that our clients' needs vary, we rapidly organize and customize our client service teams, whether for a large pharmaceutical company, a mid-sized medical device client or a development-stage biotech company. These teams are supported by international and local practitioners to efficiently meet the demands of the matter.

Our cutting-edge staffing, budgeting and billing systems, created specifically to assist our global life science clients, ensure that our teams deliver value in addition to great results.

Our life sciences team helps clients solve their biggest challenges every day. Examples of our experience include:

KEY CONTACTS

Marco de Morpurgo

Partner
Rome
T: +39 06 68 880 1

Andrew P. Gilbert

Partner
New Jersey (Short Hills)
T: +1 973 520 2553

Matt Holian

Partner
Boston
T: +1 617 406 6009

RELATED SERVICES

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

- Conducting a sensitive investigation in China
- Negotiating a complex multi-country distribution deal in Latin America
- Acting as National Counsel on a mass tort in the US
- Helping sell or acquire a major business asset
- Advising on implementation of transparency laws or the impact of other new legislation
- Devising a risk mitigation plan for a key product
- Negotiating a large vaccine contract with a global NGO
- Counselling on a multi-jurisdictional clinical trial
- Advising on the downsizing of employees in Europe
- Supporting global business conduct and compliance functions
- Outsourcing critical R&D or IT functions
- Devising an IP strategy for a promising new therapy
- Negotiating a worldwide licensing and collaboration deal
- Protecting a blockbuster drug in patent litigation

INSIGHTS

Publications

The Russian Supreme Court clarifies intellectual property legislation

30 Sep 2019

Clarifications from the Supreme Court have a significant impact on the further development of court practice in Russia.

ITC Section 337 update: Expect heavy emphasis on public interest in pharma/medical device investigations

30 Sep 2019

Difficult public interest issues may arise when a potentially life-saving drug or medical device is sought to be excluded.

The CBD problem: searching for a legal pathway for CBD in foods and supplements

20 September 2019

The current state of the laws and regulations in the US, and potential pathways to a resolution.

Treasury Department proposes regulations comprehensively implementing FIRRMA and reforming CFIUS national security review

19 September 2019

The proposed regulations affect non-controlling investments involving critical technologies, critical infrastructure, and sensitive personal data; and transactions involving real estate near sensitive national security facilities.

Brexit: The Implications for the Life Sciences Sector

1 September 2019

Brexit. If you operate within, are considering entering, or even expanding an existing footprint in either the UK or EU markets, this guide will help identify risk areas, any changes to be made, and the deadlines imposed for doing so.

Israel Group News August 2019

7 August 2019

ISRAEL GROUP NEWS

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

ITC Section 337 update: Commission decision stayed?

24 July 2019

Significant new developments.

Pharmaceuticals sector update

18 July 2019

We are pleased to present to you our periodical legal update on developments in the Russian pharmaceutical sector. It is intended to give you brief outline on key regulations and other important activities and trends in the industry.

Biomarker-based cancer diagnostics: German pricing regulator sets high validation and reimbursement standards for novel diagnostic methods

10 July 2019

On 20 June 2019, for the first time, the German Federal Joint Committee (FJC – Gemeinsamer Bundesausschuss / G-BA), the highest decision-making body of the joint self-government of physicians, dentists, hospitals and statutory health insurance funds (SHI – gesetzliche Krankenversicherung / GKV) in Germany, made the resolution that a specific biomarker-based test to support the treatment decision for or against adjuvant chemotherapy, i. e. after primary surgery, in certain breast cancer patients may be reimbursed by the SHIs.

Predictions of a No-Deal Brexit are rising...but for the Life Sciences Sector, will “science prevail” over the Brexit “doom and gloom”?

9 July 2019

This article assumes a no-deal Brexit (Hard Brexit) and highlights the key UK Government, MHRA and EMA guidance, proposed legal changes and practical consequences of a Hard Brexit on medicines, medical devices, clinical trials, manufacturing and supply.

Intellectual Property and Technology News (Asia Pacific) May 2019

15 MAY 2019

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES

Intellectual Property and Technology News (Asia Pacific) is our biannual publication designed to report on worldwide development in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

Israel Group News May 2019

9 MAY 2019

ISRAEL GROUP NEWS

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

EU Policy & Regulatory Alert - EU Publishes Artificial Intelligence Ethics Guidelines

12 APR 2019

On 8 April 2019, the EU's High-Level Expert Group ("AI HLEG") on Artificial Intelligence ("AI") published the much-anticipated "Ethics Guidelines for Trustworthy AI", setting out a horizontal framework for the development and deployment of ethical and robust AI systems across the EU

Supreme Court Corner Q1 2019

11 APR 2019

In celebration of the 10th anniversary of IPT News, we note that 10 years ago, in the first quarter of 2009, Bernard L. Bilski filed his petition in the landmark *Bilski v. Kappos*, 561 U.S. 593 (2010), forever shaping the patentability of business methods.

Pharmaceuticals Sector Update April 2019

02 Apr 2019

Welcome to the next issue of the Pharma Update covering recent developments in the Russian pharmaceuticals sector.

EU Policy & Regulatory Alert: EU Mechanism for Foreign Investment Screening to Enter into Force in April

21 MAR 2019

Today, on 21 March 2019, the new Regulation establishing a framework for the screening of foreign direct investments into the Union was published in the Official Journal of the European Union (EU).

Top of Mind: Litigation

20 MAR 2019

In this issue, our coverage of 10 big topics businesses have been thinking about this quarter.

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.

Explainability: where AI and liability meet

25 FEB 2019

Makers and users of AI face a new and interesting problem: what is the acceptable tradeoff between explanation and accuracy?

Israel Group News

12 FEB 2019

ISRAEL GROUP NEWS

In this issue, the rise of the Data Protection Officer, plus news and coming events.

Pharmaceuticals sector update

6 FEB 2019

We are pleased to present to you our periodical legal update on developments in the Russian pharmaceutical sector. It is intended to give you brief outline on key regulations and other important activities and trends in the industry.

EU Policy & Regulatory Update - EU Adds Three Iranian Persons to EU Terrorist List

14 JAN 2019

On 8 January 2019, the Council of the European Union (EU) adopted Decision (CFSP) 2019/25 amending and updating the list of persons, groups and entities subject to Articles 2, 3 and 4 of Common Position 2001/931/CFSP.

Relying on "common sense" instead of prior art in evaluating the obviousness of pharmaceutical patents

21 DEC 2018

A one-time aberration, or the start of a trend?

***Alice* in Wonderland: navigating the strange world of patenting AI**

21 DEC 2018

Like the bottle labeled DRINK ME, certain techniques can make the trip through the AI-patent rabbit hole more scalable.

Leading life science patent litigators join DLA Piper in New York

21 DEC 2018

Michael Dougherty and Tony Pezzano have joined the firm's Intellectual Property and Technology practice as patent litigation partners in New York.

Top of mind: Litigation

10 DEC 2018

Our coverage of big compliance, enforcement and litigation issues that businesses are thinking about this quarter.

EU Policy & Regulatory Alert: New Regulation on Foreign Direct Investment Screening in the EU

22 NOV 2018

The European Union is moving fast towards establishing a joint regulatory and policy framework for Europeans to seize the opportunities provided by Artificial Intelligence (AI) and to reinforce Europe's competitiveness in this field.

Russia Pharmaceuticals Sector Update

8 NOV 2018

Legal update on developments in the Russian pharmaceutical sector

Automatic acceptance of the sectoral tariff agreement if objections are not submitted by 3 November 2018

29 OCT 2018

The sectoral tariff agreement for 2019 - 2021 ("Agreement") which applies to employers in the chemical, oil and gas, biotechnological and chemical-pharma industries has now been published and enters into force on 1 January 2019.

Israel Group News

24 OCT 2018

[ISRAEL GROUP NEWS](#)

In this issue, legal developments worldwide that affect this dynamic ecosystem.

CFIUS pilot program mandates declarations for certain non-controlling investments in critical technologies

17 OCT 2018

The pilot program covers critical technologies in 27 industries.

Section 301 additional tariffs on imports of Chinese products: options for high tech and manufacturing companies

3 OCT 2018

Additional tariffs of 10 percent or 25 percent have been imposed on three different lists of thousands of imports from China. Companies can request exclusion from these tariffs.

Supreme Court Corner Q3 2018

27 SEP 2018

The court rules on recovery of lost foreign profits and ponders patentability issues in an invention's sale to a third party that is obligated to keep the invention confidential.

Intellectual Property and Technology News (Asia Pacific) September 2018

27 SEP 2018

[INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES](#)

Intellectual Property and Technology News (Asia Pacific) is our annual publication designed to report on worldwide developments in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

Pharmaceuticals sector update August / September 2018

27 AUG 2018

We are pleased to present to you our new periodical legal update on developments in the Russian pharmaceutical sector. It is intended to give you brief outline on key regulations and other important activities and trends in the industry.

The tide turns: If your company is doing business in the US, it may soon be required to collect state sales taxes

24 JUL 2018

Companies selling online products and services to customers in US states may soon be required to register, collect and remit taxes in those states.

eSignature and ePayment News and Trends

23 JUL 2018

[ESIGNATURE AND EPAYMENT NEWS AND TRENDS](#)

This regular publication from DLA Piper aims to help companies identify significant news and legal developments impacting digital transactions.

eSignature and ePayment News and Trends

29 JUN 2018

[ESIGNATURE AND EPAYMENT NEWS AND TRENDS](#)

In this issue, is your website ADA compliant? Plus news on federal and state law, federal and state regulatory activities, fresh judicial precedent and more.

Is your website ADA compliant? A brief look at the current legal status

29 JUN 2018

Websites too face regulatory issues around compliance with the Americans with Disabilities Act and other rules involving accessibility and accommodation.

EU Policy and Regulatory update: A European approach to Artificial Intelligence

18 JUN 2018

The European Union is moving fast towards establishing a joint regulatory and policy framework for Europeans to seize the opportunities provided by Artificial Intelligence (AI) and to reinforce Europe's competitiveness in this field.

Pharmaceutical Trademarks 2018/2019 - Chapter: France

5 APR 2018

Like all trademarks, pharmaceutical trademarks are subject to general trademark rules regarding validity and use. Until recently, both French and European law required a trademark to be capable of graphical representation. This requirement allowed the registration of shapes, colours and sounds, but excluded signs such as smells. The European trademark law reform, comprising EU Directive 2015/2436 and the EU Trademark Regulation (2017/1001), deleted the graphical representation requirement from trademark law. This change marks a dramatic step forward in trademark law and could make it easier to register smells and other non-traditional trademarks.

Section 301 trade action against Chinese products: time for quick action

4 APR 2018

Companies wishing to seek removal of a product from the final list have the opportunity to present their views, but less than two months remain before the window completely closes.

Regulation of medical devices - what is changing?

13 MAR 2018

After four years of deliberations, the new Medical Devices Regulation finally came into effect on 25 May 2017. This marks the commencement of a three-year transitional period for manufacturers of medical devices to update their policies and processes in order to distribute products in the EU market.

EU Data Privacy Law Presents New Challenges and New Opportunities

7 MAR 2018

Joint report from BCG and DLA Piper reveals how companies can meet—and exceed—the data privacy requirements of the EU's impending General Data Protection Regulation to become trusted data stewards.

Global Data Privacy Snapshot 2018: How does your organisation compare?

31 JAN 2018

Data protection is rising on the agenda globally: the past year has seen China introduce the PRC Cybersecurity Law, the

introduction of Australia's mandatory Privacy Amendment (Notifiable Data Breaches) Act 2017, while the EU's long awaited General Data Protection Regulation is due to come in to force in May 2018.

2018 outlook for drugs and medical devices in China: regulatory reform fueled by innovation

18 JAN 2018

The year 2017 ended with a central government directive to reform the regulatory approval system for drugs and medical devices and a subsequent flood of CFDA changes and proposed changes to the system, and we should see further regulatory reform in 2018 as the Chinese government continues to encourage domestic innovation in this sector.

Intellectual Property and Technology News (Asia Pacific) December 2017

7 DEC 2017

[INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES](#)

Intellectual Property and Technology News (Asia Pacific) is our biannual publication designed to report on worldwide developments in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

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

10 SEP 2014

[INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES](#)

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.

[EVENTS](#)

[Previous](#)

TopCo liability panel

25 JUN 2019

London

New frontiers on the abuse of dominance

18 JUN 2018

Webinar

Enforcement and compliance trends in today's life sciences environment

26 APR 2018
Webinar

NEWS

DLA Piper announces launch of Artificial Intelligence practice

14 MAY 2019

DLA Piper announced today the launch of its Artificial Intelligence practice, which will focus on assisting companies as they navigate the legal landscape of emerging and disruptive technologies, while helping them understand the legal and compliance risks arising from the creation and deployment of AI systems.

DLA Piper strengthens Intellectual Property and Technology offering in Russia

18 APR 2019

DLA Piper today announces that Julianna Tabastajewa will be joining the firm as a counsel in its Intellectual Property and Technology practice based in Moscow. Her practice focuses on IP protection and litigation in the area of pharmaceutical, competition and, media law, as well as franchising.

DLA Piper announces partnership promotions for 2019

1 APR 2019

DLA Piper is proud to announce that 77 lawyers have been promoted to its partnership. The promotions are effective as of April 1, 2019 in the United States and May 1, 2019 for EMEA and Asia Pacific. The promotions were made across many of the firm's practice areas in 43 different offices throughout 20 countries.

Galyna Zagorodniuk Re-Elected to the Public Council with the Antimonopoly Committee of Ukraine

28 FEB 2019

Galyna Zagorodniuk, Head of Competition at DLA Piper in Ukraine and member of the Ukrainian Professional Association of Corporate Governance, has been re-elected to the Public Council of the Antimonopoly Committee of Ukraine for 2019-2020.

DLA Piper enhances cross-border tax capability with new partner hire in Dublin

26 FEB 2019

DLA Piper today announces the appointment of Maura Dineen as a Tax partner in the firm's newly opened Dublin office. This is the fifth partner hire for DLA Piper in Dublin in a month, following the announcements in January of Conor Houlihan (Finance &

Projects), Éanna Mellett (Corporate), Mark Rasdale (Intellectual Property & Technology) and Ciara McLoughlin (Employment).

DLA Piper recognized as a leading private equity, venture capital and M&A firm in *PitchBook's* league tables

19 FEB 2019

For the second consecutive year, DLA Piper was the only firm to rank as one of the top five most active law firms for private equity, venture capital and M&A deal volume in *PitchBook's* 2018 global league tables report.

DLA Piper advises Ovoca Bio on its acquisition of Russia's drug development company Ivix

2 NOV 2018

DLA Piper has advised Dublin-based life sciences investor, Ovoca Bio, on its acquisition of Russian drug development company Ivix.

DLA Piper advises la Société d'Aménagement Zenata (SAZ) on landmark healthcare centre project

29 MAY 2018

DLA Piper has advised La Société d'Aménagement Zenata (SAZ), the entity in charge of the overall development of the Zenata Eco-City in Morocco, on the signature of a cooperation agreement with the Saudi German Hospital Group to develop a healthcare centre.

DLA Piper named International Law Firm of the Year in Ukraine for fifth year running at The Legal Awards 2018

24 MAY 2018

DLA Piper has been named International Law Firm of the Year in Ukraine at the 2018 Legal Awards, held by Yuridicheskaya Practika Publishing House. This is the fifth time the office has won the award.

DLA Piper announces partnership promotions for 2018

3 APR 2018

DLA Piper is proud to announce that 62 lawyers have been promoted to its partnership. The promotions are effective as of 1 April 2018 in the United States and 1 May 2018 for EMEA and Asia Pacific. The promotions were made across many of the firm's practice areas in 42 different offices throughout 20 countries.

Businesses still not fully aware of Data Protection issues

31 JAN 2018

DLA Piper has released its second Data Privacy Snapshot report, finding that once again, company global privacy programs have gaps in meeting increasingly demanding global privacy principles. Significantly, it appears that many companies are falling short of data protection obligations under the General Data Protection Regulation (GDPR), which will start to apply from 25 May 2018.

Stephen Matthews joins DLA Piper's Litigation practice in New Jersey

17 JAN 2018

DLA Piper announced today that Stephen Matthews has joined the firm's Litigation practice as a partner in the Short Hills, New Jersey, office.

DLA Piper advises Immunomedics on royalty funding and stock purchase agreements with Royalty Pharma which raised an aggregate of US\$250 million

9 JAN 2018

DLA Piper represented Immunomedics, Inc., in the sale of tiered, sales-based royalty rights on global net sales of sacituzumab govitecan (IMMU-132) to Royalty Pharma for US\$175 million. Royalty Pharma has also purchased US\$75 million in common stock of Immunomedics, at US\$17.15 per share.

DLA Piper advises on the sale of shares in one of Egypt's fastest growing pharmaceutical companies

9 NOV 2017

DLA Piper has advised Orchidia Pharmaceutical Industries (the "Company" or "Orchidia"), a leading ophthalmic generic medicine manufacturer and one of Egypt's fastest growing pharmaceutical companies, and Dr. Ossama Fouad Abbas, the founder, majority shareholder and Chairman of the Company, on the sale of a stake in the Company and two holding companies incorporated in Cyprus to Egyptian-American Enterprise Fund (EAEF).

In Russia

Our international team of lawyers, consisting of Russian, English and US qualified lawyers, are experienced in a wide range of business transactions, including franchising, brand development, life sciences, pharmaceuticals and related matters. We advise international and local pharmaceutical companies on issues related to Russian regulatory framework for manufacturing, circulation and pricing of pharmaceuticals. We also offer advice on various aspects relating to compliance with regulatory requirements for importation and distribution of medical products and medical devices, and assist clients in the licensing of medical product manufacturing technology. Finally, we also extensively advise international and local pharmaceutical companies in various forms of M&A and private equity transactions.

Sophisticated biotechnology and pharmaceutical clients want and need their lawyers to understand their business, anticipate legal problems, know how others in the industry are addressing emerging issues, know what regulators and tax professionals think, and be able to provide timely answers. It takes extensive industry involvement to provide this level of service. This is why DLA Piper is the logical choice for life sciences companies seeking a strategic legal partner in Russia.

EXPERIENCE

- Advising a major Japanese pharmaceutical company in a competitive sale process for the acquisition of over-the-counter and food supplement brands in Russia worth US\$ 1 billion, including due diligence and full transaction support.
 - Advising a major Japanese pharmaceutical company in a competitive sale process for the acquisition of over-the-counter brands in the CIS worth US\$ 500 million, including due diligence and full transaction support.
 - Advising a large Hungarian pharmaceutical company in a competitive sale process for the acquisition of a US\$ 100 million asset in Russia, including due diligence and full transaction support.
 - Advising a large Russian group of companies on the sale of the over-the-counter pharmaceuticals company in Russia to an
-

international pharmaceuticals company headquartered in Canada.

- Advising a Russian company and its group involved in organization of clinical trials (medical testing at preregistration phase) and operating in various jurisdictions across Eastern Europe and in the US, on various structuring issues in connection with the company's contemplated expansion to Western European markets, including due diligence.
- Acting for a German multinational chemical and pharmaceutical company in reorganisation and restructuring in relation to the merger of the Russian subsidiaries of Bayer and Schering-Plough (as part of the global Bayer-Schering merger), including advice on both general corporate and tax issues, and legal and tax due diligence of draft agreements regarding the Russian distribution campaign.
- Providing legal assistance to a large US life sciences company with regard to a full pre-acquisition due diligence of a St Petersburg-based pharmaceutical company.
- Advising a leading Italian life sciences multinational company on the restructuring of its US\$ 90 million IP assets acquired as part of the acquisition of a Russian bio-pharma target company, including extensive tax and IP advice specifically with respect to acquiring and restructuring all the license operations and intellectual property in Russia for the Italian group, involving the structuring of several patents, industrial designs and over 100 trademarks use for drugs and biologically active additions.
- Advising a US based global healthcare company on a joint venture project related to import and distribution of pharmaceuticals in Russia, including advice on Russian pricing regulations.
- Acting for a leading Norwegian engineering and construction company working across a number of industries, including pharmaceuticals, in its acquisition of a Russian engineering bureau. The mandate included significant regulatory support in addition to the M&A work.
- Advising a Swiss based global healthcare company on setting up a EUR 80 million greenfield project in Special Economic Zone (SEZ) Novoorlovskaya, St Petersburg, including registration of a legal entity in St Petersburg, analysis of the SEZ agreement required for granting Novartis SEZ resident status, conducting due diligence in relation to the land plot in order to detect key risks.
- Advising a leading global biopharma company in relation to general employment law matters, including reorganisation.
- Advising a leading international medical technology company and developer of hearing implants system, in the planning, structuring, negotiation and document preparation for the completion of a know-how license and distribution relationship for the manufacture and sale of medical devices in Russia.
- Representing a major world-wide pharmaceutical company in relation to the stoppage of unauthorized use of five domain names by a third party and the related settlement agreement.
- Representing a major German personal-care company in a landmark domain name cyber-squatting case.
- Advising a number of clients on regulatory and practical aspects of structuring clinical trials.



Life Sciences

As the legal matters confronting our life science clients are varied, so are the skill sets we employ. DLA Piper's life sciences team comprises lawyers with legal, scientific and medical knowledge who understand the

complexity of the business and regulatory environments in which our clients operate.

The challenges facing today's biotechnology and medical device companies are greater than ever. For companies to take promising therapies from the laboratory to the market, they must protect those therapies from IP, regulatory and reputational risks. Furthermore, the last few years have seen increasing pressure from many sides: demand for greater shareholder return, loss of key revenue streams due to patent expiration or generic challenges, fierce competition in key therapeutic areas, pricing pressures from health care payors, increased government regulation beyond core safety issues, rising costs of R&D, challenges in maximizing return in emerging markets and aggressive government enforcement action.

Our life sciences sector team is one of the largest and most active of any law firm. Operating as one team across more than 30 jurisdictions, we combine subject matter experience with considerable knowledge of the sector, including the scientific, medical, regulatory, commercial and enforcement environments facing our biopharmaceutical, medical device, research and diagnostics clients.

DLA Piper's team includes award-winning lawyers practicing litigation, compliance and investigations, IP strategy and enforcement, M&A, licensing and distribution and clinical trial advice. They also support clients across all other areas needed to address risk, including government affairs, environmental law, import/export, tax, real estate and employment law. Many of our lawyers are former sector professionals, many have PhDs or other advanced degrees in the life sciences field and others are former government officials or prosecutors.

Recognizing that our clients' needs vary, we rapidly organize and customize our client service teams, whether for a large pharmaceutical company, a mid-sized medical device client or a development-stage biotech company. These teams are supported by international and local practitioners to efficiently meet the demands of the matter.

Our cutting-edge staffing, budgeting and billing systems, created specifically to assist our global life science clients, ensure that our teams deliver value in addition to great results.

Our life sciences team helps clients solve their biggest challenges every day. Examples of our experience include:

- Conducting a sensitive investigation in China
- Negotiating a complex multi-country distribution deal in Latin America
- Acting as National Counsel on a mass tort in the US
- Helping sell or acquire a major business asset
- Advising on implementation of transparency laws or the impact of other new legislation
- Devising a risk mitigation plan for a key product
- Negotiating a large vaccine contract with a global NGO
- Counselling on a multi-jurisdictional clinical trial
- Advising on the downsizing of employees in Europe
- Supporting global business conduct and compliance functions
- Outsourcing critical R&D or IT functions
- Devising an IP strategy for a promising new therapy
- Negotiating a worldwide licensing and collaboration deal
- Protecting a blockbuster drug in patent litigation

INSIGHTS

Publications

The Russian Supreme Court clarifies intellectual property legislation

30 Sep 2019

Clarifications from the Supreme Court have a significant impact on the further development of court practice in Russia.

ITC Section 337 update: Expect heavy emphasis on public interest in pharma/medical device investigations

30 Sep 2019

Difficult public interest issues may arise when a potentially life-saving drug or medical device is sought to be excluded.

The CBD problem: searching for a legal pathway for CBD in foods and supplements

20 September 2019

The current state of the laws and regulations in the US, and potential pathways to a resolution.

Treasury Department proposes regulations comprehensively implementing FIRRMA and reforming CFIUS national security review

19 September 2019

The proposed regulations affect non-controlling investments involving critical technologies, critical infrastructure, and sensitive personal data; and transactions involving real estate near sensitive national security facilities.

Brexit: The Implications for the Life Sciences Sector

1 September 2019

Brexit. If you operate within, are considering entering, or even expanding an existing footprint in either the UK or EU markets, this guide will help identify risk areas, any changes to be made, and the deadlines imposed for doing so.

Israel Group News August 2019

7 August 2019

ISRAEL GROUP NEWS

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

ITC Section 337 update: Commission decision stayed?

24 July 2019

Significant new developments.

Pharmaceuticals sector update

18 July 2019

We are pleased to present to you our periodical legal update on developments in the Russian pharmaceutical sector. It is intended to give you brief outline on key regulations and other important activities and trends in the industry.

Biomarker-based cancer diagnostics: German pricing regulator sets high validation and reimbursement standards for novel diagnostic methods

10 July 2019

On 20 June 2019, for the first time, the German Federal Joint Committee (FJC – Gemeinsamer Bundesausschuss / G-BA), the highest decision-making body of the joint self-government of physicians, dentists, hospitals and statutory health insurance funds (SHI – gesetzliche Krankenversicherung / GKV) in Germany, made the resolution that a specific biomarker-based test to support the treatment decision for or against adjuvant chemotherapy, i. e. after primary surgery, in certain breast cancer patients may be reimbursed by the SHIs.

Predictions of a No-Deal Brexit are rising...but for the Life Sciences Sector, will “science prevail” over the Brexit “doom and gloom”?

9 July 2019

This article assumes a no-deal Brexit (Hard Brexit) and highlights the key UK Government, MHRA and EMA guidance, proposed legal changes and practical consequences of a Hard Brexit on medicines, medical devices, clinical trials, manufacturing and supply.

Intellectual Property and Technology News (Asia Pacific) May 2019

15 MAY 2019

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES

Intellectual Property and Technology News (Asia Pacific) is our biannual publication designed to report on worldwide development in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

Israel Group News May 2019

9 MAY 2019

ISRAEL GROUP NEWS

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

EU Policy & Regulatory Alert - EU Publishes Artificial Intelligence Ethics Guidelines

12 APR 2019

On 8 April 2019, the EU's High-Level Expert Group ("AI HLEG") on Artificial Intelligence ("AI") published the much-anticipated "Ethics Guidelines for Trustworthy AI", setting out a horizontal framework for the development and deployment of ethical and robust AI systems across the EU

Supreme Court Corner Q1 2019

11 APR 2019

In celebration of the 10th anniversary of IPT News, we note that 10 years ago, in the first quarter of 2009, Bernard L. Bilski filed his petition in the landmark *Bilski v. Kappos*, 561 U.S. 593 (2010), forever shaping the patentability of business methods.

Pharmaceuticals Sector Update April 2019

02 Apr 2019

Welcome to the next issue of the Pharma Update covering recent developments in the Russian pharmaceuticals sector.

EU Policy & Regulatory Alert: EU Mechanism for Foreign Investment Screening to Enter into Force in April

21 MAR 2019

Today, on 21 March 2019, the new Regulation establishing a framework for the screening of foreign direct investments into the Union was published in the Official Journal of the European Union (EU).

Top of Mind: Litigation

20 MAR 2019

In this issue, our coverage of 10 big topics businesses have been thinking about this quarter.

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.

Explainability: where AI and liability meet

25 FEB 2019

Makers and users of AI face a new and interesting problem: what is the acceptable tradeoff between explanation and accuracy?

Israel Group News

12 FEB 2019

[ISRAEL GROUP NEWS](#)

In this issue, the rise of the Data Protection Officer, plus news and coming events.

Pharmaceuticals sector update

6 FEB 2019

We are pleased to present to you our periodical legal update on developments in the Russian pharmaceutical sector. It is intended to give you brief outline on key regulations and other important activities and trends in the industry.

EU Policy & Regulatory Update - EU Adds Three Iranian Persons to EU Terrorist List

14 JAN 2019

On 8 January 2019, the Council of the European Union (EU) adopted Decision (CFSP) 2019/25 amending and updating the list of

persons, groups and entities subject to Articles 2, 3 and 4 of Common Position 2001/931/CFSP.

Relying on "common sense" instead of prior art in evaluating the obviousness of pharmaceutical patents

21 DEC 2018

A one-time aberration, or the start of a trend?

***Alice* in Wonderland: navigating the strange world of patenting AI**

21 DEC 2018

Like the bottle labeled DRINK ME, certain techniques can make the trip through the AI-patent rabbit hole more scalable.

Leading life science patent litigators join DLA Piper in New York

21 DEC 2018

Michael Dougherty and Tony Pezzano have joined the firm's Intellectual Property and Technology practice as patent litigation partners in New York.

Top of mind: Litigation

10 DEC 2018

Our coverage of big compliance, enforcement and litigation issues that businesses are thinking about this quarter.

EU Policy & Regulatory Alert: New Regulation on Foreign Direct Investment Screening in the EU

22 NOV 2018

The European Union is moving fast towards establishing a joint regulatory and policy framework for Europeans to seize the opportunities provided by Artificial Intelligence (AI) and to reinforce Europe's competitiveness in this field.

Russia Pharmaceuticals Sector Update

8 NOV 2018

Legal update on developments in the Russian pharmaceutical sector

Automatic acceptance of the sectoral tariff agreement if objections are not submitted by 3 November 2018

29 OCT 2018

The sectoral tariff agreement for 2019 - 2021 ("Agreement") which applies to employers in the chemical, oil and gas, biotechnological and chemical-pharma industries has now been published and enters into force on 1 January 2019.

Israel Group News

24 OCT 2018

[ISRAEL GROUP NEWS](#)

In this issue, legal developments worldwide that affect this dynamic ecosystem.

CFIUS pilot program mandates declarations for certain non-controlling investments in critical technologies

17 OCT 2018

The pilot program covers critical technologies in 27 industries.

Section 301 additional tariffs on imports of Chinese products: options for high tech and manufacturing companies

3 OCT 2018

Additional tariffs of 10 percent or 25 percent have been imposed on three different lists of thousands of imports from China. Companies can request exclusion from these tariffs.

Supreme Court Corner Q3 2018

27 SEP 2018

The court rules on recovery of lost foreign profits and ponders patentability issues in an invention's sale to a third party that is obligated to keep the invention confidential.

Intellectual Property and Technology News (Asia Pacific) September 2018

27 SEP 2018

[INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES](#)

Intellectual Property and Technology News (Asia Pacific) is our annual publication designed to report on worldwide developments in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

Pharmaceuticals sector update August / September 2018

27 AUG 2018

We are pleased to present to you our new periodical legal update on developments in the Russian pharmaceutical sector. It is intended to give you brief outline on key regulations and other important activities and trends in the industry.

The tide turns: If your company is doing business in the US, it may soon be required to collect state sales taxes

24 JUL 2018

Companies selling online products and services to customers in US states may soon be required to register, collect and remit taxes in those states.

eSignature and ePayment News and Trends

23 JUL 2018

[ESIGNATURE AND EPAYMENT NEWS AND TRENDS](#)

This regular publication from DLA Piper aims to help companies identify significant news and legal developments impacting digital transactions.

eSignature and ePayment News and Trends

29 JUN 2018

[ESIGNATURE AND EPAYMENT NEWS AND TRENDS](#)

In this issue, is your website ADA compliant? Plus news on federal and state law, federal and state regulatory activities, fresh judicial precedent and more.

Is your website ADA compliant? A brief look at the current legal status

29 JUN 2018

Websites too face regulatory issues around compliance with the Americans with Disabilities Act and other rules involving accessibility and accommodation.

EU Policy and Regulatory update: A European approach to Artificial Intelligence

18 JUN 2018

The European Union is moving fast towards establishing a joint regulatory and policy framework for Europeans to seize the opportunities provided by Artificial Intelligence (AI) and to reinforce Europe's competitiveness in this field.

Pharmaceutical Trademarks 2018/2019 - Chapter: France

5 APR 2018

Like all trademarks, pharmaceutical trademarks are subject to general trademark rules regarding validity and use. Until recently, both French and European law required a trademark to be capable of graphical representation. This requirement allowed the registration of shapes, colours and sounds, but excluded signs such as smells. The European trademark law reform, comprising EU Directive 2015/2436 and the EU Trademark Regulation (2017/1001), deleted the graphical representation requirement from trademark law. This change marks a dramatic step forward in trademark law and could make it easier to register smells and other non-traditional trademarks.

Section 301 trade action against Chinese products: time for quick action

4 APR 2018

Companies wishing to seek removal of a product from the final list have the opportunity to present their views, but less than two months remain before the window completely closes.

Regulation of medical devices - what is changing?

13 MAR 2018

After four years of deliberations, the new Medical Devices Regulation finally came into effect on 25 May 2017. This marks the commencement of a three-year transitional period for manufacturers of medical devices to update their policies and processes in order to distribute products in the EU market.

EU Data Privacy Law Presents New Challenges and New Opportunities

7 MAR 2018

Joint report from BCG and DLA Piper reveals how companies can meet—and exceed—the data privacy requirements of the EU's impending General Data Protection Regulation to become trusted data stewards.

Global Data Privacy Snapshot 2018: How does your organisation compare?

31 JAN 2018

Data protection is rising on the agenda globally: the past year has seen China introduce the PRC Cybersecurity Law, the introduction of Australia's mandatory Privacy Amendment (Notifiable Data Breaches) Act 2017, while the EU's long awaited General Data Protection Regulation is due to come in to force in May 2018.

2018 outlook for drugs and medical devices in China: regulatory reform fueled by innovation

18 JAN 2018

The year 2017 ended with a central government directive to reform the regulatory approval system for drugs and medical devices and a subsequent flood of CFDA changes and proposed changes to the system, and we should see further regulatory reform in 2018 as the Chinese government continues to encourage domestic innovation in this sector.

Intellectual Property and Technology News (Asia Pacific) December 2017

7 DEC 2017

[INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES](#)

Intellectual Property and Technology News (Asia Pacific) is our biannual publication designed to report on worldwide developments in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

10 SEP 2014

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES

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.

EVENTS

Previous

TopCo liability panel

25 JUN 2019

London

New frontiers on the abuse of dominance

18 JUN 2018

Webinar

Enforcement and compliance trends in today's life sciences environment

26 APR 2018

Webinar

NEWS

DLA Piper announces launch of Artificial Intelligence practice

14 MAY 2019

DLA Piper announced today the launch of its Artificial Intelligence practice, which will focus on assisting companies as they navigate the legal landscape of emerging and disruptive technologies, while helping them understand the legal and compliance risks arising from the creation and deployment of AI systems.

DLA Piper strengthens Intellectual Property and Technology offering in Russia

18 APR 2019

DLA Piper today announces that Julianna Tabastajewa will be joining the firm as a counsel in its Intellectual Property and Technology practice based in Moscow. Her practice focuses on IP protection and litigation in the area of pharmaceutical, competition and, media law, as well as franchising.

DLA Piper announces partnership promotions for 2019

1 APR 2019

DLA Piper is proud to announce that 77 lawyers have been promoted to its partnership. The promotions are effective as of April 1, 2019 in the United States and May 1, 2019 for EMEA and Asia Pacific. The promotions were made across many of the firm's practice areas in 43 different offices throughout 20 countries.

Galyna Zagorodniuk Re-Elected to the Public Council with the Antimonopoly Committee of Ukraine

28 FEB 2019

Galyna Zagorodniuk, Head of Competition at DLA Piper in Ukraine and member of the Ukrainian Professional Association of Corporate Governance, has been re-elected to the Public Council of the Antimonopoly Committee of Ukraine for 2019-2020.

DLA Piper enhances cross-border tax capability with new partner hire in Dublin

26 FEB 2019

DLA Piper today announces the appointment of Maura Dineen as a Tax partner in the firm's newly opened Dublin office. This is the fifth partner hire for DLA Piper in Dublin in a month, following the announcements in January of Conor Houlihan (Finance & Projects), Éanna Mellett (Corporate), Mark Rasdale (Intellectual Property & Technology) and Ciara McLoughlin (Employment).

DLA Piper recognized as a leading private equity, venture capital and M&A firm in *PitchBook's* league tables

19 FEB 2019

For the second consecutive year, DLA Piper was the only firm to rank as one of the top five most active law firms for private equity, venture capital and M&A deal volume in *PitchBook's* 2018 global league tables report.

DLA Piper advises Ovoca Bio on its acquisition of Russia's drug development company Ivix

2 NOV 2018

DLA Piper has advised Dublin-based life sciences investor, Ovoca Bio, on its acquisition of Russian drug development company Ivix.

DLA Piper advises la Société d'Aménagement Zenata (SAZ) on landmark healthcare centre project

29 MAY 2018

DLA Piper has advised La Société d'Aménagement Zenata (SAZ), the entity in charge of the overall development of the Zenata Eco-City in Morocco, on the signature of a cooperation agreement with the Saudi German Hospital Group to develop a healthcare centre.

DLA Piper named International Law Firm of the Year in Ukraine for fifth year running at The Legal Awards 2018

24 MAY 2018

DLA Piper has been named International Law Firm of the Year in Ukraine at the 2018 Legal Awards, held by Yuridicheskaya Praktika Publishing House. This is the fifth time the office has won the award.

DLA Piper announces partnership promotions for 2018

3 APR 2018

DLA Piper is proud to announce that 62 lawyers have been promoted to its partnership. The promotions are effective as of 1 April 2018 in the United States and 1 May 2018 for EMEA and Asia Pacific. The promotions were made across many of the firm's practice areas in 42 different offices throughout 20 countries.

Businesses still not fully aware of Data Protection issues

31 JAN 2018

DLA Piper has released its second Data Privacy Snapshot report, finding that once again, company global privacy programs have gaps in meeting increasingly demanding global privacy principles. Significantly, it appears that many companies are falling short of data protection obligations under the General Data Protection Regulation (GDPR), which will start to apply from 25 May 2018.

Stephen Matthews joins DLA Piper's Litigation practice in New Jersey

17 JAN 2018

DLA Piper announced today that Stephen Matthews has joined the firm's Litigation practice as a partner in the Short Hills, New Jersey, office.

DLA Piper advises Immunomedics on royalty funding and stock purchase agreements with Royalty Pharma which raised an aggregate of US\$250 million

9 JAN 2018

DLA Piper represented Immunomedics, Inc., in the sale of tiered, sales-based royalty rights on global net sales of sacituzumab govitecan (IMMU-132) to Royalty Pharma for US\$175 million. Royalty Pharma has also purchased US\$75 million in common stock of Immunomedics, at US\$17.15 per share.

DLA Piper advises on the sale of shares in one of Egypt's fastest growing pharmaceutical companies

9 NOV 2017

DLA Piper has advised Orchidia Pharmaceutical Industries (the "Company" or "Orchidia"), a leading ophthalmic generic medicine manufacturer and one of Egypt's fastest growing pharmaceutical companies, and Dr. Ossama Fouad Abbas, the founder, majority shareholder and Chairman of the Company, on the sale of a stake in the Company and two holding companies incorporated in Cyprus to Egyptian-American Enterprise Fund (EAEF).

In Russia

Our international team of lawyers, consisting of Russian, English and US qualified lawyers, are experienced in a wide range of business transactions, including franchising, brand development, life sciences, pharmaceuticals and related matters. We advise international and local pharmaceutical companies on issues related to Russian regulatory framework for manufacturing, circulation and pricing of pharmaceuticals. We also offer advice on various aspects relating to compliance with regulatory requirements for importation and distribution of medical products and medical devices, and assist clients in the licensing of medical product manufacturing technology. Finally, we also extensively advise international and local pharmaceutical companies in various forms of M&A and private equity transactions.

Sophisticated biotechnology and pharmaceutical clients want and need their lawyers to understand their business, anticipate legal problems, know how others in the industry are addressing emerging issues, know what regulators and tax professionals think, and be able to provide timely answers. It takes extensive industry involvement to provide this level of service. This is why DLA Piper is the logical choice for life sciences companies seeking a strategic legal partner in Russia.

EXPERIENCE

- Advising a major Japanese pharmaceutical company in a competitive sale process for the acquisition of over-the-counter and food supplement brands in Russia worth US\$ 1 billion, including due diligence and full transaction support.
- Advising a major Japanese pharmaceutical company in a competitive sale process for the acquisition of over-the-counter brands in the CIS worth US\$ 500 million, including due diligence and full transaction support.
- Advising a large Hungarian pharmaceutical company in a competitive sale process for the acquisition of a US\$ 100 million asset in Russia, including due diligence and full transaction support.
- Advising a large Russian group of companies on the sale of the over-the-counter pharmaceuticals company in Russia to an international pharmaceuticals company headquartered in Canada.
- Advising a Russian company and its group involved in organization of clinical trials (medical testing at preregistration phase) and operating in various jurisdictions across Eastern Europe and in the US, on various structuring issues in connection with the company's contemplated expansion to Western European markets, including due diligence.
- Acting for a German multinational chemical and pharmaceutical company in reorganisation and restructuring in relation to the merger of the Russian subsidiaries of Bayer and Schering-Plough (as part of the global Bayer-Schering merger), including advice on both general corporate and tax issues, and legal and tax due diligence of draft agreements regarding the Russian distribution campaign.
- Providing legal assistance to a large US life sciences company with regard to a full pre-acquisition due diligence of a St Petersburg-based pharmaceutical company.
- Advising a leading Italian life sciences multinational company on the restructuring of its US\$ 90 million IP assets acquired as part of the acquisition of a Russian bio-pharma target company, including extensive tax and IP advice specifically with respect to acquiring and restructuring all the license operations and intellectual property in Russia for the Italian group, involving the structuring of several patents, industrial designs and over 100 trademarks use for drugs and biologically active additions.
- Advising a US based global healthcare company on a joint venture project related to import and distribution of pharmaceuticals in Russia, including advice on Russian pricing regulations.
- Acting for a leading Norwegian engineering and construction company working across a number of industries, including pharmaceuticals, in its acquisition of a Russian engineering bureau. The mandate included significant regulatory support in

addition to the M&A work.

- Advising a Swiss based global healthcare company on setting up a EUR 80 million greenfield project in Special Economic Zone (SEZ) Novoorlovskaya, St Petersburg, including registration of a legal entity in St Petersburg, analysis of the SEZ agreement required for granting Novartis SEZ resident status, conducting due diligence in relation to the land plot in order to detect key risks.
- Advising a leading global biopharma company in relation to general employment law matters, including reorganisation.
- Advising a leading international medical technology company and developer of hearing implants system, in the planning, structuring, negotiation and document preparation for the completion of a know-how license and distribution relationship for the manufacture and sale of medical devices in Russia.
- Representing a major world-wide pharmaceutical company in relation to the stoppage of unauthorized use of five domain names by a third party and the related settlement agreement.
- Representing a major German personal-care company in a landmark domain name cyber-squatting case.
- Advising a number of clients on regulatory and practical aspects of structuring clinical trials.