Bird&Bird& Life Sciences & Healthcare An overview of our international capabilities



From protection to distribution & leading the industry & trusted partner & scientifically proven & distilling the essentials & deep technical understanding & that's Life Sciences & Healthcare with Bird & Bird



Intellectual Property Issues

Our intellectual property experts structure intellectual property protection strategies and assess the impact of third party rights on freedom to operate.



Funding & Partnering

We advise on all types of funding and partnering arrangements, using our corporate and intellectual property expertise.



Clinical Trials

We advise on all regulatory and contractual issues arising in connection with clinical trials.



Extracting Value

Our corporate team can assist you in negotiating and completing all forms of exits, from selling or merging your company to listing it on the stock exchange



legal services for the Life Sciences & Healthcare industry



Authorisation

Our regulatory experts are able to guide clients through the process of securing marketing authorisations and any appeals from regulatory decisions.



Life Cycle Management

Our internationally renowned team provide support in intellectual property, regulatory and contractual disputes relating to the full range of life cycle issues.



Exploitation

We advise on the full range of licensing, distribution, marketing and joint venture agreements.



Life Sciences & Healthcare

With over 240 experts globally and a wealth of hands-on experience from working inside life sciences companies and regulatory bodies, clients choose us as their strategic partner to guide them through some of their most complex legal challenges.

With increased regulatory scrutiny, pricing and cost pressures, as well as the rapid developments in genomic technology leading to a more personalised approach to medicine and healthcare, businesses and organisations in the life sciences and healthcare sector face a growing number of complex legal and regulatory challenges in order to stay competitive.

Our multidisciplinary Life Sciences and Healthcare team can advise you on every aspect of the business cycle of your product or service. We guide you through incorporation, development and financing, exploitation of IP and portfolio management, regulatory and contractual issues, clinical trials and securing marketing authorisation.

We use Bird & Bird's expertise in IT, IP and strategic partnerships to help our clients deliver smarter healthcare for the 21st century. Our focus on e-health projects, strategic partnerships, outsourcings and large-scale networked IT is complemented by the ecommerce, data protection compliance and regulatory work that Bird & Bird undertakes for clients operating in the sector.

Many of our lawyers were qualified scientists and/or worked in life sciences companies and regulatory organisations before they became lawyers, therefore they have a detailed understanding of the products and services that form the core of your business.

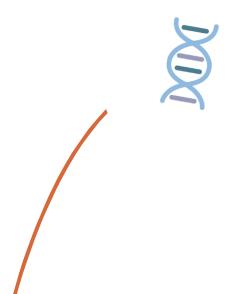
Our practice is built on the belief that it is important to understand the scientific, ethical and business challenges facing companies in the sector and take these into account in a practical and commercial way when advising our clients. We look closely at your commercial objectives and provide tailored strategic advice that will help you to achieve them.

We work with a vast array of companies including pharmaceutical, biotech and medical devices companies, start-ups and university spin outs, financial institutions, hospitals, government bodies and their suppliers, manufacturers, distributors and clinical research organisations.

We are consistently ranked in the top tier for our international life sciences work across the major legal guides including *Chambers & Partners* and *Legal 500* and are well versed in the full range of legal issues affecting the industry. According to the Forbes "*World's Biggest Company Report*", more than half of the world's largest pharmaceutical companies choose to instruct us.

We offer a full service, including advice in the following areas:

- Corporate
- Regulatory
- Licensing and commercial transactions
- Dispute Resolution
- Employment, restructuring and trade secrets
- EU & Competition
- Intellectual property
- Data protection



Intellectual Property

Bird & Bird has been at the forefront of IP for over 100 years. We are renowned for our enormous strength in the areas of IP strategy and litigation and are consistently visible on ground breaking matters.

We have one of the largest teams in the world, with over 300 specialist IP lawyers; we have tremendous resources to tap into and first-hand familiarity with the quirks of different national legal regimes and court systems, as well as extensive experience in devising international strategy.

Our team can provide you with unmatched contentious and non-contentious support in relation to all IP rights, including trade marks, patents, copyright and database rights, confidential information and data privacy. We advise on IP protection, enforcement, strategic management, valuation and monetisation of brand portfolios.

Leaders in life sciences patent litigation

Bird & Bird is universally well known for the high quality of its international patent litigation work in the life sciences sector. We have historically been involved in many leading and ground-breaking disputes in the fields of biotechnology, pharmaceuticals and medical devices.

We provide a complete advisory and dispute resolution service including patentability and patent filing strategies, R&D and licence and know-how agreements, as well as both domestic and multijurisdictional patent litigation.

Due to our geographic spread we regularly handle high-value cross-border disputes and litigate in some of the most prominent patent litigation jurisdictions, including appeals to the higher courts.

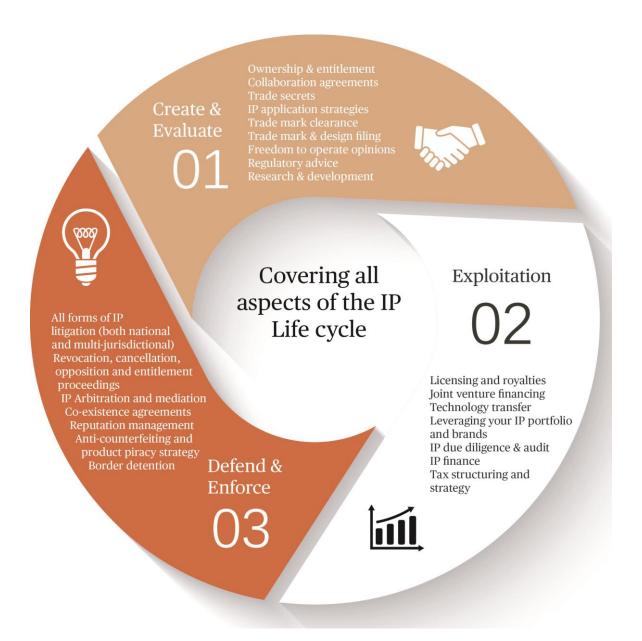
"We are confident that our case is in the best hands," especially when "international expertise is required."

We also regularly appear before the European Patent Office, as well as national validity courts. This experience provides us with invaluable knowledge on the approach and attitude of the different courts which enables us to devise and tailor litigation strategies accordingly.

- Acting for a **US biotech company** in patent revocation and non-infringement proceedings and in co-ordinating the client's general pan-European litigation strategy. The litigation was commenced in order to clear the path for launch of the company's product, a first ever treatment for Duchenne muscular dystrophy (DMD), to the European market.
- Successfully represented a **multinational pharmaceutical company** in the High Court and Court of Appeal in a breach of contract and trade mark dispute with a competitor that operates under the same name (a pharmaceutical company based in the US) the first trade mark litigation case of its kind.
- We coordinate multijurisdictional patent litigation for a global medical devices company in relation to safety intravenous catheters. The work involves prosecution work by our patent attorneys, as well as infringement and invalidity proceedings. We coordinate this work across Germany, the Netherlands, Spain, Italy and Belgium.
- Successfully defended **a global pharmaceutical company** in multijurisdictional patent infringement proceedings in relation to their treatment for Alzheimer's disease.



Key areas of our expertise



"Recognised by the IAM Patent 1000 in an impressive array of jurisdictions throughout Europe and East Asia, Bird & Bird is one of the world's foremost IP heavyweights."

IAM Patent 1000, 2017

"A 'go-to' firm for pharmaceutical and biotechnology clients, Bird & Bird LLP's clients single out the team for its 'pragmatic, commercial and solutionoriented approach' and for its ability to handle highly complex patent litigation."

Legal 500 2017



European Patent Litigation

Corporate

We have a dedicated team of lawyers experienced in advising life sciences businesses at all stages of their development.

Our corporate group is a cross-border practice, comprising over 220 lawyers across our 28 offices in the Middle East and Asia-Pacific.

We offer legal expertise in transactional matters, combined with in-depth knowledge of the markets in which our clients operate. With our comprehensive knowledge and experience of such markets we are able to ensure that commercially we provide you with the best option for your business.

Whether you manage, invest, acquire or license in the sector or wish to seek a listing on a capital market, we can advise you on a wide range of transactions, from start-ups to the largest and most complex corporate deals.

We can advise you on all forms of corporate law from private and public M&A, private equity to IPOs and joint ventures together with all of the corporate governance and company advice needed. We combine contract savvy with crucial understanding of the intellectual property, regulatory and wider market considerations. Our depth means your transactions are handled efficiently, and cost-effectively.

"Bird & Bird's 'responsive, perseverant' practice has strong cross-jurisdictional capabilities."

Legal 500, 2017

- We advised Japanese based devices and diagnostics company, **Sysmex**, on the acquisition of the Oxford Gene Technology group of companies. The acquisition complements the Sysmex business which focuses on instrumentation, whereas the OGT business focuses on the supply of reagents.
- We advised **Ziarco Pharma**, a biotech start up spun out from Pfizer, on its \$33.1 million Series B round financing. Ziarco focusses on creating innovative drug and therapeutics to treat inflammatory skin diseases. The proceeds from the Series B financing to generate clinical Proof-of-Concept data in patients for its lead compounds which will hopefully result in progress in the treatment of atopic dermatitis and psoriasis.
- We worked with **Bilthoven Biologicals** on its €48.3 million acquisition and financing of the Dutch central state's life sciences complex ALT Terrain. Bilthoven Biologicals is now a part of the Serum Institute of India, India's largest vaccine company.
- Advised Apollo Endosurgery on the acquisition of Allergan's obesity intervention businesses. Apollo Endosurgery is a specialist in endoscopic surgical solutions, particularly focused around the prevention and treatment of obesity. Their acquisition of Allergan's lap band products and expertise helps give Apollo another core competency within their business.
- We advised US-based biotech company Aduro Biotech on their €14.5 million acquisition of BioNovion Holding B.V., a Netherlands based company specialising in immune oncology antibody discovery.
- We advised Millendo Therapeutics, Inc., a US-based biotech, on the acquisition of Alize Pharma, a French biotech developing drugs for the treatment of metabolic diseases and rare diseases, by means of a share exchange.



Licensing & Commercial transactions

We apply our industry knowledge, commercial know-how and legal expertise to all transactions we undertake in the sector and our advice is tailored to provide the optimum solutions for our clients.

We provide advice on a variety of transactions from database licensing, drug development agreements, research collaboration agreements, clinical trial agreements, intellectual property acquisitions, joint development and marketing agreements, supply manufacturing and distribution agreements, joint ventures and strategic partnerships, across multiple jurisdictions.

Clients benefit from our deep knowledge of the life sciences sector. This enables us to offer advice with an extra dimension and our technical know-how, coupled with a strong commercial sense, is particularly effective when undertaking due diligence analysis, setting up corporate structures or documenting the commercial arrangements that are often crucial to transactions in this sector.

We have extensive experience in all commercial agreements related to the life sciences sector, including:

- Supply, manufacturing and distribution agreements
- Co-marketing, sales, advertising and promotion agreements
- Joint ventures, co-operation and collaboration agreements, strategic partnerships
- Licensing, research, development and exploitation agreements
- Standard terms and conditions of supply and purchase
- Registration dossiers or regulatory data licences

- Advised a **global pharmaceutical company** on their \$72.2 million purchase of a European subsidiary of another pharmaceutical company. The purchase included the European marketing rights and distribution of medicines used for the treatment of cystic fibrosis and nephropathic cystinosis. We advised on the tax, corporate, IP regulatory and anti-trust law aspects of the transaction as well as managing the transfer of rights to the client.
- Advising a major European pharmaceutical company on an exclusive licence, collaboration and supply agreement with a biotech company and a world renowned children's hospital, including the terms of development and commercialisation of the product through Phases I, II and III trials, licensing and IP ownership, regulatory applications, exploitation and commercialisation.
- Advising a US-based pharmaceutical multinational on the establishment of a centre for clinical pharmacology in Singapore for the purpose of conducting trials for the Asian market including advising on negotiations and drafting of documents for a joint venture with a Singapore hospital. This included research collaboration agreements, advising on contracts regarding clinical trial subjects; and administrative procedures for obtaining funds from grants awarded to the joint venture.



Regulatory

Our regulatory specialists have long-standing relationships with European, Asian and national regulators. We can assist you with all areas of life sciences regulatory law, from marketing authorisations to administrative litigation, to help you achieve the most effective market penetration.

Several of our lawyers have been employed in the past as legal advisers or inspectors for the European Medicines Agency (EMA) and national health authorities and/or notified bodies. Others have worked for these authorities in their capacity as lawyers. As such, we have a keen understanding of how regulators think and operate and how best to represent your interests and achieve your objectives in the regulatory and compliance arena.

We provide advice and counsel on a wide variety of regulatory issues including small molecule and biologic (including biosimilars) development and registration compliance, advertising to the public and/or to practitioners, product life cycle maintenance, dealings with healthcare professionals and trade associations, clinical trials, EC certification and assessing borderline products.

Our international team can provide advice and counsel on the full range of regulatory issues including:

- Advising and litigating on marketing authorisations
- Advanced therapy Medicinal Product (ATMP) regulation (classification issues, marketing authorisations, traceability and follow-up measures) e.g. stem cells, tissue engineered products or gene therapies
- Advertising and promotion to the public and/or healthcare professionals
- Product life cycle maintenance
- Dealings and agreements with healthcare professionals
- Clinical trials
- Classification of medical devices, demarcation issues, and borderline issues, including issues re software, biomarkers etc. and CE certification issues
- Litigation concerning imposed administrative fines
- Paediatric and Orphan drugs legislation
- Pharmacovigilance
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Pesticides and Biocides.
- Reimbursement and pricing issues

"Bird & Bird is "excellent in litigation and regulatory advice for the pharmaceuticals industry."

IAM Patent 1000, 2017



We also advise our clients on all steps regarding the launch of a new product, including the strategy of marketing and advertising activities around the product launch.

In addition to specific administrative law, we help our clients with data protection and privacy issues that need careful planning and orchestration. We also offer legal guidance on healthcare reimbursement systems and on legal challenges under these.

Our international regulatory team has also authored several publications including *The Guide to EU Pharmaceutical Regulatory Law* (published by Kluwer Law International), written entirely by the team at Bird & Bird with contributions from all of our offices. Some of our lawyers are also teachers on The Organisation for Professionals in Regulatory Affairs (TOPRA) MSc course, training students on topics such as data exclusivity and patents.

"Deep and long-standing involvement in life sciences, with expertise in regulatory and compliance matters and commercial transactions in the sector."

Chambers & Partners, 2018

- Our European and APAC teams provide regulatory advice to a **global life sciences company**, in relation to its product compliance obligations under the applicable CE marking and associated environmental regulations, which impact upon the design, manufacture, testing and labelling of its genomic and proteomic sequencing laboratory equipment and accessories.
- Advised a US biotech company specialising in genetically-targeted oncology therapeutics on a number of clinical trial agreements with local hospitals and public healthcare structures, across multiple jurisdictions. The trials relate to Phase II testing of a treatment for non-small cell lung cancer patients whose tumours carry genetic alterations.
- Advising a top multinational pharmaceutical company on the production and market launch strategies of biosimilars, particularly on the experimental use and Bolar exemptions. We are advising on regulatory issues such as requirements for marketing authorisation filings, different requirements in the US and Europe and the potential impact of the UPC.
- We regularly advise **several pharmaceutical and biotech companies**, as well as sector organisations on Advanced Therapy Medicinal Products, the regulatory framework regarding cells and tissues as well as the implementation in Europe of the EU Directive ruling the use of human cells and tissues. We also advise these clients on their needs regarding clinical trials and/or manufacturing agreements.
- Advising a leading pharmaceutical company on complex regulatory data protection matters in relation to their innovative combination product, including an analysis of the concept of "new active substance" and analysis of the scope of the "global marketing authorisation" concept, as well as advice on a possible judicial review action.
- Advising a global medical devices company on an MHRA investigation in to one of their products following reports of adverse events by patients. This has also involved advising the client on product labelling.





Data Protection

All of our Bird & Bird offices have dedicated privacy and data protection specialists and the team includes lawyers who are independently recognised as leading experts in their countries. Our international Privacy and Data Protection team is consistently ranked in the top tier by the global directories.

Our clients include a large number of pharmaceutical companies, insurers, hospitals, financial institutions and governments that are delivering medical care, or developing or investing in cutting-edge technological projects. Our clients turn to us for our expertise in the key technologies, processes and regulatory frameworks needed to deliver smarter healthcare in the 21st century.

We have a long history of advising on the intersection of healthcare, technology and privacy matters, and have advised a number of pharmaceutical companies and clinical research organisations on data protection matters, including data protection aspects of clinical trials, quality control reporting and pharmacovigilance matters.

Bird & Bird is a founder member of GA4GH, the Global Alliance for Genomic Health, and data protection co-head, Ruth Boardman, is a member of the Security Expert Working Group on that alliance.

Pragmatic solutions

We can help deliver objectives while steering you through a myriad of local differences which continue to complicate the data protection scene worldwide. Our legal advice is accurate, clear, pragmatic and business focused. We take a hands-on approach, advising not just on the letter of the law, but also making practical suggestions for clients to consider.

We have provided privacy advice for many years and are able to draw on practical experience of the ways in which organisations approach data protection compliance, to add value to our clients' businesses. The approach of data protection authorities is key to understanding procedures and risks of noncompliance. Our lawyers have often worked in-house with local regulators with whom we maintain close links.

Our services include:

- Advising on data protection requirements for direct marketing, including specific rules for behavioural targeting and children's data, advising leading ad networks, publishers and industry bodies.
- Implementing Binding Corporate Rules, rolling out data transfer agreements around the EEA and beyond, and conducting international compliance projects.
- Registrations with data protection authorities worldwide.
- We have acted on many high profile breaches across multiple jurisdictions, providing guidance on investigations by regulators.
- Handling complaints and advising on prosecutions and offences.
- Training for staff and others.
- Lobbying data protection authorities and legislative bodies, including inputting to the new draft General Data Protection Regulation being developed in Brussels.



"Renowned data protection specialists relied on for advice in relation to cutting-edge issues such as the upcoming implementation of the General Data Protection Regulation (GDPR) and the invalidation of the Safe Harbour provisions."

Chambers & Partners, 2018

Competition & EU

Our competition and procurement group covers the whole of Europe, with dedicated specialists understanding the competitive challenges for companies in the life sciences sector. Our Brussels competition team has close contacts with the EU Commission, which helps us provide clients with a head start in obtaining information or getting in touch with the proper officials.

Increasingly, competition authorities in Brussels and the EU Member States are paying close attention to the life sciences sector. Merger notifications are thoroughly investigated, and regulators carefully scrutinise settlement agreements, distribution structures, refusals to supply and agreements imposing quotas. Free movement rules are complex. In addition, we see EU and national procurement rules continue to affect the supply of pharmaceuticals and medical devices.

We assist life sciences companies on the competition law aspects of M&A transactions, on behavioural competition issues and equivalent national competition rules, as well as free movement rules. We work closely with our clients to ensure that their R&D ventures, commercial agreements, distribution policies, license structures and settlement agreements comply with competition rules. Always, our objective is to devise bespoke legal strategies that best fit our clients' competitive challenges.

Recent highlights:

- Advised a global speciality pharmaceutical company on EU competition law in relation to all aspects of its business including the commercialisation of significant new products, joint venture agreements, parallel trade and its relations with stakeholders.
- We provided detailed competition law advice to a leading pharmaceutical company, specialising in orphan drugs on parallel trade between EU member states, on related questions of possible abuse of dominant position under the competition rules, and on supply arrangements and in particular distribution and agency agreements.
- Represented a growing biotechnology company on the competition law/intellectual property interface in relation to patent licenses concluded to settle patent litigation, with particular reference to complex patent no challenge obligations.
- Advised a major global pharmaceutical company on cartel law aspects, especially with regard to cooperation in research and development.
- Acting for a leading provider of automated healthcare technology software in the CMA second phase merger control investigation that resulted in the clearance of its acquisition of a company specialised in medication management systems.



Bird & Bird LLP draws praise from clients for its "excellent knowledge of the market" and "timely responses."

Chambers Europe, 2018

Tax

Our Tax Group provides an outstanding and comprehensive international offering. The combination of deep local knowledge, profound sector understanding and a commitment to going all the way for our clients is what sets us apart.

The unique depth of expertise and experience that we have in the industries in which our clients operate enables us to deliver appropriate, practical and clear solutions to the tax issues that they face. We always work efficiently and proactively to meet our clients' needs.

Our international and fully integrated team provides a full range of business tax advisory services. We have significant experience in providing cross-border advice and in managing complex challenges across multiple jurisdictions. These services include:

- international tax planning
- setting up tax efficient group structures
- property and IP holding structures
- · R&D tax credit
- tax efficient supply chain solutions and outsourcing of services
- transfer pricing
- tax efficient remuneration planning
- tax litigation
- VAT and pharmaceutical taxes

International tax issues and the impact of changes to the international tax system arising from the G20 and OECD's project on base erosion and profit shifting (BEPS) are key issues for many of our clients, for whom the taxation of intangible assets lies at the heart of their business structures and transfer pricing models. Our international tax team contains experienced international tax advisers and transfer pricing experts. We also have a cooperation with an international transfer pricing boutique, Questro International, and provide business focussed international tax and transfer pricing advice across our network.

Recent highlights:

- We advised a NASDAQ-listed international life sciences diagnostics company, on the restructuring of their EMEA business model resulting in tax optimisation. We also continually advise them on a range of international tax issues including transfer pricing, custom audits and VAT issues. This work is coordinated across our network of offices in Europe and Asia.
- We advised Aduro Biotech, a clinical-stage cancer immunotherapy company, on its tax risk management following its acquisition (EUR 29 million + milestone payments) of the Dutch based BioNovion group on which Bird. Follow up work included the expansion of the Dutch Innovation Box tax regime ruling and corresponding tax negotiations with the Dutch tax authorities and advising the company on post-acquisition tax optimisation of the international group structure.
- We acted for a European biopharmaceutical company in advising them on the tax consequences of a cross border reorganisation.
- We assisted an international US-based life sciences company in the framework of the mapping of the VAT risks linked to its international flows. Territoriality of services, optimization of importation costs linked to the potential implementation of specific customs regimes.
- We advise several of our global life sciences clients on R&D tax credit (including in the context of M&A transaction or tax litigations).

"Clients acknowledge the firm's "international perspective" and say the team is "extremely knowledgeable."

Chambers Europe, 2017

Other key areas

Clients in the life sciences sector benefit from our strength in our ability to offer a full service capability from all of our offices. As well as core legal advice in the areas we have described above, the firm has significant strengths in:







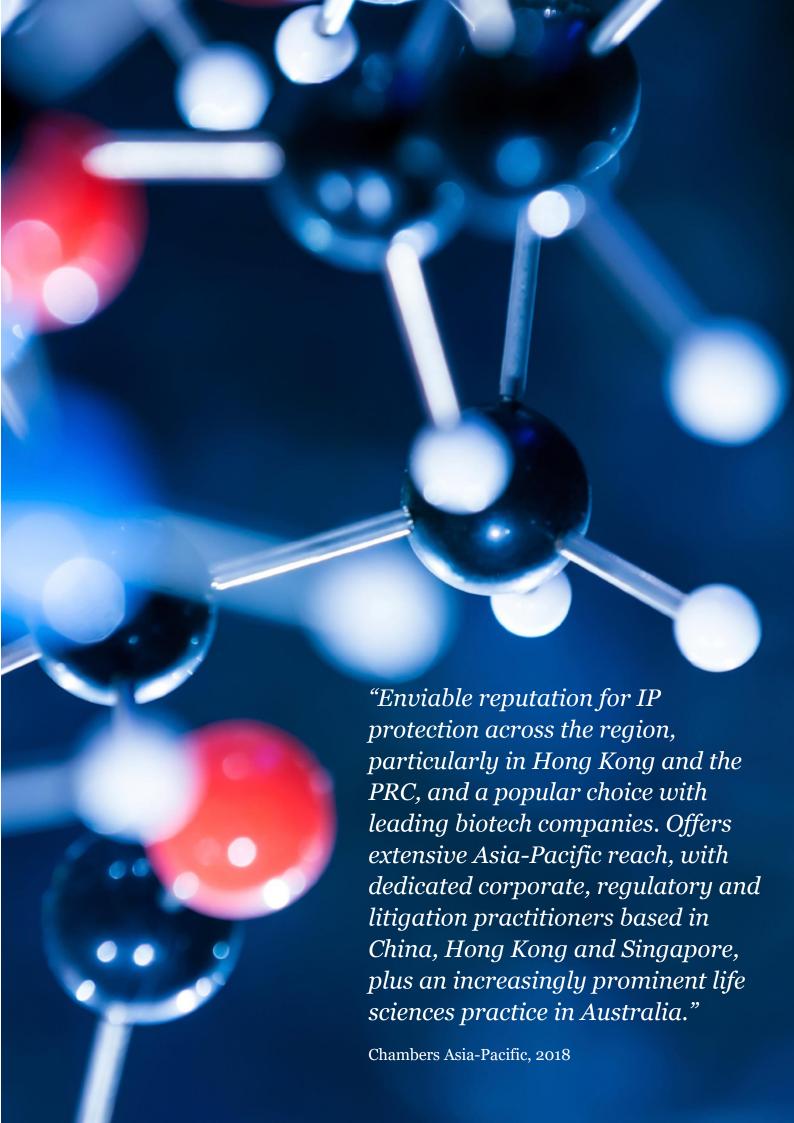


Banking

Employment

Dispute Resolution

Real Estate

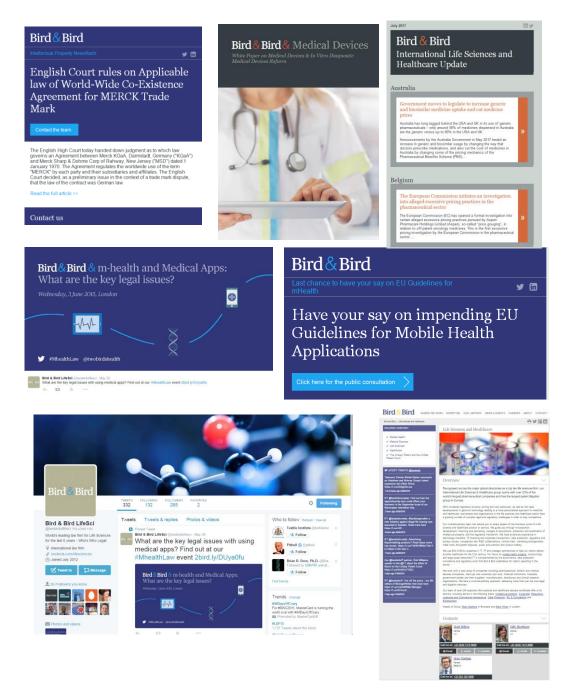


Keeping you up to date

Whether it's through twitter, an email or a phone call we keep you up to date with important developments as they happen.

We believe in talking to you on a regular basis, sharing ideas and learning from each other. Our goal is to help you navigate the constantly changing legal landscape, creating focussed newsletters, articles, tweets, or newsflashes. We bring together relevant industry best practice, thought leadership, summarised case reports and articles of interest.

Follow us at @twobirds or sign up to our newsletters by visiting www.twobirds.com



About Bird & Bird

Through a combination of our strong experience in the life sciences & healthcare sector and our legal expertise, our mission is to develop both short and long term commercial solutions that will assist you in taking your idea from inception to market place and beyond.

With more than 1,100 lawyers in 28 offices across Europe, the Middle East and Asia and clients based in 118 countries worldwide, we specialise in combining leading expertise across a full range of legal services on an international basis. We aim to deliver tailored local advice and seamless cross border services.

Our offices are located in key business centres across Europe, the Middle East and Asia-Pacific, including in Abu Dhabi, Amsterdam, Beijing, Bratislava, Brussels, Budapest, Copenhagen, Dubai, Düsseldorf, Frankfurt, The Hague, Hamburg, Helsinki, Hong Kong, London, Lyon, Madrid, Milan, Munich, Paris, Prague, Rome, Shanghai, Singapore, Stockholm, Sydney and Warsaw.

We also have close cooperation agreements in place in Russia, Portugal, Malaysia, South Korea and Indonesia and other long term working relationships in the US, India, the other ASEAN countries, the other European countries and South Africa.

As we have expanded into new jurisdictions we have established our offices as real, local, full service offerings rather than representative or franchised offices to ensure our ability to provide a consistent approach and client service experience across the firm. Operating as one, truly international partnership, with shared goals and accounting and a single profit pool, we are committed to providing our clients advice from the right lawyers, in the right offices, working together properly in the interests of our client.

Today, we maintain an open and flexible business culture, aiming to respond as rapidly as possible to the commercial pressures that our clients face and to ensure that our own business remains configured in the best way possible to provide excellent service to our clients, however they themselves define excellence.



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