Bird & Bird

Life Sciences & Healthcare

An overview of our international capabilities

February 2024

Life Sciences & Healthcare with Bird & Bird

With over 280 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 and AI 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 offer a full service, including advice in the following areas:

- Intellectual property
- Regulatory
- Corporate
- Licensing and commercial transactions
- Data protection
- Employment
- EU & Competition
- Tax
- Real Estate

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 are 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. It means they are also often called on in an advisory capacity for their specialist knowledge and insight on large international projects or disputes.

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.

Our Awards and Rankings

Chambers & Partners – Life Sciences:

- UK-wide – **Band 1**
- UK Life Sciences & Pharmaceutical Sector (International & Cross-Border) - **Band 1**
- Asia-Pacific **- Band 1**

Legal 500 – Life Sciences and Healthcare:

- Tier 1 in UK, Italy and Belgium

LMG Life Sciences Europe Awards 2023:

- European Venture Capital Firm of the Year
- European M&A Firm of the Year
- European Patent Litigation Firm of the Year: Medical Devices
- Impact Case of the Year: Fingolimod
- Impact Deal of the Year: Dr Reddy's acquisition of Nimbus Health

Who's Who Legal: Life Sciences 2023
More lawyers recommended for Patent Litigation than any other law firm.

With 'unparalleled depth of industry knowledge' and a 'dynamic team', Bird & Bird LLP is 'always focused on the client's needs and strives to deliver solution-oriented, valuable advice."

Legal 500, 2023

With you at every stage of the Business Life Cycle

Intellectual Property

With our first reported patent case dating back to the 1880's, Bird & Bird has been at the forefront of IP for over 100 years and is consistently visible on ground breaking matters in Europe and Asia.

Our team is one of the largest in the world, with over 400 specialist IP lawyers. We will provide you with solid support in relation to all IP rights, including patents, trade secrets, product design, copyright and database rights, data privacy and trade marks. We advise on IP protection, enforcement, strategic management, valuation and monetisation of IP portfolios.

Our expertise will help you protect your IP portfolio and enforce your IP rights worldwide. You'll put your IP in the safe hands of specialist lawyers who cut their teeth at the forefront of pioneering technology and in well-known, IP-rich companies. So you'll always have access to a team rich in real world experience — and real industry insight.

Leaders in life sciences patent litigation

Bird & Bird is universally well known for its work in high value multijurisdictional patent litigation work. We have acted in some of the biggest, most complex and sometimes landmark disputes in the fields of biotechnology, pharmaceuticals and medical devices.

We can help you with your overall patent strategies - both offensive and defensive - as well as providing freedom to operate advice, prior art searching and assessment, due diligence reports addressing infringement, validity and related commercial considerations and generally in relation to uncovering the value of portfolios and the like.

We also have teams of patent attorneys based in Europe and Asia. In contrast to many other major firms, we bring together lawyers and patent attorneys to provide an integrated legal and consultancy service. This ensures an optimal, consistent approach of the technical and legal aspects of any numerous oppositions carried out for clients domestically and internationally over the years.

Due to our geographic spread, we regularly handle high-value cross-border disputes, frequently conducting oppositions at the EPO and litigating in some of the most prominent patent

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.

Recent highlights:

- Successfully defended **Gilead** against NuCana in patent revocation and infringement proceedings concerned Gilead's range of anti-viral products containing the drug sofosbuvir (the key component of Gilead's new class of blockbuster antivirals that treat Hepatitis C).
- Representing **Dexcom** in multiple patent infringement and revocation actions against Abbott Laboratories in relation to their glucose monitoring devices.
- Acting for **CureVac** in patent revocation and infringement proceedings in the UK against BioNTech and Pfizer, and in parallel German infringement proceedings against BioNTech.
- We act for **The Broad Institute of MIT and Harvard** in defending key patents claiming the use of CRISPR in eukaryotes. CRISPR is revolutionary gene editing technology, able to precisely replace genes in the mammalian (including human) genome. The challenge to The Broad CRISPR patents has been described by Forbes as the "most monumental biotech patent dispute in decades". We have developed and implemented the argumentation in defending these patents.
- Successfully acted for **Teva** in high profile patent litigation proceedings against Neurim Pharmaceuticals (1991) Limited and Flynn Pharma in relation to sustained-release melatonin.
- Acting for **Edwards Lifesciences**, a global leader in patient-focused medical innovations for structural heart disease, since 2005. We advised Edwards in their settlement with Boston Scientific following long-running infringement proceedings. Recently, we acted for Edwards Lifesciences against Indian med-tech company, Meril Lifesciences, who Edwards claim copied their transcatheter heart valve replacement product.
- We manage the brand portfolio of medical devices company, **Widex** the world's 6th largest hearing aid provider and has a portfolio of over 1000 trade marks, in over 100 countries.

Ways we can help you

Create & Evaluate

- Ownership and entitlement
- Collaboration agreements
- Trade secrets
- IP application strategies
- Trade mark and design clearance
- Trade mark and design filing
- Freedom to operate
- Regulatory advice
- Research and development

Defend & Enforce

- All forms of IP litigation (both national and multi-jurisdictional)
- Revocation, cancellation, opposition & entitlement proceedings
- IP arbitration and mediation
- Co-existence agreements
- Reputation management
- Anti-counterfeiting and product piracy strategy
- Border detention

Exploitation

- Licensing and royalties
- Joint venture financing
- Technology transfer
- Leveraging your IP portfolio
- IP due diligence and audit
- IP finance
- Tax structuring and strategy

"One of the finest IP and patent litigation practices in the world, routinely co-ordinating complex cross-border disputes."

Chambers & Partners, 2024

Corporate

Science and technology excite us – and if you're taking your business to the next level through corporate transactions, you need our knowledge of the technology itself as well as corporate expertise. Your company investment will be more successful when it maximises the value of technology and IP – a cornerstone of our practice.

To succeed in today's fast-paced business environment you need advisers that bring a commercial outlook and market perspective to the table. Our focus on pre and post-transaction aspects such as planning, project management and post-deal integration leaves no stone unturned.

We believe in practical, proactive advice with a personal touch. Our 200 corporate lawyers across Europe, Asia and the Middle East advise on all forms of corporate transactions from private and public M&A to private equity, 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.

We use tech solutions to underpin smart, useful advice that benefits our clients – not for the sake of it. Whatever your size or stage in lifecycle you'll benefit from having our talented deal-makers on-board.

"I am extremely impressed by Bird & Bird's ability to navigate complex, cross-border transactions. The team is always able to offer rigorous but pragmatic advice."

Client: Chambers & Partners, 2024

Recent highlights:

- Advised **Envision Pharma Group**, a leading global technology-enabled strategic solutions partner for the life sciences industry, on their acquisition of OKRA.ai, a pioneer in developing AI solutions for the life science industry, bringing self-learning AI to optimize commercial, medical and market access decision making.
- We advised **Nimbus Health,** one of the leading pharmaceutical companies for cannabinoid-based medicinal products, on the sale of all shares to Dr Reddy's Laboratories.
- Advised **Celltrion, Mirae Asset Capital**, and Premier Partners on the US$47m series A financing of Iksuda Therapeutics, a developer of a new generation of antibody- drug conjugates (ADCs).
- Advised **M Ventures**, the venture arm of Merck KGaA, as lead investor, on a series B financing into a UK life sciences company.
- Advised **Novo Ventures** and **Sanofi Ventures** on the $83m series C financing of LAVA Therapeutics, a biotech pioneering the development of bispecific antibodies to engage gamma-delta T cells for cancer therapies.
- Advised **Serum Institute of India** on the sale of its Czech unit, Praha Vaccines a.s., to Novavax AB, subsidiary of Novavax Inc, US based, Nasdaq-listed biotechnology company developing next-generation vaccines for serious infectious diseases.
- Advised **Kiadis Pharma NV** on its €28m equity fundraising by means of an accelerated bookbuild offering, in which Jefferies International Limited acted as Sole Global Coordinator and together with Piper Jaffray & Co. as Joint Bookrunners.
- Advised **Gensight Biologics**, an innovative clinical-stage gene therapy company currently focused on discovering, developing and commercialising novel therapies for patients with severe retinal neurodegenerative diseases, on its €40m placing and listing on Euronext.

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.

You will 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:

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

"Bird & Bird's client service is great. The lawyers are knowledgeable and experienced and give good practical and commercial advice."

Chambers Global 2024

Recent highlights:

- Advised **Juvise Pharmaceuticals** on their $200 million acquisition of the commercial rights to Casodex (bicalutamide) and Armidex (anastrozole) from Astra Zeneca, in several European and African countries.
- Advising **Chiesi Farmaceutici** on the €93 million in-licence of Raxone® from Santhera Pharmaceuticals Holding AG ("Santhera"). Raxone is an orphan drug used in the treatment of Leber's hereditary optic neuropathy ("LHON"), a rare hereditary eye disease that leads to severe vision loss. Chiesi has in-licensed the rights to Raxone® in LHON and all other ophthalmological indications worldwide except in the US and Canada.
- Advised US-based **MyOme Inc**. (developer of a gene analytics technology designed to understand how DNA can impact health and well-being), with the negotiation of a licensing agreement with Cancer Research UK regarding the use of software incorporating a breast cancer risk statistical model as part of MyOme's disease risk products.
- Advised Italy-based **Sifi SpA** with the drafting and negotiation of an exclusive licence and supply agreement with Sentynyl Therapeutics regarding the licensing by Sifi to Sentynl of rights regarding the commercialisation of a product used for the treatment of certain ophthalmological conditions.
- 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 the **Dementia Discovery Fund** on its research collaboration with Bicycle Therapeutics to use Bicycle's technology for the development of novel therapeutics for neurodegenerative diseases.

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 previously worked 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 and ATMP's) as well as medical devices 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.

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.

Our team works in contentious and non-contentious matters and we represent our clients in litigation, nationally as well as on EU level. We also work closely with and/or for EU and national sector organisations on several policy questions relevant for the Life Sciences sector.

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.

We have also built up a deep knowledge of the rules and regulations regarding the use of cannabis and CBD.

Our international regulatory team has also authored several publications including *The Guide to EU and UK 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.

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

- Advising and litigating on marketing authorisations (including data exclusivity)
- Clinical trials
- 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 as well as Biobanking issues (research on cells and tissues)
- Classification of medical devices, demarcation issues, and borderline issues, including issues re software, biomarkers etc. and CE certification issues
- Product life cycle maintenance
- Paediatric and Orphan drugs legislation
- Pharmacovigilance
- Advertising and promotion to the public and/or healthcare professionals and dealings and agreements with healthcare professionals
- Reimbursement and pricing issues
- Litigation concerning imposed administrative fines
- Public Procurement in the healthcare
- Product compliance, including product liability
- Regulatory support in M&A transactions

Recent highlights

- Acting for **Polpharma** in a landmark victory in a judicial review action at the European Courts. The case concerned a challenge to the regulatory data protection (RDP, data exclusivity) of Biogen's "blockbuster" product Tecfidera (more than €4 billion a year), following a decision by the European Medicines Agency (EMA) to refuse our client's application for a generic marketing authorisation. In a judgment that sets a milestone precedent, the EU General Court ruled that the Tecfidera RDP decision made by the EMA, which was challenged in this case, was illegal. This opens the market to cheaper generic versions of Tecfidera (subject to the outcome of appeals), could have broad consequences for regulatory litigation in the future.
- Advising **a global pharmaceutical company** on the forthcoming EU AI Act, which will create significant new compliance obligations for developers of AI and users, as well as importers of AI systems, under the proposed Regulation which will have extra-territorial reach.
- Advising **Teva** to defend the grant of a Belgian medicinal product marketing authorisation, which is being challenged in the Belgian courts (Council of State). The product is a "fixed dose combination" product, and the matter concerns the correct interpretation of the scope of the legal basis for granting the marketing authorisation.
- Advised **US-based biopharma company** with the review of a master services agreement and quality agreement with an Irish pharmaceutical distributor for purposes of supplying medicines that do not yet have a marketing authorisation in the UK under the Early Access to Medicines Scheme (EAMS).
- Advising US-based biotech client, **Mirati Therapeutics**, on several clinical trial agreements across 10 jurisdictions. Our advice included reviewing and revising the contracts to ensure they are compliant with local laws.
- We advised **Roche Diagnostics** on a worldwide review of the rules applicable in the advertisement of medical devices (both commercial medical device and research-only use medical device) The comparative analysis included more than 25 countries located in different continents (Europe, Asia and Africa).
- In the **ATMP** field (Advances Therapy Medicinal Products) we have and are advising many companies on the implementation of Directive 2004/23 and the ATMP Regulation. Clients include national sector organisations (as Bio.be and Phamra.be a.o.) as well as pharmaceutical companies as Celgene, Celyad, Cryosafe, Catalent, Masthercell, Univercells, Immunicum, Novadip, Promothera, Dendreon, Erytech and many others.
- Providing advice on issues faced by the industry in the framework of the implementation of the **public procurement legislation**, new innovative collaboration frameworks, as well as litigation in this regard. In the PP field we have worked for Pfizer, Bayer, Teva, Novartis, MSD, Eli Lilly, IPSEN, Actavis, Eurogentec, Polpharma, Almirall, Sandoz, Synthon, Boehringer Ingelheim and others.
- From a UK/EU perspective, we have advised a broad range of life sciences and healthcare clients on the regulatory impact of **Brexit**.
- During the COVID-19 crisis we have represented several companies, on issues regarding vaccines, masks, and others. Issues included negotiations, litigation and settlements with competent authorities and governments.

"Bird & Bird are able to provide strong representation in multiple jurisdictions each with a particular focus on regulatory matters."

Chambers Global, 2023

Data Protection

All of our offices have dedicated privacy and data protection specialists and the team includes lawyers who are independently recognised as leading experts in their countries.

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

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

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 of the 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. Our team includes former members of data protection authorities such as the CNIL so we have a better insight that many into how this complex area of law is likely to be enforced. One of our London team members spent most of 2020 on secondment to the Information Commissioner's Office which gives us a unique insight into how the UK data protection regulator supports compliance and approaches enforcement.

We consider each matter an opportunity to further develop our expertise, pioneer new, robust solutions to legal ambiguities and impasses by delivering solutions to the varied legal challenges faced by our highly innovative clients. We support this culture through by hiring and training up excellent lawyers from a wide variety of backgrounds, to create strong, diverse and interdisciplinary teams.

Recent highlights

- **Leading Global Provider of Research and Medical Diagnostic Applications:** We provided legal advice to create an internal global Privacy and Data Protection Directive which also concerned different diagnostic applications and uses of respective equipment.
- We have been providing external DPO services to **a global leader in the Pharmaceutical Industries** since the entry-into-force of the GDPR in May 2018. As DPO, we advise our client on a near daily basis on its privacy compliance program and on privacy sensitive business activities, review data protection policies and other legally required documentation and provide hands-on support in connection with security incidents and queries from individuals or supervisory authorities. The engagement covers 27 countries in the EU
- We worked with a **leading health informatics company** as part of its team seeking to ensure maximum flexibility for use of health data for scientific research.
- Advising **a leading global pharmaceuticals conglomerate** on global privacy guidelines regarding the use of customer and patient data collected and combined by various means, including websites, medical apps and medical products.
- Advising **government affairs teams** on the legislation affecting life sciences companies and strategies to ensure that legislation takes account of specific sector requirements (including the GDPR and UK Data Protection Act 2018).

Digital Health

The rapid convergence of digital technologies with healthcare, life sciences and IT companies in recent years, further accelerated by the pandemic, has radically transformed the way in which we receive healthcare.

From medical apps, drug-dose calculators, AI diagnostic tools to blood glucose monitors, medical software and electronic personal health records, digital health plays an integral part of how we prevent, treat and manage health conditions.

The result is a patient-centric approach, focused on data-driven solutions and personalised delivery of therapies (pharmaceutical or device/app-based) using information technologies which enable a seamless flow of communication between patients, providers, researchers and health information services.

Digital Health continues to be a major focus not only for the life sciences and healthcare industry, but also for tech, telecoms and retail clients who are expanding their products and services into this space. With our market-leading expertise in the life sciences, healthcare and tech industries, we can help you navigate the complex and exciting opportunities that arise from digital health with a particular focus on **regulation, patient privacy, procurement, technology contracting, funding, reimbursement, investment and IP issues.**

"Bird & Bird is a key resource for international clients operating in the healthcare sector, including those seeking advice on matters related to e-health, IP, IT, and data protection."

Legal 500, 2023

Recent highlights:

- Advising **Biofourmis**, a Singapore-based AI healthtech start-up, on multiple matters including: (i) its US$35 million Series B equity financing round led by Sequoia Capital and MassMutual Ventures SEA; and (ii) the deployment of its AI-driven remote monitoring platform to observe patients in Hong Kong who are diagnosed with or suspected to be infected with COVID-19.
- Advising **a Cloud-based software vendor**, on the procurement of telemedicine services which are provided to the client's global cohort of employees. We assisted with commercial contract drafting, advice and supporting negotiation with vendor.
- Advising **OncoDNA**, a company specialising in medical diagnostics and patient care, in relation to the developing and rolling out of a digital platform which enables oncologists and patients to interact. Our advice encompassed regulatory issues related to such project, as well as important data privacy questions.
- Advising a **leading UK-based online pharmacy and telehealth platform provider.** We drafted the website Terms & Conditions and Privacy Policy for the client's websites relating to online doctor services and repeat prescription services to ensure compliance with applicable healthcare regulatory requirements. We further reviewed and drafted the client's template Pharmacy Fulfilment Agreement as well as Prescription & Dispensing Agreements in respect of the client's online pharmacy business.
- Providing ongoing regulatory advice to a **multinational telecommunications company** regarding a home care-related product being developed by our client and its partner, with the main question being whether the software and hardware combination of products amount to a medical device. As this product develops, further product features are contemplated and marketing material is developed, the ongoing assessment as to whether the product constitutes a medical device is required.
- Advising **Mindler**, a leading digital psychology provider, in an ongoing multijurisdictional matter on various legal issues relating to patient data, data protection and privacy and other emerging issues within digital health. We also advise them on commercial matters in relation to their international expansion across Europe.

International HR Services

We offer domestic and international employment and labour law advice throughout our network of offices in Europe, the Middle East and Asia Pacific. We provide clients with a comprehensive range of legal advice across the full spectrum of contentious and non-contentious employment law.

Each of our 31 offices is staffed with locally-qualified employment lawyers, enabling us to provide advice on national employment legislation in addition to international employment directives.

Many members of our team have in-house experience and so we recognise that good HR advice rarely involves telling the client that "they must do X", or "they must not do Y". Often there is a range of options to consider and a different risk level associated with each. We see our role as working with the client to identify available options and risks in order to find solutions which meet their business objectives. Our approach is strongly commercial, enabling our clients to capitalise on business opportunities and manage change effectively.

To complement the expertise in our own offices, we have developed tried and tested relationships with law firms in a large number of jurisdictions, through many years of working with multi-national clients on international projects.

Our key areas of advice include:

- Cross-border projects
- Policies, practice and in-house documentation (drafting, implementing and auditing)
- Terminations, redundancies and disputes
- Workforce restructuring (including TUPE)
- Outsourcing
- Conduct and resolution of claims (including dealing with trade unions)
- Works council matters
- Senior-level appointments
- Equality and diversity
- Business immigration and secondments
- Employee incentives and benefits
- Trade secrets (including team moves, restrictive covenants and injunctions).
- Day-to-day advisory issues, including assisting with disciplinary and grievance matters (we also monitor these in respect of litigation risk).

Recent highlights:

- **A high-profile American corporation (with electronic, technology and life sciences brands with over 60,000 employees):** Advising on employment issues globally, outside the US. Key projects have involved employment related aspects of a multi-billion dollar business separation, including due diligence; restrictive covenants and retirement plans; providing documentation relating to a global reorganisation; Workday and job architecture implementation and employee consultation requirements; implementation of selection and development assessments; various corporate transactions and TUPE transfers; drafting bespoke restrictive covenant provisions and employment contract amendment agreements tied with annual equity awards and promotions; providing advice on French labour reforms and operational next steps; developing HR training tools and materials on employee investigations; gender pay gap reporting; Modern Slavery Act requirements and operational next steps; and providing advice on various senior employee terminations across Europe.
- Advising **a leading global pharmaceutical company** on senior manager terminations and employment litigation. We assisted in the dismissal of the General Manager in Spain, including the negotiation of his leaving and severance terms as well as the drafting of his termination documents. We also assisted in the termination and settlement negotiation with some members of its Spanish management team (including its CFO and Commercial Manager) as a result of compliance issues detected after an internal investigation.
- We advise **a large international pharmaceutical company** on the full range of employment matters including international restructuring projects, collective issues, dismissals and litigation, due diligence, policy reviews and disciplinary sanctions to employees. This work is coordinated by our employment team across several jurisdictions including Belgium, France, the Netherlands, Germany, Italy, Spain, UK and Singapore.
- Advising **Amgen** on a range of matters including individual termination of top management, disciplinary procedure against employees' misconducts, drafting of specific employment contracts, assistance in localize bonus incentive program, introducing new form of flexibility at workplace (the so-called Smart-Working, i.e. the possibility to work at home some days per month) and reviewing the incentive plans.

Competition & EU

Our clients benefit from the experience of acknowledged leaders in the field of competition law who offer practical, commercial advice to support their strategic objectives.

We advise on all areas of national and EU competition law at a worldwide level. In addition to our strong **merger control** practice, we regularly advise clients on the competition law aspects of a wide range of **commercial arrangements**, including on- and off-line distribution, licensing and cooperation agreements. We also have extensive experience in representing clients in all aspects of **cartel** proceedings, including handling multi-jurisdictional **leniency** applications before the EU and national competition authorities including those in Australia and the Asia-Pacific region. We also advise in relation to EU settlement cases and represent clients in third party claims.

We have successfully represented both complainants and defendants **in abuse of dominance** and **misuse of market power** proceedings in various jurisdictions.

Life Sciences expertise

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. Our objective is always to devise bespoke legal strategies that best fit our clients' competitive challenges.

"'The practice specialises in swift and practical advice, meeting corporate timelines and expectations of the most demanding clients.'."

Legal 500, 2024

Recent highlights:

- Advised **Chiesi Farmaceutici S.p.A.** on, and carrying out, international merger control filings in relation to an acquisition (through licensing) of pharmaceutical product rights from Santhera. Chiesi has over 20 affiliates across the world and is present in 27 countries. Merger control filings were made and clearances obtained in Germany, Portugal and Spain, with the support of our competition law colleagues in Germany and Spain and a correspondent law firm in Portugal.
- 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.

Real Estate

Real estate today means much more than land and buildings: it's about technology, data capture, sustainability, energy efficiency, wellness, changing work patterns and much more. We support our clients as they navigate a fast-changing future and harness technology to anticipate challenges - and turn them into opportunities.

Our team works with tenants to obtain flexible leasing arrangements that allow them to customise the space as their team grows.

We also support international clients in developing and investing in flexible, multipurpose buildings which are able to respond to continuing changes and advances within the life sciences sector.

Our clients are seeing huge growth opportunities in the life sciences sector as the UK population ages and as demand for high-tech laboratory and office space currently outweighs supply.

"Bird & Bird is a notable real estate team assisting clients with both domestic and multi-jurisdictional matters thanks to the firm's strong international network. The firm's lawyers advise on asset acquisitions, disposals, and lease agreements."

Chambers Europe, 2023

Recent highlights

- Members of our team have acted for a **leading gene therapy company** in the acquisition of their head office in central London. The deal was both high value and time sensitive and saw extensive negotiation around the technical fit-out, repair and reinstatement of the onsite laboratory equipment.
- We have acted on the acquisition of land for the development of care homes, backed by **one of the largest healthcare builders in the UK** and also on the sale of a portfolio of luxury care homes in the UK to an international investor.
- We have acted for **a new entrant into the market** on their taking a lease of laboratory and office space in a science park in the UK.
- We advised **a global manufacturer and supplier of a range of pioneering intraocular, contact lens and orthopaedic materials** on issues surrounding their real estate space.
- We acted for a client who **provides medical products** on its purchase of a newly constructed warehouse facility for use for storage and distribution/logistics purposes for medical supplies.

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 co-operation 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).

"Very impressive breadth of knowledge, reactivity, international reach, and commercial understanding."

Legal 500 UK, 2024

Our latest innovations

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

We offer a suite of innovative tools to deliver a service and benefits to our clients that set us apart from our competitors. We'd like to introduce some of those key tools that we have either specifically developed or have exclusive access to.

For more information to help you choose the most appropriate solutions, see our microsite at

https://www.twobirds.com/en/client-solutions

twoBirds Access – Relationship Site

You need access to a variety of tools to enhance efficiency, improve communication, manage projects and increase knowledge sharing.

We can set up a Relationship Site to help you do this. We'll make sure that you have easy access to relevant work products, contacts and visibility on roles, responsibilities, deadlines and billing, with clear reporting so that you really understand what is going on, wherever you are.

Benefits to you in using a Relationship Site include:

- Oversight of all ongoing advice, and legal team contacts, across multiple jurisdictions
- Transparency on legal project management, including financial reporting and project planning
- Effective sharing of knowhow and training resources
- Reducing the need for email through the use of this collaborative platform

twoBirds Pattern

Pattern is our award winning patent intelligence offering. It's the only tool of its kind in the market, making it a key differentiator against other firms. It combines our extensive patent analytics expertise with a powerful, proprietary software tool.

Developed by our in-house patent specialists in order to meet client needs, Pattern allows us to advise clients in new ways, providing clients with analytics that allows them to make robust, data-driven decisions with respect to their patent portfolio.

Pattern has been used for a number of different clients and industries. We can provide analytics for any matter involving patents, including:

- Licensing strategy and determining royalty rates (especially in the "SEP"/"FRAND" world)
- M&A strategy and due diligence
- Portfolio management & strategy
- Freedom-to-operate searches
- Patent validity/infringement suits

Pattern was successfully used by Nokia in two multi-billion dollar FRAND licensing cases. The Pattern data underpinned Nokia's positions and its flexibility was instrumental in finding critical mistakes in the opponent's data. High-quality data allowed the arbitrators to make decisions on the facts and ensure a fair outcome, and the award expressly endorsed the robustness of the data.

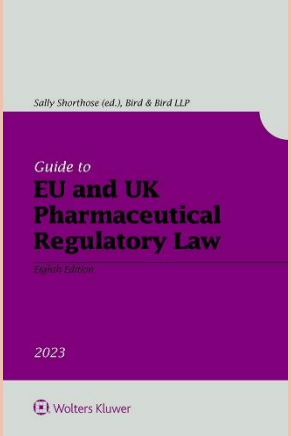
Fibonacci

Bird & Bird has always been passionate about the use of LegalTech in the delivery of legal services. We are very excited to be working with LawAdvisor to develop a next generation legal project management platform called Fibonacci.

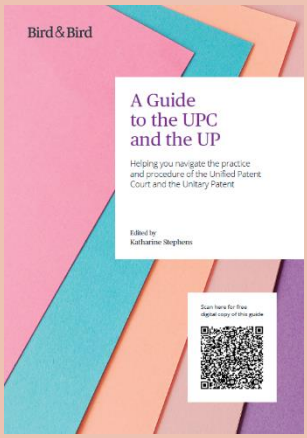
It allows clients to manage all matters with all external counsel in one platform. It also provides full transparency over all workstreams involved in the delivery of a mandate, real-time updates, document sharing, proper collaboration and clear financial tracking. It will also fully integrate with legacy and new technology systems. The platform has been approved for roll-out, so watch this space for further developments.

Our Resources

BioTalk – for all the latest news and insights in the Life Sciences world



The Guide to EU & UK Pharmaceutical Regulatory Law - The Guide, written entirely by the Bird & Bird International Life Sciences Regulatory Team, provides updated information on the full spectrum of Pharmaceutical Regulatory topics – from the processes, legislation, cases, and customs that apply to the introduction, marketing, and sale of a medicinal product in Europe, to competition law and intellectual property rights.



A Guide to the UP & UPC - free to access and provides comprehensive coverage and well-researched insights. Our commitment to staying current make it the ultimate go-to resource in the legal market for understanding and navigating the transformative landscape of the UPC and European patent law.

Click here to access the Guide.

For an international overview of the regulatory legislation regarding Telemedicine, click here

As patent litigation processes vary from country to country, it can be challenging to navigate the complexities across borders. Our team have recently made it easier for you with our Patent Litigation Country Comparator

Our international Animal Health tracker summarises the national developments and legal frameworks regarding the advertising of veterinary medicinal products. Click here to access the tracker

Our Horizon Scanning Report looks at 12 key trends influencing the global HR and employment law agenda. Click here for more info

Bird & Bird – the bigger picture

Bird & Bird is a truly international firm, organised around our clients. We match our passion and practical expertise to your vision to achieve real commercial advantage.

Everything is connected

With more than 1,400 lawyers and legal practitioners across a worldwide network of 31 offices, Bird & Bird specialises in delivering expertise across a full range of legal services. Our specialisms include advising on commercial, corporate, EU and competition, intellectual property, dispute resolution, employment, finance and real estate matters.

Europe: Amsterdam, Bratislava, Brussels, Budapest, Copenhagen, Dublin, Düsseldorf, Frankfurt, The Hague, Hamburg, Helsinki, London, Luxembourg, Lyon, Madrid, Milan, Munich, Paris, Prague, Rome, Stockholm and Warsaw.

Middle East, Africa & Asia: Abu Dhabi, Casablanca, Beijing, Dubai, Hong Kong, Shanghai, Shenzhen, Singapore and Sydney.

North America: San Francisco.

The key to our success is our constantly evolving sector-focused approach. Our clients build their businesses on technology and intangible assets and operate in regulated markets.

To better meet their needs we have developed deep industry understanding of the sectors in which they operate. Our unparalleled understanding of how our client's industries operate gives us:

- Expertise in the law and regulatory framework relating to each sector
- A practical, commercial approach to navigating the sector, supported by advisors who have worked for decades in these specific industries

Excellence in client service

Bird & Bird operates as one truly international partnership: our goals, accounting and profit pool are all shared, as is our commitment to providing our clients with advice from the right lawyers, in the right locations. Our open and flexible business culture allows us to configure ourselves to respond as quickly and effectively as possible to the commercial pressures faced by our client.

“Bird & Bird's provision of advice is "to the point, commercially focused and simple to understand," also saying: "The team I work with has become an extension of our in-house legal team in partnering with the business and has developed a keen understanding of the company's risk appetite.”

Chambers & Partners, 2022

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Thank you

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