Bird&Bird

Life Sciences & Healthcare

An overview of our international capabilities

April 2025



Life Sciences & Healthcare with Bird & Bird

With ~300 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 & IP:

- Band 1: Global, Europe, and Asia-Pacific for IP
- **Band 1**: UK Life Sciences & Pharmaceutical Sector (International & Cross-Border) and Asia-Pacific
- Legal 500 Life Sciences & Healthcare: Tier 1 in UK, Italy and Belgium
- Gold Band: IAM Patent Global 1000

LMG Life Sciences Europe Awards 2024:

- Impact Case of the Year: Gilead v Nucana
- Impact Case of the Year: Edwards Lifesciences v Meril Life Sciences
- Impact Case of the Year: Abbott Diabetes v Dexcom
- Impact Case of the Year: Xolair Litigations
- Impact Case of the Year: Stelara Litigations
- Impact Case of the Year: Joined cases C-438/21, C-439/21, & C-440/21 (*EMA v Polpharma*)
- Netherlands Firm of the Year
- Impact Deal of the Year: Envision Pharma acquisition of OKRA.ai

Who's Who Legal: Life Sciences 2023

More lawyers recommended for Patent Litigation than any other law firm.

"Its highly experienced team delivers tailored strategies that align with the unique needs of their clients. You can't go wrong with Bird & Bird."

Client: Chambers Europe-wide 2025

With you at every stage of the Business Life Cycle

How we can help

Intellectual **Property** issues



Funding / Partnering



Authorisation





















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

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

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

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

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

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

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.

Intellectual Property

Over the last century we've been lucky enough to have played a part in protecting some of the world's most ground-breaking inventions and high-profile brands and we're confident we're one of the most ambitious, energetic, dedicated groups of intellectual property professionals you're likely to meet.

Our IP 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, meaning 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 renowned 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 will assist 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. Unlike many other major firms, we bring together lawyers and patent attorneys to provide an integrated legal and consultancy service. This ensures an optimal, consistent, and cost-efficient 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 and litigate in some of the most prominent patent litigation jurisdictions, including appeals to the higher courts. We appear before the European Patent Office (EPO), as well as national 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.

- Representing **Dexcom** in several multijurisdictional patent infringement and revocation actions, including at the UPC, against Abbott Laboratories in relation to their glucose monitoring devices.
- 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).
- 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 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 longrunning infringement proceedings. Recently, we advised Edwards Lifesciences against Indian medtech 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 multijurisdictional)
- 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

"Their level of IP expertise is outstanding. Their speed attending client's queries and focus on business needs is really impressive."

Legal 500, 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.

We are an integrated, international team with a real aptitude for providing fresh and strategic legal support to companies of all sizes and industries. We understand how legal issues can impact the full strategic picture of your business. Our fresh and creative approach is coupled with expert industry knowledge which allows us to spot opportunities and help minimise risk to your business.

Businesses are increasingly operating on an international scale. Legal advisors who understand local regulators, differing business cultures, and market practices can help businesses gain a real competitive edge. Our comprehensive local market knowledge allows us to deliver practical corporate advice and handle complex multi-jurisdictional transactions and intensive due diligence exercises smoothly and efficiently.

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.

As transaction experts, we represent both buyers and sellers of businesses, from large multinationals to individual entrepreneurs, handling deals that are structured as:

Private Acquisitions and Disposals	Mergers	Joint Ventures
Public	Schemes of	Competitive
Takeovers	Arrangement	Auctions

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.
- 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 clinicalstage 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.

"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

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

"The firm's expertise is simply impressive. The organisation of the team is also perfect, with a size that adapts according to the skills required to carry out the project."

Recent highlights:

- Advised Chiesi on their acquisition of the assets and certain liabilities relating to the drug Raxone/Idebenone (treatment for Leber's hereditary optic neuropathy (LHON)) from Santhera Pharmaceuticals
- 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 an international pharmaceutical company regarding the in-licensing of various small molecules/active ingredients (API), particularly for the development and commercialisation – globally - of medicinal products including such APIs.
- 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 concerning the commercialisation of a product used for the treatment of certain ophthalmological conditions.
- European biotech company focused on genetic modifier discovery for therapeutic developments: advising the client in relation to a collaboration agreement with a global biopharmaceutical company, which involves the provision of valuable data and information to aid in the drug discovery and development process.
- 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.

Chambers Global 2025

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 advise 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 noncontentious 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.

Our international regulatory team has also authored several publications including <u>The Guide to EU and UK Pharmaceutical Regulatory Law</u> (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 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 initially set 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. The Court of Justice of the European Union subsequently overturned the judgment following an appeal by Biogen.
- 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.
- We successfully represented a European pharmaceutical company with an urgent appeal against a ruling
 of The Prescription Medicines Code of Practice Authority ("PMCPA") regarding a campaign to raise
 awareness of naloxone (a product used to negate the effects of drugs overdoses), which was said to fall foul
 of the ABPI Code of Practice. In under 2 weeks we put together an effective and powerful rebuttal, which
 was supported by many academics, government, and experts in this area, who were happy to put their
 names to our appeal.
- We are advising **a global vaccine manufacturer** on the Purchase Agreement of vaccines concluded between the client and the European Commission. The original agreement and its subsequent amendments are worth several billion euros and were made to secure sufficient vaccines (€300 Million) in the EU that would also be effective against variants and mutations.
- Advising a US-based biotech client, 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.

"Birds have a strong regulatory team, with impressive experience who are very good at handling complex matters. They have a very strong European network, with most offices at the top of their field."

Chambers Global, 2025

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 cuttingedge 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.

- 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 entryinto-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 life sciences and healthcare sectors are increasingly adopting digital technologies to improve outcomes and create efficiencies. As the sector attracts increasingly complex regulation and the links between healthcare and technology grow stronger, new challenges arise that need to be tackled to enable continued innovation.

From medical apps, drug-dose calculators, Al 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, 2025

- Advising **Biofourmis**, a Singapore-based Al health-tech 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 Al-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 **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.
- 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 carerelated 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.

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 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).

- 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

- 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.

"We faced many complex issues, and the firm supported us in sorting them out very efficiently. The team is extremely proactive and is always available."

Chambers UK, 2025

- 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

Legal Project Delivery Team

Our LPD team are uniquely placed to assume logistical responsibility of:

- designing an efficient process,
- co-ordinating all aspects of the day-to-day management and reporting for the project,
- gathering and interpreting data to inform strategic direction.

This allows the lawyers to focus on the delivery of legal advice and strategy without compromising on service delivery.

By ensuring that the right specialised skillset is applied in the most appropriate way to each task, we can provide an enhanced service to our clients.

Luminance

Our Corporate due diligence processes use market-leading Al platform, Luminance, which leverages machine learning algorithms to accelerate and enhance legal contract review. The platform also facilitates easy real-time, cross-border collaboration via its intuitive workflow tools. To complement this, we have developed a standardised international report that allows us to co-ordinate global due diligence exercises and present information to clients in a structured and clear format, regardless of where they are in the world.

Fibonacci

In partnership with a leading legal technology provider, we developed a next generation legal project management and client collaboration platform - Fibonacci.

Fibonacci provides clients with real time access to key project and matter information at any time. It provides full transparency over all workstreams involved in the delivery of a matter, real-time updates, document sharing, collaboration, and clear financial tracking. The platform fully integrates with legacy and new technology systems. So you have full visibility of the 'big picture', and the granular details, all in one place.

Relativity

This is a state of the art and widely used Albased electronic document processing, analytics and review tool from kCura.

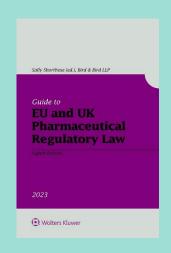
It helps reviewers to work efficiently and to focus their activity on the most relevant documents, providing immediate insight into electronic document collections.

As part of the tool, Relativity Review Manager generates forecasts and tracks the progress and time cost of human review with graphical reports. Relativity can be used for litigation, arbitration, early case evaluation and regulatory investigations.

Our Resources



<u>BioTalk</u> – for all the latest news and insights in the Life Sciences world



<u>The Guide to EU & UK</u> 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.



An International Overview of the Regulatory Legislation



For an international overview of the regulatory legislation regarding Telemedicine, click <u>here</u>



Our six-part article series examining the key legal issues that dealmakers need to consider when preparing for, negotiating and executing deals for or with companies in the life sciences space. Click here for more info



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



Keeping you plugged in and innovating ahead of the patent curve. Click here



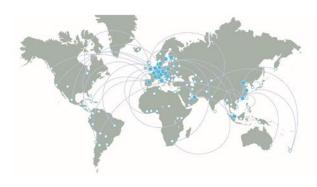
Our Horizon Scanning Report looks at 12 key trends influencing the global HR and employment law agenda. <u>Click</u> here for more info

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 1,700 lawyers and legal practitioners across a worldwide network of 32 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, Lyon, Madrid, Milan, Munich, Paris, Prague, Rome, Stockholm and Warsaw.

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

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, 2024

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