Bird & Bird &
Life Sciences & Healthcare
An overview of our international capabilities
From protection to distribution & leading the industry & trusted partner & scientifically proven & distilling the essentials & deep technical understanding & that's Life Sciences & Healthcare with Bird & Bird
Funding & Partnering
We advise on all types of funding and partnering arrangements, using our corporate and intellectual property expertise.

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

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

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

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

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

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

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

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

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

Clients benefit from the combination of our lawyers’ legal skills, in depth industry knowledge and scientific background to provide a multidisciplinary approach which delivers more than the core legal and litigation services. Many of our lawyers were qualified scientists and/or worked in life sciences companies and regulatory organisations before they became lawyers, therefore they have a fundamental understanding of the products and services that are integral to your business.

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

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

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

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

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

04 & Life Sciences & Healthcare
We have one of the largest and most respected IP teams in the world, with over 300 multi-lingual intellectual property lawyers and attorneys, many of whom hold qualifications in scientific or technical fields.

We specialise in all areas of IP including patents, trade secrets, copyright & database rights, trade marks and designs and we excel at managing complex projects across multiple regions with a seamless one-firm approach. The group also undertakes licensing, research and development agreements, due diligence, reputation and brand management.

World leaders in life sciences patent litigation

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

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

Due to our geographic spread we regularly handle high-value cross-border disputes and litigate in some of the most prominent patent litigation jurisdictions, including appeals to the higher courts. We also regularly appear before the European Patent Office, as well as national validity courts. This experience provides us with invaluable knowledge on the approach and attitude of the different courts which enables us to devise and tailor litigation strategies accordingly.

Our recent work has included:

- Representing a **global pharmaceutical company**, we obtained a ground breaking decision from the High Court in which it has awarded them declarations of non-infringement in relation to multiple designations of a competitor’s European patent for an oncology treatment. This is the first time that the High Court has exercised jurisdiction in relation to foreign designations of a European patent. This paves the way for parties to bring proceedings in relation to multiple designations of European patents in a single court, provided that validity is not in issue.

- Successfully represented a **multinational life sciences company** in the High Court in a breach of contract and trade mark dispute with a competitor that operates under the same name (a pharmaceutical company based in the US) - the first trade mark litigation case of its kind.

- We coordinate multijurisdictional patent litigation for a **global medical devices company** in relation to safety intravenous catheters. The work is coordinated from Germany, and involves prosecution work by our patent attorneys, as well as infringement and invalidity proceedings. We coordinate this work across Germany, the Netherlands, Spain, Italy and Belgium.

"One of the finest IP and patent litigation practices in the world."

Chambers & Partners, 2017
"Bird & Bird’s 300 dedicated IP professionals coordinate seamlessly across 28 offices worldwide to provide end-to-end solutions to the multifaceted needs of multinationals."

IAM Patent 1000, 2016
The future of patent litigation in Europe: The Unitary Patent Package (UPP)

The European Patent Office (EPO) and the participating countries are in the final stages of establishing the Unitary Patent and the Unified Patent Court (UPC). This represents the biggest change to patent law in Europe for 40 years: it will create a single approach to patent registration and litigation across 25 European Member States with a combined population of over 400 million. The introduction of a single system will make establishing patent protection across Europe easier and more effective, facilitating the protection of innovations and inventions. It will also make it possible to challenge patents and to obtain rulings preventing the distribution of goods and the use of patented processes across all the participating Member States.

The UPP & the Life Sciences Industry

Life sciences companies with large patent portfolios need to ensure they are prepared for the changes that the new system will entail when it comes into force in 2017.

In addition to the existing knowledge and skills that we have developed as Europe’s leading patent litigation firm, we have created a specialist UPC team to help our clients to navigate the new landscape effectively. We provide bespoke in-depth trainings and workshops on the UP and UPC, not only examining the theoretical aspects, but also and more crucially the practical and commercial steps that businesses should consider taking now in order to enable them to continue to protect their intellectual property in the new system. For more information visit www.twobirds.com/upc

The UPP & BREXIT

Since the United Kingdom voted to leave the European Union in the Referendum vote of 23 June 2016, there has been a lot of uncertainty with regard to the future of the UPC. However, during the meeting of the Competitiveness Council of the European Union on 28 November 2016, the UK announced that it is proceeding with the preparations to ratify the UPC Agreement, aimed at bringing the UPC into operation as soon as possible. This means that the UPC can open its doors for business by the end of 2017 and that it will in principle cover 25 countries, including the UK. When the UK actually leaves the EU, some additional changes will be required to the Unitary Patent Regulation and additional rules will be needed on jurisdiction and enforcement, to replace the current effect of the Brussels I Regulation with regard to the UK. Those additional rules could for instance be part of the Exit Agreement.
"The firm is absolutely superb; the lawyers are quick, understand my business and give pragmatic and commercial advice."

Chambers Europe 2016
Corporate

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

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

We can advise you on all forms of corporate finance from private and public M&A, private equity to IPOs and joint ventures together with all of the corporate governance and company advice needed.

We combine contract savvy with crucial understanding of the intellectual property, regulatory and wider market considerations. Our depth means your transactions are handled efficiently, and cost-effectively.

Our recent work has included:

• Our multi-jurisdictional team advised the American Private Equity (PE) fund, Signet Healthcare Partners, on a EUR 10m investment in the Danish company Chr. Olesen Synthesis A/S.Chr., a company which manufactures and distributes active ingredients for the pharma industry globally.

• We advised Ziarco Pharma, a biotech start up spun out from Pfizer, on its $33.1 million Series B round financing. Ziarco focusses on creating innovative drug and therapeutics to treat inflammatory skin diseases. The proceeds from the Series B financing to generate clinical Proof-of-Concept data in patients for its lead compounds which will hopefully result in progress in the treatment of atopic dermatitis and psoriasis.

• We worked with Bilthoven Biologicals on its €48.3 million acquisition and financing of the Dutch central state’s life sciences complex ALT Terrain. Bilthoven Biologicals is now a part of the Serum Institute of India, India’s largest vaccine company.

• Advised Apollo Endosurgery on the acquisition of Allergan’s obesity intervention businesses. Apollo Endosurgery is a specialist in endoscopic surgical solutions, particularly focused around the prevention and treatment of obesity. Their acquisition of Allergan’s lap band products and expertise helps give Apollo another core competency within their business.

• We advised the shareholders of Masthercell SA and Cell Therapy Holding SA on a €1.6 million convertible bond issue, and its merger with Orgenesis Inc through a share exchange agreement.

"Bird & Bird provides ‘an excellent service’ to investors and investees across the life cycle of deals, from early stage to exit."

Legal 500, 2016
We provide advice on a variety of transactions from database licensing, drug development agreements, research collaboration agreements, clinical trial agreements, intellectual property acquisitions, joint development and marketing agreements, supply manufacturing and distribution agreements, joint ventures and strategic partnerships, across multiple jurisdictions.

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

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

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

Our recent work has included:

- Acting for a global generics pharmaceutical company in Europe in relation to their major Licence and Collaboration Agreement with a biotechnology company, for the development of new formulations of some of our clients existing products. This has involved the negotiations and drafting of complex intellectual property, royalty, licensing, improvements and supply terms since the collaboration involves some of the parties’ most valuable intellectual property.

- Advising a major European pharmaceutical company on an exclusive licence, collaboration and supply agreement with a biotech company and a world renowned children’s hospital, including the terms of development and commercialisation of the product through Phases I, II and III trials, licensing and IP ownership, regulatory applications, exploitation and commercialisation.

- Advising a US-based pharmaceutical multinational on the establishment of a centre for clinical pharmacology in Singapore for the purpose of conducting trials for the Asian market including advising on negotiations and drafting of documents for a joint venture with a Singapore hospital. This included research collaboration agreements, advising on contracts regarding clinical trial subjects; and administrative procedures for obtaining funds from grants awarded to the joint venture.
We guide our clients through all aspects of regulatory law, from marketing authorisations to administrative litigation, to help them achieve the most effective market penetration.

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

We regularly advise our clients across all of our offices on the advertising and promotion of their pharmaceutical/biologic/medical device products, specifically in relation to the promotion of products prior to and after Marketing Authorisation or CE marking, consistency of promotional materials with Summary of Product Characteristics, consumer protection legislation, business ethics codes as well as on the development, revision and/or validation of advertising claims and materials in accordance with the applicable laws and regulations.

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

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

"There are certain firms that, worldwide, are established as leaders in life sciences, and of course Bird & Bird is one."

Chambers Europe, 2016
We also advise our clients on all steps regarding the launch of a new product, including the strategy of marketing and advertising activities around the product launch.

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

Our international regulatory team has also authored several publications including *The Guide to EU Pharmaceutical Regulatory Law* (published by Kluwer Law International), written entirely by the team at Bird & Bird with contributions from all 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 recent work has included:

- Our European and APAC teams provide regulatory advice to a **global life sciences company**, in relation to its product compliance obligations under the applicable CE marking and associated environmental regulations, which impact upon the design, manufacture, testing and labelling of its genomic and proteomic sequencing laboratory equipment and accessories.

- Advised a **US biotech company** specialising in genetically-targeted oncology therapeutics on a number of clinical trial agreements with local hospitals and public healthcare structures, across multiple jurisdictions. The trials relate to Phase II testing of a treatment for non-small cell lung cancer patients whose tumours carry genetic alterations.

- Advising a **top multinational pharmaceutical company** on the production and market launch strategies of biosimilars, particularly on the experimental use and Bolar exemptions. We are advising on regulatory issues such as requirements for marketing authorisation filings, different requirements in the US and Europe and the potential impact of the UPC.

- We regularly advise **several pharmaceutical and biotech companies**, as well as sector organisations on Advanced Therapy Medicinal Products, the regulatory framework regarding cells and tissues as well as the implementation in Europe of the EU Directive ruling the use of human cells and tissues. We also advise these clients on their needs regarding clinical trials and/or manufacturing agreements.

- Advising a **leading pharmaceutical company** on complex regulatory data protection matters in relation to their innovative combination product, including an analysis of the concept of “new active substance” and analysis of the scope of the "global marketing authorisation" concept, as well as advice on a possible judicial review action.

- Advising a **global medical devices company** on an MHRA investigation into one of their products following reports of adverse events by patients. This has also involved advising the client on product labelling.

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

Chambers & Partners, 2017
Data Protection

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

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

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

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

Pragmatic solutions

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

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

Our services include:

- Advising on data protection requirements for direct marketing, including specific rules for behavioural targeting and children’s data, advising leading ad networks, publishers and industry bodies.
- Implementing Binding Corporate Rules, rolling out data transfer agreements around the EEA and beyond, and conducting international compliance projects.
- Registrations with data protection authorities worldwide.
- We have acted on many high profile breaches across multiple jurisdictions, providing guidance on investigations by regulators.
- Handling complaints and advising on prosecutions and offences.
- Training for staff and others.
- Lobbying data protection authorities and legislative bodies, including inputting to the new draft General Data Protection Regulation being developed in Brussels.
Increasingly, competition authorities in Brussels and the EU Member States are paying close attention to the life sciences sector. Merger notifications are thoroughly investigated, and regulators carefully scrutinise settlement agreements, distribution structures, refusals to supply and agreements imposing quotas. Free movement rules are complex. In addition, we see EU and national procurement rules continue to affect the supply of pharmaceuticals and medical devices.

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

Our recent work has included:

- 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.

"Full-service competition practice with an excellent track record in contentious mandates."

Chambers Europe, 2015
Other key areas

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

- Banking
- Employment
- Dispute Resolution
- Real Estate
- Tax
“Highly regarded in both Europe and Asia. Excels in the patent arena and possesses considerable expertise in regulatory and transactional matters. Features several practitioners with a significant science or regulatory background.”

Chambers Global, 2016
Keeping you up to date

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

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

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

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

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


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

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

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

International Co-Heads of Life Sciences & Healthcare

**United Kingdom**
Mark Hilton
Partner
Tel: +44 (0)20 7415 6000
Mark.Hilton@twobirds.com

**Belgium**
Marc Martens
Partner
Tel: +32 (0)2 282 6000
Marc.Martens@twobirds.com

**Key Country Contacts**

**Australia**
Jane Owen
Partner
Tel: +61 2 9226 9888
Jane.Owen@twobirds.com

**Belgium**
Bruno Vandermeulen
Partner
Tel: +32 (0)2 282 6000
Bruno.Vandermeulen@twobirds.com

**China & Hong Kong**
Alison Wong
Partner
Tel: +852 2248 6000
Alison.Wong@twobirds.com

**Czech Republic & Slovakia**
Vojtěch Chloupek
Partner
Tel: +420 226 030 500
Vojtech.Chloupek@twobirds.com

**Denmark**
Peter Jørgensen
Partner
Tel: +45 72 24 12 12
Peter.Jorgensen@twobirds.com

**Finland**
Ella Mikkola
Partner
Tel: +358 (0)9 622 6670
Ella.Mikkola@twobirds.com

**France**
Yves Bizollon
Partner
Tel: +33 (0)1 42 68 6000
Yves.Bizollon@twobirds.com

**Germany**
Boris Kreye
Partner
Tel: +49 (0)89 3581 6000
Boris.Kreye@twobirds.com

**Hungary**
Bálint Halász
Senior Associate
Tel: +36 1 799 2000
Balint.Halasz@twobirds.com

**Italy**
Giovanni Galimberti
Partner
Tel: +39 02 30 35 6000
Giovanni.Galimberti@twobirds.com

**The Netherlands**
Marc van Wijngaarden
Partner
Tel: +31 (0)70 353 8800
Marc.van.Wijngaarden@twobirds.com

**Poland**
Marta Koremba
Counsel
Tel: +48 22 583 79 00
Marta.Koremba@twobirds.com

**Singapore**
Alban Kang
Partner
Tel: +65 6534 5266
Alban.Kang@twobirds.com

**Spain**
Manuel Lobato
Partner
Tel: +34 91 790 6000
Manuel.Lobato@twobirds.com

**Sweden**
Gabriel Lidman
Partner
Tel: +46 (0)8 506 320 00
Gabriel.Lidman@twobirds.com

**UAE**
Melissa Murray
Partner
Tel: +971 2 6108 104
Melissa.Murray@twobirds.com

**United Kingdom**
Sally Shorthose
Partner
Tel: +44 (0)20 7415 6000
Sally.Shorthose@twobirds.com