

BYRNE
WALLACE

YOUR
LEGAL
BUSINESS
PARTNERS

Life Sciences



Providing dedicated expertise
to a dynamic industry

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ByrneWallace is one of Ireland's largest law firms. Our clients are leading, innovative and growing public and private enterprises active in all key industry sectors.

Driven by client needs

Over the years we have earned a reputation within Ireland and internationally as a leading business law firm with an award-winning approach to client service. We offer clients more than excellent transactional and specialist advice. We want to be recognized as "Your Legal Business Partners", delivering the full benefits of a trusted legal business partnership. This means that we challenge ourselves to find ways of adding business insight as well as legal excellence.

Delivering solutions

We look to devise solutions and uncover opportunities, not just point to problems. Our job is to understand our clients, their markets and their business goals and objectives – and to tailor our services accordingly. In addition to first-rate legal expertise, we apply commercial knowledge, insight and a practical understanding of the totality of the issues to all our client work.

Resourced for success

With over 40 partners and a total staff of almost 250 people in our main offices in Dublin, we have the scale and experience to ensure that we deliver on our promises in a timely, efficient and cost-effective manner. We are accessible, approachable and properly resourced to deliver the level of service you require.

Expanding

In 2010 we opened our New York office to cater for the legal needs of our US clients looking to expand into Ireland and the rest of the EU. Through our association with leading Northern Ireland law firm Mills Selig, we meet the needs of our clients throughout the island of Ireland.

Providing focused expertise

We are a full service practice with our services divided into the following areas:

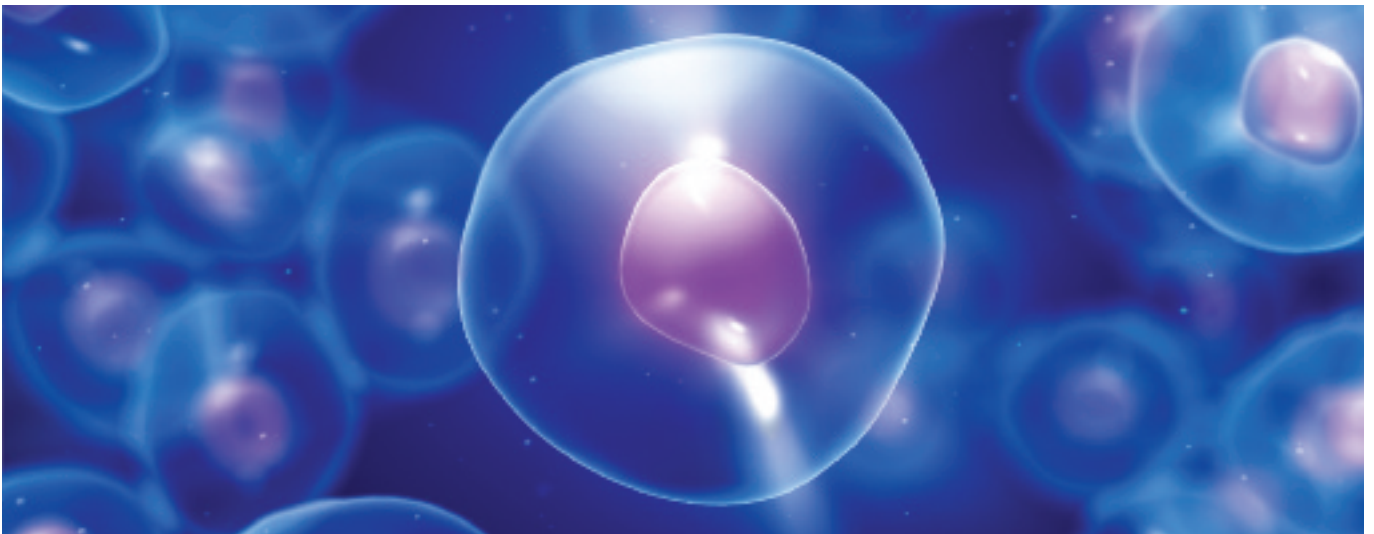
- Banking and Finance
- Capital Markets
- Corporate
- Corporate Restructuring and Insolvency
- Data Protection
- Dispute Resolution (litigation)
- Employment Law
- EU and Competition/Regulatory
- Green Economy
- Health Services
- ICT, Software & Digital Media
- Inward Investment
- Life Sciences
- Outsourcing
- Projects, Energy and Natural Resources
- Property
- Tax

Award-winning

- First Irish law firm to achieve ISO 14001 (2010)
- First Irish Law firm to win Professional Services Green Award (2010)
- Client Service Law Firm of the Year (Chambers & Partners, 2008)

The ByrneWallace Life Sciences Group

Industry-specific legal expertise from a dedicated team focused on client needs.



Life sciences is a vital industry in the Irish economy, and is a key practice area for ByrneWallace. Our dedicated Life Sciences Group is led by lawyers who previously held senior legal positions in the pharmaceutical biotech industry who have extensive international industry and regulatory experience.

The Life Sciences Group draws on the specialist skills and technical expertise of lawyers from the firm's corporate and commercial, regulatory, intellectual property, tax, product liability, EU and competition, projects and construction and other specialist practice areas. We pool our diverse and complementary skills in an integrated, practical and innovative manner according to client needs. This dynamic and flexible approach has enabled us to develop and maintain a leading position in the provision of focused advice to life sciences companies.

The firm and a number of individual lawyers in the group have consistently been highly recommended in leading independent client directories, including *Chambers & Partners Client Guide* and *Legal 500*.

"...the firm is home to what is perhaps Ireland's leading life sciences practice".

Chambers & Partners

What we do

Providing specialist advice to life sciences companies at all key stages of development of their business.



We provide legal business services to all types of enterprises active in the life sciences industry. Our clients range from the earliest stage university spin-out companies, to established later stage indigenous companies and global pharmaceutical, biotech and medical device organisations.

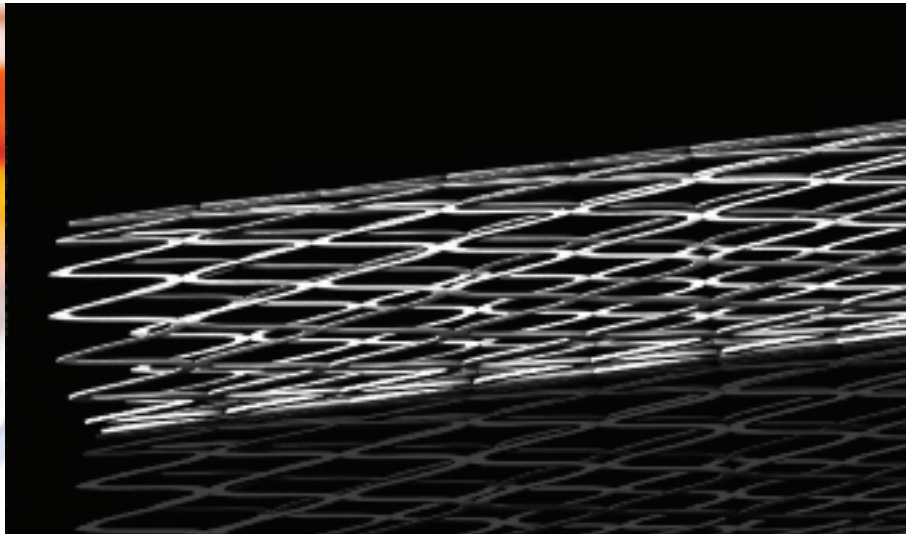
We also act for venture capital and private equity funds investing in the Irish life sciences industry, research institutions, and companies involved in the establishment and provision of healthcare services.

The specialist skill sets we have assembled, together with real industry and regulatory experience and a dedicated approach to serving the life sciences industry, enables us to provide the highest quality legal service in a focused manner.

Examples of areas where we are active include:

- Mergers, acquisitions, restructurings, joint ventures and other corporate transactions
- Licensing, research and development and other industry commercialisation agreements
- Venture capital, private equity and other fundraising structures
- Regulatory issues
- Contentious and non-contentious intellectual property
- Product liability
- EU and Irish competition issues, including parallel importing issues
- Environmental issues
- Transfer pricing and other taxation issues
- Projects and construction

A full service to the life sciences industry



EU and Competition

Our EU and Competition Unit provides tailored legal advice on all aspects of EU and Irish competition law, including dominance and pricing issues, merger control, competition compliance, state aid rules and competition litigation before the Irish and European Courts. We advise life sciences clients on the application of relevant block exemptions to their commercial agreements, such as technology transfer, vertical restraints (including distribution agreements), research and development and cooperation agreements.

Product Liability

Our Litigation department has experience in handling multi-jurisdictional product liability claims for clients, and is at the cutting edge of dispute resolution offering solutions to clients that include all forms of ADR including mediation, med-arbs (combined mediation and arbitration) and co-mediation solutions. It has a strong track record in resolving disputes quickly, effectively, and often without the need for Court intervention.

Projects, Energy and Natural Resources

Our team advises private developers, funders, state and semi-state bodies, bidders and sub-contractors on all aspects of the procurement, negotiation, financing, build and operation of large-scale projects in a range of sectors. We work seamlessly with financial, technical and other advisers to ensure the successful delivery of the project. Example projects range from healthcare and manufacturing facilities to infrastructure, waste and water, renewable energy, cleantech and combined heat and power (CHP). We also advise on carbon credits and carbon trading.

A full service to the life sciences industry

Focusing on your specific needs.



Corporate and Commercial

Our team is dedicated to life sciences clients and includes a number of lawyers with industry and regulatory backgrounds. This industry focused team is fully integrated within the Corporate and Commercial department and advises on corporate and commercial transactions, venture capital, private equity and other fundraising structures, and the full range of industry collaboration agreements.

Regulatory

Our team advises on a broad range of regulatory issues involving the FDA, the Irish Medicines Board, the National Standards Authority of Ireland and the EMA, including the product approval process and pre and post-approval matters.

Tax

Our tax team, a full service tax practice, serves a broad range of domestic and multinational clients in all major business sectors, especially in healthcare, pharmaceutical and general manufacturing. We advise on all tax aspects of establishing operations in Ireland and tax issues arising for established operations. We also have extensive experience in cross-border and international tax matters.

Intellectual Property

Our Intellectual Property Group provides expert advice on both commercial and contentious intellectual property matters. The team brings together a wealth of experience in advising clients on intellectual property, ICT and life sciences matters and regularly advises on intellectual property

rights (patents, trademarks, design rights and copyright) and related issues – including registrations, exploitation (licenses and assignments), IP due diligence and IP enforcement. Our lawyers focus on providing pragmatic solutions to the domestic and international IP issues faced by our clients.

In relation to contentious IP matters, the firm has a unit headed by a specialist intellectual property litigation partner with experience in all areas of hard and soft IP litigation, including obtaining search orders (Anton Piller relief) and using all forms of ADR from arbitration to mediation and co-mediation. Lawyers within the unit are qualified in various jurisdictions including Ireland, the United Kingdom and New Zealand, and maintain close working relationships with specialists in all the major business jurisdictions.

Life Sciences Group experience

We can help you turn your ideas into action.
Here are some of our recent transactions:

Advised Alimentary Health on a number of transactions, including agreements with Mead Johnson, Procter & Gamble and Norgine

Advised Apica Cardiovascular on the investment by Seroba Kernel and Triventures

Advised Azur Pharma on product acquisitions and commercialisation transactions, including the acquisitions of FazaClo® and Prialt®, and the merger between Azur and Jazz Pharmaceuticals

Advised Biogen Idec on various issues involving reimbursement and market access in Ireland

Advised Dignity Sciences on all legal matters relating to its establishment and various development stage agreements

Advised Elan Corporation on various transactions, including a strategic alliance with Eli Lilly, and licensing transactions with Abbott Laboratories, AstraZeneca and MAP and the merger of Elan Drug Technologies with Alkermes

Advised the vendors in the sale of Firecrest Clinical to Icon plc

Advising i360 Medical on its establishment and early stage financing and industry agreements

Advised Merrion Pharmaceuticals on its IEX flotation, and various other transactions, including two \$58m licence agreements with Novo Nordisk

Advised on the sale of Newport Pharmaceuticals Limited to Ewopharma A.G.

Advised Opsona Therapeutics on various matters, including its Phase I clinical trial and the spin-out of Trimod Therapeutics

Advised VaxyGen Vaccines on its establishment in Ireland and early stage agreements



Life Sciences team

Our dedicated team draws together extensive expertise and industry knowledge from key practice areas.

Colin Sainsbury

Partner, Corporate and Commercial

Colin is a corporate transactional lawyer with over 16 years' experience in the international life science sector and acts for a broad range of Irish and foreign life sciences companies. Colin was previously Senior VP and General Counsel of Elan Corporation's Drug Delivery Division.



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Tom Maher

Partner, Corporate and Commercial

Tom is a corporate transactional lawyer with over 15 years' experience in the international life sciences industry, split evenly between high profile industry positions and large Dublin law firms. He was previously General Counsel at Amarin Corporation plc (NASDAQ: AMRN), and VP Legal Affairs at Elan Corporation plc.



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Deirdre MacCarthy

Associate, Corporate and Commercial

Deirdre advises on a range of corporate and commercial matters and has previously worked with Alkermes plc (previously Elan Drug Technologies). At Alkermes, Deirdre worked on a variety of life sciences issues, including clinical trials, IP issues, and business collaboration arrangements.



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Catherine Dowling

Solicitor, Corporate and Commercial

Catherine advises on a range of corporate and commercial matters including specialist advice on life sciences, intellectual property, ICT and e-commerce. Her clients include life sciences and technology companies at various stages of development.



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Darren Daly

Partner, Corporate and Commercial

Darren advises on both general corporate law matters and also provides specialist advice on intellectual property, ICT, e-commerce, data protection and life sciences issues with a particular emphasis on advising technology clients in the health services, pharma, and medical device sectors.



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Caoimhe Daly

Associate, Corporate and Commercial

Caoimhe advises on a wide range of information technology, intellectual property, data protection, regulatory and confidentiality issues, as well as general corporate and commercial law matters. Her clients include life sciences companies, statutory bodies, local authorities and technology companies.



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Ursula Tipp

Partner, Tax

Ursula is a tax lawyer, dual-qualified in Ireland and Germany, with over 15 years' experience in international taxation. She was the head of the tax department in a large multinational, and joined ByrneWallace from another large Dublin law firm.



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David Hourihane

Partner, Corporate and Commercial

David is a leading expert in Irish and EU competition law, and represents a number of major pharmaceutical companies on merger control issues and competition investigations before the European Commission and the Irish Competition Authority.



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Jon Legorburu

Consultant, Litigation and Dispute Resolution

Jon Legorburu heads up the contentious intellectual property (IP) division and represents domestic and overseas clients in all areas of IP litigation, including copyright, trade mark (CTM, national and Madrid Protocol registrations), design right, database right and patent litigation. He has specialist experience of multi-jurisdictional product liability and IP disputes.



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