



Field Fisher Waterhouse



Life Sciences

Medical Devices



“ . . . meticulous, pragmatic and responsive . . . ”

*Chambers UK, 2008*

## About us

Field Fisher Waterhouse LLP is a full service European law firm. We have 130 partners and over 220 other lawyers across offices in Brussels, Hamburg, London and Paris. In addition to our European offices, we have exclusive relationships with Spanish firm Jiménez de Parga and Italian firm La Scala. We also have strong affiliations with firms in the Czech Republic, Hungary and Poland. Our relationships with firms in the US, India, China and elsewhere around the globe, coupled with first rate international project management experience will allow us to service any international project you might have, wherever your legal needs might be.

With in-depth industry expertise in life sciences, sitting alongside an international client base (including listed and unlisted companies, multinationals, banks and other financial institutions, professional partnerships, trade associations and government departments), we have a proven track record that shows our work to be both extensive yet incisive.

Our main areas of practice are corporate and commercial, IP and technology, banking and finance, regulatory and real estate. We also have particular expertise in competition & EU law, dispute resolution, employment, pensions and tax.

**How can we help you:**  
to make strong and fruitful  
alliances to develop your  
products from bench to  
bedside?

## Research, clinical trials, licensing and collaboration

Developing your products may require help from external third parties, such as those in the medical profession and universities. Your relationships with the medical professionals and other researchers with whom you work will need to be regulated by carefully crafted agreements to ensure that you retain the intellectual property rights you need to freely market your products. We have intellectual property lawyers experienced in drafting research, collaboration and licensing agreements and who will be able to not only protect the products of your research through your agreements, but who are also specialists in the compliance requirements specifically applicable to the medical devices industry.

“...Clients are ‘extremely impressed’ with Field Fisher Waterhouse LLP, particularly for its ‘deeply caring attitude’ and ‘terrific team spirit’.”

*The Legal 500, 2009*

Where you are involved in clinical trial agreements, our lawyers are experienced in negotiating the terms of these agreements, if necessary coordinating the drafting of agreements in different locations through a network of specialist lawyers. Our lawyers will be able to help you deal with issues such as liability, clinical trial regulations, obtaining consents, ethics issues and, if necessary, dealing with issues arising with your regulators.

### Supply, distribution, manufacturing, tooling agreements

For those products you are manufacturing, there are likely to be other relationships that you will need to engage in. Our commercial life sciences lawyers are experienced in negotiating supply agreements for products and materials that take into account the commercial needs of your business, as well as the regulatory requirements to which you are subject. Once manufactured, your products will need to be supplied to the market, which can happen through a variety of different routes. Whether your products are sold through sales agents, distributors or by way of responses to government tenders, we have experts to guide you through the contractual process.

### Successfully outsourcing key functions to achieve efficiencies

Many larger medical devices companies, in common with other industries, find that some services are more efficient if outsourced to a specialist provider. With one of the largest outsourcing practices in the UK, we are extremely well placed to ensure that your interests are protected and that the relationships you develop with your outsourcing partner(s) are regulated through your contracts in an advantageous, but nevertheless pragmatic, way. Our team includes lawyers who have in-house experience, or have been technology consultants, programmers or commercial managers and who are therefore able to make significant technical, financial and commercial contributions to any outsourcing projects you might have.

“ Field Fisher Waterhouse LLP’s Privacy and Information Law Group has been listed as one of the top 10 Privacy Law practices in the world by Computer World. Eduardo Ustaran was also listed as one of the top 25 privacy experts in the world. ”

*Computer World*

### **How can we help you:** to obtain regulatory approvals and stay on good terms with your local regulators?

As a medical devices company, your products, manufacturing and business operations are subject to some substantial regulatory regimes.

### **Clinical trials, CE Marking and working with competent authorities**

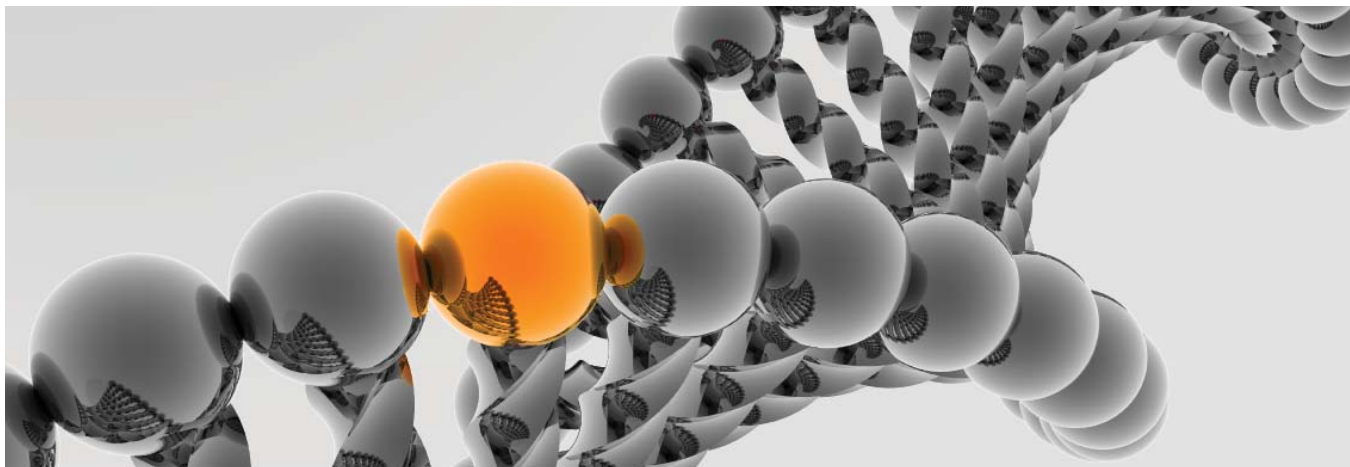
Our teams in Brussels, London, Paris and Hamburg work regularly with our client’s regulatory teams, advising where necessary to steer a clean path through the regulatory hurdles to obtaining approvals for clinical trials and, under the applicable medical devices directive, for CE marking.

Where clients run into trouble with their competent authorities and/or industry bodies, we help them resolve the issues as quickly as possible whilst maintaining a good relationship

with those authorities/industry bodies. Decisions of regulatory authorities can, in the UK, be challenged through judicial review proceedings, in which the firm has a leading practice.

### **Compliance**

There is an increasing emphasis on ethics in the conduct of companies selling medical devices. The EUCOMED rules have recently been made more stringent and several EU countries either have or are planning to institute tighter controls on the relationships between medical device companies and health care professionals. Our lawyers in the UK, France, Brussels and Hamburg work together, alongside other specialist lawyers in other jurisdictions, on European compliance policies for medical device companies and can provide you with specifically tailored training courses for your sales staff. We can also work with you to carry out audits of your current practices and procedures to ensure that they meet the more stringent requirements now being imposed. Our detailed understanding of cell and tissue law equips us to provide a comprehensive service where products include, or consist of, engineered cells or tissues.



“ This excellent outfit is in the ascendant. ”

*Chambers UK, 2010*

## REACH, WEEE and RoHS

The medical devices industry is particularly affected by the recent EU regulation of chemicals and of electrical equipment, known as REACH, WEEE and RoHS. Our Brussels office has the largest and most specialist REACH team in Europe. We can apply our expertise in this and other EU regulatory matters, to help you to achieve compliance with the increasingly complex EU legislation with minimum business impact.

## Data protection/privacy

Data protection or privacy is a particular issue for medical device companies who handle sensitive personal information in the form of clinical trial data. Our team of data protection experts are part of a 40-country network that offers international compliance advice. They can help you craft your compliance, data security and privacy policies and, should it be necessary, have extensive experience of defending companies in breaches of data protection legislation.

## Competition law/procurement

If you sell your devices through a government procurement process and need advice on the process, our competition and regulatory team can provide you with expert assistance and, if necessary, can challenge the process. Our team can also provide you with advice and training to help prevent you infringing competition or anti-trust laws, thus avoiding very substantial fines and reputational damage that could harm your business for years.

## How can we help you: to protect your valuable Intellectual Property rights?

### Patents, copyright and design rights

The results of the innovative and creative genius that puts your company ahead of its competitors in your field must be protected to ensure that you are able to exploit the full potential of your intellectual property. We can work with you to develop policies to protect your confidential information, and agreements with employees, consultants and collaborators that ensure that you retain the rights you need as the keystone for your business.

If you need to take active steps to protect your intellectual property rights from infringers, our highly experienced IP litigators will work with you to effectively protect those rights whether they are patents, copyrights or design rights.

If patent infringement proceedings are taken against you, our experience of overcoming others' patent rights, whether by assisting in developing design-arounds or vigorously defending the patent proceedings, will be available to you.

### Trade marks and branding

In building your business, you will want to obtain and maintain goodwill in your trade marks, and you will also want to ensure the highest level of protection for those marks. Our Trade Mark and Brand Protection Group, ranked top UK firm in this field for the past six years, can manage your trade marks and domain names for you with a combination of high

level skills. This group has specialist lawyers who can provide a strategic direction for your branding by coordinating where appropriate the registration, protection, defence and enforcement of your trade marks.

## How we can help you: to put in place funding to achieve your goals?

In common with other industries, growth for a medical devices company will often require external funding. The 24 partners in our corporate finance team are experienced in leading teams putting in place funding through venture capital, strategic investments, listings and secondary fund raisings (both on AIM, where we have one of the busiest UK practices, and on the London Stock Exchange). If you are seeking venture capital funding, our highly experienced team will ensure that the deal is structured appropriately for your company's business needs. Indeed, our corporate finance team has raised over \$1 billion for life sciences companies.

## How can we help you: to grow?

Our corporate lawyers in London, Brussels, Hamburg and Paris are also highly experienced in helping companies to grow through acquisitions and joint ventures, whether domestic, international or cross-border. Any acquisition finance that these transactions might require, whether through debt or equity, is an integral part of our corporate finance practice.

## How can we help you: in other ways?

### Real estate

Whether you are buying, selling or leasing property, our substantial real estate team can provide all of the support you need. Our highly rated property litigation team can also help you to efficiently and effectively negotiate rent reviews and other issues with landlords or with tenants.

### Employment and Pensions

Our expert team of specialist employment lawyers can advise you on the range of contentious and non-contentious employment law issues. We will provide your HR team with a personal service, providing a grounded commercial approach through which we will deliver focused, practical solutions and advice on your long-term strategy. Recognising the challenge of frequent changes to employment law, we can provide you with fortnightly email updates and newsletters on key employment law developments. Your HR team will be invited to attend our regular seminar and workshop programme and we can provide them with bespoke training to pre-empt issues that might arise in the workplace. We also provide a dedicated employment law website, and have a specialist pensions team to deal with any corporate pensions schemes that you might have or acquire.

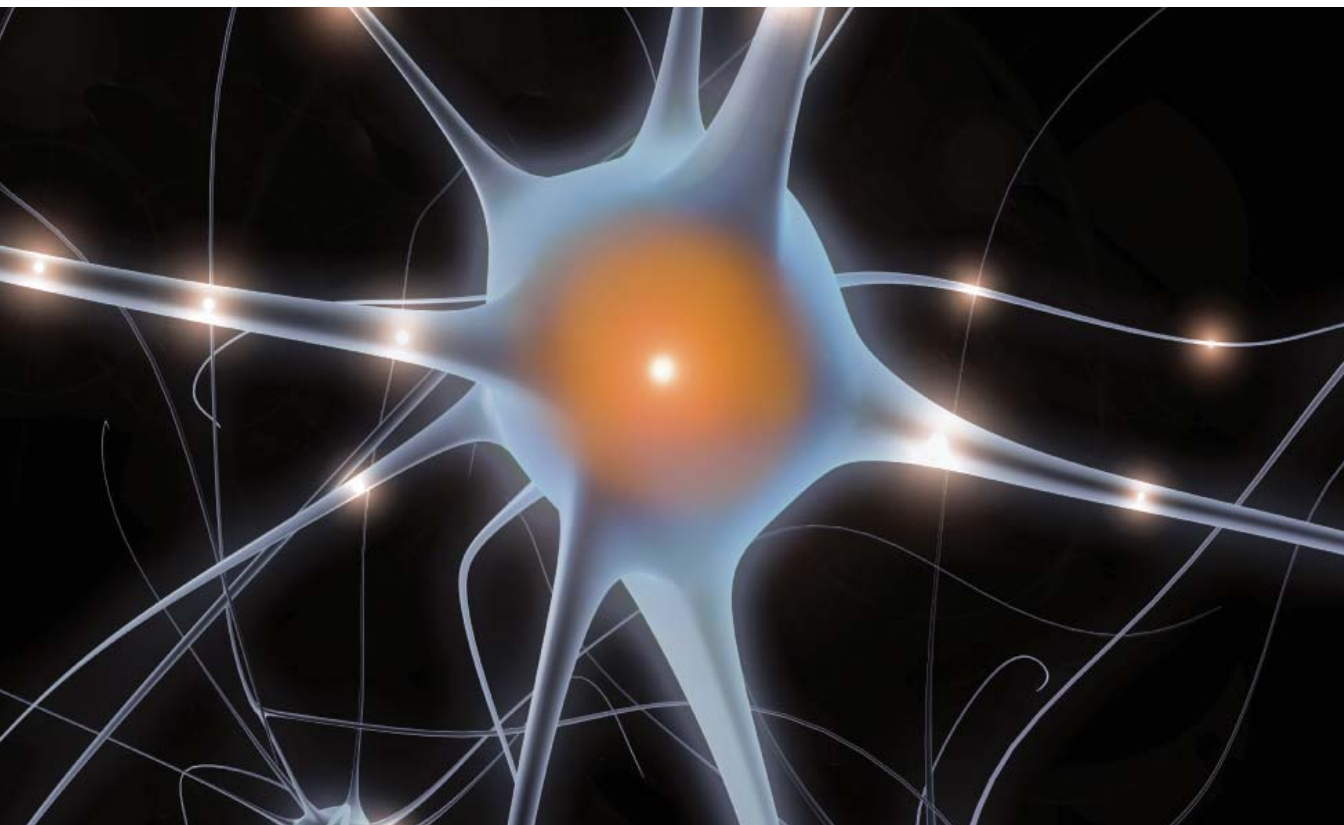
### Tax planning

Our widely recognised business tax group can provide you with tax advice on all aspects of your business and any tax planning opportunities, including with respect to research and development tax credits, VAT and stamp duty land tax. Our transfer pricing team advises on the monetary value of intellectual property and on locating intellectual property to maximise group revenues. We are also widely recognised for advising companies on employee equity incentives.

### Dispute resolution

Should you have a commercial or corporate dispute, our disputes resolution team will aim to resolve it efficiently, effectively and with minimum disruption to your business.





“ With a calm and composed style, this firm is attentive to its clients’ needs and committed to completing work smoothly and swiftly. ”

*Chambers UK, 2009*

“ The lawyers have specialised knowledge without having to do additional research ”

*Chambers UK, 2010*

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