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Health & Life Sciences

## Introduction

We live in innovative and challenging times. Technological developments in biosciences, medical research and advanced therapies are already pushing the boundaries of what we understand about our environment and the human body. At the same time, new approaches to caring for our ageing population, dealing with disease and producing the food we eat will be some of our greatest challenges as a society.

Many of Square One Law's clients operate at the very heart of the thriving health & life science economy and we are an active member of Bionow, the health & life sciences membership organisation.

We support our clients' businesses as they strive to find solutions to our future challenges and change the landscape of how we live, work and play.

## Who we are

Square One Law is an entrepreneurial, commercial law firm which has offices in Newcastle upon Tyne and Stockton-on-Tees and an associate office in Brussels, offering our clients trust, high performance and cost certainty.

We invest our time to understand what health & life sciences sector clients want to achieve and then deliver a highly proactive and commercially aware service.

What sets us apart is that we identify solutions and offer an opinion – not just give legal options. We listen to our clients and provide clear advice, focussed on the requirements of you and your business.

Our clients tell us they want to deal with experienced lawyers who are commercially minded and invest the time to understand their businesses. We have become trusted advisers, and are focussed on building long-term relationships and our team becomes an extension of our clients' teams.



## Our team delivers the following services:

### Corporate

If you are starting a business, raising capital to grow, succession planning, selling your business or exploring mergers and acquisitions.

### Commercial

Including drafting and reviewing commercial contracts and giving IP, IT and data protection advice.

### EU & competition

If you are concerned that your actions might be anti-competitive, wish to put in place a programme to achieve compliance, wish to challenge the unfair actions of a third party or require State aid advice.

### Property

If you are looking at property development or investment, need landlord and tenant advice or require assistance raising property finance.

### Litigation

Including contractual and commercial disputes, injunctions, property litigation and regulatory disputes.

## Our experience

We represent a wide variety of organisations, ranging from companies operating at a global level, to mid-tier, SMEs and entrepreneurs as well as universities and research organisations.

Our team is very active in the health & life sciences sector and regularly advises on:

- Agreements for the operation of clinical and non-clinical drug and treatment studies/trials
- Protection, enforcement and exploitation of intellectual property including in medical devices and health technologies
- Supply agreements, general terms and conditions, cross-border/ international agreements
- The provision of health and wellbeing products and services online, including website terms and policies
- Fundraising for life sciences and health tech businesses
- Contracts with the NHS
- Wholesale, distribution and retail contracts
- In licensing of technology and formulations
- Out licensing arrangements
- Manufacturing agreements including substance, product and component manufacturing
- Material transfer agreements
- Research and development agreements
- Collaborations and joint ventures
- Commercialisations and spin-outs from the NHS and universities
- Data protection and information governance, including data sharing and GDPR compliance
- Contracts for purchase and licensing of IT (including hardware, software and services, including outsourcing)
- Employment issues for life sciences businesses, including global mobility issues
- Leases for laboratories, manufacturing, warehousing and office space
- Commercial disputes
- Mergers and acquisitions
- Company secretarial and public company issues.



## Examples of our clients

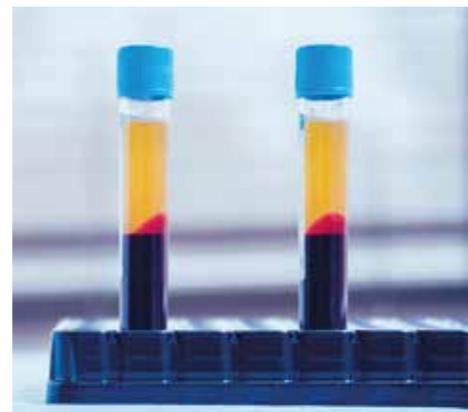
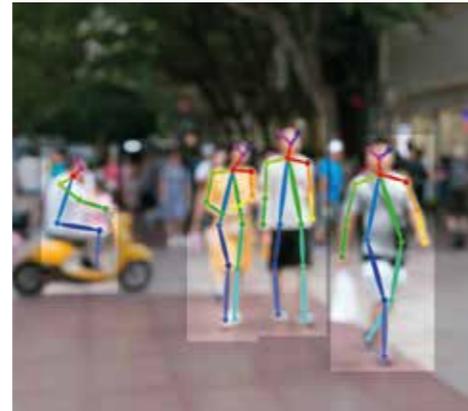


## Our projects

Our team members have substantial experience in projects within the health & life sciences sector. Some recent examples include:

- Carrying out due diligence for a pharma company acquiring a number of drug dossiers compiled for market authorisation purposes
- Advising a specials company on the in licensing of drug compounds for further development and testing
- Advising a company on the development and evaluation of a non-invasive test for CJD
- Advising on protection of approved product names and making associated trademark applications
- Providing advice on royalty and revenue sharing agreements for the exploitation of pharmaceutical products
- Advising on a complex joint venture between the NHS, a tech company and a large international pharma company concerned with the development of predictive algorithms for certain long term conditions
- Providing advice on the IP issues and licensing agreements arising out of the use of experimental drugs in a compassionate use situation
- Negotiating pharma licence agreements and pricing mechanisms for exclusive distribution in the EU
- Implementing a competition compliance system and full review of all exclusivity arrangements for a life sciences company
- Advising on competition compliance for upstream and downstream supply arrangements in the biotech sector including multiple High Court and EU Commission actions
- Advising on a CMA investigation into a pharma company's market sharing arrangements
- Advising on the competition aspects of a pharma company's exclusive distribution network including its discounting and pricing policies
- Advising a large physiotherapy group on corporate and company matters including a restructuring of its UK operations
- Advising on the sale of a pharmacy chain

- Advising on GP practice mergers
- Acting for a number of NHS Foundation Trusts on property acquisitions and disposals, estate management issues, lease renewals (including leases to GPs and pharmacies), break notices, dilapidations, easements and covenants.



## Our team

At Square One Law we have built a culture that focusses on teamwork.

The majority of our lawyers have joined us from national and international firms, bringing extensive experience and applying it in a flexible and agile way.

We listen to our clients' objectives and then provide tailored and commercial advice. We always give a view and never sit on the fence. The partners who lead our health & life sciences team are Helen Brain and Gill Hall, both of whom have significant sector experience.

Helen has published the following academic papers (under her maiden name, Smith):

**Smith H. 2009.** *Umbilical cord blood banks: Modern day alchemy.* *Journal of Commercial Biotechnology* 15(3), pp. 236-244.

**Smith H. 2008.** *New Stem Cell Legislation in Europe: Are you ready?* *Journal of Biolaw and Business* 11(1), pp 55-57.



**Helen Brain**

Commercial Partner

Helen is a partner in our corporate commercial team and joined Square One Law from the Government of Dubai Legal Affairs Department. Helen's career started in the health & life sciences arena, having worked as a Molecular Biology Research Assistant and gaining first class BSc (Hons) in Physiological Sciences, both at Newcastle University.

Helen has specialised in commercial, IP and IT law throughout her career, including five years as an Associate in the London Office of US law firm K&L Gates where she provided IP support and advice on the AIM float of a life sciences business; drafted and negotiated IP licences and joint collaboration/R&D agreements for life sciences and pharma clients. She was also involved in establishing the Stem Cell and Nanotechnology Practice Development Groups within K&L Gates.

Helen's recent experience within the health & life sciences sector includes advising listed pharma companies on commercial contracts including long term, cross border supply arrangements, licensing, manufacture and marketing authorisation arrangements, as well as procurement of goods and services throughout the business. She also advises on IP matters and data protection issues including advising a clinical trials data analytics company on various SaaS and PaaS licensing terms and personal data protection issues. Helen was also speaker on the State of the Nation Panel at the BioFocus Conference in July 2018.

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**Gill Hall**

Managing Partner and Head of Commercial

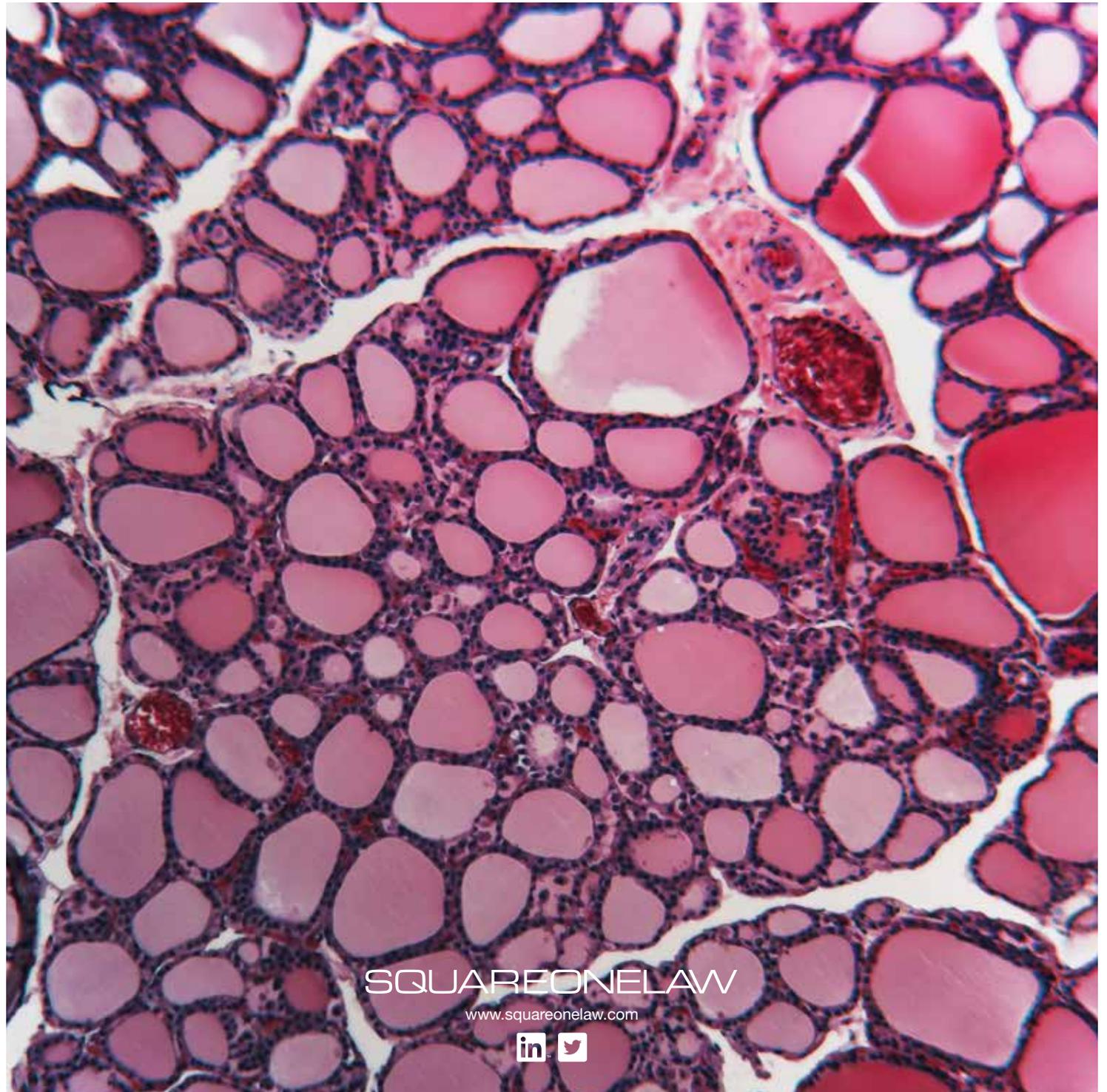
Gill Hall joined the firm in May 2018 as managing partner and head of the commercial team. Gill has over 20 years' experience in commercial law with a particular specialism in IP and IT. Gill spent 19 years at a regional firm as head of its commercial team. More recently she headed the IP and IT team at national healthcare firm, Hempsons, before moving to Square One Law.

Gill has significant expertise in drafting and negotiating commercial and IT contracts having acted for a range of clients in a variety of sectors including health & life sciences. Gill is also experienced at advising clients on the protection and exploitation of IP. She carries out IP audits and manages IP portfolios for companies and advises on IP licensing arrangements, sales and acquisitions of IP assets and joint development and collaboration agreements.

Her diverse experience includes advising a pharma company on its extensive clinical and non-clinical study arrangements with CROs overseas and in the UK; advising a medical devices company on the ownership and protection of IP in a medicines management product; advising a technology company on the development of a wearable health technology including competitor analysis of similar innovations; and advising several NHS bodies on technology products including the commercialisation of a ward safety tool and an innovative post-operative dressing.

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