HGF

# IP in Healthcare Conference 2020

Tuesday
3rd March

Manchester
Alderley Park

Thursday
12th March

London
Barber-Surgeons' Hall

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# Programme

| | |
|---|---|
| 09:00 – 09:30 | Registration & Breakfast |
| 09:30 – 09:35 | Welcome |
| 09:35 – 10:10 | The Wild East? Protecting patents and trade marks in China<br>*Hsu Min Chung / Lee Curtis & Guest Speakers Doug Clark / Tim Jackson, Rouse* |
| 10:10 – 10:45 | GDPR – Unforeseen (and unintended?) logical consequences: GDPR v IP – in coded clinical trial data<br>*Ellis Parry* |
| 10:45 – 11:20 | Parallel Session 1 – Please choose to attend A or B<br>A – CRISPR IP Saga – the latest chapter<br>*Dr Claire Irvine & Dr Leena Contarino*<br>B – Fast track or slow lane:<br>Patent strategy or IP cost control?<br>*Vanessa Stainthorpe & Guest Speakers Dr Prashant Girinath / Dr Lou Lieto, Wilson Sonsini Goodrich & Rosati* |
| 11:20 – 11:50 | Break |
| 11:50 – 12:25 | Parallel Session 2 – Please choose to attend C or D<br>C – Patenting computer-implemented healthcare inventions in AI and machine learning<br>*Dr Andrew McGettrick*<br>D – Opposition case studies<br>*Mike Nelson & Leythem Wall* |
| 12:25 – 12:55 | Lab bench to acquisition and a spin-out company:<br>Follow the client journey<br>*Dr Andrew Wells & Guest Speaker Dr Andy Chapman, Ziylo Ltd* |
| 12:55 – 13:30 | I've got the brains. You've got the looks.<br>Let's make lots of money… but how much?<br>*Janet Knowles* |
| 13:30 – 14:30 | Lunch and close |

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# Welcome

## HGF's sixth annual Healthcare Conference reviews the latest intellectual property issues in the pharmaceuticals, life sciences and medical devices sectors.

Parallel sessions: we will be holding two parallel sessions. Please choose to attend A or B from session 1 and C or D from session 2.

Presentation slides: copies of all presentations will be available after the conference.

Feedback: feedback on our conference is greatly appreciated. We have enclosed a feedback form in the pack if would like to leave any comments.

# The Wild East? Protecting patents and trade marks in China

## 09:35 – 10:10
## Hsu Min Chung / Lee Curtis & Guest Speakers from Rouse

China is already a hugely significant market for healthcare and life science related companies, whether for sales or manufacturing. It is also often seen as a country of concern when it comes to the protection and enforcement of IP rights but practice and case law relating to IP rights is developing.

China is a key jurisdiction for patent prosecution and enforcement and has seen a 50% increase in new patent filings in just the last four years. Furthermore, as companies based in China (e.g. specialist CROs) become more integral to the early R&D efforts of global pharmaceutical and life science companies, issues in respect to patenting inventions arising from China are also becoming increasingly important.

New Chinese trade mark legislation now counters brand hijacking and bad faith trade mark filings. Recent Supreme People's Court decisions about Original Equipment Manufacturing (OEM) impact anyone manufacturing branded products in China solely for export. If you sell into the Chinese market, you need to take account of certain 'quirks' of Chinese trade mark practice.

We intend to provide a brief overview of all of the above issues providing practical points on trading and manufacturing in China and the interaction with IP rights.

Image: Adi Constantin

**Hsu Min Chung, Partner**

Hsu Min specialises in the healthcare and pharmaceutical fields. Her clients include multinational generic pharmaceutical companies, pharmaceutical start-ups and multinational medical device companies. She leads on behalf of HGF in relation to our work in China. Hsu Min manages substantial patent portfolios and regularly provides clients with opinions on their freedom-to-operate in the light of third party rights. She has a wealth of experience in European oppositions and appeals and regularly represents clients at Oral proceedings at the European Patent Office.

**Lee Curtis, Partner**

Lee is a Trade Mark Attorney who manages the trade mark portfolios of some of the leading brands in the UK and globally. He is a Chartered Trade Mark Attorney, Official Representative before the European Union Intellectual Property Office (EUIPO) and Irish Trade Mark Agent. He has extensive experience in the filing and protection of trade mark and design rights in China and the interaction of such rights in the securing of client's supply chains, including successful trade mark invalidity, opposition and revocation actions before the Chinese Trade Mark Office, appeals to the Trademark Review and Adjudication Board (TRAB) and the successful defence of appeals before the Beijing IP Court.

**Doug Clark, Principal at Rouse**
*Speaking on 3 March*

Doug has practised in Asia for over 25 years. He is a widely respected litigator and arbitrator with more than a quarter of a century experience handling IP litigation and arbitration in East Asia as well as coordinating global cases. Doug has handled the entire gamut of contentious IP cases including raiding factories in China (in the early part of his career); obtaining civil search and seizure (Anton Piller) orders and freezing (Mareva) injunctions; establishing new law in relation to anti-circumvention technologies; and, running complex multi-jurisictional patent litigation. His non-contentious experience includes advising on technology transfer; conducting patent and other intellectual property audits; and, freedom-to-operate analyses.

**Tim Jackson, Principal at Rouse**
*Speaking on 12 March*

Tim is based in the firm's Shanghai office. He is a lawyer and a registered patent attorney in New Zealand and Australia. He has represented local and international clients in patent litigation before the New Zealand Courts and in pre-grant oppositions before the Intellectual Property Office of New Zealand (IPONZ) and IP Australia.

Tim has worked in the IP field for over 25 years specializing primarily in patents, although he also has experience with copyright, registered designs and trade marks as advising clients is rarely isolated to just one available right. Tim has regularly advised clients on freedom-to-operate, filing, prosecution, and commercialisation strategies in order to advance their commercial objectives locally and internationally.

# GDPR – Unforeseen (and unintended?) logical consequences: GDPR v IP – in coded clinical trial data

## 10:10 – 10:45

## Ellis Parry

As a 'Regulation' the GDPR was designed to enforce harmony across the whole of the EU 28, it allows each member state to legislate:

- Additional circumstances under which health and genetic data may be processed, creating a potentially uneven playing field across the UK and the remaining EU 27.
- Derogations from the GDPR's requirements when processing for the research purposes, including the extent to which trial participants' EU data protection rights may trump proprietary and confidentiality rights over coded trial data.

In the absence of fulsome up to date UK regulatory guidance on the topic of the GDPR's research purposes, this session will examine some of the bigger risk areas for IP owners and suggest some risk mitigating measures.

**Ellis Parry, Consultant**

Ellis has been a Specialist Information Rights Lawyer for 20 years, leading global data privacy compliance programmes in two FTSE 100 international companies. While the Global Privacy Counsel at AstraZeneca he advised the business on all aspects of its personal data processing operations, including its human biological sample handling and its clinical trial data collection, sharing, international transfer and pseudonymisation. With the advent of the GDPR, and the new Data Protection Act Ellis has continued to advise on the complex interplay between the new rules on genetic and health data and the way the new act expresses the derogations associated with the research purposes. Ellis is currently employed in the emerging field of data ethics with a particular focus on how such considerations could aid innovative research.

Image: Raw Pixel

# Parallel session 1

**Please choose A or B**

# A – CRISPR IP Saga: the latest chapter

## 10:45 – 11:20

## Dr Claire Irvine & Dr Leena Contarino

CRISPR gene-editing is proving to be a technology that few in the healthcare field can afford to, or wish to, ignore. It has many applications, ranging from discovery and validation of drug targets to the provision of new therapeutic and diagnostic strategies. Following recent important decisions arising from opposition proceedings at the European Patent Office on the lead CRISPR European Patents of both the Broad Institute and the University of California, it is an apt time to review again the CRISPR IP landscape at the Healthcare Conference.

Dr Claire Irvine and Dr Leena Contarino, Partners of the HGF CRISPR IP team, will discuss;

- The interplay between the latest chapter in the CRISPR IP saga in Europe and the US
- Freedom-to-operate issues in the absence of resolution of a standard for CRISPR gene-editing for therapy
- The growing number of CRISPR related claims outside the main battle lines
- The latest developments of CRISPR technology such as application of base-editing and prime-editing for new therapies

Image: Shutterstock

**Dr Claire Irvine, Partner**

Claire's practice lies principally in the life sciences field. She has special expertise in all aspects of biotechnology patenting, including gene-related and immunology-related inventions. Her experience includes handling high-profile patent applications in the fields of genetic diagnostics and synthetic biology, which have been the subject of considerable interest and comment beyond patent professionals. She has worked with major corporations, universities and research institutes as well as small companies on areas such as biologic therapeutics, T-cell technologies and gene-editing.

**Dr Leena Contarino, Partner**

Leena is a US qualified life science Patent Attorney with over two decades of experience in protecting inventions covering biologics, including, DNA, RNA, peptides, antibodies, and enzymes. She has also considerable experience in drafting and prosecuting patent applications covering diagnostics, cell therapies and microbiome-related inventions and reviewing patent landscapes for freedom-to-operate. She has worked on nucleic acid-related interferences and antibody-related post grant proceedings on both defence and offence, and has followed closely the US interference proceedings relating to the CRISPR-technology as part of HGF CRISPR IP team. Leena obtained her master's degree in biotechnology and her Ph.D. in biochemistry in Finland, and transferred to the patent profession after her post-doctoral work on cell biology at Harvard University. After qualifying as a US patent agent, she completed her law degree at the Suffolk University Law School evening division in Boston, MA, US, qualifying as a US Patent Attorney.

# Parallel session 1

**Please choose A or B**

# B – Fast track or slow lane: Patent strategy or IP cost control?

## 10:45 – 11:20

## Vanessa Stainthorpe & Guest Speakers from Wilson Sonsini Goodrich & Rosati

The patent application procedure is notoriously slow and driven by fixed deadlines. We are often asked how to speed up the process and then how to slow down the procedure when big costs approach, such as validation of a granted European patent. The issue becomes even more pressing when you have patent applications running simultaneously in Europe and the United States. In this session we will cover options available to speed up and slow down the patent procedures in both Europe and the United States and share our experience with other tips and tricks to get the patent application timeline to best align with your commercial milestones.

Image: Jannik Selz

**Vanessa Stainthorpe, Partner**

Vanessa's expertise covers patent matters in the physics and mechanical engineering fields, with a particular focus on medical technology. She has prosecuted and advised on numerous patents with medical subject matter, such as drug delivery devices, spinal and other orthopaedic instruments, dental, knee and hip implants, fracture fixators, ventilators, EEG systems, ophthalmic technology, cardiovascular stents and catheters.

**Dr Prashant Girinath, Associate Wilson Sonsini Goodrich & Rosati** **Speaking on 3 March*

Prashant is an associate in the Boston and Washington, D.C., offices of Wilson Sonsini Goodrich & Rosati. Prashant works with clients in various fields, including biologics, chemistry, biotechnology, pharmaceuticals, and clean technology. Over the last few years, he has worked closely with his clients in the small molecules, antibody engineering, biologics, and biosimilars spaces.

**Dr Lou Lieto, Partner Wilson Sonsini Goodrich & Rosati** **Speaking on 12 March*

Lou is a partner in the intellectual property and patent practice at Wilson Sonsini Goodrich & Rosati. Lou focuses on patent prosecution, strategic patent counseling, and IP counseling for M&A and capital markets in a variety of fields, including CRISPR, cell therapy, immunotherapeutics, medical devices, pharmaceuticals, stem cells, biofuels, and transgenic animals.

## Parallel session 2

**Please choose C or D**

# C – Patenting computer-implemented healthcare inventions in AI and machine learning

### 11:50 – 12:25

### Dr Andrew McGettrick

AI has become so important that the EPO has updated its Guidelines for Examination to focus on the patentability of innovations having an AI aspect to them. The routine implementation of AI or machine learning to solve a problem foreseeably solvable by AI is unlikely to be sufficient to obtain patent protection. It is possible, however, to patent AI inventions by carefully describing how the AI is used to operate a technical system or control a technical process e.g. the use of AI to identify irregular heartbeats in ECG data.

We will use examples, such as computer-implemented therapy, AI analysis of medical data, medical devices for implantation, computer control of surgical tools and self-learning medical devices, to explore:

- how to approach patent protecting AI inventions in the medical field;
- how to navigate the exclusions from patentability.

**Dr Andrew McGettrick, Patent Director**

Andrew is an electronics specialist and has a particular interest in technologies related to digital healthcare. Andrew qualified as a European Patent Attorney in 2011 and as a UK Patent Attorney in 2012 and has expertise related to electronics, photonics, computer software, wireless telecoms and medical devices. Andrew has drafted and prosecuted patent applications for a wide range of clients, including multinational companies, universities and high tech spin out companies, in Europe and internationally. With recent growing interest in AI related technologies, Andrew has kept pace with corresponding developments in patent practice, particularly before the EPO.

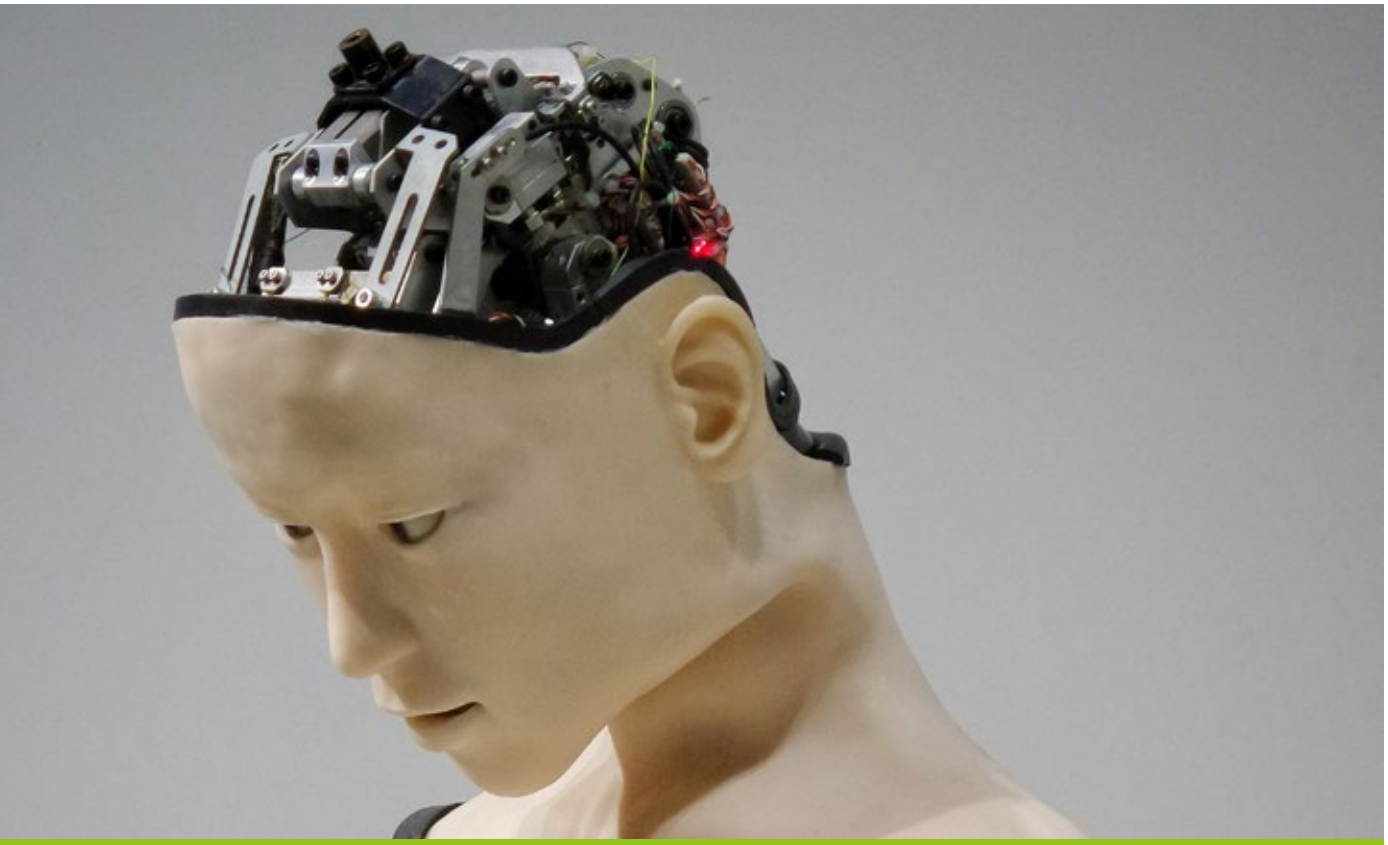

Image: Franck V

# Parallel session 2

**Please choose C or D**

# D – Opposition case studies

## 11:50 – 12:25
## Mike Nelson & Leythem Wall

Europe is one of the largest and most competitive regions for the healthcare industry. Patent protection is therefore key to succeeding in the marketplace. For third parties the EPO opposition procedure represents one of the most powerful tools for securing freedom-to-operate. For a limited period after grant, the validity of a European patent can be centrally challenged. Typically, 3 to 5% of patents granted by the EPO are opposed every year. The popularity of the proceeding is in part supported by the success rate. On average approximately 30% of patents are revoked and 40% of the patents challenged result in some reduction of claim scope. Opposition therefore represents a much more cost effective and efficient tool for invalidating patents in Europe, compared to national procedures or litigation on a country-by-country basis in Europe. These are more expensive and time consuming, and can result in varying outcomes in different jurisdictions. For patent owners the stakes are very high with the potential for loss of pan-European patent protection. It is essential that patent owners facing an opposition prepare well and develop a robust defence strategy.

In this session we will run through successful opposition case studies from the perspectives of both challenger and patentee. Following changes in the opposition timeline and, most recently, changes to the rules of the EPO Boards of Appeal, we shall also outline key strategies for taking advantage of these procedures to secure the best possible outcome, whether opposing or defending European patents.

Image: Jes Hoots

**Mike Nelson, Partner**

Mike is a European Patent Attorney and leads HGF's office in Basel, Switzerland. Mike specialises in the pharmaceutical field, particularly in the areas of small molecules, drug delivery and formulation technologies, methods of treatment and dosage regimens. He has considerable experience in patent drafting and prosecution, IP due diligence evaluations, patent term extensions and SPCs, regulatory data exclusivity, freedom-to-operate and validity opinions, global patent portfolio management and strategy, and EPO oppositions and appeals.

**Leythem Wall, Partner**

Leythem is a European and UK Patent Attorney based in HGF's office in The Hague, Netherlands. He specialises in the medical sectors, chemicals, consumer products, energy and material, and has extensive experience in oppositions and appeals, regularly representing clients in Oral Proceedings before the EPO. Leythem has had many successes in high value and business critical oppositions, both defensive and offensive, including multi-party proceedings and coordination with disputes in jurisdictions such as UK, Germany, US, China, Japan, Korea, and India.

# Lab bench to acquisition and a spin-out company: Follow the client journey

## 12:25 – 12:55
## Dr Andrew Wells & Guest Speaker from Ziylo Limited

Dr Andy Chapman will talk through the story behind one of the major spin-out exits of 2018. Ziylo limited was a spin-out from Bristol University that was acquired by Novo Nordisk in a deal that could ultimately exceed US$800m. The deal also resulted in the formation of a new spin-out company – Carbometrics Limited.

Dr Andrew Wells will outline the important IP support and guidance that HGF provided to help Ziylo along the way.

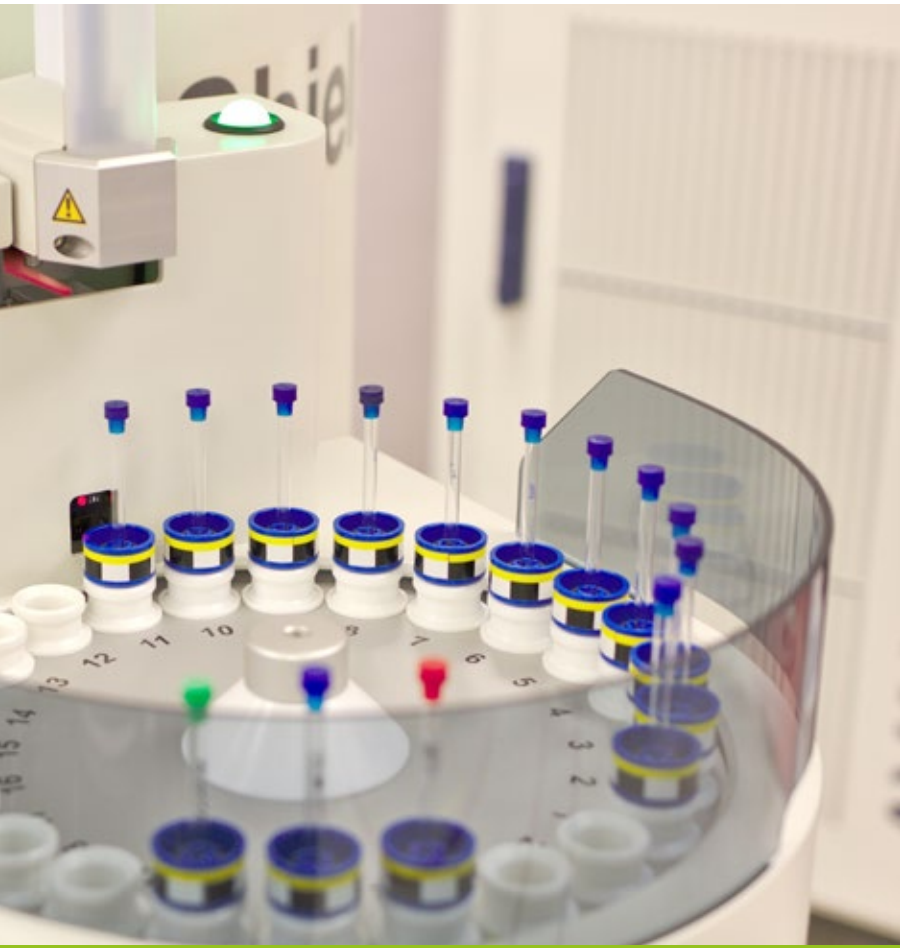

Image: Unsplash

**Dr Andrew Wells, Partner**

Andrew is the Head of HGF's Chemistry & Pharmaceutical Groups and runs the HGF office in Manchester. Andrew acts for a wide range of clients including universities, research organisations, spin-outs, SMEs, venture capital firms and large pharmaceutical / chemical companies. He specialises in the provision of commercially-focussed patent strategy advice, patent procurement & portfolio management, IP due diligence, SPCs / patent term extensions, regulatory data exclusivity, freedom-to-operate and validity assessments and handling EPO oppositions and appeals. Andrew has particular expertise in IP due diligence and regularly conducts IP due diligence evaluations for a number of his pharmaceutical and venture capital clients.

**Dr Andy Chapman, CSO of Ziylo Limited / CEO of Carbometrics Limited**

Andy graduated from the University of Bristol in 2012 with a PhD that focused on organometallic chemistry and catalysis. This area of chemistry continued to be his focus during a post-doctoral project under Professor Piet van Leeuwen at ICIQ in Spain. After his post-doctoral position, he joined a small start-up company based in London, where he put his organometallic training to practice working on a new catalyst technology for turning $CO_2$ into plastic. He then moved into academia and became a Senior Lecturer at Kingston University in London. In 2017, Andy took the decision to move back into industry, firstly as CSO at Ziylo, then later as a co-founder and CSO of Carbometrics.

# I've got the brains. You've got the looks. Let's make lots of money... but how much?

## 12:55 – 13:30

## Janet Knowles

How do you start to value your IP? The science is done. The IP is registered. You've a deal to do – but what's it worth?

Janet will look at how far IP valuation is an art or a science. She will suggest how to place yourself in the best position to get a good deal. You won't become specialists in the mathematical calculation of value. You will, however, find out the key qualitative factors and valuation models used to value IP, as well as how you can use them to your advantage in negotiations.

**Janet Knowles, Partner**

Janet has over 25 years' experience of dealing with IP and was formerly International Head of Life Sciences for a major international legal firm. She specialises in transactional IP and life sciences product life cycle transactions. Her work ranges from early R&D collaborations and clinical trials to IP licensing and commercial manufacturing and supply agreements – much is international in nature. She has worked for many years in the healthcare sector from advising multinational pharmaceutical / life sciences / medical devices companies to universities and other not-for-profit organisations. Janet is a Registered Technology Transfer Professional and recommended by the international guide IAM 1000 – Guide to the World's Patent Practitioners (2019) and an MIP IP Star (2019/20). She is a tutor on the Pharmaceutical Licensing Group's MSc Pharmaceutical Business Development.

Image: Colin Watts

# About HGF

## HGF Ltd is one of Europe's largest firms of Intellectual Property Specialists with 22 offices throughout the United Kingdom, Ireland, The Netherlands, Germany, Switzerland and Austria. The firm's patent attorneys, trade mark attorneys and IP solicitors provide an integrated IP solution for clients.

HGF offers the full range of services expected from leading patent and trade mark attorneys and solicitors, but it is our dynamic approach to oppositions and appeals, strategic portfolio development, IP litigation, licensing and due diligence that distinguishes HGF within the IP marketplace.

Our specialist teams have expertise and experience covering a range of technical fields including Chemistry, Engineering, Electronics and Life Sciences.

HGF's Healthcare team provides professional expertise and commercially focused advice to business leaders and decision makers in the healthcare fields of life sciences, pharmaceuticals and medical devices. HGF has in-depth knowledge of the sector, and the experience to provide you with high quality and commercially focused advice in relation to the protection of your IP rights. The team offers the full range of IP services including:

- IP strategy and advice;
- Patent and trade mark procurement;
- IP portfolio management;
- Freedom-to-operate advice and opinions;
- IP due diligence assessments and opinions;
- Supplementary protection certificates (SPC's) and data exclusivity advice;
- IP licences and agreements;
- IP disputes management and litigation

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# Global expertise from a European base

UK Ireland The Netherlands Germany Switzerland Austria

HGF offer a fully integrated IP solution, bringing together trade mark attorneys, patent attorneys and IP solicitors across 22 offices throughout Europe.

FT FINANCIAL TIMES statista Europe's Leading Patent Law Firms 2019

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HGF is dedicated to providing a comprehensive service both across the UK and internationally. If you would like to contact us and find out how we can work with your business, please email us at enquiries@hgf.com to be referred to the right person for you.

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