HGF Intellectual Property Specialists

IP in Healthcare Conference 2019

Thursday 14th March

Manchester
Alderley Park

Tuesday 19th March

London
Royal College of General Practitioners

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Programme

09:00 – 09:30	Registration and breakfast
09:30 – 09:35	Welcome *Janet Knowles*
09:35 – 10:15	Fighting the fakes: Counterfeit pharmaceuticals and medical devices *Martyn Fish*
10:15 – 10:55	The importance of integrating regulatory and patent exclusivity when approaching the U.S. pharmaceutical market *Nicole Stakleff and Ray Miller*
10:55 – 11:15	Break
11:15 – 11:55	Parallel session 1 – Please choose to attend A or B A – EP and US perspectives on patents for new medical uses *Mike Nelson and Leena Contarino* B – mHealth and protecting your IP assets *Chris Cottingham and Lauren Somers*
11:55 – 12:35	Parallel session 2 – Please choose to attend C or D C – Update on the CRISPR IP saga and lessons to be learnt *Dr Claire Irvine and Cath Coombes* D – Impact of Artificial Intelligence approaches on patent strategy in the healthcare area *Dr Bal Matharu and Matt Cassie*
12:35 – 12:50	Brexit bullets *Janet Knowles*
12:50 – 13:30	Navigating patent proceedings in Europe and Asia *Rachel Fetches, Joanna Deas and Dr Gareth Probert*
13:30 – 14:30	Lunch and Close

HGF Intellectual Property Specialists

Welcome

HGF's fifth 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 this pack if you would like to leave any comments.

Fighting the fakes: Counterfeit pharmaceuticals and medical devices

09:35 – 10:15
Martyn Fish

Counterfeit pharmaceuticals have been an issue for several years. Alongside this we are now seeing a large increase in fake medical devices. The statistics are shocking. It is estimated that 8% of devices and 30% of medicines on the market are fake. It is an issue that no healthcare company with a product on the market can afford not to consider. Not only is it a serious risk to public safety but it is a reputational risk that all companies in this industry need to manage.

Martyn will explain the risks posed by counterfeits in this industry, the extent of the problem, how the risks can be mitigated and proactive steps that can be taken.

Martyn Fish, Partner and Head of Law

Martyn advises healthcare companies on IP issues with a focus on patent, trade mark and design disputes. In recent years, he has acted for clients in major patent litigation in the pharmaceutical and medical device fields. He regularly advises clients on strategies for enforcing their IP rights including anti-counterfeit issues.

Image: Rawpixel

The importance of integrating regulatory and patent exclusivity when approaching the U.S. pharmaceutical market

10:15 – 10:55
Nicole Stakleff and Ray Miller

The United States represents about one-half of the world's pharmaceutical market by sales and about 25% of these sales are by generics. The United States uses a series of incentives to reward and encourage research and development while also stimulating a robust generic market to drive down the cost of important therapies. This balancing act is accomplished in part by the crucial interplay of patent monopolies granted by the USPTO and data and market exclusivity granted by the FDA.

Understanding the interplay and independence of these "exclusivities" will be crucial to the development of any innovator that views the Unites States as a viable market. Ray and Nicole bring decades of experience in guiding the development of exclusivity strategies that have permitted companies to advance their drug in the clinic and ultimately obtain approval and access to the U.S. markets. Ray and Nicole will discuss a wide range of topics, including ways to maximise patent term for new chemical entities and ways to strategize and protect pharmaceuticals that are being revived or repurposed after initial clinical development or approval.

10:55 – 11:15 – Break

Pepper Hamilton LLP
Attorneys at Law

Nicole Stakleff, Partner with Pepper Hamilton LLP

Nicole is a member of the Health Sciences Department and a member of the firm's Executive Committee. A registered patent attorney since 2002, she concentrates her practice in IP law, including developing product exclusivity strategies, strategic patent prosecution and counselling, and due diligence and transactional support in the pharmaceutical, biologic, nutraceutical, cosmeceutical, medical device, and other health and life sciences fields. She conducts IP due diligence and counsels on transaction documents involving IP, such as license agreements and collaboration agreements. She also advises clients on the interplay of FDA and patent law on pharmaceutical, nutraceutical, dietary health supplement and medical device products.

Ray Miller, Partner with Pepper Hamilton LLP

Raymond A. Miller is a partner and member of the Leadership Team of the Health Sciences Department of Pepper Hamilton LLP. Ray has spent his career identifying, protecting, securing and maximizing intellectual property in the biotechnology and life science areas. He is a Chambers USA recognized practitioner; recommended in IAM Patent 1000, a guide to the world's leading patent professionals; named an Acritas Star 2018; and is listed in The Best Lawyers in America.

Ray's clients range from academic institutions to world-class medical and research facilities. His clients include physicians, venture capital groups, startup biotechnology companies and Fortune 500 companies. Ray is particularly experienced in the areas of chemistry, medicinal chemistry, genetics, pharmaceuticals, nutraceuticals, proteomics, nanotechnology, tissue engineering, surface chemistry and cosmetics.

Parallel session 1

Please choose A or B

A – EP and US perspectives on patents for new medical uses

11:15 – 11:55
Mike Nelson and Leena Contarino

Patents covering methods of treatment can be extremely important for, for example, re-profiled drugs when often the original compound patent has expired. In such scenarios the use patent could be the only IP protecting the product and the investment in clinical trials necessary to bring the drug to market. However, securing a patent that will withstand validity attacks and which can be enforced against infringers presents challenges. Successfully protecting these inventions requires consideration of the requirements in all of the major territories where the product will be commercialised.

We will provide practical advice for securing and enforcing method of treatment patents and will discuss the sometimes differing requirements between the USA and Europe, including:

- How much data is needed to support a method of treatment patent?
  - Sufficiency/plausibility in Europe vs. written description/enablement/ possession in the USA
- When should the patent application be filed?
  - Novelty and inherency issues in Europe and the USA
- Enforcing the patent
  - The claim language really matters!

Image: Marcelo Leal

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.

Leena Contarino, Partner

Leena advises clients in protecting inventions mainly in the areas of biologics, including, DNA, RNA, peptides, and proteins, such as antibodies and enzymes. She also has considerable experience in diagnostics utilizing biomolecules, and in inventions related to cells, including microbes. Leena's expertise covers preparing and prosecuting patent applications, strategic patent portfolio review and management, due diligence, opinions regarding freedom-to-operate, non-infringement, and inventorship.

Prior to joining HGF Leena served as a VP of Intellectual Property at a global pharmaceutical company headquartered in Basel. Before repatriating to Europe, she practiced patent law for almost two decades at a major law firm in the US, where she advised clients at university technology transfer offices, start-ups and large multinational companies.

Parallel session 1

Please choose A or B

B – mHealth and protecting your IP assets

11:15 – 11:55
Chris Cottingham and Lauren Somers

The recent revolution of mobile health has sparked a wave of consumer-focused mobile applications in the healthcare sector, including apps to track health and fitness and personal medicine scheduling assistants.

Whilst the functionality of these apps may not always be protectable, their look and branding can be protected by design and trade mark rights. This session will provide an overview of suitable IP rights for protecting your mHealth apps, as well as consider strategies for best protection, such as how to protect the Graphical User Interface (GUI) and icons of the app and trade mark filing programs to ensure a clear and consistent brand message.

With consumers becoming paradoxically empowered yet distrustful, seeking more information and improved outcomes in the healthcare space, creating and protecting a strong and defensively distinctive image and brand can be key to the success of such an app.

Image: Andres Urena

Chris Cottingham, Patent Attorney

Chris is currently involved in helping clients protect innovations in mobile applications, personal healthcare devices, online gaming, robotic devices, image processing and loudspeakers both through extensive experience of drafting and prosecuting patent applications, as well as through use of registered designs and other forms of intellectual assets. Chris has a real passion for helping companies protect and grow their market position by developing and realising the value in their innovations.

Lauren Somers, Senior Trade Mark Attorney

Lauren is a Chartered Trade Mark Attorney and has experience in all areas of trade mark, design and copyright law, including IP audits, pre-filing searches, filing and prosecution strategies, the enforcement of trade mark, design and copyright rights and the cost-effective maintenance of IP portfolios. She has worked with large multinationals through to small business start-ups and university spin offs in the fields of medical devices, health related software and clinical services.

Parallel session 2

Please choose C or D

C – Update on the CRISPR IP saga and lessons to be learnt

11:55 – 12:35

Dr Claire Irvine and Cath Coombes

This session will provide an overview of the current IP situation regarding the CRISPR gene-editing technology in Europe and the US, discussion of considerations in relation to freedom-to-operate for use of the technology and an update on the lessons to be learnt from the IP issues which have inflicted major costs on those involved in the IP saga.

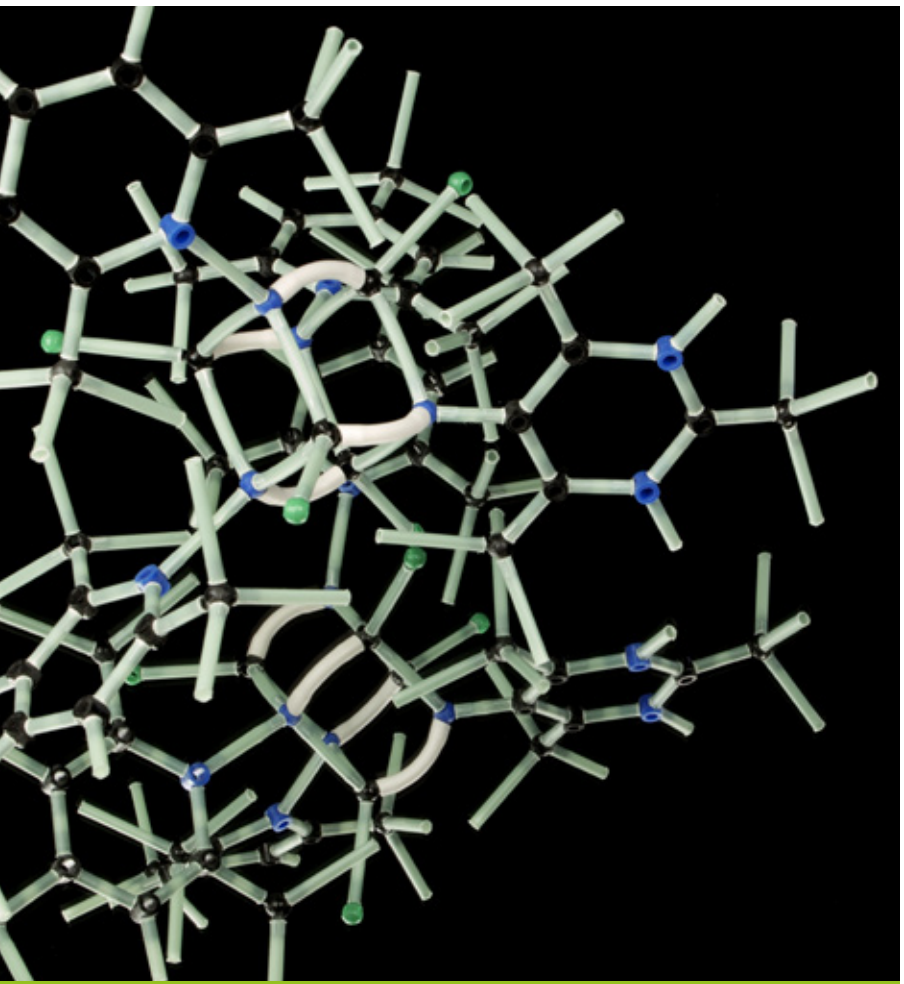

Image: Holger Link

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.

Cath Coombes, Patent Director

Cath's portfolio encompasses a wide range of biological subject matter including: biotechnology, life sciences, regenerative medicine, medical devices, molecular biology, food technology, enzymology, diagnostics & therapeutics, immunology, plant sciences, stem cells and biopharmaceuticals. She has particular experience in CRISPR technology and has published several articles on CRISPR IP.

Parallel session 2

Please choose C or D

D – Impact of Artificial Intelligence approaches on patent strategy in the healthcare area

11:55 – 12:35

Dr Bal Matharu and Matt Cassie

Artificial Intelligence approaches are playing an increasingly important role in the healthcare area with new applications in drug discovery and development, clinical trial design, diagnostics and medical devices.

Whilst such approaches are already offering significant benefits, patent systems are having to develop to adequately deal with challenges created by such technologies in relation to patentability, infringement, inventorship and ownership.

This session will explore some of the issues that can impact patent strategy where Artificial Intelligence approaches are involved.

Image: Franck V

Dr Balvinder Matharu, Partner

Bal specialises in the pharmaceutical field and has considerable experience in securing patent rights, conducting IP due diligence and providing advice in relation to freedom to operate issues. Bal also has extensive experience of co-ordinating multi-jurisdictional patent litigation across Europe. Bal has a strong technical background has spent 6 years working as a senior product development scientist within the pharmaceutical industry. Bal has also spent over 9 years working within the in-house patent department of a major global pharmaceutical company.

Matt Cassie, Partner

Matt specialises in software and computer implemented inventions and entered the IP profession in 2005 following three years in industry as a research engineer in which he developed artificial intelligence software solutions for defence and robotics applications. Matt is now a partner in our electronics team where he works to secure, defend and leverage IP rights for technology businesses in Europe and worldwide. Matt understands how innovative businesses can use IP as an asset to facilitate their growth and has a passion for helping businesses utilise the IP system effectively to be competitive in increasingly globalised market.

Navigating patent proceedings in Europe and Asia

12:50 – 13:30

Rachel Fetches, Joanna Deas and Dr Gareth Probert

For healthcare companies, a strategic understanding of the strengths and weaknesses of both your own and competitors' portfolios is essential. We will give you a practical guide to the key points to consider for consolidating your patent position, whether enforcing or defending your own patents or challenging another party's portfolio.

Europe is one of the biggest markets for healthcare companies. We will consider the different ways in which patent rights can be challenged in the key European patent jurisdictions, including the EPO. We will look at the different features of key patent litigation jurisdictions, how they interact with an EPO Opposition and the critical importance of coordinating your offensive and defensive strategies.

In addition, we will also look at Opposition procedures available in Japan and Korea, highlighting the significant differences between Oppositions at the JPO and the KIPO with oppositions elsewhere. Although China no longer has an Opposition system, we will discuss other options available to attack patent applications and the potential impact of the new national IP appeals court for high-tech/patent cases.

Image: Joel Filipe

Rachel Fetches, Partner

Rachel is an Intellectual Property / Patent Litigation Partner at HGF and has worked with clients across a broad range of sectors with a particular focus on the life sciences, pharmaceuticals, healthcare and chemicals industries. Rachel has extensive experience of litigating before the UK Patents Court, High Court and Court of Appeal as well as advising in opposition proceedings before the UKIPO, EPO and OHIM. Rachel regularly advises in relation to complex, pan-European IP litigation strategy. Rachel joined HGF in 2015 after training and working at a leading international IP litigation practice for over 10 years.

Joanna Deas, Patent Director

Joanna is an Opposition and Appeal specialist and is very experienced in representing clients in proceedings at all levels of the European Patent Office. She has achieved many successes in high value and business-critical oppositions, often working in conjunction with parallel national litigation. Joanna organises mock hearings in preparation for significant cases. She focuses on medical technology, pharmaceutical and life sciences cases, and also has considerable experience in the FMCG and food sectors.

Dr Gareth Probert, Partner

Gareth is an Opposition and Appeal specialist and is very experienced in representing clients in proceedings at all levels of the European Patent Office. He has achieved many successes in high value and business-critical oppositions, often working in conjunction with parallel national litigation. Gareth and his team organise mock hearings in preparation for significant cases. He focuses on medical technology, pharmaceutical and life sciences cases.

About HGF

HGF Ltd is one of Europe's largest firms of Intellectual Property Specialists with 17 offices throughout the United Kingdom, Ireland, The Netherlands, Germany and Switzerland. 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 trademark 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 and data exclusivity advice;
- IP licences and agreements;
- IP disputes management and litigation

HGF Intellectual Property Specialists

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With expertise in trade marks, patents and IP law HGF can protect and defend your business, product or service. For further information please contact Marketing on +44(0)113 233 0100 or email marketing@hgf.com

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