

HGF IP in Healthcare Conference 2023

Tuesday 13th June – London, Barber-Surgeons' Hall
Thursday 22nd June – Manchester, Alderley Park



Schedule

TIME	TOPIC	SPEAKERS	PAGE
9:15am	Registration and breakfast		
9:55am	Welcome	Craig Thomson	01
10:00am	Synchronising patent strategy with the commercial needs of your business	Mike Nelson and Dr Claire Irvine	02
10:30am	Bringing your clinical pathway and IP strategies together	Craig Thomson and Dr Nicola Wall	04
11:00am	“The Claim Game” – interactive session on spotting and protecting high value inventions in healthcare	Dr Janine Swarbrick, Kieran Killough and Punita Shah	06
11:40am	Break and refreshments		
12:00pm	Conventional and AI-based research tools: strategies for protecting	Dr Lauris Kemp, Dr Andrew McGettrick and Dr Benjamin Janutta	08
12:30pm	AI generated synthetic data: a challenge to IP strategies, a solution for data protection?	Dr Sofie McPherson and Michelle Davies	10
1:00pm	Strategic considerations in applying CRISPR technology	Dr Claire Irvine	12
1:30pm	Lunch		
2:15pm	Case study – C4X Discovery – IP strategy for successful drug discovery partnering	Dr Nick Ray, Dr Andrew Wells and Dr Nick Howe	14
2:45pm	Strategic patent filing in the post-sunrise era: maximising your IP protection in the Unified Patents Court and beyond	Christie Batty and Dr Jennifer Bailey	16
3:15pm	Closing remarks	Craig Thomson	
3:20pm	Networking and drinks		

Welcome

HGF's ninth annual IP in Healthcare Conference takes as its focus the importance of strategy.

An intellectual property (IP) portfolio largely derives value by having a meaningful relationship to the business, or potential business, it seeks to underpin, and by using it accordingly. Whilst serendipity can play a part, strategy is what ensures the formation of a meaningful relationship and best directs the manner of use.

At its heart an intellectual property right (IPR) strategy aims, by the strategic selection of IPRs, to build an “exclusivity cloud” that defines a space in the market that corresponds to at least the commercial focus of your business and one that is difficult for others to enter. Looking more broadly, an IPR strategy responds to the IPRs and IP strategy of competitors, and does not work in isolation with the wider activities of the business it seeks to support, e.g. funding rounds, licensing strategies, clinical approval strategies, data protection issues, collaborations and product launches.

Knowledge of the relevant industry is crucial if one is to construct a commercially appropriate IPR strategy. This is no less true for the healthcare industry; given funding requirements in order to bring a product to market, the requirement for marketing authorisations and so the extended timelines to market, and the inherent complexities of the technologies in this field.

Our expert panel of HGF attorneys and solicitors, together with industry guest speakers, look forward to sharing a conversation with you around topical issues that direct various considerations when developing commercially relevant IP strategies within the healthcare field.

Speakers



**Mike Nelson –
Partner & Patent Attorney**

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.



**Dr Claire Irvine –
Partner & Patent Attorney**

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 and is a partner of the HGF specialist CRISPR and microbiome IP teams. 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.

**Synchronising patent strategy with
the commercial needs of your business**

Throughout the journey from filing, prosecution and the grant of a patent application, a timeline is created with several significant events that may be of commercial significance to a business. Grant of a patent presents a powerful message to investors and competitors that a product potentially has exclusivity in the market. Patent applications can also be used as commercial tools long before they grant. Favourable search or examination reports may be used internally as one of the factors when judging the relative importance to the business of a patent application, as indicators of patentability to secure funding, in negotiating collaborations, and for inhibiting competitor's aspirations. However, the path from filing a patent application to securing a granted patent comes with spikes in costs for the applicant. Synchronising the events and costs of the patenting process with commercial needs of the business (e.g. good news for investors, or avoiding a clash of increased costs with a period of expected low cash-flow) can be business critical, especially for start-ups in the healthcare sector.

Without strategic considerations of where the significant and financial events occur in the patent timeline there is a risk that the IP strategy will fail to synchronise with the commercial needs of the business. This presentation will consider the tools available to influence the timeline of events during patent prosecution so that they best underpin the business need.





Craig Thomson – Partner & Patent Attorney

Craig is recognised for providing pragmatic, commercially focused advice to clients in the biotechnological, pharmaceutical and MedTech sectors, and leads HGFs microbiome IP team. As well as patent drafting and prosecution, Craig advises on the development of company-wide IP strategies, funding/acquisition due-diligence, and aggressive/defensive strategies in relation to third-party IP. Craig has a proven track record of providing successful outcomes for clients, both in a wide-range of legal proceedings (including opposition, entitlement, and USPTO interviews) and in successful IP-license/assignment deals involving patents that he both drafted and prosecuted to grant.



Dr Nicola Wall – Founder and Chief Executive Officer Afortiori Development

Dr Nicola Wall is the founder and Chief Executive Officer of Afortiori Development founded in 2016 to address the need for improved clinical trial design, planning and management to promote efficient and cost effective clinical trials. She has an exceptional background within the pharmaceutical, medical technology and healthcare sectors with over 20 years of diverse experience. She has managed multiple types of projects across a range of therapeutic areas for a number of large and small clients spanning all areas of clinical development including regulatory, data management, safety, quality and organisational effectiveness. Nicola has also managed global clinical trials in Oncology and Neurology with responsibility for 29 countries across the entire clinical trial process. She excels in strategic planning, process re-engineering, systems implementation and organisational design. She has worked for a number of years as an independent consultant for the UK national health service working on hospital operational planning, business cases and ways to implement new models of care.

Bringing your clinical pathway and IP strategies together

Bringing a healthcare product through development to market requires the application of a diverse range of specialist skills. Two of these critical specialist areas include the development of a commercially relevant Intellectual Property Rights (IPR) strategy and the development of a Clinical Pathway Strategy. This is a well-worn path for large corporates, who for the most part will have in-house teams focused on each of these areas and extensive experience of working together to ensure there is a coordinated approach. SMEs, however, do not have the advantage of having such experienced in-house departments, or indeed experience of project managing these two vital tasks. External service providers such as HGF and Afortiori are therefore normally engaged to assist at designated time points. In a time-poor environment where it is normal that one person does the job of many, it is difficult for leaders of SMEs to juggle the job of directing activities with respect to IP and clinical pathway strategies. Often the coping strategy is to put the handling of these specialist tasks into silos – there is usually no consideration of the intersection of these two vital strategies and how they impact each other. As large healthcare developers know, there are key advantages in coordination of these specialist areas, which is entirely missed by a siloed approach.

During this discussion, we will examine how and when to most efficiently co-ordinate the development of these strategies and tasks. We will also look at when to involve the related service providers and the advantages derived from doing so.



Speakers



Dr Janine Swarbrick – Patent Director

Janine is a Chartered and European Patent Attorney with a PhD in Nanoscience. She has extensive experience of helping clients, from start-ups to multinational companies, to protect inventions relating to innovations in electronics and software, including medical devices (including mobile devices, wearables, and x-ray imaging technology); applications of software and AI including in data analysis, speech recognition, VR and personalised healthcare; telecommunications, user interfaces, nanotechnology and other areas of physics. She regularly drafts and prosecutes patent applications at the forefront of modern and rapidly developing technologies, including AI, cybersecurity, and computer implemented inventions, where both the science and law are continuously being updated and developed. She is co-lead of the HGF MedTech Electronics technology group, and a member of the HGF DEI Focus Group.



Kieran Killough – Partner & Patent Attorney

Kieran has over 16 years' experience advising clients on IP matters relating to physics and engineering technologies including medical devices, detectors, spectroscopy and microscopy. His practice focuses on the strategic identification and procurement of IP rights, and he routinely works with clients to maximise the value that may be extracted from R&D work undertaken. He has extensive experience in drafting and prosecuting patent applications and is skilled at formulating innovative strategies that strike an effective balance between strategically-relevant protection of commercially valuable concepts and clients' budgets. Kieran represents a wide range of clients from start-ups to universities and international organisations. He is experienced in handling large global patent portfolios and works with associates across the world to provide his clients with proactive, commercially-focused advice, ensuring that the IP strategy complements and facilitates his clients' objectives.



Punita Shah – Patent Director

Punita's expertise lies in the area of biotechnology, with a specific focus on the technical fields of Agbio, diagnostics including point of care lateral flow tests, personalized medicine, biologics and gene therapy. Punita has over 20 years' experience in advising on IP matters to a range of clients including multinational corporations, universities. Her practice includes routinely managing large global patent portfolios, as well as conducting due diligence to support corporate acquisition and investment, conducting freedom to operate analysis, and advising her clients on third party rights and infringement. Punita aims to provide practical and commercially focussed advice to assist her clients, to assist them in building a robust patent strategy. Punita has defended her clients patent rights and commercial position in leading opposition and appeal proceedings before the EPO.

“The Claim Game” – interactive session on spotting and protecting high value inventions in healthcare

Modern healthcare businesses often operate at the intersection of several diverse fields of technology. From electronic medical records to wearable devices, personalised pharmaceuticals to artificial intelligence, modern healthcare businesses operate across traditionally diverse fields to deliver the best for patient care and business success. The ability to recognise and use synergies between different technologies can be a key driver of success, allowing healthcare businesses to provide innovative solutions. An intelligent IP strategy can help to provide strong, focussed, multifaceted protection, and increase the exclusivity and power of a business's innovation.

We invite you to play “The Claim Game” to see if you can identify a winning strategy to protect your healthcare innovations.

Aimed at everyone – from inventors to managers and in-house IP advisers – this interactive session takes a cross-disciplinary look at spotting inventions in a healthcare business, and determining how best to protect them, to align with your IP strategy and provide the best scope of protection for the business.

The Game

The cross-disciplinary HGF panel will introduce their technology specialisms, and present a healthcare business scenario to you.

Your task is to identify where there is patentable innovation, and working to a budget, determine how best to protect that innovation. You will be able to vote for the strategy you consider gives the best protection and most positive impact for the business.

The panel will conclude by presenting a successful strategy for patenting – will you match the strategy and win “The Claim Game”?



Speakers



Dr Lauris Kemp
– Partner & Patent Attorney

Lauris has a strong life sciences background with a first degree in Immunology and Biochemistry; and a PhD and 6 years post-doctoral experience covering cell expression systems, protein purification, mass spectrometry, protein crystallography and bioinformatics. Her patent work reflects this broad base and Lauris handles increasing numbers of bioinformatics applications, securing commercially useful claims for clients. She has drafted and prosecuted bioinformatics applications in metagenomic and microbiome sequencing, in silico drug testing and AI cancer diagnostics. She has also successfully defended bioinformatics patents at EPO opposition proceedings.



Dr Andrew McGettrick
– Partner & Patent Attorney

Andrew is an electronics specialist and has a particular interest in digital healthcare, as well as a growing patent practice in technologies relating to artificial intelligence (AI). Andrew qualified as a European Patent Attorney in 2011 and as a UK Patent Attorney in 2012. He has extensive experience of drafting patent applications, and directing patent prosecution, for a wide range of clients including multinational companies, universities and high-tech SMEs, in Europe and internationally. In recent years, Andrew has also gained significant experience in European patent oppositions, and applies knowledge of potential post-grant vulnerabilities obtained through his opposition practice to help his clients obtain higher quality patents.



Dr Benjamin Janutta – Senior Patent Attorney

Benjamin works with a range of clients from SMEs to large-scale enterprises. Besides drafting of patent applications and prosecution, Benjamin offers guidance to his clients in terms of patent portfolio management.

Benjamin has significant expertise in computer implemented invention, especially in the field of AI-invention. Furthermore, Benjamin has experience in semiconductor technologies and display technologies.

Benjamin also advises his clients in the fields of trade mark and design law. Benjamin is a Patentanwalt (German Patent Attorney), European Patent Attorney as well as European Trade Mark and Design Attorney.

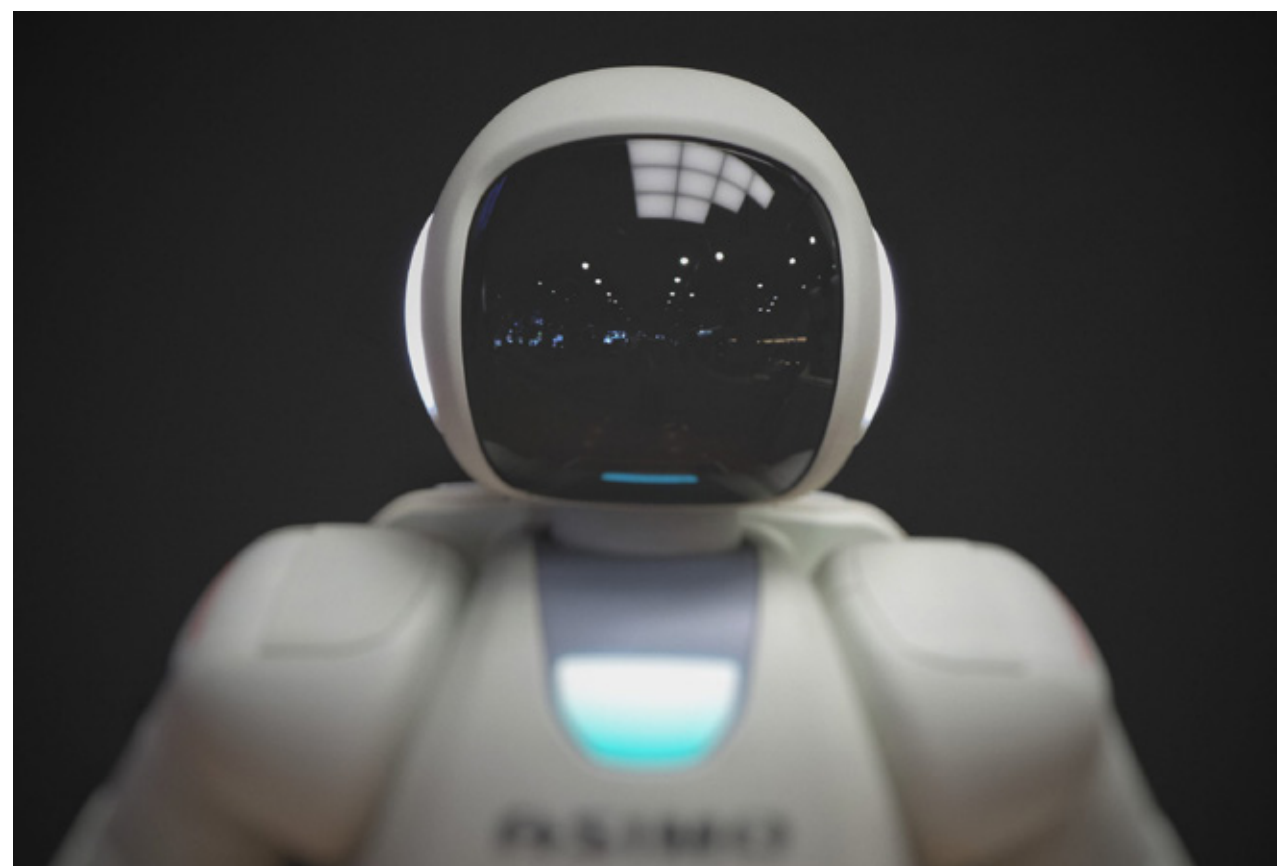
Conventional and AI-based research tools: strategies for protecting

The 3D structure of a protein is crucial to the biological function of the protein. Predicting this 3D structure and therefore how the protein works is not easily done.

AlphaFold® is the game-changing AI software from DeepMind which goes some way to solving this problem. Instead of solving a protein structure experimentally with crystallography or other similar wet lab techniques, AlphaFold® uses in silico prediction of the structure. It is fundamentally a research tool which is already being applied as a starting point in many streams of research, such as drug discovery.

However, because AlphaFold® is not a traditional lab bench research tool (like PCR or phage display for example) but instead a bioinformatics one, there are different considerations to think about for patent protection.

Using the example of AlphaFold® our panel, made up of members from our bioinformatics team, will discuss not only tips for the protection and commercialisation of research tools in general but also IP strategies for protecting bioinformatics and in particular AI inventions based on their diverse experience in areas including bioinformatics research tools, AI data analysis, AI image processing and AI-based control of lab equipment.



Speakers



Dr Sofie McPherson – Patent Director

Sofie is a Chartered and European Patent Attorney with a PhD in Biomaterials. Sofie has worked in a wide variety of technologies including medical devices, Internet of Things, software for medical applications and security related inventions. Sofie also has great experience in telecoms and standard essential patents from having worked in-house at one of the leading telecoms companies. Sofie draws upon both her highly relevant academic background and professional patents expertise to assist clients in the healthcare industry applying electronic inventions for medical applications. Sofie is a Chartered UK and European Patent Attorney and her work includes providing strategic advice on how to protect inventions and to deliver solutions that are commercially focused and relevant to the client. She easily adapts to her clients' ways of working and takes a proactive role to support their needs.



Michelle Davies – Partner

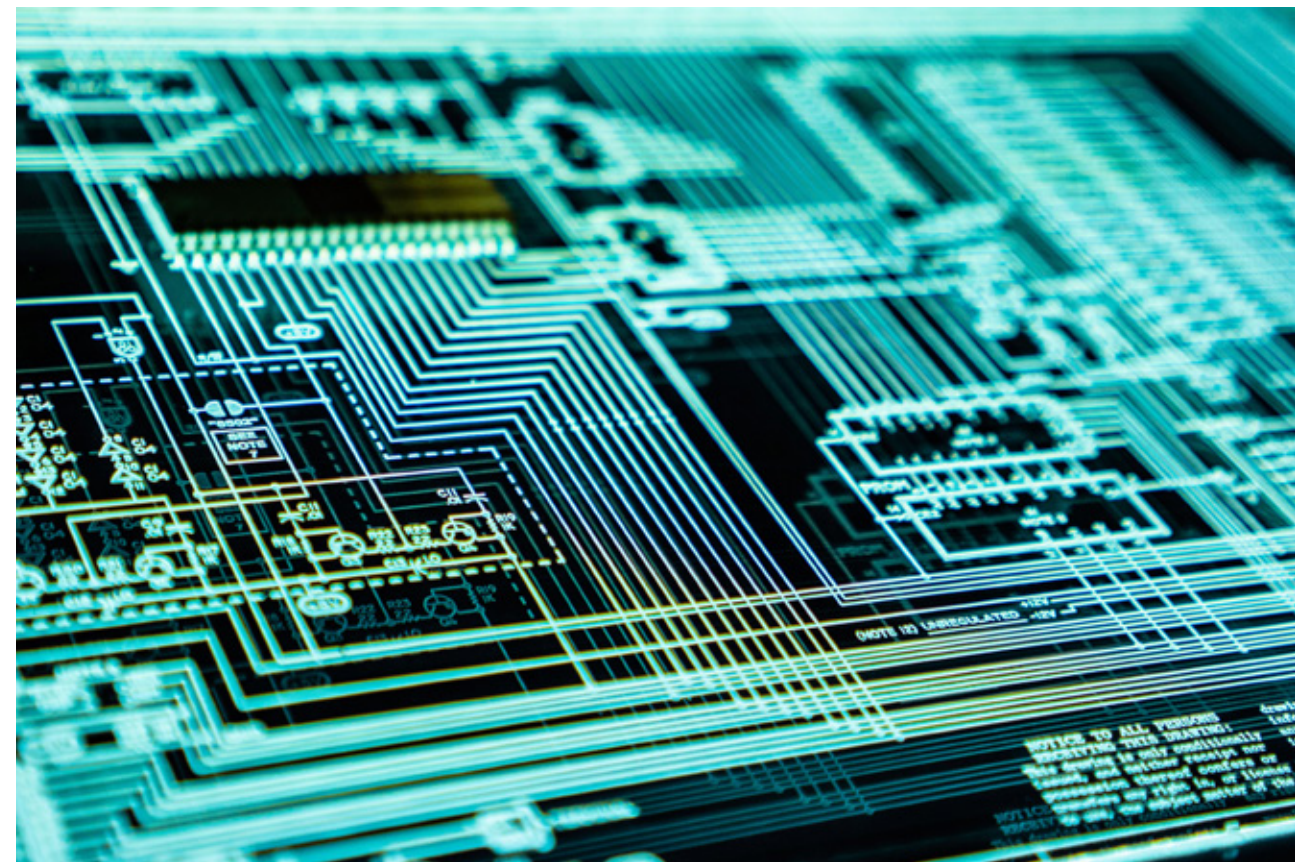
Michelle is a highly experienced transactional IP specialist. Michelle provides strategic and transactional IP advice to clients in a wide range of sectors and has specific expertise within the pharmaceutical and life sciences sector having worked 12 years with AstraZeneca and with a BSc in Pharmacology & Physiology. Michelle is experienced in the drafting and negotiation of a whole range of agreements including licensing, co-development, clinical, manufacture, services and supply contracts and has provided IP advice on a number of major corporate licensing transactions, acquisitions and business sales and works regularly with many educational institutions and their spin-out companies. Michelle regularly presents on a broad range of IP and commercial topics including licensing, strategic IP protection and GDPR. Michelle sits on a University Ethics Committee for the review of life sciences projects and is a member of the Pharmaceutical Licensing Group.

AI generated synthetic data: a challenge to IP strategies, a solution for data protection?

The use of clinical data for research, development and analysis has become increasingly important in modern healthcare. However, the use of clinical data is often hampered by legal concerns including those relating to data protection, particularly in light of regulations such as GDPR, DVG and HIPAA. These regulations impose strict rules on the collection, storage, and use of personal data, including clinical data.

One potential solution to this challenge is the use of synthetic data. Synthetic data is generated by using algorithms to create data that mimics real data, but does not contain any personally identifiable information. This approach offers the potential for researchers to analyse and experiment with data with a reduced risk of compromising patient privacy.

In this session we will explore the advantages and challenges of using synthetic data in healthcare innovations. Whilst the use of synthetic data promises to advance medical research and improve patient outcome, emerging technologies such as this often challenge conventional IP and related legal strategies. We will consider how effective the use of synthetic data might be to simplify the issues surrounding data protection, as well as how such data may affect IP protection strategies.





Dr Claire Irvine – Partner & Patent Attorney

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 and is a partner of the HGF specialist CRISPR and microbiome IP teams. 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.

Strategic considerations in applying CRISPR technology

It is now over 10 years since the Science publication of Jinek et al. showed for the first time that targeted DNA cleavage can be achieved *in vitro* with a bacterial Cas9 enzyme and single guide RNA yet the patenting situation applicable to the use of CRISPR- Cas systems still remains unclear; the on-going saga to determine who owns the foundational IP is unlikely to be resolved soon, either in Europe or the US. This lack of clarity means that companies wishing to exploit CRISPR technology do not have a clear path to establishing freedom to operate; who do they license from? This presentation by Dr Claire Irvine will review the options for navigating this IP confusion and how choice of action on the part of innovators wishing to exploit CRISPR technology is dictated by commercial factors ranging from field of use to risk perception, both internally and externally, for a business.

Claire is a key member of HGF's CRISPR team involved both in key battles in the CRISPR field and prosecuting patent applications underpinning various advances in the use of CRISPR-Cas technology including diagnostic and clinical applications. This background means that Claire is equally often asked questions by those in the commercial world needing to consider legal implications of adopting such technology-questions which raise very different but important strategic considerations. It is such questions that this presentation will aim to address.



Notes

Speakers



Dr Nick Ray – Chief Scientific Officer C4X Discovery

Nick is a medicinal chemist by training and joined C4X Discovery in 2016. Nick has more than 30 years' experience leading key programmes at large multi-national companies including Rhône-Poulenc, Celltech and Argenta/Charles River, in the therapeutic areas of oncology, respiratory diseases, inflammation, CNS, pain and metabolic diseases. To date, eight of these programmes have progressed into the clinic. As head of the chemistry department at Charles River's Harlow U.K. site, Nick was responsible for more than 70 chemists, fostering both the importance of strong medicinal and synthetic chemistry skills and championing professional development for his team, winning the Royal Society of Chemistry Retrosynthesis competition in 2015. He is a named inventor on over 75 patents and patent applications and has published 21 papers and presentation abstracts.

Nick oversees the entire C4XD Drug Discovery portfolio from target selection through to pre-clinical candidate generation and partnering alongside Dr. Clare Murray (SVP Drug Discovery at C4X Discovery). Nick also leads the medicinal chemistry, structural analysis and computational chemistry/cheminformatics teams at C4X Discovery and, together with the C4X Discovery CTO, Dr Charles Blundell, he is leading the continued development of their conformational analysis technology, 4Sight.



Dr Andrew Wells – Partner & Patent Attorney

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.



Nick Howe – Senior Patent Attorney

Nick works with a wide range of clients in the healthcare sector, spanning universities, SMEs and large pharmaceutical companies. He helps his clients with all patent aspects, including filing strategies, patent drafting and prosecution, patentability searches, freedom-to-operate analyses and due diligence support. Nick provides practical and client-focused advice borne from a wealth of experience working in-house with a major pharmaceutical company, both as a research scientist and a patent attorney.

2:15pm

Case study – C4X Discovery – IP strategy for successful Drug Discovery partnering

Dr Nick Ray, Chief Scientific Officer at C4X Discovery, will provide an overview of C4X Discovery's evolution from a small University of Manchester spin-out company to a highly successful Drug Discovery company with multiple pharmaceutical and life sciences collaborations, including out-licensing deals with Indivior, Sanofi and AstraZeneca. He will outline C4X's approach to drug development and how they have achieved success with their strategy of pursuing early-stage licensing deals. Dr Andrew Wells and Dr Nick Howe will discuss how HGF have provided a wide range of IP support to help C4X realise its commercial objectives.





**Christie Batty –
IP Solicitor**

Christie has expertise in both complex multi-jurisdictional litigation and in a broad range of licensing agreements.

Christie advises clients in relation to each of the core IP disciplines and has advised clients in enforcement actions issued in the IPEC, High Court and Court of Appeal. She also has experience of settling contentious, multifaceted disputes on favourable commercial terms for her clients.

Christie’s experience includes a six-month secondment to an international credit card company, where she worked on a range of commercial agreements.



**Dr Jennifer Bailey –
Partner & Patent Attorney**

With an academic background in both chemistry and molecular biology, Jennifer’s technical expertise spans a wide range of sectors including life sciences, chemistry, materials and food science. From her PhD days studying secondary metabolite biosynthesis in bacteria, Jennifer has a keen interest in microbiology, and has handled inventions relating to microbial cell culture, recombinant protein expression, antimicrobials, plasmids, bacteriophage, CRISPR technology, biomarkers and diagnostic assays. With her chemistry hat on, Jennifer has represented clients in fields ranging from nucleic acid synthesis to foundry, confectionery to magnetic compositions, and pharmaceuticals to wound care.

Jennifer is experienced in invention capture and filing strategy, global patent prosecution, managing worldwide portfolios, and advising on freedom-to-operate. Jennifer has also represented clients in numerous EPO Opposition and Appeal proceedings, particularly in the food and drink sector.

**Strategic patent filing in the post-sunrise era:
maximising your IP protection in the Unified
Patents Court and beyond**

As we approach the post-sunrise period, now is the time to re-consider your patent filing strategy. Failure to do so may result in missed opportunities for your IP protection and could have legal and financial repercussions. Join us for a talk on how to strategically file patents in the Unified Patents Court and beyond, and learn how to save costs, put pressure on competitors, and understand more about the value of your IP.

During the talk, we’ll discuss various aspects of patent filing strategy, including the benefits of filing in the Unified Patents Court, how to streamline your patent portfolio, and how to effectively navigate the post-sunrise period. We’ll also explore how your patent filing strategy can impact litigation and licensing, and how to create a holistic approach to intellectual property protection.

Whether you’re an individual inventor, a start-up, or a large corporation, our talk will provide you with practical tips and strategies to help you maximize the value of your intellectual property and stay ahead of the competition. Don’t miss this opportunity to learn how to take your patent filing strategy to the next level.



About the HGF Healthcare team

HGF's Healthcare Team provides professional expertise and commercially focused advice to business leaders and decision makers in the healthcare fields of pharmaceuticals, life sciences 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.

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