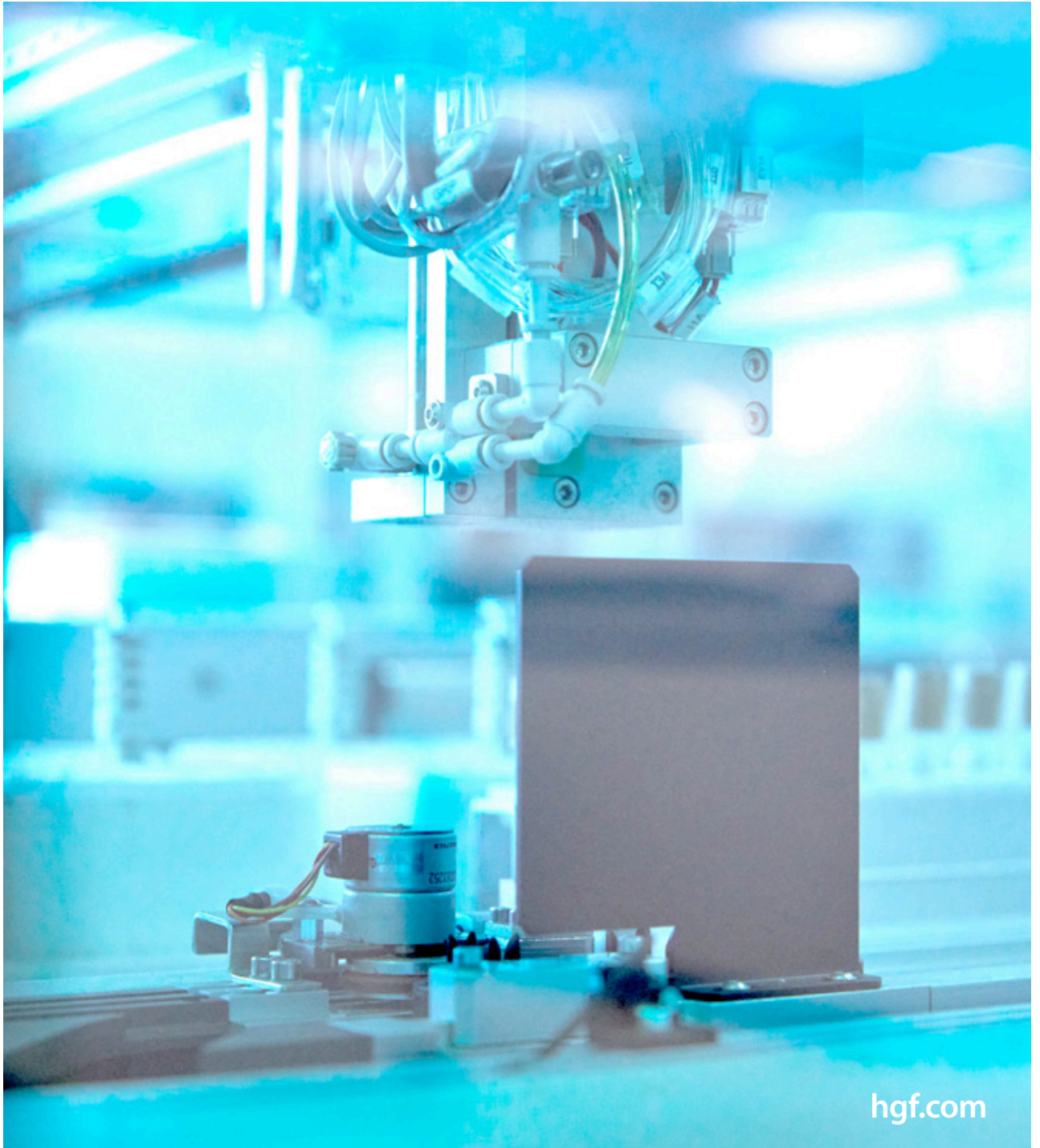


HGF IP in Healthcare Conference 2022

10th May – Manchester, Alderley Park

12th May – London, Barber-Surgeons' Hall



Schedule

| TIME | TOPIC | SPEAKERS | PAGE |
|---------|--|--|------|
| 8.45am | Registration and breakfast | | |
| 9.15am | Welcome | Janet Knowles | 01 |
| 9.20am | The Unified Patent Court and Unitary Patent – are you ready? | Michelle Davies and Rachel Fetches | 02 |
| 10.05am | <i>Parallel seminar 1 (choose session 1 or 2)</i> | | |
| | <i>Session 1 – Trade marks: The challenge of shape marks and invalidity in the healthcare sector</i> | Rebecca Field and Suzan Ure | 04 |
| | <i>Session 2 – The what, why and where of bioinformatics patenting for business leaders and wet science IP counsel</i> | Dr Lauris Kemp, Dr Claire Irvine and Dr Chris Benson | 06 |
| 10.40am | Break | | |
| 11.10am | <i>Parallel seminar 2 (choose session 1 or 2)</i> | | |
| | <i>Session 1 – IP in software-based healthcare innovations</i> | Dr Janine Swarbrick | 08 |
| | <i>Session 2 – Old drug, new use - a patent infringement of pharmaceutical use claims – a review</i> | Hsu Min Chung | 10 |
| 11.45am | Protecting in silico medicine | Dr Chris Benson | 12 |
| 12.20pm | The deals, the pandemic and the vaccine | Dr Kay Tait, AstraZeneca | 14 |
| 13.05pm | Close | Janet Knowles | |
| 13.10pm | Lunch | | |

Welcome

After a challenging couple of years, we are delighted to invite you to join us for HGF's eighth annual IP in Healthcare Conference.

We will review the latest intellectual property issues in the pharmaceuticals, life sciences and medical devices sectors. The conference will be held in-person in Manchester and London.

Our expert speakers will be covering the following topics – unitary patent, in silico medicine, patent infringement of pharmaceutical use claims, shape marks in healthcare, bioinformatics and software-based healthcare innovations. We are also delighted to welcome a guest speaker from AstraZeneca to discuss its Covid vaccine journey.

More information about the each session and the speakers can be found in this brochure.



**Michelle Davies –
Legal Director**

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 has also delivered a range of legal training focused towards compliance programmes within in-house teams, including on topics such as Good Document Practice, Handling Sensitive Information, Alliance & Post-Deal Management, Market Disclosure & Insider Trading and Issue Management Team Set-Up & Support. Michelle sits on a University Ethics Committee for the review of life sciences projects and is a member of the Pharmaceutical Licensing Group.



**Rachel Fetches –
Partner & Head of Law**

Rachel is an IP/Patent Litigation Partner and advises on contentious intellectual property matters for clients across a broad range of sectors including, life sciences, pharmaceuticals, healthcare, chemicals, food and beverage, aviation, media and telecommunications industries. She has extensive experience of litigating before the UK Patents Court, High Court and Court of Appeal. She has also regularly advised in relation to pan-European IP litigation strategy for both patents and trade marks.

The Unified Patent Court and Unitary Patent – are you ready?

The patent landscape in the EU is on the brink of the most significant change in a generation and the Unified Patent Court (UPC) and a new “unitary patent” or “European patent with unitary effect” (UP) will soon become a reality.

The Provisional Phase of the UPC is now live with a potential start date as early as 1 September 2022. This means that patentees who wish to take their existing European patents outside the UPC’s jurisdiction, will need to be ready to apply to opt-out, possibly from early summer 2022.

Equally those who wish to take advantage of the multi-jurisdictional UP designation and the possible cost savings associated with this new patent right, will also be able to take advantage of Sunrise schemes which will lead to grant of a UP shortly after the UPC goes live.

This seminar will provide an update on progress and discuss some of the practical implications for patentees considering the impact the UPC will have on the ownership, prosecution, enforcement and licensing of European patents and Supplementary patent certificates across at least 17 EU Member States (including Germany, France, Italy and The Netherlands).



Speakers



**Rebecca Field –
Trade Mark Director**

Rebecca has over 15 years of experience in the trade mark and design field. Rebecca advises a wide range of clients on new brand and design clearance searching, filing, oppositions and invalidity actions. Rebecca manages worldwide portfolios of household names down to assisting entrepreneurs launch their brand. Rebecca enjoys learning about new products and ventures, working with new people and helping a business grow their brand into a valuable asset. Brands are business and her approach to working with clients is to understand how the brand fits into the business and what the drivers are for brand growth and where the brand needs to be positioned in the future. Rebecca has experience of working with a broad range of healthcare brands, from female self-care through to energy tablets and pharmaceutical brand protection around MS.



**Suzan Ure –
Trade Mark Attorney**

Suzan joined the Birmingham Trade Mark Team in September 2016 and is a Chartered Trade Mark Attorney having studied and passed the Postgraduate Certificate in Trade Mark Law and Practice at Queen Mary University as well as passing the Nottingham Law School Certificate in Trade Mark Practice with distinction. Suzan provides full lifecycle trade mark advice from pre-filing advice, clearance searching, trade mark application prosecution and protection and enforcement. Suzan is a member of the Chartered Institute of Trade Mark Attorneys and a regular contributor to the CITMA Review. Furthermore, she is involved with Fashion+IP and Retail+IP LinkedIn groups, as well as other ongoing articles and contributions relating to trade mark current affairs.

Parallel seminar 1

– Session 1

Trade marks: The challenge of shape marks and invalidity in the healthcare sector

What is a shape mark? Why is it important to try and register shape trade marks in the healthcare sector? How can this bolster your IP portfolio?

This session will centre around the general principles from the 2021 decision of Glenmark Pharmaceuticals v Boehringer Ingelheim (C-37137) where the EUIPO declared Boehringer’s inhaler shape mark invalid on the basis that it formed a technical function. The case highlights the difficulties in registering and maintaining trade marks for medical devices and thus companies should consider registered design protection as an alternative. Unfortunately, evidence of use (distinctiveness) cannot be used to overturn a shape refusal. Further, the Cancellation division took into account patents filed for the same medical device may constitute prima facie evidence of trade mark invalidity.

Therefore, there must be a wider consideration for the whole IP portfolio when filing applications.

We will discuss generally about how trade marks last forever and thus are a great weapon for enforcement but that you need to pick and choose what to file and don’t forget about the importance of designs!



Speakers



**Dr Lauris Kemp –
Patent Director**

Lauris has a strong science background with a 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 also successfully defended bioinformatics patents at EPO opposition proceedings. Having worked directly with many US and EP in-house counsels including those in the food industry, DNA sequencing technology, microbiome bioinformatics and antibody therapies to draft applications and manage large European and global portfolios, Lauris knows how to best assist in-house counsel. She adapts her way of working to whatever fits best with the way the in-house team likes to work, effectively becoming another member of the team.



**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.



**Dr Chris Benson –
Partner & Head of
Electronics**

Chris represents a full spectrum of clients from multinational companies to start-ups and academic institutions. Chris has experience in working with inventors from academics to industrial R&D technologists. In particular, he is able to advise on the patentability of software-based inventions. He has experience in not only the nuts-and-bolts of taking inventions through to granted patents in a wide variety of different countries including Europe, the US and China, but also in advising on patent strategy, patent enforcement and patent infringement defence. As part of representing start-ups and SMEs, Chris has been involved in due diligence exercises where potential investors have scrutinised patent portfolios which he has been responsible for and have defended these portfolios such that clients have obtained investment at least partly on the basis of the IP portfolio's strength. Chris acts as client manager for one of our firm's largest clients whereby he manages our firm's timely delivery of work products by an attorney team to ensure that these products meet the client's quality expectations.

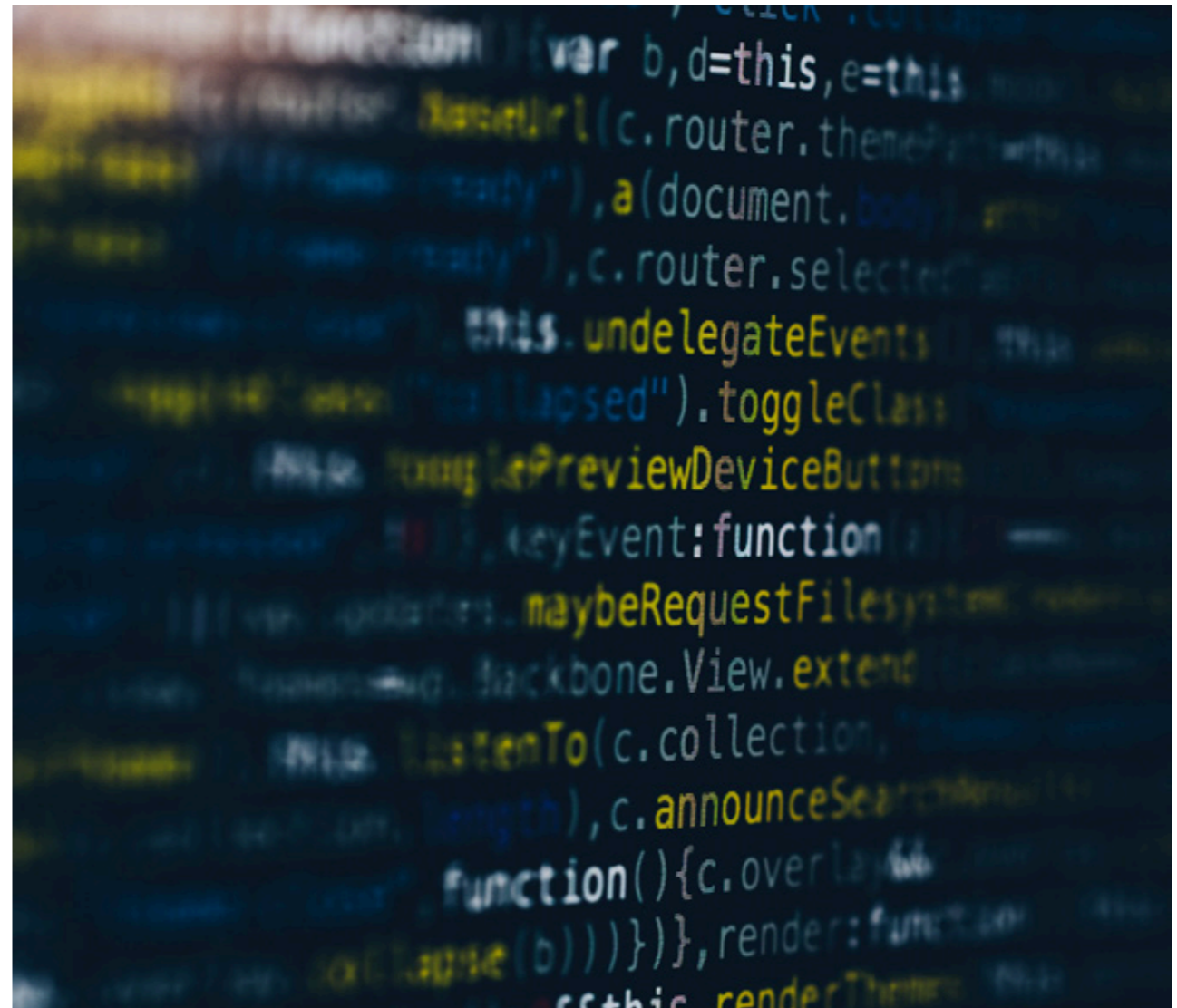
Parallel seminar 1

– Session 2

The what, why and where of bioinformatics patenting for business leaders and wet science IP counsel

The bioinformatics your company generates can form an important part of your IP strategy allowing you to compete effectively and bring in investment.

This will be a panel discussion made up of attorneys from our biotech and electronics teams. We will be discussing real questions which have been put to us by our clients on the practicalities of protecting bioinformatics. We will look at what is being patented. We will also look at the important why: why patent your bioinformatics? We will then turn to cost-effective protection in where to file and in managing your bioinformatics patent portfolio.





Dr Janine Swarbrick – Senior Patent Attorney

Janine is a Chartered and European Patent Attorney with a PhD in nanoscience. She has extensive experience of helping clients to protect inventions relating to physics-based fields including: medical devices (both hardware and software, including mobile devices, wearables, and x-ray imaging technology); applications of AI in data analysis including speech recognition; telecommunications (including 4G, LTE and 5G standards, and user interfaces); nanotechnology; electronic systems and circuits; automotive technologies; and semiconductors. She is also part of the HGF MedTech technology group, and the HGF DEI Focus Group.

Her past research work includes soft and hard x-ray spectroscopy at synchrotron facilities, scanning tunnelling microscopy, atomic force microscopy, electrospray systems, and computer modelling of molecular systems. Janine has published several scientific journal articles on her research including from her postdoctoral position at the ESRF in Grenoble, France.

IP in software-based healthcare innovations

The rise of software in healthcare in recent years is evidence of an important shift in how health monitoring and healthcare support are now possible. As businesses develop new software-based innovations in healthcare, it is important to identify where there may be IP and consider how best to protect it.

There has been a boom in recent years in software developments relating to healthcare – there are myriad mobile telephone apps for mindfulness, activity tracking, sleep monitoring, and virtual medical assistance, for example. Furthermore, emerging software such as machine learning and artificial intelligence is being increasingly used with medical data, for example to analyse image data or provide suggested conclusions to medical data input. In this session we will look at IP considerations for software-based innovation in the healthcare field, including identifying where IP may lie, patenting software-based technologies (with case studies) and looking at what may be excluded from patentability, and considerations to make when managing personal health data.





**Hsu Min Chung –
Partner & Patent Attorney**

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.

Old drug, new use – a patent infringement of pharmaceutical use claims – a review

The repurposing of known drugs is vital for the development of safe and cost-effective treatments for a wide range of conditions. We saw this during the COVID-19 pandemic, where known drugs like dexamethasone were repurposed for the treating of patients who were critically ill with COVID. Similarly, although Aspirin was developed over 100 years ago for treating pain and fever, it is currently undergoing Phase III Clinical Trials for treating colon and other cancers.

The patent system has been crucial to the importance of repurposing old drugs. Although the route to commercialisation may be simpler when old drugs are put to new use, patent protection still plays an important part if drug companies are to invest in the necessary clinical trials. Indeed, it's been nearly 40 years since the Enlarged Board of Appeal's landmark decision to grant patent protection for second medical uses. Yet today we still do not have certainty on how such medical use claims should be interpreted. The uncertainty presents a conundrum for generics when entering a market where a drug can be used for patented and off-patent indications. The generic is free to market the drug for the off-patent indication. However, if the drug ends up being used for the patented use, there is a risk that the generic will be liable for patent infringement. There has been much uncertainty over what the generic should do to manage this risk. This has been costly and, in recent years, we have even seen pharmaceutical companies sue the NHS to court in attempts to enforce their second medical use patents.

In her session, Hsu Min will provide an overview of the case law that has been developed so far and highlight the do's and don'ts for companies trying to navigate this space.



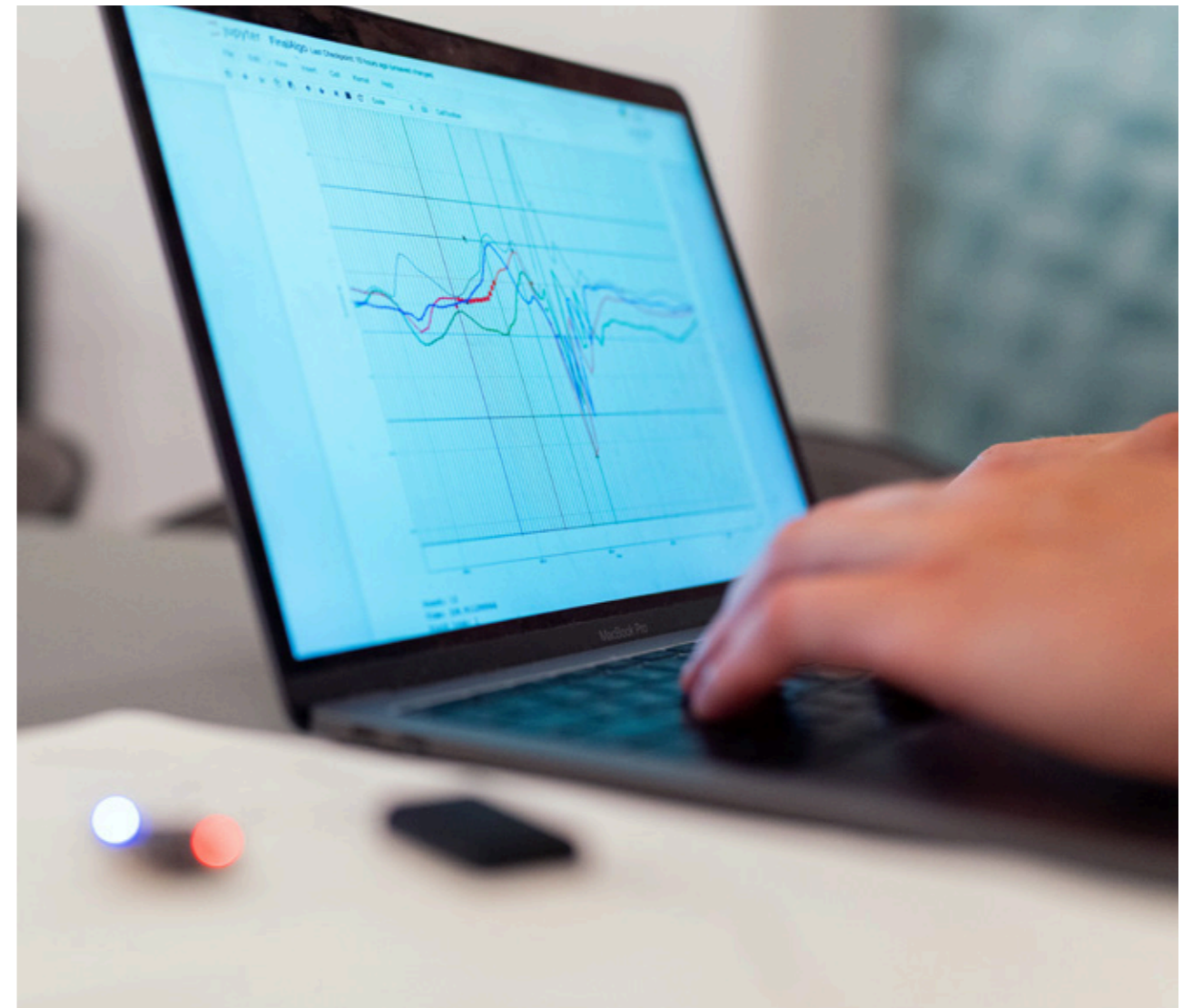
We are increasingly able to model all aspects of the real world around us, including the human body and aspects of the human body such as biological processes. Such models allow promising new treatments, including drugs e.g. in silico medicine, but also even improved treatment apparatus, to be identified inside a computer to thereby bypass much experimental work by simulating their effectiveness before ever reaching a laboratory. Whilst the results of such work may be protected per se e.g. new pharmaceutical compounds or improved devices, what about the models or simulation techniques used to arrive at these outputs? We will look at how the patent system treats the software-based techniques used to conduct such modelling and simulation and whether developments in these areas might themselves be protectable.



Dr Chris Benson – Partner & Head of Electronics

Chris represents a full spectrum of clients from multinational companies to start-ups and academic institutions. Chris has experience in working with inventors from academics to industrial R&D technologists. In particular, he is able to advise on the patentability of software-based inventions. He has experience in not only the nuts-and-bolts of taking inventions through to granted patents in a wide variety of different countries including Europe, the US and China, but also in advising on patent strategy, patent enforcement and patent infringement defence.

As part of representing start-ups and SMEs, Chris has been involved in due diligence exercises where potential investors have scrutinised patent portfolios which he has been responsible for and have defended these portfolios such that clients have obtained investment at least partly on the basis of the IP portfolio's strength. Chris acts as client manager for one of our firm's largest clients whereby he manages our firm's timely delivery of work products by an attorney team to ensure that these products meet the client's quality expectations.



Deal making in a large pharmaceutical company is a demanding and intense role at any time – add to this a global pandemic and the delivery of a life saving vaccine which the whole world is watching and waiting for – the role enters another dimension.

We are delighted to have Kay Tait join us to talk through her pandemic experience including the unique challenges she faced leading the vaccine negotiation team, her regular zoom calls with government, the logistical terms, the internal and external scrutiny, the unprecedented time lines, the PR minefield and how she coped with all this on both a personal and professional level.

Speakers



Dr Kay Tait, AstraZeneca

Dr Kay Tait has worked in the UK pharmaceutical industry for approximately 20 years and currently works as an Executive Transaction Director in AstraZeneca's Business Development and Operations team. Kay is involved in all aspects of transaction negotiation and execution across multiple therapy areas. Prior to that, Kay worked as a Business Development Director covering both search and evaluation, as well as transaction, for AstraZeneca's Oncology business.

Kay has a wealth of business development experience ranging from in and out-licensing, acquisition and partnering activities from early stage discovery through to on-market commercial opportunities. Before her business development career, Kay worked in R&D at AstraZeneca. She also holds a Ph.D. in molecular biology and a first class honours degree both from the University Manchester.



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.

Visit hgf.com to find out more.

If you have any questions about the conference, please contact Sinead Barker at sbarker@hgf.com or call +44 113 233 0100.

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