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EIPR Editorial

Special Issue: Patents in a Changing Europe

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Abstract: Significant technological and social changes, as well as global health and climate crises, are evident in the world we live in, which pose important questions for a myriad of legal fields, including for patent law and practice. At this time of change, this special issue reflects on some key aspects of how the current European patent system is affected by contemporary technological, legal and social developments. Papers within the issue are framed around three distinct yet intersecting themes: Emerging Technologies and the Public Interest; COVID-19 and Access to Health-Technologies; and the EU Unitary Patent System. We call for greater critical reflection and dialogue within – and outside – the patent community, around the role and operation of patent law, to ensure it is fit for purpose and best aligned with public interests at stake in our current society.

Introduction

In our contemporary society, we are faced with significant technological and social changes, as well as global health and climate crises, which pose important questions for a myriad of legal fields, including for patent law and practice.

Currently prevalent amongst these is the COVID-19 pandemic which, for two years, has brought ongoing and devastating health, economic and social consequences. Meanwhile, control of the pandemic has been hampered by the vast inequities which have developed between high- and low-income countries around access to vaccines and other COVID-19 technologies.[2] In this context, intellectual property rights (IPRs), including patents, have become central to debates around ensuring access to health-technologies such as medicines, vaccines, and diagnostics. Indeed, COVID-19 has amplified debate around the role, impact and effect of patent rights within the health space. It has also caused many to reconsider the underpinning rationales and justifications for patents, and to further question the scope and appropriate limits of these rights.[3]

Some argue that IPRs, including patents, are a key element of innovation in many fields.[4] However, the precise link or co-relation between patents and innovation is increasingly contested and attracts multiple perspectives.[5] Moreover, alongside the potential role of

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[2] See: Global Dashboard for Vaccine Equity, available at https://data.undp.org/vaccine-equity/.

[3] See, for example: https://blogs.kent.ac.uk/law-news/panel-discussion-to-explore-political-and-social-role-of-ip-law-in-light-of-covid-19-pandemic/; K Walsh, A Wallace, M Pavis and others, 'Intellectual Property Rights and Access in Crisis' (2021) 52 IIC 379; and N Hawkins (ed), *Patenting Biotechnical Innovation: Eligibility, Ethics and Public Interest* (Edward Elgar 2022) (forthcoming).

[4] See, for example: R Merges, *Justifying Intellectual Property* (Harvard University Press 2011).

[5] See, for example: J Bessen and MJ Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (Princeton University Press 2009); MA Heller and S Eisenberg, 'Can patents deter innovation? The anticommons in biomedical research' (1998) 280 Science 698; and HY Kang, 'Patents as

patents in incentivising certain innovation, patents can act as a double-edged sword.[6] The exclusionary nature of a patent right, which allows rightsholders to exclude others from using a patented technology, means that such rights give rise to important social questions around the implications of patents for access to technologies, including medicines and healthcare, and the development of new technologies. The ensuing debate has given rise to differing views amongst patent scholars in Europe and elsewhere, but what has become clear is that questions around the role of the public interest and the scope and limits of patent rights within the health context are not going away.

Such questions around patents, ethics and the public interest are arguably instead intensifying in our contemporary society, exacerbated by challenges posed by the application of patent rights in new and emerging technological contexts. There is increasing pressure for patent law to evolve and adapt to emerging technological contexts, particularly within the biotechnological and artificial intelligence spaces. Debates also continue on whether patents should be applicable over life forms, such as in transgenic animals, novel beings, and de-extinction contexts, as well as the implications of patents over ethically contentious technologies, such as in relation to gene editing.[7]

Alongside challenges around the scope and limits of patent law, changes are also evident in the practical operation and structure of decision-making fora for patent law in Europe. In this context, the departure of the United Kingdom (UK) from the European Union (EU) under Brexit and the attendant changes this has brought and will bring also have important consequences for research, for European trade, and for applicable patent law and practice. Moreover, the ongoing developments in relation to the EU unitary patent and Unified Patent Court (UPC), impacted by the UK's departure from the system and constitutional challenges in Germany, mean that considerable uncertainty remains surrounding the application and future operation of this system, including when the system will take effect, and what challenges and opportunities this may give rise to for European patent law.

Industry voices in the aforementioned debates are often focused on the economic role of patents, with many such voices arguing for stronger intellectual property (IP) protection on the basis of (in many cases contested) economic arguments. However, patents have a much broader role beyond an economic function, and it is for this reason that academic social science perspectives are vital within such debates to interrogate and draw out wider perspectives around the effects of patent law in practice on society. It is crucial that we have a forum to investigate the operation of the patent system as embedded within the broader legal system and its effect on wider society, such as, for example, through access to patented technologies, the right to health and the impact of such rights in human life and wellbeing. Taking a critical academic approach, which draws on interdisciplinary perspectives from social

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Assets: Intellectual Property Rights as Market Subjects and Objects' in K Birch and F Muniesa (eds), *Assetization: Turning Things into Assets in Technoscientific Capitalism* (MIT Press 2020).

[6] A McMahon, 'Accounting for Ethical Considerations in the Licensing of Patented Biotechnologies and Health-Related Technologies: A Justification' in N Hawkins (ed), *Patenting Biotechnical Innovation: Eligibility, Ethics and Public Interest* (Edward Elgar 2022) (forthcoming).

[7] See, for example: A McMahon and DM Doyle, 'Patentability and de-extinct animals in Europe: the patented woolly mammoth?' (2020) 7 Journal of Law and the Biosciences lsaa017; A McMahon, 'Patents, Governance and Control: Ethics and the Patentability of Novel Beings and Advanced Biotechnologies in Europe' (2021) 30(3) Cambridge Quarterly of Healthcare Ethics 529; O Feeney and others, 'Patenting Foundational Technologies: Lessons From CRISPR and Other Core Biotechnologies' (2018) 18 The American Journal of Bioethics 36; and D Matthews, A Brown, E Gambini, A McMahon, T Minssen, A Nordberg, JS Sherkow, J Wested, and E van Zimmeren, 'The Role of Patents and Licensing in the Governance of Human Genome Editing: A White Paper' (2021) Queen Mary Law Research Paper No 364/2021, available at https://ssrn.com/abstract=3896308.

science and the technical scientific aspects of patents, can enable different voices to be heard, with potential for a more critical evaluation and development of the law.

Patent Scholars Network

Reflecting on the need for such analysis within patent law, and to provide a focussed forum for engaging with and discussing contemporary challenges within the field, we established the UK and Ireland Patent Scholars Network in 2019. Its aims are to enhance scholarly research in patent law, to enhance collaboration between patent scholars, patent practitioners and policymakers, and to contribute to the policy debates around patent law in the UK, Ireland, and Europe more broadly. The network provides a forum for in-depth exploration of patent scholarship and practice by both academics and patent industry experts. There is much to be gained from closer involvement between academic researchers, practitioners and policymakers working in patent law and policy in the UK and Ireland, especially post-Brexit. The network seeks to facilitate such engagement. It holds regular meetings, has a website presence,[8] and includes a mailing list and Twitter account to publicise forthcoming events and other matters of interest to members and the wider community. Importantly, the network facilitates connections amongst patent practitioners and academics at all career stages, including PhD students and non-academic beneficiaries (such as industry experts and policymakers), with the aim of encouraging critical engagement and reflection on the system, aiming to inspire further research and scholarship in patent law.

At this time of change in Europe, this special issue reflects on some key aspects of how the current European patent system is affected by contemporary technological, legal and social developments. Papers within the issue are framed around three distinct yet intersecting themes: Emerging Technologies and the Public Interest; COVID-19 and Access to Health-Technologies; and the EU Unitary Patent System.

Emerging Technologies and the Public Interest

It is almost inevitable that patent law is one of the first bodies of law to grapple with emerging technologies because patents are granted for novel or new inventions only. Failing the novelty requirement will render an invention unpatentable. Patent law is therefore often the first point at which a new technology will be examined by external parties, and thus, it is well versed in adapting to and accommodating technological developments. However, current and anticipated technological developments in areas such as biotechnology, artificial intelligence, and climate change are bringing challenges which necessitate further consideration, [9] assessment and potential legislative changes or re-interpretation of existing patent law. Considering that the European Patent Convention (EPC) was adopted in 1973, existing technologies were vastly different at that time. The development of biotechnologies, for example, led to the eventual adoption of the EU Directive on the protection of biotechnological inventions 98/44/EC (Biotech Directive) following a protracted and tumultuous debate

[8] See: http://sculecentre.ex.ac.uk/patent-scholars-network/. We welcome new members. Please see the website and email one of the authors for further details.

[9] For a discussion of some of these areas, see generally: PH Lim, and P Li, 'Patentability of biofabricated human organs: "products of nature" or "products derived from nature" revisited' in N Hawkins (ed), *Patenting Biotechnological Innovation: Eligibility, Ethics and Public Interest* (Edward Elgar 2022) (forthcoming); A Brown, *Intellectual Property, Climate Change and Technology: Managing National Legal Intersections, Relationships and Conflicts* (Edward Elgar 2019); E Bonadio, L McDonagh, and P Dinev, 'Artificial Intelligence as Inventor: Exploring the Consequences for Patent Law' (2021) 1 Intellectual Property Quarterly 48; and N Hawkins, 'Patents and non-invasive prenatal testing: Is there cause for concern?' (2020) 47 Science and Public Policy 655.

spanning over 10 years from initial proposal to adoption.[10] Moreover, many aspects of that Directive, as they pertain to biotechnologies, have had to be reconsidered and re-interpreted since, given developments in this area. For example, under Art 6(2) a human embryo is unpatentable, and this provision had to be considered to assess if it would also pertain to inventions involving human embryonic stem cells,[11] and later how it pertained to parthenotes, that is, egg cells stimulated to mimic human embryos.[12] In effect, the pace of technological development raises questions for the definitional parameters of legislative provisions that can become outdated over time.

Moreover, it is not merely the nature of the developments in technology that requires patent law adaptations. It is also the important social and ethical implications of these technological developments, and the potential impact of granting a patent over such developments, including the often differential impacts patents can have on vulnerable groups, both within and outside of Europe, that requires attention. Patent law has important consequences for all such questions: it is not neutral in its operation. A number of the papers in this special issue elaborate on these vital questions.

In this context, Louise Hatherall's article 'Procedural Issues in Public Interest Patent Challenges' explores the role that public interest challenges may have in improving the balance of European patent law in favour of the public interest. Specifically, she considers the role that legal challenges by members of the public, utilising the EPC opposition procedure, can play in the protection of the public interest. Hatherall's argument has three parts. First, she contextualises her argument in light of the public interest justification for patents and the importance of balancing the private rights of the patent holder against the public interest in access to innovation. Second, she outlines the procedural rules for challenging a patent, and third, she explores the procedural barriers to public interest challenges. In her argument, Hatherall draws on the litigation around the BRCA gene patents, held by Myriad Genetics,[13] as a case study demonstrating both the importance, and limits of, public opposition to patents. She concludes that, while there is formal recognition in the European patent system of the importance of public opposition in limiting the grant or the scope of patents, there is insufficient substantive facilitation of such challenges. She proposes reform of patent databases and the introduction of mechanisms to increase public accessibility of patent information as a practical means of facilitating this important route to improving the balance within the European Patent system in favour of the public interest.

Where the voice of the public is central to Hatherall's paper, Cliona Kelly and Rachel Brady's article focuses on the broader institutional interactions between research ethics decisions and patent law. In their paper entitled 'Research Ethics and the Patent System', the authors consider the role of the morality provisions in Europe contained in Art 6(1) of the Biotech Directive and Art 53(a) EPC.[14] Kelly and Brady argue that this provision should be interpreted to include a consideration of research ethics compliance – specifically, the ethics of the

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[10] See discussion in: G Porter, 'The drafting history of the European biotechnology directive' in A Plomer and PLC Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (Oxford University Press 2009).

[11] Case C-34/10 *Oliver Brüstle v Greenpeace* ECLI:EU:C:2011:669.

[12] Case C-364/13 *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks* ECLI:EU:C:2014:2451. For a discussion, see: A Plomer and PLC Torremans (eds), *Embryonic Stem Cell Patents: European Patent Law and Ethics* (Oxford University Press 2009); E Bonadio, 'Biotech Patents and Morality after Brüstle' (2012) 34(7) EIPR 433; and E O'Sullivan, 'International Stem Cell Corporation v. Comptroller General of Patents: The debate regarding the definition of the human embryo continues' (2014) 36 EIPR 155.

[13] Such patents have important implications for access to and delivery of genetic testing in the context of many cancers, including breast and ovarian cancer.

[14] Both of which provide those inventions are unpatentable where their commercial exploitation is against *ordre public* or morality.

research methods used in the development of the invention(s) that is the subject of the patent claim(s). They build the case that the changing nature of research in Europe, including the growth of biotechnological inventions and numbers of patent applications, alongside the growing emphasis on research ethics considerations and compliance in scientific research more generally, must give us pause to consider whether the limited engagement with research ethics considerations within patent grant assessments is fit for purpose, or indeed, even tenable. Kelly and Brady's paper puts forward the case that 'the patent office has a key role to play in considering research ethics when morally assessing patent claims on an ex ante basis'.[15] Having done this, they outline a framework that, in their view, can be used to inform any 'moral' assessment of patents within European patent law in a manner that takes research ethics considerations into account.

Both papers have, as a kernel, the relationship, and often tensions, that can arise between the traditional view of patents as purely economic devices where patent law is conceptualised as a technical, esoteric and value neutral field,[16] and the contemporary reality of the potential effects of patents in practice, including the broader public interest and ethical concerns that patents can give rise to. This tension between patents and the public interest has been further highlighted by the COVID-19 pandemic, which has significant implications in Europe and globally.

COVID-19 and Access to Health-Technologies

Alongside changes in technologies and society, there are also calls as to whether patent law as currently interpreted is fit for contemporary society. Such calls have been brought into sharp relief again by the COVID-19 pandemic. The adoption of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) in 1995 meant that all World Trade Organisation (WTO) States who wish to maintain the trade benefits offered by WTO membership, were required to agree to minimum IPR protections. The TRIPS Agreement, includes Art 27(1) which states that patents must be offered in all fields of technology, including the pharmaceutical and health-technology contexts. Prior to TRIPS, States had discretion to decide if they would allow patents over technologies in particular fields, including within the pharmaceutical context, and some States decided not to do so, allowing the production of generic pharmaceutical products, and thereby increasing likely access to such medicines and other technologies. However, following the adoption of TRIPS, WTO States no longer have such discretion, and this gives rise to many concerns in the access to health context. Such issues are under increasing spotlight in the COVID-19 pandemic, where there is a vast inequity between low- and high-income countries in terms of access to COVID-19 vaccines and other health-technologies. This lack of global access to vaccines and other health-technologies gives rise to significant moral questions, and it is also self-defeating as it is threatening the control of COVID-19.[17]

IPRs, including patents, play a key role in this context, as those who hold IPRs over COVID-19 technologies have the ability to exclude others from using that technology for the duration of the patent or other IPR. Effectively, IPRs, like patents, enable rightsholders to dictate who can gain access to patented technologies first and on what terms.[18] In many cases, technologies, like vaccines, have been distributed based on private agreements between

[15] C Kelly and RC Brady, 'Research Ethics and the Patent System' (2022) 44 EIPR 209, 210.

[16] For a discussion and critique of this, see: L Bently and B Sherman, 'The Ethics of Patenting: Towards a Transgenic Patent System' (1995) 3 Medical Law Review 275.

[17] TA Ghebreyesus, 'Vaccine nationalism harms everyone and protects no one' (*Foreign Policy*, 2 February 2021) available at https://foreignpolicy.com/2021/02/02/vaccine-nationalism-harms-everyone-and-protects-no-one/.

[18] A McMahon, 'Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance' (2021) 47 Journal of Medical Ethics 142.

States and rightsholders, which often lack transparency,[19] and are facilitated by the exclusionary role provided by patents and other IPRs. Such agreements do not necessarily align with broader global health needs.

Given the global need for vaccines and other health-technologies, and the inequity between low- and high-income countries, in October 2020, India and South Africa proposed a TRIPS waiver which would temporarily suspend IPRs related to COVID-19 vaccines, therapeutics and diagnostics, in order to address the IP barriers to others manufacturing generic versions of such health-technologies. This proposal has support from over 100 countries globally,[20] by many former heads of State and Nobel laurates,[21] and from many within the IP community.[22] However, the proposal has also attracted opposition from some within the IP field.[23] Exploring these views (of which we authors have our own perspectives) is not the purpose of this editorial.[24] Instead, the core argument made here is that such debates show that IP law is in a state of flux. The field is facing deep questions about its operation, effects, and its fitness for purpose. COVID-19 has re-ignited age-old questions on the role, scope and limits of patent rights, and these questions warrant urgent reconsideration if IP is to align with the broader public interest for which it was first designed.[25] It is also vital that we resolve such issues if we are to be prepared for future global crises, including, for example, future pandemics and environmental emergencies. Indeed, such re-evaluation of the role of the public interest in patent law is crucial if we as an IP community are to contribute in a constructive manner to the broader context within which IP operates, which requires us to be cognisant of the often significant consequences that patents and other IPRs have for society more generally.

In this context, in 'The COVID-19 Pandemic: Lessons for the European Patent System', Duncan Matthews considers how European patent law has responded and can respond to the COVID-19 pandemic, and focuses on how incremental, pragmatic changes could be made in three key areas of European patent law to learn from issues that have arisen in the COVID-19 response, and to reflect on the system for future pandemic preparedness. Matthews first addresses the inadequacies of compulsory licensing as a response mechanism and argues that new approaches are required. He investigates three potential avenues which could facilitate greater transparency, address deficiencies in information, and better inform public policy debate. The article first looks specifically at the role of Art 93 EPC and facilitating early

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[19] D Matthews, 'Coronavirus: how countries aim to get the vaccine first by cutting opaque supply deals' (*The Conversation UK*, 27 July 2020) available at https://theconversation.com/coronavirus-how-countries-aim-to-get-the-vaccine-first-by-cutting-opaque-supply-deals-143366.

[20] See: A Green, 'Where are we on COVID-19 after a year of TRIPS waiver negotiations?' (*Devex*, 7 October 2021) available at https://www.devex.com/news/where-are-we-on-covid-19-after-a-year-of-trips-waiver-negotiations-101795.

[21] 'Former heads of state and Nobel laureates call on President Biden to waive intellectual property rules for COVID vaccines' (*Oxfam*, 14 April 2021) available at https://www.oxfam.org/en/press-releases/former-heads-state-and-nobel-laureates-call-president-biden-waive-intellectual.

[22] HY Kang, A McMahon, G Dutfield, L McDonagh, and S Thambisetty, 'Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal' (2021) LSE Law - Policy Briefing Paper No 46 available at https://ssrn.com/abstract=3885568 or http://dx.doi.org/10.2139/ssrn.3885568.

[23] This includes: RM Hilty, PHD Batista, S Carls, D Kim, M Lamping and PR Slowinski, 'Covid-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021' (2021); and B Mercurio, 'The IP Waiver for COVID-19: Bad Policy, Bad Precedent' (2021) 24 IIC 1.

[24] The authors are signatories of the Academic Open letter in support of the waiver. McMahon is a co-author of the letter and is a co-author of the following paper in support of the waiver: S Thambisetty, A McMahon, HY Kang, L McDonagh, and G Dutfield, 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID19 Pandemic' (2021) LSE Legal Studies Working Paper No 06/2021.

[25] N Hawkins (ed), *Patenting Biotechnical Innovation: Eligibility, Ethics and Public Interest* (Edward Elgar 2022) (forthcoming).

publication of European patent applications, particularly for health products and technologies on public interest grounds, in certain circumstances. It then highlights the potential to reconsider the sufficiency of disclosure requirement under Art 83 EPC, and explores the extent to which existing EPO examination practice is effective in enforcing the requirement of disclosure to enable production of an invention by a person skilled in the art. Finally, Matthews considers the potential to use Art 138 EPC to enable revocation of patents, such as in the context of insufficiency of disclosure. Such incremental changes are proposed as potential improvements to the European patent system and as a response to some of the challenges presented by COVID-19. The paper concludes by highlighting the need for a reappraisal of patent law in Europe and beyond, and an evaluation as to whether it is fit for purpose.

The EU Unitary Patent System

Finally, alongside substantive questions within patent law, we also see the operational and institutional mechanisms within the system in a state of flux. In this context, the European patent landscape is on the cusp of significant changes. Following years of negotiations, deliberations and delays, as well as numerous projected opening dates, it appears that the EU unitary patent and UPC will be established in the near future.

The potential impact of this new system is substantial. A single patent covering multiple jurisdictions will be available to patentees in Europe, alongside a central specialised court that will provide cross-border judgements on matters of enforcement and infringement. The aims of the EU unitary patent system are to reduce the costs and inefficiencies associated with the operation of the current European patent system. However, and despite its potential benefits, there are numerous challenges to surmount.[26]

Although unitary by name, the EU unitary patent system is limited by nature. First, as implied, the EU unitary patent system is for EU Member States only. This automatically excludes a number of countries within the European patent system but outside the EU from participating in the new system. Following Brexit, this now includes the UK.

Additionally, not all EU Member States have agreed to participate in the legislation necessary to establish the unitary patent. Further, many more have not yet ratified or have refused to ratify the Unified Patent Court Agreement to establish the UPC. There are multiple reasons for these decisions, including language pride, the expected negative impact of the new system on small/medium-sized enterprises, constitutional constraints, and a general uncertainty in relation to an untested system.[27]

As a result, the EU unitary patent system, as it stands, will likely fragment the system it attempts to unify.[28] The resulting confusion and exclusion will likely be one of the main challenges for the future operation of the European patent system.

Within the EU unitary patent system, there are also a number of remaining uncertainties, particularly in relation to the operation of the UPC. Importantly, judges will have to determine the UPC way of doing things, which is a difficult task when faced with the numerous existing approaches towards determining various aspects of validity and infringement.

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[26] For a discussion of some of these challenges, see: L McDonagh, *European Patent Litigation in the Shadow of the Unified Patent Court* (Edward Elgar 2016); J Pila and C Wadlow (eds), *The Unitary EU Patent System* (Hart Publishing 2015); and K Walsh, *Fragmentation and the European Patent System* (Hart Publishing 2022) (forthcoming).

[27] See: K Walsh, *Fragmentation and the European Patent System* (Hart Publishing 2022) (forthcoming).

[28] A McMahon, 'An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: A Fragmented Future Too Far?' (2017) 48(1) IIC 42; and K Walsh, *Fragmentation and the European Patent System* (Hart Publishing 2022) (forthcoming).

With this context in mind, in '"Pith and Marrow is Dead…Long Live Pith and Marrow": The Doctrine of Equivalents after *Actavis*', Wissam Aoun delves into various historic and current approaches towards patent claim construction across Europe, including 'pith and marrow', 'colourable evasion' and 'general inventive concept'. Taking harmonisation efforts in European patent law as his starting point and using the transition from *Kirin-Amgen*[29] to *Actavis*[30] as a case study, Aoun argues that in order to achieve goals of harmonisation in this area, a deeper acknowledgement of the differing philosophical foundations of approaches to claim construction is required. In doing so, he explores the intricacies and theoretical foundations of approaches towards claim construction, as well as the changes that have taken place since the introduction of the EPC, particularly in the UK and Germany. Aoun traces these developments and argues that *Actavis* may have missed the mark 'both in implementing a true doctrine which extends protection beyond the semantic content of the claims and achieving its harmonising objectives'.[31] In the context of the forthcoming UPC, he asks in what direction will the UPC take claim construction and infringement, and whether this will have an impact on UK patent law and practice.

Conclusion

This special issue raises several key challenges we currently face in relation to patents as they operate in a contemporary and changing Europe. While many more challenges remain and others are likely in future, the purpose of the issue is to provide a forum for the patent community to engage with such issues and to chart future challenges. Ultimately, its aim is to provoke and ignite further conversations within – and outside – the patent community as to how patent law should respond to the myriad challenges presented by contemporary social and technological changes, to reflect on whether various facets of the patent system are still fit for purpose, and to build constructive dialogue on the changes that may be needed so that patent law and public interests can more broadly align.

[29] *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46.

[30] *Actavis v Eli Lilly* [2017] UKSC 48.

[31] W Aoun, '"Pith and Marrow Is Dead…Long Live Pith and Marrow": The Doctrine of Equivalents after Actavis' (2022) 44 EIPR 231, 243.