PatentsInHumans

Patents I Bioethics I Our Human Bodies

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Report of the First International PatentsInHumans Project Workshop
Workshop Dates: 29th – 30th April 2024
Venue: Renehan Hall, Maynooth University
Report Authors: Professor Aisling McMahon & Sinéad Masterson

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Report of the First PatentsInHumans Project Workshop

Introduction: On 29th and 30th April 2024, the PatentsInHumans team hosted the first interdisciplinary project workshop organised as part of the European Research Council funded PatentsInHumans project. The workshop took place in Renehan Hall, Maynooth University.

Over the course of two days, the workshop brought together twenty-two leading national and international speakers drawn from a range of academic disciplines including law, business, health, social sciences, and practitioner fields, including experts working in legal, ethics, technology-transfer and healthcare fields. The speakers and workshop discussions focused on examining the potential bioethical issues posed by patent grant and use (including licensing and enforcement) of patents over a range of technologies related to the human body, such as vaccines, medicines, medical devices etc. It also considered a range of avenues that could be used to engage with these bioethical issues within and outside patent law in Europe, and the potential opportunities and challenges for engaging with such bioethical issues. Such issues are central to the research focus within the PatentsInHumans project. The event was attended by approx. forty people.

This report provides a brief overview of papers presented, and of some of the key aspects of discussions during the workshop.

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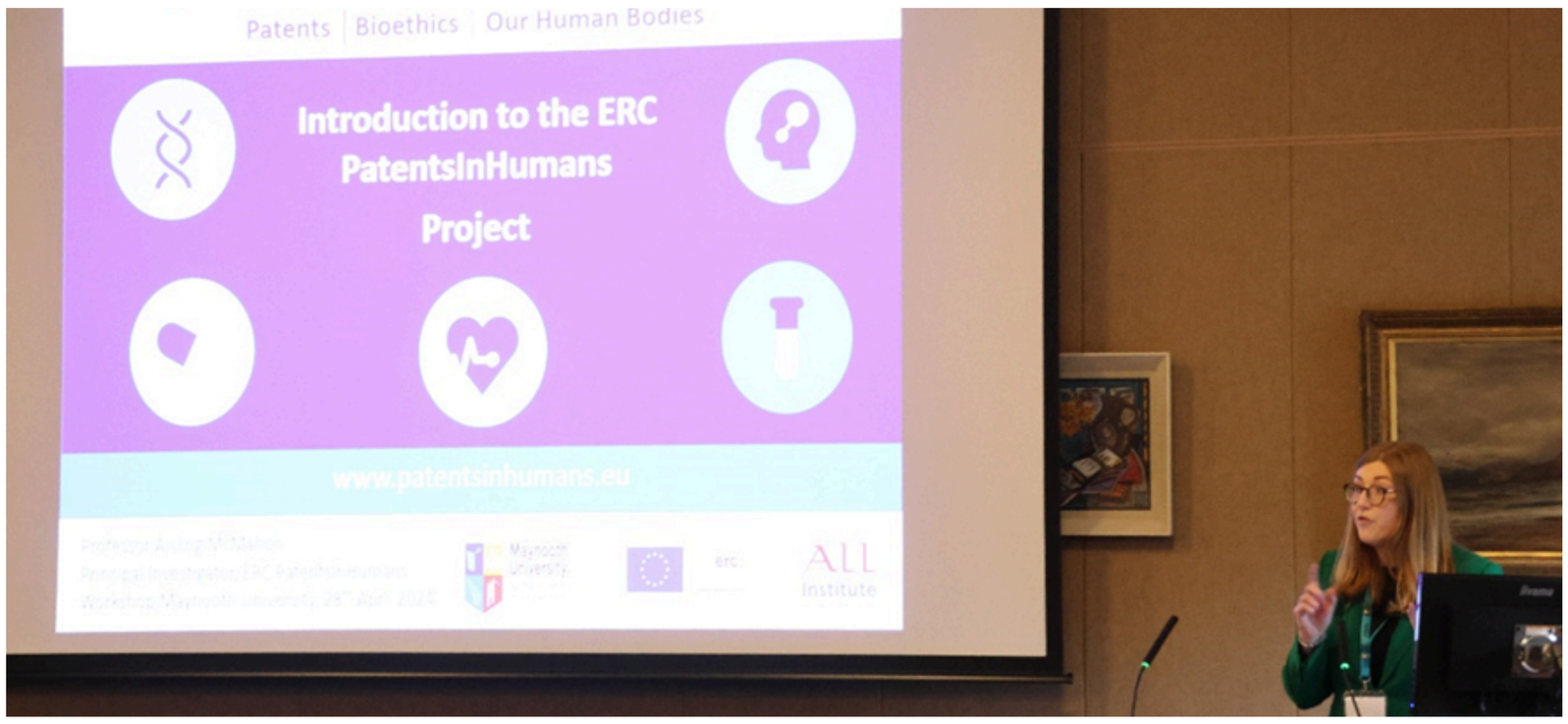
Day 1: 29th April 2024

Session 1: Welcome and Introduction to the PatentsInHumans Project

The workshop commenced on 29th April 2024 with an introduction and welcome to Maynooth University delivered by Dr Fergus Ryan, Head of the School of Law and Criminology, Maynooth University. Dr Ryan extended a warm welcome to all speakers and workshop attendees. He then provided an introduction and overview of the history of the University and School of Law and Criminology, and of the research and teaching achievements within the School of Law and Criminology. Dr Ryan then introduced the ERC PatentsInHumans team and provided a brief overview of the focus of the project and how this fits within the broader strengths of the University around interdisciplinary focused research and research focused on health and social justice themes evident across various disciplinary contexts within Maynooth University.

Following this, Professor Aisling McMahon, Principal Investigator of the ERC funded PatentsInHumans project, welcomed the participants to the workshop and gave a brief introduction and overview of the ERC PatentsInHumans project, sharing insights on the project's core research questions, and the preliminary findings emerging from phase one of the project. The PatentsInHumans project commenced on 1st November 2022, and at the time of the workshop it had reached the 18-months mark into the project. The project is a five-year interdisciplinary project which focuses on developing deeper understandings of the potential bioethical issues posed by the grant and use (including licensing and enforcement) of patents on technologies related to the human body, include medicines, vaccines, and medical devices. Ultimately, Prof McMahon explained that the project aims to bridge the gap between patent decision-making and bioethics thinking in this context, seeking to better understand the potential bioethical issues posed by patent grant and use over technologies related to the human body, and the avenues to bring bioethics understandings within decision-making systems for the grant and use of patents over such technologies in Europe.

Prof McMahon then provided an overview of the five category taxonomy of technologies related to the human body which the project examines, and potential bioethical issues which arise in each context, namely: 1) patentable 'technologies' that are in the body such as isolated human genes which are patentable in Europe; 2) patentable 'technologies' which are acting on the body, such as elements of diagnostic tests or surgical tools; 3) patentable 'technologies' that are outside body but which treat the body, such as medicines; 4) patentable 'technologies' that are integrated with the body, such as elements of medical devices; and 5) ''technologies' that can modify the human body or create beings 'akin to the body', such as neuro-technologies or various aspects of gene editing technologies. Prof McMahon provided a brief overview of the core focus of the project in each context, and some of the emerging bioethical issues and case studies arising within each context.



Having provided this overview of the core focus of the PatentsInHumans project, Professor McMahon then reflected on five key emerging preliminary findings arising from the first phase of project which include the following: First, the focus on the project is on the potential impact of patents over access, development, delivery and use of technologies related to the human body. However, as the research has progressed, an emerging finding is that in many contexts, patents are being used alongside other intellectual property rights to extend and maximize rightsholders legal control over various technologies. Thus, at times, it is not the operation of patent rights per se, but rather how such rights are strategically layered with other rights, and then used in practice, that can give rise to bioethical implications, including impacting how we treat, use and modify our bodies. For this reason, although the focus of PatentsInHumans is primarily on patents, where necessary, the interaction of patent law with other intellectual property rights will be considered, to the extent that this is relevant to deepening understandings of the bioethical issues emerging in various contexts. In doing so, the work will take a 'patents in context' approach, i.e. it will focus on patents, but look at such rights with an eye to the broader contexts within which they operate.

Second, the project focus is on the bioethical issues posed by patents over such technologies, however, in phase one, Prof McMahon noted she has considered the nature, meaning, and scope of 'bioethics' used in this context, and how this term can be differentiated from ethics or human rights issues. This theme was one that she had identified from the outset, and indeed, she noted that earlier versions of her project proposal framed the work as considering the (bio)ethical issues posed to denote this overlap around bioethics and ethics issues. As the project develops, this issue will be considered further.

Thirdly and relatedly, an emerging theme within the project in phase one is the blurring of classifications between what is deemed to be a 'technology' and what is part of the body and the significance of this for the purposes of patent law. Professor McMahon noted she has observed an oscillation in the status which can arise whereby the entity goes from being part of the body (which is not patentable) to a technology outside the body which is potentially patentable in certain contexts, to something which can again become part of the body. For example, she gave the example of the personalized cellular therapy context, where a cell/material is extracted from the body, then this biomaterial may be modified outside the body to develop a cellular product or technology, part of which may be subject to patent protection, and later, that product may be reinfused into the body becoming assimilated or part of that body. This blurring of boundaries between bodies and technologies is a critical consideration in the patentability of emerging technologies. This issue will continue to be considered within the project both in terms of its practical ramifications for patentability, and in terms of the normative status that human bodies/technologies have within contemporary patent contexts.

Fourth, she noted that within the access to health literature we often look at the impact of patents and other intellectual property rights at the final stage of the health innovation context, where there is a final product, e.g. a new medicine, and where difficulties in accessing that medicine may be caused (or contributed to) by how relevant patents and other intellectual property rights are being used. However, she highlighted that a key emerging project finding is that the potential impact of patents and bioethical issues that can arise are evident at all stages of the health innovation cycle. This finding will be explored further in emerging work. Professor McMahon concluded the presentation by highlighting the key future directions of the project, including the planned empirical work, and by welcoming comments/questions from the audience.

Session 2: Patents, Decision-Making Actors and Governance

The second workshop session featured papers by Dr Karen Walsh (Maynooth University) and Professor Duncan Matthews (Queen Mary University of London) which focused on the role of patent decision-making actors in how bioethical issues are engaged with in the European patent context, and the potential governance role of patent rights. These are key themes that are explored within the PatentsInHumans project specifically as they relate to the bioethical issues at stake.

Dr Karen Walsh's paper was entitled 'Exploring the Impact of Institutional Abundance on Ethical Decision Making in the European Patent System'' and it highlighted the range of decision-making actors involved in patent decision-making in Europe. Dr Walsh's paper demonstrated the range of actors involved in the patent arena in Europe, including: national patent offices, national courts, European Patent Office (EPO) Examination bodies, EPO Boards of Appeal, the Court of Justice of the European Union, and the Unified Patent Court. She argued that this can lead to an institutional abundance in the 'European' patent system, and then reflected on the potential impact of this on decision-making at pre-grant and post-grant stages in Europe. She highlighted the numerous links, overlaps and informal ad-hoc interactions between these adjudicatory actors and argued that we must consider the impact this is having on decision making, especially in relation to questions around the patentability of biotechnologies and ethical issues that may arise. She illustrated this point using a hypothetical scenario whereby the owner of a potential biotechnology invention may apply for and be granted a unitary patent covering participating EU members states. However, they may also apply for and be granted a national UK patent (which is outside the EU and therefore not a participant of the unitary patent system), and/or a patent in Spain, an EU State, which is not participating in the unitary patent agreement but remains bound by EU law. Using this hypothetical example, Dr Walsh highlighted the myriad potential institutional opportunities and complexities that can arise in such contexts.

The second paper was delivered by Professor Duncan Matthews (Queen Mary University of London) entitled 'The Patent Governance of Human Genome Editing'. He noted the potential use of CRISPR technologies for agricultural, health and other contexts. He highlighted the great potential of CRISPR technologies for editing out single cell gene mutations that are linked to genetic disorders such as Huntington's disease, cystic fibrosis or sickle cell anaemia. However, he cautioned that the potential benefits must be offset against the risks and uncertainties associated with such use because of unknown "off target effects" when genome editing is used to alter the germline genetic identity of human beings. He then highlighted debates on ethical issues related to CRISPR technologies in human genome editing contexts, and the consensus which emerged around not using such technologies for human reproductive purposes given the potential risks that may arise. Despite this, in 2018, He Jiankui announced that his team had used CRISPR genome editing in human embryos leading to the birth of twin girls. This announcement lead to significant criticism in particular due to the risks to the children born. Aside from the broader scientific and bioethical issues raised, he noted questions arise around the patentability of CRISPR technologies and the role that patents play in the governance of such technologies. He explained that patent system can assist with the governance and oversight of human germline genome editing but can also hinder that process if not deployed in a fair and equitable way. On the patentability of such technologies, he discussed the various questions that arise, including how the ordre public/morality exclusions under Ar 27(2) of the TRIPS Agreement (Art 53(a) European Patent Convention) - this allows States to refuse patentability for technologies whose commercial exploitation is deemed contrary to ordre public/morality - may apply to the patenting of CRISPR technologies. He also highlighted a White Paper, published in 2021 by a team of international researchers - led by Prof Matthews and which some workshop speakers co-authored - which examined the extent to which patents could be used in the governance of genome editing. This White Paper was cited as part of the World Health Organisation Report on human genome editing, and many of the recommendations proposed around the role of patents as an avenue to support broader systems for the governance of human genome editing were incorporated by this report. Professor Matthews concluded his presentation by highlighting contemporary developments and questions that remain in Europe around patents and genome editing such as how such patents may impact access to CRISPR related technologies, questions around patents in agricultural contexts, and the current litigation on patents over CRISPR technologies.

Session 3: Patents, Medicines and Access to Health

The third session of the day featured three papers which examined the potential impacts of patents on access to healthcare, and avenues to engage with such impacts.

The first paper was delivered by Dr Ciara Conlan, a medical doctor and a public health specialist. Dr Conlon is also a co-founder of 'Access to Medicines Ireland' and 'Doctor's for Vaccine Equity in Ireland' groups. Her paper was entitled: 'Patents & Access to Health: A Doctor's Perspective' and drew on Dr Conlan's experience working as a medical doctor and her research in the public health field. She focused on access to HPV vaccines in the cervical cancer context in low- and middle-income countries (LMICs). Dr Conlan first highlighted the considerable numbers of women in Malawi and other LMICs with advanced cervical cancer, where there are limited treatment options available to many patients diagnosed with such cancers. She noted that the country has one of the highest cervical cancer incidences and mortality rates in the world. There has been a highly effective HPV vaccine available globally since 2006. However, Dr Conlan noted that there has been a shortage of vaccine supplies globally, with lower income countries often most negatively affected by shortages of such vaccines, despite the healthcare needs. She noted that the vaccine shortage is expected to ease in 2024 due to new manufacturers entering the market. How patents (and other intellectual property rights) can be used over elements of such vaccines is one factor contributing to access and supply issues. Dr Conlan outlined the significant impacts the global demand for, and shortage of HPV vaccines can have in LMICs. Dr Conlan also highlighted the significant moral injury that clinicians may experience in such contexts, where they are aware vaccines are theoretically available and offered in other countries but may not be available in specific LMICs at particular times due to supply/access issues. In raising such issues, the paper highlighted the role patents can have in how patented health-technologies are allocated globally, and the broader health-related impacts that how patents over such technologies are used can have, including impacts on patients, healthcare systems, and healthcare practitioners.

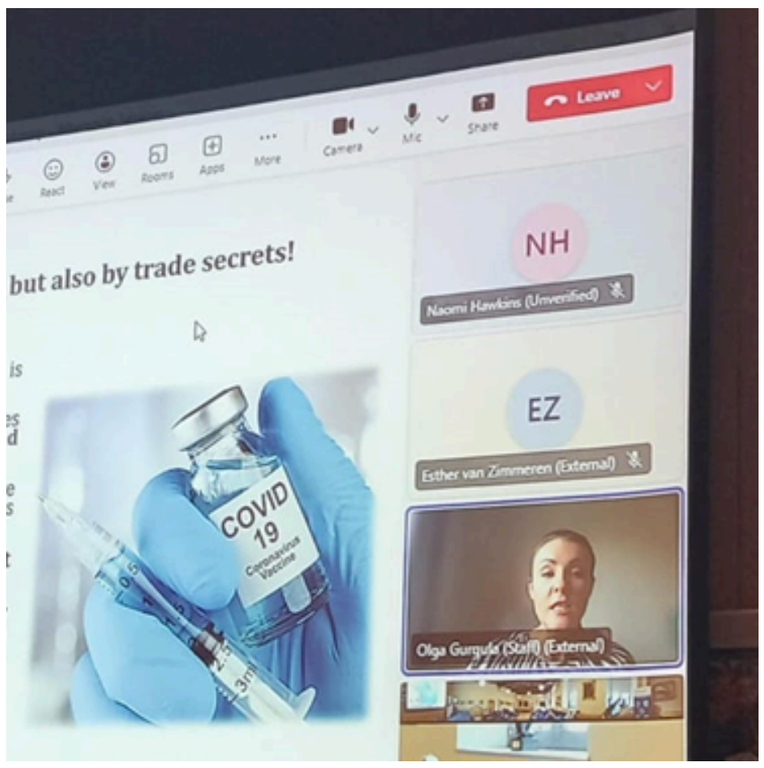
Following this, Prof Susi Geiger (UCD, Principal Investigator, ERC funded MISFIRES project) delivered a paper entitled 'Transparency Activism as a Flank Movement to the Patent-based Access to Medicines Movement' which drew on her recent work, including recently published papers in this field. In this context, Professor Geiger highlighted the focus on transparency within the drug pricing context, including the World Health Organization's adoption of a transparency resolution, which focused on transparency in the pricing of health-technologies. Professor Geiger then used the concept of 'radical flank theory'- the notion that different forms of activist movements can differentially shape broader social movements - to investigate the impacts the focus on transparency has had in shaping the broader access to medicines movement over time. She highlighted four waves of civil society access to medicines movements which have occurred over the past years, from the discussions on access to HIV medicines in the late 1980s to early 1990s, to discussion on TRIPS and access to health in late 1990s, to the third wave in 2000s involving the development of range of global institutions including GAVI, Medicines Patents Pool etc, to the most recent fourth phase where there has been a focus on high costs of personalised medicines. She concluded the paper by arguing that this focus on transparency has had a range of impacts in the access to medicines space, including giving States an avenue to argue for greater transparency on drug prices which revealed that some countries were paying more than other countries to access the same products. This led to new collaborations between States and civil society groups calling for transparency in the pricing of medicines. Moreover, it has led to a greater role for States in opposing not patents per se, but rather the various impacts that patents can have on pricing, competition, fair profits in the pharmaceutical context etc. She also noted that the transparency movement has led to greater activism by high income State actors, given the high prices of contemporary health-technologies in such States.

The third paper in this session entitled 'Should Human Dignity Play a Role in International Patent Law?' was delivered by Dr Emmanuel Oke (University of Edinburgh). Dr Oke set the context for the discussion by highlighting that contemporary developments in biotechnologies have led in some cases to moral opposition against patents over emerging biotechnologies in certain contexts, including around patents over human genome editing technologies, human embryonic stem cells and related technologies etc. A key element to this moral opposition is often based on arguments related to human dignity implications of the use of such technologies, or to the potential patentability of such technologies. Dr Oke highlighted that a key difficulty has been around how human dignity as a principle/concept can or should be defined, given that there is often no clear consensus on the scope of this concept or the grounds/scope of its application in patent law. Dr Oke's paper then explored relevant legal provisions within Europe, including, the morality provisions under Art 53(a) European Patent Convention and Article 6 of the Biotechnology Directive 98/44 EC, and under Article 27.2 of the TRIPS agreement, which enable States to deny patents where the commercial exploitation of the technology is against ordre public/morality. Dr Oke argued such provisions could be used to engage with human dignity considerations in such contexts. He examined examples in case law where 'human dignity' concerns have been raised in the patentability context to date. He concluded his paper arguing that human dignity is an important concept, which should be explored in greater detail within the patent context, including around the role and limits of denying patents in such contexts.

Session 4: Access to Health, Public Interests and Licensing Levers?

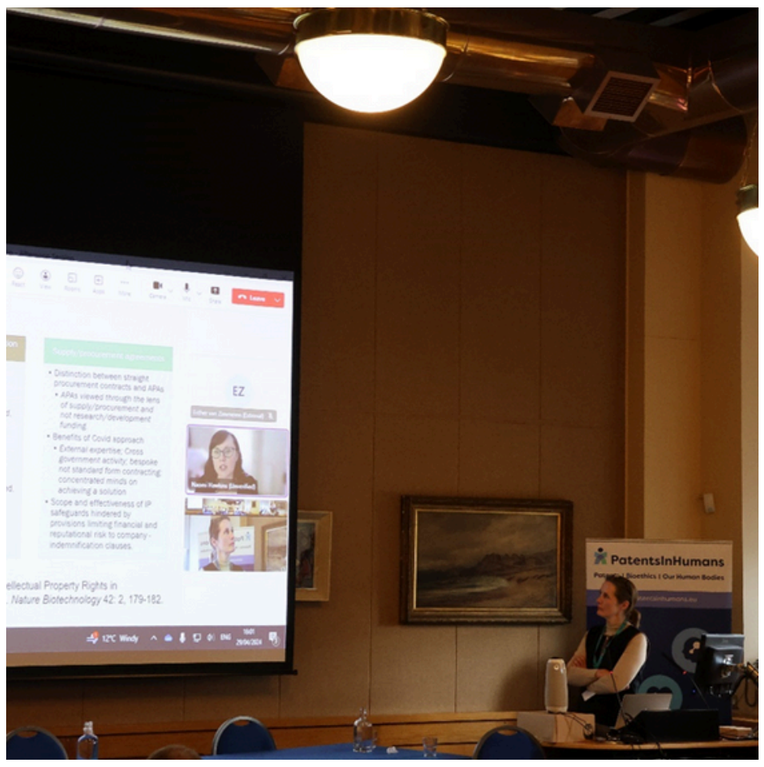
Following the lunch break, session four commenced which considered the role of patent licensing strategies to influence how patents over health-technologies are used, and how bioethical issues posed by how patents are used over technologies related to the human body are considered. It featured three complementary papers on this theme.

First, Dr Olga Gurgula (Brunel University) delivered a paper entitled "Compulsory Licensing and IP Waivers: The Role of IPRs in Pandemics and Wars?" Dr Gurgula discussed how we are living in a new era of health-emergencies, national disasters, and wars which can result in difficulties with access to essential goods such as food and medicines. She argued that access to medicines and other health-related technologies in such contexts can be impacted by how intellectual property rights (IPRs) operate over related technologies. She then made the case that the current intellectual property system was not designed for delivering equitable access to such technologies in this new era of emergencies. Dr Gurgula highlighted various mechanisms within international intellectual property law which could be used to address such access issues in times of war or crisis, including the security exemption under Art 73 of the TRIPS agreement, and compulsory licensing provisions for patents which offers avenues whereby a license can be issued without the rightsholders' permission in certain contexts.
. However, she argued that the Covid-19 pandemic highlights how these provisions are difficult to use in practice and in many cases impracticable. Dr Gurgula's paper concluded by discussing recent developments at a policy level during the COVID-19 pandemic including changes to domestic law, and remaining limitations. She then highlighted broader avenues to reform patent law flexibilities so that they can be used more effectively to ensure access to vital medicines during future pandemic or other emergency contexts.



In the second paper in this panel, Professor Esther van Zimmeren, (University of Antwerp) discussed "Responsible licensing or compulsory licensing for a more resilient health care system?" Her presentation focused on the role and potential use of responsible intellectual property licensing practices to strengthen the resilience of healthcare systems nationally and globally. Prof van Zimmeren indicated that existing provisions around compulsory licensing of patents are often framed as 'last resort mechanisms' however, she argued that such mechanisms could be used more broadly under existing laws. She then highlighted that recent proposals to address limitations within compulsory licensing avenues have often led to a narrow set of changes, including recent EU developments which have led to reforms that in practice are likely to only mainly benefit EU States. She then made the case that to deliver resilient healthcare systems given our globally connected worlds, we cannot only focus on the EU context and must instead look beyond this. Moreover, Prof van Zimmeren argued that to develop more resilient mechanisms, we must give greater consideration to the role of voluntary responsible intellectual property licensing regime(s)/practices which could be aimed at a range of actors and viewed as complementary to existing compulsory licensing and other mechanisms.

Finally, in the third paper in this session, Dr Alison Slade (University of Leicester) and Prof Naomi Hawkins (University of Sheffield) delivered a paper entitled "Safeguarding the public interest? Contracts, intellectual property rights and bioethics in translational R&D". In this paper, Professor Hawkins and Dr Slade discussed how during the Covid-19 pandemic, it became clear that commercial parties succeeded in embedding strong protection for patents and other intellectual property rights related to COVID-19 health technologies, into contracts for the procurement of such health-technologies. Focusing on the UK context, they argued that in many cases there was a failure of the State to consider broader issues around the downstream public access to health-technologies developed. For instance, during the COVID-19 pandemic context, they demonstrated how such procurement agreements embedded clauses which gave rightsholders extensive control over the redistribution of excess vaccines doses. Dr Slade and Prof Hawkins' paper highlighted the power and role of contractual provisions in such contexts which can have significant knock-on implications for access to healthcare and give rise to broader bioethical implications. They argued that there is a need for greater consideration of how to strike a balance between incentivising innovation around new health-technologies, including through intellectual property protection with also ensuring access to technologies developed. They recommended a series of safeguards should be considered and adopted in such contexts in order to balance public interests in access to and development of health technologies with private interests (and incentives) around the protection of intellectual property rights.



Session 5: Patents, Health & Emerging Considerations around Health Data and Artificial Intelligence

The fifth and final session of day one had two papers that examined topical emerging issues within the European patent context around data use/sharing in the health context and artificial intelligence, and the potential bioethical issues that may arise in such contexts.

First, Dr Ana Nordberg (Faculty of Law, Lund University) delivered a paper entitled "Health Data and Patent Rights" which focused on to what extent, if any, could relevant provisions in patent law, provide legal avenues to address or deter potential conflicts that can arise from unethical or illegitimate uses of health data within health research contexts or in the exploitation of a patented invention. She highlighted the potential risks posed by increasing uses of artificial intelligence tools in health research contexts in terms of data uses. She also discussed a range of contemporary health technologies which can lead to increasing uses/generation of health data, including wearable devices and implantable medical devices. She discussed current legal safeguards and the proposals contained within the European Health Data Space around uses of personal data. Dr Nordberg then discussed the extent to which European patent law, including provisions around ordre public/morality, and human dignity, could be invoked to deny/restrict patents in cases where data had been used in a manner that gave rise to ethical concerns (e.g. where there was inadequate/no informed consent for use of data). Having analysed relevant provisions and decisions which may apply a range of relevant scenarios, her paper concluded arguing there are a range of challenges related to the use of existing provisions within European patent law to respond to unethical uses of data in the health context.

Second, in the final paper of day one, Dr Mina Hosseini (Marie Skłodowska-Curie Postdoctoral Fellow, School of Law, University College Dublin) discussed "AI's Waltz with IP and Antitrust in the Biopharmaceutical Sector: A New Choreography for the Post-Pandemic Regulatory Agenda?" Dr Hosseini focused on the potential role of artificial intelligence (AI) in facilitating drug development and potential issues that may arise in such contexts for the purposes intellectual property rights and competition law. She highlighted that AI technologies are now being used in many areas of health innovation including to increase opportunities for and the speed of research and development and drug discovery, manufacturing, and post marketing monitoring. Dr Hosseini gave various examples to highlight the benefits that AI can have for research teams to generate more products at a faster scale. However, she then argued that this gives rise to questions for intellectual property law, as if innovation has become easier with AI, questions arise around if innovations contributed to by AI should be protected by patents, and in what contexts. Relatedly, if protected by patent rights, she argued that questions arise around if we still need a 20-year term of patent protection, or could we reduce it, and the impacts this protection can have on patients' access/use of such health-technologies? Such questions relate to the balance to be struck between protection of patent rights and broader public interests at stake. Dr Hosseini put forward proposals to address such issues. Moreover, she highlighted that the use of AI technologies in health innovation contexts could give rise to anti-competitive practices. She argued that strategies are needed to address such issues, including building a case for transparency clauses for products developed by AI, and the need for strategies to address the potential for discrimination where AI technologies are used in health research.

Day 1: Optional Guided Group Tour, Russell Library, Maynooth University

At lunchtime there was an optional guided tour of the Russell Library, Maynooth University for attendees. The Russell Library houses the historical collections of St Patrick's College, Maynooth which was founded in 1795, for more information see here. The tour provided an overview of the history of the library, and some of the collections contained within it.

Group Photo: Optional Tour Russell Library, Maynooth University. Featured: (from left to right): Dr Roisin O'Flaherty; Dr Ana Nordberg; Dr Abby Rekas; Dr Ciara Conlan; Dr Phoebe Li; Dr Lawrence Cullen; Professor Susi Geiger; Dr Opeyemi Kolawole; Professor Duncan Matthews, Professor Aisling McMahon.

Day 2: 30th April 2024

Session 6: Patents, Technological Change, Exceptions & Reforms

Day two of the workshop opened with a session which explored three papers on topics related to 'Patents, Technological Change, Exceptions & Reforms'. First, Professor Paul Torremans (School of Law, University of Nottingham) delivered a paper entitled 'The morality of embryonic stem cell patents: time for a reboot?' In this presentation, he examined relevant case law considering the applicability of Article 6 of the Biotechnology Directive 98/44EC to human embryonic stem cell related technologies in Europe. He highlighted that considerations of 'human dignity' are outlined within the text of the Directive, and that 'human dignity' is a central principle alluded to in many cases, such as Brüstle around whether or not human embryonic stem cell related technologies should be patentable.However, he then noted that there is limited consensus on the concept of 'human dignity' or what it should mean in this context for the purpose of patent law. Prof Torremans argued that it is also not clear whether this refers to 'human dignity' as it may relate to an embryo, or humankind more generally? He highlighted the potential for different outcomes on the patentability of technologies depending on how human dignity is conceptualised. Moreover, Prof Torremans highlighted the complex ethical questions that can arise in such contexts, and probed the impacts that may arise where technologies are not patentable. He also discussed emerging technologies such as CRISPR technologies, the health benefits they may have, and impacts of Article 6 on the patentability of such technologies. Prof Torremans concluded his presentation questioning whether the time has come for a reconsideration of rules around the patentability of technologies involving human embryonic stem cells in certain contexts, and the role of 'human dignity' considerations are playing in European patent law.

The next paper was delivered by Dr Phobe Li (School of Law, Politics and Sociology, University of Sussex) entitled 'Patent Exceptions in a Deglobalised World'. Dr Li commenced her presentation by highlighting a recent EU Commission Recommendation on critical technologies which highlighted that given rising geopolitical tensions security and other risks may arise around certain economic activities and technological flows. Four key technological areas were identified within this recommendation as posing potential risks, namely, in contexts related to artificial intelligence technologies, quantum computing technologies, semi-conductors and biotechnologies. Such developments highlight the tensions arising in the current global geopolitical climate, which are further exacerbated by conflict and war. Against this geopolitical backdrop, Dr Li highlighted questions can also arise in the intellectual property context around how the security exception under Art 73 of the TRIPS Agreement is interpreted in patent law. This provision allows States to take measures necessary for their security interests, including as they relate to protection of intellectual property rights. Furthermore, Dr Li noted the UK's departure from the European Union (EU) legal framework has meant that there is ongoing uncertainty in some contexts around whether the UK will continue to adopt similar legal approaches to the EU (given that it is no longer legally obliged to do so), including in patents (and other IPRs) contexts over critical technologies. Dr Li concluded by providing examples within international and UK post-Brexit trade agreements to highlight key tensions/considerations in emerging frameworks, including around the development/use of the national security exemption under Art 73 of TRIPS.

The third paper in this session was delivered by Dr Luke McDonagh (London School of Economics) and focused on "Revitalising Compulsory Licensing. Prospects in the UK, EU and Beyond." Reflecting again on similar themes raised in day one of the workshop around the role and limits of licensing strategies to address bioethical issues including access to health issues posed by patent use, Dr McDonagh's paper argued that the current compulsory licensing system is inadequate for a range of reasons, including because it applies only to patents. Compulsory licensing over patents is useful in particular for small molecule drugs which are easily reverse engineered. However, he highlighted that many vaccines (including COVID-19 vaccines) are complex biologics which are difficult to reverse engineer without other information around the manufacturing process which is typically protected by trade secrets. To address such issues, in a recent paper with Dr Gurgula, he noted they have proposed the need for a new legislative mechanism to reform compulsory licensing in the UK. Dr McDonagh outlined the key components of this proposal and the proposed mechanisms set out to enable the UK government to make an order for the compulsory licensing of trade secrets and waiving of applicable regulatory exclusivities (where relevant) to accompany a compulsory license for patents over a medicine/vaccine in certain contexts. Dr McDonagh argued that this could be used to ensure that the compulsory licensing system is more practically useable for the contemporary health innovation contexts to address access to health issues that may arise, including for future health emergencies.

Session 7: Patents, Medical Devices & Access to Health.

The second session on day two brought together three complementary papers which focused on intellectual property aspects related to the development and use of medical device technologies, and role of open-source models to encourage the development of medical device technologies. The first paper was delivered by Professor Aisling McMahon (ERC Principal Investigator, PatentsInHumans Project) and Dr Opeyemi Kolawole (Postdoctoral Researcher, PatentsInHumans) entitled 'The Role of Intellectual Property Rights over Medical Devices:Patents, Human Bodies, Technological Integration and Bioethical Implications' which aimed to set the broader context for the discussion. This paper highlighted that a range of medical device technologies are now 'integrated' with/in the human body (see: Quigley and Aydihongbe, 2018) for example, pace-makers or other devices which are designed to be implanted in the human body and restore our bodies healthy functioning. Focusing on such 'integrated' medical device technologies, they argued that important questions arise around how intellectual property rights over such technologies are used in such contexts and the extent to which this use gives rise to health/bioethical implications. Prof McMahon and Dr Kolawole provided an overview of the potential intellectual property rights that can apply to integrated medical devices, then focusing on patents as a case study, they argued that how such patents can be used can give rise to a range of bioethical issues, including impacting how devices can be developed, accessed, repaired/replaced, or used. The paper put forward a case for why greater consideration of the potential bioethical issues posed by how IPRs can be used over such medical devices is needed.

Next, the second paper was delivered by Dr Trevor Vaugh, (Design Innovation Maynooth University; Public Service Design Lead in the Department of Expenditure, NDP Delivery & Reform, Ireland; & Medical Device Innovator) entitled "Impacts of Patentability on the Development & Design of Medical Devices: An Inventors Perspective". Dr Vaugh reflected on his work as a medical device inventor, and focused on the potential impacts that intellectual property rights can have in how medical devices are designed. Using examples in the surgical robotic context, he highlighted how existing patents can require inventors to consider and in some cases design around such patents or other intellectual property rights. This can impact and shape key aspects of the development of such devices, for example, ensuring that new devices do not infringe existing intellectual property rights. Moreover, the early design process, companies will often be considering how their planned device or other technology could be protected by intellectual property rights to generate profits and a broader income stream from such technologies. He argued that such considerations are particularly critical where design is focused around profit. Dr Vaugh then highlighted how technological design can also be focused from the outset around other factors. Here he focused on projects where the design of devices is oriented towards a specific human-centred purpose. Drawing on his work as part of the Big-Life-Little Fix RTE documentary series where he brings together experts who work together in an altruistic manner as part of a design thinking process to develop solutions for individual users' needs. Using three real-life-examples featured on the programme, he highlighted the significance of putting individual users needs at the centre of a design process for medical devices and how this can lead to technological avenues which can significantly benefit users' quality of life. Ultimately, his paper concluded by highlighting the benefits of human-centred design systems focused on design for progress, where innovation is driven by insights around human behaviours, delivering benefits to address human needs in the medical device space.

The final paper of this session was delivered by Professor Muireann Quigley, (Law School, University of Birmingham; Principal Investigator, Wellcome Trust funded Everyday Cyborgs Project) and Dr Shane O'Donnell, (University College Dublin) on the topic of 'Open Source & Commons-based Innovation in Diabetes Care: Lessons from the #WeAreNotWaiting Community'. Professor Muireann Quigley and Dr Shane O'Donnell discussed how the #WeAreNotWaiting community emerged within the diabetes community – this is a group of people living with (mainly Type 1) diabetes whose medical needs mean they must monitor their glucose levels daily and administer exogenous insulin to avoid serious (in some cases fatal) health repercussions. In the absence of technological solutions from commercial providers, the community started to work together as a commons to create technological solutions to better meet their individual (and collective) needs. This resulted in the community developing automated insulin delivery systems, along with other tools, to better manage their condition. These systems and tools were developed in a collaborative and open-source manner so others could use the systems and develop them even further. Prof Quigley and Dr O'Donnell provided examples showing how the #WeAreNotWaiting movement led to significant changes within the diabetes care landscape. Previously, diabetes care tools were developed primarily in the domain of the private industry, with products often ringfenced through intellectual property protections, including patents and trade secrets. They discussed recent developments in the field using open-source models to develop medical devices in the diabetes context and concluded by highlighting alternatives to the traditional commercial sector models to develop medical devices (in the software and hardware contexts) for users' needs. Their paper highlighted how the diabetes commons example can provoke us to reimagine technological developments in the medical device contexts, and to reconsider the role that open-source models and intellectual property rights play.

Session 8: Alternative Pathways - Open Source Biotechnologies

After lunch on day two, the final paper in the workshop was delivered by Professor Jorge Conteras (University of Utah) and was entitled 'What is Open Source Biotechnology? Professor Contreras's discussion focusing on the role of and contemporary developments around open-source models for biotechnological innovation, such as in vaccine contexts. Prof Contreras first traced the development of the open-source movement through software, open science, and open-source pharma. Prof Contreras highlighted that when the movement began, a key focus was around freedom. However, overtime he argued that this motivation is shifting from freedom for developers to how open access models can facilitate greater downstream access to technologies developed. He provided a number of recent examples of open-source initiatives in the biotechnological context, including the Open Source Drug Discovery Project (2000s)(India), Open Source Pharma Foundation (2018) (US/India), Open Malaria project, and then considered recent examples, of open source models in the COVID-19 vaccine contexts. Using these examples, he highlighted some of the benefits and opportunities presented by open-source models for biotechnological development. Prof Contreras concluded by arguing that although the open-source biotechnology movement was inspired by the FOSS/OSS development, it has shifted from a focus on developer freedom to a focus on social justice-based considerations, including around how open-source models may facilitate greater access to technologies developed including in the recent open-source vaccine contexts.

Session 9: Round Table Discussion: - Patents, Licensing & Bioethical Considerations: Perspectives from Practice

The workshop concluded with a roundtable discussion chaired by Prof McMahon, which brought together experts working in a range of relevant areas of practice (broadly defined) including: technology transfer and commercialisation, patent examination, patent litigation, and health research ethics contexts. This roundtable aimed to encourage reflections on whether, and to what extent, bioethical issues (including access to health issues) are posed by the grant and use of patents over technologies related to the human body, based on panelists experiences in their relevant fields, the types of issues that may arise, and avenues that are/can be used to address these challenges. Roundtable Speakers were as follows (listed in alphabetical order by surname: Peter Conlon (Director, MaynoothWorks, Maynooth University, & Registered Technology Transfer Professional); Dr Lawrence Cullen, (Deputy Director, Biotechnology, Pharmaceuticals & SPCs, UK Intellectual Property Office): Dr Eimear Sampson, (Director Definition IP, Patent Attorney, CPA, EPA, IEPA, Irish Trade Mark Attorney, Registered European Trade Mark and Design Attorney, European Patent Litigator); and Dr Emily Vereker, (Head of the National Office for Research Ethics Committees in Ireland (NREC)).

The discussions reflected workshop participants personal views and are not a reflection of the views/position of any organisation. This section provides a summary of some of the main themes raised in the roundtable discussions and the question/answer session with workshop participants.

The roundtable discussion started with a general opening question which invited panelists to share any reflections they may have on the potential bioethical and broader access to health issues posed by patent grant and use over technologies related to the human body. A wide range of considerations were raised in this context, including: the role and limits of the patent grant system to incorporate bioethical considerations, including for example, whether morality/ordre public provisions should be used to deny patents over certain technologies; how commercialisation strategies in technology development may impact the types of technologies developed in the health contexts; relatedly, whether other models of funding may be needed in the health contexts to diversify the types of technologies being developed including for neglected diseases; at post grant stage, the discussion considered factors that can drive how patents are licensed and used, including the role that reputational factors can play in how potential bioethical issues are engaged with; consideration was given to the role of valorisation in EU discussions on technology innovation, with an emphasis on how to maximise broader societal benefits from technologies, and questions around how this may impact how patented technologies are licensed; finally, the panelists discussed the potential impact of the overlapping decision-making frameworks in the European patent system, and how the different adjudicatory bodies which exist in this context (including national patent offices, European Patent Office, Unitary Patent Court, Court of Justice of the European Union) may interpret how (bio)ethical issues can/should be considered within European patent law under relevant patent exclusions.

Next, the panel considered any potential challenges and/or opportunities to engage with bioethical issues posed by patent grant or use over technologies related to the human body in Europe. Discussions again focused on a range of issues, including: the early stage at which patents need to be applied for in practice, and how this can pose challenges because bioethical considerations may emerge at a later stage as more is known about a technology or how patents strategies develop, such issues therefore may warrant consideration at later stages; several panelists highlighted the balancing act that is needed around role of patents as incentives for certain types of technological development and impacts that certain patent uses can have on access to patentable health-technologies; consideration was given to avenues post-grant to engage with access to health issues, including, the role of patent pooling/licensing in enabling broader access to health-technologies. Panelists also noted the importance of and legal requirements around ensuring adequate informed consent within health research and the need for informed consent for research conducted to apply for patents over technologies developed using this research. Relatedly, there was a discussion on health research contexts and need to manage participant/public expectations around access to technologies developed, and the importance of public trust. Moreover, reputational drivers were again highlighted around how entities may consider future potential bioethical issues that may arise and mitigate against reputational risks of using patents/patentable technologies in certain ways.

The panel were asked to considered, the main current or likely future challenges which may give rise to bioethical issues in the patent grant/use contexts, here the discussion focused on issues including: the role of data generated through use of certain contemporary technologies, how such data is controlled, how IP protections interact with other legal protections for data use/sharing in such contexts; the role of artificial intelligence in health innovation systems, and how this may pose issues around patentability and bioethical issues; the role of open source innovation, how this may be a tool to democratize science which can pose opportunities and challenges; the changing nature of biotechnologies and bioethical issues which can emerge around patentability of biotechnologies; the contemporary health innovation system for the development of new health-technologies, and how the experiences of patients are considered in such contexts; and, finally, the need to consider how patent law interacts with other legal protections, including regulatory exclusivities in the health innovation context, and impacts on access to health-technologies developed.

Finally, the roundtable discussion was opened up to questions/comments from workshop participants which focused on a range of issues including: whether or not the current patent system is incentivizing the right types of health-technologies based on health needs, and in what contexts; whether prizes or other mechanisms could be used instead or in addition to the patent system to encourage the development of needed health-technologies; the role that public funding in health research and innovation plays, and the impact of public-private partnerships in health-innovation including, on the types of conditions adopted around access to technologies developed; the role of the patent system and of other avenues outside patent law, such as ethics committees in considering how patentable technologies can be used; and the changing nature of emerging technologies and how this can impact patentability questions in Europe.

Image: (Participants in Round Table Discussion: Left to right): Dr Lawrence Cullen; Dr Emily Vereker; Dr Eimear Sampson; Peter Conlon

Image: A selection of workshop speakers and participants at the workshop on day two.