

### Year 2 Project Report

### Principal Investigator

Professor Aisling McMahon April 2025











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## PatentsInHumans Introduction

PatentsinHumans is a five-year interdisciplinary project funded by a European Research Council (ERC) Starting grant led by Professor Aisling McMahon, School of Law and Criminology, Maynooth University, and ALL Institute, Maynooth University. The project commenced on the 1st of November 2022. This report provides an overview of the project focusing on the core project research and activities during the second year of the project (November 2023 to November 2024). We will also outline some of the key research activities and events we are planning over the coming year.





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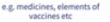
## PatentsInHumans Project Overview

The overarching research objective of the PatentsInHumans project is to develop a comprehensive understanding of the potential bioethical issues posed by patents, and how such patent rights are used, over 'technologies' related to the human body. It aims to understand whether, and to what extent we can – or should – better embed such bioethical considerations in patent decision-making, and related systems.

Five key categories of 'technologies' related to the human body will be examined



Patentable technologies which treat the body





technologies which act on the body e.g. elements of diagnostic tests



Patentable technologies that are in the body e.g. isolated human genes



Patentable technologies that can be integrated with the body e.g. elements of medical devices, prosthetics etc.



Patentable technologies that are akin to the human body or which can modify the body e.g. neuro-technologies, gene editing techniques etc.

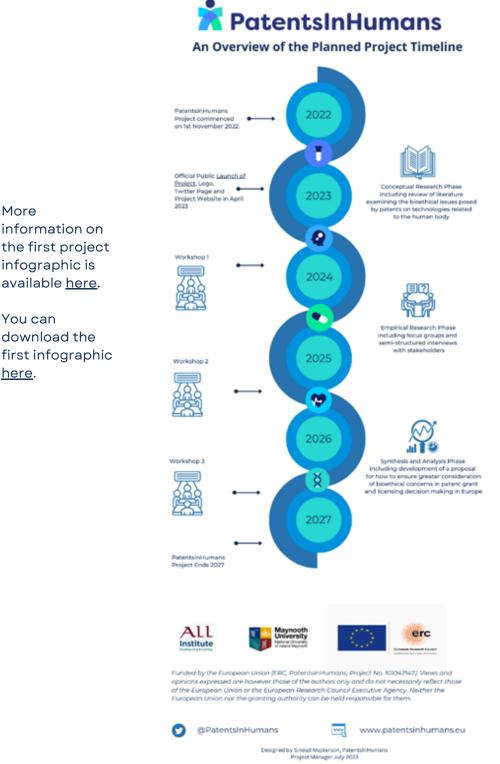
Patents allow rightsholder(s) to exclude or stop others from using a patentable technology for the duration of the patent term (generally 20 years). Accordingly, patents over technologies related to the human body, and how such rights are used, can impact how we treat, use and modify our bodies, with a range of potential bioethical implications, including implications for autonomy, dignity and bodily integrity interests.

The project will interrogate to what extent such bioethical issues are considered, if at all, within European patent decision-making systems focusing on these types of 'technologies'. Ultimately, the project aims to reimagine European patent decision-making towards a person-centred approach which further embeds bioethical considerations at patent grant and use stages (i.e. licensing and enforcement of patents) and related decision-making systems, where appropriate, for such technologies.

Overall, PatentsInHumans core objective is to disrupt traditional conceptions within patent law, bioethics and health innovation. It challenges how we view the role of bioethics within patent decision-making and how bioethical issues are considered within the broader health innovation cycle for such technologies. In doing so, the project seeks to encourage greater interdisciplinary conversations and scrutiny around the role of bioethics in how patents are granted and used over such technologies.

## **PatentsInHumans Project Overview**

To achieve these aims, PatentsInHumans is designed around three main project phases which were summarised in the first project infographic:



More information on the first project infographic is

You can download the first infographic here.

### PatentsInHumans Our Team



### **PROFESSOR AISLING MCMAHON**

PRINCIPAL INVESTIGATOR

<u>Professor Aisling McMahon</u> is a Professor of Law at the School of Law and Criminology, Maynooth University. Her research interests focus on health law, patent law and the regulation of emerging health-technologies. Aisling has published widely on these issues within leading international peer reviewed journals. In April 2024, she was appointed by the Minister for Health as a member of the Irish National Research Ethics Committee for Clinical Trials. She is a member of the International Editorial Advisory Board of the <u>Medical Law Review</u> & Legal Studies. In 2024, she was awarded Maynooth University's <u>Mid Career Research Achievement Award</u>. She previously held academic positions in Durham University and Newcastle University.



#### **DR OPEYEMI KOLOWOLE** POSTDOCTORAL RESEARCHER

<u>Dr. Opeyemi Kolowole</u> completed his doctoral program at Sutherland School of Law, University College Dublin prior to joining the PatentsInHumans Project in November 2022. His research interests intersect intellectual property rights, international trade, and development. Opeyemi obtained his LL.M degree in Intellectual Property and Information Technology Law (IP/IT) from the Sutherland School of Law, University College Dublin and his LL.B degree from Obafemi Awolowo University, Ile-Ife, Nigeria. In 2015, he was called to the Nigerian Bar as a Barrister and Solicitor of the Supreme Court of Nigeria.



#### SINÉAD MASTERSON PROJECT MANAGER

<u>Sinéad Masterson</u> is a scientist and project manager who also joined the PatentsInHumans Project in November 2022. Prior to joining the project, Sinéad worked extensively in the regulation of substances of human origin (used in human application) at the Health Products Regulatory Authority, as Blood, Tissues and Organs Section Manager and Inspector for over 10 years. Since 2016, she has been working as an external consultant collaborating in several high-profile projects with the European Commission (DG Santé) and the Council of Europe (EDQM). Sinéad completed her BSc. in Pharmacology and Chemistry at UCD and her MSc. in Biomedical Science with the University of Ulster and holds a PGDip. in Project Management from the Institute of Business and Technology Dublin.

## PatentsInHumans

### **Welcome New Team Members**



#### LAUREN KANE

#### RESEARCH ASSISTANT

Lauren joined the PatentsInHumans team as a research assistant in December 2024. She previously graduated from Maynooth University with first class honours in both her Bachelor of Laws (LLB) degree and Master of Laws (LLM) degree in Global Legal Studies. Her LLM dissertation focused on the bioethical and legal issues related to the regulation of heritable germline genome editing (HGGE) technologies for reproductive purposes, with a particular focus on human rights implications. In addition, Lauren has previously worked as a research assistant on the Irish Research Council funded 'Advanced Cancer Care: Enhancing Systems and Structures to Deliver In-House Personalised Therapies for Patients via the Hospital Exemption' (ACCESS) project, and the Irish Research Council and Rape Crisis Network Ireland (RCNI) funded 'On Relevance and Consent: Interrogating the Uses of the Victim's Previous Sexual History Evidence in Serious Sexual Offences Trials' Lauren is primarily interested in the legal and ethical issues raised by emerging biotechnologies, including considerations around access to healthcare technologies and social justice.



#### SHARON ADEDAPO

#### RESEARCH ASSISTANT

Sharon Adedapo joined the PatentsInHumans team as a Research Assistant in January 2025. She holds a Master of Laws (LLM) from the London School of Economics and Political Science (LSE) and a Bachelor of Civil Law (BCL) in Law and Business (first class honours) from Maynooth University. Sharon's academic and professional experience centers on legal research, with a particular focus on the intersection of intellectual property law, human rights, technology, and ethics. Sharon has recently worked as a legal intern with the World Bank's LEGAM (Middle East & Africa) practice group and at a leading international law firm in the Intellectual Property and Technology Practice Group. Sharon previously held the role of Director of Communications with the European Law Students Association (ELSA) Ireland. ELSA's main aim was to promote academic excellence, professional development, and social responsibility among law students and lawyers. Sharon is passionate about exploring the ethical implications of emerging technologies and their impact on society. She is excited to contribute her skills and expertise to the PatentsInHumans project, with a particular interest in examining the bioethical dimensions of patenting emerging health technologies.

### **PatentsInHumans** Research Activities - Year 2

Building upon work in year 1, a key part of the research in year 2 focused on developing deeper understandings of the potential bioethical issues posed by patents over technologies related to how we treat, use and modify the human body. Research was conducted to develop a deeper understanding of scope of the 'bioethical' implications which can arise in such contexts, and how 'bioethics' as a term is defined within the project. Relatedly, Prof McMahon developed further her research refining the five-category taxonomy used within the project of patentable 'technologies' related to how we treat, use or modify the human body, namely: 1) patentable 'technologies' that are derived from the body such as isolated human genes which are patentable in Europe; 2) patentable 'technologies' which comprise of tools acting on the body, such as tools used in diagnostic or surgical processes; 3) patentable 'technologies' that are chemical substances created outside the 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' which are intended to be used in ways that can enhance the human body, or alter the creation of future human life. The research led to refining of category 5, as although some technologies within categories 4 and 5 may overlap (such as where technologies have dual uses), for the purposes of category 5 the project is interested in the distinct bioethical implications posed by patents over technologies which are intended to be used in ways which could enhance the body in significant ways, or technologies that are intended to be used to create/change human life, such as in the assisted human reproductive or gene editing contexts.

During year 2, the project team continued to research the bioethical issues posed within each of these five categories. For instance, we developed deeper understandings of how patents (and other IPRs) can be used in the 'integrated' medical device contexts, building upon <u>Quigley and Aydihongbe</u> conception of 'integrated' goods in that context (2018) which illuminated challenges posed for law by such integration. We have an article (forthcoming in Medical Law Review) which provides a critical analysis of patents/IP in such medical device contexts. We also developed case studies within each of the categories examined which will be used to further probe the bioethical issues posed in each context, and as part of empirical work in the project.

At an institutional level, the project continued to explore avenues within and outside patent law, which could be used to engage with bioethical issues posed by patent use. As part of the work, research was conducted examining the role and limits of competition law, human rights and various patent licensing approaches to engage with potential bioethical issues that can arise. We also explored avenues relevant to specific technological categories, such as tailored injunctions against infringement, and rights to repair. The project will continue to explore how a range of avenues may be used to engage with bioethical issues posed by patent grant/use as identified in phase one of the research.

### **PatentsInHumans** Research Activities - Year 2

Furthermore, the impact of patents is often considered primarily 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 arise. However, 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, and can be impacted by a broad range of actors/systems. Thus, the project research is examining other stages/actors within the health research context which could be used to engage with bioethical issues posed by patent grant/use over the technologies considered.

For instance, in year 2, we examined biobank donation including considering the frameworks applicable for how patents (and other IPRs) over downstream technologies developed are discussed with potential donors to biobanks. In April 2024, we published an article in the Medical Law Review examining the bioethical issues which may arise in such contexts. The article argued that a more holistic approach is needed, probing the role biobanks could play in shaping access to downstream health-technologies whose development is contributed to by use of biobank samples.

Alongside this, the project research has continued to develop the theoretical institutional framework for considering how decision-making actors and other institutional factors may influence the interpretation of relevant patent law provisions and the operation of patent law in practice. This research within each workpackage on bioethics, institutional factors and governance, has strengthened our conceptual understandings, which is critical prior to embarking on empirical work within the project. In year 2, we commenced examining licensing policies and documents to consider how these engage with bioethical issues posed in certain contexts. We have also commenced work on refining the design of focus group/interview empirical work, in light of the emerging case studies and theoretical/conceptual foundations.

In year 2, the team has continued to disseminate research findings, this year we published 10 written publications including: two journal articles, a book chapter, an article in the Law Society Gazette (Ireland), three blog articles and two reports. The team delivered 16 presentations including 9 invited seminars/presentations delivered by Prof Aisling McMahon, and 7 conference presentations (by Dr Opeyemi Kolawole and Prof Aisling McMahon).

We are delighted to welcome two new team members as we enter year 3, Lauren Kane and Sharon Adedapo (Research Assistants), and look forward to working together on the PatentsInHumans project in year 3!

## **PatentsInHumans** First International Conference

On 29th and 30th April 2024, the PatentsInHumans team hosted the first interdisciplinary project workshop organised as part of the ERC PatentsInHumans project. The workshop took place in Renehan Hall, Maynooth University. Over the course of two days, the workshop brought together twenty-five 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 were as follows (in order of appearance on the programme): Professor Aisling McMahon (Maynooth University); Professor Fergus Ryan (Maynooth University); Professor Duncan Matthews (Queen Mary Intellectual Property Research Institute, London); Dr Karen Walsh (Maynooth University); Dr Ciara Conlon, (Public Health Specialist, HSE, Ireland); Professor Susi Geiger (University College Dublin); Dr Emmanuel Oke (University of Edinburgh); Dr Olga Gurgula (Brunel Law School, London); Professor Esther van Zimmeren (University of Antwerp); Professor Naomi Hawkins (University of Sheffield); Dr Alison Slade (University of Leicster); Dr Mina Hosseini (University College Dublin); Dr Ana Nordberg (Lund University); Professor Paul Torremans (University of Nottingham); Dr Phoebe Li (University of Sussex); Dr Luke McDonagh (London School of Economics and Political Science); Dr Opeyemi Kolawole (Maynooth University); Dr Trevor Vaugh (Maynooth University); Professor Muireann Quigley (Birmingham University); Dr Shane O'Donnell (University College Dublin) and Professor Jorge Contreras (University of Utah). Alongside this, five leading experts spoke at our panel discussion on bioethical issues posed by patents (detailed below).

### **PatentsInHumans** First International Conference

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 over forty people, drawn from a range of academic disciplines and practice.



Prof. Duncan Matthews Queen Mary University of London

Dr Mina Hosseini University College Dublin

Dr Ana Nordberg Lund University

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 discussion included 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 panellists 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)).

A full report of the First International Workshop is available **here**.

## PatentsInHumans

### **Dissemination Activities - Year 2**

During the second year of the project, the project team presented research findings at a total of 16 national and international events, including 7 international conference papers, and invited seminars/research events related to the project.

#### **Invited Research Presentations and Seminars**

PatentsInHumans) delivered Professor Aisling McMahon (Pl 9 invited presentations/research related seminars on her research to the PatentsInHumans project in the second year of the project, at a range of national and international research events, including at events organised in/by the World Intellectual Property Organisation (WIPO) Summer School of Intellectual Property Law; Durham University; Lancaster University & Dalhousie University, Canada.

A full list of invited presentations/seminars is as follows (listed below in reverse chronological order, with the most recent presentation listed first):

- Aisling McMahon, Panel Discussion: Cell and Gene Therapies IP Challenges, Cell and Gene UK Conference 2024, London, 6th November 2024 (Invited Panel Speaker)
- Aisling McMahon, "Delivering Sustainable Pathways For The Provision Of CAR-T Therapies To Patients: Legal, Ethical, And Regulatory Challenges And Opportunities" 8th November 2024, Cell and Gene UK Conference 2024, London, 6th November 2024 (Invited)
- Aisling McMahon, Invited Panel Speaker, Forum on the Future of Irish Bioethics Event, Royal Irish Academy, Dublin, Ireland (30th October 2024) (Invited Panel Speaker)
- Aisling McMahon, 'Patenting of Biotechnologies in Europe: The Biotechnology Directive' World Intellectual Property Organization Summer School organised in co-operation with Zhongnan University of Economics and Law (ZUEL), Wuhan China (Invited) (Online Presentation) 10 July 2024.
- Aisling McMahon, "Patents & IVG Technologies within Europe: Definitional Tests, Institutional Inertia and Bioethics Gaps?" at the Wellcome Trust funded <u>'Future of Human Reproduction</u>' 'In Vitro Gametogenesis (IVG): Ethics and Policy' Symposium, Leiden, 3-4 June 2024 (Invited)
- Aisling McMahon, "Patents & Bioethics within the European Biotechnology Directive: The Case of Human Embryo Models – Asking the Wrong Questions amidst Institutional Inertia?" at the <u>'Law and Futures'</u> Seminar Series, Newcastle Law School, Newcastle University (22 May 2024) (Invited)

## **PatentsInHumans Dissemination Activities - Year 2**

#### Invited Research Presentations and Seminars (continued)

- Aisling McMahon, "Patents and the Global Governance of Health: An Institutionalised Marginalisation of Health Needs within Patent Decision-Making Systems?" at the <u>Durham CELLS (Centre for Ethics and Law in the Life</u> <u>Sciences)</u> Seminar Series, Durham University (20 May 2024) (Invited)
- Aisling McMahon, 'Guest Seminar: TRIPS, Patents and Access to Health: A Time for Critical Reflections?', LLM Guest Seminar, University of Galway, 21 March 2024 (Invited).
- Aisling McMahon, "Patents Over Brain Computer Interface 'Technology' & Rightsholder(s)' Governance: A Blurring of the 'Technological' & Human Body," Guest Seminar, LAWS2019: Law & Technology Module, Schulich School of Law, Dalhousie University, Canada (Virtual Presentation) 11 March 2024 (Invited).

#### **Academic Conference Presentations**

Alongside these invited presentations, Professor Aisling McMahon (PI) and Dr Opeyemi Kolawole (Postdoctoral Researcher), delivered seven presentations at a range of international academic conferences, including several leading international IP conferences, ATRIP, ISHTIP and EPIP conferences. The abstract selection for these conferences was based on competitive peer review. Presenting project works-inprogress at such events allowed the project team to obtain valuable feedback from a range of intellectual property law and generalist legal audiences on the preliminary project findings and research.

A full list of these presentations is as follows (listed below in reverse chronological order, with the most recent presentations first):

- Prof Aisling McMahon and Dr Opeyemi Kolawole, "<u>Intellectual Property Rights and Control over the Repair of Medical Devices: Autonomy, Sustainability and the Need (and Challenges) for a Regulated Right to Repair for Medical Devices?", European Policy for Intellectual Property' (EPIP) conference, Scuola Superiore Sant'Anna (Pisa) University of Pisa, Italy (11th-13th September 2024).
  </u>
- Aisling McMahon, "Patents & Ethical Licensing Approaches to Steering Responsible & Ethical Uses of Emerging Technologies: A Regulatory Opportunity?" at the 'International Association for the Advancement of Teaching and Research in Intellectual Property' (<u>ATRIP</u>) Conference, LUISS University, Rome (30 June – 3 July 2024)

## PatentsInHumans Dissemination Activities - Year 2

#### Academic Conference Presentations (Continued)

- Aisling McMahon, "Patents and the Global Governance of Health: An Institutionalised Marginalisation of Health and Broader Societal Needs within Patent Decision-Making Systems?" at the <u>International Society for the History</u> <u>and Theory of Intellectual Property (ISHTIP)</u> workshop, 'Intellectual Property Law and the Anthropocene' Boston University (26-27 June 2024).
- Aisling McMahon & Opeyemi Kolawole, "Intellectual Property Rights, Control and Repair of Medical Devices: Autonomy, Sustainability and the Need (and Challenges) for a Right to Repair for Medical Devices?" at the British and Irish Law Education and Technology Association (<u>BILETA</u>) Conference, DCU Dublin, 18 April 2024. (presented by Aisling McMahon).
- Aisling McMahon, "Bioethics, Patent Decision-Making and the Biotech Directive: A Failure to Keep Pace with Scientific Developments amidst Institutional Inertia?" SLSA Conference 2024, University of Portsmouth, England 27 March 2024.
- Opeyemi Kolawole, "Competition Law and Access to Medical Technologies: Can European Competition Law Improve Patients' Welfare and Access to Medical Technologies?" SLSA Conference 2024, University of Portsmouth, England 27 March 2024.
- Aisling McMahon & Opeyemi Kolawole, "Intellectual Property Rights, Control and Repair of Medical Devices: Autonomy, Sustainability and the Need (and Challenges) for a Right to Repair for Medical Devices?" SLSA Conference 2024, University of Portsmouth, England 27 March 2024.



## PatentsInHumans

### **Publications - Year 2**

Several articles based on the PatentsInHumans research are currently under peer review in leading international peer reviewed journals (the details of which are not provided to maintain the anonymity of the double-blind peer review process). However, the following were published in Year 2:

#### **Peer Reviewed Articles**

Aisling McMahon & Opeyemi Kolawole, <u>"Intellectual property rights over 'integrated'</u> <u>medical devices: the potential health impacts and bioethical implications of</u> <u>rightsholders' control</u>" (2025) Medical Law Review.

Aisling M McMahon & Opeyemi I Kolawole. <u>"Biobank donation in search of public</u> <u>benefits and the potential impact of intellectual property rights over access to</u> <u>health-technologies developed: A focus on the bioethical implications</u>" (2024) 32(2) Medical Law Review 205-228.

#### **Peer Reviewed Chapters**

Aisling McMahon and Ciara Staunton, '<u>Managing access to health data for research</u> <u>and innovation in the EU: is a better regulatory approach possible?</u>' in Edward Dove (eds), Confidentiality, Privacy, and Data Protection in Biomedicine: International Concepts and Issues. (United Kingdom : Routledge, 2024).

#### **Other Articles**

Aisling McMahon, <u>Patently Obvious, (Law Society Gazette, Ireland</u>) (Cover Story, April Edition) pp. 27-31.

#### Reports

Aisling McMahon & Sinéad Masterson<u>, PatentsInHumans - Report of the First</u> <u>International PatentsInHumans Project Workshop Workshop</u> (Published September 2024)

Aisling McMahon & Sinéad Masterson, <u>PatentsInHumans – Year One Project Report</u>, February 2024.

#### **Blog Articles**

- Aisling McMahon, Patents & Stem Cell-Based Embryo Models in Europe: The Need for Nuanced Bioethics Scrutiny? <u>Durham Cells Blog</u> (15th November 2024)
- Aisling McMahon & Sinéad Masterson, <u>"The ERC funded PatentsInHumans</u> <u>Project – Year One Project Report and Reflections!"</u> Ideas in ALL(5th April 2024).
- Opeyemi Kolawole, <u>'Competition Law Enforcement in the EU and Access to</u> <u>Health Technologies: An Overview of the EU 2024 Competition Law Report on</u> <u>Pharmaceuticals and Medical Technologies – Update on Competition</u> <u>Enforcement in the Pharmaceutical Sector (2018-2022)</u>' Ideas in ALL Blog (25th May 2024)

### **PatentsInHumans** Publications - Year 1



In year one of the project, the team published the following outputs:

#### **Peer Reviewed Book Chapters**

Aisling McMahon, '<u>Decision-Makers, Institutional Influences and the Role of Ethical</u> <u>issues in the Patenting of Biotechnological Inventions in Europe: Enter the Unitary</u> <u>Patent System</u>' in Duncan Matthews and Paul Torremans (eds), <u>European Patent</u> <u>Law: The Unified Patent Court and the European Patent Convention (De Gruyter,</u> <u>Germany). ISBN 9783110774016</u>

#### Reports

Professor Aisling McMahon and Sinéad Masterson, <u>'A Report on the Launch Event</u> for the PatentsInHumans Project', 20th April 2023.

#### **Blog Articles**

The team published four blog articles based on PatentsInHumans research (listed below in chronological order with relevant links to websites):

1. <u>Dr Opeyemi Kolowole, 'A Right to Repair for Medical Devices?' Ideas in ALL Blog</u> <u>Article (30th June 2023)</u>

2. <u>Professor Aisling McMahon & Sinéad Masterson, 'PatentsInHumans Public</u> Launch Event: An Overview' Ideas in ALL Blog Article (14th June 2023)

3. <u>Professor Aisling McMahon, 'EU's compulsory licensing proposals, patents and</u> <u>crisis preparedness – Some steps in the right direction but more to do for future</u> <u>pandemic preparedness,' Journal of Medical Ethics Blog Article (4th May 2023)</u>

4. <u>Professor Aisling McMahon & Sinéad Masterson, PatentsInHumans ERC Project</u> <u>Commences: PatentsInHumans Explores the Bioethical Implications of Patents on</u> <u>Technologies Related to the Human Body,' Ideas In ALL Blog Article (2nd December</u> <u>2022)</u>

### **PatentsInHumans Global Reach**

### **Website**

The PatentsInHumans website (www.patentsinhumans.eu) was launched in March 2023. The website aims to provide a comprehensive and accessible overview of key aspects of the project. including about project news, events and publications. It uses language that is targeted at a public audience together with infographics to disseminate project activities and updates. We regularly update the website to provide an account of the project research developments. and news activities.

Google analytics was set up on the website in July 2023 and Active users- by Country IDas of the end of November 2023 (within the first year of the project), we knew that there were views of the website in 10 countries includina Ireland. UK. Australia, Germany, Poland. Belaium. Canada. Austria. India and Pakistan. As can be seen from the graphs, in Year 2, the project website has seen a significant increase in users from active manv countries around the world. demonstrating the broad global reach the project is gaining.





Nov 1, 2023 - Nov 1, 2024 -

View countries →

### **PatentsInHumans** Global Reach



Social Media

Our X profile (formerly Twitter) for the project, which was set up to disseminate findings, research publications and news items arising from the project to a wider audience has continued to grow. We regularly share news items related to the project's core focus around the bioethical issues posed by patents over technologies related to the human body and more general developments in the context of intellectual property rights and access to health. We currently have 245 followers and have over 200 posts since the page was established in November 2022. You can follow us at the following social media handle: <u>@PatentsInHumans</u>

In addition, we have recently set up a LinkedIn page for the project where we post information about news items. events and publications related to the project. You can follow this LinkedIn page at: <u>https://www.linkedin.com/company/erc-patentsinhumans-project/</u>

### **PatentsInHumans** Global Reach



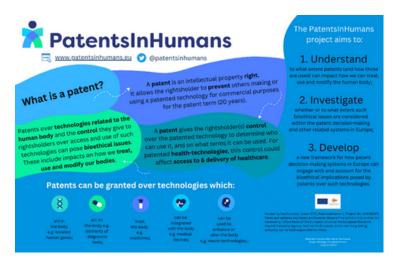
Policy and Public Engagement Activities

#### PatentsInHumans Research – Policy Engagement Activities & Impact:

Based on her research on patents and technologies related to the human body, Professor Aisling McMahon (PI) has been invited to participate in a range of high-level policy events this year. These include her participation in an invited virtual interdisciplinary roundtable workshop run by the <u>Royal Society</u> on "Addressing Technology Transience: Approaches for Future-Proofing Essential Technologies Against Obsolescence and User Abandonment" (July 2024). In June 2024, she participated in a roundtable evidence gathering meeting organised by the Nuffield Council on Bioethics in London which brought together invited experts to discuss the current science, law and governance, and ethical issues relevant to stem cell based embryo models (SCBEMs). Prof McMahon published a blog article on patents and SCBEMs in <u>the Durham CELLS blog</u> (15th November 2024). This article and a previous chapter she published on "<u>The 'ethical' regulation of 'novel being' technologies: the</u> <u>potential role for patents and ethical drivers, blockers and guiders?</u>" (2022) were cited in the <u>Nuffield Council on Bioethics Report on "Human stem cell-based embryo</u> <u>models: A review of ethical and governance questions</u>" (27th November 2024).

#### **Public Engagement Activities:**

Building upon our aim to raise public awareness of the role of patents within the broader health innovation context, we launched a second infographic in July 2024 designed by Sinéad Masterson (Project Manager, PatentsInHumans). This infographic is aimed at a public audience and provides an explanation of a patent, of overview an the potential bioethical issues associated with patents on technologies related to the human body and a definition of the five categories of technologies examined in the project. It also provides a brief description of the three main aims of the project.



## PatentsInHumans

### **Team News**

### Professor Aisling McMahon appointed as member of the Irish National Research Ethics Committee for Clinical Trials

In April 2024, <u>Professor Aisling McMahon</u> was appointed by the Minister for Health as a member of the Irish National Research Ethics Committee for Clinical Trials (CT-A) which reviews ethics applications related to Clinical Trials of Investigational Medicinal Products in Ireland. Professor McMahon was appointed to sit on NREC CT-A, one of four committees examining applications and ethics considerations surrounding Clinical Trials of Investigational Medicinal Products in Ireland. Surrounding McMahon Web Products in Ireland.

#### Professor Aisling McMahon awarded Maynooth University Mid-Career Research Achievement Award

Professor Aisling In November 2024. M<u>cMahon</u> awarded Maynooth was University's 2024 Mid-Career Research Achievement Award. The Maynooth University Mid-Career Research Award acknowledges an academic staff member who has established themselves as a significant contributor to their field. It honours those who, at the mid-point of their career, have demonstrated sustained excellence in research, making impactful contributions that advance knowledge and understanding. You can find out more about these awards here.



### Professor Aisling McMahon invited to join International Advisory Board of Legal Studies

In 2024, <u>Professor Aisling McMahon</u> was invited to join the <u>international advisory</u> <u>board</u> of Legal Studies. <u>Legal Studies</u> is the journal of the Society of Legal Scholars. It is a leading international peer reviewed generalist law journal which aims to publish peer reviewed articles representing a broad range of interests and areas across legal scholarship. You can find out more about this journal <u>here</u>.

## **PatentsInHumans** Team News

#### Dr Opeyemi Kolawole publishes work relating to his PhD Research

As well as his work on PatentsInHumans, Post Doctoral Researcher, Dr Opeyemi Kolawole's paper on "The Problems with the Nature of the Obligations in Article 66.2 of TRIPS" has recently been accepted for publication in the Journal of World Intellectual Property. This paper, which stems from his doctoral research, examines the foundations of technology transfer obligations broadly, focusing primarily on Article 66.2 of TRIPS. It offers a diagnosis of its implementational limitations and practical and policy-based solutions to addressing its limitations.



## **PatentsInHumans** Looking Ahead



### **Future Work**

As we move into year 3 of the project, we are entering the empirical phase of the project. During this phase, we are planning semi-structured interviews with relevant stakeholders in the European patent context, and related fields. This work also aims to expand our understanding of patient and healthcare practitioners' experiences, and we are planning empirical work, including focus groups, to gain such insights.

Alongside this work, we will continue to develop conceptual understandings of the range of bioethical issues posed by patents and whether, or to what extent, these are engaged with in Europe both inside and outside patent law. As noted, we are currently developing several works in progress papers arising from research in year 2 including papers examining the role of human rights and competition law within this area. The PatentsInHumans team will be presenting these papers at relevant international conferences, including the SLSA in April 2025, prior to finalising such papers for peer review submission in the coming months.

Later in 2025, we plan to commence a virtual PatentsInHumans Webinar series which will invite leading scholars in the relevant fields to discuss issues related to the potential bioethical issues posed by patents over technologies related to the body, and potential avenues to engage with such issues from within and outside patent law.

Details to follow on this and other PatentsInHumans events on our website!



## **Contact Us**



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www.patentsinhumans.eu

# PatentsInHumans

This report was designed using Canva Premium by Sinéad Masterson, Project Manager, PatentsInHumans.