

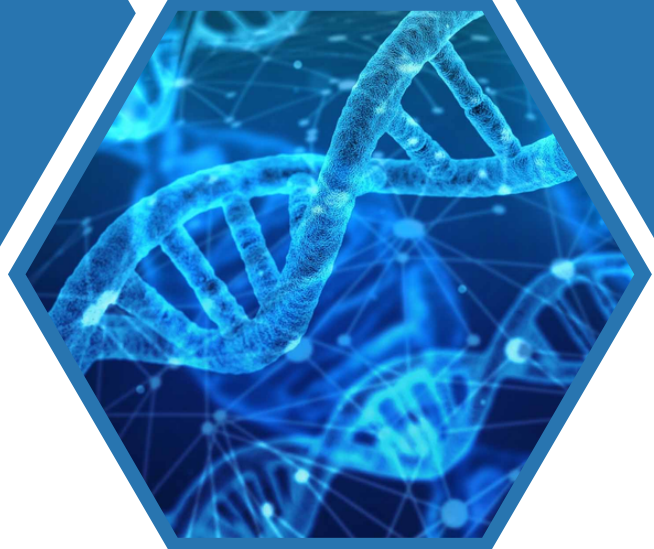


PatentsInHumans

Year 1 Project Report

**Principal
Investigator**

Professor Aisling
McMahon

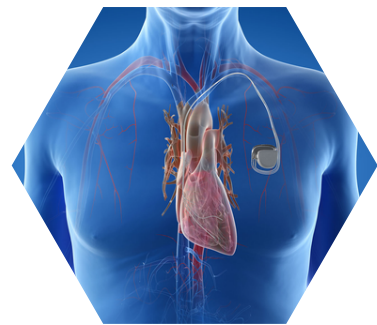
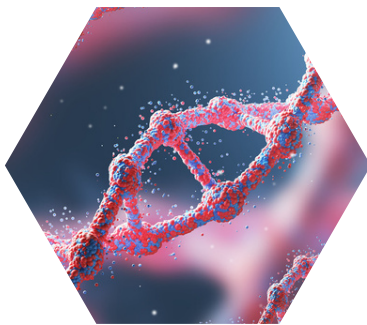


**February
2024**

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. The project commenced on the 1st of November 2022. This report provides an overview of the project and sets out what we have achieved during the first year of the project (November 2022 to November 2023) as well as outlining the research activities we are planning over the coming year.



The PatentsInHumans project is funded by the European Union (ERC, PatentsInHumans, Project No. 101042147). Views and opinions expressed are however those of the authors only and do not necessarily reflect those of the European Union or the European Research Council Executive Agency. Neither the European Union nor the granting authority can be held responsible for them.

PatentsInHumans

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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 how we can – or should – better embed such bioethical considerations in patent decision-making.

Five key categories of ‘technologies’ related to the human body will be examined in the project, namely:

- Patentable ‘technologies’ that originate from within human body e.g., isolated elements of the body such as isolated human genes;
- Patentable ‘technologies’ which act on, or reveal information about, the human body, such as patentable surgical tools or elements of diagnostic tests;
- Patentable ‘technologies’ which exist/originate outside the body and treat the human body, such as medicines or elements of vaccines;
- Patentable ‘technologies’ which may become part of or become integrated with the human body, such as elements of medical devices, prosthetics etc.
- Patentable ‘technologies’ that can be used to enhance or modify the human body e.g. neuro-technologies or ‘technologies’ which display functions similar to humans e.g. patents over ‘novel being’ technologies.

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 body, and how such rights are used, have the potential to give rise to a range of bioethical issues, including impacting how we treat, use and modify our bodies.

The project will interrogate to what extent such bioethical issues are considered, if at all, within European patent decision-making for these types of ‘technologies’. Ultimately, the project aims to reimagine European patent decision-making towards a person-centred approach which further embeds bioethical considerations in patent grant and licensing decision-making systems, where appropriate, for such technologies.

PatentsInHumans

Project Overview

To achieve these aims, PatentsInHumans is designed around three main project phases:

Phase 1: Conceptual Phase (0-18 months)

Detailed literature reviews will be undertaken to develop a more comprehensive understanding of the potential bioethical issues that may be posed by patents – and how such rights are used – over technologies related to the human body. Alongside this, an institutional framework will be developed to examine the potential avenues to account for relevant bioethical issues in these contexts, and to understand the likely institutional influences within relevant European decision-making structures.

Phase 2: Empirical Phase (19-36 Months)

Building upon the conceptual work in phase one, in phase two empirical work will be designed and carried out to reveal empirical insights into the bioethical issues posed by patent grant and use within the five categories of technologies identified. This empirical work will include: focus groups with technology users and semi-structured interviews with relevant stakeholders within the European patent systems, and related systems. This work aims to develop empirical understandings around the practical operations of European patent decision-making structures, to better understand to what extent such bioethical issues are or could/should be further accounted for within current systems for patent grant and licensing in Europe.

Phase 3: Analytical Phase (37–60 Months)

During this phase, relevant findings across all project work-packages and phases will be synthesised and analysed to develop a comprehensive understanding of the potential bioethical issues that could be posed by patents over technologies related to the human body, and how such issues are currently considered within European patent decision-making. This phase will then examine how patent decision-making in Europe can be reconceptualised, if needed, to better engage with the bioethical issues posed by the grant and use of patent rights over technologies related to the human body.

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 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

Meet Our Team



PROFESSOR AISLING MCMAHON

PRINCIPAL INVESTIGATOR

Professor Aisling McMahon is a Professor of Law at the School of Law and Criminology, Maynooth University. Aisling's research focuses on health law and intellectual property law, and she is particularly interested in the role of intellectual property rights within the health context, including the potential impacts that patent rights – and how they are used – can have on access to, and delivery of healthcare. Aisling has published widely on these issues within leading international peer reviewed journals, including in the: Journal of Medical Ethics, Medical Law Review, Cambridge Quarterly of Healthcare Ethics, Journal of Law and the Biosciences, and the Intellectual Property Quarterly.



DR OPEYEMI KOLOWOLE

POSTDOCTORAL RESEARCHER

Dr. Opeyemi Kolowole 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

Sinéad Masterson 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.

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Research Activities - Year 1

In the first year of the project, the project team developed research examining the potential bioethical issues posed by patent grant and use over a range of technologies related to the human body, and the institutional and legal systems within which such patent-decisions are taken. The team conducted research on how bioethics or bioethical issues are referred to within patent law literature and case law within Europe. Alongside this, the team delved into technologies within each of the five categories and examined how patent rights can apply over a range of technologies related to the body, of the potential bioethical implications of patent grant and use over such technologies in practice, and how such issues are engaged with by the European Patent Organisation and European Union legal systems.

Aside from the technological focus, the team conducted research on the institutional framework within the European patent system, relevant legislative provisions which apply in this context, and which could be used to engage with (bio)ethical issues, and the decision-making actors which operate in this context. Alongside this, research was conducted probing the function of patents, looking at its multi-faceted nature including its economic, governance and regulatory dimensions. Finally, the team are examining a range of avenues outside patent law that could be used to engage with the (bio)ethical issues posed by patents over technologies related to the body, including considering the role of human rights, competition law and avenues specific to certain technological categories.

As will be seen in the next section, the project team gave presentations at 17 national and international events based on works in progress arising from the project in year 1. These presentations offered an important avenue to obtain feedback on developing research which the team gratefully received. This feedback has been incorporated into the project work. In year one, the team published one book chapter, four blog articles, and a report based on project research. Alongside this, the team finalised several journal articles based on project research which were submitted and are currently under peer review with leading international peer reviewed journals (detailed information not provided to preserve anonymity in the peer review process). The team are also finalising a range of other papers for conference presentation and article submission in the coming months.

PatentsInHumans

Public Launch Event

On 20th April 2023, we were delighted to host the public launch event for the ERC PatentsInHumans project in Maynooth University. The event was attended by over 45 individuals, including, members of the public, students and academics working in a range of disciplines (including law, biology, political science, and business), practising lawyers, and technology transfer specialists.

This public launch event provided an opportunity to introduce the project to the broader community and to focus attention on the impacts that patents – and particularly, how such patents are used – can have on access and delivery of healthcare.



Dr Fergus Ryan (Head of the School of Law and Criminology) commenced proceedings at the launch event by offering a welcome address and introductory remarks.

Following this, Professor Aisling McMahon introduced the ERC PatentsInHumans project and provided a brief project overview. Professor Susi Geiger (Full Professor, School of Business, UCD) and Dr Christine Kelly (Infectious Disease Physician and Clinical Lecturer/Assistant Professor, School of Medicine, UCD) then delivered presentations which examined the bioethical and social implications of how patents are used over health-technologies, drawing on these speakers' respective disciplinary backgrounds in healthcare markets and public health.



PatentsInHumans

Public Launch Event

In the second half of the PatentsInHumans public launch event, Professor Jorge Contreras delivered the key note lecture. Professor Contreras is the James T. Jensen Endowed Professor for Transactional Law and Director of the Program on Intellectual Property and Technology Law at the University of Utah S.J. Quinney College of Law, with a secondary appointment in the Department of Human Genetics, University of Utah School of Medicine.



His lecture was on “The Civil Rights Case Against Gene Patents in America” and reflected on his recent award winning book entitled The Genome Defense: Inside the Epic Legal Battle to Determine Who Owns Your DNA (Hachette/Algonquin, 2021) which examines the background and legal challenges in the United States Supreme Court case Association for Molecular Pathology v. Myriad Genetics where patents over isolated human genes were challenged in the United States. This book has been strongly acclaimed in reviews in the New York Times, Wall Street Journal, Nature and other leading international outlets. It was named “Best Patent Law Book of the Year” in 2021 by the international IPKat blog.

The full report of the PatentsInHumans launch event was published after the event, and offers a detailed summary of the presentations at the launch event.



Patents | Bioethics | Our Human Bodies



European Research Council funded
PatentsInHumans Project

A Report on the Launch Event for
PatentsInHumans project held at Maynooth
University on 20th April 2023

Authors: Professor Aisling McMahon &
Sinéad Masterson

Publication Date: 31st May 2023

PatentsInHumans

Dissemination Activities - Year 1

Invited Research Presentations and Seminars

Professor Aisling McMahon (PI PatentsInHumans) delivered eleven invited presentations/research seminars on her research which relates to the PatentsInHumans project in the first year of the project, at a range of national and international research events, including at events organised in/by the University of Tasmania; the World Intellectual Property Organisation (WIPO) Summer School of Intellectual Property Law; Rice University's Global Center Paris; the University of Edinburgh and Newcastle University.

A full list of invited presentations/seminars related to the research conducted under this project, is as follows (listed below in reverse chronological order, with the most recent presentation listed first):

1. Aisling McMahon, 'The Ethical Regulation of Innovative Health Technologies: The role for Patents?' at the Regulation of Innovative Health Technologies Workshop, Centre for Law and Genetics, University of Tasmania, 23 -25 November 2023 (Invited Presentation)
2. Aisling McMahon, 'Patents over Brain Computer Interface 'Technology': A Blurring of the 'Technological' and Human Body with Significant Bioethical Implications' at the Beyond Boundaries: Persons, (Bio)Technologies, & the Law interdisciplinary workshop organised by the [EverydayCyborgs](#) and [HybridMinds](#) Projects, Gladstone Library, Wales, 2-3 October 2023 (Invited Presentation)
3. Aisling McMahon, 'Patents, TRIPS and the Private Governance of Public Health: A Perpetuating Institutionalised Marginalisation of Health?' at the [COMPHACRISIS](#) Public Health, Markets and Law Conference, UCD 29 September 2023 (Invited Presentation).
4. Aisling McMahon, 'Patents and Access to Health' at the World Intellectual Property Organization (WIPO) Summer School on Intellectual Property Law, (Virtual Presentation), 30 June 2023. (Invited Presentation).
5. Aisling McMahon, 'Embedding Ethical Considerations in Regulation: Patents, 'Ethical' Licensing Clauses and Self-Regulatory Spaces' at the "Engineering Life: Regulating Science, Risks, and Society in Europe Conference" 50th Anniversary of the Asilomar Conference, Rice University's Global Center Paris. (Virtual Presentation) 15 June 2023. (Invited Presentation)

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Dissemination Activities - Year 1

Invited Research Presentations and Seminars

6. Aisling McMahon, 'Patents, TRIPS and the Private Governance of Public Health: A Perpetuating Institutionalised Marginalisation of Health?' at the 'Public Health, Trade and the Role of Law' workshop, University of Edinburgh, 25 May 2023. (Invited Presentation)
7. Aisling McMahon, 'Patents, Pandemics and Public Health: Revisiting Patents Governance Role' at the AHRC funded 'Targeting Therapies: Exploring the Cultural and Normative Dimensions of 'Targeted' Approaches to Biomedicine and Public Health Workshop, University of Edinburgh, 5 May 2023. (Invited Presentation)
8. Aisling McMahon, 'Patents on Technologies Related to the Human Body: The Urgent Need for Greater Bioethics Scrutiny' Law and Futures Seminar "Technology, Medicine and the Human Body", Newcastle Law School, Newcastle University, United Kingdom. 31 March 2023 (Invited Presentation)
9. Aisling McMahon, 'The "ethical" regulation of "novel being" technologies: the potential role for patents as ethical drivers, blockers and guiders?' at the Book Launch Event: Novel Beings: Regulatory Approaches for a Future of New Intelligent Life, Newcastle Law School, 30 March 2023. (Invited Presentation)
10. Aisling McMahon, 'Patents, Pandemics and Public Health Access to Vaccines: Lessons from COVID-19 on the Bioethics Gap' at the Economic, Legal, Social, and Political Perspectives on Public Policy Conference, Department of Economics, Maynooth University 29 March 2023. (Invited Presentation)
11. Aisling McMahon, 'Patents, Access to Healthcare and Covid-19: The Role of Intellectual Property Rights & Mechanisms to Alleviate Access Issues' at the Immunology and Global Health Seminar, Maynooth University 21 March 2023. (Invited Presentation)



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Dissemination Activities - Year 1

Academic Conference Presentations

Alongside these presentations, Professor Aisling McMahon (PI) and Dr Opeyemi Kolawole (Postdoctoral Researcher), delivered a total of six further presentations at a range of international academic conferences, where abstract selection is generally based on competitive peer review. Presenting project works-in-progress at such events allowed the project team to obtain valuable feedback from a range of bioethics, health law and intellectual property law audiences on the preliminary project findings and research as the work develops. A full list of such presentations and topics is as follows (listed below in reverse chronological order, with the most recent presentations first):

1. Aisling McMahon, 'Bioethical issues posed by patents - and how they are used - over 'technologies' related to the human body: An Urgent Need for Scrutiny' at the International Australasian Association of Bioethics and Health Law (AABHL) conference, Queensland University of Technology, Brisbane, November 2023.
2. Aisling McMahon, 'The Biotechnology Directive & the Patentability of Emerging Biotechnologies in Europe: Scope for the Consideration of Bioethical Issues in Practice?' at the Joint Intellectual Property Research Exchange between Zhongnan University of Economics and Law Center for Studies of Intellectual Property Rights and Maynooth School of Law and Criminology, Maynooth University, 22 September 2023.
3. Aisling McMahon, 'Bioethics, Patent Decision-Making and the Biotech Directive: A Failure to Keep Pace with Scientific Developments amidst Institutional Inertia?' at the Conference on the 25th Anniversary of the Biotechnology Directive, Maynooth University, 15 September 2023.
4. Aisling McMahon and Opeyemi Kolawole, 'Patents over Implantable Medical Devices: Examining the Potential Impacts of Rightsholder(s) Control and Medical Device Users' Needs?' at the "Planting Seeds for the Future of IP Law Conference - A conference in honour of Margaret Llewelyn", Sheffield University 8 June 2023.
5. Aisling McMahon, 'Patents on Technologies related to the Form, Function and Modification of the Human Body: The Urgent Need for Greater Bioethics Scrutiny in Patent Decision-Making' at the Health Law Panel, Socio-Legal Studies Association (SLSA) Conference, Ulster University, 5 April 2023.
6. Aisling McMahon & Opeyemi Kolawole, 'Patenting (In) the Human Body: The 'No (Tangible) Property Rights in the Body' Principle & Patents Considered' at the Intellectual Property Panel, Socio-Legal Studies Association (SLSA) Conference, Ulster University, 5 April 2023.

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Publications - Year 1

Journal Articles

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).

Peer Reviewed Book Chapters

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

Reports

Professor Aisling McMahon and Sinéad Masterson, ['A Report on the Launch Event 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. [Dr Opeyemi Kolowole, 'A Right to Repair for Medical Devices?' Ideas in ALL Blog Article \(30th June 2023\)](#)
2. [Professor Aisling McMahon & Sinéad Masterson, 'PatentsInHumans Public Launch Event: An Overview' Ideas in ALL Blog Article \(14th June 2023\)](#)
3. [Professor Aisling McMahon, 'EU's compulsory licensing proposals, patents and crisis preparedness - Some steps in the right direction but more to do for future pandemic preparedness,' Journal of Medical Ethics Blog Article \(4th May 2023\)](#)
4. [Professor Aisling McMahon & Sinéad Masterson, PatentsInHumans ERC Project Commences: PatentsInHumans Explores the Bioethical Implications of Patents on Technologies Related to the Human Body,' Ideas In ALL Blog Article \(2nd December 2022\)](#)



PatentsInHumans

Project Logo, Website & Social Media

Logo



PatentsInHumans

In late 2022, work began on the design and consultation process for the project website and logo, and in February 2023, the PatentsInHumans logo was finalised and created by Wonder Works Studio Ltd. in consultation with Professor Aisling McMahon (PatentsInHumans Principal Investigator) and Sinéad Masterson (PatentsInHumans Project Manager).

This logo was carefully designed to represent key facets of the project in an accessible manner. The primary PatentsInHumans logo icon is an adaptation of the universal healthcare symbol (a cross) which has been flipped, narrowed and modified in a curved manner to represent a human person. This captures the focus on health-technologies and human health within the project. Alongside this, the two interlinked aspects to the body represent patent law and bioethics respectively, and these are drawn in a curved and overlapping manner to denote the core project aim of bridging the current disconnects between bioethics and patent law in a manner that allows us to reconceptualise patent decision-making in a person-centred manner. The five colours within these two interlinking elements of the main body icon represent the five-category taxonomy of patentable technologies which will be considered throughout the project (described above). These technological categories relate to key aspects of the form and functioning of the human body, and were devised by Professor McMahon within the project proposal.

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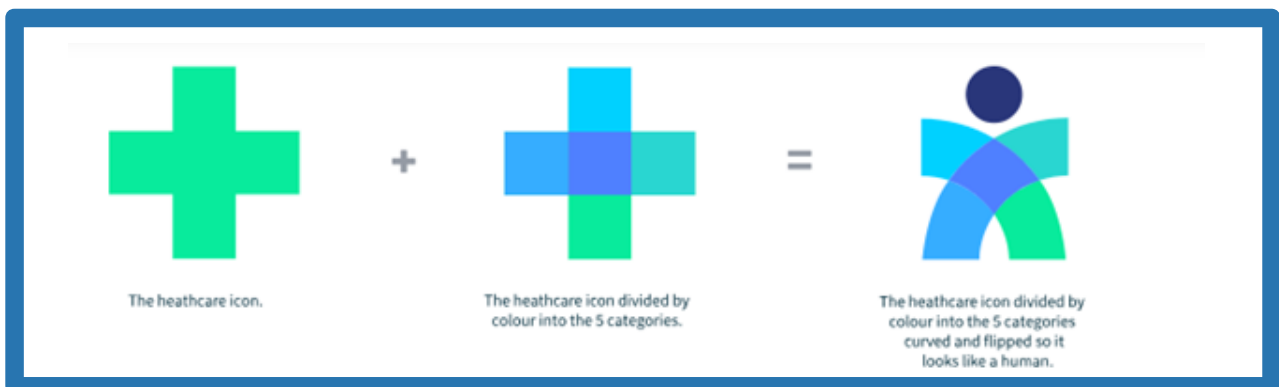
Project Logo, Website & Social Media

Logo



The secondary logo is a more detailed version of the logo which consists of our primary icon denoting the bridging of bioethics and patent law in a person-centred manner with the addition of five icons each individually representing one aspect of this five-category taxonomy described above.

A complete [description](#) of the logo and its development is available on the PatentsInHumans website.





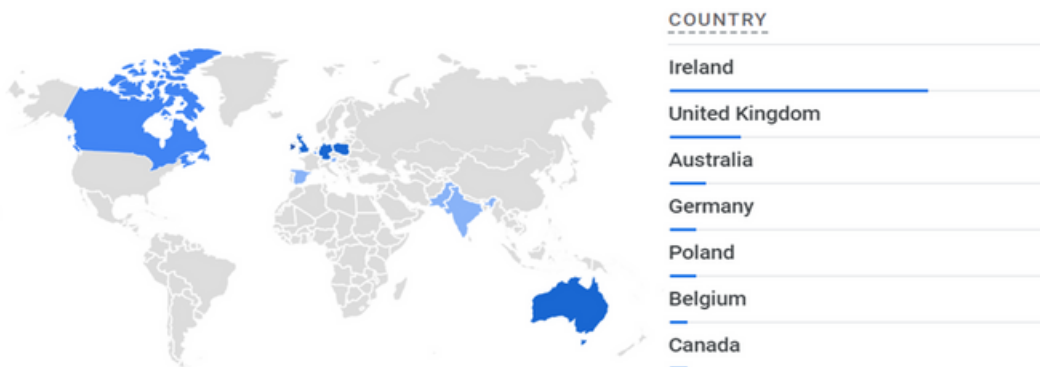
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Project Logo, Website & Social Media

Website

Following a consultation and design process involving Professor Aisling McMahon (PI), Sinéad Masterson (Project Manager) and the website designer Nitchy Web Design and Development Specialists, in March 2023, the PatentsInHumans website (www.patentsinhumans.eu) was launched. The website aims to provide a comprehensive and accessible overview of key aspects of the project, including the core project team, project news and events and publications. It uses language that is targeted at a public audience together with graphics, videos to disseminate project activities and updates. We regularly update the website to provide an account of the project research developments, news and activities.

Users by Country



Google analytics was set up on the website in July 2023 and as of the end of November 2023 (within the first year of the project), we know that there were 231 views of the website in 10 countries including Ireland, UK, Australia, Germany, Poland, Belgium, Canada, Austria, India and Pakistan. Hence showing the breadth and international reach of the website’s audience.

PatentsInHumans

Project Logo, Website & Social Media

Social Media

We also developed an X profile (formerly Twitter) for the project to disseminate findings, research publications and news items arising from the project to a wider audience. 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. You can follow us at the following social media handle [@PatentsInHumans](https://twitter.com/PatentsInHumans)

PatentsInHumans

Team News

Professor Aisling McMahon (Principal Investigator, PatentsInHumans project) awarded Irish Research Council Early Career Researcher of the Year Award 2023

In November 2023, Professor Aisling McMahon was awarded the highly prestigious national Irish Research Council (IRC) Early Career Researcher of the Year award in recognition of her research achievements. This award is presented annually to a current or former IRC awardee, who is within eight years of their PhD, and who has demonstrated an exceptional level of achievement in their field at this stage in their career. You can watch a video interview with Professor McMahon where she discusses the award and her broader research, including the PatentsInHumans project, [here](#).



Professor Aisling McMahon's appointment to Editorial Advisory Board of the Medical Law Review

Professor McMahon was recently appointed to the Editorial Advisory Board of the Medical Law Review, a leading international peer reviewed health law journal. It publishes peer reviewed articles on a range of topics related to health law, ethics and practice. You can find out more about this journal here: <https://academic.oup.com/medlaw>



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Team News

Dr Opeyemi Kolawole graduates from PhD Programme in UCD in summer 2023

Opeyemi Kolawole has recently graduated from the Sutherland School of Law, University College Dublin, obtaining a PhD in Intellectual Property Law. His thesis, titled “Re-imagining Technology Transfer Obligations in Article 66.2 of the TRIPS Agreement,” was supervised by Dr Cliona Kelly and examined by Prof Graham Dutfield and Dr Justin Jutte. Notably, a journal article from the thesis has been accepted for publication by the Intellectual Property Quarterly Journal.



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Looking Ahead

Future Work

Year 2 of the project will see the completion of Phase 1 of the project. As highlighted above, we are currently developing several works in progress papers arising from research in year 1. We plan to present these papers at relevant international conferences and to finalise such papers for submission for peer review in the coming months. We will then move into phase two of the project which will involve the development and commencement of the empirical strand of the project.

In 2024, we will host our first workshop as part of the PatentsInHumans project which will invite leading scholars and practitioners 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 our website!

Contact Us

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 www.patentsinhumans.eu



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