



PatentsInHumans

Patents | Bioethics | Our Human Bodies



European Research Council funded PatentsInHumans Project

A Report on the Launch Event for PatentsInHumans
Project

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Maynooth University

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European Research Council funded PatentsInHumans Project: Launch Report

Introduction

On 20th April 2023, we were delighted to host the public launch event for the European Research Council (ERC) funded *PatentsInHumans* project in Maynooth University. [Dr Fergus Ryan](#) (Head of the School of Law and Criminology) offered a welcome address and introductory remarks on the evening. Following this, [Professor Aisling McMahon](#) introduced the ERC *PatentsInHumans* project and outlined the project's research objective namely, to develop a comprehensive understanding of the potential bioethical issues posed by patents on technologies related to the human body, and to understand to what extent such bioethical issues are - or could be further - considered within European patent grant and licensing decision-making. This was followed by presentations from [Professor Susi Geiger](#) (UCD) and [Dr Christine Kelly](#) (UCD) who provided reflections on the potential bioethical and societal implications of how such patents are granted and used over health-related technologies based on insights from their respective fields, of health care markets and public health. In the second half of the event, [Professor Jorge Contreras](#) (University of Utah) delivered a keynote lecture on "The Civil Rights Case Against Gene Patents in America" based on his recent book, [The Genome Defence: Inside the Epic Legal Battle to Determine who owns your DNA](#) (NY: Hachette/Algonquin, 2021).

The public launch event was attended by over 45 people, including, members of the public, students and academics working in a range of disciplines including law, biology, political science, and business. Attendees also included practicing lawyers and technology transfer specialists. We would like to gratefully acknowledge the support of the European Research Council in funding this project. We are also very grateful for the support of the [School of Law and Criminology, Maynooth University](#) which co-funded the reception event following this project launch event, and we would also like to acknowledge support of the [ALL Institute](#) in Maynooth University which co-hosts the project alongside the School of Law and Criminology.

This report offers a summary of the presentations at the launch event.

You can find out more about our project and future activities and events by visiting our website: www.patentsinhumans.eu



Introduction & Welcome - Dr Fergus Ryan, Head of the School of Law and Criminology, Maynooth University.



[Dr Fergus Ryan](#), Head of the School of Law and Criminology, Maynooth University commenced proceedings by welcoming attendees to celebrate the public launch of the *PatentsInHumans* Project. Dr Ryan offered an overview of the origins and achievements of the School of Law and Criminology, which was originally established (as the Department of Law) in 2009. In particular, he noted the School's research-intensive focus with academic colleagues publishing in a range of internationally leading peer-reviewed outlets and contributing important policy work in both the national Irish and international contexts. The *PatentsInHumans* project is the second European Research Council funded project in the School, which is also home to the ERC [Dancing Project](#), which commenced in 2020. The Dancing project is funded by an ERC Consolidator Award and is led by Principal Investigator [Professor Delia Ferri](#).

Dr Ryan highlighted that Maynooth University has a strong tradition of leading work which focuses on social justice issues, and also has notable achievements within the scientific context. In the latter context, Dr Fergus Ryan highlighted the work of Nicholas Callan, a professor of natural philosophy at St Patrick's College Maynooth who invented the original [induction coil in 1836](#). Dr Ryan also highlighted the pioneering work of [Kathleen Lonsdale](#), born in Co. Kildare, and who was the [first female professor at University College London](#), whose work in crystallography included the development of x-ray mechanisms for the study of the structure of crystals.

Dr Fergus Ryan concluded by introducing the first panel's speakers: Professor McMahon who provided an overview of the PatentsInHumans project, and Professor

Susi Geiger and Dr Christine Kelly, who each provided insights from their respective disciplines (business and medicine) reflecting on the project and on how patents may impact access, use and development of health-related technologies. This first panel of the launch event was chaired, and the discussions moderated by Dr Ryan.

Professor Aisling McMahon, Principal Investigator PatentsInHumans – An Introduction to the PatentsInHumans Project

Following Dr Ryan’s introductory remarks, Professor Aisling McMahon who is the Principal Investigator of the PatentsInHumans project introduced the project. PatentsInHumans is a five-year interdisciplinary project which commenced on 1st November 2023. It is funded by an ERC Starting grant which will enable Professor McMahon to build a team of researchers to examine the bioethical implications posed by patents – and how they are used – on technologies related to the human body (including, over medicines, elements of diagnostics, medical devices, and isolated human genes).

In her talk, Aisling introduced the current project team, whose members include: Dr Opeyemi Kolawole and Sinéad Masterson who both joined the project in November 2022. Dr Opeyemi Kolawole joined as a postdoctoral researcher on the *PatentsInHumans* project. Prior to joining the project, Opeyemi completed his PhD entitled “Reimagining the Technology Transfer Obligations in the TRIPS Agreement” at the Sutherland School of Law, University College Dublin. Opeyemi holds an LL.M degree in Intellectual Property and Information Technology Law from UCD, and an 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. Opeyemi is also involved in development advocacy in sub-Saharan Africa, especially Nigeria. Opeyemi brings this experience and intellectual property knowledge to the project. Sinéad Masterson is the project manager on *PatentsInHumans* project. Sinéad holds a PGDip. in Project Management and alongside her project management expertise, she also brings important scientific insights to the project. Sinéad has extensive expertise in the regulation of substances of human origin (used in human application) having worked for the Health Products Regulatory Authority as Blood, Tissues and Organs Section Manager and Inspector of Blood, Tissue and Organ Establishments for over 10 years. Sinéad completed her BSc. in Pharmacology and Chemistry at UCD and her MSc. in Biomedical Science with the University of Ulster. Professor McMahon highlighted that the project will soon be recruiting for further team members which will be advertised over the coming months!



Dr Opeyemi Kolawole
Postdoctoral Researcher



Sinéad Masterson
Project Manager

In her presentation, Aisling then provided a brief overview of the *PatentsInHumans* project, including its central research questions, scope and the structure of the project. In this context, patents are a type of intellectual property right which give the rightsholder(s), the right to stop others using the patented technology for the duration of the patent – this is usually 20 years under the applicable international framework. Thus, depending on how rightsholder(s) use such patent rights – including how they enforce these – such rights have the potential to impact how the patented technology is used, on what terms and by whom. The human body itself is not patentable, but patents are available on a range of technologies which relate to the human body including, medicines, elements of medical devices and isolated human genes. Patents over such technologies have the potential to pose significant bioethical implications, as they can potentially impact how we treat, use and modify our bodies. *PatentsInHumans* develops a novel five category taxonomy of types of technologies related to the human body to try to understand the potential bioethical implications posed by such patent rights and how they are used. It aims to understand, the extent to which such issues are accounted for within European patent decision-making.



Building upon the analysis developed, the project will then seek to reimagine the European system to ensure that it better engages with the potential bioethical issues posed by patents and how they are used over such technologies. In conducting this analysis, the project will bring together conceptual/desk-based research and empirical work including interviews/focus groups with relevant stakeholders, to inform understandings developed over the five years. Professor McMahon noted that a central aim of the project is to challenge the current status quo approach to patent decision-making and to develop a person-centred approach which embeds broader consideration of the bioethical implications posed by patents - and how they are used

– over technologies related to the human body, within the patent grant, licensing and enforcement systems.

Professor McMahon concluded her presentation by gratefully acknowledging the support of the ERC in funding the project. She also acknowledged the support of the School of Law and Criminology, and in particular, Professor Michael Doherty and Dr Fergus Ryan (the former and current Head of the School of Law and Criminology) and of colleagues in the Research and Development Office in Maynooth University for all their support in applying for and carrying out the project. She also acknowledged the support of the ALL Institute which co-hosts the project with the School of Law and Criminology in Maynooth University and is where the *PatentsInHumans* team is based.

**Invited Speaker: Professor Susi Geiger, Full Professor, School of Business, UCD
– Are Patents Still Justified in Pharmaceutical Markets?**



[Professor Susi Geiger](#) is a Full Professor in the School of Business, University College Dublin, and the Principal Investigator of the European Research Council [MISFIRES](#) Project (2018-2024) (funded by an ERC Consolidator Grant). The MISFIRES project examines market failures in healthcare markets, exploring how relevant stakeholders/actors can address such market misfires. Prof Geiger shared her reflections based on her research from a markets perspective, and in doing so, she highlighted the potential societal implications of patents in the health context, including their impacts on access to healthcare.

Prof Geiger's presentation was entitled 'Are patents still justified in pharmaceutical markets?' and in it she reflected on the standard justification for patents, which focuses on the grant of a patent as a limited exclusionary right to rightsholders in return for downstream benefits in the form of medicines and other useful products for society. Prof Geiger argued that the current model is characterised by a failure of industry to innovate products that are most needed by society unless these are also products that attract lucrative markets. Instead, there is a focus on the development of 'me too' drugs or medicines for high income country markets. 'Downstream' failures by industry include impeding access to medicines through high costs of medicines, by being overly selective in which markets they enter, or by blocking access of generic products entering the market. Prof Geiger concluded by arguing that there is a need to delink upstream and downstream markets and more generally, a need to rethink the social contract embedded in patient-based pharmaceutical markets from the ground upwards.

Dr Christine Kelly – Patents and the Delivery of Healthcare: A Clinical Medical Perspective



[Dr Christine Kelly](#) is an Infectious Diseases Physician and Clinical Academic with a specialist interest in HIV as a chronic inflammatory disease in low-income sub-Saharan Africa. In 2012, she was awarded a prestigious Wellcome Trust Training Fellowship in Global Health and completed a PhD at the Malawi-Liverpool-Wellcome Clinical Research Programme, Blantyre, Malawi. She moved to Ireland in 2016 and is

currently working as an Honorary Clinical Research Fellow within the Centre for Experimental Pathogen Host Research at UCD where she aims to lead a programme into translational HIV research in a Global Health context.

Dr Kelly began by outlining her clinical work on HIV particularly in Malawi where she experienced first-hand the impact that patents can have on the availability of medicines. Moreover, in the COVID-19 context, she highlighted that the availability of vaccines hugely affected how clinicians could respond to and treat their patients during the pandemic. The speed at which the COVID-19 vaccine was developed, approved and available on the market was considered a key breakthrough for clinicians on the front line. However, once the vaccine was approved, the race began to secure vaccines in individual countries, and low- and middle-income countries (LMICs) were left behind. Dr Kelly highlighted that a key factor in this was that how vaccines were supplied was a matter of direct negotiations between countries and manufacturing companies (who held the relevant intellectual property rights), and COVID-19 vaccines often went first to the countries with the most buying power. This approach was contrary to both what an ethical approach would dictate and to clinical needs. She highlighted that in 2021, more people in higher income countries had received booster vaccines than had received their first dose of vaccine in LMICs.

Dr Kelly discussed the supply problem as there was a small number of companies producing the vaccine who did not have the capacity to produce vaccine on sufficient scale for a pandemic. Yet many of these companies also refused to share the technology/know-how with other companies/facilities around the world which may have had the capacity to produce additional supplies. Surplus vaccines from high income countries were eventually provided to some LMICs, and by the World Health Organisation via its COVAX system. However, the unreliable supply of vaccines to LMICs meant such countries found it difficult to roll out a national vaccine programme. This created many problems for these countries, including increasing the risks of severe outcomes from COVID-19, increases in secondary infections associated with COVID-19, and creating significant pressure on LMIC's healthcare systems. The lack of an overall global vaccine strategy which resulted in large proportions of the population not being vaccinated almost certainly led to the emergence of new strains of COVID-19. Dr Kelly surmised that the above examples demonstrate the need for discussion around vaccine allocation in how we manage healthcare response particularly for pandemics.

To address some of these issues, Dr Kelly highlighted the World Health Organisation's (WHO's) on a pandemic treaty which is seeking to develop global strategies for pandemic preparedness and a key part of this should be to consider how intellectual property rights over health-technologies can impact pandemic preparedness. Dr Kelly concluded by arguing that innovation is limited in its usefulness if the patients who require new medicines/vaccines produced ultimately do not have access to them. Therefore, she argued for the need to rethink current innovation processes around patents and health. From a clinical perspective in her view, to be prepared for the next pandemic we must urgently address these issues.

Keynote Lecture: “The Civil Rights Case Against Gene Patents in America” Prof Jorge Contreras

[Professor Jorge Contreras](#) delivered the keynote lecture at the PatentsInHumans launch event. His lecture was entitled “The Civil Rights Case Against Gene Patents in America” and reflected on his research and recent book [The Genome Defense: Inside the Epic Legal Battle to Determine Who Owns Your DNA](#) (Hachette/Algonquin, 2021) which has been strongly acclaimed in reviews in the *NY Times*, *Wall St. Journal*, *Nature* and other outlets, and was named "Best Patent Law Book of the Year" by the international IPKat blog. Professor Jorge 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. During 2023, he is serving as a visiting fellow at the London School of Economics and Political Science. Professor Contreras’s research focuses on intellectual property, antitrust law and science policy.



Professor Contreras’s keynote lecture considered the United States Supreme Court case *Association for Molecular Pathology v. Myriad Genetics* which involved a challenge to patents over isolated human genes in the United States. This topic has strong synergies and relevance for the PatentsInHumans project, as the bioethical issues posed by the patentability of isolated elements of the human body – and how

such patents are used - is one of the key categories of 'technologies' examined in the *PatentsInHumans* project.

In the US Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics*, patents on isolated human genes were successfully challenged and the result of this decision was that naturally occurring genetic sequences are no longer patentable in the United States. This contrasts to the current European approach, as under the applicable Biotechnology Directive 98/44EC patents may still be granted over isolated elements of the human body, including genes, under specific circumstances, with the attendant potential to raise similar ethical issues as were seen in the US prior to this decision.

Professor Contreras's keynote lecture focused specifically on the litigation leading to this Supreme Court decision, which involved a challenge brought by the American Civil Liberties Union (ACLU) and the Public Patent Foundation, initially instigated in 2009. The ACLU and Public Patent Foundation represented a group of twenty plaintiffs in the legal action – including scientific researchers, professional associations, medical practitioners and patients – and they argued that human genes, even when isolated from the human body, constituted “products of nature” that are ineligible for patent protection in the United States. Professor Contreras' keynote lecture gave us a flavour of his book which uncovers the layers of this remarkable Supreme Court decision through insights gathered based on interviews Jorge conducted with almost 100 attorneys, advocates, judges, patients and government officials, involved in the legal challenge. The lecture delved into a key part of the book which in his words “explains not only what happened, but why and how, and what its implications are for the future of medical research, the biotech industry and our personal relationship with our genetic makeup.”



You can find out more about the project at:

Twitter: @PatentsInHumans

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