

The social, legal and regulatory challenges of synthetic biology workshop

2-5pm, Wednesday 13 February 2019

**Terrace Room, Level 6, Sir Llew Edwards Building, The University of Queensland
St Lucia Campus**

Synthetic biology, which has been defined as ‘an emerging discipline that uses engineering principles to design and assemble biological components’, is being heralded as offering solutions to the most urgent challenges faced by humanity, including climate change, environmental degradation, population growth, and access to sustainable energy. At the same time, synthetic biology raises unique social, legal and regulatory questions that need to be addressed if the full benefits of the science are to be realised. This workshop will explore some of the key challenges that synthetic biology poses for national and international regulatory frameworks, and consider possible solutions. Additionally, the workshop will look at the ways in which these frameworks are being integrated into the developing science and what this might mean in the future for research, innovation, and development.

Program

Time	Session
2pm-2.45pm	Associate Professor Claudia E. Vickers , The University of Queensland and Director, Synthetic Biology Future Science Platform, CSIRO <i>The science of SynBio: applications and future aspirations</i>
2.45pm-3.30pm	Professor Margo A. Bagley , Emory University School of Law <i>What's Yours is Mine and What's Mine is Mine: Synthetic Biology and Ethical Benefitsharing Obligations under the Nagoya Protocol</i>
3.30pm-3.45pm	Afternoon tea
3.45pm-4.30pm	Professor Charles Lawson , Griffith University <i>How different is different enough? Definitions, taxonomies, names, PBRs and EDVs</i>
4.30pm-5pm	Close

Chair

Professor Brad Sherman, ARC Laureate Fellow, TC Beirne School of Law, The University of Queensland

Speakers

Associate Professor Claudia E. Vickers

The science of SynBio: applications and future aspirations

Our ability to engineer biology to do useful things underpins the Fourth Industrial Revolution—where biotechnology, information technology, manufacturing and automation intersect. Synthetic biology (synbio) is a rapidly emerging interdisciplinary science which seeks to apply engineering principles to biology. The aim is to develop DNA-encoded biological parts that are modular, behave reproducibly, and can be reliably assembled to build complex biological devices and even whole organisms. It builds on earlier, less developed genetic engineering approaches to provide the toolbox through which we can achieve this engineering and, as such, is driving the bioeconomy. It has the potential to deliver remarkable solutions to many global grand

challenges. Using synbio technologies and applications, we can make industrial chemicals and fuels; cure diseases; monitor and remediate our bodies and our environment; control invasive species; and myriad more applications. Synbio is a convergence of biotechnology, genetic engineering, information technology, and manufacturing. It also draws from a wide variety of other disciplines, such as systems biology, chemistry, computer engineering, evolutionary biology, physics, artificial intelligence and machine learning. Processes include design and construction of physical componentry, in vitro and in vivo assembly of components to make genetic circuitry and biological devices, testing of those devices; and ultimately development of advanced engineered organisms. It is fundamentally applied in that the aim is to achieve a useful outcome that solves a problem. Synthetic biology is a disruptive technology which will enable innovation in many different fields and disciplines; the social, ethical, legal and institutional considerations around synthetic biology are still being debated. In this presentation, I will explain what synthetic biology is, what it is being applied to, and where it may go in the future.

Associate Professor Vickers holds dual roles as Director of the CSIRO Synthetic Biology Future Science Platform at CSIRO (Australia's Federal research agency) and Group Leader in the Australian Institute for Bioengineering and Nanotechnology at The University of Queensland (UQ). She completed her PhD in cereal crop biotechnology at CSIRO Plant Industry and UQ in 2004. She held a post-doctoral position at Essex University in the UK 2004-2007, where she worked on abiotic stress and the metabolic regulation and physiological function of volatile isoprenoids in plants. She returned to UQ in 2007, joining the Australian Institute for Bioengineering and Nanotechnology to expand her research into microbial metabolic engineering. She now leads a group focussed on converting agricultural biomass to industrially useful biochemicals using advanced synthetic and systems biology approaches. Target compounds sit in the isoprenoid group of natural products, and include jet fuel, plant hormones for agricultural applications, food additives (flavours, colours, etc.), fragrances, and pharmaceuticals. Since January 2017 Associate Professor Vickers has held a joint appointment with the Commonwealth Science and Industry Research Organisation (CSIRO) to lead the CSIRO Synthetic Biology Future Science Platform (SynBioFSP), a \$60 million research and development portfolio aimed at increasing Australia's capability in synthetic biology and building a synthetic biology-based bioeconomy in Australia. The SynBioFSP is a collaborative hub, linking Australia's innovation chain with over 40 national and international research partners and >200 people contributing to >60 projects. She is also on the Executive of Synthetic Biology Australia.

Professor Margo A. Bagley

What's Yours is Mine and What's Mine is Mine: Synthetic Biology and Ethical Benefitsharing Obligations under the Nagoya Protocol

Corporate and academic synthetic biology researchers are using sequence information from untold numbers of organisms to develop improvements in diverse product areas from agriculture to therapeutics. Quite often, such information is being used without regard to the origin of the particular organism from which it was derived; in fact, the researcher may not even know or be able to easily trace the original geographic source. However, the Nagoya Protocol (NP) on Access and Benefit Sharing to the U.N. Convention on Biological Diversity (CBD), requires that users of genetic resources share the benefits of such utilization with the providers of the original resources. Although copious monetary benefits are being generated from synthetic biology-based products, there is little evidence to indicate that any meaningful benefit-sharing is taking place.

The issue of whether or to what extent sequence information is subject to such obligations is a point of significant controversy in CBD/NP discussions and generated a call for numerous studies in the recently concluded Conference of the Parties/Meeting of the Parties sessions in Sharm El Sheikh, Egypt in December 2018. This talk will explore positions on both sides of these issues as well as on the related issues of the feasibility of a global multilateral benefit sharing mechanism as a vehicle for users to comply with NP benefit-sharing obligations which are not amenable to the current bilateral benefit sharing model.

Margo A. Bagley is an Asa Griggs Candler Professor of Law at Emory University School of Law. She returned to Emory in 2016 after ten years at the University of Virginia School of Law, where she held the Hardy Cross Dillard chair. Professor Bagley served on the National Academy of Sciences Committee on University Management of Intellectual Property, and is an advisor to the Government of Mozambique in World Intellectual Property Organization (WIPO) matters. She is also Friend of the Chair in the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge, and Folklore, and is a member

of the Convention on Biological Diversity's Ad Hoc Technical Expert Group on Digital Sequence Information and Genetic Resources. She has served as a consultant to the FAO International Treaty on Plant Genetic Resources for Food and Agriculture Secretariat, and is a collaborator in the Harvard University Global Access in Action (GAIa) program. Professor Bagley has taught international and comparative patent law courses in several countries and has published numerous articles, book chapters, and monographs as well as two books with co-authors. A chemical engineer by training, Professor Bagley worked in industry for several years before attending law school and is a co-inventor on a patent for reduced fat peanut butter.

Professor Charles Lawson

How different is different enough? Definitions, taxonomies, names, PBRs and EDVs

How different does something have to be to be considered different? How different can something be and still be considered the same? The 1991 International Convention for the Protection of New Varieties of Plants (UPOV Convention) introduced the concept of "essentially derived varieties" (EDVs) expanding the scope of the plant breeder's right. The purpose of EDVs was to limit "plagiarism", "copycat breeding", "mimics", "imitations" or "cosmetic" varieties, and an unfair free riding on the original plant breeder's time and investment through minor genetic changes. The problem is how to find a measure of difference to distinguish an EDV from a new variety? The presentation addresses why the threshold legal question of EDV is more than a mere quantitative technical question requiring a technical answer, such as a statistical index or a DNA sequence. These same challenges are ahead for synthetic biology and law.

Charles Lawson is a Professor in the Griffith Law School, Griffith University. He studied science and law at The Australian National University and holds a Bachelor of Science with Honours in biochemistry and genetics and a Bachelor of Laws. He also holds a Doctor of Philosophy from the ANU's Research School of Biological Sciences in molecular biology and biochemistry and a Master of Laws from Queensland University of Technology for research into gene patenting and competition. Before joining the university sector he worked as a lawyer in both the private and public sectors, including at the Australian Government Solicitor and the Commonwealth Department of Finance and Deregulation. His research focus is on intellectual property and public administration law.