

## **LL4007/LL5007/LL6007 Biotechnology Law - Prof. Andrea Stazi**

This module will deal with the legal, policy, economic, social and ethical issues arising from the application of biotechnology techniques and the use of their methods and products in various sectors, such as medical, agricultural, etc.

The main focus will be on intellectual property and patent issues, particularly in respect of genetic, medical and pharmaceutical technology which are key sectors in Singapore and other countries.

Some specific issues that will be analyzed include patentability of biological materials, gene sequences, stem cells, plants, animals, humans, medical treatments, etc.

More generally, in an international and comparative perspective, different regulatory systems for research and development using controversial biotechnology techniques, including human genetic modification and cloning, GMOs, CRISPR, etc., will be analysed, also in light of a multidisciplinary approach which will take into account aspects like ethics of interventions on human life, access to genetic resources, sustainability, biodiversity and food sovereignty.

Apart from Singapore law, an analysis of the approaches in Europe, US, China, India, Japan and Australia will be explored.

This module will be of interest to all who wish to gain greater insights into the important and rapidly developing field of biotechnology. Prior knowledge of biology or intellectual property law will be useful but is not necessary, as all students will be introduced to the fundamentals of biology, genetics, intellectual property and patent law.

At the end of the module, participants should be able to:

- 1. Develop an awareness of the impact of recent developments in the biotechnological field and the challenges posed to law, economy, society and ethics.*
- 2. Critically analyze the challenging issues on biotechnological innovations from a multidisciplinary, international and comparative perspective.*
- 3. Understand and critically analyse and evaluate the interests, forces and legal process that influence and shape the development and application of biotechnology.*
- 4. Acquire a knowledge of the principles and concepts underpinning the application of traditional legal rules, and the development of new legal rules, to socio-economic issues raised by biotechnology.*
- 5. Develop an understanding of the critical role that intellectual property and patents play in the protection of research and development in the biotechnology industry, as well as, its intersection with public health, sustainability, access to resources and ethics.*
- 6. Be able to provide basic advice to scientists and those wanting to commercially exploit biotechnology and its outcomes on their rights and responsibilities under the law.*
- 7. Perform legal research and writing in the area of biotechnology law to elaborate solutions to complex problems arising out of the development and application of biotechnology.*

The module assessment is based on class participation (20%) and a research paper (80%), with a student presentational depending on student subscription.

The structure of the module is as follows (subject to change):

## **SEMINAR ONE: INTRODUCTION TO BIOTECHNOLOGY – HISTORY, SCOPE AND DEVELOPMENTS**

### **Readings**

#### *1) Mandatory:*

S. Bhatia, [History, scope and development of biotechnology](#)

#### *II) Suggested:*

Future of Life Institute, [Benefits & Risks of Biotechnology](#)

Khan Academy, [Intro to Biotechnology](#)

Z. Naz, [Introduction to Biotechnology](#)

S. Yup Lee, [Biotechnology: what it is and how it's about to change our lives](#)

S. Yup Lee, [How could biotechnology improve your life?](#)

V. De Lorenzo, [How biotechnology is evolving in the Fourth Industrial Revolution](#)

E. O' Day, S. Yup Lee, [Who holds the key to the future of biotechnology? You do](#)

I.Y. Abdurakhmonov, [Bioinformatics: basics, development and future](#)

A. Bartlett et al, [Bioinformatics: indispensable, yet hidden in plain sight?](#)

## **SEMINAR TWO: BIOTECHNOLOGY ECONOMY – VALUE CHAINS AND SUSTAINABILITY: THE CASE OF GMOs**

### **Readings**

#### *1) Mandatory:*

S. Wydra, [Value Chains for Industrial Biotechnology in the Bioeconomy-Innovation System Analysis](#)

A. Stazi, [Genetically modified organisms and sustainable development: regulatory approaches, access to resources and traceability](#)

#### *II) Suggested:*

E. Gawel et al, [A Path Transition Towards a Bioeconomy - The Crucial Role of Sustainability](#)

T. Heimann, [Bioeconomy and SDGs: Does the Bioeconomy Support the Achievement of the SDGs?](#)

A. Tylecote, [Biotechnology as a new techno-economic paradigm that will help drive the world economy and mitigate climate change](#)

K. Gostek, [Genetically Modified Organisms: How the United States' and the European Union's Regulations Affect the Economy](#)

A. Anyshchenko, [The Interaction Between Science, Policy and Law in the Field of Food Security: Can Biotechnology Contribute to Sustainable Agriculture?](#)

K. Kariyawasam, [Legal Liability, Intellectual Property and Genetically Modified Crops: Their Impact on World Agriculture](#)

## **SEMINAR THREE: BIOTECHNOLOGY AND THE LAW – INTERNATIONAL CONVENTIONS AND TREATIES**

### **Readings**

#### *1) Mandatory:*

M. Herdegen, [Introduction: regulation of biotechnology, between anxieties and trust in scientific progress](#)

L. Li Ching, [Synthetic Biology and Relevant International Law](#)

*II) Suggested:*

S. McCaffrey, [Biotechnology: Some Issues of General International Law](#)

R. Yotova, [The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law](#)

## **SEMINAR FOUR: SYNTHETIC BIOLOGY AND GENE EDITING – REGULATION AND GOVERNANCE IN COMPARATIVE LAW**

### **Readings**

*I) Mandatory:*

B.D. Trump, [Synthetic biology regulation and governance: Lessons from TAPIC for the United States, European Union, and Singapore](#)

*II) Suggested:*

M.M. Georgiadis, M. Ryznar, [Regulating What Has Yet To Be Created: An Introduction](#)

A. Nordberg et al, [Cutting edges and weaving threads in the gene editing \(R\)evolution: reconciling scientific progress with legal, ethical, and social concerns](#)

## **SEMINAR FIVE: BIOTECHNOLOGICAL INVENTIONS – PATENT LAW AND LIMITS OF PATENTABILITY**

### **Readings**

*I) Mandatory:*

J. Straus, [Intellectual property rights and bioeconomy](#)

*II) Suggested:*

R.R. Rao, [Patenting in Biotechnology - An Overview](#)

M. Solis, [The Effect of Changing Patent Eligibility Subject Matter in the Biotechnology Field](#)

T. Ahmad, D. Mondal, [Patentable Subject Matter and the Necessity of Limitations on It](#)

## **SEMINAR SIX: PATENT ELIGIBILITY OF SPECIFIC BIOTECHNOLOGICAL SUBJECT-MATTER: MICROORGANISMS, PLANTS AND ANIMALS – COMPARATIVE ANALYSIS OF VARIOUS JURISDICTIONS**

### **Readings**

*I) Mandatory:*

M. Laskar, [Patentability of Life Forms \(USA, Europe & Asia\)](#)

*II) Suggested:*

M. Blakeney, [Patenting of Plant Varieties and Plant Breeding Methods](#)

A. Steinbach, [Technology, Patents, and Plants: Are the Next Generation of GMOs Patentable?](#)

K. Dogvebi, [The Sui Generis System of Plant Variety Protection Under the TRIPS Agreement: An Empty Promise for Developing Countries](#)

G. van Overwalle, [Creating Universal and Sustainable Access to Plants and Seeds: The Role of Clearinghouses, Open Source Licenses and Inclusive Patents](#)

B. Stankovic, [Patenting the Minotaur](#)

## **SEMINAR SEVEN: INTERVENTIONS ON HUMAN GENES AND CELLS – BIOETHICAL AND LEGAL ISSUES**

### **Readings**

#### **I) Mandatory:**

M. Goodwin, A. Whelan, [Law, Bioethics, and Biotechnology](#)

A. Stazi, [Human genomics and surrogate motherhood: legal pluralism and the circulation of the models](#)

#### **II) Suggested:**

R. Faden, M. Powers, [Biotechnology, Justice and Health](#)

T.C. Berg, [Life Patents, Religion, and Justice: A Summary of Themes](#)

P. Enriquez, [Editing Humanity: On the Precise Manipulation of DNA in Human Embryos](#)

A. McMahon, [Gene Patents and the Marginalisation of Ethical Issues](#)

T. Minssen, [Patenting Human Genes in Europe - And How It Compares to the US and Australia](#)

M. Aboy et al, [After Myriad, What Types of Claim Amendments Change a Patent Ineligible Isolated Gene Claim Into an Eligible Patent Claim That Is 'Markedly Different' From Nature?](#)

## **SEMINAR EIGHT: PATENT ELIGIBILITY OF METHODS OF MEDICAL TREATMENTS, PRODUCTS AND MEDICINES – COMPARATIVE ANALYSIS OF VARIOUS JURISDICTIONS**

### **Readings**

#### **I) Mandatory:**

H.I. Oguanobi, [Broadening the conversation on the TRIPS agreement: Access to medicines includes addressing access to medical devices](#)

#### **II) Suggested:**

Y. Li, [Human Gene Patenting and Its Implications on Medical Research](#)

R.C. Dreyfuss et al, [Patenting Nature - A comparative perspective](#)

G. Duffield, [Healthcare innovation and patent law's 'pharmaceutical privilege': is there a pharmaceutical privilege? And if so, should we remove it?](#)

C.M. Holman, [Patent Eligibility as a Policy Lever to Regulate the Patenting of Personalized Medicine](#)

L.G. Abinader, J.L. Contreras, [The Patentability of Genetic Therapies: CAR-T and Medical Treatment Exclusions Around The World](#)

D. Friedmann, [IP Protection of Preventive TCM and Precision Medicine in China, Harnessing Holistic Research from Man to Mankind](#)

J.S. Sherkow et al, [Is it 'gene therapy'?](#)

WHO, [Intellectual property and access to medicines](#)

N. Boschiero, [Intellectual property rights and public health: an impediment to access to medicines and health technology innovation?](#)

D. Gotham et al, [Patent pooling to increase access to essential medicines](#)

## **SEMINAR NINE: THE CRISPR REVOLUTION – LEGAL REGULATION, INTELLECTUAL PROPERTY AND ETHICAL IMPLICATIONS**

### **Readings**

#### **I) Mandatory:**

I. Braverman, [Editing the Environment: Emerging Issues in Genetics and the Law](#)

*II) Suggested:*

P. Enriquez, [CRISPR GMOs](#)

A.M. Shew et al, [CRISPR versus GMOs](#)

M.O. Medvedieva, Y.O. Blume, [Legal Regulation of Plant Genome Editing with the CRISPR/Cas9 Technology as an Example](#)

H.T. Greely, [CRISPR'd babies: human germline genome editing in the 'He Jiankui affair](#)

I. Theesfeld, [The ethical dilemma with governing CRISPR/Cas genome editing](#)

R. Feldman, [The CRISPR Revolution: What Editing Human DNA Reveals About the Patent System's DNA](#)

O. Feeney et al, [Patenting foundational technologies: Lessons from CRISPR and other core biotechnologies](#)

L. Tamayo Del Portillo, [From Dissertation to Litigation: The First-to-Invent System versus the First-to-File System: A Comparative Analysis in Light of the Legal Dispute Over the CRISPR Cas9](#)

J.S. Sherkow, [Inventive steps: the CRISPR patent dispute and scientific progress](#)