

Collaboration activities between ANPCYT/SECYT and The University of Edinburgh - Centre for Intellectual Property and Technology Law”

General Objective: to explore the themes of the effective and optimal promotion, protection and regulation of biotechnology in a comparative study between the United Kingdom and Argentina.

- Particular Objective: to explore stem cell technologies, how they might be (a) effectively regulated, and (b) effectively promoted and protected through judicious use of patent and regulatory regimes in Argentina and Latin America more generally. The focus will be on the role of law as a regulatory/promotional tool; comparisons will be drawn with the regulatory/promotional regimes currently operating in Europe, and where appropriate, other legal systems, such as Brazil.

Setting the project against the crucially important social, cultural and ethical background jointly with scientific’ advances, its originality lies:

- (i) in taking a comparative *foresight* perspective to help direct innovation policy in Argentina and beyond;
- (ii) in the up-front commitment to the enterprise of various stakeholders, namely, governmental agencies, industry representatives both in Europe and Latin America, scientists and academics; and
- (iii) its objective to map the processes of developing patent and regulatory policies with the aim of identifying lessons for other countries or regions.

Broadly, three branches of overlapping research will be undertaken:

Regulation: examining the research infrastructure and approaches to control of the science/scientists - How does regulation of the science overlap with regulation of translation of the science to the clinical setting? What about regulation to protect research subjects? What balances need to be struck with the interests of science and scientists?

Protection and Promotion: commercial aspects - how well does the patent regime currently promote and protect biotech? What needs to change to provide an appropriate regime for new biotechnologies? How might Argentina better co-ordinate efforts to protect its rich biodiversity?

Interconnectedness: the patent/regulation interface - How can we better understand the complexities of the interaction and overlap of regulation and promotion regimes, and how might various laws/legal practices interact better to achieve the collective ends of such regimes?

Activities in Argentina:

The Science and Technology Agency decided to create a new and unique Advisory Commission on Cellular Therapies and Regenerative Medicine in order to have specialised advisory input on decisions about funding stem cell projects, as well as to create a specialised organisation to provide broader opinions of the socio-legal and economic issues to several actors in the country, including the National Congress and the Ministry of Health.

The Advisory Commission was established in October 2006 and has already issued technical opinions to the National Congress in respect of a Bill on “Creation of a Registry for Private Banks of Umbilical Blood Cord”.

The Commission held plenary sessions during March 2007 to consider the ethical concerns raised by a case in which a patient was treated in Regina Matter Hospital with a so-called “stem cell therapy” after paying professional fees. This treatment was an experiment which had not followed any medical protocols, nor was it under the control of the Health Authority.

The current concern of the Commission is how to address publicity and propaganda made by groups that offer stem cells therapies while safeguarding the interests and the rights of patients.

Activities of this Commission linked with the research project:

- A Cooperation and Research agreement will be signed between the Agency and the AHRC Research Centre for Studies in Intellectual Property and Technology Law at The University of Edinburgh in order to create links and exchange knowledge, experiences and technology between the Argentinean Government and the University of Edinburgh.
- A seminar will take place in Buenos Aires on 17 July 2007 as an inaugural meeting of the project, which is designed to extend over the next few years.