scripted

Volume 7, Issue 3, December 2010

SCRIPT INTERNATIONAL ROUNDTABLE WORKSHOP: OPEN SCIENCE & STEM CELL TECHNOLOGY

Carol George[*]

Old College, University of Edinburgh, 16-17 September 2010.

DOI: 10.2966/scrip.070310.568

[*] PhD Candidate at the AHRC Centre for Intellectual Property and Technology Law (SCRIPT) of the School of Law, University of Edinburgh, UK.

Background

The SCRIPT Centre

The AHRC Research Centre for Studies in Intellectual Property and Technology Law (SCRIPT) was established in 2002 with core funding from the Arts and Humanities Research Council (AHRC). Through the study and teaching of IP and IT law, medical jurisprudence and ethics as inter-related phenomena in their social, ethical, cultural and commercial contexts, SCRIPT emerged as a pioneer centre in the UK. It secured a second phase of AHRC support in 2007, extending the work of the Centre until 2012.

Beyond IP and IT, SCRIPT research is about the synergistic relationship between law, technologies, commerce and society in the widest possible sense; its work extends to the adjunct areas of biotechnology, genetics, medical jurisprudence and ethics, law and artificial intelligence, as well as regulation of electronic commerce, the Internet, media and the information society.

In its second phase, the SCRIPT Centre has been able to engage in new research targeted to the needs of industry, academe and society. It has moved beyond its project-driven approach to focus on the creation and development of new paradigms for the legal characterisation of, and response to, the demands and potentials of new technologies. It has facilitated new collaborations aimed at policy and practice-driven ends, not only with other academic lawyers, but also with scholars from other disciplines, policy-makers, practitioners, business and civil society.

Roundtable

One such initiative is the International Roundtable Workshop on Open Science and Stem Cell Technology that took place at the University of Edinburgh on the 16-17 September 2010. The event came about in connection with the PhD research of the author on 'openness, innovation and commercialisation in the field of stem cell technology'. This was the last of five studentships funded by the AHRC to augment work in areas of interest and expertise at the Centre, including that of co-director, Andrés Guadamuz, in open source in the digital context and its applications to science, and the Centre's director, Professor Graeme Laurie, in medical law and bioethics. The Roundtable also had the support and assistance of Aidan Courtney, an associate of the Centre and chief executive officer of Roslin Cells, a non-profit corporation and major producer of stem cell lines in the UK.

The goal of the Roundtable was to bring together a small number of experts from science, industry, academia, legal practice and government to stimulate and facilitate dialogue about the (practical, theoretical and legal) issues related to open science and the regulation of human stem cell technology. The first step is to identify the central questions that need to be pursued, in order to create a platform for ongoing work on policy and regulatory structures.

The number of participants was kept deliberately low, and a there was representation from a wide variety of disciplines, in order to facilitate interaction. Following the introductory comments of the convenor, the bulk of each session was given over to

discussion and debate about the feasibility of regulating stem cell technology through a publicly-funded, contractually-constructed system such as the UK Stem Cell Bank.

The AHRC Centre ultimately hosted a gathering of 17 individuals from Canada, the US and the UK, covering the costs of those from outside of Edinburgh, as well as an introductory dinner for everyone the night prior to the Roundtable. The benefits of the prefatory event at a local restaurant were evident the following day. As participants had had an opportunity to meet one another personally over a relaxed meal and to talk to a number of the others about their areas of interest and expertise, a comfortable working group had begun to coalesce by the time the Roundtable began on the morning of the 17th.

Synopsis

Five individuals were invited to introduce and convene a discussion related to one of five overlapping subject areas during the day. They were asked to provide a very brief introduction and some key questions around which the discussion could be structured. The subject areas were:

- Openness and Innovation (Andrés Guadamuz, SCRIPT, U of Edinburgh);
- Openness and Ownership (Yann Joly, U of McGill, Montreal, Canada);
- Openness, Stem Cells and Ethics (Hugh Whittall, Nuffield Council on Bioethics);
- Organisational Structures (Jerome Reichman, Duke University);
- International Collaboration (Timothy Caulfield, U of Alberta, Edmonton Canada).

The questions that were raised for discussion are set out below. A full report of the introductory presentations and content of the discussion sessions will be prepared for circulation to the participants, and possible publication in a further issue of SCRIPTed.

Session I: Openness and Innovation

Andrés Guadamuz introduced the ideas of freedom and openness present in the open source movement, which he summarised as the "freedom to tinker, freedom to create something, freedom to take some works and rework them." He addressed the difficulties associated with the translation of these principles, which in the software context are generally secured by copyright licensing, into the area of biotechnology. He suggests that, in the absence of licences, it is the fostering of innovation, of sharing your work, of making your work available in a way that allows others to reuse your work that is of real value.

Questions

The questions presented by Andrés for discussion are:

1. Are the concepts of openness and freedom prevalent in the free and open source software movement relevant and/or useful in an open science context?
2. Given the various types of protection in the scientific arena, is it useful to think of incentives to innovation from a legal perspective?

3. Are technological solutions, such as the semantic web, machine-readable data, standards etc, preferable to legal solutions in the context of openness and innovation?

Session II: Openness and Ownership

Yann Joly talked about stem cell technology, openness and ownership. He felt that innovation cannot be addressed in isolation from commercialisation and that the problem is no longer innovation but *translation*. YJ looked at four theoretical models that could be used to facilitate translation of stem cell technology: he mentioned commercial secret, but focused on the proprietary/IP model, the 'mixed' or controlled access model, and open science.

Questions

The questions posed by Yann Joly were:

1. When and how should the result of stem cell research be protected? At what stage? Upstream/downstream? When is it best to protect it, and what's the best way to protect it?
2. Can open access (open science, or a controlled model, a mixed model) constitute a viable business model for stem cell technology transfer? Can we actually go downstream with that model or is it something that can only work upstream?
3. Can open access be reconciled with the traditional IP business model? Is there a way to have a mixed model in which IP has a role to play?

Session III: Openness, Stem Cells and Ethics

Questions

The questions presented by Hugh Whittall for discussion are:

1. Should embryonic and non-embryonic stem cell lines be treated in substantially different ways? If so:
    a. Is it because there currently exist in the UK different regulatory regimes for different stem cells, depending on their derivation?
    b. Is differential treatment related to the nature of the material itself?
    c. Should ESC and non-ESC lines be treated differently at all point downstream?
2. Do ESC and non-ESC lines give rise to different responsibilities toward:
    a. providers of material (informing them of potential downstream applications); and
    b. recipients of therapies (specifying the provenance of the material)?
3. Should and how can the regulatory system be made open and transparent in a way that engenders trust from professional, public and policy perspectives?

Session IV: Organisational Structures

Questions

The questions presented by Jerome Reichman for discussion are:

1. To stimulate the sharing of upstream microbial genetic resources for research purposes, we propose a liability rule – 'take and pay' rule – applicable to downstream commercial applications of pooled materials having 'no known or likely commercial value' when contributed.
    a. Could we devise similar mechanisms for the pooling of stem cell lines and related materials?
    b. In that connection, can we devise a "chain of title" comparable to the biomarkers that track research uses of all microbial genetic resources?
2. Assuming the formation of a viable pool of upstream research materials, how can we potentiate research payoffs by digitally integrating relevant scientific data and information into distributed community-organised repositories that we call "open knowledge environments"?
3. What kinds of governance mechanisms would be needed at both the national and international levels to coordinate a global research commons for stem cells and related materials, data and information, as sketched above, given:
    a. IP restrictions on access to research assets emanating from the TRIPS Agreement of 1994; and
    b. The Convention on Biological Diversity of 1992?

Session V: International Collaboration

Questions

The questions presented by Tim Caulfield for discussion are:

1. What are the greatest challenges or hurdles to collaboration and commercialisation caused by international jurisdictional variation (including for example, international intellectual property policy, regulatory structures, research ethics rules etc).
2. Is international harmonisation desirable and necessary? If so, in what area is it most urgent?
3. What institutions and mechanisms, including open systems, are necessary and can be mobilised in order to facilitate international collaboration?

Looking ahead

The strategy for the Roundtable appears to have been successful. Feedback from the participants indicated that they felt that they had learned a great deal during the day, and that the form, content and participation were very positive. The welcome dinner and the setting of the Raeburn Room in which the meeting was held were both well received. People seemed genuinely engaged in the debate all day, were grateful to have been included, and expressed enthusiasm about the outputs to follow.

Each of the sessions was digitally recorded and the audiofiles circulated to participants for their private use. The files will be professionally transcribed, analysed, and a full briefing paper produced in due course. From this record of the work that was done at the 2010 Roundtable, it is anticipated that a draft set of principles related to the use of openness in the regulation of stem cell lines will be circulated. A further Roundtable meeting will be convened, late in 2011, to debate and formalise these principles further with the view to a Charter that might be applicable not just to stem cell lines, but to the regulation of other human biotechnologies as well.