

Intellectual Property and the Biosciences: Past trends and future directions

7th & 8th July 2014

Venue: Board Room (Room 7.16), Level 7, Webb Centre (S02), Griffith University, South Bank Campus, Brisbane.

Audio recordings will be published at ipbio.org (with approval from speakers).

Monday 7th July

8.30-9.00: Tea and Coffee

9.00-9.30: Introduction

9.30-11.00: Bronwyn Parry (KCL): Classifying Medical Devices: Predication, kinship and the construction of ‘novelty’

The regenerative medicine industry and associated product development is currently undergoing exceptionally rapid expansion worldwide. A plethora of new ‘assemblages’ including, for example, decellularised porcine hearts reseeded with autologous stem cells and synthetic polymer scaffolds infused with growth hormones are being developed for insertion in humans for therapeutic use. Protection and realisation of capital investment in this field demands both approval from both regulatory agencies such as the FDA and robust patent protection. In this paper I examine the ways in which these entities are currently characterised and classified in technical and regulatory terms. I begin by examining how their provenance is constructed ‘genealogically’ by reference to their ‘predicates’ or close relatives. In the second part of the paper I challenge this ‘origin story’ demonstrating some key inconsistencies in the way these narratives of kinship are employed - being used, on one hand, to accelerate approval of devices that should be subject to more detailed review whilst being simultaneously obscured to substantiate the claims to ‘novelty’ that a successful patent application must necessarily sustain.

11.00-11.30: Break

11.30-13.00: Jay Sanderson (ACIPA, Griffith University): Making patented life live: values and obstacles in the creation, commercialisation and death of the Enviropig

Who killed the Enviropig? Born in 2008 from the genetic enhancement of a Yorkshire pig breed, the Enviropig promised to generate less-polluting waste with “environmental benefits”. Yet, despite holding patents on the Enviropig technology, in 2012 the Enviropig project was defunded and the University of Guelph had to kill its remaining animals. Clearly patents were not enough to keep the Enviropig alive. This chapter explores the roles played by technology, law, politics, business interests and morality in the demise of the short-lived Enviropig. Patent law—and specifically questions of subject matter, novelty and obviousness—played an important role in this story but in order to understand why the pigs died we need to situate the Enviropig within the wider, relational space in which the pig lived and died. In contrast to

much of the recent literature on intellectual property in the biosciences—preoccupied for the most part with genuine concerns over patent creep—the case of the Enviropig points up the fragile nature of patented life forms, the instability of the bricolages which are necessary to bring them into the world and what it takes for patented life to really live.

13.00-14.00: Lunch

14.00-15.30: Graham Dutfield (University of Leeds): Intellectual Property, Tradition and Modernity

There are important material differences between a modern pharmaceutical product and a traditional medicine, as there are between a traditional plant variety and a scientifically bred one. Socially, culturally and epistemologically the differences between these types of knowledge systems are even greater. Resolving the relationship between tradition and the modern in these contexts has major implications for equity, promoting social welfare-enhancing innovation, and for policymaking and the development of international law;

In light of 12,000 years of supposedly unscientific crop improvement with no legal protection, how can plant variety and patent protection be justified? In what ways is modern-day crop improvement genuinely innovative in ways that traditional methods are not? Why are many traditional communities reluctant to accept a wholesale replacement of their own varieties by those developed by scientific institutions?

What is the role of traditional law, customary law, common law and community law, and how should these take precedence over more formalised legal regimes?

15.30-16.00: Break

16.00-17.30: Brendan Tobin (ACIPA, Griffith University): Disclosure of origin: A persistent distraction or a timely solution

Proposals to use intellectual property rights regimes as a means for enforcing rights over genetic resources and traditional knowledge first emerged in 1994. Twenty years on some 50 countries have reportedly adopted some form of biodiversity related disclosure system and legislation on disclosure is in force in at least 18 countries. The Andean community has had disclosure obligations in place for over a decade and negotiations for an international disclosure regime are advancing at the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property Genetic Resources, Traditional Knowledge and Folklore. All this would seem to support the argument that disclosure regimes are coming of age. But are they in fact?

This paper examines negotiations at WIPO on proposals for an international disclosure system and its relation to the regulation of access to genetic resources and traditional knowledge under the Nagoya Protocol and in regional and state implementing legislation. It pays particular attention to European legislation implementing the Nagoya Protocol and the call by the European Parliament for the adoption of disclosure requirements in international law. The paper argues that adoption of a weak disclosure of source system at WIPO may undermine national and regional disclosure regimes and may indeed serve as a distraction from the overall failure of international regulation to bring equity and fairness to the trade in genetic resources and traditional knowledge. The paper argues that robust disclosure requirements have a vital

role to play in the development of a functional global system of access and benefit sharing and it takes the view that no regime at all is better than a regime with no bite.

7.00: Dinner

Tuesday 8th July

9.00-9.30: Tea and Coffee

9.30-11.00: Matthew Rimmer (ACIPA, ANU): Patenting Geoengineering

This paper considers the role of patent law in respect of geoengineering. In light of the recent litigation in respect of *Bilski*, *Prometheus*, and *Myriad*, it is worth exploring the question,

Should patents on geoengineering be allowed? Defenders of geoengineering would maintain that such technology is legitimate, much like traditional forms of engineering. Critics, such as the ETC Group, has called for a ban on patents in respect of geoengineering. There have been fierce debates over the ethics of geoengineering. Philosophers and policy-makers such as Stephen Gardiner, Clive Hamilton, Bill McKibben and Al Gore have argued over the merits over such technologies. It is useful to situate such a discussion in the context of previous debates over intellectual property and emerging technologies - such as biotechnology, nanotechnology, synthetic biology, and clean technologies.

Moreover, this paper explores the potential for patent thickets in respect of geoengineering. What will be the impact of such patents on research, clean tech, the environment, the climate? There has also been much concern about the emergence of patent trolls in respect of geoengineering. Intellectual Ventures has developed a large portfolio of patents in this area, to the alarm of some. As such, it is worthwhile considering whether President Barack Obama's policy options for patent trolls will be useful or effective in this field.

11.00-11.30: Break

11.30-13.00: Shubha Ghosh (University of Wisconsin): Demarcating Nature After Myriad

The United States Supreme Court in its *Myriad* decision affirmed the existence of a borderline between unpatentable natural phenomena and potentially patentable inventions. However, the Court cribbed a few pages from standard biotechnology to lay out the contours of this boundary without appeal to patent law or policy. As a result, courts have read the exclusion from patenting quite broadly in subsequent cases, such as in *Ariosa* involving fetal DNA and in the recent *Roslin Institute* decision involving clones. While some may welcome this broad limitation on patenting life forms, the lack of a clear policy is worrisome for two reasons. The first has to do with arguments that US courts have undermined their credibility by assuming broad discretion, at the expense of expert agencies, in reviewing questions of science and patent law. Labels like anti-patent subvert any claim to principle. This first problem reverberates with a second class of problems: collateral limitations on patenting in the area of infringement and in competition policy. In the same term that the Court limited patents on naturally occurring DNA, it also held in *Bowman v. Monsanto* that planting a patented seed constitutes patent infringement. This decision ignored the natural processes of reproduction and regeneration and subsumed them under the patent claims. Furthermore, the Court has

moved towards finding competition limitations on the scope of patents in its *Actavis* decision, published a few weeks before its *Myriad* decision. While the Court attempted to articulate the policies of competition law that limit patents in the *Actavis* case, the Court has not recognized the competition issues that arise in the biological sciences when the nature meets the marketplace. This paper revisits the *Myriad* decision and seeks to do what the Court failed to do, namely articulate the policy basis for separating natural phenomena from patentable subject matter and identify how these policy limitations apply to issues of infringement and competition policy.

13.00-14.00: Lunch

14.00-15.30: Kara W. Swanson (Northeastern University, School of Law): Intellectual Property Where Invention Meets the Body, or, *Myriad Genetics* in Historical Perspective

In June 2013 the Supreme Court issued its decision in *Association for Molecular Pathology v. Myriad Genetics*, relying on molecular biology to distinguish between forms of human genes that are unpatentable products of nature and those that are patentable manmade inventions. This decision is the latest opinion of a series defining patentable subject matter that arguably originated with *Diamond v. Chakrabarty* (1980), in which the Court ruled that living organisms could be patentable inventions. Patents have come to mark the boundary between the natural body and emerging technologies sourced from the body, what I call “body products.” Since *Chakrabarty*, patents and the biotechnology industry in the United States have been tightly linked – patents are the basis for investment. Also since *Chakrabarty*, there has been steady criticism of the application of intellectual property law to living organisms, particularly the human body, criticism evident in the public discussions surrounding *Myriad Genetics*.

Body products were developed and used long before 1980, however. This paper examines the emergence of two of the first body products, human milk and blood, as historical case studies. These case studies reveal the long-standing tension between the natural and the technological that persistently threatened the status of earlier body products, even in the absence of intellectual property law. Based on these case studies, I argue that the current debates about patentable subject matter, insofar as they focus on patent law as the problem, are misguided. The broadening of patentable subject matter did not cause the controversy about the boundary between the natural and technological. What it has done is to disrupt the earlier approach to resolving that long-standing tension. Before the introduction of patents into the realm of body products, Americans learned to tolerate body products as technologies by considering these new technologies as personal gifts, focusing on a distinction between gifts and commodities rather than on the natural/manmade boundary. Protecting body products with patents emphasizes the commodity aspects of body products, undermining the gift narrative. The challenge for those supporting such patents is the development of a new narrative that acknowledges the personal aspects of body products in order to balance the same tensions that emerged over a half century ago.

15.30-16.00: Break

16.00-17.30: Round table (future directions & publications)

7.00: Dinner