

Chapter 1

Intellectual Property and Genetically Modified Organisms

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The first modern genetically modified organisms (GMOs) appeared on the planet in the early 1980s. Public debates about these astonishing new objects were fierce. They centred mainly on the politics of regulating risk. In the years since those first debates agricultural (green) and medical (red) GMOs have entered the marketplace in several countries. Inevitably, many areas of law have played a role in this process as GMOs are controlled to varying extents, and in several different ways, from their inception in the laboratory all the way through to their use by consumers. This entanglement of GMOs and law has evolved into a rich area of research. While the politics of regulating the risks of GMOs remain an active and incomplete project, it is the other areas of law in this entanglement that have captured our attention. Of particular interest is the convergence of GMOs with the broadly conceived area of intellectual property.

This volume sits at the intersection of two developing research fields. On the one hand the extensive literature on GMOs is increasingly coming to consider issues beyond risk. The prospective tone of early classics on regulation, such as Michael Ruse and David Castle's 2002 *Genetically Modified Foods: Debating Biotechnology*,¹ has been replaced with a more formalised tone, embodied in works such as Luc Bodiguel and Michael Cardwell's 2010 *The Regulation of Genetically Modified Organisms: Comparative Approaches*,² or Victor Tutelyan's, *Genetically Modified Food Sources: Safety Assessment and Control*.³ Authors interested in GMO have increasingly begun to publish on a broader range of issues, for example, Gary Marchant, Guy Cardineau and Thomas Redick in their 2010 edited volume, *Thwarting Consumer Choice: The Case against Mandatory Labelling for Genetically Modified Foods*⁴ move from the traditional debate of in-field

1 Ruse, M. and Castle, D. 2002. *Genetically Modified Foods: Debating Biotechnology*. Amherst, NY; Prometheus Books.

2 Bodiguel, L. and Cardwell, M. 2010. *The Regulation of Genetically Modified Organisms: Comparative Approaches*. Oxford, UK: Oxford University Press.

3 Tutelyan, V. 2013. *Genetically Modified Food Sources: Safety Assessment and Control*. London, UK; Academic Press.

4 Marchant, G., Cardineau, G. and Redick, T. (eds) 2010. *Thwarting Consumer Choice: The Case against Mandatory Labelling for Genetically Modified Foods*. Washington, DC; Government Institutes.

regulation to a consideration of in-store regulation. As scholarship on GMOs has changed focus in the last two decades, so has scholarly analysis of intellectual property. Once considered a strange and peripheral area of law, recent volumes, such as Mario Biagioli, Peter Jaszi, and Martha Woodmansee's 2011 *Making and Unmaking Intellectual Property: Creative Production in Legal and Cultural Perspective*⁵ and Alain Pottage and Brad Sherman's 2010, *Figures of Invention: A History of Modern Patent Law*,⁶ have not only placed intellectual property front and centre in the study of law, science and policy, they have also considerably broadened the scope of scholarship on intellectual property.

To explore further the law and GMO convergence, we have drawn together a range of contributors. Some of them have taken up the challenge of specifically addressing aspects of the intellectual-property-GMO-nexus. These contributions address intellectual property issues of the moment; contemporary twists on perennial themes of patentable subject matter, patents on biological material, scope of biological claims, and so on. For the other contributors, intellectual property has been broadly conceived as a point of contact on the frontiers of newer debates about competition law, disclosure, labelling and information. These eclectic analyses demonstrate the diversity of ways the law and GMOs have become entangled. The stories presented here also demonstrate the complex and exciting evolutionary character of the interactions between law and GMOs.

The various contributions in this volume do not fall neatly into discreet themes. Instead, they reflect something of the complex, messy and sprawling relations that have formed between law and GMOs. We have, accordingly, arranged them alphabetically by author. Without it being our intention, a pattern has emerged none the less. We begin with a pair of chapters in court, or courts, at signal moments of patentability adjudication. Next we have two chapters about GMOs and competition. In the first, competition between the international giants of agricultural GMO, in the second, between tradition and the ability to evolve and innovate. Two further chapters look to the future. The first takes up the gene patent story to look to the fall out of the US Supreme Court's 2013 rulings. The second looks to regulation but with a new twist, regulation of the labelling of GMO food as this regulation moves through higher and higher legislative jurisdictions to the international trade agreements which now might be set to become the final arbiters of GMO risk regulation. Finally we return to court (and the FDA), to two fine grained analyses of the making of GMOs in the mundane procedural workings of law; IP and regulatory. In this travel and return we feel the book mirrors the character of change in this evolutionary relationship. As law and GMOs have grown old

5 Biagioli, M., Jaszi, P. and Woodmansee, M. 2011. *Making and Unmaking Intellectual Property: Creative Production in Legal and Cultural Perspective*. Chicago, IL; University of Chicago Press.

6 Pottage, A. and Sherman, B. 2010. *Figures of Invention: A History of Modern Patent Law*. Oxford, UK: Oxford University Press.

together – their relationship now in its thirties – old themes have found new twists while new issues have succumbed to the structures of old debates.

In the first contribution, ‘*Cui bono?* Gauging the successes of publicly-funded plant breeding in retrospect’, Berris Charnley takes an historical approach to the 2013 US Supreme Court decision in *Bowman v. Monsanto Co.* The case, focused on Monsanto’s Roundup Ready resistant GMO-product, exemplifies a particular view of plant breeding. This view attributes successful plant breeding to private corporations and their ability to claim intellectual property. Charnley’s historical analysis reveals, however, the widespread historical reliance on public plant breeding to develop agriculture in the US and Britain. What is more, the case reveals the peculiarly extensive nature of intellectual property held over DNA sequences in modern plant gene patents, especially when contrasted to historical constructions of plant breeding work, its aims and products. History reveals that there is nothing inevitable or terminal about the particular juncture at which we find ourselves today. In the recent past public plant breeding was successful on its own terms and without the use of gene patents, contrary to the general view expressed in *Bowman*.

The next entanglement of law and GMOs in the volume is also considered from an historical view, this time, married to the technical detail of European law and the *Directive on the Legal Protection of Biotechnological Inventions*.⁷ Stephen Hubicki’s “‘The story of a love spurned’: Monsanto in the United Republic of Soy” provides a detailed analysis of the Court of Justice of the European Union’s (CJEU) decision about the European Biotechnology Directive and the intriguing background to this dispute. The dispute centred on whether a patent over a GMO extended to downstream commodity products, in this case soy products (and soy meal) exported from Argentina into Europe. Hubicki’s detailed analysis of the tumultuous history of the Directive, aimed at divining the legislative intent embodied in the various provisions of the Directive, is an ambitious project. His analysis, however, brings coherence to a perennial concern in patent law about the importation of products produced abroad using a patented process.

Charles Lawson’s ‘Competition in the agricultural seeds sector: Patents and competition at a cross-roads?’ examines the way intellectual property (essentially patents) and GMOs have converged to raise interesting competition challenges. His analysis shows that even though there are areas of competition conflict these are being resolved by the parties amongst themselves. Many of the potential problems of competition around GMOs have so far been addressed through inter-company deals. Competition and licencing law have, so far, been ‘quiet’ areas of interaction between law and GMOs, taking place not in the glare of court or legislative negotiations, but rather through the private dealings between the parties in the gaze of competition laws. His conclusion, however, is that there is an imperative in such deals on maintaining existing power among the current GMO producers

7 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

and that this shifts innovative focus in the sector away from new inventions and towards protecting existing inventions and market arrangements. His concern is that the likely consequence of reduced competition is a price squeeze on farmers as they offset higher seed prices – the result of increasingly ordered and non-competitive relations between seed firms – against long-term stability in global commodity market prices.

Also looking to future issues, Karinne Ludlow's 'Regulating for traditional innovation in agricultural organisms' assesses the risk that existing geographic indications (GI) regimes and proposed legal responses to traditional knowledge (TK) will stifle innovation, leading to farmers and communities having to continue using outdated technology and plant materials. She critically assesses the opportunities for protecting traditional innovation in agricultural organisms and what these mean for the adoption of GMOs. Ludlow concludes that if 'traditional' technology – thought of as a counterpoint to modern technology and GMOs – is to be protected then care will need to be taken in creating legal protection that ensures there is space for 'traditional' innovation.

Next Dianne Nicol's 'Myriad Genetics and the remaining uncertainty for biotechnology inventions' analyses the 2013 US Supreme Court decision in *Association for Molecular Pathology v. Myriad Genetics, Inc* as to whether gene sequences are patentable. She then reflects on the implications of this decision and traces the consequent litigation. She concludes that the impact of the decision may be significant if a broad approach to the interpretation of the decision, and the related decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, is favoured. Nicol's analysis of recent decisions suggests that both the judiciary and the US patent office appear to be adopting this approach with what could be interesting results for the agricultural biotechnology industry.

Matthew Rimmer's 'Just label it: Consumer rights, GM food labelling, and international trade' surveys the debate in the US over state, federal and international efforts to engage in GM food labelling. Rimmer's analysis reveals there has been considerable debate about state and federal GM food labelling initiatives and a lack of consensus in the US Congress. The analysis also reveals, however, that the forum for these initiatives is moving to the level of regional and international trade agreements which may stifle domestic initiatives. Rimmer concludes that there may be a need to ensure that consumer rights about food labelling are properly respected and recognised in such regional and international trade negotiations.

Next Jay Sanderson and Fran Humphries' 'Unnaturally natural: Inventing and eating genetically engineered AquAdvantage® Salmon, and the paradox of nature' examines the slippery nature of GMO salmon. Depending on the context in which the GMO salmon are situated, they have been claimed as natural and as something other than natural. This chapter fleshes out the detail of how GMO salmon that are described in a patent claim as something other than natural could also be natural when submitted for FDA safety testing.

The final contribution to the volume, Kieran Tranter's 'Information about information about information: GMOs and law as a "flexible technology"', considers the mundane and routine practice of law in an interlocutory proceeding. In order to work out whom they could sue for infringement, Monsanto needed to find out where its patented GM cotton seeds had gone. In a brief decision, authored in *Monsanto Company v. Syngenta Seeds Pty Ltd*, one of the stars of Australian jurisprudence, Justice Ray Finkelstein weighed up the merits of forcing Syngenta to disclose which of its subsidiaries was in possession of Monsanto's missing seed. Tranter, drawing on Haraway, Latour and Heidigger, argues that what appears to be the mundane and routine practice of law is actually a process of formatting the world. It is through the law, Tranter argues, that GMOs come to exist in the particular way they do in the world.

GMO discourses have overtaken discussions of risk (and the closely related topic of trust) to engage and challenge the frontiers of intellectual property – patents, GIs, TK, subject matter, information, branding – and beyond, into competition law and free speech. Clearly this is just the start of a much broader engagement between GMOs and law (and particularly intellectual property law). As GMO technology becomes increasingly more complex and increasingly more embedded in our lives we can expect to see this area of research blossom. The chapters collected here provide a map to some of the most interesting current issues of GMO and law interactions, mostly centred on intellectual property law. These chapters also point, we hope, to several of the issues most likely to arise in the future as GMO-law discourses spill over into new areas of interaction.