

Introduction: Inventing life: intellectual property and the New Biology

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The Human Genome Project represented the first foray into ‘Big Science’ by the medical and the biological science communities.¹ The initiative was promoted as ‘the moon shot of the life sciences’, the ‘holy grail of man’, ‘the code of codes’, and ‘the book of life’.² On 14 March 2000, United States President Bill Clinton and British Prime Minister Tony Blair made a joint announcement of the sequencing of the human genome.³ In February 2001, *Nature* and *Science* published rival papers reporting the sequence of the 3.2 billion base pair human genome. The *Nature* paper was by the publicly funded International Human Genome Sequencing Consortium,⁴ while the *Science* paper was by the private company Celera Genomics – led by J. Craig Venter.⁵

So what has changed in biological research since this milestone? In 2003, Francis Collins and his collaborators reflected that the success of the Human Genome Project has inspired a raft of new large-scale biology projects: ‘Large-scale genomic enterprises now extend well beyond straight-forward sequencing, as witnessed by the recent launch from our own funding agencies of other large-scale biology initiatives involving functional genomics, structural biology, microbial genomics and proteomics, and haplotype

¹ Galison, Peter and Bruce Hevly (eds) (1992), *Big Science: The Growth of Large-Scale Research*, Stanford, CA: Stanford University Press.

² Cook-Deegan, R. (2001), ‘Hype And Hope’, *American Scientist*, **89**, 62.

³ Clinton, W. and T. Blair (2000), ‘Joint Statement by President William Clinton and Prime Minister Tony Blair of the United Kingdom’, http://ipmall.info/hosted_resources/ippresdocs/ippd_44.htm.

⁴ The International Human Genome Sequencing Consortium (2001), ‘Initial Sequencing and Analysis of the Human Genome’, *Nature*, **409**, 860–921.

⁵ Venter, J.C. et al. (2001), ‘The Sequence of the Human Genome’, *Science*, **291**, 1301–4.

mapping focusing on human populations.’⁶ They noted: ‘Other candidates for the “big science” approach to biology include interagency and international approaches to biological database creation and maintenance, the construction of public small-molecule libraries for use by basic scientists in their efforts to chart biological pathways, and the large-scale application of microarray technologies with the potential for applications in a wide range of biological research settings.’⁷ The Human Genome Project has been followed by such large-scale biology research projects as the Human Genome Diversity Project, the International HapMap Project, the 1000 Genomes Project and the Rice Genome Project.⁸ The World Health Organization has facilitated international research on infectious diseases – such as HIV/AIDS, the SARS virus and avian influenza.⁹ Public funding agencies, philanthropic foundations and private entities have supported large-scale research, such as the Sorcerer II Expedition and the Genographic Project.¹⁰

Reflecting on the decade of research since the announcement in 2000, Collins observes a ‘breathtaking acceleration in genome science’.¹¹ The cost

⁶ Collins, F., N. Morgan and A. Patrinos (2003), ‘The Human Genome Project: Lessons from Large-Scale Biology’, *Science*, **300** (5617), 286–90, at 290.

⁷ Ibid.

⁸ Gitter, D. (2007), ‘Resolving the Open Source Paradox in Biotechnology: A Proposal for a Revised Open Source Policy for Publicly Funded Genomic Databases’, *Houston Law Review*, **43** (4), 1476–1521; and Rimmer, M. (2005), ‘Japonica Rice: Intellectual Property, Scientific Publishing, and Data-Sharing’, *Prometheus*, **23** (3), 325–47.

⁹ See Dukes, Graham and Frederick Abbott (2009), *Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow’s World*, Cheltenham and Northampton, MA: Edward Elgar; Rimmer, M. (2004), ‘The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines’, *Melbourne Journal of International Law*, **5** (2), 335–74; Pogge, Thomas, Matthew Rimmer and Kim Rubenstein (eds) (2010), *Incentives for Global Public Health: Patent Law and Access to Essential Medicines*, Cambridge: Cambridge University Press.

¹⁰ On the Genographic Project, see Wells, Spencer (2006), *Deep Ancestry: Inside the Genographic Project*, New York: Penguin Books and National Geographic; Rimmer, M. (2007), ‘The Genographic Project: Traditional Knowledge and Population Genetics’, *Australian Indigenous Law Review*, **11** (2), 33–55; and Grant Allen, J. (2010), ‘Group Consent and the Nature of Group Belonging: Genomics, Race and Indigenous Rights’, *Journal of Information, Law, and Science*, **20** (2), 28–59; and on the Sorcerer II Expedition, see Venter, J. Craig (2007), *A Life Decoded*, London: Allen Lane and Penguin Books, 342–9; and Rimmer, M. (2009), ‘The Sorcerer II Expedition: Intellectual Property and Biodiscovery’, *Macquarie Journal of International and Comparative Environmental Law*, **6**, 147–89.

¹¹ Collins, Francis (2010), ‘Has the Revolution Arrived?’ *Nature*, **464**, 674–5, at 674.

of DNA sequencing, that is, reading the sequence of chemical bases encoded by DNA, has reduced by a factor of about 14 000.¹² This has allowed researchers to begin comparing whole genome sequences in projects such as the 1000 Genomes Project, discussed in this volume.¹³ Through Genome Wide Association Studies, we are now able to look across the whole genome for variations that are relevant to disease risk.¹⁴ The decreasing cost and increasing efficiency of genome sequencing and genotyping can also be seen to have given rise to ‘personal genomics’, in which customers can purchase the service of having their own DNA analysed in order to illuminate their ancestry and risk of various diseases.¹⁵

However, the Human Genome Project has been criticised for not yielding the scientific answers and medical leaps promised. For example, Richard Lewontin has observed: ‘The big irony of the sequencing of the human genome is that the result turns out not to provide the answer to the chief question that motivated the project.’¹⁶ Collins’ view is that, although the clinical outcomes have so far been ‘modest’, genome science has had ‘an exceptionally powerful enabling role in biomedical advances’ and that ‘the best is yet to come’.¹⁷

Indeed, we have come to understand that the genome *sequence* is only part of the story. Although we have now elucidated the genome sequence of various organisms, ‘our understanding of the complicated network that takes place inside... cells is far from complete’.¹⁸ As Bostanci, Calvert and Joly note in their chapter in this volume, the recognition of the complexity of biology has led to the emergence of new fields of research such as systems biology and epigenetics. Systems biology is the study of the overall patterns of metabolic activity in cells. Epigenetics is the study of modifications to DNA that occur within the cell without changing the actual genetic sequence.¹⁹ These processes of modification could help us to understand

¹² Ibid.

¹³ Ibid.

¹⁴ Ibid.

¹⁵ See 23andMe Inc. <https://www.23andme.com/> and Ng, P., S. Murray, S. Levy and J.C. Venter (2009), ‘An Agenda for Personalized Medicine’, *Nature*, **461**, 724–6.

¹⁶ Lewontin, R. (2001), ‘They got the Wrong Key of Life’, *The Sunday Times*, 8 July.

¹⁷ Collins, Francis (2010), ‘Has the Revolution Arrived?’ *Nature*, **464**, 674–5.

¹⁸ Costa, F. (2008), ‘Noncoding RNAs, Epigenetics and Complexity’, *Gene*, **410** (1), 9–17, at 9.

¹⁹ Ibid.

how cells use the information contained in genes, and how the same genetic *sequence* can produce different biological results in different circumstances.²⁰

Bio-mathematics specialist Eric Schadt gave this perspective in the genome's 10th anniversary edition of *Science*:

We have learned that the human genome is much more dynamic than previously thought. Elucidating its complexity will require a more systems-level approach, including comprehensive integration with other data dimensions, such as RNA, metabolite, protein, and clinical data. For me, although this past decade has exposed many amazing aspects of the genome, it has revealed the existence of a world about which we know very little.²¹

The new field of synthetic biology can also be seen to have developed from our increased appreciation of biological complexity. Synthetic biology aims to use engineering tools and principles to reduce the complexity of biological systems.²² These complexities, and how much we are yet to understand about biology generally, were strong themes in evidence from synthetic biologists to the 2010 inquiry of the United States Presidential Commission for the Study of Bioethical Issues into synthetic biology.²³

In addition to the enabling technology of DNA sequencing, new fields of biological research such as synthetic biology have also been enabled by the increasingly powerful technology of DNA synthesis. At the same time as our ability to sequence DNA has increased exponentially,²⁴ we have developed the capacity to build DNA from its components in the laboratory. Our ability to do this is also increasing exponentially, while the costs fall rapidly.²⁵ According to Robert Carlson, 'The rate at which DNA synthesis capacity is changing is thus a measure of the improvement in our ability to manipulate biological systems and biological information.'²⁶

²⁰ Ibid.

²¹ Schadt, E. (2011), 'First Steps on a Long Road', *Science*, **331** (6018), 691.

²² Endy, D. (2005), 'Foundations for Engineering Biology', *Nature*, **438** (7067), 449–53.

²³ See the Presidential Commission for the Study of Bioethical Issues (2010), 'Synthetic Biology Meeting Transcripts', <http://www.bioethics.gov>.

²⁴ Carlson, Robert (2010), *Biology is Technology: The Promise, Peril, and New Business of Engineering Life*, Cambridge, MA and London: Harvard University Press, 66–7.

²⁵ Ibid.

²⁶ Carlson, Robert (2003), 'The Pace and Proliferation of Biological Technologies', *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, **1**, 203–14, at 203.

DNA synthesis is significant because ‘the ability to specify genetic instructions by writing DNA from scratch provides, in principle, the opportunity to specify the behaviour of biological systems’.²⁷ This opens up many new fields of biological research and potential industrial applications.

Increased capacity to sequence and compare DNA has also given rise to a great deal of experimental data. The development of powerful bioinformatics tools for data analysis has become increasingly important. We have seen the development of new professions such as curation of biological data.²⁸ Underlining the importance of learning to manage and analyse huge sets of data, Eric Schadt suggests: ‘We will have to become masters of information if we ever hope to go from the big data sets coming to dominate biology to knowledge and to understanding.’²⁹

In a 2003 report for the United States National Science Foundation, *Converging Technologies for Improving Human Performance*, Mihail Roco and William Sims Bainbridge predicted that there would be a convergence of four emerging technologies – nanoscience and nanotechnology; biotechnology, biomedicine and genetics; information technology; and cognitive sciences.³⁰ The pair invented the shorthand ‘NBIC’ to capture these converging technologies:

In the early decades of the 21st century, concentrated efforts can unify science based on the unity of nature, thereby advancing the combination of nanotechnology, biotechnology, information technology, and new technologies based in cognitive science. With proper attention to ethical issues and societal needs, converging technologies could achieve a tremendous improvement in human abilities, societal outcomes, the nation’s productivity, and the quality of life. This is a broad, cross-cutting, emerging and timely opportunity of interest to individuals, society and humanity in the long term.³¹

²⁷ Carlson, Robert (2010), *Biology is Technology: The Promise, Peril, and New Business of Engineering Life*, Cambridge, MA and London: Harvard University Press, 73.

²⁸ See e.g. Sanderson, Katharine (2011), ‘Curation Generation’, *Nature*, **470**, 295–6.

²⁹ Schadt, E. (2011), ‘First Steps on a Long Road’, *Science*, **331** (6018), 691.

³⁰ Roco, Mihail and William Sims Bainbridge (2003), *Converging Technologies for Improving Human Performance: Nanotechnology, Biotechnology, Information Technology and Cognitive Science*, AA Dordrecht: Kluwer Academic.

³¹ Ibid.

There has been much critical discussion about whether the phrase NBIC describes a historical fact or a future aspiration.³²

In 2009, the National Research Council of the National Academies released a report on *A New Biology for the 21st Century*.³³ The council preferred the term ‘New Biology’ to capture the convergence and integration of the various disciplines of biology. The National Research Council stressed: ‘The essence of the New Biology, as defined by the committee, is integration – re-integration of the many sub-disciplines of biology, and the integration into biology of physicists, chemists, computer scientists, engineers, and mathematicians to create a research community with the capacity to tackle a broad range of scientific and societal problems.’³⁴ They define the ‘New Biology’ as ‘integrating life science research with physical science, engineering, computational science, and mathematics’.³⁵ The National Research Council reflected:

Biology is at a point of inflection. Years of research have generated detailed information about the components of the complex systems that characterize life – genes, cells, organisms, ecosystems – and this knowledge has begun to fuse into greater understanding of how all those components work together as systems. Powerful tools are allowing biologists to probe complex systems in ever greater detail, from molecular events in individual cells to global biogeochemical cycles. Integration within biology and increasingly fruitful collaboration with physical, earth, and computational scientists, mathematicians, and engineers are making it possible to predict and control the activities of biological systems in ever greater detail.³⁶

The National Research Council contended that the New Biology could address a number of pressing challenges. First, it stressed that the New Biology could ‘generate food plants to adapt and grow sustainably in changing environments’.³⁷ Second, the New Biology could ‘understand and sustain ecosystem function and biodiversity in the face of rapid change’.³⁸ Third, the New Biology could ‘expand sustainable alternatives to fossil

³² See e.g. Schummer, Joachim (2010), ‘From Nano-Convergence to NBIC-Convergence’, in Kaiser, Mario, Monika Kurath, Sabine Maasen and Christoph Rehmann-Sutter (2010), *Governing Future Technologies Nanotechnology and the Rise of an Assessment Regime*, Dordrecht: Springer, 47–72 at 67.

³³ National Research Council of the National Academies (2009), *A New Biology for the 21st Century*, Washington, DC: The National Academies Press.

³⁴ *Ibid.*, 3.

³⁵ *Ibid.*, 22.

³⁶ *Ibid.*, 12.

³⁷ *Ibid.*, 4.

³⁸ *Ibid.*

fuels'.³⁹ Moreover, it was hoped that the New Biology could lead to a better understanding of individual health: 'The New Biology can accelerate fundamental understanding of the systems that underlie health and the development of the tools and technologies that will in turn lead to more efficient approaches to developing therapeutics and enabling individualized, predictive medicine.'⁴⁰

Biological research has certainly been changing direction in response to changing societal problems. Over the last decade, increasing awareness of the impacts of climate change and dwindling supplies of fossil fuels can be seen to have generated investment in fields such as biofuels, climate-ready crops and storage of agricultural genetic resources. In considering biotechnology's role in the twenty-first century, biological future-predictor Carlson's firm Biodesic states: 'The problems the world faces today – ecosystem responses to global warming, geriatric care in the developed world or infectious diseases in the developing world, the efficient production of more goods using less energy and fewer raw materials – all depend on understanding and then applying biology as a technology.'⁴¹

This collection considers the roles of intellectual property law in regulating emerging technologies in the biological sciences. Stephen Hilgartner comments that patent law plays a significant part in social negotiations about the shape of emerging technological systems or artefacts:

Emerging technology – especially in such hotbeds of change as the life sciences, information technology, biomedicine, and nanotechnology – became a site of contention where competing groups pursued incompatible normative visions. Indeed, as people recognized that questions about the shape of technological systems were nothing less than questions about the future shape of societies, science and technology achieved central significance in contemporary democracies. In this context, states face ongoing difficulties trying to mediate these tensions and establish mechanisms for addressing problems of representation and participation in the sociopolitical process that shapes emerging technology.⁴²

³⁹ Ibid.

⁴⁰ Ibid.

⁴¹ Biodesic (2010), 'Company', <http://www.biodesic.com/Company.html>.

⁴² Hilgartner, S. (2009), 'Intellectual Property and the Politics of Emerging Technology: Inventors, Citizens, and Powers to Shape the Future', *Chicago-Kent Law Review*, **84**, 197, 205–6.

The introduction to the collection will provide a thumbnail, comparative overview of recent developments in intellectual property and biotechnology – as a foundation to the collection.⁴³ Section I of this introduction considers recent developments in United States patent law, policy and practice with respect to biotechnology – in particular, highlighting the *Myriad Genetics* dispute and the decision of the Supreme Court of the United States in *Bilski v. Kappos*. Section II considers the cross-currents in Canadian jurisprudence in intellectual property and biotechnology. Section III surveys developments in the European Union – and the interpretation of the *European Biotechnology Directive*. Section IV focuses upon Australia and New Zealand, and considers the policy responses to the controversy of Genetic Technologies Limited’s patents in respect of non-coding DNA and genomic mapping. Section V outlines the parts of the collection and the contents of the chapters.

I THE UNITED STATES OF AMERICA

After experimenting with *sui generis* regimes, such as the *Plant Patent Act* 1930 (US) and the *Plant Variety Protection Act* 1970 (US), the United States courts took an expansive approach to the patenting of life forms. The decision of the majority of the Supreme Court of the United States in *Diamond v. Chakrabarty* to allow for the patenting of an oil-eating bacterium was a critical ruling.⁴⁴ Alain Pottage and Brad Sherman discuss how the decision of the Supreme Court of the United States has had the effect of ‘mechanizing nature’: ‘Just as the mechanical and chemical sciences instrumentalized inanimate nature, so biotechnology instrumentalizes animate nature, and turns organisms into manufactures.’⁴⁵ In other words, analogies have been drawn between mechanical inventions and a host of forms of biotechnology – such as nanotechnology and synthetic biology – in order to expand the limits of patentable subject matter.

⁴³ For a comprehensive introduction to intellectual property and biotechnology, see Magnus, David, Arthur Caplan and Glenn McGee (eds) (2002), *Who Owns Life?*, Amherst, NY: Prometheus Books; Rimmer, Matthew (2008), *Intellectual Property and Biotechnology: Biological Inventions*, Cheltenham and Northampton, MA: Edward Elgar; Dutfield, Graham (2009), *Intellectual Property Rights and the Life Science Industries: Past, Present and Future*, Singapore: World Scientific; and Rai, Arti (ed.) (2011), *Intellectual Property Law and Biotechnology: Critical Concepts*, Cheltenham and Northampton, MA: Edward Elgar.

⁴⁴ *Diamond v. Chakrabarty*, 447 US 303 (1980).

⁴⁵ Pottage, Alain and Brad Sherman (2010), *Figures of Invention: A History of Modern Patent Law*, Oxford: Oxford University Press, 181–2.

In the 1990s, there were both public and private efforts to sequence the human genome. A number of biotechnology and pharmaceutical companies filed patent applications in respect of genes and gene sequences, which were of medical significance. In his candid autobiography, *A Life Decoded*, J. Craig Venter reflects that the hectic ‘gold rush’ by private biotechnology companies for gene patents was not necessarily profitable:

Because a few human genes were, in fact, worth billions, it was widely assumed that there were hundreds or thousands more genes that would be equally lucrative. The logic was simple and simpleminded. The biotech companies [Human Genome Sciences] and Incyte took the lead in human gene patents, but today their stocks trade below their cash value despite their vast human gene patent portfolios. Most now understand what I have always believed: that human gene patents usually have less value than the cost to pursue them. Of the twenty-three thousand or so human genes, fewer than a dozen have generated real value for the businessman or the patent.⁴⁶

In part, this statement seems something of a post-facto rationalisation – given that Venter pursued patents in respect of express sequence tags at the National Institutes of Health, and gene patents, while engaging in shotgun sequencing at Celera Genomics.

In the United States, the American Civil Liberties Union and the Public Patent Foundation filed a lawsuit in 2009 against the validity of patents related to BRCA1 and BRCA2 held by Myriad Genetics Inc. and the University of Utah Research Foundation.⁴⁷ The action was brought on behalf of pathologists, medical practitioners, human genetics researchers, patient organisations and, most importantly, individual women affected by breast and ovarian cancer. Raising arguments about human rights and bioethics, the plaintiffs alleged that the patents were unconstitutional because they impinged upon freedom of speech by restricting medical research. They also argued that the patents were invalid because the genes were ‘products of nature’.

A district court judge, Sweet J, was sympathetic to the challenge, expressing reservations about taking a broad approach to patentable subject

⁴⁶ Venter, J.C. (2007), *A Life Decoded*, London: Allen Lane and Penguin Books, 257. See also Venter, J.C. (2011), ‘The Human Genome at 10: Successes and Challenges’, *Science*, **331** (6017), 546–7.

⁴⁷ American Civil Liberties Union (2009), ‘BRCA: Genes and Patents’, <http://www.aclu.org/free-speech/brca-genes-and-patents>.

matter.⁴⁸ The judge was particularly concerned about the impact of gene patents upon patient care, medical research and the administration of health care: ‘The resolution of the issues presented to this Court deeply concerns breast cancer patients, medical professionals, researchers, caregivers, advocacy groups, existing gene patent holders and their investors, and those seeking to advance public health.’⁴⁹ The judge held:

It is concluded that DNA’s existence in an ‘isolated’ form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to ‘isolated DNA’ containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 U.S.C. § 101.⁵⁰

The initial ruling of the District Court has been much contested by members of the biotechnology and pharmaceutical industries.

The United States Court of Appeals for the Federal Circuit overturned the initial ruling of Sweet J in 2011.⁵¹ In the lead judgment, Lourie J followed past broad, expansionist precedents on patentable subject matter and held that the composition claims covering isolated DNA sequences were patentable subject matter: ‘We therefore reject the district court’s unwarranted categorical exclusion of isolated DNA molecules.’⁵² He held that ‘the patent eligibility of an isolated DNA is not negated because it has similar informational properties to a different, more complex natural material that embodies it’.⁵³ The judge further held that: ‘If the law is to be changed, and DNA inventions excluded from the broad scope of § 101 contrary to the settled expectation of the inventing community, the decision must come not from the courts, but from Congress.’⁵⁴ Moreover, the method claim for screening potential cancer therapeutics via changes in cell growth rates was patentable.⁵⁵ However, Lourie J held that the method claims for comparing claims for comparing or analysing isolated DNA sequences were not patentable: ‘Myriad’s claimed methods of comparing

⁴⁸ *Association for Molecular Pathology v. United States Patent and Trademark Office, Myriad Genetics Inc., and the directors of the University of Utah Research Foundation*, 702 F. Supp. 2d 181 at 185 (2010).

⁴⁹ *Ibid.*

⁵⁰ *Ibid.*, 185.

⁵¹ *Association for Molecular Pathology et al. v. United States Patent and Trademark Office, Myriad Genetics et al.* 653 F.3d 1329, 2011 WL 3211513 (C.A. Fed. (N.Y.)), 99 USPQ 2d 1398.

⁵² *Ibid.*, 18.

⁵³ *Ibid.*, 20.

⁵⁴ *Ibid.*, 18.

⁵⁵ *Ibid.*, 23.

or analyzing nucleotide sequences fail to satisfy the machine-or-transformation test, and are instead directed to the abstract mental process of comparing two nucleotide sequences.⁵⁶

Moore J filed an opinion concurring in part. The judge, though, provided a somewhat circumspect line of reasoning on the issue of the patent-eligibility of DNA sequences – ultimately being swayed by the desire not to disrupt settled business expectations. The judge observed:

If I were deciding this case on a blank canvas, I might conclude that an isolated DNA sequence that includes most or all of a gene is not patentable subject matter. Despite the literal chemical difference, the isolated full length gene does not clearly have a new utility and appears to simply serve the same ends devised by nature, namely to act as a gene encoding a protein sequence. This case, however, comes to us with a substantial historical background. Congress has, for centuries, authorized an expansive scope of patentable subject matter. Likewise, the United States Patent Office has allowed patents on isolated DNA sequences for decades, and, more generally, has allowed patents on purified natural products for centuries. There are now thousands of patents with claims to isolated DNA, and some unknown (but certainly large) number of patents to purified natural products or fragments thereof. As I explain below, I believe we must be particularly wary of expanding the judicial exception to patentable subject matter where both settled expectations and extensive property rights are involved. Combined with my belief that we should defer to Congress, these settled expectations tip the scale in favor of patentability.⁵⁷

Bryson J dissented on this issue, holding that isolated human genes were products of nature: ‘The isolation of the naturally occurring genetic material does not make the claims to the isolated BRCA genes patent-eligible.’⁵⁸

The question of patentability of emerging technologies has also been considered in the *Bilski* litigation. Ostensibly, the litigation in *Bilski v. Kappos* concerned business methods. Bernard Bilski had applied for a patent in respect of a method for hedging commodities. The patent examiner rejected the application on the grounds that the invention was merely an abstract idea, and solved a purely mathematical problem. The Board of Patent Appeals and Interferences agreed with this verdict. The Court of Appeals for the Federal Circuit reviewed the patentability of business methods. In the lead judgment, Michel J stressed:

A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. We agree that future developments in technology and the

⁵⁶ Ibid., 22.

⁵⁷ Ibid., 31.

⁵⁸ Ibid., 42.

sciences may present difficult challenges to the machine-or-transformation test, just as the widespread use of computers and the advent of the Internet has begun to challenge it in the past decade. Thus, we recognize that the Supreme Court may ultimately decide to alter or perhaps even set aside this test to accommodate emerging technologies.⁵⁹

However, a number of dissenting judges expressed reservations about the impact of the ‘machine-or-transformation’ test upon emerging technologies.

In *Bilski v. Kappos*, the Supreme Court of the United States held that a patent application for method of hedging risk in the field of commodities trading in the energy market was an unpatentable abstract idea.⁶⁰ Nonetheless, in the lead judgment, Kennedy J declined to restrict the breadth of patentable subject matter, reflecting:

The machine-or-transformation test may well provide a sufficient basis for evaluating processes similar to those in the Industrial Age – for example, inventions grounded in a physical or other tangible form. But there are reasons to doubt whether the test should be the sole criterion for determining the patentability of inventions in the Information Age. As numerous amicus briefs argue, the machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals. In the course of applying the machine-or-transformation test to emerging technologies, courts may pose questions of such intricacy and refinement that they risk obscuring the larger object of securing patents for valuable inventions without transgressing the public domain ... Section 101’s terms suggest that new technologies may call for new inquiries.⁶¹

Kennedy J cites with the approval the remarks in *Gottschalk v. Benson*,⁶² that to ‘freeze process patents to old technologies, leaving no room for the revelations of the new, onrushing technology[,] ... is not our purpose’.⁶³

In the remanded case of *Prometheus Laboratories Inc. v. Mayo Collaborative Services*, the United States Court of Appeals for the Federal Circuit applied the ruling in *Bilski v. Kappos* and held that Prometheus’s asserted medical treatment claims were patentable subject matter.⁶⁴

⁵⁹ *In re Bilski*, 545 F.3d 943 (Fed. Cir., 2008).

⁶⁰ *Bilski v. Kappos* 130 S. Ct. 3218 (2010).

⁶¹ *Ibid.*, 3228.

⁶² *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972).

⁶³ *Bilski v. Kappos*, 130 S. Ct. 3218 at 3228 (2010).

⁶⁴ *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, No. 2008–1403, slip op. (Fed. Cir. 2010).

Dan Burk and Mark Lemley have long advocated that patent offices and courts should make use of existing policy levers within patent law to address and respond to new technologies.⁶⁵ The USPTO (United States Patent and Trademark Office) and the courts have applied a number of doctrines – such as novelty, inventive step,⁶⁶ utility,⁶⁷ and written description⁶⁸ – in order to tailor patent law to the particular demands and needs of biotechnology. Dan Burk and Mark Lemley have considered future directions in intellectual property and biotechnology – such as large-scale projects in genomics, proteomics, bioinformatics and metabolomics, and the emergence of synthetic biology. The pair ‘expect that as the biotechnology industry continues to evolve, new policy levers may become appropriate to allow the proper scope of innovation and reward’.⁶⁹

There have been a number of attempts to pass specialist legislation in respect of gene patents. Congressmen Xavier Becerra (Democrat, California) and Dave Weldon (Republican) have promoted the *Genomic Research and Accessibility Act* 2007 H.R. 977. The bill provides: ‘Notwithstanding any other provision of law, no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies.’ In the wake of the Myriad Genetics decision, Becerra has promised to reintroduce legislation, placing a moratorium on gene patents: ‘I will once again introduce legislation banning gene patenting to ensure patients’ access to their own medical information, reduce the costs of gene tests and increase scientific research into personalized medicine.’⁷⁰ However, it is doubtful that such legislative efforts will win broader support.⁷¹ There is, however, somewhat more hope with regard to general patent law reform. After many years of stalled attempts and efforts, the United States

⁶⁵ Burk, Dan and Mark Lemley (2009), *The Patent Crisis and How the Courts Can Solve It*, Chicago and London: The University of Chicago Press.

⁶⁶ *In re Kubin*, 561 F. 3d 1351 (C.A. Fed., 2009).

⁶⁷ *In re Fisher*, 421 F.3d 1365 (C.A. Fed., 2005).

⁶⁸ *Carnegie Mellon University v. Hoffman-La Roche*, 541 F.3d. 1115 (2008).

⁶⁹ Burk, Dan and Mark Lemley (2009), *The Patent Crisis and How the Courts Can Solve It*, Chicago and London: The University of Chicago Press, 153.

⁷⁰ Becerra, X. (2010), ‘Representative Becerra Applauds Decision on Gene Patenting’, http://becerra.house.gov/index.php?option=com_content&view=article&id=412%3Arep-becerra-applauds-court-decision-on-gene-patenting&catid=3%3Apress-releases&Itemid=26.

⁷¹ For a critique of the legislative proposal, see DeGiulio, J. (2010), ‘The Genomic Research and Accessibility Act: More Science Fiction than Fact’, *Northwestern Journal of Technology and Intellectual Property*, **8**, 292–306.

House of Representatives and the Senate passed the *America Invents Act* 2011 (US).⁷² President Barack Obama signed the legislation on 16th September 2011.

II CANADA

The Supreme Court of Canada has been divided over the question of patenting life forms – split into warring factions. In the case of *Harvard College v. Canada (The Commissioner of Patents)*, a five–four majority of the Supreme Court of Canada held that ‘higher life forms’ were not patentable subject matter in Canada.⁷³ The leading judgment by Bastarache J noted: ‘Owing to the fact that the patenting of higher life forms is a highly contentious and complex matter that raises serious practical, ethical and environmental concerns that the Act does not contemplate, I conclude that the Commissioner was correct to reject the patent application.’⁷⁴ In *Monsanto Canada v. Schmeiser*, a majority of the Supreme Court of Canada ruled that a patent in relation to glyphosate resistant canola was valid – because only a component of the plant was the subject of patent claims.⁷⁵ McLachlin CJ and Fish J noted: ‘Inventions in the field of agriculture may give rise to concerns not raised in other fields – moral concerns about whether it is right to manipulate genes in order to obtain better weed control or higher yields.’⁷⁶ Clearly, it is difficult to reconcile the tensions in the jurisprudence of the Supreme Court of Canada in respect of such matters.

In a piece for Ysolde Gendreau’s collection, *An Emerging Intellectual Property Paradigm*, Mark Perry from the University of Western Ontario surveys the competing approaches to the patenting of life in Canadian jurisprudence: ‘In *Harvard*, the Supreme Court of Canada denied a patent

⁷² *Leahy-Smith America Invents Act*, Pub. L. 112–29, §§ 14(a), 125 Stat. 284, 327 (2011); see Kappos, D. (2011), ‘Statement on the America Invents Act’, Subcommittee on Intellectual Property, Competition and the Internet, Committee on the Judiciary, United States House of Representatives, 30 March, http://www.uspto.gov/news/speeches/2011/kappos_house_testimony.jsp; and Obama, B. (2011), ‘President Obama Signs *America Invents Act*, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs’, The White House Press Office, <http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim..>

⁷³ *Harvard College v. Canada (The Commissioner of Patents)* [2002] 2 SCR 45.

⁷⁴ *Harvard College v. Canada (The Commissioner of Patents)* [2002] 2 SCR 45.

⁷⁵ *Monsanto Canada Inc. v. Schmeiser* (2004) SCC 34; 2004 SCC 34.

⁷⁶ *Monsanto Canada Inc. v. Schmeiser* (2004) SCC 34; 2004 SCC 34.

on a transgenic mouse that was undoubtedly an innovation, and in *Monsanto*, the same court found infringement in the use of a transgenic cell in a plant.⁷⁷ He reflects:

In the last two decades the Canadian Supreme Court has been challenged with life patent scenarios, most recently with two cases based on transgenic engineering. The 5–4 split decisions in these two cases have led to what is arguably a legally coherent but illogical outcome. The Canadian approach to patent claims that are based on new forms of life has been to distinguish ‘higher’ lifeforms from other lifeforms, denying patents on the former.⁷⁸

Perry notes that ‘there is little objective standard to determine what is a higher lifeform, nor are there any rational means of discriminating even between the developmental stages in the same lifeform’.⁷⁹ He concludes: ‘The pressure of science on the legal system, particularly in cutting edge areas such as biotechnology patents, requires legislation for patents that is clear and “technologically neutral” (as policymakers often claim of proposed legislation).’⁸⁰

The Canadian Biotechnology Advisory Committee produced a number of reports on intellectual property and emerging technologies.⁸¹ However, the policy body has since been disbanded. The Canadian Parliament has been reluctant to debate intellectual property and emerging biotechnologies. In the past decade, there has been a succession of minority governments, and a number of bills have lapsed, when Parliament has been prorogued for elections.

An International Expert Group on Biotechnology, Innovation and Intellectual Property led by Richard Gold of McGill University envisages that there is a new era of intellectual property upon us, marked by negotiation:

As the current era of IP wanes, a new one is emerging. It centres on the principle of granting the right amount of IP and having the private and public sectors use

⁷⁷ Perry, Mark (2008), ‘From Pasteur to Monsanto: Approaches to Patenting Life in Canada’, in Ysolde Gendreau (ed.) (2008), *An Emerging Intellectual Property Paradigm: Perspectives from Canada*, Cheltenham and Northampton, MA: Edward Elgar, 67–80.

⁷⁸ *Ibid.*, 68.

⁷⁹ *Ibid.*, 79.

⁸⁰ *Ibid.*, 80.

⁸¹ Canadian Biotechnology Advisory Committee (CBAC) (2002), *Patenting Of Higher Life Forms*, Ottawa: CBAC, June; Canadian Biotechnology Advisory Committee (2003), *Advisory Memorandum: Higher Life Forms And The Patent Act*, Ottawa: CBAC, 24 February; and Canadian Biotechnology Advisory Committee (2006), *Human Genetic Materials, Intellectual Property, and the Health Sector*, Ottawa: CBAC.

those protections more effectively. We call this the era of New IP, an era in which IP becomes a servant to, and not master of, values such as equity and fairness.⁸²

The report emphasises a number of themes – including the need to build trust and improve communication amongst stakeholders; the importance of new models of co-operation and collaboration, and scientific infrastructure; and the need for cross-cutting thinking, and data and metrics. The report suggests: ‘Once we better understand what spurs innovation, we can ensure that our discussions stay focused on the potential of biotechnology to address health, agricultural and industrial needs.’⁸³

In the absence of legislative reform, there has been scope for management of intellectual property rights. David Castle comments that there is a heated disagreement regarding the design and reform of intellectual property systems, and the rules, institutions and practices they support. His edited collection emphasises the need for contextual studies of intellectual property management – taking into account the variables of history, jurisdiction, actors, institutions, and technological and scientific fields.⁸⁴

Professor Bartha Knoppers from the University of Montreal has long argued that patent law should be linked with bioethical notions of informed consent and benefit sharing in a range of contexts – agriculture, biodiversity and medicine. She has recapitulated some of her key themes in a collection, edited with Richard Gold, entitled *Biotechnology, IP and Ethics*.⁸⁵ Knoppers comments upon the debate over convergence in the biological sciences:

The last decade has spawned what has been called the ‘cogno-info-bio-nano’ continuum. In the area of biotechnology, a field which spans all living organisms, this evolving continuum has not so much produced new ethical quandaries as it has refocused the locus, form, and content of the debate. Indeed, the ethical concerns that accompany novel technologies often play out through variations in the ‘name-game’. From neuroethics to nutrigenomics and nanotechnologies to nuclear transfer in stem cell research, the classical nature-nurture dynamic

⁸² The International Expert Group on Biotechnology, Innovation and Intellectual Property (2008), *Toward a New Era of Intellectual Property: From Confrontation to Negotiation*, Montreal: McGill University, 14.

⁸³ *Ibid.*, 10.

⁸⁴ Castle, David (ed.) (2009), *The Role of Intellectual Property Rights in Biotechnology Innovation*, Cheltenham and Northampton, MA: Edward Elgar.

⁸⁵ Gold, Richard and Bartha Knoppers (eds) (2009) *Biotechnology, IP and Ethics*, Markham, ON: LexisNexis Canada.

resurfaces as ethical debate and frameworks attempt to address what makes us distinctively human.⁸⁶

Knoppers notes that ‘certainly, stem cell research, genetically modified organisms and nanotechnologies typify such convergence’ of science, technology, politics, economics and values.⁸⁷ She contends that ‘the promise of biotechnology will become empty rhetoric, with the accompanying danger of public cynicism, if there is an absence of responsibility’.⁸⁸

The Canadian ETC Group has a long-standing interest in the legal, ethical and social implications of emerging and converging technologies:

The ability, through nanotechnology, to manipulate matter atom by atom is enabling a new fusion of powerful technologies as nanotech, biotech, information technology and neurotechnologies (brain technologies) converge into one common technology platform. ETC refers to this convergence as BANG (Bits Atoms Neurons and Genes) since it allows flexible manipulation of the bits of information, the atoms of matter, the neurons of the brain and the genes that code for life. Examples of ‘convergent’ technologies include nanobiotechnology, synthetic biology, DNA computing and neuroengineering.⁸⁹

This populist definition, again, emphasises the convergence of various emerging technologies. The ETC Group has, traditionally, been concerned about the impact of intellectual property upon agriculture and farmers’ rights. Perhaps most famously, the civil society organization led a public campaign against genetic use restriction technologies – which it dubbed ‘terminator technologies’. More recently, the ETC Group has expanded its horizons to focus on the granting of patents in respect of nanotechnology, synthetic biology, geo-engineering and clean technologies.

⁸⁶ Knoppers, Bartha (2009), ‘Biotechnology and Ethics’, in Richard Gold and Bartha Knoppers (eds) (2009), *Biotechnology, IP and Ethics*, Markham, ON: LexisNexis Canada, 59–67, 59.

⁸⁷ *Ibid.*, 67.

⁸⁸ *Ibid.*, 66.

⁸⁹ ETC Group, ‘BANG: Converging Technology’, <http://www.etcgroup.org/en/issues/bangconvergence>.

III THE EUROPEAN UNION

In the European Union, there has also been a similar reappraisal of biotechnological patents, with ongoing conflicts in the European Patent Office.⁹⁰

Aurora Plomer and Paul Torremans have reflected that the *European Union Directive on the Legal Protection of Biotechnological Inventions* 1998 (EU) has struggled to accommodate emerging technologies – such as stem cell research: ‘The emerging difficulties concerning the Directive’s implementation and interpretation 10 years on are a witness to the enduring social and ethical concerns about new biotechnologies but also disclose the complex incidental legal impact of the moral exclusion clauses within and outside patent law, the full breadth of which had not been anticipated at the time.’⁹¹ Nonetheless, the European Court of Justice has defended the validity of the *European Biotechnology Directive*, rejecting a challenge by the Netherlands Government in 2001.⁹²

The role of the patent system and the proper function of patent examining bodies in dealing with issues of ethics and morality is a controversial topic. In Europe, Article 53 (a) of the *European Patent Convention* provides that patents shall not be granted for:

(a) inventions the commercial exploitation of which would be contrary to ‘ordre public’ or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States ...⁹³

⁹⁰ Hawkins, N. (2010), ‘Human Gene Patents and Genetic Testing in Europe: A Reappraisal’, *SCRIPTed*, 7 (3), 453–73, <http://www.law.ed.ac.uk/ahrc/scripted/vol7-3/hawkins.asp>.

⁹¹ Plomer, Aurora and Paul Torremans (eds) (2009), *Embryonic Stem Cell Patents: European Patent Law and Ethics*, Oxford: Oxford University Press, xxxvii.

⁹² *Netherlands v. European Parliament* (2001) 3 CMLR 49; Scott, A. (1999), ‘The Dutch Challenge to the Bio-Patenting Directive’, *European Intellectual Property Review*, 21 (4), 212–15; Moore, S. (2002), ‘Challenge to the Biotechnology Directive’, *European Intellectual Property Review*, 24 (3), 149–54; and Beyleveld, D. and R. Brownsword (2002), ‘Is Patent Law Part of the EC Legal Order? A Critical Commentary on the Interpretation of Article 6(1) of Directive 98/44/EC in Case C-377/98’, *Intellectual Property Quarterly*, 1, 97–110.

⁹³ *Convention on the Grant of European Patents* (‘*European Patent Convention*’) of 5 October 1973, Official Journal Special Edition 1/2007 (entered into force 7 October 2000).

There has been much debate in the European Union over the meaning of *ordre public* (public morality and order).⁹⁴

In the Harvard ‘OncoMouse’ litigation in the European Union, there was significant debate as to what test was appropriate in these circumstances.⁹⁵ In the ‘OncoMouse’ decision, the Examining Division initially declined to consider the issue, taking the view that it was inappropriate for technocrats to adjudicate upon the morality of the invention.⁹⁶ The Board of Appeal suggested that there was a need to engage in a balancing exercise between the benefits and risks associated with an invention.⁹⁷ In a further consideration of the Harvard OncoMouse in 2006, the Technical Board of Appeals reiterated that the balancing test ‘clearly allows the scope or extent of, on the one hand, the animal suffering and/or environmental risk and, on the other hand, the usefulness to mankind to be considered’.⁹⁸

In the case of *Plant Genetic Systems/Glutamine Synthetase Inhibitors*, the Technical Board of Appeals provided further consideration of the requirement that a patent application is not contrary to either *ordre public* or morality.⁹⁹ Also noteworthy is the *Relaxin* case, in which the Green Party unsuccessfully objected to the Howard Florey Institute’s patent application in respect of Relaxin.¹⁰⁰ There has also been much discussion about the ethics of patenting human embryonic stem cells.¹⁰¹ Further, in the *Euthanasia Compositions* case, the Board held that when considering whether the commercial exploitation of an invention is contrary to morality or *ordre public*, ‘exploitation’ should be interpreted as the ‘normal avowed use indicated in the patent’.¹⁰² The patent should only be denied under Article 53 (a) if that intended use would infringe *ordre public* or morality.¹⁰³

⁹⁴ See for instance Bently, Lionel and Brad Sherman (2009), *Intellectual Property Law*, 3rd edn, Oxford: Oxford University Press, 455–63; and MacQueen, Hector, Charlotte Waelde and Graeme Laurie (2008), *Contemporary Intellectual Property: Law and Policy*, Oxford: Oxford University Press, 424–7.

⁹⁵ For an extended discussion of the transnational litigation involving the Harvard OncoMouse, see Rimmer, Matthew (2008), *Intellectual Property and Biotechnology: Biological Inventions*, Cheltenham and Northampton, MA: Edward Elgar, 82–107.

⁹⁶ *The Harvard/Onco-mouse* [1989] OJ EPO 451.

⁹⁷ *The Harvard/Onco-mouse* [1990] OJ EPO 490 (TBA).

⁹⁸ *Harvard/Transgenic Animals*, T315/03 [2006] OJ EPO at 98.

⁹⁹ *Plant Genetic Systems/Glutamine Synthetase Inhibitors* [1995] EPOR 357.

¹⁰⁰ *Howard Florey/Relaxin* T74/91 [1995] EPOR 541 (Op Div).

¹⁰¹ Rimmer, Matthew (2008), *Intellectual Property and Biotechnology: Biological Inventions*, Cheltenham and Northampton, MA: Edward Elgar, 263–72.

¹⁰² *Euthanasia Compositions/Michigan State University* (2005), T 0866/01; 5.7.

¹⁰³ *Euthanasia Compositions/Michigan State University* (2005), T 0866/01; 5.8.

In the area of environmental bioprospecting, the EPO (European Patent Office) has also struggled to deal with claims of ‘biopiracy’ – especially in relation to patents filed in respect of the neem tree and Nap Hal wheat.¹⁰⁴

The EPO seems to regard engaging with moral and ethical issues as outside its remit. Aurora Plomer has discussed the future of general morality exclusions with respect to biotechnology patents:

To the extent that ‘human dignity’ and more generally fundamental moral norms are implicated in the construction of the scope of exclusion of patents on biotechnological inventions, there is a clear alignment between the jurisprudence of the European Court of Justice and the jurisprudence of the European Court of Human Rights recognizing a wide margin of discretion to Member States in deference and respect for the plurality and diversity of moral cultures and state autonomy on morally sensitive questions.¹⁰⁵

In 2010, the European Court of Justice considered the question of patent infringement and biotechnology in the case of *Monsanto Technology LLC v. Cefetra BV*, ruling that the importation of soybean meal did not amount to an infringement of a gene patent.¹⁰⁶ Some commentators fear that ‘the Cefetra judgment may unintentionally inflict serious economic harm on the European biotechnology industry because countless biotechnology products may no longer be protected by what are otherwise valid and enforceable patent claims’.¹⁰⁷

The European Parliament has repeatedly expressed concerns about the breadth of patents granted by the EPO in respect of emerging technologies. In 2001, the European Parliament passed a resolution protesting against the broad patents granted in respect of the BRCA1 and BRCA2 genes.¹⁰⁸ In 2005, the European Parliament called ‘on the European Patent Office and the Member States to grant patents on human DNA only in connection with a concrete application and for the scope of the patent to be limited to

¹⁰⁴ Mgbeoji, Ikechi (2006), *Global Biopiracy: Patents, Plants, and Indigenous Knowledge*, Vancouver: University of British Columbia Press.

¹⁰⁵ Plomer, Aurora (2009), ‘Human Dignity, Human Rights, and Article 6 (1) of the EU Directive on Biotechnological Inventions’, in Aurora Plomer and Paul Torremans (eds) (2009), *Embryonic Stem Cell Patents: European Patent Law and Ethics*, Oxford: Oxford University Press, 203–26, at 223–4.

¹⁰⁶ *Monsanto Technology LLC v. Cefetra BV and others*, No. C-428/08, ¶¶ 33–50, European Court of Justice (6 July 2010).

¹⁰⁷ Mohan-Ram, V., R. Peet and P. Vlaeminck 2011, ‘Biotech Patent Infringement in Europe: The “Functionality” Gatekeeper’, *John Marshall Review of Intellectual Property Law*, **10**, 540–52.

¹⁰⁸ *European Parliament Resolution on the Patenting of BRCA1 and BRCA2 (‘Breast Cancer’) Genes*, Texts Adopted by Parliament, Provisional Edition: 04/10/2001, B5–0633, 0641, 0651 and 0663/2001.

this concrete application so that other users can use and patent the same DNA sequence for other applications (purpose-bound protection).¹⁰⁹ At the same time, the European Parliament emphasised in the resolution that the patenting of procedures involving human embryonic stem cells or cells that are grown from human embryonic stem cells was a violation of the *European Biotechnology Directive*.¹¹⁰ In a resolution adopted in November 2007, the European Parliament suggested that there needed to be greater leeway for the compulsory licensing of environmentally necessary technologies.¹¹¹ In 2009, the European Parliament passed a resolution on the regulation of nanotechnology, noting fears that the ‘broad application of patents to nanomaterials as well as the excessive cost of patenting and the absence of patent access facilities for very small businesses and small and medium-sized enterprises ... could stifle further innovation’.¹¹²

In its 2007 report on *Scenarios for the Future*, the EPO predicted that patent law, policy and practice would have to grapple with new scientific revolutions.¹¹³ The EPO explicitly cited the report of the National Science Foundation and United States Department of Commerce, which envisaged two overlapping processes of convergence – ‘the computer and communications revolution in progress today and a second, just beginning, representing the NBIC revolution, i.e. the combination of nanotechnology, biotechnology, information technology and cognitive sciences’.¹¹⁴ The EPO reflected on the implications of converging technologies for patent law, policy and administration:

Increasing ‘interdisciplinarity’ – for example, the combination of nanotechnology, biotechnology, information technology (IT) and cognitive sciences (NBIC) – is also increasing the challenges for the patent offices when it comes to

¹⁰⁹ *European Parliament Resolution on Patents for Biotechnological Inventions*, P6_TA (2005) 0407, 26 October 2005, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:272E:0440:0442:EN:PDF>.

¹¹⁰ *Ibid.*

¹¹¹ *European Parliament Resolution on Trade and Climate Change*, 29 November 2007, (2007/2003 (INI)), <http://www.europarl.europa.eu/sides/getDoc.do?Type=TA&Reference=P6-TA-2007-0576&language=EN>.

¹¹² *European Parliament Resolution of 24 April 2009 on Regulatory Aspects of Nanomaterials*, <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2009-0328&language=EN>.

¹¹³ European Patent Office (2007), *Scenarios for the Future: How Might IP Regimes Evolve by 2025? What Global Legitimacy Might Such Regimes Have?*, Munich: European Patent Office, [http://documents.epo.org/projects/babylon/eponet.nsf/0/63A726D28B589B5BC12572DB00597683/\\$File/EPO_scenarios_bookmarked.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/63A726D28B589B5BC12572DB00597683/$File/EPO_scenarios_bookmarked.pdf).

¹¹⁴ *Ibid.*, 90.

expertise. Multidisciplinary technologies create a new challenge for the people charged with administering patents: how can you expertly assess a patent application for a concept that requires top-level understanding of not one, but perhaps four different disciplines?¹¹⁵

The EPO noted that, in addition to questions of patent law, policy and practice, there were larger questions of regulations of emerging technologies: 'In the foreseeable future – and even now – ethical issues concerning certain technological developments could force us to question our moral values and the rules that ought to govern human conduct.'¹¹⁶

IV AUSTRALIA AND NEW ZEALAND

In Australia, there have been cycles of debate and controversy over gene patents and stem cell patents. In the 1990s, Senators John Coulter and Natasha Stott Despoja from the Democrats – a minor party in the Australian Parliament, since defunct – introduced bills seeking to prohibit gene patents. However, such measures did not win support from the major parties. Independent Senator Brian Harradine was successful in introducing an amendment to the *Patents Act* 1990 (Cth). The resulting section 18 (2) provides that 'Human beings and the biological processes for their generation are not patentable inventions.' IP Australia has sought to divine the meaning of this strange, ambiguous and indeterminate prohibition.

In the 2000s, the public debate over gene patents has re-emerged. A Melbourne company, called Genetic Technologies Limited (GTG), obtained broad patents on a range of scientific inventions arising out of the work of Malcolm Simons. Most significantly, the USPTO awarded U.S. Patent No. 5,612,179 to GTG for an invention entitled, 'Intron sequence analysis method for detection of adjacent and remote locus alleles as haplotypes'.¹¹⁷ The USPTO also issued U.S. Patent No. 5,851,762 to GTG for an invention entitled 'Genomic mapping method by direct haplotyping using intron sequence analysis'.¹¹⁸ The company has embarked upon a

¹¹⁵ Ibid., 91.

¹¹⁶ European Patent Office (2007), *Scenarios for the Future: How Might IP Regimes Evolve by 2025? What Global Legitimacy Might Such Regimes Have?*, Munich: European Patent Office, [http://documents.epo.org/projects/babylon/eponet.nsf/0/63A726D28B589B5BC12572DB00597683/\\$File/EPO_scenarios_bookmarked.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/63A726D28B589B5BC12572DB00597683/$File/EPO_scenarios_bookmarked.pdf).

¹¹⁷ Simons, M. (1992), 'Intron Sequence Analysis Method for Detection of Adjacent and Remote Locus Alleles as Haplotypes', U.S. Patent No: 5,612,179.

¹¹⁸ Simons, M. (1994), 'Genomic Mapping Method by Direct Haplotyping Using Intron Sequence Analysis', U.S. Patent No: 5,851,762.

vigorous licensing program – obtaining, in the process, licences in Australasia to Myriad’s patents in respect of genetic testing. In 2008, GTG announced that the company would enforce its rights in respect of these patents against public, as well as private, providers of genetic testing.¹¹⁹ Its press release sought to explain the motivations behind this: ‘Given that Genetic Technologies now offers an excellent service and has considerable excess capacity, the Company has made a commercial decision to enforce the exclusive rights granted to it by Myriad Genetics to perform diagnostic testing of the BRCA1 and BRCA2 genes in Australia and New Zealand.’¹²⁰

In response to widespread criticism of GTG, the company changed the composition of its Board of Directors, and withdrew its demands. Its somewhat more conciliatory press release noted: ‘The Company looks forward to working positively with all its partners, including other public and private testing laboratories, to continue providing these world class testing services.’¹²¹ Nonetheless, despite its position in Australia, GTG has continued to pursue litigation against biotechnology companies in other jurisdictions. In 2010, GTG filed a patent infringement suit in respect of its non-coding DNA technologies against nine parties in the United States District Court, Western District of Wisconsin. The parties were Beckman Coulter Inc., Orchid Cellmark Inc., Gen-Probe Inc., Interleukin Genetics Inc., Molecular Pathology Laboratory Network Inc., Monsanto Inc., PIC USA Inc., Sunrise Medical Laboratories and Pioneer Hi-Bred International Inc.¹²² In 2011, GTG filed a lawsuit in the United States District Court for the Western District of Wisconsin against a number of clinical pathology laboratories associated with Sonic Healthcare Limited.¹²³

¹¹⁹ Genetic Technologies Limited (2008), ‘Genetic Technologies to Enforce Rights to BRCA Patents’, Press Release, 11 July, <http://www.gtglabs.com.au/announcements/genetic-technologies-to-enforce-rights-to-brca-patents>.

¹²⁰ Ibid.

¹²¹ Genetic Technologies Limited (2008), ‘New Position re BRCA Testing’, Press Release, 2 December, <http://www.gtglabs.com.au/announcements/new-position-re-brca-testing>.

¹²² *Genetic Technologies Limited v. Berkman Coulter Inc. et al.* (2010), United States District Court for the Western District of Wisconsin, Civil Action No. 10 CV 0069; and Genetic Technologies Limited (2010), ‘Genetic Technologies Moves to Assert Its Intellectual Property Rights and Files Patent Infringement Suit in USA’, Press Release, 16 February, http://www.gtglabs.com.au/images/stories/pdf/ASX%20Announcements/Assertion_of_property_rights_February_16_2010.pdf.

¹²³ *Genetic Technologies Ltd. v. American Esoteric Laboratories et al.* (2011), United States District Court for the Western District of Texas, 1:11-cv-00057; Genetic Technologies Limited (2011), ‘Genetic Technologies Files Second Patent Infringement Suit in the USA’, Press Release, 20 January.

In June 2010, Cancer Voices Australia and Yvonne D'Arcy brought an action in the Federal Court of Australia against the validity of a BRCA1 patent – held by Myriad Genetics Inc., the Centre de Recherche du Chul, the Cancer Institute of Japan and Genetic Technologies Limited.¹²⁴ The applicants made the following arguments:

Genes and the information represented by human gene sequences are products of nature universally present in each individual, and the information content of a human gene sequence is fixed. Genetic variations or mutations are products of nature. The isolation of the BRCA1 gene mutation from the human body constitutes no more than a medical or scientific discovery of a naturally occurring phenomenon and does not give rise to a patentable invention.¹²⁵

In the alternative, the applicants argued that ‘the alleged invention is not a patentable invention in that, so far as claimed in claims 1–3, it is not a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies*’.¹²⁶ The applicants maintained that ‘the alleged invention is a mere discovery’.¹²⁷ Furthermore, the applicants contended that ‘the alleged invention of each of claims 1–3 is not a patentable invention because they are claims for biological processes for the generation of human beings’.¹²⁸

As a result of the controversy over GTG and Myriad Genetics, the Australian Law Reform Commission was instructed to undertake a review of intellectual property rights over genes and genetic and related technologies, with a particular focus on human health issues. The Commission released an issue paper in July 2003, a discussion paper in January 2004, and a final 678-page report in June 2004, which was tabled in Parliament in August 2004.¹²⁹ The Australian Law Reform Commission reflected upon how patent law accommodated successive waves of emerging technologies:

¹²⁴ *Cancer Voices Australia et al. v Myriad Genetics Inc. et al.* (2010), Federal Court of Australia, Statement of Claim, 8 June.

¹²⁵ *Ibid.*

¹²⁶ *Ibid.*

¹²⁷ *Ibid.*

¹²⁸ *Ibid.*

¹²⁹ Australian Law Reform Commission (2003), *Gene Patenting and Human Health, Issues Paper 27*, Sydney: Australian Commonwealth, <http://www.austlii.edu.au/au/other/alrc/publications/issues/27/>; Australian Law Reform Commission (2004), *Gene Patenting and Human Health, Discussion Paper 68*, Sydney: Australian Commonwealth, <http://www.austlii.edu.au/au/other/alrc/publications/dp/68/>; Australian Law Reform Commission (2004), *Genes and Ingenuity: Gene Patenting and Human Health, Report 99*, Sydney: Australian Commonwealth, <http://www.austlii.edu.au/au/other/alrc/publications/reports/99/>.

‘Once patent examiners have become familiar with genetics, they will, no doubt, be met with a new range of challenges from emerging disciplines such as bioinformatics, pharmacogenomics, proteomics and nanotechnology.’¹³⁰ Emphasizing the need for ‘technological neutrality’, the Commission did ‘not believe that concerns about the patenting of inventions involving genetic materials and technologies should be addressed by provisions in the *Patents Act* dedicated only to these types of inventions’.¹³¹ The final report contained another 50 recommendations. The key recommendation was that the Australian Government should recognise a statutory defence under patent law for experimental use. The Advisory Council on Intellectual Property conducted an independent inquiry into the desirability of a defence of experimental use in patent law. The reform body was of the view that there should be a research exemption.

In November 2010, the Senate Standing Committees on Community Affairs Reference Committee released its long awaited report on gene patents.¹³² As the executive summary indicates, the report focused upon gene patents in relation to health and medicine.¹³³ The majority of the committee were reluctant to impose a prohibition on patents being granted in the field of biotechnology, observing that it ‘heard conflicting evidence as to whether a prohibition on the patenting of genes and other biological materials (a) would be effective and (b) would not lead to unforeseen consequences in other fields of technology, particularly biotechnology research and development’.¹³⁴

A number of considerations persuaded the Committee that it would not, at this point in time, recommend that the Act be amended to expressly prohibit the patenting of genes – including uncertainty about the effectiveness of any such prohibition; international developments such as the litigation over Myriad Genetics’ patents in the United States; and national developments. Instead, the majority of the committee recommended a number of procedural and substantive reforms to improve the quality of patents granted – particularly in the area of biotechnology. However, a minority of the committee – Senators Helen Coonan and Bill Heffernan – were of the view that the *Patents Act* 1990 (Cth) should be amended to ban

¹³⁰ Australian Law Reform Commission (2004), *Genes and Ingenuity. Report 99*, Sydney: Australian Government, 64.

¹³¹ Ibid.

¹³² Senate Standing Committees on Community Affairs Reference Committee (2010), *Gene Patents*, Canberra: Australian Parliament, http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents_43/report/index.htm.

¹³³ Ibid., xi.

¹³⁴ Ibid.

the grant of patents over biological materials that are identical or substantially identical to such materials as they exist in nature.¹³⁵

A private members' bill has been introduced into the Australian Parliament, entitled the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (Cth). The sponsors include the Liberal Party members, Senators Heffernan and Coonan; Greens Senator Rachel Siewert; and Independent Senator Nick Xenophon. The rather crudely drafted bill proposes a broad prohibition: 'The following are not patentable inventions: (a) human beings, and the biological processes for their generation; and (b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.' Such a provision is ambiguous, uncertain and indeterminate in its breadth and scope. There is no accompanying definition of 'biological materials'. There has been substantive debate over the topic in the committee and the Parliament.¹³⁶ Given the weaknesses of the legislative proposal, it is doubtful that such a bill will win the support of the major parties in the Australian Parliament.

The policy debate in Australia has failed to canvass larger questions about how patent law deals with the full range of emerging technologies – not just gene patents; but also nanotechnology, stem cell research, synthetic biology and clean technologies.

In New Zealand, there has been a lively debate about the implications of the Human Genome Project for legal regulation.¹³⁷ There has also been controversy over GTG seeking licence fees from the Auckland District Health Board, and Crown Research Institutes. The *Patents Bill 2008* (NZ) 235–2 put forward a number of proposals for exclusions of subject matter from patent protection. Section 14 stipulated that 'an invention is not a patentable invention if the commercial exploitation of the invention, so far as claimed in a claim, is contrary to – (a) public order (which in this section

¹³⁵ Ibid.

¹³⁶ Senate Standing Committees on Legal and Constitutional Affairs (2011), *Patent Amendment (Human Genes and Biological Materials) Bill 2010*, Canberra: Australian Parliament, http://www.aph.gov.au/senate/committee/leg_con_ctte/patent_amendment/index.htm.

¹³⁷ Henaghan, Mark (ed.) (2006), *Choosing Genes for Future Children: Regulating Preimplantation Genetic Diagnosis*, Dunedin: Human Genome Research Project and New Zealand Law Foundation; Henaghan, Mark (ed.) (2007), *Genes, Society, and the Future*, Dunedin: Human Genome Research Project and New Zealand Law Foundation; and Henaghan, Mark (ed.) (2009), *Findings from the Law Foundation Sponsored Human Genome Research Project*, Dunedin: Human Genome Research Project and New Zealand Law Foundation.

has the same meaning as the term *ordre public* as used in Article 27.2 of the *TRIPS agreement*); or (b) morality'. Section 15 proposed excluding a number of subject matter from patentability – including 'human beings, and biological processes for their generation'; methods of human treatment; methods of diagnosis, computer programs and plant varieties.

V OUTLINE OF CHAPTERS

Rather than revisit the well-documented debate over gene patents,¹³⁸ this collection instead explores the impact of intellectual property upon 'emerging technologies' in the life sciences.¹³⁹ In April 2011, the Nuffield Council on Bioethics, based in the United Kingdom, released a consultation paper on emerging biotechnologies.¹⁴⁰ The Council considered the meaning of the term 'emerging technologies', and its derivative, 'emerging biotechnologies':

Emerging biotechnologies ... are those emerging technologies with a biological basis or use. Without settling on a definition of emerging biotechnologies for the time being we can nevertheless suggest certain features that may characterise them (although not necessarily all of them) and by which they might be recognised. The developmental pathway followed by these technologies may vary considerably. Some emerging biotechnologies that were conceived decades ago have taken a long time or have not (yet) achieved their original promise (e.g. xenotransplantation) while others have been implemented relatively quickly

¹³⁸ See Magnus, David, Arthur Caplan and Glenn McGee (eds) (2002), *Who Owns Life?*, Amherst, NY: Prometheus Books; Rimmer, Matthew (2008), *Intellectual Property and Biotechnology: Biological Inventions*, Cheltenham and Northampton, MA: Edward Elgar; Dutfield, Graham (2009), *Intellectual Property Rights and the Life Science Industries: Past, Present and Future*, Singapore: World Scientific; and Rai, Arti (ed.) (2011), *Intellectual Property Law and Biotechnology: Critical Concepts*, Cheltenham and Northampton, MA: Edward Elgar.

¹³⁹ Susan Cozzens and her colleagues identified a number of themes in a literature review of the usage of the term 'emerging technologies': 'The concepts reflected in the definitions of emerging technologies, however, can be summarised four-fold as follows: (1) fast recent growth; (2) in the process of transition and/or change; (3) market or economic potential that is not exploited fully yet; (4) increasingly science-based.' Cozzens, S. et al. (2010), 'Emerging Technologies: Quantitative Identification and Measurement', *Technology Analysis and Strategic Management*, **22** (3), 361–76.

¹⁴⁰ Nuffield Council on Bioethics (2011), *Emerging Biotechnologies*, London: Nuffield Council on Bioethics, April, http://www.nuffieldbioethics.org/sites/default/files/files/Nuffield_Council_Bioethics_Emerging_Biotechnologies_consultation_April-June_2011.pdf.

(e.g. preimplantation genetic diagnosis); some are in early stages of use with uncertain prospects (e.g. genomic medicine) while others are at early stages of research (e.g. synthetic biology) with an uncertain range of uses.¹⁴¹

The report notes that ‘Emerging biotechnologies often have an interdisciplinary character, drawing on knowledge originating in a variety of more established fields.’ Indeed, such technologies could be characterised by ‘[n]ovelty (of approach and perspective), convergence (between fields and practices), and divergence (from an established “parent” field)’.¹⁴² The Consultation Paper reflects that ‘emerging biotechnologies have the capacity to generate significant controversy’ – particularly ‘because of uncertainty or disagreement about the nature and level of associated risks’.¹⁴³

Each contributor in this collection considers a particular ‘scientific field’, to use a phrase of Pierre Bourdieu.¹⁴⁴ Such an approach will reveal commonalities between emerging technologies; as well as divergences in law, policy and practice. In this collection, scholars and researchers consider a panoply of emerging technologies. There is an exploration of genomics, biomedicine, bioinformatics, information technology, RNA interference, synthetic biology, stem cell research, nanotechnology, clean technologies, biodiscovery and traditional knowledge. Interestingly enough, under the NBIC categories, nanotechnology, biotechnology and information technology are well represented in the collection; but cognitive sciences and neurosciences do not figure highly. The fields of scientific research have multiple applications, covering agriculture, research, medicine and the environment. The contributors are a cosmopolitan group. The scholars hail from a variety of jurisdictions – including the United States, Canada, Great Britain, France, Sweden, Finland and Australia. This lends to the collection a decidedly comparative approach to understanding intellectual property and emerging technologies. The researchers consider not only intellectual property law, but also the adjoining areas of health law and bioethics, environmental law and climate law, international law, and Indigenous legal issues. Hilgartner suggests that a purely doctrinal approach to patent law is insufficient to address the politics of emerging technologies: ‘Traditional doctrine, with its emphasis on innovation and its focus on a relatively narrow group of actors, is poorly equipped for considering questions of democratic representation in decision making

¹⁴¹ Ibid.

¹⁴² Ibid.

¹⁴³ Ibid.

¹⁴⁴ Bourdieu, Pierre (2004), *Science of Science and Reflexivity*, Cambridge: Polity Press.

about the shape of future technological and social orders.’¹⁴⁵ Accordingly, the scholars here consider not only law, but also an array of intersecting disciplines. The contributors address the science of various fields, as well as the history, sociology and philosophy of science; technology and innovation policy; politics and governance; social anthropology and Indigenous studies. The researchers apply a range of methodologies to shed light upon their respective fields.

In the preliminary part of this volume, Eva Hemmungs Wirtén examines the flow and control of knowledge of plants and their potential pharmaceutical applications. She begins in the mid eighteenth century, when European countries such as Spain were colonising South America and sending botanists forth to the new colonies to explore the native flora. She traces the journey of plants and seeds, and knowledge of their useful effects, from the colonies of South America to Europe. Hemmungs Wirtén argues that, rather than being motivated only by scientific curiosity, these explorations and the knowledge they yielded were part of the colonial expansion agendas of European powers. Hemmungs Wirtén uses the cinchona tree, from which quinine is extracted to treat malaria, as her key example. This discussion raises debates about the ownership of plant resources and knowledge of their effects, as well as the preservation and stewardship of those resources. Hemmungs Wirtén argues that the struggles over the control of knowledge of useful plants, and the role of the various actors, are far from black and white. Hemmungs Wirtén shows that, in more recent times, use of plants by the pharmaceutical industry has caused nature to be seen as ‘a lucrative medicine cabinet’, emphasising the importance of the rainforest as a storehouse of genetic diversity and information. She concludes that the history described is an important part of understanding current approaches to biopiracy.

Questions about the scope of patentable subject matter are further developed in the second part of this volume.

In Chapter 2, Joly and Hemmings stress the importance of changes in subject matter patentability for the biotechnology research field. They survey United States case law on patentability of processes prior to the *Bilski* litigation, before considering the decisions in *In re Bilski* and *Bilski v. Kappos*¹⁴⁶ regarding the patentability of a method of hedging commodities.

¹⁴⁵ Hilgartner, S. (2009), ‘Intellectual Property and the Politics of Emerging Technology: Inventors, Citizens, and Powers to Shape the Future’, *Chicago-Kent Law Review*, **84**, 197 at 223.

¹⁴⁶ *In re Bilski*, 545 F.3d 943 (Fed. Cir., 2008); and *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

In the decision in *In re Bilski*, the Federal Court favoured a ‘machine-or-transformation test’, controversially holding that this was the definitive test to determine whether a process was patentable.¹⁴⁷ On appeal, the Supreme Court held in *Bilski v. Kappos* that the machine-or-transformation test only provides a clue about patentability and is not definitive.¹⁴⁸ The authors suggest that the majority judges were influenced by concerns about uncertainty over the patentability of emerging technologies such as medical diagnostic techniques. Examining the extent to which the *Bilski* decision changes the existing law, Joly and Hemmings conclude that the law has been clarified rather than altered, by making it clear that ‘physicality’ of invention is only a clue to its patentability. They analyse the case of *Amazon.com v. Canada (Attorney General)*¹⁴⁹ to demonstrate that even this small clarification can increase the scope of patentable subject matter. They consider the ramifications of *Bilski* in the specific context of genomics research, a growing field that both utilises many processes and is likely to yield a huge amount of innovation in processes for research and medical diagnosis.

In the third chapter, Joshua Sarnoff provides his perspective on the recent subject matter decisions, particularly regarding patentability of *applications* of unpatentable ideas or principles. He criticises what he sees to be an inconsistent approach in decisions of the Supreme Court of the United States – such as *Bilski v. Kappos* – and a failure to clarify the circumstances in which applications of excluded ideas will be patentable.¹⁵⁰ Sarnoff argues that in *Prometheus Laboratories Inc v. Mayo Collaborative Services*,¹⁵¹ the United States Court of Appeals for the Federal Circuit erroneously allowed a patent over a process of administering a drug, then measuring metabolites and using this measurement to determine whether to alter the drug dosage. The Court failed to treat the correlation involved as prior art and did not look for inventiveness in the specific application of the correlation at issue. The author then turns to the recent litigation in the *Myriad* decision¹⁵² over the patenting of genes implicated in breast cancer

¹⁴⁷ *In re Bilski*, 545 F.3d 943 (Fed. Cir., 2008).

¹⁴⁸ *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

¹⁴⁹ *Amazon.com v. Canada (Attorney General)* (2010), F.C.J. 1209.

¹⁵⁰ *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

¹⁵¹ *Prometheus Laboratories Inc. v. Mayo Collaborative Services*, No. 04-CV-1200, 2008 WL 878910 (S.D. Cal. Mar. 28, 2008); and *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, No. 2008–1403, slip op. (Fed. Cir. 2010).

¹⁵² *Association for Molecular Pathology et al. v. United States Patent and Trademark Office, Myriad Genetics, et al.*, 702 F. Supp. 2d 181, (S.D.N.Y. 2010), appeal docketed, No. 2010–1406 (Fed. Cir. June 22, 2010); and *Association for Molecular Pathology et al. v. United States Patent and Trademark Office*,

and related methods of genetic diagnosis. Overall, Sarnoff identifies the need for a greater understanding of the degree of creativity required for such medical and genetic applications to be patentable.

In Chapter 4, Graham Dutfield investigates the role of language in interpreting patentable subject matter. He explores the use of analogies and metaphors in the life sciences, demonstrating the move from a discourse of 'life as chemistry' to one of 'life as information'. Dutfield considers the use of the terms 'machine' and 'mechanism' to describe biological phenomena. He notes that reasoning by analogy is one of the approaches courts faced with unfamiliar patentable subject matter questions may take. In *Diamond v. Chakrabarty*,¹⁵³ Dutfield argues, the Court was able to find the modified bacterium patentable by analogising it with inanimate chemicals, whereas in the Harvard OncoMouseTM case¹⁵⁴ a modified higher organism did not fit this analogy. He then turns to the use of engineering concepts and terminology in the emerging field of synthetic biology, asking whether the metaphors and analogies being deployed by synthetic biologists are sufficient to legitimise the grant of product patents. Dutfield argues that when we are truly able to create a living organism in the laboratory, life forms will indeed become manufactured devices and the engineering analogy will 'finally fit perfectly'.

In the third part, we consider several institutional models for research in the life sciences.

In Chapter 5, Dianne Nicol and Richard Gold present a discussion of intellectual property and ethics in biobanks, providing case studies of the United Kingdom Biobank, Generation Scotland, and the Canadian CARTaGENE project. The authors identify five aspects of biobanking that form competing considerations: access to the biobank's resources for research; downstream development of research and private sector involvement; privacy and autonomy of participants; participant and public trust; and securing funding. Throughout the discussion, the authors emphasise the importance of maintaining public trust in biobanking through transparency and accountability. They also note the need to ensure benefit sharing and adequate information about benefits for participants. Nicol and Gold consider the possibilities for 'open source' or 'open access' arrangements in biobanking, concluding that there are practical reasons why open source is more difficult to apply in biobanking than in the software environment.

Myriad Genetics, et al. 653 F.3d 1329, 2011 WL 3211513 (C.A. Fed. (N.Y.)), 99 USPO 2d 1398.

¹⁵³ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

¹⁵⁴ *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76.

In Chapter 6, Donna Gitter explains that genomic research is now generating large amounts of data, so that scientific databases and policies for data access and sharing have increased in importance. She examines the 1000 Genomes Project, in which the genomes of 1000 people from across the world will be sequenced and compared with a view to obtaining a more detailed picture of how genetic variation affects disease susceptibility, response to drugs and reactions to the environment. Gitter traces the development and effectiveness of consensus principles for data sharing from the *Bermuda Statement* 1996 to the *Toronto Statement* 2009, noting that sharing tends to play out differently in large publicly funded projects from within the 'small science' context. She canvasses some options for giving due recognition to the original contributors of shared scientific data. The discussion touches on the roles of funding bodies and scientific journals in promoting and managing data sharing. Gitter also notes the importance of infrastructure for ongoing maintenance of data and specimens. Finally, she identifies certain data that are not suitable for open access models.

In Chapter 7, Alison McLennan picks up some of the intellectual property issues around synthetic biology research raised earlier in the volume. She analyses the structures established to advance synthetic biology research by the BioBricks Foundation, a group of scientists in the United States. Sharing of information and resources in synthetic biology research is facilitated by the Registry of Standard Biological Parts, which is supported by a culture of sharing in the synthetic biology community. McLennan analyses the draft legal arrangements that have been proposed to underpin these sharing activities. She considers how models for sharing in technology development, including 'open source', 'user driven innovation' and 'open biotechnology', apply to synthetic biology. She concludes that this case study can be seen as an example of a growing trend towards openness and sharing in biological research.

In the fourth part, we consider the current state of intellectual property debates in three areas of research: RNA (ribonucleic acid) interference, embryonic stem cell research and nanotechnology.

In Chapter 8, Adam Bostanci, Jane Calvert and Pierre-Benoit Joly explore recent trends in research and patenting in the field of RNA interference. RNA is an important intermediate message-carrying molecule in the process of reading and carrying out the instructions contained in the genome (gene expression). The information encoded in DNA is carried by complementary RNA molecules to the cellular machinery that produces proteins. These proteins carry out various functions within the cell. Scientists have found that introducing certain RNAs into cells can reduce or block expression of the matching gene. This effect is known as RNA

interference (RNAi). The authors identify a ‘gold rush’ of patent activity in this area and describe several significant patents including the Carnegie patent and the Tuschl patents. These patents are placed in the context of preceding controversies over gene patenting. Issues that arise include enablement problems and establishing therapeutic utility. Through this survey, the authors demonstrate the ongoing presence of ‘gene centrism’ in RNAi patent applications, as well as in the United States patenting requirements. They argue that RNAi technologies may have greater utility as research tools than as medical treatments.

In Chapter 9, Amina Agovic considers interactions between patent law and bioethics in the context of embryonic stem cell research. She compares the ethical debates taking place in the United States and the European Union regarding destruction of human embryos, creation of human embryos for use in research, and creation of mixed species embryos. Agovic analyses the European Patent Office rulings rejecting the Wisconsin Alumni Research Foundation and California Institute of Technology patent applications.¹⁵⁵ She identifies a lack of clarity in these decisions regarding interpretation of the morality clause, what constitutes morality and ethics in the European context, and how these issues affect the patentability of inventions involving embryonic stem cell technology. Considering recent developments in relation to the Wisconsin Alumni Research Foundation’s stem cell patents, Agovic argues that both the USPTO and the United States courts are reluctant to address ethical issues, deferring them to Congress. She argues that patent law should include mechanisms for addressing ethical concerns.

In Chapter 10, Alison McLennan and Matthew Rimmer survey the field of patent law and nanotechnology – highlighting matters of nomenclature and classification; the potential for patent thickets and a ‘tragedy of the anticommons’; and ethical conundrums about the potential risks posed by nanotechnology to human health, the environment and peace.

In the concluding part, we consider the ability of the intellectual property system to protect and preserve genetic resources, respond to the changing natural environment, and protect the rights of traditional holders of ecological knowledge.

In Chapter 11, by Sarah Holcombe and Terri Janke, we return to some themes raised at the beginning of the volume regarding local traditional knowledge of biological resources and appropriation of these resources by

¹⁵⁵ *Stem Cells/WARF* (T 1374/04) 2007 EPO OJ 313; *California/Stem Cells* (T 522/04) 2009 EPOR 45.

others. Holcombe and Janke outline the Australian approach to implementation of the *Convention on Biological Diversity* 1992 under federal legislation and several State and Territory acts, noting some loopholes and inconsistencies between the various regimes.¹⁵⁶ The authors compare two case studies: Mary Kay Cosmetics' application for a patent on the use of the Kakadu plum in cosmetics; and a patent on use of the Marjarla tree for pain relief. The cosmetic company is likely to have accessed the plum without following the applicable protocols and negotiating benefit sharing with Indigenous people, demonstrating inadequacies in the legal system. By contrast, the Marjarla patent was obtained through a collaborative partnership between a university and an Indigenous community, who are to receive mutually agreed benefits. Overall, the authors argue that federal government action is needed to create a consistent Australian approach to the protection of Indigenous cultural and intellectual property. Moreover, they argue that there needs to be substantive international action – above and beyond the minimalist *Nagoya Protocol* 2010.¹⁵⁷

Chapter 12 by Matthew Rimmer considers the controversies over plant breeders' rights, patent law and climate-ready crops. In the field of plant breeders' rights, plant breeders have argued that genetically modified crops will be better adapted to the environmental stresses caused by climate change. Doug Waterhouse, the registrar for Plant Breeders' Rights in Australia, observed: 'In response or in anticipation to climate change, new varieties are being developed without a chill factor requirement, they have low or no chill requirement that means that the area available for growing those plants can be moved perhaps north from where they are now.'¹⁵⁸ In the area of patents, technology developers have built significant patent portfolios in respect of climate-ready crops to deal with environmental stresses – such as heat, drought and floods. This trend has caused some consternation amongst farmers, environmental groups and civil society organisations, like the ETC Group. There has been a discussion about exceptions to intellectual property rights in respect of agricultural inventions – dealing with patentable subject matter, farmers' rights, patent pools, public sector research, technology transfer and compulsory licensing.

¹⁵⁶ *Convention on Biological Diversity* 1992, opened for signature 5 June 1992, 1760 UNTS 143 (entered into force 29 December 1993).

¹⁵⁷ *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*, COP 10 Decision, ('*Nagoya Protocol* 2010').

¹⁵⁸ Dakis, S. (2008), 'PBR Helping with Climate Change', *ABC News*, 27 August, <http://www.abc.net.au/rural/sa/content/2006/s2348159.htm>.

Chapter 13 by Matthew Rimmer considers the threat posed to plant genetic resources by global warming and climate change. The Food and Agriculture Organization of the United Nations has been concerned with climate change, and the boom in bioenergy is affecting farming and the price of seeds. The *International Treaty on Plant Genetic Resources* 2001 aims to promote ‘the conservation and sustainable use of plant genetic resources for food and agriculture’ and ‘sustainable agriculture and food security’.¹⁵⁹ The Svalbard Global Seed Vault – nicknamed the Doomsday Vault – was established and is managed by the Norwegian Government, the Global Crop Diversity Trust and the Nordic Genetic Resource Center to protect crop diversity from catastrophes, such as those caused by climate change. This ‘Big Science’ project is worth evaluating as a means of addressing intellectual property, climate change and food security.

¹⁵⁹ *International Treaty on Plant Genetic Resources for Food and Agriculture*, adopted 3 November 2001, S. Treaty Doc. No. 110–19, <ftp://ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf> (entered into force 29 June 2004).

