Introduction

In a witty satire of prevailing patenting practices, the English poet and part-time casino waitress, Donna MacLean, sought a patent application – GB0000180.0 – in respect of herself. She explained that she had satisfied the usual patent criteria in that she was ‘novel’, displayed an ‘inventive step’, and was eminently ‘useful’:

It has taken 30 years of hard labor for me to discover and invent myself, and now I wish to protect my invention from unauthorized exploitation, genetic or otherwise. I am new: I have led a private existence and I have not made the invention of myself public. I am not obvious.

MacLean quipped that she had many industrial applications: ‘For example, my genes can be used in medical research to extremely profitable ends – I therefore wish to have sole control of my own genetic material.’ She explained the serious motives that lay behind her stunt: ‘There’s a kind of unpleasant, grasping, greedy atmosphere at the moment around the mapping of the human genome . . . I wanted to see if a human being could protect their own genes in law.’ The episode raises larger questions about the philosophy, ethics and politics of ‘patenting lives’.

The contemporary debate over patent law and biological inventions is not new. There has been a long-standing controversy over the grant of monopolies in respect of scientific inventions and technologies. In the sixteenth century, English monarchs granted monopoly privileges to inventors and imports of new technology in return for the payment of royalties to the Crown. The courts objected to the Crown rewarding political patronage with trading monopolies. The English Parliament sought to constrain the exercise of such royal prerogatives. The first modern patent legislation, the Statute of Monopolies 1623 (UK), limited the grant of monopolies to the ‘first and true inventors’ of ‘any manner of new manufactures of the realm’, so long as they were ‘not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient’. As it first developed, there was no clear procedure for the grant of patents. The process of obtaining patent protection was slow, expensive and cumbersome. In the midst of the industrial revolution, the English Parliament sought to reform the administration of patents. In particular,
patent applicants were required to define their claims to an invention in written documents known as specifications. The *Paris Convention for the Protection of Industrial Property* 1883 established an international union for the protection of industrial property – including protection for patents, trademarks and designs. Since that time, there have been a number of national, regional and international legal developments, which have created the modern network of patent offices.

Patent law grants exclusive economic rights in respect of the use and exploitation of inventions, in order to benefit society through encouraging innovation, and promoting the disclosure of scientific knowledge. Binnie of the Supreme Court of Canada has described the ‘patent bargain’ in these terms:

A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the *quid pro quo* for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*. Monopolies are associated in the public mind with higher prices. The public should not be expected to pay an elevated price in exchange for speculation, or for the statement of ‘any mere scientific principle or abstract theorem’, or for the ‘discovery’ of things that already exist, or are obvious. The patent monopoly should be purchased with the hard coinage of new, ingenious, useful and unobvious disclosures.

Members of the World Trade Organization (WTO) are required to provide patent protection for ‘any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application’. The extent of patent protection is further limited in terms of territory and temporality. Patent protection is limited to the jurisdiction within which the grant was made. Nation states must provide protection of patents for 20 years from the filing date. In certain exceptional circumstances, pharmaceutical drug patents may obtain an additional extension of the patent term for up to five extra years.

Furthermore, there are a number of legal doctrines which facilitate access to patented inventions. Members of the WTO can provide ‘limited exceptions to the exclusive rights conferred by a patent’, such as a defence of experimental use, and a safe harbour for research in respect of pharmaceutical drugs. Moreover, nation states can allow for use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government. There is also scope for competition measures ‘to prevent the abuse of intellectual property rights by right holders’. Countries also have the capacity to exclude from patentability inventions on the grounds of public order and morality.
Patent law has become a sprawling empire, exercising dominion over a wide range of scientific fields and technologies, with few limits or boundaries. Over the last century, Parliaments, Courts and the Patent Offices round the world have progressively and incrementally expanded the limits of patentable subject matter, until ‘anything under the sun that is made by man’ has been considered to be patentable. Initially, patent offices granted patents in respect of micro-organisms, such as yeasts, moulds, fungi, bacteria, algae, cell lines, viruses and protozoa. Then, intellectual property rights were incrementally extended to plants: the Plant Patent Act 1930 (US) provided protection in respect of asexually reproduced varieties of plants; plant breeders’ rights offered exclusive rights in respect of sexually reproducing plants; and finally patent protection was granted in respect of traditionally bred plants, hybrid plants and genetically modified crops. Patent law also enveloped the animal kingdom: after it was recognized that polyploid oysters could constitute patentable subject matter, patents were sought in respect of the Harvard oncomouse, model organisms, such as drosophila, mice and zebra fish, and even methods to clone animals, such as Dolly the Sheep.

The prohibition against patenting methods of human treatment has been lifted in a number of Western jurisdictions. Patents have thus been sought in respect of medical devices, surgical techniques and diagnostic tests, as well as research tools, pharmaceutical drugs and personalized medicine. More recently, of course, patents have been granted in respect of human tissues, genes, stem cells and somatic nuclear cell transfer, so-called ‘therapeutic cloning’. There remain few taboo inventions under patent law: perhaps only human cloning and animal–human hybrids remain clearly outside the scope of patentable subject matter. The limits of patentable subject matter have even been stretched to accommodate frontier technologies, such as bioinformatics, proteomics, pharmacogenomics and nanotechnology.

Patent loyalists – lawyers, patent attorneys and policy makers, as well as members of the pharmaceutical and biotechnology industries – have defended the expansion of the patent system to include biological inventions. They have maintained that the patent system has achieved its objectives of encouraging innovation, boosting investment in research and development, and facilitating access to scientific information. The peak body, the Biotechnology Industry Organization (BIO), is exemplary in its defence of the extension of patent protection in respect of biotechnological inventions:

For over 200 years the carefully crafted intellectual property laws have been the driving force for innovation and progress in the United States. The U.S. patent system fosters the development of new products and discoveries, new uses for
old products and employment opportunities for millions of Americans. Nowhere is this more apparent than in the biotechnology arena. The biotechnology industry as we know it did not exist prior to the landmark Supreme Court decision of *Diamond v. Chakrabarty* in 1980, where the court held that anything made by the hand of man was eligible for patenting. Since this decision, the biotechnology industry has flourished and continues to grow. Strong intellectual property protection is essential to the success, and in some instances to the survival, of the over 1,200 biotechnology companies in this country. For these companies, the patent system serves to encourage development of new medicines and diagnostics for treatment and monitoring of intractable diseases, and agricultural and environmental products to meet global needs.17

BIO emphasizes that patent protection is an invaluable incentive for both capitalists and scientists alike: ‘Enticed by the prospect of the market exclusivity afforded by U.S. patent protection, U.S. entrepreneurs and scientists expend great resources to develop and produce cutting edge biotechnology products.’18 The peak body emphasizes: ‘Patents provide the needed assurance for investors to risk the capital necessary in the long development process; e.g. that his/her investment cannot only be recouped but also generate a profit.’19 The group believes that the model of the United States patent system should be emulated by other countries. ‘BIO takes an active role in educating policymakers, opinion leaders and the public at large, both in the U.S. and abroad, about the value of the biotechnology sector.’20

By contrast, a number of commentators argue that the patent system can accommodate new technologies within its framework, but only through the flexible use of patent doctrines and administrative guidelines. Dan Burk and Mark Lemley maintain that, under a façade of technology neutrality, the patent system is technologically specific in the way that it deals with new technologies:

This seeming paradox – a monolithic legal incentive for wildly disparate industries – is resolved by the realization that, despite the appearance of uniformity, patent law is actually as varied as the industries it seeks to foster. Closer examination of patent law demonstrates that it is unified only in concept. In practice the rules actually applied to different industries have shown increasing divergence. The best examples of such divergence are found in biotechnology and computer software cases, where the courts have applied the common legal standards of obviousness, enablement, and written description in ways that differ radically in result. As a practical matter, it appears that although patent law is technology-neutral in theory, it is technology-specific in application.21

These authors question whether patent law should explicitly attempt to tailor protection to the needs of specific industries, as many have suggested. Instead, they suggest that Patent Offices and courts should make use of existing policy levers within patent law to address and respond to new
technologies: ‘The great flexibility in the patent statute presents an opportunity for courts to take account of the needs and characteristics of different industries.’ Burk and Lemley, in particular, mention a number of existing doctrines, such as prohibition against the patenting of abstract ideas; the level of skill of a person skilled in the art; secondary considerations of inventiveness; the criteria of utility; written description requirements; various indicia of patent infringement; and the defence of experimental use. They also identify a number of other potential policy levers, such as the presumption of validity; anti-trust considerations; and the use of remedies, such as injunctions.

Law reformers have recommended that the patent system could be reformed and improved, so that it is better adapted to the unique problems presented by gene patents. They have made both recommendations for procedural reform, in terms of patent administration and examination standards, as well as substantive reform, such as raising the threshold of patent criteria in respect of novelty, inventive step and utility, and expanding the exceptions to patent infringement. In its inquiry into gene patenting and human health, the Australian Law Reform Commission (ALRC) commented:

The ALRC has adopted a nuanced approach to reform, which recognises both the generality and longevity of the patents system, on the one hand, and the new challenges generated by human genetic science and technology, on the other. There are many different points at which the patent system might be reform to address the actual and anticipated problems posed by the patenting of genetic materials and technologies. This does not mean that reform must be sought at every point, but rather that intervention – where needed – should be directed to those areas in which it will be most effective . . . The Report makes important recommendations for reform but it does not suggest any radical overhaul of the patent system.

The Commission was exemplary of a model of a minimalist, liberal and rational law reform, with its ideals of technology neutrality, regulatory flexibility and legislative compromise. Similar approaches were taken in other jurisdictions, by sister reform bodies such as the Canadian Biotechnology Advisory Committee, the Nuffield Council on Bioethics, The New Zealand Royal Commission on Genetic Modification, the National Academy of Sciences, and the National Research Council.

In a classic paper that captured the zeitgeist, Michael Heller and Rebecca Eisenberg speculated that biomedical research suffered from the ‘tragedy of the anticommons’. The authors contended: ‘A proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development’. Heller and Eisenberg elaborated:
Thirty years ago in *Science*, Garrett Hardin introduced the metaphor ‘tragedy of the commons’ to help explain overpopulation, air pollution, and species extinction. People often overuse resources they own in common because they have no incentive to conserve. Today, Hardin’s metaphor is central to debates in economics, law, and science and is a powerful justification for privatizing commons property. Although the metaphor highlights the cost of overuse when governments allow too many people to use a scarce resource, it overlooks the possibility of underuse when governments give too many people rights to exclude others. Privatization can solve one tragedy but cause another. Since Hardin’s article appeared, biomedical research has been moving from a commons model toward a privatization model.31

Heller and Eisenberg concluded: ‘An anticommons in biomedical research may be more likely to endure than in other areas of intellectual property because of the high transaction costs of bargaining, heterogenous interests among owners, and cognitive biases of researchers.’32

There have been a number of empirical studies, which have investigated the impact of gene patents upon scientific research, communication and innovation.33 The evidence has been inconclusive. Reviewing the available empirical evidence, the eminent panel of Tim Caulfield, Robert Cook-Deegan, F. Scott Kieff and John Walsh questioned whether the phenomenon of the anti-commons had materialized:

The evidence regarding the anticommons and restricted access concerns is clearer. The empirical research suggests that the fears of widespread anticommons effects that block the use of upstream discoveries have largely not materialized. The reasons for this are numerous and are often straightforward matters of basic economics. In addition to licensing being widely available, researchers make use of a variety of strategies to develop working solutions to the problem of access, including inventing around, going offshore, challenging questionable patents and using technology without a license.34

There is an important gap, though, between the opinions of the interpretative community of lawyers, patent attorneys, business managers and policy makers, and wider public opinion about patenting life forms. R. Stephen Crespi noted in his report for the Organisation for Economic Co-operation and Development (OECD) that there is ‘a large gap between the views of experts and public opinion about problems engendered by the patenting of genetic inventions’.35 Empirical evidence suggests that there is widespread community concern about genetic patents.36 Technocrats may wishfully like to think that the debate about the patentability of genes has been conclusively resolved; however, the question is still very much an open-ended subject of passionate debate in the wider community.

Bioethicists have maintained that ethical considerations are and should be relevant in assessing applications for gene patents.37 The current
manner of manufacture test is not sufficient to accommodate such considerations. An independent body should become relevant in assessing ethical considerations related to assessing applications for gene patents. In an article in the *Lancet*, Richard Gold and Timothy Caulfield argue that the patent system can address ethical concerns in biotechnology: 'The patent system provides a useful mechanism by which to address ethical and social concerns in biotechnology, not because patents are necessarily the cause of concern, but because the system for granting them provides a practical way to regulate compliance with ethical and social values.' The Canadian academics propose that patents for inventions that present social and ethical questions should be subject to suspension by an independent, transparent and responsible tribunal made up of specialists in ethics, research and economics. This suspension should be reversible so that, when the social or ethical concerns have been addressed in appropriate manner, the suspension can be lifted. Although controversial, such a flexible mechanism would assist governments and industry in enhancing public support for patents in the biotechnology area. The political philosopher, Francis Fukuyama, has called for greater regulation of genetic engineering.

A number of commentators believe that sui generis regimes of intellectual property should be minted to accommodate new technologies and scientific developments. Special legislative schemes have been developed to deal with plant breeders’ rights, and access to genetic resources. Sui generis regimes have been mooted for all manner of other subject matter, including scientific discoveries, animal breeders’ rights, genetic databases and the protection of traditional knowledge. However, such an approach seems increasingly unrealistic, given the broad expansion of patentable subject matter in national jurisdictions, and the ratcheting up of minimum obligations under international treaties.

There are also a number of patent abolitionists who contend that biological inventions should not be eligible for protection as patentable subject matter. Jeremy Rifkin has been a long-time opponent of biotechnology, generally, and gene patents, more particularly. He was involved in the *Diamond v Chakrabarty* case as a friend of the court and has supported the Human Chimera Patent Initiative as a means of critiquing the administration of the United States Patent and Trademark Office (USPTO). In *The Biotech Century*, Jeremy Rifkin summarized his concerns about the commercialization of life forms:

A handful of global corporations, research institutions, and governments could hold patents on virtually all 100,000 genes that make up the blueprints of the human race, as well as the cells, organs, and tissues that comprise the human
body. They may also own similar patents on tens of thousands of microorganisms, plants, and animals, allowing them unprecedented power to dictate the terms by which we and future generations will live our lives.\textsuperscript{41}

Rifkin warns that ‘multinational corporations and governments are already scouting the continents in search of the new “green gold”, hoping to locate microbes, plants, animals, and humans with rare genetic traits that might have future market value’.\textsuperscript{42}

Following the lead of Jeremy Rifkin and the Peoples Business Commission, a number of non-government organizations have expressed a range of ethical and moral objections to the patenting of genes.\textsuperscript{43} Peter Drahos and John Braithwaite have noted the increasing participation of civil society groups in policy debates over the intellectual property rights: ‘The decline of moral respectability of intellectual property rights has been accompanied by increasing levels of transnational activism against the use and extension of intellectual property regimes.’\textsuperscript{44} Scientists and researchers, such as John Sulston, have contended that genes should not be patented because they are scientific discoveries, products of nature and the common heritage of human kind. Folk heroes such as Percy Schmeiser and farmers’ collectives, such as the Network of Concerned Farmers, have expressed concerns that plant patents could undermine farmers’ rights to save seed, and engage in traditional agricultural activities.\textsuperscript{45} Animal rights’ activists, such as the American Anti-Vivisection Society, have protested that it is unethical and immoral to patent animals, because they are sentient beings.\textsuperscript{46} Environmental groups have objected to the patenting of plants, animals and human genes, complaining about the commodification of life forms. Greenpeace, for instance, has declared: ‘Greenpeace opposes all patents on genes, plants, humans and parts of the human body and regards the biodiversity of this planet as the common heritage of humankind.’\textsuperscript{47}

Consumer organizations, such as Ralph Nader’s Consumer Project on Technology, have campaigned for access to knowledge and access to essential medicines.\textsuperscript{48} Anti-biotechnology activists, such as the ETC Group, have protested against the creation of monopolies in respect of new biological technologies.\textsuperscript{49} Health activists, such as the Institut Curie, Médecins Sans Frontières and the Treatment Action Campaign, have contended that patents have undermined access to essential medicines.\textsuperscript{50} Religious denominations have objected to the patenting of genes and stem cells on the basis that life is sacred. Similarly, Indigenous communities and peak bodies like the Indigenous Peoples Council on Biocolonialism, have complained that they have been the victims of biopiracy through the assertion of patent rights and other related forms of intellectual property.\textsuperscript{51} Anti-globalization groups have objected to the impact of gene patents on developing countries,
noting that research dollars and the beneficial effects of patented products are concentrated in developed countries.\textsuperscript{52}

This book contends that there is a need to reform intellectual property and biotechnology in order to better accommodate scientific and technological developments. Sagely, Lester Thurow observed that the patent system has become rigid and inflexible in its ‘technology-neutral’ approach:

Fundamental shifts in technology and in the economic landscape are rapidly making the current system of intellectual property rights unworkable and ineffective. Designed more than 100 years ago to meet the simpler needs of an industrial era, it is an undifferentiated, one-size-fits-all system. Although treating all advances in knowledge in the same way may have worked when most patents were granted for new mechanical devices, today’s brainpower industries pose challenges that are far more complex.\textsuperscript{53}

It is submitted that the boundaries of patentable subject matter need to be better demarcated and delimited, so as to preserve the public domain and the scientific commons. The thresholds for the patent criteria of novelty, inventive step and utility should be raised, so as to require more than merely follow-on innovation. There should be an expansion of defences and exceptions to patent infringement, especially in respect of experimental use, farm-saved seed and medical treatment. Innocent bystanders should not be the subject of patent infringement actions. Bioethical concepts of informed consent and benefit sharing should inform the operation of the patent system. Moreover, there should be greater scope for the flexible use of compulsory licensing, Crown use and competition law. Furthermore, patent law needs to recognize the global nature of scientific inquiry, commonly featuring ‘Big Science’ projects, which involve collaborations between the public and private sectors.

In analysing intellectual property and biotechnology, this book draws upon a mixture of methodologies, including the history of science,\textsuperscript{54} the sociology of science\textsuperscript{55} and a comparative analysis of patent law, policy and practice.\textsuperscript{56}

First, this book is part of a larger project of seeking to document the historical origins of the biotechnology industry. The Oral History Office of Bancroft Library at the University of California has been conducting interviews with scientists, entrepreneurs and university administrators who were involved in the development and commercialization of the life sciences.\textsuperscript{57} Drawing upon this work, Sally Smith Hughes has written a dazzling case study of the Cohen-Boyer patent in respect of recombinant DNA.\textsuperscript{58} She argues that the patent was a turning point in the commercialization of molecular biology and a harbinger of the social and ethical issues associated with biotechnology today. Stephen Hall made an early attempt to
document the race to synthesize a human gene, focusing upon Genentech, Biogen, Eli Lilly and the University of California.\textsuperscript{59} Daniel Kevles has written about key moments in the history of intellectual property and biotechnology.\textsuperscript{60} The anthropologist Paul Rabinow has also told a number of stories about the history of biotechnology. He has written accounts of the polymerase chain reaction (PCR),\textsuperscript{61} the French genomics project\textsuperscript{62} and the Icelandic genomics project by DeCODE Genomics.\textsuperscript{63} Similarly, the sociologist Alberto Cambrosio and his collaborators have written a history of scientific research into monoclonal antibodies.\textsuperscript{64} There is much to be learned from such historical case studies.

Second, this text explores whether patent law, and allied rights, have an impact on the social norms of scientific communities: in particular, Robert Merton's key values of universalism, communism, disinterestedness and organized scepticism.\textsuperscript{65} Rebecca Eisenberg explores the potential negative impact of patent rights on scientific norms in the field of biotechnological research: ‘By providing such broad exclusive rights, patent law may aggravate pre-existing conflict between scientific norms and the reward structure of science.’\textsuperscript{66} Her collaborator, Arti Rai, supports this claim:

 Legal rules and social norms are powerful and interdependent institutions for shaping behaviour. Law-and-norms analysis represents a valuable tool for determining how these institutions should be deployed. Applying an efficiency-focused variant of law-and-norms analysis to basic research in molecular biology reveals that the federal government’s past efforts to displace information-sharing norms with intellectual property rights have failed to recognize those contexts in which invention and development goals are promoted more effectively through the public domain than through privatization.\textsuperscript{67}

By contrast, F. Scott Kieff is a naysayer who argues that intellectual property rights are consistent with the norms of science: ‘It is not even clear that the pre-1980 basic biological research community had a prescriptive norm that specifically rejected patents, as distinct from other forms of intellectual property.’\textsuperscript{68} Such arguments need to be grounded in historical and sociological work about the understanding of intellectual property by scientists at that time.

Third, this book considers how the legal problems in respect of biological inventions have been addressed in a number of key jurisdictions, including the United States, the European Union, Canada, Australia and New Zealand. There have been noticeable tensions and rivalries between the USPTO, the Court of Appeals for the Federal Circuit and the Supreme Court of the United States. The United States Congress has debated a number of legislative proposals in respect of biological inventions, such as The Genomic Research and Diagnostic Accessibility Act 2002 (US), The
Genomic Science and Technology Innovation Act 2002 (US) and the Genomic Research and Accessibility Act 2007 (US). However, the United States Government has been somewhat reluctant to implement such measures. The Supreme Court of Canada has been divided between supporters of gene patents and a cohort of naysayers who have ethical qualms about biological inventions. The Canadian Parliament has been noticeably slow to adopt the recommendations of the Canadian Biotechnology Advisory Committee.69

By contrast, the European Parliament passed the comprehensive European Union Directive on the Legal Protection of Biotechnological Inventions 1998 (EU). Nonetheless, there has been much debate amongst member states over the implementation of this Directive. There has been discord on the issues of gene patents and stem cell patents between the European Parliament, the European Patent Office and specialist law reform advisory bodies. Canada presents a striking hybrid of British, European and North American influences on patent law.

In Australia, IP Australia, the Federal Court of Australia, and the High Court of Australia have had to grapple with a number of frontier technologies. The Australian Law Reform Commission conducted an extensive inquiry into gene patenting and human health; however, the Australian Government has shown little inclination to implement its minimalist recommendations.70 The New Zealand Government has commissioned policy papers on genetic engineering, and more particularly on the impact of gene patents on human health.71

There has also been much debate about biological inventions in a number of international forums. The Paris Convention for the Protection of Industrial Property 1883 established a multilateral regime for the protection of various forms of industrial property – including patents, trademarks and designs. The UPOV Convention 1961, and its successors, the UPOV Convention 1978 and the UPOV Convention 1991, provided a blueprint for the development of a sui generis regime protection for plant breeders’ rights. The Patent Cooperation Treaty 1970 was designed to enable the filing of an international patent application, which can be assessed for novelty by a search of the prior art. The Budapest Treaty 1977 provided international recognition of the deposit of micro-organisms for the purposes of patent disclosure. The Rio Convention on Biological Diversity 1992 established a framework for access to genetic resources of sovereign nation states on the basis of prior informed consent and benefit sharing.72

The TRIPS Agreement 1994 clarified the existing criteria for granting a patent, and also confined the nature of the exclusions to patentable subject matter that can be applied in national patent laws.73 There has been much debate about access to essential medicines under the TRIPS Agreement.
1994. The *Doha Declaration on the TRIPS Agreement and Public Health* 2001 recognized that nation states could take measures under patent law to protect public health. The *WTO General Council Decision* 2003 acknowledged that member states could export pharmaceutical drugs to developing countries. The United States has sought to increase the level of patent protection through the means of bilateral agreements such as the *Australia–United States Free Trade Agreement* 2004, and regional agreements like the proposed *Free Trade Area of the Americas*. The World Intellectual Property Organization (WIPO) has hosted policy debates over intellectual property and development. The *UNESCO Universal Declaration on Bioethics and Human Rights* 2005 has promoted the principles of informed consent and benefit sharing in respect of biomedical research. The United Nations Permanent Forum On Indigenous Issues has supported a rights-based approach to the protection of Indigenous cultural heritage in order to provide better protection of traditional knowledge.

Chapter 1 investigates the progressive extension of patent protection to micro-organisms. In *Diamond v Chakrabarty*, the majority of the Supreme Court of the United States held by a majority of five to four that a new strain of bacteria produced artificially by bacterial recombination was a useful patentable invention. The decision was of wider significance. The Supreme Court stated that ‘anything under the sun made by man’ was patentable subject matter. It opened the way for the USPTO to take a broad approach to statutory subject, and grant patents in respect of micro-organisms and other biotechnological inventions. Without the sound and fury of the Supreme Court of the United States decision, other jurisdictions, such as Australia, the United Kingdom and Canada, came to similar conclusions that micro-organisms could indeed be patentable subject matter.

Chapter 2 considers the relationship between patent law and plant breeders’ rights in light of modern developments in biotechnology. It examines how a number of superior courts have sought to manage the tensions and conflicts between these competing schemes of intellectual property protection. The chapter considers the High Court of Australia case of *Grain Pool of Western Australia v the Commonwealth*, dealing with Franklin barley. It also examines the significance of the Supreme Court of the United States decision in *JEM Ag Supply Inc v Pioneer Hi-Bred International Inc* with respect to utility patents and hybrid seed. The chapter considers the Supreme Court of Canada case of *Monsanto Canada Inc v Schmeiser*, in which a Saskatchewan canola farmer was sued for infringing a patent on glyphosate-resistant canola. It considers the implications of the decision for patent protection of agricultural products, farmers’ rights and the position of innocent bystanders.
Chapter 3 explores the legal, commercial and ethical debate over the patenting of animals. There has been great litigation over the Harvard oncomouse, a transgenic animal designed to be genetically predisposed to develop cancerous tumours. The USPTO granted a patent for ‘Transgenic Non-Human Mammals’ on the 12 April 1988. The European Patent Office granted a similar patent on the Harvard oncomouse on 13 May 1992. However, there has been continuing litigation over the Harvard oncomouse in the European Patent Office. The European Patent Office modified claim number 1 to include only ‘transgenic rodents’ rather than ‘transgenic non-human mammals’. By contrast, in Harvard College v the Commissioner for Patents, the Supreme Court of Canada ruled by a five to four majority that the Harvard oncomouse was not patentable subject matter. In the leading judgment for the majority, Bastarache EMphasizes that Parliament must give an express legislative direction to authorize the patenting of higher life forms: ‘I believe that the best reading of the words of the Act supports the opposite conclusion – that higher life forms such as the oncomouse are not currently patentable in Canada.’ There has also been much controversy over the patenting of polyploid oysters, model animals and cloned animals. Of particular note has been Jeremy Rifkin and Stuart Newman’s patent application in respect of a human–animal chimera. This application challenged the USPTO to consider the morality of certain biological inventions.

Chapter 4 considers the ramifications of the ruling of the Supreme Court of the United States in Laboratory Corp. of America Holdings v Metabolite Laboratories Inc for scientific discoveries, natural principles, abstract ideas and methods of human treatment. The case involved a patent application, which claimed a process for helping to diagnose deficiencies of two vitamins, folate and cobalamin. A majority of five judges of the Supreme Court of the United States ruled that the writ of certiorari had been improvidently granted, and dismissed the action. This decision reflected the view of the judges that the written record had been insufficiently developed to consider the question of patentable subject matter. Nonetheless, Breyer J wrote a dissenting judgment, with the support of Stevens J and Souter J. His Honour emphasized: ‘Patent law seeks to avoid the dangers of over-protection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten.’ The dissenting judges ruled that the patent application should have been ruled invalid because it sought to claim natural principles and scientific discoveries. Breyer J emphasized that the position of the majority ‘threatens to leave the medical profession subject to the restrictions imposed by this individual patent and others of its kind’. Indeed, he observed: ‘Those restrictions may inhibit doctors from using their best medical judgment; they may force doctors to spend
unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; they may raise the cost of healthcare while inhibiting its effective delivery.\textsuperscript{92}

Chapter 5 analyses recent litigation over patent law and expressed sequence tags. In the matter of \textit{In re Fisher}, the agricultural biotechnology company Monsanto sought to patent express sequence tags in maize plants.\textsuperscript{93} The USPTO examiner and Board of Appeals rejected such claims on the grounds of lack of utility and enablement. Monsanto appealed to the United States Court of Appeals for the Federal Circuit, arguing that the Board applied a heightened standard for utility in the case of express sequence tags. For the majority, Michel \textit{CJ} held that the claimed invention lacked a specific and substantial utility, and the application did not enable a person skilled in the art to use the invention. His Honour rejected the argument that express sequence tags were analogous to research tools, such as a microscope. Rader \textit{J} dissented, saying that the claimed ESTs have such a utility, at least as research tools in isolating and studying other molecules. His Honour responded: ‘These research tools are similar to a microscope; both take a researcher one step closer to identifying and understanding a previously unknown and invisible structure.’\textsuperscript{94} There is a discussion of various attempts by representatives of the United States Congress to reform patent law to provide greater access to genetic inventions for scientists and patients alike.

Chapter 6 considers whether patent law should have a defence for research use and, if so, what its scope should be. It will explore the impact of such an exemption upon a number of important industries, such as agriculture, biotechnology and health care. It will also examine the repercussions of such a defence for universities, research organizations and educational institutions. In the United States, there has been much controversy over the decision of the Federal Circuit in \textit{Madey v Duke University} over patent law and experimental use.\textsuperscript{95} Gajarsa \textit{J} held that the common law defence of experimental use was circumscribed: ‘Regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.’\textsuperscript{96} The judge concluded that the district court attached too great a weight to the non-profit, educational status of Duke, ‘effectively suppressing the fact that Duke’s acts appeared to be in accordance with any reasonable interpretation of Duke’s legitimate business objectives’.\textsuperscript{97} In \textit{Merck KGaA v Integra Lifesciences I, Ltd.}, the Supreme Court of the United States considered the safe harbour for pharmaceutical
drugs, the so-called ‘Bolar’ exception.98 The case concerned whether uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the Food and Drug Administration, are exempted from infringement by 35 U.S.C. §271(e)(1). In a pithy, leading decision, Scalia observed that the safe harbour is to be read broadly: ‘Properly construed, §271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval.’99

Chapter 7 considers the litigation and controversy over the patents held by the Utah biotechnology firm, Myriad Genetics, in respect of genetic diagnostic testing for BRCA1 and BRCA2, which are related to breast cancer and ovarian cancer. In France, the Institut Curie initiated a number of opposition procedures against the patents lodged by Myriad Genetics in respect of genetic tests for breast cancer and ovarian cancer. The Institut Curie and its supporters have challenged Myriad Genetics’ patents – EP 699 754, EP 705 902 and EP 705903 (patents relating to BRCA1) and EP 785 216 (the patent relating to BRCA2).100 The European Patent Office has revoked one of its patents dealing with BRCA1, narrowed the scope of a couple of its patents dealing with BRCA1 and awarded Michael Stratton and Cancer Research UK a patent dealing with BRCA2.101 Myriad Genetics has transferred some of its rights to the University of Utah Research Foundation. Myriad may well appeal against such decisions and may also rely upon its licence from GTG to commercialize the patents with respect to non-coding DNA. This chapter considers the ramifications of this dispute for the European Union Directive on the Legal Protection of Biotechnological Inventions 1998 (EU) and its implementation by member states.

Chapter 8 examines the related debate over patents in respect of non-coding DNA and genomic mapping. The firm Genetic Technologies Limited (GTG) was able to obtain 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’.102 Furthermore, 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’.103 GTG has embarked upon an ambitious licensing programme. Most significantly, GTG has obtained an exclusive licence from Myriad Genetics to use and exploit its medical diagnostics in Australia, New Zealand, and the Asia-Pacific region. In the United States, GTG brought a legal action for patent infringement against the Applera Corporation and its subsidiaries.104 In response, Applera has counter-claimed that the patents of GTG were invalid because they fail to comply with the requirements of US
patent law, such as novelty, inventive step and written specifications. In New Zealand, the Auckland District Health Board brought legal action in the High Court, seeking a declaration that the patents of GTG were invalid, and that the Board has not in any case infringed them.\textsuperscript{105} This matter was settled. The New Zealand Ministry of Health and the Ministry of Economic Development have reported to Cabinet on the issues relating to the patenting of genetic material.\textsuperscript{106} Similarly, the Australian Law Reform Commission has also engaged in an inquiry into gene patents and human health; and the Advisory Council on Intellectual Property has considered whether there should be a new defence in respect of experimental use and research.\textsuperscript{107}

Chapter 9 explores the ethical and political controversy over patents relating to stem cell research, so-called ‘therapeutic cloning’ (nuclear transfer) and human cloning. It highlights concerns about commercialization, access to essential medicines and bioethics. The chapter questions the meaning of section 18(2) of the \textit{Patents Act} 1990 (Cth), which provides that ‘Human beings, and the biological processes for their generation are not patentable inventions.’ It considers the interpretation of section 18(2) of the \textit{Patents Act} 1990 (Cth) in two key decisions by the Deputy Commissioner of Patents: \textit{Fertilitescentrum AB and Luminis Pty Ltd} and \textit{Woo-Suk Hwang}.\textsuperscript{108} This chapter examines the strong patent protection secured by the Wisconsin Alumni Research Foundation and Geron Corporation in respect of stem cell research in the United States. It considers the challenge to the validity of such patents in the USPTO by the California-based Foundation for Taxpayer and Consumer Rights, and the New York-based Public Patent Foundation.\textsuperscript{109} This chapter investigates the marginal position of stem cell research under the \textit{European Union Directive on the Legal Protection of Biotechnological Inventions} 1998 (EU). It examines a number of decisions of the European patent office in respect of the ‘Edinburgh patent’, a Wisconsin Alumni Research Foundation patent application, and a California Institute of Technology Patent Application.\textsuperscript{110} It also considers the inquiry of the European Group on Ethics in Science and New Technologies into ‘The Ethical Aspects of Patenting Inventions Involving Human Stem Cells’,\textsuperscript{111} as well as the practice of the United Kingdom Patent Office.\textsuperscript{112}

The Conclusion considers how the patent regime will accommodate frontier technologies – in light of substantial investment in the areas of genomics, bioinformatics, proteomics, pharmacogenomics and nanotechnology. Such new scientific advancements will no doubt test the flexibility of patent law and practice. There has been much debate as to whether such new technologies can be accommodated within the framework of current law, or if they require new examination guidelines and legislative reforms.
NOTES

3. Ibid.
7. Darcy v Allen (1602) 11 Co Rep 84 (the Case of Monopolies).
15. Article 27(2) of the TRIPS Agreement 1994.
18. Ibid.
19. Ibid.
20. Ibid.
22. Ibid., 1641.


30. Ibid.

31. Ibid.

32. Ibid., at 701.


36. As part of a quantitative empirical study conducted in 2004 and 2005, I asked 199 undergraduate science students to rate on a seven-point scale whether patents should be granted upon a range of inventions. Responses ranged widely: strongly disagree (1), disagree (2), moderately disagree (3), no opinion (4), moderately agree (5), agree (6) and strongly agree (7). The results showed a spectrum of attitudes to patents across a range of technologies.

There was strong opposition to patents being granted in respect of human genes (2.28), stem cell lines (2.80) and human cloning (2.65). There was a notable dislike of patents being granted in respect of animals (2.64). There was significant resistance to patents being granted in respect of biomedical research, such as methods of human treatment (2.84), genetic diagnostic tests (2.99) and express sequence tags (3.32). There was moderate opposition to patents being granted in respect of micro-organisms (3.46), plants (3.17) and bioprospecting (3.85). There was strong support for patents being granted in respect of mechanical inventions (6.28), chemicals (5.49), research tools (4.44) and pharmaceutical drugs (4.44). Interestingly, the subjects were relatively unconcerned about patents being granted in the emerging field of nanotechnology (4.93). The findings demonstrate that community attitudes are not uniform across all biological inventions. The results demonstrate a preference towards patents being granted in respect of traditional subject matter, such as mechanical inventions, chemical and pharmaceutical drugs. The study shows a clear bias against the patenting of higher life forms, with a lesser concern about the patenting of lower life forms.


42. Ibid., 37.


89. Laboratory Corp. of America Holdings v Metabolite Laboratories, Inc. 126 S.Ct. 2921 (2006).
90. Laboratory Corp. of America Holdings v Metabolite Laboratories, Inc. 126 S.Ct. 2921 (2006).
91. Laboratory Corp. of America Holdings v Metabolite Laboratories, Inc. 126 S.Ct. 2921 (2006).
92. Laboratory Corp. of America Holdings v Metabolite Laboratories, Inc. 126 S.Ct. 2921 (2006).
106. New Zealand, Minister of Health and Associate Minister of Commerce (2003), Implications of the Granting of Patents Over Genetic Material, Cabinet Policy


