The response of businesses to paradigmatic changes in legal systems

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Abstract

Technology, and technological changes, affect the legal system. These effects are partly direct, and partly indirect, via changes to the economy and to society. Technological changes are altering the relationship of governed and government, and between government and government. Legal systems also affect the development of technology, and changes in legal systems, whether wrought by technological changes, or otherwise, can have significant effects upon business. This paper considers how business responds to major changes in legal systems, and attempts to identify some common elements which might serve to guide business during times of profound legal change.

Introduction

Technological advances in many fields (not least the Internet) challenge the boundaries of law, science, public policy, and ethics.[2] Biological research, and in particular genetic research, is especially significant in this respect. Embryonic stem cell research[3] and therapeutic cloning,[4] challenge perceptions of personality and

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[2]Christine C. Vito, "State biotechnology oversight: the juncture of technology, law, and public policy" (1993) 45(2) Maine Law Review 329-383; Organisation for Economic Co-operation and Development, *Bio technology and the changing role of government* (Organisation for Economic Co-operation and Development, Paris, 1988); Robert H. Blank, *The political implications of human genetic technology* (Westview Press, Boulder, 1981); E. Donald Elliott, "The Genome and the law: Should increased genetic knowledge change the law?" (2001) 25 Harvard Journal of Law and Public Policy 61.

[3]The US National Institutes of Health define a stem cell as "a cell from the embryo, fetus, or adult that has, under certain conditions, the ability to reproduce itself for long periods or, in the case of adult stem cells, throughout the life of the organism;" National Institutes of Health, U.S. Department of Health and Human Services, *Stem Cells: Scientific Progress and Future Research Directions* ES-2 (National Institutes of Health , Washington, 2001).

[4]The term therapeutic cloning refers to cloning embryos for use in medical research and therapy. Synonyms include research cloning, cloning-for- biomedical-research, somatic-cell nuclear transfer (or transplantation), and simply cloning (though, without further clarification, this last term may imply reproductive cloning). Some have rejected the term therapeutic cloning, largely for strategic reasons: the journal Nature "wanted to distance [human embryonic stem] cells from the term 'cloning' to insulate the research from the emotional valence of the cloning debate." Paul Root Wolpe and

society.[5] Genetic engineering[6] also has serious implications for the medical and health insurance field,[7] since illness and diseases could potentially be significantly reduced in frequency or severity by human genetic engineering. In this paper we shall examine some ways in which business responds to changes in law and technology. Although the focus is on the response of business to legal changes, in reality technology and law cannot be readily separated. What is important is the controls on technology – what may be done and what may not be done. The protection accorded intellectual property is as important as the restrictions on certain types of work, for they protect the investment which is required to undertaken further research and development work. Fundamental changes in technology necessitate, or cause, significant changes in legal systems.

Genetic engineering for agricultural purposes also has major legal implications – not least of which in that it is promoted as a solution to ongoing food production problems in the Third World.[8] Biotechnicians have altered plants and animals for improved nutritional value. They have produced potatoes with more starch[9] and pigs with an increased protein-to-fat ratio.[10] Researchers are also attempting to produce larger, faster growing, and more productive agricultural animals that require less feed.[11] Biotechnicians are already altering plants to withstand pests and disease, and those that fix their own nitrogen and resist drought and cold.[12] The first genetically-altered whole food-product to appear on supermarket shelves was a tomato that spoiled less quickly than unaltered tomatoes.[13] These developments raise hopes for an

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Glenn McGee, "'Expert Bioethics' as Professional Discourse: The Case of Stem Cells" in Suzanne Holland, Karen Lebacqz and Laurie Zoloth (eds), *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy* (MIT Press, Cambridge, 2001) 185, 188.

[5]Janet L. Dolgin, "Embryonic discourse: Abortion, stem cells, and cloning" (2002) 31 Florida State University Law Review 101.

[6]Christopher Cates, "Property in Human Tissues: History, Society and Possible Implementations" (1998) 4 Appeal: Review of Current Law and Law Reform 32.

[7]Roberta M. Berry, "The Human Genome Project and the End of Insurance" (1996) 7 Florida Journal of Law and Public Policy 205; Jennifer S. Geetter, "Coding for Change: The Power of the Human Genome to Transform the American Health Insurance System" (2001) 28 American Journal of Law and Medicine 1.

[8]See Gregory Rose, "International law of sustainable agriculture in the 21st century: The International Treaty on Plant Genetic Resources for Food and Agriculture" (2003) 15 Georgetown International Environmental Law Review 583.

[9]See David M. Stark et al, "Regulation of the Amount of Starch in Plant Tissues by ADP Glucose Pyrophosphorylase" (1992) 258 Science 287, 287-292.

[10]Henry J. Miller, "Patenting Animals" (1988-89) Issues of Science and Technology 24.

[11]Experiments are also under way to make chickens and pigs with flesh more suitable for microwaving. See Kathleen Hart, "Making Mythical Monsters" (March 1990) The Progressive 22.

[12]William K. Stevens, "Bioengineering Points to Better Rice Plant", New York Times 6 February 1990, at C1.

[13]For a description of Calgene Inc.'s Flavr Savr tomato, see "Union of Concerned Scientists, FDA Approves the Calgene Tomato, No Labeling Required" (June 1994) The Gene Exchange 1.

increase in the world's food supply and a decrease in the use of chemicals in agriculture.[14] Each of these potential developments – agricultural and human – also involve considerable investment and potentially large profits for businesses.

Biotechnology itself is a relatively old technology. The use of living organisms to make bread, wine, and cheese is a longstanding human practice. Humanity has "genetically-engineered" plants and animals, including humans, by selective breeding for desirable characteristics for thousands of years.[15] From the time people first began cultivating and harvesting cereal grains, plants and their products have been a necessary component of the material foundations upon which human societies are formed.[16]

However, because seeds are not easily commodified, until the latter part of the twentieth century the genetics of most major crop plants have been regarded as common heritage, and comparatively little private investment has been made in plant and crop improvement.[17] That is not to say there were not laws concerning intellectual property in plants and animals, but their scope and application was limited.[18]

The high-technology genetic engineering revolution – as distinct from breeding and cultivation – began at least by 1952 with the discovery by James Watson and Sir Francis Crick of the structure of the deoxyribonucleic acid (DNA) molecule – the molecule that contains our genetic information.[19] But the pace of the revolution has accellerated most rapidly in the last ten years.[20] The search for new pharmaceutical,

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[14]See Sheldon Krimsky, *Biotechnics and society: The rise of industrial genetics* (Praeger, Westport, 1991) 44, 88-89; William K. Stevens, "Bioengineering Points to Better Rice Plant" New York Times 6 February 1990, at C1.

[15]See Andrew Goudie, *The Human impact on the natural environment* (4th ed, Blackwell, Oxford, 1990) 15-20.

[16]See Jack Ralph Kloppenburg, Jr., *First the seed: The political economy of plant biotechnology 1492-2000* (Cambridge University Press, Cambridge, 1988) 1; Sheldon Krimsky and Roger P. Wrubel, *Agricultural biotechnology and the environment* (University of Illinois Press, Urbana, 1996) 9; H. Garrison Wilkes, "Plant Genetic Resources over Ten Thousand Years: From a Handful of Seed to the Crop-Specific Mega-Gene Banks" in Jack R. Kloppenburg, Jr. ed., *Seeds and Sovereignty: The use and control of plant genetic resources* (Duke University Press, Durham, 1988) 67, 68.

[17]See, generally, Jack Ralph Kloppenburg, Jr., *First the seed: The political economy of plant biotechnology 1492-2000* (Cambridge University Press, Cambridge, 1988).

[18]See, for example, Plant Variety Protection Act, 7 USC § 2402 (2003) (1970) (US) [typically, its purpose is to "encourage the development of novel varieties of sexually reproduced plants" by providing their owners with exclusive marketing rights of them in the United States. The requirements of protection are that the variety be uniform, stable, and distinct from all other varieties]; Plant Variety Rights Act 1987 (NZ); Plant Varieties (Proprietary Rights) Act 1980 (Ireland); Plant Variety Act 1997 (UK).

[19]It is a long linear polymer found in the nucleus of a cell and formed from nucleotides and shaped like a double helix; associated with the transmission of genetic information.

[20]Jennifer S. Geetter, "Coding for Change: The Power of the Human Genome to Transform the American Health Insurance System" (2001) 28 American Journal of

biotechnological or agricultural applications has led to a growing interest both from the public and from the private sector in genetic resources.[21]

The biotechnological revolution of the 1980s and 1990s enabled scientists to isolate the genetic materials of living organisms and induce precise modifications so that organisms manifest and carry desired genetic traits.[22] Biotechnology is beginning to revolutionise agriculture by developing genetically superior plants and animals,[23] and therefore has profound economic consequences. It is also offered as a solution to difficult environmental problems and challenges.[24]

It is sometimes suggested that the new biotechnologies[25] are not radical departures from these historical practices. One defender of biotechnology claimed that "centuries of selective breeding have altered domestic animals far more than the next several decades of transgenic modifications are expected to alter them."[26] Another of biotechnology's defenders argued that nature routinely reshuffles genetic material by combining genes in new ways during sexual reproduction, by altering genes through mutations, and by transferring foreign genes into already existing organisms.[27] However, other commentators suggested that the changes in the planet resulting from the creation, use, and release of biotechnical products could dwarf the changes that

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Law and Medicine 1; James Watson and Sir Francis Crick, "Genetical Implications of the Structure of Deoxyribonucleic Acid" (1953) 171 Nature 964.

[21]J. Straus, "Biodiversity and Intellectual Property" (1998) 9 AIPPI Yearbook 99, 100: "Genetic resources have become an issue of high priority to scientists, industry, politicians and even the public at large.... they form a warehouse of enormous use potentials for plant and animal breeding, food, chemical and environmental industries, pharmaceuticals and medicine".

[22]W. French Anderson, Human Gene Therapy, 256 Science 808, 810 (1992); see also Stephen A. Duzan, "The 1992 Biotechnology Agenda: A Message for Candidates Bush and Clinton" (1992) 9 Healthspan 12.

[23]Approximately twenty-five percent of all the corn and forty percent of the soybeans that are grown in the US are genetically modified. See Melinda Kimble, et al, "Press Briefing of the U.S. Delegation to the Sixth Meeting of the Working Group on Biosafety Convention on Biological Diversity", 18 February 1999, cited in Jasemine Chambers, "Patent eligibility of biotechnological inventions in the US, Europe, and Japan: How much patent policy is public policy?, (2002) 34 George Washington International Law Review 223, 237 n 4.

[24]See Stephen A. Duzan, "The 1992 Biotechnology Agenda: A Message for Candidates Bush and Clinton" (1992) 9 Healthspan 12.

[25]For a description of these technologies, see Office of Technology Assessment, Congress of the US, *New developments in biotechnology: Ownership of human tissues and cells – Special Report* (Office of Technology Assessment, Washington, 1987) pub. no. OTA-BA-337.

[26]Reid G. Adler, "Controlling the Applications of Biotechnology: A Critical Analysis of the Proposed Moratorium on Animal Patenting" (1988) 1 Harvard Journal of Law and Technology 1, 20 n126.

[27]See Lisa J. Raines, "The Mouse That Roared: Patent Protection for Genetically Engineered Animals Makes Legal, Moral, and Economic Sense" (1988) Issues of Science and Technology 67.

have resulted from the use of petrochemical products.[28] The World Resources Institute, for instance, sees genetic material as the "oil of the Information Age."[29]

Whichever view is correct, a new legal regime has evolved, to respond to what is a paradigmatic change in technology. Partly this is because of ethical, moral and religious concerns, but economic factors have also been important, for example concerns that previous laws meant that developed countries were advantaged over Third World countries which were the source of much of the raw genetic material.[30] Knowledge of itself becomes valuable, as the building blocks of organisms have economic value. Therefore business seizes the opportunity offered.

In recent years, advances in biotechnology have allowed for increased commodification of seeds not only by relying on utility patent protection for bioengineered varieties, but also by taking a new route to commodification – through biotechnical processes that, among other things, render seeds sterile or insert easily recognisable "marker" genes that identify plants' DNA strains as the intellectual property of various biotech firms.[31] It thus becomes possible to identify crops as the intellectual property of a particular company or individual. The translation of these innovations into the international realm of global trade and property protection has been awkward and at times controversial.[32] Genetic engineering has business, ethical, religious, and legal ramifications.[33] Thus as the investment increases so does the demand for legal protection of the associated intellectual property rights.

Business-wise, biotechnology has stimulated the creation and growth of small (and some medium and large) businesses, generated new jobs, and encouraged agricultural and industrial innovation.[34] It is one of the most research-intensive and innovative

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[28]Jeremy Rifkin, "Creating the Efficient Gene" in Michael Ruse (ed), *Philosophy of Biology* (State University of New York Press, Albany, 1989) 222, 223.

[29]See Jack Kloppenburg, "No Hunting: Scientific Poaching and Global Biodiversity" (1990) Z Magazine 104.

[30]See Kim JoDene Donat, "Engineering Akerlof lemons: Information asymmetry, externalities, and market intervention in the genetically modified food market" (2003) 12 Minnesota Journal of Global Trade 417. However, there is some room for optimism; see Mark Hannig, "An examination of the possibility to secure intellectual property rights for plant genetic resources developed by indigenous peoples of the NAFTA states: Domestic legislation under the International Convention for Protection of New Plant Varieties" (1996) 13 Arizona Journal of International and Comparative Law 175.

[31]See Michael Pollan, "Playing God in the Garden" New York Times, 25 October 1998 § 6 (magazine), at 44.

[32]See Charles McManis, "The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology" (1998) 76 Washington University Law Quarterly 255, 255-256.

[33]Daniel J. Kevles and Ari Berkowitz, "The gene patenting controversy: A convergence of law, economic interests and ethics" (2001) 67 Brooklyn Law Review 233.

[34]President Clinton proclaimed January 2000 "National Biotechnology Month," See Proclamation No. 7269 (2001) 3 C.F.R. 19, 19.

industries in the scientific fields.[35] But it is also carefully regulated by law – and there are detailed limits on the types of research which may be conducted, and the commercial exploitation of genetically modified organisms. So far as it is able business funds genetic research, because of its potential returns. But little research would occur – beyond the most fundamental – if no protection was accorded the results of the research. Basic research is rarely undertaken by private enterprise without some expectation of a return.

Since the 1970s much attention has been paid to the patentability of biotechnology.[36] In the US, the patent system played a critical role in the growth of the biotechnology industry. In the course of the 1990s biotechnology grew into a US$13 billion industry, and the number of biotechnology patent applications exceeded 14,000 annually.[37] Patent protection is vital to the biotechnology industry, particularly because small biotechnology companies invest enormous sums of money in research and development. Often, intellectual property is the only product that a young company can show its potential investors; and patents are ideally suited to protect technology-based intellectual property.[38]

Proponents of biotechnology patenting suggest that the new biotechnology patents, or "biopatents," are minor and logical extensions from past practice, not radical revisions.[39] Thus they rely upon the pre-existing legal processes, such as intellectual property laws – specifically patent laws.

Genetic engineering is not, of course, limited to the vegetable kingdom. Harvard University received the first patent on animal life. Its patent was for a mouse genetically altered to be susceptible to breast cancer.[40] As the project's major sponsor, Du Pont possesses commercial rights and the chemical company is selling the patented research animals.[41] It is in the animal kingdom that the legal response may have been most significant, because of the ethical issues which it raises.

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[35]Stephen A. Duzan, "The 1992 Biotechnology Agenda: A Message for Candidates Bush and Clinton" (1992) 9 Healthspan 12.

[36]Justine Pila, "Bound Futures: Patent law and modern biotechnology" (2003) 9 Boston University Journal of Science and Technology Law 326, 326.

[37]See Jenna Greene, "He's Not Just Monkeying Around", Legal Times, 16 August 1999, at 16, 20.

[38]Jasemine Chambers, "Patent eligibility of biotechnological inventions in the US, Europe, and Japan: How much patent policy is public policy?, (2002) 34 George Washington International Law Review 223, 224.

[39]See Lisa J. Raines, "The Mouse That Roared: Patent Protection for Genetically Engineered Animals Makes Legal, Moral, and Economic Sense" (1988) Issues of Science and Technology 65-66.

[40]The "oncomouse," as it is known, was developed by Harvard researchers Philip Leder and Timothy Stewart. See Sheldon Krimsky, *Biotechnics and society: The rise of industrial genetics* (Praeger, Westport, 1991) 44-45; Daniel J. Kevles, "Diamond v. Chakrabarty and Beyond: The Political Economy of Patenting Life" in Arnold Thackray (ed), *Private Science: Biotechnology and the Rise of the Molecular Sciences* (University of Pennsylvania Press, Philadelphia, 1998) 65, 65-79.

[41]See Elizabeth Corcoran, "A Tiny Mouse Came Forth" (1989) Scientific American 73.

In the 1990s, J. Craig Venter, a biologist at the National Institutes of Health ("NIH"), in Bethesda, Maryland, proposed the wholesale patenting of human gene fragments. Venter's lab, using automated machines, had sequenced not whole genes but random fragments of cDNA derived from part of the brain.[42] Such a fragment was called an "expressed sequence tag," or EST.[43] Although just 150 to 400 DNA coding pairs long, each was unique and served to identify the gene of which it was a part.[44] In June 1991, Venter and NIH filed for patents on 315 ESTs and the human genes from which they came.[45]

Venter's laboratory could produce EST sequences so quickly that NIH planned to file patent applications for 1,000 of them a month.[46] Indeed, by 1994 the number of ESTs covered by the Venter/NIH application had multiplied to almost 7,000.[47]

A number of patent experts, however, insisted that ESTs were not patentable[48] – not because there was anything inherently unpatentable about genetic engineering, but because they failed to show sufficient legal grounds. Venter's initiative also provoked denunciations from scientists anxious that EST patents, if issued, would restrict research by others on human genes. The prospect of EST patenting was of serious concern to the biotechnology industry. The Association of Biotechnology Companies in Washington, DC, which represented 280 companies and institutions, endorsed EST patenting by NIH so long as it did not favour any one company over another, for example by granting an exclusive license.[49] In addition, many of the opponents of EST patenting were concerned at the prospect that the government – through NIH – would own those patents.[50] It would be beyond the capacity of private enterprise to co-ordinate and regulate the field – and a monopoly would be too restrictive.

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[42]Mark D. Adams et al, "Complementary DNA Sequencing: Expressed Sequence Tags and Human Genome Project" (1991) 252 Science 1651; Christopher Anderson, "US Patent Application Stirs Up Gene Hunters" (1991) 353 Nature 485.

[43]Mark D. Adams et al, "Complementary DNA Sequencing: Expressed Sequence Tags and Human Genome Project" (1991) 252 Science 1651; Christopher Anderson, "US Patent Application Stirs Up Gene Hunters" (1991) 353 Nature 485.

[44]Mark D. Adams et al, "Complementary DNA Sequencing: Expressed Sequence Tags and Human Genome Project" (1991) 252 Science 1651; Christopher Anderson, "US Patent Application Stirs Up Gene Hunters" (1991) 353 Nature 485.

[45]Craig Venter and Mark Adams, "Sequences", USPTO No. 07/716,831, at 235-36 (applied 20 June 1991).

[46]Craig Venter and Mark Adams, "Sequences", USPTO No. 07/716,831, at 235-36 (applied 20 June 1991).

[47]Christopher Anderson, "NIH Drops Bid For Gene Patents" (1994) 263 Science 909, 909-910.

[48]See Leslie Roberts, "Genome Patent Fight Erupts" (1991) 254 Science 184, 185.

[49]Rebecca S. Eisenberg, "Genes, Patents, and Product Development" (1992) 257 Science 903, 903-908; ABC Statement on NIH Patent Filing for the Human Genome Patent, Biotechnology Law Report, July-August 1992, at 408-410.

[50]Rebecca S. Eisenberg, "Genes, Patents, and Product Development" (1992) 257 Science 903, 903-908; ABC Statement on NIH Patent Filing for the Human Genome Patent, Biotechnology Law Report, July-August 1992, at 408-410.

France, Italy, and Japan announced their opposition to NIH's EST patents, fearing the patents would competitively disadvantage their budding biotechnology enterprises.[51] The French Academy of Sciences condemned "any measure which, answering purely to a logic of industrial competition, strove to obtain the legal property of genetic information data, without even having taken care to characterise the genes considered."[52] However, the British Minister of Science Alan Howarth chose to join the competition, announcing in March 1992 that the Medical Research Council would also seek complementary DNA (cDNA) patents.[53] Howarth explained that "a decision … not to seek patents when researchers funded by public bodies in other countries have or may do so could place the UK at a relative disadvantage."[54] The role of privately funded researchers was less in the UK and elsewhere than in the US, where private business and research laboratories conducted much of the research.

However, initial fears of a monopoly were ended in August 1992, the US Patent Office rejected the Venter/NIH claims, calling them "vague, indefinite, misdescriptive, inaccurate and incomprehensible."[55]

Patent laws were not necessarily unavailable however to businesses engaged in genetic engineering, provided there are properly submitted. However, they may not necessarily be the same as for other patentable inventions, due to the political and ethical considerations – including international.[56]

In the summer of 1997, the European Parliament reconsidered the question of patenting biological inventions.[57] In the spring of 1998, it approved a wide-ranging directive on biotechnology designed to encourage patents while adopting explicit

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[51]Norton D. Zinder, "Patenting cDNA 1993: Efforts and Happenings" (1993) 135 Gene 295, 295-298.

[52]Academy of Sciences, Paris Bilingual Report No. 32, *The Patentability of the Genome* (Lavoisier, Paris, 1995).

[53]Anna Maria Gillis, "The Patent Question of the Year" (1992) 42 BioScience 336, 336-339. CDNA, or complementary DNA is single-stranded DNA that is complementary to messenger RNA or DNA that has been synthesized from messenger RNA by reverse transcriptase.

[54]Anna Maria Gillis, "The Patent Question of the Year" (1992) 42 BioScience 336, 336-339.

[55]Leslie Roberts, "NIH Gene Patents, Round Two" (1992) 255 Science 912, 912-913; James Martinell, USPTO, Art Unit 1805, Examiner's Action on Venter et al, Patent Application No. 07/807,195, 20 August 1992, Biotechnology Law Report, September-October 1992, at 578-596.

[56]Henrique Freire de Oliveira Souza, "Genetically Modified Plants: A Need for International Regulation" (2000) 6 Annual Survey of International and Comparative Law 129; Gilbert L. Carey, "The resurgence of states' rights creates new risk to intellectual property" (2000) 11 Albany Law Journal of Science and Technology 123.

[57]Nigel Williams, "European Parliament Backs New Biopatent Guidelines" (1997) 277 Science 472; Alison Abbott, "EuroVote Lifts Block on Biotech Patents ... But Parliament Wants Closer Scrutiny" (1997) 388 Nature 314, 314-315.

ethical restrictions – for the first time anywhere – on what can be patented.[58] Holding that biotechnology patents must safeguard the dignity and integrity of the person, the directive prohibits patents on human parts, human embryos, and the products of human cloning.[59] The directive also prohibits patents on animals if what they suffer by being modified exceeds the benefits that the modification would yield.[60]

Meanwhile basis and applied research continued, as there was no doubt that, though genetic research is expensive, great potential exists for long-term profit – provided the investment is legally protected.

The Human Genome Project (HGP), funded by the US Government, was projected to be completed in fifteen years at a cost of US$3 billion.[61] The purpose of the HGP is to decipher the human genome, which is the master control program of human biological life.[62] With knowledge gained from the HGP, diagnostic tests for genetic defects are

[58]Alison Abbott, "Transgenic Patents a Step Closer in Europe" (1997) 390 Nature 429; Alison Abbott, "Europe's Life Patent Moratorium May Go" (1998) 393 Nature 200.

[59]European Community, Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998, On the Legal Protection of Biotechnological Inventions, 213 Official Journal of the European Communities, 13-21 (1998).

[60]For example, a mouse genetically engineered to suffer physically from birth would not be patentable if the modification did not lead to greater medical understanding, therapies, or cures.

[61]The HGP was formally undertaken as a federal program in 1991 with an initial funding of approximately US$135 million. Daniel Kevles, "Out of Eugenics: The Historical Politics of the Human Genome" in Daniel J. Kevles and Leroy Hood (eds), *The Code of Codes, Scientific and social issues in the human genome project* (Harvard University Press, Harvard, 1992) 3, 36. The target date for completion was 2005; Victor A. McKusick, "The Human Genome Project: Plans, Status, and Applications in Biology and Medicine" in George J. Annas and Sherman Elias (eds), *Gene Mapping: Using law and ethics as guides* (Oxford University Press, New York, 1992) 18.

[62]The human genome consists of 46 chromosomes located in the nucleus of every somatic human cell. Daniel Kevles, "Out of Eugenics: The Historical Politics of the Human Genome" in Daniel J. Kevles and Leroy Hood (eds), *The Code of Codes, Scientific and social issues in the human genome project* (Harvard University Press, Harvard, 1992) 3, 16. If the HGP continues as planned, by the year 2005, HGP scientists will have mapped the human genome, assigning the approximately 50,000 to 100,000 human genes to their locations on the 46 chromosomes. Victor A. McKusick, "The Human Genome Project: Plans, Status, and Applications in Biology and Medicine" in George J. Annas and Sherman Elias (eds), *Gene Mapping: Using law and ethics as guides* (Oxford University Press, New York, 1992) 18, 26; see also Horace F. Judson, "A History of the Science and Technology Behind Gene Mapping and Sequencing" in Daniel J. Kevles and Leroy Hood (eds), *The Code of Codes, Scientific and social issues in the human genome project* (Harvard University Press, Harvard, 1992) 37, 38 (discussing how the history of genetics casts light on present attempts to map and sequence genes).

now available,[63] and it is hoped that cures for diseases caused by these genetic defects will follow.[64] This project proceeded despite uncertainties regarding patents, as the work itself would not produce patentable outputs – bit would rather facilitate subject genetic work.

The difficulty for patenting the "codes of life" – and their potential risk – led to government intervention, and new laws. Indeed, for human DNA, some people question whether there should be any property rights at all.[65] Such a position would seriously inhibit privately-funded research, since little or no protection would be accorded to its findings.

The intellectual property law regime has for more than two centuries struggled to keep up with rapid technological change, yet it seems always to have managed to do so in the end. The biotechnology revolution, however, will create unprecedented challenges to our intellectual property rights system, perhaps especially in the allocation of rights to balance the interests of scientists, investors and those from whom valuable genetic material is obtained.

Intellectual property law, which includes patent law, is designed to advance knowledge and to stimulate innovation for the benefit of society.[66] To encourage this

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[63]See Gina Kolata, "Tests to Assess Risks for Cancer Raising Questions", New York Times 27 March 1995, at A1 (describing the controversy surrounding the imminent marketing of simple diagnostic tests for genetic defects that predispose individuals to breast and ovarian cancer); see also A Genetic Vulnerability to Carcinogens, (1996) 149 Science News 188 (stating that in the 3 February 1996 issue of Lancet it was reported that "those who failed to inherit a functional copy of . . . [a gene that codes for a carcinogen-detoxifying enzyme] from either parent face four times the MDS [myelodysplastic syndrome] risk of those who inherited even one such gene. In the US, one in six persons lacks a working copy of this gene."); "Epilepsy Gene Identified" (1996) 149 Science News 221 ("A joint U.S.-Finnish team reports nabbing a gene that, when mutated, causes an inherited form of epilepsy."); Kathleen Fackelmann, "Forecasting Alzheimer's Disease" (1996) 149 Science News 312, 313 ("Eric M. Reiman of the Good Samaritan Regional Medical Center in Phoenix and his colleagues knew that people who inherit a gene called apolipoprotein E-IV run a 27 percent chance of developing Alzheimer's disease by age 85.").

[64]As Leroy Hood concludes: "I believe that we will learn more about human development and pathology in the next twenty-five years than we have in the past two thousand." Leroy Hood, "Biology and Medicine in the Twenty-First Century", in Daniel J. Kevles and Leroy Hood (eds), *The Code of Codes, Scientific and social issues in the human genome project* (Harvard University Press, Harvard, 1992) 136, 163; see also C. Thomas Caskey, "olecular Medicine; A Spin-Off from the Helix" (1993) 269 JAMA 1986, 1989-1990 (assessing current pharmacological applications and future genetic correction therapies drawing upon knowledge gained from the HGP).

[65]Peter J. Gardner, "U.S. Intellectual Property Law and the Biotech Challenge: Searching for an elusive balance" (2003) 29 Vermont Bar Journal 28.

[66]Linda R. Cohen and Roger G. Noll, "Intellectual Property, Antitrust and the New Economy" (2001) 62 University of Pittsburgh Law Review 453.

goal, a patent grants to an inventor a limited monopoly with which to profit from his or her invention.[67] But the detail of patent laws vary from country to country.

Australia and the UK, as well as most other countries (the US being a notable exception), adopt the "first-to-file" principle of patent law. This means that the person entitled to the patent is the first to file the application, even if he or she was not also the first person to have conceived the invention. The date at which the invention is assessed for both novelty and inventive step ("priority date") is the date on which the application was filed.[68] The principle of national treatment under the Paris Convention for the Protection of Industrial Property[69] establishes the date of first filing in a member country as the priority date for subsequent filings in other states, provided that these occur within 12 months from the original filing.[70] The effect was to encourage developers to file patents as soon as possible, but it also potentially discouraged fundamental research, the economic benefits of which – if any – might be lost simply through delayed filing. In this respect biotechnology laws may have limited the potential for further research and development.[71]

Existing intellectual property protection laws have been modified, and the only major legal shift has been with respect to human gene research. Research is now allowed, but with restrictions.[72] For agricultural research political issues have caused even more difficulties, because in addition to ethical concerns there are differences between regions, a north-south divide, and so on.

It has been argued that there is a clear need for an international regulation on genetic engineering,[73] because the lack of clear legislation has been creating uncertainty in terms of safety and international trade; has been making it more difficult to perceive when a country is violating the principle of state responsibility, just because its

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[67]Lawrence M. Sung, "Collegiality and Collaboration in the Age of Exclusivity" (2000) 3 DePaul Journal of Health Care Law 411, 412-413 (citing U.S. Const. art. I, § 8, cl. 8 (Congress shall have power "To promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.")). See also Linda R. Cohen and Roger G. Noll, "Intellectual Property, Antitrust and the New Economy" (2001) 62 University of Pittsburgh Law Review 453 (the benefit of a rights regime is the inducement effect: if creators derive personal gain from their work, they are likely to produce a more creative product).

[68]Patents Act 1990, (Cth), s. 43; Patents Act 1977, (U.K.), s. 5.

[69]March 10, 1883, as revised.

[70]Paris Convention, Art. 4A-C.

[71]Colleen Chien, "Cheap drugs at what price to innovation: Does the compulsory licensing of pharmaceuticals hurt innovation?" (2003) 18 Berkeley Technology Law Journal 853; Justine Pila, "Bound futures: Patent law and modern biotechnology" (2003) 9 Boston University Journal of Science and Technology Law 326.

[72]The type of concerns commonly expressed may be seen to echo the underlying message in Mary Wollstonecraft Shelley's *Frankenstein* ed M.K. Joseph (Oxford University Press, New York, 1980).

[73]Henrique Freire de Oliveira Souza, "Genetically Modified Plants: A Need for International Regulation" (2000) 6 Annual Survey of International and Comparative Law 129, 172.

obligations under international law are not clear;[74] makes it more difficult for a country to observe its duty to assess environmental impacts, just because scientific findings are not absolutely conclusive in this matter, creating the possibility of discussion under World Trade Organisation/General Agreement on Tariffs and Trade (WTO/GATT) (such as the Monarch Butterfly Case[75]); on the other hand makes it more difficult to identify when a country is violating its obligation not to cause environmental harm. Further, the lack of specific international legislation has been causing the impairment of commerce, and one of the consequences here may be the limitation on research and development of new biotechnology products; and has been creating a tension between international trade law and international environmental law.

At the present time, intellectual property law is the mechanism that determines international protection and control over biotechnology innovations in plant varieties – and human and animal genetic material – and the genetic resources that form the basis for those innovations.[76] The intellectual property paradigm that is utilised employs western definitions of property in order to provide a framework in which to allocate rights. This has resulted in serious distributive problems including western-specific ideas about property, authorship, and individual creative inventors.

From the perspective of the user of technology, the indigenous peoples who possessed many of the raw materials, the failure of the legal system to adapt itself to changed agricultural technology has been costly. The benefits – such as there have been – are to the major companies which already had sufficient market penetration to effectively introduce their new products.

At a practical and normative level the issues thus raised converge on eligibility, and on whether modern biotechnology, however conceived, is a suitable subject matter for

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[74]For example some actions or measures taken by an isolated state in order to protect its environment or the health of its population may violate some other international agreement.

[75]Prepared Statement of Ambassador David L. Aaron Under Secretary for International Trade, U.S. Department of Commerce, 15 June 1999, <www.ogc.Doc.gov/ogc/legreg/testmon/106f/aaron0615.htm> (as at 23 December 2003)

> Four varieties of US developed "Bt", or pest-resistant corn, have been in the European Union approval process for over two years. The Commission has not approved any biotechnology products in a year and it recently announced that it was postponing the approval of Pioneer's Bt corn application because of recent findings on the effects of genetically engineered corn on the US monarch butterfly population.

These findings resulted from a study by Cornell University, and they are available at <www.greenpeace.org/geneng/reports/gmo/gmo011.htm> (as at 23 December 2003).

[76]Lara E. Ewens, "Seed Wars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds" (2000) 23 Boston College International and Comparative Law Review 285; Keith Aoki, "Weeds, seeds and deeds: Recent skirmishes in the seed wars" (2003) 11 Cardozo Journal of International and Comparative Law 247.

patent protection, or whether it is truly beyond the normative and doctrinal capacities of the patent system as that system currently exists.[77] This has been important at an international level, but nationally patent laws have been used by companies to protect their intellectual property – and to enhance its value. Yet without this the western companies – who do most of the research – could be discouraged.

As the laws stands, it advantages existing established companies. One example of this is through sector capture.[78] For instance, Monsanto's "private property" in specific seed genomes, possessing genetically engineered characteristics such as drought and insect resistance, has been supplanting traditional agricultural understandings of seeds, and has accordingly changed farmers from seed saving "proprietors" into mere licensees of a patented agricultural technology.[79] When a farmer bought high-yield hybrid seed, the seeds from that crop wouldn't duplicate the high yield, so the farmer had to return to the seed company the next season if he or she wanted continued high yields.[80]

Similarly, in the 2001 Canadian *Schmeiser* case patent infringement liability was found on the part of a canola[81] farmer whose fields adjoined a field planted with genetically engineered and patented canola, that outcrossed with his unpatented canola variety.[82] These arrangements were of economic benefit to established suppliers, but may have a restrictive effect on others.

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[77]Justine Pila, "Bound Futures: Patent law and modern biotechnology" (2003) 9 Boston University Journal of Science and Technology Law 326, 344.

[78]In the information technology field Microsoft was found liable for similar conduct, on a sufficiently large scale to account to a breach of anti-trust law; Samuel Noah Weinstein, "United States v. Microsoft Corp" (2002) 17 Berkeley Technology Law Journal 273.

[79]Keith Aoki, "Weeds, seeds and deeds: Recent skirmishes in the seed wars" (2003) 11 Cardozo Journal of International and Comparative Law 247, 254. Given the deeply ingrained, millennia-old tradition of seed saving, it is understandable that Monsanto has continued to have problems with farmers that don't comply with Monsanto's license terms; See *Monsanto Canada, Inc. v. Schmeiser*, T-1593-98 (March 29, 2001) [2001] FTC 256, available at <http://decisions.fct-cf.gc.ca/fct/2001/2001fct256.html> (as at 23 December 2003); see also Percy Schmeiser's website, "Monsanto v. Schmeiser" at <http://www.percyschmeiser.org> (as at 23 December 2003) [There are different versions of Schmeiser's use of Roundup Ready™ canola. Schmeiser, who never bought the seeds, claims that he merely found and saved Roundup Ready™ seeds on his land. Monsanto claims he took the seeds from nearby farmer's fields].

[80]The early 1990s saw the advent of patented seed technology systems, such as Monsanto's Roundup Ready™ crops, that possessed a patented genetic sequence making them resistant to Monsanto's broad band herbicide Roundup; Keith Aoki, "Weeds, seeds and deeds: Recent skirmishes in the seed wars" (2003) 11 Cardozo Journal of International and Comparative Law 247, 303.

[81]"Canola" (Brassica napus) is also known as rape seed.

[82]Keith Aoki, "Weeds, seeds and deeds: Recent skirmishes in the seed wars" (2003) 11 Cardozo Journal of International and Comparative Law 247, 330.

The apparent economic failure in the genetically engineered crop market has been said to be because of asymmetry and the economic phenomena known as the "lemon problem".[83] Environmental and biological controversies have not helped either.[84]

There is perhaps still scope for the small research firm. Generally, however, it must be said that the response of business to the advent of generic engineering has been cautious, because of the high regulatory risks and high costs, and uncertain benefits. The major legal determinant seems to be protection of ideas. The companies work around the restrictions – but only if their ideas are safeguarded. So far this has largely been through traditional intellectual property laws. Care must also be taken to ensure that there is a proper balance between protection of intellectual property – including that of indigenous peoples – and the common pool of human knowledge. Restrictions on certain types of research, and safeguards against the escape of organisms, seem less significant. In this case the paradigm shift is yet to come.

In the case of genetic engineering, business took advantage of pre-existing legal mechanisms – predominantly patent laws – in order to safeguard their investments. They also utilised licensing to achieve market capture – as in the Monsanto example. Both of these are relatively traditional uses of legal systems. However, where the difference lies is in the scale of the utilisation of these mechanisms, and of the indirect effects – such as for indigenous peoples' property rights.

Conclusion

The changes to the legal regime governing genetic engineering – and particularly human genetics – have been influenced more by political and ethical considerations than by economic considerations. The failure of the agricultural sector, in particular, to achieve the high returns which had been predicted also emphasise the need for caution in dealing with high risk, high return technologies where the legal protection is relatively undeveloped.

[83]George A. Akerlof, "The Market for "Lemons": Quality Uncertainty and the Market Mechanism" (1970) 84 Quarterly Journal of Economics 488, 489-492; Kim JoDene Donat, "Engineering Akerlof lemons: Information asymmetry, externalities, and market intervention in the genetically modified food market" (2003) 12 Minnesota Journal of Global Trade 417, 441-443.

[84]Kim JoDene Donat, "Engineering Akerlof lemons: Information asymmetry, externalities, and market intervention in the genetically modified food market" (2003) 12 Minnesota Journal of Global Trade 417, 439-440.