ARTICLES

Genomics and Democracy - A Global Challenge

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'The John Toohey Lecture 2002'

The year 2003 is the fiftieth anniversary of the discovery of DNA by Watson and Crick. That breakthrough gave rise to the human genome project, one of the greatest scientific enterprises in history. The genome presents many puzzles for society and its laws. Some are particular: the patenting of genome developments is singled out. But the greatest puzzle is how law-making institutions (including the courts) will cope with and deliver legal solutions where doing so requires mastery of complex and changing scientific and technological data. For the law to remain silent is to make a decision. Yet how do we formulate such laws in a democracy? How do we do so at a global level? In this John Toohey lecture, High Court Justice Michael Kirby tackles these questions.

JOHN TOOHEY AND THE RULE OF LAW

For two years it was my privilege to serve as a Justice of the High Court of Australia with John Toohey. I was appointed in February 1996. He retired in February 1998. We worked closely together. We shared many of the same perceptions of the

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law and of society. In some very big cases we agreed, sometimes in separate reasons,[1] and sometimes in joint reasons.[2] Occasionally, we dissented together.[3] But if you ran one of those devilish scaleograms over our decisions you would quickly find a high level of concurrence in fundamentals.[4]

In this inaugural lecture, it is proper for me to remember some of the main milestones in John Toohey's career. He graduated from the University of Western Australia in 1950 with First Class Honours. He served as a lecturer in the Law School, not in soft subjects (if there were any in those days) but in the hardest of the hard – property law. John Toohey knew his land law, its history and importance. That knowledge was to stand him in good stead in the leading part he later took in the native title decisions of the High Court of Australia.[5]

He was appointed Queen's Counsel in 1968 and showed his mettle soon afterwards by accepting appointment as the first legal officer of the Aboriginal Legal Service in Port Hedland. From positions as a leader of the legal profession of Western Australia, he was translated in 1977 to be a judge of the Federal Court of Australia. He later became the first Aboriginal Land Commissioner. In 1987 he was appointed a Justice of the High Court. He served during a creative period with Chief Justice Mason and Justices Brennan, Deane, Dawson, Gaudron and McHugh. His date of appointment was four days ahead of Justice Mary Gaudron whose own distinguished service will shortly come to its conclusion. He took part in some of the most momentous decisions of the High Court including *Cole v Whitfield,*[6] *Dietrich v The Queen,*[7] *Minister for Immigration and Ethnic Affairs v Teoh*[8] and the succession of land rights cases. He was creative, compassionate and just – but always a true servant of the law.

Yet for John Toohey the law was not something that belonged only to judges and lawyers. In an interview for *Brief,* the journal of the Law Society of Western Australia, he said:

> The biggest challenge facing us is the need to communicate with people, to explain just what we are doing, why laws are made, why they are administered in the way that they are and the way the courts apply them in the way that they do. I think

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1. *Wik Peoples v Queensland* (1996) 187 CLR 1.
2. *Lange v Australian Broadcasting Corporation* (1997) 189 CLR 520.
3. *IW v City of Perth* (1997) 191 CLR 1.
4. Which perhaps explains why we have elicited common criticism from common critics: see H Patapan 'High Court Review 2001: Politics, Legalism and the Gleeson Court' (2002) 37 Aust J Political Science 241, 249.
5. *Mabo v Queensland (No 2)* (1992) 175 CLR 1; *Western Australia v Commonwealth* (1995) 183 CLR 373; *Wik* above n 1.
6. (1988) 165 CLR 360.
7. (1992) 177 CLR 292.
8. (1995) 183 CLR 273.

> it is incumbent on all arms of the law, including the courts, to make clearer to the community just what they are doing.[9]

John Toohey kept most of his controversies to his judicial opinions. The list of his speeches, before and after his appointment to the High Court, shows a preponderance of addresses concerning Aboriginal issues – a subject that preoccupied him in and out of court. The other subjects he chose were of the same order: minorities, legal aid and legal access, the position of victims in the judicial process and human rights.

Only one of his speeches hit the headlines. I refer to his contribution to a conference on constitutional change held in Darwin in October 1992. The speech was titled 'A Government of Laws and Not of Men?'[10] In it, in sober language, he drew attention to the fact that Australia was unusual among the Western democracies in lacking express constitutional protection for most fundamental rights. He acknowledged that individual liberties are enjoyed in Australia to a greater extent than in most other lands.[11] However, he made the point that this was 'different from the proposition that rights [here] are less *protected*'.[12] He speculated on ways in which, notwithstanding the absence of an entrenched constitutional Bill of Rights, fundamental rights could be upheld in Australia by courts with the will to do so.

In a recent opinion in the High Court I too examined this question from the standpoint of the implications to be derived from our federal Constitution.[13] For my pains, I have been criticised, much as John Toohey was for his cautious extra-curial analysis of the same problem.[14]

Judges and other citizens born in the 20th century are haunted by the memories of the horrible deprivations of human rights, the absence of the rule of law and the lack of democracy that were such features of that age.[15] Having witnessed the departures from legalism, and (more still) the misuse of law to oppress minorities, John Toohey expounded a view of democracy that was complex and yet clear. The rule of law, as such, was not enough. It did not suffice if laws were oppressive and unjust. Democracy was not enough if rampant majorities crushed the legitimate needs and aspirations of minorities. Courts had an important role to play in upholding law, democracy and constitutionalism. Amongst the functions of the law were the

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9. JG Symington, Ceremony to Mark the Retirement of Justice John Toohey (High Court of Australia transcript, 24 Oct 1997) 5.
10. (1993) 4 PLR 158.
11. Ibid, 163.
12. Ibid, 164.
13. *Durham Holdings Pty Ltd v New South Wales* (2001) 205 CLR 399, 420-432.
14. G Winterton 'Justice Kirby's Coda in *Durham*' (2002) 13 PLR 165.
15. In his lecture, Justice Toohey referred to my citation in *Builders Labourers' Federation v Minister for Industrial Relations* (1986) 7 NSWLR 372, 403 from *Oppenheimer v Cattermole* [1976] AC 249, 278.

protection of the people against the misuse of legislative or executive power and the promotion of fundamental rights and principles.[16] At the time, these views upset a number of public figures. I will return to these themes. But, first, I must take a different tack.

ENTER THE HUMAN GENOME

Next year will be the 50th anniversary of the discovery in 1953 by James Watson and Francis Crick of the structure of deoxyribose nucleic acid (DNA).[17] This great scientific breakthrough was not, of course, the first step on the path of genetics. Even in primitive societies farmers knew the benefits of mating particular domestic animals or cross-breeding particular crops. What was new about DNA was that it provided the scientific foundation and explanation of genetic differences. On the double helix shaped structure, described in 1953, was the molecule DNA that carried the genetic code that would unlock, with scientific precision, the features of inherited conditions previously known in a primitive, but largely unscientific, way.

The coincidental development of information technology provided the possibility of scientists performing the analysis necessary to examine and describe the genes present in DNA. In 1990, an international group of scientists decided to co-operate in sequencing the entire human genome, being the collection of all of the genes that go together to constitute the human being. The project so initiated became known as the Human Genome Project. Its object was to construct a 'high resolution genetic, physical and transcript map' of the human species, ultimately with a complete sequence of the human genome.

At first, it was thought that there were probably approximately 100 000 genes. It was expected that the mapping project would take 15 years. In fact, because of tremendous advances in high-powered computers and competition between the public and the private sectors, the project took 10 years. The number of genes was fewer than expected, being about 32 000 in all. The existence of those genes was described, but it remains to identify exactly what each gene does. In a process akin to that of deciphering the Rosetta Stone of ancient times, scientists, armed with information technology, have gone in search of the genetic causes of more than 4 000 inherited diseases that afflict humanity as well as many multi-factorial conditions in which genetic predisposition plays an important role.[18]

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16. Toohey, above n 10, 174.
17. JD Watson & FHC Crick 'A Structure for Deoxyribose Nucleic Acid' (1953) 171 Nature 737.
18. (1998) 9 Human Genome News 1-2; RJ Trent 'Milestones in the Human Genome Project: Genesis to Post-genome' (2000) 173 Med J Aust 591.

Scientists have already uncovered genes associated with the presence of Huntington's disease, Alzheimer's disease, cystic fibrosis, forms of breast cancer, testicular cancer and so on. However, the function of most of the genes, present on the double-stranded DNA, is still unknown.[19] As those secrets are gradually revealed, scientists will provide to the healthcare profession and to the world a great encyclopaedia of knowledge that will be the foundation of all future medical tests and therapies. It can be said without qualification that, overwhelmingly, this knowledge will be to the benefit of humanity. It carries the potential to provide early detection of disease, the means of responding with vaccines and therapies, the instruments for the reversal of genetic disorders, the reduction of pain and suffering and the postponement of premature death. Amidst the problems, practical and ethical, that I will mention, it is important not to lose sight of the wonder of this amazing collection of discoveries.

It is also vital not to be afraid of these developments. The human genome was always there. The double helix and DNA existed before Watson and Crick described them. The genes, now being unveiled, performed their functions long before humanity knew of their existence. None of them is alien to humanity. Nor should the tests and therapies, the interventions and the treatments be seen as disconnected from our species. It is essential to remember that it is human intelligence that has unravelled these secrets. If you believe in God, you will attribute these discoveries to a divine purpose emanating from the unique capacities of the human species to explore the enormities of space and the infinitely tiny realities of the atom and the genome. If you are a humanist, you will probably see these advances as just the latest spurt in the natural process of evolution, as happens in any particular species from time to time.

It is the new-found capacity of human beings, potentially, to alter the basic building blocks of living existence that presents many new ethical problems. They require much reflection and responses from theologians, philosophers, politicians and lawyers. I cannot presume to speak for other professions. But I want to devote my remarks to some of the legal issues that are raised by the advances in knowledge of the human genome. It is fitting to do so on the brink of the golden jubilee of Watson and Crick's discovery. It is also appropriate to do so in a lecture that honours John Toohey because, at the heart of my concerns, lies a question that concerned him. It relates to the capacity of law-making institutions, national and international, to respond to the complex policy questions that scientific advances present for answer.

19. J Kinderlerer & D Longley 'Human Genetics: The New Panacea?' (1998) 61 MLR 603.

MULTIPLE LEGAL ISSUES

Several legal questions are raised and a glance at legal literature will show the variety and complexity of the problems that need attention. An issue of the *Modern Law Review* a few years back was entirely devoted to legal problems of the kind that the Human Genome Project presents. Amongst the issues addressed were:

(1) how regulation will be possible in the fast moving genetic revolution given the slow pace at which legal change normally occurs;[20]
(2) what are the implications of the Project for human dignity and human rights;[21]
(3) should the law condone interventions in the human genome that will alter the genes of living persons and future generations;[22]
(4) what will be the implications of these developments for family law;[23]
(5) what consequences will arise for insurance, given the potential for genetic data to remove entirely, or greatly reduce, predictive uncertainty about an insured's likely health prognosis;[24] and
(6) will the criminal law need to be revised in so far as it posits the free will of the individual? In particular, if the conduct of some accused persons stems from their genes, should this be an exculpation, a defence or at least mitigation of criminal responsibility?[25]

Within Australia, the federal government has initiated a joint inquiry of the Australian Law Reform Commission and the Australian Health Ethics Committee into the protection of the privacy of human genetic samples and information; the protection of individuals against inappropriate discriminatory use of their genetic information; and the reflection in a regulatory framework of the ethical considerations relevant to the collection and use of human genetic samples and information.[26] In August 2002, a discussion paper, containing an intensive analysis of the problems over nearly 1 000 pages, was circulated. It examines the potential use and misuse of

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20. J Black 'Regulation as Facilitation: Negotiating the Genetic Revolution' (1998) 61 MLR 621.
21. D Beyleveld & R Brownsword 'Human Dignity, Human Rights and Human Genetics' (1998) 61 MLR 661.
22. SAM McLean 'Interventions in the Human Genome' (1998) 61 MLR 681.
23. R Deech 'Family Law and Genetics' (1998) 61 MLR 697.
24. O O'Neill 'Insurance and Genetics: The Current State of Play' (1998) 61 MLR 716; Institute of Actuaries of Australia *Genetics in Society 2001* (Sydney: IAA, 2001) 107-119, which sets out various insurance industry policy statements; JA Raeburn 'Genetic Tests and Insurance in the UK' (2001) 79 Reform 32.
25. C Wells '"I Blame the Parents": Fitting New Genes in Old Criminal Laws' (1998) 61 MLR 724; Nuffield Council on Bioethics *Genetics and Human Behaviour: The Ethical Context* (London: NCB, 2002) 87.
26. ALRC *Protection of Human Genetic Information* Discussion Paper No 66 (Sydney: ALRC, 2002) 11-13; D Weisbrot, G Spiteri & G Carney, 'Australian Inquiry Into the Protection of Human Genetic Information' (2002) 2 MqLJ 119.

genetic data in data bases, health services, insurance, employment, parentage testing, criminal investigation, forensic tests and legal proceedings. This is but one of the many subcategories of legal implications for the advance of the Human Genome Project. Indeed, it is one of the simpler and more readily solvable areas of concern.

At the other end of the spectrum lie the intensely difficult issues affecting genetic alteration. For example, should the law permit, encourage or forbid the elimination of an embryo or a foetus that manifests specific genes associated with particular genetic conditions? The elimination of an embryo or foetus, with likely profound intellectual impairment, is not now uncommon in Australia and other countries. But how far do we go down that track in the quest for the 'perfect' child? Should the law permit, or forbid, elimination for a tendency to obesity, baldness, heart disease, or homosexuality (if that turns out to be, at least in part, genetic)?[27]

Not to regulate these tests and therapies is, effectively, to permit them. Already, in less well developed countries, crude steps are taken to eliminate one of the most common genetic conditions of all: the female sex. Should the law step in or should it have nothing to say on such subjects? When it becomes possible to eliminate particular genes and transplant others, what will prevent the attempted creation of a super species? Or an under species? Or an altered species? Or a hybrid species, if such be possible? We have to be ready with answers to these questions. It should not be assumed that sermons, political press releases and the solemn resolutions of ethics committees (or even the decisions of judges) will have the power to prevent developments deemed undesirable by most of humanity.[28]

Amongst the legal issues that are already with us is one that presents significant intellectual and moral quandaries but that is bound up with very large economic implications. I refer to the operation of intellectual property law in relation to the human genome. In every country the patentability of inventions relevant to living matter of human, animal or plant origin depends upon the terms of the local law on intellectual property protection (patents, copyright, plant variety laws, etc).[29] That body of law is normally itself the product of national legislation, influenced by international law. Some commentators criticise the intrusion of intellectual property law into the scientific field opened up by the Human Genome Project.[30] They assert

27. See Nuffield Council on Bioethics, above n 25, 99-107, where the current state of research is summarised.
28. MD Kirby 'The Human Genome Project in the Dock' (2000) 173 Med J Aust 599, 600.
29. N Rogers 'Seeds, Weeds and Greed: An Analysis of the Gene Technology Act 2000 (Cth): Its Effect on Property Rights, and the Legal and Policy Dimensions of a Constitutional Challenge' (2002) 2 MqLJ 1.
30. See generally C Lawson 'Patenting Genetic Materials: Old Rules May be Restricting the Exploration of a New Technology' (1999) 6 JLM 373, 391; C Lawson 'Patenting Genes and Gene Sequences and Competition: Patenting At the Expense of Competition' (2002) 30 FL Rev 97, 101.

that the genome itself is part of the common heritage of humanity, that it belongs to the human species as a whole – some say to God – and not to private corporations engaged in research, however potentially beneficial such research may be.

Critics of developments in the field of intellectual property and the genome point out that Watson and Crick, like Fleming and Florey and most great scientists until quite recently, never attempted to obtain the slightest commercial advantage for themselves or their institutes from their discoveries.[31] Lately these things have changed. The change presents important problems for law-makers, national and international.

INTERNATIONAL DEVELOPMENTS

I am associated with three bodies that, at an international level, have been working on the implications of the Human Genome Project for ethics and the law. I am a member of the Ethics Committee of the Human Genome Organisation. This is the international scientific association which has sponsored the Human Genome Project. I am also a member of the International Bioethics Committee (IBC) of UNESCO. That Committee propounded the Universal Declaration on the Human Genome and Human Rights. That Universal Declaration is the first attempt of the international community to state the broad principles that should govern ethical and legal responses to the developments to which the Human Genome Project will give rise. The Universal Declaration was adopted by the General Conference of UNESCO in November 1997.[32]

At a meeting of the IBC due to take place in Montreal, Canada, in November 2002, the members of that body will address the possibility of elaborating a universal instrument of bioethics that starts from the Universal Declaration on the Human Genome and Human Rights and covers a range of other topics. Such topics may include:

(1) rights of global access to healthcare essential to life and human dignity;
(2) regulation of end-of-life decisions;
(3) biomedical research involving human subjects;
(4) protection for the collection and use of human genetic data;
(5) control of human organ and tissue transplantation;
(6) use of embryonic stem cells in therapeutic research;
(7) development of genetically modified organisms; and

31. See JD Watson *The Double Helix: A Personal Account of the Discovery of the Structure of DNA* (London: Penguin, 1970).
32. MD Kirby 'The Human Genome and Patent Law' (2001) 79 Reform 10.

(8) adaptation of intellectual property protection to the world of the human genome.[33]

Just to mention this wide range of topics is to indicate the number, complexity and dimension of the problems that will need to be addressed by our law-makers in the coming years. Nor does the list contained in the papers for the Montreal meeting exhaust the subjects requiring consideration. One obvious and notable omission, for example, concerns the potential risks of xeno-transplantation by which human genetic material is grown in, or in connection with, other animal or plant species. Despite stringent standards to exclude the introduction into the human species of viruses, bacteria and genetic conditions peculiar to other species, some dangers obviously exist in adventurous experiments of this kind. The puzzle of the origin of the human immunodeficiency virus (HIV) has led some scientists to conclude that it somehow jumped the species to replicate a simian virus earlier found in African monkeys. Whether this is correct or not, it will obviously be essential to ensure against the introduction into the human species of unique animal diseases or conditions against which our species may have no natural immunity.

The topics are large and baffling. They will be examined within UNESCO in the framework of that body's Universal Declaration. That instrument starts with the assertion that the human genome is the 'heritage of humanity';[34] that 'in its natural state' the human genome 'shall not give rise to financial gains'.[35] It urges all countries to disseminate scientific knowledge so that it is shared, specifically with developing countries in order that all nations and peoples will receive the full benefits of scientific and technological research.[36]

The third international body with which I am associated is an Expert Group initiated by the UN High Commissioner for Human Rights (then Mrs Mary Robinson). Its function is to examine the human rights implications of biotechnology. With clear sightedness, the Office of the High Commissioner saw that the very future of the human species was one of the likely issues of the greatest importance for the future of human rights. Acting under a resolution of the UN Commission on Human Rights,[37] the High Commissioner established an advisory group to follow up the UNESCO Universal Declaration and to consider more generally the issues deserving priority in the work of the Office of the High Commissioner in the areas of human rights and biotechnology. I was appointed by the High Commissioner to be an

33. L de Castro & G Berlinguer 'The Possibility of Elaborating a Universal Instrument on Bioethics: Preliminary Report of the Working Group of the IBC' in *Ninth Session of UNESCO's International Bioethics Committee* (Montreal, 26-28 Nov 2002).
34. Universal Declaration on the Human Genome and Human Rights (adopted 11 Nov 1997) Art 1.
35. Ibid, Art 4.
36. Ibid, Arts18-19.
37. UN Commission on Human Rights, Resolution 2001/71.

Honorary Adviser and Co-chair of the Expert Group. So far, that body has examined a number of particular issues including reproductive human cloning, discrimination in employment and insurance, gender discrimination and benefit-sharing. The group has also examined the significance for human rights of the patentability of genetic material.

Common to the activities of all three bodies with which I am associated – the Ethics Committee of HUGO, the IBC of UNESCO and the Expert Group of the High Commissioner for Human Rights – has been a consideration of intellectual property protection and the human genome. I will address that topic in more detail because it is as important as it is urgent. In the nature of these things, with common problems, shared scientific data and some overlap of personnel, common themes may be seen in the consideration of these topics in the different institutions that have a leadership role both within the United Nations and outside.

Also in the nature of these things, it is likely that those who take the initiative and chart the regulatory framework at an international level will greatly influence developments that occur downstream in subsequent national regulation. Earlier in my life I witnessed the way in which work of an OECD expert group that I chaired (on the issues of privacy in the context of trans-border data flows) could influence domestic law dealing with privacy protection, including in Australia.[38] So it will probably be in relation to issues of the human genome, including in respect of intellectual property protection and, specifically, patenting.

THE ISSUE OF PATENTING

This idea can be illustrated by reference to the way in which patenting has been addressed in this context. The topic first arose in the work of the UNESCO IBC in developing its Universal Declaration. From the start, it was obvious that this would become a major question of ethical and practical concern as the Human Genome Project advanced. I was not a member of the IBC when the Universal Declaration was being drafted. However, the President, Professor Ryuishi Ida of Japan, was. He was there when it was agreed that Article 1 of the Universal Declaration should declare that: 'In a symbolic sense' the human genome is 'the heritage of humanity'. He has subsequently explained that there was uncertainty about exactly what this meant:

> Was it no more than a metaphor? Or did it have implications for the endeavour to secure property, and thus intellectual property rights, in respect of the genome? A partial answer to that question was found in Article 4 of the [Universal

38. Privacy Act 1988 (Cth). The Privacy Principles in the Act are adapted from the OECD guidelines.

> Declaration] stating that 'the human genome in its natural state shall not give rise to financial gains'. Initially, as drafted by the IBC, the words 'in its natural state' did not appear. Those words were added to the draft prepared by the IBC by the Committee of Governments Experts who scrutinised the Draft Convention before it was presented to the General Conference of UNESCO.[39]

It was that conference which, in November 1997, unanimously adopted the Universal Declaration of the IBC, as modified by the governmental experts. In due course, in December 1998, the Universal Declaration on the Human Genome and Human Rights was presented to the General Assembly of the United Nations. It was endorsed by the General Assembly, significantly enough during the celebrations of the 50th anniversary of the Universal Declaration of Human Rights of 1948.[40]

The election of a new Director-General of UNESCO, Mr Koïchiro Matsura of Japan, early in 2000, led to a number of initiatives requesting the leaders of the G8 nations to adopt policies upholding free access of the global scientific community to data derived from human genome sequencing.

In August 2000, the Sub-Commission on the Promotion and Protection of Human Rights of the United Nations accepted a resolution expressing concern that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) of the World Trade Organisation of 1994 did not 'adequately reflect the fundamental nature and indivisibility of all human rights'. This resolution drew attention to what the Sub-Commission saw as the 'apparent conflicts between the intellectual property rights regime embodied in the TRIPs agreement, on the one hand, and international human rights law, on the other'.[41] The TRIPs agreement is part of the package deal that countries, rich and poor, must subscribe to in joining the WTO. If they want the benefits of membership of the organisation in terms of trade and investment, they are required to commit themselves to the obligations to protect intellectual property rights by enforceable laws; these are obligatory save for limited and exceptional circumstances.

This was the context in which the HUGO Ethics Committee came, in 2000, to consider the subject of benefit-sharing amongst all nations and peoples of the world in the context of extraordinary advances in knowledge about the human genome.

The HUGO Ethics Committee expressed concern that the manner in which intellectual property law was being applied might warp the development or the use of genomic knowledge. In effect, it might divert that use from development of tests

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39. R Ida, quoted in MD Kirby 'Intellectual Property and the Human Genome' (2001) 12 AIPJ 61, 71.
40. Ibid, 61-62.
41. Ibid, 61, quoting UNESCO *Intellectual Property in the Field of the Human Genome: Preliminary Analysis* (doc SHS/HPE/2001/Conf-804/3) 12.

and therapies of maximum priority to humanity in favour of tests and therapies prone to produce the greatest immediate profits for pharmaceutical and like companies and their shareholders. Moreover, it might fail to deliver to developing countries an appropriate 'genomic dividend' for the contributions which people in those countries indirectly make to knowledge of the genome by providing genetic material from which the scientific advances are often developed. Because of the ease, economy and safety of work on such subjects and inter-generational turnover of population groups in developing countries, they are often the source of vital genetic material. Only rarely are they the beneficiaries of resulting economic rewards. This fact led the HUGO Ethics Committee, in its statement on benefit-sharing, to urge that a proportion of net profits made by pharmaceutical companies on the basis of genomic research should be allocated to participating developing countries.[42]

There then followed two developments within UNESCO. In 2001, the new Director-General convened a large symposium in Paris[43] involving many of the key players of the United Nations (including UNESCO, the World Intellectual Property Organisation, the Food and Agriculture Organisation, and the World Trade Organisation), other international bodies (including the OECD), regional institutions (such as the European Patent Office in Munich) and scholars and non-governmental organisations to consider intellectual property law in the field of the human genome. I chaired the closing business section of the symposium.

I have reported elsewhere on the vigorous debates of the symposium.[44] My report reveals the strong clash of opinions that occurred. On the one hand, the proponents of intellectual property protection advanced their argument that, without major investments the tests and therapies of potential benefit to humanity would not be developed from the raw data concerning the genome, certainly in the short run. Without patent protection, the large investment funds needed would not be forthcoming.[45] On the other hand, many complaints were made about the unsuitability of current patent law, the excessive duration of patent protection and the inappropriate grant of patents, in some cases imposing unreasonable burdens, especially on developing countries already disciplined by the TRIPs agreement of the WTO.

Arising out of the Paris meeting the IBC established a Working Party on Ethics, Intellectual Property and Genomics. That body was chaired by HE Patrick Robinson (a judge of the International Criminal Tribunal for the Former Yugoslavia). I was

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42. HUGO Ethics Committee *Statement on Benefit-Sharing* (Vancouver, 9 Apr 2000). See also HUGO Ethics Committee 'Genetic Benefit-Sharing' (2000) 290 Science 49.
43. UNESCO *Symposium on Ethics, Intellectual Property & Genomics* (Paris, 30 Jan–1 Feb 2001).
44. Kirby, above n 32, 61.
45. Nuffield Council on Bioethics *The Ethics of Patenting DNA* Discussion Paper (London: NCB, 2002) 67.

elected rapporteur of the Working Party. The fundamental problem defined in the Working Party's report was: 'How to secure the benefits of the first draft of the human genome sequence for the service of humanity as a whole'.[46]

Amongst the concerns identified by the group as necessitating a new global response were:

(1) changes that are occurring in the tradition and culture of open science;

(2) accompanying changes in the balance of private and public research investment;

(3) recognition of the peculiar character of the genome as something intimate to the human species;

(4) fear of financial diversion of research priorities in the use of genomic knowledge;

(5) anxiety about the premature provision of patent protection to some genomic discoveries and the suggested degradation of the requirements of 'novelty' and 'inventive step' normal in patent law;

(6) concern about the downstream use of scientific knowledge for the utility of patented procedures;

(7) a conviction that the duration of present patent protections, typically 20 years, is excessive having regard to the rapid turnover of knowledge in the field;

(8) concern about the implications of the explosion of patents and patent applications both for developed and developing countries, particularly in their health budgets;

(9) a determination to ensure compatible developments of international law in this field as in other areas designated part of the common heritage of humanity; and

(10) a conviction that the apparent conflict between the requirements of the TRIPs agreement and requirements of fundamental human rights should be resolved in a way adequately defensive of human rights as a whole, recognising that human rights includes respect for intellectual property rights.[47]

It was in the last-mentioned context that the IBC Working Party recommended, in 2001, that the WTO should review the TRIPs agreement and clarify the exceptions for public interest considerations relevant to the protection of human life and health set out in Article 27(2) of the TRIPs agreement. It was also recommended that UNESCO should urgently promote the adoption of an international convention on

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46. UNESCO IBC *Report on Ethics, Intellectual Property and Genomics* (doc SHS-503/01/CIB-8/2), Conclusion 1.

47. The Universal Declaration on Human Rights (adopted 10 Dec 1948) Art 27.2 reads: 'Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author'. As if to demonstrate the ambivalence of basic principle, this must be read with Article 27.1, which reads that: 'Everyone has the right ... to share in scientific advancement and its benefits'.

ethical and other issues relating to intellectual property and genomics. The Working Party report reflected the concerns voiced by a majority of members of the group about the inappropriateness of the current intellectual property regime as it affects genomic discovery and the inventions flowing from them. By majority, the Working Party recommended that the Director-General of UNESCO should propose to the General Conference of UNESCO that 'appropriate steps be taken towards a global moratorium on the grant of further patents in relation to human genome sequences'.[48]

Amongst the issues considered by the IBC in Montreal in November 2002 will be progress upon the proposal for a treaty to be prepared by UNESCO, binding signatories as a matter of law to a different legal regime than that presently obtaining – one more likely to involve 'the promotion of justice by securing the benefits of scientific and technological advances for the service of humanity as a whole'.

Whilst representatives of developed countries and pharmaceutical and like corporations repeatedly point to the huge investments that are required (sometimes said to be on average $US 300 million) before ideas or raw scientific data are translated into a profitable pharmaceutical product, there can be no denying the head of steam that is building up in the majority of countries (and amongst many experts as well) critical of the present international and national regimes providing for the patenting of cell lines, genes and DNA sequences.

One of the information documents distributed for the Montreal meeting of the IBC collects the national laws on human genome patentability according to whether they are least favourable, intermediate or most favourable to securing genome patents. Amongst the laws described as most favourable are those of the United States of America,[49] Japan[50] and Australia.[51] So far as Australia is concerned, the report indicates that the Australian Patent Office considers that animals, as well as their organs or animal varieties, are not excluded from patentability and that only human beings, as such, are excluded: human organs and derived products (cell lines, genes and DNA sequences) are not excluded from patenting provided they otherwise comply with the statutory requirements.

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48. UNESCO, above n 46, Conclusion 4.
49. United States Code, Title 35, last amended by the American Inventors Protection Act 1999 (US).
50. Patent Law (Japan) s 29(1). See also Council for Intellectual Property *Towards International Harmonisation of Industrial Property Rights Systems in the 21st Century* (Tokyo, 26 May 1999).
51. Patents Act 1990 (Cth), as amended by Patents Amendment Act 2001 (Cth) which has introduced a 'balance of probabilities' test for proof of the requirements of novelty and intensive steps. Cf C Lawson & C Pickering 'Controlling Access to Genetic Resources Under the Environment Protection and Biodiversity Conservation Act 1999 (Cth) Requires an Assessment of the Effects of the Patents Act 1990 (Cth)' (2002) 13 AIPJ 109; D Nicol & J Nielsen 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 Syd LR 347, 361.

In the United States, following the Supreme Court decision in *Diamond v Chakrabarty,*[52] the Patent and Trademark Office, despite much local and international scientific criticism, has given effect to the view that patents may be granted for DNA fragments, known as Expressed Sequence Tags (ESTs) because of their potential use as probes or checking elements for tests and, potentially, therapeutic developments.

So far as the High Commissioner's Expert Group is concerned, they have 'noted the serious concerns raised regarding the appropriateness of applying patent laws to genetic material and the human genome, particularly in terms of the requirements of novelty and inventiveness'. By reference to the relevant international law of human rights, the High Commissioner's experts have recorded their particular anxiety about 'the growing trend of biotechnological research being largely restricted to developed countries, [which] risks the development of a "genetic divide" between those societies'.[53] Priority attention is urged towards facilitation of benefit-sharing involving compensation to developing countries for contributions to genomic research and technology transfer.

THE BASIC PROBLEM

The topic of intellectual property (including patents) and the human genome is not a dry subject of interest only to a few specialist lawyers. A reflection of this fact was shown in a related area concerning the demand of pharmaceutical companies for the protection of their intellectual property in drugs for the treatment of HIV and AIDS. Although these are not genomic drugs as such, they illustrate the kinds of developments that will probably occur as tests and therapies are produced as a consequence of genomic research.

In South Africa, the claims of the pharmaceutical companies to protection of their patent rights were challenged in the courts. Ultimately, the companies backed down under great local and international pressure. Large and economically powerful countries in the developing world, such as India and Brazil, are examining their obligations under the TRIPs agreement. Their representatives are suggesting that exceptions for public interest, such as health, will afford relevant exemptions from genomic patents.

Whether poorer countries will gain access to generic tests and therapies, by conforming to the stringent requirements of the TRIPs agreement without protest

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52. 447 US 303 (1980). See US Patent and Trademark Office *Guidelines for Examination of Applications for Compliance with the Utility Requirements* (2001) 66 Federal Register 1092, 1095-1097; J Doll 'The Patenting of DNA' (1989) 280 Science 689, 690.
53. Office of the High Commissioner for Human Rights *Report of the Expert Group on Human Rights and Biotechnology* (24-25 Jan 2002) para 24.

by the pharmaceutical companies in the developed world, remains a puzzle for the future. Spurred on by the victory against the pharmaceutical companies in South Africa in April 2001, many developing countries joined in a declaration at the WTO meeting in Doha, Qatar, in 2001. The Doha Declaration asserted the primacy of public health over intellectual property rights. It resolved that the least developed countries should be given until at least 2016 to introduce patent protection for pharmaceuticals. This issue remains on the agenda of WTO, UNESCO and other organs of the United Nations.[54] The controversies that exist in relation to the human genome are repeated in developments affecting plant varieties and the genome of plants (eg, rice), of vital concern to the struggling farm economies of the developing world.

How do we cope with so many problems of great sensitivity, complexity and importance? This is perhaps the greatest of the dilemmas presented by advances in genomic science and indeed by advances in biotechnology more generally.

It is essential to realise that, in these fields, not to do anything is, effectively, to make a decision. It is to accept that science and technology may take our societies where they will. History might judge that to be a good thing. For example, there has been great haste, including in Australia, to legislate for the prohibition of reproductive cloning of the human species based on intuitive objections to the very idea. More mature consideration may indicate that we need to give the subject more thought before we rush into a total prohibition.[55] In the past, there were similar initial responses to AIH (Artificial Insemination Husband), AID (Artificial Insemination Donor) and IVF (Invitro Fertilisation). Yet, apart from a few legislators, most politicians avoid the complex issues of the genome. Getting agreement at a national level is difficult enough, given the differing perspectives. Securing effective agreement at the international level will be even more difficult. But without international rules about genomic regulation, as in the case of nuclear fission and laws concerned with the Internet, national laws will never be fully effective. Faced with local legal prohibition, scientists may simply move their laboratories to countries with less restrictive laws.[56]

In August and September 2002, Australia witnessed an exception to this gloomy prognostication. The Federal Parliament engaged in a remarkable debate on embryonic stem cell research.[57] By a conscience vote, a Bill permitting such research

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54. Extracted from *The Economist,* quoted in *The Australian* (18 Sep 2002) 25.
55. UK Department of Health *Stem Cell Research: Medical Progress With Responsibility* (London, Jun 2000).
56. Kirby, above n 28, 600.
57. For the background to the debate, see D Nicol, D Chalmers & B Gogarty 'Regulating Biomedical Advances: Embryonic Stem Cell Research' (2002) 2 MqLJ 31.

was carried in the House of Representatives by 99 votes to 33.[58] The Bill was sent to the Senate where it was later passed to receive the Royal Assent.

The standard of debate in the Parliament, both by proponents and opponents of the Bill, was high. This fact suggests that, given the chance, the democratic process in Parliament can grapple with identified issues of complexity and sensitivity in biotechnology. The important point is that the very process of considering the issues publicly and thoroughly, and evaluating sharply divergent opinions, itself constitutes a useful contribution to the settling of a major ethical and legal quandary, at least for the time being.

The Commonwealth Parliament emerged strengthened by its consideration of this important and controversial topic of bioethics. As a judge, I believe that it is preferable that such topics should be resolved by an elected parliament rather than by the alternative decision-maker, namely the judiciary. But in our system of government there is never, ultimately, a gap in the law. If Parliament does not enact a law, the judiciary will fill the legal gap by analogical reasoning from earlier broad principles of the common law.

After the stem cell issue is finally resolved in Australia, many equally difficult and controversial topics await consideration. They include the operation of intellectual property law in the field of genomics. They also include protection of human genetic information explored by the Australian Law Reform Commission and the Health Ethics Committee.[59] They embrace many other topics, some only of which I have mentioned.

This brings me back to Justice Toohey's concern about the transparency of law in the community and the protection of fundamental human rights and the rule of law in Australia. In our responses to such issues, Australia will have the advantage of developments that are proceeding in the organs of the United Nations and in the inter-governmental bodies to which we belong (such as the OECD) and private bodies to which our scientists contribute (such as HUGO).

Keeping the rule of law in a good state in a world of so many complex problems is a major challenge for global and national institutions. Indeed, it is a major challenge for democracy. The likely institutional solution, it seems to me, will be the delegation of law-making detail to expert bodies, acting in conformity with very broad guidelines endorsed by Parliament.[60] I do not see any other solution being able to tackle the multitude of issues that will need resolution. In a sense, many of the problems

58. Research Involving Embryos Bill 2002 (Cth): debate reported in *The Australian* (26 Sep 2002) 2.
59. ALRC, above n 26.
60. Cf Gene Technology Technical Advisory Committee, Gene Technology Community Consultative Committee and Gene Technology Ethics Committee established by Pt 8 of the Gene Technology Act 2000 (Cth).

presented by science and technology have gone beyond the understanding even of the intelligent lay person. How many citizens really understand what the atom is? What the relativity theory of Einstein means? How a computer really works? What a gene truly is and how it operates? How the brain functions? And how it gives rise to that greatest mystery of all, intelligent consciousness?

Law cannot solve all of the problems I have mentioned. For the most part, it does not try. But science and technology present extremely urgent problems for the law and its institutions, global and local. For the good health of the rule of law, there will be a need for more parliamentary debates like that just concluded in Australia on stem cells. There will be many judicial decisions. There will be countless meetings at UNESCO, the WTO and other international agencies. And in other regional and local organisations. The science and technology of the human genome are exciting. Politicians and lawyers must pay close attention if they are to remain relevant to the issues that will unfold this century. Citizens must become engaged in these issues if they are to protect constitutionalism, the rule of law and democratic control over where scientific imagination takes humanity.