

*UNIVERSITY OF NEW SOUTH WALES LAW JOURNAL*

THEMATIC ISSUE: LAW & MEDICINE 1997

CHALLENGES OF THE GENOME

The Hon Justice Michael Kirby AC CMG

*UNIVERSITY OF NEW SOUTH WALES LAW JOURNAL*

THEMATIC ISSUE: LAW & MEDICINE 1997

CHALLENGES OF THE GENOME

The Hon Justice Michael Kirby AC CMG\*

AN ACCIDENTAL ENCOUNTER

I came upon the genome by accident. In May 1993, I was invited to participate in a conference in Bilbao, Spain. It was one of a series, convened by the BBV Foundation - a body which supports original and wide-ranging research. The conference was summoned to address the legal aspects of the Human Genome Project. As I was to discover, this is the greatest cooperative scientific project in history. It is bigger by far than the Manhattan Project, although some writers have seen parallels between the enthusiasms, complexities and dangers of nuclear technology and of genomic research<sup>1</sup>.

---

\* Justice of the High Court of Australia. Member of the International Bioethics Committee of UNESCO. Member of the Ethics Committee of the Human Genome Organisation. President of the International Commission of Jurists.

<sup>1</sup> Privacy Commissioner of Canada, *Genetic Testing and Privacy*, Ottawa, 1992.

The conference gathered together people from all parts of the world. It included Nobel Laureates in science and medicine but also lawyers, philosophers and ethicists from many countries and differing traditions. My task was to draw upon my work in the Australian Law Reform Commission. It was to offer a prediction as to whether a project of such global dimensions, economic importance and complexity could be reduced to the simplicities inherent in effective law-making. And even if this could be done in one legal jurisdiction, was there any hope of international cooperation to produce global rules for a global technology having significance for the human species everywhere in the world.

In my address to the conference I made a few short points<sup>2</sup>:

"The first is that not to act, not to adopt legal principles to deal with the problems presented by the Human Genome Project, is to make a decision. Science will then rush ahead and it will not be controlled in a way in which perhaps, in retrospect, we as human beings would want. Secondly, we

---

<sup>2</sup> M D Kirby, "Man's Freedom and the Human Genome" in *The Human Genome Project: Legal Aspects*, Vol 1, Fundacion BBV (1994) 267 at 268. See also M D Kirby, "The Human Genome Project - Promise and Problems" 11 *Journal of Contemporary Health Law & Policy* 1 (1994) and "Legal Problems: Human Genome Project" (1993) 67 *ALJ* 894.

should seek to frame our laws on the subject consistently with international human rights law ... Thirdly ... we have to consult not only the general community, but ... all involved. All people who are actually or potentially going to receive the benefits and suffer the problems of the Human Genome Project should have a chance to be heard. Fourthly, as in AIDS, we must base our laws and policies on good science, not on ignorance or mythology or even, with respect, religion. But on good science. And fifthly, in order to be effective, we have to find global mechanisms".

Since that chance involvement, my eyes have been opened to the importance of genomic research and its applications. I have been appointed to the Ethics Committee of the Human Genome Organisation, formerly based in Bethesda and now in London. I have also joined the International Bioethics Committee of UNESCO. As I shall describe, that body is working towards a Draft Declaration on the Human Genome and Human Rights<sup>3</sup>.

The purpose of this note is to describe, briefly, the work of these international bodies. But first, it is necessary to say something about the Human Genome Project itself and to identify some of the legal problems which it presents.

---

<sup>3</sup> UNESCO, Revised Preliminary Draft of a *Universal Declaration on the Human Genome and Human Rights* (CIP/BIO/97/318).

## THE HUMAN GENOME PROJECT

The project was launched in 1988. It involves a co-ordinated, international research effort aimed to identify the location of the estimated 100,000 human genes, as well as the intervening sequences. The project is the direct outcome of the discovery in April 1953 by James Watson and Francis Crick of the structure of deoxyribonucleic acid (DNA) which exists in each cell of our bodies. Watson and Crick conceived of DNA as a three-dimensional structure in the form of a double helix. To identify all of the genes and to map and describe the structure would require the input of enormous amounts of research time. Without the coincidental development of new information technology, it would simply have been impossible to perform this feat. The scientific break-through which resulted from the conception of Watson and Crick's was called "molecular biology". Allied with the burgeoning capacity of informatics to analyse data and to share it instantaneously across the room or across the world, it presented an opportunity which scientists themselves quickly realised.

The Human Genome Project was their creature. It was not invented by national governments or international agencies. The Human Genome Organisation (HUGO) established in 1989 in Geneva, Switzerland has, to this day, a very loose decision-making structure. Its recommendations carry moral weight. However, this is only because of the participation in its work of

the most respected molecular biologists in the world. HUGO is a consultative and coordinating arrangement between scientists and laboratories involved in the project. It describes itself as an "enabler" rather than a "provider" or "rule-maker". It neither funds research controlling where it should be targeted nor does it judge results. Until lately, it has taken very little part in addressing ethical, legal or economic issues. Even now, it does not purport to judge or arbitrate on such matters. It simply creates networks and channels off information to assist the flow of data. It is a non-profit making body. In legal terms, it is a non-governmental organisation constituted by its participants<sup>4</sup>.

When it was established, it was contemplated by HUGO that the Human Genome Project would take about 20 years to complete. That is to say, all of the approximately 100,000 genes would be mapped by the year 2005. The first five years of the project were spent mapping the genes and developing technologies to increase the speed and decrease the cost of sequencing. The rest of the project is to be spent sequencing sections of the DNA. Chromosome 21 and the Y chromosome have already been completely mapped. Mapping the others is well under way.

---

<sup>4</sup> F Hondius, "Man's Freedom and the Human Genome" in Fundacion BBV, above n 2, 173.

Why does this mapping matter? Why are such large budgets being expended both by private laboratories and national governments now committed to the success of the Human Genome Project? The answer to these questions is to be found in the link that is established between particular genes and the presentation of particular characteristics, some of them connected with genetically inherited or determined conditions. Already, very serious and even life-threatening conditions have been traced to particular "markers" in the DNA which it is the purpose of the Human Genome Project to identify. Thus, cystic fibrosis, Tay-Sachs Disease, Down Syndrome, Alzheimer's Disease and thalassaemia have been shown to derive from specific genes. They can be identified generically before they manifest themselves physically. At present, a major application of this form of diagnosis is to permit decisions to be made before birth concerning embryo wastage (if invitro fertilisation is involved) or termination of pregnancy (if the parents are unable to cope with the prospect of rearing a child with profound disabilities).

Hardly a week goes by but there is some new announcement of the discovery of genes responsible for particular medical conditions. Huntington's chorea. Amyotrophic lateral sclerosis. Colon cancer, the second leading cause of cancer deaths in developed societies. And so on. The only major involvement of Australian science in the Human

Genome Project is that of a unit in Adelaide under Professor Grant Sutherland. That unit has helped to locate a gene responsible for the second most common cause of mental retardation, called fragile X syndrome. So far, it is not known how fragile X gene causes the retardation, only that it does.

In addition to these targets, related to genetic diseases, much attention is now being paid to non-disease traits. These set the technologists in search of the genes responsible for height, weight, intelligence, skin pigmentation, baldness, obesity etc. It has been suggested that genomic research might find a genetically inherited marker to explain a propensity to homosexuality. It was upon that assumption that Lord Jakobovitz, former Chief Rabbi of the Commonwealth of Nations, wrote that "if we could by some form of genetic engineering eliminate those [homosexual] trends we should - so long as it is done for a therapeutic purpose"<sup>5</sup>. This comment elicited a strong response from the Union of Jewish Students in Britain and others reminding the Chief Rabbi that homosexuals had shared with Jews the stereotyping prejudices evidenced in the Nazi death camps<sup>6</sup>.

---

<sup>5</sup> Letters to *The Jewish Chronicle* (United Kingdom), July 1993.

<sup>6</sup> Quoted *Sun-Herald* (Sydney) 1 August 1993.



Reflecting upon the obvious potential of the Human Genome Project to provide the encyclopaedia for medical therapies in the coming century, but also the potential for misuse, James Watson told an earlier BBV meeting on the ethical issues of the Human Genome Project<sup>7</sup>:

"[The] genetic variability between human beings reflects the fact that the gene distribute process is not perfect and that the new genetic mutations are constantly arising. ... The variation has been the basis of our evolution. Without the differential ... we as human beings would not have our highly empowered brains that have led us to develop the languages ... that underlie the creation of our various civilisations. The question now faces us ... as to how we are going to deal with these differences between individuals. In the past, at the time of the eugenics movement ... and during the reign of racist thought in Nazi Germany, there was very little genetic knowledge. Most decisions were made without solid genetic evidence ... Now we have to face the fact that we soon will have real facts and how are we going to respond to them?"

#### FUNDAMENTAL CHALLENGES

Obviously, the preservation of genetic diversity, which has been a protection for humanity in time of epidemics, presents very large questions of policy which cannot be solved in one

---

<sup>7</sup> J Watson in Fundacion BBV, *Human Genome Project Ethics*, 27.

legal jurisdiction alone. This is why some commentators perceive the challenge of the Human Genome Project as one of the most pressing problems for human rights in the coming millennium. If it is possible to identify particular genes with identifiable consequences for the human being carrying them, it is by no means unlikely that the subject or their relatives may seek intervention to modify or remove the particular abnormality. It could be said that this is a natural and desirable development of genetic science. If, for example, it became possible to identify the gene responsible for colon cancer, which kills hundreds of thousands of people every year, that discovery could facilitate early intervention to the protection of those otherwise at risk. Early diagnosis might help save lives.

But more complicated questions are presented when an attempt is made to affect or change the passage of the gene to the next generation. This may be attempted in an imperfect way by early intervention and the termination of fetuses carrying identifiable genes, discovered by genetic tests. In a sense, this is already occurring. It happens in the case of Down Syndrome, by the procedures of amniocentesis. But much more radical and troubling even than this, is the suggestion of altering the germ line of a subject to manipulate the genes of the subject's progeny.

The prospect of interference in the human germ line alarmed the Nobel laureates at the Bilbao meeting. They called

for a moratorium on such research, arguing that it was premature in the current state of human knowledge. Yet without effective legal rules, there is an inescapable risk that scientists will engage in germ line research. At the moment cultural, scientific and funding pressures may be brought to bear to discourage germ line therapy. But the potential medical utility of such research makes it likely that it will continue in quest for a Nobel Prize or vast economic rewards if it succeeds. The fear that genomic research could actually affect the design of human beings of the future presents a risk (not wholly theoretical) that, unless brought under human control, genomic research may result in attempts to alter the human species in significant ways. This is why some writers address the human rights implications of the Human Genome Project in terms of the human rights of future generations. Who will be the "humans" to enjoy human rights if it is possible to eliminate all characteristics deemed "undesirable" and to maximise those which fit into someone's concept of the "perfect" human being<sup>8</sup>? It was this risk which James Watson

---

<sup>8</sup> *Universal Declaration of the Human Rights of Future Generations*. See K Vasak, "The Universal Declaration of Human Rights of Future Generations" in (1994) 1 *Law & the Human Genome Review* 211 at 218. See also G J Annas and M A Grodin (eds) *Nazi Doctors and the Nuremberg Code - Human Rights in Human Experimentation*, OUP, New York, 1992; C S Lewis, "The Abolition of Man", McMillan Company, London, 1947; A L Bonnicksen, "National and International Approaches to Human Germ-Line Gene Therapy" in *Politics and Life Sciences*, 13(1), 39-49 (February 1994); F Mantovani, "Genetic Manipulation, Legal Interests Under

Footnote continues

foresaw in the passage cited. Will future generations see him as the Oppenheimer of genetic research? A man whose scientific breakthrough made genomic technology possible but who came to view its potential impact on the human species with growing anxiety?

These, then, are some of the large questions which face humanity and the organs of government - national and international - which we accept for the purpose of making the rules by which we live together. The political leaders of the world are at last beginning to recognise the importance of these questions. At a summit of the seven most important nations in the middle of 1997, President Chirac of France and Chancellor Kohl of Germany raised the spectre of the cloning of the human species and the need for a common legal response to that potentiality. It seems likely that these issues will become more important in the decades ahead. In the meantime, many problems will present themselves to national legal systems and demand urgent solutions. As, in common law jurisdictions such as Australia, default on the part of the legislature will necessitate the provision of solutions by the courts, it is as well that Australian lawyers should begin to consider some of these

---

"Threat, Control Systems and Techniques of Protection" (1994) 1 *Law & the Human Genome Review* 91 at 95.

questions. Of necessity, they can be sketched only in broad and general terms.

### SOME LEGAL ISSUES

The legal issues of genomic developments range over a very wide landscape. It is impossible to do them justice.

#### (a) *Criminal culpability*

Several papers at the Bilbao meeting examined the issue of criminal culpability<sup>9</sup>. These contributors acknowledged that current genomic findings did not require a re-examination of the concepts of free will that underpin the criminal law of most civilised countries. However, a question which they pose is whether, with advances in genomic research, this concept, central to criminal law, will survive. If the fundamental notion of criminal law is that punishment may not be applied without *mens rea*, what would follow if it is discovered that (at least in some cases) *mens rea* is predetermined by genetic characteristics?

---

<sup>9</sup> H G Koch, "Analysis of the Human Genome and Issues of Criminal Responsibility" in BBV Foundation, the Human Genome Project, *Legal Aspects*, Vol II, 11 (1994).

Professor Ammon Carmi of Israel, President of the World Medical Law Association, expressed it thus<sup>10</sup>:

"The modern concept of responsibility refers to a complex notion concerning the relationship between the wrong doer and society. Criminal responsibility consists of wilfully blameworthy behaviour causing unlawful effect. The criminal mind consists of two subjective elements. The cognitive-intellectual element reflects the awareness of the nature and of the existence or the possible existence of the *actus rem* components of the offence. The emotional element reflects various sorts of feelings towards these components, like the desire that they be realised or indifference concerning such an effect. Volition is a basic component of criminal liability. In order to be regarded a criminal, an act must derive from a free conscious choice, between alternative lines of action ... The plea for exemption due to lack of will is equivalent to the allegation that there is no opportunity to choose an alternative line of action".

Contributors referred to the development of the law on specific criminal intent, automatism and mental disorder. They posed the question whether, with the development of genomic knowledge, such exceptions to free will would have to be enlarged out of recognition that some, or much, or all, human behaviour is genetically determined.

(b) *Intellectual property law*

---

<sup>10</sup> A Carmi, "The Concepts of Responsibility Facing the Human Genome Project" *ibid*, Vol II, 77.

Perhaps the most heated session of the conference concerned the intellectual property implications of the Human Genome Project. It was here that conflict emerged between proponents of the project who saw patenting of genetic discoveries as a means of funding scientific advance and opponents who saw this as a danger to the conception of the human genome as part of "the common heritage of humanity". Dr J Craig Venter, President of the Institute for Genomic Research in the United States, contested a statement in the conference brochure that the issue was "the patenting of life"<sup>11</sup>:

"I do not consider genes to be living material. They are chemical entities which we can synthesise in the laboratory in a very short period of time. We can put all human genes in a test tube. That does not create life. Genes are essential for life, some more than others. Water is essential for life, too, but it is not life. ... Genes are not living material, and in terms of much of the discussion on patents, they are actually considered under the laws covering composition of matter, because, in fact, that's what they are, non-living matter".

The patenting of new processes for obtaining living organisms has been possible for some time, at least since microbiological methods were introduced in industry at the beginning of the 20th century. Only living matter was not

---

<sup>11</sup> J C Venter, "The Patentability of Genetic Discoveries" in Vol II, *ibid* at 123.

patentable. This was because it was regarded as something existing in nature<sup>12</sup>. Then in 1980, the Supreme Court of the United States upheld the patentability of a genetically engineered micro-organism<sup>13</sup>. The Court observed that patent law could no more determine the course of biotechnology research "than Canute could command the tides". That comment was prescient. Even since the Human Genome Project began, many of the now commonplace techniques of biotechnology have been discovered<sup>14</sup>. One patent lawyer from the United States remarked<sup>15</sup>:

"In the nature of things, scientific research is exponentially dynamic while the law is ponderously incremental. Inevitably, contentious issues arise owing to this difference in pace and philosophy. Such a collision between the HGP and patent law is now manifest. The advent of rapid c DNA sequencing and the recent attempts to patent the results thereof by the NIH and others has engendered controversy, confusion and uncertainty".

---

12 C Byk, "Patenting Human Genes" Vol II, *ibid* at 127.

13 *Diamond v Chakrabarty* 477 US 303 (1980).

14 J M Collins, "The Uncertainty Principle: Traditional Patent Law Doctrine, Its Impact Upon Genetic Discoveries and the Need for Reforms" in *ibid* Vol II at 145.

15 *Loc cit.* "NIH" is the National Institutes of Health in the United States.



Many commentators from developing countries expressed objection to the patenting of genes. They contested Dr Venter's assertion that they were not living matter. For them, they were *part* of living matter. They objected to the attempts to patent sequences, often without precise knowledge of the significance of the sequence under analysis. They asserted that patenting such matter breached the second of the three fundamental preconditions of patentability, viz novelty, utility and non-obviousness. For one Argentinian lawyer, the danger of patenting of gene sequences was obvious. It would permit industry in some (*developed*) countries effectively to take control of scientific and medical developments based upon components of human life common to all human beings in all countries. It would render humans in *developing* countries hostages to medical knowledge about the human species "owned" by particular individuals or corporations. Contributors were reminded that James Watson himself professed that he was "horrified" at the thought that gene sequences could be patented<sup>16</sup>. The American Society of Human Genetics also expressed itself to be "deeply concerned" at least where genes were patented in fragments of unknown utility. HUGO took the rare step of condemning the patent applications by NIH<sup>17</sup>.

---

<sup>16</sup> L Roberts, *Science* 184 (11 October 1991).

<sup>17</sup> L Roberts, *New Scientist*, 255, 913 (19 January 1992).

Subsequently, NIH withdrew most of its patent applications. However, the basic problem of the application of intellectual property law to this new area of science remains to be solved. Are the objections of the opponents simply naive and emotional outbursts which overlook past analogies, the huge costs of research, the potential utility of discoveries and the application of the texts of patent law? Or are they human reactions giving voice to a natural concern about control by powerful investors of inalienable attributes of naturally appearing elements of the human species?

(c) *Privacy and confidentiality*

Some of the most vigorous debates about genomic research have concerned privacy and confidentiality. Most legal systems provide protection for medical information concerning an individual. Such protection reflects an attitude to the intimacy and privacy of such information which goes back to the earliest recorded time of an organised medical profession, as reflected in the *Hippocratic Oath*. It binds health personnel to respect all information secured in the healthcare relationship. However, as against this general principle, some recent international elaborations have suggested the need for modification of this rule.

In particular, it has been proposed that genetic information should be shared as a form of familial property amongst family

members who have a legitimate and common interest in that information as it affects them all<sup>18</sup>. There have been analogous suggestions about a "higher obligation" to members of society in specific situations which may authorise, as an exceptional case, breach of the general principle of medical confidentiality. Such instances include cases of psychiatric knowledge which could be relevant to the protection of the community and cases involving HIV/AIDS status where the conduct of the patient is thought to put a partner or others at risk of which such persons would otherwise be ignorant<sup>19</sup>. With the development of genomic research, having great significance to other persons who are in a genetic relationship to the subject, questions are posed as to whether the law of privacy and confidentiality needs to be rewritten. These questions have been considered by the Privacy

---

18 World Health Organisation (WHO), *Guidelines on Ethical Issues in Medical Genetics and the Provision of Genetic Services*, Geneva, WHO, 1995, D C Wersz *et al* (eds) at 7.2.2. See Knoppers, above n 16, at 4.

19 *Tarasoff v Regents of University of California* 551 P 2d 334; 17 Cal 3d 425 (1976). See "Must the Doctor Tell?" (1996) 3 *JLM* 270; "Medical Duty of Confidentiality and Prospective Duty of Disclosure" (1995) 3 *JLM* 75; "HIV/AIDS and the Law" Need for Reform in Australia" (1994) 1 *JLM* 9; "Professionals and Confidentiality" (1992) 12 *Syd L Rev* 317. Reflections of this controversy appear in the *Pugmire* case in New Zealand. See "A Matter of Balancing Rights", in *Private Word* (News by the NZ Privacy Commissioner, Issue No 14 (March/April 1997) 1, 7-8.

Commissioners in Canada<sup>20</sup>, Australia<sup>21</sup> and New Zealand<sup>22</sup>. Each has proposed the need to develop new legal protections to reflect the sensitive balances which have to be struck between the preservation of medical confidences, on the one hand, and the legitimate interests of other persons, on the other.

Even the position of the subject (ie person tested) in the case of genetic information may be different from the interests of the patient in the healthcare relationship as we have known it. With advances in genomic research it will be possible to pinpoint with accuracy, even certainty, the development of medical conditions and the likely prognosis of them as well as the patient's life expectancy. The HUGO Ethics Committee, recognising this, has recommended that participants in human genome research should be given "choices to be informed or not

---

20 Privacy Commissioner of Canada, *Genetic Testing and Privacy* Ottawa, 1992.

21 Australian Human Rights and Equal Opportunity Commission, Privacy Commissioner, *The Privacy Implications of Genetic Testing* (Information Paper No 5), September 1996. See also B A Hocking *et al* "DNA, Human Rights and the Criminal Justice System" in (1997) 3(2) *Aust J Human Rights* at 208.

22 B H Slane "Whose Genes Are They Anyway? - The Use and Misuse of Human Genetic Information". Unpublished paper for a conference organised by the New Zealand Health Research Council, 26 July 1995.

with respect to results or incidental findings"<sup>23</sup>. Such choices should be respected out of recognition that some people would wish *not* to know that they carry a particular gene which will produce serious and possibly fatal genetic disorders. In a number of countries laws have already been introduced recognising this unusual aspect of genetic discoveries<sup>24</sup>.

At the moment, family members are generally treated by international privacy principles and most domestic laws on that topic as being amongst "third parties". Genetic information on the subject may not be given to third parties without the subject's specific and informed consent. However, more recent international statements have begun to recognise the possible need to develop a new sub-classification comprising family members in the same genetic group. The special position of these "third parties" has been recognised by HUGO, the World Medical Association and an Expert Group of the World Health Organisation<sup>25</sup>. In the United States, a Presidential Commission has expressed four conditions for the disclosure of genetic

---

23 HUGO, *Statement on the Principled Conduct of Genetic Research* (1996) 3(2) *Genome Digest* 3. See Knoppers, above n 16, at 7.

24 *Ibid*, at 8-9 for a collection of these laws.

25 *Ibid*, at 9-10.

information to family members without the subject's consent<sup>26</sup>. Similar principles have been adopted in a number of countries including Canada, the United Kingdom and the Netherlands. However, without legislative change, it is open to question whether the rules of common law and of equity as to confidentiality could be adapted by court decisions where a subject complained about disclosure of medical information even to a family member<sup>27</sup>.

Much attention at the Bilbao conference, and in the literature, is devoted to the disclose of genetic information to third parties, notably insurers and employers. The current Draft of the UNESCO *Universal Declaration* requires that the confidentiality of genetic data "associated with a named person and stored or processed for the purposes of research or any other purpose, must be protected from third parties"<sup>28</sup>. At a national level, the general principles safeguarding the subject's medical data from disclosure to insurers or employers without

---

26 They were (1) that there was a real attempt to secure voluntary consent of the subject; (2) that there was a high possibility of harm if the information was withheld; (3) that the harm would be serious; (4) that appropriate precautions were taken to limit the genetic information disclosed.

27 Cf *Breen v Williams* (1996) 186 CLR 71; (1994) 35 NSWLR 522 (CA).

28 Art 9.

consent remains the norm<sup>29</sup>. Some countries have even produced statutory prohibitions to forbid contractual obligations which would give third parties a free hand<sup>30</sup>. At least one country had adopted a voluntary moratorium on access to genetic information by employers and insurers<sup>31</sup>. But in the absence of legislation, the employee or insured is extremely vulnerable to pressure to "consent" to permitting indirect access to the entirety of the subject's genetic data or to specify data. There is a significant question for legislative decision here. It is presented by a consideration of those laws which have opted for a high wall around access to ambit genetic information. Yet it is difficult, in principle, to exclude precise and accurate data whilst at the same time accepting the conduct of a battery of old-fashioned medical checks of the kind that have long been preconditions to certain forms of employment and particular insurance coverage.

A significant question arises as to the rules which should govern genetic research performed on anonymised data. In 1992

---

<sup>29</sup> M D Kirby, "OECD Cryptography Guidelines in Context" (1996) 3 *Privacy Law and Policy Reporter* 121; (1997) 7 *Journal of Law and Info Science* at 137.

<sup>30</sup> Belgium, Norway and Denmark.

<sup>31</sup> France.

the HUGO Ethics Committee approved the principle that DNA sequence data "should be openly available to the scientific community"<sup>32</sup>. The experts of the World Health Organisation agreed to access "provided that strict confidentiality is observed or that identifying characteristics are removed"<sup>33</sup>. This disjunctive formulation might be questioned by some privacy guardians. In some countries anonymised data is approved for research as necessary and useful to combat disease<sup>34</sup>. However, in other countries strict guidelines require that even anonymous genetic material should not be used without first giving the subject the opportunity of objecting<sup>35</sup>.

The position of the State and its rights of access to genetic information must also be clarified. The draft UNESCO Declaration illustrates the link between genetic information and the responsibility of the State. The State must prevent discrimination on the basis of genetic characteristics<sup>36</sup>. Yet at the same time it is obliged to foster dissemination of knowledge

---

32 Knoppers above n 16, 17 quoting HUGO *Position Statement on cDNA Patents* (1992).

33 WHO Report, above n 17.

34 For example Switzerland, cited Knoppers above n 16, 19.

35 The Netherlands and Quebec, cited Knoppers *ibid*, 20.

36 Art 8.



concerning the human genome<sup>37</sup>. Presumably these provisions can be reconciled by anonymising the data. A private draft for a *Genetic Privacy Act* in the United States proposes that, save for an exception for law enforcement, no one might be compelled to disclose genetic information to the State, including in legal proceedings<sup>38</sup>. The spectre of Big Brother, with the ultimately perfect universal identifier based upon each individual's unique genetic characteristics, concerns some observers. Will this become, in the next millennium, the ultimate medium for the control of the individual to the diminution of freedom?

In a country such as Australia, where comprehensive privacy legislation has not been enacted and where its extension has recently been rejected<sup>39</sup>, the absence of enforceable legal protection for privacy may present certain problems. It may diminish the power of the individual, in a vulnerable position, to negotiate with the State or with third parties who wish to have

---

37 Art 16.

38 *Genetic Privacy Act* proposal see G J Annas and L H Glantz and P A Roche Proposal (Boston, 28 February 1995).

39 See G Greenleaf, "Commonwealth Abandons Privacy - For Now" (1997) 4 *Privacy Law and Policy Reporter* at 1 (April 1997). Cf Merritt, "The Problem for Business: No Privacy", *Australian Financial Review*, 17 April 1997 at 14. *Ibid*, "NZ Cuts Back Privacy Laws to Suit Australia", 21 April 1997 at 9. See also M Kingston, "Push to Protect Privacy of Files" in *Sydney Morning Herald* 28 April 1997 at 1.

access to the individual's data. But equally important may be the problems presented for the movement of data in, through and out of such a country because it is unable to demonstrate to outsiders an established and effective legal regime. Medical tradition, guidelines and recommendations of the privacy guardian will go part of the way towards reassuring those concerned about the confidentiality and privacy of genetic information. However, it seems likely that the heightened potential of the combined technologies of genomic research and informatics, together with the international movement of personal data, will eventually require legislative standards in Australia. Indeed, it has recently been suggested that it will be business interests rather than privacy advocates which ultimately prove the major lobbying group in Australia to this end<sup>40</sup>.

#### INTERNATIONAL ACTION

The foregoing represents some only of the issues presented to the law by the present and likely future developments of genetic research. Some of the questions may safely be left to be sorted out within the municipal legal systems

---

<sup>40</sup> See Merritt and Kingston, above n 38. See also "70 per cent of Companies support privacy laws - Price Waterhouse Survey" (1997) 4 *Privacy Law & Policy Reporter* 21.

of each country. Thus, the implications of the genome for the criminal law, for privacy and for confidentiality are, for the most part, of purely domestic concern. Not so in relation to intellectual property law which has transnational application. Other topics raise even more acutely the requirements of international cooperation. They include the possible imposition of binding legal limits on genetic experimentation deemed bizarre or unacceptable to the human community<sup>41</sup>. In such matters, unless there were an effective international response, legal regulation by particular jurisdictions would be inadequate and ineffective.

There are substantial obstacles to achieving international cooperation and binding international law on this topic. One of the chief obstacles is the differing moral perspectives that seem to deny the creation of a single attitude to the complex and sensitive questions raised by genomic research. An even more powerful obstacle lies in the differing economic interests of different nations. Thus, those few which are at the forefront of genetic research may have a different perspective of the needs of property law than those which are not. Lethargy and the

---

<sup>41</sup> F Mantovani, "Genetic Manipulation, Legal Interests Under Threat, Control Systems and Techniques of Protection" (1994) 1 *Law & the Human Genome Review* 91.

complexities of consultation and development of international principles by hybrid bodies, comprising scientists and lawyers, present a third impediment which should not be under-estimated. The sheer complexity of the science, the speed at which research is progressing, the decentralised nature of the Human Genome Project and the cumbersome machinery of national and international lawmaking make it difficult to secure consensus about what should be done.

Nevertheless, some regional and international initiatives have been taken. They include the establishment by HUGO itself of its international Ethics Committee. This body has produced a number of recommendations, the most relevant of which is the *Statement on the Principled Conduct of Genetic Research*<sup>42</sup>. Of course, this document, like others produced by HUGO, has no binding legal force. Yet the lesson of international law is that the principles tend first to be established in interested bodies working in the intellectual milieu. Only later, are they followed through by States and by international organisations.

The other major international response to the Human Genome Project lies in the work of the International Bioethics

---

42 (1996) 3(2) *Genome Digest* at 3.

Committee of UNESCO. That body, over the past two years, has been preparing what is titled a *Preliminary Draft for a Universal Declaration on the Human Genome and Human Rights*<sup>43</sup>. A penultimate edition of that document was settled by an international group of lawyers in which I participated in Paris in December 1996. That Draft was, in turn, scrutinised by a committee of government representatives in late July 1997. It may be expected that the final document will be presented to the General Conference of UNESCO in Paris in November 1997.

If this Declaration is adopted, it will be recommended to member countries of the United Nations. It is not unusual for international treaties to be preceded by non-binding documents such as Declarations. So it was with the *International Covenant on Civil and Political Rights*. It grew out of the *Universal Declaration on Human Rights*. It is therefore important that the *Universal Declaration on the Human Genome and Human Rights* should be as accurate and as useful a statement of basic principles as can be produced at this time. The draft opens with the general proposition that the human genome is the common heritage of humanity. It contains articles concerning research on the human genome, the rights of the persons concerned, the

---

<sup>43</sup> UNESCO, Revised Preliminary Draft of a *Universal Declaration on the Human Genome and Human Rights* (CIP/BIO/97/318).

conditions for the exercise of scientific activity in relation to the genome and various duties of cooperation in relation to genomic research. It concludes with specific provisions on the promotion and implementation of the Declaration, once adopted.

Amongst the articles concerned with research is Article 5. In its current form it states:

"No research or applications should be allowed to prevail over the respect for human dignity and human rights, in particular in the fields of biology and genetics".

Amongst the articles dealing with the rights of persons are the following:

"Before ... research, treatment or diagnosis is done, the prior, free and informed consent of the person concerned shall be obtained or ... that of a representative guided by the person's best interests".<sup>44</sup>

No one shall be subjected to discrimination based on genetic characteristics that is intended to diminish or has the effect of diminishing human dignity or impairing the right to be treated equally".<sup>45</sup>

Genetic data associated with a named person and stored or processed for the purposes of research or

---

44 Art 6(b).

45 Art 7.

any other purpose must be held confidential and protected against disclosure to third parties<sup>46</sup>."

In the way of these things, the law is now beginning to respond to the challenge of the Human Genome Project. As usual, the response is slow, cumbersome and largely uncoordinated. There is no single body within the Australian legal system which is considering the specific legal and ethical implications of genomic research. No one is preparing a comprehensive legislative response that will eventually be needed. In the international community work towards the development of international law is progressing. But the basic problem remains. Science rushes ahead. Legal machinery ambles slowly along - sometimes presenting its solutions years later when the nature of the problem to be solved has changed radically.

It is not too much to say that the Human Genome Project presents a potential to alter the very concept of what it is to be a human being. That is why it is of such great significance for human rights. It also explains why it is of such importance to every legal system. It is time that lawyers became aware of it and of the importance of responding effectively to its challenge.

---

46 Art 8.