LAW AND THE HUMAN GENOME REVIEW

MEETING OUR FRIEND, THE GENOME

The Hon Justice Michael Kirby AC CMG

LAW AND THE HUMAN GENOME REVIEW

MEETING OUR FRIEND, THE GENOME*

The Hon Justice Michael Kirby AC CMG**

ENCOUNTER WITH THE GENOME

My qualifications to address this topic arose out of my work on the International Bioethics Committee of UNESCO in Paris and the Ethics Committee of the Human Genome Organisation (HUGO) in London.

Each of these bodies is considering the ethical, social and legal questions which arise out of genomic research and the genetic engineering to which it gives rise. The UNESCO Committee is busily preparing a draft of a *Universal Declaration*

---

* Based on an address to the Bioethics Advisory Panel of the Australian Catholic Bishops' Conference meeting in Canberra, Australia, 15 September 1997.

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

on the Human Genome and Human Rights. This will be considered by the General Conference of UNESCO in Paris in November 1997. The UNESCO Committee has been consulting widely about its terms. The draft has been modified as a result of these consultations. It is important to take this process seriously. It is not unusual, in international law, for a draft Declaration to give rise to a binding treaty. It was in this way that the *Universal Declaration of Human Rights* in 1948 ultimately led to the *International Covenant on International Covenant on Civil and Political Rights* and on *International Covenant on Economic, Social and Cultural Rights* in 1966.

DIFFICULTIES IN THE PATH

When we talk of the genome, we are talking about nothing less than the future of the human species. It is therefore a topic appropriate to international consideration and, eventually, international law. However, the difficulties of securing a consensus about such a topic are all too obvious. They include:

(1) The different religious, cultural and legal traditions which must be brought into harmony.

(2) The different economic interests of countries involved in the development of therapies and other countries, disparities in attitudes to intellectual property protection

and in sheer investment and the potential to make profits arising from these scientific developments.

(3) The disparate attention given to these subjects in different societies of the world and the inclination of local law makers to put such matters to one side, preferring more manageable local controversies with grater immediate political attraction.

(4) A feeling of resignation in some quarters arising out of the belief that the tide of science and technology cannot be held back by any law. That any effort by law to prevent scientists from experimenting is bound to fail and so should not be attempted. And a feeling on the part of some that, in any case, such scientific progress is bound, in the long run, to be for the betterment of humanity and is, in any case, a product of the inherent skills and abilities of human beings and thus an extension of humanity not something alien to it.

The Human Genome Project is the largest cooperative scientific activity in history. It is greater by far than the Manhattan Project which led to the development of the atomic bomb. Yet its implications are in some ways similar. It is important that the Project should be developed with a full understanding of the ethical, social and legal consequences. This is recognised by HUGO itself. It gives the impetus to the

work of the HUGO Ethics Committee and also to that of the International Bioethics Committee of UNESCO. Yet the reality is that the funds devoted to the ethical, social and legal consequences of genomic research are but a tiny fraction of those devoted to the scientific research itself. Alas, that is usually the case for ethics committees.

LEGAL & ETHICAL IMPLICATIONS

There are many practical implications which the unlocking of the mysteries of the genome will have for humanity. They include:

(1) *Medical therapies:* The discovery of the genes which "trigger" various genetic diseases which, in turn, constitute a large part of the causes of the suffering of humanity. For example, the gene which expresses the serious affliction of Huntington's disease has been chartered on the genome. Its discovery permits the conduct of extremely accurate tests which identify those who carry and those who may transmit this genetic disorder. That knowledge would, theoretically, in combination with ante-natal tests and abortion, permit the future elimination of or certainly a reduction in the numbers of carriers of Huntingtons. Is this desirable? Can it be distinguished from the abortion of a foetus with Down syndrome? Where does this process of medical elimination begin and end? Is there a less life-

destructive means of using the genetic information to delay the onset or diminish the symptoms of Huntington's disease whilst respecting the life of a person born with that "defective" gene or others like it?

(2) *Criminal Law:* For the lawyer, the discovery of genetic causes of disorders and antisocial conduct may have implications for the future of criminal law. The criminal law is ordinarily built upon the hypothesis of free will. For the crime to be proved it is normally necessary to establish both the act of the accused and the will (*mens rea*) occasioning that act. What are the implications of discovering that, in some cases and for some people, the act is practically no more than the product of a genetic characteristic? Can we persist with the unquestioned hypothesis of free will in the face of increasing scientific knowledge which casts doubt upon it?

(3) *Privacy & confidentiality:* The basic rule of the healthcare professions has long been respect for the confidences of the patient. This rule goes back to the Hippocratic Oath. It existed in ancient civilisations. But when a disorder is of a genetic characteristic, is the "patient" the individual or the entire family? Does a family in such circumstances have a right to override even the wishes of the patient and to secure data about the patient relevant to genetic features which may be of relevance to them all? Does a

patient have a right *not* to know the determinants of future medical conditions?

(4) *Third party interests:* This last question leads on to the rights of third parties. Should an employer have a right to require an employee to submit to genetic testing to show, with greater perfection, the likely future health status of the employee? Should an insurer be entitled to secure a genetic profile of the insured? Until now insurance has involved the sharing of risks within the community arising out of medical conditions which are largely unpredictable. If many conditions can be predicted with perfect or near perfect accuracy, would that not shift the scales unfairly to the advantage of insurers? Yet, given that insurers may require those seeking insurance to submit to old-fashioned medical tests, is it sensible to close off knowledge of the best medical information that may be available in the future, as by genetic tests?

(5) *Intellectual property:* One of the key issues affecting genetic research concerns the desirability of permitting the patenting of human genes or their sequences as the basis for therapeutic applications. Of course, in every country, the patentability of such matter depends upon the terms of the local law on intellectual property protection. That law is itself, normally, the product of national legislation and is generally influenced by international law. At conferences

on the genome, strong views are quite commonly expressed by participants from developing countries and elsewhere about this topic. Critics of intellectual property protection urge that the human genome is the common property 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. They point to the fact that Watson and Crick, who first described DNA, and began mankind's journey to the genome, never attempted to secure commercial advantage for themselves from their discoveries. I will return to this topic.

(6) *Human rights:* An important element in the UNESCO Committee's work is the attempt to reconcile the development of genetic technology and research on the human genome with fundamental human rights and human dignity inhering in every individual. Take the present Article 6 (formerly 8) of the draft UNESCO *Declaration:*

> "No one may be subjected to discrimination based on genetic characteristics that is intended to diminish or has the effect of diminishing human rights, fundamental freedoms and human dignity".

The eugenics movement earlier in this century was a doubtless well-intentioned attempt to eliminate, in effect, genetic characteristics in the gene pool deemed undesirable

to society. For the most part, the movement was targeted at so-called "mental defectives". However, it affected (as we now know) large numbers of persons who suffered quite modest mental impairment or none at all. The eugenics movement had strong supporters in the Nazi Party in Germany. It led to the efforts to "cleanse" the German population of so-called undesirables. That effort notoriously attacked people for their genetic identity: specifically their Jewish, gipsy or other ethnicity. But it also imposed its will upon others who presented genetic or other conditions deemed undesirable to the Nazis: homosexuals, the physically disabled and the mentally impaired. The terrible experience of the Holocaust stands as a warning to humanity of what can happen when people with a stereotyped view of human existence gain totalitarian political power. Nor should we consider that this is a problem confined to history books. It endures into our own time. We have recently seen it in the ethnic cleansing which has taken place in Serbia, Bosnia, Rwanda and Zaire. At the outset of the genomic revolution in medicine, therefore, it is timely to insist that the developments should occur in a context of respect for fundamental human rights and human dignity. The Churches and religious faiths throughout the world are well positioned to lend their support to the effort of the United Nations to insist upon such preconditions and to secure their reflection in the laws of all nations.

PATENTING GENES

One advantage of my appointments to the UNESCO and HUGO Committees is that I have the opportunity and obligation to read scientific literature. In a recent issue of *Science* magazine[1], the heat of the debate concerning intellectual property law protection of genes and gene sequences is illustrated. The journal records that the National Academy of Sciences in the United States on 14 June 1997 caused its President, Dr Bruce Alberts, to write to the Director of the US Patent and Trademarks Office about this problem. Particular concern was expressed by the Academy about the willingness of the Office to grant patents on mere fragments of human genes - particularly those known as Expressed Sequence Tags (ESTs). These can be used to identify full genes. ESTs are relatively easy to capture. However, they reveal little about the biology which they control. Dr Alberts fears that patenting ESTs - a few have been patented so far and thousands of applications are pending in the United States - could create a tangled maze of property rights which actually impedes scientific research:

---

1 *Science,* vol 277, 4 July 1997 ("Academy joins debate over DNA patents").

> "It would be sad indeed if patent policies diminished the pace of discoveries or wealth of practical applications".

The National Academy of Sciences appealed to the United States Patent Office to consider granting DNA patents only where "real world" applications were described in the patent application or detailed information about the gene was already known or supplied by the applicant.

The appeal by Dr Alberts parallels one made in March 1997 by the Director of the National Institutes of Health in the United States, Dr Harold Varmus. He wrote to the United States Patent Office after an official of that office had given a speech reportedly favouring patents on ESTs as diagnostic or research probes[2]. Dr Varmus' concern was that such patent policies might block research and development on more important discoveries such as complete genes and thus stifle beneficial gene-based therapies.

The response of the US Patent Office to pressure of this kind is predictable. It simply says that it will apply the law. If the Congress of the United States wishes to restrict the patenting of living matter, that is for the Congress to say. There

---

2 *Science,* vol 277, 11 April 1997 at 187.

are many in the United States and elsewhere who assert that patenting of genomic discoveries - and even more so gene sequences whose effects are not fully known - should have no place in intellectual property law. Such matter, they argue, belongs to all humanity. No individual or corporation should make a private profit from living matter. However, there are difficulties in such assertions so far as the law is concerned. "Man-made" micro-organisms have been patentable in the United States, at least, since 1980[3]. The potential for medical therapy of developments arising out of exploration of genes is enormous. The economic profits riding on such discoveries and their therapeutic consequences run into billions of dollars. The investment in research said to warrant intellectual property protection is likewise extremely expensive. In these circumstances, striking the right balance between respect for the common genomic heritage of humanity, protection of people in developing and other countries so that they too gain the benefits and assurance of a fair economic return to scientific investors is not at all easy to achieve[4].

---

3 *Diamond v Chakrabarthy,* 447 US 303; 65 L Ed 2d 144; 206 USPQ 193 (SC 1980). Cf *Ex parte Latimer* 46 AG 1638, 1640 (1889); *Funk Brothers, Seed Co v Calo Inoculant Co* 333 US 127 (1948). *Biogen Inc v Medeva plc* (1996) 36 IPR 438 (HL); *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 122 ALR 141 (Fed Ct, Aust).

4 J C Venter, "The Patentability of Genetic Discoveries" in BBV Foundation (Spain) *The Human Genome Project: Legal*

Footnote continues

THE GENOME & EVOLUTION

In another article in *Science* magazine[5], the authors appeal for the development of a new view of evolution arising from the contemporary study of genes. It was in the late 1970s that scientists at Harvard University began to focus on genes in order to understand evolution, including human evolution. But it was not until the mid-1980s that the new tools for studying developmental genes began to generate the data that could explain how such a remarkable myriad of living creatures found on earth - vertebrate and invertebrate - could have developed, presumably from the rudimentary living cells present at the beginning, in the comparatively short period of the Earth's existence. Recent research has shown a number of genes to be substantially common across a very wide range of animals. They have similar or related functions across completely disparate species. For example, a gene which may cause no more than a photosensitive area in a very primitive animal, may stimulate the development of a compound eye in an insect or the highly developed eye of a mammal, such as a human being. The same

---

Aspects, Vol 2 at 123; C Byk, "Patenting Human Genes", *ibid,* at 127.

5 E Pennisi and W Roush, "Developing a New View of Evolution", *Science,* vol 277, 4 July 1977 at 34.

or a very closely similar gene can operate in a related fashion across vast periods of evolutionary history. This discovery has obvious relevance to the patenting of human genes. If the same, or a closely similar, gene in an animal has the same, or closely related, functions across a very wide range of living species, and it is suggested that the patenting of human genes is somehow morally repugnant or socially undesirable, would a distinction between the human and non-human gene be a way out of this dilemma? Or would the recent discoveries indicate that if human genes are not to be patentable then no genes of living matter (human or animal) may be patented?

The exploration of the genome has also offered a possible answer to a dilemma about evolution which has puzzled biologists for some time. If evolution proceeded by a process of situations in the DNA chains of particular species, our current knowledge of mutation rates make it absolutely clear that 4 billion years (the Earth's estimated existence) is simply not long enough to arrive at the richness of the species now extant. If, however, species may use a modular genetic approach to building new genes and gene functions, this would explain the speeding up of the process of genetic change. A comparison has been drawn between one team of computer programmers starting from scratch to design a whole series of programmes to carry out a variety of widely different functions while another team starts with a number of already developed programme parts

with known functions and whose task is merely to put the modules together in new ways[6].

AN ADJUNCT TO MEDICINE OR A NEW WORLD?

At the brink of a new millennium, the fundamental question which is presented by genomic research is this. Should genetic research be seen as no more than an adjunct of improving the health of the current human species? Should it be limited by law, and otherwise, to removing this or that disease from human beings but keeping them in every other way basically as they are? In short, should genomic research and genetic engineering be viewed as nothing more than an adjunct to established medical science? To provide tests for genetic maladies? To provide the foundation for treatment of genetic disorders? According to moral conviction and law, to provide a basis for eliminating foetuses evidencing grave genetic disabilities or potentialities?

These questions are hard enough. But the lesson of contemporary science and technology is that to foresee the future we must engage in a constant process of leaps of the

---

6 Letter to the author from Dr J R Coulter, Adelaide, 29 August 1997.

imagination. It seems unlikely to me, that genomic research will stop as a mere adjunct to current medicine. If it becomes possible to alter the human species in particular potentialities, are we really talking about an aid to the human species? Or are we on the brink of considering something which may actually change the human species itself? A kind of scientific speeding up of evolution of the kind that, somehow, has certainly occurred naturally in the past?

If you alter a large number of features of the human species - eliminating Huntington's disease, expelling the potential to Alzheimer's, excluding Parkinson's, removing Down Syndrome - where does the end of this path lead? Certainly. it leads to the reduction of much human pain and misery which presently affect patients and their loved ones. But taken to extreme, may it not also lead to a change of what it is to be a human being? Add to the exclusion of serious genetic illnesses the elimination of baldness, the removal of a potentiality to obesity, the exclusion of undue height or undue shortness and you are well on the way to redesigning the human species. The experiments of Dr I Wilmut and his colleagues[7] demonstrate that

---

7 "Clone mammals ... clone man?", *Nature*, vol 380, 13 March 1997 at 119. Note that the Director-General of UNESCO (Prof Federico Mayor) In February 1997 called for a universal prohibition of cloning of human beings. See Unescopress No 97-29 (28 February 1997).

sheep embryonic eggs can reproduce the nuclei of differentiated cells, enabling the cells to develop into any type. This showed that it is possible to envisage in the near future the cloning of adult mammals in a completely asexual fashion. If it can be done with sheep, given time, it can undoubtedly be done with humans. And what will stop it?

FORBIDDEN TERRITORY OR THE NEXT STEP FOR HUMANITY?

Writers in the scientific literature talk of our era as one where human beings are passing pass from Genesis to genetics[8]. Obviously, the developments of scientific knowledge have large implications for religious faiths which accept as doctrine the teachings of a Holy Book. As scientists and technologists present their discoveries, it becomes necessary for religious teachers and theologians to explain and justify the revealed scientific truths, reconciling them with the previous understanding of scripture and the teachings of the religious faith as they were expressed in earlier times when the scientific truth was unknown.

---

8 Ted Peters, "From Genesis to Genetics" in *New Scientist,* 15 March 1997 at 42.

In the summer of 1993 a team of researchers at the United States National Cancer Institute announced that they had evidence linking male homosexuality to a gene in the region of the X chromosome[9]. If it were determined (as looks increasingly likely) that sexual orientation is indeed a genetic phenomenon - and thus beyond the choosing of a "wilful" individual bent on a particular :life-style" - prima facie to discriminate upon that basis would be as morally impermissible, and even repugnant, as to discriminate upon any other genetic basis. Gender, for example. Race or skin colour. A pre-programmed disease or characteristic over which the individual has no control. It might be said that, exceptionally, sexuality is a genetic condition that the individual should just try to struggle against and to deny. It might even be said that this is one genetic condition that should be eliminated in whatever way possible. Indeed, the former Chief Rabbi of the Commonwealth of Nations, controversially, suggested that this should be done to eliminate homosexuals "for a therapeutic purpose"[10]. His suggestion provoked cries of outrage from Holocaust survivors and other Jewish students and intellectuals. But if it is part of the genome of our species, an urgent moral question is plainly presented. By what right can we say that it is

---

9 *Ibid,* at 42.

10 Lord Jacobivitz, letter to *Jewish Chronicle,* (UK), July 1993.

not part of Nature's - or God's - great purpose? That purpose, as the Church has taught, is not always clear to us, mere mortals. We see through a glass darkly. But will it be the Human Genome Project as it develops that helps us to see[11]:

> "Face to face: now I know in part, but then shall I know even as also I am known".

In saying this I do not suggest for a minute that discrimination against people, male or female, on the grounds of their sexual orientation is morally wrong and contrary to universal human rights, whatever the origin, genetic or non-genetic, of human sexuality[12]. However, if it be genetic and therefore entirely natural, it presents, I suggest, a special problem to religious faith which for hundreds of years have taught (and other still teach) that homosexuality is unnatural and morally repugnant.

Yet an even more fundamental question than this is presented. For all those (including in the Churches and at the

---

11 1 Corinthians 13 xii.

12 See *Toonen* and *Australia,* Communication to the Human Rights Committee of the United Nations (Cm 488/1992) noted (1994) 5 *Public Law Review* (Aust) 72. Cf *Dudgeon v United Kingdom* (1981) 4 EHRR 149; *Norris v Republic of Ireland* (1988) 13 EHRR 186; *Modinos v Cyprus* (1993) 16 EHRR 485.

United Nations and its agencies) who urge that we should keep genetic alteration as an adjunct of human existence as it now is, there are others who dispute. For those disputants, genetic discoveries arise out of the intelligence of human beings. That intelligence is given by Nature - or God - to discover reality as it exists. The genome and DNA existed for millennia before we discovered them, in our generation, through the intelligence of Watson and Crick and their followers.

If the genome is discovered, and is there, it is, arguably, the outgrowth of a human development which was ordained for this era. That development will itself not stand still. It will take us further down a path that might indeed be called "evolutionary" which is itself the product of our human intelligence. It might be a path that involves leaps of evolutionary history - a kind of fast forward of the kind that seems somehow to have occurred in the past. It may even be a path that involves a reconsideration of what it is to be a human being and what, if any, are those characteristics of the human species which are to be regarded by scientists as forbidden territory. In any case, no law can stop science and technology completely. There will always be a small corner of the world which will give sanctuary to the free spirit of the enquiring scientist and the technologist at work in the laboratory. Especially will this be so if profits dangle tantalisingly at the end of the endeavour.

If the Churches take a different view, they must explain that view and argue for it. It seems unlikely that dogmatic assertion or even scriptural texts will win the argument today. Reason and a return to fundamental wisdom may help in the persuasion as may an appeal to universal notions about the things which all human beings share in common. But if the Churches do not join this debate it will surely go by default.

INFORMED DECISIONS

This is why the work of the UNESCO International Bioethics Committee and the Ethics Committee of the Human Genome Organisation is so important. For a lawyer, like a theologian, it is somewhat intimidating to stand staring at the brink of a new era of genetics. The scientist and the technologist rush ahead. The lawyer, the ethicist and the theologian amble slowly along, their heads full of puzzlement at the problems which seem so insoluble. To do nothing is to make a decision. It is to permit science and technology to take our species where they will. We know enough now to realise that there are quandaries here for human beings to answer. The question is whether we will have the will and the means and the wisdom to provide the answers.