Human Genome Project - Legal Issues

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A SCIENTIFIC REVOLUTION

It is the fate of this generation of lawyers to live in a time of the most extraordinary scientific advances. When the twentieth century is viewed in retrospect, it is likely that the assessment of its most significant developments will concern science - particularly the discovery of the atom and of nuclear fission, the advent of informatics and the elucidation of the structure of DNA. Science and its sibling technology are the great engines of our time. They present global problems and promote global solutions. Lawyers, who serve society will have to respond to these challenges. They will have to do so at an international, regional and local level.

Lawyers will only be able to respond efficiently if they are aware of the developments which are occurring and if they familiarise themselves with at least the rudiments of the science and technology which those developments reflect. Here's the rub. So rapid are the advances and so sophisticated and complex are the details of the science and the explanation of the technology, that even an informed lay person finds it difficult today to comprehend exactly what is occurring. I recently attended in Brisbane the annual meeting of the Human Genome Organisation. Its opening keynote address was delivered by Dr Craig Venter, one of the world's leading experts in the sequencing of human genes. I understood about ten percent of what he was saying. Perhaps lay people attending legal conferences feel much the same. But I was reassured to find that many of the scientists present were in much the same boat as I was. Inescapably, genetics, and the technology that has grown to respond to scientific advances, have jumped ahead of ordinary human comprehension. Yet the outcomes of genetics are vital to our society, its democratic institutions, its laws and even to the human species itself. These are not, therefore, issues that can be left to scientists alone.

An indication that lawyers are beginning to wake up to the great significance for their discipline of the revolution in human genetics is found in a recent special issue of the *Modern Law Review,* published in Britain[2]. Instead of the usual fare of problems in the law of negligence, public law and statute law, ten essays are presented which review some of the major implications of the genetic revolution for the legal discipline, both internationally and nationally.

Specific legal topics identified in the *Modern Law Review* include (1) how regulation will be possible in the fast moving genetic revolution[3]; (2) what are its implications for human dignity and human rights[4]; (3) should the law condone interventions in the human genome which alter the genetics of living persons and future generations[5]; (4) what will be the

implications of these developments for family law[6]; (5) what consequences will they present for insurance, given the potential of genetic data to remove entirely predictive doubts about an insured's likely health prognosis[7]; (6) will the criminal law need to be revised in so far as it posits the free will of the individual? If the conduct of some persons stems from their genes, should this be exculpation, a defence or at least mitigation[8]; and (7) how will intellectual property law apply to genetic discoveries? Should scientists, and those who support them, be entitled to the protection of patents in respect of their work or is the genome and its incidents an inalienable part of the common heritage of humanity so that, however temporarily, it cannot be "owned" or "controlled" by any person or corporation however big their investments?

These subjects give a clue as to a number of the principal issues which lawyers now, and in the future, will have to examine as the genetic revolution continues to unfold. In Britain, the former Conservative government established the Human Genetics Advisory Commission. It is a high powered affair. One of the first essays in the *Modern Law Review* is by Sir Colin Campbell, Chairman of the Commission. He describes the way in which the Commission is obliged, under its terms of reference, to keep under review scientific progress at the frontiers of human genetics; to report to government and society on issues arising from the new developments that can be expected to have wider social, ethical and economic consequences; and to advise on ways to build public confidence in, and understanding of, the new genetics[9]. Sir Colin describes the endeavour to bring the complex issues to a wide audience in Britain and to ensure that the Commission's advice will mirror the broad range of opinion which these complex and sensitive questions evoke.

There is no such body in Australia. The closest we get to it is the Australian Medical Health Ethics Committee which is chaired by Professor Donald ChaLmers of the Law School of the University of Tasmania. There is insufficient public debate in Australia about the genetic revolution. Most people, including politicians, opinion leaders and the overwhelming bulk of the legal profession, must depend upon articles in the popular media for the rudiments of their knowledge[10]. Inevitably, such articles tend to concentrate on highly contentious and sometimes sensational issues such as the potential for reproductive cloning of a human being. The full picture is much more complicated. Before embarking on a few of the legal themes, let me sketch, as briefly as I can, some of the general scientific background which it is essential to know.

A SCIENTIFIC PRIMER

In 1953 two scientists, one from the United States and the other from Britain, Drs J D Watson and F H C Crick, published in *Nature* an essay that was to revolutionise our understandings of the basic forms of life[11]. Not just human life, but all forms of life. They provided a model for understanding the process of the transfer of genetic information between generations of the same organism.

This article 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. In 1866 the Austrian botanist and monk Grigor Mendel described the basic

laws of hereditary based on his experiments with cross-breeding of pea plants. His findings, published in a local journal, were at first ignored. Early this century biologists experimented with the fruit fly to reveal that some genetically determined traits were linked to the particular sex of the fly. These experiments suggested that inherited traits could reside on chromosomes, tiny threads within the nucleus of cells that appeared to be constantly dividing.

The early, primitive discoveries came together, and were explained, by Watson and Crick. They proposed that the basic determinates of living matter were to be found in DNA, in a structure described as a double helix. DNA was the molecule which carried the genetic code that would unlock the truth known instinctively by farmers and described in a primitive, but accurate, way by Mendel. From that moment to this, the search has been undertaken to explore the DNA and to unlock its remaining secrets.

The coincidental development of information technology, which in large part had grown out of defence operations and miniaturisation required for the space race (in their turn propelled by nuclear rivalry) presented the technology which would help scientists to perform the analysis necessary to understand the control mechanisms residing in the DNA. In 1990 a group of scientists decided that they should cooperate in sequencing the entire human genome. The genome represents the complete set of genes and chromosomes of the organism. The intention of this project, which became known as the Human Genome Project, was to construct a "high-resolution genetic, physical and transcript map" of the human being with, ultimately, a complete sequence of the genome. The outcome is the largest research project ever undertaken. The object was to determine the location of the estimated 100,000 human genes. The purpose was to provide "the source book for biomedical science in the 21st century [which would] be of immense benefit to the field of medicine. The object is to understand and eventually treat many of the more than 4,000 genetic diseases that afflict mankind, as well as the many multi-factorial diseases in which genetic predisposition plays an important role"[12].

The 100,000 genes appear in the double strand of DNA which is of enormous length. One scientist[13]attempted to describe to a non-legal audience the dimension of the challenge:

The sequencing of genes is performed by automatic machines of the most tremendous computer power. More than 50,000 genes have already been identified. For a majority of these, the function is still unknown[14]. As described by Dr Venter in Brisbane, the acceleration of the process of sequencing, with new techniques and computers of still greater power, means that, in all probability, the fifteen year time scale originally envisaged for the completed project is likely to be met. But this will not provide us with the key to understanding the mass of data about the genes so identified. Our position will be comparable to "the possession of a very large encyclopaedia written in an unknown language". Yet gradually, in the manner of the *Rosetta Stone,* the genetic language will be deciphered. Patterns will be discovered which are distinct and which exist only in a person with known genetic conditions, such as Huntington's Disease or Alzheimer's Disease, Cystic Fibrosis and so on. Similarly, distinct patterns will be seen in the case of persons who are bald; those who are tall; those who have blue eyes; those who are disposed to obesity or other

genetic propensities. One by one, and by a process of reasoning, experimentation, logic and elimination, the encyclopaedia will be rendered into a language which human beings can understand. This is the mighty challenge of the Human Genome Project. It is already happening. Scarcely a week goes by without some new discovery which allows scientists to point to a particular gene or sequence of genes as being the cause of, or related to, the presence of some genetic condition in the human subject.

Gone will be the uncertain knowledge of Mendel. The reason for inherited traits, including painful, debilitating and also fatal illnesses will become known. Large funds are being devoted, principally in the United States of America but also in Western Europe, Japan and some in Australia, to unravelling the secrets of the human genome. The only analogies which spring to mind in the human imagination are those which concerned the mapping of the earth's surface by the great cartographers of the 15th and 16th centuries and the unravelling of the secrets of the universe by space travel and probes, in our own time. Now, after the enormity of space, we are reaching down into the infinitesimally small elements of life. Life is the particular phenomenon (but not unique) of our planet. The central challenge is to understand the peculiar and distinctive phenomenon of human existence and intelligence.

The human genome existed before Mendel and Watson and Crick. It was always there. But by the intelligence of humanity and with the aid of still further discoveries, it has become possible to unravel some of the secrets of the genome. The larger implications, including whether it will permit a rapid advance of human evolution and the nurturing of "super human beings" and even of a new species, is outside the scope of this paper. Having sketched the science, let me return to some of the basic legal issues which the science presents.

MUNICIPAL LEGAL ISSUES

Take the following problems, stated in very general terms, which the foregoing scientific developments present for legal and ethical choices.

This is a starting point for the principles of the *Declaration.* But there is much more.

INTERNATIONAL DEVELOPMENTS

In fact there are at least two important international institutional responses to the foregoing developments, apart from those which exist in universities, national bioethics commissions and other local institutes. I am fortunate to be associated with each of them. One is the Ethics Committee of the Human Genome Organisation - the international scientific association which is supervising the Human Genome Project. The other is the International Bioethics Committee of UNESCO. That Committee produced the *Universal Declaration.* It was adopted by the General Conference of UNESCO in November 1997. It represents an endeavour to state the basic principles which should provide the ethical and legal framework within which national responses may be developed to the challenge of the genetics revolution.

The opening provision of the *Declaration* states that "the human genome underlies the fundamental unity of all members of the human family". It recognises the "inherent dignity and diversity" of every individual[15]. There you have, at the outset, the assertion of a paradoxical reality which runs through the movement for universal statements of human freedom. They are global in their application. Yet they are individual in their focus.

The main substantive provisions of the new *Declaration* insist upon the requirement of rigorous and prior assessment of potential risks and benefits for any research, treatment or diagnosis affecting an individual's genome[16]. In every case, the prior free and informed consent of the person concerned must be obtained[17]. It is specifically recognised that each individual has the right to decide whether or not to be informed of the results of genetic examination[18]. No one is to be subjected to discrimination based on genetic characteristics such as will infringe that person's human rights, fundamental freedoms and human dignity[19]. Respect for the confidentiality of genetic data which can be linked with an identifiable person must be protected by law[20]. Just reparation must be provided for any damage sustained as a result of an intervention affecting a person's genome[21]. In order to protect human rights and fundamental freedoms, limitations on the principles of consent and confidentiality are only permitted where prescribed by law for compelling reasons which themselves conform to the international law of human rights[22]. No research or application of research concerning the human genome may prevail over respect for human rights, fundamental freedoms and human dignity of the individual or groups of people[23].

Much of the new *Declaration* is addressed to the responsibilities devolving on researchers to conduct genomic research with meticulous care, caution, intellectual honesty and integrity[24]and to share research outcomes in a way that fosters intellectual freedom, a prerequisite of scientific progress[25]. States are urged to provide the framework for the free exercise of research on the human genome with regard to the principles established by the *Declaration* and so as to safeguard respect for human rights, fundamental freedoms and human dignity and also to protect public health[26]. The *Declaration* proposes the establishment in each country of independent multi-disciplinary and pluralistic ethics committees to assess the ethical, legal and social issues raised by research on the human genome and its applications[27]. There are many provisions for solidarity, international cooperation and promotion of the principles established by the *Declaration*[28]. The International Bioethics Committee of UNESCO is given the task of disseminating these principles and promoting the acceptance of the *Declaration* throughout the world[29].

Running through the principles of the new *Declaration* are basic norms concerned with human freedom. There is a recognition of the intellectual freedom which is the environment in which scientific knowledge can alone move forward. But as with the original *Universal Declaration of Human Rights* of 1948, most of the core provisions of the *Genome Declaration* are concerned with the freedom of the individual who may be affected by genetic research, testing or therapy. The dignity, privacy and integrity of that individual are to be upheld. In short, scientific progress should go ahead in the belief that its tendency is not to diminish human freedom but to enhance the benefits to humanity. But it should go ahead in an environment which respects the freedoms of the individuals affected and enhances the freedoms of people everywhere. All people have a right to share in the products of research

and applications in biology, genetics and medicine which carry the promise of relieving human beings from suffering and improving the health of individuals and of humankind as a whole[30].

THE LAWYERS' APPROACH

The issues which I have outlined in this paper may seem daunting. But they are problems presented to society in our time. Unless our Constitution and laws are to be irrelevant to the major scientific developments of the age, it is necessary for lawyers to respond to such problems. It is also necessary for them to develop the institutions which can respond efficiently and the frameworks within which national responses can be rationally worked out.

Those responses will be founded on a good knowledge of genetic science. They will involve multidisciplinary dialogue such as is achieved in the United Kingdom Commission which Sir Colin Campbell leads. They will require us to think positively as human beings and as lawyers about the potential of genetics to relieve suffering and to save people from premature or unnecessary death. Lawyers will teach their fellow citizens that it is important to choose manageable issues in devising the legal responses and not to wait for a comprehensive response which answers *all* the problems. No such super response is possible.

The way of the common law involves dealing with practical problems as they present themselves. Take for example the adoption of laws and policies to govern genetic testing. When it may be done? With whose consent? Where the data will go in identifiable form? Issues of this kind are often susceptible to regulation by protocols adopted by the medical profession supplemented, if necessary, by law. Similarly, with insurance. Whether insurers may demand, before accepting a proposal for life or health insurance, the provision of a report on genetic tests of a particular, limited or general character? Such issues may be decided (at least in the first instance) by a voluntary moratorium accepted by insurers, prohibiting the demand for the disclosure of genetic test results in the case of a policy of a certain size; or excluding new genetic tests but requiring the disclosure of those already known to the proponent for insurance[31]. In the long run, the rights of insurers and the obligations of the insured, in relation to genetic data may be governed by law. So far as the results of tests already known are concerned, the universal principle that insurance is a contract of *uberrima fides* may already require disclosure to the insurer of such information, if it is known by the insured.

Much more difficult of management by the law or by effective voluntary regulation are the deeper questions. Whether genetic data is relevant to the criminal responsibility of an accused convicted of a crime of violence allegedly attributable to genetic predisposition[32]? Whether the protections of intellectual property law are apt to the patenting of mere fragments of human genes, such as those known as expressed sequence tags[33]. Or whether laws can and should ban both therapeutic and reproductive experiments with cloning involving human biomaterial[34]? In the first instance, at least, ethics committees and lawmakers will do well to concentrate on manageable, achievable tasks. The larger, more fundamental issues may require time until "the dust has settled and the emotions have been vented"[35].

Lawyers will also teach the importance of involving the public in discussion about the legal and ethical choices which genetics presents. On a global level, lawyers will endeavour to explain the difficulties of securing agreement when there are so many different regimes of religious and ethical principles. Thus global prohibitions on experimentation with foetal material are unlikely to succeed. Whereas some Christian groups regard life as beginning at the very instant of conception, Judaism and Islam consider that the embryo does not acquire human characteristics until after 40 days. Other religions and philosophies, and humanists, may choose an even later time. Clearly it is important to develop global institutions and to provide global solutions to a problem which literally concerns all humanity, involved as it is with nothing less than the future makeup of the human species. But the highest common denominator of agreement may not be very high.

CONCLUSIONS

Human beings are moral creatures. They are also gregarious. They group themselves in societies, ultimately international society. The genetic revolution will be overwhelmingly for the benefit of humanity. It will provide the universal textbook for medical science in the next century. It is happening. It is happening quickly.

Important ethical and legal challenges are presented. It is vital that the best legal minds should be engaged upon these problems and challenges. They do not only affect wealthy nations in the forefront of genomic research, such as the United States. They do not only affect countries like Australia which contribute to that research and which will benefit from the medical therapies and other advances that come in its train. The Human Genome Project concerns also countries like Vietnam. Indeed, it concerns every nation on earth and the people of every nation. It is therefore fitting that Australian lawyers, meeting at this conference in Vietnam, should reflect upon the common challenge which is presented to human beings and to their legal systems everywhere by the genetic revolution.

Our meeting in this place requires us to consider not only the responses which the Australian legal system will give to these developments. It also requires us to consider our obligations to ensure that the global response is effective and that the benefits of the Human Genome Project flow to the people of Vietnam and other developing countries as well as to our own people. Otherwise, talk of the genome as an attribute of the common property of humanity will be empty. Such exciting developments deserve to be shared with all people. Lawyers have a responsibility to promote, both in their own countries and internationally, a regime which is equitable, respectful of the dignity of the individual and mindful that the individual is always much more than a collection of his or her genes.

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