

## PLAYING GOD? OWNING GOD? – PATENTING AND THE HUMAN GENOME#

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### I INTRODUCTION

It is just over 50 years since James Watson and Francis Crick published the news of their discovery of the structure of DNA<sup>1</sup> – the molecule that encodes the genetic information present in all living organisms. Their letter, published on 25 April 1953, signified the beginning of the modern age of biology.<sup>2</sup> In 2001, as a result of the activities of public and private sector bodies working on the Human Genome Project, a draft map of the human genome was published.<sup>3</sup> It was found that the total number of genes in the human species was just over 30 000. The search is now underway to discover the operation of each of the genes so isolated.

This paper is concerned with only one of the many social, economic and legal problems that arise out of the discovery of DNA and the consequent mapping of the human genome. The topic relates to intellectual property law: more specifically, the law of patents as it affects the discoveries and inventions that arise out of the unfolding knowledge about the genome, the genes that make it up, the work that those genes and intervening matter perform, the tests that are developed to identify the likely operations of the genes and the potential therapies that will be developed to modify, eliminate and manipulate genes that cause illness and premature death.<sup>4</sup>

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1 James Watson and Francis Crick, 'Molecular Structure of Nucleic Acid: A Structure for Deoxyribose Nucleic Acid' (1953) 171 *Nature* 737–738.

2 See James Watson and John Tooze, *The DNA Story: A Documentary History of Gene Cloning* (1981).

3 David Baltimore et al, 'The Human Genome Project' (2001) 409 *Nature* 813.

4 Justice Michael Kirby, 'Intellectual Property and the Human Genome' (2001) 12 *Australian Intellectual Property Journal* 61.

## II PATENTS IN A BIOLOGICAL CONTEXT

The provision of patents, a kind of monopoly permitting the owner to enjoy a temporary exclusive right to use an invention or technique in exchange for revealing its secrets to the public, has a history, stretching back to classical times. Monopolies of this kind have received legal protection for 400 years – originally from the monarchs of England and France. The first international convention on the legal protection of intellectual property was agreed in Paris in 1883.<sup>5</sup> Since that time, there have been many national, regional and international legal developments which have created the modern network of the world's intellectual property laws.

When knowledge of DNA and the genome emerged, Watson and Crick sought no intellectual property rights with respect to it or its applications. However, instead of devising a new, specialised and specifically appropriate legal regime peculiar to the new knowledge, as with the software used in informatics, lawyers reached for the old law of intellectual property pressing it into new service. At times, this has produced less than perfect results.

With the assistance of the International Bioethics Committee ('IBC') of the United Nations Educational, Scientific and Cultural Organization ('UNESCO'), the first international response to the ethical dilemmas presented by the advance of the human genome project was developed. Thus, the *Universal Declaration on the Human Genome and Human Rights* ('Declaration') was adopted by the General Conference of UNESCO in 1997. It was later endorsed by the General Assembly of the United Nations. While it is not a binding treaty, it is a broad statement of principles designed to uphold human rights in the context of the developments affecting the human genome.

Significantly, in relation to the issue of patenting, art 1 of the *Declaration* provides:

- 1 The Human Genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

In art 4, the *Declaration* goes on to state:

- 4 The Human Genome in its natural state shall not give rise to financial gain.

In art 12, the *Declaration* states:

- 12(a) Benefits from advances in biology, genetics and medicine, concerning the human genome, should be made available to all, with due regard to the dignity and human rights of each individual.
- (b) Freedom of research, which is necessary for the progress of knowledge, is part of freedom of thought. The applications of research, including applications of biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and human-kind as a whole.

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5 *Paris Convention for the Protection of Industrial Property*, opened for signature 20 March 1883, [1972] ATS 12 (entered into force in its revised form 27 September 1975).

It is important to recognise the very useful purposes that intellectual property laws serve. They have their own foundation in ethical principles and the right of scientists to protect their intellectual property was acknowledged in the *Universal Declaration of Human Rights*.<sup>6</sup> However, the same instrument also recognises competing human rights – such as the right to life, to health, to knowledge and to share in the benefits of scientific advances.<sup>7</sup>

Converting discoveries about the human genome from raw scientific data to beneficial therapies and useful tests is ‘potentially problematic and expensive’.<sup>8</sup> This problem demonstrates the principal social argument for protecting intellectual property, in the form of new technological inventions and novel techniques. The argument is that they lead to the development of short-term legal monopolies that encourage and facilitate the investments necessary ‘for large and expensive steps in scientific and technological research’.<sup>9</sup> Intellectual property protection can provide an incentive for scientific and technological research and ensure that the outcomes of such research are disclosed to the world at large. These considerations encouraged the IBC and the wider global community to recognise that patents and their legal protections play an important role in advancing the frontiers and application of genomic science. Without such laws, it is unlikely that advances would occur as quickly and efficiently.<sup>10</sup>

Notwithstanding these beneficial features of patents, there are a number of problems which the IBC and other bodies have discerned in the interaction of research and development concerning human genetics and national, regional and international laws governing patents.

### III THE SOURCES OF CONCERN

Drawing on the debates that emerged in a Paris symposium in 2001, an IBC working group was formed. The group listed a number of sources of concern that explain why many people, in a wide variety of countries and disciplines, are expressing anxiety about the suggested over-reach of patent law in the context of expanding genomic knowledge.

First, there has been a significant change in recent years in what was formerly a global tradition and culture of open science. As the IBC group put it:

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6 *Universal Declaration of Human Rights* (1948) art 27.2.

7 *Ibid* arts 3, 25.1, 27.1.

8 *Ibid*.

9 IBC, *Report of the IBC on Ethics, Intellectual Property and Genomics* (SHS-503/01/CIB-8/2 Rev, Paris, 10 January 2002), [8] (*‘IP Report’*). With some modifications, the IBC adopted the report of its working group (*‘IBC group’*).

10 Dianne Nicol, ‘Gene Patents and Access to Genetic Tests’ (2003) 11 *Australian Health Law Bulletin* 73, 74; cf Robert Cook-Deegan, *The Gene Wars: Science, Politics and the Human Genome*, (1995) 28.

Until very recently, almost universally, pure scientific research was substantially funded publicly. It operated in a culture in which individual scientists, universities and foundations did not seek or obtain financial benefits from primary scientific advances. This explains how, between 1920 and 1970, great progress was made in pharmaceutical developments (eg penicillin and other antibiotics and vaccines) with little demand for [patent] protection. This contributed greatly to improvements in public health.<sup>11</sup>

However, during the 1970s and 1980s the situation began to change. In part, this was the result of laws enacted by the Congress of the United States ('US') during Mr Reagan's term as President. These laws were designed to enforce amongst universities and public institutions the duty to obtain patent protection for their scientific and technological innovations. Failure to comply with this duty would lead to the withdrawal of federal funding. As the IBC group put it:

An illustration of the change has recently come to light in the development of HIV therapeutic drugs. Although essential to the right to life and health of millions, the intellectual property protections effectively made such drugs mostly unavailable, except in developed countries. This led to a public outcry, development of generic drugs, abandonment of court action taken to enforce intellectual property rights in South Africa and widespread public demand for removal of some intellectual property protections in respect of these therapies.<sup>12</sup>

Although not specifically related to genomic therapies, the IBC saw the debates over HIV drugs as a predictor of what was likely to come in the field of genetic tests and therapies.

Secondly, coinciding and connected with the change in the tradition and culture of open science has been a shift in the balance of private and public investment in research in science and technology. Public funding for general research has declined in many countries while the proportion of research funded by the private sector has increased. This has a potential to shift the priority of research (and, in consequence, tests and therapies) to those diseases of major significance in developed countries that can afford to pay high prices for pharmaceuticals. The medical requirements of poorer, developing countries would consequently become of lesser priority. Maximising financial rewards rather than satisfying the greatest human needs might determine the future of scientific research on genes and their operation.

Thirdly, the foregoing developments have happened at a time when, as evident in the *Declaration*, international bodies such as the IBC, perceived the character of the genome as something specially intimate and particular to the human species. According to the IBC group:

Never before in science have individual human participants and groups been so closely involved in, and necessary to, scientific and technological advances. The genomic sequence, out of which tests and therapies are developed, begins in every case with a sample provided by an individual human being or samples provided by a group of the population concerned.<sup>13</sup>

There was a controversy about the meaning of the promise, set out in the *Declaration*, that the human genome, 'in its natural state', would not give rise to

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11 IBC, *IP Report*, above n 9, 2.

12 Ibid.

13 Ibid 3.

financial gains.<sup>14</sup> This controversy is not yet settled. There is no doubt that huge financial gains are being sought, and obtained, through patent protection and licensing arrangements. This occurs as laboratories continuously identify more genes that are useful in the *short* term for developing tests to identify the presence of inherited conditions and, in the *long* term, for therapies to treat, exclude or monitor such conditions.

Fourthly, the implications of patent law, and especially of international regulations concerning patents, have emerged as major issues for human rights and biotechnology. To the extent that, in practice, intellectual property law restricts access to tests, therapies and knowledge developed from the scientific research on the genome, it affects the human rights of millions: most notably the right to health and to life.

Finally, in addition to the foregoing concerns of a general kind, the IBC group expressed anxiety about various features of the way in which patent law operates. Of specific concern have been patents over genetic sequences claimed by applicants who

seek and secure patent rights over genomic sequences of uncertain future utility, leading to premature accumulation of intellectual property rights which may have a consequence of discouraging unimpeded research in respect of particular genes or in the proteins which they express, because of awareness of a prior intellectual property right with respect thereto.<sup>15</sup>

Many observers have concluded that the duration of typical patent protections (in most countries 20 years) is excessive, having regard to the context of genomic sequences and the rapid advance of knowledge about them.

A number of scientists from developing countries have expressed outrage about the way in which samples of source materials are being collected from subjects in developing countries for the production of tests and therapies, which would then only be available to those countries under licensing arrangements, which impose prohibitive costs. The scientists concerned pointed to the rich diversity of genetic material in many developing countries. They insisted that there must be a 'genomic dividend' for those countries and their people, lest intellectual property law (patents) enforces a new form of imperialism on the developing world. The ultimate insult, they suggest, would be for countries from which the source material comes to be required to pay exorbitant fees for tests and therapies produced from those materials.

The need for equitable benefit-sharing has become a common theme not only of the IBC but also of the Human Genome Organisation ('HUGO') Ethics Committee. In a statement on the subject, the HUGO Ethics Committee suggested that a fixed proportion of the net profits of pharmaceutical companies in the developed world should be devoted to repaying the benefits of source human genetic materials provided by donors in developing countries.<sup>16</sup>

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14 *Universal Declaration on the Human Genome and Human Rights* (1997) art 4.

15 IBC, *IP Report*, above n 9, 3.

16 See HUGO Ethics Committee, *Statement on Benefit Sharing* (2000) <<http://www.gene.ucl.ac.uk/hugo/benefit.html>> at 20 November 2003; HUGO Ethics Committee, 'Genetic Benefit Sharing' (2000) 290 *Science* 49.

#### IV THE WORLD TRADE ORGANISATION *TRIPS* AGREEMENT

Beyond these concerns, a fierce international debate continues about the operation of a treaty of the World Trade Organisation ('WTO') designed to ensure that all members of that organisation enforce intellectual property rights.<sup>17</sup> This treaty, the *Agreement on Trade Related Aspects of Intellectual Property Rights*<sup>18</sup> ('*TRIPS*') is probably the most important international agreement concerning patents signed in the 20<sup>th</sup> century. It is also the most controversial.<sup>19</sup> As Professors Peter Drahos and John Braithwaite of the Australian National University have explained:

There are three broad lines of criticism aimed at [*TRIPS*]. First is that it was the product of duress by powerful states against weak states rather than a bargain struck by sovereign equals. The second line of criticism is that it is part of a hard bargain in which developing states receive very few reciprocal gains. The third category of criticism focuses on the adverse consequences for developing countries of implementing the agreement. The debate over the impact of *TRIPS* standards on access to vital medicines is one example of this type of criticism.<sup>20</sup>

The fury felt by many countries over the attempt by developed nations with large pharmaceutical sectors (such as the US, the United Kingdom ('UK'), Western Europe and Japan) to enforce the *TRIPS* Agreement against developing countries, with little or no pharmaceutical or industrial potential and which can only procure essential generic drugs from other developing countries capable of producing such generic copies, first came to a head at a ministerial conference of the WTO held in Doha, Qatar in November 2001. There, trade ministers had to consider how international standards of intellectual property protection were to be adapted to deal with the endemic public health crises facing the developing world.

Once again, the analogy with the global HIV/AIDS epidemic made it clear that a solution was necessary. The *TRIPS* Agreement needed to be adapted to the urgent public health needs of developing countries. To find a solution to the very serious international debates and sharp divisions that had emerged over this subject, the WTO agreed upon transitional arrangements. However, the fundamental problem of reconciling the international human right to life and health with the insistence on enforcement of intellectual property (patent) rights

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17 Peter Drahos and John Braithwaite, *Information Feudalism - Who Owns the Knowledge Economy?* (2002) 192.

18 *Agreement on Trade Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1869 UNTS 299, 33 LLM 1125 (entered into force 1 January 1995).

19 Peter Drahos and John Braithwaite, 'Intellectual Property: Corporate Strategy, Globalisation: *TRIPS* in Context' (2002) 20 *Wisconsin International Law Journal* 451, 451.

20 *Ibid.*

in the *TRIPS* Agreement resulted in the various modifications suggested in the *Doha Declaration*.<sup>21</sup>

One such modification was a relatively short moratorium for WTO members in respect of breaches of their obligation to comply strictly with intellectual property rights in the field of healthcare. This was the approach that the US favoured. The approach rests on a recognition and reiteration of global enforcement of patent rights.

An alternative approach envisaged an amendment to the *TRIPS* Agreement to overcome permanently the special problem of the export of generic drugs from one developing country to another. This approach was favoured by the European Union. A third solution was to permit waiver of obligations imposed by the *TRIPS* Agreement in the case of poorer countries, particularly those designated 'least developed'.

However, the primary solution to the conflict between intellectual property rights and rights to life and public health and knowledge, advocated by developing countries, was the proposal to adopt an authoritative interpretation of art 30 of the *TRIPS* Agreement. That article recognises the right of states to regulate patent entitlements against higher and more urgent criteria. This was the approach favoured by the group of countries with incipient pharmaceutical industries capable of producing generic copies of expensive drugs that are subject to patent protection. Those countries include Brazil, India, China, Indonesia, the Philippines and Thailand.<sup>22</sup>

The negotiations towards a solution to the sharp differences over patents between the developed world and the developing world broke down on 21 December 2002. According to Professor Drahos, '[t]he cause of the problem related to the definition of pharmaceutical products' to be included in the exception to *TRIPS*.<sup>23</sup> The US trade representative expressed his concern that too broad an exception would permit some countries to claim a wide range of exempt drug products, for example Viagra (a male impotency drug), as exceptions to *TRIPS*. It was for that reason that the US suggested an interim measure expressed in terms of exceptions for 'HIV/AIDS, malaria, tuberculosis and other infectious epidemics of comparable gravity and scale'.<sup>24</sup>

The negotiations within the WTO are continuing. However, there is a fear in many of the poorer countries that, in the end, the *TRIPS* Agreement will entrench a permanent dependency on the part of developing countries upon the main pharmaceutical exporting nations. As Professor Drahos puts it:

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21 *Doha Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/1, adopted by the WTO Ministerial Conference, 4<sup>th</sup> session, on 14 November 2001.

22 Peter Drahos, 'Access to Medicines: After Doha' in *Commonwealth Trade Hot Topics* Issue No 20 (Economic Affairs Division of the Commonwealth Secretariat).

23 *Ibid.*

24 *Ibid.*

In the long run this will simply increase the dependency of least-developed countries upon individual acts of charity or politicised development aid programmes ... The breakdown of the talks does present an opportunity for developing countries to rethink their options. It is open to a developing country or more preferably a group of developing countries to draft and enact an exception based on Article 30 [of *TRIPS*] to deal with the export and import issue ... The article recognises the sovereign right of members to create exceptions to the exclusive right of patent owners ... If other WTO members took the view that the exception drafted by a group of developing countries went beyond the bounds of what was permitted by Article 30, the matter could be the subject of a WTO dispute resolution procedure.<sup>25</sup>

Some progress towards greater equity was made on 30 August 2003. On that day the members of the WTO agreed on legal changes to make it easier for poorer countries to import cheaper generic pharmaceuticals, if they are unable to manufacture them themselves. The Director-General of the WTO, Mr Supachai Patitchpakdi, said that the agreement would allow 'poorer countries to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with diseases that ravage their people'.<sup>26</sup> He stated that the compromise achieved demonstrated that the WTO 'can handle humanitarian as well as trade concerns'.<sup>27</sup> However, the fine print of the agreement suggests that it is a temporary one only. It addresses art 31(f) of the *TRIPS* Agreement. WTO member governments have agreed that the waiver is to last until that article is amended. Twenty three developed countries are listed in the decision as announcing voluntarily that they will not use the system to import generic drugs. Other countries, such as Hong Kong, China, Mexico, Singapore and Turkey have announced separately that they will use the waiver only for health emergencies and extremely urgent situations. A more detailed, conceptual and permanent reform of the *TRIPS* Agreement remains for the future. Given past experience its negotiation promises to be difficult.

## V CONCLUSIONS: GETTING THE RIGHT BALANCE

Enough has been said to show that the conflict over intellectual property and genetic discoveries is not, as such, a conflict between good and evil. As is so often the case in our complex world, it is between competing aspects of human rights and between the competing needs of those who discover and develop expensive tests and therapies and those who are in desperate need of currently available life-saving, pain-relieving, products that can significantly enhance quality of life. People in the last category live for the most part in nations that desperately need – but cannot afford – the beneficial tests and therapies, especially if they are expected to pay the patent owner's licence fee.

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25 Ibid 5.

26 WTO, 'Decision removes final patent obstacle to cheap drug imports' (Press Release, 30 August 2003) 350. Announcement on the decision to implement para 6 of the *Doha Declaration on the TRIPS Agreement and Public Health*.

27 Ibid.



In its Working Paper the IBC group emphasised the importance of cooperation between the various agencies of the United Nations. UNESCO, which created the IBC, is one such agency; so is the Office of the High Commissioner for Human Rights and the Food and Agricultural Organisation which is concerned with genomic developments affecting plants. So also are the World Bank, the International Monetary Fund and the WTO itself. In addition to being members of the United Nations family, they are also organs of the global economy. Thus, there is a great need to ensure that the economic developments that occur in relation to patent protection over essential advances affecting the human genome happen in a harmonious way with human rights developments that advance accessibility to the tests and therapies of people in all countries – not just in the developed world.

The IBC group emphasised the need for wide discussion about the legal and ethical issues presented by the human genome. The current state of international patent law and practice is not, as such, purely a question for expert lawyers, pharmaceutical corporations, bankers and investors. It is a legitimate subject of community discussion. The outcomes of the operation of intellectual property law affect the lines of product development and access to those products by patients, once they exist.

It is against this background that the IBC group called for a general review of the *TRIPS* Agreement. It suggested the need for clarification of the exceptions recognised in the *TRIPS* Agreement to the effect that, where public interest considerations and the protection of human health and life are concerned, each nation must be in a position to protect its own people.

In addition, the IBC group indicated special concern about the rapid expansion of patent applications and grants of patent protection over simple sequences of genes, the exact operation and utility of which is not yet fully known. Reflecting the diversity of opinion expressed on the subject, the group said:

While a few members of the IBC had reservations about this conclusion, if no progress is made in this matter, the IBC will at its next session consider the feasibility of recommending to the Director-General of UNESCO [that he] propose to the General Conference that appropriate steps be taken towards a global moratorium on the grant of further patents in relation to human genome sequences.<sup>28</sup>

In expressing this anxiety about the trends in intellectual property law and practice, the IBC is not alone. In 1995, the HUGO Ethics Committee indicated that it was

worried that the patenting of partial and uncharacterised cDNA sequences will reward those who make routine discoveries but penalise those who determine biological functional application. Such an outcome would impede the development of diagnostics and therapeutics, which is clearly not in the public interest.<sup>29</sup>

Similarly, in 1997, the HUGO *Statement on Patenting Issues* reaffirmed that

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28 IBC, *IP Report*, above n 9, 9.

29 HUGO, *Statement on Patenting Issues Relating to Early Release of Raw Sequence Data* (1997) Human Genome Organisation <<http://www.gene.ucl.ac.uk/hugo/ip1997.htm>> at 20 November 2003. See also Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (July 2002) 80.

HUGO does not oppose patenting of useful benefits derived from genetic information, but does explicitly oppose the patenting of short sequences from randomly isolated portions of genes encoding proteins of uncertain functions.<sup>30</sup>

The HUGO Committee called upon lawmakers ‘to enter into negotiations aimed at reaching an agreement on the introduction of a “grace period” (as in US law) to put all participants in the international network on an equal footing’.<sup>31</sup>

In 2002, the Nuffield Council on Bioethics in the UK (‘the Nuffield Council’) came to the conclusion that, in the main, the provision of exclusive rights awarded for a limited period in the form of a patent system was defensible and had generally worked for the benefit of the people. Nevertheless, the Nuffield Council considered that ‘[i]n the particular case of patents that assert property rights over DNA, consideration should be given to whether the balance between public and private interests has been fairly struck’.<sup>32</sup> The Nuffield Council further considered that sequences that had only been identified and characterised in a computer analysis should not be capable of becoming a source of patent rights and that the granting of patents that assert rights over DNA sequences should ‘become the exception rather than the norm’.<sup>33</sup>

Along with many that have gone before and commented since, the Nuffield Council demanded a return to the fundamental principles that have hitherto given strength and legitimacy to legal entitlements to patent protection. These are; (1) that what is propounded is an ‘invention’ not simply a ‘discovery appearing naturally in nature’; (2) that it is something distinctly ‘novel’, not a matter of routine; and (3) that it is ‘useful’ and thus qualifies, from a social point of view, for monopoly protection, for a limited period of time.

Out of the UNESCO Symposium on this subject in 2001, the recommendations of the HUGO Ethics Committee, the proposals of the IBC, the opinions of the Nuffield Council and many other bodies come countless suggestions on how to improve the operation of the international patent law system. However, in the face of this avalanche of advice, ethical opinion and suggestions for change, the hard-nosed trade negotiators of the WTO generally continue to insist upon compliance with internationally enforceable patent protections as a price of membership of that important global club. In the face of US insistence, individual countries can, to a large extent, adopt, or propose, exceptions for public health or otherwise. But getting these adopted by WTO has proved extremely difficult.

In December 2002, the federal Attorney-General asked the Australian Law Reform Commission (‘ALRC’) to examine Australian patent practices to ensure that they encourage genetic research and development and do not cause undue costs to the healthcare system.<sup>34</sup> The extent to which Australia, a relatively small player and substantially an importer of genetic tests and therapies, can influence

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30 Ibid.

31 Ibid.

32 Nuffield Council on Bioethics, above n 29, 69.

33 Ibid.

34 To help clarify the issues under consideration, the ALRC has recently prepared an issues paper: Australian Law Reform Commission, *Gene Patenting and Human Health*, Issues Paper 27 (2003), <<http://www.austlii.edu.au/au/other/alrc/publications/issues/27/>> at 20 November 2003.

international patent laws regimes is obviously limited. Australia is required to conform to its obligations as a party to the *TRIPS* Agreement. The current negotiations for a Free Trade Agreement with the US adds a further dimension. In all such negotiations, the pharmaceutical corporations of the US have a large and legitimate say in the American negotiating position.

If Australia faces difficulties in improving its own laws on this subject, and in asserting its national needs in the context of trade treaty obligations and negotiations, the position of the least developed countries is most acute, and even desperate.

At the recent World Genetic Congress in Melbourne, Dr Francis Collins, the US scientist who led the Human Genome Project, told the participants that the US had ‘led the world into a mess’ in gene patenting.<sup>35</sup> In response, the President of the ALRC, Professor David Weisbrot noted that ‘many concerns about the impact of patent laws on the provision of healthcare relate to claims of monopoly control over clinical genetic testing – not merely the right to set the price, but the right to limit the number of labs which may conduct the tests’.<sup>36</sup> Professor Weisbrot said:

Medical researchers also have expressed concern that the thicket of patents may restrict them from doing the further experimentation that would lead to important advances. Biotechnology is one of Australia’s fastest growing industrial sectors, and Australia is a real player – we already have a billion dollar biotech industry, world-class genetic scientists, and strong government support. It’s essential that we both get the commercial and healthcare sides of this equation right.<sup>37</sup>

The Australian project of the ALRC is, therefore, a most welcome one. This is an area of activity where it is not only essential to be inventive in the laboratory, the boardroom, the banks and the offices of patent attorneys. It is also essential that we be inventive in the lawmaking process, both in individual nations and in the world community, acting as a whole.

Unless we can do this, the bold aspiration in the *Universal Declaration on the Human Genome and Human Rights* that the human genome ‘underlines the fundamental unity of all members of the human family’<sup>38</sup> will be revealed as nothing but empty words. The aspiration that ‘the human genome in its natural state shall not give rise to financial gains’,<sup>39</sup> will be mocked by those who seek great financial gains, protected for a substantial time in a fast moving field of technology, behind the shield of patents over sometimes computer generated property rights. And beyond countries like Australia, there will be extremely poor countries that feel acutely the injustice of a lack of proper benefit-sharing and see the human genome being diverted, in its commercial application, from a source of scientific experimentation and investment of use to all humanity, to an endeavour that responds only, or substantially, to the health needs of the minority of rich countries in the world. As it is sometimes put metaphorically: a

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35 Australian Law Reform Commission, ‘Who Owns your Genes?’ (Press Release, 28 July 2003).

36 Ibid.

37 Ibid.

38 *Universal Declaration on the Human Genome and Human Rights* (1997) art 1.

39 *Universal Declaration on the Human Genome and Human Rights* (1997) art 4.

concentration on therapies for wrinkles rather than participation in the global fight against malaria, sleeping sickness, HIV, tuberculosis and the other afflictions of the mass of poorer people in poor nations.

As Australians, we must welcome the investigation of the Australian Law Reform Commission. We should give it support so that it speaks to our nation, and beyond that to the world, of reform and a more just system of intellectual property law in the exciting age of genomic science.