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BIOMEDICINE - LEGAL AND ETHICAL ISSUES

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In this paper the author examines a number of contemporary problems presented to the law by advances in biotechnology and biomedicine. He starts with a description of the extraordinary and interrelated advances in science and technology over the past 50 years. He selects a few instances to illustrate his themes: (1) demands for intellectual property law protections (generally patents) over genetic data and their applications; (2) demands for the right to procure, and conduct experiments using, embryonic stem cells; (3) demands for access to pre-implantation genetic diagnosis (PGD) to identify serious hereditary diseases in embryos; and (4) demands for access to the new anti-retroviral therapies essential for the effective treatment of HIV/AIDS. The paper finishes with a reference to the need for law reform to facilitate the prevention of the spread of HIV and emphasises the urgency of this strategy and the useful role that judges and lawyers of the Commonwealth can play in promoting the necessary law reforms.

THE SCIENTIFIC CONTEXT

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Lawyers in an age of science: It is little more than fifty years since James Watson and Francis Crick announced the discovery of the structure of DNA[1]. This is the molecule that encodes the basic genetic information present in all living organisms. The research of Watson and Crick, published on 25 April 1953, signified the beginning of the modern age of biology and biomedicine[2].

In 2001, as an outcome of this discovery and through the rival activities of public and private sector bodies working on the Human Genome Project, a draft map of the human genome[3] was published[4]. This map revealed that the total number of genes in the human species was something just over 30,000. An important aspect of contemporary biomedicine is the search to discover the operation of each of these genes, when isolated, and the significance of so-called "junk" matter in the DNA between the genes. Unsurprisingly perhaps, this "junk" (unlike a lot of that material that we see in the courts) is not worthless after all.

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1 James D Watson and Francis H C Crick, "Molecular Structure of Nucleic Acid: A Structure for Deoxyribose Nucleic Acid" (1953) 171 *Nature* 737-738.

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

3 When all the DNA in a particular organism is considered, it is called the genome.

4 (2001) 291 *Science* 1155; (2001) 409 *Nature* 813.

Few lawyers have special skills in, or knowledge of, science and technology. Most lawyers tend to be those who, as schoolchildren, excelled in subjects involving verbal skills. There have been exceptions, such as Lord Denning and Lord Reid. However, lawyers have not generally been trained in higher mathematics, still less in complex modern scientific theories and technological applications. For the most part, lawyers see these phenomena (if at all) only in litigious disputes over intellectual property[5] or contests over the admissibility of expert evidence[6]. Uncomfortably for lawyers, science and technology are now major driving forces of the world economy and global society. Moreover, they present important quandaries of a moral and ethical kind. Upon such quandaries, citizens often expect the law to speak with a clear voice. That is why this subject is important and suitable for a Commonwealth Law Conference.

Inter-related technologies: At the outset, it is important to realise how the most important modern technologies are inter-related. To win the Second World War, the Allies split the atom, harnessed nuclear fission, developed the atomic bomb and later created hydrogen bombs. For more than fifty years, the dangers presented by these weapons of mass destruction have imposed on humanity an uneasy peace,

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[5] *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 212 CLR 411; *Stephens v Kabushiki Kaisha Sony Computer Entertainment* (2005) 224 CLR 193.

[6] *Clark v Ryan* (1959) 103 CLR 486; *Ramsay v Watson* (1963) 108 CLR 642.

safeguarded to some extent by the Nuclear Non-Proliferation Treaty[7]. In recent decades, the acquisition of nuclear technology (and also nuclear weapons) by new nations, including two members of the Commonwealth of Nations (India and Pakistan), potentially symbolises the dangers for the survival of the human species inherent in any unlimited spread of that technology and the weapons that arise from it.

It was to deliver such weapons that advanced rocketry was developed to carry their payloads on intercontinental trajectories. This, in turn, led scientists to explore information technology, compacting ever-increasing data in microchips of ever diminishing size. The advance of computer technology made it feasible to perform the analysis of data about DNA and the genome. Without computers, the map of the human genome would not have been completed in its allotted time, if at all.

The great scientific advances of the last fifty years are thus integrated. Nuclear fission stimulated the birth of informatics. Informatics stimulated biotechnology. Biotechnology is now giving rise to nanotechnology which bridges living and inert materials. All of this has happened in about fifty years. Moreover, it has happened in ways that go beyond the understanding of an intelligent lay person.

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[7] Treaty on the Non-Proliferation of Nuclear Weapons, 729 UNTS 161, entered into force 5 March 1970.

There would not be many lawyers who could truly say that they understand how nuclear weapons function; how computers work; and how genes develop and express themselves in the organs and tissues of living things. Yet we know from our common experience that such scientific and technological developments have occurred. We also realise that they present challenges to our species that sometimes require legal responses.

International responses to science: Over three decades, I have enjoyed opportunities, both at a national and international level, to examine the advance of information and biological sciences and the development of legal and ethical responses to address each. In the 1970s I chaired an expert group of the Organisation for Economic Cooperation and Development (OECD) developing guidelines to respond to transborder data flows and the issues for privacy and data security presented by them[8]. More recently, in the Human Genome Organisation (HUGO) and in the International Bioethics Committee of UNESCO ("IBC"), I have participated in responses to some of the most important challenges of biomedicine in the current age[9].

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[8] Organisation for Economic Cooperation and Development, *Guidelines on Transborder Data Flows and the Protection of Privacy* (1980, Paris).

[9] UNESCO, International Bioethics Committee has produced a number of (non-binding) international instruments, particularly the Genome Declaration and the Bioethics Declaration (see below).

It would be impossible to describe all of the issues of biomedicine that confront us in the legal tradition of the common law. We know that, if the legislature and the executive government in our nations fail to develop legal responses to these challenges, in our system of law there is never ultimately a gap. In the end, the law is never silent. Where need be, it is the judges who will fill the omissions in the written law. If necessary, judges will express the legal principles that apply to a new situation presented by science or technology.

Because of the huge scope of the issues presented by biomedicine, their variety and complexity, I can do no more than to select a number of topics so as to give a glimpse of some of the challenges that lie before us as judges and lawyers. In doing this, I will draw on my experience as a member of the HUGO and IBC bodies that I have mentioned; as a participant in the WHO and UNAIDS institutions that are responding to one of the greatest challenges to biomedicine that afflicts Africa and the world (the HIV/AIDS pandemic) and as a judge of a final court in the Commonwealth of Nations. These insights may provide at least some perspectives for the issues that should engage the Commonwealth of Nations and specifically its lawyers. We must do so in an age that is indelibly affected by science and technology. In the course of this paper, I will deal selectively with some of the issues presented by advances in biomedicine. These will be:

- Intellectual property implications;
- Use of embryonic stem cells and cloning;

- Pre-implantation genetic diagnosis; and
- Issues in HIV/AIDS;

IMPLICATIONS FOR INTELLECTUAL PROPERTY LAW

Origins of intellectual property protection: One of the chief puzzles that has emerged from advancing knowledge about DNA and the human genome, has arisen in the field of intellectual property law, principally the law of patents. Legal puzzles have been presented by the discoveries and inventions that arise out of the unfolding knowledge about the genetic makeup of human and other living species.

Should it be possible for those who identify the likely operation of genes and their potential to contribute to therapies that prevent premature death and treat illness, to secure temporary monopoly protections under patent law? Is patent law, originally devised in earlier times for mechanical and similar inventions, suitable to lay claim over the identification and manipulation of special features of living matter?

It is important to note that "in general, raw products of nature are not patentable. DNA products usually become patentable when they have been isolated, purified or modified to produce a unique form not found in nature"[10]. By and large, the quandaries presented by this topic

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[10] *Human Genome Project, Patenting genes, Gene Fragments, SNPs, Gene Tests, Proteins and Stem Cells*, United States Dept

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are not puzzles of the lone scientist, working at a laboratory bench. Commonly, the claims for patent protection are made by large institutions, particularly pharmaceutical corporations. They are justified by the suggested need to raise venture capital to fund expensive and often unpredictable scientific research. Without the protection of temporary monopolies, such bodies argue that funding will not be forthcoming to promote the research that will conquer disease. Yet the distortions that can be produced by intellectual property law often give rise to the sharpest debates in the field of biomedicine. At stake is often the focus of the scientific exploration and the availability of the resulting products to people everywhere, not just in the wealthy developed countries that can afford to pay the resulting licence fees.

The central idea in intellectual property law can be traced to ancient Greece. In modern times, this body of law grew out of the monopolies granted by the monarchs in England and France for new inventions. International legal protection was first considered at a conference held in Paris in 1883. Since that time, many national, regional and international developments have combined to create a global network of intellectual property law.

Watson and Crick sought no intellectual property rights in respect of their discovery of DNA or of its immediate applications. Yet instead of

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of Energy <www.ornl.gn/TechResources/Human_Genome/elsi/patents/html#2>.

devising a new and specially appropriate legal regime peculiar to advancing knowledge of the field of biotechnology, the old law of patents was invoked and adapted. This has produced less than perfect results.

Patents and biomedical advances: The *Universal Declaration of Human Rights* of 1948 contained a provision[11] that recognised the rights of scientists to enjoy protection for their intellectual property. Nevertheless, the same instrument acknowledged the existence of competing human rights: such as the right to life, to health, to knowledge and the sharing of the benefits of scientific advances[12]. Self-evidently, converting discoveries about the human genome from raw scientific data to beneficial therapies and tests is "potentially problematic and expensive"[13]. Mr Pascale Lamy, then European Union Trade Commissioner, observed in 2004[14]:

> "Just take the example of the fight against AIDS: some consider patients on pharmaceuticals a major obstacle to securing access for all to the newest and most efficient treatments, whereas others point to the fact that, without patents, it is unlikely that any treatment would have been developed at all".

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11 UDHR article 27.2.

12 UDHR articles 3, 25.1, 27.1.

13 UNESCO, International Bioethics Committee, *Report of the IBC on Ethics, Intellectual Property and Genomics* (SHS-503/01/CIB-8/2 Rev, Paris, 10 January 2002), 8 ('IBC *IP Report*'), 2.

14 P Lamy, "Trade-Related Aspects of Intellectual Property Rights - Ten Years Later" (2004) 38 *Journal of World Trade* 923 at 923-4.

In recent years, a number of legal developments have caused concerns about the role that intellectual property law is now playing in the field of biomedicine. For example, there has been a breakdown of the previous global culture and tradition of science that involved the sharing of the outcomes of pure scientific research[15]. Domestic legislation in several developed countries, now demands that universities and research institutions secure intellectual property protections for their research[16]. This has happened at a time when humanity has come to appreciate the peculiarly intimate, pervasive and precious character of the genome of the species. It represents nothing less than the building blocks that make us what we are.

To the extent that scientific research is motivated not by sheer curiosity but by profits, there is a danger that it will concentrate unduly on profit-making objectives. This is sometimes put vividly as 'face creams rather than malaria and river blindness'. As well, abuse of intellectual property law has occurred. Thus, patents have been claimed over genetic sequences of uncertain utility[17]. Source materials for

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15 D Nicol, 'Gene Patents and Access to Genetic Tests' (2003) 11 *Australian Health Law Bulletin* 73 at 74; cf R Cook-Deegan, *The Gene Wars: Science, Politics and the Human Genome*, (New York, Norton, 1994), 28.

16 IBC *IP Report,* above n 13, 2. See also M D Kirby, "Intellectual Property and the Human Genome" (2001) 12 *Australian Intellectual Property Journal* 61 at 74-75.

17 IBC *IP Report*, above n 13, 3. In Australia, the Australian Law Reform Commission (ALRC) has recommended that there be added

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genetic investigation has sometimes been obtained from 'donors' in poorer, developing countries. This has been so because of the concentrated known areas of disease; fast inter-generational reproduction; the easy means of collection; and a low risk of litigation or demands for profit sharing.

Concerns about such abuse led the HUGO Ethics Committee to demand that a fixed proportion of net profits of pharmaceutical companies should be devoted to repaying the benefits provided by donors in developing countries, in the form of their human genetic material[18].

Upholding basic rights and core values: Confronting the issues presented by patent protection in the field of biomedicine, the Nuffield Council on Bioethics in the United Kingdom concluded in 2002 that, on the whole, the provision of exclusive rights awarded for a limited period in the form of a patent system was ethically defensible because it had generally worked for the benefit of patients and society. Nevertheless, the Nuffield Council considered that "[I]n the particular case of patents

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to national patent law a requirement of "usefulness" as a precondition for the grant of a standard patent and in the certification of an innovation patent. See ALRC, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99, (2004) 157 (Recommendation 6–3).

[18] See HUGO Ethics Committee, *Statement on Benefit Sharing* (http://www.gene.ucl.ac.uk/hugo/benefit.html); 'Genetic Benefit Sharing' (2000) 290 *Science*, 49.

that asserted property rights over DNA, consideration should be given to whether the balance between public and private interests has been fairly struck"[19].

The Nuffield Council recommended that only genetic sequences that have been identified and characterised as beneficial should be capable of attracting patent rights and that the granting of patents over DNA sequences, as such, should "become the exception rather than the norm". In effect, the Nuffield Council demanded a return to the strict observance of a fundamental principle that previously gave strength and legitimacy to legal entitlements to patent protection. This insisted that patents should only be available for "inventions" and not the "discovery of something appearing naturally in nature"; that for patent protection something distinctly "novel" was required, not a matter of routine that was produced by computers; and that the product must be immediately "useful" without which, from a social point of view, monopoly protection (even for a limited time) could not be justified.

These reminders of the core components that should inform intellectual property law in countries of the common law tradition need to be reinforced and insisted upon by the Commonwealth of Nations, including in international bodies such as the World Trade Organisation ("WTO") and the World Intellectual Property Organisation ("WIPO"). The

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19 Nuffield Council on Bioethics, *The Ethics of Patenting DNA – A Discussion Paper* (2002) 69 (para 6.2). See also para 2.10.

Commonwealth is potentially a voice for a quarter of humanity, mostly in developing countries. It should lift its voice and promote common action to uphold these core values of patent law in the field of biomedicine.

UNESCO Genome Declaration : In 1997, the General Conference of UNESCO adopted the *Universal Declaration on the Human Genome and Human Rights*[20] ("the Genome Declaration"). That Declaration acknowledged that the human genome "underlines the fundamental unity of all members of the human family"[21]. It expressed the aspiration that "the human genome in its natural state shall not give rise to financial gains"[22].

Those seeking intellectual property protection generally point to some 'value-added' that, they claim, justifies the grant of monopoly rights. So how do we reconcile the advance of knowledge about the genome; utilisation of that knowledge for therapeutic and other purposes; protection of legitimate investments to this end; but an assurance that the benefits will be available to all of humanity? This is a major challenge before the Commonwealth of Nations and the world.

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[20] Adopted 11 November 1997 by the 29th Session of the General Conference of UNESCO.

[21] Article 1.

[22] Article 4.

In UNESCO, in September 2001, the IBC drew to the attention of the Director-General its view that "there are strong ethical grounds for excluding the human genome from patentability". It recommended that the WTO, in its review of the TRIPS Agreement, should clarify, in accordance with the provision of Article 27(2) of that Agreement, that the human genome is not patentable on the basis of the public interest consideration set out in that Article. The General Conference of UNESCO invited the Director-General to draw this advice to the notice of the WTO[23]. In addition to these communications, a larger process of consultation amongst the affected agencies of the United Nations was established. An Inter-Agency Committee on Bioethics was created with a view to promoting further discussion of these issues, including those of intellectual property protection and the TRIPS Agreement of the WTO.

UNESCO Bioethics Declaration: This, in turn, led to the decision of UNESCO to initiate, through the IBC, preparation of an *Universal Declaration on Bioethics and Human Rights*[24] ("the Bioethics Declaration"). At the time, Madame Michèle Stanton Jean of Quebec, Canada, was the President of the IBC. At her invitation, and with the concurrence of the IBC, I became the chairperson of the drafting group that prepared this second Declaration.

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[23] Resolution 31C/22 available on the internet at: <http://UNESDOC.unesco.org/images/0012/001246/124687e.pdf>.

[24] Adopted 19 October 2005 by the 33rd Session of the General Conference of UNESCO.

The Bioethics Declaration sought to bring together the body of doctrine concerned with ethical principles that had evolved in the healthcare professions since the time of the *Hippocratic Oath* in ancient Greece and the more recent body of doctrine, largely developed within the legal discipline, for the protection of fundamental human rights. The Bioethics Declaration contains several principles relevant to the specific topic of intellectual property law. Thus Art 14 ("Social Responsibility in Health") and Art 15 ("Sharing of Benefits") emphasise the importance in bioethical decisions of ensuring that all members of society share in the "benefits resulting from any scientific research and its applications"[25]. The Bioethics Declaration also underlines the point that such benefits should be shared "in particular with developing countries"[26]. Such principles are harmonious with the purposes of the Commonwealth of Nations. They represent the other side of the coin of assertions of national, individual and corporate interests often expressed in municipal and international law adopted to uphold economic investments in biomedical tests and therapies.

Getting the balance right: Striking the right balance between protecting and promoting investments in these spheres, through intellectual property law, and ensuring that those investments are

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[25] Article 15(1).

[26] Article 15.

targeted at health conditions that are relevant to most of humanity and that any therapies are available at affordable cost to people everywhere, constitute issues of great importance for all countries of the Commonwealth of Nations.

It would be no bad thing if lawyers throughout the Commonwealth, and the meetings of Commonwealth leaders, added their voices to ensure that national and international laws on patenting of biomedical advances conform to the principles endorsed by the IBC of UNESCO. This is the pointy end of a practical legal issue in which it is necessary for those who truly believe in the universality of human rights (and especially the right of access to the best available healthcare) to speak out to balance those who view such questions solely from an economic point of view and often in terms of their own national or individual economic interests.

EMBRYONIC STEM CELLS

Pluripotent cells and their potential: Another development important for biomedicine, which the IBC of UNESCO has studied, is the use of embryonic stem cells in therapeutic research.

The research on this topic has focussed on human stem cells, particularly those derived from the human embryo. The embryo is not a foetus. Still less is it an aborted or stillborn baby. In terms of size, an embryo is smaller than a full-stop on a typed page. Yet scientists have

found that stem cells, obtained from the human embryo, have a capacity to develop into more than one form of human tissue. If they are derived from embryonic cells, they may be *totipotent* (able to develop into all the different types of cells needed for a complete and functioning organism); *plenipotent* (able to give rise to most types of tissue but not capable of bringing an organism into existence); or *multipotent* (being able to give rise to particular tissue types).

Because of its very nature, an embryo must be able to develop in remarkable ways. It is this feature of embryonic cells that is thought likely to have beneficial consequences for medical research and therapeutic applications. Early experimentation on the repair of damaged cells has given rise to much scientific attention to this potentiality. In particular, the apparent repair of damaged brain cells in patients with Parkinson's disease or coronary cells following myocardial infarction has led to hopes that embryonic cell research will be useful for many scientific applications. Proponents of the research have therefore demanded that the use of embryonic stem cells should be encouraged and promoted because of their potential to result in therapies to combat forms of cancer and immune diseases, diabetes and diseases of, or injuries to, the nervous system[27].

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[27] UNESCO, International Bioethics Committee, *Report on the Use of Embryonic Stem Cells in Therapeutic Research* (BIO-7/00/GT-1/2 (Rev 3) (2001), 9-13.

In most national and international statements of human rights, particular respect is accorded to human life[28]. There is a controversy as to whether such general provisions extend to prohibit the creation, preservation and use of embryonic cells for research; the extraction of particular cells for use in therapies; and the destruction of such cells when they are excess to needs.

Prohibitions and facilitations: Since the *Human Fertilisation and Embryology Act* 1990, the United Kingdom has authorised the use of supernumerary human embryos for restricted research purposes. In particular, the Act has permitted research use concerned with reproductive medicine and for the diagnosis of genetic and chromosomal disorders.

In 2001, the United Kingdom Parliament approved a law permitting the cloning of human embryos to derive stem cells, thus allowing the possibility of therapeutic cloning of human cells[29]. However, in Australia, the *Prohibition of Human Cloning for Reproduction Act* 2002 (Cth) and the *Research Involving Human Embryos Act* 2002 (Cth) were enacted by the Federal Parliament as part of a package of laws aimed at the prohibition of human cloning and other

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28 See eg *Universal Declaration on Human Rights,* Art 3; *International Covenant on Civil and Political Rights*, Art 1; *African Charter on Human and Peoples' Rights* (1981), Art 4; *American Convention on Human Rights* (1969), Art 4.

29 *Human Fertilisation and Embryology Amendment Act* 2001 (UK).

practices deemed unacceptable to the lawmakers. Each of the Australian Acts was passed by Parliament on the basis of a promise that an independent review would be conducted two years after such passage. A review was duly established. It was chaired by a retired federal judge, the Hon John Lockhart QC.

In December 2005, the Lockhart Review presented its report. The report recommended an end to the strict prohibition contained in the 2002 Australian legislation[30]. It proposed a redefinition for legal purposes of the "human embryo". It supported the introduction of a system of licensing for the creation of embryos for use for source materials for research for *therapeutic* purposes. However, the use of cloning and the experimentation with embryos for *reproductive* purposes was banned in Australia, and remains prohibited[31].

Initially, the Australian Government rejected the recommendations of the Lockhart Review. However, following strong political, scientific and media reaction, a conscience vote was taken in the Australian Parliament. In the result, amendments to permit therapeutic cloning and

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[30] Australian Government Legislation Review: *Prohibition of Human Cloning Act* 2002 and the *Research Involving Human Embryos Act* 2002, *Report*, Canberra, December 2005.

[31] *Prohibition of Human Cloning for Reproduction Act* 2002 (Cth), pt 2 Div 1.

use of human embryonic cells were enacted, albeit with only a tiny majority in the Australian Senate[32].

The main arguments that assured this result in Australia were the recognition of the pluralistic nature of the country's society; the widespread reports on the potential utility of the relevant research and experimentation; and the express conviction that experimentation would proceed in overseas countries whatever Australian legislation said. Interestingly, both the Australian Prime Minister and the Leader of the Opposition voted against the amending Act, although each acknowledged respect for the contrary views.

International debates and bans: In the international community, the global debates on the regulation of experiments using embryonic stem cells have frequently been driven by countries and individuals that, to put it politely, are not at the cutting edge of the applicable science and technology[33]. On the other hand, in recent years, the United States of America has also adopted a conservative position on these topics. Thus, federal funding of activities involving use of embryonic cells was

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[32] In the Australian House of Representatives, the vote was 82:62. See *Commonwealth Parliamentary Debates (House of Representatives)*, 6 December 2006, 127. In the Senate the vote was 34:31. See *Commonwealth Parliamentary Debates (Senate)*, 7 November 2006, 48.

[33] Thus, Honduras was the national sponsor of the United Nations ban on human cloning, reproductive *and* therapeutic. See K L Macintosh, "Human Clones and International Human Rights" (2005) 7 *University of Technology, Sydney Law Review*, 134.

forbidden by federal law in the United States although, in that country, the actual authorisation of research on embryonic cells is generally left to the laws of each State. A handful of American States continue to prohibit such research. In 1999, the National Bioethics Advisory Commission recommended that federal regulations in the United States should be amended to permit research into embryonic stem cells obtained from supernumerary embryos. In August 2006, the National Institutes of Health in the United States issues Guidelines on the circumstances in which research could be conducted on that subject by federally funded scientists. One of the conditions to be met was that no such scientist could destroy an embryo to derive cells for experimentation purposes. Such activities could only be done by privately funded scientists who might then pass the cells on to their publicly funded colleagues. Critics suggested that regulations of such a kind were absurd, allowing to be done indirectly what was prohibited directly. Other critics contrasted savagely the passionate concern over the fate of surplus embryos derived in this way with the apparently callous lack of concern for the suffering of those who might be helped by such research, and other views propounded by those who adopt religion-based starting points for bioethical conclusions.[34]

In a number of countries, the use for research purposes of embryos donated by persons following treatment against sterility and not

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[34] See eg S Harris, *The End of Faith: Religion, Terror and the Future of Reason*, (Free Press, London, 2006), 165-167.

intended for implantation ("supernumerary embryos") is legally permitted. Often the conditions imposed for such use include a prohibition on research after the fourteenth day of the existence of the embryo and the consent of the donors who originally supplied the embryo. Such is the reported practice in Canada[35].

An elusive consensus: The source of objections to the use of embryonic cells varies as between different societies. In some, the objection is explained frankly by reference to teachings based on religious beliefs. In others, it has been justified by reference to the unique respect owed to human tissue which, at least theoretically, could potentially advance to result in a human being, who would then certainly be entitled to protection of his or her human rights. The IBC investigation of this topic discovered large differences in religious and philosophical perspectives.

In some branches of Christianity (Roman Catholic and Orthodox), human life is conventionally treated as having commenced at the moment of conception. However, amongst other Christians, the appearance of the primitive streak or some later phrase of foetal development are taken as morally significant. According to most teaching in Judaism, human life does not truly begin until about 28 days from conception. Much Islamic writing recognises the 'ensoulment' of a

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35 See IBC *Report on Embryonic Stem Cells* above n 28, p 5 [19].

foetus as commencing at the end of the first trimester (3 months). Hinduism generally requires live birth as a precondition to full personhood and hence moral and legal protection. Humanists take varying positions according to the actual (as distinct from potential) capacity of an embryo/foetus to be viable and to live as a human being.

In the face of such radical differences in religious, philosophical and cultural understandings, it has proved extremely difficult, at the international level, to reach a consensus on this topic. As the recent Australian Parliamentary debates demonstrated, this is a topic that divides lawmakers as it does societies.

In such circumstances, the IBC concluded[36]:

> "Every society has the right and duty to debate and decide upon ethical issues with which it is confronted. Where there is fundamental disagreement, the society will have to decide where it stands on the issue either because the question involved relates to some fundamental value of that society or because practical considerations demand that the matter be resolved. The use of human embryos for deriving stem cells would appear to be one such issue. Human embryonic stem cells research … is a matter which each community … will have to decide itself. If the decision is reached after serious ethical debate, which allows for the expression of views in different directions, then this must be accepted if one believes in the principle of democratic resolution of public issues. Examples of this process are afforded by IVF for fertility treatment and pre-implantation diagnosis with embryo selection. There are differences of opinion on the ethical values involved and yet States have decided that these medical practices are permissible".

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[36] *Ibid*, p 13 [53]-[54].

When the IBC recommended the Genome Declaration, the document initially contained no explicit reference to cloning. The draft Declaration was expressed in very general terms, inevitable in the product of an international consensus of the participating members. When, however, the governments revised the IBC draft, the final document saw the introduction of an explicit prohibition on reproductive cloning. Thus, Article 11 of the Genome Declaration states (the added words shown with emphasis):

> "Practices which are contrary to human dignity, *such as reproductive cloning of human beings*, shall not be permitted. States and competent international organisations are invited to cooperate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected".

Not everybody agreed with the notion that reproductive cloning of human beings should be absolutely prohibited[37]. Critics point to similar expressions of intuitive revulsion when earlier forms of artificial conception first became available, such as AIH (artificial insemination husband), AID (artificial insemination donor) and IVF. They regard as absurd the notion that children, born as a result of such procedures,

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[37] J A Robertson, "Why human reproductive cloning should not in all cases be prohibited" (2001) 4 *Legislation and Public Policy* 35; Y M Shikai, "Don't be swept away by mass hysteria: The benefits of human reproductive cloning and its future" (2002) 33 *Southwestern University Law Review* 259.

experiencing entirely different lives and environmental stimuli, would end up exactly the same as their donors[38]. They refer to the unreliable potential of revulsion or repugnance to cast light on ethical responses to modern technology. They also point out that earlier generations found much (particularly racial differences) repugnant in ways that would not be treated as acceptable today. Moreover, if, say, a country with a majority Christian population prohibited forms of cloning for biomedical research, it could not be assumed that similar prohibitions would necessarily be adopted in law by a country with a different religious or ethical tradition, such as [Buddhist] Sri Lanka or [Confucian] Singapore.

Hybrids, chimeras and transgenesis: Within the diverse multi-national family that is the Commonwealth of Nations, these considerations make it difficult to agree on identical responses to technological developments of this type. The most that can be expected is an insistence on thorough ethical dialogue; a respect for different viewpoints; mutual engagement and a search for shared understandings; and the creation of institutional ethics committees to focus and promote such exchanges.

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38 Macintosh (2005) 7 *University of Technology, Sydney Law Review* 134 at 135-136 describing the resolution of the General Assembly of the United Nations of 8 March 2005. This approved a Declaration, proposed by the Sixth Committee, to "prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life". The General Assembly vote was 84 to 34 in favour with 37 abstentions.

One particular problem facing legal regulators on subjects of this kind is the speed with which developments typically occur in the field of biomedical research. Thus, until recently, there was much international consensus of the need for particular care to regulate or prohibit the creation of chimeras - hybrid embryos containing both human and animal genetic material. Various reasons have been advanced, including concern that such chimeras involve human scientists in "playing God", altering species' definitions and debasing human distinctiveness. A practical source of opposition has reflected the particular concern that inter-species experimentation or transplantation might sometimes run the risk of introducing into the human species viruses to which other species have developed immunity but which cannot be combated by human beings.

Despite these considerations, in recent years experiments have been conducted to create transgenic animals such as the Harvard onco-mouse[39]. This is a mouse into which an active human onco-gene has been introduced from the human species in order to give the mouse a genetic disposition to develop cancerous tumours and hence to be specially suitable for laboratory testing of drugs designed to destroy or control human cancer cells.

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[39] United States, National Commission for the Protection of Human Subjects on Biomedical and Behavioural Research, *Report*, 21 May 1975.

In December 2006, the United Kingdom government proposed a total ban on the creation of *any* hybrid embryo containing human material, even for research purposes. Following protests from numerous research organisations, the government reportedly relented. In May 2007, new draft regulations were published setting out a list of techniques of inter-species experimentation that could be allowed, including the creation of "cybrid" embryos - which comprise human DNA implanted into an empty animal egg and human embryos that express certain animal genes or contain animal cells.

At the time of the report on this development in *Nature Medicine* in August 2007[40], it was expected that the draft regulations would be signed into law some time in September 2007 so as to permit two research groups in the United Kingdom to proceed with their research in the Stem Cell Biology Laboratory in King's College, London. Critics of the procedure reportedly argue that the rules are too proscriptive rather than being excessively permissive. This debate indicates the level of scientific and legal complexity that issues of this kind now present to the law and its practitioners.

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[40] August 2007, Vol 13, No 8.

PRE-IMPLANTATION GENETIC DIAGNOSIS

The facility of PGD and its uses: To demonstrate further the complex character of the issues that are now arising in this field of discourse, I shift my focus to the subject of the regulation of pre-implantation genetic diagnosis. This is a topic that has recently been examined by the New Zealand Law Foundation Advisory Review Committee set up to promote debate in that country. I serve as a member of that committee which is centred on the Otago University in Dunedin, New Zealand.

Pre-implantation Genetic Diagnosis (PGD) is a technology that has been developed as an alternative to pre-natal diagnosis for couples who are at risk of passing inherited diseases to their children. With pre-natal testing, such as amniocentesis, diagnosis is commonly undertaken when the pregnancy is already established. If the foetus is discovered to be affected by a defined genetic disease, parents may be given the opportunity to consider whether to continue with the pregnancy or to terminate it and to try to establish a fresh pregnancy that will be free of the inherited disorder. The objects of PGD are to diminish the risks of passing on serious hereditary diseases; to reduce the burden and stress on the parents (especially the female parent) concerned; and to minimise the need for the termination of affected pregnancies.

Research towards a technology of PGD began in the United Kingdom in the middle 1980s. Earlier technology was developed for pre-

implantation techniques in the context of animal husbandry, chiefly in order to breed animals of a preferred sex[41]. The first successful human pregnancies using PGD were reported in 1990 for various X-linked or sex-linked disorders (where males, not females, are affected) leading to the selection of female embryos for implantation. In 1992, this experimentation was followed by a report of a live human birth after using PGD selection designed to minimise the risk of transmitting cystic fibrosis. In 2000, PGD was used in the United Kingdom to test a number of disorders caused by a single gene, namely beta-thalassaemia, sickle cell anaemia and muscular dystrophy as well as for various chromosomal disorders, including Down Syndrome. In essence, PGD contemplates the creation of embryos; the performance of embryo biopsy; the analysis of biopsied cells; and the transfer of unaffected embryos to establish a successful pregnancy free from an inherited disorder deemed undesirable. PGD incorporates the use of IVF technology as part of the process.

In some societies where termination of pregnancies is absolutely illegal and where that law is enforced, PGD represents a potential means of circumventing the abortion law. Apart from anything else, it avoids the enormous trauma to the pregnant mother (and burden, in many cases, on the father) of any abortion procedures or, alternately, the birth of a seriously handicapped child. On the other hand, PGD has

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[41] New Zealand, Law Foundation, *Choosing Genes for Future Children - Regulating Pre-Implantation Genetic Diagnosis* (2006, Dunedin), 4.

not yet become a widely used procedure, either in the United Kingdom, where it received its early development, or in other developed and developing countries of the Commonwealth. Some oppose it on moral grounds, suggesting that it denigrates people with disabilities; objectifies the process of human birth; and reduces diversity in the human gene pool.

The reason for the inquiry in New Zealand was the rapid rise in popularity of PGD techniques in that country and the fact that New Zealand was unique, amongst the nations so far offering PGD services, in providing a commitment to fund the full cost of up to two cycles of IVF/PGD for people who use PGD to test for specified serious inherited genetic disorders. As an indication of inter-Commonwealth cooperation, many of the PGD tests administered in New Zealand are actually contracted out to the IVF Unit at Monash University in Melbourne, Australia.

At the time of the New Zealand inquiry, the PGD tests were available for five major inherited conditions (namely Huntington's disease, cystic fibrosis, spinal muscular atrophy, beta-thalassaemia and fragile X syndrome). However, PGD could be approved in other cases on a specific instance basis[42].

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[42] *Ibid*, 5.

The New Zealand committee set about examining closely the scientific foundation and technological developments relevant to PGD facilities. This approach is consistent with the insistence that all modern legal and ethical investigations of biomedical issues should be based on a sound understanding of the relevant science and technology.

The controversies of PGD: As the New Zealand inquiry into PGD proceeded it discovered a number of important topics that would require attention. These included:

- The need for specific respect for the perspective of the Maori people of New Zealand concerning the sanctity of their Whakapapa (genetic inheritance) and anxiety that nothing should be done through PGD to reduce that inheritance, in all of its diversity;
- The need to consider whether PGD results in the denigration of people with disabilities or any suggestion in the community that their lives are sometimes less worthy;
- The need to examine whether PGD should be available only to married couples or also to couples in *de facto* relationships; single women at risk wishing to secure a safe and viable pregnancy; and same-sex couples in a like position?
- The need to evaluate demands on the national health budget of PGD and competing health concerns, but also keeping in mind the public cost involved following the birth of disabled children. Can

PGD be justified in a developing country? Or should other health concerns have a greater priority?

- The requirement to address the concern of many Christian groups that PGD involves a departure from the random passage of genes from one generation to the next and the introduction of scientists "playing God" to create human life after a preconceived notion of what that human life should be; and
- The necessity to consider the question of which genetic conditions may be considered as "disorders" and which of them will be approved for PGD or not approved. Thus, will manifestations of baldness in a family be disapproved and excluded? Will the earlier birth of several female children to a couple warrant PGD to ensure a male birth? Will PGD lead on to a postulate of "normal" genetics with a risk of reducing the human gene pool whose diversity has been an important protection to humanity against disease? Will developments in one country lead to demands for similar developments in other countries, despite significantly different cultural, philosophical and religious traditions?[43]

Different legislative responses: In the United Kingdom, a statutory regime has been adopted for PGD. It has been described as "one of the most liberal regulatory mechanisms in the world". The *Human*

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[43] K Ludlow, "What about me? How far do we go in the interests of the child in assisted reproductive technology?" (2007) 6 *QUT Law JJ* 214.

Fertilisation and Embryology Act 1990 (UK) contains few express prohibitions. It delegates considerable decision-making power to the Human Fertilisation and Embryology Authority (HFEA). This Authority acts as a licensing body for purposes identified in the Act. There is no express reference to PGD in the United Kingdom Act. However, the Act prohibits the creation, keeping or use of an embryo except in pursuance of a licence granted under the Act. Such licences may be provided for "treatment services". These are widely defined. They have included the safe provision of fertility services, ie by the exclusion of serious hereditary diseases.

Justifying this approach of openness and flexibility, the then Prime Minister (Right Hon Tony Blair), in a foreword to the United Kingdom Government White Paper, *Our Inheritance, Our Future*[44] wrote:

> "Our country has a remarkable scientific tradition. The extraordinary achievements of Newton, Darwin and a host of other eminent scientists have both greatly increased the understanding of our world and improved the quality of life for everyone. Our record continues to be outstanding; with just 1% of the world's population, we receive 9% of scientific citations. Nowhere has this record been more notable in recent decades than in bioscience and biotechnology. The discovery in Britain of the structure of DNA fifty years ago - perhaps the biggest single scientific advance of the last century - marked the beginning of a golden age of bioscience in Britain which continues today. It is likely to have as big an impact on our lives in the coming century as the computer had for the last generation … I am absolutely determined that the National Health Service should be able

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[44] United Kingdom, Government White Paper, *Our Inheritance, Our Future* (Cm 5761, 2003), [1].

> to respond to these advances so that the benefits of genetics and the more personalised and improved healthcare it will bring are available to all".

The New Zealand Committee recommended close monitoring of the PGD practices being adopted in New Zealand and the collection of national (or preferably Australasian) statistics. It also recommended physical and mental examination and monitoring of PGD children once born. It proposed comparative studies of the effectiveness of PGD for decreasing miscarriage rates and for increasing healthy birth rates. It recommended separate consideration of proposals for the introduction of comprehensive genomic screening for the entire population. It regarded such proposals as raising different ethical questions demanding separate investigation and report. It also recommended further study of what single gene and complex genetic disorders could justify publicly funded PGD in New Zealand[45].

Anyone at this Conference wanting an excellent review of the relevant legal precedents, both legislative and judicial[46], could hardly do better than to secure copy of the 2006 report of the New Zealand Committee. It demonstrates both the potential of biomedical technology to help people and to reduce suffering. But also their capacity to present many and varied new issues, including legal issues, requiring the attention of judges, lawyers and legislators.

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[45] NZ Report, above n 41, 58-59.

[46] *R (Quintavalle) v Human Fertilisation and Embryonic Authority* [2005] UKHL 28; [2005] 2 WLR 1061; [2005] 2 All ER 555 (HL).

HIV/AIDS AND BIOMEDICINE

A colossal epidemic and actuality: For some citizens of Commonwealth countries, discussions of pharmaceutical patents, embryonic stem cells, PGD and like advances in sophisticated biomedical technology will seem entirely remote, theoretical, non-urgent problems for law and policy.

In countries where the annual per capita expenditure on public health is extremely modest, say $US100, theorizing about such issues will seem more than a trifle unrealistic. In such Commonwealth countries, there will be much more urgent biomedical problems. Chief amongst these, in many Commonwealth countries, will be the increasing incidence of malaria, tuberculosis and HIV/AIDS. Especially is this true of parts of Commonwealth Africa

In this concluding section of this paper, I will therefore turn to some of the biomedical and social dilemmas that face us connection with HIV/AIDS. This is an issue with which I have been connected, during the entire history of the pandemic, since the early 1980s. I served on the inaugural WHO Global Commission on AIDS. I am now a member of the Human Rights Reference Group of UNAIDS - the inter-agency body of the United Nations, established to enhance the Organisation's response to the HIV virus.

For a measure of the problem we are facing, I can do no better than to quote a notable Commonwealth citizen, Justice Edwin Cameron of the South African Supreme Court of Appeal, in a recent address to the International Labour Organisation in Geneva[47]:

> "…[T]his epidemic is colossal. It is probably the biggest microbial pandemic to strike human kind in six centuries. Though the official figures are - rightly in my view - much contested, few deny that many tens of millions of people risk death from AIDS in the next decades - and that most of them are poor Africans.
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> UNAIDS estimates that nearly 40 million people world-wide are living with HIV - and perhaps 25 million have already lost their lives because of AIDS - in 2005 alone, an estimated 2.8 million. Changes in behaviour and prevention programmes (as well as the fact that the epidemic may have peaked) have reduced the incidence of HIV in many countries. Yet in the developing world, and particularly in Africa, the epidemic is still expanding. According to UNAIDS, Africa remains the global epicentre of the pandemic[48] …
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> Within Africa, the sub-Sahara region has the highest infection rates in the world. While only 10% of the world's population lives there, nearly two-thirds (about 25 million) of the world's population with HIV resides there. The dark shadow of AIDS mirrors Africa's overall burden of disease. And its darkest reflection is in the deadly toll of AIDS. In 2005 an estimated 930,000 people died of AIDS in Southern Africa alone[49]. Seen from some angles, the prevalence of my own country, South Africa, are the highest. 11% of the total population, 19% of the working-age population, and 33% of women aged 25-29 are infected with HIV. On every day of 2006, approximately 1400 people in South Africa were infected with HIV and 950 died of AIDS.

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47 E Cameron, "Legislating an Epidemic: The Challenge of HIV/AIDS in the Workplace", unpublished, 19 July 2007, ILO Geneva, 1-2 [3].

48 UNAIDS, *Report on the Global AIDS Epidemic 2006*, Geneva, 5.

49 *Ibid*, 15-23.

> We must humble ourselves before this [epidemic] in considering policy interventions that might alleviate it".

For Justice Cameron, these statistics are not impersonal data. He is himself an openly homosexual man living with HIV. He is a voice for the voiceless in this most urgent contemporary biomedical problem of the Commonwealth and of Africa. In February 2007, I had the privilege of succeeding him to participate in a seminar on HIV/AIDS organised for the judiciary of Zambia by the Zambia Aids Law Research and Advocacy Network (ZARAN). I pay tribute to Chief Justice Ernest Sakala and his colleagues for supporting and attending that important meeting. AIDS is a proper concern for all Commonwealth lawyers and judges.

Biomedical advances with ARVs: As a result of scientific and technological advances since the late 1990s, remarkable combinations of therapies (anti-retroviral drugs or ARVs) have become available for treatment of HIV/AIDS on a large scale. Anyone who has seen the effect that the administration of ARVs to people living with HIV/AIDS, medically identified and faithfully administered and monitored, will attest to the effectiveness of the drugs. They help reverse weight loss, lift the spirit and restore the will to live as well as a vital economic capacity.

This is why the Heads of Government of 189 countries, meeting in the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS in June 2001, committed the world to reversing the epidemic

and to providing ARVs, at affordable cost, to countries and patients everywhere. The result was the WHO 3x5 programme[50]; the establishment of the Global Fund to support the purchase of ARVs for distribution in developing countries; and the encouragement of national and international programmes designed to increase accessibility to these life-saving and life-enhancing drugs everywhere.

In parts of Africa, notably Botswana, there have been highly successful campaigns to provide ARVs to the population needing them. The ARVs are highly sophisticated drugs. If purchased at full North American costs, they would be unaffordable to all but a tiny fraction of Commonwealth citizens. Treating HIV/AIDS as a most urgent public health emergency has permitted exceptions to be established for the use of generic copies of patented drugs and for the supply of licensed drugs through global subventions by rich countries (especially the United States) to poor ones. Providing such drugs to the sick is but the first step. It remains necessary to monitor their use and to ensure that they are accurately administered without interruption.

Limits of biomedicine: HIV and prevention: Unfortunately, providing ARVs to the infected is not a complete answer to the HIV/AIDS epidemic. As was quickly discerned in the Lusaka ZARAN Judges'

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[50] To secure three million persons in developing countries access to anti-retrovirals by 2005. The objective was partly, but not wholly, successful.

Seminar, patients receiving ARVs remain infected. Although their HIV viral load may fall significantly because of the effectiveness of the ARVs, such patients remain capable of infecting others with HIV, principally through sexual intercourse. Generally speaking, nations (and the United Nations) have been happy to promote treatment and the availability of ARVs for *therapy* for the already infected. They have been much less willing to promote the strategies of *prevention* that have been shown to be effective in reducing the spread of the virus and the incidence of AIDS. Medicalising the AIDS epidemic is congenial for some. Tackling the vectors of HIV for prevention requires societies to take decisions that are often very difficult for them.

It is in this sense that the biggest challenge presented by HIV/AIDS to Commonwealth countries, and especially to Commonwealth Africa, is the challenge of social and legal intervention. On this subject, most Commonwealth countries in the developing world have been neglectful and apparently reluctant concerning the issue of prevention.

A study of those Commonwealth countries that have been successful in their strategies to promote *prevention* of the spread of HIV, and to reduce the rates of individual sero-conversion (the United Kingdom, Canada, Australia and New Zealand) will show with convincing data the steps that are essential to reducing the spread of HIV. Putting it simply, this can only be accomplished by behaviour modification. This, in turn, requires winning the confidence of the people most at risk; protecting their human dignity; and convincing them of the

need and utility to modify their own conduct. Only such strategies have been shown to be effective in preventing further spread of the HIV virus, so dangerous to the individual and to society.

This message cannot be proclaimed often enough or loudly enough - and in particular in Commonwealth Africa. It is the most important message that will be given at this Commonwealth Law Conference. Putting it quite bluntly, unless the strategies of *prevention* are energetically adopted, the numbers of people infected by HIV will continue to swamp the numbers of patients receiving ARVs. Those infected with HIV will continue to burden the budgets and health facilities to a growing and ultimately unendurable extent. The increasing numbers of patients on ARVs will remain a source of further infections. They will look and feel healthy. But they will remain capable of passing on the virus.

The present ARVs are likely, in many patients, to become less effective over time. New "second line" therapies will be even more expensive than the present ARVs. There is no certainty that they will continue to be provided at cheap cost. Rationality therefore tells us that there is no other realistic option for the countries of the Commonwealth but to step up the prevention strategies at the same time as they step up the treatment facilities. Yet, in Africa especially, an element of irrationality and reluctance has prevented many nations from taking the hard decisions essential for national strategies of prevention and behaviour modification.

Preventive methods that succeed: Studying the Commonwealth countries that have brought their rates of HIV sero-conversions down, it can now be said with a high level of satisfaction that the following strategies are essential and also effective. They are strategies in which lawyers, for once, can play a useful and constructive role in addressing a global epidemic:

(1) Engage in mass education campaigns with candid information about HIV transmission for the entire population, especially the young who are most at risk;

(2) Reform the law on commercial sex work (CSW) (prostitution) to promote empowerment of CSWs, education and insistence on the use of condoms;

(3) Provide sterile injecting equipment for use by injecting drug users (IDUs). In Australia, this is available from most pharmacies. It has reduced Australia's rates of IDU infections virtually to zero;

(4) Repeal the criminal laws that punish consensual adult same-sex activity (MSM) (the so-called "unnatural" offences introduced during colonial days);

(5) Enact laws to remedy discrimination against people living with HIV and AIDS;

(6) Introduce courses in schools to promote HIV awareness and also condom availability; and

(7) Engage the affected minority communities at highest risk (CSW, IDU, MSM) in the foregoing strategies and keep them consulted at all stages.

Unless these initiatives are taken, all the anti-retroviral drugs and all the biomedicine in the world will not turn around the AIDS epidemic. This is why this is the biggest biomedical challenge facing the Commonwealth today. It would be criminal if we were to ignore it at this Commonwealth Law Conference in Nairobi[51]

Instead of tackling HIV/AIDS in the foregoing ways, that have proved effective in the developed Commonwealth, too many countries have preferred the path of denial, neglect and 'respectability'. This head in the sand attitude will continue to reap a terrible harvest of suffering. It is therefore essential that lawyers, who know very well the difficulties of securing behaviour modification, should speak up clearly about the urgency of preventative action.

A step in the right direction was the recently reported statement of Professor Alloys Orago of the Kenya National AIDS Control Council (NACC). Reportedly he told the African Science News Service[52]:

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[51] J Csete, "HIV/AIDS and human rights: we've only just begun" (2005) 10 *HIV/AIDS Policy & Law Review* 1 (Canada).

[52] Reported, Sydney *Star Observer*, 22 August 2007, 5.

> "NACC knows that the gay practice in Kenya is still illegal. But NACC cannot exclude the gay community in the war against HIV and AIDS".

The Kenya NACC and equivalent bodies elsewhere should be adopting a proactive strategy to remove the impediments (including the legal impediments) to a successful strategy for prevention and therapy in the fight against AIDS. It cannot succeed if the fight is riddled with moralizing discrimination against the vulnerable groups most at risk. Their risk is every society's peril.

I do not underestimate the difficulties of adopting the above strategies for prevention of the spread of HIV and AIDS. But none of us should underestimate the price that will be paid for ongoing neglect and indifference.

The move to criminalise HIV: Instead of taking the initiatives I have mentioned, many African and other nations, in and outside the Commonwealth, have lately embraced a strategy of invoking criminal sanctions against those who knowingly infect others with HIV. Lawyers must lift their voices to explain why punitive strategies of this kind have only a tiny part to play in combating the spread of HIV.

To the extent that the law criminalises knowing infection of others with HIV, it introduces a significant penalty upon the individual's discovering his or her own HIV status. It thus discourages people from taking the HIV test. Yet taking the HIV test is often the vital first step towards self-awareness, behaviour modification and access to ARVs

where they are needed. In 2006, Zimbabwe, Lesotho and Swaziland adopted laws to criminalise knowing transmission of HIV to another person. Reportedly, Uganda is now considering such a law[53] and Kenya has enacted such a statute. This spread of ineffective laws has launched the latest epidemic to hit Africa and the world. HIL (highly inefficient laws) may become as infectious as HIV has been.

Large public resources will be devoted to prosecutions under these laws. Where the cohort of the sexually active population already infected with HIV is large, the net of criminalisation will be spread far and wide. Such laws are unlikely to have a large impact on reducing adult consensual or commercial sexual activity. And in most developing countries, the resources will not be available to permit careful genetic analysis to distinguish an innocent accused from a guilty infector[54].

I have myself participated judicially in court proceedings, confirming a conviction following a jury verdict in Australia for intentional transmission of a dangerous disease (HIV)[55]. There may indeed be a part for the criminal law in responding to wilful, deliberate or reckless infections of others. However, stepping up the criminal law to punish

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53 *Nature Medicine*, Vol 13, No 8 (August 2007), 890.

54 *Ibid*.

55 In *R v Reid* (2006) 162 A Crim R 377. An application for special leave to appeal to the High Court of Australia was refused.

infections will represent a drop in the ocean where truly effective strategies are required, but all too often neglected.

The urgent challenge for Cth lawyers: It is therefore essential and urgent that Commonwealth lawyers should become teachers of the AIDS paradox. Paradoxically, the most effective strategy to contain the HIV/AIDS epidemic by behaviour modification is to protect those most at risk. Only this will secure their cooperation in reducing the incidence of sero-conversions. This may not be a popular message in some quarters. Wisely and prudently and in Nairobi Bishop Desmond Tutu, Nobel Laureate, has admonished the all-too-human desire of people to have someone to look down on and to demonise. The developing countries of the Commonwealth of Nations have tasted the sting of such attitudes and discrimination in the past. They must not themselves now be guilty of practising what they preached against when they were struggling for their own dignity and freedom.

The time has come for a fresh Commonwealth initiative to combat HIV/AIDS. It should support and reinforce the efforts of WHO and UNAIDS that each teach the message I have given. It will require the mobilisation of lawyers and judges to address the lessons of effective behaviour modification and the limits of criminal law as a useful strategy. The instruction is there in those Commonwealth countries that have succeeded in reducing their HIV epidemic. Pumping out more drugs and biomedicine is not the answer for prevention. Initiating law reform is. For once we lawyers have a relevant role to play in combating this epidemic.

But will lawyers and law-makers be courageous enough and imaginative enough and determined enough to do so?

CONCLUSIONS

A global phenomenon: Our generation lives at an exciting and challenging time. The challenges of biomedicine are reaching us in the courts[56]. They present themselves to legislatures and policy-makers. They arise in the national, regional and global forums. It is vital that Commonwealth lawyers should be aware of them and be able to respond effectively and justly to them.

In this paper, there has been no occasion to deal with all of the challenges that biomedical decisions present to us in the law. The challenge to intellectual property law is a universal one, although it affects developing and developed countries differentially. The challenge of embryonic stem cells research and pre-implantation genetic testing illustrate examples of experimental technology that are now arising frequently in developed countries of the Commonwealth. Whilst the challenge of HIV/AIDS is universal, its burdens fall most heavily on people in the developing countries of the Commonwealth. This is

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[56] See eg *Cattanach v Melchoir* (2003) 215 CLR 1 (wrongful birth); *Harriton v Stephens* (2006) 80 ALJR 791 [6] ("wrongful life"). See H Teff, "Condoning Wrongful Suffering" (2007) 15 *Torts Law Review* 5. The earlier jurisprudence in Commonwealth countries, the United States and elsewhere is cited in the decisions of the High Court of Australia on these issues.

specially so because of the reluctance of most of those countries to take the hard decisions of law reform essential to repel the pandemic by the adoption of legal change essential to promoting effectively the necessary behaviour modification.

Law in the rear, limping: Because biomedicine, its associated technologies and problems constitute universal phenomena potentially affecting all humanity, Commonwealth countries can learn from each other. Our shared legal tradition and language makes this possible and comparatively efficient. Unless issues such as I have raised in this paper are dealt with through expert consultation and public processes, the judges will resolve them as best they can. They will do so by analogical reasoning, according to the common law. The response of the legislatures and the courts is, however, usually slow and hesitant.

As Justice Windeyer said in my Court in Australia forty years ago, the law does not keep pace with medicine but marches in the rear, limping[57]. Inter-disciplinary dialogue is essential. It is therefore timely, useful and urgent that this Commonwealth Law Conference in Nairobi should address some of these important themes. None of them is more important or more urgent than the challenge of HIV/AIDS where lawyers actually have a useful and constructive role to play. We should not leave Nairobi without resolving that we will do so.

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57 *Mount Isa Mines Ltd v Pusey* (1970) 125 CLR 383 at 395.

COMMONWEALTH LAWYERS' ASSOCIATION

LAW SOCIETY OF KENYA

15TH COMMONWEALTH LAW CONFERENCE, 2007

NAIROBI, KENYA, 10 SEPTEMBER 2007

BIOMEDICINE - LEGAL AND ETHICAL ISSUES

The Hon Justice Michael Kirby AC CMG