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BOOK ON THE UNESCO 20TH ANNIVERSARY OF BIOETHICS

BIOETHICS AND INTELLECTUAL PROPERTY LAW

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THE HON. MICHAEL KIRBY*

UNESCO AND ECONOMIC EQUITY

The foundation of the United Nations, in terms of the *Charter* of 1945, was based on aspirations of achieving international peace and security; economic equity; and development and universal human rights. As a species, we have not always succeeded in securing these goals. But UNESCO has made significant contributions.

During my service on the International Bioethics Committee (IBC) two international instruments were adopted which I must mention. The first was the *Universal Declaration of the Human Genome and Human Rights* (adopted by the General Conference in 1999)[1]. In its provisions, specific to the genome, UNESCO signalled its concern that progress in scientific research should not benefit only the wealthy. It should be available for all humanity. For example, the following provisions can be noted:

> *Art. 4. The human genome in its natural state shall not give rise to financial gain*
> *Art. 11. No research or research applications concerning the human genome… should prevail over respect for human rights, fundamental freedoms and human dignity…*
> *Art 12. Benefits from advances in biology, genetics and measures concerning the human genome shall be available to all, with due respect for the dignity of each individual.*

* Former member of the UNESCO International Bioethics Committee (1995-2005); Justice of the High Court of Australia (1996-2009); UNESCO Prize for Human Rights Education (1998).

[1] UNESCO, General Conference, Resolution 29C/Res16 at 41 (1997), adopted UN General Assembly, Res 152, UN GA OR 53rd Sess: UNDOC A/Res/53/152 (1999).

In the Universal Declaration on Bioethics and Human Rights (adopted by the General Conference in 2005) the following provisions appear:[2]

"The aims of the Declaration are:

...

(c) to promote respect for human dignity and to protect human rights;

(d) to recognise the importance of freedom of scientific research and the benefits derived from scientific and technological developments while stressing the need for such developments to occur within the ethical principles set out in this Declaration...

(f) to promote equitable access to medical, scientific and technological developments, as well as the greatest possible flow and the rapid sharing of benefits, with particular attention to the needs of developing countries;

Art 14.1 The promotion of health and social development for the people is a central purpose of governments that all sectors of society share.

Art 14.2 Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being, without distinction of... economic or social condition, progress in scientific and technology should advance:

(a) *... access to quality healthcare and essential medicines;*

Art 15.1 Benefits resulting from any scientific research and its application should be shared with society as a whole and, within the international community, in particular with developing countries..."

[2] UNESCO General Conference, adopted 19 October 2005 (33rd Sess GCFCE).

HIV/AIDS AND EXCEPTIONALISM

Substantially coinciding with the work of the IBC on the foregoing two *Universal Declarations*, was important and innovative work happening elsewhere in the United Nations system. In the early 1980s, a deadly new virus became known, namely the Human Immunodeficiency Virus (HIV). In its final stages, this virus would normally cause the death of those infected. At first, there was no effective treatment; and no preventative vaccine. There is still no cure and no vaccine. However, in the 1990s, by the genius of science, treatment with a triple combination of antiretroviral drugs (ARVs) was shown to have lifesaving effect. People with access to these ARVs began to feel better and to return to work. Moreover, the medicines had the highly beneficial effect of reducing the viral load in such people and thereby reducing their capacity to infect others, by passing on the virus.

In the early years, the ARVs were only effectively available to wealthy patients or those living in developed countries with strong systems of universal public health. They were not available in developing countries, although the centre of the epidemic was in Sub Saharan Africa and other poorer regions of the world where 30 million people became infected and many died.

It was at this time that the joint United Nations Program to combat the spread of HIV (UNAIDS) and the World Health Organisation (WHO) resolved, exceptionally, to mobilise world efforts to provide ARVs to people everywhere.

In acting in this way, these UN agencies were conforming the ethical principles inherent in the *Charter* and endorsed by *UNESCO* and the IBC. Access to the highest attainable standard of health should not depend upon the chance event of location or birthplace. It should be a birthright of every human being, in accordance with the principles expressed in the *Universal Declaration of Human Rights* (Art. 25.1) and the *International Covenant on Economic Social and Cultural Rights* (Art. 12). A great effort was mobilised to provide antiretroviral drugs to people living in developing countries who would otherwise have died. The mobilisation was supported by important initiatives, in part spurred on by the United Nations. These included the establishment of the Global Fund on AIDS, Tuberculosis and Malaria

(the Global Fund) and, in the United States, the President's Special Fund to support the same objectives (PETFAR).

At first, the objective was to ensure that 5 million people (of the estimated 30 million who had been infected with HIV) would have access to the ARVs by 2005. They, bolder goals were set to provide access to 10 million who would benefit from the drugs. As scientific knowledge advanced, it became clear that 15 million patients would benefit from access to the ARVs. However, by this stage a significant challenge loomed in the path of such access. It was challenge that manifested itself in the form of international intellectual property law (specifically the law of patents in respect of pharmaceutical drugs).

PATENT LAW AND HUMAN RIGHTS

Intellectual property law is an ancient form of protection for those who develop new inventions. Because inventiveness is universal, international treaties were developed in the 19th and 20th centuries to promote patents and to encourage uniformity between the domestic laws of nations. The chief system relevant to patenting pharmaceutical products is now expressed in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), signed in 1994. TRIPS is administered by the World Trade Organisation (WTO), a non-UN body to which most countries of the world have joined up. TRIPS introduced IP protection at a breadth never seen previously at the multilateral level. In exchange for the public revelation of the secrets of the invention, the inventor is granted a legal monopoly to sell and profit from the invention for a period of time. Under TRIPS, this period is a minimum of 20 years. The aim is to reward the inventor and to promote research and development.

IP and patent law are not incompatible with universal human rights law. They are recognised in Art. 27.2 of the *Universal Declaration of Human Rights* which provides:

> *Art 27.2* *Everyone has the right to the protection of the moral and material interests resulting from any scientific… production for which he is the author.*

Likewise, such rights are recognised in the *International Covenant on Economic, Social and Cultural Rights:*

> *Art. 15.1* *The States Parties to the present Covenant recognise the right of everyone:*
>
> *...*
>
> (b) *To enjoy the benefits of scientific progress and its applications;*
>
> (c) *To benefit from the protection of the moral and material interests resulting from any scientific ... production of which he is the author.*

Given that both the attainment of essential physical and mental health and the protection of interests from scientific inventiveness are recognised in the same international statements of human rights, the task is presented to balance and reconcile the competing claims of these rights.

Unfortunately, this reconciliation has not been well achieved in the international community. In part, this is because the international treaties on IP law largely predated the *Charter* of the United Nations and the human rights treaties that followed it after 1945. In part, the reconciliation has not occurred because human rights treaties are administered by UN agencies. International IP law has been administered in recent years by the WTO, a non-UN agency. Human rights law has developed along lines of fundamental principles. IP and patent law has developed along lines of economic interest, international, national and corporate profitability and market forces.

The need for reconciliation is rendered urgent in the case of the HIV/AIDS epidemic. This is because the initial drugs that formed the cocktail of ARVs are now demonstrating inefficiencies and unwanted side effects. Those drugs have substantially been available in cheap generic copies that ensure the necessary pharmaceuticals can be provided to poor people in poor countries at a tiny fraction of their original patented cost. But with the so-called second line and third line therapies of pharmaceuticals, the cost of new ARVs rises exponentially. The costs

become prohibitive for national governments and international bodies such as the Global Fund. The real prospect begins to loom that effective ARVs will not be available in developing countries. Moreover, some patients, already receiving such drugs, may not be able to continue. The result, potentially, will be a return to the death of millions. This is an unthinkable prospect. But it is not impossible. It arises from the want of reconciliation of conflicting branches of international law.

WHAT CAN BE DONE?

To address the issue of what can be done by the international community to achieve the essential reconciliation, a number of global bodies have addressed their attention. In 2001, the UN Commission on Human Rights who authorised a study by the High Commissioner for Human Rights who issued a report calling for action[3]. In 2012, the Global Commission on HIV and the Law, established by UNDP, delivered a report *Risks, Rights and Health[4].* Other international bodies drew attention to the urgent, approaching predicament[5]. I have served on a number of these bodies[6]. The challenge is an extremely urgent one. The answers cannot be delayed.

The UNDP Commission unanimously recommended that the UN Secretary-General should convene:

> *"… A neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceutical products. Such a regime should be consistent with international human rights law and public health requirements, while safeguarding the justifiable rights of inventors. Such a body should include representation from the High Commissioner of Human Rights, WHO, WTO, UNDP, UNAIDS and WIPO, as well as the Special Rapporteur on the Right to Health, key*

[3] United Nations Economic and Social Council, Commission on Human Rights, report of the High Commissioner for Human Rights, "The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights, E/CN.4/sub.2/2001/13 (2001)
[4] UNDP report, New York, 2012.
[5] See e.g. Commonwealth Secretariat, report of the Eminent Persons Group, *A Commonwealth of the People: Time for Urgent Reform* (2011, London), 98 ("Advocacy on HIV/AIDS: A Commonwealth Health and Economic Development Priority").
[6] On UNDP Commission; Comsec Group; and UNAIDS/Lancet Commission, Defeating AIDS – Advancing Global Health.

technical agencies and experts, and private sector and civil society representatives, including people living with HIV. ….”

In October 2013, the heads of UNDP, UNAIDS and OHCHR wrote to the Secretary-General requesting action on UNDP Commission recommendation. So far a high level expert inquiry has not been established. And meantime a number of unfortunate developments have been happening within, and under the impetus of, WTO. These have included the initiation of many so-called Free Trade Agreements which have contained provisions which have removed the possibilities of such exceptions and qualifications on protection of the right to health as exists under (“TRIPS Plus”). Negotiation of multilateral treaties such as the *Transpacific Partnership* and the proposal of international treaties such as the *Anti-Counterfeiting Trade Agreement* (ACTA) have proceeded. Far from producing the burden of IP and patent law on pharmaceuticals for poor countries, these treaties have sought to reduce capacity to use generic drugs so as to reduce the cost of medicines in the developing world.

TIME FOR BIOETHICAL ACTION

The issues referred to in this note are critical issues of bioethics. Literally, the concern matters of life and death and of human welfare, happiness and survival for millions of human beings. It must be hoped that the international community will respond to the recommendations now before the UN Secretary-General. And that the response will conform to the fundamental principles of bioethics stated in the UNESCO Universal Declarations.