Foreword
The Hon Justice Michael Kirby AC CMG

I became aware of the subjects of this book almost by accident. In the early 1980s, when HIV/AIDS so unexpectedly came upon the world, I was invited by that fine epidemiologist turned international civil servant, Dr Jonathan Mann, to join the World Health Organisation inaugural Global Commission on AIDS.

This experience threw me into close contact with some of the leaders of medical science at the time, including Robert Gallo and Luc Montagnier, the two scientists who first isolated the virus that causes AIDS. I was soon attending meetings with leading biomedical experts and hearing them describe their experiments, their dreams and hopes.

How clearly I remember the predictions of those days that we would have a vaccine against HIV transmission within a decade or so and a cure within twenty years. Despite all the talent and the investment of great resources, the world still has no safe vaccine. There is no cure, although remarkable advances have occurred in the development of antiretroviral drugs, some of them actually produced earlier and for other purposes but put to work in the battle against AIDS, often with remarkable efficacy.

Looking at those conferences from the outside, as a non-scientist, I could not help but contrast the two moods that were often present in the debates. I do not refer to the moods of optimism and pessimism, although we alternated between hope and despair as one product after another looked promising but then dashed our expectations. The contrast in moods to which I refer was between those scientists of the old school who preached that the pandemic was a great moral challenge for our species and that advances would best be secured by endeavours of pure science, working by serendipity with free sharing of knowledge and research. And those of the new school who saw the hope of progress as lying in huge investments in scientific experimentation which, they assured us, would ultimately produce the vaccine and cure and deliver a couple of Nobel prizes into the bargain.

The foremost proponent of the pure science theory was a young American biochemist, David Baltimore. A decade and more before HIV burst upon the world, he had begun investigating a rare simian retrovirus that existed in
African chimpanzees. When the human retrovirus we now know as HIV appeared, it was David Baltimore’s research that cut a decade off the time of the ensuing investigations. He had not conducted his research for the glittering prizes of financial gain and investment profits. I do not believe that he was even motivated by the hope of a Nobel Prize, although that was duly awarded to him. His basic motivation was human curiosity. He was intrigued by the peculiarities and cleverness of the virus that he studied.

Baltimore’s story provides an important antidote to those who think that the greatest leaps of science are always made in committees like that of the Manhattan Project and as a result of huge capital investments. On the contrary, sometimes the biggest leaps in scientific knowledge, essential to the most important technological breakthroughs, come about just because human beings are puzzled and want to get to the bottom of an intriguing problem.

At the HIV meetings, scientists began to speak of the biotechnology revolution that was underway in the United States following the closely divided decision of the Supreme Court of that country in *Diamond v Chakrabarty*, with which Dr Rimmer begins this book. That decision was announced by the Supreme Court in 1980. By five Justices to four, the Court found that Ananda Chakrabarty’s patent application in respect of an oil-eating bacteria, constituted either a manner of manufacture or a composition of matter and was therefore patentable under United States law.

That decision was one of those turning points in legal history, like *Donoghue v Stevenson* (1932) (on the law of negligence), *Brown v Board of Education* (1954) (on equal rights for racial minorities), or the *Engineers Case* (1920) (on the literalist interpretation of the *Australian Constitution* 1901).

It is interesting, but futile, to speculate on what might have happened for the subjects of this book if Chief Justice Burger, who wrote the majority opinion of the Court, or one of those Justices who concurred with him, had slipped on an oily substance whilst climbing the beautiful marble stairs to his chambers in the Supreme Court building, momentarily distracted by the aspirational legend: ‘Equal Justice Under Law’. If the Court had been evenly decided or if the vote had affirmatively gone the other way, the momentum of which the scientists spoke in those early AIDS colloquia might have turned out quite differently.

In the curious manner of these things, my encounter with the international scientific, legal and public health experts working on HIV/AIDS led to subsequent appointments that kept me in close touch with these fascinating experimental scientists. In quick succession, I was added to the Ethics Committee of HUGO (the Human Genome Organisation) and to the International Bioethics Committee of UNESCO (IBC).
This was an exciting time to be working with HUGO. It stood on the brink of the completion of the map of the entire human genome. That was an achievement that came to pass in 2001, suitably enough, just in time for a new millennium. In the meetings of the HUGO Ethics Committee, and of the UNESCO IBC, the participants were challenged by new developments that had arisen in the United States, possibly stimulated by the outcome in Dr Chakrabarty’s case.

One of these developments was the enactment of new federal laws, proposed by the Reagan administration, obliging American institutions, funded by federal subventions, to secure intellectual property protection for their original work as the price for the support of American public money. How many times I heard leading scientists lament the demise of the previous culture of unrestricted scientific exchange in the fields of biomedicine. Instead, now, they and their institutions were required by law to install intellectual property protection. With federal gold came obligations to defend what was increasingly seen as a crucial source of America’s national income. Coinciding with the developments in the United States, the moves in the World Trade Organisation, the negotiation of the TRIPS Agreement (1994) and the Doha Declaration on Public Health and the TRIPS Agreement 2001 sought new ways to regularise and internationalise the technological and legal culture that flowed in the wake of Diamond v Chakrabarty.

At meetings with participants from developing countries, both in the context of international responses to the AIDS pandemic (by now the responsibility of UNAIDS) and in the context of HUGO and the IBC, developments of intellectual property law in Western countries were vehemently denounced. For the civil society organisations representing the poor, the infected and the sick, the new developments of intellectual property protection of biological inventions were not exciting means to promote scientific investment and experimentation that would help cure the world’s ills. Instead, they were condemned as a new form of Western hegemony.

The old Empires might have faded away. But at conference after conference I heard delegates from poorer countries proclaim that intellectual property law, as it was advancing in the world, would strangle the poorer nations. It would put them in perpetual thrall to the pharmaceutical corporations of the wealthy states. Moreover, those states would invest their capital not in the diseases that afflicted most of humanity but in the products that would quickly recoup the largest financial returns. As it was often put: ‘Face creams before malaria’. For the critics, intellectual property law had become the medium to divert the erstwhile noble dream of medical inquiry into a debased handservant of global capital movements, many of them flowing in the direction of the United States under free trade agreements which were insistent in this respect.
In 2001, just before the preliminary draft of the sequence of the human genome was published, UNESCO convened an international symposium in Paris on the topic of Ethics, Intellectual Property and Genomics. I chaired the concluding session. Many of the debates, outlined above, came to a head. The differences seemed irreconcilable. In the outcome, the Director-General of UNESCO invited the IBC to draft a new *Universal Declaration on Bioethics and Human Rights*. I chaired the drafting committee. The object of the project was to attempt a reconciliation of the ancient discipline of medical bioethics (initiated by Hippocrates and his equivalents in ancient times and by the medical and scientific professions since) and universal human rights (largely developed by lawyers in the wake of the devastating events of the Second World War and its aftermath).

Eventually this *Declaration* was adopted by the IBC. It was modified by governmental committees to reflect political and economic concerns. As so modified, it was adopted unanimously by the General Conference of UNESCO in October 2005. Some of the provisions of the *Declaration* reflect biological debates that emerged in the early days of HIV/AIDS and later as the Human Genome Project moved its conclusion.

This is not the place to explain the principles that were endorsed in the *Declaration*. However, the headings will indicate the guiding rules which the international community accepted in principle. Thus, Article 3 insists on respect for human dignity and human rights. Article 4 demands a balance between benefits and risks of harm. Article 8 insists on respect for human vulnerability and personal integrity. Article 10 asserts the fundamental equality of all human beings and the demand that they be treated justly and equitably. Article 11 expresses the principle of non-discrimination and non-stigmatisation. Article 12 reflects the need for respect for cultural diversity and pluralism. Several articles (13, 15 and 16) are concerned with human solidarity and cooperation across borders; the obligation to share benefits of science and technology; and the need to protect future generations. Article 14 insists on the obligation of science to respect social responsibility and to advance human health. Article 17 demands protection of the environment, the biosphere and biodiversity.

There are many other provisions in the *Declaration* that are worthy of attention. They grow out of the recognition, reflected in Dr Rimmer’s book, that we stand on the brink of amazing and exciting developments of science and technology that, overwhelmingly, will be for the benefit of humanity. We must ensure that these developments occur and go forward in a world that understands and cherishes the essential unity of the human species and its interdependence with other living things in a biosphere, itself a living phenomenon.

In a sense, human beings are trustees for all living things. Law is ultimately a servant of our species. At the present moment in human history,
It is unfortunate that we have not had the time, the will or the imagination to think freshly about the intellectual property regimes that would be suitable for the astonishing advances that are occurring about us. Instead, beginning with *Diamond v Chakrabarty*, we have built on the old legal regimes that were originally created for the age of sailing ships, wheels and cogs and machinery. Some developments in the applicable law have occurred. They are described in these pages. However, the fundamental ethical questions remain those debated in *Diamond v Chakrabarty* and reflected in the UNESCO *Universal Declaration on Bioethics and Human Rights*.

Dr Rimmer’s book is a marvellous introduction to a crucial topic of our time. He writes engagingly, provocatively and always with good humour. A highly technical and complex area of law has been reduced to clear descriptions and searching analysis. Truly, this is an important book on an essential topic that will help define the ethics of a future that includes nothing less than the future of our species.

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