



Précis Paper

Balancing Intellectual Property Rights and the Right to Access Essential Medicines

The Honourable Michael Kirby AC CMG and Kevin Connor SC discuss the international frameworks governing intellectual property protection and their impact on global public health and access to essential medicines.

Discussion Includes

- Framework of the TRIPS Agreement and the Doha Declaration
- The proliferation of free trade agreements and implications for IP protection
- The HIV/AIDS epidemic and access to essential medicines
- The Sustainable Development Goals
- History and procedure of the High Level Panel on Access to Medicines
- High Level Panel's Report of September 2016 on Promoting Innovation and Access to Technologies
- Striking a balance between intellectual property rights and the right to health and access to essential medicine

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Balancing Intellectual Property Rights and the Right to Access Essential Medicines

1. In this edition of BenchTV, the Honourable Michael Kirby AC CMG (Member of the Secretary General's High Level Panel on Access to Medicines & Chair of the Technical Advisory Group within the Panel) and Kevin Connor SC (Maurice Byers Chambers, Sydney) discuss the *Report of the United Nations Secretary-General's High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies* of September 2016.

The TRIPS Agreement and the Doha Declaration

2. Prior to 1994, there was no international agreement governing intellectual property protection. In 1994, following meetings organised by the World Trade Organisation (WTO), the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement) was signed into force. The TRIPS Agreement is an international agreement administered by the WTO that sets down minimum standards for many forms of intellectual property regulation. Specifically, TRIPS requires WTO members to provide copyright rights and patent protection and provides for enforcement procedures and remedies.
3. Mr Kirby AC CMG notes that the TRIPS Agreement did not come about as a result of negotiations following a global meeting of nations states, as is the usual way with international treaties. The Agreement was designed by the WTO, which is not an agency of the United Nations but essentially represented the interests of wealthy member countries. Therefore the aim of TRIPS was not to balance the rights of all interested parties, but was weighted in favour of the wealthy developed nations who were members of the WTO at the time.
4. Following the TRIPS Agreement, there was a proliferation of free trade agreements at the international level, including between Australia and the United States. Free trade agreements were not confined to issues relating to intellectual property, but sought to increase free trade and eliminate tariff barriers. These free trade agreements tended to underline and reinforce the TRIPS Agreement, by requiring countries to provide protection for intellectual property rights and remedies for their breach.
5. In the mid-1980s, the world was struck by the AIDS epidemic. Initially, no drugs were available to treat AIDS, but by the mid-1990s, anti-retroviral drugs had been developed to treat the virus. The cost of the drugs were around \$10,000 for a dose per person per year, a sum that was prohibitive for most people in developing countries affected by AIDS. In response to the cost of the drugs, steps were taken in a number of developing countries,

including Brazil and India, to license copies of the drugs, and hence generics developed that provided access to the drugs for a fraction of the price charged by the pharmaceutical developers.

6. The AIDS crisis therefore highlighted the problems with existing market mechanisms under the TRIPS Agreement – while the rights of patent holders were protected, they failed to enable access to essential medicines for those in need. As Mr Kirby AC CMG noted, the 18 million people who now live on anti-retroviral drugs “would not have been possible had the market mechanisms envisaged by the World Trade Organisation and the TRIPS Agreement been enforced”. Mainly led by Brazil, great pressure was exerted to install exceptions in the TRIPS Agreement and to protect those exceptions already in place.
7. The Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO Ministerial Conference of 2001 and promised that where a country declared a national health crisis, exceptions to the obligations under the TRIPS Agreement would apply. Paragraphs 4 and 5 of the Declaration provide:

4. The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and

8. Following its implementation in 2001, however, the Doha Declaration and its interpretation of TRIPS ran into trouble due to the implementation and expansion of free trade agreements. Notwithstanding the strong language of the Declaration, free trade agreements contained terms that required poorer countries to sign away their TRIPS exemptions and Doha protections. Mr Kirby AC CMG acknowledged that free trade agreements play an important role in improving human rights, as the economic improvements brought about by free trade lead to improvements in other rights such as education and housing. Nonetheless, this has meant that countries have had to decide to trade off their TRIPS protections in order to achieve the other benefits that free trade provides.

The Secretary General's High Level Panel on Access to Medicine

9. In considering the role of the High Level Panel and the implications of its recent report, Mr Kirby AC CMG first gave some background to the contextualise the creation of the Panel.
10. In July 2012, the Global Commission on HIV and the Law published its report, *HIV and the Law: Risks, Rights and Health*. The Global Commission was intended to address the legal impediments to successful strategies to combat HIV/AIDS. The Report discussed well-known legal impediments, including laws against gay men, injecting drug users, sex workers, refugees, dependent persons such as prisoners, and some laws relating to women and children.
11. Chapter 6 of the Report also discussed an issue that was less widely discussed at the time, the impediments created by intellectual property protections. Chapter 6 drew attention to the evolving impact of TRIPS, the Doha Declaration, and the proliferation of free trade agreements, and suggested that these intellectual property protections created barriers to accessing the essential medicines needed to treat AIDS. The Report recommended that the UN Secretary General establish an inter-agency expert body to examine the imperfections of intellectual property law in the international system
12. A second historical marker that helps understand the lead up to the High Level Panel was the adoption of the Sustainable Development Goals (SDGs) by the UN General Assembly in September 2015. These followed on from the Millennium Development Goals (MDGs) adopted in 2000, which contained a specific goal to combat AIDS. This MDG was addressed, to a large extent, through the establishment of UNAIDS within the United Nations framework, as well as the establishment of the President's Emergency Fund for AIDS Relief in the US and the support by the US under the presidency of George W. Bush for the Global Fund to Fight AIDS, Tuberculosis and Malaria.

13. The SDGs include Goal #3 on Good Health and Wellbeing, which refers to access to medicine and provides in relevant part:

The aim is to achieve universal health coverage, and provide access to safe and affordable medicines and vaccines for all.

14. It was against this backdrop that the High Level Panel was created and convened. In September 2016, the High Level Panel published its report, *Promoting Innovation and Access to Technologies*.

15. The Report contained core opinions, as well as supplementary opinions that sit on different ends of the spectrum in their support for intellectual property protection. On one end, some members of the Panel considered that the developments that have occurred in pharmaceuticals and medical technologies under the current intellectual property regime have been incredible, and nothing should be done that discourages or downplays the need for investment in the chancy business of developing new pharmaceutical products. On the other end of the spectrum was view that the entire system of international protection of intellectual property rights should be reconsidered, in order to determine how to better protect the right to access essential medicines.

16. Mr Kirby AC CMG was a member of the High Level Panel and the Chair of the Technical Advisory Group within the Panel. His view was that it was necessary to consider the best practical way of improving the current situation, and he agreed with the consensus of the Panel, which ultimately opted for a cautious approach. The consensus view was that the WTO should put in place strong procedures to punish member countries that do not respect the Doha Declaration and which have required other countries to give away their TRIPS flexibilities. The WTO should also take effective steps to stop free trade agreements from excluding citizens of poor and middle income countries from protection where they have a national health crisis.

17. In summary, the key recommendations of the Report included that:
- WTO Members should commit themselves to respecting the letter and spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies.
 - Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the rights of WTO Members to use TRIPS flexibilities. WTO Members should report such behaviour and punitive action should be taken to redress it.

- Bilateral and regional trade agreements should not include provisions that interfere with the right to health. Governments entering into such agreements should undertake public health impact assessments and ensure that the commitments under the proposed trade agreement will not endanger or impede the human rights and public health obligations of the country.
 - Governments increase their current levels of investment in health technology innovation to address unmet needs.
 - Governments should review the situation of access to health technologies in their countries in light of human rights obligations and make data publicly available to increase transparency.
 - An independent review body should be established by the Secretary-General, tasked with assessing progress on health technology innovation and access. This body should monitor progress in implementing recommendations of the High Level Panel and under the ambit of the SDGs.
 - In the private sector, biomedical companies involved in health technology innovation and access should report on actions they have taken to promote access to health technologies.
18. The work of the High Level Panel was an attempt to extrapolate from the experience with the HIV/AIDS epidemic to the treatment of serious health crises, and consider what lessons have been learnt on the international stage that should be applied going forward, including how to ensure the accessibility of crucial drugs at affordable prices.
19. The international community will need to determine where to strike the balance between protection of intellectual property rights and the right to access essential medicines promoted by SDG #3, which is undefined in scope. What is "essential" will depend upon the development of drugs at any point in time, as well as epidemiological developments and changes throughout the world. Mr Kirby AC CMG considered that it should at the least encompass the most important drugs that are necessary for essential healthcare, and would include those medicines on the World Health Organisation's Essential Medicines List. Moreover, despite medical advancements over the past decades, the intellectual property regime remains relevant to those affected by HIV/AIDS, as anti-retroviral drugs have started to lose their effectiveness and new drugs and technologies are required.
20. Mr Kirby AC CMG closed the presentation by commenting that much will depend on the attitude taken on the world stage in coming years as well as the incoming Secretary-General. On the whole, he remains optimistic "because of the importance and essentiality of this issue for all of us and for humanity, for our survival, and also for justice and the triumph of moral principles in our dealings with one another".

BIOGRAPHY

The Honourable Michael Kirby AC CMG

The Hon. Michael Kirby AC CMG is a former Justice of the High Court of Australia. He has served as Commissioner on the Global Commission on HIV and the Law and led a Commission of Inquiry into human rights abuses in North Korea. He is a Member of the Secretary General's High Level Panel on Access to Medicine and Chair of the Technical Advisory Group within the Panel.

Kevin Connor SC

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Kevin initially trained as a doctor and was admitted as a lawyer in 1987 after working as Associate to Justice Gaudron of the High Court of Australia. He was called to the Bar in 1987 and appointed Senior Counsel in 2007. He has research experience and continuing interests in the area of neuroscience.

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Link to Report

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