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HUMAN RIGHTS AND GLOBAL PHARMA CONVERGE

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In this article, based on the annual public oration of the Australian Centre for Health Law Research at QUT, Michael Kirby explores the interaction between the discovery of life saving and health preserving pharmaceuticals and international intellectual property (IP) law. He explains the investigation of this topic in a number of transnational bodies in which he has worked. He outlines the specific benefits of antiretroviral medicines for treatment of HIV causing AIDS and HCV (Hepatitis C). He explains the advent of the United Nations Sustainable Development Goals in 2015 and his participation in a High Level Panel created by the UN Secretary General to ensure their attainment. The article closes with some suggested further directions in international IP law and health access.

I INTRODUCTION

The dramatic fall in the price of antiretroviral drugs in the past decade has been instrumental in improving access to HIV/AIDS treatment in low- and middle-income countries.[1] However, a series of pricing scandals, involving large pharmaceutical manufacturers, has recently highlighted the potential for conflict between an individual's right to health and an innovator's right to benefit from their invention. While a number of countries, including Brazil, Venezuela and South Africa, have established legal protections which safeguard their citizens' right to health, pharmaceutical patent holders maintain significant power to control the national and global prices of drugs including by way of bilateral and multilateral trade agreements.[2] Given the millions of lives and trillions of dollars[3] that are at stake, it is fundamentally important to examine the role that national and international intellectual property (IP) law plays in the campaign for better global health.

II INTELLECTUAL PROPERTY LAW AND ACCESS TO MEDICINE

A *The Personal*

My interest in international health law and access to essential medicines was sparked in 2011 when I became a member of the Eminent Persons Group on the Future of the Commonwealth of Nations.

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[1] Médecins Sans Frontières, *Untangling the Web of Antiretroviral Price Reductions* (16th ed, 2013) 2 <https://www.msf.org/sites/msf.org/files/msf_access_utw_16th_edition_2013.pdf>.

[2] Global Commission on HIV and the Law, *HIV and the Law: Risks, Rights & Health* (2012) 76–7 <https://hivlawcommission.org/report/ >.

[3] 'Drug Price Scandals Hit Global Pharma Growth Forecasts', *The Telegraph* (online), 20 June 2017 <http://www.telegraph.co.uk/business/2017/06/20/drug-price-scandals-hit-global-pharma-growth-forecasts>.

This was an advisory body to the Commonwealth of Nations that aimed to examine avenues for legal and policy reform.[4] One of the issues addressed by the Eminent Persons Group was the United Nations' decision to use average per capita income as a qualifying measure for access to the Global Fund to Fight HIV/AIDS.[5] This criterion disqualified certain nations with significant income disparity within their populations from accessing the Global Fund despite the vulnerable status of many, perhaps most, citizens.[6] The exigent consequences stemming from this removal of access were augmented by concerns about intellectual property obligations being imposed on developing Commonwealth nations under bilateral free trade agreements and the proposed Anti-Counterfeiting Trade Agreement (ACTA) that was being negotiated at the time.[7] This experience opened my eyes to the pressures borne by developing nations under the global system of intellectual property, chiefly overseen by the World Trade Organization (WTO). It seemed to me that the developing world's capacity to bring healthcare to their populations was being inhibited in a way that was disproportionate and unjust.

In 2012 I was appointed to the United Nations Development Programme's Global Commission on HIV and the Law, chaired by Fernando Henrique Cardoso, the former president of Brazil. [8] The purpose of the Global Commission was to identify and consider national laws and policies which hindered successful strategies to tackle the AIDS epidemic. The Global Commission described policy areas where aspects of national legal systems served as impediments to a successful response to the HIV epidemic, including laws targeting sex workers, injecting drug users, men who have sex with men, transgender persons and other vulnerable groups. The Global Commission's examination of these issues emphasised the need for practical protections rather than antagonistic legislation. Prosecuting vulnerable persons such as sex workers and injecting drug users interfered with their capacity to protect themselves, their clients, and their sexual partners.[9] Police seizures of protective devices, such as condoms, as evidence of prostitution, diminished the sex workers' capacity to deal with the risks of HIV and prevent the spread of the epidemic.[10] In contrast, the implementation of health initiatives which empower and protect vulnerable populations has successfully slowed the spread of HIV in nations, including Australia.

The success of this policy was evidenced by the public health initiatives undertaken in Australia during the 1980s. Between 1984 and mid-1985, Australia was assailed by the HIV/AIDS epidemic: the rate of infections rose by 540 per cent and public fear was stoked by some media outlets' references to the 'gay plague'.[11] Neal Blewett, the Minister for Health in the Hawke Labor

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[4] Commonwealth Network, *Eminent Persons Group*, Commonwealth of Nations <http://www.commonwealthofnations.org/commonwealth/eminent-persons-group/>.

[5] Eminent Persons Group (Commonwealth of Nations), *A Commonwealth of the People: Time for Urgent Reform: Report to Commonwealth Heads of Government* (2011, Commonwealth Secretariat) 99 <http://www.sirronaldsanders.com/Docs/EPG%20Report%20FINALprintedVersion.pdf>.

[6] Ibid.

[7] Ibid 102.

[8] Global Commission on HIV and the Law, *The Commissioners* <https://hivlawcommission.org/overview/commissioners/>.

[9] Global Commission on HIV and the Law, above n 2, 29–35, 37.

[10] Joint United Nations Programme on HIV/AIDS, 'Annex 1: The Legal and Policy Environment and the Rights of Sex Workers', in *UNAIDS Guidance Note on HIV and Sex Work* (revised ed, 2012) 5 <http://www.unaids.org/en/resources/documents/2012/20120402_UNAIDS-guidance-note-HIV-sex-work>.

[11] Sarah Dingle, 'Neal Blewett and Peter Baume Honoured for Bipartisan Work against AIDS Epidemic of 1980s', *ABC News* (online), 16 July 2014 <http://www.abc.net.au/news/2014-07-16/poltical-rivals-honoured-for-joint-aids-

Government, and Peter Baume, the Shadow Minister for Health in the Coalition opposition, took a bipartisan approach to protecting Australia from the spread of HIV/AIDS. Radical programmes were implemented, such as the decriminalisation of injecting needle distribution and the development of needle and syringe exchange.[12] As a result, Australia has very low rates of HIV transmission among people who inject drugs — a significant achievement, as this can be an important vector by which the virus spreads within the general population.[13] In Australia, the prevalence of HIV among people who inject drugs was 1.7 per cent in 2015.[14] This rate is significantly lower than that of the United States, where the approximate prevalence of HIV among people who inject drugs was 3.6 per cent in 2016; Canada, where it was 11 per cent in 2015; and Russia, where it was 18 to 31 per cent in 2013.[15] The rates have increased in the Russian Federation since that time.

In preparing its report, the Global Commission reviewed national laws and policies affecting other groups that are vulnerable to HIV transmission, including men who have sex with men, prisoners, and migrants.[16] While many of the Commission's recommendations were familiar, there was a sixth chapter of the report, which raised a novel issue: global intellectual property law as a barrier to the availability of antiretroviral medicines.[17]

B *Developments in Access to Antiretroviral Medicine*

The provision of intellectual property patents is a relatively new development in the pharmaceutical industry. Historically, most countries did not allow intellectual property patent law protections for such products that gave, for a time, exclusive control to the inventor.[18] Underlying this proscription was the rationale that pharmaceuticals, which deal with human life and human suffering, are specially precious and distinct from, for example, a steam engine or other useful inventions with wheels and cogs. Pharmaceuticals were regarded as something outside the field of patents. However, the number of countries granting patents in this area rose over time, culminating in the establishment of the Agreement on Trade Related Aspects of Intellectual Property Rights (commonly known as TRIPS) on 1 January 1995, under the aegis of the WTO.[19] TRIPS demands that countries which aspired to membership of the WTO, with the exception of the 'least developed countries', agreed to provide a minimum of twenty years protection for the intellectual property

work/5598392>; Ruth Pollard, 'From Harm and Injustice', *Sydney Morning Herald* (online), 3 October 2002 <http://wwwsmh.com.au/articles/2002/10/02/1033538674717.html>.

[12] Richard G A Feachem, *Valuing the Past ... Investing in the Future: Evaluation of the National HIV/AIDS Strategy 1993–94 to 1995–96* (Australian Government Publishing Service, 1995) <http://www.hivpolicy.org/Library/HPP000170.pdf>.

[13] Skye McGregor, Hamish McManus, Richard Gray, *HIV, Viral Hepatitis, Sexually Transmissible Infections: Annual Surveillance Report* (Kirby Institute for Infection and Immunity in Society, 2016) 24 <https://kirby.unsw.edu.au/sites/default/files/kirby/report/SERP_Annual-Surveillance-Report-2016_UPD170627.pdf>.

[14] Ibid 11.

[15] Katie Stone, *The Global State of Harm Reduction 2016* (Harm Reduction International, 2016) 48, 98 <https://www.hri.global/files/2016/11/14/GSHR2016_14nov.pdf>.

[16] Global Commission on HIV and the Law, above n 3, 44–50; 51–8; 59–61.

[17] Ibid 76–87.

[18] Ibid 79.

[19] World Trade Organization, *Overview: The TRIPS Agreement* <https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm>.

belonging to nationals of other members of the WTO.[20] Effectively, this meant that when developing countries like Vietnam or Cambodia joined the WTO, they were required to agree to protect and respect the intellectual property of inventors of medicines in powerful economies such as the European Union, the United States of America, Japan, and Switzerland. Free trade agreements were negotiated with WTO support, under which participant countries could agree to the imposition of higher requirements than the TRIPS Agreement itself required. TRIPS-plus obligations meant that those countries, even where in the grips of a health crisis, could not exclude the patenting of intellectual property on pharmaceutical drugs, diagnostic tests, vaccines and other therapies.[21] This was a significant reversal of the pre-existing law.

Medical innovation's interaction with intellectual property law was particularly relevant in the fight against HIV/AIDS, which was enlivened by the discovery of antiretroviral drugs in the mid-1990s. These drugs offered treatment as protection by reducing the viral loads of infected persons and their capacity to spread the virus to other people. When HIV antiretroviral drugs first became available, the annual market price of a course of drugs was between $USD10 000 and $USD15 000 per person.[22] The prohibitive cost kept antiretrovirals out of reach for most poor communities in India, Africa, the Caribbean, and Latin America, where the disease struck with significant impact.

During this period, Brazil and India were prominent in safeguarding access to medicines against the operation of the TRIPS Agreement.[23] India's long-standing refusal to grant patents over medicines allowed its generic drug industry to flourish, causing India to become a kind of pharmacy to the world.[24] The availability of Indian and Brazilian generics caused the price of antiretroviral drugs to fall very rapidly from over $10,000 a year per person in June 2000 to less than $100 in June 2010.[25] As well as greater affordability of antiretroviral drugs, the fight against HIV/AIDS, during this era, was bolstered by George W Bush's instigation of the United States President's Emergency Plan for AIDS Relief (PEPFAR), and by the establishment of the Global Fund against AIDS, Tuberculosis and Malaria.[26] Such efforts meant that, by June 2017, 20.9 million people throughout the world were able to access antiretroviral drugs.[27] That is, over 20 million people are now able to reclaim life with a reduced viral load so that infection rates will decrease and the epidemic will, one hopes, begin to wane. The battle against HIV/AIDS, although not yet won, is illustrative of how other serious health conditions might be treated.[28]

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[20] World Trade Organization, 'Patents' in *Intellectual Property: Protection and Enforcement* <https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm>.
[21] Global Commission on HIV and the Law, above n 2, 82.
[22] Ellen Hoen et al, 'Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All' (2011) 14 *Journal of the International AIDS Society* 1, 15, doi: 10.1186/1758-2652-14-15.
[23] Global Commission on HIV and the Law, above n 2, 79.
[24] Jessica Washington, '"This is About Life and Death": Pharmaceutical Patents Threaten India's Generic Drug Industry', *ABC News* (online), 28 September 2017 <http://www.abc.net.au/news/2017-09-28/what-india-pfizer-patent-decision-means-for-region-health/8981206>.
[25] Global Commission on HIV and the Law, above n 2, 77.
[26] US President's Emergency Plan for AIDS Relief, *About Us* [Archive] <https://www.pepfar.gov/>.
[27] UNAIDS, *Fact Sheet: Latest Statistics on the Status of the AIDS Epidemic* (2017) <http://www.unaids.org/en/resources/fact-sheet>.
[28] Global Commission on HIV and the Law, above n 2, 78.

C *The Conflict Between the Right to Health and Intellectual Property*

When I was in school in early 1949, my teacher gave me a copy of a little document which had come from the United Nations Headquarters in New York. It was the *Universal Declaration of Human Rights* and it had been developed by a committee chaired by Eleanor Roosevelt. The committee reported in 1948.[29] It is interesting to reflect on the fact that, in the *Universal Declaration of Human Rights*, there is one provision which essentially states the right to health and the obligation of states to protect essential healthcare,[30] while another provision declares that authors are entitled to proper rewards for sharing their inventions with society.[31] These two human rights have never been successfully reconciled. A potential accord has been further impaired by the obligations of patent protection imposed by bilateral agreements and the WTO.

The Global Commission on HIV and the Law recognised that the issue of intellectual property law in pharmaceutical drugs needed the attention of the international community. It called upon the then United Nations Secretary General, Ban Ki-moon, to create an interagency expert body to examine the disconnection between intellectual property law and the right to health.[32] In September 2015, the Sustainable Development Goals were adopted by the United Nations General Assembly. The third Sustainable Development Goal was expressed as to '[e]nsure healthy lives and promote well-being for all at all ages' and an important target of this goal was ending the 'epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases' by 2030.[33] Soon after the unanimous adoption of the United Nations Sustainable Development Goals,[34] Ban Ki-Moon took the bold, controversial, and in some circles unpopular, step of establishing the High-Level Panel on Access to Medicines for the purpose of examining the interrelationship of intellectual property law patents and the universal right to health.[35] Its two co-chairs were Madam Ruth Dreifuss, the former President of the Swiss Confederation, and Mr Festus Gontebanye Mogae, the former President of Botswana.[36] I was appointed to the High-Level Panel by Ban Ki-moon and I was also appointed as the chair of the technical advisory group that advised the Panel on legal and other relevant issues.[37]

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[29] *Universal Declaration of Human Rights*, proclaimed by UN General Assembly, 10 December 1948, GA Res 217 A (III) <http://www.un.org/en/universal-declaration-human-rights/>; *The Drafters of the Universal Declaration of Human Rights*, United Nations <http://www.un.org/en/sections/universal-declaration/drafters-universal-declaration-human-rights/index.html>.

[30] *Universal Declaration of Human Rights*, art 25 <http://www.un.org/en/universal-declaration-human-rights/>.

[31] Ibid art 27.

[32] Global Commission on HIV and the Law, above n 2, 86.

[33] United Nations, *Sustainable Development Goals: Goal 3: Ensure Healthy Lives and Promote Well-Being for All at All Ages* <http://www.un.org/sustainabledevelopment/health/>.

[34] United Nations Sustainable Development Summit, 'Historic New Sustainable Development Agenda Unanimously Adopted by 193 UN Members (News, 25 September 2015) <http://www.un.org/sustainabledevelopment/blog/2015/09/historic-new-sustainable-development-agenda-unanimously-adopted-by-193-un-members/>.

[35] United Nations, *United Nations Secretary General's High-Level Panel on Access to Medicines* <http://www.unsgaccessmeds.org/#homepage-1>.

[36] United Nations Secretary General's High-Level Panel on Access to Medicines, *The Panel* <http://www.unsgaccessmeds.org/new-page/>.

[37] Ibid.

The High-Level Panel met on a number of occasions in New York and also held public hearings in London, South Africa and by video link to Bangkok, Thailand.[38] We sought agreement on recommendations designed to remedy the policy incoherence which had emerged at the juncture of intellectual property patents and public health. For me, the most powerful stories at these hearings concerned young people in Africa who had been exposed to tuberculosis. In parts of Africa and India there has developed a so-called multidrug resistant tuberculosis.[39] In fact, the number of multidrug resistant diseases is now very great and the amount being spent trying to overcome this problem is not keeping pace with the dimension and urgency of the crisis.[40] The stories that were told of the suffering of people in these situations, the lack of medical care, and the great expense of such care when accessed, evoked for me memories of the early days of the HIV/AIDS crisis before the antiretroviral drugs plunged in price.[41]

One of the most thought-provoking presentations to the High Level Panel public hearing in London was given by a member of the Ministry of Foreign Affairs of The Netherlands. He urged us not to think of the overpricing of drugs as a problem only for developing countries. Predatory pricing was also a significant issue for developed nations as their governments found it difficult or impossible to sustain the costs that are being charged for essential life-saving medicines. It was submitted to the High Level Panel that overpricing was causing budgetary difficulties as citizens of The Netherlands and like countries, were demanding drugs that the government had to subsidise.[42]

Coincidentally, the first day that the High Level Panel met in New York, the *New York Times*[43] and *USA Today*[44] ran articles about an astronomical price hike on a drug for the treatment of cancer by the hedge funder Martin Shkreli. According to these articles, Mr Shkreli had financially analysed Turing Pharmaceuticals, a small pharmaceutical company which owned the intellectual property in the drug Daraprim. Daraprim was proving very useful in the treatment of certain forms of cancer and, at the time of the analysis, the drug cost about US$13.50 a tablet.[45] As a result of his evaluation, Mr Shkreli proposed, and his shareholders agreed, that they should take over Turing Pharmaceuticals, acquire its patents and raise the price of Daraprim by 4000 per cent to US$750 a

[38] United Nations Secretary General's High-Level Panel on Access to Medicines, *Events* <http://www.unsgaccessmeds.org/public-hearing-one/>.
[39] World Health Organization, 'What is Multidrug Resistant Tuberculosis (MDR-TB) and How Do We Control It?' (Online Q&A, reviewed January 2018) <http://www.who.int/features/qa/79/en/>.
[40] World Health Organization, 'Antimicrobial Resistance' (Fact Sheet, 15 February 2018) <http://www.who.int/mediacentre/factsheets/fs194/en/>.
[41] United Nations Secretary General's High-Level Panel on Access to Medicines, *Report: Promoting Innovation and Access to Health Technologies* (2016) 15 <http://www.unsgaccessmeds.org/final-report/>.
[42] Ibid 21.
[43] Andrew Pollack, 'Drug Goes From $13.50 a Tablet to $750, Overnight', *New York Times* (online), 20 September 2015 <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?_r=0>.
[44] Christine Rushton, 'Company Hikes Price 5,000% for Drug that Fights Complication of AIDS, Cancer', *USA Today* (online), 18 September 2015 <https://www.usatoday.com/story/news/health/2015/09/18/company-hikes-price-5000-drug-fights-complication-aids-cancer-daraprim/32563749/>.
[45] Pollack, above n 43.

tablet.[46] This decision was met with expressions of public outrage. However, Mr Shkreli claimed that he was simply fulfilling his legal duty to his shareholders.[47]

Later in its hearings, material was placed before the High Level Panel about the costs of Sofosbuvir, a drug for the treatment of Hepatitis C. Hepatitis C is a very prevalent and debilitating condition which, if left untreated, is often fatal.[48] It is a blood-borne virus which can result from poor hygiene in hospitals as well as injecting drug use.[49] If faithfully administered over 12 weeks, Sofosbuvir can not only palliate the condition, but actually rid the body of the Hepatitis C virus.[50] It is a tremendously valuable life-saving drug. The market price of Sofosbuvir, which is sold under the brand name Solvaldi, was initially averaged at $USD84,000 for a 12 week course of treatment in the United States. At that time, buying the drug wholesale in Australia cost A$1300 per tablet, or A$110 000 for a 12 week course of treatment.[51] Under the Pharmaceutical Benefits Scheme, Sofosbuvir is now available in Australia for between $6.20 and $38.30 a tablet.[52] In Egypt, the same drug course is available for about $USD900.[53] The public health implications of this pricing regime has led the director of health policy and outcomes at Memorial Sloan Kettering Cancer Centre in New York, Dr Peter Bach, to claim that buying Gilead Sciences Inc, the company that manufactures the drug, rather than the drug itself, could be a cost-saving exercise for the United States government and certainly in the long term.[54]

In February 2017, *The Australian* newspaper published an article detailing the public outcry surrounding the US Food and Drug Administration's decision to grant approval to Marathon Pharmaceuticals to sell the drug Deflazacort in the United States.[55] Deflazacort is regarded as a potential treatment for Duchenne Muscular Dystrophy, a rare disease affecting about 12,000 boys in the United States.[56] The drug was priced at US$89,000 per person, per year.[57] This price upset the parents of the children with this relatively rare disease as they had previously been able to import it for US$1,200 annually.[58] Criticism by US lawmakers, particularly Senator Bernie

[46] Ibid.
[47] Julie Creswell and Andrew Pollack, 'Martin Shkreli, the Bad Boy of Pharmaceuticals, Hits Back', *New York Times* (online), 5 December 2015 <https://www.nytimes.com/2015/12/06/business/martin-shkreli-the-bad-boy-of-pharmaceuticals-hits-back.html>.
[48] World Health Organization, 'Hepatitis C' (Fact Sheet, 18 July 2018) < http://www.who.int/mediacentre/factsheets/fs164/en/>.
[49] Ibid.
[50] Swathi Iyengar et al, 'Prices, Costs, and Affordability of New Medicines for Hepatitis C in 30 Countries: An Economic Analysis' (2016) 13 *Plos Medicine* 5, 4; Greg Dore and Marianne Martinello, 'Weekly Dose: Sofosbuvir — What's the Price of a Hepatitis C Cure?', *The Conversation* (online), 3 August 2016 <https://theconversation.com/weekly-dose-sofosbuvir-whats-the-price-of-a-hepatitis-c-cure-63208>.
[51] Dore and Martinello, above n 50.
[52] Ibid.
[53] Iyengar et al, above n 50, 4.
[54] Alison Kodjak, 'Should the US Government Buy a Drug Company to Save Money?', *NPR* (online), 17 March 2017 <http://www.npr.org/sections/health-shots/2017/03/17/520430944/should-the-u-s-government-buy-a-drug-company-to-save-money>.
[55] 'Marathon Pharmaceuticals Delays Drug Over "Predatory Pricing"', *The Australian* (online), 15 February 2017 <http://www.theaustralian.com.au/business/wall-street-journal/marathon-pharmaceuticals-delays-drug-over-predatory-pricing/news-story/3098b7ccb72d3ed699d65d3f64485d64>.
[56] Ibid.
[57] Ibid.
[58] Ibid.

Sanders and Representative Elijah Cummings, caused the company to delay the launch of the drug.[59] On 16 March, while still mired in controversy, Marathon Pharmaceutical sold the drug and its associated assets to PTC Therapeutics for US$140 million.[60] On 8 May, PTC Therapeutics announced the new price of Deflazacort would be US$35,000 annually for a patient in the United States weighing 25 kilograms, with the price increasing according to a patient's weight.[61]

D *Future Directions of Intellectual Property and Health Access*

The Daraprim, Sofosbuvir, and Deflazacort case studies serve as specific examples of the issues raised by The Netherlands Foreign Ministry during the High Level Panel hearings. Predatory pricing of essential pharmaceuticals is an issue for both developing and developed nations. A new pricing mechanism needs to be developed which reconciles both intellectual property rights and the right of access to essential healthcare. Innovation in the pharmaceutical industry is vitally important and can be encouraged by the financial incentives inherent in market pricing. However, market prices may not drive innovation in diseases that are rare, such as Duchenne's Muscular Dystrophy, or endemic's in developing nations, such as Ebola or Zika. Instead, market forces may drive innovation to combat 'first world' maladies such as high blood pressure and penile erectile dysfunction. However, this does not mean that a fair balance, as anticipated in the *Universal Declaration of Human Rights*, cannot be achieved.

In support of delivering a just balance, the majority of the UN High Level Panel recommended allowing countries faced with healthcare crises to impose compulsory licences in order to ensure access to medicines while still giving innovators their fair reward.[62] This recommendation provides a middle course in which respect for the current state of intellectual property law is coupled with additional capacity for countries to insist on treatment in health crises and special treatment for vulnerable populations, such as people with the Hepatitis C virus or young boys with Muscular Dystrophy. The Panel took a radical new stance on a highly divisive issue. Its report is now before the world community — and, one hopes that it will result in action.

Fair access to healthcare is a problem for us all. The global community needs to find a solution. It is imperative that the campaign for global health should reconcile the two important rights in the *Universal Declaration of Human Rights.* We will achieve this, not with a bold combative step, but by finding the middle ground that is fair to all concerned.

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[59] Katherine Greifeld, 'Marathon Delays Introduction of Duchenne Drug After Price Outcry', *Bloomberg Quint* (online), 14 February 2017 <https://www.bloombergquint.com/business/2017/02/13/sanders-cummings-blast-marathon-for-89-000-price-on-old-drug>.

[60] Dana Goldman and Jay Bhattacharya, 'Sky-High Drug Prices for Rare Diseases Show Why Orphan Drug Act Needs Reform', *Huffington Post* (online), 18 March 2017 <https://www.huffingtonpost.com/entry/sky-high-drug-prices-for-rare-diseases-show-why-orphan_us_58cd353de4b07112b6472ded>.

[61] Meg Tirrell, 'New Price for Muscular Dystrophy Drug Draws Criticism', *CNBC* (online), 8 May 2017 <https://www.cnbc.com/2017/05/08/new-price-for-muscular-dystrophy-drug-draws-criticism.html>.

[62] United Nations Secretary General's High-Level Panel on Access to Medicines, above n 41, 23.