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978-0-521-11656-5 - Incentives for Global Public Health: Patent Law and Access to Essential Medicines

Edited by Thomas Pogge, Matthew Rimmer and Kim Rubenstein

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Introduction

Access to essential medicines: public health and international law

THOMAS POGGE, MATTHEW RIMMER
AND KIM RUBENSTEIN

1. Prologue

Historically, there have been intense conflicts over the ownership and exploitation of pharmaceutical drugs and diagnostic tests dealing with infectious diseases.

Throughout the 1980s, there was much scientific, legal and ethical debate about which scientific group should be credited with the discovery of the human immunodeficiency virus and the invention of the blood test devised to detect antibodies to the virus.¹ In May 1983, Luc Montagnier, Françoise Barré-Sinoussi and other French scientists from the Institut Pasteur in Paris published a paper in *Science*, detailing the discovery of a virus called lymphadenopathy ('LAV').² A scientific rival, Robert Gallo of the National Cancer Institute, identified the AIDS virus and published his findings in the May 1984 issue of *Science*.³ In May 1985, the United States Patent and Trademark Office awarded the American patent for the AIDS blood test to Gallo and the Department of Health and Human Services. In December 1985, the Institut Pasteur sued the Department of Health and Human Services, contending that the French were the first to

¹ Hal Hellman, 'Chapter 10, Gallo versus Montagnier, the AIDS War', *Great Feuds in Medicine: Ten of the Liveliest Disputes Ever* (2001), 165–84.

² Françoise Barré-Sinoussi, 'Isolation of a T-lymphotropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)' (1983) 220 *Science* 868–71.

³ Robert Gallo *et al.* 'Frequent Detection and Isolation of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and at Risk for AIDS' (1984) 224 *Science* 500–3; J. Schupbach *et al.* 'Serological Analysis of a Subgroup of Human T-lymphotropic Retroviruses (HTLV-III) associated with AIDS' (1984) 224 *Science* 503–5; and Mangalasseril G. Sarngadharan *et al.* 'Antibodies Reactive with Human T-lymphotropic Retroviruses (HTLV-III) in the Serum of Patients with AIDS' (1984) 224 *Science* 506–8.

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identify the AIDS virus and to invent the antibody test, and that the American test was dependent upon the French research.

In March 1987, an agreement was brokered by President Ronald Reagan and French Prime Minister Jacques Chirac, which resulted in the Department of Health and Human Services and the Institut Pasteur sharing the patent rights to the blood test for AIDS.⁴ In 1992, the Federal Office of Research Integrity found that Gallo had committed scientific misconduct, by falsely reporting facts in his 1984 scientific paper.⁵ A subsequent investigation by the National Institutes of Health, the US Congress and the US Attorney-General cleared Gallo of any wrongdoing.

In 1994, the US Government and the French Government renegotiated their agreement regarding the AIDS blood test patent, in order to make the distribution of royalties more equitable.⁶ Under the agreement, the US and French research institutions would keep 20 per cent of royalties made from testing kits that each team has developed from its own laboratories. The remaining 80 per cent would be pooled. A quarter of the pool was allocated to the World AIDS Foundation. Under the new agreement, the French received two thirds of the remainder and the Americans one third. In a written statement, Gallo observed he had 'consistently acknowledged the significant contributions of the Pasteur scientists' and that 'it is now time for this episode to be permanently closed'.⁷ By 2002, Gallo and Montagnier were sufficiently reconciled to write a joint paper for *Science*, expressing the common belief that 'a global coordinated response is required to fight the scourge of AIDS'.⁸

As a coda to the dispute, Montagnier and his compatriot Françoise Barré-Sinoussi were awarded a Nobel Prize in Physiology or Medicine in 2008 for the discovery of the human immunodeficiency virus. The Nobel Assembly noted in a press release: 'never before has science and medicine been so quick to discover, identify the origin and provide treatment for a new disease entity'.⁹

⁴ Luc Montagnier *et al.* 'Human Immunodeficiency Viruses Associated with Acquired Immune Deficiency Syndrome (AIDS), a Diagnostic Method for AIDS and pre-AIDS, and a Kit Therefore', United States Patent No: 4,708,818. See also Luc Montagnier, *Virus: The Co-Discoverer of the Virus Tracks its Rampage and Charts its Future* (1999).

⁵ Philip Hiltz, 'Federal Inquiry Finds Misconduct by a Discoverer of the AIDS Virus', *The New York Times*, 31 December 1992.

⁶ Philip Hiltz, 'Key Patent on AIDS to Favor the French', *The New York Times* (12 July 1994).

⁷ *Ibid.*

⁸ Robert Gallo and Luc Montagnier, 'Prospects for the Future' (2002) 298 *Science* 1730–1.

⁹ The Nobel Assembly at Karolinska Institute, 'The Nobel Prize in Physiology or Medicine in 2008', 6 October 2008, nobelprize.org/nobel_prizes/medicine/laureates/2008/press.html.

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Although Gallo was not included in the Nobel Prize citation, Montagnier did acknowledge the contribution of his sometime colleague and sometime rival. In return, Gallo released a statement, observing: 'I am pleased my long-time friend and colleague Dr Luc Montagnier, as well as his colleague Françoise Barré-Sinoussi, have received this honor.'¹⁰ He added: 'I was gratified to read Dr Montagnier's kind statement this morning expressing that I was equally deserving'.¹¹

The dispute between Luc Montagnier and Robert Gallo was not an isolated case of scientific rivalry and patent races. It foreshadowed further patent conflicts over research in respect of HIV/AIDS.¹² Michael Kirby, former Justice of the High Court of Australia, diagnosed a clash between two distinct schools of philosophy – 'scientists of the old school ... 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'.¹³ Indeed, the patent race between Robert Gallo and Luc Montagnier has been a precursor to broader trade disputes over access to essential medicines in the 1990s and 2000s.¹⁴ The dispute between Robert Gallo and Luc Montagnier captures in microcosm a number of themes of this book: the fierce competition for intellectual property rights; the clash between sovereign states over access to medicines; the pressing need to defend human rights, particularly the right to health; and the need for new incentives for research and development to combat infectious diseases as both an international and domestic issue.

2. Connecting public and international law

This volume is the second in a new series bringing public and international lawyers and public and international policy-makers together to examine key issues in the twenty-first century. This series broadens both

¹⁰ Robert Gallo, 'Statement', *New Scientist* (7 October 2008), www.newscientist.com/commenting/thread?id=dn14881-4.

¹¹ *Ibid.*

¹² See for instance the dispute in the Supreme Court of Canada over the patent ownership of AZT in *Apotex Inc. v. Wellcome Foundation Ltd*, [2002] 4 S.C.R. 153.

¹³ Justice Michael Kirby, 'Foreword' in Matthew Rimmer, *Intellectual Property and Biotechnology: Biological Inventions* (2008), vi. See also Ian Freckleton and Hugh Selby (eds.) *Appealing to the Future: Michael Kirby and his Legacy* (2009).

¹⁴ Patricia Thomas, *Big Shot: Passion, Politics and the Struggle for an AIDS Vaccine* (2001); Anne-Christine D'Adesky, *Moving Mountains: The Race to Treat Global AIDS* (2004); and Lawrence Gostin, *The AIDS Pandemic: Complacency, Injustice, and Unfulfilled Expectations* (2006).

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public and international laws' understanding of how these two areas intersect and is unique in consciously bringing together public and international lawyers to consider and engage in each other's scholarship. What can public lawyers bring to international law and what can international lawyers bring to public law? What are the common interests? What tensions become apparent when we consider public and international law together?

This second volume focuses on these questions in the context of the contemporary debate over access to essential medicines.

This debate takes place against the background of staggering health discrepancies: both between affluent and less-developed countries and also, within the latter, between rich and poor households. Among the world's poor, some 18 million die annually from Group I causes – communicable diseases, maternal and perinatal conditions and nutritional deficits – which cause only minimal harm among the affluent. Eighteen million is equivalent to just over 30 per cent of all human deaths.¹⁵ And this percentage is considerably larger when, taking age at death into account, one estimates how many years of human life are lost due to Group I causes.¹⁶ Life expectancy is 79.4 in the high-income countries and 49.2 in the African region.¹⁷ Similarly dramatic health inequalities exist within the less-developed countries. In Peru, under-five mortality is 11 per 1,000 among the richest 20 per cent of the population versus 63 among the poorest 20 per cent, for example, and in Nigeria the corresponding figures are 79 versus 257.¹⁸

These huge health discrepancies stem in part from the fact that poor people are at greater risk of disease, due to lack of food, shelter, uncontaminated water, clothing and physical security. Another crucial factor is that the world's poor have little access to medical care and, in particular, to the medicines that could help them cope with their debilitating and often life-threatening conditions.

This lack of access to essential medicines has three components. First, medicines for diseases concentrated among the poor are neglected by pharmaceutical research. This phenomenon has come to be known as the 10/90 gap, alluding to the claim that 'only 10 per cent of global health research is devoted to conditions that account for 90 per cent of the

¹⁵ World Health Organization, *The Global Burden of Disease: 2004 Update* (2004), 10, 17–18.

¹⁶ *Ibid.*, 23. ¹⁷ *Ibid.*, 5.

¹⁸ United Nations Development Programme, *Human Development Report 2007/2008* (2007), Table 8, 255–6.

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global disease burden'.¹⁹ Pneumonia, diarrhoea, tuberculosis and malaria, which account for over 20 per cent of the global burden of disease, receive less than 1 per cent of all public and private funds devoted to health research.²⁰ And diseases confined to the tropics tend to be the most neglected: of the 1556 new drugs approved between 1975 and 2004, only 18 were for tropical diseases and 3 for tuberculosis.²¹

The second component of the access problem of the poor is that existing medicines are, during their initial years on the market, typically priced vastly higher than their cost of production.²² Such high prices are facilitated by patents, which grant the patentee the exclusive right to produce and distribute the medicine. Patents are conferred in nearly all national jurisdictions for the purpose of incentivizing and rewarding innovation. A firm enjoying such market exclusivity will price its product to maximize profit, which is (simplifying slightly) its mark-up multiplied by its sales volume. In view of the prevailing huge inequalities in income and wealth, the optimal price tends to be high. If a medicine is important, sales to, or for, the people in affluent countries and the affluent individuals in the poor countries will not be spoiled by a high price. And reaching some of the remaining 80 per cent of humankind is simply not worthwhile because the patentee would lose more from the necessary price reduction than it would gain through an increased sales volume. Interestingly, this holds even *within* many poor countries, where the profit-maximizing price often excludes a majority of the national population.²³

¹⁹ Drugs for Neglected Diseases Working Group, *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases* (2001) also at www.msf.org/source/access/2001/fatal/fatal.pdf, 10. See also Louis Currat, Andres de Francisco, Sameera Al-Tuwaijri, Abdul Ghaffar and Susan Jupp, *Global Forum Health 10/90 Report 2003–2004* (2004).

²⁰ *Ibid.*, 122.

²¹ Pierre Chirac and Els Toreele, 'Global Framework on Essential Health R&D' (2006) 367 *The Lancet* 1560; Drugs for Neglected Diseases Working Group, *Fatal Imbalance*, see above n. 19, 10. See also Patrice Trouiller, Piero Olliaro, Els Torrele, James Orbinski, Richard Laing and Nathan Ford, 'Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure' (2002) 359 (9324) *The Lancet* 2188, 2189.

²² See Oxfam International, 'Investing for Life: Meeting Poor People's Needs for Access to Medicines through Responsible Business Practices' (Briefing Paper No 109, Oxfam, November 2007), 20, giving examples of high prices with mark-ups of up to sixty times what a generic supplier would charge.

²³ Sean Flynn, Aidan Hollis and Mike Palmedo, 'An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries' (2009) 37 *Journal of Law, Medicine & Ethics* 184.

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The third component of poor people's lack of access to essential medicines is the dearth of even minimally adequate local health infrastructure. In most of the less-developed countries, there is great scarcity of clinics and hospitals, of diagnostic equipment, as well as of doctors and nurses who are often very actively recruited to move to more affluent countries. In the year 2000, some 65,000 physicians and 70,000 nurses born – and mostly also trained – in Africa were working overseas,²⁴ leaving behind huge gaps in their home countries' healthcare coverage as well as in their education budgets. The effect of poor health infrastructure is that poor patients get no competent diagnosis and then end up with no medicine at all, with the wrong medicine, with fake or diluted medicine (often sold by street vendors), or without instruction about how to take the medicine for optimal effect. Medicine that is diluted or not taken properly can contribute to the emergence of drug-specific resistance as patients are not exposed to enough of the active ingredient for a sufficiently long period to kill off the more resilient pathogenic agents. The emergence of drug-resistant strains of communicable diseases (such as multi-drug-resistant and extensively drug-resistant tuberculosis) can greatly aggravate the damage done by a disease – especially among the poor who are unable to afford the more advanced second-line and third-line therapies which are typically still under patent.

This thumbnail sketch of the access to medicines problem brings out the interplay of national and international dimensions and, in particular, the great challenges the national health systems of poorer countries confront on account of an international environment they can do very little to influence. To be sure, poor countries agreed to adopt a US-style pharmaceutical patent regime when they signed the Trade-Related Aspects of Intellectual Property Agreement ('TRIPS Agreement') – but they had little choice as refusing to sign would have meant exclusion from the World Trade Organization ('WTO').²⁵ Moreover, many poor countries lack pharmaceutical manufacturing capacity and therefore were much more severely affected by India's accession to the TRIPS

²⁴ Michael Clemens, and Gunilla Pettersson, 'New Data on African Health Professionals Abroad' (2008) 6(1) *Human Resources for Health*, www.human-resources-health.com/content/6/1/1.

²⁵ Marrakesh Agreement Establishing the World Trade Organization, opened for signature 15 April 1994, 1867 UNTS 3, annex 1C (Agreement on Trade-Related Aspects of Intellectual Property Rights) (entered into force 1 January 1995) ('TRIPS Agreement').

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Agreement than by their own.²⁶ Poor countries also have little control over the doctors and nurses they train – they cannot force them to stay, nor pay them anything like the salary they are being offered by foreign recruiters. Recipient countries might implement legislation that would constrain the importation of medical professionals from poor countries or would at least require employers to cover the antecedent expenses of training these professionals. But a recipient country is unlikely to pass such legislation on its own, as it would only disadvantage itself in the competition with other rich countries over the gains from recruiting doctors and nurses from the developing world.

Given the enormous magnitude of the access to medicines problem, it is fairly obvious that this problem cannot be overcome through the various global health initiatives of recent years, even though these have indeed been impressive. As stated in the recent *WHO Global Strategy*:

Member States, the pharmaceutical industry, charitable foundations and nongovernmental organizations have taken initiatives in recent years to develop new products against diseases affecting developing countries and to increase access to existing health products and medical devices. However, these initiatives are not sufficient to surmount the challenges of meeting the goal of ensuring access and innovation for needed health products and medical devices.²⁷

In addition to these initiatives, substantial progress calls for an integrated solution that combines public law and international law elements to form an effective reform package: ‘Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of

²⁶ India is home to some of the largest pharmaceutical manufacturing firms, which used to supply the less-developed countries with cheap generic versions of medicines that were still under patent in the affluent states. An editorial for *The New York Times* has observed: ‘But when India signed the World Trade Organization’s agreement on intellectual property in 1994, it was required to institute patents on products by Jan. 1, 2005. These rules have little to do with free trade and more to do with the lobbying power of the American and European pharmaceutical industries. India’s government has issued rules that will effectively end the copycat industry for newer drugs. For the world’s poor, this will be a double hit – cutting off the supply of affordable medicines and removing the generic competition that drives down the cost of brand-name drugs.’ (Editorial, ‘India’s Choice’, *The New York Times*, 18 January 2005).

²⁷ *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, World Health Assembly 61st mtg, Res WHA61.21 (2008) (*‘WHO Global Strategy’*).

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health products and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries'.²⁸

This volume considers the design and assessment of national and international law governing the discovery, development and delivery of advanced medicines. It seeks to advance creative solutions to the long-standing problems in respect of intellectual property and access to essential medicines. Drawing upon international trade law, innovation policy, intellectual property law, health law, human rights and philosophy, this volume encourages interdisciplinary collaboration in regard to two important objectives: encouraging and rewarding worthwhile pharmaceutical innovation and ensuring affordable access to advanced medicines, even for the poor. These objectives can stand in some tension with each other: affordable access for the poor is likely to reduce the profitability of patent monopolies and hence also the incentives for conducting pharmaceutical research.

In bringing together public and international lawyers as well as experts in public health, economics and moral philosophy, this volume facilitates dialogue among academics, governments, industry and civil society over access to essential medicines and enlarges our understanding of the intersections at play. We hope this dialogue will not merely enrich the various academic disciplines, but also stimulate new reform ideas and implementation efforts that will improve access to important medicines worldwide.

3. The international institutions

On the international level, trade, intellectual property rights and health have been governed by several international institutions, including the World Trade Organization, the World Intellectual Property Organization and the World Health Organization. This section of the introduction sets out basic information about these key international institutions, and the treaties and declarations they administer, as background to the chapters that follow.

3.1 *The World Trade Organization*

The World Trade Organization²⁹ has been a key actor in the debate over patent law and access to essential medicines. The TRIPS Agreement

²⁸ *Ibid.*, article 4. ²⁹ World Trade Organization, www.wto.org/.

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requires WTO members to establish minimum standards for protecting and enforcing intellectual property rights.³⁰ In particular, members of the WTO are required to provide patent protection for pharmaceutical drugs for at least twenty years. Nonetheless, the treaty does recognize the countervailing need of member states to protect public health. Article 8 of the TRIPS Agreement declares: 'Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.' The TRIPS Agreement contains a number of provisions designed to promote the public interest in the field of public health. It allows governments to provide for exceptions, exclusions and limitations to rights in order to address national emergencies, to facilitate public non-commercial use or to remedy anti-competitive practices.³¹ This can be done, for example, in the form of compulsory licensing,³² exhaustion regimes³³ and other types of exceptions, such as the defence of experimental use³⁴ and the 'Bolar' exemption for pharmaceutical drugs, provided certain conditions are fulfilled.³⁵

³⁰ TRIPS Agreement, above n. 25; Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (2nd edn, 2003); and Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* (2003).

³¹ Article 30 of the TRIPS Agreement deals with exceptions to rights conferred; and article 31 of the TRIPS Agreement considers other uses of patented inventions, which do not require the authorization of the rights holder.

³² By issuing a compulsory licence, a state allows for the use of a patented invention in return for reasonable compensation. Gervais, *The TRIPS Agreement*, above n. 30, 244–53.

³³ Under the system of international exhaustion, once a patented invention has been placed onto the market with authorization, the patent holder loses control over the actions performed on it by the buyer. Gervais, *The TRIPS Agreement*, above n. 30, 111–15.

³⁴ The defence of experimental use allows users to experiment on a patented invention, without seeking permission or paying royalties to the patent holder. The US common law defence of experimental use is limited to amusement, idle curiosity and strictly philosophical inquiry; whereas the European Union directive in respect of experimental use covers potentially both commercial and non-commercial use. See Matthew Rimmer, *Intellectual Property and Biotechnology: Biological Inventions* (2008), 162–73.

³⁵ A 'Bolar exemption' is named after a legislative response to the decision in *Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc.*, 733 F 2d 858 (Fed Cir, 1984). It is a safe harbour exemption that allows generic companies to conduct research and tests in preparation for regulatory approval of a generic version of a pharmaceutical drug that is still under patent. There has been legal debate over the scope of the safe harbour provided by the Drug Price Competition and Patent Term Restoration Act 1984 ('the Hatch-Waxman' Act) (United States): *Merck KGAA v. Integra Lifesciences I, Inc.*, 545 US 193 (2005). Some jurisdictions have equivalent 'springboarding' provisions: section 119A of the Patents Act 1990 (Cth)

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There have been dramatic battles over patent law and access to medicines under the shadow of the TRIPS Agreement. These conflicts have involved international law, constitutional law, intellectual property law, competition law and trade law. While patent law had been around for centuries, the TRIPS Agreement marked the first time patent protection for pharmaceutical products was available and, more significantly, enforceable on a global scale. The repercussions were significant. The fact that intellectual property rights were now tied to the international trading regime meant that mechanisms for the enforcement of these rights were far more effective than previously. Countries, such as Canada, accustomed to issuing compulsory licences for the generic manufacturing of medicines began to face challenges from other states and from pharmaceutical companies.³⁶

After a number of high-profile conflicts over access to essential medicines in South Africa³⁷ and Brazil,³⁸ and a panic over bioterrorism in North America,³⁹ the WTO issued the Declaration on the TRIPS Agreement and Public Health ('Doha Declaration') at the fourth WTO Ministerial Conference in Doha in 2001.⁴⁰ Susan Sell and John Odell have suggested that the Doha Declaration was made possible by a

allows springboarding as an exception to patent infringement on any pharmaceutical patent at any time for purposes solely in connection with gaining regulatory approval of a pharmaceutical product in Australia or another territory. See Rimmer, *Intellectual Property and Biotechnology*, above n. 34, 173–81.

³⁶ WTO Panel Decision on *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R.

³⁷ *The Pharmaceutical Manufacturers' Association of South Africa v. Government of South Africa*, Notice of Motion, Case Number 4183/98, in the High Court of South Africa (Transvaal Provincial Division).

³⁸ *Brazil – Measures Affecting Patent Protection*, WT/DS199/4, G/L/454, IP/D/23/Add.1, 19 July 2001, (01–3506). For an archive of documents on the WTO challenge by the United States against Brazil, see: www.cptech.org/ip/health/c/brazil/. Paul Champ and Amir Attaran, 'Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of the U.S.–Brazil Patent Dispute' (2002) 27(2) *The Yale Journal of International Law* 365–93.

³⁹ Ciprofloxacin dispute over compulsory licences during the 2001 anthrax scare, www.cptech.org/ip/health/cl/cipro/; Project Bioshield Act 2004 (United States); and David Resnik and Kenneth De Ville, 'Bioterrorism and Patent Rights: "Compulsory Licensure" and the case of Cipro' (2002) 2(3) *The American Journal of Bioethics* 29–39.

⁴⁰ Declaration on the TRIPS Agreement and Public Health: Adopted on 14 November 2001, WTO Doc WT/MIN(01)/DEC/2 (2001) ('the Doha Declaration'); and Frederick Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 *Journal of International Economic Law* 469–505.