BRITISH ACADEMY LAW LECTURE

Patents and Public Health: Principle, Politics and Paradox

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I. Introduction: extremities and disparities

WE LIVE IN A WORLD OF EXTREMES. The huge access of affluence that has befallen Western societies over the last fifty years is confined in its benefits to a fraction of the world's population of six billion. It contrasts starkly with the poverty, disease, malnourishment and short lifespans that burden most human lives.

Some of the disparity can be rationalised away. Those living in affluence often do not see, still less have any contact with, people who suffer from preventable illness, avoidable hunger and remediable destitution. Or they think of them as less deserving, or of their condition as self-inflicted. Certainly they acknowledge no functional connection between the prosperity of the West and the impoverishment of the rest. Distance, ideology and the inevitable frailties of human understanding and connection help maintain comfort.

But some issues pierce the insulation. AIDS in particular has done so. The epidemic was first diagnosed just more than two decades ago in the affluent West. But within a few years it became plain that its severest effects would be felt in Africa and other resource-poor parts. In the 1980s,

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the main burden of death and disease seemed to be in North America and Western Europe. Yet as the death toll from AIDS among Africans mounted in the mid-1990s, among affluent Westerners it started to fall dramatically.

The reason was a medical breakthrough. At the XI International AIDS Conference in Vancouver in 1996, results of clinical trials were announced, showing evidence of a momentous advance in treating HIV/AIDS. They revealed that combinations of antiretroviral (ARV) medicines ('highly active ARV therapy' or HAART)[1] could bring replication of the virus within the human body to an effective standstill.[2] Once viral activity was suppressed, the damaged immune system could be restored. The results were life-savingly immediate—those suffering the horrific effects of AIDS experienced miraculous improvements in their health. AIDS-related illnesses and deaths in the West declined dramatically.

For many, these developments have transformed the meaning of the AIDS epidemic: from a severely debilitating and inevitably fatal disease, AIDS has become a chronic but manageable medical condition. The fact that AIDS can be treated has also changed the social nature of the disease: stigma and fear have diminished. A turning point in the world's worst pandemic[3] since Europe's Black Death in the thirteenth century seemed to have been reached.

[1] ARV medicines work by interfering directly with the lifecycle of HIV. By preventing HIV from replicating, HAART allows the immune system to recover, largely preventing the onset of further opportunistic infections (OIs) and resulting in a radical truncation of both mortality and morbidity. See generally, Robin Wood, affidavit in *Hazel Tau and Others v GlaxoSmithKline SA (Pty) Ltd and Others*, in case no. 2002Sep226 before the Competition Commission of South Africa, available online at *www.tac.org.za/Documents/DrugCompaniesCC/Tau_v_GSK-Wood_affidavit.doc*. The first anti-retroviral drug to be registered as a treatment for HIV infection was zidovudine, or AZT (Mathilde Krim and Darrell E. Ward, Ch. 20: 'The Emergence and Early Years of the HIV/AIDS Epidemic' in Darrell E. Ward, *The AmFAR AIDS Handbook: The complete guide to understanding HIV and AIDS* (New York, 1999, p. 381). The US Food and Drug Administration (FDA) registered it for the treatment of HIV infection in March 1987, only a few months after the application for its registration. After AZT, it took more than four long years before the second ARV (didanosine, also known as ddI) was registered for the treatment of HIV—and a further five before a near-miraculous discovery in AIDS treatment was announced in 1996. Didanosine (ddI) was registered on 9 Oct. 1991. To date, the FDA has registered a total of 27 ARV drugs, including various combinations of individual ARV active ingredients and improved versions of existing drugs. See FDA, 'Drugs Used in the Treatment of HIV infection', available online at *www.fda.gov/oashi/aids/virals.html*.

[2] See C. C. Carpenter *et al*., 'Antiretroviral therapy for HIV infection in 1996: Recommendations of an international panel', *The Journal of the American Medical Association*, 276 (1996), 146–54.

[3] Between 20 and 40 million people are estimated to have died in the influenza pandemic of 1918–19. According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), there have been more than '20 million deaths since the first AIDS diagnosis in 1981'. See, UNAIDS,

Yet that turning point has eluded most of those with HIV or AIDS. It continues to do so. For most, the disease remains a grievous threat to life, terrifying in its effects and threatening in its mystique. In conditions of poverty, its exaction in human suffering remains extreme. About six million people in the developing world living with HIV/AIDS need access to treatment now.[4] Of these, less than twelve per cent (some 700,000) have access to medication.[5]

The 'un-met' need is not uniformly distributed across the developing world. As much as forty-one per cent of the need for anti-retroviral treatment is in three countries: India, Nigeria and South Africa. Sub-Saharan Africa accounts for approximately seventy-two per cent. Since more than two-thirds of those with HIV or AIDS live in Africa,[6] at this moment close to six million poor people are dying of AIDS.

Their deaths are unnecessary. Modern medical advances make them unnecessary. Yet modern medications are not accessible to them. Their lack of access condemns them to a grievous fate that those with AIDS in the world's more affluent regions are now routinely spared.

Avoidable death by AIDS, in a world that has the knowledge and the means and the capacity to produce the medication that can save lives and prevent suffering, does more than tell a story about an epidemic. It highlights inequity in access whose root causes demand a moral accounting. That is the primary focus of this paper. It seeks to understand some of the causes for the disparity between the effects of AIDS in the affluent and the resource-poor world.

Those causes lie amidst roots tangled in inaction and lack of vision and incapacity. But there can be little doubt that the high prices of ARV medicines, which result in large part from the way in which the affluent world regulates the productive exploitation of knowledge, have added significantly to the terrible toll of AIDS. Our thesis is that, directly and

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'2004 Report on the global AIDS epidemic', 3, available online at *www.unaids.org/bangkok2004/report.html*. According to the most recent UNAIDS statistics, 3.1 million people were estimated to have died from AIDS-related illnesses in 2004 alone, with a further 39.4 million people estimated to be living with HIV/AIDS at the end of that year. See UNAIDS, 'AIDS epidemic update: December 2004', 1, available online at *www.unaids.org/wad2004/report_pdf.html*.

[4] Of an estimated 40 million people living with HIV/AIDS globally, approximately 95 per cent live in developing countries ('Treating 3 million by 2005: Making it happen—the WHO strategy' (World Health Organization: Geneva, 2003, p. 3).

[5] See WHO/UNAIDS/Global Fund/US Government Joint Media Release, '700,000 People Living with AIDS in Developing Countries Now Receiving Treatment', 26 Jan. 2005, available online at *www.unaids.org/en/media/press+releases.asp*. This contrasts with coverage within the developed world of more than 75 per cent (see above, n. 4).

[6] Ibid.

indirectly, the international enforcement of the patent system has hobbled and inhibited access to life-saving medications in a way that lacks moral warrant.

This paper begins by exploring how patent protection has been used to limit access to essential medicines. After considering how patents can be justified, the paper attempts to show how and why the 'principle of balance', which lies at the heart of patent protection, has been subverted by the discourse of property rights—talking about patents as though they are equivalent to other forms of rights in property. This involves a discussion of the World Trade Organization (WTO) *Agreement on Trade-Related Aspects of Intellectual Property Rights*,[7] or TRIPs.

This concludes with a consideration of the *Declaration on the TRIPs agreement and public health* ('the Doha Declaration'),[8] which the WTO adopted in November 2001, and which represented a significant return to the principle of balance. This is followed by an analysis of the puzzling inaction on the part of developing country governments, which have largely failed to take advantage of the breakthrough that was achieved at Doha.

We acknowledge that innovative products would not be developed and commercialised without an appropriately designed system of rewards and/or incentives. But this does not in itself justify a patent system, let alone a highly protective form of that system. That would require rejection of all alternatives that might better encourage innovation and exploitation. And even if the patent system were better, it would not necessarily justify the existence of patents and minimum standards of patent protection in *all* countries in respect of all innovative products and processes.

We conclude that true appreciation of the value of the patent idea requires resistance to the current demand for uniform and rigid global enforcement of patents. That demand we blame in part for the inhibition that many developing world governments currently display toward alternatives that would better enable them to deal with pressing health crises.

[7] The full text of the TRIPs Agreement has been published as *General Agreement on Tariffs and Trade—Multilateral Trade Negotiations (The Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights* (15 Dec. 1993), *International Legal Materials*, 33 (1994), 81, and is also available online at *www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs*.

[8] *Declaration on the TRIPs Agreement and Public Health*, WTO Res. WT/MIN(01)/DEC/2, 4th Sess., Ministerial Conference, 20 Nov. 2001, available online at *www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_TRIPs_e.doc*.

II. Causes and effects: patent rights and death by AIDS

Treatment advocates have long understood that barriers inhibiting access to essential medicines are many and varied. These include lack of political will, lack of capacity to prescribe and dispense drugs safely and effectively, and limited resources. Saddled with incapacitating debt, many developing nations simply cannot purchase essential medicines even when these are competitively priced.

At the same time, advocates have focused attention on the impact of high medicine prices: and once high prices are acknowledged to be part of the problem, the central role that the enforcement of patents plays in limiting access to a sustainable supply of affordable medicines for poor people becomes critical.

Some defenders of high levels of patent protection point out that '[i]f the patient does not have access to a physician, or lacks accurate information, prices are irrelevant'.[9] This may be true, but it obscures the role that protection and enforcement play in limiting access to a sustainable supply of affordable essential medicines. In a similar way, the price of water is generally irrelevant to a thirsty man in the desert. But this is not the case if a metered oasis is available. This truth cannot be avoided. In access to medicines for treating AIDS, six million lives speak it.

But what is it about a patent that all too often results in price exploitation? Is this inevitable? To answer these and related questions, we need to understand what lies at the heart of patent protection.

A patent is 'an exclusive right granted for an invention, which is a product or a process that provides a new way of doing something, or offers a new technical solution to a problem'.[10] It ordinarily entitles its holder to 'exclude other persons from making, using, exercising, disposing or offering to dispose of, or importing the invention' in

[9] R. P. Rozek and N. Tully, 'The TRIPS Agreement and Access to Health Care', *The Journal of World Intellectual Property*, 2 (1999), 813–19.

[10] See World Intellectual Property Organization (WIPO), 'Inventions (patents)', available online at *www.wipo.int/about-ip/en/patents.html*. US law, for example, recognises that '[a]ny new and useful process, machine, manufacture, or composition of matter, or any new or useful improvement thereof' may be patented (35 USC § 101). Without defining what is meant by a patent, TRIPs recognises in Article 27.1 that, subject to certain limited exceptions, 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.'

question.[11] It is in other words a state-sponsored guarantee of market exclusivity.[12]

Nevertheless, patent protection does not automatically entitle the inventor to place his or her innovation on the market. The state still has a role to play in regulating the use of the invention. A new medicine, for example, needs marketing clearance by a drug regulatory authority tasked with assessing its safety, efficacy and quality.

The negative right that allows the holder to exclude others is coupled with a duty. Countries do not grant such rights with the expectation that innovations will be put in a drawer. Simply put, the reason the state sponsors the right is the public interest: 'the Western intellectual property tradition is rooted in the idea that intellectual property rights are property rights created by the state for the benefit of the commonwealth.'[13]

In other words, public benefit lies at the heart of patent protection. Promotion of research and development—and the investment necessary for this purpose—doubtless forms part of that benefit, and is promoted so that innovative products can be marketed. (Research and development are not promoted for their own sakes, but rather to ensure that innovative products reach the market. This is evident in the requirement that a patent be granted only for an invention that has commercial application.)

Yet, paradoxically, market exclusivity creates artificial market conditions that too often permit unwarrantable exploitation in prices. The result has been that the patent system has deprived too many of the benefits of scientific developments. This undermines the public interest, which requires that such benefits be both available and accessible.[14]

[11] This definition, which is taken from section 45(1) of the South African Patents Act, 57 of 1978, is substantially similar to definitions found in comparable laws in the US and elsewhere.

[12] An added rationale for patents may be the grant of the exclusive right for a limited period in exchange for the disclosure of the knowledge. But this does not account satisfactorily for pharmaceutical product patents. Even without 'disclosure of knowledge', it is now possible to copy the product—through reverse engineering—where processes alone have been patented. Some suggest that without patent protection for drugs, the inventions may not be put on the market at all because they would be easy to copy. This would not be the case where a formula or 'recipe' is difficult to copy.

[13] P. Drahos, 'The Universality of Intellectual Property Rights: Origins and Development' in *Intellectual Property Rights and Human Rights* (World Intellectual Property Organization in collaboration with the Office of the United Nations High Commissioner for Human Rights, Nov. 1998), p. 14.

[14] See, for example, The Royal Society, 'Keeping science open: the effects of intellectual property policy on the conduct of science' (2004), available online at *www.royalsoc.ac.uk/displaypagedoc.asp?id=6343*.

Our case in point is essential medicines. These are those that 'satisfy the priority health care needs of the population'.[15] Since April 2002, the WHO has recognised ARV drugs as essential medicines. They have also been included in the WHO's model Essential Drugs List (EDL), which provides 'a template for countries seeking to establish their own national lists of priority medicines'.

It is access to these medications that determines life, and all too often death, for people in poor countries. It is these medications that have formed the focus of intense campaigns by treatment activists, who challenge governments and corporations whom they see as unjustifiably blocking access to them.

Here, the damaging consequences of excluding competition have been reinforced by inelastic demand. When demand for innovative products expands and contracts, market forces may temper a patent holder's ability to set prices. But demand for essential medicines is largely inelastic. With such essential products, higher prices do not mean that demand diminishes. They remain essential no matter their price. Patent enforcement has here created acute problems.

Treatment advocates nevertheless concede—as they must—that most essential drugs, including ARV medicines, to some extent owe their existence to exclusive rights in patents. Even though strong patent protection can be abused, if it did not exist in certain key industrialised nations and in the absence of any other system of rewards or incentives, these medicines may very well never have been developed or marketed.

Yet the role of patent protection in researching and developing new pharmaceutical products, in particular ARV medicines, has been unduly exaggerated. It was in fact public money that funded much of the essential basic research in the development of the first ARV medicines. So too was much of the groundwork that paved the way for the development of newer classes of ARV medicines.[16]

Consider zidovudine (AZT), the first ARV drug registered for the treatment of HIV infection. Though never marketed as a cancer drug, it

[15] This World Health Organization (WHO) definition continues as follows: 'They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.' See 'The 12th WHO Model List of Essential Medicines' (April 2002), available online at *www.who.int/medicines/organization/par/edl/eml_intro_eng.doc*.

[16] See Consumer Project on Technology, 'Additional notes on government role in the development of HIV/AIDS drugs', available online at *www.cptech.org/ip/health/aids/gov-role.html*.

was first developed in 1964 by the Michigan Cancer Foundation. Significantly, this was with the help of United States (US) federal funding. AZT failed as a cancer treatment, but had a dramatic second life as a treatment for HIV infection (failing initially as monotherapy, but succeeding in combination with other drugs). Burroughs Wellcome (now GlaxoSmithKline (GSK)) received approval to market AZT for HIV on the basis of relatively little privately-funded study that utilised existing publicly funded German and US research.[17] The point is that vital drugs can be and have been developed through publicly funded research and development.

So patents have an indispensable—though often overstated—role in the development and commercialisation of essential drugs. The dark side is that exclusive rights in patents have been used to extract 'monopoly rents' from high-profit markets, while denying access to potentially life-saving medicines for people who live in countries that constitute low- or no-profit markets.

It should be remembered that patent protection by itself has not always ensured that innovative products are exploited commercially. In the US in the 1970s, the government owned intellectual property (IP) created by federally funded research, but government failed to exploit it. So Congress passed the Bayh-Dole Act in 1980: it gave recipients of federal grants exclusive rights to the IP they had developed, in exchange for their undertaking to exploit those rights commercially.[18] This included taking active steps to commercialise the IP in question.

This history is suggestive. It invites speculation that the US patent system may have been developed over time to encourage commercialisation more than innovation. Innovation could continue even without patent protection: it may draw on a combination of direct funding, the pursuit of knowledge for its own sake, and the rewards of peer recognition. Patent protection may in other words not be indispensable for innovation.

But, more significantly, we must note that the Bayh-Dole statute adapted the patent system by transferring ownership of federally funded research from the federal government to the innovators themselves. It did so to resolve a problem particular to the domestic United States. Without the context-specific adjustment it introduced, the commercialisation of

[17] For further detail, see James Packard Love, expert affidavit in *Hazel Tau and Others v Glaxo-SmithKline SA (Pty) Ltd and Others*, available online at *www.tac.org.za/Documents/DrugCompaniesCC/DrugCompaniesCC.htm*.

[18] See 'Chapter 18—Patent rights in inventions made with federal assistance', 35 USC §§ 200–212.

important health products might not have occurred. The fact is that other domestic situations may require equally specific adjustments. Demands that patent protection be universalised overlook this.

Although difficult to attain, an appropriate balance between innovation and access has to be struck, both domestically and internationally. In practice, patent systems have developed over time in response to changing domestic circumstances and identified priorities. In some cases, the public interest has been at the forefront. But increasingly, other factors unrelated to the public interest have come to dominate.

At what level, and at what cost, should essential medicines be protected by patent, if at all? The answer to that question depends on the underlying justification for patent protection.

III. Justifying patent protection

The protection of patents must find justification in the connection between innovation and commercialisation (and thus financial reward). The strongest argument for protecting patents is instrumental. It operates from the premise that little incentive to innovate exists when others can reap the rewards from the innovation at little or no cost—the classic 'free-rider' problem.[19] In other words, the argument asserts, innovative products would not become commercially available unless market exclusivity is guaranteed. This is regarded as the essential condition for the levels of investment necessary for socially beneficial innovation and commercialisation.

But this argument is in concept flawed. This is because patents in effect restrict the current use of existing inventions so as to increase the development and thus the future availability of new inventions: these, in turn, will be subject to the same restrictions on their use.[20] The patent

[19] Michael J. Trebilcock and Robert Howse, *The Regulation of International Trade*, 2nd edn (London, 1999), p. 309. In this regard, it is interesting to note that imperial China, for example, 'achieved spectacular outcomes in science and innovation, yet it did not rely on intellectual property rights or a customary equivalent'. Eighteenth-century England, on the other hand, adopted this 'distinctly instrumental' justificatory approach to IP (Peter Drahos, *A Philosophy of Intellectual Property* (Aldershot, 1996), pp. 14–15). For a more detailed account of the basis of early English IP law, see Drahos, ibid., pp. 29–33. But, warns May, '[o]nly by conceiving of the public benefit as exclusively the promotion of innovation can pharmaceutical patents appeal to an instrumental justification. To conceive of the public interest as the right to health undermines the[se] arguments' (Christopher May, *A Global Political Economy of Intellectual Property Rights: The new enclosures?* (London, 2000), p. 101).

[20] E. C. Hettinger, 'Justifying Intellectual Property', *Philosophy and Public Affairs*, 18 (1989), 31–52, 48.

system in other words relies on the paradoxical justification that it operates by 'slowing down the diffusion of technical progress . . . [in order to ensure] that there will be more progress to diffuse'.[21] We limit access to innovative products now, to enhance the incentive to innovate and commercialise new products, in respect of which access will also be limited.[22]

The effect of this paradox may be ameliorated where people are willing and able to pay a premium for innovative products. In other words, if society is rich enough, inventors can be rewarded without slowing progress. Where the market can bear the prices that ordinarily flow from the patent's guarantee of market exclusivity—thus providing access—the paradox seems to fall away.

But this is not so in developing countries: they are not rich enough to pay the full premium that getting access to patented goods requires.[23] This is also the case amongst poor communities within industrialised countries who lack equitable access to health care services. Here, the power to charge a premium for a patent-protected medicine translates into patent exclusivity that deprives poor people of life and health.

The weakness in the 'incentives to innovate' argument is highlighted in 'marginal' markets. To call markets in Africa 'marginal', as they are, does not mean, of course, that there is no need or demand for essential drugs in Africa—on the contrary. It refers to the ability to purchase drugs at the prices charged.

The market for ARV drugs in Africa is a telling instance. Despite the fact that AIDS is pandemic, and although other diseases are rampant, the African 'market' accounts for little more than one per cent of worldwide sales of pharmaceutical products.[24] In such a market, 'incentives to innovate' cannot justify the enforcement of exclusive rights in patents, because the profits from the sales of patented drugs are—to say the least—unlikely to have any impact on further innovation.[25]

[21] Joan Robinson, quoted in Dorothy Nelkin, *Science as Intellectual Property* (New York, 1984), p. 15.

[22] We do not contend that scientific progress stops: only that the grant of the patent is usually followed by limited access. Thus dependent patents and experimental use are exceptions to the rule. But even this is changing. In the US, for example, experimental use has been virtually eliminated. See *Madey v Duke University*, 307 F.3d 1351 (Fed. Cir. 2002); *Integra Lifesciences Ltd v Merck KgaA* (2003) 331 F.3d 860 (dissent).

[23] Depending on their wealth, some developing countries (such as Brazil and South Africa) may be able to pay something over marginal cost.

[24] Andy Gray and Thulani Matsebula, Chapter 9: 'Drug Pricing' in Antoinette Ntuli *et al*. (eds.), *South African Health Review 2000* (Durban, 2001), available online at *www.hst.org.za/uploads/files/chapter9_00.pdf* at 205.

[25] Trebilcock and Howse, pp. 311–12, see above, n. 19.

Such markets thus have no impact on incentives to innovate. Where the requisite purchasing power does not exist, patents play no role in spurring either innovation or commercialisation. So seen, it is not difficult to understand why current privately funded pharmaceutical research focuses on health and cosmetic products that primarily benefit people living in wealthy countries: drugs, a colleague has said, 'to grow hair, relieve impotence and otherwise brighten life, and not on the epidemics and pandemics of the South'. [26] If patent systems were truly designed to secure innovation they would encourage also basic research without commercial application. This would yield essential medicines for diseases of poverty.

The instrumental justification for patent protection thus depends on highly contingent circumstances. It is persuasive only under specific conditions of social wealth. Where these do not exist, it becomes harder to find the moral justification for enforcing patents.

In some cases, the existence of patents inhibits rather than creates incentives for further innovation. Patents in products, for example, often limit innovation in respect of process. Such innovation ordinarily follows only after the patent has expired, as generic manufacturers compete for market share. But if the protection offered by a product patent did not exist, a process patent may provide an incentive to develop the product in another (potentially more efficient) way.

This has for many years been the case in India.[27] Because generic manufacturers have to compete on the basis of cost alone (given that all products must satisfy the same safety, efficacy and quality standards), they have a strong incentive to innovate processes—to make the product as quickly and cheaply as possible. But product patent-holders can exclude

[26] L. T. C. Harms, 'Offering Cake for the South', *European Intellectual Property Review*, 10 (2000), 451–3 (footnote omitted). But see R. T. Rapp and R. P. Rozek, 'Benefits and Costs of Intellectual Property in Developing Countries', *Journal of World Trade*, 24 (1990), 75–102 where the authors claim that patent and trademark protection is vital to create an 'incentive for pharmaceutical firms to devote local resources to R&D'. It is difficult to see how patent protection could ever be an incentive to develop drugs for which there is no market.

[27] India's obligations under TRIPs only became effective on 1 Jan. 2005. On that date, the Patents (Amendment) Ordinance, 2004, promulgated by the President of India on 27 Dec. 2004 (when Parliament was not in session), came into effect. Amongst other things, the ordinance amended the Indian Patents Act, 1970, to introduce product patent protection for drugs, food and chemicals. The 2004 Ordinance was repealed by the Patents (Amendment) Act, 15 of 2005, which was assented to by the President on 4 April 2005 and published in the *Gazette of India* the following day. According to section 1(2) of Act 15 of 2005, which is available online at *www.patentoffice.nic.in/ipr/patent/patent_2005.pdf*, certain provisions of the new law 'shall come into force on such date as the Central Government may . . . appoint', with the remaining provisions being 'deemed to have come into force on the 1st day of January, 2005'.

competition: they therefore do not have to innovate to assure profit margins—they can simply charge more.[28]

In any event, it does not automatically follow that the grant of exclusive rights in patents is the most appropriate way to ensure the development and commercialisation of new 'inventions'. Given the way in which the patent system may limit access to the benefits of scientific progress, and that it responds mainly to financial incentive, the concept seems open to question: 'If the allocation of these property rights is simply a means to an end, namely, to make the fruits of creativity and research available to users, then one must ask if the means is the most effective way to that end.'[29]

Moreover, how much protection many patent systems ordinarily confer is open to question. It is true that the sheer cost of innovation would often present an insurmountable obstacle if patent protection (or a comparable reward system) did not exist. But there comes a point where sufficient incentives to innovate exist, yet where increased protection serves no public interest. To the contrary, increased protection may actually serve as a disincentive to innovate, since it is often precisely the 'looming expiration'[30] of a patent that impels innovation.[31]

A weaker justification for patent protection invokes the logic of Locke's labour theory of property. This asserts that one owns the fruits of one's labour.[32] On this approach, the monopoly element held to be common to all property rights is ascribed to patents. But Locke's theory is subject to two provisos under which labour justifies property rights in a thing

[28] There is also the different question of 'new use'—which involves determining whether new use is sufficiently inventive to qualify for patent protection. In *Apotex Inc v Wellcome Foundation Ltd* [2002] 4 S.C.R. 153, the Supreme Court of Canada, for instance, upheld the AZT new use patent as being sufficiently inventive to satisfy the test under Canadian law. But see section 3(d) of the Indian Patents Act, 1970 (as amended), which excludes from patentability 'the mere discovery of any new property or new use for a known substance'.

[29] See D. Vaver, 'Intellectual Property Today: Of Myths and Paradoxes', *Canadian Bar Review*, 69 (1990), 98–128.

[30] See A. B. Engelberg, 'Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness? A Political, Legislative and Legal History of U.S. Law and Observations for the Future', *IDEA: The Journal of Law and Technology*, 39 (1999), 389–425 (footnote omitted).

[31] Unsuccessful research is factored in. Well-established risk ratios exist for different phases of development. The most risky is basic science research. Yet once a product shows promise, the risk drops radically. This is usually the point at which drug companies enter. It should be noted that small biotechnology firms (rather than the drug companies themselves) now do much of the work between basic science research and actual product development. See generally Love, above, n. 17.

[32] R. E. Meiners and R. J. Staaf, 'Patents, Copyrights, and Trademarks: Property or Monopoly?', *Harvard Journal of Law and Public Policy*, 13 (1990), 911–40.

produced.[33] Exclusive rights in IP run afoul of both of these provisos.[34] Yet even though this is weaker than the instrumental justification, the property rights approach has dominated the discourse.

In addition, it is false to equate patent rights with traditional forms of property such as land.[35] Patents are different since knowledge, unlike other forms of property, is 'infinite in time and space'.[36] This leads to two distinguishing features. In the first place, the exclusive appropriation of finite resources (such as food, shelter, land) depends on the implicit or explicit exercise of force. For one to have, another must not have: and the resultant exclusivity can be maintained or overcome only by the exercise of physical constraint. By contrast, once public, the appropriation of another's idea requires no force. Because the idea is intangible it is susceptible to unlimited non-coercive appropriation through copying.

Second, it is only by creating property rights in knowledge—and thereby 'manufacturing scarcity'—that knowledge is transformed into a limited resource.[37] Knowledge can command a price only once it is accorded commodity status.[38] But unlike other forms of property, scarcity does not exist in the absence of state intervention. It is state-created (we distinguish between state-creation and state regulation of forms of property entitlement). Patents for this reason enjoy 'less of a moral right than other property claims'.[39]

[33] The first proviso states that after the appropriation of a thing from a state of nature, there must be 'enough and as good left in common for others'. (John Locke, 'The Second Treatise of Government: An Essay Concerning the True Original, Extent, and End of Civil Government' in John Locke, *Two Treatises of Government*, ed. Peter Laslett (Cambridge, 1988), ch. V, section 27.) In other words, as long as others are left no worse off as a result of one's appropriation, there can be no objection to owning the fruits of one's labour (Hettinger, 44, see above, n. 20) The second proviso states that one must not take more than one can use, subjecting the legitimate acquisition of property rights to a prohibition against spoilage: 'As much as any one can make use of to any advantage of life before it spoils; so much he may by his labour fix a Property in' (Locke, 'Second Treatise', ch. V, section 31).

[34] See J. Berger, 'Tripping Over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity', *Connecticut Journal of International Law*, 17 (2002), 157–248.

[35] See May, pp. 46–7 (above, n. 19). May suggests that the attempt to understand IP on the same basis as material property is a mechanism for asserting—rather than establishing—legitimation (ibid., 47).

[36] Vaver, 126, see above, n. 29.

[37] Ibid.

[38] May, p. 49, see above, n. 19.

[39] R. Weissman, 'A Long, Strange TRIPs: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining Legal Alternatives Available to Third World Countries', *University of Pennsylvania Journal of International Economic Law*, 17 (1996), 1069–1132.

Creative activity in any event does not take place in a vacuum. Context means the contributions of other creators: these can never be minimised.[40] Primary research in both developed and developing countries—including basic science research without which many new pharmaceutical products would not have been developed and brought to market—plays an important contributory role in innovation. Yet it is much less rewarded.

Hence trying to justify patent protection on the basis of a labour theory of property may paradoxically undermine the regime itself.[41] Drahos explains:

> Within an interdependent, differentiated society the labour of any one individual is made possible by the labour of others. If we define a direct contribution of labour in terms of a contribution that enables the production of an abstract object, this forces a recognition of the fact that many ostensibly individually owned abstract objects are in reality collectively owned by virtue of joint labour.[42]

Yet even if we assume that Lockean arguments provide a reasonable basis for justifying patent protection, this does not tell us what form the reward should take. There is no inevitable connection between compensation and proprietary entitlements.[43] Reward and compensation can take many different forms. An inventor can be rewarded with honours, privileges other than patents, public esteem. It does not follow that exclusive rights are the appropriate form of compensation for developing or commercialising new medicines.

Neither of the two justifications ordinarily advanced in support of patent protection, we suggest, affords a convincing case for the grant of long-term market exclusivity that is unqualified by some accompanying duty to act reasonably, or a usufruct. All they do is to establish the need for *some* system of rewards and/or incentives, as well as to raise significant doubt regarding the appropriateness of granting exclusive property-like rights for the purpose of ensuring innovation and commercialisation. What is left is a nagging doubt: is there not perhaps some other more efficient and less harmful way to achieve the desired outcomes?

[40] Trebilcock and Howse, p. 308, see above, n. 19. While the development of more traditional forms of property such as land may not take place in a vacuum either, other contributors to the property development are rewarded for their labour or other contributions. The inventor, on the other hand, merely appropriates the prior work of others.

[41] Drahos, p. 52, see above, n. 19.

[42] Ibid.

[43] Trebilcock and Howse, p. 308, see above, n. 19.

IV. From the principle of balance to a property rights discourse

As a matter of history, many countries have chosen to adopt patent systems to pursue innovation and subsequent commercialisation. In so doing, they have sought to give legal expression to the 'principle of balance'. This is simple to state: patent regulation should achieve balance between innovation and access. The principle recognises that while exclusive rights in patents are to some extent about the creation of incentives to innovate, and the just deserts of hard labour, they are essentially 'liberty-inhibiting privileges' that impose duties on their holders.[44]

The grant of a patent in other words requires the holder to exercise the entitlement to exclude others in a way that does not undermine the purpose sought to be attained by granting the guarantee of exclusivity. 'Exclusive rights are the exception, not the rule, and they need to be justified.'[45] Thus the right may be exercised only so as to give effect to the bargain. Seen thus, the privilege inhibits the holder of the right from doing with it what he or she pleases.[46]

South African patent law is instructive. The Patents Act of 1978 is based in part on the recognition, the Supreme Court of Appeal has said, that 'the limited statutory monopoly afforded a patentee is seen as a means of encouraging inventors to put their inventions into practice'.[47] An 'essential quid pro quo of the theory' is that the grant of statutory exclusivity must be to the benefit of the public.[48]

The public interest served by the grant of a patent thus lies at the core of the 'liberty-inhibiting' privilege granted by statute. If its grant is not in

[44] Drahos, p. 220, see above, n. 19.

[45] L. T. C. Harms, 'The Role of the Judiciary in the Enforcement of Intellectual Property Rights: Intellectual Property Litigation under the Common Law System with Special Emphasis on the Experience in South Africa', *European Intellectual Property Review*, 26 (2004), 483–92, 488, adapting a statement of Laddie J.

[46] Drahos, p. 220, see above, n. 19. Drahos also refers to a non-instrumental justification based on intrinsic duties in support of this point (ibid., p. 221). A similar line of thinking was expressed in *Special Equip. Co. v Coe*, where a four judge minority characterised a patent as 'a privilege "conditioned by a public purpose"' (1945) 323 U.S. 386, 415). But see, for example, *Hartford-Empire Co. v United States*, where a narrow majority of the US Supreme Court held that a 'patent is property, protected against appropriation both by individuals and by government' (1945) 323 U.S. 386, 415); and *Schenck v Notron Corp*., where the US Court of Appeals for the Federal Circuit held that a 'patent right is but the right to exclude others, the very definition of "property"' (713 F.2d 782 (Fed. Cir. 1983), 786, n. 3).

[47] *Syntheta (Pty) Ltd (formerly Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another* 1999 (1) SA 85 (SCA), 88I, per Plewman JA.

[48] Ibid., 88I-J.

the public interest or lacks a public value, the existence of the patent cannot be justified.[49]

If patents are designed to balance innovation with access, their rationale is to ensure that new products are not only created and marketed—but also made accessible.[50] All too often, creation and marketing only are attained, yet access is severely limited. The result is that exclusive rights are enforced in a way that is at odds with the rationale for patent protection.

A telling instance arises from South Africa. The Patents Act, 57 of 1978, provides avenues for government and the courts to enforce compulsory licences.[51] Yet this has never happened.

The state has yet to make use of a statutory power that entitles it to 'use an invention for public purposes'. If the terms and conditions of such government use—which would include licensing generic companies to reduce drug prices—cannot be agreed upon, the state must approach

[49] Harms, p. 451, see above, n. 26 (footnotes omitted).

[50] See, for example, Commission on Intellectual Property Rights, 'Integrating Intellectual property Rights and Development Policy' (London, Sept. 2002), available online at *www.iprcommission.org*, where the conferring of exclusive rights in intellectual property is recognised 'as an instrument of public policy, which should be designed so that the benefit to society . . . outweighs the cost to society . . . [and] as one of the means by which nations and societies can help to promote the fulfilment of human economic and social rights' (at 10). See also Department for International Development, 'Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical sector' (London, March 2005), available online at *www.dfid.gov.uk/pubs/files/pharm-framework.pdf*; and Nuffield Council on Bioethics, 'The ethics of patenting DNA: a discussion paper' (23 July 2002), available online at *www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf*, which questions whether 'the application of the patent system to DNA sequences is achieving its goals, namely the stimulation of innovation for the public good, and the rewarding of people for useful new inventions' (at xi).

[51] Section 4 (State bound by patent) provides as follows:

> A patent shall in all respects have the like effect against the State as it has against a person: Provided that a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee.

Section 56(1), part of the provision dealing with a '[c]ompulsory licence in [the] case of abuse of patent rights', provides that any 'interested person who can show that the rights in a patent are being abused may apply to the commissioner [a High Court judge] in the prescribed manner for a compulsory licence under the patent'. In terms of section 56(2), the rights in a patent are deemed to be abused if within a stated period of years there is without satisfactory reason inadequate or no commercial exploitation; if demand is not being met adequately and on reasonable terms; and if 'by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a licence or licences should be granted'.

the court for assistance. Yet there are no reported judgments on terms and conditions associated with such compulsory licences. This almost certainly indicates that none have ever been granted. (Although threats of applications have—as we show below—led to industry licences, we know of no case where a government threat has been similarly productive.)

There are four reported decisions on court-granted compulsory licences under s. 56.[52] None was successful. The spectre of a court challenge under this provision has, however, been used successfully at least once to induce a major pharmaceutical company to grant a voluntary licence.[53] While the licensee may initially charge much the same as the patentee, once there is real competition between multiple licensees, prices necessarily drop, sometimes radically. Naturally generic manufacturers are committed to profit rather than the public benefit. But it is competition that will lower prices.

Have such licences never been granted or sought because there is no need for them? Treatment activists would say No: the need is palpable; yet the system of patent protection has not granted it recognition. It is true that the risk that a licensee may itself become the target of litigation may be an inhibition, as may reluctance to antagonise large competitors. But if the regulatory framework was easier (and less risky) to use there seems little doubt that such licences would more readily be sought.

Fair implementation of the principle of balance has thus proved difficult to attain. Balance, one would expect, would find varying expression

[52] In addition to the *Syntheta* judgments referred to above (before the Commissioner of Patents and the Supreme Court of Appeal), the two other judgments are *Sanachem (Pty) Ltd v British Technology Group plc* 1992 BP 276 and *Afitra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd* 1992 BP 331.

[53] On 26 Sept. 2003, two not-for-profit organisations formally requested 'from Boehringer Ingelheim Pharmaceuticals Inc and Boehringer Ingelheim Pharma KG as co-patentees of South African patent number 90/9246, with the consent of Boehringer Ingelheim International GmbH and Ingelheim Pharmaceuticals (Pty) Limited as licensees under South African Patent No. 90/9246, non-exclusive voluntary licences to import into South Africa, and to use, offer to dispose of and dispose of in South Africa, and to export from South Africa, nevirapine' (see TAC Electronic Newsletter (29 Sept. 2003), 'Generic Antiretroviral Procurement Project (GARPP) and TAC Treatment Project Request Permission to Import Generic Nevirapine', available online at *www.tac.org.za/newsletter/2003/ns28_09_2003.htm*). The threat of section 56 litigation, coupled with the *Hazel Tau and Others v GlaxoSmithKline SA (Pty) Ltd and Others* complaint before the Competition Commission and that body's decision to refer the matter to the Competition Tribunal for adjudication (see 'Media Release 30: Competition Commission finds pharmaceutical firms in contravention of the Competition Act', available online at *www.compcom.co.za/resources/Media%20Releases/MediaReleases%202003/Jul/Med%20Rel%2030%20f%2016%20Oct%202003.asp*) resulted in the grant of non-exclusive royalty-free voluntary licences to the Generic Antiretroviral Procurement Project and the TAC Treatment Project. The agreement is available online at *www.tac.org.za/Documents/DrugCompaniesCC/GARPP-BI-Settlement-20031209.pdf*.

in a diverse range of regulatory contexts. Instead, the principle has been overlain by a discourse of property rights. To describe a patent in undifferentiated terms as 'the grant of a property right'[54] is to overlook the essentially negative nature of IP rights. And it is to imply ascription to such rights of the monopoly element common to all private property rights.[55] IP, David Vaver has said, 'is supposed to represent a balance of interests, but that balance itself is upset by property nomenclature'.[56]

The way in which exclusive rights in patents have been exercised in many countries has further tended to eviscerate their public interest dimension. This has supported and perpetuated the discourse of property rights, which in turn has worked 'to obscure the contingent nature of the patent'.[57]

V. Enter TRIPs

The shift from the principle of balance to the undifferentiated assertion of patents as property rights has found its most significant manifestation in the TRIPs Agreement, which has been described as 'probably the most important international intellectual [property] agreement that was signed in the 20th century'.[58] Regardless of domestic need or whether a country's comparative advantage lies in innovation or adaptation, TRIPs requires all WTO members to have a patent system and to offer certain minimum standards of protection for all new inventions.

The demand for TRIPs arose primarily because the property rights paradigm proved insufficiently persuasive to secure full patent protection in important developing country markets such as India and Brazil, where the principle of balance was maintained. At the time of TRIPs' adoption, Indian law did not recognise pharmaceutical product patents. Brazilian law was to the same effect.

[54] See US Patent and Trademark Office, 'General Information Concerning Patents', available online at *www.uspto.gov/web/offices/pac/doc/general*.

[55] Meiners and Staaf, 915, see above, n. 32.

[56] D. Vaver, 'Canada's intellectual property framework: a comparative overview', *Intellectual Property Journal*, 17 (2004), 125–88. The Canadian Supreme Court has recently taken this balancing route in respect of copyright cases. See, for example, *Théberge v. Galerie d'Art du Petit Champlain inc*., [2002] 2 S.C.R. 336; and *CCH Canadian Ltd. v. Law Society of Upper Canada*, [2004] 1 S.C.R. 339.

[57] Weissman, 1087, see above, n. 39.

[58] P. Drahos and J. Braithwaite, 'Intellectual Property, Corporate Strategy, Globalisation: TRIPs in Context', *Wisconsin International Law Journal*, 20 (2002), 451–80.

Nor did the property paradigm enable the World Intellectual Property Organization (WIPO) to expand market access for developed-country industries that had come to rely heavily on patent protection.[59] TRIPs was thus designed to effect international harmonisation of minimum standards of patent protection.

But as David Vaver has explained:

> . . . TRIPs may have imposed standardised IP norms on much of the world, but it has not made believers in the new faith out of everyone. The IP system was developed in the West to serve the needs of the industrialised world. It does not necessarily fit with other cultures and other economies at different levels of development. To many countries who became WTO members, believing that access to world markets would benefit them overall, the TRIPs section of the Agreement seems presently to be delivering more detriments than benefits.[60]

How did TRIPs come into being? The Uruguay Round of trade negotiations resulted in the formation of the WTO in 1994. This provided the ideal opportunity for the pharmaceutical and other IP-reliant industries to advance their cause. Using significant influence, the IP lobby ensured a United States-led movement to include minimum standards of IP protection as an integral part of the Uruguay Round Final Act.[61] Membership of the WTO is conditional on the full acceptance—without reservation—of almost all WTO agreements.[62] Hence the door was opened for the international harmonisation of enforceable IP rules.

At the time of the Uruguay Round, the benefits of expanding the trade arena to include IP seemed clear to the US. First, enforceable minimum standards of IP protection at the international level would go some way towards procuring frequently higher levels of protection than what was at that stage available to American companies operating outside of the US.[63]

[59] See S. K. Sell, 'TRIPs and the Access to Medicines Campaign', *Wisconsin International Law Journal*, 20 (2002), 481–522.

[60] Vaver, 188, see above, n. 56.

[61] Trebilcock and Howse, p. 320, see above, n. 19. See generally, Michael Ryan, *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property* (Washington, DC, 1998).

[62] *See General Agreement on Tariffs and Trade—Multilateral Trade Negotiations (The Uruguay Round): Final Act Embodying the Results of the Uruguay Round of Trade Negotiations* (15 Dec. 1993), *International Legal Materials*, 33 (1994), 1, 2. The Agreement has four annexes, the first three of which are integral parts of the agreement. Annex 1 deals with substantive trade agreements on trade in goods, trade in services and trade-related aspects of IPRs. Annex 2 deals with dispute resolution, with annex 3 providing for a process of multilateral surveillance of national trade policies. Only annex 4 deals with agreements that are not necessarily binding on member states.

[63] See Trebilcock and Howse, pp. 320–1 (above, n. 19).

Second, the WTO seemed to provide a better enforcement mechanism than previously existed. Until that point, many argued that existing international obligations were effectively unenforceable as there was no credible institutional framework for resolving IP disputes.[64]

Third, the US sought to ensure that new technology-based forms of innovation would be protected internationally in a manner endorsed by industrialised countries.[65]

In other words, the US sought to ensure the establishment of certain minimum standards of IP protection globally that would give effect to the balance between innovation and access necessary to satisfy its own domestic needs.[66] What it failed—or chose not—to see were the inevitably negative implications of imposing high levels of patent protection for developing countries.

The result of the TRIPs Agreement has been to bolster the international protection of patents in a way that has narrowed the scope for differentiation within national patent policies. This in effect has deprived domestic legislators of the power to give effect to the principle of balance.

The formation of the WTO thus saw the adoption of TRIPs even though the enforcement of IP stands at odds with the principle of free trade. This is because IP is regarded as 'restricting trade in certain goods'.[67]

From a classic trade perspective it is impossible to contend that all countries should be obliged to maintain the same level of patent protection.[68] What constitutes a valuable economic activity to any one country in relation to innovation depends on circumstances and conditions particular to that country.

A rational patent policy—assuming that in the circumstances it is rational to have patent protection at all—would in part be based on whether a country's comparative advantage lies in innovation or rather in imitation and adaptation of other innovations. Further, a rational policy

[64] See Trebilcock and Howse, pp. 320–1 (above, n. 19).

[65] Ibid.

[66] The US policy seems to have been to open its borders to the import of cheap foreign raw materials and the borders of developing and least-developed countries to the export of value-added IP material, as well as to clamp down on low-cost imitation or outright copying in such countries. It certainly did not intend to encourage domestic innovation and the export of competing finished IP-protected product goods, however much it said that IP would encourage that sort of domestic innovation.

[67] Weissman, 1069, see above, n. 39.

[68] Trebilcock and Howse, p. 307, see above, n. 19.

would need to consider not only the interests of innovators, imitators and adaptors, but also the interests of consumers.[69]

It is true that the medicines in question are not protected by patents in most—if not all—African countries, with the signal exception of South Africa. In theory, therefore, they should be available at marginal cost in these countries. Generally they are not. Most African countries do not provide the requisite 'market' for these medicines, nor do they have—or are they able to develop—local manufacturing capacity.[70] But the lack of patent protection for ARV drugs in most of Africa does not mean that patents do not matter. They do. Where patents matter to industry (where there are markets or where there is domestic generic manufacturing capacity), products will if possible be patented. Here the 'exceptional' case of South Africa proves the point.

Some have argued that minimum levels of patent protection are necessary for development.[71] There is no convincing basis for this claim, which could only have validity in countries with a solid science infrastructure that could develop new drugs itself. This does not exist in most developing countries. Put simply, there is no evidence to suggest that the protection by developing countries of exclusive rights in patents necessarily gives rise to economic development. Instead, the available evidence suggests that the 'need for patents varies with the level of development'.[72]

Many developed countries 'used weak patent protection in their early stages of industrialisation, increasing protection as they approached the leaders'.[73] Countries such as Korea and Taiwan, for example, took advantage of weak patent protection to develop local technological capacity and build strong domestic industries.[74] Others such as France, Germany, Japan, Switzerland, Italy and Sweden did not introduce pharmaceutical patents until their industries had reached an advanced level of development.[75] Full patent protection was adopted in each case only when it was of net value to the country concerned. Some, like Spain and Portugal,

[69] Ibid., p. 308.
[70] This issue is considered in further detail below.
[71] See generally, Rapp and Rozek, above, n. 26.
[72] Sanjaya Lall, 'Indicators of the Relative Importance of IPRs in Developing Countries', UNCTAD-ICTSD Project on IPRs and Sustainable Development Issue Paper No. 3, 1.
[73] Ibid.
[74] Ibid.
[75] *The TRIPs Agreement: A Guide for the South—The Uruguay Round Agreement on Trade-Related Intellectual Property Rights* (South Centre, Geneva: 1997), 36–7 n. 29, available online at *www.southcentre.org/publications/trips/tripsmain.pdf*.

strengthened patent protection for pharmaceutical products only when forced to do so by partners in trade agreements.[76]

High levels of patent protection are usually associated with correspondingly high levels of development;[77] and strong patent protection has generally been introduced in countries only once they have reached an advanced stage.[78] Even so, many developed countries remain sceptical. Take the US itself: it did not join the Berne Convention on copyright till 1989. And before approximately 1982, its courts generally recognised the importance of striking an appropriate balance between the interests of patent holders and the broader public.[79]

The conditions justifying high levels of protection do not apply to developing countries. The AIDS epidemic has underscored the gaping hole in patent theory and practice. Given the necessary implications of TRIPs for access to essential medicines, its adoption and implementation seemed unlikely to advance the interests of developing countries. The early years of its existence provided confirmation.

In the first few years after the adoption of TRIPs, the WTO's Dispute Settlement Body (DSB) considered two complaints regarding domestic standards of patent protection that were alleged to violate international trade law obligations. Their resolution has proved illuminating. Both decisions proceed from the assumption that TRIPs is primarily concerned with protecting IP—even though the Agreement plainly recognises the objective of protecting and enforcing exclusive rights in IP for the purpose of contributing 'to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.[80]

In *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, the DSB's Appellate Body had to consider whether

[76] Carlos Correa, 'Formulating Effective Pro-development National Intellectual Property Policies' in Christophe Bellmann *et al.*, (eds.). *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (London and Sterling, VA, 2003), p. 210.

[77] See generally, Rapp and Rozek, above, n. 26.

[78] J. M. Finger, 'The WTO's Special Burden on Less Developed Countries', *Cato Journal*, 19 (2000), 425–37.

[79] See A. N. Littman, 'Restoring the Balance of Our Patent System', *IDEA: The Journal of Law and Technology*, 37 (1997), 545–70, 545, where the author argues that 'the neutral balance between patent holders and the public domain created by the constitutional and statutory system has been shifted by the United States Court of Appeals for the Federal Circuit to one that unduly favors the patent holder'.

[80] Article 7 of TRIPs.

India had complied with its obligations under TRIPs in respect of 'a means for the filing of patent applications for pharmaceutical and agricultural chemical products'.[81] It was common cause that India's obligations to provide minimum standards of patent protection would become effective only ten years after the adoption of TRIPs (that is, in 2005).

India unsuccessfully defended the original complaint lodged by the US (and largely supported by the European Union) before a DSB panel.[82] It was largely unsuccessful in its attempt to overturn the panel decision on appeal. The Appellate Body decision tempered some of the more disagreeable aspects of the panel's findings. But its reasoning views the main object and purpose of TRIPs as 'the need to promote effective and adequate protection of intellectual property rights'.[83] In its view, TRIPs is simply about the protection of IP.

The principle of balance suffered a similar fate in *Canada—Patent Protection of Pharmaceutical Products*.[84] In that case, a DSB panel had to deal with three issues. First, does TRIPs permit the production and stockpiling of pharmaceutical products prior to patent expiry?[85] Second, does the agreement allow for generic manufacturers to start and complete the drug regulatory process prior to patent expiry?[86] Third, can pharmaceutical products be treated differently from inventions in other fields of technology?[87]

Importantly, not one of the provisions of Canadian patent law under attack would have allowed for the introduction of generic competition during the life of a pharmaceutical patent. Collectively, they merely sought to eliminate delays in bringing generic medicines to market upon patent expiry. In other words, the provisions would have allowed for generic competition immediately upon patent expiry, because drugs would have already been registered and produced in advance.

[81] See Report of the Appellate Body, AB-1997-5, 19 Dec. 1997 at paragraph 1, available at *www.wto.org/english/tratop_e/dispu_e/distabase_wto_members2_e.htm*.

[82] See Report of the Panel, WT/DS50/R, 5 Sept. 1997, also available at *www.wto.org/english/tratop_e/dispu_e/distabase_wto_members2_e.htm*.

[83] See Report of the Appellate Body (above, n. 81), paragraph 57.

[84] Report of the Panel, WT/DS114/R, 17 March 2000, available online at *www.wto.org/english/tratop_e/dispu_e/distab_e.htm*. This decision was not taken on appeal, and has found its way into Canadian domestic law (see *Regulations Repealing the Manufacturing and Storage of Patented Medicines Regulations*, S.O.R./00–373).

[85] See Report of the Panel (above, n. 84), paragraph 3.1.

[86] Ibid.

[87] Ibid.

In its decision, the WTO panel declared the stockpiling provision to be in violation of TRIPs. It upheld the early registration of pharmaceutical products. And it sidestepped the differential treatment question. On the surface, the outcome appeared almost acceptable. The direct consequences for Canada were fairly minimal. This was because the loss of the right to stockpile meant little more than that generic drugs produced in Canada reached the market about three weeks later.

Yet the position was critically different for countries with weaker generic manufacturing capacity. And it would be shortsighted to view the decision solely from the point of view of its impact on Canada. The panel's interpretation of the general exceptions clause (whose existence signifies the need for a mechanism to resolve 'legitimate, competing policy interests') provides cause for general concern. Seemingly heedless of the principle of balance that lies at the core of patent protection, the panel considered the TRIPs provision Canada invoked to justify its statute solely in the light of 'how much the rights holder might lose, not in how much society might gain, from a given exception. It never asked what scope the exception might require to achieve the social purposes at issue.'[88]

To quote Vaver again:

> The pressure for greater intellectual property protection suggests the suppression of other values and a drift towards an economic system where the protection under the aegis of IP of any investment of time, money or labour is fast becoming the norm and competition is becoming the exception.[89]

VI. Regaining some balance at Doha

During the original TRIPs deliberations, the voice of consumers was largely absent. However, a global struggle for access to essential medicines followed the coming into being of TRIPs. This began with a US-based campaign for access to essential medicines in 1995.[90] The WTO's adoption of the Doha Declaration reflects international consensus on the true balance TRIPs strikes in patent protection. This Declaration was eventually agreed at the WTO's ministerial meeting in Doha in November 2001. It constituted a significant breakthrough in this struggle.

[88] R. Howse, 'The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times', *Journal of World Intellectual Property*, 3 (2000), 493–507.
[89] Vaver, 188, see above, n. 56.
[90] See Sell (above, n. 59), 498–509.

Somewhat ironically, US trade pressure on South Africa and Thailand in 1997 triggered and galvanised criticism of TRIPs.[91] This laid the basis for the developments that took place in Doha a few years later. Seeking to increase access to essential medicines through various TRIPs-compliant regulatory mechanisms, both Thailand and South Africa suddenly found their domestic laws under attack from the Pharmaceutical Research and Manufacturers of America (PhRMA) and the office of the US Trade Representative (USTR).[92]

Thailand was quick to abandon its plans. South Africa, however, enacted the Medicines and Related Substances Control Amendment Act, 90 of 1997. President Mandela signed it into law in December 1997. But before the statute could be brought into force, the local representatives of the pharmaceutical industry (the Pharmaceutical Manufacturers' Association of South Africa—'the PMA'), sought an interdict on constitutional grounds that prevented President Mandela from promulgating it.

Most controversial of the new provisions the 1997 Act introduced was section 15C. This dealt with parallel importation and (ostensibly) with compulsory licensing.

Although the matter came before the High Court in early 2001, as a result of delays on all sides, the statute was effectively put on ice. Without court order or settlement agreement, the PMA had managed to block the new law from coming into effect. Sheer weight of resources and legal tactics had succeeded in thwarting a TRIPs-compliant amendment to the law.

But by the time the matter came for hearing in March 2001, the ground had shifted significantly. In the US, Vice President Al Gore's campaign for the Democratic Party's presidential nomination in 2000 provided activists with an opportunity to criticise his 'PhRMA-friendly stance'. Activists ensured that the Clinton administration withdrew its objections to South Africa's 1997 Act in the week that Gore formally declared his intention to run for president.[93]

In South Africa, the XIII International AIDS Conference held in Durban in June 2000 provided a platform to consolidate international opposition to the PMA lawsuit. The activities of the Treatment Action Campaign (the TAC) provided a spearhead. The conference radically shifted international attitudes to patent enforcement in poor countries,

[91] Ibid., 500.
[92] Ibid.
[93] Ibid., 502–4.

and strengthened the movement for worldwide access to life-saving drugs.

The TAC obtained permission from the High Court to intervene in the proceedings (as *amicus curiae*, or a friend of the court). This turned 'a dry legal contest into a matter about human lives'.[94] Six weeks later, following worldwide protests against the pharmaceutical industry, the PMA withdrew its lawsuit on 19 April 2001.[95] Although the government apparently undertook to abide by TRIPs and to give the industry an input in the drafting of the regulations, the 'settlement' was never made an order of court; and at no point did government concede that its actions or the impugned legislation were inconsistent with TRIPs. (Whether in reality an agreement or understanding was reached to inhibit government action on pharmaceutical products and patents is something we consider later.)

In June 2001, the United Nations General Assembly convened a Special Session on HIV/AIDS (UNGASS). The Session formally pronounced AIDS a 'global emergency'.[96] The UNGASS declaration recognised that the African epidemic threatened development, political security and the very fabric of society. It also emphasised the need for 'urgent and exceptional national, regional and international action' on AIDS.[97] The stage was set for the WTO meeting in Doha later that year.

From a legal perspective the Doha Declaration does not break new ground. What it does is to achieve two important—but legally insubstantial—goals.

First, it clarifies the extent of existing rights and obligations in TRIPs: it recognises that the agreement 'does not and should not prevent [WTO] members from taking measures to protect public health'. Reaffirming 'the right of WTO Members to use, to the full, the provisions . . . which provide flexibility for this purpose', the Declaration asserts that TRIPs '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'.[98]

[94] M. Heywood, 'Debunking "Conglomo-talk": A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilisation', *Law Democracy & Development*, 5 (2001), 133–62.

[95] See e-drug, 'DOH and UNAIDS Media release', 20 April 2001, available online at *www.essentialdrugs.org/edrug/archive/200104/msg00068.php.*

[96] *Declaration of Commitment on HIV/AIDS: 'Global Crisis—Global Action'*, UN GA, 26th Spec. Sess. (27 June 2001) at paragraph 2, available online at *www.unaids.org/whatsnew/others/un_special.*

[97] Ibid., paragraph 8.

[98] *Doha Declaration*, paragraph 4, see above, n. 8.

To protect against abuses such as excessive pricing and a failure to satisfy demand, many patent systems have historically made provision for compulsory licences: these allow for the introduction of generic competition even without the patent holder's consent. Recognising 'the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics', the Declaration expressly states that countries have 'the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted'.[99]

Second, the Declaration identifies the key way in which the TRIPs agreement may limit access to essential medicines for poor countries (the Paragraph 6 problem). In response, it recognises that 'WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement'.[100]

Given the DSB's disappointing approach to TRIPs, and well-documented intentions by many with vested interests to promote minimum enforceable standards in IP protection through international trade law, the Doha Declaration was remarkable: it represented victory for developing countries over narrowly sectional corporate interests. To some extent, it also represented a shift back towards the principle of balance, although not a complete return given that TRIPs still required WTO members to provide patent protection for all technologies.

In addition, the Doha Declaration represents the first public acknowledgement by the WTO that all may not be well with TRIPs. In expressly identifying the Paragraph 6 problem, it instructs 'the Council for TRIPs to find an expeditious solution to this problem'.[101]

VII. The puzzle of post-Doha inaction

The Doha Declaration creates space for national legislators to give proper effect to the principle of balance. Yet, paradoxically, this may entail a victory for the patent system. Almost three years after its adoption, and more than a year after the adoption by the WTO General Council of its decision on the *Implementation of paragraph 6 of the Doha Declaration on*

[99] Ibid., paragraphs 1 and 5(b) respectively.
[100] Ibid., paragraph 6.
[101] Ibid., paragraph 6.

the TRIPs Agreement and public health (the 30 August decision),[102] international consensus on a shift back to the principle of balance has for the most part still not been translated into domestic policy and law.

Despite significant positive developments, developing countries have been slow to act. Few have made use of their existing laws to increase access to essential medicines.[103] Most have failed to take advantage of existing statutory powers to make it easier to import or produce locally cheaper generic alternatives.

Even fewer have taken legislative steps to amend patent laws so as to take advantage of the public health flexibilities and safeguards permitted under international law.[104] Some, in amending patent laws to give effect to their WTO obligations, have enacted new provisions that go beyond the requirements of TRIPs.[105] So far, only Canada, Norway and India have effected changes to their laws to facilitate the implementation of the 30 August decision.[106]

[102] WT/L/540, 1 Sept. 2003, available online at *www.wto.org/english/tratop_e/TRIPs_e/implem_para6_e.htm*. To date, the WTO has yet to agree on a permanent amendment to TRIPs that resolves the paragraph 6 problem conclusively.

[103] For a summary of three of the key compulsory licences issued in developing countries to increase access to essential medicines, see 'WTO and medicines: from Doha to Cancún', WHO/EDM Technical Briefing Seminar (27 Sept.–1 Oct. 2004), available online at *www.who.int/medicines/organization/par/briefing/tbs2004/Seminar2/tbs2004_2.shtml*. See also Treatment Action Campaign, 'Zimbabwe declares emergency to use generic antiretrovirals—TAC welcomes step but urges democratic accountability and return to rule of law' (5 June 2002), available online at *www.tac.org.za/newsletter/2002/ns05_06_2002.txt*.

[104] See, for example, section 84 of the Malaysian Patents Act of 1983 (as amended on 15 May 2002), which provides as follows:

> '(1) Notwithstanding anything containing in this Act—
>
> (a) Where there is national emergency or where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the Government, so requires; or
>
> (b) Where a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive, the Minister may decide that, even without the agreement of the owner of the patent, a Government agency, or a third person designated by the Minister may exploit a patented invention.'

[105] Section 84(1) of the recently amended Indian Patents Act, 1970, imposes an initial three-year 'ban' on the use of compulsory licensing following the grant of a patent. In so far as pharmaceutical patents are concerned, this provision—which prior to the 2005 amendment applied only to the grant of compulsory licences in respect of patented processes—has effectively been extended to apply to the grant of compulsory licences in respect of patented products. TRIPs imposes no such time restriction on the use of compulsory licensing.

[106] See Canada's 'Bill C-9: An Act to amend the Patent Act and the Food and Drugs Act', available online at *www.parl.gc.ca/37/3/parlbus/chambus/house/bills/government/C-9/C-9_4/C-9_cover-E.html*. In the case of Norway, see 'Regulations amending the Patent Regulations (in accordance with the decision of the WTO General Council of 30 August 2003, Paragraphs 1(b) and 2(a))',

The question is: why have those countries that fought so hard to ensure their right to take appropriate steps to protect public health either failed to act or taken retrogressive steps?

Almost three years later, South Africa (for instance) has failed to take any steps towards implementing the Doha agreement. A government-use provision in the Patents Act allows 'a Minister of State . . . [to] use an invention for public purposes'.[107] Civil society groups have repeatedly asked the government to invoke this power, which is TRIPs-compliant. Yet the South African government has failed to issue—or even threaten to issue—compulsory licences for the importation or local production of affordable generic ARV medicines. The executive has not given a public explanation of why.

Instead, the state has watched advocacy work in this direction being done by independent organisations such as the TAC and the AIDS Law Project (ALP).[108] They and their allies have employed creative strategies to make best use of a statutory framework that, from the point of view of private actors, is at best inadequate.[109]

After much public contestation, and many life-costly delays, the South African government eventually on 19 November 2003 adopted an *Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa*.[110] This includes free provision of ARV treatment through the public health system. Even here, however, the government seems to have undermined its own legal framework in so far as access to affordable medicines is concerned. Instead of harnessing the

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available online at *http://odin.dep.no/ud/engelsk/p2500832/p30003923/032121-990069/dok-bu.html*. Most recently, India became the first developing country (importantly one with significant local manufacturing capacity), to adopt a compulsory licensing mechanism to allow for the local production of generic medicines solely for export to countries with limited or no domestic manufacturing capacity (see section 92A of the Patents Act, 1970 (as amended)). The European Union has begun taking steps towards the implementation of the 30 Aug. decision. See Commission of the European Communities, 'Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems', available online at *www.europa.eu.int/comm/internal_market/en/indprop/patent/draft_medicines_en.pdf*.

[107] Section 4 of the Patents Act, see above, n. 51.

[108] See *www.alp.org.za*.

[109] The ALP acted as the legal representative of the TAC and the other complainants in *Hazel Tau and Others v GlaxoSmithKline SA (Pty) Ltd and Others*, see above, n. 1, and on behalf of the Generic Anti-retroviral Procurement Project and the TAC Treatment Project in their successful attempts to secure voluntary licences to import generic nevirapine products (see above, n. 53).

[110] The plan is available online at *www.info.gov.za/issues/hiv/careplan19nov03.htm*.

expertise that civil society can provide, the state disclaimed knowledge of the regulatory framework that would make implementation easier.

Not only is the Operational Plan vague on the steps that are to be taken to ensure access to a sustainable supply of affordable ARVs, but it misconceives and misstates the nature and extent of many of the available regulatory options.[111]

The legislature has a better record, although also insufficient and somewhat contradictory. The only move by Parliament to amend patent legislation to increase access to medicines has been to enact the so-called 'Bolar amendment',[112] which permits generic manufacturers to take all necessary steps to secure marketing approval from the relevant drug regulatory authority before the patent expires.[113] But the very same amendments eased the requirements regarding disclosure when an applicant seeks a patent. The effect was to ensure that knowledge remains not only protected but also secret.[114]

Given the inability or unwillingness of government to use its statutory powers, and the inhibiting effect of existing case law on third-party applications for compulsory licences, Parliament's failure to amend certain key provisions of the Patents Act seems both unfathomable and inexcusable.

[111] See 'Chapter VII: Drug Procurement', ibid., 143–54.

[112] The so-called 'Bolar amendment' gets its name—in part—from the US Court of Appeals for the Federal Circuit case of *Roche Products, Inc. v Bolar Pharmaceutical Co*., 733 F.2d 858. This case held that testing for the purpose of drug regulatory authority approval could not take place before the patent had expired. As a result of the case, lawmakers in the United States amended patent legislation in 1984 so that it would permit generic companies to complete all drug registration requirements for their products without infringing existing patents.

[113] Section 69A of the Patents Act. Marketing approval does not necessarily mean market access. If a company sells generic medicines before patent expiry or without a voluntary or compulsory licence, the patent holder may still sue for patent infringement.

[114] Prior to the amendments, a complete patent specification had to deal with a number of issues. One of these requirements was 'fully [to] describe, ascertain and, where necessary, illustrate or exemplify the invention and the manner in which it is to be performed' (section 32(3)(b) of the Patents Act), with another being to 'disclose the best method of performing the invention known to the applicant at the time when the specification is lodged' (see sections 32(3)(b) and (c) of the Patents Act prior to their amendment by the Patents Amendment Act, 58 of 2002). These requirements went to the very heart of patent protection, which grants market exclusivity in part in exchange for a full disclosure of relevant information. The second of these requirements has now been dropped, with the first being significantly amended so that now all that is required is that the patent specification should 'sufficiently describe, ascertain and, where necessary, illustrate or exemplify the invention and the manner in which it is to be performed in order to enable the invention to be performed by a person skilled in the art of such invention' (section 1 of the Patents Amendment Act, 58 of 2002). In effect, the public is now getting even less in exchange for the state's protection. While such information may be available offshore in jurisdictions with better disclosure requirements for the corresponding patents, the amendment nevertheless raises the costs of search for material that should be in the public domain.

Not only has it failed to legislate: it has not even placed the issue on its agenda for debate.

VIII. Understanding the inaction

South Africa's ambivalent and hesitant response to essential medicines access almost certainly derives in part from the fact that the struggle against patent abuse has become linked to the question of public provision of ARV medicines. President Mbeki has publicly questioned of the aetiology of AIDS and the science of ARV treatment.

According to the dogma of AIDS denialism (which we distinguish from ordinary 'denial', a common feature of responses to AIDS), ARV drugs are poisons that cause, and do not treat, the symptoms of AIDS.[115] The intrusion of this pseudo-scientific dogma has tragically skewed national debate about the epidemic, particularly what part ARVs should play in the national response to AIDS. So the question of broader access to medicines could almost not be effectively managed without a resolution of the ARV treatment debate. Many hoped that the adoption of the Operational Plan signified a decisive end to the ideology of HIV denialism as an inhibiting factor in debate about access to medicines. More than a year later, these hopes have not been realised.[116]

Although because of the AIDS denialist debate South Africa is a special case, most of the developing world has likewise failed to take simple legislative and executive steps that would probably make a significant difference in essential medicines supply. In this, states are ignoring their international human rights commitments,[117] such as Revised Guideline 6 of the International Guidelines on HIV/AIDS and Human Rights. In part, it provides as follows:

[115] See E. Cameron 'AIDS Denial and Holocaust Denial—AIDS, Justice and the Courts in South Africa', *South African Law Journal*, 120 (2003), 525–39.

[116] For continuing apparently denialist tendencies, see for example, 'Health: Nevirapine, drugs & African guinea pigs', ANC Today: Online Voice of the African National Congress (Volume 4, No. 50: 17–23 Dec. 2004), available online at *www.anc.org.za/ancdocs/anctoday/2004/at50.htm*.

[117] See, for example, Article 27(1) of the Universal Declaration of Human Rights, which states that '[e]veryone has the right freely to . . . share in scientific advancement and its benefits'; and Articles 12 and 15(1)(b) of the International Covenant on Economic, Social and Cultural Rights, which state that everyone has the right 'to the enjoyment of the highest attainable standard of physical and mental health' and to 'enjoy the benefits of scientific progress and its applications' respectively.

> States should enact legislation to provide for the regulation of HIV-related goods . . . so as to ensure . . . safe and effective medication at an affordable price . . . [and] should also take measures necessary to ensure for all persons, on a sustained and equal basis, the availability and accessibility of . . . safe and effective medicines.[118]

In many cases they are also disregarding powerful domestic constitutional obligations regarding the right of access to health care services:[119] this in the face of manifest threats to public health and economic development.

Is it simply neglect? Or an unwillingness to engage with civil society? Or is there perhaps another reason? What could possibly explain this tragic inaction?

The Bush administration has without question sought to limit the practical impact on patent protection of the Doha consensus. It has pushed for bilateral and regional free-trade agreements (FTAs) that in exchange for access to US markets extract promises of regulatory frameworks that exceed TRIPs.[120] For example, former US Trade Representative Robert Zoellick made it clear that TRIPs is seen as a floor: the administration openly plans to use the FTA negotiations with the Southern African Customs Union (SACU) to 'address barriers . . . to U.S. exports—including . . . inadequate protection of intellectual property rights'.[121]

This approach seeks to undermine multilateralism when it proves inconvenient to US corporate interests. And it is not confined to the international trade arena. But in this context it is particularly worrying. The active role the US played—and continues to play—in seeking the international harmonisation of enforceable IP rules makes it so. The same interests that led to the adoption of TRIPs now drive the FTA agenda, even though the context has shifted dramatically and the world has changed fundamentally since TRIPs.

Countries like Chile, Israel, Jordan, Morocco and Singapore have already, in response to pressure from the United States, signed TRIPs-

[118] Revised Guideline 6 is available online at w*ww.unaids.org/en/in+focus/hiv_aids_human_rights/international_guidelines.asp#guideline_6*.

[119] See, for example, section 27 of the Constitution of the Republic of South Africa, 1996.

[120] This is troubling, particularly given that developing countries were already promised access to such markets upon signing up to agreements such as TRIPs. In theory, therefore, there should be no need for TRIPs-plus agreements to give greater access.

[121] See Zoellick's letters to Congress on 4 Nov. 2002, available online at *www.ustr.gov/Trade_Agreements/Bilateral/Southern_Africa_FTA/Section_Index.html*.

plus FTAs.[122] Others such as Bangladesh, Nepal and Yemen have committed themselves to cooperation agreements with the European Union with similar restrictions. Two of the world's poorest nations, Laos and Cambodia, have done both.[123] That such standards of patent protection should be exacted from such desperately poor countries—where innovation and commercial exploitation can hardly serve as rationales—is an indication of how irrationally far the demand for uniformity is pressed.

Nevertheless, attempts to exact more from developing countries than TRIPs requires do not always prosper. Political leadership and organisational mobilisation in countries such as Canada and Brazil have shown that pressure can be resisted. Even though it is a member of NAFTA and has close geographic and historical ties with the US, Canada was able to implement the 30 August decision. Brazil, on the other hand, has had some measure of success in dealing with the 'TRIPs-plus agenda' in the negotiations for an FTA of the Americas (the proposed FTAA).[124] And even though the negotiations about a US/Southern African Customs Union (SACU) FTA have apparently stalled because of a range of issues including IP,[125] the benefits African countries already have under the Africa Growth and Opportunity Act (AGOA) have been extended.[126]

South Africa, as the major power within SACU, has little reason to push through with a disadvantageous FTA when it already has significant access to US markets.

A country like South Africa provides a potentially illuminating case study of resource-poor nations. Why does it not act, when significant access to essential medicines is still lacking? Has the government convinced itself that the adoption and implementation of the Medicines Act and its two sets of regulations[127] are sufficient—even though treatment

[122] For more information, see Office of the United States Trade Representative, 'Trade Agreements', available online at *www.ustr.gov/Trade_Agreements/Section_Index.html*. There are also framework agreements with most Arab states as a prelude to full FTAs. See, for example, *http://mumbai.usconsulate.gov/wwwhwto46.html*.

[123] Correa, pp. 211–12, see above, n. 76.

[124] See Alexandre Zourabishvili, 'Brazil's position in the Free Trade Agreement of the Americas Negotiation Process', South African Institute of International Affairs Trade Policy Briefing (No. 5 Feb. 2004), available online at *http://saiia.org.za/images/upload/tpb5.pdf*.

[125] See Lukanyo Mnyanda, 'US-SACU trade talks grind to a halt', Business Day (22 Sept. 2004), available online at *www.bilaterals.org/article.php3?id_article=799*.

[126] See HR 4103 AGOA Acceleration Act of 2004, available online at *www.agoa.gov/agoa_legislation/AGOAIII_text.pdf*.

[127] On 20 Dec. 2004, the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances (*Government Gazette*, No. 26304 of 30 April 2004) were 'declared

activists point to manifest evidence that this framework has not dealt effectively with barriers created by pharmaceutical manufacturers?[128] Or does the answer lie in the conclusion of some Faustian bargain?

We can think of three possible answers that may shed light on the South African problem: they may indeed operate in tandem.

First, government may have convinced itself that the appropriate balance has already been struck, considering that the current system can and already has been used effectively. Such an approach could find warrant in the fact that in two separate but related matters, civil society organisations made effective use of existing patent and competition law to pressure two multinational pharmaceutical companies to grant licences to a specified number of generic competitors.

Properly considered, however, the evidence continues to suggest that the regulatory framework is inadequate. The manner in which access to certain generic ARVs has been assured is decidedly unsustainable in the long term. The victories mentioned above required lengthy and expensive legal battles and advocacy campaigns. These are no substitute for a comprehensive, access-friendly regulatory framework that encourages generic manufacturers to act on their own.

If the belief in the adequacy of the regulatory framework is the cause of the inaction, then further research, targeted advocacy and persuasive reason may yet advance access.

Second, government may believe that 'weakening' patent protection could have too high a cost. In short, tinkering with an already well-developed legal framework may send out a negative message to potential investors that South Africa does not respect private property. In other words, anxiety about ensuring market conditions that are propitious for foreign direct investment (FDI) may explain the inaction. This consideration, if true, could be seen as the inauspicious product of the 'property rights' discourse that has surrounded the debate about patents. Tinker

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invalid and of no force and effect': *Pharmaceutical Society of South Africa v Minister of Health* [2005] 1 All SA 326 (SCA) para 96. The Constitutional Court heard the application for leave to appeal against this decision on 15 and 16 March 2005. At the time of writing, judgment had yet to be delivered.

[128] See Jonathan Berger, 'What about Big Pharma', *Mail & Guardian* (28 Jan. 2005), 29. See also Jonathan Berger, 'Joint Submission on the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances Made in Terms of Section 22G of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)', (5 March 2004), available online at *www.tac.org.za/Documents/Other/pricingregs_submission.doc*. Most of the concerns relating to the draft regulations' relatively 'soft' approach to the manufacturing industry were not addressed in the final pricing regulations, which were subsequently set aside by the SCA on 20 Dec. 2004.

with any aspect of patents, the pro-patent argument seems to imply, and next you will be violating the fundamentals of all private property.[129]

The truth is that anxiety about FDI could quite adequately be accommodated by drafting amendments to patent law that deal narrowly with products necessary for public health. Other inventions would remain protected by TRIPs-plus provisions.

Third, government may have endorsed and adopted the contentions of the pharmaceutical industry. This, if true, would be the most difficult to address. But it may be the most rational explanation for inaction, and may explain other related policy developments. In a media release following the withdrawal of its legal challenge to various aspects of the 1997 Act, for example, the PMA spoke of a 'negotiated settlement' in which the South African government had committed itself 'to adhere to its international obligations including . . . TRIPs . . . [and] to include the industry in the drafting and finalisation of regulations that will give effect to the law'.[130]

In her media release, South Africa's Minister of Health said that government proposed 'to set up a joint working group with the pharmaceutical industry in order to consult on and consider broad issues in the area of health care' and 'that there should be a mechanism for regular interaction'.[131] She too spoke of 'settlement'. The final pricing regulations issued in terms of the 1997 Act took drastic action at certain levels of the supply chain but left drug manufacturers relatively unscathed.[132] This may reflect the nature of the 'settlement' in Pretoria in 2001.

In many complex respects, South Africa is clearly quite different from the rest of the African continent. What then accounts for inaction in other countries in Africa? Does the push for TRIPs-plus FTAs offer the explanation? The answer probably lies elsewhere.

Because of limited domestic capacity, many developing countries rely on WIPO 'for expert advice and commentary on new draft legislation'. The result has been that WIPO has played 'a prominent role in providing technical assistance'. But in so doing, it has 'emphasized the benefits and

[129] In practice, only the US holds this view, and then only for patents. Both copyright and trademark rights are substantially qualified in the US. Even in respect of patents, US courts can refuse injunctions on public interest grounds. In this regard, see Vaver (above, n. 56), 180.

[130] See PMA, 'Media Release: Industry Welcomes Settlement of SA Court Case and Partnership with Government', in e-drug, 'DOH and UNAIDS Media release' (above, n. 95).

[131] Dr Manto Tshabalala-Msimang, 'Drug companies withdraw case against SA Government', in e-drug, 'DOH and UNAIDS Media release', see above, n. 95.

[132] See above, n. 128.

largely ignored the costs of IP . . . protection, and has generally failed to present the range of options that developing countries may have to pursue their own interests, including the flexibilities allowed by the TRIPs Agreement.'[133]

Furthermore, the promotion of IP no longer relies entirely on coercion or external 'technical support'. In an apparent attempt to comply with TRIPs, the sixteen francophone African countries (including eight least developed countries) that make up the African Intellectual Property Organization (OAPI) in 1999 concluded a revision of the 1977 Bangui Agreement under which they 'declined their right to use the flexibilities that the TRIPs Agreement recognizes in relation, for instance, to parallel imports, compulsory licences . . . and the protection of data submitted for the registration of pharmaceutical . . . products'.[134] The 1999 agreement has yet to be revised in the light of recent developments. Ironically, it came into effect only on 28 February 2002, three months after the adoption of the Doha Declaration.[135] Francophone African countries seemed to be volunteering to give up their rights in favour of unnecessary (and, we contend, unjustifiable) levels of IP protection.

Again, some African governments may be anxious at all costs to avoid the wrath of the developed world and its patent-protected industries. In Mozambique, for example, a compulsory licence was recently issued to a generic manufacturer in respect of a three-in-one ARV drug.[136] Yet drugs cannot yet be patented in Mozambique at all. Why then issue a compulsory licence? It seems absurd. One commentator has described the licence as 'defensive in nature, providing that if any patents exist on the AIDS product in Mozambique', they can be used by the licensee subject to a royalty payment.[137] The tale seems to show that developing countries will go to superabundant lengths to protect patent rights even when they do not exist within their jurisdiction.

[133] Correa, p. 214, see above, n. 76. WIPO has recently come under pressure from a developing country initiative (spearheaded by Brazil) to adopt a 'Development Agenda'. This has come up against the vehement opposition of the USTR. See, for example, *www.wipo.int/documents/en/document/govbody/wo_gb_ga/pdf/wo_ga_31_11.pdf*.

[134] Ibid. at 212.

[135] Rosine Jourdain, 'Intellectual Property Rights and Public Health in the Revised Bangui Agreement, in Christophe Bellmann *et al*. (eds.). *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (London and Sterling, VA, 2003), p. 144.

[136] See 'Compulsory Licence no. 01/MIC/04', a translated version of which is available online at *http://www.cptech.org/ip/health/c/mozambique/moz-cl-en.pdf*. See also 'WTO and medicines: from Doha to Cancún' (above, n. 103).

[137] See e-drug, 'Mozambique issues a compulsory license for ARVs', available online at *http://www.essentialdrugs.org/edrug/archive/200405/msg00031.php*.

IX. Conclusion

The notion of a patent is essentially legal. It is a concept originated and developed by lawyers. While it has been shown to have utility, it is an idea that has in some significant ways been allowed to run rampant and become uncontained. It is an example of a conception that has demanded fidelity to itself in ways that have not always found justification in the originating concept.

Our concern is the moral crisis of AIDS that involves lives in peril. The uncontained development and application of the patent idea has contributed significantly to that peril. It has done so in a number of related ways.

First, the idea has become self-justifying, self-reinforcing and self-validating, with the damaging result that its disciples have sought its dissemination on an undifferentiated basis that takes no account of the contingent circumstances that are necessary for its justification. Proponents of patents have sought to enforce them throughout the world in circumstances where this has been quite inappropriate.

Second, the idea has been internalised to the extent that those who wish to join the global community and are committed to adopting 'acceptable' trade and economic policies see the patent system as an intrinsic part of globalisation and a prerequisite for the attraction of FDI. The patent idea has thus been internalised in a way that has inhibited the productive exploitation of knowledge.

Third, the threat of patent protection is so pervasive and minatory that some developing world governments are inhibited by the spectre even when patents do not exist. We have mentioned Mozambique. There are certainly other instances.

Fourth, actual patent protection and enforcement has until relatively recently made it impossible for people in countries such as South Africa to gain access to affordable ARV treatment. A significant degree of access has been achieved only through sustained mobilisation, advocacy and legal activism.

Our argument has rested on a series of paradoxes. Without patents or a comparable system of rewards and/or incentives, the drugs that can save six million lives in the developing world would probably not exist. Yet the system that made possible their creation helps ensure that the drugs remain inaccessible to those who need them most desperately.

The rights to exclusivity that lie at the heart of patent enforcement were developed in conditions of affluence that ill suit the conditions of

most of the world's people: in particular, those nations most severely affected by the world-wide AIDS pandemic. Yet despite significant progress in asserting the entitlement of poor nations to exploit knowledge productively to counter the ill effects of AIDS, those nations themselves have done relatively little to expand access.

Some, at least, of this inaction must be ascribed not to the formal constraints of international patent enforcement—for after courageous activist interventions they have been significantly relaxed—but to the constraining power of those with most to gain from continuingly rigid enforcement of that system.

True appreciation of the value of the patent idea demands resistance to this trend. In some cases, this could entail the comprehensive adoption and active use of the public health safeguards identified at Doha. In others, it could entail a departure from certain forms of IP protection in respect of certain innovations, such as product patents for pharmaceuticals. But in many—if not most—developing country scenarios, this might require much more, quite possibly including the adoption of new methods to encourage innovation and commercialisation.

One possibility is to replace market exclusivity with a royalty-based system in which any company that produces safe and effective generic medicines can sell its product and pay a percentage of the sale price to the patent holder. What constitutes a reasonable royalty would have to be determined to ensure a careful balancing of incentives to innovate versus increasing access. This would mean particularly low—or no—royalties in respect of products produced for developing countries.

To encourage the development of new medicines for neglected diseases, a one or two per cent tax could be introduced on all medicine sales worldwide. A multilateral institution could administer the proceeds of this global tax, distributing funds to research groups developing such medicines.

David Vaver has suggested that the future challenge for IP may be 'to make itself more coherent and persuasive, not only domestically but also internationally': 'To achieve that goal may mean a movement away from the present insistence on rigid standardised norms towards greater toleration of diversity and flexibility'.[138]

This plea may well contain the key to disinhibiting those resource-poor countries that have feared the power of governments and corporations in exercising their entitlements to balance the rights of IP holders

[138] Vaver, 188, see above, n. 56.

with those of the sick and dying. It might also restore some faith in patents by ensuring that they are used appropriately.

The imperative needs of six million dying people requires creativity and determination, in exploiting the productive capacities that patent enforcement can unleash, and in adjusting the system to nurture creativity without withholding access to its benefits.

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