

1. Introduction

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The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

– Constitution of the World Health Organization (WHO, 1946, Preamble)

[T]heir relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living.

– Marrakesh Agreement Establishing the WTO (WTO, 1994, Preamble)

1. JUSTICE, GOVERNANCE AND ACCESS TO ESSENTIAL MEDICINES

The global AIDS pandemic remains the greatest health challenge of the twenty-first century. The cost of HIV/AIDS is immense, above all in terms of human suffering, but also through its impact on broader human welfare and development in the Global South. Our response to the pandemic is first and foremost a matter of justice. The chances of being affected by HIV/AIDS are crucially determined by established inequalities of class, 'race', gender, geographical location and national origin. The prospects of those already affected by HIV/AIDS are similarly determined. These inequalities are man-made and man-sustained. They benefit some; they harm others. In so far as we fail to meet the challenge presented by the pandemic, we collude in and perpetuate this structural violence; we turn our backs on the insistent and pre-eminent claims of global justice.¹

The injustices of AIDS have called forth practical responses across the range of human activity: in the natural sciences, clinical medicine, public health, education, public administration and law. The availability of essential drugs has been a central focus for these responses. With the development of effective antiretrovirals (ARVs) in the mid-1990s, public health campaigns aimed at prevention were augmented by a drive to

secure access to therapy. This has been largely successful in developed countries thanks to the internal redistribution of health resources through insurance and various forms of socialized medicine. Local injustice is tempered to varying degrees in Europe and North America. That has not been the case in developing countries. For one thing, internal inequalities are much wider, with access to health care depending to a far greater extent on the private resources of the individual. For another, the poorer nations are bound into a global political economy shaped by colonial domination and resource extraction and now structured by trading relations of inequality and dependency. The development, production, distribution and purchase of ARVs are crucially influenced by these broader structures. High prices ration access to life-saving drugs, and these prices are a function of the international intellectual property (IP) regime. The entitlements of patent holders – enabling them to extract monopoly rents – set the baseline for legal, political and economic interventions to extend access.

The patent system, as part of the world trade system, favours the rich over the poor, the centre over the periphery, developed over developing nations. As Thomas Pogge has shown, the contemporary political economy of drug access, including its legal underpinnings, demands *both* a profound justice-based critique *and* hard-headed strategies for overcoming man-made scarcity in meeting health needs.² The chapters in this book take up the challenge of global injustice in the context of HIV/AIDS by investigating critically the different legal, political and economic determinants of drug access. As such, this collection contributes to our understanding of the emerging field of global health governance.³ All chapters go beyond the merely descriptive, however. All are concerned with the practical question of how elements of the governance regime can be adapted, reformed or removed in order to increase the availability of affordable ARVs.

At the heart of the different arguments in this book lies the central tension between IP and access to essential medicines. Legal scholars, policymakers, and civil society activists have been occupied with unravelling the strands of this difficult legal and political problem since the end of the Uruguay Round of Multilateral Trade Negotiations in 1994. The most remarkable feature of the Uruguay Round was the transformation of the international trading system from the flexible framework of the General Agreement on Tariffs and Trade (GATT) to the ‘rule-based’ international trade architecture that is now built on the pillars of the World Trade Organization (WTO) – a multilateral organization that is equipped with powers to enforce trade norms and agreements (Jackson, 1997; Malhotra, 2003; Matsushita, Schoenbaum and Mavroidis, 2006;

Trebilcock and Howse, 2005). The implementation of the 1994 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) raises critical questions for the right to health and the availability of ARVs. The TRIPs Agreement obliges WTO member states to establish minimum patent protection for drugs, whether produced locally or by multinational pharmaceutical corporations.⁴

TRIPs provides the decisive legal underpinning for the governance of access to essential medicines. It calls into being a worldwide network of patent granting and enforcing institutions, from national courts, legislatures and patent offices to the dispute settlement mechanisms and negotiating fora of the WTO itself.⁵ The network extends beyond official state governance to include private pharmaceutical manufacturers, university research laboratories and philanthropic bodies (Santoro and Gorrie, 2005; Zacher and Keefe, 2008). The globalized patent regime mandated by TRIPs does not simply result in a cascade of legal norms from international to regional, national and local levels. It also sets the horizon for private and public investment in scientific research and drug production. An adequate practical response to global injustice in the context of HIV/AIDS will have to be sensitive to the multiple dimensions of the access problem and to the specific ways in which they are manifested at different points in the governance network.

Struggles over the relative weight to be given to IP rights and the protection of health have played out most prominently at the WTO (Joseph, 2003; Thomas, 2002). The tension between trade and health is reflected in the terms of TRIPs itself. The Agreement provides for certain flexibilities, allowing the patent regime to be suspended or derogated from in cases of emergency. In the years after 1995, activists and developing countries became aware of the dangers to public health of granting maximal IP rights over pharmaceuticals (Drahos and Braithwaite, 2002; Sell, 2004). This awareness was focussed by the spreading catastrophe of HIV/AIDS in the poorest regions of the world. Pressure from developing countries and civil society organizations from North and South forced the WTO to clarify and confirm TRIPs flexibilities in relation to essential medicines ('t Hoen, 2002; Orbinski, 2002). Thus, the Doha Declaration on the TRIPs Agreement and Public Health of November 2001 stated that developing countries could override patents in the interest of public health by issuing compulsory licenses for the import or production of affordable generic drugs (Abbott, 2002; Charnovitz, 2002; Gathii, 2002). The Declaration failed to address the vital question of exports to needy countries that lacked facilities for pharmaceutical production. Was India, for example, permitted to allow its drug manufacturers to sell generic versions of on-patent medicines in

African states affected by the pandemic? This issue was addressed by the 2003 Decision of the General Council on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (General Council Decision). The Decision provided that such sales would not amount to a violation of TRIPs. However, it set conditions of extreme complexity for the lawfulness of exports. Commentators agree that the gains for access embodied in Doha have been recouped by the General Council Decision (Abbott, 2005; Correa, 2004).

As has been mentioned, legal provisions interact with the commercial calculations of drug producers in determining the availability of affordable medicines. From this perspective it is important to note that the dynamic pharmaceutical industries of India, Brazil and South Africa are increasingly shifting their focus to research-led production. The consequent imperative on these states to reform their IP laws to comply with TRIPs means that the supply of generic drugs in both these countries and other less developed countries is seriously at risk. In addition, the leading industrialized countries are continuously seeking, and have increasingly achieved, TRIPs-plus protection for major multinational companies through bilateral and regional free trade agreements (FTAs) or economic partnership agreements (EPAs) (Blouin, Heymann and Drager, 2007; Malhotra, 2003). These developments in the global economic arena present complex challenges for global health governance, especially for the right to health as codified in a number of international human rights treaties.

The chapters in this book are grouped under three main themes. The first concerns the governance contexts which frame access to essential medicines – the legal and political landscape of neo-liberal globalization, the structure of the global pharmaceutical industry and the multiple stratification of patient groups. The second set of chapters focuses on the specifically legal aspects of the access problem, attending to both the impact of human rights norms and the evolving content of IP law rules. The essays in the third group all propose concrete strategies for improving the availability of ARVs. These range from the creative use of patent licensing contracts to the alignment of market incentives with real health needs to the creation of South-South alliances in international trade diplomacy.

2. GOVERNANCE CONTEXTS

In his chapter, Obijiofor Aginam highlights key features of global health governance and explores the shortcomings of this framework in the

context of HIV/AIDS. Relying on Paul Farmer's postulation that international policy initiatives and governance responses to the global AIDS crisis have so far been a failure, the author posits his discourse on two levels of inquiry. The first level focuses on the tensions between human rights and IP rights. The second level focuses on the opportunities and impediments for South-South cooperation to increase access to ARVs in developing countries. The promise of these two levels, according to Aginam, is limited by the normative parameters of contemporary global governance. Scholars have long contended that whenever there is a need to rank IP rights and human rights, the latter should be given more weight. Aginam argues that although this position remains popular in the academy and in the activist domain of global civil society, it is yet to be fully tested pragmatically in IP-driven disputes at the WTO. On the opportunities for, and impediments to, post-TRIPs South-South cooperation, this chapter considers the limits of TRIPs flexibilities, especially the General Council Decision. Based on the difficulties encountered by Canada's Access to Medicines Regime (CAMR), the author proposes South-South cooperation to increase access to drugs in the less developed South. One example of such cooperation is the 2007 joint venture agreement between the Government of Uganda and Cipla, an Indian generic drug manufacturer, to produce cheaper generic ARVs in a local facility in Uganda.

Most political and ethical claims for increased access to ARVs assume a ready supply of generic medicines. All that is required are sufficient resources to purchase them. Kenneth Shadlen's chapter questions this assumption in the light of the changing patient needs and developments in the structure of global pharmaceutical production. Increasing drug resistance means that the precise composition of ARV treatment must be continually renewed. Expensive, on-patent drugs will have to be substituted for cheap, off-patent equivalents. However, there is a decreasing likelihood that supplies of new generics will become available to bring down the price of the necessary new therapies. Why? Over half of generic ARVs are currently produced in India. The prospects for adequate supply are therefore crucially influenced by the legal and business landscape in that country. In particular, the implementation of a TRIPs-compliant patent regime has pushed the Indian pharmaceutical industry away from cheap generics and towards more costly drugs for sale in the developed countries. If India, then, is no longer the 'pharmacy of the developing world', how can affordable ARVs be made available? Shadlen considers a number of different responses to this problem, from reforming TRIPs, or increasing production capacity in the poorest countries, to a programme of expanded ARV access in India itself with spill-over

benefits for developing countries. All are, however, subject to political, legal and economic obstacles.

Avram Denburg and Kelley Lee analyse a significant specific gap in global health governance/policy literature – access to paediatric medicines in the global political economy of drug production and supply. Focusing on paediatric HIV/AIDS and ARVs, Denburg and Lee argue that ‘while the challenges facing paediatric medicines are global, this neglect is felt more acutely in developing countries’. Children, they argue, face unique barriers to access to essential medicines due to factors such as price discrepancies vis-à-vis adult medicines, missing appropriate dosages and formulations, or a lack of data from pharmacokinetic studies for research and development (R&D). Additionally, as developed countries move towards universal patent protection under TRIPs, increased product segmentation within the generic market is limiting the financial viability of the production of ARVs for children in most developing countries. These developments have been exacerbated through the neglect of paediatric drugs by global health institutions. Only a few years ago, emerging policies such as the 2007 World Health Assembly’s Resolution 60.20 entitled ‘Better Medicines for Children’ and the subsequent WHO campaign to ‘Make Medicines Child Size’ in 2008 have been developed, due, in part, to civil society influence. As to the way forward, Denburg and Lee highlight future challenges and propose sustainable strategies for increasing access to paediatric medicines. These strategies include improving the financing and development of generic fixed dose combinations for children through South-South cooperation, public-private partnerships, and legal/regulatory reforms, especially those related to TRIPs, that create incentives for voluntary licensing. According to the authors, ‘efforts to address these challenges will require a coordinated response from multiple echelons of governance, in concert with industry and civil society, if they are to effect lasting change’.

3. LEGAL DEVELOPMENTS

Concern with global justice in access to ARVs is commonly articulated in the language of human rights (e.g., Hunt and Leader, 2010; O’Connell, 2010). However, as James Harrison argues, the full potential of human rights is not realized where they are used solely as a tool of political mobilization. Developments in international human rights law, particularly in the field of social and economic rights, mean that they can have a significant additional effect as legal norms. General Comments produced by the UN treaty-monitoring bodies have given precision and force

to state obligations to protect and promote the right of all to the highest attainable standard of health. More than this, detailed authoritative guidance is now available concerning the relationship between the human right to health and the interests protected by IP. The objective of patents, to stimulate scientific progress by endowing inventors with limited monopoly rights, needs to be aligned with other important social concerns, such as public health. The strategic gain from taking the legal nature of human rights seriously is evident in the crucial context of international trade law. The legal instruments of the WTO, exemplified in the General Council Decision and in TRIPs itself, as well as the implementing provisions of national law, are highly technical and detailed. If the right to health is to do the work of justice on the terrain of law it will have to partake of the same form. Of course, the scope and meaning of the right to health depends on what is understood by 'health'. The norm has to be 'thickened out', with public health standards defining the content of the obligation and providing evidence of its violation. In this regard, Harrison argues that human right to health impact assessments (HRIAs) have a crucial role to play in evaluating the effect of IP law on access to ARVs. He accepts that the rallying potential of human rights must not be neglected – the access question can never be finally depoliticized. But the struggle for essential drugs is waged in many fora, each with different terms of engagement.

Legal engagement for access to medicines is not limited to human rights. As Tahir Amin argues, the terms of patent law are subject to interpretation and application in a more or less pro-patient fashion. He presents a comparative evaluation of how a select group of developing countries have timed and implemented patent protection under TRIPs to safeguard access to essential ARVs. Under the Agreement, developing countries had 10 years to create pharmaceutical product patent regimes, but not all countries have used the flexibilities provided by TRIPs during this period. Some complied with TRIPs sooner than was legally required, while others went further by agreeing to TRIPs-plus provisions in FTAs which were even more restrictive of access to essential medicines. Amin focuses specifically on three well-defined elements of national patent laws. Countries such as India and the Philippines define the 'scope of patentability' narrowly – small or merely incremental changes to a pharmaceutical product will not justify an extension of the patent and, thus, the continued exclusion of lower-priced generics from the market. In addition to this, India and Brazil have facilitated opposition and observation procedures whereby public health bodies and civil society groups are afforded procedural rights to challenge dubious applications, either before or after they are granted. According to Amin, these are

significant steps toward democratizing the patent system. Finally, he considers the extent to which authorities have resorted to compulsory licensing and government-use provisions in order to increase supply and reduce prices. In the latter context, he too emphasizes the importance of public health science as a guide to when there is in fact a 'health emergency' such as would justify governments overriding the interests of drug patent holders.

The availability of ARVs is affected not only by the changing IP regime in producer countries of the South, but also by the posture of authorities in the North. In this regard, Frederick Abbott examines a number of recent cases where Dutch customs authorities have seized generic drugs in transit through Amsterdam's Schiphol Airport. Medicines lawfully produced in India and destined for lawful sale in Brazil or Nigeria simply happened to be passing through the Netherlands owing to the established pattern of global transportation routes. This allowed multinational patent holders to disrupt the vital trade at its 'weakest link'. As Abbott shows, the actions of the Dutch authorities, subsequently endorsed by local courts, run counter to the fundamental principle of the territorial nature of patents laid down in TRIPs and in the Paris Convention for the Protection of Industrial Property. These legal moves facilitate the business strategy of patent holders seeking to snuff out competition from generic producers by eliminating their foreign markets. The political consequences are stark. Abbott argues that the current world trade regime was crafted precisely to take account of the dependence of developing countries on India as a source of generic drugs. The 'long-arming' of European jurisdiction in the Dutch cases is a frontal assault on this compromise, one which risks undermining the legitimacy of the global patent regime as a whole.

4. STRATEGIES FOR IMPROVING ACCESS

Political strategies to overcome or modify TRIPs will play an important role in guaranteeing access to ARVs. However, incremental legal reform and the provision of economic incentives for drug production may be more effective in the medium term. In this spirit, Gail Evans analyses the content and scope of restriction clauses in patent licensing contracts to assist in building research capacity in developing countries and in ensuring wide availability of essential medicines. Evans reviews models of technology transfer from academia to private business in developing and least developed countries, the impact of restructuring the global pharmaceutical industry, and the entry of new manufacturing companies

from emerging economies like India and China on public-private partnerships with research institutions. At first glance the growing commodification of academic knowledge seems to run counter to the core scholarly and humanitarian values of universities. However, it is through their very position as patent holders – i.e., through the exercise of property rights – that universities can control the development and distribution of those pharmaceutical products which their basic research has made possible. Evans carefully details the different types of license which could be used by patent holders, setting them in their broader legal context, particularly having regard to the limits set by competition law. She concludes that contract doctrine is sufficiently flexible to carve out a space for the development of much-needed health products.

Laura Biron discusses the proposal made by Aidan Hollis and Thomas Pogge in 2008 for the establishment of a Health Impact Fund (HIF), which aims at supplementing the IP system to ensure widespread access to essential medicines. She notes that a patent confers a time-limited monopoly on inventors, allowing them to recoup the huge costs of drug development. However, as has been seen throughout this collection, patents price many potential buyers out of the market for drugs. These buyers could pay somewhat more than the cost of production, but not the amount of the monopoly rent extracted by the patent holder. The HIF aims to address this market failure by rewarding pharmaceutical innovators directly on the basis of the health impact of their products. The greater the number of Quality Adjusted Life Years (QALYs) a registered drug produces, the larger the company's share of the Fund. In return producers agree to sell at cost price, effectively making the drugs available to those in greatest need. Like Evans, Biron argues for pragmatic innovation with tangible results, rather than radical change. Implementation of the HIF would leave the global patent system untouched, making the cooperation of pharmaceutical companies more likely. Of course it could not function without significant financial support from the developed countries. Biron notes that a contribution of 0.03 per cent of gross national income would generate a fund of US\$6 billion. While this would be considerably greater than most current overseas aid budgets, it would be considerably less than the drug expenditure of the wealthier countries.

The need for cooperation between developing countries is a notable theme in many of the chapters in this volume. Commercial joint ventures for the production of generic drugs, policy learning as regards the creative use of flexibilities in IP law and scientific collaboration between researchers and producers are all instances of fruitful exchange between developing countries. In his chapter, Peter Yu explores the potential for

South-South alliances in trade negotiation. In doing so, he returns us to the broader governance context within which the legal and economic framework for drug access is established. The likelihood of millions of people living with HIV/AIDS gaining access to essential medicines is crucially determined through processes of multilateral bargaining at the WTO, the World Intellectual Property Organization (WIPO), and in regional and bilateral fora. The gains to the developed countries and their commercial interests codified in TRIPs and the General Council Decision, as well as in subsequent FTAs or EPAs, have been achieved as a result of the isolation and weakness of developing countries in these negotiations. Yu explores the potential of what he calls 'IPC4D' – IP coalitions for development – as a means of resisting this 'divide and conquer' tactic. He is cautiously optimistic about the benefits of IPC4D – legal expertise can be pooled, negotiation fatigue overcome and the costs of dispute settlement reduced. The latter is particularly salient given the importance of the WTO's adjudication machinery in determining the precise content of states' obligations under TRIPs. The potency of South-South coalitions is enhanced where civil society organizations and concerned academics in the North can be enrolled as allies. Yu is careful to point out the likely obstacles to successful IPC4D. The interests of the least developed countries, often those worst affected by the AIDS pandemic, do not fully coincide with those of middle-ranking states, whose own industries themselves seek the protection of IP rights. Historical antagonisms and varying economic structures as between states may also be impediments to cooperation.

In the epilogue, Yu continues to explore the 'rugged road ahead' for HIV/AIDS governance, due in part to the ongoing tensions between the protection and enforcement of IP rights and the need for access to essential medicines and in part to the growing complexity of the international regulatory environment. He identifies some promising changes that have taken place in this environment since the launch of the Doha Development Round of Trade Negotiations. He also outlines the many remaining challenges that continue to haunt the HIV/AIDS governance regime while reducing access to essential medicines in developing countries.

To provide handy references, we include in the appendices selected provisions of the TRIPs Agreement, the Doha Declaration, the General Council Decision and the accompanying chairperson's statement, the proposed amendment to the TRIPs Agreement (Article 31*bis*), as well as other key WTO documents that have been discussed in this volume. Due to the limited space in this volume, we have omitted all the footnotes in the documents.

Access to essential medicines is a highly complex problem, at both the global and domestic levels. While this book does not resolve once and for all the highly acrimonious South-North debate that often pitches developing countries and civil society groups against the global pharmaceutical giants and their supportive developed countries, each contributor in this volume offers pragmatic insights into addressing at least one or more aspects of the complex interactions between the protection and enforcement of IP rights and access to essential medicines, with a primary focus on access to drugs for the treatment of HIV/AIDS.

NOTES

1. For a reflection on the nature of global health justice, see Baxi (2010).
2. Pogge has addressed both demands in his scholarly and practical work: see Pogge (2002, 2006) and Chapter 9 in this volume.
3. For an elaboration of the idea of global health governance, see Dodgson, Lee and Drager (2002) and Chapter 2 in this volume.
4. For a detailed analysis, see Matthews (2002).
5. On network governance in global health, see Burris (2004).

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