Failing the Global South: Power and Resistance in Medicines Governance

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Thesis submitted in fulfilment of the requirement for the degree of Doctor of Philosophy

Deakin University
August 2014
I am the author of the thesis entitled **Failing the Global South: Power and Resistance in Medicines Governance**

submitted for the degree of Doctor of Philosophy

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Acknowledgements

My deepest appreciation is for my supervisor and mentor Hans Löfgren for the guidance, knowledge, time, and diligence that he gave me in my journey as a PhD student and as an emerging health activist. Hans opened my eyes to the political economy of health and I am so very thankful for his mentorship and for the doors he opened for me to meet other inspiring and knowledgeable health activists. The end of this thesis journey is bittersweet with the sudden passing of Hans. I am committed to taking up the torch as best I can to continue to fight for a more equitable system in global health.

I also thank Steven Slaughter for your helpful advice on structure and argument, and for your support following Hans passing. Thanks to Nick Henry for your constructive comments and Colleen Keane for proofreading the thesis. Thank you Evelyne de Leeuw for pushing me to publish and for urging me to examine the history of contemporary developments. I would also like to acknowledge the support and friendship of David Legge and Deborah Gleeson from PHM Australia. Thanks for bringing me on board and for the opportunity to participate in the WHO WATCH and see firsthand the political dynamics of health. Finally, thank you to my partner Michael for your humour and support, to my family, friends, the TRIBE and to my fellow PhD students Helen, Michael and Petra who have provided immense support.
Publications


Abstract

Global medicines governance is failing to meet the health needs of the South. Despite decades of international policymaking, problems of lack of access to essential medicines, insufficient research and development (R&D) to meet the health needs of the poor, and irrational use of drugs continue with devastating consequences. This thesis examines the history, conflicts and transformations in the evolution of global medicines governance over the last 70 years. The research draws on records, reports and policy statements of intergovernmental organisations and central actors. Developments in medicines R&D, production, access, and regulation are situated within broader shifts in the global political economy. This enables an understanding of specific events over time, including turning points, major actors and interests served. This critical historical approach of the long term patterns of ideas and power is absent in the literature. The thesis demonstrates that global medicines governance has evolved through battles that principally reflect the North-South divide. The United States and its allies have blocked several multilateral initiatives that threaten the profits of their pharmaceutical firms. The pharmaceutical industry has exercised significant power and influence over governments, the World Health Organization (WHO) and other international institutions. Resistance on the part of many countries of the South has shaped a pattern of forum-shifting by governments, firms, and globally networked advocacy non-government organisations. This interplay of power and resistance is reflected in discursive conflicts, detailed in this thesis, through which the norms, and rules for global medicines governance have evolved. The findings show that in general, the counter-hegemonic discourses of the global South have not been effective against the material power of well-
resourced governments and private actors. It appears that, in the face of stark inequities in material power, the dominant discourse has been controlled by powerful actors. When the South has been effective, it is mainly because the interests of NGOs and local pharmaceutical firms have aligned. This raises important implications for health advocacy NGOs and those seeking to resist the status quo. The thesis has found examples where resistance has been most successful in national contexts, such as in courts in South Africa, India and Kenya. This suggests that the national level is where NGO may have a more substantive impact. This does not mean that protest and advocacy should not occur at the global level, rather global advocacy is strengthened if it is interlinked with the national or local context.
Table of Contents

Chapter One: The Evolution of Global Medicines Governance 1
  Approach 5
  Sources 11
  Terminology 14
  Thesis structure 17

Chapter Two: A New International Economic Order: Health for All and Essential Medicines 22
  Medicines policy and the WHO in the 1940s 23
  Medicines and the Third World 25
  A New International Economic Order and Health for All 34
  The battle for essential medicines 44
  Conclusion 53

Chapter Three: Neoliberalism: Selective Health Care and Private Rights 54
  Medicines under neoliberalism 55
  Selective Primary Health Care and essential medicines 63
  The Tropical Disease Research Program: failing the global South 69
  Intellectual property ‘rights’ 72
  Conclusion 82

Chapter Four: AIDS Exceptionalism, Safeguards and Patents 84
  AIDS exceptionalism and private rights 85
  The South African lawsuit 96
  The battle for a revised drug strategy 100
  Public health safeguards 104
  Safeguards, IP and medicines R&D 110
  Conclusion 117
**Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>ACT</td>
<td>artemisinin-based combination therapy</td>
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<td>ACT UP</td>
<td>AIDS Coalition to Unleash Power</td>
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<td>APBI</td>
<td>Association of the British Pharmaceutical Industry</td>
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<td>APED</td>
<td>Action Programme on Essential Drugs</td>
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<td>API</td>
<td>active pharmaceutical ingredient</td>
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<td>ARV</td>
<td>Anti-retroviral</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>CPAA</td>
<td>Cancer Patients AIDS Association (India)</td>
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<td>CpTech</td>
<td>Consumer Project on Technology</td>
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<td>CRO</td>
<td>Contract Research Organisation</td>
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<td>DANIDA</td>
<td>Danish International Development Agency</td>
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<td>DND</td>
<td>Drugs for Neglected Diseases working group</td>
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<tr>
<td>DNDi</td>
<td>Drugs for Neglected Diseases initiative</td>
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<tr>
<td>EC</td>
<td>European Commission</td>
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<tr>
<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associations</td>
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<td>EML</td>
<td>Essential Medicine List</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<td>EWG</td>
<td>Expert Working Group: Financing and Coordination</td>
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<td>FAPMA</td>
<td>Federation of African Pharmaceutical Manufacturers Associations</td>
</tr>
<tr>
<td>FDA</td>
<td>Federal Drug Administration</td>
</tr>
<tr>
<td>FDC</td>
<td>Fixed-dose combination</td>
</tr>
<tr>
<td>FTA</td>
<td>Free trade agreement</td>
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<tr>
<td>GATT</td>
<td>General Agreement on Tariffs and Trade</td>
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<td>GAVI</td>
<td>Global Alliance for Vaccines and Immunisation</td>
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<tr>
<td>GFATM</td>
<td>The Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria</td>
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<tr>
<td>GCP</td>
<td>Good Clinical Practices</td>
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<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
</tr>
<tr>
<td>GSP</td>
<td>Generalized System of Preferences</td>
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GSPA-PHI Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
G-77 Group of seventy seven
HAI Health Action International
HIV/AIDS Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
IARC International Agency for Research on Cancer
IBFAN International Baby Food Action Network
ICH International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IFPMA International Federation of Pharmaceutical Manufacturers and Associations
IGWG Intergovernmental Working Group
IP intellectual property
IMF International Monetary Fund
IMPACT International Medicines Product Anti-Counterfeiting Taskforce
INTERPOL International Criminal Police Organization
IPAB Intellectual Property Appellate Board (India)
ISI Import-substitution industrialisation
KEI Knowledge Ecology International
MDR-TB Multidrug-resistant tuberculosis
MMV Medicines for Malaria Venture
MNC Multinational Corporation
MPP Medicines Patent Pool
MSF Médecins Sans Frontières
NACP National AIDS Control Program
NAFDAC National Agency for Food and Drug Administration and Control
NGO Non-government organisation
NIEO New International Economic Order
NIH National Institutes of Health
ODA Official Development Assistance
OAPEC Organization of Arab Petroleum Exporting Countries
OECD Organization for Economic Co-operation and Development
OPEC Organization of the Petroleum Exporting Countries
OTC Over the counter
PDP product-development partnership
PEPFAR United States President’s Emergency Plan for AIDS Relief
PhRMA Pharmaceutical Research and Manufacturers of America
PLWA People living with AIDS
PMA Pharmaceutical Manufacturers Association of South Africa
PMG-MAN Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria
PTNCs Pharmaceutical transnational corporations
R&D Research and Development
SPHC Selective Primary Health Care
TAC Treatment Action Campaign
TAN Transnational Advocacy Networks
TRIPS Agreement on Trade-Related Aspects of Intellectual Property Rights
UNAIDS Joint United Nations Programme on HIV/AIDS
UNICEF United Nations Children’s Fund
UNCTAD United Nations Conference on Trade and Development
UNCTC United Nations Centre on Transnational Corporations
UNDP United Nations Development Programme
UNECLAC United Nations Economic Commission on Latin America
UNESC United Nations Economic and Social Council
UNIDO United Nations International Development Organization
USTR United States Trade Representative
UNASUR Union of South American Nations
UNESD UN Department of Economic and Social Development
USSR Union of Soviet Socialist Republics
WHA World Health Assembly
WHO World Health Organization
WIPO World Intellectual Property Organization
WTO World Trade Organization
CHAPTER ONE

The Evolution of Global Medicines Governance

Medicines advance the health of society to the extent that they protect, maintain and restore people’s health (WHO 2004d)\(^1\). The provision of effective, therapeutic, safe and affordable medicines has long been a core concern of governments and policymakers. This thesis demonstrates that the interrelated issue areas of research and development (R&D), production, quality control, and regulation of medicines have been on the agenda of the ‘directing and coordinating authority on international health’, the World Health Organization (WHO), since its creation (WHO 1946). Medicines also serve an economic value as commodities (Löfgren 2013). They generate billions of dollars in profits annually for business firms, and when they are traded internationally, contribute positively to the trade balance of exporting countries\(^2\). In 2013, the top ten international pharmaceutical firms accumulated more than $430 billion (US) in revenue from the sale of medicines and health products (FiercePharma 2014).

These functions create tensions for governments, which are often constrained by imperatives to create conditions favourable to pharmaceutical industry investments (Schrecker 2009; 2011). This tension is particularly acute when medicines policy threatens to constrain the profits of pharmaceutical firms. Policy to strengthen the rational use of medicines, for example, requires regulation that

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\(^1\) It is also the case that some medicines can cause harm. Some studies, for example, have shown adverse drug reactions in over fourteen per cent of hospital in-patients (Davies et al 2009).

\(^2\) In 2009 the United Kingdom had a positive trade surplus of £7 billion in the pharmaceutical sector, the largest surplus of all industrial sectors (Association of the British Pharmaceutical Industry 2011).
constrains profits. Medicines are used irrationally when they are not therapeutically effective or safe, not prescribed for the right condition or acceptable to a patient, not administered correctly, and/or are unnecessarily expensive (Basco 2004; Laing N.D.; WHO 2013b). In contrast, medicines are used rationally when people have affordable access to essential medicines that are used appropriately, in doses that meet their requirements, and for an adequate period of time (WHO Expert Committee on the Selection of Essential Drugs 1997).

Conflict between the economic and health functions of medicines is also reflected in the uneven distribution of medicines research and development (R&D). Because of profit motives, R&D remains skewed towards health conditions and ailments in wealthy countries (Evans, Shim and Ioannidis 2014). There is insufficient R&D for conditions that predominantly affect populations in the global South. Existing treatments are often not adapted to health needs in poor countries, nor are they of optimal dosage or appropriate for children (Leach, Paluzzi and Munderi 2005: 10; MDG Gap Task Force 2008: 44).

From the perspective of the global South, there is an urgent need to strengthen global governance to support the health value of medicines. Fifty per cent of all deaths in the global South are preventable, in that adequate treatment exists but is not readily accessible (MDG Gap Task Force 2012; Médecins Sans Frontières 2012).

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3 The irrational use of medicines increases the risk of adverse drug reactions and drug resistance (WHO 2013b; Woroń et al. 2007). Drug resistance contributes to increases in the frequency and severity of epidemics, to re-emerging transmission rates and to increasing fatality rates (Bloand 1999).

4 As a student of both politics and health, this health need informs my perspective in examining the global governance of medicines.
Irregular supply, unaffordable prices, incorrect prescribing and poor compliance have created a situation in which the WHO (2013a) reports that more than 50 per cent of all medicines are used irrationally (see also Kar, Pradhan and Mohanta 2010; Pablos-Méndez et al. 1998).

Drug resistance to key treatments has spread, creating drug resistant strains of tuberculosis, malaria and tropical diseases (Pablos-Méndez et al. 1998). This is not limited to the global South, with multi-drug resistant tuberculosis (MDR TB) spreading amongst the poor in New York for over two decades (Pablos-Mendez et al. 1990). Experts in malaria warn that increasing resistance could be a ‘disaster for the control and treatment of malaria and bring eradication efforts to a standstill’ (Dondorp et al. 2011). Similarly, the increasing spread of resistance would reverse the downward trend in Human African trypanosomiasis prevalence, leading to resurgence in a form that resists available medicines (Barrett et al. 2011).

The thesis hypothesis is that the aforementioned problems are not principally the result of a lack of scientific knowledge or world resources, rather they reflect political conflict, power and a crisis of global governance (Kay and Williams 2009b; Kickbusch 2005; Lee 2009a; McInnes and Lee 2012a). Indeed, medicines policy is increasingly governed at the global level in which the ‘rules and norms

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5 These include anthelminthic drugs albendazole and mebendazole, the only effective onchocerciasis medicine ivermectin, medicines for sleeping sickness eflornithine and melarsoprol and antileishmanial drugs (Albonico, Engels and Savioli 2004; Bryceson 2002; Gloeckner et al. 2009; Hotez et al. 2007).

6 While it is beyond the scope of this thesis, a broader conflict in health is that of the dominance of biomedicine and the often neglected social and economic determinants of health (see Commission on Social Determinants of Health 2008; Schrecker 2011).
governing world order’ are shaped by the interactions of governments, intergovernmental institutions, multinational corporations and non-government organisations (Held et al. 1999: 50; Rosenau 1992). In this thesis I ask, why is the global governance of medicines failing to meet the health needs of the global South?

In order to address this research question I pose three subsidiary questions for investigation:

Who are the actors that have shaped the global governance of medicines?

What discourses have shaped global medicines governance?

What have been the turning points in the evolution of this domain?

The thesis finds that global medicines governance has evolved through a battle that principally reflects the North–South divide. This divide is shaped by the conflict of interest between capital and health which is taking place transnationally at the global level. The United States and its allies have blocked several multilateral initiatives that have aimed to strengthen the health value of medicines when these have threatened the profits of their pharmaceutical firms. The pharmaceutical industry has exercised significant influence over governments, the World Health Organization (WHO) and other international institutions. The capacity of global medicines governance to meet the needs of the South is constrained by the power of the international pharmaceutical industry.

Health advocacy NGOs have become important allies to governments in the global South in their resistance to the industry. Through their global operations

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7 The nuances of the North-South divide are explored in the thesis.
and dense linkages of exchange and participation, these NGOs exhibit characteristics of a global advocacy network (see Keck and Sikkink 1998: 8; 1999: 92). The thesis suggests that NGOs can play a key role in supporting governments to resist pressures from the industry, particularly when the ambitions of local firms and NGOs align. To remain independent, however, NGOs must assess their participation in new global health partnerships, in which they work closely alongside international pharmaceutical firms.

**Approach**

This research contributes to an emerging field of political inquiry into the global governance of health policy. Research in this field has proliferated since Kickbusch and de Leeuw (1999), Lee, Buse and Fustukian (2002b) and Lee et al. (2003) identified a lack of scholarship in this field (see Buse, Hein and Drager 2009; Cooper and Kirton 2009; Cooper, Kirton and Schrecker 2007; Fidler 2001; 2008; 2009; Foller and Thorn 2008; Hein, Bartsch and Kolhmorgen 2007; Kay and Williams 2009a; Keefe and Zacher 2008; Kickbusch 2009; Kirton and Guebert 2009; Labonté, Blouin and Forman 2009; Poku, Whiteside and Sandkjaer 2007; Rushton and Williams 2011; Schrecker 2009). Research in global health can be separated into two phases based on the central research questions, themes and arguments. The first phase correlates to emerging research in globalisation and health in the late 1990s. The core research questions in this period were explanatory, focused on globalisation and its impact on health. Lee and Dodson

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(2003:137) coined the phrase ‘paradox of globalisation’ to illustrate the concern that globalisation was exacerbating inequality. In this period, scholars drew on a few political science theories and concepts to investigate global health. These include Manuel Castell’s ‘network society’ (Kickbusch and de Leeuw 1999), Kuhn’s ‘paradigms’ (Kickbusch 2003), Haas’ ‘epistemic communities’ (Lee and Goodman 2002) and Cox’ ‘transnational managerial class’ (Lee and Zwi 2003).

The second phase from the mid to late 2000s focused on understanding health problems as governance issues. The practice of governance was a key focus, as health partnerships emerged such as UNAIDS, GAVI and the Global Fund. Since the mid-2000s scholars have increasingly framed global health problems within the politics of global governance (Kickbusch 2005). Key themes of scholarship include the effect of neoliberalism on health policy (Ingram 2009; Lee, Buse and Fustukian 2002b; Lee and Zwi 2003; McGregor 2001; Navarro 2007; Porter, Lee and Ogden 2002; Rowden 2009; Rushton and Williams 2012; Sanders 2003; Schrecker 2009; Sparke 2009), responses to HIV/AIDS (Foller and Thorn 2008; Harman and Lisk 2009; Hein, Bartsch and Kolhmorgen 2007; Lisk 2010; Poku 2004; Poku, Whiteside and Sandkjaer 2007; Worgart 2009), the securitisation of health policy (Altman 2003, 2008; Elbe 2006; Fidler 2007; McInnes and Lee 2006; Rushton 2010), the global governance of influenza (Kamradt-Scott and Lee 2011; Lee and Fidler 2007), the emergence of global health partnerships (Bartsch 2007; Bull and McNeill 2007; Buse 2004; Buse and Walt 2000b, 2002; Williams 2012) and the role of philanthropists and private foundations in global health (McCoy et al. 2009; Moran 2011; Rushton and Williams 2011).
More recently, scholars have identified a gap in the literature. What has ‘largely
gone unexplored’ are the underlying preferences, ideas, worldviews and
motivations of actors in global health governance (see Bartsch, Huckel and
Kohlmorgon 2009; Buse et al. 2009; Lee 2009a; McInnes and Lee 2009; Sparke
2009). Fidler (2008: 60), for example, has lamented that ‘none of the leading
theories adequately captures what is happening with the rise of non-state actors…
particularly the growing ability of these actors to exercise material capabilities
vis-à-vis states and each other, and the resulting impact of this ability on how
ideas play a role’. This thesis is a response to this lacunae and call for a ‘new
research agenda’ (McInnes and Lee 2009).

This thesis traces the history, conflicts and transformations in the evolution of
global medicines governance over 70 years. This critical historical approach
‘stands apart from the prevailing order of the world to ask how that order came
about’ (Cox 1996: 24). This analysis of long term patterns of ideas and power is
often absent in the literature, yet it enables an understanding of specific events
within broader shifts and changes over time, including identifying turning points,
major actors and whose interests have been served. Developments in the issue-
areas of medicines R&D, production, access, and regulation are situated within
broader political economic shifts over time, including the rise and fall of the New
International Economic Order (NIEO) and the dominance of neoliberalism in the
global political economy. This historical perspective also enables a long-term
view of the role of the World Health Organization in medicines governance.
The thesis is informed by critical theory which gives attention to the role of ideological forces in reconciling society to the imperatives of capitalism, with the aim of emancipating from such forces (Held 1980). The thesis draws on an interpretive framework which explains change in society through the combined effect of structures and actors (see Adler 1997; Finnemore 1996; Raskin 2002; Sell 2003; Wendt 1992: 7). In this perspective, social structures are the common understandings, shared discourses, and worldviews which shape actors’ preferences (see Dryzek 2006b; Holzschneider 2011; Risse 2007; Steffek 2003). The thesis uses the term ‘discourse’ to encapsulate these narratives. A discourse is a set of assumptions which provide a narrative for thinking about a particular topic in a particular historical moment. Discourses are often unspoken and taken for granted, yet they are widely shared and ‘hold a powerful grip on our imaginations and psyches because they offer the promise of resolution for scary problems’ (Stone 2002: 139).

The term ‘discourse’ is used in different ways (see Dryzek 2006a; Fairclough 1992; Foucault 1980; Howarth 2000). On the one hand, actors are embedded in social structures which constrain their actions. On the other, actors can reproduce these discourses in ways that suit their ambitions (Sell 2003). The thesis conceptualises discourse within a ‘co-constitutive relationship between agents and social structures’ by which actors can challenge, contest and transform discourses (Risse 2007). This follows its usage by the political theorist John Dryzek (1997), whose study of environmental politics identified competing discourses like human rights and environmental sustainability. This use of discourse is compatible with

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9 Nation-state sovereignty, for example, is a social construction that did not exist pre-Westphalia (Castells 2008).
the term ‘frame’ by those in social movement literature (see Keck and Sikkink 1998; Tarrow 1998) and more recently in global health (McInnes and Lee 2012b). The purpose of studying discourse is to investigate how framing processes shape understanding, and identify whose interests are served by discourse.

The thesis demonstrates that whether medicines are valued primarily for their curative qualities or for their economic returns is the outcome of social dynamics and power relations. Whether access to medicines is considered a human right, or whether medicines are considered a private intellectual property ‘right’ of pharmaceutical firms is the result of power. The discourses that dominate reflect the interests of the actors who shape the ‘underlying rules of the game’ (Adler 1997: 336; Barnett and Duvall 2005:2; Held and McGrew 2004: 8).

This type of investigation is emerging in the field of global health (see Labonte´ and Gagnon 2010; Lee 2009a; McInnes et al. 2012; Rushton 2012; Shiffman 2009: 38). In their study of foreign policy and health, McInnes and Lee (2006) assert that a ‘health security frame’ is prioritising foreign security concerns of the West over public health policy and the health needs of the developing world. Sell (2007) and Sell and Prakesh (2004) characterise global changes in intellectual property rules as a ‘battle to change the terms of discourse’. Hein (2007) depicts global health as a struggle between ‘market creation’ and ‘social creation’ interests, while Kickbusch’ (2003) reflects on the role of paradigms in health. More recently, Rushton and Williams (2012: 153) argue that neoliberalism is a ‘deep core’ of contemporary global health governance that combines in ‘powerful ways with the dominant paradigms’ to constrain problem solving options
(Rushton and Williams 2012: 163). Indeed, this ‘deep core’ of neoliberalism is reflected in the evolution of global medicines governance.

In this respect, the thesis also contributes to literature on the rise of non-state actors in global governance (see Avant, Finnemore and Sell 2010; Castells 2008; Hale and Held 2011; Rushton and Williams 2011; Stone 2008). Globalisation has enabled non-state actors to acquire authority (Hall and Biersteker 2002: 4). Authority is not only the capacity for brute force, and it is distinguished from coercion because it is a recognition of deference, whether explicit or implicit (Avant, Finnemore and Sell 2010; Cutler 1999: 2). Non-state actors can acquire material, institutional, ideational (principled or moral), expert or capacity-based authority in global governance (Avant, Finnemore and Sell 2010: 5). Non-state actors may be ‘delegated’ authority by states, such as the World Trade Organization (WTO), they may acquire expert authority if they are perceived by the global community to be experts in a field, or they may possess capacity-based authority because they have shown to effectively produce results (Avant, Finnemore and Sell 2010: 11). Claims to authority affect agency and the roles of non-state actors in agenda-setting, mobilising public opinion, coalition building and, ultimately, influencing politics.

The thesis demonstrates the power and influence of the international pharmaceutical industry in global medicines governance. The industry has material, institutional, expert and capacity-based authority and has considerable influence on many governments and intergovernmental institutions. Health-advocacy NGOs, such as Health Action International (HAI), Médecins Sans
Frontières (MSF), Knowledge Ecology International (formerly Consumer Project on Technology), the Treatment Action Campaign (TAC) and Oxfam, have opposed the industry’s attempts to shape global medicines governance. These NGOs have led public advocacy campaigns based on naming and shaming and mobilising public opinion, and have participated in institutional advocacy through access to elites and decision-makers (Losey 2014). NGOs have acted in an informal advocacy network that has exhibited characteristics of a ‘transnational advocacy network’ as defined by Keck and Sikkink (1999: 98). NGOs have co-hosted international conferences, engaged in formal collaborations, issued joint policy statements, shared strategies, and created international information sharing through the internet.

**Sources**

The thesis draws on a critical analysis of primary source documents (see Appendix Two and below). The primary sources were selected throughout the research as I proceeded to identify the intergovernmental institutions and actors that were shaping global medicines governance. I initially focused on institutions and actors identified in secondary literature, such as the World Health Organization and World Trade Organization. Through the research I conducted a rigorous collection of primary sources from a number of institutions. For example, I read all of the resolutions and decisions of the governing bodies of the World Health Organization from the 1940s to the present. I read all over the World Bank annual development reports. I searched the GATT archive for all documents that referred to ‘medicines’, ‘intellectual property’, ‘R&D’ and ‘pharmaceuticals’. I also searched archives of UNCTAD and UNIDO for
‘pharmaceuticals’ in the 1970s. I initially began my analysis in the 1970s because that is when the WHO’s essential medicines policy was established. However, from this research I became aware that these debates went back earlier and so searched for reports on meetings in the early years of the WHO (1940s).

The analysis involved reading the sources to identify the actors that were seeking to shape medicines governance, their positions and their strategies, including the way that they framed the debate. This was the first layer of analysis. The second layer was to identify the outcome of the conflicts – the outcome of the debates in various intergovernmental institutions and events to identify who ‘won’. The third layer was to situate these struggles within a broad historical narrative, including what was occurring in different institutions at the same time, and what was occurring over time within and across these institutions.

The primary source documents that I have analysed include summary records and resolutions of the governing bodies of the WHO, the United Nations Conference on Trade and Development (UNCTAD), United Nations General Assembly, General Agreement on Tariffs and Trade (GATT), World Trade Organization (WTO), Conference of Non-Aligned Countries, United Nations Sub-Commission for the Protection and Promotion of Human Rights and United Nations Economic and Social Council (UNESC)\(^\text{10}\). These primary sources also include reports of the aforementioned organisations along with those from the World Bank, United Nations International Development Organisation (UNIDO), the World Intellectual Property Organisation (WIPO), the Joint United Nations Programme on

\(^{10}\) In the case of GATT, I searched the GATT Digital Archive Depository of Documents between 1947 and 1995 for the term ‘intellectual property’ and/or ‘R&D’.
HIV/AIDS (UNAIDS), United Nations Children’s Fund (UNICEF), the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, the International Medicines Anti-Counterfeiting Taskforce (IMPACT), UNITAID, Medicines for Malaria Venture (MMV), Drugs for Neglected Diseases initiative (DNDi), and the Medicines Patent Pool (MPP).


I have also examined policy statements and reports from non-state actors, including the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the Pharmaceutical Research and Manufacturers Association of America (PhRMA), and health advocacy non-government organisations like Health Action International (HAI), the AIDS Coalition to Unleash Power (ACT UP), Médecins Sans Frontières (MSF), Treatment Action Campaign (TAC) and the Consumer Project on Technology (CpTech). Academic literature also serves as primary source evidence, including Third World economic papers in the 1960s and 1970s and academic publications by staff of
NGOs. This material is supported by secondary literature, drawing on the work of scholars in a range of fields including law, politics and health. I also conducted informal discussions with experts and activists at the Third People’s Health Assembly (PHA3) in Cape Town, South Africa in July 2012 and in my participation in the People’s Health Movement ‘WHO Watch’ at the January 2013 Executive Board meeting of the WHO in Geneva, Switzerland.

**Terminology**

A number of concepts and terms used in the thesis require clarification. The global South traditionally refers to those countries defined by the United Nations Development Program (UNDP) as ‘developing countries’. The relevance of the terms ‘South’ and ‘North’ is called into question by some, in particular since the UNDP has very recently classified several of these countries as ‘highly’ developed. However, this divide is still relevant as the global North refers to the 47 countries determined to be ‘very highly’ developed (United Nations Development Programme 2013). Essential medicines are defined by the WHO Expert Committee on the Selection and Use of Essential Drugs (2000) as ‘those medicines that satisfy the priority health care needs of the population, which should be available at all times and in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and community can afford’. Prior to the early 2000s, the term ‘essential drugs’ was widely used (Laing 2003). For simplicity, the thesis uses the term essential medicines (except in quotes). ‘International pharmaceutical firms’ refer to those multinational pharmaceutical companies that operate as global entities and in global space and are headquartered predominantly in Europe and the
United States (Fortune Global 500 2009; see Appendix One for a glossary of more terms). These firms are also referred to as pharmaceutical transnational corporations (PTNCs). The thesis uses the terms HIV and AIDS interchangeably and the acronym HIV/AIDS (Sabatier 1989: 1). Where the terms ‘low-income’ or ‘middle-income’ are used, the thesis draws on sources which have generated data using the World Bank’s income categories (see World Bank 2013).

Terminology to describe poor-quality medicines is politically charged. Substandard medicines, for example, are typically defined as medicines produced by licensed manufacturers which fail to pass quality standards (WHO N.D.g). In the WHO, the terms ‘spurious/falsely labelled/falsified/counterfeit’ refer to medicines that are ‘deliberately and fraudulently mislabelled with respect to identity and/or source’ (WHO 2014b). This definition is broader than the definition of substandard and includes medicines which contain correct ingredients (WHO 2014b). While scholars have recently proposed new definitions (see Attaran et al. 2012), this conflation of terms around quality of medicines and intellectual property remains a significant issue in global health, as this thesis demonstrates in chapter five.

International health refers to the ‘traditional forms of interstate co-operation on health through diplomacy, treaty-making and the creation of international institutions’ (Rushton 2008). Rapid spread of diseases, environmental issues and problems of access to medicines are examples in which one’s health can no longer be ‘viewed in isolation from that of another’ (Kickbusch 2005). Health issues increasingly ‘circumvent, undermine or are oblivious to the territorial boundaries
of the state... and are beyond the capacity of state institutions to address alone’ (Buse et al 2002: 270). We now speak of global governance to refer to ‘not only the formal institutions and organisations through which the rules and norms governing world order are (or are not) made and sustained... but also the organisations and pressure groups – from MNCs, transnational social movements to the plethora of non-governmental organisations – which pursue goals and objectives and have a bearing on transnational rule and authority systems’ (Held et al 1999:50).

In addition, new communication technologies such as the internet have facilitated a global public sphere. This global public sphere is a ‘space of communication and ideas that emerge from society’ outside the state system, operating beyond the ‘limits of national boundaries’ (Castells 2008: 78; Dryzek 2006; Nanz and Steffek 2004: 321; Scholte 2005: 283)\(^{11}\). Global civil society is the organised component of the public sphere that is comprised of voluntary associations seeking to shape social rules (Castells 2008: 78; Scholte 2005: 214). Civil society is said to be global when these voluntary associations have a global focus, use global infrastructure, and are financed globally (Castells 2008; Kaldor 2005; Scholte, 2007: 311).

Authority is the ability to ‘induce deference in others’ (Avant et al 2010: 10). Authority is bound with power, and governance and power are ‘inextricably linked’ (Barnett 2005: 2). Power is more than force and is produced ‘in and through social relations’, shaping ‘the capacities of actors to determine their own

\(^{11}\) The public sphere does not exist in a vacuum, however, and exists alongside and interacts with the state system (Lipschutz 2005).
circumstances and fate’ (Barnett 2005). Barnett and Duvall (2005) have usefully identified a framework for power. Compulsory power refers to direct control, such as the use of force. Institutional power is the exercise of indirect control, through for example international institutions. Structural power is the ‘constitution of social capacities and interests of actors in direct relation to each other’, such as labor and capital under the capitalist system (Barnett and Duvall 2005:3). Finally, productive power is the ‘production of subjectivity in systems of meaning and signification’ that includes discourse and systems of knowledge (2005:3). These aspects of power inform the thesis research.

**Thesis structure**

The thesis is structured according to its historical approach, with each chapter examining a particular time period. In addition to the review of relevant literature presented in this chapter, the empirical chapters of the thesis each contain a literature review integrated in the text. Chapter two commences the historical study with the creation of the World Health Organization in the 1940s and concludes with the formation of the WHO’s essential medicines policy and Action Programme on Essential Drugs in the early 1980s. The chapter situates developments in international medicines policy in this period within broader shifts in international politics that were the result of demands by the global South for a fairer international system. The chapter demonstrates that Third World discourse enabled the global South to champion their economic and health ambitions, and shape the vision of a New International Economic Order (NIEO) and ‘Health for All’. The chapter shows, however, that over four decades the United States government opposed and prevented a role for the WHO in
addressing the medicine needs of developing countries, in particular when such policy threatened the profits of its pharmaceutical firms. The chapter argues that, despite the NIEO ambitions, the international governance of medicines in this period was inadequate to meet the health needs of the global South.

Chapter three commences in the early 1980s and concludes with the establishment of the World Trade Organization’s Trade Related Agreement on Intellectual Property Rights (TRIPS) in the mid-1990s. The chapter argues that the global governance of medicines in this period privileged the economic interests of international pharmaceutical firms and failed to address the health needs of the global South. Medicines governance was transformed through shifts in economic, health and trade policy in this period that were the result of a broader forum-shifting strategy of the United States and its allies to block the New International Economic Order. In the domain of economic policy, neoliberal economic restructuring strengthened the dominance of international pharmaceutical firms in global medicines research and development (R&D), production, and trade. In health policy, the World Bank and UNICEF promoted ‘selective’ primary health care, which complemented economic reforms by providing a rationale and justification for a narrow role for government in health. Finally, shifts in international trade policy in this period presented new global architecture for medicines R&D that privileged the private ‘rights’ of patent holders over the health needs of the global South.

Chapter four examines developments in global medicines governance through the 1990s to the World Trade Organization’s Doha Declaration on TRIPS and Public
Health in 2001. The chapter demonstrates that the global governance of medicines in this period strengthened a global norm for intellectual property ‘rights’ as a prerequisite for medicines research and development (R&D). This legitimised the historical neglect of the health needs of developing countries, because it framed this neglect as a logical outcome in the absence of IP protection. The chapter shows that the Doha Declaration was a product of resistance on the part of several developing countries and NGOs against pressures to enforce IP measures beyond those of TRIPS. These actors championed a discourse for ‘public health safeguards’ which enabled them to reassert health needs against patent ‘rights’. The chapter argues, however, that this discourse was co-opted by the United States and the international pharmaceutical industry, who framed the protection and enforcement of their IP ‘rights’ as a safeguard for the development of new medicines. I show that the World Health Organization shifted its position in support of the enforcement of strong IP ‘rights’ as a strategy to reclaim its authority in global health.

Chapter five examines the globalisation of regulatory requirements for medicines and the diffusion of intellectual property ‘rights’ in global medicines regulatory initiatives in the 1990s and 2000s. The chapter argues that the international pharmaceutical industry and its proponents played a key role in raising minimum international regulatory standards, beyond mere health and safety benefits, as part of their strategy to block foreign competition from generic firms. It situates the creation of the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, the WHO’s pre-qualification program and the United States bilateral aid program for HIV/AIDS within this strategy and the broader historical struggle over the
production and supply of medicines. The chapter subsequently highlights the role of Nigeria as a global advocate for the industry-led IMPACT in the WHO. The chapter shows that Nigeria’s support for IMPACT has created a division in the global South over the WHO’s role in this initiative. This has enabled the pharmaceutical industry to continue to pursue the enforcement of IP in IMPACT and has delayed effective governance to address the problem of a lack of capacity in the South to regulate medicines.

Chapter six examines the evolution of the global governance of medicines for tropical diseases, culminating in the rejection of an R&D treaty in the WHO in 2012. The chapter shows that the plight of communities living with tropical diseases re-emerged on the global agenda in the 1990s through the advocacy of Médecins Sans Frontières (MSF) and a global network of activists and NGOs. These actors championed a counter-discourse to TRIPS that was premised on conceptualising essential medicines as ‘public goods’. The chapter argues that this ‘public goods’ discourse was the broader political context in which pharmaceutical firms and their proponents created product-development partnerships (PDPs) that became the dominant mode of governance for R&D for tropical diseases. This model principally serves to reinforce global norms for the protection of intellectual property ‘rights’. Indeed, the chapter argues that the creation of PDPs enabled the United States and its allies to block an R&D treaty in the WHO that threatened to replace IP as a global norm for medicines R&D.

Finally, chapter seven examines the contemporary situation of power and resistance in global medicines governance. It demonstrates that the status quo is
one in which the United States government and the pharmaceutical industry are attempting to raise global norms for the protection and enforcement of pharmaceutical intellectual property ‘rights’ beyond the requirements of TRIPS. This ‘TRIPS PLUS’ agenda threatens access to new medicines in developing countries because it inhibits generic competition and affordable access to medicines. The chapter focuses on recent landmark corporate litigation in India that has been led by some international firms in an attempt to secure ‘TRIPS PLUS’ IP standards. India is significant for the global South because many developing countries rely on Indian manufacturers for their essential medicines. The chapter shows that India has resisted the TRIPS PLUS agenda with the support of a loose alliance of generic firms and health advocacy NGOs. This suggests that when economic and health objectives align, governments in the global South can resist industry pressure. These alliances are also evident in an increasing counter-movement amongst middle-income countries.
CHAPTER TWO

A New International Economic Order: Health for All and Essential Medicines

This chapter commences this historical and empirical study with the creation of the World Health Organization in the 1940s and concludes with the formation of the WHO’s essential medicines policy in the early 1980s. The chapter situates developments in medicines policy in this period within broader shifts in international politics that were the result of demands by the global South for a fairer international system. The chapter demonstrates that through the rise of Third World discourse, many developing countries articulated a set of demands related to medicines research and development (R&D), production, access and regulation through the United Nations (UN). This discourse enabled the global South to champion their economic and health ambitions, and shape the vision of a New International Economic Order (NIEO) and ‘Health for All’. The chapter shows, however, that over four decades the United States government opposed a role for the WHO in addressing the medicine needs of developing countries, particularly when such policy threatened the profits of its pharmaceutical firms. Indeed, in the late 1970s, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) played a key role in weakening the WHO’s essential medicines policy. The chapter argues that, despite the NIEO ambitions, the international governance of medicines in this period was inadequate to meet the health needs of the global South.
The chapter draws on an analysis of records, resolutions and reports of the WHO, United Nations Conference on Trade and Development (UNCTAD), United Nations International Development Organisation (UNIDO), United Nations Conference on Transnational Corporations (UNCTC), Non-Aligned Movement, United Nations General Assembly and Third World academic literature (see Appendix Two).

**Medicines policy and the WHO in the 1940s**

The World Health Organization was formally created in 1948 as a specialised agency of the United Nations. Upon its formation, the organisation appeared to have multiple claims to authority. Member-states seemingly delegated authority to the WHO through its mandate as the ‘directing and coordinating authority for international health’ (WHO 1946). The WHO was also imbued with a moral authority through its objective for ‘all peoples of the highest possible level of health’ as a ‘fundamental right’ (WHO 1946). Shortly after it was established, and in response to the creation of new medicines like penicillin, the WHO Secretariat asserted a role for the organisation in setting international standards and non-proprietary names for medical substances (Chisholm 1950: 1022; WHA3.11 [1950] in WHO 1973a: 128)\(^\text{12}\). This technical function and expert authority was welcomed by its member states, of which there were 59 in 1949. That year, member states of the WHO agreed that the coordination of biomedical research was an ‘essential function’ of the WHO (WHA3.19 [1949] in WHO 1973a: 23).

\(^{12}\) Prior to 1945 little drug development occurred in the pharmaceutical industry. The discovery of penicillin during World War Two, however, led to the expansion of public sector investment in R&D in industrialized countries and the proliferation of pharmaceutical R&D firms which to this day remain headquartered in Europe and the United States (see Cockburn 2004; Dutfield 2003; Grabowski 2011; Sunder Rajan 2006; Taggart 1993).
The WHO’s early work thus focused on developing control plans for malaria, tuberculosis and venereal diseases, and the coordination of research for medicines for malaria (Chisholm 1950: 1022; EB5.R10 [1949] in WHO 1973a: 67). However, the WHO’s authority became politically contested amongst member-states shortly after it was created. Indeed, conflict over the role of the WHO in the governance of medicines threatened the WHO’s broader claims to authority.

In 1947, the first Expert Committee on the Unification of Pharmacopoeias\(^{13}\) called for ‘a comprehensive list of the drugs considered to have outstanding value in medical practice…to be divided into a primary list of the most essential drugs’ (cited in WHO Expert Committee on the Selection of Essential Drugs 1977). It would be another 30 years, however, before the WHO would formally adopt an essential medicines policy (see below). This significant delay was the result of politics. In 1949, the problem of inadequate access to medicines was first raised internationally at the World Health Assembly (WHA)\(^{14}\). Several countries with limited resources asserted that ‘it was the function of WHO…to provide essential medical supplies…to countries which do not produce these commodities and which, because of the lack of necessary currencies, are unable to import them’ (cited in Chisholm 1950: 1025). This view of the role of the WHO was shared by the first Director General of the WHO, Brock Chisholm, who argued that the objective of the organisation was to ‘make it possible for all people to share in the

\(^{13}\) This committee was set up by the WHO interim Commission to carry on the work of the League of Nations to implement an international agreement for the unification of pharmacopoeias (WHO 2006g: ix).

\(^{14}\) The World Health Assembly is the decision-making and governing body of the WHO which comprises all member-states of the United Nations. It meets annually in Geneva Switzerland.
benefits of medical and sanitary sciences’ (Chisholm 1950: 1022). The United States, however, opposed this role for the WHO and claimed that ‘medical supplies, like other commodities, should now be obtained through the normal peacetime economic machinery’ (Chisholm 1950: 1025). These contrasting positions were indicative of early tensions over the role and function of medicines in society.

The broader political economic context in which the 1949 World Health Assembly took place was the emergence of the Cold War, in which conflict between the Soviet Union and the United States took place on numerous political fronts. The 49 member states of the WHO were politically divided. The United States linked its support for health programs like malaria to its anti-Communist efforts (Farley 2008: 159). Indeed, the Soviet Union briefly left the WHO in 1949 (Lee 2009b). Despite the one-state one-vote mechanism upon which the organisation was established, the WHO was oriented to creating consensus amongst the divided member states. Because of US resistance, however, member-states could only agree that the WHO would make medicines available on an ‘extremely limited scale and under special circumstances’ (Chisholm 1950: 1025; EB6.R3 [1950] in WHO 1973a:21). Thus, in the 1940s the United States was effective in determining a limited role for the WHO in the provision of medicines.

**Medicines and the Third World**

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15 Brock Chisholm promoted ‘social medicine’ beyond a narrow focus on biomedicine and disease, much like the contemporary public health focus on the social determinants of health (Farley 2008: 113; Lee 2009b: 17).

16 The two year delay between the signing of the WHO constitution in 1946 and its formal establishment in 1948 was due to the onset of the Cold War (Lee 2009b).
This chapter has so far shown that medicines emerged on the agenda of the newly-formed WHO in the 1940s amidst political conflict. In this section I demonstrate that the 1950s and 1960s saw the rise of Third World discourse in which the global South formed a critique of the international system, including the dominance of international pharmaceutical firms in the supply of medicines. This movement emerged outside the United Nations, yet it was influential on many UN organisations. The section shows, however, that it was not until the 1970s that the global South secured UN support for its vision of a fairer international system, including a restructuring of the governance of medicines.

As the previous section has explained, the WHO was formed in the broader political context of the Cold War. This period, in particular the 1950s and early 1960s, was also characterised by rapid decolonisation (Rowden 2009: 56). Across Asia and Africa, newly independent developing countries shared a common desire for freedom and independence. Despite their different cultural and economic backgrounds, their leaders began to foster a common ambition. In 1955, the first Asian-African conference in Bandung Indonesia was significant for the formation of a project for the Third World. Opening the conference, Indonesia’s President Sukarno celebrated that:

Irresistible forces have swept the two continents. The mental, spiritual, and political face of the whole world has changed and the process is not complete…hurricanes of national awakening and reawakening have swept over the land, shaking it, changing it, changing it for the better (Sukarno cited in McTurnan 1956: 43–44).
The 29 governments in attendance at Bandung were united by ‘a common detestation of colonialism in whatever form it appears…and a common determination to preserve and stabilise peace in the world’ (President Sukarno cited in McTurnan 1956: 43–44). To achieve this aim, they agreed that they would not enter into strategic alliances with either the Soviet Union or United States, and subsequently came to be known as the Non-Aligned Movement (Sneyd 2005; Thompson 2003)\(^\text{17}\). Their aspirations were forged in solidarity as a project for the Third World, one premised on political and economic independence, non-violent international relations, and a focus on the United Nations as the prime institution for global justice (Asian-African Conference of Bandung 1955; Prashad 2007: 27). This emphasis on peace and security in Third World discourse aligned well the ambitions of the United Nations. The Non-Aligned Bandung communiqué, for example, came to inform the Charter of the United Nations International Atomic Energy Agency (Prashad 2007: 58).

At the core of Third World discourse was a common set of economic and political objectives that were premised on this critique of colonialism. ‘Dependency theory’ arose in academic and political circles to reflect developing countries’ opposition to the dominance of former colonial countries in the international economic system (see Baran 1957; Cardoso and Falsetto 1979; Frank 1967). In Third World discourse, ‘neo-colonialism’ and ‘imperialism’ were terms used to describe the continuing cultural and economic domination of colonial countries over the Third World (see Singham 1976: 8). Based on this critique, a group of countries in the global South promoted a number of economic objectives to end

\(^{17}\) Despite this policy rhetoric for non-alignment, six of the 29 states at Bandung did have military-economic arrangements with the US and Britain (Prashad 2007: 53).
this dependence. The United Nations Economic Commission on Latin America (UNECLAC) championed import-substitution industrialisation (ISI) to promote local industrialisation. The policy instruments of ISI involved direct government participation in industries and the protection of domestic industry through protective tariffs, special preferences and preferential exchange rates (Baer 1972: 98). Throughout the 1950s and early 1960s, several developing countries, in Latin America in particular, implemented policies aimed to enhance their economic autonomy through the local production of essential goods, including medicines\(^\text{18}\).

In the 1960s, the global supply of medicines was dominated by pharmaceutical firms headquartered in Europe and the United States (Ballance, Pogany and Forstner 1992; Lall 1974: 144)\(^\text{19}\). Even India, the most advanced of the developing countries with respect to pharmaceutical production, was dominated by a small number of international corporations (UNCTAD 1976: 4)\(^\text{20}\). International companies maintained an oligopoly through their ownership of subsidiary firms, through licensing arrangements, and their concentration of patents. In the 1960s, Third World discourse enabled a critique of the international patent system which subsequently led to shifts in patent law in several countries in the global South.

The patent system in existence in the 1960s was the Union of the Paris Convention on Industrial Policy which established rules of non-discrimination for

\(\text{18}\) Aside from India and Korea, most developing countries did welcome foreign investment for local manufacturing under ISI (Sell 1998: 56). The process of ISI did achieve economic growth in some countries. Brazil, for example, expanded its industrial product growth rate by over 260 per cent by the mid-1960s (Baer 1964: 415).

\(\text{19}\) These firms were ‘highly integrated’ in that they conducted R&D, production, manufacturing, and marketing (Malèrba and Orsenigo 2001; Taggart 1993).

\(\text{20}\) In Mozambique, international pharmaceutical firms supplied 90 per cent of the medicines by brand name (Turshen 2001: 201).
the protection of trade in ‘industrial property’ (Paris Convention for the Protection of Industrial Property 1883). While only one-fifth of the developing world had officially joined the Union, several countries had modelled their patent laws on former colonial powers (Deere 2008; Okediji 2003; Ricketson 1987; UNCTAD 1975: 4; WTO 1947). In 1961, Brazil, the only member developing country since the inception of the Paris Convention, raised the issue of patents and their effect on developing countries’ industrialisation at the General Assembly of the United Nations (UNESA, UNCTAD and WIPO 1975: 35). Brazil proposed that the UN Secretary General prepare a study on the effects of patents on developing countries. After political manoeuvring between member states, however, this resolution was largely stifled by the United States and its allies, which were supportive of the patent system (May 2010; United Nations General Assembly 1961: 23). Nonetheless, what emerged throughout the 1960s and 1970s was a widespread critique of the patent system amongst academic and political circles in the Third World (see Greer 1973; Grundmann 1970; Penrose 1973; Vaitsos 1972).

The two main targets of criticism of the patent system by Third World academics were the overwhelming ownership of patents by foreign entities, and the fact that many patents were not used to develop products in developing countries. Vaitsos (1972: 74) documented, for example, that in Chile, foreign ownership of pharmaceutical patents increased from 35 per cent in 1937 to over 98 per cent in 1967. This increase in foreign patents was not translated into usage with the

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21 The majority of those developing countries that had joined the Union had done so after the main principles were established and had little influence on amendments to the Convention (UNCTAD 1977: 6). These rules were not uniform because different governments had ratified different versions of the Union (UNCTAD 1975: 5).
majority of pharmaceutical patents going unexploited, meaning they were not used for production and not licensed to third parties. In Columbia in the 1960s, for example, only 10 out of over 3000 patents were produced (Vaitsos 1972: 78). The government of India was scathing in its critique and asserted that the real rationale for patents was not that they were an incentive for domestic activity as claimed, but that they were used to protect export markets from competition (cited in Vaitsos 1972: 78).

Thus, several developing countries revised their patent laws in this period to promote local production (Sell 1998). In 1970, member states of the Andean community strengthened their national regulations over the operations of foreign businesses including limits on foreign investors’ use of patents (Decision 24 1970 in UNCTAD 2001: 47). That same year India reduced the period of patent protection for pharmaceutical processes from 16 to 7 years and ruled out patents for pharmaceutical products (Lall 1974: 165). The following year, Brazil amended its Patent Law so that chemical, pharmaceutical or nutritional products were not eligible for patents (Deere 2008; Gontijo 2005). Several other countries in the global South (and North) chose not to implement product and/or process patents for industrial technology (Deere 2008).

A noteworthy exception to these revisions of the patent system was the paradoxical creation of the World Intellectual Property Organization (WIPO) in the late 1960s. In 1967, 39 member states – 9 of which were developing countries – agreed to establish WIPO with the aim of promoting ‘the protection of

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22 The Andean Community is a trade bloc that was founded in 1969 by Bolivia, Chile, Colombia, Ecuador, and Peru.
intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization’ (Convention Establishing the World Intellectual Property Organization 1967).

The creation of WIPO reflected tensions between Third World demands for reduced patent protection on the one hand, and the position of the United States, which favoured more stringent protection on the other. Indeed, WIPO was likely a political response to the creation of two United Nations bodies a few years earlier, UNCTAD and the United Nations Industrial Development Organization (UNIDO). Both UNCTAD and UNIDO were established in the mid-1960s to promote and accelerate the industrialisation of developing countries. In UNCTAD, developing countries had begun to negotiate preferential tariff rates between themselves with the aim of ‘increasing export earnings, promoting industrialisation and accelerating economic growth’ (Generalised System of Preferences [1968], Resolution 21 (ii) in UNCTAD N.D.)

23. The creation of WIPO did little to stem the widespread critique of the patent system in the 1960s, however. This conflict would come to a head over 20 years later (see next chapter).

In addition to this critique and revision of industrial and patent systems, Third World discourse also enabled a language in which scholars, academics and policy makers could criticise the high price charged for medicines by international firms.

23 The US and its allies initially responded to the demands of the global South through the multilateral General Agreement on Tariffs and Trade (GATT) by adopting the Declaration on Promotion of Trade of Less-Developed Countries (1962) which called for ‘immediate steps’ to be taken for the ‘progressive reduction and elimination of barriers to the exports of less developed countries’ (GATT 1962: 24; United Nations Department of Economic and Social Affairs 1963). This was mainly rhetorical, however, and UNCTAD and UNIDO became the favoured forum for the Group of 77 to negotiate trade preferences.
in the global South (Antezana 1981). Throughout the 1960s, expenditure on medicines in several developing countries doubled to nearly four times that of the growth of their Gross National Product (GNP) (Piachaud 1980). In former French colonies Algeria, the Congo, and Tunisia, the price of medicines by French companies were higher than they were in France (Turshen 2001: 202). The rising price of medicines, which did little to stimulate economic industrialisation in the global South, contributed to significant cost pressures on governments. Throughout the 1960s, over one-third of the health budget in Thailand and over two-thirds of the health budget in Bangladesh was spent on medicines (UNESC 1981: 4). The need to reduce the price of medicines became a national issue across the global South, and indeed in industrialised countries (Mamdani 1992: 12). Through both pricing and patenting, Third World discourse enabled a critique of the oligopoly of foreign pharmaceutical firms in the supply of medicines in the global South (UNIDO 1978: 9)

As the supply and pricing of medicines received increasing attention, medicines regulation emerged on the agenda of the WHO. The catalyst was the thalidomide disaster in 1962, in which the over-the-counter (OTC) medicine thalidomide was the cause of birth defects in several countries. In 1963, member states of the WHO granted the organisation a new role in medicines governance by agreeing to communicate to the WHO any detection of ‘serious adverse side effects’ of medicines (WHA16.35 [1963] in WHO 1973a: 159). Shortly after, several developing countries called for the WHO to exert international authority over international pharmaceutical firms, which they claimed were pressuring them to allow unregulated medicines sales. This culminated in a request to the second
Director General of the WHO, Marcolino Gomes Candau, to examine ways to ensure the quality control of medicines (WHA16.38 [1963] in WHO 1973a: 130). As a Brazilian public health specialist, Candau was sympathetic to these calls (Kaplan 1983). Nonetheless, it was not long before member states were publicly critical of the ‘unsatisfactory situation’ by which they claimed that the WHO had not adequately assisted them in implementing quality control measures (WHA18.36 [1965] in WHO 1973a: 131).

In the late 1960s, the WHO developed a set of principles and guidelines for pharmaceutical and manufacturing quality control, known as Good Manufacturing Practices (GMP) (WHA22.50 [1969] in WHO 1973a: 133). These guidelines were based on the practices of the American Food and Drug Administration (FDA) which was emerging as a ‘gold standard’ in medicine regulation (Carpenter 2010: 694). Indeed, American-based international pharmaceutical firms played a key role in promoting the WHO GMP because they could meet the standards at a lower cost than generic firms based in the global South (Carpenter 2010: 715). Many developing countries appeared more concerned about the ‘widespread misleading information’ on the effectiveness of medicines by pharmaceutical advertising (EB41.R24,WHA21.41 [1968] in WHO 1973a: 144). Despite their calls for WHO support, however, they did not secure consensus from other member states to provide a role for the WHO in regulating pharmaceutical marketing.

In parallel to these conflicts over medicines regulation, the rise of Third World discourse saw new attempts by the WHO to strengthen its role in health research.
In the mid-1960s the Chief of the WHO Tuberculosis Unit, Halfdan Mahler, was receptive to the Third World movement and made a passionate call for a ‘radical reappraisal and perhaps equally radical extension of our efforts in health research’ (cited in WHO 1964). Around this time, the WHO Secretariat proposed that member states establish a World Health Research Centre to meet this purpose. Tensions were evident in the WHA, however, as several states refused to acknowledge such a role for the WHO. Eventually the idea of a World Health Research Centre was abandoned in place of a division of research on epidemiology and communications science within the WHO (WHA17.37 [1964], WHA18.43 [1965] in WHO 1973a: 28; WHO 2008d: 91)24.

This chapter has so far demonstrated that the rise of Third World discourse in the 1950s and 1960s enabled several developing countries to revise their industrial, trade and patent laws, which affected the governance of medicines. Notably, this movement formed outside the United Nations through the Non-Aligned Movement. While the UN was receptive to this project, its organisations were constrained by the opposition of the United States government. Third World discourse led to renewed debates in the WHO over medicines pricing, advertising, production, regulation and the coordination of research in this period. These conflicts laid the groundwork for subsequent battles, as the thesis will show.

A New International Economic Order and Health for All

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24 This conflict over the role of the WHO in medicines research re-emerges 40 years later (chapter six).
This section shows that it was a combination of the oil crisis and the broadening of the Non-Aligned Movement in the early 1970s which forced a softening of the United States opposition to the Third World project. This enabled the Declaration for a New International Economic Order (NIEO) in the United Nations that reflected the demands of the global South. This section demonstrates that the NIEO discourse emboldened UNCTAD to critique the international patent system, informed the creation of the WHO’s Tropical Disease Program, and was translated into a vision for ‘Health for All’ in the WHO. These developments were conducive to the health ambitions of the global South with respect to the governance of medicines.

A turning point for the global South in the ambitions for the Third World project was the oil crisis and the outbreak of the fourth Arab-Israeli war in the early 1970s. In 1973 the United States effectively ended the fixed-rate exchange system by removing its currency from the Gold Standard, triggering a dramatic fall in the price of oil. That same year, the Middle-East was occupied by the outbreak of the fourth Arab-Israeli war. In response to both the collapse of the oil price and the war, the Organization of Arab Petroleum Exporting Countries (OAPEC) raised the price of their oil and embargoed their oil exports to the United States (and the Netherlands) in an attempt to pressure the United States to withdraw its support for Israel. Within a year the international price of oil had increased by more than 500 per cent. This commodity power exercised by the Arab oil-exporting countries took the industrialised economies by surprise. Despite the rising

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This Accord had been established in the 1940s to promote a fixed exchange rate system whereby countries’ currencies were either fixed to the US dollar or the standard set by the dollar (Rowden 2009: 55).
oil prices, non-oil-exporting developing countries remained united alongside their
Arab counterparts in calls for a fairer international economic system26. Soon after,
the Non-Aligned Movement shifted its position away from ‘non-alignment’ to an
anti-imperial stance and welcomed as members socialist countries like Cuba. This
was a cause for concern for the US and led to a softening of the US opposition to
the Third World demands, in particular when ‘it became clear that the
conservative members of OPEC were going to join the radical ones in bidding for
the political leadership of the Third World’ (Thomas Enders, Assistant Secretary
of United States and American envoy to the United Nations General Assembly
cited in Frank 1975: 1481; Gosovic and Ruggie 1976).

In softening their stance against the Third World, the United States and its allies
(Germany, France, Japan and the UK) agreed to the adoption of a Declaration on
the Establishment of a New International Economic Order in the United Nations
(1974)27. This Declaration reflected the discourse of the Third World and was
centred on a ‘commonality of ideas’ for equity, sovereign equality,
interdependence, justice and peace (Cox 1979: 260; United Nations General
Assembly 1974: 1). The NIEO Declaration asserted that the ‘greatest obstacles’ to
the full emancipation and progress of developing countries were the remaining
‘vestiges of alien and colonial domination, foreign occupation, racial
discrimination, apartheid and neo-colonialism in all its forms’ (United Nations
General Assembly 1974). It aimed to facilitate a fairer international system for

26 Brazil, for example, reported that 40 per cent of its export earnings went to oil
payments in the early 1970s (Gosovic and Ruggie 1976: 320; Toye and Toye 2005; 169).
27 The US, Germany, France, Japan and the UK annexed several reservations to the text.
For example, in response to the oil mobilisation, the United States asserted that ‘such
artificial attempts to manage markets which ignore economic realities and the legitimate
interests of consumers as well as producers run the risk of political confrontation on the
one hand and economic failure on the other’ (American Ambassador Scali cited in White
1975: 548).
developing countries (United Nations General Assembly 1974). At the core of the NIEO was the sovereign equality of states and the sovereign rights of states over their economic and social systems as an ‘inalienable right’\textsuperscript{28}. In the 1970s the Declaration for a NIEO was widely considered as evidence of the increasing political power of the global South (see White 1975: 543; White and Bidwell 1978: 626).

The rise of the NIEO in the United Nations emboldened the agencies of the UN to introduce and implement rules that were aligned with these ambitions. Notably, UNCTAD finally commenced negotiations to create new international rules for technology transfer and the patent system with the ambition of promoting local production, including for medicines. While this was opposed by the United States and its allies, developing countries retained a majority of votes within UNCTAD to pursue their objective (Vaitsos 1976: 85). In the mid-1970s UNCTAD released its review of the patent system (UNCTAD 1975). This report clearly reflected the NIEO, it emphasised the importance of ‘public rights’ in patent laws (UNCTAD 1975: 8) and was critical of the Paris Convention for an imbalance that favoured the private sector (see also UNCTAD 1977: 4). UNCTAD (1975:19) asserted that the Paris Convention was in ‘direct opposition to the objective of promoting domestic industrialization in the developing countries’.

Notably, UNCTAD (1975: 2) cautioned developing countries against relying on measures like compulsory licensing, which were provisions in the Paris Convention that enabled governments to override patents without patentee

\textsuperscript{28} This conception of natural rights would later be challenged under neoliberalism (see chapter three).
consent, based on certain conditions. UNCTAD (1975: 2) largely saw these measures as ineffective because of ‘examination procedures, the behaviour of transnational corporations (TNCs), and lack of know-how’. It stressed the need to employ a full range of policy instruments and ‘move away from the limited and limiting emphasis on one single policy, namely compulsory licensing, which has proved such a poor remedy’ (UNCTAD 1975: 17). This is significant in light of the re-emergence of this debate two decades later, in which the global South came to rely on compulsory licensing ‘safeguards’ and appeared to ignore these earlier cautions (see Chapter four).

In its review, UNCTAD (1975: 2) concluded that the ‘international patents system is not, in its present form, proving to be of benefit to the developing countries and that it is instead having a negative effect on their development’. Interestingly, the newly established WIPO requested to be included as a co-author on the UNCTAD report, despite having a very different ideological approach to the patent system. According to May (2010: 24), this was a strategy of the WIPO Director General, Arpad Borsch, to ‘link up’ with the UN and increase the exposure of WIPO to the global South. In 1975, UNCTAD (1975: 17) recommended that a revision of the Paris Convention take place to give member states the right to adopt legislative measures, ‘providing for use or expropriation by the government of patented inventions for whatever purposes are deemed necessary for national development’. This revision process commenced shortly after in WIPO, and signalled the success of Borsch in convincing developing countries that WIPO was the appropriate venue for such deliberations (see more in following chapter). Soon after, UNCTAD commenced its own negotiations on a Draft Code of
Conduct on Technology Transfer, which aimed to facilitate technology transfer and research and development in developing countries (more detail in following chapter; Roffe [Chief of Legal Policies UNCTAD] 1985: 693; Thomas 1998: 2107-8). These developments would ultimately fail in the 1980s with the demise of the NIEO (see next chapter). The point for this chapter is that the global South was successful in shifting the policy approach of the United Nations in the 1970s when the NIEO was at its peak.

The NIEO Declaration was also a turning point for a shift in the WHO. In parallel to the NIEO Declaration, Halfdan Mahler, former Chief of the Tuberculosis Unit was appointed as the third Director General of the WHO in 1973 (WHO 1973b). Mahler brought the issue of the need for effective medicines in developing countries back on the WHO agenda (WHO 1973b, 1974b). Indeed, Mahler linked the health needs of developing countries to the moral authority of the WHO by claiming that the NIEO gave the WHO a ‘moral imperative’ (Mahler 1975b):

There is an urgent need to ensure that the most essential drugs are available at a reasonable price and to stimulate research and development to produce new drugs adapted to the real health requirements of developing countries (Mahler 1975a).

As Mahler promoted the medicine needs of the global South, medicines became a significant point of focus in the Non-Aligned Movement. In 1975, developing countries through the World Health Assembly called on the WHO to assist in the formulation of national medicines policies that would link research, production and distribution of medicines with ‘real health needs’, and to advise governments
on ‘the selection and procurement, at reasonable costs, of essential medicines’ (paragraph 3(b) WHA28.66 [1975] in WHO 1985a: 73; WHO 1975c). The following year, the conference of the Non-Aligned Movement began to coordinate amongst the member states plans for cooperation in the production, procurement and distribution of medicines (Fifth Conference of Heads of State or Government of Non-Aligned Countries 1976). Sri Lanka, Papua New Guinea, Cuba, Costa Rica, India, Egypt, Mexico, Pakistan, and Peru shared their experiences in creating national medicines formularies with the broader movement (Antezana 1981; Capo 1983; Mamdani and Walker 1985; Turshen 2001: 204). It was within the Non-Aligned Movement that developing countries formed a concerted policy for medicines which linked industrial and social objectives. The fifth Conference of the Non-Aligned Countries called for the exclusion of pharmaceutical patents, the removal of brand names, the adoption of generic names, and the creation of regional co-operative pharmaceutical production and technology centres (Fifth Conference of Heads of State or Government of Non-Aligned Countries 1976: 2).

The Non-Aligned Movement was influential in the United Nations. The UN Secretary General attended the 1976 conference and committed the UN as a global body that would respond to its concerns (Singham 1976: 4). Soon after, UNCTAD, WHO and UNIDO formed a joint task force to implement the Non-Aligned Movement’s recommendations (Greene 2010; United Nations General Assembly 1976; WHA22.54 [1969] in WHO 1973a: 134). The WHO adopted policies to promote the use of generic names in national medicines formularies, as well as price regulation (WHA31.32 [1978] in WHO 1985a: 75). WHO Director
General Mahler responded to calls for WHO assistance in the regulation of medicines by calling for member states to grant the organisation ‘not just technical but political and moral authority to protect developing countries’ (WHO 1975b).

The NIEO also emboldened the WHO to intensify its work in co-ordinating biomedical research (WHO 1974a; WHA28.70 [1975] in WHO 1985a: 33). In 1976 the WHO’s Advisory Committee for Medical Research approved the establishment of a Special Programme for Research and Training in Tropical Diseases (TDR) under the purview of the WHO (WHO 1976). The objective of TDR was to develop tools for the control of eight diseases; malaria, leprosy, schistosomiasis, visceral and cutaneous leishmaniasis, onchocerciasis, lymphatic filariasis, Chagas disease and human African trypanosomiasis (HAT), and to strengthen the research capacity of the affected countries themselves (WHO 1978).

TDR received widespread support within the United Nations and was co-sponsored by the United Nations Children’s Fund (UNICEF), the United Nations Development Programme (UNDP) and the World Bank. Member states of the WHO initially allocated 11 million dollars to TDR, which at the time represented about two-thirds of global spending on research into tropical infectious diseases (WHO 2008d: 106). WHO Director General Mahler also adopted WHO research policy guidelines, which gave attention to the role of WHO in strengthening national research capabilities and promoting cooperation and transfer of existing and new scientific knowledge ‘to those that need it’ (WHA30.40 [1977] in WHO
Through TDR, the WHO strengthened its role in co-ordinating biomedical research with the aim of developing new and effective medicines for the global South.

The aforementioned developments in the WHO led to the creation of a new international health policy framework. In 1978, at the first international conference on Primary Health Care in the Union of Soviet Socialist Republics (USSR), the WHO and UNICEF translated the NIEO into the vision of ‘Health for All’. This was encompassed within the Declaration of Alma Ata (WHO and UNICEF 1978) which asserted that:

…the existing gross inequality in the health status of peoples is of common concern to all countries and must be drastically reduced. An equitable distribution of health resources, both among countries and within countries, leading to universal accessibility to Primary Health Care and its supporting services is therefore fundamental (WHO 1981a).

Through Alma Ata, member states of the WHO agreed that their ‘main social target’ would be the attainment ‘by all people of the world of a level of health that will permit them to lead a socially and economically productive life by the year 2000’ (WHO 1981a)29. Access to medicines was a clear objective: ‘essential health care will be accessible to all individuals and families, in an acceptable and affordable way, and with their full involvement’ (WHO 1981a).

29 The World Health Assembly subsequently launched the *Global strategy for health for all by the year 2000* at the thirty-fourth World Health Assembly in 1981 (WHA34.36 [1981] in WHO 1985a).
The most urgent need regarding drugs at this stage is to make it possible for the vast majority of the world's people who live in the developing countries to have access at a cost they can afford. The aim of such a drug policy should be to ensure the constant availability of and access to efficacious drugs of acceptable quality and safety to all in need wherever they live and whatever their socioeconomic status, including dwellers in urban slums and rural areas (Director General Halldfan Mahler cited in WHO 1985b).

This discourse of ‘Health for All’ enabled the WHO to present a strong case for medicines policies that centred on improving the health of society. For the WHO (WHO 1981a) this meant ‘selecting technology that is appropriate for the country… adaptable to various local circumstances, acceptable for whom it is used and to those who use it, and maintainable with resources the country can afford’. At the core of ‘Health for All’ was the responsibility of governments in providing health care. This included, but was not limited to, establishing national medicines policies and legislation, the selection of medicines, pricing, regulation, procurement, quality assurance, and providing ethical criteria for medicine promotion and enforcement (WHO 1981a). In this way, the ambitions for ‘Health for All’ with respect to medicines were aligned with the industrial economic objectives of the global South. Indeed, as explained in more detail below, the bodies of the UN linked the two ambitions together. UNIDO (1978), for example, promoted the local production of medicines within this vision of improving R&D for health needs in the global South. Similarly, in their industrial economic policies, both UNCTAD and UNIDO linked the practices of international pharmaceutical firms with the WHO’s health concern over the irrational use of medicines (UNCTAD 1980: ix; UNIDO 1978: 23).
The NIEO and the new policy for ‘Health for All’ finally led the WHO to publish its first *Model List of Essential Drugs* in 1977, which comprised 208 generic medicines and vaccines known to be therapeutically effective (WHO Expert Committee on the Selection of Essential Drugs 1977). The WHO defined essential medicines as of ‘utmost importance, and hence basic, indispensable and necessary for the health needs of the population. They should be available at all times, in the proper dosage forms to all segments of society’ (WHO Expert Committee on the Selection of Essential Drugs 1977). The creation of this list was symbolic in conceptualising essential medicines as public goods rather than mere commodities (Greene 2010: 483). The WHA subsequently endorsed the establishment of an Action Programme on Essential Drugs and Vaccines (APED) within the WHO to address the problem that ‘large segments of the world’s population do not have access to the most essential drugs and vaccines that are indispensable to their health care’ (WHA31.32 [1978] in WHO 1985a: 74, see more below). WHO Director General Mahler located the Action Programme in the office of the Director General, signifying its importance to the Secretariat.\(^{30}\)

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**The battle for essential medicines**

\(^{30}\) Despite the eventual weakening of essential medicines policy at the international level, many European governments did introduce laws consistent with the WHO’s medicines policy. Germany introduced rules for the rational prescription of medicines in the public health system (UNCTAD 1982: iv). Norway, Denmark and Holland legislated restrictions on ‘nonessential’ medical products (Walt and Harmmeijer 1992: 30). The Netherlands was instrumental in establishing the international conference on the Rational Use of Drugs in Nairobi in 1985 which expanded the work of the WHO beyond advising on selection and procurement encompassing advice on distribution, rational use of medicines, and quality assurance (WHO 1985b). Even some states in the United States introduced laws permitting pharmacists to substitute generics in place of branded medicines (Chowdury 1995: 10).
The WHO’s Model List of Essential Medicines (1977) triggered a significant political contest in and outside the WHO. In this section I demonstrate that the WHO’s ambitious vision for essential medicines policy was weakened by the strong opposition of several international pharmaceutical firms and the government of the United States. Essential medicines policy was not abandoned, however, and I highlight the key role of the bodies of the United Nations, which engaged in a public discursive contest with the pharmaceutical industry. The international health advocacy network, Health Action International (HAI), was also formed by national consumer non-government organisations in this period to counter the voice of the IFPMA. Indeed, conflict over medicines policy was a catalyst for and, in part, an outcome of the emerging influence of non-state actors in international medicines policy.

In 1968, several international firms headquartered in Europe and the United States formed their global lobbying association, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), in response to the Third World project (see IFPMA. N.D.). As discussed above, developing countries had successfully brought the patent system onto the agenda of UNCTAD and had begun to revise their patent laws to enhance local production of medicines. These moves threatened the profits of the international firms, who had maintained an oligopoly on drug supply in most developing countries. The international firms also created national and regional lobbying associations under the umbrella of the IFPMA, including the Pharmaceutical Manufacturers of America (PMA; 1958), the Japan Pharmaceutical Manufacturers Association (1968), the European Federation of Pharmaceutical Industries and Associations
(EFPIA; 1978), and the Association of the British Pharmaceutical Industry (APBI).

In 1971, the WHO granted the IFPMA status in the organisation as an officially recognised non-government organisation (NGO) (EB39.R44 [1971] in WHO 1973a: 550). This enabled the IFPMA to attend the WHO governing bodies as an observer and to lobby the member-state delegations in attendance. Initially, the WHO sought to appease the IFPMA by consulting the organisation over its plans for its Model List of Essential Medicines (Walt and Harnmeijer 1992: 30). After the release of the list in 1977, however, the IFPMA publicly declared the concept of essential medicines ‘completely unacceptable’ (cited in Tiefenbacher 1977: 23).

The IFPMA began a concerted attack on the WHO’s Medicine list by framing the list as a threat to public health (IFPMA cited in Laing et al. 2003). The IFPMA argued to governments and to national medical associations that the use of restricted lists ‘could severely retard medical care and would discourage investment by the pharmaceutical industry in research’ (cited in Reich 1987: 49). The lobbying group sought to undermine the WHO by convincing medical associations that the essential lists would restrict the ‘rights’ of prescribers and would threaten the quality of medicines. This strategy was effective in several countries (see Chowdury 1995: 9; Lasagna 1979: 232). In Sri Lanka and in Bangladesh, for example, private medical doctors joined local representatives of the international pharmaceutical industry in opposing reforms (Chowdury 1995: 67; Reich 1995: 61). In Brazil, an early scheme for essential medicines was
opposed by the medical profession (UNCTAD 1976: 8). On the international scene, the largest ally for the industry was the United States government, which echoed the industry claims. Several of the international firms, such as Pfizer, were headquartered in the United States. Despite the ambitions of the global South, in the WHO the US delegation framed the WHO medicines list as one that would ‘prevent therapeutic progress, be a major disincentive to research, and prevent the important discovery of new indications for drugs’ (WHO 1985b).

This discursive challenge by the IFPMA and US was accompanied by their flexing of material power. The international pharmaceutical firms of the IFPMA represented a significant proportion of the source of the world’s medicines. Acting as a bloc, the IFPMA members refused to cooperate with the WHO and UNICEF’s plans for a bulk purchasing scheme for essential medicines in African nations, as requested by the Non-Aligned Movement (see above; Walt and Harnmeijer 1992: 33, 41). In the WHO, the United States opposed the Director General Mahler’s call for member-states to grant the organisation ‘not just technical but political and moral authority to protect developing countries’ (WHO 1975a, 1975b). The US even withheld its financial contribution to the WHO in 1986 and 1987, which many attribute to its anger over the WHO’s position on medicines (Hardon 1992: 60; Turshen 2001: 203)31. This resistance was felt in the budget of the WHO. Only France provided the extra-budgetary resources for the WHO Action Programme in its early years (Walt and Harnmeijer 1992: 32)32.

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31 In the 1980s the United States contributed 25 per cent of the WHO’s budget (Chowdury 1995: 138).
32 The WHO’s budget relies on assessed contributions from member-states based on a percentage of their GDP and on extra donations.
Despite the material constraints on the WHO in this period, the United Nations organisations played a key role in keeping the concept of essential medicines alive by maintaining a strong discursive challenge to the IFPMA and US. WHO Director General Mahler was outspoken in rejecting the US claim that the WHO was overstepping its role in medicines policy. Instead, Mahler asserted that such a role was within the constitutional mandate of the organisation (WHO 1985b). UNIDO was vocally critical of the ‘continuous state of dependence’ in the global South ‘on expensive, inappropriate technology developed and controlled by foreign transnational corporations’ (UNIDO 1978: 33). UNCTAD (1980: 21) shared this critique. When the IFPMA asserted that a program of centralised bulk procurement for medicines would reduce the availability of medicines, UNIDO publicly refuted this claim, pointing to the quickness of non-patent-observing producers in making medicines available (UNIDO 1978: 13). UNIDO and the United Nations Conference on Transnational Corporations (UNCTC) praised the efforts of developing countries like Sri Lanka and Brazil who had turned to centralised procurement and tendering for generic suppliers from non-patent-observing sources (Reich 1995; UNCTC 1984; UNIDO 1978). Despite the refusal of the IFPMA firms to cooperate with UNICEF and WHO, UNICEF strengthened its Packing and Assembling Centre (UNIPAC) and enhanced its competitive tendering and bulk purchasing through generic sources (UNICEF-WHO Joint Committee on Health Policy Session 1987). With few extra-budgetary funds for its Action Programme on essential medicines, the WHO turned to supporting essential medicines projects that were sponsored by development agencies, such as the Danish International Development Agency (DANIDA) (Walt and Harnmeijer 1992: 33).
The role of the patent system in medicines R&D was a significant source of political conflict between the UN organisations and the IFPMA. The IFPMA claimed that strong pharmaceutical patent protection was needed in the global South to recoup R&D costs, ‘to reduce the price of drugs would be to reduce the amount of research carried out and put a brake on medical progress’ (IFPMA in WHO 1985b). UNIDO and the UNCTAD directly challenged this claim and pointed out that for those medicines developed primarily for developed economies, ‘there was no lack of incentive created by poor countries buying elsewhere’ (UNCTAD 1980: 7; UNIDO 1978: 13). UNCTAD (1976:4) revealed that the R&D expenditures of IFPMA firms were not as high as their marketing and sales figures, which damaged the industry’s claims (see also Chew 1985; SCRIP 1988). UNCTAD (1980: 4) asserted that much of the ‘so-called research in industrialised countries goes into the development of more pleasing tastes, colours and packaging…towards the unnecessary and inappropriate consumption of medical drugs’. The WHO DG Mahler was critical of the lack of transparency within the pharmaceutical industry:

It is still difficult to know how much money is required to generate new drugs. In my humble opinion the only way to even start to sort out this question is to collect relevant and coherent facts; they are very difficult to get hold of (Mahler cited in WHO 1985b).

The UN organisations not only opposed the IFPMA’s claims, they advocated for a socially oriented system for medicines R&D that did not prioritise patents. For the WHO DG Mahler, ‘the consequential pattern of drug development, with its
emphasis on treatment and prevention of the common diseases of affluent communities, draws criticism as being ill-adapted to global therapeutic needs’ (WHO 1985b). Thus, Mahler called for ‘socially oriented approaches to new drug development’ (Mahler 1975a). UNCTAD (1980: 25) emphasised the strong role of government in supporting local R&D, ‘no developing country – in fact no country at all – can afford laissez-faire in research; this activity should be directed towards certain specific goals and objectives reflecting national needs’. UNIDO (1978) also foresaw a different system, one in which developing countries would contribute towards R&D according to their incomes and health needs. These proposals for a socially-oriented approach to medicines R&D would re-emerge thirty years later, albeit in different forms through different actors (see Chapter six).

Illustrative of the strong position taken by the UN organisations in this period was the WHO policy on patents. In this context of ‘the need for affirmative action’, member-states of the WHO agreed that:

It shall be the policy of the WHO to obtain patents...or interests in patents on patentable health technology developed through projects supported by WHO, where such rights and interest are necessary to ensure development of the new technology: the organization shall use its patent rights, and any financial or other benefits associated therewith, to promote the development, production, and wide availability of health technology in the public interest (WHA35.14 [1982] in WHO 1985a: 82).

This conflict between the IFPMA and the UN was a catalyst for the formation of the international health advocacy network Health Action International (HAI) in
1981. In response to the IFPMA’s pressure on the WHO, over 50 consumer organisations from 26 countries established Health Action International (HAI) with the stated aim to resist ‘the ill-treatment of consumers by multinational drug companies’ (Fazal 2006: 4).\(^{33}\) HAI was supportive of the WHO’s proposals for restrictive medicines lists and for improved medicines registration and went even further in seeking the ‘decommercialisation’ of medicines (Fazal 1983; 2006: 5; Hardon 1992: 57). As a consumer health group, HAI supported medicines policy that strengthened its health value. In the early 1980s, HAI and the IFPMA engaged in a discursive battle at the World Health Assembly and the Executive Board of the WHO. Indeed, HAI and the IFPMA became embroiled in a struggle over the issue of medicines marketing and regulation in the early 1980s. This conflict (explained below) exemplifies the rising influence of non-state actors in the WHO in this period, and demonstrates the powerful resistance of the IFPMA and the United States to attempts to establish medicines policy that threatened the profits of these firms.

The catalyst for the battle over an international code of marketing for medicines was the WHO’s International Code of Marketing of Breast Milk Substitutes (WHO 1981b) that was secured through the advocacy of the International Baby Food Action Network (IBFAN) (Laing 2003; Lee 2010: 7).\(^{34}\) For HAI, IBFAN’s success in securing this code demonstrated what could be achieved in medicines regulation. HAI subsequently advocated for an international code on the

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\(^{33}\) The intention of HAI was and remains to ‘resist such obstruction through community action at the grassroots level’ (Roland Fett spokesperson for BUKO cited in Fazal 2006: 4).

\(^{34}\) This code was approved by all member states of the WHO except the US. While it was a landmark case for health regulation of transnational corporations, the code ‘fell short’ because it does not penalise actors who do not comply (Lee 2010).
marketing of medicines (Health Action International 1982). The IFPMA preempted HAI’s proposal, however, and in 1982 released its voluntary code of marketing, which was rejected by HAI and by several developing countries. The IFPMA resistance was stronger than that of Nestle and HAI was unable to garner support from several member states, in particular those headquartered by the IFPMA firms. Eventually, after years of struggle in the WHO, Charles Medawar of HAI lamented that it was ‘unrealistic to expect WHO to become involved in formal, full-scale international regulation’ (see Medawar 1985). Years later, the WHO eventually developed the weaker ethical criteria for marketing to serve as ‘general principles…that did not constitute legal obligations’ (WHA 41.17 [1988] in WHO 1993: 89).

In addition to weakening international rules on marketing and regulation, the WHO’s essential medicines policy was also weakened to serve as a guideline for the public sector in developing countries. This coincided with the IFPMA shifting its position from outright opposition to the concept of essential medicines to acceptance (at least in public rhetoric) that essential medicines policy could be used in the public sector in developing countries (see Greene 2010; Peretz 1983). By the early 1980s, most of the member states of the WHO agreed to weaker text which recognised essential medicines policy as primarily for the public sector in developing countries (Chowdury 1995; Laing 2003: 42). This was still opposed by the United States, and Japan and West Germany abstained from voting. This weaker focus on guidelines was pushed by the IFPMA who argued that the WHO ‘could not perform as a supranational regulatory body’, which was subsequently confirmed by the WHO Secretariat (IFPMA 1985; WHO 1985b).
Conclusion

This chapter has examined the evolution of international medicines governance between the creation of the WHO and the formation of the WHO’s essential medicines policy. The chapter has shown that over four decades, the United States government opposed and prevented a role for the WHO in international medicines policy, in particular when such policy threatened the profits of its pharmaceutical firms. The chapter has situated developments in international medicines governance within broader shifts in the global political economy in this period. In the 1960s, Third World discourse enabled the global South to demand international governance in the issue-areas of medicines research and development (R&D), production, access and regulation. This strengthening of solidarity between Soviet, Middle-Eastern, Asian and African countries in the early 1970s forced the softening of the opposition of the United States, which enabled the vision of a New International Economic Order in the United Nations. The adoption of the NIEO informed the WHO’s project of Health for All and the WHO’s Model List of Essential Drugs in the late 1970s. These developments were the catalyst for the formation of the international pharmaceutical lobby group, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), which exerted economic power and shaped a weakening of the WHO’s essential medicine policy.
CHAPTER THREE

Neoliberalism: Selective Health Care and Private Rights

Following on from the previous chapter, this chapter commences the study in the early 1980s and concludes with the establishment of the World Trade Organizations’ Trade Related Agreement on Intellectual Property Rights (TRIPS) in the mid-1990s. The chapter shows that shifts in the global governance of medicines in this period privileged international pharmaceutical firms and failed to address many of the health needs of the global South. Medicines governance was transformed through shifts in economic, health and trade policy that were the result of a broader forum-shifting strategy of the United States and its allies to block the New International Economic Order and promote neoliberalism.

The chapter demonstrates that neoliberal economic restructuring strengthened the dominance of international pharmaceutical firms in global medicines research and development (R&D), production and trade. In health policy, I show that the World Bank and UNICEF promoted a turn to ‘selective’ primary health care (SPHC) that complemented economic reforms by providing a rationale and justification for a narrow role of government in health. Under this approach, several core aspects of the WHO’s essential medicines policy were neglected and shifted to the periphery, with a devastating effect on health. In addition, shifts in international trade policy in this period, in which the TRIPS agreement was finalised, presented new global architecture for medicines R&D that privileged the private ‘rights’ of patent holders over the health needs of the global South. The chapter highlights the role of international pharmaceutical firms in shaping
TRIPS, and the role of the World Bank and General Agreement on Tariffs and Trade (GATT) in diffusing neoliberal reforms in international economic, health, and trade policy.

The chapter draws on an a critical analysis of summary records, resolutions, and reports of the governing bodies of the World Health Organization (WHO), the United Nations Conference on Trade and Development (UNCTAD), the General Agreement on Tariffs and Trade (GATT), as well as World Bank reports, annual reports of the United States Trade Representative (USTR), and statements by government leaders (see Appendix Two).

Medicines under neoliberalism

In this section I demonstrate that neoliberal economic restructuring in the 1980s extended the dominance of international pharmaceutical firms in the global supply of medicines. The United States played a key role in creating the structural conditions which enabled the World Bank and International Monetary Fund to emerge as dominant sources of financial aid for developing countries in the 1980s and 1990s. Through this position of dominance, these global economic institutions imposed conditional loans premised on neoliberal policy reforms that contributed to an overall decline in the share of world medicines production and consumption in the global South.

In the early 1980s, the United States government strengthened its opposition to the ambitions of many developing countries in the New International Economic
Order. This coincided with the spread of neoclassical economic theory within academic and political circles in the US and the UK. In contrast to Third World discourse, neoclassical economic theory is premised on a critique of Keynesian government intervention in the market (see Hayek 1944). In political circles, neoclassical economics was intertwined with liberal assumptions of the primacy of the individual, and individual rationality and responsibility (McGregor 2001; Rowden 2009; Sambala, Sapsed and Mkandawire 2010). The President of the US, Ronald Reagan, and the United Kingdom’s Prime Minister, Margaret Thatcher, were influenced by neoliberalism (Thatcher 1993: 169; Sell 1998: 97). Reagan and Thatcher viewed the private sector, or the ‘free market’ as the most effective form of governance (Harvey 2005; Ranelagh 1991; Reagan 1984, 1988; Thatcher 1993: 169)35. Both leaders implemented neoliberal policies domestically by deregulating their economies, reducing government expenditure and privatising publicly owned entities (Harvey 2005; Navarro 2007).

Neoliberalism provided the United States and its allies with a new language to oppose the NIEO. American neoclassical economists framed the Third World demands for international social justice and re-distribution as ‘monopolistic’ and ‘discriminatory’ (see Johnson 1976: 13). In contrast to the Third World critique of the structural inequalities within the international system, these inequalities were depicted under neoclassical economics as the result of ‘laziness, recklessness and lack of individual responsibility’ within developing countries (see Johnson 1976: 13). The United States government reformed its foreign aid program in the early

35 Despite this rhetoric to the ‘free market’, neoliberalism does not do away with the role of the state. As the chapter and thesis demonstrates, the state and government remain crucial to protecting and promoting the market (Löfgren and Benner 2007; Rowden 2009; see more below).
1980s in support of private enterprise (Livingston 1992). This signified a shift in the position of the US and its allies against the NIEO. Whereas the US had softened its stance in the early 1970s amidst the oil crisis (see previous chapter), in the 1980s Reagan and Thatcher aggressively opposed the NIEO in the United Nations. Instead they asserted that developing countries adopt and promote trade liberalisation, foreign investment and privatisation to meet their economic objectives (Goldstein 1982; Livingston 1992; Toye and Toye 2005).

Because the United Nations organisations were strong supporters of the NIEO, the United States turned to the World Bank as an ally. Unlike the United Nations, the United States exerted significant influence over the World Bank. While the US is the largest funder to the UN and to the World Bank, UN organisations work on ‘one state one vote’. At the World Bank, however, the US retains over fifteen per cent of the voting power through its financing role, and has effective veto power because the Bank requires at least eighty-five per cent agreement from votes (Stein 2008: 7). In 1981, former Bank of America President A.W Clausen became President of the Bank and initiated sweeping reforms, replacing many staff with American economists (Rowden 2009). By 1991, over 80 per cent of all Senior Staff of the policy, research and external affairs departments of the Bank had been trained in US or UK universities (Woods 2000). This coincided with a refinement of the policy ambitions of the Bank towards poverty reduction through ‘facilitating capital investment, private foreign investment and international trade’ (World Bank 1989). These internal shifts occurred at the same time that the Non-

36 By the early 1980s the World Bank had been in existence for over thirty years, and was mainly a source of financial loans for European countries in post-war restructuring.
Aligned Movement was demanding that the global economic institutions be made more democratic (New Solidarity International Press Service 1976; WIPO N.D.)\textsuperscript{37}. The World Bank was soon at odds with the United Nations over favoured industrial economic and development policy for the global South. While the United Nations was supportive of the NIEO, the World Bank’s annual ‘development’ reports formed a critical view of the role of the state in economic development (World Bank 1981, 1983, 1985). The Bank opposed several UN-supported policies, such as subsidised interest rates, minimum wage laws and price restrictions (World Bank 1983: 53). At the same time, the World Bank was not highly critical of tariff barriers imposed by the United States and other industrial countries, which UNCTAD rejected (UNCTAD 1975, 1976, 1977, 1980).

A turning point for the demise of the NIEO was in the early 1980s when the World Bank emerged as the only source of ‘quick dispersing foreign exchange’ for developing countries (Weaver 1995: 4). This was a result of a combination of policy shifts by the United States and by private commercial banks. Commercial banks had increased their loans to developing countries eight-fold in the 1970s as a result of the declining price of raw commodities, which a majority of developing countries relied upon for their essential imports, like crude oil (Baer 1964; Singham 1976; United Nations Department of Economic and Social Affairs 1963: 1; World Bank 1985: 4)\textsuperscript{38}. In the late 1970s the United States government and several commercial banks increased their interest rates, with the US

\textsuperscript{37} The Non-Aligned movement sought to reform these economic institutions, viewing them as agents of structural asymmetries in the international system (WIPO N.D).

\textsuperscript{38} If the terms of trade had remained stable over the 1960s, the aggregate purchasing power of developing countries would have been greater by over two billion dollars (United Nations Department of Economic and Social Affairs 1963: 2).
increasing its interest rates from less than one per cent to 11 per cent (Helleiner 1994; Soederberg 2004). Within two years between 1978 and 1980, the debts of oil-importing developing countries increased from 26 billion to over 708 billion dollars (World Bank 1981: 1). This rising debt was met with US restrictions on money supply and the suspension of new loans by private commercial banks. In 1982, the debt crisis was made manifest when Mexico announced that it could not finance its debts. The World Bank and the International Monetary Fund, another entity in which the US held veto power (Stein 2008), emerged as the only source of foreign exchange for several developing countries.

Through their newfound position of dominance in global lending, the World Bank and the IMF required that recipients of their loans implement neoliberal policy reforms. These ‘national structural adjustment loans’ were oriented to ‘shock’ recipient countries towards expanding exports through trade liberalisation, deregulation, and privatisation (Homedes and Ugalde 2005; Joyce 2000; Labonté and Schrecker 2009: 12; Rowden 2009; Weaver 1995: 4; World Bank 1980: iii; World Bank 1981: 55, 103). Core policy prescriptions included the de-valuation of national currencies and the reduction of government expenditure in favour of privatisation (Ballance, Pogany and Forstner 1992; Joyce 2000; Labonté and Schrecker 2007; Weaver 1995: 9, 152; World Bank 1993: 45). In the 1980s and 1990s, the World Bank and IMF negotiated over 950 of these structural adjustment loans with countries in the global South (Easterly 2001). These kinds of reforms were also implemented by governments of their own accord, without prompting from the World Bank. Several Asian and Latin American governments, for example, strongly promoted foreign investment and
privatisation throughout the 1980s (Hansen 1989: 51). This reflected the diffusion of neoliberalism and the demise of the NIEO, which was also a result of the breakdown in solidarity between developing countries in this period. Arab oil-exporting countries, Latin American countries and Asian countries had negotiated separate trade deals with the US and industrial countries, which led to the breakdown of solidarity between the Group of 77 countries (Toye and Toye 2005).

These reforms contributed to an overall decline in the share of world medicines production in the global South by 1990 (excluding South and East Asia) (Ballance, Pogany and Forstner 1992: 3, 23). Production in developing countries represented nearly 23 per cent of total world production in 1975, yet it decreased to just over 18 per cent in 1990 (Ballance, Pogany and Forstner 1992: 23). The de-valuation of national currencies, which was a core policy prescription of the economic institutions, led to significant increases in the price of raw material imports, making the production of medicines prohibitively expensive for several countries (Ballance, Pogany and Forstner 1992: 152; Nur, Postma and de Wilde 1989: 236; Owino 1996: 158). De-valuation also increased the price of imported medicines39. In Tanzania, the de-valuation of the shilling caused the price of medicines to rise by over 300 per cent (Turshen 2001: 99). Instead of increasing their share in export trade, the share of global trade in the global South declined to less than 10 per cent (of total global trade) (WHO 1988b: 25)40.

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39 As a whole, developing countries still relied on imports for over 40 per cent of their essential medicines. This figure was higher in African nations, who sourced 96 per cent of their essential medicines from Europe (WHO 1988b: 26).

40 India was an exception and doubled its medicines exports in one year between 1988 and 1989 (Ballance, Pogany and Forstner 1992: 196; Bhutta 2001). This was because India did not implement these kinds of neoliberal reforms. India’s Drugs Policy (1978)
The debt crisis and the aforementioned policy reforms also contributed to an overall decline in developing countries’ share of the world consumption of medicines (Bhutta 2001; Holm 1995: 102; Tevera 1995; World Bank 1996: 714). By the late 1980s, less than 15 per cent of all medicines were consumed in developing countries, three-quarters of which in only eight countries (Ballance, Pogany and Forstner 1992: 204; Bol, Polderman and Schonhals 1989: 186; Hansen 1989: 53; WHO 1988b: 9). Decreasing government expenditure on health and a lack of foreign currency for medicines procurement were particularly destructive. In Nigeria, the health budget in 1985 was one third of the 1981 health budget (Bol, Polderman and Schonhals 1989: 189). Lack of access to essential medicines remained a crucial problem for many developing countries (Ballance, Pogany and Forstner 1992: 216). By the early 1990s, over 80 per cent of countries in the African region were deemed to have ‘very low’ access to essential medicines (WHO 2004d: 62).

In contrast to the austerity measures imposed in the global South, the United States, Japan and Germany expanded their public expenditure on medicines research and development (R&D) in this period (Cockburn and Henderson 1997; Commission on Health Research for Development 1990: 57; Malerba and Orsenigo 2001: 9; WHO 2004d: 13). Throughout the 1980s over three-quarters of global pharmaceutical R&D was located in seven countries: the US, France, Germany, Italy, Japan, Switzerland, and the UK (Cockburn 2004; Dutfield 2003; reserved major areas of the market for the Indian sector (Gupta 1999: 154; see more Chapter seven).

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41 This figure decreased from the 23.9 per cent of the total share of world medicine consumption in 1975 (Ballance, Pogany and Forstner 1992: 31).
Grabowski 2011; Sunder Rajan 2006; Taggart 1993; WHO 1988b: 35). In addition to expanding their public expenditure on R&D, Germany (1968), Japan (1976), Switzerland (1977), Italy (1978) and France (1978) strengthened their pharmaceutical patent protection at the request of the international pharmaceutical firms (Boldrin and Levine 2008: 3).

The United States implemented the strongest levels of patent protection as it brought all molecular biology under its patent system (Angell 2004; Boldrin and Levine 2008; Chu 2008; Cockburn 2004). The 1980 Bayh-Dohl act enabled public institutions in the US to patent and commercialise research (Di Maio 2010). In 1984 the Drug Price Competition and Patent Term Restoration Act introduced patent linkage in the US, by which intellectual property was linked to medicines regulation through the US Federal Drug Administration (FDA). These reforms led to a proliferation of private biotechnology companies. By the late 1980s, 95 per cent of all new medicines were developed in the US, UK, France, Germany, Italy, Japan, and Switzerland (WHO 1988b: 37). In parallel, this period was characterised by numerous mergers and acquisitions in the pharmaceutical industry, which transformed the industry landscape by creating an increased concentration of large international pharmaceutical firms. This was, in part, a response to the threat of generic competition, as several ‘blockbusters’ were coming off patent in the aforementioned countries (Ballance, Pogany and Forstner 1992: 179).

42 These firms initially held strong positions of linkage with the larger R&D companies. By 1990, however, their importance decreased as large international firms once again dominated industry partnerships (Roijakkers 2006: 431).

43 Several of these were ‘blockbuster’ medicines which generated billions of dollars in sales annually (Ballance, Pogany and Forstner 1992; Grabowski 2011: 110).
As a result of these policy reforms in the global South and North, by the late 1980s, 25 international pharmaceutical firms, 14 of which were located in the US, accounted for over half of all medicines sales (Ballance, Pogany and Forstner 1992: 110). Over 70 per cent of their sales were exports (Taggart 1993; WHO 1988b: 33). Their dominance in supply varied in the global South, from 50 per cent of supply in Argentina, to 70 per cent in India and 78 per cent in Brazil, 90 per cent in Ecuador and nearly 100 per cent in most African countries (Olukoshi 1996; Tevera 1995; WHO 1988b; 28).

**Selective Primary Health Care and essential medicines**

In this section I demonstrate that the World Bank and UNICEF adopted and promoted an approach for ‘selective’ primary health care (SPHC) that shifted international health policy under neoliberalism. This approach complemented neoliberal economic reforms by providing a rationale and justification for a narrow role for government in health. Under this approach, several core aspects of essential medicines policy were neglected and shifted to the periphery, with devastating effect on health in the global South. This shift in international health policy was part of a broader forum-shifting strategy of the United States to block the NIEO and move international health policy to the purview of the World Bank.

In the 1970s international health policy was shaped by the WHO’s vision of ‘Health for All’, which emphasised the responsibility of government and the public sector in providing health care (see previous chapter). In the late 1970s, the United States turned to the World Bank to contest ‘Health for All’ as part of a
broader forum—shifting strategy to block the NIEO. In 1979, at the request of the US Agency for International Development, the World Bank first entered the health domain by establishing its own Population, Health and Nutrition Department (Ruger 2005; World Bank 2011). The World Bank and the US Agency for International Development, in collaboration with the Canadian Development Agency, the Rockefeller Foundation and the Ford Foundation, began to promote a different approach to health policy which they called ‘selective’ primary health care (Cueto 2004; World Bank 1981). The foundation for this approach was a policy paper co-authored by Kenneth Warren of the World Bank titled *Selective Primary Health Care: An Interim Approach to Disease Control in Developing Countries* (see Walsh and Warren 1979).

In contrast to ‘Health for All’, SPHC was premised on the primacy of economics and the principle of ‘cost effectiveness’ in assessing health interventions (Walsh and Warren 1979). Whereas ‘Health for All’ conceptualised health as the state of complete mental, spiritual and physical wellbeing, under SPHC health was viewed within a narrow lens as merely the absence of disease (Magnussen, Ehiri and Jolly 2004; Walsh and Warren 1979). SPHC focused on the individual and technological level, which reflected the neoliberal emphasis on the primacy of the individual (Gupta 1999; Walsh and Warren 1979: 971). Social and environmental determinants of disease were overlooked as outside the remit of health policy. Importantly, the discourse of SPHC provided a rationale for a narrow role of government in health care, which complemented reductions in government expenditure on health as required by economic reforms in many developing countries in this period (see above; Berman 1982; Gish 1982; Wisner 1988).
As SPHC became the motto of the World Bank, the Bank came into conflict with the WHO, which resisted this shift away from ‘Health for All’ (Mahler 1980). The Bank found allies, however, in numerous national medical associations who viewed the social and economic objectives of ‘Health for All’ as largely unattainable (Cueto 2004). A turning point for this battle was the adoption of SPHC within the United Nations Children’s Fund (UNICEF). UNICEF was more receptive to this approach because it had historically targeted aid through this kind of ‘vertical program’ in its work donating emergency supplies in response to disease outbreaks. In the 1980s the World Bank and UNICEF began to work together to promote a select number of health interventions in the global South, mainly immunisation programs, oral rehydration programs, and breastfeeding education campaigns (known as GOBI) (Cueto 2004; Homedes and Ugalde 2005: 83; Wisner 1988: 967; World Bank 1980: 57). These programs reflected the SPHC emphasis on the individual. In parallel, the United States led a shift in donor health funding to the World Bank. By 1990 the Bank had superseded the WHO as the largest source of funding for health (World Bank 1993: 166) 44.

The World Bank maintained the concept of essential medicines under SPHC. This was because the idea of a narrow list of the most essential medicines aligned well with the SPHC emphasis on cost-effectiveness (World Bank 1981: 100, 1993: 145). The World Bank played a key role in re-orienting medicines governance that was ultimately detrimental to the health needs of the global South. In accordance with the prioritisation of the private sector as the most efficient form

44 Through this influence the World Bank would later develop a new method for assessing disease mortality, Disability Adjusted-Life Years (DALYs), that would become commonplace in health policy (World Bank 1993: 152, see Chapter six).
of governance, the World Bank encouraged the procurement of medicines through the private sector. Indeed, as much as two-thirds of all medicines purchased in developing countries in the 1980s were procured through ‘private rather than public channels’ (Ballance, Pogany and Forstner 1992: 203). Through this turn away from the public-sector ambitions of ‘Health for All’, medicines became detached from the broader primary health care vision of strengthening public health systems (World Bank 1980: 56). This contributed to medicines shortages in public health systems and inadequate public systems of distribution in a majority of developing countries (Bhutta 2001: 714; Bol, Polderman and Schonhals 1989: 203; Mwega and Kabubo 1993; Owino 1996: 163; Tefera 1995: 84; Third World Network 1994; WHO 1988b: 54). Indeed, several scholars have attributed these reductions in expenditure in public health systems as a significant contributing factor to the resurgence of diseases in developing countries that were once thought to be under control, such as malaria, guinea worm and cholera (Farmer 2001; Lee 2003; Lee and Dodgson 2003; Popoola 1993; Porter, Lee and Ogden 2002).

The World Bank also required several countries to remove pharmaceutical price controls as a condition of receiving loans, such as in Jamaica in 1991 (see Appendix in Marston 1991). Throughout the 1980s and early 1990s price regulation was abandoned in over half of low and middle-income countries (WHO 2004d: 72). The World Bank and UNICEF also required recipients to introduce user fees for health services and essential medicines as a cost recovery

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45 The World Bank responded to criticisms of its policy approach in the early 1990s by co-opting the language of ‘Health for All’, however, it essentially retained the same policy prescriptions (see Cueto 2004; Newell 1988; for criticisms see Werner and Sanders 1997; World Bank 1993).
mechanism, known as the Bamako Initiative (World Bank 1987). These were often out of reach for the poor and contributed to a lack of access to essential medicines (Holm 1995; Lunde, Mamdani and Maitai 1989: 148; Mwega and Kabubo 1993; Tevera 1995; Walt and Harnmeijer 1992: 41; World Bank 1993: 118).

Through this position of dominance in financial lending for medicines, the World Bank required recipients to procure essential medicines through UNICEF (World Bank 1993: 146). This effectively removed the sovereignty of recipient developing countries to retain national control over medicines procurement. It also led to a re-emergence of medicines regulation issues on the international agenda. This was because UNICEF required that medicine manufacturers meet the WHO Good Manufacturing Practices (GMP) (see previous chapter). In the 1980s a majority of developing countries did not adhere to the GMP because they could not satisfy inspection standards required by UNICEF and donors as a result of a lack of resources (Ballance, Pogany and Forstner 1992; Bol, Polderman and Schonhals 1989: 200; Islam and Rifkin 1989; Lunde, Mamdani and Maitai 1989: 149; Nur, Postma and de Wilde 1989: 12, 17; Owino 1996: 157; World Bank 1993: 152)\(^{46}\). This was due to the debt crisis and to reductions in government expenditure as a consequence of economic reforms. The UNICEF/GMP standards, in the absence of economic support to developing countries, contributed to the overall decline in developing countries’ share of world medicines production in this period (Elliot 1993). In this way the World Bank’s

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\(^{46}\) In 1992 the WHO Executive Board noted that many drug regulatory authorities did not have the resources to regulate drug advertising (EB89.R2 [1992] in WHO 1993). India was an exception.
economic reforms and medicine policies worked together against the interests of the people of the global South.

As the World Bank shaped medicines governance in this period, the WHO was hamstrung by donors and had limited resources. A review of the WHO’s Action Programme on Essential Drugs (APED) in the late 1980s found that the organisation lacked the staff and resources to adequately assist governments to develop essential medicines policies (see Islam and Rifkin 1989: 22). As detailed in the previous chapter, the ADEP relied on limited extra budgetary funds to operate. A consequence of this inadequate funding was that several core aspects of essential medicines policy could not be implemented. By the mid-1990s, almost two-thirds of all countries had failed to implement a national medicines policy (WHO 2004d: 53). A majority of developing countries also lacked public resources to fund work on the rational use of medicines, such as adequate training for health workers (Ascobat, Dabelstein and Hausman 1989: 73,153). As a result, the irrational use of medicines continued as a widespread problem throughout the 1980s and 1990s, in both the North and the South (WHO 2004d: 75).

These policy failures reflected US and international pharmaceutical industry pressure on the WHO and developing countries to not implement policies that threatened industry profits. In the 1980s and 1990s, the US and UK threatened trade restrictions on several developing countries when they attempted to implement essential medicines policies in the private sector (Mamdani 1992; Tan
In some countries, like Colombia, the European Economic Commission explicitly prevented the use of their financial aid to fund programs for the rational use of medicines (Hansen 1989: 50). Several donor governments also explicitly tied their foreign aid to the procurement of medicines from their international pharmaceutical firms (Turshen 2001: 202). In 1988 the incumbent Director General of the WHO, Hiroshi Nakajima, relocated the ADEP out of the office of the Director General, a move seen by many as a response to US pressure (Greene 2010).

### The Tropical Disease Research program: failing the global South

In this section I situate the failure of the WHO’s Tropical Disease Research program in the 1980s and 1990s within these developments in economic and health policy in this period. Through neoliberal economic re-structuring, governments in the global South allocated meagre resources to medical research. While the US and several European governments increased their R&D spending, R&D became increasingly concentrated on conditions affecting wealthy countries. In the main, international pharmaceutical firms refused to co-operate with the WHO’s TDR. The discourse of ‘selective’ primary health care reinforced and provided a justification for this continued neglect.

In the 1980s, pharmaceutical R&D was significantly concentrated in a few countries in Europe and the United States. The debt crisis, combined with neoliberal economic re-structuring, meant that governments in the global South

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47 Some international pharmaceutical companies sent private ‘consultants’ to lobby and pressure developing country governments not to implement national medicines programs (Turshen 2001: 203).
had few resources for R&D. Only 0.0025 per cent of global expenditure on health research was directed towards capacity building for R&D in the global South (Commission on Health Research for Development 1990: 75). This R&D concentration in a select group of high-income countries led to an increasing share of new medicines developed specifically for conditions affecting wealthy countries (Ballance, Pogany and Forstner 1992: 19; WHO 1988b: 17). Tropical diseases received low R&D priority, and less than five per cent of the total global expenditure on health research was devoted to the health needs of developing countries (Commission on Health Research for Development 1990: 33; WHO 1988b: 45).

The discourse of ‘selective’ primary health care (SPHC) that had become dominant through the World Bank and UNICEF lending reinforced the neglect of R&D for tropical diseases. SPHC was premised on a model by which governments would ‘select’ health care interventions according to a narrow range of criteria. These included the prevalence of disease morbidity and mortality, whether disease controls existed, and above all, the price of interventions (see Walsh & Warren 1979: 972). Those diseases and health conditions that primarily affected developing countries, but did not have adequate existing medicines, including Lassa fever, Chagas disease, African trypanosomiasis, leprosy, leishmaniasis and filariasis, were categorised by proponents of SPHC as ‘low priority’ (see Walsh & Warren 1979: 968).

This neglect was evident in the lack of financial resources for the WHO’s Tropical Disease Research program. The TDR’s budget remained stagnant at 20
million dollars per annum throughout the 1980s (WHO 1988a: 71). In 1986, the WHO Executive Board noted that member state contributions to TDR had fallen short of requirements to meet health needs (EB77.RD [1986] in WHO 1993: 110). That same year, the US withheld its contribution to the WHO, and the subsequent World Health Assembly made no mention of the problems besieging the TDR (WHO 1993). Shortfalls in the budget revenue of the WHO meant that technical support for TDR also declined (WHO 1988a: 66).

Overall, the international pharmaceutical industry refused to co-operate with the WHO’s tropical disease research program (WHO 2007c: 34). In an attempt to entice industry, the TDR appointed scientists from the private sector on its advisory committees, a move unparalleled in other health institutes. In the mid-1980s TDR did succeed in convincing the pharmaceutical firm Merck to donate to WHO its TDR-sponsored ivermectin for treatment of onchocerciasis. This appeared to be a one-off case, however, as it soon emerged that the TDR had no control over the medicines it sponsored. Throughout the 1980s the TDR could not find industry partners to develop artemisinin-based medicines for malaria (WHO 2007c: 37, see more Chapter six). The derivatives could not be patented and therefore could not be used to generate blockbuster profits for the industry. In the early 1990s, international pharmaceutical firm Aventis (now Sanofi-Aventis) stopped production of its TDR-sponsored elfornithine for sleeping sickness, citing reduced profits. TDR did not publicly push the company to re-commence production. A later review of TDR confirmed that TDR did not investigate

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48 Reflecting the turn to ‘selective’ primary health care, an independent review committee of the TDR program emphasised ‘efficient resource utilisation’ in the face of severe budget constraints placed on the program (WHO 1988a: 16).

49 The US withheld its contributions to the WHO in 1986 and 1987 (see previous chapter).
implementation after it sponsored medicines and suffered from problems of control (UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases [TDR] 2000). The TDR faced similar pressures as the WHO to remain a technical ‘neutral’ organisation without a political or advocacy role (WHO 1985b).

In the early 1990s, member states of the World Health Assembly formally ‘appealed’ to the international pharmaceutical industry to increase R&D collaboration with TDR (WHA43.18 [1990] in WHO 1993: 111). Not long after, the World Bank entered the debate over medical R&D. In its report *Investing in Health* (World Bank 1993: 153), the Bank argued that the low levels of R&D for tropical diseases required more public support for the private sector in the global South (World Bank 1993: 153). In 1986-1987, for example, member states gave 49.5 million to TDR for tropical disease research, a fraction of the 30 billion global investment in health research (Commission on Health Research for Development 1990:40). The World Bank began to champion strong intellectual property patent laws for medicines as the appropriate governance for improving R&D for the health needs of developing countries (see World Bank 1993: 152). This position reflected the ambitions of the international pharmaceutical firms, who had long opposed the NIEO moves to weaken patent laws in the global South (see previous chapter).

**Intellectual property ‘rights’**
In this section I demonstrate a third policy shift in global medicines governance under neoliberalism, by which an international intellectual property ‘rights’ agreement was established by member states of the newly formed World Trade Organization. The Trade Related Aspects of Intellectual Property Rights agreement (TRIPS) extended intellectual property and patent protection for a range of products and processes, including medicines. TRIPS presented new global architecture for medicines R&D that privileged the private ‘rights’ of patent holders over the health needs of the global South. This agreement was part of the broader forum-shifting strategy of the United States to block moves to weaken patent law in UNCTAD and WIPO through the NIEO. The formation of the TRIPS agreement has been studied by several scholars (see Drahos 1995; Muzaka 2011; Sell 2003). I contribute to this scholarship by highlighting the role and agency of the GATT Secretariat in the negotiations which led to TRIPS.

In the late 1970s, the US strengthened its opposition to the NIEO proposals for a weakening of international patent rules in UNCTAD and in WIPO (Braithwaite and Drahos 2000; Deere 2008; Muzaka 2011; Roffe [Chief of Legal Policies UNCTAD] 1985; Sampath and Roffe 2012; Sell 2003; United Nations General Assembly 1985). The US was significantly influenced by international pharmaceutical firms which saw the NIEO revisions in UNCTAD as a threat to their profits. US-based firms like Pfizer gained political access to the US government through the appointment of its representatives on government business councils and through its financing of public institutions like the American Enterprise Institute (Drahos and Braithwaite 2002). Drahos (1995) and Drahos and Braithwaite (2002) and Sell (2003) have detailed how pharmaceutical
firms collaborated with the US government to persuade their industry counterparts in Japan, Europe and Canada to lobby respective governments to oppose the NIEO patent revisions. Through the late 1970s and early 1980s, the US and allied governments formed the view that a strong international IP agreement was necessary to protect their exports, in particular their medicines exports (see Angell 2004; Cockburn 1992; National Economic Development Office 1986; Sell 2003; Taggart 1993).

In the late 1970s the United States began a concerted campaign to shift the deliberations on intellectual property in WIPO to the General Agreement on Tariffs and Trade (GATT). This was part of a broader strategy by the US to block the NIEO proposals, including those that weakened international patent norms. Like the World Bank and IMF, the GATT was a multilateral economic institution that has presided over world trade rules since the mid-1940s. While the GATT was favoured by the US, throughout the 1970s the organisation had been neglected by the global South, which had negotiated trade rules primarily through UNCTAD (see previous chapter). As part of this forum-shifting strategy, the US framed intellectual property as a matter of trade and of specific importance to trade liberalisation. In their first submission to the GATT on intellectual property matters in 1979, the US and European Economic Commission (EEC) jointly framed intellectual property as a trade issue by arguing that infringement of IP or ‘counterfeiting’ blocked legitimate trade and reduced exports of IP-intensive countries (GATT 1979). This view of intellectual property was in stark contrast to the NIEO critique in UNCTAD, in which developing countries saw IP rules as a

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50 The GATT sought to allay developing countries demands in the mid-1970s when it implemented reforms for preferential and non-reciprocal treatment for developing countries in trade as requested by UNCTAD (1975: 24).
barrier to their trade and economic growth. The Non-Aligned Movement initially opposed this attempt to shift negotiations on IP rules to the GATT (GATT 1989).

A turning point for the US and EEC was the ongoing stalemate over the revisions to the Paris Convention in WIPO. The United States and its allies refused to negotiate on the UNCTAD proposal to weaken IP rules in the Paris Convention. In an attempt to break the stalemate, the developing country members of the GATT eventually agreed to a request by the US to task WIPO and GATT with a joint study to examine the ‘appropriateness’ of action on ‘counterfeiting’ and trade within GATT (Director General of the General Agreement on Tariffs and Trade 1983; Drahos and Braithwaite 2002: 109; Ministerial Declaration 1982 in GATT 1983: 1). This tactic provisionally brought IP onto the agenda of GATT in 1983.

Throughout the mid-1980s the United States, European Economic Community and Japan increasingly framed intellectual property as a trade matter and an inalienable ‘right’ of the private sector (GATT 1986b: 3; GATT Information and Media Relations Division 1990: 12; GATT Negotiating Group on Trade-Related Aspects of Intellectual Property Rights 1987: 3, 25; GATT Secretariat 1987; Government of Sweden 1994: 37; Sell 2003: 45). The Non-Aligned Movement continued to oppose this move. At the 1986 Non-Aligned Conference of Heads of State, the Non-Aligned Movement agreed that that the GATT ‘did not have the jurisdiction in the area of services, intellectual property and investment’ (GATT 1986a: 6). India led the Non-Aligned Movement within the GATT (GATT 1989).
The GATT Secretariat played a key discursive role in convincing several developing countries that intellectual property was a trade matter and that the GATT was the most appropriate site for IP rules. Just as UNCTAD was a proponent of the NIEO, the GATT Secretariat emerged as a key supporter of IP within its trade remit (GATT 1984b; GATT Secretariat 1985: 10). In the mid-1980s, the GATT Secretariat conducted its own review of the Paris Convention on Industrial Property, albeit with no formal mandate from its member states. The GATT Secretariat concluded that governments had only two options, that of either maintaining the current IP standards in the Paris Convention or of strengthening these IP rules (GATT Secretariat 1985). The Secretariat ignored the decade-long work by UNCTAD, and the work underway in WIPO to weaken the Paris Convention rules on IP (see previous chapter). Furthermore, the GATT Secretariat began to use the term ‘piracy’ to refer to the unauthorised use of intellectual property (GATT Secretariat 1985). This reflected the view of the US and its allies (home to international pharmaceutical firms in particular), which claimed that intellectual property was a ‘right’, and that to ignore this ‘right’ was ‘piracy’ (GATT Council 1991b: 88; 1994c: 22; Sell 2003).

Indeed, through its joint task force with WIPO, the GATT Secretariat was influential in convincing the WIPO Secretariat that IP was a trade matter appropriate for GATT. Shortly after the joint task force commenced, WIPO began to criticise measures like parallel importation on the grounds that they were ‘obstructing trade’ (Director General of the General Agreement on Tariffs and Trade 1983; GATT Secretariat 1985: 29). In the report of the joint task force of GATT and WIPO, both organisations claimed that an international agreement on
‘counterfeits’ was necessary for ‘consumer safety’ (GATT Secretariat 1985: 14; GATT 1983). This was the first time that these economic institutions would appear to conflate intellectual property matters with issues of consumer safety and regulation although, as this thesis demonstrates, they would not be the last (see Chapter five).

As the GATT Secretariat and WIPO Secretariat began to support a strong international intellectual property agreement through GATT, developing countries found fewer allies in the international system. The World Bank and the IMF publicly supported the GATT as the ‘appropriate’ venue for negotiations on intellectual property rules (Braithwaite and Drahos 2000; World Bank 1993: 3). The United Nations Centre on Transnational Corporations (UNCTC) and the United Nations Department of Economic and Social Development (UNESD), which were strong supporters of the NIEO in the 1970s, were significantly downsized in the early 1990s at the request of the US, Japan and EEC (Lipschutz and Rowe 2005). In 1993, the United Nations Industrial Development Organization (UNIDO), once an outspoken critic of the international pharmaceutical firms, was re-structured to service private sector development (see UNIDO N.D).

In addition to these pressures on the global South, in the GATT negotiations the US and its allies tied their proposal for an international agreement on IP to a broader set of trade negotiations known as the Uruguay Round (Sell 2003). This meant that the negotiations on reducing tariffs, a long-held objective of the global South, would only commence when member-states agreed to negotiate on IP in
the GATT. This eventually led to an agreement among the member states that they would commence negotiations on an agreement on ‘counterfeit trade’ on the proviso that the intellectual property measures agreed upon ‘do not become barriers to legitimate trade’ (GATT 1986a; GATT Group of Experts on Trade in Counterfeit Goods 1985b, 1985c, 1985d; GATT Preparatory Committee 1986: 10, 13).

This political power exerted by the US and EEC inside the GATT was also reflected in trade pressure outside the multilateral system. In 1984, the United States revised its Trade and Tariff Act to require the US President, then Ronald Reagan, to consider the ‘extent of adequate protection’ of US intellectual property ‘rights’ when determining trade benefits with other countries (GATT 1984a: 3). Known as Special 301, this law also required the United States Trade Representative to release annual reports that identified those governments that, according to the USTR, ‘deny adequate and effective protection of intellectual property rights or fair and equitable market access for US exporters’ (Office of the United States Trade Representative 1994). The Pharmaceuticals Research and Manufacturers of America (PhRMA), the lobby group for the pharmaceutical industry, was a driving force behind these revisions to the Trade Act (Pugatch 2004)\(^5\).

In 1985, the US promoted its revised Trade Act to all member states of the GATT as a show of force (GATT Group of Experts on Trade in Counterfeit Goods

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\(^5\) The PhRMA was formerly named the Pharmaceutical Manufacturers of America (PMA) (1958). It was renamed in the late 1990s as firms sought to project their image as global innovators. The PhRMA filed 301 objections to the USTR with respect to alleged patent infringement in Brazil in 1987, before the Trade Act was officially amended (Pugatch 2004: 67).
1985a). Soon after, the US suspended trade benefits with India, who was the most vocal developing country in opposing pharmaceutical intellectual property protections (GATT Council 1994c: 165). In the early 1990s, the United States Trade Representative (USTR) named Brazil, India, Chinese Taipei, and Thailand as Priority Watch countries in its Special 301 reports (GATT Council 1994c). Brazil, South Korea, Taiwan, Hong Kong and Singapore subsequently faced increased tariffs on their exports to the US (Grimwade 2003: 51). The European Union was a ‘quiet free rider’ on the US efforts, often bringing in negotiators after the US had started to take action on a country (Drahos cited in Deere 2008: 50; see also Panagariya 2002). The US and EEC aimed to pressure developing countries to extend intellectual property measures and to agree to an international agreement on intellectual property that included pharmaceutical patent protection (Braithwaite and Drahos 2000; Drahos and Braithwaite 2002; Pugatch 2004: 106).

As mentioned above, the GATT Secretariat was instrumental in bringing IP onto the agenda of GATT. Through the late 1980s and early 1990s, the GATT Council and the GATT Secretariat played a key role in pushing developing countries to agree to an international agreement on intellectual property. The GATT Council increasingly framed intellectual property as an inalienable ‘right’ of the private sector (GATT Council 1991b, 1992b, 1994a, 1994c). The GATT Council commenced Country Trade Reviews in which it reviewed domestic intellectual property laws and accepted complaints from international pharmaceutical firms (GATT Council 1991a; 1991b: 88).
The GATT Secretariat and GATT Council echoed the demands of international pharmaceutical firms by framing intellectual property as a prerequisite for research and development for new medicines (GATT Council 1994c: 22; GATT Secretariat 1994: 1). In 1992, the GATT Council praised the Pharmaceuticals Manufacturers Association of Canada (PMAC), a national association of the IFPMA, when it announced that it would increase expenditure on R&D in Canada if Canada strengthened its patent protection (GATT Council 1992a: 135). The following year, Canada removed provisions for the compulsory licensing of medicine patents in its Intellectual Property Law Improvement Act of 1993, claiming that it had done so to generate a ‘more positive investment climate…by improving IPR thereby encouraging basic R&D in many sectors’ (GATT Council 1995: 20; see also GATT Council 1994a). In its trade review of Canada a year later, the GATT Council again reiterated the industry view that Canada’s IP rules in the 1980s which allowed for compulsory licenses were the cause of the past poor R&D investment in the country (GATT Council 1994a).

The US and GATT pressure proved to be too much and several developing countries undertook reforms to strengthen intellectual property protection for medicines in this period (namely Argentina, Bangladesh, Benin, Brazil, Burkina Faso, Chile, China, Columbia, Ecuador, Indonesia, the Republic of Korea, Malaysia, Mali, Mexico, Paraguay, Peru, Thailand and Venezuela) (Deere 2008: 51). This signified a collapse of solidarity between the global South, with countries like India maintaining the Non-Aligned position. It was not just developing countries but also Austria, Denmark, Greece, the Netherlands, Spain,
and Sweden who extended pharmaceutical patent protection for medicines (Taggart 1993).

Ultimately, the negotiations in GATT reflected a power imbalance between the North and South. Over 70 per cent of the material submitted to the IP negotiating group of the GATT came from the US and EU (Drahos 2004). Many developing countries did not have enough resources to maintain their delegates in the negotiations, and only 20 governments were involved in the end stage of finalising the agreement on IP (Deere 2008; Drahos and Braithwaite 2002: 10). Ascension to the newly forming World Trade Organization (WTO), which was to replace the GATT, was tied to agreement on IP, meaning developing countries would need to agree on IP rules to access trade benefits in the WTO (Braithwaite and Drahos 2000; Deere 2008: 197; Sell 2003). The foundations of the numerous agreements on trade negotiated in this period, including the agreement on IP rules, were premised on non-discrimination, most-favoured-nation and national treatment. These differed markedly from the principle of preferential treatment for developing countries that was a core focus of trade deliberations in the 1970s (see previous chapter; GATT Secretariat 1994: 15; UNCTAD 1975: 24). Indeed, they reflected the collapse of the NIEO as neoliberalism became dominant in global economic institutions.

The culmination of the negotiations on an IP agreement in GATT was the Trade Related Aspects of Intellectual Property Rights agreement (TRIPS) in 1994.

52 The US, EU and Switzerland also made use of the GATT Country Trade Review mechanisms to push countries who sought to join the WTO, like Panama, to align their national IP legislation to their demands). (GATT 1994: 48; GATT Council 1994b: 7, 9, 17; WTO 1996a: 39).
Overall, TRIPS represented a win for the US and its allies as it required signatories to extend intellectual property protection for medicines and other products for a minimum of 20 years and grant exclusive marketing rights for the duration of patent terms (Article 28, Article 33, WTO 1994)\textsuperscript{53}. The agreement represented a significant shift away from the ambitions of the Non-Aligned Movement to weaken patent laws under the Paris Convention. Instead, TRIPS strengthened these patent rules, notably through requirements on both product and process patents for medicines. TRIPS was designed as a set of principles to be implemented in national law and did contain flexibilities on the definitions of novelty, as well as provisions to protect public health and promote socioeconomic and technological development (Article 8, WTO 1994)\textsuperscript{54}. Nonetheless, the IP agreement represented new global architecture for the governance of medicines that privileged the private sector (May 2010). This was because, under TRIPS, measures like compulsory licensing could not be easily granted on economic grounds, such as the insufficient workings of a patent in-country, which were a central case made by developing countries under the NIEO (Pugatch 2004: 143, see previous chapter). Indeed, TRIPS legitimised a discourse by which IP was seen as a private ‘right’ of firms (Sell 2003).

\textbf{Conclusion}

\textsuperscript{53} Developing countries were granted five years extension on implementing the agreement, and least developed countries were granted 11 years extension (GATT Secretariat 1994: 14).

\textsuperscript{54} Member states can exclude from patentability inventions to protect human, animal or plant life or health (Article 27.2 WTO 1994). They can also exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals’ (Article 27.3a WTO 1994).
This chapter has demonstrated that shifts in the global governance of medicines in the 1980s and early 1990s privileged international pharmaceutical firms and failed to adequately meet many of the health needs of the global South. The governance of medicines was transformed through shifts in economic, health and trade policy that were the result of a broader forum-shifting strategy of the United States and its allies to block the New International Economic Order. The chapter has highlighted the role of the World Bank and the General Agreement on Tariffs and Trade (GATT) in diffusing these reforms. In health, the turn to ‘selective’ primary health care complemented economic reforms by providing a rationale and justification for a narrow role for government. The rise of the World Bank in health lending coincided with resource constraints on the WHO, which prevented the organisation from delivering on its mandate. In particular, the WHO’s Tropical Disease Research program failed to deliver new medicines for the global South. Under ‘selective’ primary health care, several core aspects of essential medicines policy were neglected and shifted to the periphery, with devastating effect on health. Finally, the TRIPS agreement presented new global architecture for medicines R&D that privileged the private ‘rights’ of patent holders over the health needs of the global South.
The previous chapters have examined the evolution of the global governance of medicines from the end of the Second World War to the establishment of the World Trade Organization (1994). Through the rise and fall of the NIEO, they have situated shifts in international medicines policy within broader transformations in the global political economy. In this chapter I examine developments in global medicines governance through the 1990s to the World Trade Organization’s Doha Declaration on TRIPS and Public Health in 2001. I demonstrate that the global governance of medicines in this period strengthened a global norm for intellectual property ‘rights’ as a prerequisite for medicines research and development (R&D). This legitimised the historical neglect of the specific health needs of developing countries, because it framed this neglect as a logical outcome in the absence of IP protection and profit motive.

The Doha Declaration is widely praised by public health advocates because it confirms that governments have flexibility in implementing their intellectual property laws under TRIPS to address the health needs of their population (Abbott and Reichman 2007; ‘t Hoen 2002; Sun 2004). Indeed, this chapter shows that the Doha Declaration was a product of resistance on the part of several developing countries and NGOs against pressures to enforce IP measures beyond those of TRIPS. These actors championed a discourse for ‘public health safeguards’ which enabled them to re-assert health needs against patent ‘rights’. I argue, however, that this discourse was co-opted by the United States and the
international pharmaceutical industry, who framed the protection and enforcement of their IP ‘rights’ as a safeguard for the development of new medicines. I demonstrate that corporate litigation against South Africa, which was the catalyst for this struggle, was a strategy of the international firms to narrow the debate over medicines and patents to a legal interpretation of the TRIPS agreement. I show that the World Health Organization enabled this narrowing of the debate as it shifted its position in support of the enforcement of strong IP ‘rights’ as a strategy to reclaim its authority in global health.

The chapter draws on an analysis of records, resolutions and reports of the governing bodies of the World Health Organization (WHO), General Agreement on Tariffs and Trade (GATT), World Trade Organization (WTO), United Nations Conference on Trade and Development (UNCTAD) and United Nations Sub-Commission for the Protection and Promotion of Human Rights, reports of the Joint United Nations Programme on HIV/AIDS (UNAIDS), World Bank, United States Center for Disease Control (CDC), United States Trade Representative (USTR), statements by government leaders and staff of global institutions, the Pharmaceutical Research and Manufacturers of America (PhRMA), CIPLA, Health Action International (HAI), Médecins Sans Frontières (MSF), ACT UP, and the Treatment Action Campaign (TAC) (see Appendix Two).

AIDS exceptionalism and private rights

The HIV/AIDS epidemic was a catalyst for shifts in international medicines governance in the late 1980s and early 1990s that ultimately privileged the private
‘rights’ of international pharmaceutical firms over the health needs of the global South. This section demonstrates that a discourse of AIDS exceptionalism emerged on the international agenda in the late 1980s, and that this discourse enabled a shift in the international response to AIDS because it aligned with ‘selective’ primary health care (SPHC). I situate the development of effective HIV/AIDS medicines within broader shifts in this period, including the finalisation of the TRIPS agreement, a reduced role for the WHO in health research, and the loss of the WHO’s international authority over HIV/AIDS. When effective antiretroviral therapy for HIV/AIDS was finally developed, it was patented and priced out of reach of the majority of people living with AIDS (PLWA).

In the early 1980s scientists at the US Center for Disease Control (CDC) discovered a ‘rare pneumonia’ amongst a group of gay men (Centers for Disease Control 1981). Unknown to the scientific community at the time, the illness was a virus that was spreading across the globe with high rates of morbidity and mortality. Because the first detection of the virus was amongst gay men it was initially called ‘gay-related immunodeficiency syndrome’ (Centers for Disease Control 1981). The disease was re-named ‘acquired immunodeficiency syndrome’ (AIDS) in 1982 when it became clear that heterosexual couples and children were also infected (UNAIDS 2008). Nonetheless, HIV/AIDS came to be associated with marginal groups in society and gay men, drug users, sex workers and the poor were framed as ‘risk groups’ by the scientific community due to higher rates of infection than the general population (Sabatier 1989: 69).

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55 In the early 1980s death rates were high for people who contracted the virus (Sabatier 1989: 5).
How governments responded to HIV/AIDS was shaped by ideology and politics. The conservative US President Ronald Reagan was slow to respond to the spread of the disease and remained publicly silent on HIV/AIDS for most of his presidency (1981-1989). When he did finally acknowledge the disease, Reagan framed HIV/AIDS within a discourse of moral conservatism and individual responsibility (Reagan 1987d). Reagan initially opposed expansion of the US government’s budget for basic research in order to develop effective medical treatment for HIV/AIDS (Bush 1990; Reagan 1987c). Morality, he argued, would ‘teach the same lesson for prevention as medicine’ (Reagan 1987c).

Due to a lack of scientific knowledge on the epidemiology of the virus, and because the disease was associated with marginal groups in society, people living with AIDS (PLWA) endured significant stigma and discrimination. In the United States, for example, people of Haitian nationality were prevented from donating blood due to fears that the virus had spread from Haiti. West Germany, Cuba, Iceland, South Africa and the Soviet Union imposed quarantine restrictions on PLWA (Sabatier 1989: 70). Over 34 countries implemented travel restrictions on PLWA in an attempt to prevent the spread of the virus (Chang et al. 2013). Wild theories that the virus had emerged from human copulation with monkeys in Africa inflamed anti-colonial and anti-racist sentiment in African nations. In response, many African countries denied the existence of AIDS or blamed it on former colonial powers (Sabatier 1989). Government disinterest, denial, and stigma meant many PLWA received little support. This was compounded by neoliberal economic re-structuring in several developing countries, which reduced

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56 Reagan only publicly spoke about the disease on six occasions, all in the last half of his presidency (Reagan 1987a, 1987b, 1987c, 1987d).
public services and imposed user fees on health care (see previous chapter, Farmer 2001; Lee and Zwi 2003; Poku and Sandkjaer 2007; Rowden 2009; Sanders and Sambo 1991).

Government inaction was reflected at the international level in the slow response of the WHO to the spread of the disease. The WHO had no member-state mandate to address HIV/AIDS and it was also suffering from significant budget constraints (see previous chapter). In the early 1980s member states provided WHO with resources to employ one staff member to work on sexually transmitted diseases (UNAIDS 2008: 13). The United States CDC therefore led the initial response, developing the first mother-to-child transmission guidelines and organising the first AIDS conference in 1985 (US Department of Health and Human Services 2011). In the late 1980s, member states finally agreed to establish international surveillance of HIV/AIDS in the WHO. Few developing countries participated in surveillance, however, which was a consequence of anti-colonial tensions and limited public resources in developing countries to fund health surveillance (Sabatier 1989; UNAIDS 2008: 13).

It was in this context of strained government health services, denial and discrimination that PLWA and their supporters formed non-government organisations and advocacy groups. These groups, which formed in several countries including Brazil, Uganda, South Africa, Thailand and the United States, advocated for their governments to respond to HIV/AIDS as a human rights issue (UNAIDS 2008). In the United States, NGOs demanded that PLWA ‘be included in all AIDS forums with equal credibility as other participants, to share their own
experiences and knowledge’ (Advisory Committee of the People with AIDS 1983). Advocacy on the part of NGOs and activists in Brazil eventually led to the Brazilian government forming its Brazilian National AIDS Control Program (NACP) in 1986 (Mandisa 2013). Gay rights groups and AIDS groups came together in the US to form the AIDS Coalition to Unleash Power (ACT UP). ACT UP organised mass protests and ‘die ins’ and demanded a co-ordinated government response to AIDS that included investment in medical research57.

This discourse for the human rights of PLWA was accommodated under neoliberalism and was soon adopted, at least rhetorically, at the international level. The idea of individual human rights for PLWA aligned with the emphasis on the rights of the individual under neoliberalism (see previous chapter). Language to this effect emerged in resolutions on the human rights of PLWA in the WHO; [there is] ‘no rationale for measures that limit the rights of the individual’ (WHA45.25 [1992] in WHO 1993: 127)58. Neoliberalism was also the broader context by which member states of the World Health Assembly agreed to support AIDS NGOs and include NGO representatives on their national AIDS committees (WHA42.34 [1989] in WHO 1993: 124; see also Harvey 2005). In the WHO, health as a human right ‘without distinction of race, religion, political belief, economic or social condition’ had been a guiding principle since its constitution (WHO 1946). In 1988, the World Health Assembly agreed that discrimination against people with HIV/AIDS was against human rights and

57 ‘Die ins’ were a strategy by which activists would chain themselves in government buildings or the headquarters of international pharmaceutical companies to bring media attention to their cause.
58 Despite these commitments, the US only recently repealed Section 212(a) of its Immigration and Nationality Act which prevented non-citizens with a ‘communicable disease of public health significance’ from admission in the country without a waiver (see Rushton 2012).
established a Special Programme for AIDS within the WHO (WHA41.24 [1988] in WHO 1993)\(^5^9\). Jonathan Mann who headed the WHO Special Program was a strong supporter of this human rights discourse: ‘the protection of the uninfected majority depends precisely and is inextricably bound with the protection of the rights and dignity of infected persons’ (Jonathan Mann cited in Sabatier 1989: iv; Mandisa 2013; UNAIDS 2008).

As HIV/AIDS was increasingly framed as a human rights issue, a discourse of AIDS exceptionalism emerged on the international agenda. This was in part a result of a strategy of some staff of the WHO to garner financial support for their HIV/AIDS program amidst a broader decline in funds for the organisation (WHO 1987, see previous chapter). Staff of the WHO program on HIV/AIDS framed AIDS as an exceptional disease that required exceptional funding. This aligned with the World Bank and UNICEF’s approach to ‘selective’ primary health care (SPHC) under neoliberalism (see previous chapter). HIV/AIDS was infectious with high rates of mortality and morbidity and it therefore met two criteria of SPHC (See Walsh and Warren 1979). No effective treatment existed in the 1980s, which was the third criteria for assessing health interventions under SPHC. The individual nature of HIV/AIDS transmission, however, meant that advocates could point to individual responsibility as a preventative measure (See Walsh and Warren 1979). Thus, this discourse of HIV/AIDS exceptionalism was accommodated under SPHC which enabled governments to justify public expenditures in health care. By 1990, the WHO programme for HIV/AIDS was

the largest funded program in WHO history (UNAIDS 2008: 16). In its first report dedicated to ‘Investing in Health’, the World Bank (1993: 16) called for ‘billions more dollars’ in government aid to combat the disease.

The rise of AIDS exceptionalism was a turning point in which the US government expanded its public support for R&D into HIV/AIDS treatment. In the late 1980s, the Reagan administration finally increased the US government budget for research from a meagre 10 million to 400 million dollars (Reagan 1987c; Mandisa 2013). So exceptional was HIV/AIDS that in 1987 the US Department of Health and Human Services and the French Institute Pasteur agreed to ‘share the patent’ of an AIDS antibody test kit (Reagan 1987a). Reagan’s successor, George Bush, increased the HIV/AIDS budget to over three billion dollars in his first year of office (Bush 1990). In 1995, Bush’s successor Bill Clinton establishment a Presidential Advisory Council on HIV/AIDS, which included representatives of US-based international pharmaceutical firms (Clinton 1995a, 1996). Clinton asserted that a cure for AIDS was his administration’s ‘top priority’, and that he would ‘oppose any effort to undermine the research effort in the face of budget cuts’ (Clinton 1995b).60 These increases in US government support for medical research were directed to US-based international pharmaceutical firms. President Clinton convened high level meetings between US government politicians, scientists and leaders of the US-based international pharmaceutical industry, and praised the private sector as the champion for a cure (Clinton 1996). It is noteworthy that this shift in the US occurred in parallel to neoliberal economic restructuring in the global South, by which several developing countries allocated

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60 Bush’s successor President Clinton spoke about AIDS publicly on 39 occasions in his tenure, the most of any US President (Clinton 1993a, 1993b).
no resources for government expenditure on medical research (see previous chapter).

As the US intensified its R&D efforts to develop effective treatment for HIV/AIDS in collaboration with US-firms, the role of the WHO in co-ordinating health research appeared to weaken. In January 1986, members of the WHO Executive Board called for the Director General to co-ordinate clinical trials of antiretroviral drugs that showed promise (EB77.R12 [1986] in WHO 1993: 120). This text was deleted from the resolution, however, by the time it reached the World Health Assembly later that year. Again in 1992, member states of the WHO Executive Board asked the Director General to ‘intensify biomedical research’ in the organisation (EB89.R19 [1992] in WHO 1993: 126). This text was subsequently altered in the World Health Assembly to request the Director General to ‘continue negotiations with the pharmaceutical industry to facilitate access to affordable vaccines and drugs’ (WHA45.35 [1992] in WHO 1993: 128). This had broader implications beyond HIV/AIDS, and appeared to signal the demise of the WHO in co-ordinating health research.

These shifts occurred in parallel to the finalisation of the TRIPS agreement (see previous chapter). Indeed, shortly after TRIPS was finalised, in 1996 the US initiated and won the first disputes over alleged pharmaceutical IP infringement with India and Pakistan in the newly-formed World Trade Organization. At issue was Article 70(8) of TRIPS which required that developing countries implement ‘mailbox’ provisions for pharmaceutical patent protection to backdate patent applications from 1995 onwards (Office of the United States Trade
Representative 1996; WTO 1996b, 1996c, 1996f). The USTR reported that it initiated the disputes on the behalf of several US pharmaceutical companies, which claimed they stood ‘to lose significant revenues if the longer TRIPS patent term is not applied to their existing patents’ (USTR Ambassador Michael Kantor, cited in Office of the United States Trade Representative 1996; WTO 1996d, 1996e). The United States targeted India because it had the most developed domestic production capacity for medicines in the global South. Pakistan was likely targeted because it had the largest recorded shift away from originator medicines to generics, in terms of domestic market share, of any developing country (WHO 2004d: 41). In addition, both countries had increased their domestic medicine exports in the 1980s unlike the majority of developing countries (WHO 2004d: 26).

In this same period, a new smaller UN organisation was created which gained international authority over HIV/AIDS. This was enabled by tensions between WHO staff over the exceptional status of HIV/AIDS in the organisation. The incumbent third Director General of the WHO, Hiroshi Nakajima, felt that the disease received too much attention at the expense of other conditions, like child diarrhoea (New York Times News Service 1990). Indeed, the vertical focus of the WHO’s Special Programme on a single disease was in contrast to the broader vision of ‘Health for All’ that still guided much of the WHO’S work (Bayer 1994; England 2008; Lazzarini 2001). Nakajima wanted to rein in the AIDS programme so that resources were devoted to the regional and country level offices of the WHO (Lisk 2010: 22). Jonathan Mann, Director of the WHO Special Programme on HIV/AIDS, was opposed to this move. Mann subsequently resigned in protest
to Nakajima and to what he saw as government inaction to meet the health needs of those with HIV/AIDS (New York Times News Service 1990; Pincock 2013; UNAIDS 2008: 17). According to the former Executive Director of the WHO Special Program for HIV/AIDS, Michael Merson (2006), Mann’s resignation only exacerbated tensions between WHO and the World Bank, which had formed its own HIV/AIDS program and was competing with WHO for donor resources. These tensions enabled donors to forum shift HIV/AIDS away from the WHO to a new organisation, the Joint United Nations Programme on HIV and AIDS (UNAIDS) in 1994 (UNESC 1994).

UNAIDS was hailed as an ‘innovative partnership’ because it was designed to tap into the work of the ‘coordinating bodies’ including the WHO, United Nations Population Fund, International Labour Organization, United Nations Development Programme, UNICEF and the World Bank (PEPFAR N.D). Critically, in contrast to the WHO, UNAIDS was created with a small ‘Programme Coordinating Board’ of only 22 member states allocated from five regions. The ‘Western Europe and other’ region, which comprised European nations, the US, Canada, and Australia were allocated the largest representation of seven seats on the Board (nearly one third of all votes). Thus, the US and its allies obtained a greater share of power over decision-making in UNAIDS than they had previously had in other UN bodies61.

Finally, in 1996, US-based international pharmaceutical companies announced that they had developed effective highly-active antiretroviral (ARV) therapy for

61 Japan, China, India, Russia (minus 3 years), and the United States (minus 4 years) have maintained long-term membership on the PCB of UNAIDS since it was created (UNAIDS N.D).
AIDS. These medicines were seen as lifesaving and they demonstrated significant reductions in mortality rates (Carpenter 1997; Gulick 1997; Hammer, Katzenstein and Hughes 1996). The ARVs were patented and were prohibitively expensive for a majority of PLWA because the international firms charged over 20,000 (US) dollars per patient per year (Schwattrander, Grubb and Perriens 2006). Indeed, the cost of the ARVs were a contributing factor to them not being included on the WHO’s Essential Medicines List in 1997 (WHO Expert Committee on the Selection of Essential Drugs 1997: 13). AIDS NGOs reacted angrily to the prohibitive prices and the United States government responded to domestic advocacy by purchasing the ARV treatments for US citizens through its AIDS Drugs Assistance Program (ADAP) (Luiz and Silva 1996; Nunn 2009: 85). The United States and its allies initially rejected a proposal for a global fund to assist developing countries to purchase the ARVs, however, citing the expensive cost of medicines and the ‘parlous nature of developing country health services’ ([1997] in UNAIDS 2008, see more next chapter).

The consequence of forum-shifting HIV/AIDS from WHO to UNAIDS soon became evident when UNAIDS formed a ‘partnership’ with five international pharmaceutical companies. In 1997 UNAIDS offered a trial group of developing countries [Chile, Cote d’ivoire, Uganda and Vietnam] a reduced price on the HIV/AIDS ARVs to around 7000 dollars (US) per person per year (UNAIDS 2008: 69). The firms were seeking IP protection in exchange for the price offers,

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62 The following year, only one ARV zidovudine was added to the WHO list with a warning that triple drug therapy was ‘beyond the budgets’ of most national medicines programs (WHO Expert Committee on the Selection of Essential Drugs 1998: 35).
63 An estimated one in three PLWA in the United States currently rely on the program as of 2013. The ADAP continues to procure only patented medicines from US pharmaceutical companies (AVERTing HIV and AIDS N.D; NASTAD 2013).
which were still prohibitively expensive. This demonstrated that UNAIDS was privileging the private ‘rights’ of the international pharmaceutical firms over the health needs of PLWA in the global South.

The South African lawsuit

In this section I show that a group of international pharmaceutical firms sued the government of South Africa in 1997 as a strategy to narrow the international debate over medicines and patents to a legal interpretation of the TRIPS agreement. This litigation, which took over five years before it was withdrawn by the firms, effectively blocked South Africa from ensuring access to HIV/AIDS medicines for its citizens. I first explain the context for the litigation and then demonstrate that the industry lawsuit was a catalyst for the mobilisation of health advocacy NGOs.

In 1996, South Africa had one of the highest rates of HIV prevalence in the world (Mba 2007). HIV prevalence amongst pregnant women in Lesotho was at an all-time high at 26 per cent (Zungu-Dirwayi et al. 2004: 17). The development of effective HIV/AIDS ARVs that year provided a shimmer of hope for PLWA. The price of ARVs, however, at up to 20,000 dollars per patient per year, made them unaffordable for the majority of South Africans (Schwatlander, Grubb and Perriens 2006). Pharmaceutical firms did not offer a reduced price for their ARVs to South Africa through UNAIDS. Even if they had, the ARVs would still have been out of reach for a majority of South Africans.
These prohibitive prices created tension for the new anti-apartheid government, which had recently affirmed the right to health in its new constitution. Specifically, the constitution provided for a Bill of Rights which included the right of ‘everyone’ to ‘have access to...health care services, including reproductive health care’ (section 27.1(a) Constitution of Republic of South Africa 1996: 1255)\textsuperscript{64}. The right to health was in tension with the ‘rights’ of patent holders to charge what they liked through monopolies granted by the patent system, and at the time South Africa granted 20 years patent protection. In December 1997, the South African government introduced legislation through the ‘Medicines and Related Substances Control Amendment Act 90’ which gave the Minister power to improve the supply of affordable medicines through measures like compulsory licensing and parallel importation (Section 10(15C) Medicines and Related Substances Control Amendment Act 90 of 1997: 10)\textsuperscript{65}. These measures, which were outlined in the TRIPS agreement, meant the government could enable domestic generic firms to produce the ARVs or they could import generic ARVs from other countries when they became available.

This promise of more affordable ARVs was blocked that year when a group of 40 international pharmaceutical firms sued the government and obtained a High Court interdict, which prevented the Act from becoming law (Mandisa 2013: 139; PhRMA 2000f). This was an unprecedented move which demonstrated the power of the international pharmaceutical industry. The firms claimed that the proposed

\textsuperscript{64} The Bill also required that the government of South Africa ‘must take reasonable legislative and other measures, within its available resources to achieve the progressive realisation of … these rights’ (section 27.1 Constitution of Republic of South Africa 1996: 1255).

\textsuperscript{65} This Act also covered other issues of medicines governance including traditional medicines.
Medicines Act was a ‘violation’ of the South African constitution and the TRIPS agreement (PhRMA 2000f). This litigation prevented South Africa from implementing the legislation. Thus, the firms effectively prevented access to life-saving medicines for millions of South Africans. This was evident when the South African government added several HIV/AIDS ARVs on its national Essential Medicines List in 1997, with a warning that the medicines were ‘very costly and cannot be provided on a mass scale by the public health services…it may only be provided on a limited and selective basis or for academic and research purposes only’ (cited in Laing 2003)66.

The South African lawsuit was a strategic move by the international pharmaceutical companies to pressure South Africa and other developing countries to implement intellectual property measures beyond the requirements of TRIPS. In public, the PhRMA claimed that the Act was a ‘violation’ of TRIPS (PhRMA 2000f). In private, however, the PhRMA admitted that the provisions of the Act ‘has some basis in fact’ (United States Department of State 1998). The international firms were aware that South African Medicines Act was ‘not actionable through WTO dispute settlement procedure’, a glaring admission that they knew that the agreement was consistent with TRIPS (PhRMA 2000f; United States Department of State 1998). Nonetheless, the PhRMA firms called on the US government for support, warning that the Act posed a ‘serious threat to the viability of American pharmaceutical investment in South Africa’ (PhRMA 2000f).

66 Notably, the official UNAIDS account of this period neglect any mention of the corporate lawsuit in South Africa (see UNAIDS 2008).
The United States Trade Representative supported the industry lawsuit and added South Africa on the US Special 301 Watch List with the rationale that South Africa’s proposed Medicines Act granted the health minister ‘ill-defined authority…to abrogate patent rights’ (Office of the United States Trade Representative 1998, 1999). Unlike the international firms, the USTR did not publicly assert that the Act was inconsistent with TRIPS. It did not have to however, because it had recently amended its Trade Act which enabled the USTR to accuse any country that it denied ‘adequate’ IP protection, even if it were in compliance with TRIPS (Office of the United States Trade Representative 1994, 1995).

The South African litigation confirmed the fears of international NGOs, which had begun to share information amongst themselves about the potential implications of TRIPS for access to medicines. The US NGO Consumer Project on Technology (CpTech) was an important organisation in this informal network. James Love of CpTech had attended meetings on TRIPS at the WTO organised by Argentinean generic pharmaceutical firms in the mid-1990s. According to Love (2011b), the then Head of IP at the WTO, Adrien Otten, was sceptical of the possibility of generic production of patented medicines in TRIPS signatory countries. CpTech subsequently began coalition-building with other NGOs and contacted the international advocacy NGO Health Action International (HAI), which had been active in international medicines policy since the early 1980s (see Chapter two). The two NGOs held the first of several meetings on TRIPS and medicines in Bielefeld Germany in 1996, which was attended by several health
and development NGOs, including Médecins Sans Frontières (MSF) and Oxfam (Sell 2003).

The developments in South Africa in 1997 confirmed the NGO’s fears, and they began to advocate for the United States to drop its support for the pharmaceutical litigation. This public advocacy was initially centred on a legal interpretation of TRIPS, in response to the firms’ accusation that South Africa’s Act was inconsistent with TRIPS. The NGOs pointed out that measures like compulsory licensing and parallel importation were consistent with TRIPS (see Nader, Love and Weissman 1997). They also created issue-linkage by demonstrating that the pharmaceutical litigation was preventing more affordable access to medicines. The NGOs began to frame the industrial property measures like compulsory licensing and parallel importation as necessary ‘public health safeguards’ (Nader, Love and Weissman 1997). This was a counter-discourse to intellectual property ‘rights’ which had been diffused through the World Trade Organisation and was at the centre of the firm lawsuit in South Africa.

**The battle for a revised drug strategy**

In this section I demonstrate that the United States and its allies opposed and prevented an attempt by many developing countries and NGOs to prioritise health over IP in the WHO. I first show that a discourse for ‘public health safeguards’ emerged amongst NGOs in response to the litigation in South Africa and enabled several developing countries to forum-shift deliberations on medicines and patents back to the WHO. The United States and its allies strongly opposed this
move and they subsequently diminished the WHO’s authority by requiring the WHO to consult the WTO on all matters related to IP and medicines. Indeed, conflict over a Revised Drugs Strategy in the WHO ultimately led to a policy shift by the WHO Secretariat through which the incumbent Director General, Gro Harlem Brundtland, promoted IP as a prerequisite for medicines R&D.

In early 1998, shortly after corporate litigation commenced in South Africa, the Zimbabwean Health Minister, Dr Timothy Stamps, asked staff of the NGO Health Action International (HAI) to assist in the drafting of a Revised Drug Strategy (Sell 2003: 148). In the draft resolution presented to the World Health Assembly, the Health Ministry of Zimbabwe invoked a discourse of ‘public health safeguards’ as a strategy to get member states of the WHO to prioritise public health over commercial interests (Paragraph 1(2) in United States Department of State 1998). This draft resolution also called for governments to review their options under the WTO TRIPS agreement to ‘safeguard access to essential drugs’ (Paragraph 1(2) in United States Department of State 1998). Not only did this move demonstrate an attempt by Zimbabwe to forum-shift the debate over medicines and IP back to the WHO, but it also illustrated that the NGOs were engaged in both public and institutional advocacy.

At the 1998 World Health Assembly the NGOs played a key role in information-sharing and diffusing their counter discourse for ‘public health safeguards’. The NGOs held a series of workshops at the event in which they stressed to public health officials of several developing countries that compulsory licensing and parallel importation were ‘public health safeguards’ and were consistent with
TRIPS (Love 1998). James Love and Ralph Nader of CpTech told developing countries officials that the United States was spreading misinformation regarding TRIPS (Love 1998; Nader, Love and Weissman 1999). The NGOs distributed their own material to the member-state delegations in which they repeated their call for governments to protect ‘public health safeguards’ (Consumer Project on Technology 1998). Several delegations, such as South Africa, explicitly drew on the NGO material as they supported the Revised Drug Strategy (Consumer Project on Technology 1998; Goosen 1999; United States Department of State 1998). The diffusion of this ‘public health safeguards’ discourse was also evident in the WHO Action Programme on Essential Drugs, which released a report at the time of the Assembly promoting compulsory licensing and parallel importation measures as ‘public health safeguards’ (Action Programme on Essential Drugs 1998)\(^{67}\).

The United States and its allies, in particular the UK, Germany, Australia, the EU and Switzerland, strongly opposed the draft resolution. Privately, the EU mission concluded that ‘no priority should be given to health over intellectual property considerations’ (European Commission 1998). The EU mission also privately reported that the language of the resolution was of ‘considerable concern among the pharmaceutical industry in EU member states and likeminded members of the U.S.A’ (European Commission 1998). This suggests that the US and its allies were strongly influenced by their respective pharmaceutical firms. The United States was particularly opposed to the report of the WHO’s ADEP, which supported the use of ‘public health safeguards’ (Action Programme on Essential

\(^{67}\) The report came with the disclaimer that it presented the views of the authors only and not the WHO. One of the authors was Pascale Boulet, who went on to work for MSF’s Access campaign and the Medicine Patent Pool (see Chapter six).
Drugs 1998). This was because, in the US view, the ADEP had confirmed these ‘safeguards’ without consensus from the World Health Assembly. The US argued that the WHO had no grounds for comment on matters that related to intellectual property and trade (Holmer 2000; United States Department of State 1998). It attacked the WHO for ‘bias’ and put strong pressure on the Director General of the WHO, Gro Harlem Brundtland, and the Secretariat to maintain ‘WHO impartiality’ (United States Department of State 1998).

This political conflict over the Revised Drug Strategy ultimately led to a policy shift by the WHO Secretariat, which was a key turning point for the global governance of medicines. The Director General, Gro Harlem Brundtland, sought to allay US concerns by requiring the Action Program on Essential Drugs to revise its report with input from the World Trade Organization. In the revised report of the ADEP, Brundtland publicly claimed that the ‘protection of intellectual property rights goes hand-in-hand with successful research and development’ (cited in Action Programme on Essential Drugs 1998). This signified a shift in the WHO which had historically been sceptical of the industry claims that IP enforcement was clearly linked to R&D (see WHO 1985b). When the text of the Revised Drug Strategy was finally agreed upon by member states at the subsequent World Health Assembly, the United States insisted on language in the resolution that required the WHO to consult the WTO on all trade matters (Holmer 2000; United States Department of State 1998; WHO 1998b, 1998c, 1999b). This move effectively diminished the authority of the WHO and elevated the WTO as authoritative in matters relating to norms and rules guiding medicines R&D and production.
Public health safeguards

In this section I demonstrate that a coalition of NGOs and developing countries were more successful in diffusing the discourse for ‘public health safeguards’ at the World Trade Organization than they were at the WHO. I show that NGOs intensified their networking and created an informal global advocacy network through which they shared information and strategies. Through coalition-building between NGOs and developing country delegations at the World Trade Organization, these actors were ultimately successful in pressuring the WTO to confirm these ‘public health safeguards’ as consistent with TRIPS. Not long after, the Indian generic firm CIPLA announced the development of a fixed-dose combination (FDC) ARV, which it offered to developing countries at a substantially lower price than the originator firms. This development and the resultant discourse around it was a significant turning point in global medicines governance.

In the late 1990s domestic and international NGOs expanded their networking and campaigning for access to HIV/AIDS medicines, which demonstrated their ability to set agendas and shape global politics. In South Africa, which was still facing corporate litigation, AIDS rights activists joined together with anti-apartheid activists to form the Treatment Action Campaign (TAC)\textsuperscript{68}. Members of the TAC engaged in coalition-building with Thai AIDS activists at international conferences. Through this networking a specific campaign emerged regarding fluconazole, an essential medicine for the management of cryptococcal

\textsuperscript{68} The TAC would later take the South African government to court and win over the government’s responsibility under the new constitution to provide ARV treatment for mother-to-child transmission, extended counselling and testing services for HIV/AIDS (UNAIDS 2008: 109).
meningitis, a common infection in PLWA (Love 2011b). In 1998, Thai AIDS activists successfully lobbied the Thai government to enable generic production of fluconazole, of which Pfizer had been granted exclusive marketing rights. As part of a strategy of public shaming, awareness raising, and securing affordable medicines, the TAC began to smuggle the Thai generics into South Africa.

Pfizer also had a monopoly over fluconazole in South Africa through the patent system. Whereas the Pfizer originator was priced at R80.24 and R28.57 in the private and public sectors, the Thai smuggled generic was secured by TAC for R1.78 (Mandisa 2013: 154). The international NGOs MSF, HAI and Cptech took to the *Lancet* to publicise the stark price differences as part of a strategy of public shaming and awareness raising (see Perez-Casas et al. 2000; Wilson et al. 1999). Indeed, the international NGOs linked the fluconazole campaign to the broader issue of access to medicines and the pharmaceutical litigation against South Africa (see Perez-Casas et al. 2000). This generated significant public pressure on Pfizer, which ultimately led to Pfizer offering its branded fluconazole free to the public sector in South Africa for the treatment of cryptococcal meningitis and oesophageal candidiasis in AIDS patients (Hardwick [Senior Vice President of Pfizer] 2001; Perez-Casas et al. 2000)69. The NGOs had shamed Pfizer, and in doing so had demonstrated their discursive power. The success of the fluconazole campaign emboldened the NGOs in their broader campaign against the corporate litigation in South Africa. Indeed, following the fluconazole campaign, MSF won the Nobel Peace Prize for its humanitarian work and used the winnings to form its own Access to Medicines campaign. MSF then began to work with the TAC to

69 Pfizer refused to offer a voluntary licence to South Africa for generic production of fluconazole.
create its own treatment program for PLWA in Khayalitsha, South Africa (Mandisa 2013: 109, see more on MSF in Chapter six).

Networking between NGOs in South Africa and the US served as a ‘boomerang’ effect by which the NGOs brought the US-supported corporate litigation against South Africa onto the agenda of the American public elections (Keck & Sikkink 1999). In 1999, AIDS rights groups and activists in the US formed the ‘Global Health Access Project’ (Health GAP) in solidarity with the South Africa activists. That year, US group ACT UP followed the Presidential Campaign of Al Gore across the country, publicly shaming the US for supporting the pharmaceutical litigation against South Africa. The activists in both countries used symbolism and issue-linkage in which they framed the corporate lawsuit as a form of medical apartheid, chanting ‘Gore’s greed kills’ at public events (Borger 1999; Mandisa 2013: 149). Information-sharing was also intensified in this period as the NGOs developed the email list serve ‘E drug’ to ‘speed up’ communications between health professionals and activists in support of the concept of essential medicines (E-DRUG 1999).

A turning point for developing countries and NGOs was at the World Health Assembly in 1999. A defiant South Africa revealed that the WTO had privately advised that the ‘clauses in question’ at the core of the South litigation were compliant with TRIPS (Goosen 1999). This information confirmed for developing countries that measures like compulsory licensing and parallel importation were consistent with the TRIPS agreement. Not long after, the Brazilian President Cardoso issued a Presidential Decree that amended Brazil’s Industrial Property
law so as to expand the conditions by which the government could issue a compulsory licence (Brazil 1999). Like South Africa, Brazil had promised to provide all ‘individuals living with HIV/AIDS…free of charge … all medication necessary for treatment’ (Article 1 Law 9313 1996). The prohibitive price of ARVs meant that Brazil could not deliver on its promise. The Brazilian Health Minister Serra justified the policy in the context of the health needs of PLWA;

There is a Presidential decree that allows for patents to be broken in the case of abusive prices, and two of our AIDS drugs are candidates for this clause. … Not that our motivations are just economic…it’s human, it’s about solidarity (Serra Pressiona Laboratórios 1999; see also Nunn 2009: 11).

The discourse for ‘public health safeguards’ enabled a language through which developing countries could revise their industrial patent laws in ways that met health needs, and as a consequence, also met the economic ambitions of their domestic generic firms. One month later, at the World Trade Organizations’ Seattle Ministerial, developing countries presented a unified group and demanded that the WTO recognise that ‘public health safeguards’ were compliant with TRIPS. Indeed, several developing countries re-asserted demands with respect to medicines policy that were reminiscent of the New International Economic Order (see Chapter two). Zambia, Jamaica, Kenya, Pakistan, Sri Lanka, Tanzania, Uganda and Zimbabwe all made submissions to the WTO Ministerial in which they asserted that price controls on essential medicines were ‘public health safeguards’ (WTO 1999a). Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka and Uganda also made submissions in which they sought for the TRIPS agreement to exclude from patentability those medicines on the WHO’s Model List of Essential
Drugs (WTO 1999a). These moves demonstrated a counter forum-shifting strategy after the US blocked their attempts to reassert a role for the WHO in the Revised Drug Strategy (see above).

NGOs were active at the WTO conference and played a key role in pressuring the WTO to respond to the demands of the global South. Indeed, the broader context of the Seattle conference was the international protests, popularly known as the anti-globalisation movement (Castells 2004: 97). Health advocacy NGOs held their own meetings on ‘access to medicines and TRIPS’ at the Seattle Conference, which were attended by more than 350 delegates from over 50 countries, as well as the United Nations Development Program (UNDP), the WHO, and the WTO (Health Action International, Médecins Sans Frontières and Consumer Project on Technology 1999). Facing a broad range of criticisms that centred on the WTO as an agent of the global North, the WTO also held a number of NGO-focused forums in which it invited the health advocacy NGOs, as well as the PhRMA and IFPMA to attend70. The WTO issued a booklet at the Seattle Ministerial in which it responded to the main sources of criticism. This booklet finally confirmed that measures like compulsory licensing and parallel importation were ‘safeguards’ consistent with TRIPS (WTO 1999b)71. This was significant, despite the WTO Ministerial ultimately collapsing due to disagreements principally between the US and EU over agricultural tariffs (Muzaka 2011).

70 At the event, the IFPMA argued that the TRIPS agreement was ‘globalizing research’ and represented the ‘first global attack on counterfeit drugs’ (International Institute for Sustainable Development 1999).

71 The WTO was also critical of ‘misinformation’ on TRIPS that had spread through ‘bilateral discussions’ (WTO 1999b: 41).
The WTO’s confirmation of ‘safeguards’ led to intensified advocacy by the NGOs. In 2000 the South African TAC and the US Health Gap jointly organised the first march for universal access to HIV treatment at the Durban International AIDS conference in South Africa. Together, the NGOs demanded the ‘right to access to treatment’ and framed the denial of this right as ‘tantamount to genocide’ (ACT UP 2000). At the conference, Brazil announced that it had achieved price reductions of up to 70 per cent for its HIV/AIDS antiretrovirals since it had commenced generic production (Mandisa 2013: 113). This demonstrated to the international community the benefits of generic production for affordable access to medicines. In addition, CpTech and MSF made affidavits to the South African Supreme Court in which they linked the health needs of PLWA to the provisions of the Medicines Act under threat in the industry litigation (Love 2001a).

A significant turning point in this struggle came in September 2000 when Yusuf Hamied, long-time Executive Director of the Indian generic pharmaceutical firm CIPLA, announced that CIPLA had developed the first fixed-dose combination (FDC) ARV comprising stavudine, nevirapine and lamivudine (Hamied 2000). Hamied offered the FDC to developing countries at a price of 800 dollars per patient per year (Raaj 2013: 58). This was a significant price reduction from that offered by the international firms for the individual ARVs. While CIPLA had economic objectives in providing generic ARVs, Hamied framed his decision to produce the generics as a symbol of support for the health needs of the ‘Third World’ (Hamied 2000). HIV prevalence in India was low, ranging from half a per cent of the population in northern states to two per cent in southern states [in
2000] (Arora et al. 2008). Hamied invoked the ‘human tragedy’ of HIV/AIDS and the lack of access to medicines amongst the world’s poor as the rationale for generic production when he wrote to the originator firms requesting voluntary licences (CIPLA 2000a, 2000b).

Safeguards, IP, and medicines R&D

In this section I demonstrate that the United States and the international pharmaceutical industry co-opted the ‘public health safeguards’ discourse by framing IP ‘rights’ as a necessary safeguard for medicines research and development (R&D). I demonstrate that this strategy was enabled by the WHO Secretariat, which shifted its position in support of IP ‘rights’ as it sought to remain a relevant organisation under neoliberalism. The Doha Declaration on TRIPS and Public Health confirmed the presence of safeguards, but at the same time it diffused a global norm that IP ‘rights’ are a prerequisite for medicines R&D. In doing so, it legitimised the historical neglect of the specific health needs of the global South as a logical outcome in the absence of patent monopolies.

Following the announcements by CIPLA to supply generic ARVs, the United States appeared to soften its stance in Africa and subsequently withdrew its formal support for the pharmaceutical litigation against South Africa. In December 2000, President Clinton issued a Presidential Executive Order on HIV/AIDS which declared that the US would not pressure sub-Saharan African countries to revise their IP laws with respect to the regulation of HIV/AIDS medicines (Paragraph 1(a) Clinton 2000a). This order was largely rhetorical,
however, because it did not prohibit US officials from ‘consulting’ sub-Saharan African governments over their IP laws (Section 3(a) Clinton 2000a). Indeed, it presented a strategy by the US to absorb the developing country and NGOs claims for ‘public health safeguards’ within its broader push for the enforcement of strong intellectual property protection for medicines.

In response to the threat of CIPLA’s generic ARV, Clinton proclaimed that sub-Saharan African countries could implement ‘flexibilities’ while at the same time ensuring that ‘fundamental intellectual property rights of US businesses and inventors’ are protected (Clinton 2000b). In parallel, however, the USTR released its annual Special 301 report, which maintained India on its annual Priority Watch List. The rationale for including India was because ‘although not required to do so under the TRIPS Agreement until 2005, India has yet to provide patent protection for pharmaceutical and agricultural chemical products’ (Office of the United States Trade Representative 2000). Inclusion on the Priority Watch List signalled impending trade sanctions as a punitive measure. Thus, while the US appeared to soften its stance against Africa, where no generic firms developed ARVs, it sought to prevent Indian generic firms from supplying more affordable life-saving generics to Africa. International pharmaceutical firms also adopted a new strategy after the WTO confirmed that ‘safeguards’ were consistent with TRIPS. The PhRMA asserted that any governments which implemented ‘safeguard’ measures were required under TRIPS to ensure compensation ‘equal to the market value of the patent’, meaning the monopoly price (PhRMA 1999c). The international firms used this claim to reject CIPLA’s request for voluntary licences based on an offer of five per cent royalties (CIPLA 2000a).
While in public the United States withdrew its support for the pharmaceutical litigation against South Africa, in private the US intensified its collaboration with pharmaceutical firms to pressure countries to adopt IP measures beyond those required by the TRIPS agreement. In 1999 and 2000, at the request of the PhRMA, the US pressured Israel to withdraw a proposed Act that would have allowed parallel importation of medicines (Office of the United States Trade Representative 1999, 2000; PhRMA 2000b). As part of this strategy, both the USTR and PhRMA framed the alleged infringement of their ‘rights’ as ‘pharmaceutical piracy’ and ‘pirate production’ of ‘pirate products’ by ‘pirate companies’ (Office of the United States Trade Representative 1999; PhRMA 2000c, 2000e; Sell 2003). The USTR and PhRMA positions were so closely aligned that the USTR Special 301 report in 2000 mostly reflected complaints raised by the PhRMA (Office of the United States Trade Representative 2000; PhRMA 2000a, 2000b, 2000e, 2000f, see Appendix Three).

While developing country governments were under significant pressure by the US and the industry, NGOs and CIPLA continued their resistance. In February 2001, CIPLA announced on the front page of the *New York Times* that it would sell its FDC ARV to MSF for only 350 dollars per patient per year (McNeil 2002). This offer dramatically shifted perceptions in the international community about the affordability of ARVs for the global South. Indeed, it appeared to indicate that the

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72 The PhRMA also pressured several developing countries to weaken their essential medicines policies in this period. The PhRMA opposed Vietnam’s attempt to de-register several foreign pharmaceutical products in 1996, in which it convinced the US to require Vietnam to back down as part of US-Vietnam trade negotiations (PhRMA 1999c). PhRMA drafted a bill in Venezuela on the issue of generic promotion and substitution and pricing that was ‘positive’ for industry (PhRMA 2000d). It also pressured the governments of Japan and Taiwan to withdraw reference pricing schemes for pharmaceuticals (PhRMA 1999a, 1999b).
writing was on the wall for the pharmaceutical industry in its corporate litigation against South Africa.

A significant turning point in global medicines governance in this period was a policy shift of the WHO in support of the private ‘rights’ of international pharmaceutical firms, over the ambitions of the global South. In April 2001, two months after the dramatic CIPLA price offer, the WHO organised the first international meeting on financing essential medicines. The WHO was required to jointly host the meeting with the World Trade Organization as mandated through the Revised Drug Strategy. At the meeting, the WHO Secretariat promoted a new partnership it had established with five international pharmaceutical firms that offered low-income countries a reduced price on their ARVs (Brundtland 2001a; Piot 2001; WHO 2001b: 1,2). This deal appeared to mimic that of the UNAIDS partnership in 1997 (see above). The international firms called for recipient countries to increase their patent protection and to reduce price controls on medicines in exchange for the price reductions (Bale 2001; Hardwick [Senior Vice President of Pfizer] 2001). At approximately 7000 dollars per patient per year (WHO 2001b: 1,2), the ARVs were still out of reach for a majority of PLWA and were significantly more expensive than the generics produced in Brazil and by Indian generic firms\textsuperscript{73}.

The WHO ARV deal represented a policy shift in the WHO to promote ‘differential pricing’, by which international pharmaceutical firms offer tiered pricing according to government income levels, as the ‘appropriate’ measure for

\textsuperscript{73} A Ugandan treatment centre shifted away from the WHO initiative to source cheaper generic ARVs through CIPLA (Schwatlander, Grubb and Perriens 2006).
achieving affordable access to medicines in developing countries (Commission on Macroeconomics and Health 2001: 114). NGOs opposed this shift and in the WHO they continued to promote the safeguard measures like compulsory licensing and parallel importation (Nader 2001; ’t Hoen and Moon 2001). Nonetheless, the WHO Director General Brundtland was convinced that the IP system was a necessary ‘safeguard’ for the development of new medicines. Indeed, Brundtland asserted that ‘WHO’s position is clear: intellectual property rights must be protected. We depend on them to stimulate innovation’ (Brundtland 2000, 2001b).

This policy shift in the WHO was part of a broader move by Brundtland to re-assert a role for the organisation in promoting economic development (Commission on Macroeconomics and Health 2001; Lee 2009b: 114)\textsuperscript{74}. Brundtland, who was appointed on her credentials as Norway’s former Finance Minister, was under significant pressure by donors to reform the organisation so as to meet their interests (Lidén, 2014). In 2001 the WHO was over 20 million dollars in deficit and the US had reduced its contributions to the regular budget fund (Lee 2009b: 43). Brundtland commissioned a group of economists from the World Bank, IMF and American universities to create a new vision for the role of the WHO. This Commission worked closely with international pharmaceutical firms and adopted the language of intellectual property ‘rights’ as a necessary prerequisite for the development of new medicines (Commission on

\textsuperscript{74} The Commission reflected the turn to ‘selective’ primary health care (SPHC) (see Chapter three). For example, while the Commission acknowledged that sanitation, water and agricultural investments were important, it saw these as existing outside the health sector (Commission on Macroeconomics and Health 2001: 10).
Macroeconomics and Health 2002: 84, 14)\(^75\). Indeed, the Commission ignored the Brazilian and Indian generic developments and instead promoted differential pricing by international pharmaceutical firms as the most appropriate mode of governance for meeting the health needs of the global South.

This shift in the WHO was a blow to the ambitions of NGOs and several developing countries to elevate health needs over IP ‘rights’. As a consequence, many developing countries forum-shifted back to the WTO, which had appeared more receptive to their vision of ‘safeguards’ than the WHO. In June 2001, the Africa group (member states of the African region) requested a special session of the WTO on access to medicines. At the session Zimbabwe submitted a draft resolution on behalf of a large group of developing countries, which asserted that ‘nothing in the TRIPS Agreement should prevent Members from taking measures to protect public health’ (Consumer Project on Technology et al. 2001; Submission by the Africa Group et al. 2001). In the subsequent deliberations, India made the case for local medicines production within a broader context of unworked patents. This claim was broader than public health, and it resembled that of the earlier demands of developing countries in the 1970s under the New International Economic Order (see Chapter two). The US and Switzerland vehemently opposed India’s proposal, however, slamming such an ‘industrial development policy’ as inconsistent with TRIPS (Consumer Project on Technology et al. 2001). This demonstrated that the discourse of public health safeguards was narrower than the NIEO, in which UNCTAD (1975) had

\(^75\) The Commission even suggested that high-income countries extend intellectual property protection and exclusivity ‘rights’ beyond the requirements of TRIPS (Commission on Macroeconomics and Health 2002).
cautioned governments against solely relying on measures like compulsory licensing because of longstanding issues over technology transfer\textsuperscript{76}.

In the draft resolution at the WTO, the US and its allies demanded that text be inserted alongside Zimbabwe’s that ‘patents are important for public health policies because they provide incentives for research and development into new drugs…TRIPS is part of the solution and not part of the problem of meeting public health crises in poor countries’ (WTO TRIPS Council 2001; Zoellick 2001). In this way the discourse of safeguards was absorbed within the broader push for IP ‘rights’. In December that year the member states of the WTO finally agreed to the Doha Declaration on TRIPS and Public Health:

\begin{quote}
Recognising that intellectual property protection is important for the development of new medicines (paragraph 3 WTO 2001)...We agree that the TRIPS agreement does not and should not prevent members from taking measures to protect public health...we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ rights to protect public health and, in particular, to promote access to medicines for all (paragraph 4, WTO 2001)\textsuperscript{77}.
\end{quote}

Through this Declaration, governments confirmed and extended a global norm by which IP ‘rights’ were required for the development of new medicines. In doing so, they legitimised the historical neglect of the specific health needs of developing countries as a logical outcome due to the absence of IP protection.

\textsuperscript{76} In 1997 UNCTAD offered a weak assessment of TRIPS, merely cautioning developing countries for ‘balance’ (UNCTAD Secretariat 1997).
\textsuperscript{77} The Declaration also extended the deadline for TRIPS implementation with respect to patents for medicines for least-developed countries to 1 January 2016 (WTO 2002).
After the Doha Declaration, the group of international pharmaceutical companies finally withdrew their corporate litigation against South Africa (Love 2011b).

**Conclusion**

This chapter has examined developments in global medicines governance which led to the World Trade Organization’s Doha Declaration on TRIPS and Public Health. I have argued that the global norm for IP ‘rights’ in medicines R&D was strengthened. AIDS emerged on the global agenda through a discourse of AIDS exceptionalism. In the late 1990s, corporate litigation against South Africa became a core conflict by which NGOs, generic pharmaceutical firms and developing countries asserted a discourse for ‘public health safeguards’ which enabled them to reassert health needs against patent ‘rights’. The production of generic HIV/AIDS antiretrovirals in India was a significant turning point which forced the United States and international pharmaceutical industry to respond to the demands of this informal coalition and advocacy network. The chapter has shown, however, that the United States and international pharmaceutical industry co-opted this counter-discourse by framing IP ‘rights’ as a safeguard for new medicines. The World Health Organization enabled this co-option by siding with international firms as it sought to reclaim its authority under neoliberalism. The chapter has also highlighted the increasing power and influence of non-state actors in global medicines governance. International pharmaceutical firms exerted significant material power through corporate litigation and their influence on governments and the World Health Organization. They were met with resistance by health advocacy NGOs, which demonstrated discursive power through their
role in agenda setting, information-sharing, issue-linkage and coalition-building. The Indian generic firm CIPLA also exerted its own form of material power through its generic production of ARVs. This resistance was no match, however, for the power of the industry, which influenced the international forums through which governments negotiated global rules and norms that were favourable to the industry.
CHAPTER FIVE

Counterfeits, Regulation and IP

This chapter examines the globalisation of regulatory requirements for medicines and the diffusion of intellectual property ‘rights’ in global medicines regulatory initiatives in the 1990s and 2000s. The chapter demonstrates that shifts in the global governance of medicines in this period facilitated the enforcement of intellectual property ‘rights’ under the aegis of the WHO through an International Medicines Product Anti-Counterfeiting Taskforce (IMPACT). The chapter shows the pharmaceutical industry and its proponents diffused a discourse of ‘counterfeits’ that enabled the conflation of the health-regulation for medicines with the enforcement of intellectual property (IP).

Effective medicines regulation serves a public health function by ensuring that medicines are of good quality, are safe and are distributed correctly (WHO 2014a). This chapter argues that in the 1990s and 2000s, the international pharmaceutical industry and its proponents played a key role in raising minimum international regulatory standards, beyond mere health and safety benefits, as part of their strategy to block foreign competition from generic firms. I situate the creation of the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, the WHO’s pre-qualification program and the United States bilateral aid program for HIV/AIDS within this strategy and the broader historical struggle over the production and supply of medicines. In this broader context, the chapter shows that Nigeria emerged as a global advocate for the industry-led IMPACT in the WHO. Since the early 2000s, Nigeria and its generic firms have targeted India
and China as the source of ‘counterfeits’ as part of their domestic strategy to facilitate local production. In doing so, Nigeria and many African countries have become unofficial allies with the United States and the pharmaceutical industry at the international level through their support of IMPACT. The chapter shows that Nigeria’s support for IMPACT has created a division in the global South over the WHO’s role in this initiative and the terms in which to address the public health problem of substandard medicines. This has enabled the pharmaceutical industry to continue to pursue the enforcement of IP in IMPACT and has delayed effective global governance to address the problem of lack of capacity to regulate medicines in the global South.

**Counterfeits, quality-assurance and the WHO**

This section demonstrates that the international pharmaceutical industry brought the issue of ‘counterfeits’ onto the agenda of the WHO in the 1990s. This was a strategy of the IFPMA to conflate the health-regulation of medicines with the enforcement of IP through a discourse of ‘counterfeits’. The section shows that in parallel to the emergence of this ‘counterfeit’ discourse in the WHO, the industry also secured harmonised regulatory standards between the United States, Europe and Japan in the International Conference on Harmonization. These actors then sought to promote these industry-led standards as de facto global standards through the WHO.

The IFPMA first called on the WHO to ‘combat criminal counterfeiting’ at the WHO’s Nairobi Conference on the Rational Use of Drugs in 1985 (see WHO 1985b). It was not clear at the meeting precisely what the IFPMA meant by ‘criminal counterfeiting’, but the industry was strongly opposed to the WHO’s essential medicines policy (see Chapter two). A few years later, language to this effect appeared in a World Health Assembly resolution which called on member states to ‘cooperate with pharmaceutical manufacturers’ to detect and prevent the exportation of ‘falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations’ (WHA41.16 [1988] in WHO 1993: 189). This terminology was again undefined, but the resolution implicitly indicated different issues facing regulators. A falsely labelled medicine, for example, is a different issue to that of a medicine containing inadequate pharmaceutical ingredients, though the two can be related. Indeed, the IFPMA strategically used this lack of definition to conflate public health matters related to poor-quality medicines with
the protection and enforcement of intellectual property (see IFPMA in WHO 1992: 5).

The enforcement of IP was a clear objective of the IFPMA and its proponents at the first international meeting on ‘counterfeit drugs’ held jointly by the IFPMA and WHO in 1992. In attendance were representatives of the International Criminal Police Organization (INTERPOL), World Customs Organization (then Customs Cooperation Council), International Narcotics Control Board, General Agreement on Tariffs and Trade (GATT), and member states principally from the North (WHO 1992). At the meeting, the IFPMA framed counterfeiting as an IP issue that deprived ‘the manufacturer of his just rewards’ (cited in WHO 1992: 5). Indeed, representatives of the IFPMA suggested that the WHO call on national regulatory agencies to block the registration of ‘legitimately marketed products’ that ‘may be confused with established products based on superficial appearance of the trademark’ (WHO 1992: 8). The GATT delegation presented the TRIPS agreement, then still under negotiation in the GATT, as a solution that would enable private companies to enforce their trademarks through the seizure of suspected counterfeits (WHO 1992).

The WHO’s final report of the meeting also conflated quality-assurance and IP by attributing the causes of ‘counterfeiting’ to poor regulation, lack of access to medicines and poor IP protection (WHO 1992: 11-12). This conflation was also evident in the WHO’s subsequent definition of counterfeits that was shaped by the IFPMA:

a counterfeit is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and
generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging (WHO 1993: 1).

Less than two years later, the TRIPS agreement defined counterfeits as goods that infringed upon trademark ‘rights’ (Article 51, WTO 1994). The conflation of IP with health-regulation subsequently emerged in many studies on ‘counterfeit medicines’ which did not differentiate between substandard registered medicines, fake unregistered medicines, and medicines alleged to infringe upon IP ‘rights’ (Shakoor, Taylor and Behrens 1997: 840). This conflation also emerged in legislation in several countries. In 1996 the Philippines introduced a law on counterfeit medicines in response to these developments in the WHO and GATT. This law defined counterfeits as medicines with ‘insufficient quantities of active ingredients’ alongside ‘medicines without authorization, trade mark, trade name…or any likeness to that which is owned in the Bureau of Patent, Trademark and Technology’ (WHO 1999a: 10). This reflected the view of the IFPMA, that counterfeit medicines include those ‘close copies of the original that do not appear to pose a hazard to health’ (cited in WHO 1996: 45).

In addition to bringing ‘counterfeits’ onto the agenda of the WHO, in this same period the international pharmaceutical industry sought to use the WHO to promote industry-led regulatory standards as de facto global standards. In the early 1990s, the international pharmaceutical industry secured the support of the regulatory agencies of the United States, European Commission and Japan to harmonise their technical standards for the approval and registration of new
medicines (ICH 2010: 7). This harmonisation was premised on the rationale that it would lead to improved efficiency, reductions in costs and drug approval times, and facilitate access to medicines (Vogel 1998: 10). Indeed, the industry push for harmonisation was enabled by the advocacy of AIDS groups in the United States in this period, who mounted a campaign against the US FDA for perceived lengthy delays in approving potential life-saving medicines (Carpenter 2010; see Chapter four).

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was created in 1991 between the regulatory agencies of the US, EC and Japan and the national and regional associations of the IFPMA (ICH 2010). By the late 1990s, the pharmaceutical industry had driven the negotiation of 45 technical ICH guidelines, which included efficacy testing such as clinical trial design, clinical safety and good clinical practice, quality testing such as stability testing, impurities and pharmacopoeia, and safety testing (Trouiller et al. 2002b: 146). These were of a ‘high scientific level…using state-of-the-art-technology’ (WHO 2000). Many of these standards were not evidence based, nor did they demonstrate additional health and safety benefits (WHO 2000). Guidelines on clinical trials, for example, promoted placebo-controlled trials rather than assessing efficacy against a comparator medicine. As Trouiller et al. (2002b: 148) point out, this method is an ‘inflationary way of promoting pseudo innovator

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78 In 1992 the European Commission established a centralised application procedure for the registration of biotechnology and innovator products amongst its member states, the European Medicines Evaluation Agency (EMEA) (Braithwaite and Drahos 2000: 370).

79 In 1989 the FDA allowed people living with AIDS a ‘personal use exemption’ to import medicines for personal use if they had been approved by another regulatory agency, such as Europe (Vogel 1998: 10). In 1992, the FDA began to charge ‘user fees’ to pharmaceutical firms which coincided with a reduction in drug approval times.
medicines or me-too drugs’. While the ICH process initially applied to the registration of new medicines, the EU subsequently required that all products registered in the EU meet many of the ICH standards (WHO 2002d: 1). Indeed, the ICH countries and firms began to promote the industry-led standards as de facto international standards (ICH 2010; WHO 2002d: 13).

The WHO, which was an observer of the ICH Steering Committee, subsequently became a member of the ICH Global Cooperation Group, without the approval of its governing bodies (WHO 2000). The WHO shared the contact details of its national information officers with the ICH Secretariat, which was based at the headquarters of the IFPMA (WHO 1996). The WHO also revised its Good Clinical Practice guidelines (GCP) in light of the ICH requirements (WHO 2002d: 19). The United States, Europe and Japan subsequently used the WHO’s International Conference of Drug Regulatory Authorities (ICDRAs), which had been established jointly between the US FDA and WHO, to promote global adoption of the ICH standards (WHO 1996, 1999a: 15).

India and Brazil led a group of developing countries that became critical of the WHO’s involvement in the ICH, in particular in the absence of approval from the governing bodies and in light of the industry-led standards. In 1999 the WHO subsequently established an independent review of WHO’s role in the ICH (WHO 2000: 145). This independent review found that most of the ICH guidelines were not founded on evidence and did not demonstrate additional health and safety benefits, but did contribute to significant costs for manufacturers (WHO 2002d:

80 In recent years, Pfizer representatives have called on middle-income countries to ‘harmonise’ their regulatory requirements within a discourse of improving access to medicines by reducing ‘drug delays’ (Wileman and Mishra 2010).
ICH Q3A ‘Impurities in new drug substances’, for example, was not premised on evidence of additional safety benefits. Indeed, the review raised ‘serious concerns’ that if the ICH guidelines became global standards, local manufacturing in developing countries could be ‘squeezed out’ (WHO 2000: 145). Remarkably, despite these findings, the review panel ultimately recommended that the WHO establish mechanisms to review, modify and/or adopt ICH standards as WHO guidelines (WHO 2000).

The WHO, Global Fund and PEPFAR

This section demonstrates that the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, the WHO pre-qualification program and the United States bilateral aid program for HIV/AIDS were part of a broader global struggle over the production and supply of medicines. I argue that the catalyst for these developments was the production of generic HIV/AIDS ARV’s in India. I argue that the United States forum-shifted to its unilateral aid program, PEPFAR, as part of a strategy to raise minimum international regulatory standards and block competition from foreign generic firms.

In February 2001 the Indian generic firm CIPLA announced significant price reductions for its new fixed-dose combination antiretroviral containing lamivudine, stavudine and nevirapine (CIPLA and Médecins Sans Frontières 2001). This was a turning point in the battle over access to HIV/AIDS antiretrovirals in the global South (see Chapter four). In the following month, the

ICH Q3A determines that a substance requires safety to be established if any ‘organic impurity’ is present in the amount of 0.1 per cent or more (in some cases 0.05 per cent) (WHO 2002d: 21).
WHO launched a pilot pre-qualification program to assess HIV/AIDS medicines against ‘international’ quality standards. The public rationale for this program was that many developing countries did not have sufficiently-resourced national regulatory authorities and were at risk of ‘substandard, counterfeit and/or contaminated medicines’ (WHO 2001c). WHO also framed the program as a potential strategy by which developing countries could resist the application of ‘unrealistic’ ICH standards that could block the supply of essential generic medicines (WHO 2000: 149). Indeed, the WHO pre-qualification program initially appeared to be a point of resistance to the industry-led ICH from becoming de facto global regulatory standards.

In April 2001 international pharmaceutical firms began to publicly call for a global fund to assist developing countries to procure essential medicines for HIV/AIDS, tuberculosis and malaria (cited in Durman 2001). They were joined by senior leaders in the United Nations organisations (see Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases 2001; Bellamy 2001). In June 2001, the United States and its allies in the Group of 8 announced that they would launch such a fund for this purpose82. While the US and its allies had initially opposed the idea of a fund in the late 1990s, the catalyst for this policy shift appeared to be the development of cheaper Indian generic ARVs.

Shortly after the Global Fund announcements, in late 2001 a group of experts designed the WHO pre-qualification program with the strongest requirements of any national regulatory body at the time (’t Hoen et al. 2014).

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82 The Group of 8 is a forum of the leaders of the United States, UK, Japan, France, Italy, Canada, Germany, and Russia which includes the EU (the EU does not have voting rights in the organisation).
seeking pre-qualification from the WHO were required to comply with the newly established WHO guidelines that included proof of bioequivalence for generics (WHO N.D-a, 1998a). Manufacturers were directed to submit a dossier of data on formulation, manufacturing, specifications, stability testing results, labelling, patient information, interchangeability, pharmacology, toxicology, efficacy, and sites of manufacture. Upon a successful application, the WHO subsequently inspected manufacturers for their compliance with Good Manufacturing Practices, sampled and tested drugs, and examined storage and distribution (WHO 2001c).

In early 2002 it became clear that the transitional working group of the Global Fund was advising developing countries that only patented HIV/AIDS ARVs would be eligible for procurement through the fund (Médecins Sans Frontières 2002a). This appeared to be based on an assumption that medicines which had not been assessed by the regulatory authorities of the ICH were at risk of being poor quality (’t Hoen et al. 2014). Indeed, this was the line advanced by IFPMA, which released several ‘studies’ framing Indian generics as substandard and of poor quality in this period (McNeil 2002). This policy contradicted the longstanding practice of UNICEF, which had procured essential medicines through the WHO’s Good Manufacturing Practices (GMP) for decades without issue (CIPLA and Médecins Sans Frontières 2001; UNICEF 2000, 2013). Indeed, by 2000 Indian generic firms were the largest suppliers to UNICEF (UNICEF

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83 Two pharmaceutical products are bioequivalent ‘if they are pharmaceutically equivalent and their bioavailability after administration are similar to such a degree that their effects can be expected to be essentially the same’ (WHO 1998a).

84 The Global Fund was created as a mechanism for distributing aid, which comes mainly from governments. The Board of the Fund allocates aid to organisations for the procurement of medicines once they are approved by local ‘Country Coordinating Mechanisms’ that are local boards of the Fund in-country. Eligible countries are assessed according to income level, disease burden, and G20 membership (The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria N.D-b).
CIPLA had also received FDA approval for its manufacturing facilities in 1985 (CIPLA N.D). This suggests that the proponents of the fund were requiring higher ICH regulatory standards as a strategy to block the procurement of Indian generics.

In addition to this strategy, the transitional working group of the Global Fund was unclear on whether recipient countries could use funds to import medicines produced under compulsory licences in other countries. While the Doha Declaration had recently clarified the use of ‘public health safeguards’ under TRIPS, the agreement required that such safeguards be used ‘predominantly for the domestic market’ (Article 31f-WTO TRIPS Council 2001). In ongoing negotiations in the WTO, developing countries, NGOs and generic firms were fighting to expand the terms of use of safeguards for countries with little manufacturing capacity, which the United States opposed (Medpro Pharmaceutica 2002; Muzaka 2011: 94; 't Hoen 2009; 't Hoen & Chirac 2002). This struggle was prominent on the global agenda throughout 2001 and 2002, which detracted from the issue of medicines regulation. Nonetheless, MSF responded to the industry claims of poor-quality Indian generics by forming its own pre-qualification program. In 2001 and 2002 MSF sent its own pharmacists and experts to manufacturers in India and Brazil to assess HIV/AIDS ARV product dossiers and manufacturers according to the WHO’s Good Manufacturing Practices, and subsequently published a guide to ARVs (Médecins Sans Frontières 2002c; Médecins Sans Frontières, World Health Organization and UNAIDS Secretariat 2003).
In March 2002, the WHO released its first list of pre-qualified HIV/AIDS medicines which included 36 products, five of which were generics produced by CIPLA (WHO N.D-e)\(^{85}\). The NGOs called on the Global Fund to recognise the WHO pre-qualification program and the pre-qualified ARVs (Health GAP Coalition 2001; Médecins Sans Frontières 2002c). The Global Fund subsequently established a formal policy that it would only procure medicines that were pre-qualified by the WHO or by one of the ICH countries (Waning et al. 2010). UNICEF also changed its policy to require approval by WHO or one of the ICH countries for the procurement of ARVs and anti-malarials (UNICEF 2011; WHO N.D-f). In addition, the newly-created Global TB Drug Facility also required WHO or ICH-country approval for TB medicines for national tuberculosis programs (Matirua and Ryana 2007)\(^{86}\).

In early 2003 the United States shifted its funding for HIV/AIDS to a unilateral initiative, the President’s Emergency Plan for AIDS relief (PEPFAR). This policy shift was in part shaped by a strategy to secure the WHO pre-qualification program as a ‘floor’ for global regulatory standards, and to maintain the monopoly of international firms in the supply of ARVs procured through PEPFAR. The new entity was endowed with 15 billion dollars in its first five years, making it the largest government aid program for health in history. This aid was targeted at 15 African countries for the treatment and care of people living with AIDS (The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria 2003: 17).

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\(^{85}\) In the case of antimalarials, Novartis received a monopoly on pre-qualification until the WHO finally pre-qualified Chinese and Indian generic antimalarials in late 2005 (WHO 2013c).

\(^{86}\) The Global TB Drug Facility was established in 2001 to distribute medicines for tuberculosis.
The US Global AIDS program that hosted PEPFAR determined that it would only procure ARVs that had been approved by ICH countries (United States General Accounting Office 2004; Venkatesh, Mayer and Carpenter 2012; Waning et al. 2010: 7). The Director of the program, Randall Tobias, framed his decision as one based on scepticism of the safety of the WHO pre-qualification program: ‘maybe these drugs are, in fact, exact duplicates of the research-based drugs. Maybe they aren’t. Nobody really knows’ (cited in Associated Press in Dyer 2004). This position was also promoted by the international firms, and the IFPMA publicly claimed that the WHO pre-qualification of generics could ‘spread the current plague of substandard and counterfeit medicines’ (IFPMA cited in McNeil 2002).

This scare tactic preserved the monopoly of originator firms through PEPFAR because the US FDA practiced patent linkage, meaning that the FDA would not approve generic versions of medicines that were patented in the United States (Ferriter 2007; see Chapter three).

It was around this time that the United States finally agreed to expand the terms of ‘safeguards’ for countries with little manufacturing capacity in the World Trade Organization. This was only negotiated, however, after the US collaborated with international pharmaceutical firms to strike an informal agreement with a number of countries that they would only use the safeguards in the case of emergencies (WTO 2003). This paralleled announcements by the Global Fund that it would require recipients to comply with international trade agreements (The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria 2003: 17).

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87 Tobias was previously CEO of the international pharmaceutical firm Eli Lilly (Bristol 2006).
The US PEPFAR policy was not popular in the international community because it slowed progress on the WHO’s plan to increase ARV treatment coverage to an additional three million people by the end of 2005 (WHO/UNAIDS 2006). It was also increasingly untenable after academic experts and NGOs released studies in early 2004 that demonstrated the effectiveness of CIPLA’s generic FDC through clinical trials conducted in Cameroon and southern India (Kumarasamy et al. 2005; Laurent et al. 2004). In March 2004, staff of the WHO revealed that the FDA had approved originator FDCs on the basis of bioequivalence without the need for clinical trials (Rago 2004: 13). This called into question the assertion of the industry and the FDA that the WHO pre-qualification program should require clinical trials for the generic FDC ARVs (’t Hoen et al. 2014). Nonetheless, to secure higher regulatory norms through the WHO, the United States continued to call into question the WHO pre-qualification program and created its own ‘review’ process in the FDA to tentatively approve generic ARVs for use in PEPFAR programs (Office of the US Global AIDS Coordinator 2005). This was in parallel to a policy change in UNICEF by which the organisation began to require recipient countries to provide the patent status of ARVs ‘according to international and national law’ (UNICEF 2011: 6). This was a first in UNICEF’s history and demonstrated the diffusion of IP ‘rights’ as a global norm in the UN.

In August 2004, the WHO temporarily withdrew three Indian generic ARVs from its pre-qualification list. This followed reported ‘discrepancies’ in bioequivalence data submitted by the independent contract research organisations (CROs), and their lack of compliance to the WHO’s Good Clinical Practices and Good
Laboratory Practices (WHO 2004a). These withdrawals sent a wave of panic across the international community and led MSF and others to temporarily suspend its supply of these ARVs (‘t Hoen et al. 2014). At issue was not that the ARVs were a threat to health. Indeed, both CIPLA and Ranbaxy (the firms affected) contracted new CRO’s to conduct bioequivalence studies and the ARVs were subsequently pre-qualified by the WHO (WHO 2004b, 2005b). The damage was done, however, and the tentative withdrawals served to support the US scare campaign. The US FDA subsequently took over two years to approve CIPLA’s FDC (Raaj 2013: 61).

Counterfeits and Nigeria

This chapter has so far demonstrated that in the 1990s and early 2000s, the pharmaceutical industry and its proponents played a key role in raising minimum international regulatory standards by forum-shifting between the WHO, Global Fund, and PEPFAR. In addition, the industry brought the issue of ‘counterfeits’ onto the agenda of the WHO as part a strategy to conflate the health-regulation of medicines with the enforcement of intellectual property. This section shows that these developments contributed to additional barriers on medicine production in the global South. It specifically focuses on Nigeria because in the early to mid-2000s, the Nigerian government became a global advocate for international action on ‘counterfeits’. The chapter argues that this move by Nigeria was part of a

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88 By 2004, the WHO Secretariat was calling on member states to ‘meet international standards’ for quality assurance (WHO Secretariat 2003).
89 After the FDA finally approved generic ARVs, the price of originator ARVs began to drop (WHO/UNAIDS 2006: 21). There is no public information on whether PEPFAR has procured any Indian generics, what is known is that procurement from originator firms increased by 70 per cent after PEPFAR began to approve non-originator generics (WHO/UNAIDS 2006: 21). USAID finally accepted the WHO pre-qualification program in 2011 (‘t Hoen et al. 2014).
domestic strategy to facilitate local production. Nigeria and its generic firms targeted India and China as the source of ‘counterfeits’ as part of their domestic strategy, and in doing so they became unofficial allies to the United States and the pharmaceutical industry at the international level. Nigeria is the focus of this section because Nigeria is a key supporter of IMPACT, as shown in the final section of the chapter.

As an oil-dependent nation, Nigeria was dramatically affected by the collapse in oil prices in the early 1980s (Orubuloye & Oni 1996: 303, see Chapter three). Like many developing countries, Nigeria was forced to adopt structural adjustment reforms as a condition of IMF loans in the 1980s and 1990s that dramatically altered the health system (see Chapter three). In 1984, the government introduced user fees for health services, a first in Nigeria’s history (Orubuloye and Oni 1996: 303). Government spending on health decreased throughout the 1980s to less than two per cent of total government expenditure (Popoola 1993). Infant mortality subsequently rose and the country became dependent on donor funding for health (Orubuloye and Oni 1996; UNIDO 2011: 7). The devaluation of the Naira under structural adjustment led to a significant increase in the price of medicines, and was met with the withdrawal of all major international pharmaceutical firms from Nigeria by the late 1980s. This transformed the drug distribution system that was previously organised through wholesale distribution by the international firms (Peterson 2014: 132). Local and Indian generic firms stepped in to fill the gap, but the system of distribution shifted predominantly to unofficial markets.
In 1989, over 100 children died in the Nigerian towns of Ibadan and Jos after consuming a paracetamol syrup containing toxic ethylene glycol solvent instead of propylene glycol (NAFDAC 2005). It is unknown whether the syrup was a poor-quality legitimate medicine or an unregistered fake medicine. However, the incident led to claims by Nigerian generic firms that half of all the medicines in Nigeria were fake (cited in NAFDAC 2005)\(^9\). It was around this time that Nigeria supported a WHA resolution on counterfeit medicines (see above). The Nigerian government subsequently legislated its *Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act* (1990). This Act established a Task Force on Counterfeit and Fake Drugs to enforce laws prohibiting the manufacture, trade and sale of ‘counterfeit and fake’ medicines (Mwalimu 2009: 477). In 1993, Nigeria established an independent National Agency for Food and Drug Administration and Control (NAFDAC), shifting regulatory authority out of the Ministry of Health due to perceived ineffectiveness on combating fake medicines. While these moves were framed domestically in terms of addressing public health, the World Trade Organization (WTO 1998) asserted that the Nigerian government’s actions in this period were in response to calls for better enforcement of intellectual property ‘rights’ in WTO Trade Policy Reviews. Indeed, the Nigerian definition of counterfeits was broad enough to encompass issues of IP, including ‘any drug or drug product which is not what it purports to be….which label or container or anything accompanying the drug bears any statement, design or device which makes a false claim for the drug or which is false or misleading’ (Section 14 in Federation of Nigeria 1999).

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\(^9\) Subsequent academic studies suggested that the core problem was not widespread fakes but poor quality-control in manufacturing (Taylor et al. 2001).
By the late 1990s, Nigeria’s health care system was ranked the fifth poorest of all member states of the WHO. HIV/AIDS, respiratory diseases and malaria were the top three causes of mortality, and the country had the fourth highest prevalence of tuberculosis in the world (UNIDO 2011). Nigeria had become reliant on donor funding for health aid, and in 2002 through Global Fund resources the government initiated one of the first free HIV/AIDS ARV programs in Africa with supplies from CIPLA (Peterson 2014). Indeed, the Global Fund has provided most of the funding for treatments for people living with malaria and tuberculosis in Nigeria, with the country receiving over one billion dollars from the Fund (as of 2009, UNIDO 2011: 12). Since 2003, the United States PEPFAR program has also provided the largest contribution of funds for HIV/AIDS in Nigeria, donating approximately 270 million dollars per year and supplying 83 per cent of Nigeria’s ARVs (UNIDO 2011: 18). This increase in health aid has increased access to some essential medicines in the country, but Nigerian firms have been locked out of procurement through international organisations because they have not yet secured WHO pre-qualification or approval from ICH countries.

In the same period that the Global Fund and PEPFAR began to fund the procurement of many essential medicines in Nigeria, the United Kingdom funded the re-structuring of NAFDAC (PATHS2 2014). This aid enabled an expansion of NAFDAC, including a refurbishment of laboratories and extended training for regulators (Garuba, Kohler and Huisman 2009). The United States pharmacopeia also provided financial support to NAFDAC, and the international firm Novartis

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91 Despite this funding, TB prevalence tripled in Nigeria between 2002 and 2008 (UNIDO 2011). This was a reflection of the poor state of the public health system.

92 In the 1980s and 1990s UNICEF required manufacturers of essential medicines to meet WHO Good Manufacturing Guidelines, but they were not required to meet the stringent ICH standards that are now applied under the WHO pre-qualification program.
began to fund training, stock management and drug distribution for malarial programs in Nigeria and several other African countries (NAFDAC 2013; Novartis 2012). This re-structuring was in parallel to the appointment of new staff, including a new NAFDAC Director General, Dora Akunyili, who took a strong stance on corruption in the agency and fired many other staff. Akunyili also began a concerted public campaign against ‘counterfeit medicines’. The new NAFDAC framed the problem of poor quality medicines in the country as a problem of fake medicines and claimed that India and China were the source of these ‘fake/counterfeit’ medicines (NAFDAC 2005). Indeed, India was ultimately forced to respond to NAFDAC allegations by enabling NAFDAC officials to set up a base in India to assess medicines for export to Nigeria before they left the country (Raufu 2002, 2003)\textsuperscript{93}.

NAFDAC’s campaign against Indian and Chinese ‘counterfeits’ intensified in the mid-2000s as the government introduced laws to strengthen local production. In 2004 the government legislated Nigeria’s amended National Drug Policy (2004) that aimed to secure local firms as the source of at least 70 per cent of the country’s medicine needs by 2008 (UNIDO 2011: 1). At the time, capacity utilisation of Nigeria’s 120 local pharmaceutical firms was less than 40 per cent (UNIDO 2011: 41). Through the newly-formed Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN), local firms called on the government to secure Nigeria as the ‘leading distributor and manufacturer of essential medicines for Africa’ (cited in UNIDO 2011: 1)\textsuperscript{94}.

\textsuperscript{93} In 2009 India introduced life imprisonment and China introduced the death penalty for individuals responsible for the export of substandard finished products to Nigeria and other countries (UNIDO 2011: 30).
\textsuperscript{94} Nigeria has the largest number of pharmaceutical companies in West Africa.
NAFDAC subsequently required that importers produce drugs in Nigeria within 10 years of registration and introduced a ban on imports for several medicines that were produced locally (NAFDAC 2005; UNIDO 2011: 49). NAFDAC continued to accuse India as the source of ‘fake drugs’ and called on the WHO to support Nigerian firms to secure WHO pre-qualification to ‘reduce the importation of counterfeit medicines’ (NAFDAC 2005; Orhii 2013: 19). Under a pharmaceutical production project sponsored by Germany, UNIDO (2011: iii) also echoed these calls for Nigeria to support local firms ‘to reduce the penetration of counterfeit products’. Indeed, Nigeria’s strategy appeared to be that of targeting India and China as the source of ‘counterfeits’ to bolster local production and secure pre-qualification for its generic firms.

At the 11th international conference of drug regulatory authorities in 2004, Nigeria was a key advocate for an international convention on counterfeit medicines (NAFDAC 2005). This meeting, hosted by the WHO, was principally focused on the enforcement of intellectual property. INTERPOL, the World Customs Organization and World Intellectual Property Organization reported on extensive training provided to regulatory authorities on IP ‘crime’ and enforcement (WHO 2004c: 11,13). WHO representatives confirmed that the WHO definition of counterfeits ‘encompassed’ IP protection and enforcement under TRIPS and called on member states to ‘implement and enforce anti-counterfeiting legislation’ (WHO 2004c: 14).

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95 This included tariffs of 50 per cent on medicine imports that local manufacturers had the capacity to produce (UNIDO 2011: 49).
NAFDAC continued to promote action on counterfeits with a definition that encompassed IP measures: ‘clones of fast moving drugs… [and] drugs with the same quantity of active ingredients of the genuine brand’ (NAFDAC 2005). NAFDAC (2005) claimed that the ‘counterfeit drug problem’ was due to ‘countries in Asia which have little regard for patent protection… companies may be producing legitimate goods at one end of the factory and counterfeits at the other’. This position brought NAFDAC into conflict with AIDS activists in Nigeria, as Peterson (2014) observed at a conference on ARVs in 2005. At issue was the parallel importation of medicines, a safeguard under TRIPS. NAFDAC officials claimed that parallel importation would enable the importation of fake drugs, while activists focused on the need to secure the provision of generics (Peterson 2014: 136).

It is notable that while Nigeria championed an international convention on counterfeit medicines premised on the enforcement of intellectual property, IP laws in Nigeria remain ‘more or less non-existent’ (UNIDO 2011: 53). The WTO has accused Nigeria of becoming ‘more protectionist’ in light of its legislations on local medicines production (WTO 2005). Despite this criticism, Nigeria has not faced any sanctions for non-compliance with TRIPS in the WTO. This may be because Nigerian firms produce off-patent essential medicines and have not secured WHO pre-qualification (UNIDO 2011: 1)\(^{96}\). A second explanation is that WTO trade sanctions would hurt multinational oil companies that are the main exporters of oil and gas from Nigeria (in joint ventures with the government), which represent 90 per cent of Nigeria’s industrial activity (Peterson 2014).

\(^{96}\)The local pharmaceutical manufacturing industry is currently able to meet 25 per cent of local demand for medicines (UNIDO 2011: 31).
Counterfeits and intellectual property: IMPACT

In 2006, the WHO Secretariat began hosting an International Medicines Product Anti-Counterfeiting Taskforce (IMPACT) that was principally driven by the international pharmaceutical industry and its proponents to promote the enforcement of IP ‘rights’. This section shows that Nigeria led a group of African countries in blocking attempts by India, Brazil, and several developing countries to disengage the WHO from IMPACT. This division in the global South enabled the industry to continue to pursue IP through IMPACT, by conflating health—regulation with IP through the ‘counterfeits’ discourse. Indeed, ongoing political struggles in the WHO over both terminology and leadership delayed effective global governance to address structural problems of a lack of capacity to regulate medicines in developing countries.

The idea of an international convention on counterfeit medicines was first proposed at the 11th international conference of drug regulatory authorities in 2004 (see above). In 2006, the WHO presented a draft proposal to the 12th international conference of drug regulatory authorities that had been developed by a private consultant and former advisor to the private sector, Michelle Forzeley (WHO 2006b). The paper on which IMPACT was founded made the case for an international taskforce on ‘counterfeit medicines’ to expand criminal punishment for the ‘production, manufacture, sale, distribution, delivery, importation and exportation of any counterfeit drug’ (WHO 2006b: 19). Counterfeiting was vaguely defined as ‘a forgery: a copy or imitation…made without authority or right’ (WHO 2006b: 6). Participants at the meeting, which included the IFPMA,
INTERPOL and some regulatory authorities such as NAFDAC, called on WHO to establish an entity along these lines (WHO 2006c).

IMPACT was formed later that year as a voluntary taskforce between international firms, regulatory authorities, INTERPOL, the World Customs Organization, WIPO and WHO. The WHO Secretariat agreed to co-ordinate IMPACT and to provide one-third of the taskforce’s funds (WHO Secretariat 2008). The remaining two-thirds were donated by the European Commission, Australia, Germany, Italy and the Netherlands. The WHO Secretariat also hosted IMPACT in its ‘Health Technology and Pharmaceuticals Cluster’ at the WHO headquarters in Geneva and agreed to disseminate IMPACT reports and documents with official WHO insignia (IMPACT 2006: 5). The WHO did not seek the approval of its governing bodies, the Executive Board or World Health Assembly when it established IMPACT (Legge et al 2014). Indeed, IMPACT would operate in the WHO Secretariat for two years before it was placed on the agenda of the governing bodies in 2008.

International pharmaceutical firms were key drivers behind IMPACT. The Director General of the IFPMA was appointed chair of its technology working group and was tasked with conducting workshops for medicines regulators to facilitate ‘knowledge sharing’ between regulators and industry (IMPACT Secretariat 2011: 42). The DG of the IFPMA was also responsible for creating and disseminating an ‘information checklist’ for regulators to assist in

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97 That same year when WHO member states sat to appoint a new Director General, the Under Secretary of the United Nations emphasised the need for WHO to combat ‘counterfeit drugs’ (WHO 2006f: 12).
determining the authenticity of medicines. The European Federation of Pharmaceutical Industries and Associations (EFPIA) drafted a revision of the WHO’s Good Distribution Practices for Pharmaceutical Products, that emphasised close relationships between customs agencies and regulatory authorities and the seizure of suspected counterfeits (IMPACT 2008; WHO 2009b: 10). These were later presented to the World Health Assembly by the WHO Secretariat as the work of ‘IMPACT’, obfuscating the role of the IFPMA.

IMPACT operated for two years out of the public spotlight and without the knowledge of several member states. In this period, reference to ‘counterfeits’ re-emerged on the agenda of the governing bodies of the WHO. At the WHO Executive Board meeting in 2007, Liberia and Kenya voiced separate concerns that ‘counterfeit medicines’ were a threat to health (WHO 2007a: 203; WHO 2007h: 62). The EU and Switzerland subsequently secured language in a WHA resolution on malaria that called on member states to ‘implement policies that prohibit the production, marketing, distribution and the use of counterfeit antimalarial medicines’ (EB120.R16 [2007] in WHO 2007a: 123; WHA60.18 [2007] in WHO 2007g: 76). This was met with calls by the United States for the WHO Secretariat to promote action on ‘counterfeiting’, which was re-affirmed by the Assistant General of the WHO (WHO 2007h: 68, 72). Text in a resolution on ‘Health Technology’ was also proposed by the WHO Secretariat, which called on member states to ‘fight against counterfeit medical devices’. This was subsequently removed, however, after Bahrain questioned the conflation of counterfeits with intellectual property (EB120.R21 [2007] in WHO 2007a: 308). The UN International Narcotics Control Board also called on member states to
combat ‘counterfeiting of medicines and their distribution’ in an obscure WHA agenda item on Cervical Cancer (WHO 2007h: 287).

At the 2008 World Health Assembly, Nigeria on behalf of the Africa group, called on member states to establish and enforce legislation on counterfeit medicines and support IMPACT (WHO 2008c: 116)\(^98\). Now in the public spotlight, India and the South-East Asian region of member states and several South American member states criticised the initiative as an agency for intellectual property protection (WHO 2008c). Speaking at the meeting, the IFPMA attempted to refute this critique by arguing that counterfeiting was not a matter for ‘patents’ (cited in WHO 2008c). Outside the WHO, however, Pfizer was urging the US Senate Finance Committee to negotiate an ‘anti-counterfeiting’ agreement ‘to defend IP protection around the world’ (Kindler 2008: 6).

Indeed, the Organisation for Economic Cooperation and Development (OECD) issued a report on the ‘economic impact of counterfeiting and piracy’ in this period, which clearly framed the IMPACT initiative as a governance mechanism to enforce and protect intellectual property (OECD 2008)\(^99\). This report outlined a rationale for the protection and enforcement of trademarks to extend monopolies, because ‘trademark duration is typically longer than patents’ (OECD 2008: 356). The OECD report also focused on alleged IP infringements of active pharmaceutical ingredients (APIs) in India (OECD 2008: 346). Not long after the report was issued, the WHO introduced the pre-qualification of APIs using

\(^{98}\) At the previous Executive Board meeting the U.A.E and Tunisia had requested an agenda item on IMPACT for the WHA (WHO 2008a: 171).

\(^{99}\) IMPACT defines ‘counterfeits’ as ‘when there is a false representation in relation to identity and/or source…including any misleading statements with respect to name…or marketing authorisation holder’ (IMPACT Secretariat 2011: 53).
stringent industry-led ICH standards (such as Q3A) that were not based on evidence of additional health and safety benefits (WHO 2001c, 2013b) (see footnote 79 on page 124). This suggests that the WHO pre-qualification of API’s was not principally driven by concerns over public health quality matters, but rather IP considerations. This conflation has appeared more recently in the United States Trade Representative’s 2014 Special 301 Watch Report (Office of the United States Trade Representative 2014: 20) which alleges that IP-infringing ‘counterfeit’ medicines are made with API’s that are ‘not made according to Good Manufacturing Practices’

A turning point which brought IMPACT onto the public agenda was in late 2008 when Kenya introduced an Anti-Counterfeiting Act that threatened access to generic medicines. The Kenyan Ministry of Industry introduced an Anti-Counterfeiting Act which outlined criminal measures against ‘counterfeiting’ and contained a broad definition of counterfeits as:

> the manufacture, production…or making, whether in Kenya or elsewhere, of any good whereby those protected goods are initiated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods (Ngugi 2012: 19).

AIDS rights activists in Kenya initiated a lawsuit in response to the Act in the High Court, claiming that it limited access to medicines and infringed upon Kenya’s constitutional guarantee for the right to health (Ngugi 2012: 2). This advocacy by AIDS rights groups informed a subsequent policy shift by the

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100 WHO has increasingly aligned its regulatory standards with the ICH guidelines ‘wherever possible’ (Smid 2010; WHO N.D-h).
Kenyan Ministry of Health, which dissented from the African group’s support for IMPACT at the WHO. Speaking at the World Health Assembly, the Kenyan delegation questioned the true intentions of IMPACT and WHO for allowing the taskforce to use official WHO insignia (WHO 2010c)\textsuperscript{101}.

In addition to this apparent conflation of IP and public health, in this same period customs authorities in the Netherlands seized at least 17 shipments of legitimate generic medicines in transit from India to Brazil, Peru, Columbia, Ecuador, Mexico, Portugal, Spain and Nigeria, on the alleged grounds of suspected counterfeiting (Mara and New 2009; Shashikant 2009). It was apparent that customs agencies were acting on the complaints of international firms. India and Brazil led a group of developing countries in protesting the seizures, and they were supported by the health advocacy NGOs (Third World Network 2010). Brazil criticised the seizures at the subsequent WHO Executive Board in 2009 but was met with protest from the European Commission, which argued that the WHO was not an appropriate forum for discussions of ‘trade disputes’ (WHO 2009a). Yet at the World Trade Organization two months later, the European Commission framed the seizures on the grounds of protecting public health (cited in Mara and New 2009)\textsuperscript{102}.

These developments led to intensified efforts by the South-East Asian and South American blocs at the WHO to remove IMPACT (WHO 2009a, 2009e, 2010c).

\textsuperscript{101} The Ministry of Industry had legislated the Act without consulting the Ministry of Health (WHO 2010c). Four years later in 2012 the High Court of Kenya ultimately agreed with the AIDS groups that the Act could threaten access to medicines and required revisions to remove discrepancy (Ngugi 2012).

\textsuperscript{102} India and Brazil initiated informal dispute settlement with the EU at the WTO in May 2010, which was withdrawn in 2011 (Press Information Bureau Government of India 2011).
The new WHO Director General, Margaret Chan, attempted to distance the organisation by claiming that WHO only participated in IMPACT ‘in the public health dimension’ (WHO 2009d: 59). At the request of Thailand, Chan commissioned an external review of the activities of IMPACT and potential conflicts of interest in the organisation, yet the report of this review was never publicly released (WHO Director General 2011). Despite the efforts of several developing countries, the WHO did not disengage from IMPACT. This was because Nigeria and the Africa group (excluding Kenya and South Africa) refused to support the South- East Asian and South American countries (WHO 2010c). Indeed, the new NAFDAC Director General, Paul Orhii, claimed that IMPACT was not about IP:

I cannot see how fighting counterfeits can negatively affect generics…this public health topic has become the victim of another debate…on trade and intellectual property that is certainly legitimate but that should take place in other fora…and not affect our efforts aimed at protecting public health from the threat of counterfeits (IMPACT Secretariat 2011: 5).

Nigeria’s refusal to disengage WHO from IMPACT is the result of a structural problem in global medicines governance in which African firms have been locked out of supplying many essential medicines to their populations. Indeed, Kenya’s main pharmaceutical firm Cosmos and Ghana’s Danadam are reportedly compliant with the WHO’s Good Manufacturing Practices, yet they have been unable to secure WHO pre-qualification because it requires more stringent regulatory standards and associated prohibitive costs (Osewe, Nkrumah and Sackey 2008: 35, 37). Thus, while the WHO pre-qualification program was initially conceived to prevent the ‘squeezing out’ of local firms in the supply of
essential medicines, it has inadvertently become a barrier for generic firms in the
global South, particularly in Africa.

The WHO pre-qualification program has so far failed to address lack of capacity
in national regulatory authorities. This is because the WHO has received few
funds from donors for this purpose (WHO 2005a)\textsuperscript{103}. In the absence of effective
national regulatory authorities, the WHO pre-qualification program is a bandaid
solution that does not address the issue of poor-quality and substandard medicines
in use in developing countries. Donors have selectively targeted bilateral aid to
regulatory authorities in Africa that appears to be offered in exchange for their
government support for IMPACT. The United States Agency for International
Development is presently funding sub-Saharan African government agencies to
implement ‘actions against counterfeit medicines’ (Office of the United States
Trade Representative 2014: 20). This has created a divide between Africa and
Asia and Latin America in the WHO\textsuperscript{104}.

In addition to these barriers, the Global Fund has also prevented African firms
from supplying medicines to their populations, even when they have received
WHO pre-qualification. Zimbabwe’s main pharmaceutical firm Varichem finally
received WHO pre-qualification for its ARVs in 2010. It has been unable to
secure supply in the Global Fund, however, because its ARVs are priced higher
than some foreign generics (The Herald 2012). These higher prices are in part a

\textsuperscript{103} The WHO has also been unable to source sustainable funding from member states for
its basic pre-qualification program (‘t Hoen et al. 2014).

\textsuperscript{104} The United States Trade Representative (Office of the United States Trade
Representative 2014: 20) continues to conflate the issue of quality-assurance with
intellectual property via a discourse of ‘counterfeits’. The USTR has recently framed
Brazil, China Indonesia, Peru, Russia and ‘especially India’ as the source of alleged
pharmaceutical ‘counterfeits’ that create ‘consequences for health and safety’ (Office of
the United States Trade Representative 2014).
result of the Global Fund and other agencies requiring WHO pre-qualification of API’s. The Board of the Global Fund has blocked attempts by some African countries to procure locally produced ARVs that are more expensive than Indian generics (United States General Accounting Office 2003: 31)\textsuperscript{105}. This reflects the tensions between the Fund’s finite resources on the one hand, and the need for sustainable medicines production on the other. This tension also demonstrates an emerging conflict between the South, namely India, China and African nations over generic medicines production.

In light of these constraints, African manufacturers have recently launched the Federation of African Pharmaceutical Manufacturers Associations (FAPMA), which is founded on a critique of ‘unfair competition from Asian importers’ and premised on a vision for an ‘African-based industry that would leave very little room for infiltration by counterfeit and fake medicines’ (Federation of African Pharmaceutical Manufacturers Associations N.D)\textsuperscript{106}. This demonstrates that African firms are putting pressure on their governments to support local production by framing foreign generics as threats to public health. In the WHO, this has translated into a stalemate between member states over appropriate terminology to address the problem of ‘spurious, substandard, falsely labelled, falsified, counterfeit medicines’ (referred to as SSFFC) (WHO 2011c)\textsuperscript{107}. This has

\textsuperscript{105} In the Global Fund, the United States and its allies have nine seats compared to six seats for countries in the South. Non-state actors also have voting rights, including two NGOs, one private sector representative (currently Merck), and one private foundation (currently the Gates Foundation) (The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria N.D-a, see more chapter seven). It is unclear if India or China would support efforts by African countries to change the Global Fund rules to enable the procurement of generics from African firms.

\textsuperscript{106} The IFPMA has funded African regulatory conferences since the mid-2000s.

\textsuperscript{107} While IMPACT eventually moved out of the WHO headquarters in Geneva, the WHO did not officially dissociate itself from IMPACT.
delayed effective global governance to assist the global South in addressing the public health problem of lack of capacity to regulate medicines.

**Conclusion**

This chapter has examined the globalisation of international regulatory standards for medicines and the diffusion of IP ‘rights’ in global medicines regulatory initiatives in the 1990s and 2000s. The chapter has demonstrated that the international pharmaceutical industry and its proponents played a key role in raising minimum international regulatory standards for medicines, beyond mere health and safety requirements, as part of a strategy to block competition from generic firms. The chapter has shown that the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, the WHO’s pre-qualification program and the United States’ aid program PEPFAR, were part of this broader struggle over the production and supply of medicines. This struggle principally focused on HIV/AIDS ARVs and to a lesser extent medicines for malaria and TB, with other conditions and medicines left somewhat on the periphery. The chapter has demonstrated that the pharmaceutical industry brought the issue of ‘counterfeits’ onto the agenda of the WHO as part a strategy to conflate the health–regulation of medicines with the enforcement of intellectual property. This has broader implications for many diseases and medicines. The chapter has specifically examined how these developments led to the government of Nigeria becoming a global advocate for international action on ‘counterfeits’ in the WHO. Nigeria and its generic firms have targeted India and China as the source of ‘counterfeits’ as part of a domestic strategy to facilitate local production. In doing so, Nigeria and
many African countries have become unofficial allies with the United States and the pharmaceutical industry at the international level through their support of the industry-led IMPACT. Nigeria has led a group of African countries in blocking attempts by India, Brazil, and several developing countries to remove the WHO from IMPACT. This has enabled the industry to continue to pursue IP through IMPACT by conflating health-regulation with IP through the ‘counterfeits’ discourse. Indeed, ongoing political struggles in the WHO over both terminology and leadership have delayed effective global governance to address public health issues facing the global South.
CHAPTER SIX

Neglected Tropical Diseases, Partnerships and IP

This chapter examines the evolution of the global governance of medicines for tropical diseases, culminating in the rejection of an R&D treaty in the WHO in 2012. The chapter demonstrates that product-development partnerships (PDPs) have become the dominant mode of governance for the research and development (R&D) of medicines for tropical diseases. This model principally serves to reinforce global norms for the protection of intellectual property ‘rights’. Indeed, the chapter argues that the creation of PDPs enabled the United States and its allies to block an R&D treaty in the WHO that threatened to replace IP as a global norm for medicines R&D.

The chapter shows that the plight of communities living with tropical diseases re-emerged on the global agenda in the 1990s through the advocacy of Médecins Sans Frontières (MSF) and a global network of activists and NGOs. These actors contested the TRIPS rationale for IP ‘rights’ as a prerequisite for R&D to meet the health needs of the South. They championed a counter-discourse that was premised on conceptualising essential medicines as ‘public goods’. A core proposal of the NGOs was that of a globally binding R&D treaty. This was envisioned to catalyse the development of medicines for tropical diseases as public goods, and create new norms for R&D that challenged the IP ‘rights’ system. Brazil, Kenya and many developing countries took up the NGO call for an R&D treaty at the WHO in the mid-2000s. The chapter argues that this ‘public goods’ discourse was the broader political context in which pharmaceutical firms
and their proponents created product-development partnerships and the WHO administered industry-donated drugs. Throughout the 2000s, international pharmaceutical firms and NGOs forum-shifted between different partnerships, in an attempt to establish their preferred norms for medicines R&D. While the turn to partnerships resulted in industry participation in much-needed R&D for tropical diseases, this shift ultimately contributed to the collapse of the R&D treaty in the WHO. The chapter shows that the international pharmaceutical industry gained privileged access to WHO ‘expert’ commissions in this struggle, which embroiled the WHO in controversy and raised questions over its independence.


**MSF and the drugs for neglected diseases network**
This section demonstrates that MSF played a key role in raising the issue of medicines for tropical diseases back on the global agenda in the 1990s and early 2000s. MSF established a coalition of academics and activists who shared a critique of IP ‘rights’ as a global norm for medicines R&D. These actors focused on ‘neglected’ tropical diseases to champion a counter-discourse that was premised on abandoning the patent monopoly system and de-linking the costs of R&D from the price of new medicines. At the core of this counter-discourse was a proposal for a globally binding R&D treaty in the WHO.

MSF was formed as an emergency medical relief organisation in the late 1970s (Dodier 2011: 8). It expanded its operations in African and Asian countries throughout the 1980s, coinciding with structural economic reforms in many that constrained government health spending (Redfield 2008: 132, see Chapter three). In the absence of sufficient public health systems, MSF developed ‘emergency health kits’ for its medical volunteers, which were eventually authorised and distributed by the World Health Organization (Vidal and Pinel 2011: 30, see Chapter three). Through this fieldwork, MSF staff became increasingly aware of the lack of available treatment for several health conditions specific to developing countries. Moreover, many treatments recommended by the WHO were ‘archaic, ineffective and toxic’ (see MSF 2001a: 2). This led MSF to challenge the WHO over several of its treatment guidelines. In the late 1980s, for example, MSF called on the WHO to amend its guidelines for the treatment of meningitis, a

108 MSF was formed by former staff of the French Red Cross who left the organisation in protest after the Nigerian army attacked medicines volunteers amidst the Nigerian civil war (Dodier 2011).
leading cause of mortality in developing countries (d’Alessandro 2011). MSF created its own epidemiology centre and conducted clinical and epidemiological studies in Uganda, Sudan, Nigeria, Mali and Ethiopia. Eventually, after intensified public advocacy, the WHO amended its treatment guidelines for meningitis in line with MSF’s recommendations (d’Alessandro 2011; WHO 2001a: 117).

In the mid-1990s, the international pharmaceutical firm Aventis ceased production of elfornithine, MSF’s preferred treatment for the condition of African trypanosomiasis, citing reduced profits. The WHO’s Tropical Disease Research program had funded the development of elfornithine, but was unwilling to publicly criticise Aventis and unable to secure a new source of production (Corty 2011: 143). This was a catalyst for MSF to intensify public advocacy on the basis of its newfound expertise in tropical diseases (see Varaine 1997). MSF’s first campaign targeted the pharmaceutical company Bristol-Myers-Squibb (BMS) after MSF discovered that BMS marketed an elfornithine-based depilatory cream for hair removal. MSF also campaigned for the WHO to change its treatment guidelines for malaria to artemisinin-combination therapies (ACTs), which was eventually adopted by the WHO’s Tropical Disease Research program (Le Pape and Defourny 2001: 68, see more below).

In the late 1990s, MSF joined CpTech, Oxfam and Health Action International in a global campaign to support the government of South Africa against an international pharmaceutical industry lawsuit (see Chapter four). Through

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109 MSF argued that two doses of the medicine oily chloramphenicol were more effective than the WHO’s recommendation of eight days treatment of intravenous ampicillin.
networking with the NGOs and activists, MSF subsequently established a formal ‘Drugs for Neglected Diseases’ (DND) advocacy group comprising academic experts and activists from around the globe, including some staff of the WHO TDR (see Depoortere, Legros and Torreele 2001; MSF 2001b; Trouiller et al. 2002a; Walgate 2002). The participants shared a critique of the assumption that the enforcement of IP ‘rights’ and monopoly pricing was a prerequisite for medicines R&D (see Chapter four). MSF and the DND sought to expose problems with the market-based R&D system by publishing studies which demonstrated that R&D was significantly skewed to conditions affecting wealthy countries (see Ford & Torreele 2001; Health Action International, Médecins Sans Frontières and Consumer Project on Technology 1999; International Institute for Sustainable Development 1999; Pécoul et al. 1999; Trouiller et al. 2002a). A key finding by the DND, which became a frequently cited figure, was that between 1975 and 1999 only 16 of all new medicines developed in the world were for tropical diseases (see Trouiller et al. 2002a).

In the countries in which MSF worked, tropical diseases such as African human trypanosomiasis, Chagas disease, intestinal parasitic diseases, leishmaniasis, leprosy, lymphatic filariasis, malaria, schistosomiasis, onchocerciasis and tuberculosis were leading causes of death and disability (Trouiller et al. 1999). The neglect of tropical diseases by the pharmaceutical industry was justified by the discourse of ‘selective’ primary health care, which evaluated tropical diseases as ‘low priority’ (see Chapter three, Walsh & Warren 1979). MSF and the DND began to frame tropical diseases as ‘neglected tropical diseases’ to bolster their
critique of the market-based IP driven system\textsuperscript{110}. This advocacy led to a wider global debate about the relevance of intellectual property for those conditions predominantly affecting developing countries (Drahos and Braithwaite 2002: 8). MSF and the DND championed a counter-discourse to TRIPS, which called for essential medicines to be re-conceptualised as ‘public goods’ rather than the private ‘rights’ of firms (see Ford and Torreele 2001; Hubbard and Love 2004; Médecins Sans Frontières 2002c; Medicines Patent Pool 2013; Trouiller et al. 2002a). This was premised on the principle that medicines for tropical diseases be funded by the public sector, be made affordable through de-linking price from the costs of R&D, produced as generics without IP ‘rights’, transferred to developing countries, and be provided to communities on a not-for-profit basis (see MSF 2001a; Pécoul 2000; Trouiller et al. 2002a: 28).

This counter-discourse was reminiscent of the WHO’s earlier attempts to re-orient medicines R&D in the 1960s and 1970s (see Chapter two, Mahler 1975a). The WHO’s Tropical Disease Research program that was established in the 1970s to address this problem had largely failed due to the resistance of the pharmaceutical industry (see Chapter three). Access to medicines in the post-TRIPS environment was also affected by bilateral trade agreements through which the United States exercised pressure for the adoption of patent laws beyond the requirements of TRIPS (Consumer Project on Technology et al. 2001; Love 2001b, Love 2002, see Chapter seven). In this broader political context, the NGOs coalesced around a shared vision for a globally binding R&D treaty in the WHO. They envisioned this treaty as a catalyst for the development of medicines for tropical diseases and

\textsuperscript{110} To the author’s best knowledge the phrase ‘neglected tropical diseases’ emerged on the international agenda through the MSF-led DND.
as a mechanism to create new norms for governments to resist bilateral trade pressures (see DNDi 2002; Ford and Torreele 2001; Love 2001b; MSF 2001a; Pécoul 2000; Walgate 2002). Core aspects of the proposed treaty were that it would be funded by the public sector based on a percentage of GDP, allocate R&D to health needs, de-link prices from the cost of research, expand the market for generics, and transfer technology to the global South (Pécoul 2000). MSF raised the idea of a globally binding R&D treaty on the international agenda at the inaugural WHO/World Bank Ministerial Conference on Tuberculosis and Sustainable Development and the International Conference on Infectious Diseases in 2000 (Orbinski 2000; Pécoul 2000).

**The turn to product-development partnerships: 2000–2002**

In the early 2000s, pharmaceutical firms and their proponents created product-development partnerships (PDPs) for medicines for tropical diseases. In this section I argue that these PDPs were a response to the NGO’s ‘public goods’ discourse that had emerged on the global agenda. I highlight the key role of private philanthropists in the turn to partnerships and show that these PDPs enforced IP ‘rights’. NGOs responded to the creation of partnerships by establishing their own PDP, the Drugs for Neglected Diseases initiative (DNDi).

Amidst the NGO advocacy for a new ‘public goods’ system for the research and development of medicines for tropical diseases, the Bill and Melinda Gates Foundation emerged on the global health landscape. The Gates foundation was a philanthropic initiative of Bill Gates, founder of the software firm Microsoft
(McCoy and McGoey 2011: 146). In 2000, shortly after the NGOs began their campaign for an R&D treaty, Gates donated 25 million dollars to support a new PDP, which came to be known as the Medicines for Malaria Venture (MMV) (Medicines for Malaria Venture 2009: 8)111. This was followed by a one million dollar donation from the multinational oil and gas corporation Exxon Mobile, and led to the forum-shifting of the MMV out of the WHO’s Tropical Disease Research program to an independent entity (Medicines for Malaria Venture 2009: 8). This signalled the effective demise of the WHO’s TDR, which subsequently became a partner among many in PDPs (WHO 2007c: 65).

Shortly after the formation of the Medicines for Malaria Venture, Gates and the Rockefeller Foundation financed the creation of a Global TB Alliance to develop medicines for tuberculosis (Global TB Alliance N.D-c)112. This coincided with the launching of a ‘Global Health Initiative’ in the World Economic Forum by Gates, Nestle and several international pharmaceutical firms with the purpose of ‘actively promoting public–private partnerships’ (The World Economic Forum N.D-a)113. Gates and other private foundations have played a key role in the turn to product-development partnerships for medicines, representing over 90 per cent of all funding for PDPs (Commission on Intellectual Property Rights Innovation and Public Health 2006: 75; Policy Cures 2011: 90)114.

111 The first global health partnerships were the International AIDS Vaccine Initiative (1996), Roll Back Malaria (1998) and STOP TB Partnership (1998) (see Bartsch 2011).
112 The Rockefeller Foundation has a long history in international health since the early 1900s (Williams & Rushton 2011: 4) and has been a key advocate of the turn to ‘selective’ primary health care since the 1980s (see Chapter three).
113 The World Economic Forum is an international organisation comprising over 1000 multinational corporations (The World Economic Forum N.D-b).
114 The Gates foundation also provides funds to the United Nations Population Fund (UNFPA), UNAIDS, the World Bank and the WHO (Moran 2011; Rushton and Williams 2011).
The Gates Foundation and the pharmaceutical industry were appointed as voting members on the new PDP governing boards (Medicines for Malaria Venture N.D; Global TB Alliance N.D-a). This was indicative of the entry of private sector representation in global governing bodies (see Buse 2004; Buse and Walt 2002). The Global Fund to Fight HIV/AIDS, Malaria and Tuberculosis, a partnership created in this period to finance the distribution of medicines, maintains private sector representation on all of its governing bodies (Transitional Working Group of the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria 2001: 1, see Chapter five)\(^\text{115}\). Similarly, the Global Alliance for Vaccines Initiative (GAVI), another partnership created with funding from Gates to distribute vaccines to developing countries, maintains private sector representation on its global and national boards (GAVI Alliance 2013 N.D; WHO 2002c). The inclusion of private actors as voting members was new in global health and, as Buse (2004: 24) has shown, many of these partnerships ‘overlooked’ the need for effective policies to prevent undue commercial interests.

The MMV and Global TB Alliance were founded on strong support for the enforcement of intellectual property ‘rights’ (Buse and Walt 2002; Pugatch, Chu and Tortensson 2012: 39). This reflected not only the interests of the international firms but that of Gates, who as head of Microsoft was a strong advocate of the TRIPS agreement. Indeed, Microsoft has publicly opposed any measures that

\(^{115}\) On average, representatives from the private sector and civil society (44 per cent) and bilateral and multilateral institutions (18 per cent) outweigh government sector representation on the national boards of the Global Fund (The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria 2003: 67). Gates maintains a permanent position on the Global Fund Board despite the fact that the Fund is predominately funded by governments (The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria 2013). In addition, nearly half of the recipients of the Global Fund for HIV/AIDS treatment are non-state actors (The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria 2006: 31).
would ‘weaken’ intellectual property in the global South (see Microsoft 2002). This suggests that the turn to PDPs was as much about countering the ‘public goods’ discourse of the NGOs as it was about facilitating R&D.

In addition to sponsoring PDPs, many international pharmaceutical firms responded to the NGO advocacy for a ‘public goods’ R&D system by offering drug donations and price reductions on their existing medicines for tropical diseases to the WHO (WHO 2001b: 4, see Appendix Five). Sanofi-Aventis finally agreed to resume production and to donate its TDR-sponsored elfornithine for sleeping sickness (see section above). In 2001, Novartis and the WHO signed a 10-year agreement in which Novartis offered its patented malaria artemisinin-combination therapy (ACT) artether/lumefantrine (Coartem) at a reduced price of USD 1.57 per treatment for distribution to endemic countries through the WHO (Novartis 2011).

MSF and the DND initially responded to this turn to PDPs by creating their own not-for-profit product-development partnership, the Drugs for Neglected Diseases initiative (DNDi). In 2002, MSF secured the support of the Indian Council of Medical Research, the Kenyan Medical Research Institute, the Malaysian Ministry of Health, the Oswaldo Cruz foundation/Fiocruz Brazil, Institute Pasteur (France), and the WHO’s TDR to create DNDi as a public-oriented partnership to develop new medicines for tropical diseases (Boulet 2011; DNDi 2002, 2010, N.D; Kant, Seth and Sharma 2005; Médecins Sans Frontières 2002b; Walgate
Former MSF-staff Bernard Pécoul and Pascale Boulet were appointed to head the entity (DNDi 2003). In contrast to MMV and the Global TB Alliance, DNDi was premised on the principle that any medicines that it developed would be ‘public goods’ and not accorded any intellectual property protection. MSF and the DND wanted to demonstrate that they could develop medicines for tropical diseases without intellectual property protection and with the transfer of technology to the global South. MSF maintained its call for an R&D treaty and argued that partnerships like DNDi were not a panacea and did not relieve governments of their responsibilities in health R&D (Pécoul cited in WHO 2003d: 4).


This conflict over the norms guiding product-development partnerships for medicines for tropical diseases was part of a broader struggle over the global rules for medicines R&D. In this section I show that these competing visions of the R&D system were evident in the WHO’s Commission on Macroeconomics and Health (2002) and the United Kingdom’s Commission on Intellectual Property Rights (2002). While Brundtland’s Commission on Macroeconomics and Health (2002) supported the industry perspective, the United Kingdom’s Commission on Intellectual Property Rights (2002) recommended that developing countries implement pro-competitive patent systems. These international commissions were

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116 DND is headquartered in Geneva with network offices in Asia, Africa, Japan, India and Latin America (Kant, Seth and Sharma 2005). DNDi initially identified sleeping sickness, Chagas disease, leishmaniasis and malaria as its focus (Boulet 2011).
a turning point that finally brought the issue of IP and medicines onto the agenda of the WHO’s governing bodies.

The Commission on Macroeconomics and Health was established by the Director General of the WHO, Gro Harlem Brundtland, to secure the organisation’s health mandate under the prevailing neoliberal order (see Chapter four). Brundtland sought to frame health as a necessary requirement for economic development, and she appointed economists from American universities, the World Bank and IMF as expert Commissioners to make this case. The Commission subsequently worked closely with international pharmaceutical firms and devoted a considerable section of its report to the issue of medicines for tropical diseases. Indeed, the commissioners explicitly acknowledged the advocacy of CpTech, Health Gap, MSF, Oxfam, and the Treatment Action Campaign in bringing this issue onto the global agenda (Commission on Macroeconomics and Health 2001: 126).

In contrast to the NGOs, the Commissioners argued that the lack of R&D for medicines for tropical diseases was a problem of ‘poverty not patents’, and praised the industry for its drug donations (WHO 2012c: 88). They created a ‘typology’ that segmented diseases according to markets ability to pay, and in doing so carved off ‘type three’ diseases that ‘overwhelmingly affect poor countries’ (Commission on Macroeconomics and Health 2001: 78). The Commissioners framed the problem of the ‘neglect’ of tropical diseases as one of insufficient support for the private sector (Commission on Macroeconomics and Health 2001; 2002: 84, 88, 114). This was indicative of a policy shift by the
WHO Secretariat under Brundtland in which the WHO supported IP ‘rights’ and public-private partnerships (WHO 2002a, 2002b, N.D-c). Brundtland praised these partnerships for ‘bridging the gap between market opportunities and people’s needs’ (cited in Global TB Alliance N.D-b).

A turning point in this unfolding conflict was the release of the report of the United Kingdom’s Commission on Intellectual Property Rights that same year (Commission on Intellectual Property Rights 2002). The UK Commission had been established in response to the conflict over HIV/AIDS medicines and TRIPS in the late 1990s (paragraph 149, Secretary of State for International Development 2002: 6, see Chapter four). The UK Commissioners were experts in IP and medicines R&D and included Argentinian activist lawyer Carlos Correa and the Director General of the Indian Council of Scientific and Industrial Research, Ramesh Mashelkar (Commission on Intellectual Property Rights 2002: 2). Like the WHO Commission on Macroeconomics and Health, the UK Commission concluded that intellectual property did ‘little to stimulate research on diseases that particularly affect poor people’ (Commission on Intellectual Property Rights 2002: 14). Unlike the WHO Commission, the UK Commission was more supportive of the demands of developing countries. The Commissioners recommended that:

… developing countries should, within the constraints of international and bilateral obligations, provide a pro-competitive patent system that limits the scope of subject matter that can be patented; applies strict standards of patentability; facilitates competition; includes extensive safeguards against abuses of patent rights; and encourages local innovation (Commission on Intellectual Property Rights 2002: 23).
The UK Commission report was widely praised by the NGOs, who welcomed the report as a ‘powerful evidence-based critique of the health and development problems caused by the one-size-fits-all approach of WTO patent rules’ (Oxfam, cited in International Centre for Trade and Sustainable Development [ICTSD] 2002). In contrast, the IFPMA, PhRMA and Microsoft opposed the report, with Microsoft issuing a public statement that the recommendations would ‘seriously undermine developing world efforts to become significant producers…of software and other IP’ (IFPMA 2002; Microsoft 2002; PhRMA 2002).117

The UK Commission appeared to be a catalyst for the WHO Secretariat to finally include the issue of intellectual property and medicines on the agenda of the governing bodies of the WHO (WHO 2003c). Shortly after the UK report was released, the WHO Secretariat issued its own report on medicines and IP to the World Health Assembly. This report largely ignored the findings of the UK Commission and instead promoted differential pricing and partnerships with industry as the preferred mode of governance to deliver affordable medicines (WHO 2003c). This signalled the Secretariat’s policy shift to support IP ‘rights’ and led NGOs to accuse the Secretariat of watering down the Doha Declaration on TRIPS and Public Health (Love 2003; MSF Campaign for Access to Essential Medicines et al. 2003).

Despite the WHO Secretariat’s support for IP, developing countries were emboldened by the work of the UK Commission. At the 2003 World Health Assembly, Brazil led a group of developing countries in calling on the WHO to

117 Shortly after the release of the UK Commission report, the Gates Foundation donated a further 40 million dollars to the Medicines for Malaria Venture (Medicines for Malaria Venture 2009: 14).
establish an independent commission on medicines and intellectual property (Médecins Sans Frontières et al. 2003; WHO 2003a). They were met with strong opposition from the United States. Indeed, the United States and its allies refused to support the creation of a WHO Commission on medicines, IP and R&D until member states agreed to narrow the scope of the commission to examine those diseases that disproportionately affect developing countries, ‘type three diseases’ (see Thompson 2003). The United States also insisted on text in the resolution that emphasised ‘the importance of intellectual property rights’ in fostering R&D for essential medicines (WHA56.27 [2003] in WHO 2003b).

**Neglected tropical diseases and the WHO: 2004–2006**

This section examines key developments in the period between 2004 and 2006, in which the WHO Commission on Intellectual Property Rights, Innovation and Public Health worked. I argue that increasing calls in the public sphere for an R&D treaty were the broader political context in which the WHO re-prioritised tropical diseases. The WHO established a new department for the Control of Neglected Tropical Diseases (NTDs) and began a partnership with industry to administer seven industry-donated drugs to communities ‘at risk’ of one or more tropical diseases. This action on NTDs was unprecedented and it demonstrated a significant policy shift in response to intensified calls for a new R&D framework.

The WHO Commission on Intellectual Property Rights, Innovation and Public Health was formally established in 2004 and tasked with evaluating the role of intellectual property in the creation of new medicines for those diseases that
‘particularly affect poor people’ (Commission on Intellectual Property Rights Innovation and Public Health 2006: iv). The WHO Director General appointed commissioners that included government ministers, economists, public health academics, the activist lawyer Carlos Correa and the Director General of the Association of the British Pharmaceutical Industry (ABPI). In the two years that the WHO Commission met with stakeholders, support for a public-oriented system for R&D intensified. The former head of the World Bank, Joseph Stiglitz, supported a medical innovation prize fund premised on de-linking the costs of R&D from the price of medicines (Stiglitz 2006). Several members of the US House of Representatives, UK House of Commons, and European Parliament joined academics, CpTech, Third World Network, MSF, Oxfam and HAI in collectively calling on the Commission to evaluate the NGO’s proposal for a global biomedical R&D treaty (Allen et al. 2006; CpTech 2005; Love 2006a).

As public support for an R&D treaty increased, the WHO held several international meetings on tropical diseases. The first of these, attended by member states, experts, NGOs and the pharmaceutical industry, centred on competing discursive perspectives, namely neoliberalism, human rights, and public goods (WHO 2003d). By the time of the second WHO meeting in 2005, neoliberal ‘health economics’ dominated the discussion (WHO 2005c). The WHO applied the World Bank’s disability-adjusted life years (DALYs) formula to highlight the economic impact of tropical diseases on productivity (WHO 2006h: 16). WHO argued that Chagas disease in Latin America, for example, caused over one

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118 DALYs is a formula for quantifying the burden of disease from morbidity and mortality (World Bank 1993). It is calculated as a sum of Years of Life Lost (YLL, number of deaths x standard age of life expectancy at death in years) plus Years Lost due to Disability (YLD, number of incident cases x average duration of case x severity of disease) (WHO N.D-d).
billion dollars a year in lost economic productivity (WHO 2006h: 16). Tropical diseases were framed within the language of ‘selective’ primary health care (SPHC) (WHO 2005c: 33). While they had previously been considered ‘low priority’ under SPHC, the WHO now argued that the industry drug donations were ‘cost effective’ measures that enabled the re-prioritisation of tropical diseases (see Walsh & Warren 1979; WHO 2006h: 18; Chapter three).

The WHO subsequently established a Department of Control of Neglected Tropical Diseases, signalling a policy shift in the organisation to address tropical diseases as a group (WHO 2007f: 7). Shortly after, the WHO released its first manual on treatment guidelines for four tropical diseases, namely lymphatic filariasis, onchocerciasis, schistosomiasis, and soil-transmitted helminthiasis. The guidelines recommended the regular mass administration of several industry-donated medicines as ‘preventative chemotherapy’ for communities perceived to be at risk (WHO 2006h: 4)\textsuperscript{119}. This covered many member states of the WHO. All four diseases were prevalent in most of the African region, soil-transmitted helminthiasis was prevalent across the South American and South-East Asian regions and most of the Western Pacific region, and lymphatic filariasis was prevalent across most of the South-East Asian and Western Pacific regions (WHO 2006i: 37-38). Thus the firms stood to gain considerable brand awareness through their donations\textsuperscript{120}.

\textsuperscript{119} The frequency of mass administration ranges from once to twice a year (WHO 2006i: 22).

\textsuperscript{120} This new WHO policy was articulated in a Global Plan to combat NTDs 2008–2015 and was met with expanded drug donations by industry (WHO 2007b: 39, see Appendix Five).
Indeed, these policy shifts in the WHO were met with intensified action on tropical diseases by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). The IFPMA shifted its public position to support new governance mechanisms for ‘health products which the market fails to deliver’ (IFPMA N.D). The IFPMA also began to produce a ‘status report’ on industry engagement in ‘neglected tropical diseases’, with several IFPMA firms establishing R&D ‘centres for neglected diseases’ in India, Spain, the United States, Singapore and Italy (IFPMA 2012b; Jenner [Director Intellectual Property and Trade IFPMA] 2010: 1).

These moves by the industry did not detract from developing countries taking up the NGO’s proposal for an R&D treaty. At the WHO’s Executive Board meeting in January 2006, Kenya, Brazil, Sudan and Pakistan called for the establishment of a global framework on health R&D which resembled that of the R&D treaty (Gerhardsen and New 2006; Love 2006b; ‘t Hoen 2006; WHO 2006a: 111). This draft resolution reflected the key principles of the ‘public goods’ discourse and was based on a public-oriented system for medicines R&D that de-linked the price of medicines from the costs of research. This resolution was put forward by the developing countries before the release of the report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health. This enabled Japan to stall the negotiations and shift the proposal to the World Health Assembly after the expected release of the report (WHO 2006a).

Prior to the 2006 World Health Assembly, the NGO Intellectual Property Watch alleged that the IFPMA had accessed and commented on the draft report of the
WHO Commission (Gerhardsen and New 2006). According to an anonymous commission member, comments from the IFPMA had appeared in the tracking records of the draft report. This news was met with anger amongst many developing countries and NGOs. Yet one month later, the Commission report was released. The WHO Commission echoed the main findings of the WHO Macroeconomics and UK Commissions and concluded that IP was not a ‘significant boost’ to develop medicines for diseases that predominantly affected developing countries (Commission on Intellectual Property Rights, Innovation and Public Health 2006: 85). The report was criticised, however, by its own Commission members Carlos Correa and Pakdee Pothisiri (Senior Deputy Permanent Secretary of Health to the Thai Government) for not sufficiently elaborating on ‘profound distortions’ in the patent system that obstruct generic competition (Commission on Intellectual Property Rights, Innovation and Public Health 2006: 201). This dissent and the revelations of industry influence suggest that the WHO Commission was constrained along the North-South divide.

Despite these constraints, many developing countries tried to negotiate on a global framework for health R&D at the World Health Assembly. On this occasion the European Commission led the opposition to the developing countries’ proposal (WHO 2006e: 63). Leaked documents by the NGOs revealed that the European Commission was strongly influenced by the IFPMA in its position to block the treaty (Balasubramaniam 2006). On a parallel agenda item, the United States blocked an attempt by Cuba, South Africa and Bolivia to create a role for the WHO in assessing the public health impact of trade agreements
The United States and European Commission ultimately weakened the resolution on the report of the WHO Commission to merely note that IP was an ‘inadequate incentive’ for medicines R&D in ‘uncertain markets’ (WHA 59.24 in WHO 2006d). This demonstrated the power of the United States and its allies in preventing the WHO from acting on the mandate of the global South for a new health R&D framework.

**Partnerships: 2007–2012**

As the call for a global ‘public goods’ R&D framework intensified in the WHO, international pharmaceutical firms and NGOs forum-shifted between different partnerships in an attempt to establish their preferred global norms for medicines R&D. This section demonstrates that firms and their proponents principally supported and created initiatives that enforced their IP ‘rights’. In contrast, NGOs used their partnerships to promote the ‘public goods’ model and ‘name and shame’ companies to share their patents and knowledge. I argue that the enforcement of IP in some PDPs created problems for access to medicines. This in turn created tensions for NGOs, in particular when NGOs supported initiatives that appeared to contradict their principled objectives.

The first medicines developed under the MSF-led Drugs for Neglected Diseases initiative (DNDi) were two fixed-dose combination antimalarials artesunate/amodiaquine (ASAQ) and artesunate/mefloquine (ASMQ) (DNDi 2007). ASAQ was developed by DNDi in association with the international firm Sanofi-Aventis,

121 The United States alleged that the WHO was demonstrating bias (WHO 2005a; WHO 2006d: 37).
and ASMQ with the public institute Fiocruz Brazil (Wells, Diap and Kiechel 2013). DNDi secured a technology-transfer between Brazil and CIPLA and the medicines were offered at a ‘no profit no loss’ price to public organisations, international organisations and NGOs in endemic countries. Unlike the Medicines for Malaria Venture, none of the DNDi partners acquired intellectual property for ASAQ or ASMQ. Indeed, the NGOs promoted the medicines as evidence of successful R&D without the need for IP.

In addition to DNDi, NGOs played a key role in establishing a Medicines Patent Pool (MPP) to develop new fixed dose combinations and generic HIV/AIDS medicines (Médecins Sans Frontières 2010f; Stop AIDS campaign N.D; UNITAID 2011). In 2009 MSF and Knowledge Ecology International (formerly CpTech) convinced the United Nations General Assembly and the board of UNITAID to host the Patent Pool (Medicines Patent Pool 2013; UNITAID and WHO Secretariat 2009; United Nations General Assembly 2011)122. Ellen ‘t Hoen, former Director of MSF’s Access campaign, was appointed to head the initiative. The MPP relies upon the voluntary participation of IP-holding entities to share their patents and knowledge in order to facilitate generic production and new combination ARVs. MSF subsequently began a global campaign to name and shame companies to share their patents with the MPP (Médecins Sans Frontières 2010f; Stop AIDS campaign N.D; ’t Hoen 2011; UNITAID 2011, see Appendix Six)123. The United States National Institute of Health was the first

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122 The IFPMA strongly opposed this initiative and the United States blocked the involvement of the WHÖ in the Medicines Patent Pool beyond pre-qualifying medicines (IFPMA 2009; WHO 2010c).

123 DNDi also developed a combination of two sleeping sickness medicines, elfenthidine and nifurtimox, which was approved by the WHO Essential Medicines List in 2009 (WHO Expert Committee on the Selection of Essential Medicines 2009).
entity to donate its IP on the ARV drug darunavir to the MPP in 2011 (UNITAID 2011)\textsuperscript{124}.

In response to these developments in the DNDi and MPP, international firms’ forum-shifted their negotiations over R&D for medicines for tropical diseases to the World Intellectual Property Organization (WIPO). In 2011, Pfizer led the establishment of an R&D-based partnership in WIPO called WIPO Re:Search (IFPMA 2011; WIPO Magazine 2013). This was a strategy of the firms to maintain their control over IP. Unlike the DNDi and MPP, WIPO Re:Search was founded on a strong commitment to IP ‘rights’. The firms claimed that they would collaborate through WIPO Re:Search to share compound and patent information to promote the development of medicines for tropical diseases (IFPMA 2012a; WIPO Magazine 2013; WIPO Secretariat 2005). These moves paralleled an expansion of the Gates Foundation’s donations to the Medicines for Malaria Venture of a further 100 million dollars to subsidise the procurement of antimalarials in the private sector in developing countries (Medicines for Malaria Venture 2009: 32). This program reflected the private sector orientation of Gates and MMV as the appropriate mode of governance for the distribution of medicines.

This section as so far demonstrated that NGOs and international firms were engaged in a battle over the global norms guiding R&D in PDPs. These norms have real life implications, in particular when the enforcement of IP creates barriers for access to medicines. The first, and only, medicine developed so far

\textsuperscript{124} Johnson and Johnson has refused to share its patent on darunavir, however, and has thwarted the access ambitions of MPP for the drug.
under the Global TB Alliance, for example, is bedaquiline for multi-drug resistant TB. This medicine was launched by an affiliate of Johnson & Johnson in 2013, nearly a decade after the firm secured patent protection in many countries, including in India until 2023 (MSF 2014, N.D; Walker and Tadena 2013). Johnson & Johnson has not yet disclosed what it will charge for the drug in India. However, it has suggested that it will charge 3000 dollars for a six-month course in middle and upper-middle income countries (MSF 2014). This makes the drug prohibitively expensive for the estimated 66,000 people living with multi-drug resistant TB in India (Travasso 2013).\footnote{The FDA has raised some concerns over the drug because it increases the risk of death by nine per cent (Mahajan 2013).}

The problem of ensuring access to medicines in product-development partnerships has created tensions for NGOs when they have supported initiatives that appear to contradict their principled objectives. In the case of the Medicines Patent Pool, NGOs have supported licences between international and generic firms that exclude middle-income countries, such as Brazil and Mexico (Burke 2013). Two hundred thousand people living with AIDS in Mexico, and half a million in Brazil, have been locked out of these licensing arrangements (UNAIDS 2012). This appears to contradict the MPP’s principled ambitions of ensuring access to medicines for all (Dodier 2011; Saez 2012).\footnote{In a similar example, MSF was initially appointed by the WHO to negotiate with pharmaceutical firms to reduce the price of TB medicines in the Global TB Drug Facility. MSF had little negotiating power because many countries granted firms patent protection. Thus, the price of second line TB medicines remains ‘exorbitantly priced’ and out of reach for many communities in the global South (Staff member of the WHO Global TB Drug Facility Matiru 2009: 1–3). MSF subsequently called on governments to use TRIPS ‘safeguards’ to secure cheaper prices (see Gupta et al. 2001).}
Similarly, while MSF has criticized WIPO Re:Search for locking out patients living outside ‘least developed’ countries from its licensing arrangements, DNDi has joined WIPO Re:Search (DNDi 2011; von Schoen-Angerer 2011). This has enabled WIPO Re:Search to make claims to principled authority through its association with these global advocates for the poor. To the extent that NGOs appear to compromise their principled authority in order to strengthen their capacity-based authority in R&D partnerships, their legitimacy as advocates for the poor may be threatened.

The demise of the R&D treaty: 2007-2012

In the same period that NGOs and firms forum-shifted between partnerships, calls for an R&D treaty intensified in the World Health Organization. Between 2007 and 2012, member states of the WHO agreed to a Global Strategy and Plan of Action and created two expert committees to resolve the problem of R&D for the health needs of the South. This section demonstrates that the international pharmaceutical industry gained privileged access to these WHO ‘expert’ commissions, which embroiled the WHO in controversy and raised questions over its independence. It also shows that solidarity in the South weakened in this period, in part as a result of industry drug donations and the creation of PDPs.

127 According to the United Nations Development Index, there are 34 WTO members classified as ‘least developed’ (UN-OHRLLS 2013).
128 Many PDPs rely on NGO involvement to appear legitimate (Buse and Walt 2000a). The International AIDS Vaccine Initiative (IAVI), for example, relies upon NGO involvement to advocate governments and ‘build demand’ for an AIDS vaccine (Chataway and Smith 2006: 21, 23).
129 When NGOs channel ‘putative discontent into activities that do not upset the status quo’ they are vulnerable to this critique (Dryzek 2012: 110). Lipschultz (2005) has shown that NGO campaigns in labor, trade and environment are often focused on markets and distributive politics and do not challenge the underlying status quo and the constitutive ‘rules of the game’.
Indeed, I argue that the United States and its allies successfully blocked the proposal for an R&D treaty proposal by appealing to PDPs as the appropriate global governance for medicines for tropical diseases.

In 2007 the WHO convened its first ‘strategic and technical advisory group’ for the prevention and control of NTDs. This group of experts subsequently defined 17 diseases as ‘neglected tropical diseases’, namely Buruli ulcer, Chagas, taeniasis/cysticercosis, dengue, dracunculiasis, echinococcosis, Endemic treponematoses (Yaws), foodborne trematodiases, Human African trypanosomiasis, Leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, rabies, schistosomiasis, trachoma and soil-transmitted helminthiases (WHO 2007e). The criteria for this categorisation were unclear and many diseases, like malaria and tuberculosis, were left out. The WHO definition of NTDs appeared to be based on whether or not product-development partnerships had been created.

That same year, member states of the WHO formed an inter-governmental working group in response to the recommendations of the WHO Commission on Intellectual Property Rights, Innovation and Public Health. The inter-governmental negotiations, which lasted between 2007 and 2009, aimed to develop a strategy for ‘sustainable R&D for diseases disproportionately affecting developing countries’ (WHA59.24 [2006] in WHO 2006d). In the negotiations, a group of South American countries fought for the inclusion of the biomedical R&D treaty on the agenda (WHO 2008b)\(^{130}\). While they were successful in

\(^{130}\) They were supported by the WHO Commission on Social Determinants of Health (Commission on Social Determinants of Health 2008: 137), which called on member states to evaluate ‘mechanisms other than patents’ for the development of medicines for conditions predominantly affecting developing countries. This Commission had been
raising the R&D treaty as a proposal on the agenda, in late 2008 the WHO was mysteriously removed as a ‘stakeholder’ from their proposal (objective 2.3(c) in WHO 2008b). This sparked anger from Bolivia and Suriname, but Switzerland refused to re-instate the WHO as a stakeholder on the R&D treaty item (WHO 2008b, 2009c, 2009d). This was indicative of the tensions between the North and South, in which member states could only agree to a set of ambitions that failed to reconcile substantive issues over medicines and IP (WHA61.21 [2008] WHO 2011b: 1).

Following the end of the inter-governmental negotiations, the WHO member states established a second independent group of experts. The WHO Expert Working Group on R&D: Financing and Coordination (EWG) was formed to independently assess a range of proposals to create sustainable funding and international co-ordination of R&D to address the specific health needs of the global South. The EWG was embroiled in allegations of corruption, however, in late 2009 when WikiLeaks revealed that the IFPMA had accessed the draft report (WikiLeaks 2009). Following this leak, committee member Cecilia Lopez Montaño of Colombia publicly urged member states to reject the forthcoming report, citing manipulation by corporate interests (Montaño 2010). Indeed, the final report of the EWG demonstrated that the committee had assessed proposals according to their ‘acceptability’ to the pharmaceutical industry (Expert Working Group 2010: 18). The EWG rejected proposals for milestone prizes by Bangladesh and the NGOs after the pharmaceutical industry opposed them because they operated ‘outside the IP system’ (Expert Working Group 2010: 63).

established by member states to collect global evidence on the social determinants of health and their impact of health inequity.
The EWG had also rejected the proposal for a global R&D treaty yet gave no explanation as to why (Expert Working Group 2010: 86). WikiLeaks revealed that the IFPMA strongly opposed the treaty (WikiLeaks 2009).

South Africa, Colombia, Bolivia, India, Suriname, Bangladesh, Kenya and Thailand were scathing of the EWG for the apparent influence of the industry and its lack of transparency (Governments of Bolivia and Suriname 2010; WHO 2010a; 2010c: 3, 4)\textsuperscript{131}. The Union of South American Nations (UNASUR), Kenya, India, Indonesia and Brazil called for a new working group to re-evaluate and expand the number of proposals under consideration (WHO 2010c: 3, 4)\textsuperscript{132}. The United States, European Commission and French delegations initially opposed creating a new group, yet they eventually agreed when they secured the membership of Paul Herrling, head of corporate research at international firm Novartis (CIDEPRO et al. 2011)\textsuperscript{133}. Thus, in 2010 a new Consultative Expert Working Group (CEWG) was established under the WHO to ‘take forward’ the work of the EWG (WHA 63.28 [2010] in WHO 2010b).

This Commission, which worked between 2010 and 2012, ultimately supported many of the proposals that reflected the ‘public goods’ discourse, including pooled funds, milestone prizes, patent pools and a globally binding R&D treaty (Consultative Expert Working Group on Research and Development: Financing

\textsuperscript{131} Margaret Chan, Director General of the WHO subsequently conducted an internal investigation that did not reveal who had leaked the report to the IFPMA (Mullard 2009; WHO 2010a).

\textsuperscript{132} The Union of South American Nations (UNASUR) include Argentina, Bolivia, Chile, Colombia, Ecuador, Guyana, Paraguay, Peru, Suriname, Uruguay and Venezuela (Bolivarian Republic of) (WHO 2012c: 54).

\textsuperscript{133} As Head of Novartis research department, Herrling would subsequently play a key role in litigation against India over its granting of a compulsory licence for cancer medicine Glevic (see Chapter seven, Novartis 2013a).
and Coordination 2012: 63)\textsuperscript{134}. In addition, the CEWG supported the removal of ‘TRIPS PLUS’ measures like data exclusivity, which the United States was pressuring other countries to adopt through its bilateral trade agreements (Consultative Expert Working Group on Research and Development: Financing and Coordination 2012: 54, see Appendix Four). The CEWG was widely praised by the NGOs and led Kenya and the South American region to once again call for a binding R&D convention at the 2012 World Health Assembly (WHO 2012c).

The R&D treaty ultimately collapsed in the WHO due to a weakening of solidarity amongst the global South and strong opposition from the United States and its allies. Solidarity amongst developing countries was weakened because countries such as Thailand began to publicly support strong IP protection for medicines (WHO 2007h)\textsuperscript{135}. In addition, by the late 2000s the WHO had administered industry drug donations for tropical diseases to over 670 million people (WHO 2010d: ii). Indeed, shortly before the release of the CEWG report in 2012, the Gates Foundation, WHO and several international firms announced the highly-publicised \textit{London Declaration}, in which many firms committed to expanding their drug-donation programs for tropical diseases (Bill and Melinda Gates Foundation Press Release 2012, see Appendix Five)\textsuperscript{136}. These drug

\textsuperscript{134} NGOs which made submissions to the CEWG on the R&D treaty included Health Action International, Initiative for Health & Equity in Society, Knowledge Ecology International, MSF, Third World Network, All India Drug Action Network, Berne Declaration, People’s Health Movement and the Centre for Trade and Development India (CENTAD) (Consultative Expert Working Group on Research and Development: Financing and Coordination 2012: 50).

\textsuperscript{135} Only a year earlier, senior Thai government official Pothisiri had criticised ‘profound distortions’ within the patent system (Commission on Intellectual Property Rights, Innovation and Public Health 2006: 201, see above).

\textsuperscript{136} This widely publicised campaign of drug donations failed to acknowledge increasing evidence of drug resistance to several of the key industry donated treatments, including the only effective onchocerciasis medicine ivermectin, medicines for sleeping sickness eflornithine and melarsoprol and antileishmanial drugs (Albonico, Engels and Savioli 2004; Bryceson 2002; Gloecknera et al. 2009; Hotez et al. 2007).
donations, along with the development of some new medicines in the product-development partnerships, enabled the United States, European Commission, Switzerland, Australia, Canada, Japan and Monaco to block the R&D treaty at the World Health Assembly (WHO 2012b, 2012c)\(^{137}\).

**Conclusion**

This chapter has examined the evolution of the global governance of medicines for tropical diseases, culminating in the demise of an R&D treaty in the WHO. It has shown that MSF played a key role in raising the issue of medicines for tropical diseases back on the global agenda in the 1990s and early 2000s. MSF established a coalition of academics and activists that championed a ‘public goods’ norm for medicines R&D that was premised on abandoning the patent monopoly system and de-linking the cost of R&D from the price of new medicines. This ‘public goods’ discourse was the broader political context in which pharmaceutical firms and their proponents created product-development partnerships (PDPs) and the WHO began the administration of industry-donated drugs. The chapter has demonstrated that international pharmaceutical firms and NGOs forum-shifted between different partnerships in an attempt to establish their preferred global norms for medicines R&D (see also Williams 2012). The enforcement of intellectual property ‘rights’ in some PDPs created barriers for access to medicines, which in turn created tensions for those NGOs that participated in these initiatives. Nonetheless, the turn to PDPs as the dominant form of governance for medicines for tropical diseases ultimately enabled the

\(^{137}\) As of early 2014 the discussion over R&D at the WHO was focused on existing partnerships.
United States and its allies to block the R&D treaty at the WHO. Furthermore, the chapter has shown that the international pharmaceutical industry gained privileged access to WHO ‘expert’ commissions in this period, which embroiled the WHO in controversy and raised questions over its independence.
CHAPTER SEVEN

Power and Resistance

This chapter examines the contemporary situation of power and resistance in global medicines governance, with a particular focus on India. I demonstrate that the status quo is one in which the United States government and the pharmaceutical industry are attempting to raise global norms for the protection and enforcement of pharmaceutical intellectual property ‘rights’ beyond the requirements of TRIPS. This ‘TRIPS PLUS’ agenda threatens access to new medicines in developing countries because it inhibits generic competition and affordable access to medicines.

This dynamic of power and resistance is evident in recent landmark decisions of corporate litigation in India that have been led by some international firms in an attempt to secure ‘TRIPS PLUS’ IP standards. India is significant for the global South because many developing countries rely on Indian manufacturers for their essential medicines. The chapter shows that India has resisted the ‘TRIPS PLUS’ agenda with the support of a loose alliance of generic firms and health advocacy NGOs. This suggests that when economic and health objectives align, governments in the global South can resist industry pressure. These alliances are also evident in an increasing counter-movement amongst middle-income countries. The chapter draws on an analysis of texts of trade agreements, court documents, reports of the United States Trade Representative, the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, and NGOs (see Appendix Two).
The TRIPS PLUS agenda

This section demonstrates that the contemporary situation in global medicines governance is one in which the United States government is seeking to elevate global norms for IP ‘rights’ for pharmaceuticals beyond the requirements of TRIPS. Since the Doha Declaration on TRIPS and Public Health (WTO 2001), the United States has intensified its bilateral and regional trade negotiations in which it pressures other countries to raise IP measures in an apparent exchange for trade benefits. This ‘TRIPS PLUS’ agenda threatens access to new essential medicines in developing countries to the extent that it creates longer patent duration and monopoly rights.

Since the negotiation of TRIPS in the World Trade Organization in the mid-1990s, the United States government has finalised ‘free trade’ agreements (FTAs) with 20 other countries (Office of the United States Trade Representative N.D-a). The title ‘free trade agreement’ reflects the neoliberal objective of open markets and de-regulation. These agreements have been negotiated bilaterally with one other country, such as Australia, or regionally, with a group of countries such as the ‘Dominican Republic-Central America-United States’ FTA with Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and the Dominican Republic. Like the WTO agreements, these FTAs are negotiated in private between governments, with the text kept confidential from citizens until they have been signed by the negotiating parties.

In these trade agreements, the United States government has offered improvements in market access through measures like reducing tariff barriers, in
exchange for stronger intellectual property protection and enforcement protection for pharmaceuticals beyond the requirements of TRIPS (Bhardwaj, Raju and Padmavati 2013; Public Citizen 2011). These higher standards of IP protection are often outlined in separate intellectual property ‘chapters’ in the trade agreements, which participating governments must negotiate in order to secure benefits for trade market access (see Australian Fair Trade and Investment Network [AFTINET] 2013; Cohen-Kohler, Forman and Lipkus 2008; Collins-Chase 2008; Correa 2009; de Albuquerque Possas 2008; Drahos 2007; Drahos et al. 2004; Koivusalo 2003; Koivusalo, Schrecker and Labonté 2009; Malpani 2009; Médecins Sans Frontières 2013b; Office of the United States Trade Representative N.D-a; Sell 2007; TAC 2013).

The first of these TRIPS PLUS trade agreements was the North American Free Trade Agreement (NAFTA) between the United States, Canada and Mexico that was finalised in the same year as TRIPS. In the NAFTA agreement, Canada and Mexico agreed to the United States demands for stricter conditions on the granting of compulsory licences, and to establish border enforcement procedures for IP ‘rights’ beyond trademark and copyright (Office of the United States Trade Representative N.D-c: 187,189). These measures were ‘TRIPS PLUS’ because they were not required in the TRIPS agreement and they were more stringent than TRIPS.

After the Doha Declaration on TRIPS and Public Health in 2001, the United States intensified its bilateral trade negotiations and signed two more agreements with Chile and Singapore in 2003. In the United States–Chile trade agreement,
Chile agreed to ‘TRIPS PLUS’ measures, including the provision of extensions for patent terms, limits on the grounds for revoking a patent, preventing public interest objections to patents, and preventing the registration of generics through test data protection (Office of the United States Trade Representative 2013-a: 16; OXFAM 2004). Similarly, in the United States–Singapore trade agreement, Singapore agreed to measures for the extension of patent terms, to limit the grounds for revoking a patent, extend IP protection to ‘biotech plants and animals’, protect pharmaceutical test data for five years, and prevent marketing approval for ‘patent violating products’ (Office of the United States Trade Representative N.D-b: 6,7, see Appendix Four).

Likewise, in the United States–Australia trade agreement (2004), Australia agreed to limit the grounds for revoking a patent, provide measures to extend patent terms, protect pharmaceutical test data for five years (for marketing approval), and prevent the marketing of medicines that infringe patents (patent linkage) (Office of the United States Trade Representative N.D-e)\textsuperscript{138}. These IP chapters in the post-Doha trade agreements were ‘broadly consistent’ with the objectives of the US-based pharmaceutical industry. Indeed, the US Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters, which included representatives from PhRMA, saw the IP measures as key ‘precedential provisions’ for US trade agreements in the future (Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy

\textsuperscript{138} Australia limited the grounds for revoking a patent to only those claims that would justify the refusal to grant a patent in the first place (Office of the United States Trade Representative N.D-e).
Matters 2004: 2)\textsuperscript{139} The industry viewed these ‘TRIPS PLUS’ provisions as a ‘baseline’ for IP standards in future FTAs (Office of the United States Trade Representative 2013a: 4).


\textsuperscript{139} IFAC-3 aims to ‘promote the adequate and effective protection of intellectual property rights on a global basis’ and advises the US government. It includes representatives of the PhRMA and individual pharmaceutical firms (Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters 2004: 3, 22).

\textsuperscript{140} The United States has proposed stronger penalties on IP infringing ‘counterfeits’ in the TPP agreement under negotiation (see WikiLeaks 2013).
In addition to these trade agreements, the United States Trade Representative continues to ‘name and shame’ countries in its Special 301 Priority Watch List for alleged pharmaceutical intellectual property infringement (see Chapter three). This often results in trade sanctions against those perceived IP infringing countries. The majority of those countries included on the 2014 Special 301 Watch List and second-tier Watch List, for example, were for alleged pharmaceutical IP infringement (Office of the United States Trade Representative 2014)\(^\text{141}\). The key points for this chapter with respect to the contemporary situation of global medicines governance is that these trade agreements and trade pressures have reinforced TRIPS as a ‘floor’ rather than a ‘ceiling’ for global IP norms for medicines. These ‘TRIPS PLUS’ measures threaten to delay access to new essential medicines because they limit the scope that governments have to refuse or revoke IP ‘rights’ or use the hard-fought public health safeguards of TRIPS (see Kerry and Lee 2007).

The broader consequences of these trade agreements for global medicines governance is that they are shaping the structural conditions that reinforce the United States dominance in the global political economy. Since the United States–Australia free trade agreement (2004), for example, US exports to Australia have increased by 33 per cent (to nearly 19 billion dollars annually), while exports from Australia to the United States have only increased by three and a half per cent (just shy of eight billion dollars) (Office of the United States

\(^{141}\) USTR Priority Watch List (2104): China, India, Russia, Algeria, Argentina, Indonesia, Pakistan, Thailand and Venezuela. Watch List: Brazil, Canada, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, Finland, Guatemala, Paraguay, Peru, Turkey, and Vietnam (Office of the United States Trade Representative 2014).
Similarly, since the US–Singapore trade agreement, US exports to Singapore have increased by 31 per cent (to 21.5 billion), while exports from Singapore to the US have only increased by two per cent (to 15 billion) (Office of the United States Trade Representative 2013c, N.D.-c). The trade agreements appear to be reinforcing US dominance, which in turn enables the United States to exert pressure on other countries to raise IP norms.

**Novartis versus India: ‘the pharmacy of the developing world’**

This chapter has so far shown that the contemporary situation in global medicines governance is one in which the United States government, on behalf of the US-based pharmaceutical industry, is raising global IP ‘rights’ norms for pharmaceuticals. The following sections examine this interplay between power and resistance in India in the recent decade. The outcome of these struggles in India has global implications because many developing countries rely on Indian generics for their essential medicines (Hafner and Popp 2011; UNICEF 2011). After a brief summary of India’s historical position in medicines governance, this section examines the landmark case of corporate litigation initiated by Novartis after India rejected Novartis patent application for cancer medicine Glevic in 2006. This case, which lasted over seven years, demonstrates Novartis attempt to enforce ‘TRIPS PLUS’ measures in India. The case also shows the dynamic

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142 Similarly, since the United States–Chile FTA, the United States has maintained a positive trade surplus with Chile (of nearly three billion dollars), despite trade between the two countries decreasing considerably (US has reduced imports from Chile by a third and Chile has reduced imports from US by a quarter) (Office of the United States Trade Representative 2013a).

143 Since NAFTA, US exports to Canada and Mexico have increased by over 270 per cent, representing over a third of the total US exports in 2013. This figure was lower than US imports from Canada and Mexico (at 613 billion) because many companies subsequently moved to Mexico to take advantage of lower environmental and labor standards (Strachan 2011).
alliances between domestic and global NGOs and generic firms that have strengthened India’s resistance to this corporate pressure.

Unlike many developing countries, India strengthened its domestic pharmaceutical manufacturing capacity in the 1970s, 1980s and 1990s. In 1970, India led demands for a New International Economic Order (NIEO), and introduced legislation that reduced the period of patent protection for pharmaceutical processes and removed patents for pharmaceutical products (Lall 1974: 165). In the late 1970s, India introduced a Drugs Policy (1978) that reserved major areas of medicine production for the Indian sector (Gupta 1999: 154). Throughout the 1980s, India was insulated from World Bank structural adjustment reforms and doubled its medicine exports (Ballance, Pogany and Forstner 1992: 196; Bhutta 2001; WHO 2004d: 26). India led resistance to the TRIPS agreement, yet it was forced to concede after the United States suspended trade benefits with the country, and the solidarity of the Non-Aligned Movement declined (GATT 1989; GATT Council 1994c: 165).

In the mid-1990s, India was forced to introduce ‘mailbox’ provisions for pharmaceutical patent protection after the United States won a formal dispute in the World Trade Organization (WTO 1996c, 1996f, see Chapter four page 93). India introduced trademark legislation through its Trade Marks Act in 1999 (Government of India 2013: 108). As a developing country, India was not required to implement laws compliant with TRIPS until 2005. This enabled Indian generic firms to produce cheaper HIV/AIDS antiretrovirals (ARVs) and

144 India’s legal framework was influenced by the former British colonial rulers. India had introduced patent legislation through the Protection of Inventions Act as early as 1856 (Government of India 2013: 107).
become the largest supplier of generic ARVs in the world (Hamied 2000; Raaj
2013: 55, see Chapter four). By the early 2000s, Indian generic firms were the
largest suppliers of essential medicines to UNICEF and to many countries in the
global South (Hafner and Popp 2011; UNICEF 2000: 5).

In 2005 India became compliant with TRIPS through its Patent (Amendments)
Act (Indian Ministry of Law and Justice 2005). Reflecting India’s historical
opposition to the enforcement of pharmaceutical patents, the Act contained strict
conditions for the conferral of IP ‘rights’, including local working requirements
and measures for affordability (Basheer 2006; Indian Ministry of Law and Justice
2005). The Act sought to strike a balance between IP and the public interest, and
it was designed to prevent pharmaceutical ‘evergreening’, a practice in which IP
holders extend the term of monopoly ‘rights’ through measures such as
incremental changes to existing products (Faunce and Lexchin 2007; Madras
High Court 2007). Section 3(d) of India’s Patent Amendments Act excluded from
patentability:

…the mere discovery of a new form of a known substance which does not
result in the enhancement of the known efficacy of that substance…or any
new property or new use for a known substance…or the mere use of a
known process [in the absence of a new product or new reactant] (Section
3(d) Indian Ministry of Law and Justice 2005).

According to the Act, salts, esters, ethers, polymorphs, isomers, complexes,
combinations and other derivatives of known substances do not satisfy the criteria
of inventiveness and are not eligible for IP protection, ‘unless they differ
significantly with regard to efficacy’ (Indian Ministry of Law and Justice 2005).
India’s Patent Amendments Act represented a national interpretation of TRIPS that was premised on strict conditions for IP protection. It was also the beginning of an intensified period of patent litigation in India with respect to product patents and pharmaceuticals (see Nair, Fernandes and Nair 2014: 80).

Shortly after India’s Patent Amendments Act was finalised, the Indian generic firms NATCO, Hetero and CIPLA filed pre-grant patent oppositions to Novartis’ application for a patent on its cancer medicine Glevic (imatinib mesylate). This patent opposition centred on Section 3(d) of India’s amended Patent Act, in which the firms argued that Glevic, the beta crystalline form of imatinib mesylate, was not inventive and was previously published in an earlier patent outside India (Assistant Controller of Patents and Designs 2006).\textsuperscript{145} Novartis had filed a patent application for Glevic in India in 1998 under the ‘mailbox’ provisions (see page 93). In 2003, before the ‘mailbox’ was due to be opened, Novartis had secured exclusive marketing rights in India that prevented the Indian generic firms from producing and selling their generic versions of the drug. This exclusivity led to a tenfold increase in the price of the drug, which was considered a life-prolonging treatment for chronic myeloid leukaemia and gastrointestinal stromal tumours that require ongoing lifelong treatment (Ecks 2008: 167; Nair, Fernandes and Nair 2014: 80).

Hetero, NATCO and CIPLA were joined by the Indian Cancer Patient Aid Association (CPAA) that also filed a patent opposition to Novartis’ Glevic. The Indian Cancer Patient Aid Association’s pre-grant patent opposition centred on

\textsuperscript{145} The base compound of imatinib mesylate was previously patented in other countries but was not eligible for a patent in India because it was created before the TRIPS Agreement was finalised in 1994 (Menghaney 2012: 22).
the issue of lack of access to Glevic in India due to the high prices charged by Novartis (Cancer Patients Aid Association 2005). At the time Novartis was charging 30,000 dollars (US) per patient per year, a price out of reach for the majority of cancer patients in India (Menghaney 2012: 15)\textsuperscript{146}.

In January 2006, the Indian Assistant Controller of Patents and Designs denied Novartis’ application for a patent for Glevic on the grounds of lack of inventiveness, citing Section 3(d) of India’s Patent Amendments Act (Assistant Controller of Patents and Designs 2006)\textsuperscript{147}. This move was praised by health advocacy NGOs, yet it was strongly opposed by Novartis (Novartis 2007). In a similar vein to the pharmaceutical lawsuit against South Africa in the late 1990s, Novartis initiated litigation in the Madras High Court to secure IP protection for Glevic. This litigation was not simply about Glevic, however, as Novartis explicitly sought to invalidate India’s Amended Patent Act, in particular Section 3(d), on the grounds that it was inconsistent with TRIPS and violated India’s Constitution (see below Madras High Court 2007; Novartis 2013a)\textsuperscript{148}. Thus, the lawsuit had broader implications for medicines production in India and access to medicines in the global South.

The Novartis litigation drew considerable criticism from Indian patient advocacy groups and global NGOs that began to work together to ‘name and shame’ Novartis to withdraw its litigation. MSF began a global petition ‘Novartis: Drop

\textsuperscript{146} The price of Glevic increased tenfold after 2003 when Novartis secured the exclusive marketing rights (Nair, Fernandes and Nair 2014: 80).

\textsuperscript{147} At issue was that Novartis claim for Glevic was for a beta crystalline form of imatinib mesylate. The base compound of imatinib mesylate was not eligible for a patent in India because the TRIPS Agreement was finalised in 1994 (Menghaney 2012: 22).

\textsuperscript{148} Novartis asserted that Section 3(d) was unworkable, vague, arbitrary and conferred ‘un-canalised powers on the Patent Controller’ (Madras High Court 2007: 35).
the Case!’ which collected over half a million signatures in less than a year and was supported and promoted by the South African anti-apartheid Archbishop Desmond Tutu and the former Swiss President (Médecins Sans Frontières 2013c). The NGOs engaged in both public and institutional advocacy. In the Madras High Court proceedings, the Cancer Patient AIDS Association was the voice for the NGOs. The CPAA was represented by Anand Grover, who later became Special Rapporteur for the United Nations Human Rights Council. In the court, Grover argued that the high prices charged by Novartis for Glevic violated the ‘right to health’ in the Indian constitution (cited in Ecks 2008: 174). Grover also charged that the High Court did not have the jurisdiction to determine whether Section 3(d) was consistent with TRIPS, nor did Novartis have the legal standing to invoke the TRIPS because it was a private legal company (Arup 2012; Madras High Court 2007: 129).

In 2007, after no more than a year of court proceedings, the Madras High Court ultimately agreed with Grover that the court did not have the jurisdiction to determine whether Section 3(d) was consistent with TRIPS (Madras High Court 2007). The Indian government subsequently transferred Novartis patent appeal for Glevic to the newly-established Intellectual Property Appellate Board (IPAB). IPAB had been established in 2003 to hear appeals on trademarks and amended in 2007 to hear appeals from the decision of the Controller of patents (Lee 2014: 288). The remaining broader issue of whether Section (3d) of India’s Patent Amendments Act was unconstitutional remained with the Madras High Court. In late 2007, the Madras High Court determined that India’s Patent Amendments Act was constitutional. The Judge cited the intentions of the Act to prevent
evergreening, provide access to medicines, and meet constitutional obligations to provide ‘good health care’ to its citizens (Madras High Court 2007). This represented a win for the NGO movement and demonstrated the importance of the NGO’s public health advocacy in enabling resistance to Novartis’ pressure.

In 2008 IPAB rejected Novartis’ appeal for a patent on Glevic, echoing the decision of the Assistant Controller that Glevic did not satisfy the criteria of ‘inventiveness’ under Section 3(d) and did not show significant signs of efficacy. This decision was not only about the issue of inventiveness, with the IPAB explicitly criticising the high price charged by Novartis and problem of lack of access to medicines in its decision:

Rs 120,000/- per month for a required dose of the drug from a cancer patient…in our view is too unaffordable to the poor cancer patients in India. Thus, we also observe that a grant of product patent on this application can create havoc to the lives of poor people and their families affected with the cancer for which this drug is effective. This will have disastrous effect on the society as well (cited in Supreme Court of India 2013: 11).

The IPAB judgement did little to stem Novartis, and in early 2009 Novartis subsequently filed a Special Leave Petition in the Indian Supreme Court challenging the High Court and Assistant Controller’s decisions on Glevic. Like its first litigation, Novartis’ litigation in the Indian Supreme Court was not simply

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149 IPAB partly reversed the decision of the Patent Controller and held that the beta crystalline form was novel and inventive, however, it maintained that Bayer did not satisfy 3(d) because it did not show enhancement of efficacy (Nair, Fernandes and Nair 2014: 81).
about Glevic, but was a legal challenge and ‘test’ of India’s Patent Act, in particular Section 3(d) (see Novartis 2013b).

This litigation was again met with intensified advocacy on the part of both domestic patient organisations in India and international health advocacy NGOs. ACT UP France, the Berne Declaration, Avaaz, and MSF began global campaigns to name and shame Novartis, accusing the firm of blocking access to medicines (see ACT UP Basel 2013; Avaaz 2013; Bayer 2012; Berne Declaration 2012; Médecins Sans Frontières 2010b, 2010c, 2010e; von Schoen-Angerer et al. 2013)150. This advocacy resembled the ‘boomerang effect’ of transnational advocacy networks as detailed by Keck and Sikkink (1999). The international NGOs served as allies to domestic NGOs and brought international attention to the litigation and its consequences. The NGOs linked the national struggle in India with the broader implications for access to medicines by framing India as the ‘pharmacy of the developing world’ (Médecins Sans Frontières 2010a, 2010b, 2010e; von Schoen-Angerer 2010).

In 2013, after seven years of litigation, the Indian Supreme Court ultimately rejected Novartis appeal for a pharmaceutical product patent for Glevic (Arup 2012: 129; Government of India Ministry of Commerce & Industry 2013). Like the Assistant Controller and IPAB, the Supreme Court ruled that the application for Glevic, for the beta crystalline form of Imatinib Mesylate, ‘fails in both the tests of invention and patentability as provided under section 2(1) and section

150 Avaaz.org is an online campaign platform that was created in 2007 and has over 37.5 million members from over 194 countries (Avaaz 2014). The Berne Declaration is a Swiss NGO that has campaigned for more equitable North-South relations since 1968 (Berne Declaration 2014).
3(d)’ of India’s Patent Act (Supreme Court of India 2013: 96). The decision was widely praised by the NGO community and demonstrated successful resistance by India to the corporate industry pressure to implement ‘TRIPS PLUS’ rules and norms.151

**Bayer versus India: patent linkage and public health safeguards**

This section examines a second landmark case of corporate litigation in India, that of Bayer and its cancer treatment Nexavar (sorafenib tosylate). Like Novartis, Bayer attempted to create ‘TRIPS PLUS’ intellectual property measures in India through litigation. In a similar dynamic to the Novartis litigation, I demonstrate that India resisted this pressure with the support of an alliance of domestic and global NGOs and local generic firms.

In 2008, amidst the Novartis lawsuit over Glevic, a second landmark case in corporate pharmaceutical litigation commenced in India. The catalyst for this litigation was CIPLA’s application for marketing approval to the Drug Controller General (DCGI) for its generic version of Bayer’s then-patented Nexavar (sorafenib tosylate), a treatment for kidney cancer and advanced renal cell carcinoma. When Bayer became aware of this marketing application, it subsequently initiated a lawsuit in the Delhi High Court to block the Drug Controller from granting the licence to CIPLA. Bayer argued that CIPLA’s generic was ‘spurious’ under Section 17B of India’s Drugs and Cosmetics’ Act

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151 The Vice Chairman and Managing Director of Novartis India subsequently framed the Supreme Court ruling as a ‘setback for patients that will hinder medical progress for diseases without effective treatment options’ (cited in Novartis 2013b).
According to this Act, a drug is considered spurious in India:

…if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug (Delhi High Court 2010).

This litigation represented an attempt by Bayer to create patent linkage in India by conflating trademark protection with broader IP ‘rights’ protection. Bayer’s claim that CIPLA’s generic was ‘spurious’ was not about trademarks, rather Bayer attempted to conflate patent ‘rights’ with the trademark protections in the Drugs and Cosmetics Act. Patent linkage is not a requirement of TRIPS and is a ‘TRIPS PLUS’ measure for the protection and enforcement of IP ‘rights’. If Bayer’s litigation were to succeed, it would have broader implications for access to medicines because it would block marketing approval for generics that were alleged to infringe on any number of IP ‘rights’. Indeed, after Bayer filed its suit, the Delhi High court granted an interim injunction that prevented the DCGI from granting marketing approval to CIPLA until the court resolved the matter. While this injunction was only for the drug in question, the DCGI initially refused to accept any applications for marketing approval from any generic companies (Action Against AIDS Germany 2009).

In a similar vein to the ongoing Novartis litigation, the Indian Cancer Patient Aid Association requested that it be included as an interested party in the Bayer case in the Delhi High Court. This was subsequently confirmed, and the CPAA
became a vocal ally in support of CIPLA. In the court proceedings, the CPAA argued that any patent linkage would negatively affect public health, and it was critical of Bayer for its attempt to link the two separate systems for patents and regulatory approval. It was the CPAA’s legal team that called on the court to clarify that its injunction only referred to Bayer’s drug and not all generics applying for marketing approval, which the court subsequently confirmed (cited in Delhi High Court 2010). CIPLA made similar arguments and in 2010 the Delhi High Court ultimately agreed with CPAA and CIPLA and rejected Bayer’s suit. The court determined that patent law and the regulatory approval of medicines were ‘separate’ in India, and that the Director Controller General could only ensure that generic applications for marketing did not contain a similar name to the brand name (trademark) (Bouchard et al. 2011; Delhi High Court 2010). The CPAA praised the court decision and publicly ‘named and shamed’ Bayer for attempting to introduce patent linkage that ‘would have seriously impacted the early entry of generic drugs…’ and thus affect access to medicines (Grover in Ermet and Mara 2009). The High Court Judge was also critical of the firm for what he called ‘vexations or luxury litigation’, and he ordered Bayer to pay Rs 675,000 to India and CIPLA (Ermet and Mara 2009).

Following the High Court’s rejection of Bayer’s litigation, the Indian firm NATCO formally requested a voluntary licence from Bayer to produce a generic version of the drug, which Bayer subsequently refused (Nair, Fernandes and Nair 2014: 85). NATCO then submitted an application for a compulsory licence for Nexavar on the grounds of lack of affordability. At issue was that Bayer’s version was sold at Rs. 285,000 per month (approx. USD 4743.00), a price out of reach
for the majority of cancer patients in India (Menghaney 2012: 39). In its compulsory licence application, NATCO cited Section 84(1) of India’s Patent Act that enabled compulsory licensing if ‘the patented invention is not available to the public at a reasonably affordable price’ (Indian Ministry of Law and Justice 2005; Nair, Fernandes and Nair 2014: 85). Once again, NGOs weighed in to the court case, with James Love of Knowledge Ecology International (KEI) supporting NATCO and filing affidavits to the Controller of Patents (Love 2011a):

If the government determines that a price of Rs 280,430 per month for a cancer drug is reasonably affordable, then the law does not provide meaningful protection to people living in India, and it does not meet the standard adopted by the World Trade Organization in 2001 to implement intellectual property laws in a manner to promote access to medicine for all (Love 2011a: 16).

On March 9 2012 the Indian Controller General of Patents, Designs and Trademarks issued India’s first compulsory licence to NATCO to produce a generic version of Nexavar. The Controller General determined that Bayer had not met the health needs of people with cancer in India. Bayer was ‘neglectful’ because it only imported limited quantities, had not taken ‘adequate steps’ to manufacture the product in India, and priced the drug ‘out of reach’ of most of the people in need (Controller of Patents 2012: 13). The order included provisions that NATCO make the medicine affordable at R8,800 for a month’s therapy and pay six per cent royalties to Bayer. This landmark decision was widely praised by NGOs, and James Love of Knowledge Ecology International framed the compulsory licence as a ‘big win for cancer patients’ (James Love cited in Chatterjee 2013).
Not satisfied with the outcome, Bayer subsequently appealed the decision in the Intellectual Property Appellate Board, arguing that the order ‘weakens the international patent system and endangers pharmaceutical research’ (cited in Bayer 2012; International Centre for Trade and Sustainable Development 2012). In 2013, less than a year later, IPAB rejected Bayer’s appeal and maintained the compulsory licence to NATCO, extending the royalty payment from NATCO to Bayer to seven per cent (Dhar 2012; Intellectual Property Appellate Board 2012; Löfgren 2012; Srivastava and Satyanarayana 2014). Again, NGOs hailed the outcome as a win for access to medicines. MSF urged India to issue more compulsory licences for new essential medicines and to challenge the ‘pursuit of excessively high profits over health needs’ (Médecins Sans Frontières 2013a).

Like the landmark Novartis case, the Bayer litigation in India was symbolic of the dynamics between power and resistance in contemporary global medicines governance. Bayer’s attempt to create patent linkage and prevent the compulsory licence on Nexavar through multiple lawsuits demonstrated the firms’ aggressive promotion of the ‘TRIPS PLUS’ agenda. Bayer and Novartis were supported by the United States government, which has maintained India on its Special 301 Priority Watch List for alleged pharmaceutical IP infringement and explicitly cites India’s compulsory licence to NATCO in its rationale (Office of the United States Trade Representative 2014: 40). The intervention of domestic and global NGOs in the Bayer litigation and in public advocacy around the litigation demonstrate the key role that NGOs have come to play in supporting local firms and governments in their resistance to this TRIPS PLUS agenda. Indeed, the

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152 Bayer appealed to the Bombay High Court in April 2014. On 15 July 2014 the Bombay High Court dismissed Bayer’s appeal and upheld the compulsory licence.
Bayer lawsuit confirms that affordable access to medicines is a key factor for consideration in IP law in India, which is a significant development for access to medicines in the global South.

**Emerging resistance in the global South**

In this section I demonstrate that resistance to the TRIPS PLUS agenda appears to be increasing in global medicines governance in a number of middle-income countries. Like India, I show that the dynamic alliances between local firms and NGOs are unfolding in other countries, and I highlight the role that NGOs have come to play in championing the health needs of poor patients.

In similar moves to India, in 2008 the Thai government secured free treatments of Novartis’ Glevic for cancer patients after it threatened to issue a compulsory licence for the drug (Moon 2009: 13). That same year, Thailand granted compulsory licences for cancer medicines docetaxel, letrozole, and erlotinib (see Appendix Seven). Also in 2008, the Bangladesh Department of Patents, Designs and Trademarks suspended the approval of pharmaceutical patents until 1 January 2016 (while preserving ‘mailbox’ requirements, see page 91) (Azam and Richardson 2010: 9). This was for Bangladesh firms to take advantage of the TRIPS extension for pharmaceutical patents for ‘least developed’ countries, of which Bangladesh is the only country with adequate local pharmaceutical manufacturing capacity (Yusuf and Alam 2008). These moves demonstrate some resistance to the ‘TRIPS PLUS’ agenda in key middle-income and low income countries.
Recent developments in China also appear to show increasing resistance to the ‘TRIPS PLUS’ agenda. In 2011, the Chinese generic firm Aurisco applied to the State Intellectual Property Office for a compulsory licence for Gilead’s HIV/AIDS and hepatitis B medicine Viread (tenofovir disoproxil fumarate) (China Ministry of Commerce 2012; Ellis 2013). At 240 dollars per month, Viread was beyond the reach of most Chinese patients, of which there were an estimated 90,000 people living with AIDS and up to 130 million people living with hepatitis B (Ellis 2013). In May 2012, China’s State Intellectual Property Office revised its Measures for Compulsory Licensing of Patent Implementation to enable the issuance of compulsory licences to local firms in cases of public interest, including ‘for reasons of public health’. In 2013, China became no longer eligible for Global Fund grants to procure treatments for HIV/AIDS (The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria 2014: 17). That year, China’s State Intellectual Property Office revoked Gilead’s patent for Viread, citing a lack of novelty and inventiveness (Ellis 2013)\textsuperscript{153}. This decision reflected India’s earlier revocation of Novartis’ Glevic on the same grounds, and it demonstrated that China was also willing to override stringent IP enforcement for pharmaceuticals to meet the health needs of patients. China’s revocation of Gilead’s patent for Viread was not only about health needs, however, with Aurisco likely to compete with Indian and South African generic firms in international procurement agencies like the Global Fund (The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria 2014: 17).

\textsuperscript{153} The USTR recently elevated China to its Special 301 Priority Watch List for allegedly enabling the marketing approval of generic medicines prior to the expiration of data exclusivity periods (Office of the United States Trade Representative 2014: 36).
Health advocacy NGOs have often led the charge against ‘TRIPS PLUS’ measures in developing countries. The Indian Network for People living with HIV/AIDS, Uttar Pradesh Network of People Living with HIV/AIDS, the Network of Maharashtra People living with HIV and the Initiative for Medicines Access & Knowledge (IMAK) have filed many patent oppositions in India since 2005 (MSF N.D). In Kenya, in 2012 the Kenyan High Court ruled in favour of litigation brought by AIDS activists that the Kenyan Anti-Counterfeiting Act (2008) was a threat to access to medicines and to Kenya’s constitutional right to health (Ngugi 2012, see Chapter five). These developments suggest that the contemporary situation in global medicines governance is one which NGOs and local firms can help governments to resist pressure by the international pharmaceutical industry.

Conclusion

This chapter has examined the contemporary situation in global medicines governance. It has demonstrated that the status quo is one in which the United States government and international firms are pursuing a ‘TRIPS PLUS’ agenda. Through trade agreements, the United States has secured the ‘ratcheting up’ of IP in many countries. These measures raises serious concerns over access to new medicines because they inhibit governments from using the hard-fought ‘public health safeguards’. The chapter has examined two landmark cases in India that has seen increasing patent litigation since it became compliant with TRIPS in 2005. Novartis and Bayer are two firms that have attempted to create TRIPS PLUS measures through litigation in many court forums. India has so far resisted
these pressures with the aid of a loose alliance of local generic firms and health advocacy NGOs that, while having differing motivations, have coalesced around shared objectives that benefit both citizens and local firms. NGOs have played a key role in championing the health needs of patients and have engaged in both institutional and public advocacy through their participation in legal proceedings and public campaigns. Similar developments are unfolding in China and other middle-income developing countries. This suggests that resistance to industry pressure in the global South is possible, in particular when the economic interests of local firms and health objectives of NGOs align.
Conclusion

This thesis took as its starting point the failure of global medicines governance to meet the health needs of the world’s poor. Despite over 70 years of international policymaking, the problems of lack of access to essential medicines, insufficient research and development to meet health needs, and irrational use of medicines persist with dire consequences (MDG Gap Task Force 2012; Médecins Sans Frontières 2010d; United Nations 2010; WHO 2011d). From this standpoint, I asked, why is the global governance of medicines failing to meet the health needs of the global South? I posed three subsidiary questions for investigation: who are the actors that have shaped the global governance of medicines? What discourses have shaped global medicines governance? What have been the turning points in the evolution of this domain?

The thesis has examined the history, conflicts and transformations in the evolution of the global governance of medicines over several decades. Commencing with the formation of the World Health Organization (WHO) in the 1940s, the thesis has situated shifts in international medicines policy within broader transformations in the global political economy. In doing so, the research has drawn on an emerging field of scholarship in global health that investigates the actors and discourses that shape policy, and the interests that these actors and discourses serve (see Labonté and Gagnon 2010; Lee 2009a; McInnes et al. 2012; Rushton 2012; Shiffman 2009: 38).
The historical focus of the thesis has enabled a long-term analysis in which specific events and turning points are situated in a broader struggle that has unfolded over many decades. This demonstrates that global medicines governance has evolved principally through a battle that reflects the North–South divide. Since the 1940s, the United States government and its allies have repeatedly weakened multilateral initiatives that could have secured more equitable and affordable access to medicines and promoted the rational use of medicines, because these initiatives threatened the profits of their pharmaceutical firms. The political and economic power of the United States is reflected in the ultimate demise of the New International Economic Order (NIEO), through which the global South had sought to transform international medicines governance in the 1970s. Since the early 1980s, neoliberalism has remained the dominant political economic ideology that has shaped global governance, and facilitated the dominance of the international pharmaceutical industry in the production and supply of medicines. The pharmaceutical industry has exercised significant power and influence over governments, the World Health Organization (WHO) and other international institutions. The story told in this thesis demonstrates that the capacity of global medicines governance to meet the needs of the South has been, and continues to be, constrained by the power of the international pharmaceutical industry.

This thesis has also demonstrated the building of a counter-movement of resistance amongst developing countries, their generic pharmaceutical firms, and domestic and globally networked health advocacy non-government organisations (NGOs). It has argued that this resistance has been most successful when
developing countries have acted in solidarity *en bloc*, and when the objectives of local firms and health advocacy NGOs have aligned. India, in particular, has led resistance to corporate litigation and trade pressures with the support of both local firms and a global network of NGOs. This suggests that claims to ‘human rights’ for access to medicines are a useful point of resistance in global medicines governance (see Schrecker 2011: 161), in particular when local industry and NGOs coalesce around shared goals.

The thesis has shown that health advocacy NGOs have secured principled, expert and capacity-based authority in global medicines governance. Domestic and international NGOs have formed an informal global network through which they have engaged in public and institutional advocacy, and acted as global advocates for the world’s poor. They have also secured positions of influence in new global health partnerships, through which they often work alongside those same firms that they ‘name and shame’ in their public advocacy. Indeed, the presence of NGOs on partnership boards provides these partnerships with claims to principled authority and legitimacy. This dynamic can create tensions for NGOs to the extent that they can appear to support initiatives that do not reflect their principled objectives.

This finding is significant for the legitimacy of health advocacy NGOs in global medicines governance, now and into the future. To the extent that NGOs appear to privilege claims to capacity-based authority, by participating in initiatives that do not reflect their principled objectives, their legitimacy may be weakened. This has consequences for their alliances with local generic firms and developing
country governments. Addressing this tension must be on the agenda of NGOs, particularly as the NGO landscape becomes more complicated with the emergence of patient organisations that receive funding from the pharmaceutical industry (see Jurberg 2008; Lambert 2009; Schrecker 2011: 160). To remain independent from corporate influence, NGOs must assess their participation in new global health partnerships in which they work closely alongside pharmaceutical firms.

This thesis has also contributed to knowledge about the key role of discourse and ideas in shaping the underlying rules and norms for global medicines governance. The thesis has shown that whether medicines are valued primarily for their curative qualities or for their economic returns is the outcome of social dynamics and power relations. Whether access to medicines is considered a human right, or whether medicines are considered a private intellectual property ‘right’ of pharmaceutical firms, for example, is the result of power. Understanding the consequences of this discursive struggle can contribute to improved knowledge of the reasons for the continued failings of global governance in addressing the health needs of the South.

The thesis has shown, for example, that intellectual property ‘rights’ norms have become the status quo in global medicines governance. Despite the hard-fought ‘public health safeguards’ in TRIPS, few countries have implemented these

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154 The UK charity Cancerbackup and some arthritis charities have been linked to providing unbalanced support for some cancer and arthritis medicines that are produced by the international firms from which they have received funding (Lambert 2009: 5). Similarly, in Brazil, international firms have paid patient organisations to initiate litigation with the government for access to their medicines (Jurberg 2008; Schrecker 2011: 160).
because of political pressures and lack of capacity (see Appendix Seven). Instead, differential pricing schemes have also become the status quo. These have been limited, however, to vaccines, contraceptives, and ARVs in least-developed countries and are not as effective as generic competition (Waning et al. 2009: 5)\textsuperscript{155}. Middle-income countries with poor populations have also been locked out of these schemes (Hellerstein 2004; Maskus and Ganslandt 2002; Scherer and Watal 2002; Yadav 2010). Yet, because these schemes reflect the intellectual property ‘rights’ agenda, they remain dominant in global medicines governance.

More broadly, the thesis finds that in general, the counter-hegemonic discourses of the global South have not been very effective against the material power of well-resourced governments and private actors. When the South has been effective, it is mainly because the interests of NGOs and local pharmaceutical firms have aligned. This calls into question the discursive power of these counter-hegemonic discourses. It appears that, in the face of stark inequities in material power, the discursive power of the materially weak has not been very effective and that the dominant discourse has been controlled by powerful actors.

This finding raises important questions for health advocacy NGOs and those seeking to resist the status quo. The thesis has found examples of where resistance has been most successful in national contexts, such as in national courts in South Africa, India and Kenya. This suggests that the national level is where NGO may have a more substantive impact. This does not mean that protest and advocacy should not occur at the global level, rather global advocacy is strengthened if it is

\textsuperscript{155} More than 80 per cent of HIV/AIDS ARV’s commonly purchased through differential pricing are between 23 and 500 per cent more expensive than generics (Waning et al. 2009: 25).
interlinked with the national or local context. In addition, the partnering between local generic producers and health advocacy NGOs can to some extent serve both interests. In addition, NGOs have appeared more effective when they have brought health into trade forums. Unfortunately, they have not been as successfully in bringing trade issues into health forums. This is required, and strategies to engage government health ministers with trade issues is necessary.

This historical study has also enabled a critique of the role of the World Health Organization in global medicines governance over time. As a member-state driven organisation that is oriented to consensus, the WHO has been constrained by power asymmetries between North and South. In recent decades, the WHO has become even more dependent on the will of donor states which have made the organisations’ budget increasingly reliant on voluntary donations that are earmarked for specific objectives. As a result of this donor dependence, the WHO has been unable to deliver on its mandate to strengthen national drug regulatory authorities, has not secured sustainable financing for its pre-qualification program, nor has it been able to effectively negotiate material transfer agreements for influenza vaccines (’t Hoen et al. 2014; WHO 2005a, 2011e: 132; 2013a).

As a member state driven organisation, the WHO is constrained. Ultimately, more cohesion is required in the global South to enable the organisation to meet its

156 Up to 80 per cent of the WHO’s revenue is now from earmarked donations (Brown, Cueto & Fee 2006; WHO 2011c). The WHO’s operating budget is merely equivalent to that of the Massachusetts General Hospital (van der Rijt and Pang 2013).

157 Despite many years of negotiations, the WHO’s Pandemic Influenza Preparedness Framework (2011) has failed to secure improved access to vaccines in poor countries (see Kamradt-Scott and Lee 2011: 839).
objectives. Developing countries need to call for a shift in the balance of funding away from voluntary contributions that are earmarked, and towards assessed contributions. This means that developing countries, in particular middle-income countries must improve their financing of the organisation. Changes in financing and a cohesive voice of the ‘South’ are required to strengthen the WHO.

The WHO has increasingly turned to partnerships in lieu of the constraints. The thesis has shown that the WHO has engaged in many partnerships with industry that have ultimately privileged the IP ‘rights’ of private firms over the health needs of the South. The International Medicines Product Anti-Counterfeiting Taskforce (IMPACT) is the most notable example of industry influence on the WHO, in which firms continue to pursue their IP agenda under the rhetoric of medicine safety and quality. In addition, the Gates Foundation, which has driven product-development partnerships that cement IP ‘rights’ as a global norm in medicines R&D, is now one of the main donors to the WHO (Sridhar, Frenk and Moon 2014). In light of these findings, the thesis argues that the WHO should not, as some scholars have recently suggested, ‘embrace the private sector’ (Sridhar and Gostin 2011; Sridhar, Gostin and Yach 2012; van der Rijt and Pang 2013: 3) if it is to deliver on its mandate of improving medicines governance to meet health needs. The WHO must work to counter the influence of the pharmaceutical industry if it is to secure effective medicines governance for the global South. The WHO is currently (as of October 2014) revising its terms of engagement with non-state actors. The WHO must strengthen its conflict of interest policies with respect to its engagement with the pharmaceutical industry. Again, it is member states and developing countries that must take a cohesive and strengthened
approach to support the WHO in this regard. The arguments presented in this thesis also contribute to a discussion about the structural and political reasons for core aspects of effective medicines governance remaining on the periphery of global governance. The rational use of medicines, a key part of the WHO’s essential medicines policy, remains neglected by most governments, creating a situation in which at least 50 per cent of all medicines used worldwide are used irrationally (WHO 2013a). The global R&D system is based on monopoly pricing and IP ‘rights’, and relies on the widespread irrational use of medicines to recoup R&D costs. This points to a structural constraint on the pursuit of effective global medicines governance to meet the health needs of all peoples, in both the South and the North.

According to Lee (2009a:40), ‘the purpose of political analysis and interrogation of global health is to raise the quality of contemporary debate about strengthening global health governance’. This thesis has contributed to the scholarly research of global health through the critical historical study of the changing nature of power and discourse in the evolution of global medicines governance. It has demonstrated that the capacity of global medicines governance to meet the health needs of the South has been, and continues to be, constrained by the power of the international pharmaceutical industry. The contemporary debate about strengthening global health and medicines governance requires critical attention to the role of power and discourse in order to enable opportunities for resistance and effective governance to meet the health needs of the world’s poor.
**Appendix One: Glossary**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compulsory licensing</td>
<td>an authorization to a person other than the patentee to do, without authorisation of the patentee, acts which would otherwise by excluded by the patent (UNESA, UNCTAD and WIPO 1975).</td>
</tr>
<tr>
<td>Differential pricing</td>
<td>differential pricing (also called tiered pricing) is the adaptation of product prices to the purchasing power of consumers in different geographical or socio-economic segments (Yadav 2010: 8).</td>
</tr>
<tr>
<td>Essential medicines</td>
<td>‘those medicines that satisfy the priority health care needs of the population, which should be available at all times and in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and community can afford’ (WHO Expert Committee on the Selection and Use of Essential Drugs 2000).</td>
</tr>
<tr>
<td>Export purchasing power</td>
<td>‘export earnings deflated by the general price level for internationally traded goods’ (World Bank 1981: 21)</td>
</tr>
<tr>
<td>Gross national product</td>
<td>an estimate of the total value of all legal goods and services produced in a country in a specified time plus income earned by domestic residents from overseas investments, minus income earned in the</td>
</tr>
</tbody>
</table>
domestic market accruing to overseas (foreign) residents

**Most-favoured-nation** any advantage a Member gives to the nationals of another country must be extended immediately and unconditionally to the nationals of all other Members, even if such treatment is more favourable than that which it gives to its own nationals (GATT Secretariat 1994: 15)

**National treatment** nationals of other Members must be given treatment no less favourable than that accorded to a Member's own nationals

**Patent** an ‘exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem’ (WIPO 2013)

**Rational use of medicines** defined as when people have affordable access to essential medicines which are used appropriately, in doses that meet their requirements, and for an adequate period of time (WHO Expert Committee on the Selection of Essential Drugs 1997).

**Tariff** a tax levied on products when they cross the boundary of a customs area

**Technology transfer** the transfer of systematic knowledge for the manufacture of a product, for the application of a
process or for the rendering of a service (UNCTAD 1985: 694).
Appendix Two: Key Primary Source documents

Chapter Two


Chapter Three


Chapter Four


Chapter Five


**Chapter Six**


Chapter Seven


Controller of Patents. 2012. Determination on NATCO Application for Compulsory License under Section 84(1) of the Patents Act. New Delhi.


Madras High Court. 2007. Decision on Novartis vs Union of India. New Delhi.


Supreme Court of India. 2013. Supreme Court of India Civil Appellate Jurisdiction: Novartis AG versus Union of India and Others. New Delhi.


## Appendix Three: USTR 301, 1995–2000 Pharmaceuticals

<table>
<thead>
<tr>
<th>Year</th>
<th>USTR 301 Priority Watch List (Pharmaceuticals)</th>
<th>USTR 301 Watch List (Pharmaceuticals)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td>Costa Rica, Egypt, Pakistan, Guatemala</td>
<td></td>
</tr>
<tr>
<td>1996</td>
<td>Costa Rica, Egypt, Guatemala, Columbia, Kuwait, Oman, Peru, Jordan, Romania, Brazil, Australia</td>
<td></td>
</tr>
<tr>
<td>1997</td>
<td>Egypt, European Union, India</td>
<td>Australia, Costa Rica, Guatemala, Columbia, Kuwait, Oman, Jordan, Korea, Pakistan, the United Arab Emirates, Venezuela</td>
</tr>
<tr>
<td>1998</td>
<td>Egypt, Israel</td>
<td>Australia, Costa Rica, Jordan, Qatar and South Africa</td>
</tr>
<tr>
<td>1999</td>
<td>Argentina, the Dominican Republic, Egypt, Indonesia, Israel</td>
<td>Australia, Costa Rica, Ecuador, Hungary, Oman, Pakistan, the Philippines, Qatar, UAE, Vietnam, Jordan, Korea, Romania, South Africa</td>
</tr>
<tr>
<td>2000</td>
<td>Argentina, Egypt, India, Israel</td>
<td>Brazil, Lebanon, Vietnam, Qatar.</td>
</tr>
</tbody>
</table>

### Appendix Four: ‘TRIPS PLUS’ US Free Trade Agreements

<table>
<thead>
<tr>
<th>Agreement</th>
<th>Year</th>
<th>‘TRIPS-Plus’ provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chile</td>
<td>2003</td>
<td>No public interest objectives and principles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Provides for extension of the patent term</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Limits grounds for revoking a patent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prevents registration of generics during entire patent term provides for test data protection</td>
</tr>
<tr>
<td>Singapore</td>
<td>2003</td>
<td>No public interest objectives and principles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Provides for extension of the patent term</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Limits grounds for revoking a patent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Provides patent holders with means to block parallel importation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Provides for test data protection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prevents registration of generics relying on originator test data during the entire patent term</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Limits grounds for using compulsory licensing</td>
</tr>
<tr>
<td>Australia</td>
<td>2004</td>
<td>Restrictions on issuing a compulsory licence</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Data exclusivity for five years</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Drugs under a patent claim cannot be marketed</td>
</tr>
</tbody>
</table>

Sources: (Drahos et al. 2004; OXFAM 2004).
# Appendix Five: Global Medicine Donation Programs

<table>
<thead>
<tr>
<th>Year</th>
<th>Company</th>
<th>Medicine / health need</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998</td>
<td>Pfizer</td>
<td>Zithromax / blinding trachoma</td>
</tr>
<tr>
<td>1998</td>
<td>Merck</td>
<td>Mectizan / Onchocerciasis</td>
</tr>
<tr>
<td>1998</td>
<td>GlaxoSmithKline</td>
<td>Albendazole / lymphatic filariasis</td>
</tr>
<tr>
<td>2000</td>
<td>Pfizer</td>
<td>Diflucan (fluconazole) / HIV/AIDS</td>
</tr>
<tr>
<td>2000</td>
<td>Novartis</td>
<td>Multidrug therapy/ leprosy</td>
</tr>
<tr>
<td>2001</td>
<td>Sanofi -Aventis</td>
<td>Pentamidine, melarsoprol and elfornithine / sleeping sickness</td>
</tr>
<tr>
<td>2002</td>
<td>Bayer</td>
<td>Germanin / sleeping sickness</td>
</tr>
<tr>
<td>2007</td>
<td>J&amp;J</td>
<td>Mebendazole / intestinal worm</td>
</tr>
<tr>
<td>2007</td>
<td>Merck</td>
<td>Cesol/ schistosomias</td>
</tr>
<tr>
<td>2007</td>
<td>Bayer</td>
<td>Lampit (nifurtimox)/ Chagas</td>
</tr>
<tr>
<td>2007</td>
<td>Novartis</td>
<td>Triclabendazole/ fasciolias</td>
</tr>
<tr>
<td>2009</td>
<td>Bayer</td>
<td>Nifurtimox and elfornithine / sleeping sickness</td>
</tr>
<tr>
<td>2011</td>
<td>Gilead Sciences</td>
<td>amBisome / visceral leishmanias</td>
</tr>
<tr>
<td>2012</td>
<td>Eisai</td>
<td>2.2 billion tables diethylcarbamazine (DEC) / lymphatic filariasis</td>
</tr>
</tbody>
</table>

Appendix Six: Example of NGO Naming and Shaming

Source: (Stop AIDS campaign N.D)\textsuperscript{158}.

\textsuperscript{158} Stop AIDS campaign is an initiative of the United Kingdom Consortium on AIDS and International development, a network of over 80 organisations, including Oxfam, which formed in the late 1980s and which advocates the British government (UK Consortium on AIDS and International Development N.D).
### Appendix Seven: Compulsory Licensing Practices

**Medicines 2001–2012**

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Disease</th>
<th>Year</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sildenafil (Viagra)</td>
<td>Erectile</td>
<td>2002</td>
<td>Egypt</td>
</tr>
<tr>
<td></td>
<td>dysfunction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV/AIDS medicines</td>
<td>HIV/AIDS</td>
<td>2003</td>
<td>Zimbabwe</td>
</tr>
<tr>
<td>Lamivudine</td>
<td>HIV/AIDS</td>
<td>April 5 2004</td>
<td>Mozambique</td>
</tr>
<tr>
<td></td>
<td></td>
<td>September 21</td>
<td>2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>October 5 2004</td>
<td></td>
</tr>
<tr>
<td>Stavudine</td>
<td>HIV/AIDS</td>
<td>April 5 2004</td>
<td>Mozambique</td>
</tr>
<tr>
<td></td>
<td></td>
<td>September 21</td>
<td>2004</td>
</tr>
<tr>
<td>Nevirapine</td>
<td>HIV/AIDS</td>
<td>APRIL 5 2004</td>
<td>Mozambique</td>
</tr>
<tr>
<td></td>
<td></td>
<td>September 21</td>
<td>2004</td>
</tr>
<tr>
<td>Didanosine (ddl)</td>
<td>HIV/AIDS</td>
<td>September 29</td>
<td>2004</td>
</tr>
<tr>
<td>Zidovudine (AZT)</td>
<td>HIV/AIDS</td>
<td>September 29</td>
<td>2004</td>
</tr>
<tr>
<td>Drug/Combination</td>
<td>Indication</td>
<td>Date</td>
<td>Country</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>----------------</td>
<td>-----------</td>
<td>-----------</td>
</tr>
<tr>
<td>lamivudine + zidovudine</td>
<td>HIV/AIDS</td>
<td>September 29, 2004</td>
<td>Malaysia</td>
</tr>
<tr>
<td>All HIV/AIDS medicines</td>
<td>HIV/AIDS</td>
<td>2005</td>
<td>Ghana</td>
</tr>
<tr>
<td>Efavirenz</td>
<td>HIV/AIDS</td>
<td>November 29, 2006</td>
<td>Thailand</td>
</tr>
<tr>
<td></td>
<td></td>
<td>March 2007</td>
<td>Indonesia</td>
</tr>
<tr>
<td>Kaletra (LPV+RTV)</td>
<td>HIV/AIDS</td>
<td>January 25, 2007</td>
<td>Thailand</td>
</tr>
<tr>
<td>Plavix (clopidogrel bisulfate)</td>
<td>Heart disease</td>
<td>January 25, 2007</td>
<td>Thailand</td>
</tr>
<tr>
<td>lamivudine + nevirapine + stavudine</td>
<td>HIV/AIDS</td>
<td>July 2007</td>
<td>Rwanda</td>
</tr>
<tr>
<td>docetaxel</td>
<td>cancer</td>
<td>2008</td>
<td>Thailand</td>
</tr>
<tr>
<td>letrozole</td>
<td>cancer</td>
<td>2008</td>
<td>Thailand</td>
</tr>
<tr>
<td>erlotinib</td>
<td>cancer drug</td>
<td>2008</td>
<td>Thailand</td>
</tr>
<tr>
<td>sorafenib tosylate (Nexavar)</td>
<td>cancer drug</td>
<td>March 2012</td>
<td>India</td>
</tr>
</tbody>
</table>

Sources: (Beall & Kuhn 2012; Love 2007; ’t Hoen 2009).
Reference List


Brazil. 1999. Decreto no. 3.201 de 06 de Outubro de 1999.


Health Action International. 1982. Not to be Taken, at least Not to be Taken Seriously. Amsterdam.


Madras High Court. 2007. Decision on Novartis vs Union of India. New Delhi.


Mara, K. and New, W. 2009. Concerns Continue Over Generic Drug Seizures As Legality Debates Begin. Intellectual Property Watch. 5 March. URL:


Supreme Court of India. 2013. *Supreme Court of India Civil Appellate Jurisdiction: Novartis AG versus Union of India and Others*. New Delhi.


WTO. 1998. *Press Release: Structural reforms and Increased Transparency Needed to Generate Trade and Growth in Nigeria*. PRESS/TPRB/75. URL:


Zoellick, R.B. 2001. Statement by H.E. Mr. Robert B. Zoellick, United States Trade Representative to the Fourth WTO Ministerial Conference, WT/MIN(01)/ST/3 World Trade Organization, Doha, Qatar.