

**Negotiating Health**  
Intellectual Property and  
Access to Medicines

Edited by

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# Introduction: Legal Fictions and Public Health

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Today, a growing number of international treaties govern all our lives. When our governments negotiate these treaties they help shape laws that come to bind us. The legal fictions they create set the frameworks within which we act. Some of these treaties are relatively 'soft' – they set aspirations and give guidance but there are no penalties for not following their rules. Others make hard law – what is agreed internationally must be enforced nationally and failure to do so carries consequences such as sanctions.

Most treaties and conventions are of the first kind. They deal with things such as the environment, food, genetic resources, health, human rights, and sustainable development. Others in the trade area are of the second kind. Those that fall under the World Trade Organization (WTO) are backed by a binding dispute settlement mechanism, which is underpinned by sanctions. This makes the WTO a very different kind of international organization from most others.

In a world with growing levels of economic globalization – companies that operate and trade globally, products that sell everywhere, and global markets – those players that trade globally like global rules. They are also best placed to influence national governments in developing such rules, especially governments of the countries in which they are based and which often see their national interests linked to the competitive position of the large firms that operate there.

Big changes are taking place in our world. Some are due to the effects of human activity on the environment in which we live. Some are due to the opportunities scientific and technological revolutions open up for the way we do things. Others are due to the new rules our rulers are developing by which we then have to live or which shape the way people and institutions behave. And there is an interplay between these.

Any major scientific and technical changes bring new opportunities and threats, produce desirable and undesirable outcomes, and present unforeseen problems. They may shake up and transform old ways of doing things or organizing businesses by allowing things to happen that could not be conceived of before. New scientific understandings – about the nature of living organisms,

information and digital codes – underpin rapid technological changes that are revolutionizing the ways we can communicate with each other, share knowledge and information, repackage it, and even redesign living organisms.

In this process some people and businesses will benefit while others will lose out. Some models of doing business, of seeking innovation, will be undermined or superseded and replaced by new ones. Who controls and benefits from these changes will differ depending upon how they are managed and governed. The sustainability of human activities will be influenced by them.

That is the bigger backdrop to the issues discussed in this book – issues that affect the ability of countries to deal with the health problems facing their peoples, that decide what research is done on which diseases, and who can afford treatment when it is needed. Three of the Millennium Development Goals directly focus on health – reducing child mortality, improving maternal health, and combating HIV/AIDS, malaria and other diseases. Another goal – to eradicate extreme poverty and hunger – is increasingly affected by the health of the population in many developing countries, especially in rural Africa where HIV/AIDS is devastating farming families and undermining their ability to farm.

Health is just one area affected by struggles over who will control and benefit from the scientific and technological changes underway. They could lead to major shifts in the distribution of wealth and power in the world, and the big players that currently have power know it and want to frame the rules in ways that mean they will be able to retain their positions. And for this to happen, as some of the key industries recognized over 30 years ago, they need global rules on patents, copyright, trademarks and other things that have come to be called ‘intellectual property rights’. Not only did they recognize this, but they acted to achieve them – and succeeded in the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement) that is one of the many agreements under the WTO (Braithwaite and Drahos, 2000; Drahos, 2002; Sell, 2003).

That is why we have this book. What were complex and relatively obscure legal fictions – made up initially by European countries over hundreds of years, and designed and framed according to their particular national advantage – are now key pillars of the international economy. They underpin the future prospects of the major transnational actors in the film, music, software, pharmaceutical and agri-biotech industries. They increasingly affect people’s daily lives and their ability to access medicines, seeds and knowledge.

The best form of patent, copyright and other such rules in the past for poorer, economically and technologically weaker countries was simply not to have them. The European countries (then North American and, later, some Asian countries) that did adopt patent, copyright and other rules at various times since the late 19th century did so in ways that suited their national interest. Some countries did not allow foreigners the same rights as nationals, or only granted them copyright if they printed their books nationally. Others only allowed patents on some goods, not others.

The reason was that patents, copyright and the like were always seen as a kind of bargain – giving privileges to some that allowed them to exclude others in the society from using their works or products without permission and/or payment in exchange for encouraging things that benefited society – such as encouraging

invention and innovation or artistic creativity. Crucially, these rules were national, made in the national interest. Other countries were free to ignore the restrictions, and did, as they copied others to catch up. Only when they had enough to protect did they introduce comparable laws. This option is no longer available to developing countries that are Members of the WTO. It is part of a process that one academic calls 'kicking away the ladder' – removing the mechanisms the now industrialized countries benefited from so that others cannot (Chang, 2003).

That is what the TRIPS Agreement has done – but not completely enough for those industries that pressed for it, as they seek to have its flexibilities removed and tougher standards imposed (for example, through bilateral trade deals being negotiated by the US with other countries).

The effects of this new international economic order – very different from that envisaged by developing countries in the 1970s, and to some extent a reaction to their proposals then – have been most clearly brought to public attention by a wide range of civil society activity through its impact on access to medicines and the cost of drugs. Indeed this collection of papers is largely drawn from continuing civil society work, in particular through a series of dialogues organized in Bellagio and various regions by the International Centre for Trade and Sustainable Development (ICTSD) as part of a joint ICTSD/UNCTD project on TRIPS and Development Capacity Building. These dialogues were designed to stimulate innovative thinking in current negotiations at the multilateral, regional and bilateral levels.

In Part 1 of this book, the different authors examine various aspects of the contemporary dynamics of medicinal patent power. In Chapter 1, Roffé, Spennemann and von Braun briefly review the historical development of the patent regime and medicines from the first international agreement in Paris to the incorporation of patent rules into the binding trade rules under WTO in the far-reaching TRIPS Agreement, as well as responses to concerns about that through the Doha Declaration on TRIPS and Public Health (Annex 1). The growing realization about the impact of TRIPS upon medicine pricing – a crucial element, but only one, in ensuring access to medicines in developing countries – has been the issue that has brought intellectual property to the most widespread public attention.

Developing countries did not want intellectual property in the WTO, and those few that were aware of the implications resisted it strongly in the Uruguay Round Negotiations. But given the strength of the developed countries' desires to have it there, and for poorer countries' need for market access to those countries in areas such as agriculture and textiles they had to agree, but did succeed in introducing some flexibilities into the Agreement.

These flexibilities were reiterated in the Doha Declaration on TRIPS and Public Health. This was developed following massive action to draw attention to the issues and supported by a range of NGOs and academics, some of which were active globally, others providing a supportive role to the negotiators in Geneva who had to produce the legally-sound text for the Declaration. However, the Declaration, as finally adopted, failed to deal with the problems facing countries without sufficient medicine production capacity and the subsequent protracted and difficult discussion in WTO TRIPS Council left many feeling that they had

seen an exercise in bad faith – with a final Agreement emerging of unnecessary complexity (Annex 2).

The current trends in negotiations are discussed by Abbott in Chapter 2. He also examines the major trends related to the WTO TRIPS Agreement, worldwide consolidation of the patent and pharmaceutical sector companies, the regulatory response and counter-responses, and issues of pharmaceutical regulation in the post-2005 world, where TRIPS applies to generic manufacturers in developing countries. In Chapter 3, Timmermans further discusses the implications of 2005, the effects on availability of new drugs and future drugs, and the challenge to transform the business model, and proposes various actions to preserve and expand access to basic and life-saving medicines in developing countries.

In Chapter 4, Levis reviews the situation in Latin America, the role of the national pharmaceutical sector there and the significance of national generics industries, as well as the challenges facing Latin America under the new intellectual property rules ushered in by the TRIPS Agreement and, increasingly, by free trade agreements (FTAs). This is complemented by Rosenberg's discussion (Chapter 5) of pharmaceutical industry trends, the industry's increasing market consolidation and her analysis of the importance and causes of mergers and acquisitions globally. She also outlines the pharmaceutical market structure and its market failures, presenting common anti-competitive practices in the sector and targets for anti-trust policies from a developing countries perspective, suggesting related issues that need to be addressed to ensure competition and avoid abuse of the monopoly privileges that patents bestow.

Part 2 comprises four papers that look at new ways in which the industry is trying to prevent competition and retain control over its products through data protection. In Chapter 6, Correa provides an overview of the content and importance of test data, the industry's viewpoint on its protection, and the obligations imposed by the TRIPS Agreement and more recent FTAs with the US. Pugatch (Chapter 7) examines different formulas of data exclusivity legislation at the national, regional and international levels. He focuses on the economic significance of data exclusivity, the ways it affects market exclusivity, the role and ambiguities in international agreements and the trade-policy pressures from the US and EU vis-à-vis developing countries.

Reichman (Chapter 8) provides a detailed and clear legal analysis of the evolution and limitations of data exclusivity in the TRIPS Agreement. He also proposes an alternative approach that avoids the exclusivity problems – the compensatory liability option – and a more radical approach to treating clinical trials as public goods. In Chapter 9, Weissman discusses whether generic companies seeking marketing approval should have to compensate the data generator and, if so, how. He outlines four approaches to this: misappropriation; cost-sharing; data exclusivity; and several public health variants of the data-exclusivity approach, including language that could be used in legislation to implement these. He recommends approaches that do not follow the data-exclusivity route.

The final section (Part 3) brings together innovative solutions currently being explored or which might be explored in promoting access. Berger (Chapter 10) looks at the use of competition policy as a way to deal with problems, seeks to learn lessons on the interface between intellectual property and competition from

the developed world, examines the means used to stop the abuse of market dominance, asks if competition policy can be used in the developing world, and gives an example of South Africa's approach.

In Chapter 11, Widdus outlines the major 'public-private partnerships' to address health problems in developing countries, where intellectual property management fits into product development partnerships, the barriers to access to medicines and the role of public authorities. Rovira (Chapter 12) examines the medium- and long-term strategies for creation and improvement of domestic manufacturing capacities, current policies, the legal environment for pharmaceutical production and the feasibility of increasing domestic production, with some cases studies. Finally, Love (Chapter 13) makes four proposals to deal with access to medicines issues.

In the final chapter, I summarize some of the conclusions from the various dialogues at which the different chapters were originally presented as papers. In working through the book and engaging with the often complex legal issues, I suggest the challenge is not to get lost in the detail and to remember that intellectual property is always about power, interests and benefits – whose interests are being served and who is benefiting. The details of any particular form of intellectual property, whether a patent, copyright or trademark, may be legally and technically complex, but that should not mask the context in which it should be seen. When it comes to health, the issue is how far intellectual property is producing the social and societal benefits it is supposed to. Treatments for the diseases affecting poor people, the ability to access the medicines available and sharing of the knowledge necessary to spread the capacity to research these diseases are key measures against which the system should be judged. If the legal fictions are not delivering, then they should be rewritten, not people made to conform to them.