

Public health related TRIPS-plus provisions in bilateral trade agreements

A Policy Guide
for negotiators
and implementers
in the WHO
Eastern Mediterranean Region

Mohammed K El Said



International Centre for Trade
and Sustainable Development



**World Health
Organization**

Regional Office for the Eastern Mediterranean

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Mohammed K El Said
Lecturer in international trade law, Lancashire Law School,
University of Central Lancashire, United Kingdom



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“Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.”

Recommendation no: 4.26
Public Health, Innovation and Intellectual Property Rights
Report of the Commission on Intellectual Property Rights,
Innovation and Public Health
April, 2006

“The Fifty-seventh World Health Assembly ... 2. URGES Member States, as a matter of priority: ... (6) to take into account in bilateral trade agreements the flexibilities contained in the Agreement on Trade-related Aspects of Intellectual Property Rights and recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the World Trade Organization Ministerial Conference (Doha, 2001)”.

WHA57.14: Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS.
Fifty-seventh World Health Assembly

Preface

Access to essential medicines and health technologies, now and in the future, is a huge public health challenge, especially in developing countries. There are many stumbling blocks to ensuring equitable access, some local and some global, but ultimately, without access, it is the sick and poor who suffer. In many developing countries the majority of the poor lack any form of social protection and health systems are under-resourced. Superimposed on this tragic situation are the challenges of globalization, among which are the long and strong patent regimes introduced by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995 and the TRIPS-plus provisions of many bilateral trade agreements thereafter. These regimes impinge upon the already precarious situation with regard to improving access to medicines. Countries in the WHO Eastern Mediterranean Region are not immune to these difficulties.

WHO has not been oblivious to this situation. From 1995 onwards the subject has been under regular debate and scrutiny by its governing bodies – the World Health Assembly, Executive Board and regional committees of the six WHO regions. In 2003, the World Health Assembly requested the WHO Director-General to “cooperate with Member States, at their request, and international organizations in monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Member States ... are able to maximise the positive and mitigate the negative impact of those agreements” (WHA56.27). The Director-General set up the independent Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) in 2004, which reported to the Health Assembly in 2006¹, and an Intergovernmental Working Group for Global Strategy and Plan of Action for Public Health, Innovation and Intellectual Property in 2006, which reported in

¹ *Public health, innovation and intellectual property rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health.* Geneva, World Health Organization, 2006.

2008. WHO is now implementing the global strategy and plan of action endorsed by the Health Assembly.

Within the context of this history of WHO's involvement in these issues, and in the wake of many regional and bilateral trade agreements which were negotiated after 1995 and which further aim to strengthen and prolong patent regimes beyond the TRIPS standards, the CIPIH recommended that "Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries". In making the recommendation the Commission was fully conscious of the sensitive nature of bilateral relations between the countries and of their sovereignty and right to agree mutually on what they consider important for them. Yet it was also aware of the growing number of bilateral trade agreements between countries which were stipulating higher levels of patent protection than the TRIPS Agreement and which could have negative effects on access to medicines in less resourceful partners in these agreements.

In the Eastern Mediterranean Region this trend became clear as one after another such agreement was finalized and, much later, came to public knowledge. The idea for this policy guide matured with this background. An additional and important concern was that ministries of health were hardly involved at all in these bilateral trade negotiations. Yet they have had, and will have, to deal with the implications of the TRIPS-plus provisions in terms of difficulties they will face in making available new and patent protected medicines and health technologies of public health importance to their populations. Not only were they generally not involved in these negotiations, but most ministries of health also lacked capacity to take part in these discussions, let alone analyse the implications and develop strategic responses.

As the free trade agreements from the Region, especially those of Jordan and Morocco, caught international attention, the Regional Office recognized a need for a clear and frank analysis of the subject from a purely public health perspective, that would be available and accessible to policy-makers in ministries of health as well as ministries of trade, commerce, finance, foreign affairs and all those who take part in trade negotiations on behalf of their citizens. Such an analysis should provide a comprehensive background to the subject, the implications of TRIPS-plus for access to essential medicines and health technologies, and guidance on how to deal

with these complex issues. This publication was commissioned with these aims.

This publication is a result of close collaboration between WHO Regional Office for the Eastern Mediterranean and the International Centre for Trade and Sustainable Development (ICTSD). The need for such a policy guide was highlighted by the participants of a regional dialogue organized by ICTSD, Bibliotheca Alexandrina and the United Nations Conference on Trade and Development (UNCTAD) in Alexandria, Egypt in 2005, following which ICTSD and the Regional Office joined hands and the project was jointly established. Both organizations supported this publication technically and financially. The author's work has been thoroughly reviewed by the collaborating organizations and also by eleven renowned international experts in the field. Their comments were fully taken on board, assessed and appropriately incorporated. The Regional Office and ICTSD acknowledge the input of all those who contributed to the guidance contained in this publication, which will undoubtedly contribute to the debate on how to improve access to medicines for the most vulnerable citizens in the Region, and throughout the world.

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This policy guide—the first of its type specifically directed at the World Health Organization’s Eastern Mediterranean Region—benefited from the extensive comments and feedback provided by a number of individuals. The author would like to thank in particular the following:

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The views expressed in this guide are, however, those of the author and do not necessarily reflect the views of any of the above individuals or institutions. The author is solely responsible for the final text.

Abbreviations

AA	Association agreement
AIDS	Acquired immunodeficiency syndrome
ARV	Antiretroviral drug
ASEAN	Association of Southeast Asian Nations
BIRPI	United International Bureaux for the Protection of Intellectual Property
CAFTA	Central America Free Trade Agreement
CAP	Common Agricultural Policy
CDIP	Committee on Development and Intellectual Property
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
CM	Common Market
CU	Customs union
DDA	Doha Development Agenda
DSP	Dispute settlement procedure
EEC	European Economic Community
EFTA	European Free Trade Association
EPA	Economic partnership agreement
EPO	European Patent Office
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	US Food and Drug Administration
FDI	Foreign direct investment
FTA	Free trade agreement
GATS	General Agreement on Trade and Services
GATT	General Agreement on Trade and Tariffs
GCC	Gulf Cooperation Council

GSP	Generalized System of Preferences
IACC	International Anti Counterfeiting Coalition
ICJ	International Court of Justice
ICSCR	International Convent of Economic, Social and Cultural Rights
ICSID	International Centre for the Settlement of Investment Disputes
ICTSD	International Centre for Trade and Sustainable Development
ICT	Information and communication technology
IIA	International investment agreement
IIPA	International Intellectual Property Alliance
IMF	International Monetary Fund
IP	Intellectual property
IPRs	Intellectual property rights
JPO	Japanese Patent Office
LDC	Least developed country
LMICs	Low and middle-income countries
MAI	Multilateral agreement on investment
MENA	Unicef Middle East and North Africa Region
MERCOSUR	Custom union comprising Brazil, Argentina, Paraguay and Uruguay
MFN	Most favoured nation
NAFTA	North American Free Trade Agreement
NGO	Non-governmental organization
OECD	Organization for Economic Co operation and Development
PCT	Patent Co-operation Treaty
PhRMA	Pharmaceutical Research and Manufacturers of America
PLT	Patent law treaty
PTA	Preferential trading agreement
R&D	Research and development
RTA	Regional trade agreement

SPLT	Substantive patent law treaty
TBR	Trade barriers regulation
TIFA	Trade and investment framework agreement
TPA	Trade promotion authority
TPRB	Trade policy review body
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TWN	Third World Network
UKPO	United Kingdom Patent Office
UN	United Nations
UNAIDS	United Nations Joint Programme on HIV/AIDS
UNCITRAL	United Nations Commission on International Trade Law
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNICEF	United Nations Children’s Fund
UPOV	International Convention for the Protection of New Varieties of Plants
US	United States
USPTO	United States Patent and Trade Mark Office
USTR	United States Trade Representative
WB	World Bank
WCO	World Customs Organization
WCT	WIPO Copyright Treaty
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WPPT	WIPO Performances and Phonograms Treaty
WTO	World Trade Organization

1. Introduction

The establishment of the World Trade Organization (WTO) in 1995 marked the beginning of a new era in global trade. The WTO's main agreements, which include the General Agreement on Tariffs and Trade (GATT), the General Agreement on Trade and Services (GATS) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), subsequently came to form the main pillars of the new international trade order.

During the past decade, the world has witnessed a remarkable upsurge in the number of regional and bilateral free-trade agreements concluded between the developed and developing countries.¹ One notable feature of these agreements is their extensive coverage of many issues and aspects, including trade in goods, trade in services, labour, environment, intellectual property, electronic commerce, competition law, human rights—including increased recognition of civil society and democratic reform—and immigration.

However, the proliferation of regional and bilateral trade arrangements has given rise to a vast number of challenges for both the global multilateral trading regime and for developing and least developed countries.² In most cases, these arrangements often contain additional demands on these countries beyond what is required from them under the multilateral trading regime. They are often referred to as WTO-plus, and it is argued that the standards which they set increasingly hinder the pace of those countries' development and progress.

The effects of WTO-plus obligations may extend to many areas, including food, agriculture, transfer of technology, development, competition law, government procurement and democratic reform.³ However, one notable area where such additional demands may result in a negative impact is the area of intellectual property and its effect on public health and access to medicines.⁴

The evolution and development of intellectual property protection have been highly controversial since its early beginning around the middle of the 15th century. Even today, intellectual property

law represents one of the most contentious and dynamic areas of legal research and specialization.⁵ This is strengthened by the fact that intellectual property has come to play a pivotal role in many aspects of our lives.

The consistent trend of incorporating chapters dedicated to the protection of intellectual property which are of a TRIPS-plus nature—containing protection levels beyond that required by TRIPS—under bilateral trade arrangements signed between a developed country on the one hand and a developing or least developed country on the other, creates challenges for the public health regimes of these poorer countries. The higher intellectual property standards erode the flexibilities available to these countries under the international framework through limiting their ability to use the available policy space in accordance with their national needs, priorities and development plans.

Although the effects and implications of these bilateral trade arrangements on public health are not confined to a single region or country, these concerns are clearly visible in the case of WHO's Eastern Mediterranean Region, which in addition to Afghanistan, Pakistan and the Islamic Republic of Iran, comprises the majority of the Arab world.⁶ Accordingly, several countries in the Region, including Bahrain, Jordan, Morocco, and Oman, have already signed bilateral free-trade agreements (FTAs) with the United States of America which include TRIPS-plus obligations. Moreover, a large number of countries in the Region have also signed bilateral association agreements (AAs) with the European Union in addition to several bilateral free-trade agreements with a number of European countries under the European Free Trade Association (EFTA) agreements, which also contain intellectual property chapters which are of a TRIPS-plus nature.⁷ Currently, several countries in the Region are in the process of negotiating FTAs and AAs with both the United States and the European Union.⁸ A detailed matrix at the end of this chapter provides useful information about the situation with regard to bilateral trade agreements and intellectual property regimes in all the countries in the Eastern Mediterranean Region (Table 1). As a result of signing these agreements, countries in the Region increasingly face difficulties in creating the proper and adequate public health regimes and in ensuring the availability and access to drugs and medicines for their populations.⁹

The higher intellectual property standards erode the flexibilities available to these countries under the international framework

The relationship between intellectual property and public health has been debated for a considerable period of time nationally and internationally. However, this issue gained international prominence following the establishment of TRIPS and the restrictions which that agreement imposes upon the production and importation of pharmaceutical products. Other developments, such as the rise and active participation of civil society groups and nongovernmental organizations (NGOs) during the past decade, have also contributed to raising the profile of the debate on the issue. More important, widening inequalities, numerous health crises and the worsening position of the poor across the globe are placing developing and least developed countries under additional pressure to cater for the needs of their citizens and to push further the drive of economic and industrial development.¹⁰

A large number of developing and least developed countries, including countries in the Region, have characteristically suffered from a lack of adequate knowledge and expertise in the area of intellectual property regulation. In the case of countries in the Region, this issue has become of greater concern more recently, particularly during the negotiations of bilateral trade and association agreements, because of the impact these agreements have on public health and access to medicines. The complex and technical nature of many of the issues covered by these agreements meant that negotiators from countries in the Region often found themselves out-argued and unable to negotiate on equal terms and with an objective agenda with the developed countries' negotiators, who in contrast were highly organized. This asymmetry and imbalance in expertise and knowledge may have contributed to the acceptance of commitments embodying grave repercussions for the citizens of these countries. The area of public health is one of the areas most affected by these bilateral agreements.

This policy guide has emerged as a result of these developments and their implications for public health. One needs to be reminded that the health-related impact of these agreements does not only affect the few, but rather extends to millions of lives. However, it must be acknowledged that intellectual property expertise alone may not be sufficient in achieving a more balanced intellectual property protection regime in any country if that expertise is not supported by political will in that country. In the context of international and bilateral trade negotiations and from the experience of

Several countries in the Region, including Bahrain, Jordan, Morocco, and Oman, have already signed bilateral free-trade agreements

This guide also aims to provide both policy and technical guidance and assistance with respect to intellectual property provisions included under bilateral trade agreements

the majority of countries in the Region, it has been realized that the asymmetry in economic and political power plays more decisive role in determining the final outcome of the negotiation process than any other element.

The main focus of this policy guide—the first of its type solely dedicated to the Region—is to study the effect of these bilateral trade agreements on public health regimes and access to medicines in the countries of the Eastern Mediterranean Region. It also aims to provide both policy and technical guidance and assistance with respect to intellectual property provisions included under bilateral trade agreements that potentially have an adverse effect on public health. At the outset, it should be made clear that the issues of concern discussed in this policy guide are not solely confined to the countries of the Region. On the contrary, some of these issues are shared by the majority of other developing and least developed countries, hence the importance of this policy guide and its applicability to other countries outside the Region.

This policy guide provides those concerned in the Region with a comprehensive account and a detailed analysis of the issues under discussion. In discussing and explaining the issues, this policy guide draws on a wide variety of sources and an extensive list of references and materials. These include analysis and reports by specialized international organizations in the area of intellectual property and public health; opinions, views and publications of renowned international scholars, experts and academics in the field; declarations, decisions and resolutions of various international organizations; texts of bilateral, regional and multilateral trade agreements, treaties and conventions; reports from national governmental agencies and departments; analysis of health-related provisions covered under bilateral trade arrangements; texts of national laws and legislation; in addition to several other secondary sources. The guide also refers to many practical examples and case studies observed in both the developed and developing countries. It also provides some suggested model provisions which may be incorporated under national legislation.

This policy guide consists of six chapters. Chapter 2 provides a general historical background of the development of the modern multilateral trading regime up to the present time. It also sheds light on some of the basic principles and characteristics of the General Agreement on Tariffs and Trade, created in 1947, and the

subsequent multilateral trading rounds held under its auspices. In addition, the chapter discusses the evolution of the WTO and its main foundations. It also touches upon the phenomenon of regional and bilateral trade agreements, their evolution, types, nature and compatibility with the rules of international trade law. The chapter will provide a brief review of intellectual property provisions included under regional and bilateral trade agreements. Chapter 2 will further discuss the historical role of developing and Arab countries' participation in multilateral trade negotiations and some of the complexities and dangers associated with the process of negotiating regional and bilateral trade agreements.

Chapter 3 will focus on the historical and legal development and evolution of intellectual property. In particular, the chapter will focus on the inclusion of intellectual property under the GATT multilateral framework during the Uruguay Round of trade negotiations and the resulting TRIPS regime. Moreover, the chapter will touch upon the main characteristics and flexibilities of TRIPS and will examine the phenomenon of TRIPS-plus in greater depth, including its evolution and characteristics. Special attention will be paid to the role of the United States and the European Union in creating the TRIPS-plus phenomenon. More important, the chapter will discuss some of the challenges facing the global regulation of intellectual property in the post-TRIPS era in the area of public health and some of the recent developments in this field. This will be carried out by placing the issue of public health within the framework of recent bilateral free-trade agreements and initiatives. Finally, the chapter will place the work of the relevant international organizations, including the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO), in the context of the latest developments in this field.

Chapter 4 will outline the main flexibilities of TRIPS in the area of public health. It will also explain the health-related TRIPS-plus provisions prevailing under several bilateral trade arrangements with countries in the Region. The policy guide identifies a number of areas whereby TRIPS-plus health-related provisions emerge from these agreements. These include the elimination and reduction of transitional periods; data exclusivity and marketing approval requirements; extension of patent protection term; restrictions on parallel importation; restrictions on research and early working exceptions (Bolar exception); "new use" patentability; conditions on the granting of compulsory licensing and government use;

The policy guide identifies a number of areas whereby TRIPS-plus health-related provisions emerge from these agreements

Chapter 5 will study the process of negotiating bilateral trade agreements by focusing on the health-related aspects and provisions of these bilateral agreements

patentability criteria, exemptions and revocation of patents; and accession to several TRIPS-plus agreements. The chapter analyses these provisions in a uniform and systematic structured manner by defining their subject matter, explaining the issues and concepts behind them and undertaking a comparative analysis of the subject as dealt with under TRIPS and bilateral trade arrangements. The public health implications of these TRIPS-plus provisions on countries in the Region will also be examined together with policy proposals aimed at reducing the negative effect and impact of these provisions.

Chapter 5 will start by examining the implementation of TRIPS generally in developing countries at the national level and the policy space available to member states under this process. This chapter will also study the process of negotiating bilateral trade agreements by focusing on the health-related aspects and provisions of these bilateral agreements. For the sake of clarity, the chapter will divide the process into three phases: the pre-negotiation phase, the negotiation phase and the post-implementation phase. The chapter will shed light on each phase through suggesting certain mechanisms and policies aimed at maximizing the benefits and reducing the costs of negotiating and implementing bilateral trade agreements under national law, particularly for those countries in the Region which have already signed such agreements or are in the process of doing so. It will also derive some useful lessons from the experience of other countries in the area of bilateral trade agreements and public health. Chapter 6 concludes and provides general recommendations.

Table 1. The Region's bilateral trade agreements and intellectual property regimes¹

Country	WTO status	US FTA	US BIT	US TIFA	EU AA	EFTA	TRIPS-plus regime
Afghanistan				Signed September 2004			
Bahrain	Member since 1 January 1995	Signed 14 September 2000	Signed 29 September 1999	Signed June 2002	No ^c	No ^c	Yes
Djibouti	Member since 31 May 1995	No	No	No	No	No	
Egypt	Member since 30 June 1995	No ^c	Signed 1 March 1986	No	Signed 25 June 2001	Signed 27 January 2007	Yes
Iran, Islamic Republic of	Observer	No	No	No	No ^c	No	
Iraq	Observer	No	No	Signed 2 June 2004	No	No	Yes^d
Jordan	Member since 11 April 2000	Signed 24 October 2000	Signed 2 July 1997	Signed 15 March 1999	Signed 24 November 1995	Signed 21 June 2001	Yes^e
Kuwait	Member since 1 January 1995	No ^c	No	Signed 2004	No ^c	No ^c	
Lebanon	Observer	No	No	Signed 2006	Signed 16 June 2002	Signed 24 June 2004	Yes
Libyan Arab Jamahiriya	Observer	No	No	No	No	No	
Morocco	Member since 1 January 1995	Signed 15 June 2004	Signed 22 July 1985	Signed 1995	Signed 26 February 1996	Signed 19 June 1997	Yes

¹ Source: the author.

Country	WTO status	US FTA	US BIT	US TIFA	EU AA	EFTA	TRIPS-plus regime
Oman	Member since 9 November 2000	Signed 15 November 2004	No	No	No ^c	No ^c	Yes^b
Pakistan	Member since 1 January 1995	No ^c	No ^c	Signed June 2003	No	No	
Palestinian Authority	Observer	No	No	No	Signed 24 February 1997	Signed ^d 30 November 198	Yes
Qatar	Member since 13 January 1996	No	No	Signed 2004	No ^c	No ^c	
Saudi Arabia	Member since 11 December 2005	No	No	Signed 19 March 2004	No ^c	No ^c	Yes^b
Sudan	Observer	No	No	No	No	No	
Syrian Arab Republic	Observer	No	No	No	Signed 19 October 2004	No	Yes
Tunisia	Member since 29 March 1995	No	Signed 15 May 1990	Signed 2002	Signed 17 July 1995	Signed 17 December. 2004	Yes
United Arab Emirates	Member since 10 April 1996	No ^c	No	Signed 2004	No ^c	No ^c	
Yemen	Observer	No	No	Signed 2004		No	

^a Arrangement contains reference to “highest standards” of intellectual property protection (undefined).

^b TRIPS-plus commitments as a result of joining WTO as well.

^c Agreement under discussion or negotiation.

^d The Iraq intellectual property regime includes TRIPS-plus commitments as a result of United States Coalition Provisional Authority orders.

Endnotes

1. The number of trade agreements notified to the GATT/WTO increased from 20 in 1990 to 86 in 2000 and to 159 in 2007. See UNCTAD. *Trade and development report 2007*. UNCTAD/TDR/2007. New York and Geneva, United Nations, 2007, at viii. For more see Trakman L. The proliferation of free trade agreements: bane or beauty? *Journal of world trade*, 2008, 42(2):367–88.
2. The term “bilateral trade arrangements is used throughout this policy guide to refer to various types of bilateral trade agreement including free-trade agreements, bilateral investment treaties, association agreements and intellectual property agreements and treaties. Generally speaking, countries are designated by the United Nations as least developed on the basis of national income per capita, human assets and economic vulnerability. See UNCTAD. *World investment report 2004: the shift towards services*. New York and Geneva, United Nations, 2004. Also see Bhagwati J. *Termites in the trading system: how preferential agreements undermine preferential trade*. Oxford, Oxford University Press, 2008.
3. On the relation between intellectual property and food see Tansey G. Patenting our food future: intellectual property rights and the global food system. *Social policy and administration law*, 2002, 36(6):575–92.
4. See Oxfam International. *All costs, no benefits: how TRIPS-plus intellectual property rules in the US–Jordan FTA affect access to medicines*. Oxfam Briefing Note. Oxford, March 2007.
5. One noticeable feature about the development of intellectual property regulation is the broadening of its subject matter over time hence bringing more items within its boundaries, while at the same time limiting the exceptions and restricting the flexibilities available to users of these properties. This process has been remarkably accelerated in the global sphere, particularly during the past few decades. See in general May C. *A global political economy of intellectual property rights: the new enclosures?* London, Routledge, 2000; also see Boyle J. The second enclosure movement and the construction of the public domain. *Law and contemporary problems*, 2003, 66:33–74.
6. Throughout this policy guide, reference to countries in the WHO Eastern Mediterranean Region shall be understood to encompass the following unless otherwise specified: Afghanistan, Bahrain, Djibouti, Egypt, Islamic Republic of Iran, Iraq, Jordan, Kuwait, Lebanon, Libyan Arab Jamahiriya, Morocco, Oman, Pakistan, occupied Palestinian territory, Qatar, Saudi Arabia, Somalia, Sudan, Syrian Arab Republic, Tunisia, United Arab Emirates and Yemen.
7. The European Union Mediterranean partners are Algeria, Egypt, Israel, Jordan, Lebanon, Morocco, Palestinian National Authority, Syrian Arab Republic, Tunisia and Turkey. In addition, there are several bilateral free-trade agreements signed between the European Free Trade Association countries (Iceland, Liechtenstein, Norway and Switzerland) and other

- countries in the Region including EFTAs with Jordan, Egypt, Lebanon, Morocco, the Palestinian Authority and Tunisia.
8. There are currently FTA negotiations between the United States and several countries in the Region including those with Egypt, Kuwait, Pakistan and United Arab Emirates. In addition, the European Union has for years been negotiating a comprehensive AA with the countries of the Gulf Cooperation Council (GCC).
 9. This is also resulting in denying generic manufacturing competition and entry into the markets of developing and least developed countries. According to Khor, "A few years ago, there was a public outcry after public health and development organizations highlighted how the monopoly granted by patents enabled the maintenance of excessive prices of medicines for HIV-AIDS. The cost of treatment of patented drugs per patient per year was US\$10,000–15,000 in developed countries, whereas some generic producers in developing countries were able to provide them for as low as US\$300. The generic cost has now dropped to US\$100–150. If developing countries are able to make or import these generic drugs at cheaper cost, that would significantly increase access to medicines." Khor M. Patents, compulsory licensing and access to medicines: some recent experiences. *Third World Network*, February 2007, at 1.
 10. Generally see Bhagwati J. *In defense of globalization*. New York, Oxford University Press, 2004; and Stiglitz J. *Making globalization work*. London, Allen Lane, 2006.

2. International trade relations: bilateralism, regionalism and multilateralism

This chapter provides a general historical background to the development of the modern multilateral trading regime until the present time. It also sheds light on some of the basic principles and characteristics of the General Agreement on Tariffs and Trade (GATT), created in 1947, and the subsequent multilateral trading rounds held under its auspices.

The chapter will briefly discuss the evolution of the WTO and its main foundations. It will also touch upon the phenomenon of regional and bilateral trade and association agreements and their evolution, types, nature and compatibility with the rules of international trade law. It will make brief reference to intellectual property provisions included under regional and bilateral trade agreements. Finally, this chapter will discuss the historical role of the developing and Arab countries' participation in multilateral trade negotiation rounds and some of the complexities and challenges affiliated with the process of negotiating and concluding international trade agreements.

It is important for anyone concerned with the issue of public health to be aware of the historical development of public health and its correlation with international trade law. This is due to the fact that the issue of public health has been greatly influenced and linked to the developments taking place in international trade. A close link in this regard was established as far back as 1947, when the GATT made reference to health under the General Exceptions Clause of the agreement.¹ However, this issue has become more controversial in recent years, following the creation of the WTO in 1995 and the introduction of pharmaceutical patent protection under TRIPS. Adding more to this controversy was the rise in global economic inequality; rising disease rates, particularly of acquired immunodeficiency syndrome (AIDS) and tuberculosis (TB); and the strengthening of pharmaceutical patent protection as

a result of the conclusion of several TRIPS-plus bilateral free-trade and association agreements.

The modern global economic and trading regime

The roots of the modern global trading regime may be traced back to the immediate aftermath of World War II

The Uruguay Round of Multilateral Trade Negotiations (1986–94) was the most recent successfully completed multilateral trade negotiation round. The round culminated in the creation of the WTO in 1995, which represented a turning point in modern international trade and economic relations. The round was also credited with widening and extending the global trading agenda to cover the less regulated “new issues” at the time,² and for creating for the first time in history a viable international dispute settlement procedure. Perhaps most important, the round ushered in a new era whereby developed and developing countries alike were able to resolve their trading disputes under a rule-based multilateral framework, rather than resorting to unilateral and bilateral policies and practices instead.

However, the Uruguay Round was not the first of its type. In fact, the round was the eighth multilateral negotiation round, which built upon over a half of a century of international collaboration in the area of trade dating back as far as 1943. Thus, it is important for those interested in the achievements of the Uruguay Round to understand the origins and concepts which preceded its evolution and led to its formation.

The roots of the modern global trading regime may be traced back to the immediate aftermath of World War II, a time in which high levels of tariffs and quotas, discriminatory economic arrangements and unilateral and bilateral practices by states were rife. The above was also coupled with a global depression resulting from two devastating world wars.³

Moving towards avoiding the mistakes of the past with the aim of building a stable and secure future, the main global economic players at the time, particularly the United States and a number of European countries, sought to strengthen the role of international and multilateral institutions.

In the field of trade, calls were made to abolish discriminatory practices, reduce barriers to trade and increase international cooperation. Thus, in 1944, negotiators at the United Nations Monetary and Financial Conference, held at Bretton Woods in New Hampshire, reached an agreement to establish the International Monetary Fund (IMF) and the International Bank for Reconstruction and Development (now the World Bank).⁴ Other international agreements followed, including the Convention on International Civil Aviation in 1944 and, more important, the Agreement on the United Nations Charter in 1945.

Although trade discussions commenced as early as 1943 during the Bretton Woods negotiations between the United States and the United Kingdom, concrete initiatives to create a global trading organization came at a later stage.⁵ The proposed International Trade Organization (ITO), which aimed to remove barriers to international trade and prevent protectionism by states, never materialized, primarily as a result of the United States Congress's lack of enthusiasm and opposition to its content and coverage.⁶ Although the GATT was intended to be attached to the ITO Charter, many states felt that it was not possible to wait until the ITO Charter was finished to bring the GATT into force. In January 1948, the GATT became the cornerstone agreement for international trading and economic relations and remained so for over a half of a century.⁷

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The characteristics of the GATT

The GATT has been described as the first “world major trade-liberalization organization”.⁸ Although it was not originally negotiated under the Bretton Woods regime, the GATT is often seen as a part of the Bretton Woods system of global economic and financial management. This is due to its emergence around the same period of time and its close affiliation with the various trade, economic and financial organizations and agreements. Initially, the GATT emerged as a treaty without a secretariat but with a Protocol of Provisional Application. It was only in 1994 that the GATT was transformed into an organization at the end of the Uruguay Round as a result of the creation of the WTO.⁹

The establishment of the GATT in 1947 was influenced by several strands of thought. The United States believed that the opening up of markets and tariff reduction would be beneficial to its

The primary objectives of the agreement were raising of living standards and fostering growth across the globe

ever-growing base of industrial production. Other industrialized countries, especially Japan and some European states, also concluded that protectionism would be harmful to their economic and political development and therefore the need for a freer trade policy in the global market was imperative. There was also the belief that a prospering world economy would minimize the chances of another global war. The increased emphasis on the growth of technology, and the ever-increasing importance of global trade, also had a dramatic influence upon the structure of the new agreement.

The GATT's main focus was on tariff reduction and free trade. This was facilitated by the introduction of a dispute settlement procedure to resolve issues arising from the interpretation and implementation of the agreement. Over time, the GATT widened the number of treaties brokered under its patronage and auspices, reaching in 1990 to more than 180 treaties.¹⁰

The GATT's main aims and principles

The foundations and aims of the GATT were expressed in its preamble, which states *inter alia*:¹¹

Recognizing that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, developing the full use of the resources of the world and expanding the production and exchange of goods,

Being desirous of contributing to these objectives by entering into reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international commerce.

From the above, it is clear that the primary objectives of the agreement were raising of living standards and fostering growth across the globe. In order to achieve these objectives and aims, the GATT relied on a number of principles and approaches. These are found in Part I of the agreement and include the following.

1. The most favoured nation (MFN) principle

This principle demands that trade between countries should be undertaken equally and on a non-discriminatory basis. Accordingly, Article I of the GATT stipulates that:

[a]ny advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.

...the agreement stipulates that countries must maintain the tariff levels included under the agreement's schedules

2. No increase in trading barriers between member states

The GATT aimed towards creating liberal trade rules and removing barriers to trade between member states. Accordingly, the agreement stipulates that countries must maintain the tariff levels included under the agreement's schedules. Thus, the only deviation allowed (and even encouraged) from these schedules is the reduction of barriers between member states. The GATT Article II.1 (a) states:

Each contracting party shall accord to the commerce of the other contracting parties treatment no less favourable than that provided for in the appropriate Part of the appropriate Schedule annexed to this Agreement.

3. The national treatment principle

This extended principle of non-discrimination, which applies to all goods, dictates that international taxes, charges and other regulations must not be imposed so as to discriminate between domestically produced and imported products. Article III of the GATT stipulates:

[t]he contracting parties recognize that internal taxes and other internal charges, and laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products, and internal quantitative regulations requiring the mixture, processing or use of products in specified amounts or proportions, should not be applied to imported or domestic products so as to afford protection to domestic production.

4. The transparency principle

Enforcement of commitments requires access to information on the trade regimes that are maintained under the GATT agreements. The GATT-administered agreements—and those of the WTO subsequently—incorporated mechanisms designed to facilitate communication between member states on many issues. For example, members are required to publish their trade regulations, to establish and maintain institutions allowing for the review of administrative decisions affecting trade, to respond to requests for information by other members and to notify changes in trade policies to the GATT/WTO. It is believed that this will reduce the pressure on the dispute settlement system, as measures can be discussed in the appropriate WTO body. Frequently, such discussions can address perceptions by a member that a specific policy violates the GATT/WTO; many potential disputes are defused in informal meetings in Geneva. Transparency is also vital for ensuring “ownership” of the GATT/WTO as an institution—if citizens do not know what the organization does, its legitimacy will be eroded.¹² Article X of the GATT states that:

[l]aws, regulations, judicial decisions and administrative rulings of general application, made effective by any contracting party, pertaining to the classification or the valuation of products for customs purposes, or to rates of duty, taxes or other charges, or to requirements, restrictions or prohibitions on imports or exports or on the transfer of payments therefore, or affecting their sale, distribution, transportation, insurance, warehousing inspection, exhibition, processing, mixing or other use, shall be published promptly in such a manner as to enable governments and traders to become acquainted with them. Agreements affecting international trade policy which are in force between the government or a governmental agency of any contracting party and the government or governmental agency of any other contracting party shall also be published. The provisions of this paragraph shall not require any contracting party to disclose confidential information which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private.

The founders of the GATT envisioned the need for regular and periodic meetings and negotiations between member states in order to strengthen the rule of the multilateral trading regime

5. Regular periodic meetings and negotiations

The founders of the GATT envisioned the need for regular and periodic meetings and negotiations between member states in order to strengthen the rule of the multilateral trading regime, reduce trade barriers between countries and resolve any disputes facing the global trading regime. Accordingly, Article XXVIII bis of the GATT states:

[t]he contracting parties recognize that customs duties often constitute serious obstacles to trade; thus negotiations on a reciprocal and mutually advantageous basis, directed to the substantial reduction of the general level of tariffs and other charges on imports and exports and in particular to the reduction of such high tariffs as discourage the importation even of minimum quantities, and conducted with due regard to the objectives of this Agreement and the varying needs of individual contracting parties, are of great importance to the expansion of international trade. The contracting parties may therefore sponsor such negotiations from time to time.

The GATT also paid special attention to the relationship between international trade and public health

The GATT granted member countries the freedom and flexibility to apply the above principle. The GATT did not stipulate a specific period of time in which to hold these meetings and negotiations, but rather left it for contracting states to decide. It also did not restrict the scope of these meetings or the levels of tariff reductions to be applied during these rounds. Thus, under this principle, seven negotiation rounds were held in the period between the creation of the GATT and the commencement of the Uruguay Round.

There were two attempts to revise the GATT. The first attempt was in 1955, with the objective of transforming the GATT into a formal international organization under the ITO. As mentioned, the attempt failed, and no agreement was concluded. The second attempt took place in 1965, when new guidelines in favour of developing countries were incorporated as Part IV of the agreement.

The GATT also paid special attention to the relationship between international trade and public health.¹³ Accordingly, Article XX, relating to the general exceptions of the GATT, provides that “nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures ... (b) necessary to protect human, animal or plant life or health”.¹⁴ The only requirement that the GATT demanded from member states in

this regard was that “such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade”.

Multilateral trade negotiation rounds under the GATT

These four multilateral rounds laid down the foundations for facilitating the manner of multilateral trade negotiations between the growing number of the GATT’s contracting parties

At the time of the GATT’s creation in 1947, the world was reeling from the devastation of World War II. The United States was emerging as the main superpower, while most of Europe was in early stages of financial and economic recovery. In addition, most of Africa and major parts of Asia and the Middle East were still under direct European rule.

Gradually, this situation started to change during the early 1960s and 1970s as a result of the creation and strengthening of the European Economic Community (EEC), the independence of the majority of developing countries and the emergence of the Soviet Union as a counterweight superpower against the United States on the international scene.

There was an urgent need to amend the GATT to respond to these changes. This was achieved through several multilateral trade negotiation rounds. As envisioned by the drafters of the GATT, the first of these rounds was the Geneva Round, which was held concurrently with the drafting of the GATT itself between April and October 1947. This round was followed by the 1949 Annecy Round in France, the 1951 Torquay Round in England, the 1956 Geneva Round in Switzerland, and the 1960–61 Dillon Round in Geneva.¹⁵ These four multilateral rounds established the conditions of accession of new entrants to the agreement and the levels of tariff reductions between member states and laid down the foundations for facilitating the manner of multilateral trade negotiations between the growing number of the GATT’s contracting parties.

However, the creation of the EEC and the political and economic weight it came to possess at the international level in the late 1950s and early 1960s created both risks and opportunities for the United States. From a political perspective, the United States welcomed the establishment of a united and stable Europe;

however the creation of a customs union between European countries raised some economic fears.¹⁶ Thus, the United States sought the launching of a new negotiation round; first, in order to define its relationship with the emerging EEC, and secondly, to reduce international tariff levels by negotiating across-the-board tariff reductions. Thus, the Kennedy Round of trade negotiations was launched in Geneva in 1964.¹⁷ The principal achievements of the round were to introduce further substantial tariff reductions between the main global economic powers.

The Kennedy Round reduced tariffs on industrial goods to levels where they were no longer viewed as an impediment to international trade. This by itself led to shifting the debate and focus of the subsequent trade multilateral negotiation rounds to other non-tariff barriers.¹⁸ Thus, by the early 1970s, the major trading players, including the United States and EEC, believed that in order to capitalize on the gains made during the Kennedy Round, a fresh broad multilateral negotiation round should be launched. Accordingly, the Tokyo Round of multilateral trade negotiations was launched in 1973 and lasted until 1979.¹⁹

Although addressing several contentious issues, which were reflected in the various positions taken by member states, some attribute the significance of the Tokyo Round to its preservation of the unity and consistency of the GATT multilateral regime itself by limiting its results to a set of codes accepted only by the developed countries and a few developing countries, which ultimately resulted in pressure for a single undertaking to conclude the Uruguay Round.²⁰

This becomes evident if we take into consideration the fact that the Tokyo Round was marred by several major global economic and political crises including the collapse of the international monetary regime, global recession and an international energy crisis. More important from the point of view of developing countries, the Tokyo Round made permanent under the enabling clause the principle of “special and differential treatment for developing countries”, which was originally adopted under a waiver in 1971. Accordingly, a decision of 28 November 1979 allows derogations to the MFN and non-discrimination treatment in favour of developing countries. The decision also permits developing countries to undertake preferential arrangements among themselves in goods trade. The decision was later

...the Tokyo Round made permanent under the enabling clause the principle of “special and differential treatment for developing countries”...

included as a part of the GATT in 1994 under the World Trade Organization:

[n]otwithstanding the provisions of Article I of the General Agreement, contracting parties may accord differential and more favourable treatment to developing countries, without according such treatment to other contracting parties.

Developing countries were less keen on the inclusion of both services and intellectual property under the GATT

The Tokyo Round was more comprehensive than any of the previous rounds and it introduced seven codes—applicable only to countries that decide to join—dealing with technical barriers to trade, customs valuations, import licences, subsidies and countervailing measures, antidumping, governmental procurement and trade in civil aircraft. Although the Tokyo Round took a longer period than its predecessors to conclude, it is notable that it was the least concerned with the issue of tariff reduction.

The expanding trade deficit between the United States and other industrialized countries, particularly the EEC and Japan, during the 1980s triggered a shift towards protectionism within the United States. It identified several areas, including intellectual property, services and investment, in which it held a comparative advantage and which were not subject to global regulation, as being responsible for the growing trade deficit. Accordingly, the United States urged the launching of a new and more comprehensive global multilateral trade negotiation round.

Initially, the developing and some developed countries, particularly the EEC, demonstrated little enthusiasm for the proposed new round. However, the United States' persistence eventually succeeded in its launch. Thus, in September 1986, the Uruguay Round for multilateral trade negotiations was launched in Punta del Este, Uruguay, with an original agenda covering 15 subjects. The 1986 Punta del Este Declaration, as it came to be known, stated the aims of the negotiation round as follows.

Negotiations shall aim to develop understandings and arrangements:

1. To enhance the surveillance in the GATT to enable regular monitoring of trade policies and practices of contracting parties and their impact on the functioning of the multilateral system;

2. To improve the overall effectiveness and decision-making of the GATT as an institution, including inter alia, through involvement of ministers;
3. To increase the contribution of the GATT to achieving greater coherence in global economic policy-making through strengthening its relationship with other international organizations responsible for monetary and financial matters.

Some view the Uruguay Round as an extension of the Tokyo Round, dealing with some of the “unfinished business” of that round. Although, this may be true to a certain extent, in essence the Uruguay Round’s main aims were to deal with and regulate the so-called “new issues”—a term that has often referred to the regulation of investment, services and intellectual property—under the GATT framework.

Backed by influential domestic special interest groups in Europe, Canada and Japan, the United States intended to include the issues of services and intellectual property in the draft proposal for the Uruguay Round.²¹ However, developing countries were less keen on the inclusion of both services and intellectual property under the GATT. They would have preferred a more sympathetic organization such as the World Intellectual Property Organization or the United Nations Conference on Trade and Development (UNCTAD), in which they were in the majority, to deal with the issue of intellectual property.

Both developed and developing countries were becoming weary of the United States’ departure from the GATT rule-based regime through its use of unilateral and bilateral practices based on its domestic trade laws and regulations. This, as Drahos and Braithwaite explain, was one of the primary reasons why developing countries reluctantly changed their position during the negotiations of the Uruguay Round. Drahos and Braithwaite state that “... the costs to other countries of the US acting on its threat (clearly articulated) to scotch trade multilateralism by abandoning the Uruguay Round were much higher than the costs of the threats (not clearly articulated) by other countries to engage in their own brand of multilateralism”.²²

As it turned out, the Uruguay Round was the most ambitious and contentious round ever conducted under the auspices of the GATT. The round lasted until 1994,²³ and bringing it to a successful conclusion was not an easy task. The divergent positions of the

The Uruguay Round was the most ambitious and contentious round ever conducted under the auspices of the GATT

participating countries meant that negotiations of the round often broke down in disarray. However, contrary to general belief, disagreements were not confined to those between the developed and developing countries, or as it came to be known, the North–South debate. Crucially, the success of the round hinged on resolving the disagreement between the United States and the EEC in relation to agricultural subsidies and the European Common Agricultural Policy (CAP).

However, as a result of the changing political circumstances during the early 1990s, the imposition of several unilateral and bilateral measures by the United States and the EEC, and the promises of concessions made towards developing countries, the Uruguay Round was successfully concluded in 1994. Consequently, the round culminated in the signing of the agreement establishing the World Trade Organization in Marrakesh in April 1994.²⁴

The Doha Round of multilateral trade negotiations

The Doha Round, referred to as the Doha Development Agenda (DDA), was launched in Doha, Qatar, in November 2001.²⁵ The round was supposed to start in 1999 in Seattle but due to the differences between developing and developed countries and the demonstrations by antiglobalization protesters, the launch of the round was delayed until 2001.²⁶ The WTO Ministerial Conference at Doha produced three key documents: the Declaration on the TRIPS Agreement and Public Health, the Decision on Implementation-related Issues and Concerns, and the Doha Ministerial Declaration (Box 1).²⁷

Box 1. The Doha Ministerial Decision, 2001

International trade can play a major role in the promotion of economic development and the alleviation of poverty. We recognize the need for all our peoples to benefit from the increased opportunities and welfare gains that the multilateral trading system generates. The majority of WTO members are developing countries. We seek to place their needs and interests at the heart of the Work Programme adopted in this Declaration.

The main issues of the Doha Round were the negotiations related to the opening of agricultural and manufacturing markets, services and intellectual property protection. The theme of the round, as reflected in its title, was to focus on economic development by redressing the imbalance of the previous rounds, particularly in relation to developing and least developed countries.²⁸ Emphasizing this, the Doha Ministerial Declaration uses the expression “least developed countries” (LDCs) 29 times and “developing countries” 24 times. The Doha Round was supplemented by several unfruitful ministerial meetings held in Cancun in 2003 and Hong Kong in 2005.

At the time of writing, the Doha Development Round was still facing an impasse as a result of the disagreements and divergent interests of the many key players and particularly between industrialized countries themselves. The rise of bilateralism and the disagreement on several contentious issues relating to the opening up of agricultural and industrial markets in various countries and the farm subsidies awarded by the developed countries to their local farmers are undermining and blocking a successful outcome to the round.²⁹ Most observers agree that the round is unlikely to be successfully concluded in the near future due to the widely divergent positions of the negotiating states, the preoccupation with the global economic financial crisis, the change in the United States administration and the lapse of the United States president’s fast-track authority, which means that any trade agreement must now be ratified by the United States Congress.³⁰

The GATT, the GATS and TRIPS came to represent the main pillars of the new global trade order

The WTO and the new world trading regime

The advent of the WTO in 1995 marked a new beginning in international trade and economic relations. Accordingly, the GATT, the GATS and TRIPS came to represent the main pillars of the new global trade order. With time, the WTO’s membership grew substantially.³¹

For the first time in international trade the WTO, unlike its predecessor, introduced the notion of the “single undertaking” coupled with a strong dispute settlement arm.³²

The WTO is an intergovernmental organization with an active and influential secretariat which relies on the will of its member States to set and push its agenda forward

Moreover, the WTO also established a Trade Policy Review Body (TPRB), which is concerned with the systematic surveillance of international trade issues and ensures member states' compliance with the WTO agreements. For these accomplishments, the WTO has been described by some as the "greatest trade agreement in history".³³

However, the WTO must not be viewed in isolation from the GATT. The WTO should be treated as an extension of the GATT by transforming the agreement into an organization and by widening its scope to include a viable dispute settlement mechanism. In fact, this is reiterated by the member states themselves under Article XVI (1) of the Marrakesh Agreement establishing the World Trade Organization, which states:

[e]xcept as otherwise provided under this Agreement or the Multilateral Trade Agreements, the WTO shall be guided by the decisions, procedure and customary practices followed by the CONTRACTING PARTIES to GATT 1947 and the bodies established in the framework of GATT 1947.

The WTO is an intergovernmental organization with an active and influential secretariat which relies on the will of its member states to set and push its agenda forward. Accordingly, the WTO adopts all of the principles established under the GATT including the MFN and national treatment principles. However, while one of the aim of the WTO is to establish a permanent forum of multilateral trade negotiations between member states, its primary aim is explained by Article II of the WTO agreement, which is to:

[p]rovide the common institutional framework for the conduct of trade relations among its Members in matters related to the agreements and associated legal instruments included in the Annexes to the Agreement.

In addition to the above, Article III of the agreement more specifically spells out the main functions of the WTO by stating that:

1. The WTO shall facilitate the implementation, administration and operation, and further the objectives, of this Agreement and of the Multilateral Trade Agreements, and shall also provide the framework for the implementation, administration and operation of the Plurilateral Trade Agreements.

2. The WTO shall provide the forum for negotiations among its Members concerning their multilateral trade relations in matters dealt with under the agreements in the Annexes to this Agreement. The WTO may also provide a forum for further negotiations among its Members concerning their multilateral trade relations, and a framework for the implementation of the results of such negotiations, as may be decided by the Ministerial Conference.
3. The WTO shall administer the Understanding on Rules and Procedures Governing the Settlement of Disputes (hereinafter referred to as the "Dispute Settlement Understanding" or "DSU") in Annex 2 to this Agreement.
4. The WTO shall administer the Trade Policy Review Mechanism (hereinafter referred to as the "TPRM") provided for in Annex 3 to this Agreement.
5. With a view to achieving greater coherence in global economic policy-making, the WTO shall cooperate, as appropriate, with the International Monetary Fund and with the International Bank for Reconstruction and Development and its affiliated agencies.

The WTO's objectives include increasing standards of living, the attainment of full employment, the growth of income and effective demand and the expansion of production of, and in, goods and services. More important, and of great relevance to developing and least developed countries, the Preamble of the WTO Agreement also makes reference to the issue of "sustainable development".³⁴ These objectives are to be achieved through reciprocity, non-discrimination and the extension of mutually advantageous arrangements between all member states.

The WTO's objectives include increasing the standards of living, the attainment of full employment, the growth of income and effective demand and the expansion of production of, and in, goods and services

Regional and bilateral trade agreements and the GATT/WTO

During the past five decades, the world has witnessed an upsurge in the number of regional and bilateral free-trade and preferential agreements. These regional and bilateral arrangements cover a substantial share of world trade in goods and services.

The spread of regional and bilateral free-trade agreements must be studied with caution. Thus, these arrangements, often referred

to as “preferential” in nature, are in fact exceptions to the general rule of MFN, which is one of the main foundations of the modern multilateral trading regime.

The legal basis of this exception finds its roots under the GATT 1947 whereby the agreement contained provisions (Article XXIV.5) which allow the formation of these exceptional arrangements upon fulfilling certain conditions.

The drafters of the GATT 1947 and later the WTO believed that the agreement must contain several exceptions to the non-discrimination rule

The provisions of this Agreement shall not prevent, as between the territories of contracting parties, the formation of a customs union or of a free-trade area or the adoption of an interim agreement necessary for the formation of a customs union or of a free-trade area ...

During the 1930s, the use of anticompetitive practices coupled with protectionist and discriminatory measures surged. This eventually led to a backlash and further resentment against the use of these measures. Accordingly, there were several voices calling for restricting and abolishing these measures in exchange for non-discrimination between all countries. This notion gained strength, particularly after World War II, and became the main foundation of the newly established GATT.

The drafters of the GATT 1947 and later the WTO believed that the agreement must contain several exceptions to the non-discrimination rule. The justification for these exceptions varied between political, security and economic bases. In relation to the latter, it was believed that allowing parties to offer each other more favourable treatment in economic and trading matters than they would offer to others would be beneficial to both regional and international trade integration provided that certain conditions and obligations were met. The creation and formation of these regional and bilateral trade agreements fall under Article XXIV of the GATT 1947 and were subsequently adopted by the WTO in 1994. Accordingly, Article XXIV.4 of the GATT 1947 stipulates:

[t]he contracting parties recognize the desirability of increasing freedom of trade by the development, through voluntary agreements, of closer integration between the economies of the countries parties to such agreements.

Although the GATT and later the WTO did not define in detail the shape that “regional trade agreements establishing customs unions and free-trade areas” must undertake, they both laid down

a number of conditions which must be met in order for these arrangements to be GATT- and WTO-compatible. Accordingly, the GATT defines customs union as:

- ... the substitution of a single customs territory for two or more customs territories, so that
- i. duties and other restrictive regulations of commerce (except, where necessary, those permitted under Articles XI, XII, XIII, XIV, XV and XX) are eliminated with respect to substantially all the trade between the constituent territories of the union or at least with respect to substantially all the trade in products originating in such territories, and,
 - ii. subject to the provisions of paragraph 9,³⁵ substantially the same duties and other regulations of commerce are applied by each of the members of the union to the trade of territories not included in the union.

Moreover, the GATT (Article XXIV.8.b) defines free-trade areas as follows.

A free-trade area shall be understood to mean a group of two or more customs territories in which the duties and other restrictive regulations of commerce (except, where necessary, those permitted under Articles XI, XII, XIII, XIV, XV and XX) are eliminated on substantially all the trade between the constituent territories in products originating in such territories.

The difference between a customs union and a free-trade area is rooted in the relationship that each has with third parties. Bossche explains that a free-trade area “establishes only a standard for the internal trade between constituent members, unlike customs union, which also deals with the relationship with third parties”.³⁶

The conditions and purposes which must be met for the formation of these arrangements are explained under Article XXIV.4 of the GATT 1947 and the preamble to the WTO’s Understanding on Article XXIV.

The contracting parties ... also recognize that the purpose of a customs union or of a free-trade area should be to facilitate trade between the constituent territories and not to raise barriers to the trade of other contracting parties with such territories [GATT 1947].

Reaffirming that the purpose of such agreements should be to facilitate trade between the constituent territories and not to

A free-trade area shall be understood to mean a group of two or more customs territories in which the duties and other restrictive regulations of commerce ... are eliminated

raise barriers to the trade of other Members with such territories; and that in their formation or enlargement the parties to them should to the greatest possible extent avoid creating adverse effects on the trade of other Members [WTO].

Broadly put, the purpose of the above exception is the creation and facilitation of trade between member states through the lowering and removal of trade barriers. However, as a result, these arrangements should not adversely affect other non-party members to these arrangements.

As a result of the rise in the numbers of regional and bilateral trade arrangements in recent years, many have suggested that these arrangements have spread much more widely than the framers of the original GATT agreement envisaged. As the WTO explains, these agreements have grown out of a narrow area as an “exception” to the main principles of non-discrimination to becoming increasingly the norm under international relations (Box 2).³⁷

As we speak, the discussion about the compatibility and compliance of these agreements with the multilateral trading rules remains inconclusive and is subject to academic debate. However, it is noteworthy to mention that in order to ensure compliance and transparency with the international rules, the GATT demands from contracting parties the notification of any regional trade agreement (RTA) or free-trade agreement. Accordingly, Article XXIV.7.a sets the obligation for parties to an RTA to notify other

Box 2.

Yet nearly five decades after the founding of the GATT, MFN is no longer the rule; it is almost the exception. Certainly, much trade between the major economies is still conducted on an MFN basis. However, what have been termed the “spaghetti bowl” of customs unions, common markets, regional and bilateral free-trade areas, preferences and an endless assortment of miscellaneous trade deals has almost reached the point where the MFN treatment is exceptional treatment. Certainly the term might now be better defined as LFN, Least-Favoured-Nation Treatment.

Source: *The future of the WTO: addressing institutional challenges in the new millennium.* Geneva, World Trade Organization, 2004.

members, and to make available to them “... such information regarding the proposed union or area as will enable them to make such reports and recommendations to contracting parties ...”. The GATT rules also state that upon receiving information concerning an RTA or FTA, other WTO members are entitled to make recommendations, which the RTA or FTA parties should be ready to consider (Article XXIV.7.b).

However, it is worth stating that there has been no reported incident when either the GATT or the WTO made a recommendation in accordance with the above requirements and notification procedures to abolish a certain preferential arrangement between member states despite the fact that there is an ever-growing opinion proclaiming that the formation of some of these agreements might be inconsistent with the rules of the GATT and the World Trade Organization (Box 3).³⁸

More recently, there has been a growing volume of literature alerting to the negative effects and implications of bilateral trade arrangements on both the global trading regime and on developing countries.³⁹ In addition to the fact that their economic impact has yet to be fully evaluated, some suggest that preoccupation with these arrangements is in fact discouraging countries from reaching multilateral trade agreements, hence slowing down the pace of multilateral trade negotiations. At the same time, since most of these agreements contain obligations which often go beyond the established multilateral rules, developing and least developed countries are increasingly limiting their freedom to devise policies compatible with their level of progress and development. This is particularly evidenced in the area of intellectual property and the

Box 3.

Out of 89 working parties established by GATT during its 47-year existence to examine proposed PTAs, 15 did not complete their work before GATT was subsumed in the WTO, 5 did not report and out of the 69 which reported, only six explicitly acknowledged the conformity with Article XXIV of the agreements they examined.

Source: Srinivasan T. Developing countries in the world trading system: from GATT, 1947, to the third ministerial meeting of WTO, 1999. *World economy*, 1999, 1047–64.

emergence of the TRIPS-plus obligations under these agreements and their impact on the public health of many developing and least developed countries. This issue will be looked into in more detail in the ensuing chapters. The next part will provide a brief description of the main characteristics and types of both bilateral and regional trade agreements.

RTAs are “institutionalized cooperation among groups of states to give trade benefits to each other that may or may not extend to third parties”

Regionalism versus bilateralism⁴⁰

This part identifies the main characteristics and types of regional and bilateral trade agreements. As will be seen, these arrangements often vary in content coverage and level of integration depending on their member states and their progress and development stages.

1. Regional trade agreements (RTAs)

RTAs are “institutionalized cooperation among groups of states to give trade benefits to each other that may or may not extend to third parties”.⁴¹ Moreover, Stoeckel et al. define “trade blocs” by stating that this term “can be used to cover a number of different trading arrangements. What they have in common is a set of market access conditions among member countries which differ from those for countries outside the bloc”.⁴² Examples of these arrangements include the European Union (EU), the Association of Southeast Asian Nations (ASEAN), the free-trade area comprising Argentina, Brazil, Paraguay and Uruguay (MERCOSUR), the Andean Community⁴³ and the North American Free Trade Agreement (NAFTA).

RTAs take several forms and shapes. The main division between their types depends on the level of cooperation and harmonization achieved within these arrangements. The level of RTA integration ranges between shallow integration and deep integration. Some examples of these arrangements are bilateral exchanges of tariff preferences (preferential trading areas) and the establishment of an economic union, where two or more countries agree to unify their fiscal, monetary and social policies. They also include free-trade areas, where two or more regions or countries abolish all import duties on their mutual trade, but retain their existing tariffs against the rest of the world. Customs unions fall within such arrangements where the abolition of mutual import duties is matched by the adaptation of a common external tariff on imports from the rest

of the world. A common market is established where the members of a customs union also agree to allow the free movement of all factors of production between member countries.⁴⁴

Regional integration has long been acknowledged. Some trace its roots as early as the 16th century in relation to the proposed economic and political union between England and Scotland during 1547–48. Although RTAs were known long before the establishment of the GATT in 1947, the agreement provided the first framework for the procedures and rules that should regulate the creation of these arrangements under the international multilateral system.⁴⁵

The establishment of the EEC in 1958 and the European Free Trade Association in 1960 were the beginning of organized waves of regional integration globally. They were supplemented by the ASEAN Regional Trade Agreement in 1967. This pattern of regional cooperation re-emerged during the 1980s and 1990s, which witnessed the creation of a number of new regional trade agreements including the NAFTA in 1994.

The WTO estimates that, as of July 2007, it had been notified of more than 380 RTAs.⁴⁶ This number is expected to rise to 400 agreements by 2010.⁴⁷ Although the debate about regionalism remains inconclusive, some suggest that these agreements may result in benefits by providing market expansion and fostering world trade integration and liberalization through regional harmonization.⁴⁸ On the other hand, others proclaim regionalism as a first step towards full global liberalization, thus promoting multilateral integration. An opposite view fears that regionalism might undermine multilateralism by diverting attention away from it.⁴⁹ Winters takes a more pragmatic view about these agreements by stating that “RTAs are like street gangs: you may not like them, but if they are in your neighbourhood, it is safer to be in one”.⁵⁰

Regardless of the above, one thing that a large proportion of scholars agree on is that RTAs “tend to be more liberalising than GATT”,⁵¹ a fact that also applies to certain RTAs as far as the protection of intellectual property is concerned.⁵²

Although the content varies from one agreement to another, the coverage of these RTAs generally includes the regulation of various issues ranging from tariffs reduction, services, competition rules, labour, environment, investment and market entry in addition to detailed provisions on intellectual property protection.⁵³

The WTO estimates that, as of July 2007, it had been notified of more than 380 RTAs

2. Bilateral free-trade agreements (FTAs)

The scope of bilateral trade agreements has been expanding in recent times. FTAs cover wide-ranging issues including investment, trade, labour, services, environment, competition rules, e-commerce, dispute settlement and intellectual property. However, FTAs are referred to as bilateral agreements because they are concluded either between two states or two trading blocs.

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The world has experienced a noticeable increase in the number of bilateral FTAs in recent times, not only between developed countries but also between developed and developing countries. For example, the United States has already completed several bilateral FTAs and is negotiating further number of bilateral agreements, mainly with developing countries.⁵⁴ Other developed nations are also signing such agreements. The European Union has recently completed a large number of economic partnership agreements (EPAs) in addition to more than 30 bilateral association agreements (AAs) with countries located in the Eastern Mediterranean Region and eastern Europe while Japan has already signed several bilateral free-trade agreements with Asian and Latin American countries.⁵⁵

Some of the noteworthy features of the majority of these bilateral trade arrangements are their complex and extensive coverage of various issues related to trade, investment, labour, environment and, most important, to the protection and regulation of intellectual property. In fact, a number of these free-trade agreements go beyond the established international standards of TRIPS, hence resulting in the so-called TRIPS-plus effect.

The collapse of the 1999 WTO ministerial conference in Seattle may mark the beginning of a contentious era for the global multilateral trading regime. The subsequent abrupt failure of the Cancun and Hong Kong ministerial conferences in 2003 and 2005 respectively and the Doha Round's current impasse and missed deadlines have led many to believe that the future of the world's multilateral trading framework cooperation is in real jeopardy. In this regard, it may be highlighted that during the period when multilateral efforts were in retreat, there was some evidence that bilateral efforts and initiatives were intensifying.⁵⁶

The forms of bilateral agreement

Bilateral trade agreements which include intellectual property provisions may be divided into two categories:⁵⁷ the first are regional or country-specific bilateral trade agreements, the second are subject-specific bilateral trade and cooperation agreements. The following is a brief examination of the characteristics of each type.

1. Regional or country-specific bilateral agreements

This category covers a comprehensive type of agreement that deals with various issues related to trade, environment and investment in addition to the regulation of intellectual property. These agreements are often based on a number of economic, political, geographical or social justifications. Accordingly, these agreements may take one of the following three models.

A. Trade and investment framework agreements (TIFAs)

A trade and investment framework agreement is an initial agreement concerned with laying down the foundations for negotiations of a bilateral free-trade or investment agreement between two countries (Box 4). A United States modality, these agreements establish a legal and political commitment between one country and another

Box 4.

A TIFA is a bilateral accord used by the United States, often as a precursor and pre-condition for a free-trade agreement (FTA). TIFAs are negotiated mainly with countries whose economies were once closed or isolated and are now beginning to open to international trade and investment. Also established by TIFAs are other joint working groups between the United States and its partner country to discuss how an FTA might proceed. These working groups address issues pertaining to trade and investment liberalization, including intellectual property protection, labour and the environment, small and medium size enterprises (SMEs), and trade capacity building.

Source: Bhala R. *Dictionary of international trade law*. Newark, New Jersey, LexisNexis, 2008.

Some estimate that there are currently 159 effective agreements of this type in the world. ... more than three-quarters of world trade passes through the jurisdiction of these agreements

to foster, encourage and enhance bilateral trade and investment through increased liberalization and removal of trade barriers. Examples of US TIFAs signed with countries in the Region include the 1995 US–Morocco TIFA, the 1997 US–Jordan TIFA and the 2002 US–Bahrain TIFA.

TIFAs are often brief agreements that in most cases do not exceed five pages in length. However, in the area of intellectual property protection, these agreements occasionally include brief references to improving and enhancing intellectual property protection between member states. TIFAs often include the provision requiring “adequate and effective protection and enforcement of intellectual property rights and of membership in and adherence to intellectual property rights conventions” without defining what such standards and conventions are.⁵⁸

B. Free-trade agreements (FTAs)

Some estimate that there are currently 159 effective agreements of this type in the world.⁵⁹ The importance of these types of agreement has grown tremendously, especially since the mid 1990s, when most of these agreements were concluded. This is manifested by the fact that more than three-quarters of world trade passes through the jurisdiction of these agreements. Examples of these types of agreement include the 2001 US–Jordan FTA the 2003 US–Singapore FTA and the 2006 US–Oman FTA.

Most recent FTAs incorporate special chapters containing extensive provisions dealing with issues related to investment, trade, tariff reduction, e-commerce, labour and the environment. In addition, these types of agreement often incorporate very detailed sections dedicated to the protection of intellectual property which aim towards upgrading and strengthening the levels of protection so that they at least conform to the level of protection required by international standards. As discussed earlier, a large number of these FTAs go even further by providing their own independent enforcement measures and dispute settlement procedures (Box 5).

The danger emanating from adhering to these types of agreement is that they often operate outside the framework of the WTO and its dispute settlement procedure. Although they are notified to the WTO’s secretariat,⁶⁰ from a practical point of view, the WTO has no power to interfere or amend the provisions of these agreements due to the requirement of consensus of all WTO members, which

Box 5.

An FTA is an agreement among two or more countries (more specifically, customs territories) to drop all internal trade barriers as among the countries. Each party to an FTA, however, retains its own separate schedule of tariffs for imports from third countries, thus making the FTA a less economically integrated entity than a customs union. The formation of FTAs is subject to the requirements—which are quite slender—set forth in GATT Article XXIV.

Source: Bhala R. *Dictionary of international trade law*. Newark, New Jersey, LexisNexis, 2008.

is difficult—if not impossible—to achieve in a situation like this. In recent years, these types of agreement were subject to criticism because of their inclusion of TRIPS-plus obligations. The effect of such agreements on the public health regimes of developing and least developed countries will be subject to further analysis in chapters 3 and 4.

C. Bilateral investment treaties (BITs)

A BIT is an agreement establishing the terms and conditions for private investment by nationals and companies of one state in the state of the other. This type of investment is called foreign direct investment (FDI).

The first known BIT was concluded between the Federal Republic of Germany and Pakistan in 1959. Since then, many industrialized countries including, Germany, France, Switzerland and the United States have made BITs part of their foreign trade policy. However, of all these countries, the United States has been using this model of treaties more extensively in relation to intellectual property protection during the past two decades.⁶¹ This came at a time during the 1980s when the United States linked its bilateral investment treaty programme to the goal of enhancing the protection of intellectual property worldwide by including the protection of intellectual property as an investment-related issue. As a result, by 1987, the United States had already signed 11 BITs, mainly with developing countries.⁶² As we speak, there are about 2573 BITs in force, mostly between developed and developing countries (Box 6).⁶³ Examples of this are the US–Bahrain BIT, the US–Jordan BIT and the US–Jamaica BIT.

BITs often deal with wide ranging investment-related issues. Accordingly, BITs often define what is meant by an “investment”, emphasizing the need for providing “fair and equitable treatment” between the parties of the treaty and reaffirming the need for the provision of “full protection and security” for the investment. BITs also provide conditions for cases of expropriation, compensation and alternative dispute settlement procedures other than that available internally in the host state.

BITs have a clear impact on the protection regime of intellectual property as their coverage extends to include the protection of intellectual property within their definition of investment. For example, the failed proposed draft for the OECD’s Multilateral Agreement on Investment (MAI) explicitly defines investment to include “every kind of asset owned or controlled, directly or indirectly, by an investor, including ... intellectual property rights”. Some BITs explicitly mirror the above approach by indicating the types of intellectual property to be covered and included under the BIT, agreement. An example is the US–El Salvador BIT concluded in 1999, which specifies that investment explicitly includes “copyrights and related rights, patents, rights in plant varieties”.⁶⁴

One can see that the protection awarded under some of these BITs through the requirement that countries must provide intellectual property protection in accordance with the “highest international standards” in a “fair and equitable” manner without any elaboration

Box 6.

The number of international investment agreements (IIAs) has continued to grow, reaching a total of almost 5,500 at the end of 2006: 2,573 bilateral investment treaties, 2,651 double taxation treaties and 241 free-trade agreements and economic cooperation arrangements containing investment provisions. The number of preferential trade agreements with investment provisions has almost doubled in the past five years. Developing countries are becoming increasingly important participants in international investment rule-making, partly reflecting growing South–South FDI.

Source: UNCTAD. *Trade and development report 2007*. New York and Geneva, United Nations, 2007. UNCTAD/TDR/2007.

on what is meant by these standards.⁶⁵ Historically, the fair and equitable standards were considered to have been breached when a state's behaviour was of an "egregious and shocking nature"; in recent times it has been applied to other conduct even if committed with good faith by any state.⁶⁶ This loose and broad reference may create a lot of complications, especially for developing countries that are parties to these agreements.⁶⁷

Moreover, from a practical standpoint, when one refers to the highest international standards of protection, it is presumed that this concept may include any standards adopted under an international instrument which is recognized and accepted by all parties. However, this may not necessarily be the case. As Correa argues, "this would, however, impose too broad obligations on the concerned countries. 'International' may reasonably be understood as covering multilateral and not merely bilateral or regional agreements that were in force at the time such an obligation was accepted".⁶⁸ Notably, the concept of international standards does not exist in that sense in relation to the regulation of intellectual property as an investment issue, hence engulfing the interpretation of these bilateral arrangements with additional vagueness and inconsistency.

D. Bilateral cooperation, partnership and association agreements (AAs)

Although bilateral cooperation, partnership and association agreements are often affiliated with aid and development, increasingly these agreements contain obligations demanding that member states upgrade and incorporate higher levels of intellectual property protection within their national law.⁶⁹ The European Union has signed a number of AAs and advocates these types of agreement, which also focus on market reforms, human rights, democracy, investment and protection of intellectual property (Box 7).

These agreements are also considered major sources of extensive intellectual property protection and TRIPS-plus provisions. In fact AAs rank only second to FTAs in this aspect. In 2001, it was suggested that "[t]he EU Partnership Arrangements either completed or under negotiation under the Barcelona Process (to establish a Common Mediterranean Market), with Bangladesh or with Mexico are all geared toward trade liberalisation and include TRIPS-Plus".⁷⁰ This can be viewed in accordance with a

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Box 7.

A European Union Association Agreement is a treaty between the European Union and a non-EU country that creates a framework for co-operation between them. Areas frequently covered by such agreements include the development of political, trade, social, cultural and security links.

Source: www.bilaterals.org (2008).

vast number of partnership and association agreements in which member states are required to forgo certain transitional periods and to accede to several international agreements related to the protection of intellectual property outside their TRIPS obligations.⁷¹

The conclusion of these types of agreement is not confined to the European Union. Accordingly, in addition to the European Union's AAs, there are several other bilateral free-trade agreements signed between European countries and a number of states in the Eastern Mediterranean Region under the EFTA programme.⁷² These agreements also incorporate several extensive WTO and TRIPS-plus provisions. Examples of these agreements are the 1997 EFTA with Morocco, the 2002 EFTA with Jordan and the 2004 EFTA with Lebanon. In certain agreements, these EFTAs often incorporate TRIPS-plus provisions that go beyond what have already been established under both the WTO and the European Union's bilateral association agreements.

2. Subject-specific bilateral treaties and agreements

This category of agreement often deals with a specific activity or a certain kind of cooperative arrangement between its parties. It may also deal solely with a certain specific type of issue such as the protection of intellectual property. Accordingly, these agreements may take one of the following two models.

A. Bilateral science and research and development cooperation agreements

The number of bilateral science and research and development cooperation agreements has greatly risen during the past decade. Some estimate that the United States alone has over 800 bilateral agreements of this type in force with over 60 countries.⁷³ Australia has about 55 bilateral research cooperation agreements with 25 countries while the European Union has about 30 bilateral science and technology cooperation agreements with other countries.

These agreements often deal with activities related to research and development (R&D) of foreign corporations around the world. Some of these agreements also deal with projects related to the environment and environmental technologies, marine research, geosciences and material sciences. Examples of this type of treaty include the 2008 US–Libyan Arab Jamahiriya bilateral science and technology cooperation agreement, the 1992 US–Republic of Korea agreement on science and technology, and the Canada–West Germany bilateral agreement on cooperation in science and technology signed in 1971.

Controversy engulfs some of these agreements, especially in relation to the ownership of intellectual property. Under such agreements, a protocol to enhance the protection of intellectual property is often incorporated, which requires the parties to these agreements to provide adequate protection for intellectual property under their domestic legislation; if one of the parties fails to provide adequate protection, the other party will solely enjoy the benefits of the rights arising from the project without any consideration for the rights of the other (Box 8).⁷⁴ An example

Box 8.

At present, the US still uses the 1990 model text in its Bilateral Science and Technology Agreement with countries that have “inadequate” IPR laws. Countries whose patents laws are more in line with US preferences are subject to a revised 2000 Protocol which is more flexible.

Source: GRAIN. *TRIPS-plus: through the back door: how bilateral treaties impose much stronger rules for IPRs on life than the WTO*. 2001. Available at <http://www.grain.org/briefings/?id=6>.

of disputes related to these types of agreements is the US–India dispute over the development of vaccine drugs, which lasted from 1987 to 1992.

B. Bilateral intellectual property agreements

These types of agreement are specifically linked to the protection and enforcement of intellectual property. They may require their parties to enhance the protection of all or a particular branch of intellectual property beyond what is required under the existing international agreements. These agreements may also require their parties to accede to an international intellectual property agreement or agreements not incorporated into TRIPS, resulting in a TRIPS-plus effect.⁷⁵ This category belongs to the old generation of FTAs that has been replaced more recently by the new generation of bilateral FTAs including the US–Jordan, US–Oman and US–Bahrain FTAs.

These agreements are often accompanied by the promise of aid, funds and technical assistance from a more advanced developed country in exchange for the enhanced intellectual property protection. They often target and deal with a specific problem, such as the counterfeiting of sound recordings or piracy of software products.⁷⁶ Examples of these agreements include the US–Bulgaria Understanding on Intellectual Property,⁷⁷ the US–Nicaragua Bilateral Intellectual Property Rights Agreement⁷⁸ and the US–China Bilateral Intellectual Property Treaty.⁷⁹

Box 9.

From the 1980s to the end of the 1990s, it was common for industrialised country governments to impose bilateral agreements specifically aimed at upgrading intellectual property rights legislation and enforcement in developing countries. Sometimes these were stand alone bilateral IPR agreements; sometimes in specific cases, like China, they were special components of bilaterally negotiated WTO accession agreements. ... Today, however, strong IPR rules are more commonly being pursued in the context of comprehensive FTAs.

Source: http://www.bilaterals.org/rubrique.php3?id_rubrique=60. 2008.

Developed countries including the United States and the European Union have been active in pursuing these types of agreement. They have often targeted developing countries that do not have adequate protection of intellectual property or countries that are weak on enforcement and implementation matters through signing such agreements in exchange for financial aid and technical assistance (Box 9).

The participation of developing and Arab countries in multilateral trade negotiations

The history of multilateral trade negotiations conducted under the auspices of the GATT reveals that developing countries, including those in the Eastern Mediterranean Region, have often acted as “bystanders”, “passive” and “defensive” during these multilateral trade negotiation rounds.⁸⁰ Accordingly, these countries did not engage significantly in the mutual exchange of concessions with other countries and at the same time failed to contribute to the agenda during these meetings.⁸¹ This was particularly notable during the seven GATT negotiation rounds which preceded the start of the Uruguay Round. Although certain changes occurred during the Uruguay Round which meant that many developing countries became more active participants both individually and in coalitions with other countries, the truth of the matter is that, save few exceptions,⁸² the majority of those countries had little say and influence in the end to affect the final outcomes of the Uruguay Round.

Moreover, as a result of their inactive participation under the multilateral negotiation rounds and the preferential treatment awarded to them in certain sectors, developing countries (in particular those of the Region) saw no need to participate in the reduction of tariffs resulting from these rounds, thus maintaining higher levels of tariffs on numerous imports.

Despite the fact that developing countries vehemently opposed the notion of bringing intellectual property rights and services—the latter to a lesser extent—under the GATT’s umbrella, these countries were unable to stop the tide led by the developed countries from the inclusion of TRIPS and GATS under the WTO’s regime.

The history of negotiations conducted under GATT reveals that developing countries, including those in the Eastern Mediterranean Region, have often acted as “bystanders”

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International trade negotiations are a complex exercise. The task becomes even more difficult if a large number of participants are discussing a vast number of contentious and technically complex issues. Moreover, bilateral and international trade negotiations often require the presence of specialized negotiators at all levels, including lawyers, economists, health specialists and environmentalists, in addition to officials and diplomats. In this regard, it is not uncommon to hear that some of the developed countries' negotiating teams under both bilateral and multilateral forums amounted to hundreds of highly specialized individuals.⁸³

In addition, as more complex issues are being negotiated on wider-ranging global agendas, international negotiations are increasingly taking longer to conclude. It is therefore crucial that these specialized negotiators be available on a full-time basis to follow up, prepare for, respond to and attend meetings and deliberations. This is an area where developing countries in general often lag behind other countries due to several reasons. Preoccupation with other pressing priorities, lack of resources and funding, scarcity of specialized individuals and poor capacity-building have in fact resulted in weakened bargaining and negotiation positions of these countries in both international and bilateral negotiation forums. Commenting on why developing countries accepted the imbalanced outcome of the Uruguay Round agreements, Finger and Norgues explained that this was primarily due to the "lack of assessment of the impact of the agreements and even the data needed to conduct such assessment" by these countries.⁸⁴

Until recently, a large number of developing countries did not maintain offices at the WTO mission in Geneva. Moreover, several developing countries operate joint missions—missions housing representatives to all international agencies in Geneva whose formal head is the ambassador accredited to the United Nations. Even those that maintain offices at the WTO in Geneva do so with very small missions and thus lack adequate and qualified representation.⁸⁵

The above deficiency becomes a serious problem if we take into consideration the fact that since many developing countries lack adequate numbers of qualified personnel, a busy multilateral and bilateral negotiations schedule may lead to inadequate representation in addition to negotiation-fatigue for these countries' representatives. For example, in the case of the WTO alone, Blackhurst estimates that there were approximately 40–45

scheduled WTO meetings in the average working week in 1995–96 alone.⁸⁶ Of course these meetings—at least in theory—should be preceded by a number of meetings and sessions credited with the purposes of preparing, analysing and drafting claims and proposals. The extent of the problem increases if we add to this the number of meetings which these overstretched representatives and diplomats have to attend to under other national, regional and bilateral trade negotiations (Box 10).⁸⁷

This also means that the majority of developing and least developed countries often lack the ability to undertake the vital analysis, research and empirical work needed for evaluating the effects of new proposals and agreements on their economies. This also explains why such countries have been unable to respond to and develop their own proposals; thus they fail to actively participate in setting the negotiations agenda.⁸⁸

Moreover, the above has also restricted developing and Arab countries' ability to use the WTO's dispute settlement procedure (DSP). This is reflected in the fact that until now, no Arab country has ever initiated a case before a WTO panel as a complainant, and until 2004 Egypt was the only Arab country that had acted as a respondent, in four cases. More specifically, it was remarked that as of April 2007, 24 cases were brought before the DSP regarding TRIPS and another four related to TRIPS enforcement. Every case was brought by the United States, European Union member states or Canada, except for one by Brazil. Nineteen of these were instituted by the United States, plus all four of the TRIPS enforcement cases.⁸⁹

The issues highlighted above become even more problematic under the bilateral negotiations which are conducted between developing and developed countries with the aim of concluding

Box 10.

In trade negotiation, information and expert knowledge is everything. ... Negotiators that are able to draw on expert legal knowledge will have an advantage in a negotiation.

Source: Drahos P. Intellectual property and pharmaceutical markets: a nodal governance approach. *Temple law review*, 2004, 77:401–24.

bilateral free-trade, investment and association agreements. As these negotiations often lack transparency and public debate, it has been observed that the negotiators of developing countries have often accepted stricter and tighter obligations and conditions which they would not have otherwise accepted under the multilateral forums.⁹⁰

Proper and adequate participation in setting the agenda has been reflected positively on the ground. Research conducted shows that those developing countries, particularly India and Brazil, which actively participated in the TRIPS negotiations during the Uruguay Round have been the most successful ones in implementing and incorporating the flexibilities of TRIPS within their national legislation.⁹¹ The opposite can be said of those developing and least developed countries which were less active during the negotiations on intellectual property and TRIPS throughout the Uruguay Round. As will be explained in more detail in the next chapter, the case of intellectual property protection illustrates the complexities associated with this issue as a result of its links with several wide-ranging concerns.

Developing and Arab countries need to prioritize investment in human resources and capacity-building of their trade negotiators and diplomats. This investment must be viewed as a part of these countries' development agendas and strategies. As more of these countries are expected to join an increasing number of agreements within the coming few years, the need for legal and technical expertise becomes crucial for the negotiation, implementation and interpretation of these agreements and treaties.

The significance of these issues will not only be realized during the negotiation stages. Such a national capacity and expertise are also needed so that international commitments and obligations are applied and implemented nationally in accordance with the needs and priorities of each country. This will also enable officials and civil servants to properly and adequately explore and use the policy space available under international law thus maximizing their countries' gains from these agreements.

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Endnotes

1. The GATT, Article XX.b.
2. “New issues” is a phrase which often refers to the regulation of intellectual property, investment and services.
3. On the GATT and Cold War relations see McKenzie F. GATT and the Cold War: accession debates, institutional development and the Western alliance, 1947–1959. *Journal of Cold War studies*, 2008, 10(3):78–109.
4. The aim of the IMF was to put in place an international monetary system that contained a stable exchange rates regime. On the other hand, the aim of the World Bank was to help foster the economic and industrial reconstruction of Europe and to help developing countries achieve industrialization. Both the IMF and World Bank are often referred to as the “Bretton Woods Regime”.
5. For more see Braithwaite J, Drahos P. *Global business regulation*. London, Cambridge University Press, 2000; and Lowenfeld A. *International economic law*. New York, Oxford University Press, 2002.
6. Other countries were also sceptical about the organization since they viewed it as too favourable for government intervention, and too pro free trade. See Lowenfeld, *ibid*.
7. Twenty-three contracting parties signed on to the GATT in 1947: Australia, Belgium, Brazil, Burma, Canada, Ceylon, Chile, China, Cuba, Czechoslovakia, France, India, Lebanon, Luxembourg, Netherlands, New Zealand, Norway, Pakistan, Southern Rhodesia, Syria, South Africa, the United Kingdom and the United States.
8. Daniels J, Radebaugh L. *International business: environments and operation*, 7th ed. Reading, Massachusetts, Addison-Wesley Publishing, 1995, at 226.
9. Braithwaite and Drahos, *supra* 5, at 177.
10. Jackson J. *Restructuring the GATT system*. London, Chatham House, 1990, at 26.
11. The GATT, Preamble.
12. Hoekman B. The WTO: functions and basic principles. In Hoekman B, Mattoo A, English E, eds. *Development, trade, and the WTO: a handbook*. Washington DC, World Bank Publications, 2002, at 44.
13. Micklitz H. International regulation on health, safety, and the environment—trends and challenges. *Journal of consumer policy*, 2000, 23:3–24.
14. The exact scope of this expression has not been considered in many GATT/WTO cases. See Button C. *The power to protect: trade, health and uncertainty in the WTO*. Oxford, Hart Publishing, 2004, at 25. Also see the *WTO Report of the Panel on the European Communities—measures affecting asbestos and asbestos-containing products*. Geneva, WTO, 2000. WT/DS135/R.
15. Named after Douglas Dillon, the United States’ Undersecretary of State for Economic Affairs under President Dwight Eisenhower.

16. As Lowenfeld states, “there was a fear in some quarters that the EEC might become an inward-directed, high tariff area, inimical to the trading interest of the United States”. Lowenfeld, *supra* 5, at 49.
17. Named in memory of United States’ President John Kennedy.
18. Non-tariff barriers are trade barriers that restrict imports but are not in the usual form of a tariff, such as quantitative restrictions which include quotas, prohibitions and subsidies.
19. Thus missing the projected deadline initially proposed as of 1975.
20. Lowenfeld, *supra* 5, at 58.
21. In the area of intellectual property, the initial basis of the protection was to deal primarily with the issues of pharmaceutical patents, counterfeiting and piracy. See Primo-Braga C. The economics of intellectual property rights and the GATT: a view from the South. *Vanderbilt journal for transnational law*, 1989, 22(2):243–64; also see Subramanian A. TRIPs and the paradigm of the GATT: a tropical, temperate view. *World economy*, 1990, 13(4):509–21.
22. Drahos and Braithwaite, *supra* 5, at 179–80.
23. This outcome was referred to as the “grand bargain” in which the developed countries promised to liberalize trade in agriculture and textiles in return for the reduction of tariffs and acceptance of new rules on intellectual property, services and investment by the developing countries. See generally Bhagwati J. *In defense of globalization*. New York, Oxford University Press, 2004; and Stiglitz J. *Making globalization work*. London, Allen Lane, 2006.
24. The Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco, on 15 April 1994. See www.wto.org.
25. See generally Finger M. *The Doha agenda and development: a view from the Uruguay Round*. Manila, Asian Development Bank, 2002. ERD Working Paper Series No 21.
26. The events of 11 September 2001 and the change from a Democratic to a Republican administration contributed to a major change in attitude both inside and outside the United States.
27. See http://www.wto.org/english/tratop_e/dda_e/dda_e.htm.
28. Deardorff and Stern explain that the Doha Round was “christened the Doha Development Agenda, not because its purpose was to achieve the policies that would stimulate development, but because it was intended to pursue the usual objective of trade liberalization with the unusual proviso that developing countries would not be sidelined or put at a disadvantage”. See Deardorff A, Stern R. *What should developing countries do in the context of the current impasse of the Doha Round?* Kiel Institute for the World Economy, Research Seminar in International Economics, Discussion Paper 559, February 2007, at 6–7.
29. Defrosting Doha. *The economist*, 17 July 2008.
30. The Trade Promotion Authority (TPA) granted under the Trade Act of 2002 to United States president George W. Bush. Any trade pact or agreement must now be approved by the United States Congress with the possibility of amendments, which creates an additional burden on the United States negotiators and decreases the willingness of other countries to participate in any negotiations. For more see VanGrasstek C. *U.S. trade policy and developing countries: free trade agreements, trade preferences, and the Doha Round*. Geneva, International Centre for Trade and Sustainable Development, 2007. Also see

VanGrasstek C. *U.S. trade promotion authority and the Doha Round*. Geneva, International Centre for Trade and Sustainable Development, 2007.

31. As of July 2008, the WTO's membership comprised 153 countries with an annual budget reaching 182 million Swiss francs. The WTO's secretariat currently employs 625 individuals. See WTO website at www.wto.org.
32. In this regard, the WTO's single undertaking mandate compels governments to accept agreements as a complete package rather than on an individual basis.
33. Statement by Peter Sutherland, the former GATT director-general, cited in Dunkley G. *The free trade adventure: the WTO, the Uruguay Round and globalisation—a critique*. London, Zed Books, 2000, at 3.
34. At Doha, trade ministers stated “we strongly reaffirm our commitment to the objective of sustainable development. ... We are convinced that the aims of upholding and safeguarding an open and non-discriminatory multilateral trading system, and acting for the protection of the environment and the promotion of sustainable development can and must be mutually supportive”. For more see Sampson G. *The WTO and sustainable development*. Tokyo, United Nations University Press, 2005.
35. The GATT, Article XXIV, Paragraph 9, states:

The preferences referred to in paragraph 2 of Article I shall not be affected by the formation of a customs union or of a free-trade area but may be eliminated or adjusted by means of negotiations with contracting parties affected. This procedure of negotiations with affected contracting parties shall, in particular, apply to the elimination of preferences required to conform with the provisions of paragraph 8 (a) (i) and paragraph 8 (b).
36. Bossche P. *The law and policy of the World Trade Organization*. Cambridge, Cambridge University Press, 2006, at 659. For more on the history of GATT Article XXIV see Goto J, Hamada K. Regional economic integration and Article XXIV of the GATT. *Review of international economy*, 1999, 7(4):555–70.
37. *The future of the WTO: addressing institutional challenges in the new millennium*. Geneva, WTO, 2004.
38. Even if that were the case, the Article does not specify the consequences for failure to comply with a panel's recommendation.
39. See Bhagwati J. Regionalism and multilateralism: an overview. In De Melo J, Panagariya A, eds. *New dimensions in regional integration*. New York, Cambridge University Press, 1993, at 22–51; also Mansfield E, Reinhardt E. Multilateral determinants of regionalism: the effect of GATT/WTO on the formation of preferential trade arrangements. *International organization*, 2003, 57(4):829–62.
40. This section is largely based on El Said M. *The development of intellectual property protection in the Arab world*. New York, Edwin Mellen Press, 2008.
41. Barry D, Keith R. *Regionalism, multilateralism, and the politics of global trade*. Vancouver, University of British Columbia Press, 1999, at 3.
42. Stoeckel A, Pearce D, Banks G. *Western trading blocs: game, set or match for the world economy?* Canberra, Centre for International Economics, 1990.
43. A free-trade agreement and the oldest trading bloc in the western hemisphere. Established in 1969 by the Cartagena Agreement, whose original members were Bolivia, Columbia, Ecuador and Peru. See Bhala R. *Dictionary of international trade law*. Newark, New Jersey, LexisNexis, 2008, at 24.

44. Blakeney M. The role of intellectual property law in regional commercial unions. *Journal of world intellectual property*, 1998, 1(4):691–709, at 699.
45. See the GATT, Article XXIV. This principle was subsequently enshrined under the WTO Agreements. However, as discussed above, the GATT perceived “trade blocs” as one of the “exceptions” to the general rule of MFN under Article I in which preferential treatment may be awarded to members of these arrangements without applying the MFN principle regarding other members outside such arrangements.
46. WTO website, at http://www.wto.org/english/tratop_e/region_e/region_e.htm.
47. *ICTSD-Bridges*, 4, July 2007, at 1. www.ictsd.org.
48. See Van Dijk M, Sideri S. *Multilateralism versus regionalism: trade issues after the Uruguay Round*. London, Frank Cass, 1996.
49. See generally De Melo J, Panagariya A, eds. *New dimensions in regional integration*. Cambridge, Cambridge University Press, 1993.
50. Quoted in Crawford J, Laird S. Regional trade agreements and the World Trade Organization. *North American journal of economics and finance*, 2001, 12(2):193–211.
51. See Dunkley, *supra* 33, at 97.
52. See the North American Free Trade Agreement (NAFTA).
53. A clear example of a strongly regulated regional agreement in regard to intellectual property protection is NAFTA, which incorporates a comprehensive framework for the protection of intellectual property that exceeds the TRIPS standards of protection. For example, NAFTA, Article 1701, requires member states to ratify the Geneva, Berne and Paris Conventions and the International Convention for the Protection of New Varieties of Plants, 1978 (UPOV Convention). or the revised UPOV Convention of 1991.
54. These include five FTAs signed with countries of the region: Israel, Jordan, Morocco, Bahrain and Oman.
55. See for example the Japan–Singapore FTA, signed in 2000, the Japan–Malaysia FTA, signed in 2005, and the Japan–Chile FTA, signed in 2007.
56. *The economist* observes that “if every one of the WTO members were to strike a free-trade deal with every other, the world would be criss-crossed by 11,026 bilateral deals”. See Least favoured nation. *The economist*, 3 August 2006. This issue will be discussed in more detail in the following chapters.
57. See El Said, *supra* 40.
58. For example the 2004 US–Qatar TIFA stipulates in its preamble:

Recognizing the importance of providing adequate and effective protection and enforcement of intellectual property rights and of membership in and adherence to intellectual property rights conventions.
59. See UNCTAD. *Trade and development report 2007*. New York and Geneva, United Nations, 2007. UNCTAD/TDR/2007.
60. See TRIPS, Article 63.2.
61. Vandeveld K. The U.S bilateral investment treaties: the second wave. *Michigan journal of international law*, 1993, 14:621–704.
62. China and India have also been active in pursuing BITs with other developing countries. Accordingly, as of the year-end of 2001, China had entered into 71 BITs while India had signed 11 BITs. See Lowenfeld, *supra* 5, at 473.

63. UNCTAD. *World investment report 2003: FDI policies for development: national and international perspectives*. New York and Geneva, United Nations, 2003. Also see UNCTAD. *Bilateral investment treaties 1959–1999*. Geneva, United Nations, 2000. UNCTAD/ITE/IIA/2, internet edition, available at <http://www.unctad.org/en/docs/poiteiiad2.en.pdf> (last visited 21 September 2005) at III; and UNCTAD. *Trade and development report 2007*. New York and Geneva, United Nations, 2007. UNCTAD/TDR/2007.
64. MAI, Part II, Para 2. Also see US–El Salvador BIT, Article 1 (d).
65. For example, the US–El Salvador BIT provides in Article II.3 (a) that:
Each party shall at all times accord to covered investments fair and equitable treatment and full protection and security, and shall in no case accord treatment less favourable than that required by international law [emphasis added].
66. See Cosbey A, Mann H, Peterson L, von Moltke K. *Investment and sustainable development: a guide to the use and potential international investment agreements*. Winnipeg, International Institute for Sustainable Development, 2004.
67. See El Said, *supra* 40.
68. Correa C. *Bilateral investment agreements: agents of new global standards for the protection of intellectual property rights?* Barcelona, GRAIN, 2004. Available at <http://www.grain.org/briefings/?id=186> (last visited 22 June 2005).
69. See the EU–Jordan AA, the EU–Egypt AA. and the EU–Tunisia AA.
70. See Correa, *supra* 68.
71. See the EU–Egypt AA, Annex VI, and the EU–Morocco AA, Annex 7, Article 1.
72. The EFTA is an intergovernmental organization promoting free trade and strengthening economic relations for its member states. EFTA's member states are Iceland, Liechtenstein, Norway and Switzerland. For more see <http://www.secretariat.efta.int>.
73. A recent survey by GRAIN concludes that the United States developed several protocol models for the protection of intellectual property under such agreements in line with each country's development and levels of intellectual property protection. See *TRIPS-plus through the back door: how bilateral treaties impose much stronger rule for IPRs on life than the WTO*. Barcelona, GRAIN, 2001.
74. For example, the Indo–US Science and Technology Forum Agreement, Article VII, states:
(1) Activities under this Agreement shall be subject to the laws and regulations in each country and the availability of funds.
(2) Nothing in this Agreement shall be construed to prejudice other arrangements for cooperation between the two countries. The Parties shall use their best efforts to ensure compatibility between the operation of this Agreement and other such Agreements. The Forum shall neither sponsor, nor permit under its auspices, any activity that would be proscribed by either Party's national laws or regulations.
75. The US–Bulgaria Intellectual Property Agreement stipulates in Article 1:
The Republic of Bulgaria will, on a priority basis, accede to the Geneva Convention for the Protection of Producers of Phonograms against unauthorized duplication of their phonograms (1971).
76. See the 1997 US–Vietnam Copyrights Agreement.

77. Concluded in 1995; consequently Bulgaria undertook certain obligations regarding the protection of intellectual property and in particular copyrights. In addition, Bulgaria acceded to the Geneva Phonograms Convention as required under the understanding.
78. Concluded on 16 December 1997. The agreement committed Nicaragua to adopt a modern legal and enforcement regime that will promote effective protection of intellectual property. Moreover, this agreement obliges Nicaragua to provide a higher level of protection than TRIPS within 18 months, ahead of the time that Nicaragua would otherwise be required to implement TRIPS alone.
79. The 1995 and 1996 bilateral IPR agreements between the US and China.
80. Finger M. Developing countries in the WTO system: applying Robert Hudec's analysis to the Doha Round. *World economy*, 2008, 31:887–904, at 892.
81. In fact a large number of these countries were excluded from the discussions on important issues including intellectual property. For example, Odell explains that “in the GATT, the informal ‘green room’ meeting became a regular feature. During the Uruguay Round Director-General and Chairman Arthur Dunkel invited chief negotiators from the states representing three-fourths of world trade to meet off the record, first in a small conference room in the DG’s office suite. Other members were not notified that a meeting would occur, no written summary of remarks was prepared, and each participant was free to speak personally. After complaints from the excluded, Dunkel shifted to hosting private dinners in his home. The table accommodated up to 24 chairs and no deputies—only chief negotiators as he called them—were welcome”. Odell J. Chairing a WTO negotiation. *Journal of international economic law*, 2005, 8(2):425–48, at 433.
82. Egypt being the most active member from the region. Pakistan was also active more recently though its participation in the Group of 22 countries.
83. Ross explains that “during my work on the UN Security Council, I had often been struck by a very obvious imbalance—between the diplomatic resources and skills of the powerful countries, and everyone else. ... The numerous smaller UN missions struggle to cover the enormous and proliferating agendas of the UN General Assembly, Security Council and specialized committees with just one or two horribly overworked and under-equipped diplomats. ... Often those with most at stake are not even allowed into the room where their affairs are being discussed. This imbalance of course does not serve those marginalized, but nor, paradoxically, does it serve the powerful. In this complex and interconnected era, agreements that fail to take into account the interests of all concerned parties are not good or sustainable and they often fall apart. The ultimate effect is a less stable world. If people are ignored, they tend to find ways—sometimes violent—to get heard”. Ross C. *Independent diplomat, dispatches from an unaccountable elite*. London, Hurst & Co, 2007.
84. Finger M, Nogués J. The unbalanced Uruguay Round outcome: the new areas in future WTO negotiations. *World economy*, 2002, 25(3):321–40.
85. Michalopoulos C. *The participation of the developing countries in the WTO*. Washington DC, World Bank, 2000. Policy Research Working Paper 1906.
86. Blackhurst R. The capacity of the WTO to fulfill its mandate. In Krueger AO, ed. *The WTO as an international organization*. Chicago, University of Chicago Press, 1997.
87. Moreover, research conducted by Drahos found that “expert tracking of so many areas is not, as the interviewees readily conceded, a realistic possibility.

Instead many negotiators stumble from one meeting to another with little evidence-based understanding of what they are dealing with, largely repeating what they have picked up in conversation or read in a summary briefing paper that has found its way onto their desk". See Drahos P. Four lessons for developing countries from the trade negotiations over access to medicines. *Liverpool law review*, 2007, 28(1):11–39, at 27.

88. See generally Nogués J. *Unequal exchange: developing countries in the international trade negotiations*. Paper presented at the Murphy Institute Conference on the Political Economy of Policy Reform, New Orleans, 2002. Available at <http://ctrc.sice.oas.org/geograph/south/Nogues.pdf>
89. Yueh L. Global intellectual property rights and economic growth. *Northwestern journal of technology and intellectual property*, 2007, 5(3):436–48, at 438–9.
90. Drahos P. When the weak bargain with the strong: negotiations in the World Trade Organization. *International negotiations*, 2003, 8:79–109.
91. For more details see discussion in chapter 4.

3. The global architecture of intellectual property protection and bilateral trade agreements

This chapter provides a general background to the purpose and nature of intellectual property and its evolution and global development. In particular, the chapter will focus on the inclusion of intellectual property under the GATT multilateral framework during the Uruguay Round of trade negotiations and the resulting TRIPS regime. Moreover, the chapter will touch upon the main characteristics and flexibilities of TRIPS and will examine the phenomenon of TRIPS-plus in greater depth, including its evolution and characteristics. Special focus will be on the role of the United States and the European Union in strengthening the levels of intellectual property protection globally. More important, the chapter will discuss some of the challenges facing the global regulation of intellectual property in the post-TRIPS era in the area of public health and some of the recent developments in this field. It examines the issue of public health within the framework of recent bilateral free-trade agreements and initiatives. Special attention will be given to the work of WIPO and WHO in the field of intellectual property regulation.

The nature and purpose of intellectual property

The UK Intellectual Property Commission defines intellectual property as “rights awarded by society to individuals or organizations principally over creative works: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce. They give the creator the right to prevent others from making unauthorized use of their property for a limited period”.¹

Box 11. The main categories of intellectual property

A patent is an exclusive right awarded to an inventor to prevent others from making, selling, distributing, importing or using the invention, without licence or authorization, for a fixed period of time. In return, society requires that the patent applicant disclose the invention in a manner that enables others to put it into practice. This increases the body of knowledge available for further research. The minimum term of patent protection under TRIPS is 20 years from the date of filing.

A copyright is the term used to describe the area of intellectual property law that regulates the creation and use that is made of a range of cultural goods such as books, songs and films, in addition to computer programs. The intangible property protected by copyright law is distinctive in that it arises automatically and usually for the benefit of the author. The minimum term of copyright protection under TRIPS is 50 years plus the life of the author.

Trade marks are a source of information and identifiers of origin. They are the by-product of market enterprise and marketplace competition. Trade marks identify goods and services in the same way that names identify individuals and companies, and have the advantage of being able to do so in attractive and internationally recognizable ways. The term of trade mark protection under TRIPS is 10 years renewable for similar periods indefinitely.

With time, the scope of intellectual property grew to encompass areas that included copyrights and related rights, trade marks, geographical indications, patents, industrial designs, undisclosed information, breeder's rights, plant varieties and layout designs. Each one of these rights is subject to a special legal protection regime, which was the fruit of many years of evolution and development (Box 11).

The main theme behind intellectual property law is the creation of a property right in intangible things or, as some suggest, the creation of a "market in ideas".² By doing so, intellectual property law restricts certain activities and grants them statutory legal protection for a certain purpose and for a specific period of time.

Box 11. The main categories of intellectual property (cont.)

are indications which identify a good as originating in the territory of a member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin (TRIPS, Article 22.1). TRIPS grants member states the freedom to determine the legal means of protection. Special rules for the protection of wines and spirits apply under TRIPS, Article 23. protect the appearance of objects. The practice of design covers a variety of domains. These range from industrial design, urban planning, graphic design and stage design to costume design, fashion design, product design and packaging design. The owner of a protected industrial design shall have the right to prevent third parties not having the owner's consent from making, selling or importing articles bearing or embodying a design which is a copy, or substantially a copy, of the protected design, when such acts are undertaken for commercial purposes (TRIPS, Article 26.1). The minimum term of industrial design protection under TRIPS is 10 years.

awards protection for confidential information which has an economic and commercial value such as know-how, trade secrets and business plans as long as such information is not disclosed into the public domain. TRIPS also protects secret data submitted for the approval of new chemical entities for pharmaceutical and agrochemical products.

The law of intellectual property is unique. This is because some forms of intellectual property protection preserve and protect “monopolies”, as opposed to other legal instruments whose main purpose is often to fight and eliminate anticompetitive and antimonopolistic practices (Box 12).

Monopolies versus properties

The debate about the ownership of ideas and knowledge has existed for centuries. For example, the ancient Greeks did not think of knowledge as something that could be possessed, traded or

Box 12.

We therefore consider that an IP right is best viewed as one of the means by which nations and societies can help to promote the fulfilment of human economic and social rights. In particular, there are no circumstances in which the most fundamental human rights should be subordinated to the requirements of IP protection. IP rights are granted by states for limited times (at least in the case of patents and copyrights) whereas human rights are inalienable and universal.

Source: *Integrating intellectual property rights and development policy*. London, Intellectual Property Rights Commission, 2001.

sold. Moreover, under Confucianism, it is believed that knowledge and ideas are transmitted rather than created by individuals. In Islam it is held that all knowledge comes from one source, which is God (Allah) and consequently it belongs to no one.³

However, prior to the establishment of modern intellectual property legislation during the 15th century, monopolies were granted by rulers through public or open letters addressed to the public in general. More important, during that time, these rights were fluid insofar as there was no clear division between each branch of them. They therefore lacked any institutionalized or organized legislative manner; in addition, the monopoly term awarded to each type also differed from one grant to another and from one place to another.⁴

Intellectual property monopolies were granted for various reasons. Patents for example were originally granted by rulers with the objective of securing new technologies for the enrichment of the territories they controlled. Queen Elizabeth I of England issued patents to support courtiers in financial difficulty by enabling them to profit from monopolies and to reward favourites.⁵ Moreover, monopolies were also used to attract skilled labour⁶ and much needed know-how from abroad.⁷ With the growth in trade between different cities, trade mark monopolies were awarded to identify proprietary marks, which represented a way of indicating the ownership of the goods in cases of shipwreck or theft as well as assisting the illiterate who came into contact with goods bearing these marks.⁸

During these times, monopolies were treated as an exception to the general norms. It was strongly believed that knowledge was not

and should not be owned by any individual. This “public good” nature of ideas and knowledge presupposes that knowledge and information must be available to and accessed by all members of the public freely or with little cost.⁹

Accordingly, the connotations of the monopoly and privilege terminology and language which were associated with the emergence of intellectual property were an important factor which had a negative impact upon its development for a long period of time.¹⁰ Recognizing the negative impact and the image problem created by such terminology, intellectual property advocates spared no effort in refining and transforming such terminology to suit the mood of the societies in which they resided and operated. Their emphasis was directed towards redefining, softening and treating these objects as property rights rather than privileges and monopolies, hence changing the surrounding negative public perception through affiliating such rights with creativity, innovation and public good (Box 13).

A turning point in the history of intellectual property regulation was the presentation of these monopolies as natural rights to the public to which people should be entitled without any reservations and restrictions. By redefining and proposing intellectual property as natural rights, right holders also managed to sideline those who criticized these monopolies by treating such criticism as “unnatural”.¹¹ Moving in this direction also meant that the focus should be on these rights as *private* rights rather than collective rights, which by definition means that intellectual property rights are exclusionary rights which prevent others from using

Box 13.

To consider these to be privileges underscores their temporary and unstable nature. The sovereign may grant privileges but is in no way obliged to do so. Shifting to the term “rights” suggests that it is the sovereign’s duty to uphold them. The difference is not merely semantic. The way that issues are framed can make a great deal of difference in terms of what is and is not considered legitimate.

Source: Sell S. *Private power, public law: the globalization of intellectual property rights*. Cambridge, Cambridge University Press, 2003.

Box 14.

The contention that stronger intellectual property rights always boost economic performance is not in general correct. It is an example of how special interests—those who do benefit from stronger intellectual property rights—use simplistic ideology to advance their causes.

Source: Stiglitz J. *Making globalization work*. London, Allen Lane, 2006.

and enjoying such properties without the permission of the intellectual property owner (Box 14). This change and evolution in terminology survived through the years and became the norm even in today's global intellectual property protection regime.¹²

The origins of intellectual property: national legislation

The roots of intellectual property's legal protection at the national level may be traced back to the 15th and 16th centuries when several European countries introduced a number of statutory laws dedicated to the protection of certain types of intellectual property. In this regard the first recognized statutory patent law was one inaugurated in Venice in 1474 which granted inventions a 10-year protection period while the first modern copyright act was the 1709 English Statute of Anne.¹³ Other European countries followed suit, and by the end of the 18th century a number of countries had patent and copyright laws and legislation in place.¹⁴ The United States inaugurated its first modern patent act in 1836, which was called "An Act to promote the progress of useful arts, and to repeal all acts and parts of acts heretofore made for that purpose".

However, the unprecedented spread of globalization and growth in technology and communication methods provided greater urgency to protect and regulate intellectual property in all of its forms at both national and global levels.

The global expansion of intellectual property protection

The prevailing view during the 15th and 16th centuries was that intellectual property protection was a territorial issue that should be confined to a state's natural boundaries. Thus, protection was a strictly national matter where states inaugurated laws of their own design which complied with the prevalent local customs and culture. The standards of protection also corresponded with each country's level of progress and development. More important, most of these national laws granted legal protection for certain types of intellectual property to their own nationals without extending it to foreigners.

The development of new methods of communication and transportation and the expansion of international commerce added more urgency to the need to expand beyond the borders of one state. More important, technological advancements also provided new opportunities for mass production of products and reduction in their costs. At the same time these improvements also made the duplication and mass reproduction of intellectual property easier and more feasible. As Braithwaite and Drahos state, "intellectual property owners faced a classic free-riding problem, or, put it another way, some countries were the beneficiaries of positive externalities".¹⁵

In the early 19th century European, particularly British, authors and publishers often complained of "widespread" piracy of their books abroad. Reprinting books was perfectly legal in many other countries; in fact, the reprinting of British copyright works was legal and even encouraged in the United States. For example in 1820, by some estimates, 70% of American books manufactured were the work of British authors.¹⁶

As a result of these developments, calls to provide protection to intellectual property beyond state boundaries started to emerge and eventually prompted several European states during the first half of the 19th century to negotiate a number of bilateral agreements dealing with intellectual property protection (Box 15).¹⁷ These agreements marked the beginning of the international age for the regulation of intellectual property.¹⁸

The standards of protection also corresponded with each country's level of progress and development

Box 15.

Thus, in marked contrast to the contemporary arguments, those in favour of free global trade regarded intellectual property rights as a privilege that could not be supported between jurisdictions as it constrained the free trade in goods that included claims of intellectual property. Indeed, this political dispute was perhaps the last time a concerted effort would be undertaken by those who supported free trade to suggest intellectual property rights were in fact less than legitimate rights.

Source: Sell S, May C. Moments in law: contestation and settlement in the history of intellectual property. *Review of international political economy*, 2001, 8(3):467–500.

In 1883 the Paris Convention for the Protection of Industrial Property (Paris Convention) was signed.¹⁹ The conclusion of the Paris Convention was followed by the signature of the Berne Convention for the Protection of Literary and Artistic Works in 1886 (Berne Convention).²⁰ These two agreements, often labelled as the “Great Conventions”,²¹ remained in force for a long period of time. In 1994, the key provisions of both agreements were adopted by TRIPS.

Following the conclusion of the Paris and Berne Conventions, there were further attempts to regulate and strengthen the levels of the various types of intellectual property. Accordingly, in 1891 the Madrid Agreement for Trademarks Registration was concluded, creating for the first time an international authority for the registration of trade marks.²² Moreover, an international agreement for depositing industrial designs and models was also concluded in 1925 in the Hague. Furthermore, the Universal Copyright Convention was concluded in Geneva in 1952.

The First World War and Second World War cast their shadow over international economic relations. During these wars, unfair practices in trade and attempts to deceive consumers about the origin of products flourished. As far as the Paris and Berne Conventions were concerned, the interruption in international economic relations did not diminish or alter these conventions’ important leading standing in the field of intellectual property protection.

Intellectual property, the GATT and beyond

The emergence of the GATT in 1947 represented the beginning of new era in international trade. However, due to the fact that the Paris and Berne Conventions were open-ended and unlimited in duration, coupled with the continuous periodical revision process of those conventions, states did not find it necessary to raise the protection of intellectual property beyond the indirect reference to those rights under the GATT. Accordingly, the protection of intellectual property under the GATT was aimed at making sure that the domestic intellectual property legislation adopted was consistent with the GATT's principles, including the principles of national treatment and non-discrimination.²³

After the establishment of the GATT, the United States took the leading role in the management of the international monetary and economic system. Strengthened by its growing economy and technological advances, the United States managed to maintain this leading position while at the same time aiming to help other industrialized countries to improve their trade competitiveness. This role started to decline in the early 1960s when the United States could not maintain such a unilateral leading global role after suffering from balance of payment deficits and economic slowdown. These developments prompted the need to create a sound multilateral trading system with the purpose of stabilizing the world's economy.²⁴

The importance of intellectual property to the economies of the developed countries grew during the 1960s. The United States and the European Union realized the comparative advantage they had in the field and complained that the prevailing global levels of intellectual property protection did not meet their aspirations and economic goals. The belief that developing and least developed countries were *free-riding* on the technological advances of the developed world became gained strength within the developed countries.

Several developing countries, particularly those that had recently gained independence, expressed their opposition to any strengthening of international intellectual property protection. These countries insisted that they should be granted favourable and preferential treatment under any new arrangement. Subsequently, this stance played a pivotal role in the establishment of new organizations sympathetic to their needs including UNCTAD,

The protection of intellectual property under the GATT was aimed at making sure that the domestic intellectual property legislation adopted was consistent with the GATT's principles

Several developing countries expressed their opposition to any strengthening of international intellectual property protection

which was established in 1964 as a “direct result of pressures in the UN system by the developing countries” in order to “further their campaign for global economic justice”.²⁵ UNCTAD played a pivotal role in the debate on issues related to the transfer of technology and awareness campaigns related to other intellectual property issues including patents and trade marks.²⁶

In 1967, WIPO was established in order to “encourage creative activity and promote the protection of intellectual property throughout the world”.²⁷ Later on, WIPO became the administrator of the major international conventions in this field, including the Paris and Berne Conventions.²⁸ Today, WIPO plays a leading role in advising developing countries and assisting them in upgrading and drafting their intellectual property laws and legislation.

Developed countries were frustrated as developing countries continued their resistance to any further attempts to strengthen the protection of intellectual property worldwide. This prompted the developed countries to search for an alternative strategy to secure such increased levels of protection. Championing the need to shift the discussion on intellectual property to a new paradigm were the influential special interest groups which managed to influence and shape their governments’ (particularly the United States’) strategy by arguing that their country’s growing trade deficit and economic struggles were due to the inadequate level of international intellectual property protection and the free-riding of other nations on their technological achievements.²⁹

Intellectual property and trade

The differences between the developed and developing countries towards intellectual property regulation and the inability of the concerned organizations such as WIPO, UNCTAD and the United Nations Educational, Scientific and Cultural Organization (UNESCO) to achieve any consensus between developing and developed countries on the issue between the 1960s and mid 1980s led to the slowing down of multilateral intellectual property regulation. During the late 1970s and 1980s, the developed countries, especially the United States, Japan and the European , Economic Community pursued a more aggressive policy in order to achieve higher levels of intellectual property protection.

This aggressive strategy was encouraged by many domestic interest groups, including Western multinational companies

Box 16.

Pharmaceutical companies spent \$759 million to influence 1,400 congressional bills between 1998 and 2004; the pharmaceutical industry ranks top in terms of lobbying money and the number of lobbyists employed (3,000). Their success reflects their investment ... the US government has made their interest paramount in international trade negotiations, and under the new Medicare drug benefit the government is proscribed from bargaining for lower prices—a provision worth billions of dollars just by itself.

Source: Stiglitz J. *Making globalization work*. London, Allen Lane, 2006.

(particularly the pharmaceutical and entertainment industries), which had complained for many years of inadequate protection of intellectual property in developing countries. Prior to the 1970s, multinational companies sought to solve such issues locally by either negotiating separately with host country governments or by seeking the assistance of their own embassies abroad. However, during the 1970s and 1980s, a new set of definitions and ideas related to the protection of intellectual property started to emerge. This rethinking of policies emphasized the linkage between trade and intellectual property and claimed that any distortion and inconsistency in its protection would affect the free flow of trade in goods and services globally and would result in a harmful outcome for both developed and developing countries (Box 16).³⁰

Other developments and factors led to this rethinking of policies. The process of eliminating trade barriers and improving market access, which started with the establishment of the GATT, encouraged the flow of higher levels of FDI into the developing countries.³¹ Therefore, the need for higher and more extensive levels of intellectual property protection was also vital for the smooth operation of those multinational corporations in their new host countries (Box 17).

The emergence of organized corporate groupings and special interest alliances in the 1970s and 1980s became noticeable.³² These groups decided to pursue their own agenda, which focused on fighting and curtailing global piracy levels by exerting more pressure on their respective governments to take action against those countries which failed to provide the desired levels of intellectual property protection.³³

Box 17.

Such perspectives were promoted by industrial lobbies (pharmaceuticals, software, phonogram industries), which convinced the US government about the need to link trade and intellectual property rights in order to increase the return of research and development (R&D) and to prevent imitation.

Source: Correa C. *Intellectual property rights, the WTO and developing countries*. London, Zed Books, Third World Network, 2000.

In addition, high externalities in the production of knowledge associated with the rise of new technologies prompted the need to reform the existing intellectual property regimes in an attempt to create or reinforce these new exclusive rights. Furthermore, during the late 1970s and throughout the 1980s, many of the Organization for Economic Co-operation and Development (OECD) countries reshaped their production policies by shifting from local production industries to externally oriented export sectors, as the global reach of multinationals expanded through various technological, communicational and marketing techniques. This also emphasized the need to protect their assets abroad while at the same time maintaining their local and international competitiveness. Therefore, the impetus to introduce higher levels of intellectual property protection was accelerated as a result of these activities.³⁴

Consequently, the industrialized countries, particularly the United States and the European Union, “deemed it necessary to revise and upgrade the current levels of intellectual property in order to maintain their technological comparative advantage and to appease their expanding influential local industries”.³⁵

The United States and the regulation of intellectual property

During the 1970s and 1980s, the United States started the process of reforming its domestic trade laws by establishing more forceful unilateral enforcement tools to be applied against countries failing to protect its intellectual property. The United States believed that

this would be imperative if it was to “maintain its technological superiority into the next century”.³⁶

In 1984, the United States extended the scope of its Trade and Tariffs Act of 1974 under the so-called Section 301 to enable its government to retaliate against countries that did not provide adequate protection levels for intellectual property. The United States went further and used Section 301 to impose higher levels of protection than those available under existing international treaties. Section 301 became the cornerstone of the United States’ strategy for the protection and enforcement of intellectual property globally, even after the conclusion of TRIPS.³⁷

In addition, in 1984 the United States extended its Generalized System of Preferences (GSP), a programme that provided duty-free tariff treatment on specified goods from around 140 developing countries, to cover goods related to intellectual property. Thus, any country applying for tariff exemption must initially have an adequate intellectual property protection regime or otherwise it would not be granted any preferences under the scheme.³⁸

More was still to come during the 1980s. In 1988, the United States inaugurated its 1988 Omnibus Trade and Competitiveness Act. The main aims of the act were to enhance the competitiveness of American industry by authorizing the negotiation of reciprocal bilateral and regional trade agreements, strengthening United States trade laws and improving the development and management of the United States’ external trade policy. The act brought many changes to the United States trade law, inter alia, significant changes to Section 301 and the adoption of Section 301 variants called “Super 301”.³⁹ Moreover, in 1989 and 1990, the United States Trade Representative⁴⁰ was assigned with the task of identifying priority practices (trade distorting practices whose elimination might substantially increase United States exports) and priority countries (countries with the highest trade barriers and best markets for the United States exports) and to initiate Section 301 investigations against these practices.

The United States’ strategy during the 1980s led several countries to bow to pressure by revising their intellectual property laws to comply with the required higher levels which the United States sought.⁴¹ Taiwan and Singapore, for example, were forced to change and amend their trade mark and copyright laws as a result of United States pressure. Brazil and India were also subjected to Special 301

Section 301 became the cornerstone of the United States’ strategy for the protection and enforcement of intellectual property globally

procedures and to pressures during the 1980s to upgrade their patent protection laws. However, this forceful approach failed to achieve the United States' aim of creating a universal protection regime for the protection of intellectual property. This motivated the United States to renew its calls for a new multilateral trade negotiation round which would primarily deal with the new issues. This subsequently resulted in the launching of the Uruguay Round in 1986.

The United States' strategy during the 1980s led several countries to bow to pressure by revising their intellectual property laws. In 2004, the European Patent Convention (EPC) countries, together with the United States and Japan, held around 83 % of existing patents in the world

The European Union and the regulation of intellectual property

The European Union has for long been a key player in the global regulation of intellectual property.⁴² Indeed in 2004, the European Patent Convention (EPC) countries, together with the United States and Japan, held around 83 % of existing patents in the world.⁴³

The European Union's focus and interest in protecting intellectual property in third countries preceded the Uruguay Round. Motivated by its industry interests, the European Union (then the EEC) followed the United States' footsteps in the early 1980s, its agenda comprising a number of unilateral, bilateral and multilateral policies.⁴⁴ Thus, in 1984, the EEC inaugurated its first equivalent tool to the United States Trade Act Section 301 as a countermeasure against other countries' "illicit trade and commercial practices".⁴⁵ This regulation, often referred to as the New Commercial Policy Instrument, provides a mechanism by which European private parties may challenge and complain about trade practices of other countries and obtain retaliatory action through the European Commission and Council of Ministers if countries fail to provide intellectual property protection which meets the aspirations of the European Union.⁴⁶

Following the inauguration of the new regulation, the European Union initiated several investigations under it which mainly targeted developing countries.⁴⁷ In addition to this, the European Union linked its tariff and preferences programme in which developing countries are awarded preferential access to European Union markets in exchange for adequate levels of intellectual property protection and enforcement.

The European Union continued the reform of its external policies regarding the enforcement of intellectual property during the 1990s. In 1994, the European Union replaced its New

Commercial Policy Instrument by issuing its Trade Barriers Regulation (TBR)⁴⁸ thus providing the Union with additional powers aimed at eliminating obstacles facing and hindering its international trade expansion. The TBR's reach extends to cover trade in goods—including the protection of intellectual property—and trade in services.

The European Union's interest in preserving its global innovative advantage continues today by aiming towards becoming the most dynamic and competitive knowledge-based economy in the world by 2010.⁴⁹ In order to sustain its current position and to achieve its aspirations, the European Commission proposed a new strategy for the enforcement of intellectual property in third countries in 2004.⁵⁰ Inter alia, the Commission proposes to make more active use of the European Commission's TBR mechanism in cases where the interest of European intellectual property right holders is compromised. This therefore allows retaliatory measures to be initiated by the European Union against countries that fail to provide adequate intellectual property protection and enforcement.⁵¹ The strategy also calls upon member states to make available customs measures including detention of goods in transit and for export in the case of suspicion of an infringement of intellectual property.⁵²

Once compared, one can detect the resemblance between the European Union's strategies and those of the United States in the field of international intellectual property protection. Although the United States preceded the European Union in extending the reach of its domestic trade laws to third countries, the European Union developed similar tools; this enables it to also extend its enforcement reach to third countries.

Intellectual property and the GATT negotiation rounds

During the earlier GATT multilateral trade negotiation rounds, the debate on intellectual property protection was absent from the agenda, which mainly focused on tariff reduction and economic liberalization.⁵³ However, during the sixth round of multilateral negotiations, the so-called Kennedy Round, which lasted between 1964 and 1967, the process of broadening the scope of the multilateral regime beyond the ambit of tariff reduction started as the contracting parties concluded an anti-dumping agreement for the first time.

In order to sustain its current position and to achieve its aspirations, the European Commission proposed a new strategy for the enforcement of intellectual property in third countries in 2004

Some trace the beginning of the real debate on intellectual property to the Tokyo Round of negotiations (1973–79)

Some trace the beginning of the real debate on intellectual property to the Tokyo Round of negotiations (1973–79).⁵⁴ This round was more comprehensive than the previous rounds and it came out with seven codes dealing with technical barriers to trade, customs valuations, import licences, subsidies and countervailing measures, antidumping, governmental procurement and trade in civil aircraft.

During the Tokyo Round, the United States, backed by its domestic interest groups, took the initiative and made proposals to raise the international levels of intellectual property protection.⁵⁵ Thus, the United States proposed a draft code named the Agreement on Measures to Discourage the Importation of Counterfeit Goods, also known as the Anti-Counterfeiting Code. However, the proposal found no backing and ultimately failed to find its way to the final stages of the Tokyo Round.⁵⁶

This did not deter the United States from pursuing its goals. Pushing for the inclusion of intellectual property protection within the global trading regime remained a priority for the United States and other European countries and their domestic industries. Thus, in 1982 during the preparations for the Uruguay Round, the GATT Ministerial Declaration included a section called Trade in Counterfeit Goods. The statement came about as result of the European and United States' coordinated efforts in advocating the strengthening of intellectual property protection globally.⁵⁷ Although no agreement was initially reached to include intellectual property protection within the GATT framework, it was believed that this declaration came to represent a major step towards the inclusion of intellectual property protection in the following multilateral rounds.⁵⁸

The failure to introduce intellectual property into the Tokyo Round and of subsequent attempts to bring protection under the GATT umbrella led the developed countries, especially the United States and European Union, to pursue their efforts for a stronger regime of intellectual property protection through a vigorous unilateral and bilateral agenda. At the same time, the United States and European Union also intensified their multilateral efforts. Thus, at the beginning of the Uruguay Round in 1986, the developed countries pushed once again to include the “new issues” under the GATT multilateral framework. Supported by influential domestic special interest groups in Europe, Canada and Japan, the United States intended to include intellectual property into the draft

Box 18.

Indeed, developing countries came to realize that their choice was not between WIPO and GATT (the old status quo), but rather between GATT and Super 301.

Source: Sell S. *Private power, public law: the globalization of intellectual property rights*. Cambridge, Cambridge University Press, 2003.

proposal for the Uruguay Round on the basis of dealing primarily with the issue of counterfeiting and piracy.⁵⁹

After a contentious debate, participants reached an initial agreement to include intellectual property in the Uruguay Round resulting in the so-called “Grand Bargain” approach. Under this bargain, developed countries made promises to award the developing countries more concessions in other important and vital sectors including agriculture and textiles in exchange for intellectual property protection.⁶⁰ The inclusion of intellectual property also came about as a result of the unilateral pressure exerted by the developed countries, especially the United States and European Union, to bring a number of developing countries to the negotiation table through the use of their unilateral and bilateral policies (Box 18).⁶¹

Although the negotiators agreed to include intellectual property in the discussion, this did not mean that there was any consensus on the topic. It simply meant that due to various reasons and promises, countries were willing to discuss and elaborate on the topic in order to achieve an acceptable compromise. Therefore, the “trade-off” element had to be acknowledged.⁶² The Ministerial Declaration of Punta del Este represented a masterpiece of diplomatic compromise by adopting this flexible approach (Box 19).

The Punta del Este Declaration adopts a flexible approach on how multilateral negotiations on intellectual property should be conducted. Therefore, the declaration in no means reflects the evolution and development of a unified approach towards the protection of intellectual property. Rather, the declaration reflects the importance of dealing with the main priorities at that time, which stems from extending the scope of patent and trade mark protection and fighting piracy and counterfeiting.

Box 19. Punta del Este Declaration

In order to reduce the distortions and the impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines. Negotiations shall aim to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeiting goods, taking into account work already done in the GATT. These negotiations shall be without prejudice to other complementary initiatives that may be taken in the WIPO and elsewhere to deal with these matters.⁶³

However, developing countries criticized this very same fluid and flexible approach to the declaration during the early stages of negotiations. Ironically, some of these countries claimed that any multilateral negotiation round should deal with all branches of intellectual property collectively, believing that they would be able to block or defer any deal on the issue of intellectual property protection to future negotiation rounds. Some special interest groups in developed countries also shared this view for other reasons; such groups in the United States thought that the adoption of an agreement related to trade mark protection and counterfeiting might delay and set aside the conclusion of a more comprehensive agreement covering all forms of intellectual property.⁶⁴

Until the early 1990s, progress on intellectual property under the Uruguay Round was very slow. During that time, the United States continued the reinforcement and use of its unilateral and bilateral tools to achieve higher levels of protection and pressured more developing countries to submit to the GATT multilateral negotiations. It also managed to break the resistance of some of the major opposing developing countries such as India, Brazil and Egypt by listing them on the priority watch list of its Special Section 301 and subjecting many others to trade and economic sanctions.⁶⁵

Contentious negotiations on intellectual property—often referred to as informal “green room” consultations—intensified in early 1990,⁶⁶ when proposals in the form of legal texts were tabled by the EEC, United States, Japan, Switzerland and a group of 14

developing countries. Australia also tabled a partial text dealing with geographical indications. The Swedish chairman, Lars Anell, drafted what came to be referred to as the “chairman’s draft” or the “compromise draft text”. It identified the main proposals and acknowledged the differing issues. The draft became a formal document after several informal meetings and discussions and was presented as the “*Chairman’s report to the Group of Negotiations on Goods*”, which was due to be presented to a ministerial conference in Brussels in December 1990. The conference failed to bear fruit due to the various growing differences, which also threatened the collapse of the negotiations round as a whole. A year later a further meeting was held, producing a draft version of TRIPS which was endorsed and included in the round as “Draft Final Act embodying the results of the Uruguay Round of Multilateral Trade Negotiations”. This was the same text that was signed in Marrakesh in 1994.

The final draft of this text included several proposals. It proposed granting developing countries transition periods to enable them to offset the expected repercussions of tougher intellectual property protection. The United States also declared that it would stop its unilateral and bilateral policies in enforcing intellectual property in developing countries if an international agreement was reached.⁶⁷ The draft also included further promises of potential concessions in exchange for raising the minimum levels of protection on all forms of intellectual property, technical and financial assistance, and the introduction of a new mechanism for dispute settlement under the WTO.

Contentious negotiations on intellectual property—often referred to as informal “green room” consultations—intensified in early 1990

The TRIPS Agreement

TRIPS is the most comprehensive global agreement ever concluded in the field of intellectual property. It contains provisions which provide minimum standards for each protected branch of intellectual property, including the protection of copyrights, patents, trade marks, geographical indications, layout designs and trade secrets as well as unfair competition. Under TRIPS, each of these branches is defined: the subject matter to be protected, the rights to be conferred and permissible exceptions to those rights, in addition to the minimum duration of protection periods. For creating this unified consensus regarding the approach in dealing

with intellectual property protection, some referred to TRIPS as “one of the success stories of the Uruguay Round”.⁶⁸

The strength of TRIPS lies in its enhanced enforcement provisions and its incorporation of the WTO dispute settlement procedure. All pre-TRIPS intellectual property agreements lacked detailed rules on transparency and the enforcement of intellectual property before national, international judicial and administrative authorities. They also lacked any efficient dispute settlement procedure.⁶⁹

TRIPS is the most comprehensive global agreement ever concluded in the field of intellectual property

Moreover, TRIPS built upon some of the existing international agreements in the intellectual property field, including the Paris and Berne Conventions. Thus, TRIPS standards concerning the availability, scope and use of intellectual property refer to and reproduce Articles 1–12 and 19 of the Paris Convention, Articles 1–21 of the Berne Convention and Articles 2–7 and 16 of the Washington Convention. TRIPS also refers to the above-mentioned conventions with regard to the enforcement of intellectual property as well as the acquisition and maintenance of these rights. TRIPS also complements the issues that were neglected by these agreements thus often being referred to as Paris and Berne-plus.⁷⁰ TRIPS consists of seven parts and 73 articles.

There has been much debate about whether TRIPS belongs to the mandate of WTO.⁷¹ Some believe that intellectual property and TRIPS are not connected to trade and should fall outside the jurisdiction of the World Trade Organization (Box 20). Others contend that intellectual property is in fact closely affiliated with trade and should be embedded in economic relations. Therefore, they argue, TRIPS is rightly placed within the WTO.⁷² Regardless of what is said about TRIPS, it is clear that TRIPS is likely to remain within the remit of the WTO for some time to come. Accordingly, developing and least developed countries are advised to deal pragmatically with TRIPS on this basis, and to try to implement the agreement “creatively” in order to maximize their gains and minimize their losses.

Box 20.

Then there was the question of intellectual-property protection, and the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement—another potential obstacle. Intellectual property does not belong in the WTO, since protecting it is simply a matter of royalty collection. But the matter was forced onto the WTO's agenda during the Uruguay Round by the pharmaceutical and software industries, even though this risked turning the WTO into a glorified collection agency. The move gave multilateral legitimacy to the use of trade sanctions to replace unilateral means of collecting royalties from developing countries, embodied in the tariff-retaliation provisions of the Special 301 legislation in the 1988 Omnibus Trade and Competitiveness Act. Tough restrictions were enacted under the TRIPS agreement on the manufacture of generic drugs and their sales to poor countries.

Source: Bhagwati J. *In defense of globalization*. New York, Oxford University Press, 2004.

TRIPS and the protection of pharmaceutical patents

TRIPS had a major impact on the regulation of public health and pharmaceutical patent protection. Prior to TRIPS, most countries, including those in the Eastern Mediterranean Region, retained considerable freedom in the area of public health and patent regulation. This was no longer available after the creation of TRIPS. Abbott and Reichman explain this development by stating that it “otherwise left states free to devise and implement their own patent systems and, as many chose to do, even to deny any patent protection for pharmaceutical products at all”.⁷³ Clearly, the introduction of TRIPS had a restrictive impact on countries' ability to freely regulate matters related to patent protection and public health.⁷⁴

The argument for pharmaceutical patent protection is as follows. For the pharmaceutical industry, patent protection is essential as an incentive for investing in the development of new medicines, clinical trials and in R&D-related activities which takes considerable effort, resources, and time. It is therefore true that pharmaceutical companies have one of the highest ratios of R&D

The important issue is striking the right balance between the social effects of patent protection and the interest of pharmaceutical producers

to sales and most drug products can easily be copied.⁷⁵ Justifiably, in order for the pharmaceutical companies to recoup their effort and investment, and to keep their incentive, pharmaceutical patent protection is needed.

However, the important issue in this regard is striking the right balance between the social effects of patent protection and the interest of pharmaceutical producers. In the light of recent changes, some have argued that the 20-year patent protection period provided under TRIPS is sufficient to reward and compensate pharmaceutical producers for their investment and therefore criticized any extension of the term of patent protection, which may have adverse impact on both society and innovation.⁷⁶ This issue will be subject to further discussion in chapter 4 of this guide.

Objectives and general provisions of TRIPS

TRIPS incorporates a comprehensive framework for the protection of intellectual property. The main objectives of TRIPS as stipulated in its preamble include inter alia “the need to promote effective and adequate protection of intellectual property rights” and “recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives”. TRIPS also emphasizes the nature of intellectual property as “private rights” while also acknowledging the special needs of developing and least developed countries.

Moreover, TRIPS defines the rights protected (copyrights, patents, trade marks, geographical indications, trade secrets, industrial design, protection against unfair competition), the subject matter of each of these rights, the duration of protection and the maintenance and preservation of these rights through the notion of minimum standards of protection. TRIPS also provides civil and criminal penalties in addition to enhanced border and custom measures. Most important, TRIPS makes the protection of intellectual property subject to the WTO dispute settlement procedure.

TRIPS also adopts the well established principles of national treatment and MFN under Articles 3 and 4.⁷⁷ In relation to the principle of national treatment, TRIPS contains additional substantive provisions in respect of the procedural, administrative and remedial measures necessary for the enforcement and implementation of intellectual property.⁷⁸ This for example,

Box 21.

The enforcement provisions of the TRIPS Agreement are the most promising sections in the Agreement.

Source: Heald P. Trademarks and geographical indications: exploring the contours of the TRIPS Agreement. *Vanderbilt journal of transnational law*, 1996, 26(2):635–60.

contrasts with the position under the Paris Convention in which national treatment simply required member states to offer the same level of protection to foreigners as they did to nationals. Furthermore, the judicial and administrative procedures were excluded from the scope of the national treatment principle.

Part III of TRIPS deals with enforcement. Unlike the Paris Convention, which adopts a rather flexible enforcement approach towards this issue,⁷⁹ TRIPS requires and obliges member states to take positive steps in providing adequate and efficient enforcement tools against the infringement of intellectual property that are provided and protected under this agreement. It also requires members to provide appropriate civil and administrative procedures and remedies to the right-holders to enable them to protect and defend their intellectual property (Box 21).⁸⁰

In addition to dealing with the infringement and protection of pharmaceutical patents, TRIPS also pays special attention to the activities of piracy and counterfeiting. Accordingly, additional criminal procedures and penalties are required against cases of “wilful trade mark counterfeiting and copyright piracy on a commercial scale”.⁸¹ These are incorporated and provided by virtue of the additional monetary and imprisonment remedies against the perpetrators of these activities.

Disputes arising under TRIPS are subject to the WTO’s dispute settlement procedure, which contains detailed and substantive provisions based on transparency and efficiency in resolving disputes related to the interpretation of TRIPS.⁸² It also reiterates the fact that member countries must not resort to unilateral or bilateral policies or sanctions to resolve disputes arising between members. Once again, this was stressed in the TRIPS preamble, which states:

Unlike previous international intellectual property agreements, TRIPS is a part of a “single package”

... emphasizing the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures.

Unlike previous international intellectual property agreements, TRIPS is a part of a “single package”—those countries seeking the membership of the WTO have to adhere to all or nothing. Today, countries seeking WTO membership have to accept and implement all obligations as required by the WTO agreements, including TRIPS, the GATS and the GATT.⁸³ This requires that countries joining the WTO—although least developed countries may apply transitional periods—must ensure that their domestic legislation conforms to TRIPS requirements before signing up to the organization.

However, in order to offset and cope with the envisioned short-term costs and challenges and to enable member states to prepare their accession to the WTO, several flexibility tools and transition periods were agreed upon and provided under TRIPS in 1995. The following section will briefly discuss some of these flexibilities.

The flexibilities of TRIPS

In general terms, there are four broad categories of flexibility available under TRIPS that countries may use. These are as follows.

First: flexibilities related to implementation

Article 1.1 of TRIPS stipulates that:

[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

This provision leaves the door open for member states to abide by TRIPS through the “creative implementation” of the agreement. TRIPS requires certain standards, but provides no definition for their implementation. Examples of those flexibilities include concepts related to patentability such as novelty, new inventions and inventiveness.

Transitional periods also fall under this type of flexibility. Developing and least developed countries were given the right not to implement TRIPS with immediate effect but instead to make use of the transitional periods provided under the agreement for their benefit.⁸⁴

Second: flexibilities related to substantive standards of protection

These are flexibilities which give a member state the autonomy to either provide and define its own standards or to provide higher standards and requirements of intellectual property protection. Examples of defining the standards of protection are the introduction of exceptions to rights conferred such as the research and experimental use and the “Bolar” exceptions; and the limitation to the use of trade marks in packages and advertisement of products considered prejudicial to health (like alcohol and tobacco).

Examples of raising the level of protection are: the introduction of temporary protection of industrial property rights before the grant of protection; the extension of the term of patents to compensate for delays in granting the marketing approval of products; and the extension of the scope of patentability and/or registerability of trade marks beyond the minimum standards established, respectively, by Articles 15 and 27 of TRIPS.⁸⁵

Third: flexibilities related to enforcement

Although TRIPS provides for certain enforcement requirements under Part III of the agreement, which countries must adhere to, the agreement grants member states the right and discretion to establish their own national legal and judicial systems to implement and enforce the intellectual property standards of protection as stipulated under the agreement.

Fourth: flexibilities of areas outside the scope of TRIPS

TRIPS does not deal with all areas of intellectual property. Accordingly, for those areas which fall outside TRIPS, member states have the right and discretion to create their own protection

In general terms, there are four broad categories of flexibility available under TRIPS that countries may use

regime in accordance with their priorities and national plans. For example, a developing country can adopt legislation related to the protection of traditional knowledge which can be extended to foreigners on the basis of reciprocity only if it deemed that such a regime is beneficial to its local industry and national priorities.

Regime shifting, TRIPS-plus and the regulation of intellectual property

The post-TRIPS era may be best described as a dynamic one. Contrary to the developing countries' belief that TRIPS would put an end to the regulation of intellectual property globally,⁸⁶ the post-TRIPS era has witnessed the intensification of efforts to strengthen the protection levels of intellectual property beyond those established under TRIPS, creating the TRIPS-plus phenomenon. The European Union and the United States continued their efforts to "regime shift" the discussion on intellectual property to new forums.

Regime shifting is not a new concept in international trade (Box 22). It refers to the exercise of shifting the discussion and decision-making from one venue to another. Such a technique may take several shapes, including moving a regulatory agenda from one organization to another, abandoning an organization or pursuing the same agenda in more than one organization at the same time.

The concept of regime shifting has clearly been used in the area of intellectual property by both developed and developing countries at different times. Historically, developed countries were the primary shifters of the debate on intellectual property from one

Box 22.

Regime shifting is an attempt to alter the status quo ante by moving treaty negotiations, law making initiatives, or standard setting activities from one international venue to another.

Source: Helfer L. Regime shifting: the TRIPS Agreement and new dynamics of international intellectual property lawmaking. *Yale journal of international law*, 2004, 29(1):1-83.

venue to another. It is within this context one should view the proliferation of bilateral free-trade and association agreements. Bilateralism in intellectual property represents the third wave of this process, which builds upon the first wave, which started with shifting the discussion on intellectual property from the ambit of the international organizations such as UNCTAD and UNESCO to WIPO, and the second wave, which started with the shifting of the discussion from the ambit of WIPO to the umbrella of the GATT and the WTO.

The developing countries' belief that the developed countries and in particular the United States and the European Union would refrain from pursuing unilateral and bilateral policies to enforce intellectual property protection did not materialize.⁸⁷ This was also coupled with the lack of enthusiasm of these countries to open their markets and cut down their subsidies. Additional regional and bilateral initiatives pursued by the United States and the European Union resulted in the creation of the so-called TRIPS-plus recipe.⁸⁸ Examples of regional arrangements can be found in the Free Trade Agreement of the Americas (FTAA) while examples of bilateral trade agreements include the US–Bahrain FTA, the US–Australia FTA and the US–Morocco FTA.

One important factor that led to the intensification of bilateral initiatives and forum shifting during the past decade relates to the success and effectiveness of developing countries themselves in several international forums including the TRIPS Council. The growing opposition by these countries and the lack of progress on issues related to the implementation of TRIPS has led a mood of frustration within the developed countries themselves hence triggering the intensification of their TRIPS-plus bilateral trade initiatives.⁸⁹ The following part will explain and define what is meant by TRIPS-plus in more detail.

The meaning of TRIPS-plus

TRIPS lays down minimum standards of intellectual property protection (Box 23). Thus, all WTO member countries have to adhere to these standards and may not derogate or provide lower levels of intellectual property protection. Although not obliged to do so, members have the right to apply and incorporate higher and more extensive levels of protection if they opt to do so willingly as long as they apply the general principles of MFN and national treatment.

The concept of regime shifting has clearly been used in the area of intellectual property by both developed and developing countries at different times

Box 23. TRIPS Agreement, Article 1.1

Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

In short, TRIPS-plus may be interpreted and achieved in several ways. Accordingly, if a country implements more extensive levels and standards of intellectual property protection than of those required under TRIPS, or undertakes the elimination of an option which was awarded to it under the agreement, it may be said that this country is implementing a TRIPS-plus regime. TRIPS-plus may also mean that countries interpret TRIPS in a narrower sense thus ensuring the compliance of these countries in accordance with this agreement with the highest and utmost levels of efficiency.⁹⁰

Most of the recent bilateral free-trade and association agreements signed between the United States and the European Union, on one side, with developing countries, including those in the Eastern Mediterranean Region, contain provisions of a TRIPS-plus nature. The following section will give a brief preview of some of the components of the TRIPS-plus provisions incorporated under these agreements.

The components of TRIPS-plus

There can be no fixed definition for the term TRIPS-plus. Recent bilateral agreements with countries in the Eastern Mediterranean Region suggest that TRIPS-plus is an evolving concept and has proven to be case- and country-specific. In the case of the Region, these bilateral initiatives often took an upward direction resulting in the strengthening of the levels of intellectual property protection.⁹¹

However, the TRIPS-plus effect is not only achieved as a result of bilateral trade arrangements between states. The case of the Arab world also indicates that the process of accession to the WTO itself

might result in the imposition of TRIPS-plus obligations on the countries seeking WTO membership. This is the case because the WTO does not expressly limit the “entry fee” imposed on newly acceding members to an equivalence of concessions with existing members.⁹² Jordan, Saudi Arabia and Oman are Arab countries that joined the WTO with TRIPS-plus obligations.⁹³

Following are some general examples of TRIPS-plus obligations under various bilateral agreements. However, it is important to note that this is not an exhaustive or a conclusive list of conditions, hence we are most likely to experience a variation in its features from one agreement to another and with the conclusion of more agreements in the future.

First, TRIPS gives member countries the freedom to exempt and exclude plant and animal patent protection from their national patent laws. Accordingly, Article 27.3(b) of TRIPS stipulates that:

[m]embers may also exclude from patentability:

...

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.

Several developing countries, including some in the Region, as a result of signing these bilateral agreements relinquished this right by awarding protection for plant and animal patents. A good demonstration of this trend is the US–Bahrain FTA, which explicitly commits Bahrain to provide protection for plant patents.⁹⁴ Thus, Article 14.8(2) of the US–Bahrain FTA stipulates:

Each Party shall make patents available for plant inventions. In addition, the Parties confirm that patents shall be available for any new uses or methods of using a known product, including products to be used for particular medical conditions, subject to the exclusions provided in Article 8.1 and the conditions of patentability.

Furthermore, although compulsory licensing and government use are allowed under TRIPS provided that the conditions set forth are met and the licensing is taken to protect the public interest

Jordan, Saudi Arabia and Oman are Arab countries that joined the WTO with TRIPS-plus obligations

A TRIPS-plus effect may relate to extending certain periods of protection beyond the requirements of TRIPS

in accordance with Article 31 of TRIPS,⁹⁵ recent bilateral trade agreements are depriving member states from resorting to and using this right freely by restricting its use to a limited number of situations.⁹⁶

Second, a TRIPS-plus effect may relate to extending certain periods of protection beyond the requirements of TRIPS in addition to forgoing certain benefits related to the enjoyment of transitional periods. An example of the earlier scenario is clearly manifested by the US–Chile FTA, which provides that protection for copyrights should be calculated on the basis of the life of the author plus 70 years,⁹⁷ a clear extension of that protection period as proposed under TRIPS, which provides that protection should be the life of the author plus 50 years.⁹⁸

Other bilateral agreements are obliging member countries to extend the protection of pharmaceutical and plant protection products (agrochemicals) beyond the protection period of 20 years provided under TRIPS⁹⁹ to 25 years.¹⁰⁰

In addition, under TRIPS, the period for the protection of industrial designs is a minimum period of 10 years.¹⁰¹ However, a number of bilateral trade arrangements have already extended this protection period to at least 15 years. Accordingly, the EU–Morocco AA stipulates that:

[t]he states parties to this agreement shall ensure in their national laws at least the following: adequate and effective protection of industrial designs by providing in particular a period of protection of five years from the date of application with a possibility of renewal for two consecutive periods of five years.¹⁰²

Examples of agreements forgoing privileges related to the transitional periods under TRIPS are also clearly manifested under several bilateral agreements, including the EU–Jordan AA, in which Jordan was required to implement shorter periods of transition regarding the protection of patents.¹⁰³

Third, a TRIPS-plus arrangement may oblige countries to join a specific international agreement or treaty related to a specific field of intellectual property that is not a part of TRIPS or the WTO structure. This is clearly demonstrated by the requirement under the US–Jordan FTA and the EU–Jordan AA requiring Jordan’s submission to a number of agreements and treaties such as the

WIPO internet treaties.¹⁰⁴ There is also the requirement of Jordan submitting to the International Convention for the Protection of New Varieties of Plants (UPOV Convention)¹⁰⁵ and the WIPO Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks of 1999.¹⁰⁶ Similar provisions can also be found in several other bilateral agreements including the US–Singapore FTA, the EFTA with Tunisia and the EU–Egypt AA.

Fourth, TRIPS' strength lies in its extensive provisions related to enforcement. Accordingly, any bilateral agreement that modifies and adds to such measures and procedures will result in a TRIPS-plus effect. A clear model of this is the US–Jordan FTA that obliges Jordan to raise its criminal penalties to JD 6000¹⁰⁷ for copyright and trade mark counterfeiting and piracy.¹⁰⁸ Other United States FTAs with countries in the Region also provide that, in the event of copyright piracy and trade mark counterfeiting, authorities may initiate criminal actions and border measures without the need for a formal complaint.

Fifth, the requirement of several bilateral trade and investment agreements for countries to adhere and implement “the highest international standards” of intellectual property protection also makes such agreements subject to the TRIPS-plus criteria.¹⁰⁹ Although these standards are not defined precisely under these bilateral arrangements, there is a fear that these standards are being included to pave the way for the subsequent conclusion of a multilateral investment treaty based on the already concluded bilateral investment treaties. Therefore, the effect of these provisions may not be felt initially but is most likely to be felt in relation to various issues related to investment and FDI in the future.¹¹⁰

Sixth, the creation of a dispute settlement procedure under some bilateral agreements other than that of the WTO is also considered as a TRIPS-plus clause. In a number of agreements, new dispute settlement procedures are being proposed to solve disputes arising from the implementation and interpretation of these agreements. Some of these procedures include the International Centre for the Settlement of Investment Disputes (ICSID), the International Chamber of Commerce and the United Nations Commission on International Trade Law (UNICTRAL).¹¹¹ Although some of these agreements give the complaining party the right of “choice of form”, there may still be implications for a developing country if the complaining party was a developed country that opted for

Bilateral agreements are obliging member countries to extend the protection of pharmaceutical and plant protection products (agrochemicals) beyond the protection period of 20 years

a dispute settlement procedure other than that provided under the WTO. This would prevent developing and least developed countries from adequately using the multilateral dispute settlement procedure available under the WTO. In most cases, developing countries have neither the resources nor the expertise to compete against the developed countries under these bilateral dispute settlement procedures, thus leaving these states with more restricted options regarding the implementation of these agreements.¹¹²

New dispute settlement procedures are being proposed to solve disputes arising from the implementation and interpretation of these agreements

Changes and developments in the post-TRIPS era

One of the notable developments of the post-TRIPS era lies in the fact that the debate on intellectual property is no longer confined to nation states. The rise of non-state actors including nongovernmental organizations and civil society groups into the international arena in recent years has made a huge contribution to the efforts of developing and least developed countries, particularly in the area of public health and access to medicines. Through targeting the public, the media, international institutions and organizations, pharmaceutical companies and those mostly affected by disease, nongovernmental organizations and civil society groups have managed to position the issue of public health and access to medicines at the forefront of global attention. In fact, the efforts of these organizations and groups contributed largely to the issuance of the Doha Declaration on the TRIPS Agreement and Public Health in 2001.

Moreover, the post-TRIPS era has witnessed the proliferation of several new venues and forums involved in the debate on intellectual property: there are now more forums and venues than ever. Thus, in addition to the WTO and WIPO, debates and discussions on intellectual property are now taking place concurrently in venues including UNESCO, UNDP, WHO, UN, the World Customs Organization (WCO)¹¹³ and the Food and Agriculture Organization of the United Nations (FAO). Moreover, the raging debate related to intellectual property and public health under such various avenues has resulted in a number of high profile events, actions, and processes. These included the adoption of the Doha Declaration, as well as the 30 August 2003 Decision and the subsequent amendment to the TRIPS Agreement on 6 December

2005, implementing paragraph 6 of the Doha Declaration; the report of the UK Commission on Intellectual Property Rights; the various WHA resolutions.¹¹⁴

Although discussions on intellectual property have been undertaken in various forums, this does not mean that such discussions are in fact disconnected and sporadic. If one takes a deep look at these discussions it becomes apparent that they were often prompted by a number of considerations including domestic, regional and international ones. Moreover, these discussions also represent another form of regime shifting between key international players, aiming to maintain their economic interest and power, and reactions on the other hand to these players by the developing and least developed countries.

The next part will provide a brief background to the important debates and discussions taking place under a number of non-governmental organizations, particularly the WTO, WIPO and WHO, in the field of intellectual property and public health and their effect on the global regulation of intellectual property and the implementation of TRIPS.

The efforts of these organizations and groups contributed largely to the issuance of the Doha Declaration on the TRIPS Agreement and Public Health in 2001

TRIPS, the WTO and the Doha Development Round

According to WHO, in the early years of the 21st century three million people died of HIV/AIDS annually, with 2.3 million in sub-Saharan Africa alone. Mortality from malaria was estimated at one million per year and tuberculosis at two million. Moreover, by the end of 2007, an estimated 33.2 million people worldwide were living with HIV, 2.5 million were newly infected with the virus and 2.1 million had died of HIV/AIDS.¹¹⁵

With the rise in the numbers of the poor in developing countries suffering from various health concerns and epidemics, the inclusion of the issue of intellectual property—as a result of its affiliation with access to medicines and drug manufacturing—under any new multilateral trading negotiation round was imperative. Accordingly, a group of countries led by the Africa Group, Brazil and India adopted the issue of access to essential medicines in November 2001. Participating trade ministers reiterated and

clarified this during deliberations prior to the official launching of the Doha Development Round in 2001.¹¹⁶

Intellectual property protection, public health and access to medicines received special attention under the Doha Development Round.¹¹⁷ Thus, in addition to featuring in several issues under the WTO's Doha Ministerial Decision of 2001 related to implementation, protection of geographical indications, and the relationship between TRIPS and other international organizations, the 2001 Doha Declaration on the TRIPS Agreement and Public Health was of particular importance to developing and least developed countries (Box 24).¹¹⁸

Described as a “net benefit” for countries seeking to improve access to medicines,¹¹⁹ the Doha Declaration on the TRIPS Agreement and Public Health reiterated each country's right to implement TRIPS in a manner that takes into consideration its levels of development and progress. The declaration also emphasized that TRIPS “does not and should not prevent member governments from taking measures to protect public health”. The declaration also affirmed the governments' right to resort to the use of TRIPS' flexibilities (with particular reference to compulsory licensing and parallel importation).

However, the fact that the majority of WTO member states are not major producers of pharmaceuticals and rely heavily on imports created some difficulty for these countries to fully benefit from the flexibilities available to them under TRIPS. Following a number of proposals made by the European Union, the United States, Brazil on behalf of developing countries, Kenya on behalf of the African Group, and the United Arab Emirates,¹²⁰ the 2001 Doha Ministerial Declaration instructed the TRIPS Council to find a practicable solution to the problems facing developing and least developed countries which had insufficient or no manufacturing pharmaceutical capacities. This solution subsequently came under the 30 August 2003 Decision on Implementation of Paragraph 6 of the TRIPS Agreement and Public Health, which granted developing countries the right under a waiver from TRIPS to import generics as long as they complied with the conditions set forth under TRIPS and the importation was undertaken only to supply the needs of the domestic market.¹²¹

Moreover, in December 2005, the WTO General Council acting in accordance with the Doha Declaration on the TRIPS Agreement

Intellectual property protection, public health and access to medicines received special attention under the Doha Development Round

Box 24. Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health

14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, TB, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members, right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
 - a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
 - b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
 - c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, TB, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

Box 24. Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (cont.)

- d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.
6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed country Members pursuant to Article 66.2. We also agree that the least developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

and Public Health adopted the Protocol on the Amendment of TRIPS (Box 25). However, in order for the amendment to take place permanently and replace the waiver under the 30 August 2003 decision, two-thirds of the WTO members must accept the Protocol by 1 December 2007 or such later date as may be decided by the Ministerial Conference.¹²² As a result of the lack of number of countries needed to ratify the amendment, in December 2007, the WTO Council extended this until 31 December 2009 or such later date as may be decided by the Ministerial Conference.¹²³

Although it is too early to judge the practical outcome of these decisions, some have already voiced their concern about the

Box 25. WTO protocol amending the TRIPS Agreement

Decision of 6 December 2005

The General Council;

Having regard to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization (“the WTO Agreement”);

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in Paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in the proposed amendment of the TRIPS Agreement, the importance of a rapid response to those needs consistent with the provisions of the proposed amendment of the TRIPS Agreement;

Recalling paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;

Having considered the proposal to amend the TRIPS Agreement submitted by the Council for TRIPS (IP/C/41);

Noting the consensus to submit this proposed amendment to the Members for acceptance;

Decides as follows:

1. The Protocol amending the TRIPS Agreement attached to this Decision is hereby adopted and submitted to the Members for acceptance.
2. The Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.
3. The Protocol shall take effect in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement.

efficiency of the proposed process. One of the reasons behind this is the complex and technical nature of the 2003 WTO Paragraph 6 Decision itself and its “unnecessary administrative hurdles”.¹²⁴ Others refer to the inability of many countries to implement domestic regimes which take into consideration the 2003 WTO Counsel Decision under their national law.¹²⁵ As Abbott and Reichman remark, what is clearly needed in this regard is a “combination of political will, good lawyering, financial support for appropriate implementation efforts and collective action”.¹²⁶

The above developments within and outside the WTO reflect the growing influence and active participation of developing and least developed countries in these multilateral institutions and organizations. However, it remains to be seen if these countries can in fact sustain and capitalize on the above recent success through the use and incorporation of these achievements under national laws and legislation.

WIPO and the development challenge

Established in 1967, WIPO became a specialized organization within the United Nations in 1974. Its main objectives are to “encourage creativity and promote the protection of intellectual property throughout the world” (Box 26). The reach of WIPO extends to more countries than TRIPS. Accordingly, as of July 2008, 184 countries were members of WIPO. Moreover, WIPO currently administers 23 treaties on different issues related to intellectual property.

The creation of the WTO in 1995 posed a “dilemma of survival” for WIPO, which had been the primary institution concerned with the global regulation of intellectual property for many decades. In fact, the insistence of the United States and its domestic industry on shifting the discussion away from WIPO during the GATT Uruguay Round to a new paradigm undermined the organization or, as May proclaims, “at least demonstrated the lack of commitment to the organization by those countries whose corporations controlled significant intellectual property-related resources”.¹²⁷

Moving to reestablish its authority in this field, WIPO had to work with the WTO for the administration and implementation of TRIPS.¹²⁸ Within the implementation process that has developed

Box 26. WIPO's foundations

Article 3 of the WIPO Convention sets out its objectives:

- to promote the protection of IP throughout the world through cooperation among states, and, where appropriate, in collaboration with any other international organization; and
- to ensure administrative cooperation among the unions (such as Berne and Paris) which are administered by WIPO.

Article 4 of the WIPO Convention lists the functions of WIPO, which, as well as a variety of administrative functions, include:

- promoting the development of measures designed to facilitate the efficient protection of IP throughout the world and harmonizing national legislations in this field;
- encouraging the conclusion of international agreements designed to promote the protection of IP; and
- assembling and disseminating information concerning the protection of IP, carrying out and promoting studies in this field, and publishing the results of such studies.

out of the WTO agreements, WIPO has found a specialization by providing technical assistance to developing countries and in advising them in upgrading their intellectual property laws and legislation.¹²⁹

However, WIPO's role was not solely confined to the above. Feeling marginalized over time and weakened by the idea of including intellectual property under the auspices of the GATT during the 1980s and early 1990s, WIPO started to broaden and strengthen the scope of intellectual property protection globally by conceiving that TRIPS would in fact establish the platform for such minimum levels of protection.¹³⁰

Thus in 1989 the United States, motivated by its local giant software industries, sought to broaden the scope of the Berne Convention by proposing the addition of the protection of digital technologies into the realm of the convention as administered by WIPO (Box 27). Although an agreement was not achieved then, the United States' persistence eventually paid off, and in 1996 the WIPO Copyright Treaty (WCT) was signed, taking into

Box 27.

As the WIPO was perceived by many private interests as having failed to fully support these sorts of rights during the period prior to the establishment of the TRIPS agreement, to return itself to the center of the global governance of intellectual property the WIPO needed to demonstrate that it understood and could react to the demands of the major knowledge industries, and their supporters.

Source: May C. *The World Intellectual Property Organization: resurgence and the development agenda*. New York, Routledge, 2007.

consideration most of the United States' demands. In the same year, the WIPO Performances and Phonograms Treaty (WPPT) was also adopted, thus extending the rights of performers globally to new levels. The WIPO internet treaties as they became to be known contain obligations which are of a TRIPS-plus nature.¹³¹

Despite the fact that developing countries were historically more sympathetic to WIPO, its work has come under some criticism from these countries in recent years. WIPO's primary focus on the protection and harmonization of intellectual property without taking into consideration the related social and economic costs of such protection in developing and least developed countries has been questioned. In effect, some observe that WIPO's approach has been affected by its willingness to appease the United States and other developed countries in order to retain its influence in the decision-making process as far as the protection of intellectual property is concerned. WIPO has also been criticized for its failure to take into consideration the concerns of developing countries and its primary focus on technical intellectual property protection and implementation.¹³²

These feelings were exacerbated by the launching of the WIPO's Patent Agenda. The core of this agenda, which was initiated in 2001, lies in its calling for a "universal system" of patent protection building on the international procedure available under the Patent Cooperation Treaty (PCT).¹³³ This would restrict and minimize the role of developing countries' national patent examination offices by adopting the standards already set by the more developed countries' examination offices.

To achieve this agenda, WIPO commenced negotiations on two major agreements in the field, the Patent Law Treaty (PLT),¹³⁴ which defines a unified set of procedural rules for preparing, filing and managing patents in signatory countries, and the Substantive Patent Law Treaty (SPLT), which is yet to be finalized and deals with the scope of the patent subject matter, exclusions and rules for deciding between competing claims. In addition, the SPLT seeks to limit exceptions from patentability and harmonize the definition of “prior art” within patent examination, which if adopted would lead to the erosion of TRIPS flexibilities and the policy space available to developing countries.¹³⁵ Although negotiations on the SPLT are currently at a standstill, if eventually approved, the agreement is likely to have grave repercussions on developing and least developed countries’ patent regimes, particularly in the area of public health and access to medicines as a result of the SPLT’s extensive TRIPS-plus agenda.¹³⁶

Unhappy with WIPO’s Patent Agenda, in early 2004, the Group of Friends of Development,¹³⁷ joined by a number of other developing countries, civil society groups and nongovernmental organizations led by Brazil and Argentina, circulated a proposal which was eventually adopted for the launching of the WIPO Development Agenda. The proposal was considered at the WIPO General Assembly, in its 31st (15th Extraordinary) Session held in Geneva in September 2004.¹³⁸

The proposed development agenda questions WIPO’s understanding of the notion of “intellectual property promotion” in the light of its nature as an agency of the UN and not as a private agency influenced by special interest groups. The agenda calls on WIPO to focus more on the needs of developing and least developed countries and to view intellectual property as one of many means for development, not as an end in itself.¹³⁹ There have been several proposals and intersessional intergovernmental meetings held related to the agenda.¹⁴⁰

Moreover, the development agenda proposal also recognizes that access to information and knowledge are essential elements in fostering innovation and creativity in the information age. The development agenda also calls for WIPO’s technical assistance programme to ensure that national intellectual property laws are tailored to meet each country’s level of development and that developing countries are trained in and familiarized with the use of the flexibilities (oriented to public objectives and policy space)

Despite the fact that developing countries were historically more sympathetic to WIPO, its work has come under some criticism from these countries in recent years

available under TRIPS and other intellectual property agreements. Stiff opposition by a number of developed countries including the United States to a wider scope of the agenda as proposed by developing countries has delayed the agreement on the parameters of the agenda for some time.

In 2007, after a long and contentious debate, member nations of WIPO finally agreed to establish a development agenda for WIPO and submit a development agenda report for the General Assembly in September 2007. The agenda is based on 45 recommendations covering six main areas of activities, including technical assistance and capacity-building; norm-setting, flexibilities, public policy and public knowledge; technology transfer, information and communication technology (ICT) and access to knowledge; assessments, evaluation and impact studies; and institutional matters including mandate and governance.¹⁴¹ Member nations also authorized a new WIPO committee on development and intellectual property. Subsequently, the Committee on Development and Intellectual Property (CDIP), established by the General Assembly of WIPO in October 2007, having already held its first two meetings (in March and July 2008), moved forward in discussing the implementation of the WIPO development agenda. The CDIP has already held detailed discussions on developing a work programme for implementation of the recommendations approved by the General Assembly.¹⁴²

It is too early to evaluate the accomplishments of the WIPO's development agenda. However the positive effect of the agenda is in starting the debate about WIPO's role in today's global intellectual property regulation and paying more attention to the role of the development aspect of intellectual property protection, particularly with respect to developing and least developed countries.¹⁴³

WIPO has also been criticized for its failure to take into consideration the concerns of developing countries and its primary focus on technical intellectual property protection and implementation

The World Health Organization, intellectual property and public health

At common standing with WIPO, WHO is a specialized agency of the UN system of agencies (Box 28).¹⁴⁴ WHO membership comprises 193 countries, making it one of the biggest organizations in terms of country membership in the world.

WHO has become one of the leading organizations in the discussion on intellectual property, public health and access to medicines in the post-TRIPS era. WHO achieved such an elevated status through many reasons, including the adoption of resolutions, spreading knowledge and awareness through conducting worldwide workshops and seminars, publications, capacity-building initiatives and programmes, monitoring global and regional developments affecting access to medicines, and cooperation with other international organizations. Indeed, as Volansky remarks, “today, WHO remains the predominant figure that guides, monitors, teaches, and even regulates Member States on global health”.¹⁴⁵

WHO’s work and involvement in the area of trade, development, public health and access to medicines have developed spectacularly during the past decade. However, this is not to suggest that this involvement is a recent phenomenon. As Homedes states, “some 30 years ago, WHO recognized that health systems need sound pharmaceuticals policies and since then has provided world leadership in implementing rational drug programmes, preparing useful manual [s] and guidelines, and offering technical assistance”.¹⁴⁶ In fact, WHO’s constitution expressly grants it the legal ability and mandate to enact conventions, agreements and

Box 28.

WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

Source: www.who.int

WHO membership comprises 193 countries, making it one of the biggest organizations in terms of country membership in the world

recommendations within the competence of its work.¹⁴⁷ Thus, by undertaking work in this field, WHO sees itself as merely undertaking and “performing its constitutional duties”.¹⁴⁸

WHO’s role and deeper involvement in the area of intellectual property and public health have grown tremendously during the past decade. Sell remarks that since TRIPS, “WHO increasingly has been drawn into trade issues, and NGOs have had considerable access to the institution”.¹⁴⁹

Operating under the umbrella of international human rights law,¹⁵⁰ as primarily codified under the right to health, WHO focuses its efforts on intellectual property protection and access to essential medicines under that theme. Seuba states that “WHO’s joint effort with the United Nations Committee on Economic, Social and Cultural Rights, the body in charge of the surveillance of the International Covenant of Economic, Social and Cultural Rights (ICESCR), has resulted in the inclusion of access to essential medicines in the core content of the right to health”.¹⁵¹

Through its General Assembly,¹⁵² WHO has issued several resolutions of vital importance in the area of intellectual property and public health. Accordingly, since 1999, the World Health Assembly (WHA) resolutions have increasingly given a broader mandate to WHO to analyse the effects of intellectual property, TRIPS and trade agreements on public health, and to assist countries in the use of the flexibilities and public health safeguards available to them under TRIPS.

The May 2003 WHA on improving access to essential medicines was particularly important. During the discussions, the United States, fearful of WHO’s deeper involvement in this area, presented an industry-friendly resolution which ignored the Doha Declaration on the TRIPS Agreement and Public Health. Furthermore, the United States’ proposal recommended that WHO should refrain from becoming involved in issues related to the implementation of TRIPS and should rather direct any such issues raised by Member States to the WTO and WIPO for assistance.

Countering the United States proposal, a number of developing countries led by Brazil,¹⁵³ encouraged by the recent success achieved through the WTO’s Doha Declaration on the TRIPS Agreement and Public Health, tabled their own proposal. The developing countries’ proposal reflected their concerns about access to medicines and called for an independent commission to examine the relationship

between intellectual property, innovation, public goods and public health and the negative impact of patent protection on access to medicines. After a prolonged contentious discussion between both camps, a compromise was worked out by the United States and the developing countries which culminated with the establishment of a time-limited independent commission: the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) (Box 29).¹⁵⁴ The CIPIH was set up by the Director-General of WHO in February 2004.

The commission's main focus was on reviewing existing research and development efforts, examining the role of intellectual property in stimulating innovation and making concrete proposals for action by national and international stakeholders in order to encourage research on diseases prevalent in the developing and least developed countries.

In April 2006, WHO's Commission on Intellectual Property Rights, Innovation and Public Health finally issued its final report, making numerous recommendations for improving health in developing and least developed countries.¹⁵⁵ These recommendations cover many areas related to institutional, legislative, health and negotiations policies. For example, the CIPIH Report explicitly warns against the spread of TRIPS-plus measures by stating that "bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries".¹⁵⁶ Moreover, the CIPIH Report urges developing countries to enhance their national regimes of checks and balances through the creation of legislative and institutional tools such as competition laws and regulations.¹⁵⁷

Box 29. Resolution of the World Health Assembly establishing the CIPIH, 2003 (WHA 56.27)

... to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries

...

The CIPIH was established by the Director-General of WHO in February 2004

Following the issuance of the CIPIH Report at the WHA in May 2006, Member States adopted a resolution titled “Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action”,¹⁵⁸ calling for the establishment of an intergovernmental working group, open to all Member States, in order to develop a global strategy and plan of action to provide a framework to enhance research and development into diseases that disproportionately affect developing countries. An intergovernmental working group and secretariat were established to facilitate implementation of the recommendations contained in the CIPIH Report.

After two years of discussion, in May 2008 the Sixty-first WHA adopted a resolution that strengthened the mandate of WHO to undertake work on the interrelated issues of public health, intellectual property, innovation and access to medicines through a global strategy and plan of action. The global strategy underscores that “WHO shall play a strategic and central role in the relationship between public health and innovation and intellectual property within its mandates (including those contained in relevant Health Assembly resolutions), capacities and constitutional objectives, bearing in mind those of other relevant intergovernmental organizations. In this context, WHO, including its regional and, when appropriate, country offices, needs to strengthen its institutional competencies and relevant programmes in order to play its role in implementing this global strategy with its plan of action”.¹⁵⁹

At regional and national levels, WHO is undertaking several projects and initiatives related to spreading knowledge and capacity-building through the work of the Regional Committee for the Eastern Mediterranean.¹⁶⁰ Its objectives include halting the spread of HIV/AIDS, affordability of medicines and accessibility of essential medicines and vaccines. It also holds regular workshops and seminars in the Region aimed at spreading awareness and enabling member countries to take a more positive role in devising their national intellectual property policies and institutions.

Endnotes

1. See *Integrating intellectual property rights and development policy*. London, Commission on Intellectual Property Rights, 2002 [the IPRs Commission Report], at 12.
2. See May C. The denial of history: reification, intellectual property rights and the lessons of the past. *Class and capital*, 2006, 88:33–56.
3. Hesse C. The rise of intellectual property, 700 BC–AD 2000: an idea in the balance. *Daedalus*, spring 2002, 26–45, at 26.
4. Accordingly, the terminology used today in describing these rights as intellectual property is more of a modern one. In fact the term *intellectual property* itself appeared for the first time in the literature in 1845, according to the Oxford English Dictionary.
5. Federico quotes David, stating that “for instance, two courtiers who received a starch monopoly were heavily in debt to the Queen and she apparently hoped to reimburse herself by helping them to make money at the expense of her subjects”. Federico P. Origin and early history of patents. *Journal of the Patent Office Society*, 1929, 11:292–305, at 299.
6. Chang elaborates on this issue by stating that “however, until the mid-nineteenth century, when machinery became the key embodiment of technological knowledge, the most important means of technological transfer was the transfer of skilled workers, in whom most technological knowledge was then embodied”. Chang J. Intellectual property rights and economic development: historical lessons and emerging issues. *Journal of human development*, 2001, 2(2):287–309, at 288.
7. Federico also explains that such grants were awarded to servants instead of salaries. For example, in relation to awarding a patent for salt it was stated that the “said grant was given unto him by her Majesty in some reward of his service and is a principal part of his maintenance”. Federico, *supra* 5, at 299. Also see El Said M. *The development of intellectual property protection in the Arab world*. New York, Edwin Mellen Press, 2008
8. See Schechter F. The rational basis of trademark protection. *Harvard law review*, 1927, 40:813–33.
9. In certain places, it was even socially unacceptable to receive payment for someone’s intellectual work. As Goethe, the famous German writer, proclaimed during the 18th century when describing German poets, “the production of poetical works was looked upon as something sacred. It was considered almost simony to accept or to bargain for payment for them”. Quoted in Hesse, *supra* 3, at 29.
10. Sell explains that it was “only in the early to mid 1930s that the courts quit referring to patents as monopolies in the United States”. Sell S. *Private power, public law: the globalization of intellectual property rights*. Cambridge, Cambridge University Press, 2003, at 178.
11. Kramer H. *Legal theory, political theory and deconstruction: against Rhadamanthus*. Bloomington, Indiana, Indiana University Press, 1991, at 237.

12. El Said, *supra* 7.
13. Termed an “Act for the Encouragement of Learning”.
14. Such as the 1799 Swiss patent law.
15. Braithwaite J, Drahos P. *Global business regulation*. Cambridge, Cambridge University Press, 2000, at 58.
16. Seville C. From pirates to eagles: America’s changing view of copyright. *European intellectual property review*, 2007, 29(10):406–10.
17. See, for example, the treaty of commerce between Great Britain and Russia, 31 December–12 January 1859, and the declaration of 24 October 1877 between the United States and Great Britain for the protection of trade marks.
18. Historically, with the exception of several copyright treaties—unlike trade marks, patents and designs, it was then understood that copyrights were non-commercial and were beyond the remit of trade and commerce—the majority of bilateral agreements related to the protection of intellectual property came to represent only a part of a wider range of trade and commerce treaties. For example, Article X of the convention of 28 February 1882 between Great Britain and France to regulate commercial and maritime relations stipulates:

The subjects of each of the two High Contracting parties shall, in the dominion of the other, enjoy the same protection and be subject to the same conditions as native subjects in regard to the rights or property in trade marks, names of firms, and other distinctive marks showing the origin or quality of goods, as well as in patterns and designs for manufacturers.

For more see Ladas S. *Patents, trademarks, and related rights: national and international protection*, vol. 1. Cambridge, Massachusetts, Harvard University Press, 1975, and El Said, *supra* 7.
19. The Paris Convention signed on 20 March 1883 became the first ever comprehensive multilateral agreement dedicated to the protection of industrial property. It came to represent the main global instrument for protecting patents, trade marks and trade names, and at the same time dealt with various issues, including unfair competition. The main principle of this agreement was the introduction of national treatment into the area of intellectual property.
20. The Berne Convention is the most important international convention in the field of copyright protection. The Berne Convention provides a framework for the recognition and protection of copyrights between member countries and reiterates the principle of national treatment and non-discrimination.
21. Maskus K, Reichman J. The globalization of private knowledge goods and the privatization of global goods. *Journal of international economic law*, 2004, 7(2):279–320.
22. Madrid Agreement for the International Registration of Trademarks of 14 April 1891.
23. The GATT, Article III.
24. El Said, *supra* 7, at 83. Endeshaw explains that the US demand for rigorous international protection “emanated from its desire to forestall perceived US technological decline as well as to reduce growing trade deficit in the 1980s and 1990s”. See Endeshaw A. The paradox of intellectual property lawmaking in the new millennium: universal templates as terms of surrender for non-

- industrial nations, piracy as an offshoot. *Cardozo journal of international and comparative law*, 2002, 10(1):47–77, at 57.
25. Williams M. *International economic organisations and the Third World*. London and New York, Harvester Wheatsheaf, 1994, at 179. Also see Rolland S. Developing country coalitions at the WTO: in search of legal support. *Harvard international law journal*, 2007, 48(2):483–551.
 26. In 1976, UNCTAD published a widely read report that criticized the Paris Convention by describing it as a tool of the industrialized countries and at the same time hailed foreign trade marks as harmful to the economies of some developing countries. See UNCTAD. *The role of trademarks in developing countries*. New York, United Nations, 1976. Doc sales no. E. 79.II.D.5. Also see UNCTAD. *The role of the patent system in the transfer of technology to developing countries*. New York, United Nations, 1975. Doc sales no. E-75.II.D.6.
 27. The WIPO Convention, preamble.
 28. The United International Bureaux for the Protection of Intellectual Property (BIRPI) was an international organization. It was set up in 1893 to administer the Berne Convention for the Protection of Literary and Artistic Works and the Paris Convention for the Protection of Industrial Property. The BIRPI was the predecessor of WIPO. BIRPI is an acronym for Bureaux internationaux réunis pour la protection de la propriété intellectuelle. For more see May C. *The World Intellectual Property Organization: resurgence and the development agenda*. New York, Routledge, 2007.
 29. See Braithwaite and Drahos, *supra* 15. Also, see El Said, *supra* 7, at 85.
 30. See generally Correa C. *Intellectual property rights, the WTO and developing countries*. London, Zed Books, Third World Network, 2000. See also Gad M. Impact of multinational enterprises on multilateral rule making: the pharmaceutical industry and the TRIPS Uruguay Round negotiations. *Law and business review of the Americas*, 2003, 9:667–98, and, El Said, *ibid*.
 31. On the relation between intellectual property protection and FDI see Mansfield E. *Intellectual property, foreign direct investment and technology transfer*. Washington DC, International Finance Corporation of the World Bank Group, 1994. Discussion paper 19.
 32. Once again, these interest groups played an important role in drafting some of the national policies and regulations in the field of intellectual property. Landes and Posner state that it is “noteworthy that most of the statutory language of the Copyright Act of 1976 was not drafted by members of Congress or their staffs at all. Instead, the language evolved through a process of negotiation among authors, publishers, and other parties with economic interests in the property rights the statute defines”. See Landes W, Posner R. *The political economy of intellectual property law*. Washington DC, AEI-Brookings Joint Centre for Regulatory Studies, 2004, at 14.
 33. One of the leading groups lobbying for more extensive multilateral intellectual property protection regime was the group representing the United States pharmaceutical lobby, referred to as Pharmaceutical Research and Manufacturers of America (PhRMA). In the United States, this sector was one of the leading export-orientated sectors for many years with an R&D expenditure of US \$50 billion annually. Another pressure group with a notable influence in this field was the International Intellectual Property Alliance (IIPA). Established in 1984, its main aim was to represent and defend the United States copyright industries in bilateral and multilateral forums by advocating higher levels of intellectual property protection globally.
 34. For more see El Said, *supra* 7.

35. El Said, *ibid.* at 89.
36. President Ronald Reagan's State of the Union Speech in 1983. Cited in Gadbow M. Intellectual property and international trade: merger or marriage of convenience? *Vanderbilt journal of transnational law*, 1989, 22(2):223–42, at 234.
37. The statutory authority on which the United States' Special 301 provisions are based notes that a country "can be found to deny adequate and effective intellectual property protection even if it is in compliance with its obligations under the TRIPS Agreement". See 2003 *Special 301 report*. Washington DC, Office of the US Trade Representative, 2003, at 9.
38. See Section 505 of the United States Trade and Tariff Act of 1984. For more on the GSP see Murray T. *Trade preferences for developing countries*, London and Basingstoke, Macmillan, 1977.
39. Articles 1302 and 1303 of the 1988 United States Omnibus Trade and Competitiveness Act.
40. The Office of the United States Trade Representative (USTR) is an agency which negotiates directly on behalf of the United States with foreign governments to create trade agreements, resolve disputes and participate in global trade policy organizations. The USTA also meets with governments, business groups, legislators and public interest groups to gather input on trade issues and explain the president's trade policy positions. The agency was founded in 1962 and has offices in Washington DC, Geneva and Brussels. For more see <http://www.ustr.gov/>.
41. The European Union also followed suit, with lesser vigour, by incorporating several mechanisms aimed towards pressuring developing countries to provide the intellectual property protection it desired. See El Said M. The European TRIPS-plus model and the Arab world: from cooperation to association—a new era in the global IPRS regime. *Liverpool law review*, 2007, 28(1):143–74. Also see Santa-Cruz M. *Intellectual property provisions in European Union trade agreements implications for developing countries*. Geneva, Switzerland, ICTSD Programme on IPRs and Sustainable Development, International Centre for Trade and Sustainable Development, 2007. Issue Paper 20.
42. The role of European interest groups, especially the pharmaceutical industry, in formulating and shaping the policies aimed towards the introduction of higher levels of intellectual property protection globally is instrumental. For a detailed analysis about this role, see Pugatch M. *The international political economy of intellectual property rights*. Cheltenham, Edward Elgar, 2004. Also see Santa-Cruz, *ibid.*
43. *Compendium of patent statistics*. Paris, OECD, 2005, at 35. Available at <http://www.oecd.org/dataoecd/60/24/8208325.pdf>. Moreover, it is estimated that between 3% and 9% of the total world trade in goods is pirated. Between 1998 and 2002 the number of counterfeit or pirated goods intercepted at the European Union's external frontier increased by more than 800%. See *Strategy for the enforcement of IPRs in third countries: facts and figures*. Brussels, EU Directorate General for Trade, European Commission, June 2004. MEMO/04/25523. Moreover, Japan also shares this vision. According to the website of the Japanese Patent Office, Japan's aim is to become "the world's most advanced IP-based nation". See <http://www.jpo.go.jp>.
44. See Drahos P. Developing countries and international intellectual property standard-setting. *Journal of world intellectual property*, 2002, 5(5):765–89. El Said, *supra* 41.
45. See EU Council Regulation EEC No. 2641/84 O.J 1984, L 252/1.

46. El Said, *supra* 41.
47. Such as the 1987 IFPI case against Indonesia and the 1988 Smith Kline & French Laboratories Ltd case against Jordan. For more see Arnold M, Bronckers M. The EEC new trade policy instrument: some comments on its application. *Journal of world trade*, 1988, 22(6):19–38.
48. The text of the TBR can be found in Council Regulation (EC) No. 3286/94, 22 December 1994.
49. See the European Union Lisbon Strategy/Agenda, 2000.
50. For more on this see: http://europa.eu.int/comm/trade/issues/sectoral/intell_property/strategy_tc.htm. (Last visited 13 January 2009).
51. See the European Commission Strategy, *supra* 43. Also see Mahnkopf B. *EU–multi level trade policy: neither coherent nor development-friendly*. Berlin, Germany, Global Labour University, 2008. Working paper 2.
52. In enforcing this strategy, the Dutch government recently seized an amount of 500 kg of losartan potassium, an active pharmaceutical ingredient used in the production of medicines for arterial hypertension in transit in Rotterdam (while en route from India to Brazil) on the basis of an alleged patent infringement hence triggering a row between the EU and the developing countries on the legality of such a procedure. For more see TWN. *Developing countries attack Dutch seizure of generic medicines*. TWN Info Service on Intellectual Property Issues (Feb09/02), 6 February 2009. Available at www.twinside.org.sg.
53. Intellectual property was almost considered to be an exception to free trade and was usually handled through the GATT Article XX (d) exception.
54. See Primo-Braga C. The economics of intellectual property rights and the GATT: a view from the South. *Vanderbilt journal for transnational law*, 1989, 22(2):243–64. On the history of the Tokyo Round see Demart P. The metamorphoses of the GATT: from the Havana charter to the World Trade Organization. *Columbia journal for transnational law*, 1996, 34:123–72.
55. In 1978 the International Anti-Counterfeiting Coalition (IACC) was formed. It consists of more than 150 multinational companies representing a cross-section of industries in the United States including the automotive industry, motion pictures, apparel, luxury goods, footwear and pharmaceuticals. The total collective annual revenues of this coalition exceed US \$500 billion. The main aim of the IACC is to work as a coalition to pressure the government to pursue whatever means possible to strengthen the protection levels of intellectual property globally and to fight piracy and counterfeiting. By the early 1980s, the IACC's mandate was expanded to include all forms of intellectual property. Later on, the recommendations and reports regarding the implementation of intellectual property worldwide became a valuable source of information for the United States Trade Representative (USTR) when imposing sanctions through the Special 301 provision against those countries which lack or do not provide adequate levels of protection for intellectual property.
56. However, a partial agreement between the United States and the European Union to coordinate their efforts to fight piracy and counterfeiting globally eventually took place.
57. Ministerial Declaration of November 1982, GATT Doc. No. 1328 BISD/29S/9 1983 Available at <http://www.jus.uio.no/wto.gatt.thirty.eighth.session.ministerial.declaration.1982/non.tariff.html>
58. For more see Primo-Braga, *supra* 54.

59. Primo-Braga, *ibid*.
60. For most developing countries, agriculture represents the backbone of their economies, thus any reforms in the existing framework of market access were badly needed.
61. Drahos P. Developing countries and international intellectual property standard-setting. *Journal of world intellectual property*, 2002, 5(5):765–89, at 774.
62. El Said, *supra* 7.
63. GATT, Ministerial Declaration of Punta Del Este, September 1986.
64. May, commenting on this, states that “finding that they had a reasonably free hand, a group of international corporations ‘helped’ the US government establish their negotiations position on the issue, and pushed for a much wider ranging agreement”. See May C. Why IPRs are a global political issue. *European intellectual property review*, 2003, 25(1):1–6.
65. El Said, *supra* 7, at 107.
66. The “green room” is a phrase taken from the informal name of the GATT director-general’s conference room in Geneva. On the history of the Uruguay Round and TRIPS see UNCTAD–ICTSD. *Resource book on TRIPS and development*. Cambridge, Cambridge University Press, 2005.
67. See Abbott F. Commentary: the international intellectual property order enters the 21st century. *Vanderbilt journal of transnational law*, 1996, 29:471–79; Rosenthal D. A comment on the 1998 “Special 301 annual review” of the US Trade Representative. *Journal of world intellectual property*, 1998, 1(5):742–5.
68. Vandoren P. The implementation of the TRIPS Agreement. *Journal of world intellectual property*, 1999, 2(1):25–34, at 27.
69. For example, the Paris and Berne Conventions allowed recourse only to the International Court of Justice (ICJ), which was non-binding on member states.
70. See TRIPS, Articles 2.1 and 2.2. Also see UNCTAD–ICTSD, *supra* 65.
71. See Bhagwati J. *In Defense of Globalization*. New York, Oxford University Press, 2004.
72. For more discussion see the IPRs Commission Report, *supra* 1.
73. Abbott F, Reichman J. The Doha Round’s public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions. *Journal of international economic law*, 2007, 10(4):921–87.
74. For a discussion of the ethics of pharmaceutical patents see Sterckx S. Patents and access to drugs in developing countries: an ethical analysis. *Developing world bioethics*, 2004, 4(1):58–75. On costs and benefits of pharmaceutical patent protection see Nogués J. Social costs and benefits of introducing patent protection for pharmaceutical drugs in developing countries. *Developing economies*, 1993, 31(1):24–53.
75. Nogués J. *Unequal exchange: developing countries in the international trade negotiations*. Paper presented at the Murphy Institute Conference on the Political Economy Policy Reform, New Orleans, 2002, at 13. Available at <http://ctrc.sice.oas.org/geograph/south/Nogues.pdf>.
76. Posner R. *Pharmaceutical patents*. December 2004. Available at http://www.becker-posner-blog.com/archives/2004/12/pharmaceutical_1.html.
77. Although the MFN principle has been established for a long period of time, TRIPS is the first multilateral intellectual property agreement that refers to this principle explicitly. However, TRIPS acknowledges the already established exceptions under the current agreements including the Paris and

- Berne Conventions. See TRIPS, Article 3.1. For more on the MFN see Saggi K. Tariffs and the most favored nation clause. *Journal of international economics*, 2004, 63(2):341–68.
78. TRIPS, Part III.
 79. Paris Convention, Article 9.6 states:

If the legislation of a country permits neither seizure on importation nor prohibition of importation nor seizure inside the country, then, until such time as the legislation is modified accordingly, these measures shall be replaced by the actions and remedies available in such cases to nationals under the law of such country.
 80. TRIPS, Articles 41–50.
 81. TRIPS, Article 61.
 82. TRIPS, Part V, Articles 63 and 64.
 83. TRIPS, Article 72, states:

Reservations may not be entered in respect of any of the provisions of this Agreement without the consent of the other Members.
 84. TRIPS, Article 65.
 85. Most of these issues will be explained and dealt with in depth in the following chapter.
 86. Correa remarks that the adaptation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) “was regarded by developing countries as the end of a process of substantial strengthening of IPRs protection”. Correa C. Bilateralism in intellectual property: defeating the WTO system for access to medicines. *Case Western Reserve journal of international law*, 2004, 36(1):79–94, at 79.
 87. In fact, it became evident that the United States and the European Union were adamant about strengthening the levels of intellectual property protection above those prescribed under TRIPS through various unilateral, bilateral and regional trade agreements and initiatives. Accordingly, the number of United States trading partners that were placed under the USTR’s Special 301 Section in 1996 increased by 25% in 1997. Sell S. Industry strategies for intellectual property and trade: the quest for TRIPS, and post-TRIPS strategies. *Cardozo journal of international and comparative law*, 2002, 10:79–108.
 88. El Said M. The road from TRIPS-minus to TRIPS to TRIPS-plus: implications of IPRs for the Arab world. *Journal of world intellectual property*, 2005, 8(1):53–66.
 89. Drahos states “despite the US sending delegations of 10 to 12 to TRIPS Council meetings there is ‘lots of deadlock’ and progress on the implementation of TRIPS has been slow. For the US the full benefits of TRIPS are tied to full implementation. Concluding bilateral agreements on IP with states like Chile that have ‘modern views’ is seen by the US as a way forward”. Drahos P. *Developing countries and international intellectual property standard-setting*. Commission on Intellectual Property Rights, 2001. Study paper 8, at 28.
 90. See Drahos P. BITS and BIPS: bilateralism in intellectual property. *Journal of world intellectual property*, 2001, 4:791–808.
 91. However, recent FTAs signed by the United States (with Peru, Columbia and Panama) show a decrease in the level of intellectual property protection in the area of public health when compared to previous FTAs. For more discussion on this see chapter 4.

92. Abbott F, Correa C. *World Trade Organization accession agreements: intellectual property issues*. Geneva, Quaker United Nations Office Global Economic Issue Publication, May 2007.
93. For example, Jordan's entry into the WTO was conditional on its implementation of several TRIPS obligations with immediate effect. Accordingly, Jordan was requested during the negotiations phase to submit an action plan detailing the steps to be undertaken by the country to meet its TRIPS obligations at the time of accession, hence forgoing its right as a developing country to use the WTO's transition periods. See the *Report of the Working Party on the Accession of the Hashemite Kingdom of Jordan*, WT/ACC/JOR/33 and WT/MIN(99)/9, Geneva, World Trade Organization, 1999, Para. 192.
94. Also see the US–Morocco FTA, Article 15.9 (3).
95. For more see discussion below on the amendment of Article 31 of the TRIPS Agreement.
96. See US–Jordan FTA.
97. US–Chile FTA, Article 17.5 (4) states:

Each Party shall provide that where the term of protection of a work (including a photographic work) is calculated: (a) on the basis of the life of a natural person, the term shall be not less than the life of the author and 70 years after the author's death, and (b) on a basis other than the life of a natural person, the term shall be: (I) not less than 70 years from the end of the calendar year of the first authorized publication of the work, or (II) failing such authorized publication within 50 years from the creation of the work, not less than 70 years from the end of the calendar year of the creation of the work.

Also see US–Morocco FTA, Article 15.5 (5) and US–Oman FTA, Article 15.4 (4).
98. TRIPS, Article 12.
99. TRIPS, Article 33.
100. The EU–Macedonia FTA signed on 19 June 2000, Annex V, Article 3, states:

Adequate and effective patent protection for inventions in all field of technology on a level similar to that in the European Patent Convention 5 October 1973, as well as, before 1 January 2002, additional protection of up to five years for pharmaceutical and plant protection products.
101. TRIPS, Article 26.3.
102. EU–Morocco AA, Annex 5, Article 3.1.
103. See EU–Jordan AA, Annex VII, Article 3.
104. These include the WIPO Copyright Treaty 1996 and the WIPO Performances and Phonograms Treaty 1996.
105. Joining the UPOV Agreement is a TRIPS-plus condition because it is a system for protecting plant breeders' rights in new and distinctive plant varieties which is not mentioned in TRIPS. Rather, TRIPS allows members to develop *sui generis* protection systems for plants which could be less restrictive than UPOV on the member states. See chapter 4 for more discussion.
106. See Article 4.1 (1–2) US–Jordan FTA, and Annex VII of the EU–Jordan AA, Article 1.
107. Approximately US \$9000.

108. Memorandum of Understanding on Issues Related to the Protection of Intellectual Property Rights Under the Agreement between the United States and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, Article 3.
109. See EU–Tunisia AA 1998, Annex 7, and the EU–Mexico Agreement of 2000, Articles 36.2 and 36.4.
110. El Said, *supra* 88.
111. See US–Chile FTA, Article 22 (1–6), and US–Morocco FTA, Article 20 (1–7).
112. For a discussion on United States dispute settlement under FTAs see Drahos P. Weaving webs of influence: the United States, free trade agreements and dispute resolution. *Journal of world trade*, 2007, 41(1)191–210.
113. For more on the involvement of the WCO in the area of intellectual property see Yash T. Editorial: WIPO, WCO, intellectual property and border guards. *South bulletin*, 15 May 2008, 16. For more on this and other initiatives see Sell S. *The global IP upward ratchet, anti-counterfeiting and piracy enforcement efforts: the state of play*. Geneva, IQsensato, June 2008.
114. Musungu S. Benchmarking progress in tackling the challenges of intellectual property, and access to medicines in developing countries. *Bulletin of the World Health Organization*, 2006, 84:366–70.
115. See progress report by WHO, UNAIDS and UNICEF: *Towards universal access: scaling up priority HIV/AIDS interventions in the health sector*. Geneva, 2008. Available at www.who.int. Also see WHO's annual world health reports at www.who.int.
116. *Doha Ministerial Declaration on the TRIPS Agreement and Public Health*. WTO, 14 November 2001. WT/MIN(01)/DEC/W/2.
117. It must be stated that the right of access to medicines is a human right long acknowledged by several other global institutions including the United Nation's Agreement on the Universal Declaration of Human Rights (Article 25.1), the Convention on the Rights of the Child (Article 24) and the International Convention of Civil and Political Rights (Article 6).
118. On the effect of the Doha Declaration on Africa see Haakonsson S, Richey L. TRIPS and public health: the Doha Declaration and Africa. *Development policy review*, 2007, 25(1):71–90.
119. See Abbott and Reichman, *supra* 73.
120. For a discussion of all proposals see Shanker D. The Paragraph 6 solution of the Doha Public Health Declaration and export under the TRIPS Agreement. *Journal of world intellectual property*, 2004, 7(3):365–400.
121. Interestingly, the WTO describes the Paragraph 6 decision as removing the “final patent obstacle to cheap drug imports”. See <http://www.pubmedcentral.nih.gov> [press release] 30 August 2003. On the complexity and details of the decision see Abbott and Reichman, *supra* 73.
122. Once two-thirds of members have formally accepted it, the amendment will take effect in those countries and will replace the 2003 waiver for them. For each of the remaining members: the waiver will continue to apply until that member accepts the amendment and it takes effect. Countries which have accepted the amendment so far are the United States (17 December 2005), Switzerland (13 September 2006), El Salvador (19 September 2006), Republic of Korea (24 January 2007), Norway (5 February 2007), India (26 March 2007), Philippines (30 March 2007), Israel (10 August 2007), Japan (31 August 2007), Australia (12 September 2007), Singapore (28 September 2007), Hong Kong,

- China (27 November 2007), China (28 November 2007), European Union (30 November 2007). For more see www.wto.org.
123. *The decision of 18 December 2007: Amendment of the TRIPS Agreement—extension of the period for the acceptance by members of the protocol amending the TRIPS Agreement*. Geneva, WTO, 2007. WT/L/711.
 124. See Abbott and Reichman, *supra* 73.
 125. For a discussion on this see Abbott and Reichman, *supra* 73; Rimmer M. Race against time: the export of essential medicines to Rwanda. *Public health ethics*, 2008, 1–15; and Vandoren P, Eechhaute J. The WTO decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: making it work. *Journal of world intellectual property*, 2003, 6(6):779–93.
 126. Abbott F, Reichman J. *Strategies for the protection and promotion of public health arising out of the WTO TRIPS Agreement amendment process*. Geneva, WHO, 2007. At http://www.who.int/phi/public_health_hearings/second/contributions_section1/Section1_Abbott&Reichman.pdf.
 127. May, *supra* 28, at 32.
 128. In 1995 WIPO entered into a cooperation agreement with the WTO to provide technical assistance to developing country members of the WTO on TRIPS-related issues.
 129. *WIPO's legal and technical assistance to developing countries for the implementation of the TRIPS Agreement from 1 January 1996 to 31 December 2000*. Geneva, WIPO, June 2001.
 130. See May, *supra* 28.
 131. The WCT and the WPPT have been referred to as the WIPO internet treaties.
 132. See May, *supra* 28.
 133. In fact, around 90% of WIPO's funding comes from the private sector by way of fees paid by patent applicants (most of which are from developed countries) under the Patent Cooperation Treaty (PCT).
 134. The PLT had been negotiated by 2000. The WIPO Patent Agenda aimed to ensure its wider implementation. It also intended to reform the PCT to move from having a non-binding patentability standard which would have posed a threat to national patent offices. The PLT entered into force on 28 April, 2005.
 135. See May, *supra* 28, at 87.
 136. Reichman J, Dreyfuss R. Harmonization without consensus: critical reflections on drafting a substantive patent law treaty. *Duke law journal*, 2007, 57(1):85–130.
 137. The group comprises Argentina, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Egypt, Islamic Republic of Iran, Kenya, Peru, Sierra Leone, South Africa, United Republic of Tanzania, Uruguay and Venezuela.
 138. The proposal was submitted by Brazil and Argentina and supported by Bolivia, Cuba, Dominican Republic, Ecuador, Islamic Republic of Iran, Kenya, Sierra Leone, South Africa, United Republic of Tanzania and Venezuela. The General Assembly welcomed the initiative and decided to convene intersessional intergovernmental meetings to examine the proposals. For more see www.wipo.org.
 139. Musungu and Dutfield remark in this regard that WIPO “must show to the USA and its industry that it can deliver new standards faster and more efficiently. This reasoning underlies WIPO's TRIPS-plus agenda”. See Musungu S, Dutfield

- G. *Multilateral agreements and a TRIPS plus world: the World Intellectual Property Organisation*—(WIPO). Geneva, Quaker United Nations Office, 2003, at 11. TRIPS Issue Papers 3. Moreover, others relate such conduct to its establishment phase: “the shift from WIPO to GATT to TRIPS was not intended to eclipse WIPO. Rather, it established a new venue for trade-related IP lawmaking, in effect creating a bimodal IP regime within which the two organizations shared authority according to their respective areas of expertise”. Helfer L. Regime shifting: the TRIPS Agreement and new dynamics of international intellectual property lawmaking. *Yale journal of international law*, 2004, 29(1):1–83, at 25; Boyle J. A manifesto on WIPO and the future of intellectual property. *Duke law and technology journal*, 2004, 9:1–12.
140. In November 2004, 500 renowned economists, Nobel laureates, legal experts, academics, scientists and public citizen groups adopted the “Geneva Declaration on the Future of the World Intellectual Property Organization” and urged WIPO to embrace a more balanced agenda for promoting creativity and technology transfer in line with public interest.
 141. For more see www.wipo.org.
 142. For the latest update on the committee’s work see www.wipo.org.
 143. See May, *supra* 28, at 87.
 144. The United Nations adopted WHO under Article 57 of the UN Charter. See the Agreement between the United Nations and the World Health Organization, 12 November 1948.
 145. Volansky M. Achieving global health: a review of the World Health Organization’s response. *Tulsa journal of comparative international law*, 2002, 10:223–59, at 223–24.
 146. Homedes N. Making medicines affordable: studying WHO initiatives. *Bulletin of the World Health Organization*, May 2006, 84(5):424.
 147. The Constitution of the World Health Organization, Articles 19–23.
 148. Sell S. TRIPS-plus free trade agreements and access to medicines. *Liverpool law review*, 2007, 28(1):41–75.
 149. Sell, *ibid*.
 150. On the relationship between TRIPS, health, and human rights see Cullet P. Patents and medicines: the relationship between TRIPS and the human right to health. *International affairs*, 2003, 79:139–160.
 151. Seuba X. A human rights approach to the WHO model list of essential medicines. *Bulletin of the World Health Organization*, May 2006, 84(5):405–11, at 405.
 152. The World Health Assembly is the supreme decision-making body for WHO. It generally meets in Geneva in May each year, and is attended by delegations from all 193 Member States. Its main function is to determine the policies of the Organization. The Health Assembly appoints the Director-General, supervises the financial policies of the Organization and reviews and approves the proposed programme budget. It similarly considers reports of the Executive Board, which it instructs in regard to matters upon which further action, study, investigation or report may be required. The Executive Board is composed of 34 members technically qualified in the field of health. Members are elected for three-year terms. The main Executive Board meeting, at which the agenda for the forthcoming Health Assembly is agreed upon and resolutions for forwarding to the Health Assembly are adopted, is held in January, with a second shorter meeting

- in May, immediately after the Health Assembly, for more administrative matters. The main functions of the Board are to give effect to the decisions and policies of the Health Assembly, to advise it and generally to facilitate its work. Information from www.who.int.
153. Supported by Bolivia, Ecuador, Indonesia, Peru, Venezuela and South Africa.
 154. World Health Assembly, Resolution of the World Health Assembly: Intellectual Property Rights, Innovation and Public Health, WHA56.27. Geneva, WHO, 2003. At <http://www.who.int>. WHO, Commission on Intellectual Property Rights, Innovation and Public Health. *Public health: innovation and intellectual property rights*. Geneva, WHO, 2006 [hereinafter the CIPIH Report]. At <http://www.who.int/intellectualproperty>.
 155. CIPIH Report.
 156. CIPIH Report, recommendation 4.21.
 157. CIPIH Report, recommendation 4.20 states that “developing countries should adopt or effectively implement competition policies in order to prevent or remedy anti-competitive practices related to the use of medicinal patents, including the use of pro-competitive measures available under intellectual property law”.
 158. *Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action*. Geneva, WHO, 27 May 2006. A59/A/Conf. Paper No. 8. At www.who.int.
 159. See TWN. *WHO: WHA strengthens WHO’s mandate on IP and health*. Published in SUNS, 6482, 27 May 2008. Available at <http://www.twinside.org.sg/title2/health.info/2008/twnhealthinfo20080602.htm>. Also see www.who.int.
 160. Each regional committee is composed of representatives of the Member States and Associate Members in the region concerned.

4. Health-related TRIPS-plus provisions in bilateral trade arrangements

The strength and importance of intellectual property stem from the fact that it affects and regulates important aspects of human activities including but not limited to agriculture, health, environment, food, human rights, transfer of technology and, increasingly, civil liberties. Based on this, the impact of intellectual property is not confined to trade and economics, but rather extends beyond to many other areas.

In fact, it is the area of public health and access to medicines where the effects of intellectual property are most acute. Accordingly, the concern and focus of this chapter will be on the health-related TRIPS-plus provisions emerging under bilateral free-trade agreements concluded between several countries of the Region and the United States and the European Union.¹

Accordingly, this chapter will start by briefly outlining the flexibilities of TRIPS in the area of public health and then move to shed light on the health-related TRIPS-plus issues and provisions prevailing under several bilateral trade arrangements with countries in the Region. The chapter will deal with and analyse these provisions using a uniform and structured approach by identifying the main issues of concern and explaining the concept behind each issue; examining the position of TRIPS in relation to the issue; examining the situation under the bilateral agreements in relation to the issue; discussing the public health implications of these TRIPS-plus provisions on these countries and suggesting several policy measures which countries should consider in order to circumscribe the negative effects and impacts of these clauses on their public health regimes.

Health-related flexibilities under TRIPS

As explained, the area of public health and access to medicines has been one of the most affected areas associated with the issue of strengthened intellectual property protection. This stems from the close association of patent protection with both the availability and prices of medicines and the implications for the poor, particularly those in the developing and least developed countries.

In recent years, this issue has received considerable attention by various groups, particularly nongovernmental organizations and civil society representatives. However, much of the criticism has been directed toward profitable multinational pharmaceutical corporations and their efforts to strengthen the protection of their patents, thus depriving developing and least developed countries from resorting to the flexibilities available to them under TRIPS.

Prior to TRIPS, patent protection for pharmaceutical products was not compulsory. In fact, during the Uruguay Round, more than 50 countries did not provide such protection, which illustrates that countries had different approaches and considerable discretion in dealing with patent protection.² However, after the conclusion of TRIPS, pharmaceutical patent protection became compulsory for all WTO member states, thus conferring substantial benefits to the multinational pharmaceutical companies.

Although expanding the scope of pharmaceutical protection drastically, TRIPS provides its member countries (developing and least developed countries in particular) with some leeway and policy space to mitigate their losses and to ensure that drug and medicine production and availability are not impaired in certain and special circumstances. Several measures were incorporated into TRIPS to ensure that intellectual property protection did not override the rights and health of the developing and least developed countries' poor. In general, these public health-related flexibilities include the following.

Transitional periods. These transitional periods correspond with each country's level of development and economic progress. Accordingly, developed countries were granted a one-year transitional period to bring their intellectual property

These transitional periods correspond with each country's level of development and economic progress

protection into conformity with TRIPS.³ In addition, developing countries were granted an additional four years⁴ and least developed countries were granted ten years for the same purpose, a period that was due to lapse on 1 January 2005 but was later (under the Doha Declaration on the TRIPS Agreement and Public Health) extended for ten years from 1 January 2006 to apply TRIPS' pharmaceutical patents protection and until 1 July 2013 for TRIPS compliance.⁵

Compulsory licensing. TRIPS allows the authorization by the state of a third party to exploit patented inventions, generally against a remuneration to the patent holder and in accordance with several conditions set under TRIPS. The aim behind this is to circumvent anti-competitive behaviour and ensure the transfer of technology and dissemination of knowledge.

Government use exceptions. This grants the state the right to use the patent without obtaining the consent of the patent holder for the public interest, including public health purposes. Although conditions are similar to compulsory licensing, government use exceptions gives the flexibility of the fast-track approach, which grants the government the right to use the pharmaceutical patent without the need for prior negotiations with the owner.

Parallel importation. This gives the right to obtain patented products when they are lawfully available in a foreign country at a lower price, thus enabling countries to shop for cheaper patented products. This requires as a prerequisite that a country adopt an exhaustion regime suitable to its needs and priorities.⁶

Exceptions to patents rights. Article 30 of TRIPS provides that members "may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties". However, the above clause does not define the scope or nature of the permissible exceptions thus awarding member countries some discretion to operate. Examples of these exceptions include the Bolar exception and the research and experimental use exception.

Standards of patentability. Under TRIPS, patent protection must be granted for products and processes which are *new*, involve an

TRIPS allows the authorization by the state to a third party to exploit patented inventions

TRIPS plus provisions have a direct impact on public health, pharmaceutical production and the availability of and prices of medicines

inventive step and are *industrially applicable*. However, these criteria are not defined and can be interpreted and applied by member states in accordance with their national priorities. For example, TRIPS does not specify the patenting of new uses of known products, including pharmaceutical drugs, thus allowing member countries the possibility of rejecting these new uses for lack of novelty, inventive step or industrial applicability.

It must be noted that although these flexibilities are available for member states to use, in many instances the above flexibilities do not apply automatically but require a great deal of legislative and institutional preparation. Accordingly, in certain instances, committees at the national level must be created, legislative tools and bylaws must be inaugurated, proper judicial training must be undertaken and creative implementation of the above flexibilities must be pursued by member states.

Health-related TRIPS-plus provisions under bilateral trade agreements

This section will study several TRIPS-plus provisions arising under bilateral trade agreements which have a direct impact on public health and access to medicines. However, since this part will focus only on the bilateral agreements signed with countries falling within the scope of this study, such a list of provisions should not be treated as an exhaustive one; thus there may be other health-related TRIPS-plus provisions arising from bilateral arrangements concluded with other countries outside the Region.

These TRIPS-plus health-related provisions include the elimination and reduction of transitional periods, data exclusivity protection, extension of patent protection terms, restrictions on parallel importation, patentability of new use of known medical substances, restrictions on compulsory licensing, patenting of life forms, limitations on patentability criteria and accession to a number of international TRIPS-plus agreements. In short, these provisions have a direct impact on public health, pharmaceutical production and the availability of and prices of medicines.

1. The elimination and reduction of transitional periods

In order to cope with the short- and long-term costs of enhanced intellectual property protection and to enable member states to meet their WTO and TRIPS accession commitments, several transitional periods were agreed upon and provided during the Uruguay Round. The main aim of these grace periods is to give countries the opportunity to undertake the necessary legal, economic, administrative and social reforms in order to mitigate the downside effects of stronger intellectual property protection. Accordingly, the length of these periods corresponds to each country's level of development and economic progress.

Developing countries were granted an additional four-year transitional period under Article 65.2 of TRIPS

Transitional periods under TRIPS

Under TRIPS, developed countries were granted a one-year transitional period to bring their intellectual property protection into conformity with the agreement. Accordingly, Article 65.1 of TRIPS states:

... no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

Developing countries were granted an additional four-year transitional period under Article 65.2 of TRIPS. which states:

A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

In addition to the above, countries which did not provide product patent protection for pharmaceuticals or agrochemicals were provided an additional periods of five years to put in place such protection regimes. Finally, least developed countries were also granted an additional ten years for the same purpose, a period that was due to lapse on 1 January 2005 but was later extended for ten years from 1 January 2006 to apply TRIPS' pharmaceutical patents protection, and until 1 July 2013 for TRIPS compliance.⁷

Accordingly, it is clear that these transitional periods are a right granted to each member state in accordance with its levels of development. TRIPS nowhere nor for any reason dictates that a member state should forgo or apply these periods ahead of time. At the time of TRIPS' conclusion, these transitional periods were automatically applicable hence no reservation at the time of approving the WTO agreements was required by member states.

Under several bilateral trade agreements, a number of developing countries forego privileges related to their transitional periods

Transitional periods under bilateral trade arrangements

Under several bilateral trade agreements, a number of developing countries forgo privileges related to their transitional periods.⁸ For example, the 1997 EU–Jordan AA stipulates that Jordan must provide patent protection for chemicals and pharmaceuticals within a three-year period, two years before the period provided under TRIPS for a developing country like Jordan. Accordingly, Annex VII.3 of the EU–Jordan AA states:

Jordan undertakes to provide for adequate and effective protection of patents for chemicals and pharmaceuticals in line with Articles 27 to 34 of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights, by the end of the third year from the entry into force of this Agreement or from its accession to the WTO, whichever is the earliest.

Although reference to this provision under more recent FTAs and AAs has ceased since the transitional periods awarded to developing countries lapsed in 2005, the possibility remains that such a provision may reemerge under other bilateral trade agreements made by the United States and the European Union with least developed countries or in the case of the accession of least developed countries to the WTO, thus obliging these countries to apply stronger intellectual property protection before the lapse of their extended transitional period.

The public health implications of shorter transitional periods

Implementing TRIPS before strictly necessary will preclude developing and least developed countries from undertaking the necessary legislative and administrative steps needed to establish an intellectual property regime which takes into consideration their national public health needs and priorities. It will also facilitate

the introduction and entry of expensive patented pharmaceutical products ahead of time hence raising the prices of pharmaceutical products substantially as a result of royalty payments to multinational pharmaceutical companies. It will also prevent the national production of generic medicines or their importation into the country.

The experience of India, which has been described as the “pharmacy of the world”, provides a good example.⁹ This country took full advantage of the transitional period offered to developing countries under TRIPS before it introduced product protection on pharmaceuticals and chemicals in 2005. Indeed this approach provided India with many benefits and advantages achieved through various policies, including the establishment of an incentive scheme for domestic producers, the promotion of research and development, and an enabling patent protection regime.¹⁰ It is believed the “transitional period without product patent protection permitted India to develop a thriving pharmaceutical industry, supplying pharmaceutical products domestically and globally (including low-cost active pharmaceutical ingredients). This development created conditions for some of the companies in the industry to initiate investment in R&D” (Box 30).

Box 30. The impact of transitional periods on India’s pharmaceutical industry

The central question concerns the impact this transitional period had on R&D and innovation in the industrial sector. The evidence suggests that industry R&D increased very modestly from 1990 to 2000, rising from just over 1% of sales to about 2%, with total investment of US\$ 73.6 million in 2000. Since 2000, there has been a very rapid increase in pharmaceutical R&D. By 2003/2004, the combined investment of 12 of the leading companies was estimated to be US\$ 230 million annually, representing nearly 8% of turnover.

Source: WHO. *CIPHI report*, 2006.

Policy options and recommendations

Countries should use and benefit from the transitional periods granted to them under TRIPS. Although this may be of no use for those developing countries which by 2005 had been obliged to provide full patent pharmaceutical protection under TRIPS, it is vital to state that least developed countries still enjoy a transitional period for pharmaceutical patents and test data protection at least until 2016 by virtue of the TRIPS Council's decision of 27 June 2002.¹²

However, the use of these transitional periods should be part of a national strategy aimed towards encouraging pharmaceutical production and investment in R&D. Least developed countries and those countries in the Eastern Mediterranean Region which are yet to become members of the WTO should emulate and take notice of India's experience in this regard. As Dhar and Rao state:

However, the overall impact of this mix of policies was favourable for the industry. This is evident in the relative performance of the pharmaceutical industry in the industrial sector as a whole, and of the performance of the pharmaceutical industry in the 1990s, when it surpassed that of all other major industrial sectors in India. In a phase where most industries were devising strategies to meet the challenges posed by the opening up of the Indian economy, the pharmaceutical industry was in a league of its own. Since the 1970s, government policy initiatives were aimed at increasing the production of bulk drugs in India from as basic a stage as possible. This objective had been largely achieved by the year 2000.¹³

Moreover, least developed countries including those in the Region which already provide pharmaceutical patent protection are advised to revise their national patent laws in order to reap the benefits of the extended transitional period awarded to them under the Doha Declaration on the TRIPS Agreement and Public Health.

In this regard, the IPRs Commission Report recommends:

LDCs should be granted an extended transition period for implementation of TRIPS until at least 2016. The TRIPS Council should consider introducing criteria based on indicators of economic and technological development for deciding the basis of further extensions after this deadline. LDCs that have already adopted TRIPS standards of IP protection should be free to

Countries should use and benefit from the transitional periods granted to them under TRIPS

amend their legislation if they so desire within this extended transition period.

The report also states:

Though developing countries have the right to opt for accelerated compliance with or the adoption of standards beyond TRIPS, if they think it is in their interests to do so, developed countries should review their policies in regional/bilateral commercial diplomacy with developing countries so as to ensure that they do not impose on developing countries standards or timetables beyond TRIPS.¹⁴

The national drug regulatory authority often functions in a separate capacity from any national patent office

2. Data exclusivity and marketing approval

In most countries, there is an independent national drug regulatory authority concerned with ensuring that medicines and drugs are safe for use and compatible with quality standards before they are made available in the market. Accordingly, to be successful, the registration process of a medicine with such an authority must prove that this medicine meets safety, quality and efficacy requirements.

This national drug regulatory authority often functions in a separate capacity from any national patent office. Thus, national patent offices are more concerned with ensuring that the application of a patent meets the requirements of patentability (such as novelty, inventiveness and industrial applicability), unlike national drug regulatory authorities, which are concerned with the quality and safety of the drug. Moreover, most of these national drug regulatory authorities are affiliated with or have linkages with national health ministries.

One of the issues that the United States and the European Union, to a lesser extent, have sought to incorporate under their bilateral trade arrangements with countries in the Region relates to data exclusivity (Box 31). Accordingly, data exclusivity provisions refer to a practice whereby, for a fixed period of time, national drug regulatory authorities prevent and block the registration files of an originator to be used to register a therapeutically equivalent generic version of that medicine without obtaining the consent of the patent holder unless the generic manufacturer actually reconducts the clinical trials.¹⁵

Box 31. Data exclusivity vs. data protection

Data exclusivity has nothing to do with protecting research data. Long after the data exclusivity period has expired, the originator documentation remains protected by copyright laws and other legal provisions. Data exclusivity merely extends the originator company's market monopoly over a product by not allowing the authorities to process an application for marketing authorization.

Source: European Generic Medicines Association.
www.egagenerics.com.

Data exclusivity is a completely separate form of protection from patents. The rationale behind the provision of this protection as pharmaceutical companies claim is that this protection is needed to compensate them for the “considerable effort” they undertake in the compilation of these data in addition to their investment of millions of dollars in clinical and experimental trials and tests. On the other hand, those opposing this type of protection argue that such data should be in the public domain because they contain important medical information not available elsewhere and that excessive secrecy has undesirable effects (for example, the data might be usefully reanalysed to understand side-effects only detected after marketing). Moreover, some argue that it is in the best interests of society that the data be freely available and that it is a waste of resources and effort for a potential generic competitor to repeat very expensive and lengthy tests if the biopharmaceutical equivalence of their version of the drug can be reliably demonstrated. Based on this, data exclusivity can be a barrier to generic entry irrespective of whether the drug was patented or if the patent period has expired.¹⁶

Data exclusivity under TRIPS

Undisclosed information “has never been the subject of any multilateral agreement until the adoption of TRIPS”.¹⁷ As for data exclusivity, TRIPS does not oblige member states to provide exclusive rights specifically to the originator of data but rather calls for the protection of “undisclosed data” against “unfair” and “non-commercial use” of these data.¹⁸ In addition, TRIPS states that countries have the discretion to require the submission of undisclosed test or any other data. Accordingly, Article 39.3 of TRIPS stipulates:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Under TRIPS, a country is said to be in compliance with its commitments as long as it provides protection to undisclosed test or other data from “disclosure” and “unfair commercial use”. Thus, as Reichman argues, “if a state forgoes such a requirement, as by relying upon the health and safety decisions of other jurisdictions, or on the published medical literature, or a combination of both, it arguably incurs no liability whatsoever under article 39.3”.¹⁹

Moreover, Article 39.3 of TRIPS, in contrast to patents, does not require the provision of specific forms of rights but rather the protection of undisclosed test or other data against unfair commercial use. Therefore, it does not create a property right or a right to prevent others from relying on the data for the marketing approval of the same product by a third party, or from using the data except where unfair (dishonest) commercial practices are involved.

The language of Article 39.3 of TRIPS also gives member states the freedom and discretion to determinate what constitutes “unfair” and “just” in accordance with Article 10bis of the Paris Convention,²⁰ thus providing countries with additional flexibility and policy space in this regard. In accordance with the same article, if noncommercial use of such data has taken place (such as use by any government or national department to avoid any health and safety risks), then that member state shall not be in breach of Article 39.3 of TRIPS. More important, TRIPS does not specify a minimum period of data exclusivity that WTO members have to adhere to.

TRIPS does not specify a minimum period of data exclusivity that WTO members have to adhere to

Data exclusivity under bilateral trade arrangements

The United States and European Union have pursued the inclusion of data exclusivity protection under their bilateral trade

All United States FTAs with countries in the Region contain TRIPS-plus requirements in many respects in relation to data exclusivity

arrangements with countries in the Region. One notable feature of United States FTAs in this regard is ratcheting up levels of protection. Accordingly, while the US–Jordan FTA contained two brief provisions dealing with data exclusivity (covering less than half a page), the subsequent US–Oman FTA contained four long, detailed provisions spreading over three pages solely dedicated to the issue of data exclusivity.²¹

The main provisions of United States bilateral agreements tend to tighten and limit the above discussed flexibilities awarded to countries under TRIPS. Thus, all United States FTAs with countries in the Region contain TRIPS-plus requirements in many respects in relation to data exclusivity.

First, the United States FTAs oblige their member states to provide a regime of *exclusive rights* in test data. Moreover, unlike TRIPS, these FTAs also stipulate a minimum period of protection during which data exclusivity protection must be provided. For example, the United States FTA with Morocco stipulates that:

If a Party requires, as a condition of approving the marketing of a new pharmaceutical and agricultural chemical product, a) the submission of safety and efficacy data, or b) evidence of prior approval of the product in another territory that requires such information, the Party shall not permit third parties not having the consent of the person providing the information to market a product on the basis of the approval granted to the person submitting such information for at least *five years for pharmaceutical products and ten years for agricultural chemical products* from the date of approval in the Party. For purposes of this paragraph, a new product is one that contains a new chemical entity that has not been previously approved in the Party [emphasis added].²²

In addition to the five-year exclusivity period mentioned above under the US–Morocco FTA, the FTA also demands that Morocco accord another three years of data exclusivity for “new clinical information”,²³ such as previously unapproved uses of approved products, thus additionally enhancing the period of protection.²⁴

Some FTAs tend to interpret Article 39.3 of TRIPS in a broader sense. While the language used under the United States FTA with Jordan refers to “undisclosed test or other data” — which is TRIPS compliant — which means that the obligation upon national

authorities not to use such information or data as grounds for marketing approval does not apply in case of the information or data becoming public, more recent FTAs adopt a looser approach by referring broadly to “information”, which implies that reliance on original data is precluded even in cases where the information has become available in the public domain.²⁵

Additionally, while TRIPS’ reference was confined to “new chemical entities”, recent United States FTAs encompass a more comprehensive category of products for data exclusivity protection. For example, the US–Bahrain FTA extends this to cover “new chemical products” as well.²⁶

The FTAs are also restricting the period under which national drug regulatory authorities can recognize foreign marketing approval decisions (referred to as the “non-reliance obligations”). Moreover, they also prevent the domestic regulatory authorities from relying on “safety or efficacy information submitted in support of the prior marketing approval in the other territory, for at least five years for pharmaceutical products from the date of marketing approval of the new product in the Party”.²⁷

Notably, there has been a change in the United States’ FTA position in dealing with the issue of data exclusivity since 2007 as a result of the Democrats gaining the majority in the US Congress. Thus, the USTR’s “Bipartisan Agreement on Trade Policy: Intellectual Property”, which emerged after the Democrats took control of Congress in January 2007, was intended to revise the FTA chapters of a number of agreements (with Colombia, Panama and Peru) in order to facilitate their ratification by relaxing the FTA’s demands on several of the health-related provisions.

The changes related to data exclusivity provide that if a party relies on marketing approval granted by the other party, for example by the United States Food and Drug Administration (FDA), and if that party grants approval within six months of an application for marketing approval by a person that produced the data, the five-year period begins when the drug was first approved in the United States (a so-called “concurrent period”). Although this will not completely abolish data exclusivity, it will shorten the period of protection awarded to data exclusivity by commencing the protection period in the country where the drug was first approved.²⁸

The FTAs are also restricting the period under which national drug regulatory authorities can recognize foreign marketing approval decisions

Several European Union AAs in the region include data exclusivity protection within their scope

The European Union also shares the United States' interest in the area of data exclusivity. The European Union's approach in this regard is less stringent and detailed than that of the United States. Several European Union AAs in the Region include data exclusivity protection within their scope. For example, the EU–Tunisia AA provides that data exclusivity must be provided for a period of at least five years from the date of approval. Accordingly, Annex V, Article 4 of the AA states:

The Parties to this Agreement shall protect undisclosed information in accordance with Article 39 of the TRIPS Agreement. Parties shall prevent applicants for marketing approval for pharmaceuticals and agricultural chemical products from relying on or referring to undisclosed test or other data submitted by prior applicants to the competent approval authorities for a period, from the date of approval, of at *least five years*, except where approval is sought for original products, or unless the first applicant is adequately compensated. Nothing in the present Article shall be interpreted as preventing Parties from disclosing data, as far as necessary, to protect public health against harmful effects of the products. The period of protection shall not exceed the period applying to the identical product in the country of origin or in the exporting country [emphasis added].²⁹

Notably, the above provision provides each country with the option of permitting the use of data as long as “adequate compensation” is made. In this case, the subsequent user may be required to pay compensation in order to be able use the information as long as the original owner of the data is compensated. The important issue for either country interested in using this option is to establish the guidelines needed for the award and determination of the adequate compensation.

Finally, several EFTA agreements also oblige parties to provide “adequate and effective protection of undisclosed information”³⁰ without defining what is meant by such adequate and effective protection levels, hence resulting in further ambiguity and vagueness in regard to the implementation of these agreements. However, in contrast to the United States and European Union FTA and AA approach, which extends data exclusivity to a minimum of five years, some EFTA agreements explicitly limit this period for a period not exceeding five years.³¹

The public health implications of data exclusivity

Data exclusivity is an independent monopoly which provides for an additional period of protection, even where no patent exists. Providing data exclusivity protection beyond those levels and boundaries prescribed under TRIPS restricts and limits the ability of states from using the flexibilities of TRIPS in accordance with their national needs and priorities. This also leads to “patent evergreening”, an expression referring to the process of maintaining patent protection for longer periods of time than would normally be permissible under the law.

One of the primary effects of data exclusivity will be on medicines that are not patented, particularly for those countries that are not members of the WTO and are not yet bound by TRIPS. Data exclusivity will also significantly affect those member states that did not recognize pharmaceutical product patents prior to TRIPS, as many products that are off-patent may be protected under test data protection. Accordingly, generic producers will have to wait for at least five years from the date of approval of the original medicine before obtaining registration for their own generics. This explains the rationale behind multinational pharmaceutical companies’ aggressive support for data exclusivity provisions under these bilateral agreements. As Sell explains, “Brand name pharmaceutical firms favour data exclusivity provisions because they offer new rights and opportunities to maximize returns on their products by delaying competition”.³²

On the other hand, where patent protection is awarded, data exclusivity may delay the introduction of cheap generic drugs into the market, thus maintaining higher monopoly prices of medicines for a longer period of time. Such measures prevent national regulatory drug authorities from using the clinical data developed by the originator to establish the safety and efficacy of a medicine in order to approve the marketing of a generic medicine that has already proven to be equivalent to the original one (Box 32). Moreover, even where approval is obtained from the patent owner, this is most likely to take place against high fees in royalties which would transfer the price burden to patients resulting in substantially raising the prices of medicines. This issue is extremely important because generic competition is one of the most effective market mechanisms for reducing the prices of medicines.³³

Data exclusivity is an independent monopoly which provides for an additional period of protection, even where no patent exists

Box 32.

The main effect of this provision will be on drugs which are not under patent, as the generic manufacturer will still be unable to use the originator's test data to obtain registration. In such an instance, data exclusivity acts as a *de facto* patent, preventing competition.

Source: Médecins sans frontières. *Access to medicines at risk across the globe: what to watch out for in free trade agreements with the US*. Geneva, 2004.

Growing evidence supports the claims that data exclusivity is more likely to result in significant price increases for medicines in developing countries, including some of those in the Region.³⁴ Data exclusivity will also deter generic manufacturers from seeking registration for their drugs given the costs of test data and low margins of generic production.³⁵

These effects have been particularly evident in the case of the US FTA with Jordan.³⁶ According to a recent Oxfam report, data exclusivity provisions under the US–Jordan FTA have resulted in delaying the introduction of generic drugs into the market, while also increasing the costs of medicines as a result (Box 33). This was also a key factor behind the increase in the prices of medicines which the country experienced during the past few years.

Data exclusivity will also empower pharmaceutical companies at the expense of public health and citizens' rights. Accordingly, this protection may in fact lead to a "complete lack of availability of essential medicines (either generic or originator versions) if originator companies decide for whatever reason not to market a drug in a given country"³⁷ as a result of the withholding power of patents which raises opportunities for anticompetitive conduct and monopoly pricing. This would arise when a brand-name originator drug does not even have to be registered (and thus available) in the country for generic competitors to be blocked from entry.

The protection of data exclusivity may in certain circumstances circumvent compulsory licensing. Arguably, if a generic producer in a certain country is granted a compulsory licence to overcome the patent, the producer will not be able to make effective use of the licence if they have to wait for the expiry of data exclusivity before

Box 33. The effects of data exclusivity requirements under the US–Jordan FTA

- TRIPS-plus rules, particularly data exclusivity, independently prevent generic competition for 79 per cent of medicines launched by 21 multinational pharmaceutical companies since 2001.
- Additional expenditures for medicines with no generic competitor, as a result of enforcement of data exclusivity, were between \$6.3m and \$22.04m.

Source: Oxfam. *All costs, no benefits: how TRIPS-PLUS intellectual property rules in the US–Jordan FTA affect access to medicines.* Oxford 2007.

the producer can get its generic version approved by the national drug regulatory authority and then put on the market.

Finally, some argue that data exclusivity protection has an unethical dimension.³⁸ Oxfam explains this by stating that “data exclusivity prohibits generic competition for a specified period of time. The alternative would be for generic manufacturers to repeat clinical trials of drugs to prove their safety and efficacy. However, doing this would violate medical ethics because clinical trial methodologies would require some patients be given placebos. Giving placebos when the safety and clinical validity of the medicine being tested is already established is unethical”.³⁹

Policy options and recommendations

Provision of public health and access to medicines should be placed at the forefront of countries’ priorities. Accordingly, developing countries must reject the inclusion of data exclusivity provisions under FTA and AA agreements. Moreover, these countries are advised to apply TRIPS’ provisions as the basis for protection standards. This is consistent with the IPRs Commission Report, which warned developing countries about the implications of data exclusivity by stating:

Countries may allow health authorities to approve equivalent generic substitutes by “relying on” the original data. Developing countries should implement data protection legislation that facilitates the entry of generic competitors, whilst providing

appropriate protection for confidential data, which may be done in a variety of TRIPS-compatible ways. Developing countries need not enact legislation the effect of which is to create exclusive rights where no patent protection exists or to extend the effective period of the patent monopoly beyond its proper term.⁴⁰

Moreover, the CIPIH Report also reaffirms this under Recommendation 4.20, which states:

“A public health justification should be required for data protection rules going beyond what is required by the TRIPS agreement”

Developing countries need to decide in the light of their own circumstances, what provisions, consistent with the TRIPS agreement, would benefit public health, weighing the positive effects against the negative effects. A public health justification should be required for data protection rules going beyond what is required by the TRIPS agreement. There is unlikely to be such a justification in markets with a limited ability to pay and little innovative capacity. Thus, developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS.

However, for those countries in the Region which have already signed FTAs and AAs, creative and strategic implementation of such agreements must take precedence. Accordingly, these countries’ aim should be focused on limiting the effects of data exclusivity provisions through the introduction of exceptions to data exclusivity protection within national legislations such as obliging an originator drug company to forfeit data exclusivity if the company fails to submit an application for marketing authorization in the country within one year of marketing authorization worldwide.⁴¹ Countries may also seek explicitly to express that data exclusivity be waived in the case of a compulsory licence or government use order.⁴²

Countries which signed agreements that include the option of permitting the use of data exclusivity against the payment of compensation to the original owner of the data should also use this regime. However, it is important for these countries to establish clear guidelines for the use of data and its compensatory regime.

Countries which have already signed bilateral agreements containing data exclusivity obligations, especially with the United States, are advised to enter into negotiations to revise their

agreements in order to benefit from the recent changes introduced by the United States Congress under the 2007 Bipartisan Agreement on Trade Policy in this regard.

Finally, countries of the Region must interpret data protection requirements in light of their national health policies bearing in mind the need and priority to facilitate the entry of generic manufacturers into their domestic market. Their point of reference should be Paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health, which states that the provision of protection should be “interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular to promote access to medicines for all”.

Countries of the Region must interpret data protection requirements in light of their national health policies

3. Extension of patent protection term

Patent protection is the most direct method of monopolizing and protecting pharmaceutical drugs and products. Longer patent protection means longer market monopoly standing hence less competition from other producers.

Before obtaining a patent, pharmaceutical companies normally file for patent registration at the research stage, before the company applies for drug registration.⁴³ However, depending on each country’s regime, the process of registering a drug may take up to eight years in some countries. The period of obtaining the patent grant may be the same as, or even longer, depending on the country.

Supported by multinational pharmaceutical companies, the United States has extended the period of patent protection under its bilateral FTAs with countries in the Region in order to compensate the originator of the drug for the time lost during the patent application and drug registration procedures. The United States views this as a legitimate right which must be granted in order to “compensate” its pharmaceutical companies for any “unreasonable” delays throughout patent examination or the registration process.

Patent protection term under TRIPS

Under TRIPS, patent protection is granted for 20 years from the date of filing. Accordingly, Article 33 of TRIPS states:

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.

The United States has been working towards extending the patent term beyond the 20 years prescribed under TRIPS through its bilateral FTAs

TRIPS is clear regarding this term of protection. It does not specify that a member state is obliged to extend the patent protection term for any reason (including delays in registering drugs or issuing patents) beyond the term prescribed under Article 33.⁴⁴ In fact, developing countries rejected this particular European and United States demand during the Uruguay Round. From what is taking place, it appears the developed countries are reopening this issue under bilateral trade agreements with developing and least developed countries.

Extension of patent term under bilateral trade arrangements

The United States has been working towards extending the patent term beyond the 20 years prescribed under TRIPS through its bilateral FTAs. The United States seeks to compensate its pharmaceutical producers for any “unreasonable” time which national patent offices or drug authorities take to approve the patent application.⁴⁵

The United States relies on the interpretation of the language of Article 33 itself by stating that TRIPS only provides the minimum period of protection. Therefore, countries may and should provide a longer patent protection period in order to maintain and attract higher levels of pharmaceutical FDI into the country. Several FTAs concluded with countries in the Region call for such an extension.

For example, although Article 17 of the 1999 Jordanian Patent Law provides that “the term of protection shall be twenty years beginning from the date of filing the application for registration pursuant to the provisions of this law”, the US–Jordan FTA extends that under Article 4.23 (a) by stating:⁴⁶

With respect to pharmaceutical products that are subject to a patent:

(a) Each Party shall make available an *extension of the patent term* to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process [emphasis added].

More recent FTAs have gone even further by demanding that an automatic patent term extension shall apply based on an extension in another country. For example, the US–Bahrain FTA, Article 14.8 (7), provides that:⁴⁷

When a Party provides for the grant of a patent on the basis of a patent granted in another territory, that Party, at the request of the patent owner, shall extend the term of a patent granted under such procedure by a period equal to the period of the extension, if any, provided in respect of the patent granted by such other territory.

More recent FTAs further extend the term of patent protection by linking test data protection to the patent term—thus linking drug regulatory authorities and patent protection by the national patent office—with the effect that for new products which are also patented, no generic drug can be registered, except with the consent of the patent owner, during the term of the patent including where the patent term is extended based on marketing approval “delays” as discussed above or due to delay in issuing the patent.⁴⁸

The public health implications of patent term extension

Additional patent term of protection will extend the patent holders’ monopoly rights term, thus maintaining higher prices of medicines for a longer period of time. This will also prevent generic producers from entering the market at an earlier stage, thus reducing the availability of generic drugs. It will also stifle competition and innovation in the pharmaceutical market.

Further, the vagueness of the terminology used in some of these bilateral agreements raises some practical difficulties. It is not clear what is meant by “unreasonable” delays, particularly if we take into consideration that countries have different human, physical and administrative resources and capabilities. This would make the process of establishing a unified global approach to what constitutes a “reasonable” practice more of an impossible task.

The costs of patent term extension are grave. For example, a recent study in the Republic of Korea concluded that the extension of patent terms is likely to cost the Korean National Health Insurance Corporation what amounts to 504.5 billion won (US \$529 million) for extending drug patents for three years and 722.5 billion won (US \$757 million) if it has to agree to a four-year extension as proposed under FTA negotiations with the United States.⁴⁹

Additional patent term of protection will extend the patent holders’ monopoly rights term, thus maintaining higher prices of medicines for a longer period of time

Policy options and recommendations

Countries must design their patent laws to take into consideration their levels of progress, needs and priorities. The patent protection regime should take into consideration the public health concerns of each country and should not prolong protection of pharmaceutical patents beyond those levels prescribed under TRIPS.

Countries negotiating FTAs must reject any provisions that may prolong the patent term beyond those prescribed under TRIPS. Alternatively, countries may insist or at least stipulate that a minimum period of time lapse before an extension could be required, or alternatively provide for a maximum period for such extension.⁵⁰ They must maintain the flexibilities awarded to them under TRIPS in this area. Therefore, developing countries must view this demand as a “legitimate” one that applies even in a number of developed countries. In this regard, the CIPIH Report recommends that:

Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.⁵¹

Countries which have already entered into FTAs extending and prolonging the term of patent protection must seek ways to clarify that such provisions do not hamper their access to and acquisition of medicines. When possible, these countries must seek ways to amend and clarify the FTA provisions to ensure that such protection does not impede the availability of medicines and the timely entry of generics into the market. In addition, these countries are advised to revise their agreements in order to benefit from the recent changes introduced by the United States Congress under the 2007 Bipartisan Agreement on Trade Policy in this regard.⁵²

4. Restrictions on parallel importation

The issue of parallel importation is closely affiliated with the exhaustion of intellectual property rights. Parallel imports are patented goods that have been purchased once those products have been placed legitimately in the market. A patent holder may have the exclusive right to manufacture its product and to put it on the market, but once the product is placed on the market, the principle of exhaustion means that the patent holder has no further right over the product. Thus, a patent holder cannot prevent the

Countries negotiating FTAs must reject any provisions that may prolong the patent term beyond those prescribed under TRIPS

subsequent resale of that product since its rights over the product have been exhausted by the act of selling it.⁵³

Parallel importation plays an essential role in the area of public health and access to medicines. This is an important tool to enable access to affordable medicines by taking advantage of price differences of pharmaceutical products in different markets. Accordingly, permitting some form of parallel imports provides opportunities for developing and least developed countries to shop for better-priced patented pharmaceutical drugs and medicines.

Parallel importation under TRIPS

TRIPS recognizes parallel importation by explicitly stating that intellectual property restrictions do not curtail its use. Accordingly, TRIPS allows member states to devise their own policies and exhaustion regime in relation to this issue, thus treating it as a national prerogative.

Accordingly, Article 6 of TRIPS states:

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

In addition, Article 28.1 of TRIPS also states:

A patent shall confer on its owner the following exclusive rights:

- (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;

However, the footnote to the same Article provides that "this right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6", which means that TRIPS does not oblige member states to confer an exclusive right to the title holder to import the protected product.

More recently, the Doha Declaration on the TRIPS Agreement and Public Health explicitly reaffirmed TRIPS' approach by emphasizing the right of developing countries to use this safeguard

This is an important tool to enable access to affordable medicines by taking advantage of price differences of pharmaceutical products in different markets

The issue of parallel importation has been of primary interest to the United States under its bilateral negotiation agenda

by permitting each country to set its own parallel importation and exhaustion regime in accordance with its priorities and levels of development. Article 4 (d) of the Doha Declaration on the TRIPS Agreement and Public Health states inter alia:

Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

- d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to *leave each Member free to establish its own regime for such exhaustion* without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4 [emphasis added].

Parallel importation under bilateral trade arrangements

The issue of parallel importation has been of primary interest to the United States under its bilateral negotiation agenda. Through its bilateral FTAs with a number of countries in the Region, the United States pressed hard to incorporate provisions seeking to restrict the ability of member states to use the flexibilities awarded to them under TRIPS in this area.

The United States has traditionally advocated a national exhaustion regime.⁵⁴ Although no explicit reference has been inserted to that effect under its FTAs, at least one FTA in the Region seems to restrict this option. The US–Morocco FTA, Article 15.9 (4) states:⁵⁵

Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory.

However, the footnote to the same article stipulates that:

A Party may limit application of this paragraph to cases where the patent owner has placed restrictions on import by contract or other means.

Although Morocco incorporated a national exhaustion regime prior to signing the FTA with the United States,⁵⁶ the FTA's provision not only limits and restricts parallel importation, but in fact prohibits its use by allowing the patent holder, through

contractual arrangements and contract laws, to segment markets and subsequently maintain price discrimination in order to preserve its patent right.

The public health implications of restricting parallel imports

Restrictions on and prohibitions of parallel importation will prevent developing countries, including those in the Region, from resorting to TRIPS flexibilities by not being able to use and benefit from the worldwide variation in prices of pharmaceutical drugs and medicines.

Moreover, these restrictions will also strengthen the pharmaceutical companies' dominant position as a result of the abuse of market monopolies. Research conducted in a number of countries supports this claim. In Kenya, for example, it was found that parallel importation reduced the price of first-line antiretroviral medicines to one-third of the price of the patented version.⁵⁷

These restrictions will therefore reduce developing and least developed countries' ability to import cheaper drugs, and will subsequently result in the maintenance of higher pharmaceutical prices in the country, reducing the affordability and availability of cheaper drugs and medicines in the domestic market. Take the cases of Glivec, an anti-blood-cancer drug, and Norvasc, a hypertension drug (the patent for which expired in 2007), for example. While both drugs were cheaply available in their generic form in India, the drugs were being sold in their patented form in the Philippines with a 90% increase in the price on the Indian market.⁵⁸

Policy options and recommendations

It is important to keep in mind that although this "flexibility" is available under TRIPS, it does not apply automatically but rather requires the enactment of a number of national legislative laws and tools. Accordingly, countries must nationally establish the legislative and regulatory framework needed for the creation of an exhaustion regime that takes into consideration their needs and priorities (Box 34).

Countries negotiating bilateral agreements must retain this flexibility by opposing the introduction of any restrictions and limitations on parallel importation and by adopting an

In Kenya, for example, it was found that parallel importation reduced the price of first-line antiretroviral medicines to one-third of the price of the patented version

international exhaustion regime. It is laudable to mention in this regard that a number of developing countries that have entered into FTAs recently, such as Chile, several Central American Free Trade Agreement (CAFTA) countries and Singapore, have managed to retain this flexibility by adopting an international exhaustion regime. As the IPRs Commission Report states:

Developing countries should not eliminate potential sources of low cost imports from other developing or developed countries. In order to be an effective pro-competitive measure in a scenario of full compliance with TRIPS, parallel imports should be allowed whenever the patentee's rights have been exhausted in the foreign country. Since TRIPS allows countries to design their own exhaustion of rights regimes (a point restated at Doha), developing countries should aim to facilitate parallel imports in their legislation.

Box 34. Types of exhaustion regime

1. Members may adopt the principle of *international exhaustion* of patent rights. Adoption of this principle in the national patent law would allow any party to import into the national territory a patented product from any other country in which the product was placed on the market by the patent holder or any authorized party.
2. Members may adopt *regional exhaustion* of rights, where adoption of this principle would allow the possibility of importing into the national territory a patented product originating from any other member state of a regional trade agreement.
3. The third option is that of *national exhaustion* of rights. This principle limits the circulation of products covered by patents in one country to only those put on the market by the patent owner or its authorized agents in that same country. In this case, there can be no parallel importation.

Source: Musungu S, Oh C. *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?* Geneva, South Centre and WHO, 2006.

Moreover, the CIPIH Report, Recommendation 4.19, states:

Developing countries should retain the possibilities to benefit from differential pricing, and the ability to seek and parallel import lower priced medicines.

Countries that have already committed themselves to restricting parallel importation under FTAs should seek and explore ways to amend or revise their national exhaustion regimes thus taking into consideration the flexibilities of TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health. Countries of the Region may also wish to consider cooperation by entering into an intraregional exhaustion arrangement similar to that applicable between the European Union member states. Alternatively, an international exhaustion regime would be preferable to the majority of developing and least developed countries including those in the Region.

Finally, countries of the Region which have not signed bilateral trade agreements—or signed such agreements without restrictions on parallel importation—and adopt a national exhaustion regime should review this regime and consider the adoption of an international exhaustion regime due to the benefits which this regime would offer, particularly in the field of accessing cheaper and more affordable drugs and medicines.

“Developing countries should retain the possibilities to benefit from differential pricing, and the ability to seek and parallel import lower priced medicines”

5. Early working exceptions (Bolar exception)

All patent laws provide for exceptions to the exclusive rights granted by a patent; however the scope and content of these provisions may vary from one country to another.⁵⁹ This confirms that patent rights are not absolute but rather subject to constraints and limitations. Exceptions are often designed to foster and promote the transfer of technology, to prevent the abuse and anticompetitive practices of intellectual property, to foster research and innovation, and to protect public policy priorities and health.

In the field of pharmaceutical drugs, the early working exception, or the so-called “Bolar exception”, is frequently used in a number of developed countries such as Canada. This important exception facilitates the production and introduction of generic medicines into the market on the date of patent expiry. Accordingly, this exception permits the use of an invention for the purpose of obtaining approval of a generic product before the patent actually

This important exception facilitates the production and introduction of generic medicines into the market on the date of patent expiry

expires and without having to obtain the patentee's approval. This exception has important implications for developing countries and their ability to obtain generic drugs in a speedy manner.⁶⁰

This exception was first introduced under the 1984 United States Drug Price Competition and Patent Term Restoration Act to permit the testing of a patented medicine to establish the bioequivalency of generic products before the expiration of the relevant patent. The WTO ruled that the use of this exception is TRIPS-compliant.⁶¹

Early working exception under TRIPS

In conjunction with its proviso, Article 30 of TRIPS states:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

This provision applies provided that such an exception is drafted under the national patent law. More important, the article does not define the nature of the permissible exceptions; it grants countries considerable discretion in this area. The key point is to ensure that the exception “does not unreasonably conflict” with the normal exploitation of the patent, “does not unreasonably prejudice” the legitimate interests of the patent owner, and “takes into account” the legitimate interests of third parties.

Paragraph 5(a) of the Doha Declaration on the TRIPS Agreement and Public Health also stresses the importance of the object and purpose of TRIPS in the implementation and interpretation of the agreement, justifying the incorporation and use of such exceptions under the national laws and legislation of the member states.

It is noteworthy to state that this controversial issue was touched upon by the dispute between the European Union and Canada under the *Canada—patent protection of pharmaceutical products* case; the WTO in its final decision stated that such an extension was allowed under TRIPS. Accordingly, the WTO Dispute Settlement Panel residing over the case concluded that:⁶²

On balance ... the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced

by delays in marketing approval was neither so compelling nor so widely recognized that it could be regarded as a “legitimate interest” within the meaning of Article 30 of the TRIPS Agreement.

In addition to the Bolar exception, there is another exception which falls under the Article 30 category of exceptions; it is the “exception for research or experimental use” of an invention. This exception—which is widely included in many national patent laws around the world⁶³—allows the use of a patented product in experimentation, for both scientific as well as commercial purposes, without the consent of the patent holder. This exception plays a significant role in the process of encouraging innovation, dissemination of knowledge and transfer of technology.⁶⁴

The early working exception under bilateral trade arrangements

A number of United States FTAs with countries in the Region contain restrictions and limitations on the use of the early working exception. For example, under the Moroccan Industrial Property Law, the early working exception falls under Article 55.b of the law which provides that “The rights conferred by a patent shall not extend to ... (b) acts performed for experimental purposes relating to the subject-matter of the patented invention”. However, Article 15.9 (6) of the US–Morocco FTA adopts a more restrictive approach in this regard by stating:⁶⁵

... If a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product, that Party shall provide that any product produced under such authority shall not be made, used or sold in the territory of that Party other than for purposes related to generating information to meet requirements for approval to market the product, and if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party.

Once again, the provisions of such bilateral FTAs are in fact placing restrictions on generic pharmaceutical companies by limiting the use to meeting requirements for approval. Although the Bolar exception allows generic producers to import, manufacture

A number of United States FTAs with countries in the Region contain restrictions and limitations on the use of the early working exception

and test a patented product prior to the expiry of the patent and without obtaining the approval of the patentee, the above restrictions limit the use to only meeting the requirements for approval while the export restriction on the other hand means that exports are only allowed for the purposes of seeking registration in the host-exporting country.

The provisions of such bilateral FTAs are in fact placing restrictions on generic pharmaceutical companies by limiting the use to meeting requirements for approval

Public health implications of restricting early working exceptions

The early working exception is vitally important to both producers and importers of generic drugs and medicines. For producers of generics, the early working exception will enable them to produce drugs at an earlier time to compensate for the lapse of the patent. This can speed up the process by up to three years. For importers of generic drugs and medicines, incorporating this exception nationally will enable generic products of a foreign pharmaceutical generic producer to gain regulatory approval and to enter the market soon after the expiry of the patent.

The practical interpretation of these provisions under these discussed FTAs may result in limiting TRIPS' flexibilities. Under these FTAs, exportation is only permissible for the purpose of registration. Accordingly, this will restrict and delay the generic producer by forcing it to conduct all the needed tests in addition to the production of quantities necessary for marketing approval to be undertaken in each country where the registration is sought, hence resulting in additional costs and consuming more time.⁶⁶

This will have negative implications by delaying pharmaceutical generic manufacturers from marketing their generic drugs and medicines at an earlier stage. This will affect the affordability and prices of pharmaceutical products in many developing and least developed countries as well.

In addition, restrictions on the research and experimental use of inventions are also likely to restrict developing and least developed countries' ability to use the knowledge available and may preclude them from developing their national innovative capacity.

Policy options and recommendations

Countries of the Region must preserve their interests and discretion in this area by incorporating the early working exception and

the research and experimental exception within their national patent legislations. Moreover, for those countries in the process of negotiating bilateral trade agreements, it is crucial that they retain their autonomy through the preservation of their right to incorporate patent exceptions aimed at ensuring public health and access to medicines.

Countries are advised to also use the 2000 WTO ruling approving the legality of this exception as their starting point in their negotiations.⁶⁷ Moreover, the CIPIH Report, Recommendation 4.24, states:

Countries should provide in national legislation for measures to encourage generic entry on patent expiry, such as the “early working” exception, and more generally policies that support greater competition between generics, whether branded or not, as an effective way to enhance access by improving affordability. Restrictions should not be placed on the use of generic names.

Moreover, the IPRs Commission Report also affirms this by stating that:

Developing countries should include an appropriate exception for “early working” to patent rights in their legislation, which will accelerate the introduction of generic substitutes on patent expiry.⁶⁸

Countries which have already signed FTAs containing restrictions on the use of the early working and the research and experimental exceptions must undertake vital measures to either revise their FTA agreements by allowing generic producers to rely on this exemption not only for registration purposes but to also manufacture and produce the drug and by also removing the requirement that the export is only permissible for purposes of registration in the country from where the export emanates and to clarify (through revision of the agreement if necessary) that export is permissible for purposes of obtaining marketing approval in third countries. Alternatively, these countries should aim to obtain reassurances from their FTA partners explaining that these provisions would not stand in the way of ensuring the timely entry of generics into the domestic markets of these countries.

6. Patentability of “new use”

As previously explained, the term of patent protection is 20 years from the date of filing. In addition to the above discussed

Countries of the Region must preserve their interest and discretion in this area by incorporating the early working exception

exceptions against a patent's exclusive rights, there is also the possibility for member countries to exclude from patentability "new uses" of patents.

The idea behind "new uses" patent protection is to allow new uses of known substances to be protected all over again. Accordingly, "new use" refers to issuing a patent on the new use(s) of an already known substance (Box 35). Therefore, if a certain drug was found to work in another field that it was not protected under, a further additional period of patent protection would be awarded for such an already known and registered drug. This could result in extending patent protection for a substantial period of time.

This issue has been enormously important for the United States and some European pharmaceutical capabilities. The rationale behind their position is that providing protection for "new use" gives pharmaceutical companies the incentive to extend the original use of the product and provides an additional opportunity for originator companies to recoup their investment where marketing approval occurs late in the patent life, so that the additional protection afforded extends beyond the duration of patent protection term.

However, the importance of this issue can be seen when one takes a look at recent figures of new approved chemical products. For example, the number of new chemical entities approved for use by the United States Food and Drug Administration (FDA) declined to 27 in 2000, compared to about 60 in 1985 while the number of patents

Patentability of "new use" could result in extending patent protection for a substantial period of time

Box 35. Defining "new use"

"New use" patents arise in one of two circumstances;

1. Where a new pharmaceutical use is discovered for a product not previously used as a pharmaceutical product—that is, the first medical indication; and
2. Where a product already known to have pharmaceutical use(s) is discovered to have a further pharmaceutical use that is unrelated to the known use(s)—that is, the second medical indication.

Source: Musungu S, Oh C. *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?* Geneva, South Centre and WHO, 2006.

granted in the main patent class for new drug compositions (424) was 6730 in 2000.⁶⁹ These figures indicate that the majority of recent patents are related to variations in production processes, new formulations or crystalline forms, new combinations of known products and new uses of known drugs.⁷⁰

“New use” under TRIPS

TRIPS obliges member states to provide protection for pharmaceutical products and processes in accordance with the criteria prescribed under Article 27. Accordingly, Article 27.1 of TRIPS provides that:⁷¹

... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

TRIPS does not oblige member countries to grant patent protection on new uses of existing substances.⁷² As Correa explains, “such an invention relating to the use of a product may be deemed as a non-patentable because it consists of the discovery of an existing property rather than a new development, or because it falls under the exclusion from patentability (allowed by the Agreement—TRIPS—and most national laws) of therapeutic methods”.⁷³ Therefore, what TRIPS requires in relation to patentability criteria is that inventions must be *new*, include an *inventive step* and be *capable of* industrial application, and therefore countries may deny the patentability of new uses for lack of novelty, inventive step or industrial applicability.⁷⁴ In this regard, the WTO member countries enjoy a considerable amount of policy space and freedom to determine how to address and draft such criteria.

Patentability of “new use” under bilateral trade arrangements

The United States is leading the way in pushing for the inclusion of “new use” patentability protection within its bilateral trade agreements signed with countries of the Region. However, the United States does not take a uniform approach to this issue in its FTAs; it tends to vary from one agreement to another.

**The US–Morocco
and US–Oman
FTAs extend
protection for all
new uses**

For example, the US–Morocco FTA stipulates that:

The Parties confirm that patents shall be available for any new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals.⁷⁵

Moreover, Article 15.9 (1) b of the US–Oman FTA provides that:

Each party confirms that it shall make patents available for any new uses for, or new methods of using, a known product, including new uses and new methods for the treatment of particular medical conditions.

Thus, the US–Morocco and US–Oman FTAs extend protection for *all* new uses despite the fact that both countries' national patent legislations do not provide protection for new uses. The subsequent United States FTAs shows that more demands—and thus less flexibility—have been incorporated under these FTAs in this respect.

Public health implications of patenting “new use”

One of the serious implications of the introduction of patentability for new use under bilateral trade agreements relates to the area of pharmaceutical innovation for new medicines. New uses will in fact prolong the monopoly of pharmaceutical patents thus strengthening multinational pharmaceutical companies' standing in the market.

As is known, the pharmaceutical industry is an extremely competitive one in which the levels of innovation range between major “blockbuster” breakthroughs to minor improvements of already existing medicines. More recently, research conducted has indicated that the majority of registered new innovations are not new but rather are used merely for a new purpose. For example, according to a 2005 survey published in France, it was found that 68% of the 3096 new products approved in France between 1981 and 2004 brought “nothing new” in comparison to previous preparations.⁷⁶

Awarding protection to new uses will stifle innovation and restrict the ability of pharmaceutical companies, particularly those in the developing world, from producing advanced medications needed for eradicating local disease. This requirement will also block the introduction of generics, particularly in those countries

where pharmacy laws do not permit generic substitution and/or generic prescribing. Consequently, this will have anticompetitive consequences and bring higher prices of medications.

Policy options and recommendations

Countries are encouraged and advised to make use of the policy space for patentability criteria available to them under TRIPS. Developing and least developed countries must undertake immediate and serious steps to explicitly exclude new uses from patentability criteria under their national patent legislation.⁷⁷ In this regard, the CIPIH Report provides under Recommendation 4.27 that:

Governments should take action to avoid barriers to legitimate competition by considering developing guidelines for patent examiners on how properly to implement patentability criteria and, if appropriate, consider changes to national patent legislation.

Moreover, the IPRs Commission also recommends that:

Most developing countries, particularly those without research capabilities, should strictly exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products.⁷⁸

Countries that have already signed FTAs should undertake the needed legislative steps to use what is left to them of policy space. They should also take the necessary steps to revise and even amend their FTAs to ensure that there are no long-term negative consequences for their national pharmaceutical innovation and the transfer of technology arising from these FTA requirements.

7. Conditions on the granting of compulsory licences and government use

Compulsory licensing was one of the important safeguards which was retained under the Uruguay Round as a result of the developing and some developed countries' insistence. Exceptionally, compulsory licensing, a central and essential element for any public health regime, permits the production or importation of a generic medicine without the consent of the

**New uses will
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Countries that have already signed FTAs should undertake the needed legislative steps to use what is left to them of policy space

patent holder (subject to it receiving adequate compensation) in certain situations including, but not limited to, public health emergencies and epidemics. In addition, compulsory licensing may be granted to enable the production of generic versions of patented medicines or their importation from foreign producers.

In addition to compulsory licensing, there is also the issue of public, noncommercial use of patents or what is referred to as “government use” licensing. Although similar in concept, the difference between compulsory licensing and government use is that government use patents may be “fast-tracked” because of the waiver of the requirement for prior negotiations with the patent holder, thus speeding the process of issuing the licence. Moreover, government use is limited to public, noncommercial purposes, whereas compulsory licensing would also cover instances of private and commercial use.

The importance attached to this issue has increased over the past few years, particularly after the Doha Declaration on the TRIPS Agreement and Public Health, which also affirmed the right of countries to resort to this flexibility in accordance with TRIPS. Moreover, reliance on this flexibility by a number of developing countries during the past few years is also growing. For example, in 2003, Malaysia became the first country in Asia to issue a “government use” licence for the importation of generic antiretroviral (ARVs) drugs following the Doha Declaration on the TRIPS Agreement and Public Health. Subsequently, this resulted in reducing the average cost of the Malaysian ministry of health’s treatment per patient per month from US \$315 to US \$58, an 81% reduction.⁷⁹ Musungu and Oh explain:

In 2003, the Malaysian government used the provisions of its patent law to allow for the importation of generic ARVs from India for use in public hospitals. In 2004, both Mozambique and Zambia issued compulsory licences for the local production of ARVs. In the same year, the Indonesian President also issued a decree authorizing the government use of patents related to two ARVs, empowering the Minister of Health to appoint a pharmaceutical company to undertake local production of these medicines. ... In South Africa and more recently Kenya, licences have been granted to local manufacturers by patent holding companies for the production of ARVs.⁸⁰

It is interesting in this regard to note that historically, developed countries—Canada in particular—were the primary users of compulsory licensing in the area of pharmaceuticals. In addition, the United States has also been active in using compulsory licensing and government use in many sectors, including pharmaceuticals.⁸¹

Compulsory licensing and government use under TRIPS

TRIPS and the 2001 Doha Declaration on the TRIPS Agreement and Public Health explicitly acknowledge compulsory licensing and government use licensing and grant member states considerable flexibility to determine their grounds.

TRIPS pays special attention to the issue of compulsory licensing and government use. This clause under TRIPS is one of the most detailed articles. The agreement deals with this issue under Article 31, which states:

Where the law of a Member allows for other use⁸² of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected ...

The article goes on to provide the general conditions needed for granting compulsory and government use licences. Thus, it refers to the steps needed to be undertaken before or after the issuance of a licence. To obtain a compulsory licence, the individual seeking the licence must prove that efforts were undertaken to obtain the licence from the right holder by offering reasonable commercial terms.⁸³ Moreover, the article also states that the scope and duration of the licence should be limited to the purpose of the licence and that the licence should be nonexclusive and nonassignable.⁸⁴

The article also stipulates that the use of the licence must be confined to the “predominant” supply of the domestic market, and that the right holder must be adequately compensated against the issuance of the licence.⁸⁵

Regardless of these general obligations, TRIPS does not stipulate the circumstances under which compulsory licences must be issued but rather leaves the door open for individual member states to determine such grounds. Moreover, in relation to government use, TRIPS does not define what is meant by “public, noncommercial purposes”, thus granting member states additional space and

In 2003, Malaysia became the first country in Asia to issue a “government use” licence for the importation of generic antiretroviral drugs

There are seven possible grounds for granting the compulsory government use licences

freedom to define such “purposes”. It is important in this regard that member states undertake the necessary legislative steps to include such grounds under their national legislations since these grounds do not apply automatically.

A recent survey based on an analysis of the various state practices around the world concluded that there are seven possible grounds for granting the compulsory government use licences.⁸⁶ These are as follows.

1. Refusal to license

This applies to instances in which the patent holder has refused over a reasonable period of time, to enter into a voluntary licensing agreement on reasonable commercial terms offered by the applicant. Such grounds are available, for instance, under German patent law, the patent law of the People’s Republic of China and Argentine patent law.

2. Public interest

This applies in cases in which the licence is issued to serve and preserve the public interest. Although this ground is available in some patent laws around the world, the scope of public interest often remains general, thus leaving the competent national authority the discretion and freedom to determine the ambit of public interest. Under some jurisdictions, public health has been identified as one of these grounds.

3. Public health and nutrition

This applies in cases in which the ground is explicitly authorized to serve and preserve the public health and nutrition within the country. This ground also covers steps undertaken to ensure the availability and affordability of medicines within the country. The French and the Egyptian intellectual property laws provide such a ground.

4. National emergency

This ground is also available under many legislations, which allow the use of the patent without the consent of the patent holder in situations of national emergency. Under this ground, the requirement for prior negotiations for a voluntary licence is also waived. There is also full space for countries—also reiterated under the Doha Declaration on the TRIPS Agreement and Public Health⁸⁷—to

determine what constitutes a national emergency, which may also apply in cases of large-scale national disease epidemics.

5. Anticompetitive practices

This ground is justified in order to curtail any anticompetitive practices by the right holder. TRIPS itself attaches specific importance to this issue by referring to this ground explicitly under Article 31(k). TRIPS allows for the waiver of certain conditions, including the requirement for prior negotiations for a voluntary licence, in order to meet this ground. Article 31(k) also provides the need to correct anticompetitive practices may be taken into account in determining the amount of remuneration in such cases.

6. Dependent patents

Under this ground, a compulsory licence may be granted on the basis of certain conditions, in which a new invention requires the use of a preexisting patented invention for working. Article 31(l) of TRIPS specifically refers to this ground.

7. Failure to exploit or insufficiency of working

This ground applies if a patent has been granted but the invention is not being exploited in the territory of the country or is insufficiently exploited. The working of a patent is understood to be the execution or exploitation of the patent in the country of registration. This ground is referred to and included under Brazilian patent law.⁸⁸

Moreover, the 2001 Doha Declaration on the TRIPS Agreement and Public Health confirmed that countries have the right to use the necessary measures to protect public health and to define the grounds for compulsory licensing within their national legislations. Accordingly, Articles 4 and 5(b) of the declaration state:

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

Public health and nutrition also cover steps undertaken to ensure the availability and affordability of medicines within the country

5. (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

As mentioned, TRIPS states under Article 31(f) that compulsory licensing may be allowed as long as it is used for the “predominant” supply of the domestic market. This however poses some difficulties for those developing and least developed countries with inadequate pharmaceutical production capacity, thus preventing them from resorting to this valuable flexibility when needed. This issue was dealt with by adopting the waiver of Articles 31(f) and 31(h) of TRIPS under the 30 August 2003 WTO decision. This was later finalized under the agreement reached in December 2005 by transposing it into a permanent amendment to TRIPS.⁸⁹

“Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”

Compulsory licensing and government use under bilateral trade arrangements

In the Region, only one of the four existing FTAs signed appears to have restrictions on compulsory licensing and government use—the US–Jordan FTA. The US–Jordan FTA restricts the grounds under which a compulsory licence and government use may be granted when compared to the national law.⁹⁰ Article 4.20 of the FTA states:

Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances:

- (a) To remedy a practice determined after judicial or administrative process to be anticompetitive;
- (b) In cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or
- (c) On the ground of failure to meet working requirements, provided that importation shall constitute working.

Where the law of a Party allows for such use pursuant to subparagraphs (a), (b) or (c), the Party shall respect the provisions of Article 31 of TRIPS and Article 5A(4) of the Paris Convention.

Clearly, the US–Jordan FTA—signed prior to the Doha Declaration on the TRIPS Agreement and Public Health—substantially erodes the flexibility of TRIPS for Jordan by specifying that the country can

resort to compulsory licensing and government use only in quite limited circumstances. For example, unlike the national patent law, the FTA restricts the use of the compulsory licence and government to “the use by government entities or legal entities acting under the authority of the government”.

In contrast to TRIPS’ permissive approach and the Doha Declaration on the TRIPS Agreement and Public Health’s awarding member states the right to determine the grounds for compulsory licensing within their national legislations, the US–Jordan FTA does the opposite by restricting this option to only the three grounds mentioned.⁹¹

Implications for restricting compulsory licensing and government use

Compulsory licensing and government use are vital tools for balancing the interest of users and patent right holders. Accordingly, restricting and limiting the ground of resorting to such flexibility would have a negative effect on public health and access to medicines upon developing and least developed countries (Box 36).

Box 36. Compulsory licensing in South Africa

In South Africa, the private sector is the major provider of medicines. Presently, the antibiotic azithromycin sells on the private market in South Africa for US\$18.42 per 500 mg tablet. Generic versions of the drug already existed—for example, in western Africa, Médecins sans frontières uses versions costing only US\$0.20 per 250 mg capsule or US\$0.40 for 500 mg. Suppose South Africa agreed to restrictions on compulsory licences in the Southern African Customs Union agreement with the US. This would mean that no generic manufacturer of azithromycin could receive a compulsory licence to market a more affordable version of the drug in the private sector. Patients would still be required to pay the more expensive price (or do without the drug).

Source: Médecins sans frontières. *Access to medicines at risk across the globe: what to watch out for in free-trade agreements with the US*. Geneva, 2004.

Restricting and limiting the ground of resorting to such flexibility would have a negative effect on public health and access to medicines

For example, World Bank research indicates that if the United States and Thailand went ahead and signed a proposed FTA, compulsory licensing that could have reduced the cost of second-line ARVs by 90% in Thailand would have been severely restricted. The World Bank concludes that issuing compulsory licences for second-line ARVs would represent a saving of US \$3.2 billion for the Thai national health budget over 20 years.⁹²

Moreover, restrictions on compulsory licensing and government use are likely to block the entry of essential generic drugs and medicines into the domestic market thus allowing pharmaceutical companies to retain market monopoly and higher prices of medicines. This will also have a negative effect on competition in the pharmaceutical market, especially in situations of emergency, urgency and public noncommercial use as a result of preventing governments from resorting to such remedy. In addition, these restrictions and limitations can undermine a government's ability to bargain for cheaper patented drugs or to promote competition by generic products that can reduce prices and increase access to medicines. Thus, even if not frequently used, the existence of compulsory licensing and government use in the domestic national legislation is most likely to act as a balancing tool and a bargaining chip in the hands of governments and national health authorities (Box 37).

Compulsory licensing may also be restricted by data protection. This is the case where some FTAs demand from a country the provision of data protection for a certain period (e.g. five years in the case of the US–Bahrain FTA) from the moment a product is given regulatory approval in that country. This protection amounts to an effective bar on compulsory licensing for that period of protection since this would prevent generic drugs from entering the market—even if the patent term has expired, and even if countries have issued compulsory licences that would otherwise allow them to sell on the market while a product is under patent—until the data protection expires because the generic producers cannot submit a marketing approval during that period.

Policy options and recommendations

Compulsory licensing and government use are central to public health policy. Although they may not be the answer to all public health problems, compulsory licensing and government use

Box 37. Compulsory licensing in Brazil

Brazil's efforts to freely provide ARVs are an often cited example of how the [Doha] declaration has strengthened the position of low and middle-income countries (LMICs). The Brazilian policy, announced in 1996, was made possible by the production and import of generic first-line and second-line treatments. With Brazilian compliance to TRIPS in 2005, the latter was no longer permitted and the cost of second-line became problematic. Threatening to introduce compulsory licensing, as permitted under the Doha Declaration, the Brazilian government pressured Abbott, Merck and Roche (manufacturers of lopinavir, indinavir, nelfinavir and saquinavir respectively) to substantially reduce prices, thus enabling more than 100 000 people to receive free treatment. In this case, while the threat of compulsory licensing yielded concessions by pharmaceutical companies, the flexibilities remained untested in practice.

Source: Kerry VB, Lee K, TRIPS, the Doha Declaration and Paragraph 6 decision: what are the remaining steps for protecting access to medicines? *Global health*, 2007, 3:3.

are an important balancing tool which should be nurtured and embedded within any national legal patent protection regime. Accordingly, countries in the Region should consider drafting adequate and accessible compulsory licensing and government use provisions within their national patent legislations. According to the UK Intellectual Property Commission, "an important barrier to compulsory licensing in developing countries is the absence of straightforward legislative and administrative procedures to put it into effect".⁹³

When embarking on such a process, developing and least developed countries are advised to incorporate as many grounds for compulsory licensing and government use as possible under their national patent legislation in order to maximize the benefits of the regime.⁹⁴ Moreover, it is vital that adequate, transparent, representative and simple guidelines and decision-making procedures are also created in line with the national law to facilitate the implementation and enforcement of these provisions.⁹⁵

Fixing remuneration and compensation rates due upon issuance of compulsory licensing and government use licences will also be

Compulsory licensing and government use are an important balancing tool which should be nurtured and embedded within any national legal patent protection regime

in line with the requirements of TRIPS. For example, the UNDP suggests the adoption of royalty guidelines to reduce uncertainty and to facilitate speedier decision making.⁹⁶ In addition, the CIPIH Report, Recommendation 2.10 states:

Countries should provide in their legislation powers to use compulsory licensing, in accordance with the TRIPS agreement, where this power might be useful as one of the means available to promote, inter alia, research that is directly relevant to the specific health problems of developing countries.

The IPRs Commission Report affirms this as well by stating that:

Developing countries should establish workable laws and procedures to give effect to compulsory licensing, and provide appropriate provisions for government use.⁹⁷

Moreover, countries in the Region must supplement their legislative effort by nationally incorporating Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, which was adopted on 30 August 2003 by the WTO's General Council.⁹⁸ Although it is loaded with many technical difficulties and ambiguities, developing and least developed countries are still advised to translate and implement the requirements of the Paragraph 6 solution under national law.⁹⁹

In this regard, the CIPIH Report asserts that:

- the Doha Declaration clarifies the right of governments to use compulsory licensing as a means of resolving tensions that may arise between public health and intellectual property and to determine the grounds for using it: developing countries should provide in their legislation for the use of compulsory licensing provisions, consistent with the TRIPS Agreement, as one means to facilitate access to cheaper medicines through import or local production
- developed countries and other countries with manufacturing and export capacity should take the necessary legislative steps to allow compulsory licensing for export consistent with the TRIPS Agreement
- the WTO decision agreed on 30 August 2003, for countries with inadequate manufacturing capacity, has not yet been used by any importing country: its effectiveness needs to be kept under review and appropriate changes considered to achieve a workable solution, if necessary.¹⁰⁰

However, as for these countries which have already signed FTAs containing restrictions on compulsory licensing and government use in the Region, it is recommended that they seek revision of their FTAs in order to clarify their willingness to resort to TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health in accordance with international standards. This may be undertaken by amending the agreements themselves through emphasizing their right to use such flexibility in accordance with their national interest in order to preserve their national public health regimes and institutions.

8. Patentability criteria, exemptions and revocation of patents

As discussed, the patentability criteria under TRIPS require patents to be *novel*, *inventive* and *capable of industrial application*. Although there is a common understanding that once such conditions are met, a patent must be granted, the truth of the matter is that these requirements are not strictly defined. Therefore they may vary from one country to another. Member countries have considerable freedom and discretion to draft these definitions under their national laws (Box 38). In this regard, a large number of countries do not define what an *invention* is since it is essential to allow a progressive adaptation of patent law to the advancement of science and technology.

In addition, the international intellectual property regime has for long exempted and denied protection to certain patentable inventions on a number of grounds and justifications such as those for the preservation of public order and morality.

Box 38. Standard for patentability criteria

There is no agreed international standard of absolute novelty, and, within limits, the developing countries may pick and choose from among the different approaches recognized in the domestic patent laws.

Source: Reichman JH. From free riders to fair followers: global competition under the TRIPS Agreement. *New York University journal of international law and politics*, 1997, 29:11–93.

The patentability criteria under TRIPS require patents to be novel, inventive and capable of industrial application

However, the manner of dealing with the issue of the scope of patentability differs from one country to another since this issue heavily relies on each country's level of progress, development and technological advancement. The definition of an *invention* itself constitutes a key aspect of any patent policy, with implications in other areas, such as industrial and public health policies. Therefore, for countries with high national innovative and technological production, drafting a broad and minimal scope of patentability would encourage and foster innovation within that country as a result of high levels of competition. On the other hand, for those countries which are net importers of technologies, their priority should be to focus on narrowing the scope of patentability in addition to incorporating as many exceptions as possible under the patent national law in order to be able to develop and create a viable technological base. This also applies in the case of pharmaceutical products.

On another related issue, most legal jurisdictions also provide a mechanism for the revocation and forfeiture of patents. This in most cases permits the revocation or forfeiture of the protected patent in the country on several grounds, including but not limited to the following:¹⁰¹ if the invention was not a patentable invention; if the patent did not comply with the requirements of national law; if the patent was granted to a person who was not the only or true owner of the patent; or if the patent specification did not disclose the invention in a clear manner to be performed by someone who is expert in the field.

The rationale behind this is that patent protection is provided in order to benefit society, and therefore awarding protection for patents that were obtained by misrepresentation or fraudulently, for failing to comply with the national laws, or not disclosing the invention in a proper and adequate manner so that society can benefit in exchange for protection; then these patents should not qualify for legal protection and should be subject to revocation.

Patentability criteria, exemptions and revocation under TRIPS

TRIPS does not define what is meant by an invention. The wording of Article 27.1 indicates that members have been left room to interpret in good faith the concept of "invention" within their legal systems. For example, members may define what is meant by "pharmaceutical substance" or "new form discoveries", if they

so wish. Accordingly, Article 27.1 provides that patents “shall be available for any inventions ... provided that they are new, involve an inventive step and are capable of industrial application”.

“Novelty” means that the claimed subject matter should be new in absolute terms, which means that it should not have been part of the “prior art” anywhere in the world.¹⁰² Accordingly, most countries in the world apply an absolute novelty requirement. Exceptionally, some countries maintain a double standard of novelty depending on whether the disclosure of the invention has taken place within or outside their territory. TRIPS however, does not demand a particular concept of novelty hence members may define this in accordance with their national plans.

Interpreting the requirement of inventive step may be more problematic in this regard. Correa explains that “defining ‘non-obviousness/inventive step’ is one of the most critical aspects of a patent regime, as it determines the level of technical contribution required to obtain a patent and the corresponding limitation on competition”.¹⁰³ This so since patent examiners are required to evaluate not only what is disclosed in the prior art but also what a person skilled in the art (such as a person trained and experienced in the field) could consider obvious in the light of such prior art.¹⁰⁴ Since TRIPS does not define this concept either, members are free to determine whether they want a system under which a myriad of incremental innovations¹⁰⁵ is patentable or one aimed at rewarding more substantive departures from the prior art.¹⁰⁶ Patent offices and courts can apply more or less lax or stringent criteria to determine nonobviousness/inventiveness.

There is the requirement of “industrial applicability”. Again, TRIPS does not define this. For example, in some countries, such as the United States, it is sufficient to show that the invention has utility, which obviously allows for a broader scope of patentability than the narrower concept of “industrial applicability”. The application of these requirements is problematic in chemistry and biosciences in the absence of concrete experimentation, since some of these are based on empirical sciences with low predictive capacity about the specific properties of obtainable substances. Patent claims should contain, as a minimum, a technically viable solution and not merely an unresolved problem or a speculative or intended result.

TRIPS does not define what is meant by an invention

The aim of the patent regime is the disclosure of information and spread of knowledge

One notion which is also important to the process of granting patents is related to disclosure. Article 29.1 of TRIPS provides that:

Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

Since the aim of the patent regime is the disclosure of information and spread of knowledge, the above article provides that lack of sufficient disclosure may be a reason for refusal of an application or invalidation of a patent. Correa stresses that this requirement “has particular importance in the chemical and pharmaceutical fields to enable the reproduction of the invention during the patent term (for instance, in the case of a compulsory license) or after patent’s expiry. A special consideration should be given to cases in which a large number (sometimes millions) of compounds belonging to a group characterized by common elements is claimed”.¹⁰⁷

In addition to the flexibility awarded in drafting the patentability criteria, TRIPS explicitly provides for a number of exemptions which may be excluded from patentability. Accordingly, Article 27.2 of TRIPS states:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

The fact that TRIPS does not define *ordre public* protection and morality gives member states additional room for flexibility. However, in addition to these general exemptions, TRIPS also specifically gives member countries the choice to exclude diagnostic, therapeutic and surgical methods and plant and animal varieties (these are often referred to as the patenting of life forms) from protection. Accordingly, Article 27.3 of TRIPS states:

Members may also exclude from patentability:

- (a) Diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

- (b) Plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.¹⁰⁸

It is clear that TRIPS grants member states considerable discretion in defining these aspects within their national legislation. In accordance with this approach, some countries established broad exceptions in this regard. For example, under the 1996 Brazilian law, the exception refers to all “living beings” except “transgenic microorganisms”.

Moreover, regarding the controversial issue of patenting of life forms, TRIPS obliges all member states to provide patent protection for all technologies, including protection for *some* life forms. Accordingly, patenting of microorganisms is obligatory while for plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than nonbiological and microbiological processes,¹⁰⁹ patent protection is optional. In relation to plant varieties, TRIPS grants member states the right either to protect these under their national patent laws or under some “effective *sui generis* system” of intellectual property protection. However, this system is not defined in TRIPS, nor what is needed for it to be “effective”. TRIPS does not require that states adopt the International Union for the Protection of New Varieties of Plants (UPOV) convention for plant variety protection. Once again, each country is free to choose in accordance with its national intellectual property objectives.

In relation to revocation and forfeiture of patents, Article 32 of TRIPS merely states:

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Thus TRIPS grants member states some freedom to determine and decide the conditions of patent revocation and forfeiture within their domestic laws as long as member states provide a judicial review mechanism for individuals to challenge the revocation or forfeiture of the patent nationally.

TRIPS also specifically gives member countries the choice to exclude diagnostic, therapeutic and surgical methods and plant and animal varieties

TRIPS grants member states some freedom to determine and decide the conditions of patent revocation and forfeiture

Patentability criteria, exemptions and revocation under bilateral trade arrangements

Some FTAs restrict member countries' ability to use the space available to them under TRIPS in the area of patentability criteria, exemptions and revocation under bilateral trade arrangements. This is achieved through defining the patentability criteria and limiting the scope of patentability exemptions by obliging member countries to provide protection for those exemptions that are explicitly excluded from TRIPS' ambit of protection.

For example, the US–Morocco FTA defines the “utility” criterion in accordance with the definition of the United States Patents and Trademark Office (USPTO) Guidelines. Accordingly, Article 15.9 (12) of the US–Morocco FTA states:¹¹⁰

Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.

Interestingly, the above language, which is based on the “utility guidelines” of the USPTO,¹¹¹ may be problematic for other developing countries where such guidelines are not in place, particularly in the context of biotechnological inventions where patent applicants “are known to claim information the effects and application of which they really do not know”.¹¹² In addition, the wording of the provision itself is not clear, particularly when one attempts to define what is meant by a *specific, substantial* and *credible* utility, hence allowing the possibility of considerably expanding the scope of patentability in this regard.

On the issue of patenting of life forms, both the United States and the European Union have shown considerable interest (Box 39). Although TRIPS gives member states the discretion to exclude patents for plants and animals under Article 27.3, a number of bilateral trade agreements contains obligations to provide patent protection for these types of patent. For example, the US–Morocco FTA, Article 15.9 (2), states:¹¹³

Each Party shall make patents available for the following inventions:

Plants and animals. In addition, the Parties confirm that patents shall be available for any new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals.

Box 39. Patenting of life forms

EFFECTIVE SUI GENERIS SYSTEM: Under TRIPS, all WTO members must start patenting life forms. Patenting of microorganisms is obligatory. For plants and animals, it's optional. Plant varieties, however, must either fall under countries' patent laws or some "effective *sui generis* system" of intellectual property protection. This system is not defined in TRIPS and no mention is made of UPOV. On several occasions, the EU has outlined what it understands by "an effective *sui generis* system", and it is essentially the UPOV approach.

UPOV: The UPOV Convention, a treaty governing the Union for the Protection of New Plant Varieties, gives patent-like rights to plant breeders working in the formal seed industry. It rewards a very narrow type of plant breeding, geared toward genetic uniformity and large scale monocultures. The 1991 Act of the Convention, which is the latest version and the one the EU pushes developing countries to comply with, has no Union-wide provision to respect the rights of farmers. It only says that member states that wish to provide some kind of derogation for farm-saved seed may do so only without affecting the basic monopoly rights that UPOV provides to the seed industry.

BUDAPEST: The Budapest Treaty on the Deposit of Microorganisms for the purpose of patent protection (1977) creates a union of countries operating common rules on filing samples of patented microorganisms. It is administered by the World Intellectual Property Organisation (WIPO). While TRIPS Agreement says that microorganisms must be patented, it says nothing about countries having to adopt and comply with the Budapest Treaty standards.

Source: GRAIN. *TRIPS-plus must stop*. Barcelona 2003. <http://www.grain.org/briefings/?id=119>.

This approach may be suitable and convenient for an industrial country that possesses an active national research base; however the situation will be different for the majority of developing and least developed countries with limited research capabilities, thus resulting in additional costs as a result of their inability to compete with foreign producers.

A number of bilateral trade agreements refer to the issue of revocation of patents. For example, the US–Bahrain FTA, Article 14.8 (4), states:¹¹⁴

Each Party shall provide that a patent may be revoked only on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation or inequitable conduct may be the basis for revoking or holding a patent unenforceable. Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available prior to the grant of the patent.

Although TRIPS awards member states some freedom to determine the grounds of patent revocation, the above provision places certain limitations on these states by prohibiting the revocation of patents on grounds other than those that would have justified a refusal to grant the patent: fraud, misrepresentation or inequitable conduct. The above limitation would also preclude measures to provide for forfeiture of the patent in the case where the grant of compulsory licence is insufficient to prevent abuse that might arise from the exercise of patent rights.¹¹⁵ Finally, the above restriction may also impose an administrative hurdle manifested in the prevention of pregranting of patent oppositions in the country.

Implications for restricting patentability criteria, exemptions and revocation

It does not seem to be in the interests of the majority of developing countries to strengthen patentability criteria along the lines of the FTAs and AAs. Developing and least developed countries will lose rather than gain anything from adopting wider patentability criteria in this area and from providing protection for plant and animal varieties due to high levels of competition with multinational pharmaceutical companies that invest much more in research and development than their counterparts in developing countries.¹¹⁶

These TRIPS-plus terms will have long-term negative implications upon innovation, technology transfer and the dissemination of technology in the pharmaceutical sector in developing countries. Patentability of plant and animal varieties is likely to become even more contentious in certain industries including that of

the biotechnology industry. In addition, these provisions are likely to strengthen the monopolistic position of multinational pharmaceutical companies by discouraging pharmaceutical companies in developing countries from investing in this area.

Limiting the grounds of patent revocation will deprive states from using policy space available to them under TRIPS. This will also extend protection to foreign-owned patents even if they have failed to disclose adequate information related to the invention. This will prevent local pharmaceutical companies from benefiting from the disclosure requirements and will preclude their efforts in conducting research and development based on the information already available and disclosed.

Policy options and recommendations

Countries must design their patent laws and patentability criteria to privilege their national priorities and objectives.¹¹⁷ TRIPS grants countries substantial discretion in relation to what may be patented. There is little evidence that defining patentability criteria in accordance with the provisions under the recent bilateral trade agreements will benefit developing and least developed countries in any manner.

Countries in the Region must draft patentability criteria that encourage research and foster creativity. Moreover, these countries must retain the policy space and flexibilities of TRIPS by rejecting obligations demanding the patenting of plant and animal varieties and for diagnostic, therapeutic and surgical methods. In support of this, the IPRs Commission recommends that:

Most developing countries, particularly those without research capabilities, should strictly exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products.¹¹⁸

The CIPIH Report provides some practical recommendations to be taken into consideration while implementing and drafting patentability criteria. Accordingly, Recommendation 4.27 of the CIPIH Report states:

Governments should take action to avoid barriers to legitimate competition by considering developing guidelines for patent examiners on how properly to implement patentability criteria

These TRIPS-plus terms will have long-term negative implications upon innovation, technology transfer and the dissemination of technology in the pharmaceutical sector in developing countries

and, if appropriate, consider changes to national patent legislation.

In the course of negotiating bilateral trade agreements, countries are advised to insist on retaining TRIPS' flexibilities. They may also use some preemptive strategies by already defining (and sticking to such definitions in negotiations) patentability criteria, exclusions and patent revocation grounds within their national legislation. Countries should also insist on the inclusion of a provision in their bilateral trade agreements which explicitly provides that nothing in these agreements shall be construed to prevent their adoption of measures aimed towards anticompetitive practices.¹¹⁹ Those countries which have already signed FTAs restricting their ability in this area need to undertake serious legislative steps to address this issue and exploit whatever available policy space is left to them in this regard.

Countries in the Region must draft patentability criteria that encourage research and foster creativity

9. Accession to certain TRIPS-plus agreements, treaties and conventions

TRIPS builds upon a number of international intellectual property agreements which were in force at the time of its creation in 1995. For example, TRIPS' standards for the availability, scope and use of intellectual property refer to and require compliance with Articles 1–12 and 19 of the Paris Convention, Articles 1–21 of the Berne Convention and Articles 2–7 and 16 of the Washington Convention.

Based on this, Article 2 of TRIPS states:

In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

Apart from these agreements and provisions that TRIPS explicitly incorporates and refers to, there is no obligation on member countries to accede and implement any other international intellectual property agreements, treaties, or conventions.

The situation under bilateral trade arrangements

The majority of bilateral free-trade association agreements signed between the United States and the European Union on the one hand and countries of the Region on the other oblige parties to join to several international intellectual property agreements outside the ambit of TRIPS.

For example, the US–Bahrain FTA, Articles 14.2 and 14.3, states:¹²⁰

2. Each Party shall ratify or accede to the following agreements:
 - a) The Patent Cooperation Treaty, as revised and amended (1970);
 - b) The Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite (1974);
 - c) The Protocol relating to the Madrid Agreement Concerning the International Registration of Marks (1989);
 - d) The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1980);
 - e) The International Convention for the Protection of New Varieties of Plants (1991) (UPOV Convention);
 - f) The Trademark Law Treaty (1994);
 - g) The WIPO Copyright Treaty (1996); and
 - h) The WIPO Performances and Phonograms Treaty (1996).
3. Each Party shall make best efforts to ratify or accede to the following agreements:
 - a) The Patent Law Treaty (2000); and
 - b) The Hague Agreement Concerning the International Registration of Industrial Designs (1999).

Moreover, the EU–Egypt AA, Annex VI, states:¹²¹

1. By the end of the fourth year after the entry into force of the Agreement, Egypt shall accede the following multilateral conventions on intellectual property rights:

TRIPS builds upon a number of international intellectual property agreements which were in force at the time of its creation in 1995

- the Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations (Rome, 1961);
- the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure (1977, amended 1980);
- the Patent Cooperation Treaty (Washington 1970, amended in 1979 and modified in 1984);
- the International Convention for Protection of New Varieties of Plants (UPOV) (Geneva Act 1991);
- the Nice Agreement concerning the international Classification of Goods and Services for the Purpose of the Registration of Marks (Geneva Act 1977 and amended in 1979);
- the Protocol relating to the Madrid Agreement concerning the international registration of Marks (Madrid 1989).

The obligations to accede to several TRIPS-plus agreements and conventions were not only confined to United States and European Union FTAs and AAs but are also included under EFTA bilateral agreements with several countries in the Region. For example, Annex V, Articles 2 and 3, of the EFTA agreement with Morocco states:¹²²

2. The States Parties to this Agreement which are not Parties to one or more of the agreements listed below shall undertake to obtain their adherence to the following multilateral agreements before 1 January 1999:
 - Patent Co-operation Treaty of 19 June 1970 (Washington Act, amended in 1979 and modified in 1984)
 - Protocol of 27 June 1989 relating to the Madrid Agreement concerning the International Registration of Marks;
 - Nice Agreement of 15 June 1957 Concerning the International Classification of Goods and Services for the Purposes of the Registration [of] Marks (Geneva Act 1977 amended in 1979).
3. The States Parties to this Agreement which are not parties to one or more of the Agreements listed below shall undertake to obtain their adherence to the following multilateral agreements before 1 January 2000:

- Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure
- International Convention of 2 December 1961 for the Protection of New Varieties of Plants (UPOV Convention);
- International Convention of 26 October 1961 for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations (Rome Convention).

Bilateral trade agreements make the signing and conclusion of these arrangements conditional upon the accession to these TRIPS-plus agreements by the partner developing country. While in the majority of cases, the United States or the European Union would have already joined these TRIPS-plus agreements, these bilateral agreements place the onus on developing and least developed countries to do so, without giving them choice to scrutinize and assess the value of acceding to these agreements upon their national economies and public health.

Moreover, a large number of these international agreements and conventions are controversial in nature and are likely to have a negative impact on developing and least developed countries—unless the country is well prepared in advance prior to joining these agreements—due to the limitations on policy space prescribed under these agreements. In fact, these agreements are not only controversial in developing and least developed countries but have also been opposed by a number of developed countries as well. For instance, until now, Canada refuses to ratify the WIPO internet treaties due to their negative impact and restrictive copyright requirements. It has been observed that the UPOV Convention¹²³ and the WIPO internet treaties stand out as having the most severe TRIPS-plus effect on the developing and least developed countries.¹²⁴

Implications for joining TRIPS-plus agreements

As discussed, there is no obligation which obliges member states to join any international agreement outside the ambit of TRIPS. Gradually, bilateral FTAs and AAs are in fact creating a complex web of international intellectual property agreements that are due to come in force upon their ratification by member states. If developing and least developed countries join these agreements

with little preparation and without taking into consideration their economic, social and legal effects, they will likely be burdened with more obligations and erode the flexibilities granted to them under the WTO and TRIPS.

However, it must be clarified that the implications of joining non-WTO intellectual property agreements are not uniform and are likely to vary from one country to another and from one agreement to another depending on the level of progress and technological development of each state. For example, the implications of the WIPO internet treaties for countries with high levels of information technology will vary from the implications for countries that do not have the capacity in the field of technology, hence having greater negative impact on the latter.

The implications of joining the Patent Cooperation Treaty (PCT) for developing and least developed countries are also grave. The agreement, which was signed in June 1970 in Washington and came into effect in June 1978—modified twice, in 1984 and 2001—provides for a system of international filing of patent applications in different countries through filing in one place. According to WIPO, the international application is subjected to what is called an “international search”. That search is carried out by one of the major patent offices¹²⁵ and results in an “international search report”: a listing of the citations of published documents that might affect the patentability of the invention claimed in the international application.

The problem with the PCT lies in the fact that a functioning system of patent protection in developing countries is still far short of the level in developed countries. The PCT, it is claimed, can assist developing states by increasing efficiency and reducing costs, but this objective is still too far from achievement. Although developing countries will benefit from the system, a lot more benefit will go to multinationals as they can file a single patent application for patent protection in various countries.¹²⁶ Joining the PCT means that developing countries must surrender their right to conduct and implement patent law, and this will make them dependent on the patent offices of the developed countries. Moreover, the PCT standards may increase the pressure on national patent offices to adopt low standards of patentability.

While joining these agreements may require little legal and economic effort on the part of the developed countries, developing and least developed countries will have to substantially raise their

Bilateral trade agreements make the signing and conclusion of these arrangements conditional upon the accession to these TRIPS-plus agreements

intellectual property standards, which will result in imposing additional economic, social, administrative and human resource costs on these countries.

Policy options and recommendations

Countries in the Region are advised to maintain the standards of TRIPS by not acceding to international intellectual property conventions or treaties which fall outside the WTO and TRIPS. However, if countries decide to join any of these agreements, a full cost-benefit analysis must be conducted first, to determine the likely effects of joining such a treaty or agreement. Accordingly, countries can accede to these agreements if they conclude that this will result in additional benefits to them.

The IPRs Commission Report also advises developing countries to consider the effects before joining these agreements by stating that¹²⁷ “developing countries should think very carefully before joining the WIPO Copyright Treaty” as a result of the restrictive nature this agreement has on the flow of knowledge and transfer of technology.

Incorporating the Doha Declaration into national patent law

This chapter outlines several issues with an impact on access to drugs and medicines arising from bilateral trade agreements and provides specific policy recommendations for countries in the Region. However, a further recommendation may be made in this regard in the light of the recent changes taking place under international law in the context of bilateral trade agreements.

The recommendation relates to the incorporation of the Doha Declaration on the TRIPS Agreement and Public Health into national patent law. Accordingly, countries in the Region which have already signed bilateral agreements or are in the course of negotiating such agreements should undertake the necessary steps to incorporate the provisions of the Doha Declaration on the TRIPS Agreement and Public Health under their national law.¹²⁸ In addition, countries in the Region should also insist on emphasizing the importance of public health by referencing the Doha Declaration on the TRIPS Agreement and Public Health under any bilateral agreement which deals with intellectual property protection. For example, Article 15.12 of the 2005 US–Panama FTA states:¹²⁹

A functioning system of patent protection in developing countries is still far short of the level in developed countries

1. The Parties affirm their commitment to the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2).
2. The Parties have reached the following understandings regarding this Chapter.
 - (a) The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all.
 - (b) In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540) and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively, the "TRIPS/health solution"), this Chapter does not and should not prevent the effective utilization of the TRIPS/health solution.
 - (c) With respect to the aforementioned matters, if an amendment of the TRIPS Agreement enters into force with respect to the Parties and a Party's application of a measure in conformity with that amendment violates this Chapter, the Parties shall immediately consult in order to adapt this Chapter as appropriate in the light of the amendment.

Endnotes

1. Recent bilateral free-trade arrangements have often taken a standard form and in certain cases even have identical chapter numbering. For example, intellectual property chapters under the US–Morocco and US–Oman FTAs are chapters 15 for both agreements, while intellectual property under the US–Australia and US–Chile FTAs are chapters 17.
2. For more see Coriat B, Orsi F, d’Almeida C. TRIPS and the international public health controversies: issues and challenges. *Industrial and corporate change*, 2006, 15(6):1033–62. Mirza states that “prior to the WTO Agreements many countries (India, China, Brazil, Malaysia, Thailand, Mexico, Argentina, Egypt, Canada) had either excluded pharmaceuticals from their patent systems or provided only process patents”. Mirza Z. WTO/TRIPS, pharmaceuticals and health: impacts and strategies. *Development*, 1999, 42(4):92–7, at 94.
3. TRIPS, Article 65.1. Article 65.4 of TRIPS also provides transitional periods for areas of technology not protected at the time of entry to TRIPS. It states that:

To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.
4. TRIPS, Article 65.2.
5. TRIPS, Article 66, and the 2001 Doha Declaration on the TRIPS Agreement and Public Health. However, for the purposes of these articles, developing country status is determined by the WTO and is based on a self-selection criterion. On the other hand, least developed countries are those countries identified as such by the United Nations criterion, which generally relies on the country’s national income, human resource weakness and economic vulnerability. For more on this classification see www.un.org and www.wto.org.
6. For an interesting analysis of the link between parallel trade and innovation see Li C, Maskus K. The impact of parallel imports on investments in cost-reducing research and development. *Journal of international economics*, 2006, 68:44–55.
7. TRIPS, Article 66, states that:

In view of the special needs and requirements of least developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least developed country Member, accord extensions of this period.

However, in the 2001 WTO Ministerial Meeting in Doha, least developed countries were granted an extension until 1 January 2013 to apply TRIPS’

- provisions, with the possibility of extension, and until 1 January 2016 for pharmaceutical patents. See WTO document IP/C/W/25.
8. For example, the US–Chile FTA, Article 17.12 (1) states:

Except as otherwise provided in this Chapter, each Party shall give effect to the provisions of this Chapter upon the date of entry into force of this Agreement
 9. See Cook D. *India's cheap drugs under patent threat*. BBC online, 15 February 2007.
 10. For more see Dhar B, Rao C. *Transfer of technology for successful integration into the global economy: a case study of the pharmaceutical industry in India*. Geneva, UNCTAD, 2002.
 11. *Public health, innovation and intellectual property rights: report of the Commission on Intellectual Property Rights, Innovation and Public Health*. Geneva, WHO, 2006 [hereafter the CIPIH Report], at 84.
 12. There are several LDCs in the Eastern Mediterranean Region: Afghanistan, Djibouti, Sudan and Yemen.
 13. See Dhar and Rao, *supra* 10, at 42.
 14. *Integrating intellectual property rights and development policy*. London, Commission on Intellectual Property Rights, 2002 [the IPRs Commission Report], at 162 and 163.
 15. Data exclusivity was first introduced in 1987 in a number of European countries to compensate for insufficient product patent protection. However, strong product patents are now available in all 27 EU member states. The rules on data exclusivity have been changed in the new European Union pharmaceutical laws adopted in 2004. See European Generic Medicines Association. Available at <http://www.egagenerics.com>.
 16. See IPRs Commission Report, *supra* 14, at 50.
 17. Watal J, ed. *Intellectual property rights in the WTO and developing countries*. London, Kluwer Law International, 2001, at 4.
 18. TRIPS, Article 39.3. In fact during the Uruguay Round, many countries rejected language requiring data exclusivity protection. For more see Correa C. *Protection of data submitted for the registration of pharmaceuticals: implementing the standards of the TRIPS Agreement*. Geneva, South Centre, 2002. See also UNCTAD–ICTSD. *Resource book on TRIPS and development*. Cambridge, Cambridge University Press, 2005.
 19. Reichman J. *Undisclosed clinical trial data under the TRIPS Agreement and its progeny: a broader perspective*. UNCTAD–ICTSD dialogue on moving the predevelopment IP agenda forward: preserving public goods in health, education and learning, Bellagio, Italy, 29 November–3 December 2004, at 11. Available at: http://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman_Bellagio4.pdf.
 20. Article 10bis, Paris Convention provides:
 - (1) The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.
 - (2) Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.
 - (3) The following in particular shall be prohibited:
 1. all acts of such a nature as to create confusion by any means whatever

- with the establishment, the goods, or the industrial or commercial activities, of a competitor;
2. false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;
 3. indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.
21. Due to domestic electoral changes, the United States recently loosened data exclusivity provisions under the FTAs with Columbia, Panama and Peru. For more see Roffe P, Vivas-Eugui D. A shift in intellectual property policy in US FTAs? *Bridges*, 5, August 2007, at 15. Available at www.ictsd.org. Also see IP Watch at <http://www.ip-watch.org/weblog/index.php?p=622>.
 22. US–Morocco FTA, Article 15.10.1. Also see the US–Oman FTA, Article 15.9.1(a).
 23. See US–Morocco FTA, Article 15.10.2. The same is also required under the US–Bahrain FTA, Article 14.9.2.
 24. The US–Bahrain FTA includes additional commitments which extend data protection beyond patent protection term. Article 14.9(3) of the FTA states:

When a product is subject to a system of marketing approval pursuant to Article 9.1 or 9.2 and is also covered by a patent in the territory of that Party, the Party *shall not alter* the term of protection that it provides pursuant to Articles 9.1 and 9.2 in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in Articles 9.1 and 9.2 [emphasis added].
 25. See US–Morocco FTA and US–Oman FTA, Articles 15.9.1(a).
 26. See US–Morocco FTA, Article 15.10.1, US–Bahrain FTA, Article 14.9.1(4), US–Oman FTA, Article 15.9.1, and US–Bahrain FTA, Article 14.9.1(b)(i).
 27. US–Bahrain FTA, Article 14.9.1(b)(i). Also see US–Oman FTA, Article 15.9.1(b)(i).
 28. For example, the US–Columbia FTA, Article 16.10(2)c, states:

Where a Party relies on a marketing approval granted by the other Party, and grants approval within six months of the filing of a complete application for marketing approval filed in the Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.
 29. On the other hand, the EU–Lebanon AA stipulates that data exclusivity must be provided for a period of at least six years from the date of approval. Thus, the EU–Lebanon AA, Annex V, Article 4, states:

The Parties to this Agreement shall protect undisclosed information in accordance with Article 39 [of] TRIPS. The Parties shall prevent applicants for marketing approval for pharmaceuticals and agricultural chemical products from relying on or referring to undisclosed test or other undisclosed data submitted by prior applicants to the competent approval authorities of the respective Parties for a period, from the date of approval, of at least six years, except where approval is sought for original products, or unless the first applicant is adequately compensated [emphasis added].

30. EFTA–Jordan, Annex VI, Article 3.
31. EFTA–Egypt, Annex V, Article 3(e) states:
Protection of undisclosed information in accordance with Article 39 of the TRIPS Agreement. The competent authorities, who receive undisclosed information as defined in paragraph 3 of Article 39 of the TRIPS Agreement, shall protect it against disclosure and unfair commercial use from the date of its submission to the competent authorities until it is no longer confidential, or for a period not exceeding five years, whichever comes first.
32. Sell S. TRIPS-plus, free trade agreements and access to medicines. *Liverpool law review*, 2007, 28(1):41–75.
33. In this regard, WHO’s 2002–03 medicines strategy provides that “generic substitution, in particular, has considerable potential for contributing to increased financial access. In fact, it is a proven cost-effective strategy for containing drug expenditure. The average price of generic drugs can fall by as much as 30% of the innovator drug price when the number of generic versions of the drug on the market increases”. *Medicines strategy: framework for action in essential drugs and medicines policy 2000-2003*. Geneva, WHO, 2003; available at www.who.int.
34. See El Said H, El Said M. TRIPS-plus implications for access to medicines in developing countries: lessons from the Jordan–United States Free Trade Agreement. *Journal of world intellectual property*, 2007, 10(6):438–75.
35. In Canada, the generics medicine industry, for instance, has estimated that a new data exclusivity law introduced into Canada will have a significant impact on access to medicines. According to their figures, if data exclusivity had been introduced in Canada, between 2001 and 2006, the additional cost to the Canadian government and consumers would have equalled US \$600 million. Canada recently introduced eight years of data exclusivity due to pressure exerted by the USTR and the pharmaceutical industry. The Canadian generics industry has now asked a Canadian court to overturn this decision. See *Generic drug makers launch legal challenge to new federal data exclusivity rules*. Canadian Generic Pharmaceutical Association, 14 November, 2006.
36. *All costs, no benefits: how TRIPS-plus intellectual property rules in the US–Jordan FTA affect access to medicines*. Oxford, Oxfam Briefing Note, March 2007.
37. *Access to medicines at risk across the globe: what to watch out for in free trade agreements with the US*. Geneva, Médecins sans frontières, MSF Briefing Note, May 2004.
38. See Correa C. Protecting test data for pharmaceutical and agrochemical products under free trade agreements. In Roffe P, Tansey G, Vivas-Eugui D, eds. *Negotiating health: intellectual property and access to medicines*. London, Earthscan Ltd, 2006; and Yu P. The political economy of data protection. *Chicago-Kent law review*, in press.
39. See Oxfam, *supra* 36.
40. IPRs Commission Report, *supra* 14, at 49.
41. See generally Oxfam, *supra* 36.
42. The Chilean experience provides some useful insight in this regard. Under its national law, the Chilean government sought to restrict the effects of the data exclusivity provisions provided under the US–Chile FTA by expressly excluding several issues from the scope of protection. For more on this see chapter 5.

43. MSF, *supra* 37.
44. Once again, it should be noted that patent term extensions were proposed and rejected by developing countries during the Uruguay Round. For more see UNCTAD-ICTSD. *Resource book on TRIPS and development*. Cambridge, Cambridge University Press, 2005.
45. This provision has its origins in the United States Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch–Waxman Act). This act, by granting an extension of the patent term for administrative delays in the FDA, awarded extensions for delays during the granting of the patent.
46. Similarly, the US–Morocco FTA, Article 15.10.3, states:
 With respect to any pharmaceutical product that is subject to a patent, each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.
 In this regard, Oxfam explains that “these measures even exceed US law, which includes limitations to ensure that the product is a truly novel medicine and which put a ceiling on the extension period”. Oxfam, *supra* 36, at 27.
47. US–Oman FTA, Article 15.8.7, provides:
 When a Party provides for the grant of a patent on the basis of a patent granted in another territory, that Party, at the request of the patent owner, shall adjust the term of a patent granted under such a procedure by a period equal to the period of the adjustment, if any, provided in respect of the patent granted in the other territory.
48. US–Bahrain FTA, Article 14.9(4) provides:
 Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the Party or in another territory, that Party:
 (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved method of use during the term of that patent, unless by consent or acquiescence of the patent owner; and
 (b) shall provide that the patent owner shall be notified of the identity of any such other person who requests marketing approval to enter the market during the term of a patent notified to the approving authority as covering that product.

The same requirement is also found under the US–Oman FTA, Article 15.9(4).

49. US FTA may cost drug industry \$1.2 billion: govt, *Hankyoreh*, 17 October 2006. Available at http://english.hani.co.kr/arti/english_edition/e_business/165065.html (last visited 21 January 2009).
50. For example, the US–Australia FTA limits this to a five-year period. See US–Australia FTA, chapter 17.
51. The CIPIH Report, *supra* 11, Recommendation 4.26.
52. See note 19. However, Under the United States 2007 Bipartisan Agreement revising the FTAs with Peru, Columbia and Panama, the mandatory *shall* obligation was changed to *may* with respect to patents on pharmaceutical products. See also US–Panama FTA, Article 15.9.6, which states:

With respect to any pharmaceutical product that is covered by a patent, each Party *may* make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in that Party [emphasis added].

53. Musungu S, Oh C. *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?* Geneva, South Centre and WHO, 2006, at 47.
54. Roffe P. *Bilateral agreements and a TRIPS-plus world: the Chile-USA Free Trade Agreement*. Ottawa, Quaker International Affairs Programme, 2004. TRIPS Issues Papers 4, at 19.
55. As for FTAs outside the Region placing restrictions, see the US–Australia FTA.
56. Article 53 of the Moroccan Industrial Property Law provides:
The following shall be prohibited, save with the consent of the patent owner:
(a) Making, offering, putting on the market or using a product that forms the subject-matter of a patent, or importing or stocking that product for such purposes.
57. See Oxfam, *supra* 36, at 32.
58. *Patents versus patients: five years after the Doha declaration*. Oxford, Oxfam Briefing Paper, November 2006.
59. See generally Garrison C. *Exceptions to patent rights in developing countries*. Geneva, International Centre for Trade and Sustainable Development, August 2006. ICTSD Project on IPRs and Sustainable Development. Issue Paper 17. Also see Correa C. *The international dimension of the research exception*. SIPPI Project, AAAS, Washington, DC, 2005. Available at http://sippi.aaas.org/Pubs/Correa_International%20Exception.pdf.
60. The early working exception, for example, has a significant impact on patent rights by speeding up the approval of generic competition by as much as three years. See Musungu and Oh, *supra* 53, at 54
61. The WTO Canada–EU Report states:
The “Bolar exemption” had been in existence for several years before the TRIPS Agreement was negotiated, and negotiators must have known of its existence. They apparently did not take issue with the proposition that it was a limited exception. Accordingly, the “Bolar exemption” must be an example of the type of exception that was intended to come within Article 30.
See *Canada—patent protection of pharmaceutical products*. Geneva, WTO, 2000. WTO Dispute Panel Report, WT/DS114/1 [hereafter WTO Canada–EU Report], at 28.
62. See Para 7.82 of the WTO Canada–EU Report, *ibid*.
63. According to Musungu and Oh, “national laws reviewed in Latin American and Caribbean countries all contained provisions relating to the research or experimental use exception; in Asia, 85% of the national laws reviewed provided for this exception, although the figure is lower in Africa at 59%”. Musungu and Oh, *supra* 53, at 56. Moreover, a large number of countries in the Region do incorporate such an exception under their national patent laws. For example, Article 14 of the 2002 GCC Uniform Patent Law states:

The rights under the patent shall not extend to acts carried particularly for scientific research purposes

Moreover, Article 21.2.c of the 1999 Jordanian Patent Law (as amended in 2001) contains both Bolar and research exceptions. The article states:

Notwithstanding the provisions of this Law or any other legislation, carrying out research and development, and submitting applications for obtaining approvals to market a product prior to the expiry date of the patent protection shall not be considered an act of civil or criminal infringement.

64. See Correa, *supra* 59.
65. The same article can be found under the US–Bahrain FTA, Article 14.8(5), and the US–Oman FTA, Article 15.8(5).
66. See Musungu and Oh, *supra* 53, at 114.
67. See the WTO Canada–EU Report, *supra* 61. The report found that Canada’s patent law (Section 55.2[1]), to allow early working for the purpose of obtaining marketing approval for pharmaceutical products, was not inconsistent with TRIPS, but that Section 55.2(2), allowing the manufacture and storage of articles intended for sale after the date on which the term of the patent expired, was not consistent with TRIPS.
68. IPRs Commission Report, *supra* 14, at 50.
69. IPRs Commission Report, *supra* 14, quoting *The odyssey continues: charting a path towards Pharma 2010*. Presentation given by Simon Hughes, PwC Consulting, at the DIA Euro Meeting, Barcelona, March 2001. Source: www.uspto.gov.
70. A *Harvard law review* paper comments on the issue of “minor variations” by stating that, “particularly in the case of the pharmaceutical industry, many ‘new’ drugs are only minor variations of existing products and do not provide any new therapeutic benefits. They are ‘invented’ solely to circumvent rival companies’ patents. Harvard Law Review Association. Standards of obviousness and the patentability of chemical compounds. *Harvard law review*, 1974, 87(3):607–28, at 613–4.
71. A footnote to the article states that “[f]or the purposes of this Article, the terms ‘inventive step’ and ‘capable of industrial application’ may be deemed by a Member to be synonymous with the terms ‘non-obvious’ and ‘useful’ respectively”.
72. In fact, some countries (such as the Andean countries) have explicitly excluded new use from their patent laws.
73. Correa C. *Intellectual property rights, the WTO and developing countries*. London, Zed Books, Third World Network, 2000, at 56.
74. Correa explains that under the TRIPS Agreement, “countries are free to expand patent protection beyond the general principles of patent law, but they are under no obligation to do so. WTO member countries are thus free to decide whether or not to allow the patentability of products for *first indication*”. See Correa C. *Integrating public health concerns into patent legislation in developing countries*. Geneva, South Centre, 2002, at 22.
75. US–Morocco FTA, Article 15.9(2). Also see US–Bahrain FTA, Article 14.8(2).
76. See Prescrire. A review of new drugs in 2004: floundering innovation and increased risk-taking. *Prescrire international*, 2005, 14(76):68–73.

77. Such an approach was followed under India's 2005 Amended Patent Law, which explicitly excludes new use from protection.
78. IPRs Commission Report, *supra* 14, at 50. Moreover, Malaysia continues to explore the flexibilities of TRIPS by encouraging domestic manufacturers of non-patented drugs. Ling explains that in 2003, "stavudine and nevirapine which are not patented in Malaysia were registered for local production in order to increase access to these drugs". Ling C. *Malaysia's experience in increasing access to antiretroviral drugs: exercising the "government use" option*. London, Third World Network, 2006.
79. Khor M. *Patents, compulsory licensing and access to medicines: some recent experiences*. London, Third World Network, February 2007, at 6.
80. Musungu and Oh, *supra* 53, at xv and xvi.
81. For example, in 2001 the United States authorities threatened to issue compulsory licences with regard to stockpiling Cipro (ciprofloxacin) following the anthrax scare. For more on use of compulsory licensing by the United States and Canada see Reichman J, Hasenzahl C. *Non-voluntary licensing of patented inventions: the law and practice of the United States*. Geneva, ICTSD-UNCTAD, 2003. Issue Paper 5.
82. "Other use" refers to use other than that allowed under Article 30.
83. See TRIPS, Article 31(b). However, in case of government use licensing, there is no need for such a process.
84. TRIPS, Article 31(c-f).
85. TRIPS, Article 31(f and h).
86. Musungu and Oh, *supra* 53.
87. Article 5.c of the Doha Declaration on the TRIPS Agreement and Public Health states:
Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
88. This ground has been credited with reducing the prices of key antiretroviral AIDS drugs including efavirenz and indinavir by 64% and 77% respectively. See Passarelli C, Terto V. *Good medicine: Brazil's multifront war on AIDS*. *NACLA report on the Americas*, 2002, 35(5), at 37.
89. Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003, WT/L/540, 1 September 2003. Several developed countries (including Canada, the Netherlands, Norway and Switzerland) have already moved since 2003 to change their domestic legislation to permit their producers to act as exporters under the compulsory licence regime agreed in WTO. Moreover, India's 2005 legislation also implemented the waiver. Notably, the amendment is not yet approved. For more on the waiver see the discussion in chapter 3.
90. Article 22.b of the 1999 Jordanian Patent Law states that:
1. The Minister may grant licences for the exploitation of an invention to other than the patentee and without his consent in any of the following cases: For relevant government departments or third parties licensed by such departments to use the patent, if such use is necessary for national

security, emergency situations, or for public non-commercial public benefit, provided that the patentee is notified as soon as practicable.

2. If the patentee fails to exploit the patent, or if exploitation thereof is insufficient, prior to the lapse of three years from the date of granting the patent, or four years from the date of filing the patent application, whichever period lapses later. However, the Minister may decide to grant the patentee extension period, if the reasons for non-use or insufficient use are beyond the patentee's control.

3. If it is decided judicially or administratively that the patentee practises his rights in a manner that deters third parties from fair competition.

91. However, the US–Jordan FTA was signed in 2001, prior to the Doha Declaration on the TRIPS Agreement and Public Health. In addition, several EFTA agreements with countries in the Region state that licences granted on the “grounds of nonworking shall be used only to the extent necessary to satisfy the domestic market on reasonable commercial terms”. See the EFTA agreements with Jordan, Tunisia and Morocco.
92. See Revenga A et al. *The economics of effective AIDS treatment: evaluating policy options for Thailand*. Washington DC, World Bank, 2006.
93. IPRs Commission Report, *supra* 14, at 44.
94. Interestingly, the World Bank argues that even in the absence of such national legislation, governments are not prevented from taking action to protect the public interest in a national emergency. *HIV/AIDS medicines and related supplies: contemporary context and procurement–technical guide*. Washington DC, World Bank, 2004, at 89.
95. It may be advisable to set up a multiagency committee at the national level, in order to enable the relevant agencies to discuss and take joint decisions in this regard. This approach would also avoid emphasis on litigation, which is an obvious benefit given that the legal systems in most developing countries are already overburdened. Notably, TRIPS does not prohibit administrative decision-making on compulsory licences and government use of patents.
96. UNDP. *Human development report 2001: making new technologies work for human development*. New York, Oxford University Press, 2001, at 107–8.
97. The IPRs Commission, *supra* 14, at 44.
98. See Abbott F, Puymbroeck R. *Compulsory licensing for public health: a guide and model documents for implementation of the Doha Declaration Paragraph 6 decision*. Washington DC, World Bank, 2005.
99. For a comprehensive and detailed overview see Abbott F, Reichman J. The Doha Round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions. *Journal of international economic law*, 2007, 10(4):921–87.
100. The CIPIH Report, Recommendations 4.13, 4.14 and 4.15 subsequently. In 2007, Rwanda became the first to notify the WTO of its plans to import the HIV drug ApoTriAvir from the Canadian company Apotex and that it will not enforce any patents granted in that respect in the country. See *Rwanda notification under Paragraph 2(a) of the Decision of 30 August 2003 on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*. Geneva, WTO, 19 July 2007. Doc. IP/N/9/RWA/1.
101. For example, the 1977 UK Patent Act, Section 72, prescribes the grounds of revocation to if and only if:

- (a) the invention is not a patentable invention;
 - (b) the patent was granted to a person who was not the only person entitled under section 7(2) above to be granted that patent or two or more persons who were not the only persons so entitled;
 - (c) the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art;
 - (d) the matter disclosed in the specification of the patent extends beyond that disclosed in the application for the patent, as filed, or, if the patent was granted on a new application filed under sections 8(3), 12 or 37(4) above or as mentioned in section 15(4) above, in the earlier application, as filed;
 - (e) the protection conferred by the patent has been extended by an amendment which should not have been allowed.
102. Correa, *supra* 73, at 57. Also see Correa C. *A guide to pharmaceutical patents*, vol 1. Geneva, South Centre, 2008.
 103. Correa C. *Guidelines for the examination of pharmaceutical patents: developing a public health perspective*. Geneva, ICTSD, WHO, UNCTAD, 2006.
 104. In the United States for example, in order to be patentable, an invention needs to be non-obvious for an ordinary scientist or engineer specialized in the art/field at the time the invention was made.
 105. “Incremental innovations” (as opposed to “major” innovations) are modifications such as improvements or adaptations of existing products and processes. Irrespective of their practical usefulness, such improvements may be obvious to develop for a person having ordinary skills in the art. See Correa, *supra* 103.
 106. Correa, *supra* 103, at 4.
 107. Correa, *ibid.* at 29.
 108. TRIPS requires a review of Article 27.3(b), which deals with whether plant and animal inventions should be covered by patents and how to protect new plant varieties. However, the discussion was broadened after the Doha Declaration made it clear that the TRIPS Council should also look at the relationship between TRIPS and the UN Convention on Biological Diversity (CBD) and at the protection of traditional knowledge and folklore. Most recently discussed are proposals on disclosing the source of biological material and associated traditional knowledge. For more on the review see www.wto.org. On the relationship between TRIPS and CBD see Roffe P, Santa-Cruz M. *Intellectual property rights and sustainable development*. New York, Economic Commission for Latin America and the Caribbean (ECLAC), United Nations, 2007.
 109. Correa explains that, “this obligation may be interpreted as applicable only to genetically modified or transgenic microorganisms, and not to those preexisting in nature”. See Correa, *supra* 73, at 67-68.
 110. The same article is also available under the US–Oman FTA, Article 15.8.11(b).
 111. These guidelines were specifically developed to resolve the problems relating to the patenting of biotechnology inventions, in particular the difficulties in granting patents before identifying the industrial application of genes and gene sequences. The guidelines also aim to prevent patents on things about which little is known.

112. In Musungu and Oh, *supra* 53, quoting Drahos P. *Submission to the Senate Committee on Australia–United States Free Trade Agreement*, memo, 2004, at 115.
113. The US–Bahrain FTA, Article 14.8.2, also demands that patents be available for plant inventions.
114. Similarly, the US–Oman FTA, Article 15.8(4), states:
- Each Party shall provide that a patent may be revoked only on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation, or inequitable conduct may be the basis for revoking a patent or holding a patent unenforceable. Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available before the grant of the patent.
- And the US–Morocco FTA, Article 15.9(5) states:
- Each Party shall provide that a patent may be revoked only on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation or inequitable conduct may be the basis for revoking or holding a patent unenforceable. Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available prior to the grant of the patent.
115. Kuanpoth J. *Current developments and trends in the field of intellectual property rights: harmonisation through free trade agreements*. UNCTAD/ICTSD/HKU/IDRC Regional Dialogue “Intellectual Property Rights (IPRs), Innovation and Sustainable Development”. 8–10 November, 2004; Hong Kong, People’s Republic of China.
116. The World Bank also recommends that developing countries should apply a strict criterion of patentability. See *Global economic prospects and the developing countries 2002: making trade work for the world’s poor*. Washington DC, World Bank, 2002.
117. For example, the United States adopts a high standard in interpreting the inventive step. See *KSR International* decision and its interpretation of combination inventions under United States law. *KSR International Co. v. Teleflex Inc. et al.* Available at <http://www.supremecourtus.gov/opinions/06pdf/04-1350.pdf>.
118. IPRs Commission Report, *supra* 14, at 50.
119. Some of the United States FTAs with a number of Latin American countries incorporate this provision. For example, the US–Peru FTA, Article 16.1(5), provides:
- Nothing in this Chapter shall be construed to prevent a Party from adopting measures necessary to prevent anticompetitive practices that may result from the abuse of the intellectual property rights set forth in this Chapter, provided that such measures are consistent with this Chapter.
120. Similar provisions are found under the US–Jordan FTA, the US–Morocco FTA and the US–Oman FTA.
121. Similar provisions are found in almost all of the European Union association agreements with the region, including the EU–Jordan AA, the EU–Lebanon AA, the EU–Syria AA, the EU–Algeria AA, the EU–Morocco AA and the EU–Tunisia AA.

122. Similar provisions are also included under other EFTA agreements including those with Jordan, Lebanon, Tunisia and Egypt.
123. GRAIN explains that the UPOV is a TRIPS-plus agreement, stating that TRIPS “makes no reference to UPOV, a convention that was crafted in Europe 40 years ago as a special kind of patent system for commercial plant breeders and to which mostly industrialised countries subscribe. Requiring countries to align with UPOV is very clearly TRIPS-Plus, since TRIPS does not define ‘effective *sui generis* system’ and WTO members have been told time and time again that the absence of a definition and the absence of any mention of UPOV both indicate sufficient flexibility. Under discrete bilateral agreements with different developed countries, Cambodia, Jordan, Morocco, Tunisia and Vietnam are now obliged to join UPOV. (Singapore may be in the same boat.) Bangladesh, Ecuador, Mexico, Nicaragua, Trinidad & Tobago and Vietnam were dealt the phrase “must make every effort to” instead. While at first glance, this ‘effort’ terminology may sound less binding, it nevertheless implies a TRIPS-Plus obligation. Because in practical terms, to make an effort to accede to UPOV, a government must draft a plant variety protection bill that aims to conform with the UPOV Convention and it must seek the Union’s advice on that draft. And in some cases, the ‘make every effort’ formula is accompanied by an obligation to implement the substantive provisions of UPOV in the meantime. As to the Free Trade Area of the Americas (FTAA), the draft negotiating text makes several references to UPOV”. See GRAIN. *TRIPS-plus: through the back door: how bilateral treaties impose much stronger rules for IPRs on life than the WTO*. 2001. Available at <http://www.grain.org/briefings/?id=6> (last visited 21 January 2009), at 2.
124. For instance, the controversial nature of the PCT, as explained in more detail in chapter 3, stems from its effect on public health and access to medicines as a result of the restrictions on patentability and the erosion of the TRIPS flexibilities because of the conditions included under this treaty on member states.
125. According to WIPO these are: the patent offices of Australia, Austria, Canada, China, Finland, Japan, the Republic of Korea, the Russian Federation, Spain, Sweden, the United States of America and the European Patent Office act as international searching authorities under the PCT (situation on 1 November 2005).
126. Kuanpoth J. *Negotiations toward a free trade area: US demands for greater IPR privileges*. GRAIN, 2006, at 7. Available at <http://www.grain.org/rights/tripsplus.cfm?id=23>.
127. IPRs Commission Report, *supra* 14, at 109.
128. For example, India incorporated into its national law the relevant provision of the TRIPS Agreement which sets out that a majority of production must be for domestic use. TRIPS Article 31(f) states that any use of the patented material without authorization of the rights holder “shall be authorized predominantly for the supply of the domestic market of the member authorizing such use”.
129. Similar provision may also be found under the US–Columbia FTA, Article 16.13.

5. Strategic implementation of intellectual property provisions in bilateral trade agreements

Intellectual property is one important element for development. Developing and least developed countries must design an intellectual property protection environment that takes into consideration their levels of development and local needs. These countries should use the policy space available to them under TRIPS. This assumption is based on the historical foundations of the industrialized countries themselves (Box 40).¹

Creating a functional intellectual property regime for any country must be viewed from an institutional angle and not merely from a protectionist legal one. Thus, the proper and sound functioning of an adequate and balanced intellectual property regime anywhere necessitates the existence of a number of complementary checks and balances.

Box 40. Commission on history of intellectual property

... [H]istorically IP regimes have been used by countries to further what they perceive as their own economic interests. Countries have changed their regimes at different stages of economic development as that perception (and their economic status) has changed. For instance between 1790 and 1836, as a net importer of technology, the US restricted the issue of patents to its own citizens and residents. Even in 1836, patents fees for foreigners were fixed at ten times the rate for US citizens (and two thirds as much again if one was British!).

Source: *Integrating intellectual property rights and development policy*. London, Commission on Intellectual Property Rights, 2002.

Intellectual property is linked to human, educational, social and health conditions too

As the history and experience of most developed countries demonstrates, the creation of these arrangements and policies takes a gradual course and often reflects and corresponds to the level of progress experienced by each country. Therefore, in order to reap the benefits and rewards of the institution of intellectual property and to ensure its proper functioning, it is pivotal that countries which are in the course of building and establishing intellectual property regimes pay careful attention to these elements.

Another justification for taking an institutional perspective on intellectual property is the fact that most of these elements are interwoven. As discussed, public health is highly affected and influenced by intellectual property and patent protection; hence a strengthened patent regime is likely to have a direct impact on the availability and affordability of medicines within any country. Moreover, emerging research also establishes a direct link between education and public health. In fact, it has been generally realized that higher literacy levels are more likely to contribute to better health status. The World Bank has reported that the “average mortality rate for children under 5 was 144 per 1000 live births when their mothers had no education, 106 per 1000 when they had primary education only, and 68 per 1000 when they had some secondary education”. This underscores the fact that intellectual property is not only trade-related. Intellectual property is linked to human, educational, social and health conditions too. Therefore, developing and least developed countries that are in the process of negotiating and signing bilateral trade agreements must ensure that these agreements do not hamper their efforts and national development plans.²

The conclusion of a bilateral trade agreement between any two countries does not end with the ceremonial process of signature and ratification. The implementation process which follows such a conclusion is an ongoing exercise that demands various administrative, legislative, economic and social undertakings and commitments. Implementing these agreements is one of the most challenging aspects of negotiating and concluding bilateral trade arrangements, particularly from the perspective of developing and least developed countries.

The content and implementation of the bilateral agreement itself often relies heavily on the negotiation process which precedes the final agreement. Thus, a well informed and prepared negotiating team with a clear negotiation mandate, well defined objectives,

thoughtful planning and a coherent national agenda would provide a “safety net” that would ensure adequate negotiations and, later on, the implementation of the bilateral agreement at the domestic level in accordance with a country’s priorities and national interests.

This chapter will start by examining the implementation of TRIPS in developing countries at the national level and the policy space available to member states under this process. Moreover, this chapter will study the process of negotiating bilateral trade agreements by paying special attention to the health-related aspects and provisions of these bilateral agreements. For the sake of simplicity, the chapter will divide the process into three phases as follows: the pre-negotiation phase; the negotiation phase; and the post-implementation phase. The chapter will shed light on each phase through suggesting certain mechanisms and policies aimed towards maximizing the benefits and reducing the costs of negotiating and implementing bilateral trade agreements, particularly for those countries in the Region which have already signed such agreements or are in the process of doing so.

Due to wide differences between countries in the Region, it must be clarified that this chapter does not propose that all countries in the Region should address and approach bilateral trade negotiations in the same manner, particularly if we take into consideration that the Region is home to countries that are ranked within the top and lowest in terms of GDP per capita income levels in the world.³ This discrepancy and the varied economic capability of countries also play a major role in shaping the way countries address and approach negotiations on issues related to intellectual property protection and public health. For example, while pharmaceutical patent protection might have a more profound impact on the poorer developing and least developed countries in the Region, this may not be the case for the richer countries. What is important in this regard for policy-makers is to be aware of some of the dangers and challenges affiliated with the process and the necessary steps needed to offset any negative impact which may arise in the course of negotiation and implementation of these agreements.

One should also be aware that some countries might simply sign a bilateral trade agreement because they feel that the benefits accruing from signing such an agreement would outweigh its costs. Thus, a country may decide that the expected losses due

Pharmaceutical patent protection might have a more profound impact on the poorer developing and least developed countries in the Region

to be suffered as a result of the TRIPS-plus conditions in the pharmaceutical sector would simply be compensated by market access or economic aid from the partner developed country.

The strategic implementation of the TRIPS Agreement

TRIPS also recognizes the various national differences which exist between the members of the WTO

As Vivas-Eugui and von Braun explain, the implementation by any country of its international commitments requires that a set of “political, legal and administrative reforms be undertaken by national authorities once a particular international arrangement has been signed and ratified”.⁴ This process encompasses several steps and procedures that often vary from one country to another depending on a country’s legal, economic, social and constitutional structure.⁵

For most developing countries, including those in the Region, the implementation of TRIPS under national law is a lengthy and costly process.⁶ This was one of the reasons why countries negotiating TRIPS during the Uruguay Round were granted transitional periods, in order to enable them to incorporate the agreement’s requirements gradually. Accordingly, countries seeking membership of the WTO are obliged to incorporate the agreement’s minimum levels of protection gradually in accordance with the transitional periods granted to them. Apart from the least developed countries, which were granted an additional transitional period in 2005, all WTO member states were expected to fully comply with TRIPS requirements by January 2005 through bringing their national intellectual property laws and legislation in conformity with the standards of TRIPS.

TRIPS also recognizes the various national differences which exist between the members of the WTO. Accordingly, Article 1.1 of TRIPS states:

Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

Although TRIPS strengthens the protection levels of intellectual property across the globe through the notion of “minimum standards” of protection, it does not lead to a complete unification

of all intellectual property laws and legislation around the world. As discussed, member countries are granted several flexibility mechanisms and tools in relation to the implementation of TRIPS under national law. Therefore, it is up to these countries to make use of and benefit from these flexibilities.

One area where such autonomy exists is enforcement. Member states were granted considerable discretion in relation to the enforcement provisions under Part III of TRIPS. These relate to several areas and procedures, including:

- civil and administrative procedures, in particular civil and judicial procedures, including injunctions, award of damages and disposal of pirated goods
- provisional measures ordered by the judicial authorities
- measures taken at the border by customs authorities to seize counterfeit or pirated goods
- criminal procedures and penalties in cases of counterfeit or copyright piracy activities undertaken on a commercial scale.

In order to be able to devise and implement an intellectual property regime geared towards promoting development and fostering innovation, developing countries, particularly those in the Region, must develop and build extensive knowledge and understanding about the nature of intellectual property and its affiliation with other economic, legal and social issues. Therefore, in order to create the necessary balance between the interests of intellectual property holders and the public, the implementation and enforcement of intellectual property regimes often rely on the existence of other complementary and supportive national legislation and tools. These include but are not limited to: adequate competition laws, high levels of investment in research and development, capacity-building, education, advanced national public health infrastructure, and functioning social security, pension and insurance schemes. Moreover, there is also the need for an empowered and vibrant consumer movement supported by consumer protection laws and legislation.⁷ The proper functioning of this supportive legislation and instruments is often guided and aided by an independent judiciary and a national institutional framework and policy aimed towards encouraging and enhancing creativity and innovation within these countries (Box 41).

Member states were granted considerable discretion in relation to the enforcement provisions under Part III of TRIPS

Box 41.

One of the challenges faced by developing countries is that in the area of IP these countries import systems of protection that have been tried and experienced in more advanced and legally sophisticated countries that among others possess a system of 'checks and balances'. This system is codified in legislation and regulation, and some of it arises out of court interpretation.

Source: Roffe P. *Intellectual property provisions in bilateral and regional trade agreements: the challenges of implementation*. Washington DC, Center for International Environmental Law, 2006.

In addition to creating the above checks and balances, the primary challenge facing developing countries today is how to implement TRIPS in a manner that is more conducive to their economic development rather than focusing on the protection of intellectual property as a form of private rights.⁸ Therefore, developing and least developed countries can (and should) use the policy space available to them under TRIPS to implement the agreement strategically and innovatively within the framework of their national laws and legislation. This entails treating the national intellectual property protection regime as one component of many others rather than as a standalone matter.

Most specifically, this approach should be applied in the area of public health. Developing and least developed countries should shift their attention to using the intellectual property regime in order to preserve public health, transfer technology, ensure adequate and affordable pharmaceutical production, and permit access to medicines by their poor. In following this path, developing and least developed countries must stress that they are doing so in conformity with the explicit provisions and principles of international law, particularly those of TRIPS and the subsequent Doha Declaration on the TRIPS Agreement and Public Health (Box 42).

Many institutions, organizations, experts and academics support and encourage this pro-development approach. This approach resembles that of the majority of developed countries that, while going through similar stages of political and economic development as those currently experienced by the developing countries, they

Box 42.

The preamble to TRIPS states:

Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives.

Article 7 of TRIPS states:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8 of TRIPS states:

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 66 of TRIPS states:

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members in order to enable them to create a sound and viable technological base.

used the regime of intellectual property to facilitate the transfer of technology, dissemination of information, and development of their own countries. The IPRs Commission Report reiterates this by stating:

Developing countries must ensure that their intellectual property laws and legislation adopt a pro-development view

We therefore conclude that far more attention needs to be accorded to the needs of the developing countries in the making of international IP policy. Consistent with recent decisions of the international community at Doha and Monterrey, the development objectives need to be integrated into the making of IP rules and practice.⁹

Moreover, the CIPIH Report demands that the developed countries and the WTO take a more active role and try harder to ensure that the transfer of technology for pharmaceutical products and medicines is actually undertaken. Accordingly, Recommendation 4.18 of the CIPIH Report states:

Developed countries and the WTO should take action to ensure compliance with the provisions of Article 66.2 of the TRIPS Agreement, and to operationalize the transfer of technology for pharmaceutical production in accordance with paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

Developing countries including those in the Region must ensure that their intellectual property laws and legislation adopt a pro-development view by taking into consideration to the widest possible extent the flexibilities and policy space available to them under TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health.

The strategic implementation of bilateral trade arrangements

The implementation of bilateral trade arrangements under national laws must be dealt with in a comprehensive manner. For any country seeking to ensure the success of its bilateral negotiation strategy and the preservation and enhancement of its public health, the process should not start with the signing and ratification of the bilateral agreement itself, but rather should be viewed as a component of a well defined and coherent national agenda (Box 43).

Negotiating and concluding a bilateral trade agreement is a ponderous and complex exercise. The situation is made worse when as a result of the differences in resources, economy, market size and levels of development, the negotiating parties lack

Box 43.

The term “negotiation” originates from the Latin word *negotari* which means to carry on business. Negotiation may be defined as a process whereby two or more parties seek an agreement to establish what each shall give or take, or perform and receive in a transaction between them.

Source: Saner R, *The expert negotiator: strategy, tactics, motivation, behaviour, leadership*. Leiden, Martinus Nijhof Publishers, 2005.

adequate negotiating balance. From the developed country’s perspective, the conclusion of negotiations marks the beginning of the implementation process, which entails intensive involvement with the partner country at various levels and stages. As Box 44 demonstrates, such a process often entails persistent and ongoing surveillance, technical assistance and monitoring mechanisms aimed at ensuring the partner’s compliance with its commitments and obligations undertaken under the bilateral agreement.

In order to explore and gauge the full potential of these bilateral trade agreements in general and to be able to ensure that public health is not impaired or restricted, several steps may be carried out by developing and least developed countries, including those in the Region, at various stages.¹⁰ Certain measures may be undertaken prior to entering the negotiation of a bilateral trade agreement; other measures may be undertaken during the negotiations process itself; and finally measures may be undertaken after the conclusion of negotiations and ratification of the agreement. For the purposes of simplicity, each stage will be dealt with separately.

Before moving to discuss this in detail, it is important to note that although on the face of it, bilateral trade agreements are about trade and economics, if one takes a deeper look it becomes clear that there are other reasons why countries would actually sign such arrangements other than the economic rationale.¹¹ Although trade liberalization and gaining market access to the more advanced country is a clear motivation for some countries to seek a bilateral trade agreement, political and national security considerations rank amongst the main reasons why bilateral trade agreements are being sought with countries in the Region.¹²

Box 44. The US FTA implementation of health-related commitments

USTR oversees FTA partners' implementation of the pharmaceutical-related IP provisions agreed to in the FTA in order to ensure that the negotiated standards are implemented as intended. In order for an agreement to enter into force, the President determines with the advice of USTR whether the FTA partner has met all obligations. A USTR official explained that USTR works with the trading partner to ensure that its IP laws are aligned with the provisions agreed to in the FTA. The USTR official further explained that, at the start of the implementation process, the trading partner provides USTR a comprehensive list of its laws related to each provision in the IP chapter of the FTA. The trading partner also provides USTR a list detailing the intended legal changes necessary to bring its laws into compliance with the agreement. USTR reviews the laws and proposed changes and provides the trading partner with comments regarding their degree of compliance. USTR monitors the changes in the other country, and has numerous exchanges with the trading partner on any legal changes necessary. One USTR official stated that they are careful to ensure that the agreement is implemented exactly as it was negotiated.

A USTR official explained that when the legal changes are complete and USTR is comfortable with the new legislation, USTR makes a recommendation to the President for the agreement to enter into force. The administration then makes a determination about the legal compliance before the agreement can officially enter into force. USTR and other agencies also provide technical assistance on implementing related IP provisions to FTA partner and non-partner governments.

Source: US Government Accountability Office. *Intellectual property: U.S. trade policy guidance on WTO declaration on access to medicines may need clarification*. Washington DC, 2007.

In this regard, the experience of developing countries shows that the decision to enter into a bilateral trade agreement is often a political decision taken with little preparation and in the absence of extensive and transparent national debate. In some cases, the developing country itself initiates discussion for the conclusion of a bilateral trade agreement. However, due to the national management structure of many developing and least developed

countries, this would result in the trade and foreign affairs ministries' handling of the process of discussing and negotiating the content of the trade agreement. This in some cases—such as lack of an obligatory national organized network—may further lead to the exertion of pressure against other national stakeholders, including health officials and institutions, to go along with the proposed agreement. Improving national cohesiveness must be a priority for developing and least developed countries, particularly those in the Region, to ensure a better outcome of such a process.¹³

Pre-negotiation strategies

Officials involved in the negotiation process are often under extreme pressure to deliver an agreement in the shortest period of time, particularly if foreign financial and economic aid and promises of market access are made conditional upon the signing of the bilateral agreement. Intellectual property and its link with public health provide additional complexities, especially in cases about which negotiators lack adequate knowledge, personnel and technical expertise. This issue is made even more complex by the fact that the impact and economic assessment of intellectual property may not be a straightforward exercise, unlike other areas such as trade in goods, which is easier to assess.

However, being well prepared for the negotiation process might in fact partially compensate for this lack of expertise and at the same time reduce external pressure. Accordingly, before entering into negotiations with the aim of signing a bilateral trade agreement, countries in the Region need to take several steps to minimize the negative impact such a process might entail. These steps are aimed at providing a built-in mechanism which would use the available policy space and serve the country's pro-development plans.

First, one cannot stress enough the need for any country to heavily invest in human resources and personnel capacity-building.¹⁴ In this we particularly refer to the negotiators, diplomats and officials involved in the process of negotiating and implementing various international agreements and commitments. As discussed earlier, the lack of qualified personnel with extensive legal, economic and technical expertise has often negatively affected the negotiation position of developing countries and led to an unbalanced international legal regime of intellectual property protection.

Bilateral trade agreements are about trade and economics

Box 45.

Over the years of a negotiation, individual negotiators who become “fixtures”, particularly those who follow an issue across fora (for example the CBD and FAO), acquire an intimate historical knowledge of the issues, countries’ positions and, like good swimmers, a knowledge of the currents and what is possible in them.

Source: Drahos P, Tansey J. Postcards from international negotiations. In Tansey G, Rajott e T, eds. *The future control of food: a guide to international negotiations and rules on intellectual property, biodiversity and food security*. London, Earthscan, 2008

Since capacity-building cannot be had overnight, governments should view this as a long-term investment by seeking to attract highly qualified expertise into these official positions and to retain those individuals with considerable experience in the field (Box 45).

Second, there is a pressing need for countries in the Region to each draft a comprehensive and a clear development-focused national agenda and for this agenda to be revised and updated accordingly. This agenda must encompass national plans for the country’s competitive sectors and industries (such as agriculture, services and manufacturing). These plans should be supplemented by other issue-based specific goals (such as attraction of FDI, fostering innovation and encouraging the creation of intellectual property). This overall national development agenda should then be used as the bedrock and platform for any negotiation process.

As a part of this national agenda, countries in the Region must put in place a national public health strategy that focuses on developing public health and in ensuring the proper and adequate access to pharmaceutical drugs and medicines. This strategy must focus on building local pharmaceutical infrastructure capable of producing those medicines which are essentially needed in the country. This strategy should also focus on increasing investment in R&D, building and establishing nationwide public health insurance schemes, and upgrading local human resource capacity-building.¹⁵

The issue of investing in the production and manufacturing of drugs and medicines is of particular relevance to countries in the Region and will also affect the availability of drugs and medicines

Box 46. CIPIH, Recommendation 4.10

Governments need to prioritize health care in their national agendas and, given the leverage to determine prices that patents confer, should adopt measures to promote competition and ensure that pricing of medicines is consistent with their public health policies. Access to drugs cannot depend on the decisions of private companies but is also a government responsibility.

Source: *Public health, innovation and intellectual property rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health. Geneva, World Health Organization, 2006.*

at the regional and international levels. Recent research shows that there are many countries in the Region with no or little medical manufacturing capabilities, hence these countries substantially rely on foreign-produced drugs and medicines.¹⁶ The case of some (Gulf Cooperation Council) countries demonstrates this trend in the Region. To these countries, the issue of ensuring the availability and affordability of medicines may not be an immediate challenge because of their relative ability to spend on public health. Subsequently, due to the lack of manufacturing capabilities and no or little local competition in these countries, multinational drug companies will have no incentive to relinquish their dominant position thus keeping the prices of drugs and medicines high (Box 46).

However, a related question which arises in this context is, can these countries maintain the status quo, and if so, for how long? It becomes clear that investment in this sector and in related R&D activities should be placed at the forefront of these countries' national development agendas and should be viewed as an important pillar of their long-term progress and self reliance.

Third, entering into a bilateral trade agreement is similar to negotiating a business deal. Countries must undertake a feasibility study and assess the costs and benefits of entering into such a deal. In the area of public health, the country needs to evaluate the effect of the agreement on its national public health framework and its ability to provide treatment and medications to its citizens without being restricted by the terms and conditions stipulated within the bilateral agreement. Clearly, public health must be placed at

the forefront of each country's negotiation agenda and should be looked at as a fundamental element of its national independence and sovereignty.¹⁷

In order to be able to provide a more precise assessment of the costs and benefits of signing a bilateral trade agreement in the area of public health, governments may use the draft of the most recent signed bilateral agreement in the Region in order to speculate on the potential terms and conditions that are likely to be included in the negotiations. Experience and research conducted in relation to the Region shows that subsequent agreements often build upon existing ones and are more likely to contain more extensive intellectual property chapters than previous ones.¹⁸ This clearly applies to the chapters on intellectual property and public health. Such a cost-benefit analysis would be extremely useful in order to anticipate and initiate a balanced, well informed and transparent public discussion and debate on the issue.

Based on the outcome of this assessment exercise, a country might conclude that it will be against its interests to include intellectual property in the negotiations of the bilateral trade agreement, thus emphasizing its commitment at the outset to apply the prevailing multilateral rules under TRIPS in this regard. This was the path followed under the 2003 Australia-Thailand Free Trade Agreement which only requires the parties' commitment to respect the provisions and standards of TRIPS and any other multilateral agreements relating to intellectual property to which both countries are parties to.¹⁹ Another approach would be to set a firm milestone for the negotiating team for exchanges of drafts, breach of which (as often happens during bilateral negotiation rounds) should signify a suspension of discussions and negotiations in that sector.

Fourth, prior to entering into bilateral trade negotiations with the aim of concluding a bilateral trade agreement, a country should prepare its national stakeholders including various government departments, the judiciary,²⁰ the legislature, academic institutions, the private sector, civil society organizations, unions and various other institutions through broad consultation, informed national debate and submission of proposals and feedback.²¹ The extreme importance of this issue should be emphasized since these are the segments of society which will be primarily affected by the outcome of any agreement. Implementing these techniques will also create a sense of "ownership" within the country hence facilitating the full implementation and enforcement of the agreement in the longer

Prior to entering into bilateral trade negotiations with the aim of concluding a bilateral trade agreement, the country should prepare its national stakeholders

run. Also, coordination between the private sector and public sector representatives is extremely important in this regard.

Moreover, governments should view these groups as their “safety net” by encouraging and empowering them to be active players in the national debate.²² Accordingly, governments must assess and carefully evaluate the developing domestic general mood and feedback emanating from this process. In certain instances, governments can use public outcry and resentment against the potential bilateral trade agreement in order to obtain additional concessions and further preferential treatment from the developed country negotiation partner.

Countries could also complement the ongoing national debate by initiating nonbinding preliminary discussions and joint study groups with their potential bilateral trade partner. This discussion might be used strategically to refer to the ongoing national debate and general mood about the potential bilateral agreement. Moreover, these nonbinding negotiations could be used as “testing labs” which would help to clarify certain ambiguities and might give a hint about the other party’s flexibility and the manner under which the official negotiations will be conducted. The Australia–Japan FTA provides a valuable example of such nonbinding consultations (Box 47).

Finally, upon taking the decision of proceeding with the official negotiation process and after determining the issues to be included in the negotiations, governments must prepare their negotiating teams adequately. The implications of bilateral trade agreements are not confined to trade but extend to many other areas. The task of negotiating these agreements should not rest solely with the ministries of trade, foreign affairs or commerce. Collaboration and coordination between various official and governmental agencies and institutions is absolutely essential both in preparation for, and throughout the negotiation process.

Since bilateral negotiations often target many areas, proper representation from the concerned groups should be part of this strategy. For example, in the area of public health and intellectual property protection, representatives and submissions from various governmental departments should be formulated and sought. Officials from the national patent office, the ministry of health, the ministry of trade, national drug regulatory authorities, local pharmaceutical manufacturers, and national and private institutions involved in R&D should form an integral part of this negotiating

**Governments
must prepare their
negotiating teams
adequately**

Box 47. The proposed Australia–Japan FTA pre-negotiation phase

I am very pleased to address this gathering. I know how much the bilateral economic cooperation committees contribute to the Australia–Japan relationship and we recognise and greatly value your support for an FTA between Australia and Japan.

Having heard your repeated calls for governments to move to an FTA as a matter of urgency, I am glad to say that we have come a long way towards beginning negotiations on an FTA.

I'd like to share with you today some of the results emerging from the joint study. The FTA feasibility study was initiated by Prime Minister Howard and Prime Minister Koizumi in April 2005.

Since then a joint government study group has met five times and canvassed all of the issues, chapter by chapter, that we would expect to arise in negotiating an FTA.

Importantly, the study group has heard from the private sector, under the Chatham House rule, at two of its sessions. The views of the private sector have been invaluable in highlighting the benefits an FTA could bring, and such views will inform the joint study group's report, which is now being drafted.

At the beginning of November, I will meet with my counterpart, Deputy Minister Yabunaka of the Japanese Ministry of Foreign Affairs to finalise our report to Prime Ministers, which they will consider later in the year.

Source: Statement of Geoff Raby, Australian Department of Foreign Affairs and Trade, 2006. Available at http://www.dfat.gov.au/media/speeches/department/061016_japanfta.html.

team, in addition to representatives from both domestic and international nongovernmental organizations, civil society groups, academics, experts, lawyers and patient groups. As indicated below, this is a fact of life in the developed countries, including the United States, which is often an FTA partner with countries in the Region.²³

Participation from all concerned parties may play an important role in strengthening a country's negotiation position and its bargaining stand. This will also put pressure on the other negotiating team to

provide more concessions, particularly if civil society groups are allowed to play an active role throughout this process as a result of their savvy access to the media. History shows that during the past decade, civil society groups have been an important ingredient of the success that developing countries achieved in bilateral and multilateral forums, particularly in the area of public health and access to medicines. The Doha Declaration on the TRIPS Agreement and Public Health is a good case in point.

The negotiation process

Much of what may actually be achieved in the negotiation phase itself often depends on the planning preceding this process. Subsequently, once an informed decision is reached nationally to enter into a bilateral trade agreement with another country, the next phase would be to commence official negotiations with the potential partner.

The next question that arises in this context is what are the issues to be included for discussion under the proposed bilateral trade agreement? Here, there can be no single answer since such a decision will have to correspond to each country's priorities, its development level and its predetermined national development agenda. However, countries in the Region must take additional measures and extensive analysis if they agree to the inclusion of intellectual property protection under the proposed bilateral agreement. Special emphasis should be undertaken to assess the effect and likely impact of enhanced intellectual property protection on national public health, pharmaceutical production and access to drugs and medicines.

The starting position of countries in the Region in this regard is to stress their commitment to using TRIPS' levels as the main standards of protection under the bilateral agreement. Least developed countries and other countries which have yet to become members of the WTO must explicitly state their adamant position of retaining their right of enjoyment of the transitional periods granted to them by TRIPS and the WTO. In addition, countries should stress their commitment and intention to retain and use the flexibilities awarded to them under TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health by translating these flexibilities under national laws and legislation.²⁴

Countries should stress their commitment and intention to retain and use the flexibilities awarded to them under TRIPS and the Doha Declaration

Negotiators must stress the importance of conducting negotiations in a fair, open and transparent manner

Upon the commencement of negotiations, negotiators must be wary of accepting any demands related to setting a shortened timetable or deadlines for the conclusion of the bilateral negotiations. Generally speaking, bilateral trade agreements, unlike multilateral ones, attract little attention and are often conducted secretly.²⁵ While this may suit the more advanced, developed country's strategy, which often attends to these negotiation rounds with its position clarified and aided by comprehensive and coherent negotiation agendas and teams, this often works against the interests of the weaker, developing country. The issue becomes more complex if the negotiations include discussions on various technical issues that need extensive analysis and assessment. This is especially the case for issues related to patent protection, public health and pharmaceutical production.

Essentially, intellectual property negotiations should stress the importance of the promotion of innovation and technological development as well. Some reference to this was achieved under the US–Columbia FTA which provided that:²⁶

The Parties recognize the importance of promoting technological innovation, disseminating technological information, and building technological capacity, including, as appropriate, through collaborative scientific research projects between or among the Parties. Accordingly, the Parties will seek and encourage opportunities for science and technology cooperation and identify areas for such cooperation and, as appropriate, engage in collaborative scientific research projects.

The Parties shall give priority to collaborations that advance common goals in science, technology, and innovation and support partnerships between public and private research institutions and industry. Any such collaborative activities or transfer of technology shall be based on mutually agreed terms.

Negotiators must stress the importance of conducting negotiations in a fair, open and transparent manner.²⁷ This includes disclosing and making the draft texts of the proposed bilateral agreement under negotiation accessible and available to members of the public.²⁸ This requirement has often been absent from the bilateral trade agreements signed with countries in the Region hence raising additional concerns about these agreements' undemocratic nature and lack of transparency. Given these agreements' far reaching effects on many aspects of life, public awareness and participation

Box 48.

Citizens' right-to-know laws (like America's and Britain's Freedom of Information Acts) are necessary to promoting both meaningful democracy and accountability.

Source: Stiglitz J, *Making globalization work*. London, Allen Lane, 2006.

should be seen as an essential element of the national discussion on the issues under consideration.²⁹

During negotiation rounds, it is also important that the public be kept informed about progress being made in negotiations (Box 48). In the case of a concession being obtained or conceded, officials must explain the reasons and advantages or disadvantages of such a decision.

These demands may be supplemented under national laws and legislation by requiring that upon the conclusion of each negotiation round, results and propositions related to public health must be presented and disclosed back in the home country in accordance with national procedures and formalities such as access to data and freedom of information laws and legislation. Moreover, in the area of public health, national laws may be drafted to ensure the stakeholders' right to seek, receive, access and impart information on matters related to and affecting public health.³⁰ By drafting these obligations into national law, countries in the Region may justify their demand of making such information available to members of their public. The legal mandate for these laws derives from several international agreements and declarations which the majority of developing and least developed countries, including those in the Region, are signatories to, including the International Covenant on Economic, Social and Cultural Rights, the Universal Declaration of Human Rights, and the Convention on the Rights of the Child (Box 49).

The negotiation teams themselves should be prepared for these negotiation rounds properly and well in advance. Ensuring full-time and adequate numbers of qualified negotiators that include wide representation from various official and governmental departments is important in this regard. Although lawyers must be an integral part of these teams, it is no less important to ensure that economic, social, scientific and public

Box 49. International obligations on provision of and access to information

The International Covenant on Economic, Social and Cultural Rights was adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966 and entered into force 3 January 1976, in accordance with article 27. General Comment 14 (2000), on the right to the highest attainable standard of health, states:

36. The obligation to *fulfil* requires States parties, *inter alia*, to give sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation and to adopt a national health policy with a detailed plan for realizing the right to health.

The Universal Declaration of Human Rights, adopted and proclaimed by United Nations General Assembly Resolution 217 A (III) of 10 December 1948, Article 19, states:

Everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers.

The International Covenant on Civil and Political Rights, adopted and opened for signature, ratification and accession by United Nations General Assembly Resolution 2200A (XXI) of 16 December 1966, entered into force on 23 March 1976. Article 19.2 states:

Everyone shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of his choice.

The Convention on the Rights of the Child, adopted and opened for signature, ratification and accession by General Assembly Resolution 44/25 of 20 November 1989, entered into force on 2 September 1990, in accordance with article 49 Article 13.1, states:

The child shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of the child's choice.

health expertise and advice are also available and easily accessible to the negotiating team. Researchers must be available in order to compile and assemble various information requested or to support the proposals and submissions of the negotiating team.³¹ As Box 50 shows, national participation under the US–Peru FTA negotiations provides an interesting case in this regard.

Box 50. National stakeholder participation in the US–Peru FTA negotiations

At the start of the negotiations, a total of 131 institutions were accredited, which included twenty-three Regional Governments, twelve Ministries, twenty-two public organs, forty management unions, eleven universities and postgraduate schools, three work unions, five professional academies, five research centers, five associations, and five foundations. The participation of public institutions focused on technical support for the different thematic tables of the negotiation, under the responsibility of leaders and coordinators. Twenty-nine public entities directly participated in the process, contributing 150 professionals and technical people during the negotiations.

The active and direct participation of officials of the Ministry of Health should be noted in relation to the intellectual property negotiable table. Participation of officials of entities responsible for administering different systems, directly or indirectly involving elements of intellectual property should also be highlighted.

In this regard, the Ministry of Health, given the relevance of issues under negotiation, sought to safeguard access to medicines and ensure flexibilities in the face of public health problems. In this sense, the Minister of the sector claimed that, “... as long as trade agreements block access to medicines through provisions such as patents and other restrictions, there will be serious difficulties for people to access these medicines [emphasis in original]”.

The Ministry of Health identified a series of provisions that, if applied, could have a significant negative impact on access to medicines for a large sector of the population through restricting the use of flexibilities established in TRIPS, limiting the entry of generic medicines into the market and affecting conditions of competitiveness.

Source: García L. *Intellectual property in the US–Peru trade promotion agreement*. Washington DC, Center for International Environmental Law, July 2008.

Before and during the negotiations on issues related to intellectual property and public health, representatives from the ministry of health and other stakeholders should be thoroughly briefed and allowed to attend and submit their feedback. A collaborative and coherent effort must be established. Those teams should also have clear methods of communication in addition to having access to researchers, consultants and academics back in their home country who would be able to scrutinize proposals and assess the impact of these proposals and provisions on public health, access to medicines and pharmaceutical production nationally (Box 51). In this regard,

Box 51. Involvement of United States health officials and agencies in bilateral trade agreements

USTR has obtained some input on IP rights and public health in trade negotiations through the formal interagency trade policy process, but public health perspectives on USTR's negotiating approach to pharmaceutical issues in FTA negotiations are primarily technical in nature and have not included an examination of the public health impacts of FTA provisions. USTR coordinated with the Department of Health and Human Services (HHS) when it first began to formulate its basic policy goals for negotiating FTAs, and HHS has had the opportunity to review draft FTA texts through the interagency advisory system. However, HHS has had limited involvement in the actual trade negotiations. According to USTR, most public health issues are worked out in advance of the negotiations. HHS and USTR occasionally convene an interagency working group to discuss IP rights and public health issues that arises at WHO or in other multilateral fora.

Although USTR routinely briefs HHS after each round of FTA negotiations, OGHA [Office of Global Health Affairs] officials stated that the health agency's role in trade, IP rights, and the negotiation of pharmaceutical-related IP provisions in FTAs has primarily involved providing technical expertise through its subagencies when requested by USTR...

In January 2007, public health representatives were added to the two technical ITACs most relevant to pharmaceuticals and IP rights—the chemicals committee (ITAC-3) and the IP committee (ITAC-15)—where the multiple brand-name pharmaceutical companies serve.

Source: US Government Accountability Office. *Intellectual property: U.S. trade policy guidance on WTO Declaration on access to medicines may need clarification*. Washington DC, 2007.

the 2008 WHO Global Strategy and Plan of Action on Public Health stresses the need to promote “active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs”.³²

Finally, during the negotiations, it is important that negotiators avoid the acceptance of any “cloudy”, “ambiguous” and “vague” proposals and commitments which are related to public health and pharmaceutical protection before undertaking full analysis and assessment of the likely effects and impacts of these issues on their national public health regimes (Box 52).³³

The post-negotiation (implementation) phase

Translating the legal requirements of the signed bilateral trade agreement into national law is one of the major challenges facing developing and least developed countries, including countries of the Region which have already signed similar agreements. Thus, signing a bilateral trade agreement should not be viewed as the end of the process, but rather the beginning. The real work often starts after the conclusion of the agreement through the transformation of its legal requirements into national law. Once again, this process is not a standalone one but often relies heavily on the negotiation process itself.

In the past, the majority of developing and least developed countries took a passive approach in terms of implementing their TRIPS obligations under national law thus aiming to avoid “future

Box 52. CIPIH, Recommendation 4.21

In bilateral trade negotiations, it is important that governments ensure that ministries of health be properly represented in the negotiation, and that the provisions in the texts respect the principles of the Doha Declaration. Partners should consider carefully any trade-offs they may make in negotiation.

Source: *Public health, innovation and intellectual property rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health.* Geneva, World Health Organization, 2006

Countries must establish the necessary checks and balances in order to ensure that intellectual property protection is not restricting the provision of public health

conflicts over intellectual property”.³⁴ However, history has proved the failure of this approach in bringing any success in terms of development and progress to the majority of these countries. In order to avoid the failures of the past, countries must take a more proactive role in implementing their obligations under these bilateral trade agreements by exploring the remaining policy space available to them through the creative implementation of these agreements. What makes this more pressing in the case of bilateral agreements is the fact that the majority of bilateral trade agreements establish a joint committee which is concerned with the task of monitoring and implementing the provisions of the agreement thus imposing greater need for compliance. The next section will provide several examples and propositions related to the implementation process of these agreements under national law.

Setting the objectives of the intellectual property regime nationally

As discussed elsewhere, intellectual property is not only trade-related. In fact, the far-reaching effects of intellectual property protection are found in areas apart from trade, including public health, education, transfer of technology and development.

It should be remembered that the available historical analysis of the evolution and development of intellectual property protection itself varies from one place to another and from one period of time to another. Indeed this process might be best described as a “personal” one that should not be imposed upon all countries with a “one size fits all” approach.

Generally, a successful national intellectual property agenda must set its sights on striking the balance between the creation of intellectual property and its dissemination to the widest possible audience. It should also focus on increasing R&D activities and encouraging creativity and innovation without harming the public interest. In the area of public health, countries must establish the necessary checks and balances in order to ensure that intellectual property protection is not restricting the provision of public health, by exploiting the available policy space available to them under international law.

Exploring and enhancing the policy space

Every effort should be made to incorporate the flexibilities of TRIPS under national laws to the broadest possible extent. As discussed in the previous chapter, although available to all member states, the majority of TRIPS' flexibilities do not apply automatically under national law but rather require a considerable amount of effort, planning and coordination in order to be adequately activated.

Bilateral trade agreements often restrict and erode this space as a result of TRIPS-plus obligations. This however, should not preclude countries from seeking to use the remaining space available to them under these bilateral agreements.

From a policy perspective, it is imperative for policy-makers in developing and least developed countries to first be aware that the majority of TRIPS-plus obligations incorporated into bilateral trade agreements often correspond with those levels prevailing in the developed countries. Accordingly, those levels of protection are designed to deal with local problems arising within the legal and business environment of these communities that are different from the problems and challenges facing developing and least developed countries. Subsequently, policy-makers in developing countries must formulate and shape these commitments in a way that is more relevant to their countries' level of development and progress and in the light of local legal and administrative needs and structures. This understanding is a prerequisite for the proper exploitation of the remaining policy space and the implementation of these commitments locally.

Education, awareness and participation are the best methods to guarantee any country's proper use of the remaining intellectual property flexibilities. Unfortunately, a large number of developing and least developed countries have failed to incorporate TRIPS' flexibilities under national law because they were unaware of their existence or because they simply did not know how to translate them into national law as a result of lack of resources, expertise and human capital.³⁵ The same could also be said in the case of the implementation process arising from bilateral trade agreements.

Every effort should be made to incorporate the flexibilities of TRIPS under national laws to the broadest possible extent

No country in the Region has so far issued any compulsory or government use licence

Moreover, proper participation and negotiation, in addition to a vigorous national debate also lead to raising the levels of awareness. Those countries that were most active in intellectual property negotiations under the Uruguay Round (including India and Brazil) later proved to be the most active and successful ones in applying the flexibilities of TRIPS under their national laws.

As a result of the highly technical nature of the issues concerned, large numbers of developing countries, including the majority of countries in the Region (even those which have local pharmaceutical generic manufacturing capabilities), have failed to make use of these flexibilities.³⁶ For example, no country in the Region has so far issued any compulsory or government use licence.

However, as a result of the complexity of these issues and intellectual property protection in particular, sometimes this problem might not solely be confined to developing and least developed countries. There is growing empirical evidence that confirms that even generic drug manufacturers in developed countries may not be fully aware of the flexibilities available to them under international law. The case of the complexity and technical nature of the Doha Declaration on the TRIPS Agreement and Public Health exemplifies this issue. Research conducted by Drahos looking at the impact of the Doha Declaration and free-trade agreements on public health in Australia concluded that:

All those interviewed saw the WTO solution as somewhat remote from their interests and plans. Dealing with risk and uncertainty was a recurring theme in the interviews with the companies reporting that they were seeing higher levels of patenting by brand companies and that navigating through these patents was increasing their costs. The companies were not well informed about the details of the Paragraph 6 solution. In the one or two cases where they had more information about it they saw no real value in it. The companies interviewed in Australia spoke about the need for simple clear export rules that would allow them to access markets in a timely fashion. One company pointed out that in any implementation of the Paragraph 6 solution where a large pharmaceutical company was given the opportunity to hinder or stop export by a generic company that large company would always take that opportunity. This would be a rational business practice. This kind of observation is consistent with the gaming of patent rules that can be seen more broadly within the pharmaceutical industry.³⁷

Even after the inclusion of several TRIPS-plus restrictions and obligations under bilateral agreements, countries may still have considerable amount of space which should be further exploited. Some of these spaces are discussed below.

1. Compulsory licensing

Apart from Jordan, for which the US–Jordan FTA, considerably limits the grounds for issuing compulsory licensing,³⁸ WTO and non-WTO member countries in the Region still have the freedom and discretion to define the grounds for the issuance of compulsory licensing and government use as dictated under TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health.

There are several provisions that may be included under national law to enable member states to make more extensive use of this flexibility.³⁹ As previously explained, these grounds do not apply unless they are actively drafted under national law. In order to fully benefit from this flexibility, countries in the Region are advised to undertake an active legislative effort aimed towards incorporating as many grounds as possible for the issuance of compulsory licensing and government use under their national laws and regulations.⁴⁰ In this regard, the following box provides a suggested model provision which may be incorporated under national legislation (Box 53).

More important, governments in the Region must also ensure that these grounds are easily explained and applied domestically through raising local awareness and understanding about the benefits, advantages and procedures of resorting to these flexibilities (Box 54). As Musungu and Oh explain:

In many cases, the most significant barrier to the use of compulsory licensing is the absence of simple, straightforward legislative and administrative procedures, which establish clear decision-making processes and responsibilities. A multi-agency committee may be set up at the national level, to enable relevant agencies to discuss and take joint decisions. The setting of adequate remuneration or

Policy-makers in developing countries must formulate and shape these commitments in a way that is more relevant to their countries' level of development

Box 53. Compulsory licensing: model provision

- a) Non-exclusive compulsory licenses shall be granted in any of the following cases:
- i. when the patentee has refused to grant a voluntary license under reasonable commercial terms and conditions, and the working or efficient working of any other patented invention which makes a substantial technical contribution is prevented, or the establishment or development of commercial or industrial activities are unfairly prejudiced;
 - ii. in cases of declared national emergency;
 - iii. when required for reasons of public health, such as to ensure the availability to the population of essential drugs, or when required in the public interest, including for security reasons;
 - iv. to remedy anticompetitive practices;
 - v. when required by the government or a public entity to provide to the population goods and services for health care or other public purposes, on a non-profit basis;
 - vi. when the patent fails to be worked or is insufficiently worked in the country, and working is necessary for health care or to promote a sector of vital interest for socioeconomic development;
 - vii. to use a patent which cannot be exploited without infringing another patent, provided that the former patent covers an invention that involves an important technical advance of considerable economic significance, and the owner of the latter patent is entitled to a cross license on reasonable terms.
- b) A compulsory license can be conferred to import or to locally produce the patented product or a product directly made with a patented process.
- c) The license shall be granted for the remaining lifetime of the patent, unless a shorter term is justified in the public interest.
- d) Except in the cases mentioned in b), e) and f) above, a compulsory license shall be granted if the requesting party has made efforts to obtain authorization from the patent holder on reasonable commercial terms and conditions, and such efforts have not been successful within 150 days from the request. In situations of

Box 53. Compulsory licensing: model provision (cont.)

national emergency or other circumstances of extreme emergency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.

- e) A compulsory license shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use.
- f) The use of a compulsory license shall be predominantly for the supply of the domestic market, except in cases of paragraph a) above.
- g) The remuneration for a compulsory license shall be determined as a percentage of net sales, taking into account the value of the license in the relevant domestic market and the average royalty rates usually paid in the sector or branch to which the invention belongs. The remuneration can be reduced or excluded when the license is granted to remedy anticompetitive practices.
- h) The patent office shall have the authority to review, upon motivated request, the continued existence of the circumstances that led to the granting of a license, and may admit or refuse a request to terminate the license. The eventual termination shall be subject to the adequate protection of the legitimate interests of the persons authorized to use the invention, particularly when the licensee has made serious preparations or commenced to execute the invention.
- i) The patentee shall have the right to request from a competent higher authority the review of any decision relating to the legal validity of a compulsory license or to the remuneration determined by the national authority. An application for review shall not suspend the effects of a granted license.

Source: Correa C. *Integrating public health concerns into patent legislation in developing countries*. Geneva, South Centre, 2000.

Box 54. Compulsory licensing and developing countries

An important barrier to compulsory licensing in developing countries is the absence of straightforward legislative and administrative procedures to put it into effect. Because legal systems in most developing countries are overburdened, it would be most appropriate to legislate for a quasi-judicial and independent administrative system for implementation of compulsory licensing. The essential elements would include:

- Straightforward, transparent and fast procedures.
- Procedures for appeals that do not suspend the execution of the licence.
- Legislation that fully exploits the flexibilities in TRIPS for determining the grounds for compulsory licensing, as well as for non-commercial use by government, including production for export.
- Clear, easy to apply, and transparent guidelines for setting royalty rates (which may vary).

Source: *Integrating intellectual property rights and development policy*. London, Commission on Intellectual Property Rights, 2002.

compensation (as required by Article 31(h) of TRIPS), such as the adoption of royalty guidelines, should also be predictable and easy to administer, to reduce uncertainty and to facilitate speedier decision-making.⁴¹

2. Parallel importation and exhaustion regimes

TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health reiterate the right of member states to adopt the exhaustion regime which they favour in accordance with their national priorities.⁴² Although the US–Morocco FTA affects this by limiting parallel imports to cases where the patent owner has placed restrictions on importation by contractual arrangements, other bilateral trade and association agreements with countries in the Region do not appear to include such a limitation.

Countries in the Region which already do not have an exhaustion regime in place or those with a national exhaustion regime are advised to immediately explore this policy space further by

Box 55. Parallel importation: model provision

A patent holder shall not have the right to prevent acts of importation of any product covered by a patent that has been put on the market in any country by the patent holder or by any party authorized to use the invention.

Source: *Manual on good practices in public health-sensitive policy measures and patent laws*. Penang, Malaysia, Third World Network, 2003.

adopting an international exhaustion regime that takes into consideration their priorities, plans and levels of development.

Box 55 provides a suggested model provision which may be incorporated under national legislation.

3. Definitions, exceptions and criteria

The majority of bilateral trade agreements restrict and adopt stricter definitions and criteria for patentability than those available under TRIPS. Nevertheless, member states are advised to explore the remaining policy space in accordance with their national agendas.

In the area of patent protection and public health, recent bilateral trade agreements leave countries with a considerable space to define what is meant by several definitions and terms including novelty, invention, therapeutic use and public use. The use of these flexibilities is important in order to create “opportunities to allow legitimate access to many inventions”.⁴³ Moreover, some of these agreements still leave the door open for member states to design their own regime of patent exemptions and exceptions. Thus, the definition of “invention” itself may be drafted in a manner which may exclude a number of products from its scope.⁴⁴ The following box provides a suggested model provision which may be incorporated under national legislations when defining “novelty” and “inventive step” (Box 56).

The same approach also applies to the protection of plant varieties. As mentioned, there is no obligation under TRIPS to protect plant varieties. Rather countries are given the choice to determine the protection regime as long as such a regime is “effective”.⁴⁵ This gives countries considerable leeway in determining what is meant by effective, thus providing the possibility of protection through a sui generis system, or even through installing a reward system for inventors instead.⁴⁶ If a country in the course of negotiating

Box 56. “Novelty”: model provision

- a. An invention shall be deemed to be new when it does not form part of the state of the art. The state of the art shall comprise everything made available to the public in any country by means of a written or oral description, by use or in any other way.
- b. The state of the art, as defined in paragraph (a), shall include knowledge developed by or in possession of a local or indigenous community.
- c. The state of the art shall also comprise unpublished patent applications filed at the national Patent Office, where such applications are subsequently published.

“Inventive step”: model provision

- a. Patents shall not be granted in respect of a product or processes which [are] obvious to a person skilled in the art.
- b. In particular, an invention shall be deemed obvious when the prior art provides motivation to try the invention, or when the method of making a claimed product is disclosed in or rendered obvious by a single piece or any combination of pieces of prior art.

Source: Correa C. *Integrating public health concerns into patent legislation in developing countries*. Geneva, South Centre, 2000.

a bilateral trade agreement incorporates such a regime prior to entering into negotiations, it is more likely that the country will be able to resist pressures to provide patent protection for plant varieties in accordance with the developed country's system of protection, hence avoiding additional restrictive TRIPS-plus measures.

Even where certain agreements may require specific commitments such as the provision of protection for undisclosed data and for marketing approval, countries may strive to implement these commitments creatively by relying on national legislation to curtail their effect. For example, national legislations might confine the period of data to a “maximum” period of time rather than a “minimum” one. In cases where such period is not defined, countries should aim to provide a shorter a period of protection than prevailing in other industrialized countries.

The Chilean experience provides some useful insight in this regard. Under its national law, the Chilean government sought

to restrict the effects of the data exclusivity provisions provided under the US–Chile FTA by explicitly excluding several issues from the scope of protection. Accordingly, Chilean law states:

Protection will not be granted or continue in cases of:

- anticompetitive behaviour,
- in matter of public health, national security, noncommercial public use, national emergency,
- if the pharmaceutical product is subject of a compulsory licence,
- if the product has not been commercialized in Chile within 12 months from the date of registry or sanitary approval in the country,
- if the product has a registry or authorization in a foreign country of more than 12 months.⁴⁷

The Australian experience also provides some useful insights in this regard. In order to limit the effects of linking safety, efficacy and quality regulatory approval with patent status arising from the US–Australia FTA, the Australian government sought to limit this TRIPS-plus requirement by passing legislation at the time of implementing the FTA (treaties are not self-executing under Australian law) that amended the Australian Therapeutic Goods Act of 1983 by adding penalties for evergreening and allowing its drug safety regulatory authority to accept as prima facie valid a certificate of compliance put out by a generic manufacturer. This meant that the Australian drug and safety regulation organization did not have to become a patent compliance-checking organization too.

Finally, countries in the Region are encouraged to explore and incorporate a wide range of exceptions under their national patent laws including the defence of the public order and national interest, private and noncommercial use, encouragement of local research, scientific and technological development, public health exceptions, Bolar exception and the facilitation of international travel and international trade.⁴⁸ Box 57 provides a suggested model provision which may be incorporated under national legislation.

Countries in the Region are encouraged to explore and incorporate a wide range of exceptions under their national patent laws.

Box 57. Exceptions to exclusive patent rights: model provision

It shall not be an infringement of a patent to use the patented invention without the authorization of the patent holder in any of the following circumstances:

- a. to carry out any acts related to experimental use of the patented invention, whether for scientific or commercial purposes;
- b. to make use of a patented invention for teaching purposes;
- c. to carry out acts, including testing, using, making or selling a patented invention, solely for the purposes reasonably related to the development and submission of information required under any law of the country or of a third country which regulates the manufacture, construction, use or sale of any product;
- d. to make use of the patented invention in relation to the preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription; and
- e. to manufacture and export to a third country a patented healthcare invention where the export of the invention addresses a health need identified by the third country, provided that (i) the product is not patented in the third country; or (ii) the government of the third country has authorized use of the patent without consent of the patent owner, and that the production for export of the invention is intended for only the market of the third country.

Source: *Manual on good practices in public health-sensitive policy measures and patent laws*. Penang, Malaysia, Third World Network, 2003.

4. The role of other non-intellectual property laws and institutions

Intellectual property laws in developed countries do not operate independently of other spheres of regulation. These regimes are the fruit of a long period of accommodation, progress and development and are often supported and supplemented by other legal, judicial and institutional instruments and arrangements.

Intellectual property protection is not merely about intellectual property, but is linked to other areas of law and regulation. Therefore, in order to create the necessary balance between the interests of intellectual property holders and the public, the

implementation and enforcement of intellectual property often rely on the existence of other complementary and supportive national laws and tools. One of the important areas in this regard is the existence of adequate competition laws and policies.

The next section will thus focus on two issues with considerable influence on public health policy and access to drugs and medicines that have been neglected by countries in the Region for a long time. These are competition law and policy, and the role of national patent offices.

Competition law and policy

Since intellectual property protection is an exclusive statutory monopoly, overprotection and abuse of these properties will have a negative impact and anticompetitive outcome for the economy and members of society. One of the most influential tools needed to curb the abusive and anticompetitive practices of intellectual property is competition law and policy.

The term “competition policy” is a broad term covering several aspects and areas ranging from government action, legislation, judicial decisions and regulations aimed at curbing anticompetitive practices. Due to various inputs, this makes it difficult if not impossible to devise a comprehensive definition for this term. Because of this, Maskus and Lahouel described competition policy as being “complex in its intentions and effects”.⁴⁹

Competition policy is a part of everyday life in developed countries. The IPRs Commission Report states:

In the US particularly, but also in other developed countries, pro-competitive regulation of intellectual property rights and control of related restrictive business practices are key features of anti-trust legislation and these are regularly put into effect by the courts, competition authorities and by other relevant government agencies.⁵⁰

This essential balancing tool has often been either weak or absent from the legal and institutional structure of the majority of developing and least developed countries. As Correa states, “in fact, in most of these countries IPRs have been broadened and strengthened in the absence of an operative body of competition

Competition policy is a part of everyday life in developed countries.

law, in contrast to developed countries where the introduction of higher levels of IP protection has taken place in normative contexts that provide strong defences against anti-competitive practices".⁵¹ Moreover, according to a recent survey of competition laws in developing countries it was found that only five out of 33 countries ban intellectual property agreements that restrict competition, compared with nine out of 22 industrial countries.⁵²

The implications associated with abusive practices in relation to public health and intellectual property are many.⁵³ For example, practices by giant exporting pharmaceutical companies may still impair competition in importing countries, even in the absence of government restrictions. In the absence of well established competition law and policy, these firms may enter into exclusive or selective arrangements and impose the prohibition of parallel imports on their branded products hence affecting the availability and affordability of drugs and medicines. Therefore, one of the primary objectives of competition law and policy in this area is the preservation and encouragement of fair and adequate competition within the economy.⁵⁴

In acknowledging the role and importance of competition law, TRIPS provides member states with the freedom to curb intellectual property abuses and distortions through the use of competition law and policy.⁵⁵ TRIPS therefore incorporates several provisions which may be used to enhance and institutionalize competition law and policy in member states in order to foster the flow and dissemination of know-how and technology (Box 58).

Significantly, these competition provisions as contained under TRIPS are permissive in nature rather than mandatory; hence they do not require any minimum standards to be applied by countries as in the case of intellectual property protection. This lack of standardization has made the creation of competition policies and regulations more complex and sophisticated, particularly for those developing and least developed countries lacking the necessary legal and technical expertise and qualified human resources.

Countries in the Region, due to various reasons, including the lack of adequate legal expertise needed to draft a comprehensive framework of laws, regulations and policies, are yet to capture the full benefits of competition law and policy. Without the existence and proper enforcement of this complementary policy,

The implications associated with abusive practices in relation to public health and intellectual property are many

Box 58. Competition law and policy under TRIPS

Article 8.2 of TRIPS states:

Appropriate measures, provided that they are consistent with the provisions of this agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 31 of TRIPS states:

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.

Article 40 of TRIPS states:

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.
2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

the institution of intellectual property itself might fail to achieve its main goals of fostering competition and encouraging creativity.

Even for those countries in the Region that have already introduced some competition laws, little activity in the field of

enforcement can be detected. For example, commenting on the Tunisian experience—one of the first Arab countries to inaugurate a competition law back in 1991—Lahouel explains, in relation to the work of the Tunisian Competition Council, that:

[a] salient feature of the Council's record is its low level of activity since its creation and the very small number of cases brought to it by the Ministry or private firms. Over a six-year period, from its creation in mid-1991 to mid-1997, it issued only three decisions, two of which were rejections of the complaints and one a condemnation of abusive conduct of a dominant position (involving a domestic poultry company). It also issued its opinion on five occasions on draft legislation submitted for consultation by the Ministry of Commerce. Eleven cases were pending as of mid-1997.⁵⁶

A recent World Bank report alerts developing and least developed countries to the implications of not developing and institutionalizing the appropriate and adequate competition policy within their national jurisdictions. The World Bank report stated:

Unless developing countries rapidly establish adequate competition frameworks and regulatory institutions that also address monopoly abuse of intellectual property rights, it is possible that increasing intellectual property right protection could result in welfare losses from monopoly behavior.⁵⁷

Designing a competition law and policy for any country is a difficult endeavour that requires high levels of collaboration, coordination and implementation. When designing these legislative tools and policies, developing countries must take a number of factors into consideration. This presupposes one vital understanding: that there can never be a standardized competition law and policy since these will vary from one country to another. Appropriate policies depend upon a number of factors including the size, type and concentration of the economy and its market structure. In addition, it is necessary to create a vibrant competition policy that is capable of differentiating and accommodating all types of practices which might have an effect on competition.

In order to use competition law and policy in the area of public health, countries in the Region need to undertake additional legislative steps. For example, in the area of compulsory licensing, countries may choose to include these grounds under competition laws in addition to those available under patent laws. In addition,

Designing a competition law and policy for any country is a difficult endeavour that requires high levels of collaboration, coordination and implementation

countries may also stipulate that compulsory licensing will also be applicable in cases of anticompetitive behaviour such as in the case of the patent holder's unilateral refusal to grant a licence (refusal to deal).

The above have been practised and established by a number of competition authorities in the developed countries. For example in 2007 following an investigation launched into possible abuse of a dominant position by the companies Merck & Co. Inc. and Merck Sharp & Dohme (Italia), Italy's Competition Authority took measures to reduce the costs of medicines by introducing as early as possible competition (from generic medicines) into the market. The Italian Competition Authority decided that the Merck Group would be obliged to grant free licences to allow the manufacture and sale in Italy of the active ingredient finasteride and related generic drugs⁵⁸ two years before the 2009 expiration of the Supplementary Protection Certificate provided in European Union law. In a press release, the Competition Authority stated that this ruling "needs to be seen in the wider context of the Authority's efforts to encourage businesses to adopt commitments aimed at improving market conditions, competition and consumer choice. In the pharmaceuticals sector in particular the Competition Authority's initiative is aimed at encouraging more widespread use of generic products, taking advantage of notifications from the Italian Office of Patents and Trademarks within the Ministry of Economic Development which are based on regulations governing patents in this sector".⁵⁹

Competition law also may play a pivotal role in relation to the activities of several government agencies. For example, competition law may be applicable in the case of obtaining pharmaceutical patents in an unjustified and fraudulent manner (Box 59). In addition, "poor quality" and "frivolous" patents can be scratched under competition law.⁶⁰ Other regulatory practices such as marketing approval and data exclusivity also might be circumscribed and curtailed under national competition laws.⁶¹ Finally, courts also play a pivotal role in creating competitive environment by limiting the rights conferred by intellectual property regimes.⁶²

Countries may also stipulate that compulsory licensing will also be applicable in cases of anticompetitive behaviour

Box 59. Tackling competition practices in developing countries

Interestingly, the South African Competition Commission had set a precedent in this regard in 2003. It found that pharmaceutical firms GlaxoSmithKline South Africa (Pty) Ltd (GSK) and Boehringer Ingelheim (BI) had contravened the Competition Act of 1998. The firms were found to have abused their dominant positions in their respective anti-retroviral (ARV) markets, in particular, the firms had “denied a competitor access to an essential facility.” Although the Commission decided to refer the matter to the Competition Tribunal for determination, the case was later settled as the firms accepted to grant voluntary licences. As a result, there was no further elaboration on the application of the essential facilities doctrine.

Source: *Correa C. Intellectual property and competition law: exploration of some issues of relevance to developing countries.* Geneva, International Centre for Trade and Sustainable Development, 2007.

The importance of national patent offices

Another important national body that has often been neglected by developing and least developed countries, including those in the Region, is the national patent office and its role in the preservation of public health, access to medicines and transfer of technology.

In general, national patent offices play an administrative role by applying “patent standards that are decided and defined by others—the courts, legislatures or the executive acting in the context of treaty negotiation”.⁶³ Unlike some of the developed countries’ national patent offices, which have existed for a long time, national patent offices in countries in the Region are a more recent phenomenon. For example, the United States Patent and Trademark Office (USPTO) was established in 1790 to undertake activities related to patent protection and enhancement of science in the United States. The number of individuals working for this office in 2006 was 6855 employees.⁶⁴

By contrast, developing countries, including those in the Region, lack such an institutional capacity. Accordingly, national patent offices often suffer from an evident lack of resources, qualified personnel and a defined legal and economic role. For example, in comparison to the United States Patent and Trademark Office, the Egyptian Patent Office, one of the oldest and biggest national patent offices in the Region, was created in 1951, and the number of its employees does not exceed 200.⁶⁵

Countries in the Region need to invest more in their national patent offices. These offices must be placed at the heart of the national development agenda and its public health goals and objectives.⁶⁶ Governments should recruit additional specialized personnel and upgrade these offices' current technological, technical, human and financial abilities.

In an ideal world, patent examiners should take policy concerns into account when performing their examinations. Unfortunately they often seem to perceive their role as being merely technical. The more advanced and sophisticated the national patent office becomes, the more likely it will be able to explore the policy space available under national and international patent laws. A recent example is the decision by the Indian Patent Office to reject an application for critical AIDS drugs by adopting a strict interpretation of patentability criteria under the Indian Patent Law thus using the important safeguards available under the law to ensure that frivolous applications are not granted at the cost of public health.⁶⁷

Moreover, national patent offices should regularly be informed and consulted about issues related to patent protection, public health and access to medicines. Collaboration between national patent offices and other national health departments and agencies including the ministry of health should be encouraged. One technique that has proved its success in developing countries is the Brazilian model, which forces patent offices to coordinate with health experts and even seeks the prior consent of the public health service (ANVISA) before granting a pharmaceutical patent.⁶⁸ The latter are in a much better position than patent examiners to assess the contribution of an invention to innovation and public health and welfare.

Officials from the national patent office should also be involved in the observance and negotiation of bilateral, regional and

Countries in the Region need to invest more in their national patent offices

international trade agreements and their implementation in a pro-development manner. As the case of the United States demonstrates, the USPTO forms an integral part of any United States negotiation team.

More important, there is the need to spread awareness and knowledge within society about the role and importance of national patent offices. In describing this lack of collaboration and awareness, Drahos found that health officials in developing countries “did not know the first thing about the operations of their patent offices and how those operations might impact on access to medicines. Clearly, knowledge about what patent offices do (knowledge in the old fashioned sense of knowing the truth about their operations, including their relations with pharmaceutical companies, their relations with the Trilaterals [the USPTO, the European Patent Office (EPO) and the Japanese Patent Office (JPO)] and the quality of their examination systems) is a first step if developing country governments want to integrate their patent offices into a national public health strategy on access to medicines”.⁶⁹ Research conducted by the author looking into the relationship between various official departments and agencies and patent protection in a number of countries in the Region found a clear lack of coordination and collaboration between the various governmental departments and agencies on the one hand and the national patent offices on the other. In an interview by the author in one of the countries of the Region, one major pharmaceutical agent did not even know about the existence of the national patent office in the country.⁷⁰

Although foreign technical and financial assistance is welcomed (Box 60), countries in the Region must pay special attention to the kind and type of assistance provided to their national patent offices by ensuring that it serves their national interests and plans rather than the interest of the donors and multinational pharmaceutical companies.⁷¹ More important, countries receiving foreign assistance in this area should avoid over-reliance on such assistance—particularly if the assistance was shaped by the developed countries’ views on patent issues—without proper and adequate scrutiny.

Moreover, countries in the Region must not limit themselves to assistance from the main trilateral patent offices but rather should seek assistance from other experienced patent offices including those in other developing countries.⁷² The success of the Brazilian

Countries in the Region must pay special attention to the kind and type of assistance provided to their national patent offices by ensuring that it serves their national interests

Box 60. Gowers review, Recommendation 5

United Kingdom Patent Office (UKPO) should undertake joint working with African patent offices from mid-2007, with the aim of:

- Helping them to take advantage of the flexibilities currently existing in the WTO/TRIPS architecture where appropriate; and
- Encouraging them to make positive use of IP rights through dissemination of information in patents.

Source: *Gowers review of intellectual property*. Landon, HM Treasury, 2006.

Patent Office in this regard may provide several valuable lessons to developing and least developed countries in the Region.⁷³

Thinking strategically outside the bilateral zone

Although some bilateral trade agreements may confer certain benefits, including financial assistance and market access for certain sectors of the economy, countries in the Region should view bilateralism as the “second best option”; the long-term strategic interest of these countries lies under a more stable multilateral trading regime. In addition to undertaking the necessary legislative and administrative steps nationally, countries in the Region should never abandon the multilateral track in exchange for a bilateral one. To the contrary, developing countries, including those in the Region, should become proactive in pursuing their interests multilaterally. This recommendation corresponds with, and is supported by, the growing number of recent calls alerting the developing countries to the negative impact of bypassing and abandoning the multilateral trading regime in favour of a bilateral approach.⁷⁴ This attitude must be weighed in light of the implications arising from the application of these bilateral trade agreements.

Countries in the Region should be fully aware of the nature and effect of the commitments they are undertaking in the area of public health and intellectual property as a result of bilateral

The TRIPS-plus provisions introduced through these bilateral agreements have no time limit and are likely to remain in force permanently

trade agreements. While tariffs have been historically low in the developed countries, the situation is not the same in developing countries, in which tariffs represent an important source of income needed to fund national projects and infrastructure including public health, education and social security. Thus, in attempting to open their markets through bilateral agreements, developing countries must assess the impact this may have upon their national industries and development agenda.

Moreover, the TRIPS-plus provisions introduced through these bilateral agreements have no time limit and are likely to remain in force permanently, thus diluting any temporary preferential benefits countries in the Region may obtain from these agreements. Accordingly, once a multilateral agreement is eventually concluded or more bilateral trade agreements are agreed on with other countries, the United States and the European Union will be bound to liberalize and open up their markets as a result of tariff and quota reductions on a nondiscriminatory basis. On the other hand, the privileged market access concessions obtained by countries in the Region due to these bilateral agreements will be gradually eroded as more countries sign FTAs; hence what will remain in place are permanent and restrictive TRIPS-plus obligations.

Countries in the Region need to develop national mechanisms and safety nets before they can accept any additional TRIPS-plus obligations. The United States' approach provides some valuable lessons in relation to the implementation of its commitments and obligations under the bilateral trade agreements concluded with developing countries, including those in the Region. Accordingly, in order for the United States to ratify a bilateral trade agreement, the partner country must ensure that its national laws and legislation incorporate the commitments made under the bilateral agreement. However, this is not the same in the United States, in which the effect of such bilateral agreements is not self-executing. For a bilateral agreement to enter into force, the United States Congress must first approve it by specifically enacting implementing legislation for that purpose.⁷⁵ This approach gives the United States one more chance to scrutinize the agreement and even revise it if it collides with US national interests and priorities.⁷⁶

Medicine and drug regulations and national health authorities are also important in this process since effective drug regulation contributes to the promotion and protection of public health. In addition, an effective national medicines authority is vital in

allowing for the effective operation of compulsory licences and parallel importation, since these two flexibilities must generally be used at the country level.⁷⁷ In addition, drug regulations can also drastically speed up the process of obtaining generic drug approval hence improving the overall access to medicines in a country.

In addition, countries in the Region must strengthen their international presence and representation through building regional and international coalitions and networks. Helpfully, Drahos differentiates between coalitions and networks by stating that the “former consist of governments that coordinate, while the latter consist of nodal actors (whether state or non-state) that coordinate”.⁷⁸ Although both types of arrangements are vital, Drahos refers to the benefits of networks, which often remain outside the realm of political and financial pressure. The Doha Declaration on the TRIPS Agreement and Public Health has often been cited as a success story achieved through intensive networking and collaboration.

This networking and coalition building will also enable countries to exchange information and learn about the experiences—either successful or not—of other countries (Box 61).

Box 61.

Another problem that exacerbates the lack of technical expertise to implement TRIPS flexibilities in national laws is the inability to access information on best practices. Developing countries are generally not aware of the measures undertaken by their counterparts around the world. As a result, even countries within a region with similar or the same access problems adopt different strategies, with varying degrees of success. More importantly, while most developed countries are quick to provide assistance and to give examples of best practices on how to protect patent rights, there is never a best practice guide or technical assistance, for example, on the extensive use by the United States of compulsory licensing or antitrust legislation to curb abuse of patent rights and serve other public interest purposes.

Source: Musungu S, Villanueva S, Blasett R. *Utilizing TRIPS flexibilities for public health protection through south–south regional frameworks*. Geneva, South Centre, 2004

Regional cooperation and collaboration... is particularly vital for example in the area of national patent offices

Countries in the Region should work towards enhancing their international negotiation position through forging links and collaborations with other like-minded countries and international agencies. Although the number of developing country coalitions and groupings has risen recently to include the G-20, the G-33, the Least Developed Countries Group and the African, Caribbean and Pacific Group, to name but a few, until this moment, countries in the Region have failed to create their own independent international coalition and agenda in the area of intellectual property in accordance with their national priorities and interests.

Regional cooperation and collaboration between various institutional and administrative authorities should also be encouraged within the Region. This is particularly vital for example in the area of national patent offices. Further coordination and exchange of knowledge and expertise between national drug regulatory authorities would also have a positive impact on these institutions and upon collaboration in the Region.

Moreover, civil society and nongovernmental organizations in the Region must be empowered to play a more positive and constructive role in the area of intellectual property and public health (Box 62). The strength of these organizations lies not only in the fact that they can deliver their voices and the voices of millions of people; they can also play an active and critical role in educating people and providing vital services to society.⁷⁹

Developing countries including those in the Region need to use the political circumstances in other developed countries to obtain further concessions or even attempt to renegotiate and relax the obligations stipulated under the concluded bilateral trade agreements. A telling example is the recent signs of a shift in the United States' bilateral FTA policy due to the recent changes in its domestic political climate through the revision and relaxation of the intellectual property chapters of several already negotiated FTA agreements (Panama, Columbia and Peru).⁸⁰ The same should also apply in the cases of the bilateral association agreements signed with the European Union and the EFTA countries.⁸¹

Additional steps should be undertaken to remind developed countries that they have a moral responsibility towards the citizens of developing countries. TRIPS-plus provisions are likely to raise the prices of medicines in these countries and will restrict their ability to deal with national health emergencies and epidemics,

Box 62.

The WTO and WIPO should increase the opportunities for civil society organisations to play their legitimate roles as constructively as possible. For instance, this could be done by inviting NGOs and other concerned civil society groups to sit on, or observe, appropriate advisory committees and by organising regular public dialogues on current topics in which NGOs could participate.

Source: *Integrating intellectual property rights and development policy*. London, Commission on Intellectual Property Rights, 2002.

adding more to the woes of these countries. Therefore, developed countries must revise their policies and refrain from pursuing their TRIPS-plus agenda, which may put the lives of millions of people in jeopardy. The IPRs Commission Report concludes that:

Higher intellectual property standards should not be pressed on developing countries without a serious and objective assessment of their development impact. We need to ensure that the global intellectual property IP systems evolve so that they may contribute to the development of developing countries, by stimulating innovation and technology transfer relevant to them, while also making available the products of technology at the most competitive prices possible. We need to make sure that the IP system facilitates, rather than hinders, the application of the rapid advances in science and technology for the benefit of developing countries.⁸²

More important, developing and least developed countries should grasp that they themselves have a moral and ethical responsibility towards other developing and least developed countries that did not yet sign similar bilateral agreements. Adhering to TRIPS-plus agreements and abandoning other developing countries, thus forcing them to go it alone, will make the position of these countries more difficult and will eventually push them to accept harsher commitments and obligations in many areas including intellectual property. Successful negotiations under bilateral agreements are also likely to restore balance under the international intellectual property regime in favour of developing and least developed countries by achieving greater prominence for public goods and by improving the global intellectual property standards-setting initiatives.

Box 63.

However, experience shows that there is a need for policy instruments specifically designed with the aim of helping countries at lower stages of development to converge on the levels of efficiency and affluence achieved by the more advanced economies, and to improve the welfare of all groups of the population. Making this the principle for policy design at both the domestic and international level requires recognition of the fact that successful development and integration of the developing countries is in the mutual interest of all countries, as longer-term growth and trading opportunities of the more advanced economies also depend on the expansion of industrial capacity and markets in the poorer economies.

Source: *Trade and development report, 2004*. Geneva, UNCTAD, 2004.

In short, countries that have successfully negotiated regional or bilateral trade agreements that preserve all of the TRIPS flexibilities should guide and support other developing countries engaged in the negotiation process (Box 63).

Finally, it is vital that countries in the Region seek supplementary and alternative options for fostering innovation and encouraging research and development in the area of public health.⁸³ In this regard, the CIPIH Report contains reference to many successful stories in a number of developing countries, including Cuba, India and Brazil, in the area of public health. The Report also makes numerous recommendations in this regard including increased investment in human resources, encouraging national and regional networks, increasing R&D and nurturing transfer of technology.⁸⁴

In addition, Stiglitz, for example, suggests a prize-funding system, whereby governments could finance a prize fund which would award the biggest prizes for developers of treatments for, or preventions of, costly diseases affecting hundreds of millions of people.⁸⁵ On the other hand, Pogge proposes a health impact fund, which aims to increase access to medicines by creating additional incentives for innovation in the health sector. According, by choosing to register a new drug with the fund, the patent holder would be rewarded for ten years through treaty-backed payments proportional to the drug's global health impact. In exchange,

patent holders agree to sell the drug at a designated low price and to offer zero-priced licences for manufacturing and selling the product after the conclusion of the reward period.⁸⁶ It is important to bear in mind that these examples might not be suitable for all countries in the Region due to various economic, institutional and political differences. What is important is that policy-makers be informed and made aware of such alternatives so that an informed effort to try and select the most suitable option for their countries is undertaken.⁸⁷

Endnotes

1. For a discussion see Falvey R, Foster N, Greenaway D. Intellectual property rights and economic growth. *Review of development economics*, 2006, 10(4):700–19; Gould M, Gruben W. The role of intellectual property rights in economic growth. *Journal of development economics*, 1996, 48:323–50; Mansfield E. *Intellectual property protection, foreign direct investment and technology transfer*. Washington DC, World Bank and International Finance Corporation, 1994. IFC Discussion Paper 19.
2. *World development report: knowledge for development*. Washington DC, World Bank, Oxford University Press, 1998, at 17.
3. For example, the level of GDP per capita income in some GCC countries including Kuwait, Qatar and the United Arab Emirates is the highest in the world, while at the same time, other countries in the Region including Yemen and Djibouti have the lowest per capita income rates in the world. See *Human development report 2007–2008: fighting climate change*. New York, UNDP, 2008.
4. Vivas-Eugui D, von Braun J. *Beyond FTA negotiations—implementing the new generation of intellectual property obligations*. Geneva, ICTSD, August 2006, at 2.
5. For example, some countries apply a system of self-execution for international commitments whereby the ratification of international commitments has automatic legal effect without any need for other formalities. On the other hand, other countries may apply a different system whereby parliament or its equivalent may be requested to ratify a commitment before it comes into effect under national law.
6. This is confirmed by recent empirical research. For example, a World Bank study found that “to get up to speed in three areas, customs valuation, TRIPS, and sanitary/phytosanitary measures, would cost each country some 150 million dollars”. See Finger M, Schuler P. *Implementation of the Uruguay commitments: the development challenge*. Washington DC, World Bank, October 1999. Development Research Group, Policy Research Working Paper 2215. Another study by the World Bank found that developed countries would be the major beneficiaries of TRIPS and its enhanced patent protection, with the United States reaping an estimated US\$19 billion annually. *Global economic prospects and the developing countries 2002: making trade work for the world’s poor*. Washington DC, World Bank, 2002, at 133. In addition, UNCTAD estimated that strengthening the scope of authorities and their personnel in Egypt because of TRIPS was expected to cost US \$1 million. UNCTAD. *The TRIPS Agreement and developing countries*. New York, United Nations, 1996. UNCTAD/ITE/1, at 23 and 24.
7. See Abbott F. *Intellectual property provisions of bilateral and regional trade agreements in light of US federal law*. Geneva, ICTSD Project on IPRs and Sustainable Development, January 2006.
8. See Gervais D. Intellectual property, trade & development: the state of play. *Fordham law review*, 2006, 74:505–36.

9. *Integrating intellectual property rights and development policy*. London, Commission on Intellectual Property Rights, 2002 [the IPRs Commission Report], at 8.
10. It must be understood that the ensuing analysis does not propose an exhaustive list of measures. As a result of the complexity of trade negotiations and the ongoing development in methods and techniques, countries must upgrade and define their own policies in line with ensuing developments and their levels of progress.
11. See Jackson J. *The trading system: law and policy of international economic relations*, 2nd ed. Cambridge, Massachusetts, MIT Press, 1997. Also see Looney R. U.S Middle East economic policy: are trade-based initiatives an effective tool in the war on terrorism? *Strategic insights*, Center for Contemporary Conflict, 2005, IV(1).
12. This is clear from the case of United States FTAs in the Region. For example, the United States exported to Jordan what was worth US \$404 million in 2002; United States shipments to Morocco amounted to US \$565 million in 2002 and to Bahrain US \$419 million in 2006. For more see Mekay E. Oman pact boosts US agenda in Middle East. *Inter press service*, 2006, 21 January; Murphy E. Charting the transnational dimension of law: U.S. free trade agreements as benchmarks of globalization. *Houston journal of international law*, 2004, 27(1):47–71; Folsom R. *Trading for national security? United States free trade agreements in the Middle East and North Africa*. Legal Studies Research Paper Series, No. 07-113, 2007. Available at www.ssrn.com.
13. Nogués comments on this by stating that “the Ministries of Foreign Affairs are [obviously] advised by other government offices. The problem here is that most of these other offices also have no experience in dealing with trade negotiations and often they feel removed from the long-run consequences of the advise they may give. In practice therefore, except for institutionalized interactions with the Ministries of Economy, the Ministries of Foreign Affairs often decide by default”. Nogués J. *Unequal exchange: developing countries in the international trade negotiations*. Paper presented at the Murphy Institute Conference on the Political Economy of Policy Reform, New Orleans, 2002. Available at <http://ctrc.sice.oas.org/geograph/south/Nogues.pdf>, at 16.
14. See generally Barton J. *New trends in technology transfer and their implications for national and international policy*. Geneva, ICTSD, 2007. Programme on IPRs and Sustainable Development, Issue Paper No. 18.
15. In this regard, the 2002 UNDP Arab Human Development Report states that institutional reform in the health sector needs to “focus on ensuring more efficient use of resources so that resources can be freed up to achieve wider social coverage. In addition to optimizing the allocation of health budgets, personnel and facilities, consideration should be given to providing health services through schemes that combine publicly owned clinical services, social and private insurance systems, and patient payments based on income. The financing of such schemes should have a positive bias in favour of the poorest segments of society. They could include targeted subsidies for transparently managed community health insurance schemes in rural areas”. UNDP. *Arab human development report 2002: creating opportunities for human generations*, New York, Arab Fund for Economic and Social Development, UNDP, 2002, at 102.
16. El Said M. *Intellectual property regime, infrastructure, and related procedures: enhancing access to treatment: intellectual property protection and HIV/AIDS: state of Kuwait*. Study prepared for WHO (EMRO), TWN and UNDP, June 2008.

17. As Yamin states, “decision-makers in governments, international financial institutions and even multinational corporations must come to view health and health care as non-negotiable entitlements, not as matters of governmental largesse or productivity”. Yamin A. Protecting and promoting the right to health in Latin America. *Health and human rights*, 2000, 5(1), at 134.
18. El Said M. Surpassing checks, overriding balances and diminishing flexibilities: FTA-IPRs plus bilateral trade agreements: from Jordan to Oman. *Journal of world investment and trade*, 2007, 8(2):243–68.
19. Article 1302 of the Australia–Thailand FTA states:

The Parties shall fully respect the provisions of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights and any other multilateral agreement relating to intellectual property to which both are parties.
20. The role of the judiciary is extremely vital in restoring the balance between the conflicting interests in this regard, as the below case from Thailand demonstrates.

In January 2004 Bristol-Myers Squibb (BMS), a US pharmaceutical group, dropped a long-standing court battle against two Thai people living with HIV/AIDS over the patent for didanosine, an HIV/AIDS treatment drug. BMS decided to withdraw its appeal and give up its exclusive right to produce didanosine in Thailand claiming that it had decided to “dedicate the patent to the people of Thailand.” In October 2002 the Thai Central Intellectual Property and International Trade Court issued a landmark ruling stating that patients have the right to challenge a patent because the “lack of access to medicines due to high prices prejudices the human rights of patients to proper medical treatment.” In coming to this conclusion, the Thai court explicitly referred to the Doha Declaration on TRIPS and Public Health.

The case began in 1999 when the Thai Government Pharmaceutical Organization (GPO) sought a compulsory licence from the Thai Department of Intellectual Property in order to produce a generic version of didanosine for the treatment of 700,000 Thai HIV/AIDS patients. This request was supported by a number of local NGOs, the Thai Network for People living with HIV/AIDS (TNP+) and Médecins Sans Frontières (MSF). However, following thinly veiled threats of trade sanctions against Thailand from the US government, the Thai Commerce Ministry refused the licence. In May 2001 the Thai Aids Access Foundation, together with two people living with HIV/AIDS, filed the lawsuit against the BMS patent.

The victory in obtaining this ruling demonstrates that the right to health and the right to life can be protected by challenging patents and not yielding to threats from industrialized countries. In practical terms, the ruling means that GPO should now be able to produce a generic formula of didanosine at considerable cost savings to HIV/AIDS patients.

Practical guide to the WTO. 3D Forum Asia. 2004, at 40. Available at <http://www.3dthree.org/en/complement.php?IDcomplement=36>.
21. On the major categories of stakeholders identified by the World Bank, see *A practical guide to negotiations*. Washington DC, World Bank Institute, 2004. Macroeconomic and Policy Assessment Skills Paper, Module 9.
22. A good case study in this regard is what happened in Sri Lanka in 2003. When Sri Lanka introduced new patent legislation in 2003 the law failed to

make the most of the policy flexibilities for compulsory licensing and parallel imports permitted by the Doha Declaration. Three petitioners challenged the bill in the Supreme Court arguing that it violated fundamental rights and contravened the constitution. The Supreme Court determined that there was a violation and referred the bill back to the National Intellectual Property Office for redrafting. The Ministry of Health requested Health Action International—Asia Pacific to organize a national seminar on TRIPS and public health and advise on appropriate compulsory licensing and parallel import provisions. The seminar was convened in July 2003, and participants unanimously adopted the draft provisions on compulsory licensing and parallel imports. These were sent to the National Intellectual Property Office. The amended bill included these provisions. This was passed by the parliament in November 2003. See 3D Forum Asia, *supra* 20, at 39.

23. Drahos explains that in the case of “agreements that relate to intellectual property the technical detail of these agreements is monitored by a third tier committee, the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC). The membership of IFAC is made up of 20 members drawn from Industry Sector Advisory Committees and another 20 drawn from the private sector areas who provide the committee with technical expertise in intellectual property. This technical expertise is vital to the committee’s work and complements the strategic work of ACTPN [US Advisory Committee for Trade Policy and Negotiations]. Under its charter IFAC is to provide detailed technical advice on trade agreements negotiated by the USTR. In the case of the US–Singapore FTA, IFAC, in the words of its report, ‘advised U.S. negotiators on, and reviewed draft texts, of the U.S.-Singapore FTA intellectual property chapter’. Importantly, IFAC reviewed the US–Singapore FTA in the context of other multilateral and bilateral agreements and initiatives that the US had achieved. In other words, IFAC is a committee that gets its hands dirty by reviewing and drafting specific agreements. It does this technical work across all US trade initiatives in intellectual property, whether bilateral, regional and multilateral. It is thus able to co-ordinate at a technical level the work it does across these different fora, thereby ensuring that US trade negotiating initiatives push intellectual property standards in the direction that US industry would like. The technical expertise on IFAC, as well as the expertise available to it from the corporate legal divisions of its members means that, for example, it can evaluate a country’s intellectual property standards in detail when that country seeks WTO accession and it can provide detailed assessments of the standards that USTR negotiators must bring home in a negotiation.” Drahos P. *Expanding intellectual property’s empire: the role of FTAs*. Barcelona, GRAIN, November 2003. Available at www.grain.org/rights/tripsplus.cfm?id=28.
24. See discussion in chapter 4.
25. Schoenborn B. Public participation in trade negotiations: open agreements, openly arrived at? *Minnesota journal of global trade*, 1995, 4:102–40.
26. US–Columbia FTA, Article 16.12. Notably, the provision focuses on *scientific* cooperation but fails to make reference to *technological* cooperation in this regard.
27. Although some may argue that keeping the details of negotiations confidential will enable negotiators to speak frankly and be more flexible, in the case of bilateral trade agreements between developed and developing countries this situation is reversed. In this case, weak and small developing countries often suffer as a result in the asymmetry of power and lack of bargaining balance between the negotiating parties. For more see Katt W. The new paper

- chase: public access to trade agreement negotiating documents. *Columbia law review*, 2006, 106:679–707.
28. These demands were also made within the United States. In a motion for summary judgment filed by public advocacy group plaintiffs insisted that “[d]isclosure of all or part of the documents would permit Plaintiff and other members of the US public to provide useful and informed input to the US government”, but warned that the documents only had value while time remained to modify US positions. “If the public is not informed of the exact terms of the [agreement] until the conclusion of the process, then any opportunity for meaningful input is lost.” See Katt, *ibid.* at 686.
 29. Some developing countries managed to achieve this demand. For example, during its FTA negotiations with the United States, the Columbian government managed to make the text of the intellectual property section of the bilateral agreement public and to openly debate it nationally.
 30. An interesting initiative in India in the form of a “right to information” campaign led the government to enact “right to information” legislation in 2006. Similar laws are also available in other developing countries including Mexico, Ecuador and Thailand.
 31. For a detailed explanation of what information may be generally needed during negotiations see Bhattacharya D. *Least developed countries in trade negotiations: planning process and information needs*. Dhaka, Centre for Policy Dialogue, September 2005. Paper 52.
 32. *Global strategy and plan of action on public health, innovation and intellectual property*. Geneva, WHO, 2008. 61st World Health Assembly, WHA 61.21.
 33. Indeed the interpretation and defence of these issues after the implementation of the agreement might raise some difficulties for developing countries. Drahos and Tansey explain that “before developing countries seek the refuge of compromise or ambiguity they should ask whether in reality they are simply opening the door to defeat”. Drahos P, Tansey J. Postcards from international negotiations. In Tansey G, Rajotte T, eds. *The future control of food: a guide to international negotiations and rules on intellectual property, biodiversity and food security*. London, Earthscan, 2008, at 216; also see Drahos P. Four lessons for developing countries from the trade negotiations over access to medicines. *Liverpool law review*, 2007, 28(1):11–39.
 34. Roffe P. *Intellectual property provisions in bilateral and regional trade agreements: the challenges of implementation*. Geneva, CIEL, ICTSD and TRALAC, October 2006, at 6.
 35. For example, during Cambodia’s final preparations to join the WTO in 2002, the nongovernmental organization Médecines sans frontières (MSF) warned that the draft patent law, drafted with WIPO’s assistance to Cambodia, did not take into account TRIPS flexibilities and the Doha Declaration on the TRIPS Agreement and Public Health. The draft also failed to inform Cambodia that as a least developed country, it was not required to grant or enforce patents for pharmaceutical products until 2016. *Doha derailed: a progress report on TRIPS and access to medicines*. Geneva, MSF, 2003. Policy Note, at 5. Moreover, Kerry and Lee state that currently “many LDCs have stricter IPR protection than is minimally required by TRIPS. Of thirty African LDCs, only two do not grant patents for pharmaceuticals. Furthermore, low and middle-income countries (LMICs) can only assert available flexibilities and enhance their purchasing power if appropriate national drug policies are in place, backed by a legislative framework concerning such issues as use of generics, drug pricing and taxation”. Kerry VB, Lee K. TRIPS, the Doha Declaration and

Paragraph 6 decision: what are the remaining steps for protecting access to medicines? *Global health*, 3, 2007, at 3. Also see Correa C. *Health economics and drugs: essential drugs and medicines*. WHO, Geneva, 2002. Policy Series 12, Implications of the Doha Declaration on the TRIPS Agreement and Public Health. Available at <http://www.pubmedcentral.nih.gov>.

36. As stated, “many developing countries have not incorporated the TRIPS flexibilities into their laws for various reasons. What TRIPS permits and what countries actually do are two different things. In the end, it is national law and practice that will be decisive, both in terms of providing access to medicines, and in establishing a domestic framework in which TRIPS rules will be interpreted. One major reason many developing countries have not incorporated TRIPS flexibilities into their national laws is lack of technical expertise”. Musungu S, Villanueva S, Blasetti R. *Utilizing TRIPS flexibilities for public health protection through south–south regional frameworks*. Geneva, South Centre, April 2004, at 24. Matthews adds that the “suspicion is that those in charge of the legislative process in developing countries are simply unaware of the flexibilities available, or possess insufficient technical expertise to utilize these flexibilities”. Matthews D. TRIPS flexibilities and access to medicines in developing countries: the problem with technical assistance and free trade agreements. *European intellectual property review*, 2005, 11:420–7, at 423.
37. Drahos, *supra* 33, at 30.
38. US–Jordan FTA, Article 4.20.
39. See discussion in chapter 4.
40. Some developing countries are becoming active in issuing compulsory licences. For example, Thailand became the first developing country in 2008 to issue a compulsory licence for a breast cancer medicine produced by Novartis. See TWN. *Compulsory licensing for cancer drugs in Thailand*. Penang, Malaysia, TWN Info Service on Intellectual Property Issues, February 2008. Available at www.twinside.org.sg.
41. Musungu S, Oh C. *The use of flexibilities in TRIPS by developing countries; can they promote access to medicines?* Geneva, South Centre and WHO, 2006, at xviii.
42. The Doha Declaration on the TRIPS Agreement and Public Health, Paragraph 5(d) states:

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge.
43. Heald P. Mowing the playing field: addressing information distortion and asymmetry in the TRIPS game. *Minnesota law review*, 2004, 88:249–314, at 276.
44. For example, Heald recommends in this regard that this omission “may permit a patent office to deny patents for gene sequences or natural isolates from animal or plant tissues”. Heald, *ibid.* at 279.
45. TRIPS, Article 27.3.
46. For more see Dhar B. *Sui generis systems for plant variety protection: options under TRIPS*. Geneva, Quaker United Nations Office (QUNO), 2002. Available at www.quano.org/economicissues/intellectual-property/intellectualLinks.htm.
47. Decree 153 (2005) of the Health Ministry, Mechanisms for the Protection of Undisclosed Data. In Roffe, *supra* 34, at 14.

48. Garrison C. *Exceptions to patent rights in developing countries*. Geneva, International Centre for Trade and Sustainable Development, August 2006. ICTSD Project on IPRs and Sustainable Development, Issue Paper 17.
49. Maskus K, Lahoul M. Competition policy and intellectual property rights in developing countries. *World economy*, 2000, 23(4): 595–611, at 595.
50. IPRs Commission Report, *supra* 9, at 148.
51. Correa C. *Intellectual property and competition law: exploration of some issues of relevance to developing countries*. Geneva, International Centre for Trade and Sustainable Development, 2007. ICTSD Project on IPRs and Sustainable Development Programme, Issue Paper 21, at 1.
52. *World development report: building institutions for markets*. Washington DC, World Bank, 2002, at 147.
53. Fink explains that the “application of competition law to IPRs-related business practices has largely been confined to developed countries”. Fink C. *Promoting checks and balances in a world of strengthening intellectual property policies*. Bellagio, Italy, UNCTAD–ICTSD Dialogue on IPRs and Sustainable Development: Intellectual Property and Sustainable Development: Revising the Agenda in a New Context, 24–28 October 2005, at 2.
54. Anderson R. The interface between competition policy and intellectual property in the context of the international trading system. *Journal of international economic law*, 1998, 655–78. Moreover, some differentiate between two types of practice which may result in certain anticompetitive consequence:
 - practices related to abuse of a dominant position. These include restricting access to essential facilities, refusal to grant a licence and monopoly pricing.
 - practices related to restrictive vertical licensing. These include exclusive dealing and tying arrangements.
 See Fink, *supra* 53, at 77.
55. For example see TRIPS, Articles 8.2, 31 and 40.
56. Lahouel M. *Competition laws in MENA: an assessment of the status quo and the relevance of a WTO agreement*. Cairo, Economic Research Forum, 2000. Working Paper 2011, at 10.
57. “Ministerial Declaration of November 1982, GATT Doc. No. 1328 BISD/29S/9 1983. Available at <http://www.jus.uio.no/lm/wto.gatt.thirty.eighth.session.ministerial.declaration.1982/non.tariff.html>.”
58. Finasteride is used in the treatment of hypertrophy of the prostate as well as male pattern hair loss.
59. *Italy compels pharmaceutical companies to issue licences to generic competitors*. Penang, Malaysia, TWN Info Service on Intellectual Property Issues, April 2007. Available at http://www.twinside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.040701.htm.
60. Arguably these should never be granted in the first place. However, lack of resources and proper examination in developing countries may allow for such registrations. In these situations, competition law plays an important role.
61. Correa, *supra* 51.
62. For example, Correa explains that the US Supreme Court “denied a permanent injunction in a case of patent infringement. It stated that ‘the

- decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts.’ This decision effectively amounts to granting a compulsory licence on ‘equity’ grounds”. Correa, *ibid.* at 2.
63. Drahos P. *Trust me: patent offices in developing countries*. Canberra, Centre for Governance of Knowledge and Development, November 2007. Working Paper, at 1.
 64. *US Patent and Trademark Office: transforming to meet the challenges of the 21st century*. Washington DC, National Academy of Public Administration Report, August 2005. Report for the US Congress and the US Patent and Trademark Office.
 65. For more see El Said M. *The development of intellectual property protection in the Arab world*. New York, Edwin Mellen Press, 2008.
 66. Gowers Review, Recommendation 24, states:

The Patent Office should develop stronger links with universities and other research institutions, including through short placements, to ensure that IP examiners are aware of recent developments in technology.

Gowers review of intellectual property. London, HM Treasury, 2006. Available at www.hm-treasury.gov.uk.
 67. For more see TWN. *Indian patent office rejects AIDS drug patent application*. Penang, Malaysia, TWN Info Service on Intellectual Property Issues, 23 June 2008. Available at www.twn.org.sg.
 68. Under Brazilian law, ANVISA has the authority (and the responsibility) to grant prior consent to patent applications on pharmaceutical products and methods that were either pending or filed after 15 December 1999. This authority was part of the national enabling legislation under which TRIPS intellectual property protection for pharmaceuticals became part of Brazilian law (Article 229-C). Paraguay and Bolivia have established similar rules. See Noonan K. *Recent developments in pharmaceutical patenting and compulsory licensing of pharmaceutical patents in developing countries*. 8 July 2008. Available at http://www.patentdocs.net/patent_docs/2008/07/recent-developm.html. Also see Shadlen K. *The politics of patents and drugs in Brazil and Mexico: the industrial basis of health activism*. Boston, Massachusetts, Global Development and Environmental Institute, Tufts University, December 2007. Working Paper 07-05.
 69. Drahos, *supra* 63, at 26.
 70. El Said M. *Intellectual property regime, infrastructure, and related procedures: enhancing access to treatment: intellectual property protection and HIV/AIDS: State of Qatar*. Study prepared for WHO (EMRO), TWN and UNDP, June 2008.
 71. Generally see Roffe P, Vivas D, Veá G. *Maintaining policy space for development: a case study on IP technical assistance in FTAs*. Geneva, International Centre for Trade and Sustainable Development and the UK Department of International Development, 2007. ICTSD Programme on IPRs and Sustainable Development Series, Issue Paper 19.
 72. The USPTO, the European Patent Office (EPO), and the Japanese Patent Office (JPO) are the main providers of assistance in this regard. See www.uspto.gov and www.jpo.go.jp.
 73. Drahos describes the success of the Brazilian Patent Office experience by stating that it is a “preventive strategy that avoids the high costs of attempting to remove patents that have been granted. It is also an integrative regulatory strategy. It links patentability criteria in the area of pharmaceuticals to the goal of welfare-enhancing innovation in the health sector”. Drahos, *supra* 62, at 28.

74. See for example the IPRs Commission Report, *supra* 9; *Public health: innovation and intellectual property rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health*. Geneva, WHO, 2006 [hereafter the CIPIH Report]; and *Trade and development report*. New York and Geneva, UNCTAD, 2007, which states “thus the developing country partner in bilateral FTAs can be expected to incur additional costs as a result of IPR obligations that go beyond the already onerous ones of the WTO TRIPS Agreement”. UNCTAD/TDR/2007, at 62.
75. As Abbott explains, “Congress has made a practice of expressly denying self-executing effect of the FTAs in its implementing legislation”. Abbott F. *Intellectual property provisions of bilateral and regional trade agreements in light of US federal law*. Geneva, International Centre for Trade and Sustainable Development, January 2006. ICTSD Project on IPRs and Sustainable Development, at 7. Moreover, Roffe states that the USTR has “expressly advised the Congress that it may adopt subsequent legislation inconsistent with the terms of an FTA. USTR has also advised Congress that decisions of dispute settlement panels under FTAs do not affect US Federal law unless those decisions are expressly given affect by Congress”. Roffe, *supra* 34, at 10.
76. For example, the Thai government is in the process of amending certain clauses in the 2007 Thai Charter, including Article 190, which requires the government to place any international treaty it plans to sign before parliament for scrutiny. See Macan-Markar M. IPR violations high on Bush visit agenda. *Inter press service*, 29 July 2008.
77. For more see Gray A. *Access to medicines and drug regulation in developing countries: a resource guide for DFID*. London, DFID Health Systems Resource Centre, 2004.
78. Drahos, *supra* 63, at 35.
79. IPRs Commission Report, *supra* 9, at 166.
80. Roffe P, Vivas D. A shift in intellectual property policy in US FTAs? *Bridges*, August 2007, 5, at 15.
81. In fact this is already happening in other non-intellectual property sectors. For example, the European Union has just declared its intention to revise its association agreement with Algeria with respect to competition and enhanced security interests. The European party agrees amending the association agreement. *El Khabar* [in Arabic], 10 February 2008. Available at www.bilaterals.org.
82. See IPRs Commission Report, *supra* 9, at 8.
83. In this regard, Yu explains that as far as policy options are concerned, “there is a misguided tendency for policymakers in both developed and less developed countries to assume that the property rights model is the only model, or the best one, that is compliant with the TRIPs Agreement or other commitments under the international intellectual property regime. However, other models, such as compensatory liability rules, awards and prizes, and non-property-based moral rights-like protection, may be equally compliant. They may also be more efficient and economically attractive, and perhaps even less harmful. In addition, commentators have discussed the potential of using government procurement, publicly-funded research grants, public-private partnerships, and open source and collaborative models to generate incentives. Without evaluating all of these alternatives, it is hard to determine whether the property rights model is as superior as its advocates have claimed”. Yu P. The political economy of data protection. *Chicago-Kent law review*, in press.

84. See the CIPIH Report.
85. Stiglitz J. Prizes, not patents. *Post-autistic economics review*, May 2007, 42:48–9. Available at <http://www.paecon.net/PAERReview/issue42/Fullbrook42.htm>. Also see Knowledge Ecology International, at http://www.keionline.org/index.php?option=com_frontpage&Itemid=1.
86. See Incentives for Global Health (IGH), available at <http://www.patent2.org/index.html>; and Pogge T. Human rights and global health: a research program. *Metaphilosophy*, 2005, 36:182–209; and Love J. Measures to enhance access to medical technologies, and new methods of stimulating medical R&D. *University of California Davis law review*, 2007, 40:681–715.
87. Other proposals encourage open-source research. See Ho C. A new world order for addressing patent rights and public health. *Chicago-Kent law review*, 2007, 82(3):1469–515.

6. Conclusion and recommendations

The entry into force of TRIPS in 1995 brought several fundamental changes to the global regulation of intellectual property. TRIPS affected many fields, but most severely affected pharmaceutical patents. This area is particularly troubling given its close association with one of the fundamental human rights—the universal right to health.

Before the establishment of TRIPS, developing countries enjoyed considerable space—if not a free hand—in designing their public health regimes. Therefore, it was enough for any country to apply the national treatment principle to be in compliance with its international intellectual property obligations. Based on this, the majority of developing countries, and even some developed countries, denied protection to pharmaceutical patents. This was no longer an option under TRIPS, which obliged countries, after granting several transitional periods depending on each country's level of development, to provide protection for both pharmaceutical products and processes.¹

In addition to the transitional periods, TRIPS included several flexibilities aimed towards creating a balance between intellectual property protection and the public interest. In the area of patent protection and public health, the agreement permits several practices to balance intellectual property protection with the right to health and access to medicines. These include, in addition to many others, the right of compulsory licensing and government use, parallel importation and patentability criteria, in addition to several exemptions from patent protection.

Although TRIPS represented the highest ceiling of intellectual property protection at the time of its conclusion, this was not enough for the leading industrialized countries, particularly the United States and the European Union, which recognized the benefit of increasing the levels of intellectual property protection for their local industries. Following TRIPS, the developed countries

intensified their unilateral, bilateral and multilateral efforts. Using their leverage as leading global markets and promising huge packages of financial aid and economic assistance, the United States and the European Union successfully managed to raise the levels of intellectual property protection to new heights through the conclusion of several TRIPS-plus bilateral trade arrangements with a number of developing countries.

Intellectual property laws cannot be viewed in isolation from other national laws and policies

The introduction of higher standards of intellectual property protection and the erosion of TRIPS flexibilities have several implications for public health regimes, particularly in developing and least developed countries. These include raising the prices of medicines; depriving developing countries from retaining TRIPS' flexibilities; delaying the introduction of genetic medicines for additional periods; and discouraging generic competition.

One of the objectives of this resource guide, which focuses primarily on the countries of the Eastern Mediterranean Region, is to contribute to the ongoing global debate on the issue of public health and intellectual property protection. The guide also aims to provide policy and technical guidance to those involved in the process of drafting, negotiating and implementing national intellectual property plans and agendas. The guide also provides several practical recommendations derived from the experience of countries from across the globe in the area of public health and access to medicines. This guide makes several general recommendations as follows.

First, intellectual property laws cannot be viewed in isolation from other national laws and policies. As this guide explains, intellectual property regulation may take place under other non-intellectual property laws such as health regulations and competition law and policy. This necessitates treating intellectual property protection as one component of an institutional web of connected laws and policies within any country. Accordingly, countries in the Region need to put in place a pro-development national plan which uses intellectual property protection for steering and encouraging innovation and creativity rather than dealing with intellectual property protection for the purposes of solely protecting private rights. Provision of public health and access to medicines must be a core component of this national plan.

More specifically, countries in the Region need to place public health at the forefront of their national priorities. Drafting national

public health plans and agendas that take into consideration each country's needs, creating and strengthening national public health insurance schemes and focusing on increasing investment in research and development in the pharmaceutical sector should form an integral part of this plan. Introducing other measures including price controls on medicines, encouraging and participating in national and regional pooling procurement strategies²—thus taking advantage of economies of scale—would also contribute to improving the Region's public health regimes, affordability and access to medicines.³

Second, intellectual property standard-setting at the national, regional and international levels is a complex exercise. These standards are often the result of a long process of negotiation, bargaining and debate. Investment and capacity-building in those heavily involved in negotiating and delivering commitments related to trade, health and intellectual property protection are vital. As the experience of many countries shows, the existence of well trained individuals with high levels of knowledge and expertise is important for any country to be able to use the flexibilities available internationally without falling short on its international commitments and obligations. The existence of this base will also contribute to the country's "creative implementation" of its commitments by using the available policy space hence avoiding the negative impact of increased standards of intellectual property protection. In this field, international nongovernmental organizations, such as the South Centre, the Third World Network (TWN) and ICTSD, and international organizations, including WHO, UNCTAD and WIPO, can play a pivotal role in assisting developing and least developed countries.⁴

Third, although TRIPS grants its member states several flexibility tools in the area of public health, in reality, a large number of these flexibilities do not apply automatically under national laws. In order to activate the flexibilities related, for example, with compulsory licensing, parallel importation, patentability criteria, public health exemptions, competition law, the Doha Declaration on the TRIPS Agreement and Public Health, and many others, developing country policy-makers need to translate these into their national law. The successful implementation of this approach demands a clear vision and a nationwide collaborative approach involving all stakeholders.⁵

Investment and capacity-building in those heavily involved in negotiating and delivering commitments related to trade, health and intellectual property protection are vital.

Countries must view public health considerations as paramount to any other benefits which might be offered during the course of bilateral trade

Fourth, intellectual property protection in any country does not solely rely upon the enactment of laws and legislation. Developing and least developed countries, including those in the Region, need to mobilize numerous national institutions, agencies and groups to participate in the national intellectual property debate. Adequate coordination between various institutions and authorities, including the judiciary, educational institutions, national patent offices, ministries of health and trade, national drug regulatory authorities, competition agencies, consumer protection movements, nongovernmental organizations and civil society groups, is extremely important throughout this process.

Fifth, once negotiating bilaterally, countries need to take into consideration several issues and factors. Countries need to undertake a cost-benefit analysis of the pros and cons of negotiating bilaterally. They must resist any temptations to accept TRIPS-plus obligations by affirming their position of abiding by and insisting upon the standards stipulated by TRIPS. Countries must view public health considerations as paramount to any other benefits which might be offered during the course of bilateral trade negotiations even if this means declining the bilateral arrangement. No deal is better than a bad one.

Sixth, governments must be aware that signing a bilateral trade arrangement is not the end of the road, but rather the beginning of a more demanding one. The monitoring of the implementation of the agreement and full compliance with its obligations is an ongoing process. From a public health perspective, countries that have already signed such deals still need to explore the remaining policy space available to them under these agreements in order to minimize the negative impact on public health and access to medicines. This may also require the strengthening of competition laws, investment in human resources and upgrading the status of national patent offices in order to become more active in interpreting the available flexibilities under national law.

Seventh, countries in the Region should seek supplementary and alternative options for fostering innovation and encouraging research and development in public health other than patent protection such as awards and prize funds.⁶

Finally, countries in the Region need to be more proactive in setting the agenda for the global regulation of intellectual property. They must resist and change the status quo, moving from being “net

recipients” of intellectual property regulation to setting the agenda in accordance with their interests and comparative advantage. Countries in the Region should also consider the possibility of implementing TRIPS as part of wider national, regional and international action to address public health problems affecting many developing and least developed countries. This is mandated by the language of the Doha Declaration on the TRIPS Agreement and Public Health itself which stresses the “need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems”.

At the regional level, countries may enhance cooperation by concluding regional arrangements which would define competition and/or compulsory licensing principles in the area of pharmaceutical patents and public health. Regional medicine procurement schemes might also play a role in reducing the costs of drugs and medicines for countries in the region. Countries in the Region should also consider the application of an intraregional exhaustion regime for pharmaceuticals between them.

There is growing evidence that following the Doha Declaration on the TRIPS Agreement and Public Health, developing countries have become more active players in this field. The proposed WIPO Development Agenda, the TRIPS Council deliberations and the developing countries’ attempt to have TRIPS amended to deal with the problem of “biopiracy” are all supportive of this view.

One must not forget the regulation of intellectual property internationally is constantly moving, shifting and changing. This requires that countries in the Region engage in coalition and network-building with other countries and organizations that share their interests in order to set their own agenda. They need to also become more active in the TRIPS Council in order to be able to submit their views and proposals that meet their aspirations and expectations. The sooner such measures are taken, the better the prospects of the Region and its citizens are.

Countries in the Region need to be more proactive in setting the agenda for the global regulation of intellectual property

Endnotes

1. TRIPS, Article 27.1.
2. In the Region, the GCC Group Purchasing Programme is a good example. For more, see DeRoeck D, Bawazir S, Carrasco P, Kaddar M, Brooks A, Fitzsimmons J, Andrus J. Regional group purchasing of vaccines: review of the Pan American Health Organization EPI revolving fund and the Gulf Cooperation Council group purchasing programme. *International journal of health planning and management*, 2006, 21:23–43; Khoja T, Bawazir S. Group purchasing of pharmaceuticals and medical supplies by the Gulf Cooperation Council States. *Eastern Mediterranean health journal*, 2005, 11(1/2):217–25.
3. See *Public health: innovation and intellectual property rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health*. Geneva, WHO, 2006. For more proposals on regional cooperation see Reichman J. *Procuring essential medicines under the amended TRIPS provisions: the prospects for regional pharmaceutical supply centers*. Paper prepared for the Seminar on Intellectual Property Arrangements: Implications for Developing Country Productive Capabilities in the Supply of Essential Medicines, UNCTAD, Palais des Nations, Geneva, Switzerland 18–20 October 2006; Outterson K. Patent buy-outs for global disease innovation for low- and middle-income countries, *American journal of law and medicine*, 2006, 32:159–73.
4. On the possible options for the involvement of the World Bank in this regard see Cohen J, Illingworth P. The dilemma of intellectual property rights for pharmaceuticals: the tension between ensuing access of the poor to medicines and committing to international agreements. *Developing world bioethics*, 2003, 3(1):27–48.
5. The experience of Kenya provides some valuable lessons in this regard. For more see Sihanya B. *Patents, parallel importation and compulsory licensing of HIV/AIDS drugs: the experience of Kenya*. Geneva, WTO, 2005. Managing the challenges of WTO participation: case study 19. Available at http://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm.
6. See discussion in chapter 5.

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Access to essential medicines and health technologies is a huge public health challenge, especially in developing countries where the majority of the poor lack any form of social protection and health systems are under-resourced. The long and strong patent regimes introduced by the Agreement on Trade-Related Aspects of Intellectual Property Rights in 1995 and the TRIPS-plus provisions of many bilateral trade agreements are among the challenges to improving this access. Mandated by the World Health Assembly, the Commission on Intellectual Property Rights, Innovation and Public Health recommended that “Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries”. In the Eastern Mediterranean Region ministries of health have been little involved in bilateral trade negotiations, yet they are having to deal with the implications of the TRIPS-plus provisions. This publication presents a clear and frank analysis of the subject from a purely public health perspective. It should be of interest to policy-makers in ministries of health as well as other ministries and all those who take part in trade negotiations on behalf of citizens.

