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Health economics is of increasing relevance in the formulation and development of national drug policies that promote equity and rationalize the use of community and state resources. In many countries the new economic context and the global increase in pharmaceutical prices has highlighted the socio-economic aspects of drug use and accessibility. In this process, national drug policies have evolved from a primarily technical and pharmacological focus to encompass social and economic dimensions.

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# IPR, INNOVATION, HUMAN RIGHTS AND ACCESS TO DRUGS

## AN ANNOTATED BIBLIOGRAPHY

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IPR, innovation, human rights and access to drugs. An annotated bibliography

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## Abbreviations and acronyms

AFRO	WHO Regional Office for Africa
AIDS	acquired immunodeficiency syndrome
DND	Drugs for Neglected Diseases initiative
ECHR	European Court of Human Rights
ECJ	European Court of Justice
ESCWA	Economic and Social Commission for Western Africa
EU	European Union
FDA	Food and Drug Administration
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
HAI	Health Action International
HIV	human immunodeficiency virus
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
IPP	intellectual property protection
IPR	intellectual property rights
MSF	Médecins sans Frontières
NAFTA	North American Free Trade Agreement
NGO	nongovernmental organization
NOC	notice of compliance
OECD	Organisation for Economic Co-operation and Development
OTC	over-the-counter (drug)
PCT	Patent Cooperation Treaty
PPP	public-private partnerships
R&D	research and development
S&T	science and technology
SEARO	WHO Regional Office for South-East Asia
SPS	Sanitary and Phytosanitary Measures (Agreement on)
TBT	Technical Barriers to Trade (Agreement on)
TDR	UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TRM	traditional medicine
TWN	Third World Network
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UPOV	International Union for the Protection of New Varieties of Plants
WCC	World Council of Churches
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WPRO	WHO Regional Office for the Western Pacific
WTO	World Trade Organization

## Introduction

Since 1999, the issue of globalization, patents and drugs has undergone a dramatic evolution that has placed it at the top of the public agenda. Under this spotlight, the debate has taken on a higher degree of complexity, often resulting in a confusion in terms, positions and consequences. Issues that had not been traditionally considered in the analysis have grown in importance as HIV/AIDS was transformed from a public health care challenge into a global pandemic requiring urgent responses, but ones which were too costly to implement. Even though we are on the verge of eradicating polio, largely thanks to international cooperation, forgotten illnesses continue to kill thousands of people reopening debates on the issues involved. Approaches that some years ago were not considered suitable for the public health domain are currently being vindicated due to their comprehensiveness and adaptability.

Analysing globalization, patents and drugs now requires not only close attention to the public health consequences of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), but also an in depth study of the figures for the research and development (R&D) of new drugs. There is a need to establish what obligation, if any, international actors, such as private companies and national authorities, have in guaranteeing access to drugs. This bibliography brings together very different points of view from the most diverse quarters, ranging from academic experts to health professionals, including publications of pharmaceutical companies and nongovernmental organization (NGO) reports.

Updating this bibliography, which was previously revised in 2001, constitutes clear evidence of the growing volume of literature (scientific, legal and other) being produced around the issue of access to drugs and globalization. A human rights perspective has been incorporated into this edition in order to enlarge the scope of arguments and opinions. This is necessary in order to better understand the inherent complexity of the issue and the role played by a wide range of factors and elements. The debate is far from closed but the sense of urgency and the need for a coherent response have prompted more constructive approaches. The discussion is no longer exclusively centred on the benefits or prejudices of the WTO TRIPS Agreement but rather focuses on the existing opportunities to adapt to ever-changing realities, particularly in developing countries where those in greatest need live.

The fact that discussions at the WTO are having an impact on the debates organized by the United Nations Human Rights Commission, while the deliberations at the World Health Assembly are increasingly being listened to in trade circles, are yet more examples of the interconnections and the need for a comprehensive approach to this issue.

This edition has been enriched with over 60 new references. Basic literature on TRIPS, patents, R&D and human rights and access to drugs are to be found among the general articles. More focused works are referenced in the specific

sections that have been included in this version or, in some cases, in the chapter pertaining to country studies by region. Indeed, the geographical division of previous editions is combined with a thematic approach, adding three new sections: TRIPS and patents, R&D and human rights and access to drugs. The aim of this new approach is to better capture the global nature of the issue while taking into consideration possible domestic implications and effects. New electronic addresses have been incorporated, reflecting the wider range of information sources on the subject that are now available, including newsletters, institutional web sites and other electronic initiatives.

# 1. General articles

**Abbott FA. First report (final) to the Committee on International Trade Law of the International Law Association on the subject of parallel importation. *Journal of International Economic Law*, winter 1998, 607-636.**

This report approaches the exhaustion/parallel imports question in broad economic terms, asking whether there may be an economic and social welfare benefit to permitting holders of intellectual property rights (IPR) to block parallel imports that outweighs the potential harm to liberalized trade. It addresses each major form of IPR separately and concludes with respect to each form that the evidence of benefits that might flow from allowing parallel imports to be blocked is insufficient to justify the potential inhibition of trade. The report observes that most objectives that holders of IPR seek to achieve by the allocation of geographical markets can be attained through less trade-restrictive means, namely through the vertical allocation of distribution territories by contract. The interests of the developing countries are a focus of the report, which concludes that developing and developed countries are better served by open markets and the operation of comparative advantage. The report recommends that the WTO adopt a rule precluding governments from blocking parallel imports except in certain exceptional cases.

**Bala K, Lanza O, Kaur SR. Retail drug prices: the law of the jungle. *HAI News*, April 1998, 1-16.**

The retail prices of 21 commonly used drugs were collected in 39 countries, analysed, and the results are presented in this report. The authors assert that there are wide and indiscriminate variations in retail drug prices among developing and developed countries, with retail prices even higher for some drugs in least developed countries than in countries of the Organization for Economic Co-operation and Development (OECD). For example, the retail prices of 10 out of 13 commonly used drugs for which comparable data are available are more expensive in Tanzania than in Canada. In India, 100 tablets of Zinetac cost US\$ 2 while, in Chile, 100 tablets of Zantac cost as much as US\$ 196, the report states. The authors conclude that international price discrimination is a characteristic feature of the pharmaceutical world market. Policy measures should be implemented to make low-priced drugs freely available in all countries. Generic prescribing or substitution and parallel imports are two policy measures which, according to the authors, will allow consumers easy access to low-priced, quality drugs.

**Bala K, Sagoo K. Patents and prices. *HAI News*, April-May 2000, 1-9.**

This report is the result of a survey on the retail prices of 16 drugs at the leading retail pharmacy in 36 capital cities in July/August 1999. The authors claim that there are wide variations in retail prices between countries, ranging from 1:4 to

1:59. Multinational drug firms marketed their proprietary brands at widely different prices in different developing countries while the retail prices of generic equivalents did not show these very wide variations. Moreover, the average retail prices of some of the proprietary drugs are higher in the developing countries in Africa or Latin America compared to much more affluent OECD countries. The authors conclude that compulsory licensing and parallel imports are two provisions that should be in all national legislation on IPR.

**Balasubramaniam K. Heads-TNCs win: tails-South loses or The GATT/WTO/TRIPS Agreement. Penang, Consumers International, Regional Office for Asia and the Pacific, April 1998.**

The WTO TRIPS Agreement has a far-reaching impact on consumer health. This report warns that pharmaceutical and biotechnology industries have taken away the power of economic decision-making from national governments, which in turn will have a significant impact on people's health. It starts by describing the evolution of the TRIPS Agreement. The author then shows the possible impact of this Agreement on the pharmaceutical sector in developing countries. He asserts that developing countries will face considerable cost in terms of higher prices and payment of profits and royalties abroad. The poor's accessibility to essential drugs will be drastically reduced. Several strategies are suggested for developing countries to mitigate the negative impacts of TRIPS, including the provisions related to the principle of exhaustion of rights, compulsory licensing and the transitional period. Moreover, the author urges WTO to carry out a study on the impact of the TRIPS Agreement on transfer and diffusion of technology, foreign direct investment, R&D capabilities and drug prices in developing countries.

**Bale HE. Patent protection and pharmaceutical innovation. New York University Journal of International Law and Politics, 1997, 29(1/2): 95-107.**

This paper discusses briefly the major issues with respect to developing countries. The author insists on how pharmaceutical innovation is dependent on patent protection and on the benefits for the local industry and consumers, in terms of prices and of new drugs put on the market. Finally, the author regrets that the TRIPS transition provisions allow countries such as Argentina, India and the Republic of Korea "an unfortunate grace period, allowing them to exploit consumers".

**Bale HE. The conflicts between parallel trade and product access and innovation: the case of pharmaceuticals. Journal of International Economic Law, winter 1998, 637-653.**

In this paper, the case is laid out for restricting parallel trade in products protected by IPR, and pharmaceuticals in particular. The paper responds to three arguments made in favour of open parallel trade. First, it is argued that in the case of patented products with high fixed costs, such as pharmaceuticals, parallel trade may decrease global economic welfare. Attention is drawn to price controls within the Member States of the European Union (EU) as a distortion which is inconsistent with open market principles. Second, it is suggested that

rules restricting parallel trade are a necessary corollary to pharmaceutical price discrimination in favour of developing countries. Finally, the paper indicates that restrictions on parallel trade in the pharmaceutical sector are necessary to protect the public against risks arising from inadequate supervision of the secondary market, such as risks from inappropriate repackaging, inadequate storage and handling procedures and counterfeit products.

**Benkimoun P. Morts sans ordonnance. Paris, Hachette, 2002**

This book seizes the struggle to improve and enlarge access to drugs in developing countries. The author identifies the actors, issues and interests that influence this process; their agendas, declared goals and hidden targets are presented as logical components of a market-driven humanitarian crisis. The WTO-sponsored TRIPS regime is singled out as one of the main obstacles to guaranteeing access to drugs at affordable prices where they are most needed. The author also refers extensively to the role played by the pharmaceutical industry and the type of strategies used in their desperate attempt to defend their monopolistic prerogatives and huge profits. The author accompanies the civil society movement (comprising, among others, NGOs, health professionals and grass root movements) that, both in industrialized and developing countries, has set up alliances and networks to defend the principle that human dignity and health should come before private interests and profits. This is a long battle, where small victories and painful setbacks do not count as much as the passing time with its deadly toll for those who might not be able to wait for much longer.

**Braverman M, Holsomback T. Patent and trademark infringement involving generic drugs and medical devices – the potential liability impact on pharmacists. Journal of the Patent and Trademark Office Society, 1992, 74(1): 51-65.**

The use of generic formularies, medical devices and unit-dose packaging often presents hospital pharmacies with potential infringement liability. In the USA, pharmacists can be held liable for patent infringement if they participate in "making, using, selling" an unpatented copy of a brand-name or medication or a medical device already protected by a patent. Selected patent and trademark infringements are discussed with regard to their impact on the practice of pharmacy. A variety of legal cases are cited and used as examples to evaluate the impact of patent and trademark infringement on hospital pharmacists in particular.

**Bulard M. Les firmes organisent l'apartheid sanitaire. Le Monde Diplomatique, January 2000.**

This article explores the issue of limited access to essential drugs, by providing various examples in the developing world. Inadequate R&D, and discontinued manufacturing of specific tropical medicines due to financial disincentives, are two of the many examples given. The author states that patent protection and international trade agreements can be seen as the tools of the pharmaceutical industry, so denying basic human needs by putting necessary treatment beyond the reach of the poor.

**Challu PM. Adaptation of national legislation to the TRIPS Agreement of GATT's Uruguay Round, aimed at assuring inhabitants best accessibility to pharmaceuticals. Buenos Aires, Centro Industrial de Laboratorios Farmacéuticos Argentinos, 1995.**

The TRIPS Agreement sets out with precision some of the obligations undertaken by WTO Members, while other obligations are subject to diverse interpretation frames and degrees of freedom. This opens up the possibility of analysing the best way to draw up laws that the countries must enact to fulfil the commitments undertaken in the Uruguay Round, so that they comply with the requirements of health and social policies. The author outlines the balance of objectives and interests within the TRIPS Agreement, which can be found in the preamble and general principles. This balance makes it possible to establish local rules that take into account the need to guarantee people the best possible access to drugs. The article therefore analyses the potentialities in the Agreement to minimize the monopoly conferred by a patent in order to improve the supply of and access to pharmaceutical products: exceptions to exclusive rights, increased supply through importation, compulsory licences, reaction to anti-competitive practices in licence contracts and transitional periods.

**Challu PM. The consequences of pharmaceutical product patenting. World Competition, 1991, 15(2): 65-126.**

This study presents the results of research based on historical statistical series. The results shed light on the various effects of a patent system. The first part analyses the benefits attributed to patenting pharmaceutical products and shows that patent protection is rather a reflection of the degree of economic development that a country has already achieved. The second part assesses the welfare loss experienced by consumers due to monopoly prices of patented drugs, and also the public cost, or the amount that must be spent by the public sector to maintain pharmaceutical consumption at a level equal to that which would occur in a fully competitive market. Finally, the study evaluates the costs that would be imposed on Argentina in order to adopt a product patent system.

**CIPR. Integrating intellectual property rights and development policy. London, Commission on Intellectual Property Rights, September 2002.**

This report is the result of the work of the ad hoc Commission on Intellectual Property Rights, created in May 2001 by the UK Department of International Development. It addresses a number of issues related to IPR and their impact on development in a variety of fields: health, agriculture, traditional knowledge, new technologies and patent reform. The Commission acknowledged the recent increase in the submission of patents, expressing concern about the low quality and broad scope of many of them. The Commission had set itself the fundamental task of considering whether the rules and institutions of intellectual property protection (IPP) can contribute to development and the reduction of poverty in developing countries. According to the report, the impact of IPP in developed countries also affects developing countries as, for example, most of the research on diseases that affect developing countries is conducted in developed ones. While accepting that the IPP system does provide incentives for research and innovation, the Commission noted that these incentives have

different impacts depending on the economic and social circumstances of the country where they are being applied. It considers IPR as a public policy instrument which should be translated into a means for the promotion of human economic and social rights. The Commission stressed that under no circumstances should fundamental human rights be subordinate to the requirements of IPP. In this context, the report considered that a further extension of IPR should take into consideration the weaker position of developing countries and the need to explore how these countries could adapt their domestic IPP systems to their own conditions. The Commission concluded that IPP is not the only factor that affects poor people's access to health care but it can play a very negative role. Among the policies that both developed and developing countries can adopt to promote cheaper prices for medicines without adversely affecting the incentives for research on relevant diseases, the Report recommends the compulsory licensing mechanism while observing that, to date, the IPP system has done little to stimulate research on diseases that particularly affect poor people in developing countries.

**Correa CM. Implementing the TRIPS Agreement: general context and implications for developing countries. Paper presented at a Seminar on Some Current Issues in the WTO, Geneva, 2 October 1997.**

This is a background paper on the TRIPS Agreement that presents the context of, and reasons for, its negotiation, the issues at stake, and the North and South asymmetries with regard to IPR. The paper presents the main provisions of the Agreement regarding all kinds of IPR and concludes by discussing the implications for developing countries.

**Correa CM. Implementing the TRIPS Agreement in the patents field: options for developing countries. *The Journal of World Intellectual Property*, 1998, 1(1): 75-100.**

This article shows that, with respect to the specific area of patents, the TRIPS Agreement does not constitute a uniform law. It provides a number of minimum standards that will substantially increase the degree of harmonization in IPP, but it leaves considerable scope for national laws to define a number of important aspects. The room for manoeuvre left by the Agreement derives, in some cases, from the wording of its provisions, such as Articles 30 and 31, and in other cases from the absence of any specific rule. The author argues that developing countries can opt for a number of approaches aimed at fostering access to technology and promotion of innovation at national level in a way that is fully consistent with the TRIPS Agreement.

**Correa CM. Integrating public health concerns into patent legislation in developing countries. Geneva, South Centre, June 2000.**

Developing countries today face the complex challenge of implementing various international agreements, including the TRIPS Agreement. This document was prepared to assist them in adapting their laws to the standards set by TRIPS in relation to pharmaceutical products and processes, as such legislative reform can have a major impact on people's access to drugs and on public health policies. It

includes chapters on patentable subject matter, scope of claims, patentability requirements, disclosure of the invention, exceptions to exclusive rights, examination and observation procedures, claim interpretation, and compulsory licensing. A model of legal options is presented in each chapter to provide elements for national legislation based on the existing Agreement provisions. According to the author, all the issues presented are important for the design of a public health sensitive patent law, but priority should be given to: (1) those relating to the patentable subject matter and the treatment of the specific cases concerning pharmaceuticals, (2) the crafting of exceptions to patents rights, especially for experimentation and early working, and (3) the development of a sound compulsory licensing system. The author asserts that national laws dealing appropriately with these issues would be an important step forward.

**Correa CM. Intellectual property rights and foreign direct investment. *International Journal of Technology Management (special issue on the management of international intellectual property)*, 1995, 10(2/3): 173-199.**

This paper discusses the relationship between foreign direct investment and IPR. It aims to provide an analytical framework with which to understand this relationship and to deal with it. The multiple variables that affect the relationship, the industries involved and the degree of development of countries are considered first. The main developments at that time in national legislations and within WIPO, UPOV and GATT are outlined with regard to strategies and decisions for foreign direct investment. An analytical framework is then presented and the significant differences it exposes when applied to different types of intellectual property are exemplified by case studies.

**Correa CM. Intellectual property rights, the WTO and developing countries: the TRIPS Agreement and policy options. London and New York, Zed Books Ltd., and Penang, Third World Network, 2000.**

There are many minimum standards with which the countries that signed the TRIPS Agreement are obliged to comply. This book is the result of research undertaken by the author to explore the implications of the TRIPS Agreement, focusing on developing countries. It explores the possible room for manoeuvre these countries have at national level. Some aspects relating to the incorporation of the Agreement's provisions into national laws are also covered. The book looks at interpretation and implementation problems that have arisen. It presents some of these problems in the implementation process faced by developing countries, particularly in Latin American and the Caribbean. Finally, issues relating to the possible revision of the TRIPS Agreement and the revision of its implementation are described and discussed. An annex includes a report, (updated and revised by an Expert Group on the TRIPS Agreement and Developing Countries), on the options for implementing the TRIPS Agreement in developing countries.

**Correa CM. Protection and promotion of traditional medicine. Implications for public health in developing countries. Geneva, South Centre, 2002.**

This study highlights the value of traditional medicine (TRM) in developing countries while describing how it might be affected by the implementation of, among other things, the TRIPS Agreement. The author first identifies some characteristics of TRM relevant to IPP issues. He then considers the rationale behind the need for protection of TRM under IPR (either existing or to be created). Thirdly, he discusses the extent to which existing modes of IPR (notably patents, trade secrets, trademarks and geographical indications) may be applied to TRM. Particular emphasis is given to the discussion of patents, with the other forms of IPR being analysed more briefly. Fourthly, the study presents those policy options available for the protection and promotion of TRM in the broader context of health policy. Finally, the author raises the issue of IPR protection of TRM within the framework of public health policy, considering that *"policies on TRM should aim at balancing considerations of equity and public health"*, protecting and rewarding knowledge without reducing access to TRM for those most in need.

**Correa CM. The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: new standards for patent protection. European Intellectual Property Review, 1994, 16(8): 327-335.**

The TRIPS Agreement is perhaps the most far-reaching international instrument ever adopted on IPR. This article analyses the main provisions of the TRIPS Agreement in the area of patents. Its purpose is to provide a preliminary interpretation of the most relevant aspects of the text, namely new patentable fields of technology, criteria of patentability, the non-discrimination clause, rights conferred and exceptions, conditions for patent applications, compulsory licensing, reversal of the burden of proof and transitional arrangements.

**Correa CM. The Uruguay Round and drugs. WHO Task Force on Health Economics. Geneva, World Health Organization, 1997 (unpublished document WHO/TFHE/97.1).**

The aim of this study is to examine the possible effects of the TRIPS Agreement on the development, production and marketing of drugs, as well as access to them. The author reviews the areas of intellectual property that are the most relevant to the pharmaceutical sector, namely patents and "confidential information" (trade secret). The provisions on transitional periods and on the mechanism for the settlement of disputes are also analysed. The last part of the study reviews the possible implications of the Agreement for innovation, foreign direct investment and the price of drugs. The analysis focuses on the effect of the new intellectual property rules in developing countries.

**Correa CM. Trends in drug patenting. Case studies. Buenos Aires, Ed. Corregidor, 2001.**

This study focuses on the shortcomings that cast doubt on the use of patents as a tool to protect innovation. The author highlights the low standards being

applied to notions such as non-obviousness and usefulness in the examination and granting of patents, particularly in the field of drugs. It examines 9 specific cases: Paroxetine, Amlodipine, Alendronate, Clarithromycin, Omeprazole, Fluconazole, Ofloxacin, Fexodenadine and Recombinant Erythropoietin. On the basis of objective technical considerations, this analysis illustrates types of patenting that potentially divert patents from their real purpose of encouraging and providing reward to genuinely inventive efforts, while negatively affecting early access to cheaper alternative products for the public. The selected drugs represent a broad range of products whose value as medicines differs. Their common trait is the use of the occasionally excessive flexibility of the patent system to set up barriers to legitimate competition. Finally, as regards the issue of R&D of new drugs and its relation to patents, the author concludes that "*a substantial part of the R&D budget that pharmaceutical firms claim is devoted to the development of new products is, in reality, allocated to developing a vast array of patents around existing products, with the clear intent of expanding and/or extending over time the exercise of exclusive rights.*"

**Cosbey A. The sustainable development effects of the WTO TRIPS Agreement: a focus on developing countries. Proceedings of the Second Annual Sustainable Development Conference, Islamabad, Pakistan, 4-10 August 1996. Winnipeg, Canada, International Institute for Sustainable Development, 1996.**

This paper examines the TRIPS Agreement and tries to analyse those areas in which the Agreement will impact, either positively or negatively, on sustainable development in developing countries. After brief introductions to the Agreement itself, and to the concept of IPR, the paper turns to examining the possible effects of the Agreement, focusing on agriculture and biodiversity, pharmaceuticals and copyrighted goods. It ends by proposing a number of policy actions which contribute to sustainable development in the context of the Agreement.

**Csizer Z. Opportunities and risks to develop domestic pharmaceutical industry in Asia-Pacific developing countries. Paper presented at the UNCTAD Workshop on Expansion of Trading Opportunities for Asia-Pacific Developing Countries, Subic Bay, Philippines, 15-17 November 1995.**

This paper provides an analysis of the challenges to the pharmaceutical industry such as the increase in R&D costs and competition from generic manufacturers. It also studies the implications of the Uruguay Round Agreements for the local pharmaceutical industry, in particular the TRIPS Agreement and its consequences in Argentina, Brazil, India and the United States of America.

**Health Action International. Power, patents and pills: an examination of GATT/WTO and essential drugs policies. Seminar report, HAI-Europe, 1997.**

This report by Health Action International (HAI) contains a brief description of the GATT and the WTO, their history and development, and the main provisions of the new trade agreements. The position of the consumer movement is presented, emphasizing the influence of the pharmaceutical industry lobbies on

the establishment of development costs of pharmaceutical products. WHO's view on the WTO Agreement on Technical Barriers to Trade (TBT) and the TRIPS Agreement is set out. There is a description of the work of the WTO and its position in the pharmaceutical field. Finally, the view of an NGO is presented, stressing the unjustified advantage that the TRIPS Agreement gives to multinational corporations at the expense of developing countries and of public health.

**Heath C. Parallel imports and international trade. *International Review of Industrial Property and Copyright Law (IIC)*, 1997, 28(5): 623-632.**

The courts in two industrialized countries, England and Japan, have recently confirmed the lawfulness of parallel importation of patented products in the absence of any indication to the contrary. Continental law follows a different philosophy and assumes absolute limits of IPR within the principle of exhaustion of rights. However, applying the principle of international exhaustion has sometimes been objected to by invoking the principle of "territoriality of patents" of the Paris Convention. The author analyses the parallel import provision of the TRIPS Agreement which, he recalls, is meant to remove trade barriers and to ensure a balance of rights and obligations. However, the author argues for harmonization on this matter as a conclusion.

**ICDA. An alternative report on trade: an NGO perspective on international trade. Brussels, International Coalition for Development Action, February 1995.**

The Uruguay Round deals that were finalized in 1994 include the little known (at that time) general Agreement on TRIPS. While representatives of big companies were sitting at the drafting table, little account was taken of the consequences of increased prices for medicines in the South. A preliminary assessment points to a negative outcome.

**IFPMA. GATT/TRIPS and the pharmaceutical industry: a review. Geneva, International Federation of Pharmaceutical Manufacturers Associations, 1995.**

This publication presents the view of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) on the TRIPS Agreement. It covers developments concerned with the general provisions, the rules relating to patents, the means of ensuring respect for IPR, the settlement of disputes and the transitional provisions.

**IFPMA. The question of patents: the key to medical progress and industrial development. Geneva, International Federation of Pharmaceutical Manufacturers Associations, 1998.**

This publication sets out to discuss many of the issues raised in discussions of patent issues. According to the authors, pharmaceutical patent protection brings a number of economic benefits: it is an indispensable element of economic development and growth; it encourages local inventors to disclose and

commercialize their inventions; it improves a country's credibility and recognition as a dependable supplier; and it is an essential element in the provision of more cost-effective health care. Moreover, strong IPP is particularly important for pharmaceutical products, owing to their unique characteristics. The paper then discusses the "reality" of patent protection for pharmaceuticals in response to the fears and doubts expressed with regard to monopolistic price increases, foreign direct investment and the demise of the local pharmaceutical industry. Finally, an entire chapter is dedicated to the "long, expensive and painstaking journey" involved in the development of a new drug.

**Institut Universitaire d'études du développement. Propriété Intellectuelle. Quels enjeux pour les pays en développement? Accord TRIPS – Brevetabilité du vivant – Accès aux médicaments et brevets. Dossier de l'Annuaire Suisse-Tiers Monde 1998. Geneva, Institut Universitaire d'études du développement, July 1999.**

In this report, the authors focus on the question of IPP after the TRIPS Agreement was concluded in the framework of the Uruguay Round. What are the concerns of developing countries regarding this Agreement? The more advanced developing countries are afraid of increasing prices of products protected by patents - such as medicines - which they can produce by reverse engineering. Most of the developing countries are worried about the necessity to protect plant varieties with a patent or an efficient *sui generis* system and about the effects of such an obligation on their indigenous populations. The least developed countries are especially preoccupied by the new legislation they have to adopt and by the institutions they have to create or develop according to the terms of the Agreement. This report explores these problems, beginning with the articles analysing the potential effects of the TRIPS Agreement on developing countries.

**Keayla BK. TRIPS Agreement on patent laws: impact on pharmaceuticals and health for all. Paper presented at the International Conference on Global Health Laws, New Delhi, India, 5-7 December 1997.**

The Indian pharmaceutical industry made excellent progress within the framework of the 1970 patent law, as is evident from process research and production data. This paper deals extensively with the comparative analysis of the existing and the new patent system and the safeguards which have to be provided in the public interest to accomplish the goals of "health for all". The first part introduces the basic elements of the patent system and its history. The second part offers a picture of the global and of the Indian pharmaceutical market. Then, after a very detailed presentation of the framework of the TRIPS Agreement, the author demonstrates that this Agreement is indeed an extreme compromise of public interest and assesses what may be the impact on the availability of pharmaceutical products. He concludes with recommendations on the approach developing countries should adopt.

**Kinnon C. WTO: what's in it for WHO? WHO Task Force on Health Economics. Geneva, World Health Organization, 1995 (unpublished document WHO/TFHE/95.5).**

The WTO TBT Agreement is designed specifically to encourage application to traded goods of internationally agreed standards, including WHO's quality standards for pharmaceutical, biological and food products. The Agreement on Sanitary and Phytosanitary Measures (SPS) sets out to harmonize national measures to protect human, animal and plant life or health, stipulating application of the food quality standards drawn up by the WHO/FAO Codex Alimentarius Commission. By virtue of the General Agreement on Trade in Services, Members may open up their domestic market to foreign suppliers of hospital and medical services; and the TRIPS Agreement raises concerns about the continued accessibility of adequate drug supplies at reasonable cost in developing countries. Public health personnel may not always be provided with adequate information on an area that is not directly related to their work. With this in mind, this paper reviews the several agreements within the Final Act of the GATT Uruguay Round, which have implications for WHO's work, outlining their purpose, main provisions and obligations, with particular reference to developing countries. In each case, information is given on the WHO activity involved, pinpointing what is already being done to protect health, and, in some cases, how public health work can facilitate trade relations.

**Kolker PL. Patents in the pharmaceutical industry. Patent World, January 1997, 34-37.**

The pharmaceutical industry claims that patent protection of inventions is crucial and that healthcare innovation is indeed totally dependent on patents. This article considers why pharmaceutical R&D relies so much on patents, what constitutes effective patent protection for that industry and how the patent system might develop in the future, particularly in Europe.

**Labonte R. World trade and investment agreements: implications for public health. Canadian Journal of Public Health, 1998, 89(1): 10-12.**

Globalization puts pressure on governments' abilities to regulate taxes on wealth and labour, and on cultural and environmental as well as public health standards. Who will benefit from these new agreements? The need for a social clause campaign is growing.

**Lobo F, Velázquez G. eds. Medicines and the new economic environment. Papers presented at the seminar on Social Studies on Health and Medicines, Madrid, 29-31 March 1995. Madrid, Civitas and World Health Organization, 1998.**

This book incorporates all the papers presented in the Seminar on Social Studies on Health and Medicines held at the Universidad Carlos III, Madrid from 29 to 31 March 1995. Experts in health economics, medicines and from the pharmaceutical industry gave presentations and discussed the effects on health services of the new economic environment and of the changing situation in the international economy and the pharmaceutical markets. The book covers the role of the state and the reform of health care systems, together with the implications for

medicines, drug regulation and changes in the structure of the pharmaceutical industry.

**Love J. L'Europe et les Etats-Unis prolongent l'apartheid sanitaire. Le Monde Diplomatique, March 2003, 28-29.**

According to the author, despite the promise made by the WTO in 2001 in Doha, Northern pharmaceutical companies and wealthy Western nations are still preventing Southern countries from accessing desperately needed drugs at an affordable price; wealthy countries such as Canada, the countries of the European Union, Japan and the USA, want to backtrack on the Doha Declaration on the TRIPS Agreement and Public Health of November 2001 and US intransigence scuttled last-minute WTO talks in Geneva in December 2002. The author says that the argument is about the right of countries to provide health care by overriding drug patents. Wealthy countries, which have a virtual monopoly on drug patents, compiled a list of suitable diseases: AIDS, tuberculosis, malaria and a few mainly tropical ailments of little commercial interest. They were trying to apply the Doha Declaration only to these diseases with no provision for cancer, diabetes or asthma. Paragraph 6 of the Doha Declaration called on the WTO Council for TRIPS to resolve restrictions on drug exports. When a country issues a compulsory licence for a patent, any generic copies made by local companies are assumed to be primarily for the domestic market. However, the author asks if countries manufacturing generic drugs cannot export them, how can a country without a domestic pharmaceutical industry acquire generic drugs? The author concludes by saying that the Doha Declaration was a good-faith effort aimed at removing the main legal barriers preventing developing countries from achieving universal access to medical care. However, since November 2001, it has been sabotaged by the world's wealthiest countries, best-off in living standards and health care facilities.

**Mann J, Gostin LO, Gruskin S, Brennan T, Lazzarini Z, Fineberg H. Health and human rights. Health and Human Rights, Fall 1994, 1(1): 6-23.**

Health and human rights are complementary approaches for defining and advancing human well-being. This article presents a three-part provisional framework for exploring potential collaboration in health and human rights. The first relationship involves the impact (positive and negative) of health policies, programmes and practices on human rights; the goal is to negotiate an optimal balance between public health goals and human rights norms. The second relationship posits that violations of rights have important health effects, generally unrecognized, that must be described and assessed. The third and most fundamental relationship proposes that promotion and protection of health are inextricably linked to promotion and protection of human rights and dignity. The interdependence of health and human rights has substantial conceptual and practical implications. Research, teaching, field experience and advocacy are required to explore this intersection. This work can help revitalise the health field, contribute to enriching human rights thinking and practice, and offer new avenues for understanding and advancing human well-being in the modern world.

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**Marks D. Life beyond the patent. *Managing Intellectual Property*, January/ February 1994, 13-19.**

All inventors and manufacturers of new pharmaceutical products want to be able to maintain their exclusive right to exploit the invention by protecting it with a patent. However, manufacturers protest that they are unable to exploit the patent until they have obtained marketing authorization, and that therefore effective patent protection is reduced to eight or nine years. This article examines three ways in which companies can apply European and national law to breathe commercial life into a product beyond the patent term: patent term extension through Supplementary Protection Certificates, marketing exclusivity, and over-the-counter (OTC) switches.

**Marques MB. Brazil-USA controversy on the impact of patenting in biotechnology: some relevant questions for pharmaceuticals. *Science and Public Policy*, June 1994, 165-172.**

This study tries to identify some of the most relevant determinants and constraints that could, in a medium-term perspective, influence the diffusion of biomedical innovations in the health sector in Brazil. The controversy over IPR in biotechnology between Brazil and the USA is discussed at length, with the main arguments used, negotiation strategies and their legal challenges described. The author concludes that current harmonization trends in IPR do not discriminate developed from developing country competitors, and thus may jeopardize the development of local capacity in some newly industrialized countries like Brazil. The article concludes that these trends will be detrimental in the international legal and commercial framework, and that increasing difficulties in accessing scientific and technological information are likely.

**Maskus KE. Price effects and competition aspects of intellectual property rights in developing countries. *1998 World Development Report*. Washington, D.C., World Bank, 1998.**

This paper focuses on concerns raised about the additional market power created by stronger property rights in technology and information. It sets out the basic theory of fundamental trade-offs posed by IPR in open economies. The limited evidence available on potential price impacts of stronger protection is reviewed in three key areas: pharmaceuticals, plant varieties and software. The paper also considers the role of IPR in supporting restrictive conditions in licensing contracts. Finally, it discusses aspects of competition policy that might be used to ensure that stronger IPR promote dynamic competition rather than foster competitive abuses.

**Mayne R, Drahos P. *Global intellectual property rights*. Oxford, Oxfam, 2002.**

This book analyses the impact of the TRIPS Agreement and suggests ways in which the intellectual property system can be changed to serve development goals. It synthesizes the views of academic experts and NGOs at the cutting edge of current campaigning and debate. IPR, such as patents, can reduce access to

knowledge in genetics, health, agriculture, education and information technology, particularly for people in developing countries. The authors show how the new global rules of intellectual property have been the product of the strategic behaviour of multinationals, rather than democratic dialogue. The final section of the book suggests strategies to develop more flexible standards for poor countries and to keep knowledge in the public domain.

**Merz JF. Disease gene patents: overcoming unethical constraints on clinical laboratory medicine. *Clinical Chemistry*, 1999, 45, 324-330.**

The rapidly growing number of disease gene patents – patents that claim all methods for diagnosis of a particular genetic condition – threaten the ability of physicians to provide medical care to their patients. This article discusses some of the ramifications of creating a monopoly over a medical service, assesses the implications of disease gene patents for clinical laboratories, and proposes some strategies for responding to this new phenomenon. The analysis concludes with a recommendation that the patent law be amended to require compulsory licensing of medical process patents. Indeed, according to the author, *"it is time to evaluate the need for such a provision for medical process patents in light of the serious harms to the practice of medicine, and arguably, to the public health, that may result from a refusal to license"*.

**Mezrich JL. The patentability and patent term extension of life-saving drugs: a deadly mistake. *Journal of Patent and Trademark Office Society*, 1992, 74(2): 77-95.**

This article discusses the unique situation of drug patents with reference to R&D costs and Food and Drug Administration (FDA) testing. It critiques the aftermath of patent term extension under the US Hatch-Waxman Act and the economic behaviour of pharmaceutical manufacturers, with a focus on life-saving drugs and the AIDS crisis. The author reminds readers that the consumer was meant to be the real winner of this reform and concludes that *"maybe patenting is not a good idea in the area of life- saving pharmaceuticals"*.

**Moufang R. Methods of medical treatment under patent law. *International Review of Industrial Property and Copyright Law (IIC)*, 1993, 24(1): 18-50.**

During recent years, case law in Europe has quite frequently dealt with the interpretation of the exclusion of medical methods from patentability. This article first presents the historic roots and development of the exclusion of medical methods, from national developments to European patent law harmonization. It then examines in detail the scope and limitations of the prohibition on patenting of surgical, therapeutic and diagnostic methods.

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**NERA, SJ Berwin & Co, YRCR Ltd. Issues of intellectual property protection. Policy relating to generic medicines in the OECD (Chapter 18). Final report prepared for the European Commission, DG III. December 1998.**

All OECD countries surveyed have a standard "baseline" harmonization of patent law, largely as a result of implementation of the obligations set out in the TRIPS Agreement. EU Member States have achieved additional harmonization of extended patent term legislation. More significant variations exist between EU Member States and other OECD jurisdictions, as well as between the non-EU OECD States, as regards the scope and operation of permitted exceptions to exclusive patent rights, where different balances have been struck between the interests of patentees and the promotion of effective generic competition. Important differences also exist between European Patent Convention Contracting States and other OECD countries in respect of the scope of patentability of second medical uses for known drug substances, or the linking of the granting of marketing authorizations to non-infringement of the patent rights of the original patentee. Finally, the report does not find a significant bearing of compulsory licensing and issues of exhaustion of IPR on the development of the generic industry.

**Netherlands Ministry of Foreign Affairs. Medicines for the poor. The WTO and the developing countries. Report of a public debate held on 16 December 1999. The Hague, Netherlands Ministry of Foreign Affairs, 2000.**

This publication reports on an open discussion which gathered voices from some of the main actors involved in the issue of TRIPS and access to drugs: a developed country government, academic experts, the pharmaceutical industry and the international civil society. This variety is reflected in the different points of view expressed in connection with the enforceability of patent protection rights, the use of exceptional mechanisms such as compulsory licensing and parallel importing and the funding of R&D of new drugs. Held before the November 2001 WTO Ministerial Conference in Doha, the debate does not include any reference to the Doha Declaration on the TRIPS Agreement and Public Health. It does, however, reflect shared concerns such as the need for a greater involvement of the international community in the issue or the adaptation of the TRIPS Agreement to meet the domestic realities of developed countries. Other questions raised about pharmaceutical company investment levels in R&D and how they should be compensated are currently the object of another global debate.

**Nogues J. Patents and pharmaceutical drugs: understanding the pressures on developing countries. *Journal of World Trade*, 1990, 24(6): 81-104.**

This article offers a discussion on the question of why there are pressures on developing countries for introducing and/or reinforcing patent protection for pharmaceutical drugs. It first reviews the worldwide pattern of patent policies and the pressures from industrialized countries on developing countries for modification of patent laws relating to pharmaceutical drugs in particular. It then presents evidence on the relative importance of patents for the pharmaceutical industry. It discusses changes in effective patent duration as

modified by regulatory policies. It finally presents evidence on the growing importance of competition between brand-names and the generic drug industry, and the impact of this competition on drug prices. The potential size of developing country markets for patented drugs is no longer trivial.

**Nogues J. Social costs and benefits of introducing patent protection for pharmaceutical drugs in developing countries. *Developing Economies*, 1993, 31(1): 24-53.**

In the Uruguay Round, industrialized countries proposed that developing countries extend patent protection to pharmaceutical drugs. By looking at the pharmaceutical industry, this paper argues that neither side has a strong case in its favour and that more research is needed before an economically sound decision is made. The paper starts by offering a political economy discussion of why industrialized countries have reached a consensus in favour of introducing patent protection for pharmaceutical drugs. The central point of the paper is then supported by further analysis that discusses the social costs and benefits of introducing patent protection for pharmaceutical drugs in developing countries.

**OECD. Directorate for Science, Technology and Industry. *Tableau de bord de l'OCDE de la science, de la technologie et de l'industrie. Vers une économie fondée sur le savoir*. Paris, OECD, 2001.**

This report of the OECD focuses on the knowledge-based economy and its implications for different fields and domains. It acknowledges the growing importance of R&D, closely linked to the innovation capacity, in contributing to economic progress. The report notes the existing disparities in terms of R&D investments between OECD members and industrial sectors, with specific mention of private pharmaceutical companies. Particular attention is devoted to R&D in the health domain and the linkage between R&D and biotechnological patents. The report illustrates the rise in public spending on health R&D in recent years, in contrast with the decline in funds devoted to defence research. It concludes by stressing the growing partnership between private companies and universities in the field of scientific research, a partnership and collaboration which is increasingly transnational, just like the property of most inventions.

**Otten A. The implications of the TRIPS Agreement for the protection of pharmaceutical inventions. *Proceedings of the International Conference of Drug Regulatory Authorities, Bahrain, 10-13 November 1996*. WHO Drug Information, 1997, 11(1): 12-16.**

The protection of pharmaceutical inventions was one of the key issues in the Uruguay Round negotiations as a whole and perhaps the key issue in the North-South axis of negotiations. It was the last issue to be resolved. At that time, it was clear that there would be no TRIPS Agreement without a commitment to make available patent protection for pharmaceuticals for 20 years. The question therefore was: on what terms would countries' delegations accept such an obligation, in particular in regard to matters such as the exhaustion of rights, compulsory licensing, the control of anti-competitive practices, test data

protection and transitional arrangements? The paper takes up each of these aspects.

**Oxfam. Dare to lead: public health and company wealth. Oxford, Oxfam Briefing Paper No. 1, 2001.**

This is the first in a series of papers that analyse the human development impact of transnational corporations. It reviews the role of GlaxoSmithKline, a UK-based pharmaceutical company, and outlines what Oxfam views as the three critical challenges facing this and other global pharmaceutical companies wishing to increase access to medicines. The paper states that they must ensure that changes in global IPP do not increase the price of medicines in developing countries. Secondly, companies must meet the acute need for R&D into diseases associated with poverty. Finally, the paper highlights the need to curb corporate marketing and lobbying activities when they run "counter to the public interest". Oxfam believes that if companies fail to meet these challenges they face the threat of more stringent government regulation and loss of public support.

**Oxfam. Fatal side effects: medicine patents under the microscope. Oxford, Oxfam, 2001.**

The document argues that with millions already unable to afford essential medicines, and public health threatened by new diseases and drug-resistant variants of old killers, WTO patent rules will further reduce access to modern medicines for the poor. The report sets out Oxfam's concerns about the way management of the international trading system puts corporate interests before poverty reduction. It describes the health crisis in developing countries, before examining what Oxfam believes are the likely adverse effects of WTO patent rules on drug prices and on local pharmaceutical industries. The authors discuss the role of the government in filling the gaps in pharmaceutical research and increasing health sector support. The document concludes with a series of recommendations, focusing on TRIPS reform, and on the need for rich countries and transnational companies to stop pressuring developing countries on patent issues.

**Oxfam. Formula for fairness: patient rights before patent rights. Oxford, Oxfam Company Briefing Paper No. 2, 2001.**

Pfizer is the largest and most profitable multinational pharmaceutical company and, as such, is analysed in this Oxfam report, taking into consideration its position on TRIPS, generic licences and lobbying within the framework of corporate accountability and social responsibility. According to the report, Pfizer (the market value of which is larger than the combined national incomes of the eighteen biggest economies in sub-Saharan Africa) has not shown much flexibility on pricing and patent enforcement in poor countries. With regard to generics, its policy seems to be not to issue licences to generic manufacturers, the result being high priced drugs to which people in developing countries have no access. Pfizer had strongly lobbied the US Government to put intellectual property on the trade agenda and for the adoption of the TRIPS Agreement. It

has, in addition, encouraged the US administration to take unilateral economic sanctions against those countries that it believes offer inadequate patent protection. The report issues some recommendations for the Pfizer management team in order to adopt a more constructive leadership role. Among other suggestions, it invites Pfizer to acknowledge that the price of life-saving medicines in developing countries is linked to patents and TRIPS and encourages it too participate in research programmes aimed at diseases that affect poor countries by contributing to the proposed global research fund.

**Oxfam. Patent injustice: how world trade rules threaten the health of poor people. Oxford, Oxfam, 2001.**

In this paper Oxfam argues that by restricting the right of governments to allow the production, marketing and importation of generic drugs, WTO rules will restrict competition, increase prices and further reduce the already limited access of poor populations to vital medicines. The paper states that the implementation of WTO patent rules is taking place against the backdrop of a sustained campaign led by the pharmaceutical industry. Oxfam believes this campaign may well erode the public health protection offered by safeguard provisions in patent legislation, such as compulsory licensing and parallel imports. The document looks at the role of public-private initiatives in making medicines more widely available. It argues that the main problem with them is that drugs are often offered in limited quantities, and at prices which compare unfavourably with generic-equivalent products. The authors make eight recommendations for immediate action to improve access to medicines.

**Oxfam. US bullying on drug patents: one year after Doha. Oxford, Oxfam Briefing Paper N° 33, November 2002.**

According to this Oxfam report, forty million people currently live with HIV/AIDS around the world and fourteen million people are dying each year of preventable infectious diseases, mostly women and children from developing countries. WTO patent rules, set out in the TRIPS Agreement, are acknowledged as further restricting poor people's access to life-saving medicines by raising their price. Yet the US Government's bilateral policy seeks even higher standards of patent protection for medicines. Oxfam commissioned a review of the US Government's bilateral policies on patents and medicines, looking also at the lobbying record of the giant pharmaceutical companies and their influence over US Government policies. The findings showed how, despite public pressure and the Doha Declaration on the TRIPS Agreement and Public Health, US bilateral policy on patents and medicines is still heavily influenced by the narrow commercial interests of the pharmaceutical companies. Contradicting one of the pharmaceutical industry claims, the report documents how the number of complaints against developing countries submitted by Pharma to the US Trade Representative remained unchanged during the period of time since the adoption of the Doha Declaration. The report concludes by issuing several recommendations to developed countries, such as making their bilateral policies fully compatible with the Doha Declaration and making expert guarantees, tax concessions and other government incentives. The report recommends that

WTO play a more active role in ensuring developed country compliance with the Doha Declaration.

**Panos Institute. *Beyond our means?* London, Panos Institute, 2000.**

Two primary factors prevent widespread access to treatment for AIDS in the developing world: inadequate health services and lack of drugs. This report from the Panos Institute explores the problems of access to treatment for people living with HIV/AIDS. It puts the main focus on the issue of the high cost of treatment. The price of a drug charged to an individual, insurance company or government health service is determined by a series of factors, including the cost of R&D, manufacture, company overheads, distributor's costs and commission, taxes and fluctuating exchange rates. But the most important factor is the price the consumer can afford or is willing to pay. Uniform patent protection under the TRIPS Agreement is seen as one of several means the pharmaceutical companies use to protect their markets and their profit. The report discusses the possibility of using compulsory licensing for AIDS-related medicines, and other ways to bring down the price of pharmaceutical products. The author concludes that compulsory licensing, preferential pricing and parallel importation in themselves are not the complete solution to the problem of providing full access to treatment for AIDS. Questions of production capacity, national monopolies and manufacturing standards, and the threats of counterfeiting and the black market still need to be resolved. However, compulsory licensing, in particular, would seem to represent, on the one hand, no threat and, on the other, a potential source of income considerably greater than that which the pharmaceutical companies currently receive from most of Africa and Asia.

**Pécoul B, Chirac P, Trouiller P, Pinel J. Access to essential drugs in poor countries: a lost battle? *Journal of the American Medical Association*, 1999, 281(4): 361-367.**

While drugs offer a simple, cost-effective solution to many health problems, effective treatment for many diseases is lacking in poor countries. This article focuses on the problems of access to quality drugs for the treatment of diseases that predominantly affect the developing world. Poor-quality and counterfeit drugs are not rare in developing countries. Fluctuating production or prohibitive costs also account for the lack of availability of essential drugs. The development of field-based drug research is needed to determine optimum use and re-motivate R&D for new drugs for the developing world. Potential consequences for the availability of old and new drugs are expected from recent WTO agreements.

**Perez-Casas C. HIV/AIDS medicines pricing report. Setting objectives: is there a political will? Available on the web at <http://www.accessmed-msf.org>**

The author stresses that prevention of HIV/AIDS is very important and should be a main strategy, but that treatment cannot be neglected. The high price of drugs is claimed to be a major barrier to appropriate treatment for people with HIV/AIDS. This study examines the price of HIV/AIDS-related medicines that are patented in many countries, and drugs that are no longer patented but still

remain expensive (e.g. Ceftriaxone). It compares the USA price with the price in eight countries, and shows that prices are set differently in different countries. The author claims that the existence of market monopolies is the single most important determinant of these differences. The widely divergent prices found in the study put into question current drug price-setting mechanisms and highlight the lack of transparency with regard to the relationship between the production costs and prices. According to the author, competition can be an important factor that can lead to dramatic reductions in price. This can be promoted by using three safeguards provided in the TRIPS Agreement, namely compulsory licensing, parallel imports and the 'Bolar' provision. The report concludes by saying that the means to dramatically reduce prices are within reach, but what is needed is the political will to mobilize resources on a global scale.

**Raghavan C. *Recolonization: GATT, the Uruguay Round and the Third World.* Penang, Third World Network, 1990.**

This book is an effort to place in the hands of the Third World public, and concerned groups, information on the Uruguay Round and its implications. It is not intended to be an academic or objective exercise, but has been written from a Third World perspective and is aimed at filling the gap in other publications. Part one deals with the political economy of the Uruguay Round and its broad implications in terms of South-North relations. Part two deals with the new themes on the agenda of the Round and their interlinkages. Part three looks at some of the traditional and old issues of trade and market access, particularly those of importance to the Third World countries. In this light, part four looks at issues with systemic implications. Part five deals with the progress in the negotiating processes in the first two years and the outlook in the light of the mid-term review. The book also updates the situation up to 1990 and presents some views on what positions the Third World countries should take.

**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(1-2): 12-93.**

The article identifies the sources of tension between developed and developing countries, and evaluates the impact of the TRIPS Agreement on developing countries' capacity to acquire the knowledge and skills they need to compete on the market of technological goods. It argues that developing countries have much to gain by accepting the challenge implicit in the Agreement to become fair followers in the worldwide quest for technical innovation. The author outlines a pro-competitive strategy for implementing the TRIPS Agreement in developing countries in five points: tilt their intellectual property laws in favour of local competitors; distance themselves from protectionist measures being adopted in the developed countries; institute incentive structures to stimulate innovation at the local level; resist any further elevation of international intellectual property standards beyond the TRIPS Agreement; and resort to the global information infrastructure to acquire scientific and technical knowledge.

**Reichman JH. Universal minimum standards of intellectual property protection under the TRIPS component of the WTO Agreement. *The International Lawyer*, 1995, 29(2): 345-388.**

According to the author, "*the absorption of classical intellectual property law into international economic law will gradually establish universal minimum standards governing the relations between innovators and second comers in an integrated world market*". This article provides a detailed and comprehensive picture of all the important substantive provisions contained in the TRIPS Agreement, including patents, trademarks and the ongoing trade-based initiatives, such as the compensation expected by developing countries and the uncertainties of the dispute settlement process. A section specifically discusses the issue of compulsory licences and the new dimension of the public interest exception under the TRIPS Agreement.

**Remiche B, Desterbecq H. Les brevets pharmaceutiques dans les accords du GATT: l'enjeu? *Revue Internationale de Droit Economique*, 1996/1: 7-69.**

The TRIPS Agreement is indeed a major event in the history of intellectual property law. This study examines the impact of this Agreement on patent law in the pharmaceutical sector in developing countries. It suggests reconsideration of the sensitive issue of the balance of interests that the patent system is designed to ensure. It analyses the various provisions of the TRIPS Agreement that leave a certain margin of freedom to Members in the organization of the patent system. The application of general principles, together with respect for conditions for the limitation of patent rights, allows a number of measures that may take into consideration national development and public health needs.

**Revue Internationale de Droit Economique. Special edition : pharmaceutical patents, innovation and public health. Bruxelles, *Revue Internationale de Droit Economique*, 2001.**

This special issue of the International Revue of Economic Law (RIDE) reproduces the main contributions to the symposium organized by the International Association of Economic Law (AIDE) in Toulouse at the end of January 1999 on the theme "Pharmaceutical patents, innovations and public health". Contributors include Carlos Correa, Claude Crampes, Vincenzo Di Cataldo, Jérôme Dumoulin, Jean-Christophe Galloux, Alain Gouyette, Georges Houin, Christian Huveneers, Jacques Larrieu, Marília Bernades Marques, Franz Muennich, Adrian Otten, Sylvaine Poillot Peruzzetto, Norbert Reich, Bernard Remiche, Frederick Scherer and Germán Velásquez.

**Rozek RP, Berkowitz R. The effects of patent protection on the prices of pharmaceutical products: is intellectual property protection raising the drug bill in developing countries? *The Journal of World Intellectual Property*, 1998, 1(2): 179-243.**

The authors studied prices of pharmaceutical products in nine developing countries with and without patent protection over a period of 11 years to determine whether enacting intellectual property law increases the price of

drugs. Their conclusion is that escalating prices seem unlikely for a number of reasons: therapeutic competition among many pharmaceutical products, monopsony buyers and price-regulation schemes for pharmaceuticals in developing countries, and the fact that new intellectual property laws usually do not apply to existing products.

**Rozek RP, Rapp RT. Benefits and costs of intellectual property protection in developing countries. *Journal of World Trade*, 1990, 24: 75-102.**

The costs and benefits of patent protection is an issue that has been hotly debated for decades. The aim of this study is to assess whether denying patent protection to pharmaceuticals is a sensible public policy. The authors argue that there are substantial benefits for developing countries from IPP. Benefits, including investment and technology flow and enhanced prospects for economic growth, far outweigh the costs, in terms of lack of competition. The authors then conclude that protecting intellectual property should be a public policy goal of developing countries seeking sustainable economic growth.

**Rozek RP, Rapp RT. Parallel trade in pharmaceuticals: the impact on welfare and innovation. NERA Working Paper No. 16, 1992.**

Differences in drug price-setting across countries - with respect to political, social, economic, legal and regulatory factors - create opportunities for parallel trade. Parallel trade creates lower prices in the short-run in the high-price countries and offers potentially more profit opportunities to parallel traders. It can also increase competition in the market. However, according to the authors, there are some market situations in which parallel imports may reduce welfare and weaken the IPR of innovators. This paper, supported by the Pharmaceutical Manufacturers Association, argues why, in some situations, a policy that restricts either parallel trade or incentives for parallel trade will yield net economic benefits to society.

**Rozek RP, Tully N. The TRIPS Agreement and access to health care. *The Journal of World Intellectual Property*, 1999, 2(5): 813-819.**

Access to health care is a basic human right that should be applied to all. According to the authors, access to care is a complex problem that should not be examined solely in terms of pharmaceuticals or the impact of the TRIPS Agreement. This article argues that barriers which are not related to availability and prices of pharmaceuticals exist, and result in the restriction of access to health care. These can be classified into six main areas: physical, informational, financial, political, social and ethnic. The authors conclude that, in many instances, the prices of pharmaceuticals are not the cause of access problems. They also suggest that access problems in particular countries may differ. It is therefore important for WHO to identify the set of causes for access problems and formulate country-specific reform plans to improve access to drugs.

**Savina J. The patentability of the second therapeutic application – why must the law be changed? Patent World, August 1995, 32-35.**

Problems arise when a drug is already known for one or more therapeutic applications and another, hitherto unknown, curative or preventive property of that drug is subsequently discovered. This article addresses the legal difficulties raised by the patentability of the second therapeutic application with regard to the novelty and the industrial application of such an invention.

**Schroeder L. Substance of the TRIPS provisions of the GATT as they relate to developing countries. Paper presented at the Drug Information Association Annual Meeting, Orlando, USA, 27 June 1995.**

*"The TRIPS Agreement meets the objectives that the United States established for the negotiation",* says the author. This Agreement sets forth minimum standards for the protection of IPR and provides for effective enforcement of these rights internally and at the border. An enhanced dispute settlement regime is also available to address shortcomings in meeting TRIPS obligations. Obligations have to be met by all countries, within the transitional arrangements.

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

This book shows how power in international politics is increasingly exercised by private interests rather than governments. To illustrate this point, the author uses the example of the TRIPS Agreement, adopted by the WTO in 1994, which dictated to states how they should regulate the protection of intellectual property. According to the author, final approval of the TRIPS Agreement resulted from lobbying by twelve powerful CEOs of multinational corporations (among them several major pharmaceutical companies) who wished to mould international law to protect their markets. This book examines the politics leading up to the TRIPS Agreement, the first seven years of its implementation, and the political backlash against TRIPS in the face of the HIV/AIDS crisis. Focusing on global capitalism ideas, and economic coercion, this work explains the politics behind TRIPS and the controversies created in its wake. It is an in depth study of the influence of private interests in government decision-making, and in the shaping of the global economy.

**South Centre. Intellectual property rights and the use of compulsory licences: options for developing countries. Trade-Related Agenda, Development and Equity (T.R.A.D.E.) Working Paper No. 5. Geneva, South Centre, October 1999.**

The possible use of compulsory licences as one of the tools to mitigate the impact of exclusive rights is receiving growing attention. This paper aims to provide concrete examples of how compulsory licences have been provided for in national laws. The author explores all the grounds and conditions under which such licences have been granted in specific instances. The emphasis of the study is on the ways in which compulsory licences have been actually provided for or used in order to satisfy diverse public interests. It focuses mainly on the

application of compulsory licensing in the field of patents. Three main conclusions, particularly relevant for developing countries, are: (1) compulsory licences should be considered as an essential element in patent laws and other intellectual property regimes; (2) the grounds and conditions for compulsory licences should be carefully determined by national laws; (3) developing countries should preserve the maximum possible freedom under international rules to design their compulsory licensing systems according to their own interests and needs.

**South Centre. The TRIPS Agreement: a guide for the South. The Uruguay Round Agreement on Trade-Related Intellectual Property Rights. Geneva, South Centre, 1997.**

This document forms part of the programme of work carried out by the South Centre as a contribution to the Economic Agenda for Priority Action 1992-1995 of the Non-Aligned Movement. The document is intended as an introductory overview of the TRIPS Agreement for developing countries. In addition to highlighting some of the central issues for the South, the document draws attention to the aspects to which policy-makers and technical personnel should pay special attention when formulating policy and legislation in this field. In particular, the document points out that "maximum advantage must be taken of those areas where the Agreement leaves some room for choice in an effort to ensure that national policies and legislation are formulated in a manner that helps to achieve their development objectives". Also, it is suggested that there are a number of areas in which developing countries could cooperate to great mutual advantage, with respect both to the formulation of national legislation and the planned review of the Agreement.

**Stolley PD, Laporte JR. The public health, the university and pharmacoepidemiology. Pharmacoepidemiology, third edition, 2000, 75-89.**

Pharmacoepidemiology is the study of the effects of drugs on populations and of the factors influencing drug use. Its prime goals are the gathering of information leading to the protection of the health of populations, and improving the efficacy and safety of medicines. The authors state that in each country the ultimate effectiveness of drugs depends on a number of factors. These include the priorities of the pharmaceutical industry, local drug regulation and drug policies, drug supply, the priorities of the health care system, training and continuous education of health professionals, etc. These factors have a great influence on the patterns of prescribing, dispensing and use. The document argues that four processes have contributed to shaping globalization in the field of pharmaceuticals: the TRIPS Agreement, health sector reform and liberalization, moves to closer harmonization (in particular the International Conference on Harmonization) and pharmaceutical company mergers.

**Subramanian A. Putting some numbers on the TRIPS pharmaceutical debate. *International Journal of Technology Management (special issue on the management of international intellectual property)*, 1995, 10(2/3): 252-268.**

This paper estimates the changes in prices, profits and social welfare arising from increased patent protection of pharmaceuticals in a number of developing countries. Two market structures are proposed (perfectly competitive market and Nash-Cournot duopoly) and comparisons are made between the situation where there is no patent protection and after the introduction of patent protection. Lags between the adoption of legislation and its impact are discussed and the effects of retroactive legislation compared with non-retroactive patenting. Prices of patented drugs in three countries (Argentina, India and Malaysia) are then compared and possible price changes discussed. Finally, for larger countries, or a group of small countries, the effects of patent protection are calculated for the same scenarios and the incentives for increased R&D are examined. The paper concludes that the effects of patent protection are sensitive to assumptions about market structure and price elasticity.

**Tarabusi CC, Vickery G. Globalization in the pharmaceutical industry, part I. *International Journal of Health Services*, 1998, 28(1): 67-105.**

This report provides an overview of the characteristics of the industry and current trends in its growth and structure: production and consumption, employment, R&D, capital investment, firm and product concentration and product competition, and pricing. A discussion follows on international trade covering intra- and interregional, intra-firm and intra-industry trade.

**Templeman S. Intellectual property. *Journal of International Economic Law*, 1998, 603-606.**

This paper discusses the nature of the rights characterized as intellectual property. The author asserts that the term intellectual property is a pernicious fiction because it serves to disguise the creation and enforcement of monopolies, which are contrary to the public interest. A number of specific recommendations to minimize the injurious effects of these monopolies are made. They include adopting a more receptive attitude toward compulsory licensing, examining patent holders' books to determine how monopoly profits are being spent, increasing attention to the impact of the TRIPS Agreement on developing countries and recognizing a universal doctrine of exhaustion of rights.

**The Royal Society. Keeping science open: the effects of intellectual property policy on the conduct of science. London, The Royal Society, April 2003.**

This report of the UK's independent scientific academy looks on how intellectual property policies impact on the evolution of scientific work, paying particular attention to three areas: patents, copyright and database copyright. While accepting the potential benefits of IPR for science by, for instance, stimulating innovation, the report also warns about the possible tensions created due to their monopolistic nature. As regards the current trend in British research funding,

centred around wealth creation and associated IPR, the report demands that research be based on quality, as it is only high quality research that will, in the long-term, be beneficial for society. The climate of secrecy that patents might encourage can, according to the report, limit the free flow of ideas and information which are critical for productive research. At the same time, research may be constrained by patents being excessively broad, which could have a very negative impact, particularly in the early stages of development of a given discipline. With regard to the TRIPS Agreement, intended to harmonize intellectual property laws at the international level, the report wonders whether there is not sufficient flexibility or whether the flexibility accorded is sufficiently utilized. It notes that, for developing countries, the disadvantages of TRIPS implementation outweigh the possible benefits. It is required that developing countries not be obliged to implement legislation until they achieve a certain level of development. The report concludes that the original balance established by intellectual property law, where the right-holder obtains exclusive rights in exchange for rights to the society, should be improved in order to guarantee just sufficient incentive to encourage R&D by potential right-holders while retaining a high level of benefit for society. The report considers that new intellectual property legislation that unreasonably restricts freedom of access and use of information goes against this desirable balance.

**Thurow L. Needed: a new system of intellectual property rights. Harvard Business Review, October 1997.**

According to the author, "*Fundamental shifts in technology and in the economic landscape are rapidly making the current system of IPR unworkable and ineffective. Designed more than 100 years ago to meet the simpler needs of an industrial era, it is an undifferentiated, one-fits-all system*". Four main reasons explain the problems with the old system: the centrality of IPR, the decline of public knowledge, the emergence of new technologies and the globalization of the economy. Thus, a new system of IPR should strike the right balance between the production and the distribution of new ideas, but should also be really enforceable, quick and efficient. A revised system should reflect diverse interests, such as public versus private knowledge, developed versus developing countries and different types of industry, knowledge and inventors.

**TWN. Options for implementing the TRIPS Agreement in developing countries. Report of an expert group on the TRIPS Agreement and developing countries. Penang, Third World Network, April 1998.**

The expert group was convened by the Third World Network (TWN) with the objective of bringing together a team of individuals with in-depth knowledge of IPR in order to provide guidelines and proposals to policy-makers and the public in developing countries on the options available to them during the process of implementing the TRIPS Agreement. The TRIPS Agreement had been actively promoted by industrialized countries with the aim of obtaining worldwide protection for the innovations and technologies generated by their corporations. The implementation of the Agreement could have some serious adverse consequences for developing countries, including placing greater obstacles in the way of their technological development. This report points out the options

available in various aspects of the TRIPS Agreement, and proposes recommendations on options which would be more appropriate to and consistent with the interests of developing countries. The report focuses on the provisions related to patents, undisclosed information, computer programmes and restrictive practices in contractual licences.

**UNAIDS/WHO. Patent situation of HIV/AIDS related drugs in 80 countries. January 2000. Available on the web at: <http://www.who.int/medicines> or <http://www.unaids.org>.**

The problem of affordability is a major factor contributing to the lack of access to drugs. Since patent protection allows exclusive rights to an invention and prevents generic competition, the question of whether a drug is under patent protection is of significant importance for drug procurement decisions. This document assesses the patent situation of HIV/AIDS related drugs, anti-infectives and antiretrovirals in about 80 countries for which data are available. It shows the approximate date on which the patent of each particular drug will expire, calculated from the date of application for the first patent.

**UNAIDS/WHO. Pharmaceuticals and the WTO TRIPS Agreement: questions and answers. March 2000. Available on the web at: <http://www.who.int/medicines> or <http://www.unaids.org>.**

This document provides the answer to some frequently asked question related to the TRIPS Agreement and pharmaceuticals. The meaning of TRIPS, its application, and the obligations for developing countries are explained in an easily understandable way. Further reading is also recommended

**UNCTAD. The TRIPS Agreement and developing countries. New York and Geneva, United Nations Conference on Trade and Development, 1996 (UNCTAD/ITE/1).**

This report provides an initial assessment of the costs of implementing and enforcing the specific IPR standards stipulated in the TRIPS Agreement. A preliminary section sets out the main findings and conclusions, the key issues and the role that international organizations can play in assisting developing countries in their efforts to implement the TRIPS Agreement. Part one assesses the economic implications of the Agreement for developing countries, focusing on market-related costs and benefits, as well as the direct costs stemming from the implementation of the TRIPS Agreement. It also summarizes the results of selected country case studies carried out for the purpose of this study. Part two deals with the main disciplines covered by the TRIPS Agreement. It highlights the principal provisions of each of the disciplines discussed, their main economic and legal implications, general issues arising from their implementation and the costs involved in their implementation. Finally, an annex provides an overview of the literature on the impact of introducing pharmaceutical product patents.

**UNDP. Human Development Report 2001. Making new technologies work for human development. New York, United Nations Development Programme, 2001.**

The 2001 edition of the Human Development Report of the United Nations Development Programme (UNDP) devoted considerable attention to the issue of TRIPS and patents in connection with the Millennium Development Goals. The report showed how IPR are being tightened worldwide. As signatories to the TRIPS Agreement, developing countries are now implementing national systems of IPR following an agreed set of minimum standards, such as 20 years of patent protection. In this new global regime, two problems are creating new hurdles for progress in human development. First, consensus is emerging that IPR can go too far, hampering rather than encouraging innovation and unfairly redistributing the ownership of knowledge. Second, there are signs that the cards are stacked against fair implementation of TRIPS. Views vary tremendously on the expected impact of the TRIPS Agreement on developing countries. Under TRIPS, countries can use compulsory licensing (permitting the use of a patent without the consent of the patent holder) in a number of circumstances, which they must embody in their own legislation. TRIPS also allows countries to choose whether or not to permit patented goods to be imported from other countries where they are sold by the same company but at cheaper prices. Yet, under pressure and without adequate advice, many developing countries have not included these possibilities in their legislation, or are challenged when they try to put them to use. In some circumstances, such as national emergencies, public non-commercial use and antitrust measures, the Agreement allows governments to issue compulsory licenses to domestic or overseas producers of generic drugs. First introduced in British intellectual property legislation in 1883, compulsory licensing has been part of the law and practice of many industrial countries for more than a century, including Australia, Canada, Germany, Ireland, Italy, New Zealand, the United Kingdom and the United States of America. In contrast, not one compulsory licence has been issued south of the equator. Why? Pressure from Europe and the United States of America makes many developing countries fear that they will lose foreign direct investment if they legislate for or use compulsory licences. Turning compulsory licence provisions into feasible policy options means creating a legal structure suited to developing countries.

**Velásquez G. Hold-up sur le médicament. Le Monde Diplomatique, July 2003, 26-27.**

This article sets out the perception of essential drugs and medicines as public goods, to which no exclusive rights or patents shall be applied as they primarily belong to those who are most in need. The author looks at the current situation of the AIDS pandemic, but also at other illnesses that are much less publicised but are also taking a heavy toll in terms of human lives in developing countries. Bearing this in mind, the author expresses the need for a new approach to those drugs that can make a difference for millions of people, not only as regards distribution but also invention and production. This approach needs to be consistent with the global nature of the situation and the multiplicity of involved factors. He considers it critically urgent to change many of the apathy and discoordination patterns that contributed to the current extent of the AIDS pandemic.

**Velásquez G, Boulet P. Essential drugs in the new international economic environment. *Bulletin of the World Health Organization: International Journal of Public Health*, 1999, 77(3): 288-292.**

The new international economic and social context is likely to have an important effect on the equitable access of populations to health and to drugs, especially in developing countries. The new rules in the area of intellectual property could increase these countries' dependence still further. In implementing the TRIPS provisions at the national level, developing countries should be aware that there are some options for ensuring access to essential drugs for the poorest populations, as some provisions of the TRIPS Agreement may be used to protect public health goals. Therefore, say the authors, each country's strategy in regard to globalization in the field of the production and distribution of drugs will have to be incorporated into its national pharmaceutical policy, a component of national health policy.

**Velásquez G, Boulet P. Globalization and access to drugs: perspectives on the WTO/TRIPS Agreement. Geneva, WHO, Health Economics and Drugs, EDM Series No. 7 (Revised). 1999.**

This book is divided into two sections. The first part aims to inform people with limited legal background about the impact of globalization, especially the TRIPS Agreement, on access to drugs. It includes an introduction to the international trade system and its development, followed by an analysis of the TRIPS Agreement in relation to drugs. The second part of the book contains presentations at a meeting of an ad hoc working group on the revised drug strategy, held in Geneva on 13 October 1998, from various stakeholders, including WHO, WIPO, WTO, the South Centre, HAI, IFPMA and the International Generic Pharmaceutical Alliance. The main recommendation of the book is that public health concerns should be a priority consideration when implementing the TRIPS Agreement.

**Velásquez G, Correa CM, Weissman R. Cost-containment mechanisms for essential medicines, including antiretrovirals, in China. Mission report, Beijing, 11 to 13 December 2002. Geneva, WHO, Health Economics and Drugs, EDM Series No. 13, 2003.**

The purpose of the Mission to the People's Republic of China was to explore, together with the Chinese authorities, the range of cost-containment options for antiretrovirals and other essential medicines, assessing the experiences of other countries in this domain and mapping out those options that are compatible with the TRIPS Agreement. Notions such as voluntary and compulsory licensing or government price controls are extensively developed. Experiences of other countries, such as Brazil and Indonesia, are used as possible useful examples for the Chinese authorities in their attempts to contain the cost of essential medicines at the national level. Special attention is paid to the right of countries to be protected in voluntary agreements for reduction of prices of medicines as well as practical aspects of the implementation of compulsory licensing. The report concludes by stressing the importance of public health considerations in the design of policies for cost-containment, while detailing some of the problems that

may appear in the negotiation process for voluntary licences or voluntary price reductions.

**Verma SK. Exhaustion of intellectual property rights and free trade – Article 6 of the TRIPS Agreement. *International Review of Industrial Property and Copyright Law (IIC)*, 1998, 29(5): 534-567.**

By bringing IPR within the context of the GATT/WTO, the exclusivity aspect of IPR has been made subject to the rules of international trade and competition. This study examines the issue of IPR exhaustion in the GATT/TRIPS context, and tries to analyse whether territorial exhaustion fits into the GATT stated objective of free trade, its legality under the GATT/WTO provisions, and its effects on developing countries. The author argues for world-wide rather than territorial exhaustion, for the sake of free trade and international competition. In this context, the study first briefly discusses the concept of IPR exhaustion and current practice thereon, as exhibited in the legal systems of the EU, Japan and the USA. That is followed by an analysis of the legal and economic commitments to international exhaustion within the GATT/WTO framework. Finally, the issue is examined from the point of view of developing countries.

**Verma SK. TRIPS: development and transfer of technology. *International Review of Industrial Property and Copyright Law (IIC)*, 1996, 27(3): 331-363.**

At the time of writing the article, the operation of the new intellectual property regime had yet to be seen but, given the intense negotiations which accompanied its adoption, a few pertinent questions were asked about the efficacy of the new regime for developing countries. Patenting in pharmaceuticals is still open to considerable debate in most developing countries. Would the emerging new regime work in the national interest of the developing countries? Would it encourage the transfer of technology to them from developed countries and help them become competitive in world trade? Would it help in boosting the inventive and innovative capacity in these countries? These are some of the issues addressed in this article, which for this purpose explores at the outset relevant provisions of the TRIPS Agreement.

**Warren A. A mouse in sheep's clothing: the challenge to the patent morality. *European Intellectual Property Review*, 1998, 20(12): 445-454.**

With the debate on cloning still ringing in one's ears, it was not entirely unexpected that Dolly, the cloned sheep, would be the basis of a patent application. This article addresses the problems of applying a morality criterion through the patent system and looks to both the Oncomouse case and the impending patent application on cloning in order to consider whether the morality of patenting is being addressed on a realistic basis.

**WCC. The implications of the TRIPS Agreement from the perspective of developing countries. Report from the Pharmaceutical Advisory Group of the World Council of Churches on 30 October 1997. Geneva, World Council of Churches, 1997.**

According to the report, the meeting at the World Council of Churches (WCC) established that the protectionism promoted by the TRIPS Agreement works against the interests of developing countries. Speakers at the meeting included Professor Carlos Correa (Argentina), Dr Mira Shiva (India), Dr Zafar Mirza (Pakistan) and representatives from WHO and WTO. The report provides speakers' presentations, which include a background to the issues raised by the TRIPS Agreement, the effect of TRIPS on local manufacturing and concerns about justice following the TRIPS Agreement

**Weissman R. A long, strange TRIPS. University of Pennsylvania Journal of International Economic Law, 1996, 17(4).**

IPP has become a central part of the free trade agenda and of the global WTO agreements. This article considers how this state of affairs came to be and what it means for developing countries. Its crucial concern is with the range of pharmaceutical patent policy options that remain open to them. Part I provides some background on the range of possible patent regimes, to emphasize that there is no single approach to patent policy. Part II recounts the United States pharmaceutical industry's political offensive over the last 15 years, designed to ensure that all nations adopt restrictive patent laws. Part III undertakes a close analysis of the TRIPS Agreement and argues that, despite its appearing highly restrictive at first glance, the Agreement leaves in fact a number of options open to developing countries. Part IV considers the costs and benefits of some patent policy alternatives, especially compulsory licensing, and, in a concluding section, outlines a patent policy approach for developing countries that would better serve their national interests.

**Wheeler C, Berkley S. Initial lessons from public-private partnerships in drug and vaccine development. Bulletin of the World Health Organization: International Journal of Public Health, 2001, 79(8): 728-34.**

In recent years, venture capital approaches have delivered impressive results in identifying and funding promising health discoveries and bringing them to market. This success has inspired public sector experiments with "social venture capital" approaches to address the dearth of affordable treatment and prevention for diseases of the developing world. Employing the same focus on well-defined and measurable objectives, and the same type of connections to pool and deploy resources as their for-profit counterparts, social venture capitalists seek to use the tools and incentives of capitalism to solve one of its biggest failures: the lack of drugs and vaccines for diseases endemic to low-income populations. As part of a larger trend of partnerships emerging in health product donation and distribution, public-private partnerships for pharmaceutical development have led R&D efforts to generate more accessible and efficacious products for diseases such as malaria, tuberculosis, and AIDS. In this article, three R&D-focused partnerships are explored: the International AIDS Vaccine Initiative; the Medicines for Malaria Venture; and the newly-formed Global Alliance for TB

Drug Development. The article highlights key elements essential to the success of these ventures.

**Woodward D et al. Globalization and health: a framework for analysis and action. Bulletin of the World Health Organization: International Journal of Public Health, 2001, 79(9): 875-881.**

Globalization is a key challenge to public health, especially in developing countries, but the linkages between globalization and health are complex. Although a growing amount of literature has appeared on the subject, it is piecemeal, and suffers from a lack of an agreed framework for assessing the direct and indirect health effects of different aspects of globalization. This paper presents a conceptual framework for the linkages between economic globalization and health, with the intention that it will serve as a basis for synthesizing existing relevant literature, identifying gaps in knowledge, and ultimately developing national and international policies more favourable to health. The framework encompasses both the indirect effects on health, operating through the national economy, household economies and health-related sectors such as water, sanitation and education, as well as more direct effects on population level and individual risk factors for health and on the health care system. Also proposed is a set of broad objectives for a programme of action to optimize the health effects of economic globalization. The paper concludes by identifying priorities for research corresponding to the five linkages identified as critical to the effects of globalization on health.

**WTO/WHO. WTO Agreements and Public Health. A joint study by the WHO and the WTO secretariat. Geneva, 2002.**

This report deals with the relevant WTO Agreements and the way they may influence health and health policies. Initially, the report examines the main WTO Agreements related to health and health policies, namely the Agreements on TBT, SPS, Trade in Services (GATS) and TRIPS. The TRIPS Agreement contains several provisions that enable governments to implement their intellectual property regimes in a manner which takes account of immediate and longer-term public health considerations. It also provides for some flexibility in its implementation by allowing countries to limit patent owners' exclusive rights, for instance by granting compulsory licences and allowing parallel importation of patented products. This flexibility was reaffirmed by the WTO Members at the Doha Ministerial Conference in November 2001 with the adoption of the Declaration on the TRIPS Agreement and Public Health. This Declaration was seen as an important step to prevent situations where countries have considered themselves under pressure, from industry and/or foreign governments, not to avail themselves fully of the flexibility provided in the TRIPS Agreement.

## 2. Country studies by region

### 2.1 Africa

**Annas G. The right to health and the Nevirapine case in South Africa. *New England Journal of Medicine*, 20 February 2003, 348(8): 750-754.**

Occurring just after the legal procedures initiated by several major pharmaceutical companies against the South African Government, the Nevirapine case offers one of the finest examples of the complexity of the current human rights and health care context. This new situation was created by the apparition on the market of new antiretroviral drugs, tested to be effective and life-saving but which are far too expensive for developing countries to be able to afford them. Regarded as a human rights and health policy issue, the Nevirapine case confronted the South African Government and provincial authorities with an array of organizations headed by the Treatment Action Campaign. This article clearly reflects what was considered to be critical in the Nevirapine case: namely the State's responsibility in fulfilling the human right to health of South African people, as stated in the Constitution, and whether it could be considered as rational not to develop a comprehensive and integral national programme to tackle HIV mother-to-child transmission through the use and administration of Nevirapine (a drug that had been tested effective and endorsed by WHO). The Treatment Action Campaign's victory in this case represented a huge leap forward for all activists and advocacy organizations working to grant greater access to drugs for populations in developing countries.

**Bond P. Globalization, pharmaceutical pricing and South African health policy. *International Journal of Health Services*, 1999, 29(4).**

The article examines the case of South Africa after legislation aimed at lowering drug prices was passed by Parliament. The Medicines and Related Substances Control Amendment Act ('Medicines Act') of 1997 provides room for generic substitution by pharmacists. Scheduling of medicines, licensing of dispensers, establishment of a pricing committee and prohibition of pharmaceutical bonusing and rebates for bulk buyers are included in the Act. More controversially, it also allows parallel imports and compulsory drug licensing. The author describes the strong response by the pharmaceutical industry and some governments towards the Medicines Act, which was the subject of legal proceedings.

**du Plessis E. South Africa: pharmaceutical reform. The battle over making medicines affordable. *Managing Intellectual Property*, June 1998, 14-17.**

Controversial reforms to reduce drug prices in South Africa have angered the pharmaceutical industry and led to the country being threatened with sanctions

by the USA. The author relates the history of the Medicines Amendment Act culminating in court action. She then examines what she sees as the faults of the proposed legislation with a close look at section 15C, the main source of controversy, and the threat of parallel imports and compulsory licensing.

**Ngwenya C. The recognition of access to health care as a human right in South Africa: is it enough? *Health and Human Rights*, 2000, 5(1): 29-32.**

The right of access to health care services is among the economic and social rights guaranteed by the Constitution of South Africa. However, given the jurisprudential novelty of such a right and its dependence on economic resources, its realization is likely to be difficult to secure. This article discusses the scope and limitations of the right of access to health care in South Africa. Even if, when this article was published, the country's courts had not yet developed clear principles for the interpretation of the right of access to health care, the obstacles identified by the author (country's pervasive poverty, gross income disparities and extremely high burden of disease) were acknowledged as such by South Africa's constitutional court in the Nevirapine case.

**WHO/AFRO. Trade-related aspects of intellectual property rights (TRIPS) and the implementation of TRIPS safeguards in relation to pharmaceuticals in the WHO African Region. Summary Report of a Workshop, Zimbabwe, August 2001. Brazzaville, WHO Regional Office for Africa, 2002.**

The main goal of this workshop, organized by the WHO Regional Office for Africa (AFRO), was to develop strategies for the implementation of the TRIPS Agreement, taking into consideration safeguards related to health and pharmaceuticals. Special attention was paid during the meeting to the interaction between TRIPS and national legal frameworks on pharmaceuticals, while some proposals were put forward in connection with principles of model legislation on the implementation of TRIPS safeguards and the type of support that would be required to undertake necessary reforms. The participants, coming from 15 countries of the African Region, represented ministries of health, justice, finance and trade. They concluded the two days of discussions by issuing a set of recommendations, such as the need for increased regional collaboration (both at intercountry and subregional levels) on all TRIPS-related issues and the necessity for concerned countries to formulate national legislation to implement TRIPS safeguards.

**Yusuf AA. Intellectual property protection in the countries of Africa. *International Journal of Technology Management (special issue on the management of international intellectual property)*, 1995, 10(2/3): 269-292.**

This paper examines the state of IPR and their protection and exploitation in African countries. Listed are the coverage of intellectual property laws, the subject matter of protection and the scope of rights conferred. It is shown that African legislation is generally comparable to that in developed countries with regard to terms of protection, compulsory licensing, subject matter and government and public interest use. A comparison is made between developed

countries and African members of GATT in regard to fields excluded from protection. The results of surveys of some individual African countries reveal the extent of registration of patents and technology transfer to these countries. Finally, the possible impact of new legislation, especially in the context of the TRIPS negotiations of the Uruguay Round, is considered.

## 2.2 Asia

**Ahuja SD. GATT and TRIPS: the impact on the Indian pharmaceutical industry. *Patent World*, September 1994, 28-34.**

This article from an Indian firm describes the discussions in India between Indian firms, the Government and the multinational drug industry on the issue of pharmaceutical patents and TRIPS. The author analyses the shortcomings of the 1970 Indian Patent Act *vis-à-vis* the TRIPS Agreement and the amendments necessary for compliance with the TRIPS provisions. He then presents the status of pharmaceutical patents in the pre-GATT era and discusses the post-GATT implications, including the future for R&D.

**Blakeney M. The impact of the TRIPS Agreement in the Asia Pacific Region. *European Intellectual Property Review*, October 1996, 18(10): 544-554.**

The last decade has witnessed a virtual revolution in the protection and enforcement of IPR in the Asia Pacific Region. Almost every single country in the region has either replaced or substantially renewed its intellectual property laws. Counterfeiting and piracy in Asia were perceived as a damaging issue in international trade. The author notes that the special 301 Section of the United States Trade Act has been intensively used in the Region to support the views of the United States of America at the Uruguay Round negotiations and the adoption of the TRIPS Agreement. This article describes the various developments and law reviews that have occurred in each country of the Region, as well as on a regional basis.

**Debroy B. Beyond the Uruguay Round: the Indian perspective on GATT. New Delhi, Response Books, 1996.**

This book looks beyond the Uruguay Round and is an Indian perspective on the new GATT/WTO agreement. Beginning with a quick sketch of the current global economic scenario, the author explains the details of the individual WTO agreements, including TRIPS. A special chapter is devoted to patents and pharmaceuticals that are the subject of an amendment in India and to the resultant impact on the Indian pharmaceutical sector. The issue of the protection to be granted to plant varieties and microorganisms is also discussed.

**Dubey M. An unequal treaty: world trading after GATT. New Delhi, New Age International Publishers, 1996.**

This publication analyses the impact of the various WTO agreements and the WTO system on developing countries, with a special focus on India. A chapter is devoted to the TRIPS Agreement. It relates the history of the difficult negotiations leading up to the signing of the Agreement, and discusses the negative effects of the Agreement for developing countries in terms of development, technological dependence and losses. Finally, the author insists on the various possibilities for making the obligations under the Agreement more flexible.

**GATT. Thailand restrictions on importation of and internal taxes on cigarettes. Report of the Panel adopted on 7 November 1990 (DS10/R - 37 S/200).**

In this trade dispute between the United States of America and Thailand, the GATT ruled against the Thai efforts to ban imports of cigarettes when there was no equivalent measure taken against the sale of domestically produced cigarettes. However, this case is important for WHO's action in defending public health interests for two reasons. First, the GATT established a precedent in consulting WHO on a trade issue involving public health. Second, the GATT indicated that a ban on the advertising of cigarettes, while potentially harmful to the interests of importers who were not well known, was justified for public health reasons.

**Henderson E. TRIPS and the Third World: the example of pharmaceutical patents in India. European Intellectual Property Review 1997, 19(11): 651-663.**

The author reviews the TRIPS patent provisions and considers arguments for and against requiring less developed countries to implement Western levels of patent protection. She then addresses the particular example of pharmaceutical protection in India, by reviewing the country's current patent law and discussing the likely effect of TRIPS on the Indian pharmaceutical industry and the Indian population. The article concludes that "*there are justifiable fears that patent protection will do more harm than good in developing countries*".

**Karandikar SM. Indian drug industry after GATT. Bombay, MVIRDC World Trade Centre, 1994.**

This publication is a product of desk research and creative interaction with entrepreneurs, executives, scientists and doctors. It firstly presents the changing international environment with regard to the economic role of pharmaceuticals. It then introduces the public health scenario in India and the drug industry. The last part of the book focuses on the issue of GATT, patents and drugs, comparing the Indian Patent Act with other intellectual property instruments, and discussing the cost of new drugs and how to do without newer drugs.

**Kettler H, Modi R. Building local research and development capacity for the prevention and cure of neglected diseases: the case of India. *Bulletin of the World Health Organization: International Journal of Public Health*, 2001, 79(8): 742-747.**

This paper examines the proposal to build R&D capabilities for dealing with neglected infectious and tropical diseases in countries where they are endemic, as a potentially cost- and time-effective way to fill the gap between the supply of and need for new medicines. With reference to the situation in India, the competence and incentives required by companies are considered so that their strategy can be shifted from reverse engineering of existing products to investment in R&D for new products. This requires complex reforms, of which intellectual property is only one. The authors consider whether Indian companies that are capable of conducting R&D are likely to target neglected diseases. Patterns of patenting and of R&D, together with evidence from interviews conducted, suggest that Indian companies, like multinational corporations, are likely to target global diseases because of the prospect of much greater returns. Further studies are required on how Indian companies would respond to push and pull incentives originally designed to persuade multinational corporations to carry out more R&D on neglected diseases.

**Kramer R. Growth is keynote in China. *Les Nouvelles*, December 1994, 175-181.**

This article concentrates on the pharmaceutical industry's prospects with regard to China. The author explains why many international pharmaceutical companies are focusing their interest on China as one of the major pharmaceutical markets in Asia. Pharmaceutical patent protection is described as well as the place of OTC drugs, quality and drug lists, pricing, the strategy of pharmaceutical investment through joint ventures and the local pharmaceutical industry.

**Krishna Iyer VR, Chinnappa Reddy O, Desai DA, Rajinder Sachar. Report of the People's Commission on GATT. The constitutional implications of the Final Act embodying the results of the Uruguay Round of multilateral trade negotiations. New Delhi, Centre for Study of Global Trade System and Development, 1996.**

Concern over the impact of the Final Act of the Uruguay Round on India's sovereignty, democracy and the Constitution led to the creation in 1993 of a non-official judges' panel, entitled the People's Commission on GATT, to examine the constitutional implications of the Final Act. The report of the People's Commission begins with a detailed chronology of events which provides a basis for understanding the domestic and international context in which the Final Act was negotiated. A background is provided on the functioning of the previous GATT and the numerous rounds of negotiations preceding the Uruguay Round. The report describes the Indian Government's handling of the Uruguay Round and then examines the critical sections of the Final Act and their implications for the political economy. An annex reproduces the text of a paper on the Indian view of the future TRIPS Agreement presented at a meeting of a negotiating committee under the Uruguay Round (1989).

**Kwon H. Patent protection and technology transfer in the developing world: the Thailand experience. *George Washington Journal of International Law and Economics*, 1995, 28: 567-606.**

This paper explores the complex relationship between the protection of IPR and the process of international technology transfer to developing countries. It examines the impact of Thailand's patent reform in 1992 on the state of technology investment in the country. The study found that patent amendments have had little or no impact on the flow of technology transfer to Thailand via foreign direct investment. The lessons from Thailand have emphasized that the provision of increased patent protection involves substantial effort and risk for countries with underdeveloped and developing economies.

**Lambert PH. Vaccines for the world: major challenges for the future. *South-East Asian Journal of Tropical Medicine and Public Health*, 1997, 28, suppl. 2, 122-126.**

Vaccination is at a turning point. The global use of common infant vaccines has led to a remarkable decrease in the disease burden associated with measles, pertussis or diphtheria, while rapid progress is being made towards the eradication of poliomyelitis through mass immunization campaigns. However, new disease targets are now emerging and research priorities, at a global level, encompass the development of a series of new vaccines. Recent technological advances have made this possible but the challenge of universal immunization is likely to require particular approaches. For example, it will be essential, in the near future, to define optimal ways to use the capacity of the immune system to generate long-lasting protective responses against intra-cellular micro-organisms, to develop vaccines that are efficient soon after birth and to devise new systems to simplify immunization. It will also be a real economic challenge to ensure that new vaccines become available for those who are at the highest risk, usually in the least developed countries.

**Otten A. The GATT/TRIPS Agreement and health care in India. *National Medical Journal of India*, 1995, 8(1): 1-3.**

According to the author, much of what has been said about the implications of India's commitment to provide patent protection for drugs, and particularly regarding pharmaceutical prices, *"has been alarmist and has created needless anxiety"*. This article sets out to provide a dispassionate examination of the facts. It indicates that any effect on prices will be very gradual and modest. Also, the author suggests that this issue be considered in the context of policies aimed at the better availability of drugs to treat diseases prevalent in India.

**Pillai AM. Impact of GATT Agreement on drug prices. *Journal of the Indian Medical Association*, 1995, 93(3): 1-3.**

The main concern expressed in India about the extension of product patents to pharmaceuticals relates to the increase in drug prices, limited local manufacturing, limited access to new technology and inhibited R&D. In this article, the author suggests that the adverse effect on the growth of the

pharmaceutical industry can be reduced if the pharmaceutical industry, the medical profession and the policy-makers rise to the occasion and give a new direction to the drug industry regarding research, drug production and utilization.

**Redwood H. New horizons in India: the consequences of pharmaceutical patent protection. Felixstowe, UK, Oldwicks Press Ltd, 1994.**

The objective of this study is to examine an issue common to several developing countries, but specifically in relation to the situation in India. Part one of this book relates the rise of the Indian pharmaceutical industry and the decline of multinationals in India as a result of the Patent Act of 1970, and the dispute over pharmaceutical patent protection which led to the signing of the TRIPS Agreement. Part two analyses the facts, myths and expectations relating to the implementation of the TRIPS Agreement in India: the speed and depth of patent penetration of India's drug market, the effects on prices, and the expectations for R&D of new products. The last part explores possible future options for Indian pharmaceutical companies, the Indian Government and research-based multinational drug companies.

**Sen B. The Uruguay Round: implications for world trade. New Delhi, Jawahar Publishers, 1996.**

This book discusses the possible impact of the new WTO agreements on developing countries. With regard to the TRIPS Agreement, it focuses on patents for pharmaceutical and biotechnology products and their economic impact in respect of innovative capacity, foreign investment, technology transfer and domestic prices. The author also assesses the particular implications in India for pharmaceutical prices and the Indian drug industry, the impact on microbiology and the significance for plant varieties

**Shah S. Illuminating the possible in the developing world: guaranteeing the human right to health in India. Vanderbilt Journal of Transnational Law, March 1999, 436-485.**

Deprivations such as malnourishment and under-nourishment are currently endured by around one fifth of the world population; this article considers this fact to be a major human rights offence. Furthermore, the article amounts these deprivations as resulting in the systematic disempowerment of individuals as citizens. This set of circumstances partly explains the involvement of the human rights movement in the matter. According to the author, the recognition of the social right to health largely contributes to a greater sense of citizenship on the part of individuals. The second part of the article is devoted to the potential of social human rights and the positive impacts that they could have on the situation in the developing world. The author stresses the notion of state obligation, particularly with regard to guaranteeing human dignity. This obligation is explored in the third part of the article, with particular attention to the challenges posed by the implementation of social rights at the national level. The fourth part is entirely devoted to the notion of a human right to health and other social rights, taking into consideration not only the conceptual and

practical problems posed but also the critical role of the right to health in the empowerment of individuals. The author identifies those conditions necessary for good health as also being essential for promoting human dignity. The final part of the article focuses on the experience in social rights (and the right to health) in India, noting the positive potential impact on economic institutions, social priorities and power imbalances. The author concludes that the Public Interest Litigation Scheme is being used by the Indian judiciary to recognize the rights of individuals to live with dignity. Acknowledging the right to health allows judges and courts to address human suffering through social entitlements and conditions. The article considers how the Indian experience could be useful for other countries learning how to make social rights justiciable and develop appropriate methods for their implementation and enforcement.

**Shanker D. India, the pharmaceutical industry and the validity of TRIPS. *The Journal of World Intellectual Property*, May 2002, 5(3): 315-371.**

This article deals with the attempts by developing countries to bring their patent regimes into line with the provisions of the TRIPS Agreement, e.g., in India, through the Second Amendment in 1999 of the Indian Patent Act, and how this development is viewed by pharmaceutical industries abroad (in particular Pharma), governments and supporting institutions. This analysis suggests that it is nearly impossible for developing countries to do so, as the interpretations of these provisions by the pharmaceutical industries, their supporting institutions and indulgent governments, are continuously changing. The issue of compulsory licensing and the effect of the WTO Panel Report in the Canada patent protection case on compulsory licensing have been analysed in detail due to their important consequences for patenting practices in developing countries. The article also analyses other developments, such as the removal of business methods from non-patentable items from the US Patent Act because of certain interpretations of that Act by the Court of Appeal which failed to acknowledge a number of US Supreme Court judgements; the article also refers to the partial modification of Section 48(3) of the UK Patent Act which removed local working conditions as a result of the WTO Act, 1999, and the introduction of computer programmes as patentable subject-matter, as well as many other indiscreet interpretations which were never part of the original TRIPS Agreement.

**Steele P. Patenting of pharmaceuticals in Korea. *Curr Opin Ther Patents* 1994, 4(1): 1-5.**

The patent system in the Republic of Korea has been integrated with international patenting since 1986. Therefore, the author investigates the number of pharmaceutical patents in the Republic of Korea, who files patent applications in that country and what types of invention dominate. In addition, he indicates how non-Republic of Korea companies protect their inventions and to what extent the Patent Cooperation Treaty (PCT) route is being used.

**Supakankunti S et al. Study of the implications of the WTO TRIPS Agreement for the pharmaceutical industry in Thailand. WHO Regional Office for South-East Asia, 1999.**

The TRIPS patent system is expected to have a strong impact on the health sector. It is argued that it may affect national drug production, drug prices, availability of essential medicines and pharmaceutical technology and numerous other factors in the developing and least developed countries. This study reviews the impacts of the 1992 Thai Patent Act, which first recognized drug product patents, on pharmaceutical industries in Thailand. It focuses on the foreign direct investment situation and the transfer of technology after the new Patent Act was promulgated. The study shows that, contrary to the claimed benefit of patent recognition, there has not been much technology transfer or foreign investment in the local drug industry since 1992. Pharmaceutical firms responsible for the invention are found to perform better than generic firms after 1989 and their share of the original drug market increased to 67% in 1997. The gap in equivalent prices between original and generic products is varied and unpredictable. The author proposes an "Eleven Ps Strategy" to alleviate the potential negative impacts resulting from the obligations set out in the TRIPS Agreement.

**Tancer RS. The pharmaceutical industry in India - adapting to TRIPS. The Journal of World Intellectual Property, 1999, 2(2): 171-188.**

India actively debated the enactment of a new patent law to comply with its obligations under the TRIPS Agreement. This debate reflected the ambivalence existing in India with regard to modifying a patent regime that has served the Indian pharmaceutical industry well since 1970. This sector has developed without the benefit of product patent protection, and delivered drugs at affordable prices. According to the author, a new patent law in compliance with the TRIPS Agreement may create uncertainties and some disruption to a *status quo* that Indians believe is working to their advantage.

**Than Sein U, Chang Rim P. TRIPS and access to medicines. Regional Health Forum: WHO South-East Asia Region, 2001, 5(1): 49-61.**

Written prior to the WTO Ministerial Conference in Doha in 2001, this article sheds light on the possible implications of the TRIPS Agreement on access to medicines. The article focuses on a detailed description of the TRIPS regime from a health policy perspective, paying particular attention to patentability clauses which could lead to monopolistic practices in relation to life-saving medicines. The authors warn about the danger of considering drugs and medicines as any other merchandise which are subject to trade laws and for which no exceptions or special situations are considered. They recall how, in different sessions of the World Health Assembly, the issue had been addressed amid lively discussions as evidence of the high stakes associated with the issue.

**Watal J. Introducing product patents in the Indian pharmaceutical sector: implications for prices and welfare. *World Competition*, 1996, 20(2): 7-21.**

The issue of prices of pharmaceuticals is very controversial in India. The present study, using a different methodology compared with previous studies, attempts to estimate the quantum of price rise if currently patentable drugs were to receive patent protection in India, and calculate welfare losses with such protection. It concludes that no more than 10% of the total pharmaceutical market is likely to be affected, and that the price increase will range between 0 and 64%.

**Watal J. Pharmaceutical patents, prices and welfare losses: policy options for India under the WTO TRIPS Agreement. *World Economy*, 2000, 23: 733-752.**

The implications of the TRIPS Agreement for drug prices is a major debate in the international arena. The current Indian Patent Act, which excludes the patentability of pharmaceutical products, is widely credited to be one of the factors that has brought Indian pharmaceutical prices down to one of the lowest levels in the world. This study simulates the maximum likely increase in pharmaceutical prices and the reduction of welfare in India from the introduction of product patents. It further analyses the extent to which policy measures such as price controls and compulsory licences can help to attenuate the adverse effects of patent monopoly. It shows that prices are likely to increase and welfare is likely to decrease if the country moves from the current market structure to a patent monopoly. Price controls and compulsory licences are believed to be effective in reducing prices and welfare losses. These two policy measures are justifiable and acceptable under current international law, the article states.

**WHO/SEARO. The TRIPS Agreement and pharmaceuticals. Report of an ASEAN workshop on the TRIPS Agreement and its impact on pharmaceuticals. Jakarta, May 2000. Directorate General of Drug and Food Control, Jakarta and WHO Regional Office for South-East Asia, New Delhi, 2000.**

This report gives an overview of the TRIPS Agreement and its possible implications for the pharmaceutical sector in developing countries - the issues and options. It sketches the broad picture in order to address these issues at national level and to draft legislation that balances the interests of producers and users of technology. Cooperation between the ministry of health, the ministry of trade and the intellectual property office is of the utmost importance. The first, and main, part of this report has been compiled on the basis of input from resource persons at the workshop. Section II provides essential background information on WTO and IPR, with substantial input from major stakeholders, since policy makers will encounter their important, differing and firm views and will have to take them into consideration. Section III deals with technical issues and how they translate into social and public health realities, and section IV provides initial reflections on how several of these concepts relate to the specific areas of TRM and biotechnology.

**WHO/SEARO. The Uruguay Round and health. The agreement of the World Trade Organization: a review of its impact on health in countries of the South-East Asia Region. New Delhi, WHO Regional Office for South-East Asia, 1996.**

This document is intended to serve as a brief for ministries of health in the Region which may help them identify measures necessary to deal with the impact of the WTO Agreements. It is an attempt to review both the possible impact of the Agreements and WHO's efforts to protect health in an environment of trade liberalization.

**WHO/SEARO. TRIPS and the health sector in the South-East Asia Region. New Delhi, WHO Regional Office for South-East Asia, September 1998.**

The TRIPS Agreement has serious implications for the health sector in the countries of the South-East Asia Region. SEARO has a vital role to play in helping Member States to understand the provisions of this Agreement. This paper outlines the salient features of the TRIPS Agreement and examines the patent situation in each country of the Region. It then assesses the implications of patenting of pharmaceutical products in Bangladesh, India, Indonesia, Maldives, Myanmar, Sri Lanka and Thailand, and the changes in national legislation, and discusses the role of WHO.

**WHO/SEARO. WTO multilateral trade agreements and their implications on health - TRIPS. Report of a Regional Consultation, Bangkok, Thailand, 16-18 August 1999. New Delhi, WHO Regional Office for South-East Asia, 2000.**

More and more countries realize the importance of the implications of the TRIPS Agreement on health. This book is a report from a South-East Asian Regional Consultation on the topic in 1999. There were several presentations and panel discussions on the topics of multilateral trade agreements, the current situation of patent legislation in the countries of the Region, the issue of biotechnology patents and the implications of the TRIPS Agreement on generic drugs and TRM. The impact of TRIPS for consumers and the use of the compulsory licensing system and parallel imports are further elaborated. Two case studies, from India and Thailand, are presented.

**WHO/WPRO. Pharmaceuticals in the Trade Related Aspects of the Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO). A briefing on TRIPS. Manila, WHO Regional Office for the Western Pacific, August 2000.**

This report, written before the WTO Ministerial Conference in Doha in 2001, offers very practical and concise information about basic elements of the TRIPS Agreement, critical for a better understanding of its implications for public health. The document addresses the necessary combination between the implementation of TRIPS and other public policy objectives, such as consumer protection or guaranteeing access to essential drugs, while issuing a set of recommendations directed at national policymakers.

**Wilson D, Cawthorne P, Ford N, Aongsomwang S. Global trade and access to medicines: AIDS treatments in Thailand. *The Lancet*, 1999, 354 (9193): 1893-95.**

This article from Médecins sans Frontières (MSF) describes the problem of access to HIV/AIDS treatment in Thailand. It alleges that pressure from the USA is one important factor that has limited access to affordable treatment for Thai patients. The article concludes by emphasizing the importance for developing and least developed countries of understanding fully the implications of trade agreements.

## **2.3 Europe**

**Barth R. Patent protection of biotechnology, pharmaceutical and chemical inventions in Eastern Europe. *Patent World*, December 1993/January 1994, 27-29.**

The disintegration of the former Soviet Union and Yugoslavia resulted in changes in the patent laws of the Newly Independent States. In 1994, most of the new States set up their own patent offices. This article provides an overview of the legal situation in Eastern Europe. It includes a table showing whether the various jurisdictions protect biotechnology, pharmaceutical and chemical inventions.

**Challu PM. Effects of the monopolistic patenting of medicine in Italy since 1978. *International Journal of Technology Management (special issue on the management of international intellectual property)*, 1995, 10(2/3): 237-251.**

The paper discusses the effect that the patenting of medicine in Italy has had since the current legislation was passed in 1978. Comments focus on four areas: the influence of patents on prices, the attitude of the national laboratories and the consequences for national production, the effect of monopolistic patents on the capacity for innovation, and the influence of patents on Italy's balance of trade in pharmaceuticals.

**Cook TM. Pharmaceutical patents and the generic sector in Europe. *Patent World*, February 1997, 36-40.**

The strategies adopted by the research-based companies in the pharmaceutical industry to hamper generic competition after patent expiry are many and varied. In some cases, they will take the form of further patents with later expiry than the original one protecting the product, but relating for example to formulations or processes. However, the research-based company can also make the most of its original patents, as discussed in this article, which seeks to summarize developments in Europe over recent years in the underlying legal framework affecting the balance between the generic sector and the research-based sector of this industry.

**Darbà J, Rovira J. Parallel import of pharmaceuticals in the European Union. Paper presented at the Symposium on Dynamics of the International Pharmaceutical Marketplace: Major Forces in the Late 1990s, Talloires, France, 24-25 July 1997.**

Differences among EU Member States in political, social, economic, legal and regulatory regimes cause differences in pharmaceutical prices, which in turn create opportunities for parallel trade. This paper looks at the current state of parallel trade of prescription medicines in the EU, with a particular focus on Spain as a source of parallel exports. It also analyses some policy implications derived from parallel trade. Finally, it develops a simple microeconomic model for assessing the effects of parallel trade.

**European Generic Medicine Association. A proposal to include a development and testing provision for generic medicines in national and EU laws. Brussels, EGA Position Paper, July 2000.**

This paper proposes to the EU that national and EU laws be amended in line with the WTO Panel Decision (WT/DS114/R) of 17 March 2000. This Decision relates to the dispute between Canada and the EU on the issue of the development, testing and experimental work required for the registration of a generic drug before the expiration of patent protection. The WTO Panel held that testing, development and production of samples is compatible with TRIPS. This paper argues that incorporating this development and testing provision into national and EU laws would provide Europe with major economic benefits in the areas of investments, employment, balance of trade, public health and know-how, with no negative effect on patent holders.

**European Generic Medicine Association. TRIPS Article 39.3 does not require data exclusivity provisions (a critical issue for access to medicines). Brussels, EGA Position Paper, July 2000.**

This paper contends that the clause “protect such data against unfair commercial use” provided in Article 39.3 of the TRIPS Agreement is not the same as “data exclusivity” which is operated in the EU or USA. It emphasizes the difference between the “repression of unfair competition” and other forms of IPP. Furthermore, it maintains that the interpretation that Article 39.3 requires data exclusivity is beyond the agreed terms of the TRIPS Agreement. According to the author, Article 39.3 cannot be interpreted in a way to prevent a regulatory authority from using/relying on the data registered for a particular product in order to assess and register other “similar” products, as in the case of generic pharmaceuticals. The paper also includes the definition and examples of unfair competition as provided by WIPO, together with other supporting evidence.

**Kucher E. Taking control of parallel trade in Europe. Scrip Magazine, February 1999, 14-16.**

Parallel trade is not specific to the pharmaceutical industry and happens wherever there are price differentials. It increases the effectiveness of the market and usually benefits the customer. However, to reap these benefits, the markets

must be free. In the pharmaceutical industry, markets are not free and different strategies are required to stem the rapid growth in parallel trade within the EU. According to the author, the outlook for parallel trade may seem bright in the short-term but too many factors speak against a prosperous future beyond that, the most crucial being pan-European pricing strategies.

**Scherer FM, Weiburst S. Economic effects of strengthening pharmaceutical patent protection in Italy. *International Review of Industrial Property and Copyright Law (IIC)*, 1995, 26(6): 1009-1024.**

The Italian experience of introducing pharmaceutical patent protection is particularly interesting because it presages legal changes that are likely to happen in some developing countries in the WTO TRIPS era. This article investigates how Italian producers adapted to the intellectual property regime changes of 1978. In particular, it undertakes a detailed statistical analysis of changes in drug R&D expenditures and patenting. In addition, it supplements that with information on new drug product introductions, foreign direct investment by multinational enterprises and import-export balances.

**Segura P. The peculiar patent and generic situation in Spain. Available from: URL: <http://www.egagenerics.com>**

When Spain modified its law on generics, it introduced an unusual and controversial set of regulations. This article looks at these changes, and provides the industry point of view.

**Senior I. Patents and parallel trade in prescription medicines within the EU. *Patent World*, October 1996, 26-32.**

This article deals first with the issue of parallel trade in the EU: its link with price regulation, how parallel trade takes place, whether it results in a market correction or distortion, what are the main exporting and importing countries and those driving parallel trade. It then stresses the importance of the judgement at the European Court of Justice (ECJ) , *Merck & Co. v. Primecrown Ltd.*, and of Bayer's appeal against the Commission's decision regarding Adalat.

**Watts J, Treacy P. Parallel imports: reaffirming euro-puritanism. *Patent World*, February 1997, 28-32.**

The ECJ's judgement in *Merck & Co. v. Primecrown Ltd.* confirmed that patentees cannot exclude from patented territories goods which they or their licensees have sold in EU Member States where the goods have no patent protection. This article argues that patentees who do not obtain, and maintain, Europe-wide coverage for their entire patent portfolio are faced with a continued choice between selling Europe-wide at close to unpatented prices, and leaving unpatented territories unexploited.

## 2.4 Latin America

**Ahlert IB. New Brazilian industrial property law. *International Review of Industrial Property and Copyright Law (IIC)*, 1997, 26(5).**

After five years of discussions in the National Congress and ratification of the WTO TRIPS Agreement, the new industrial property law was signed in 1996. It includes several innovations in the patent chapter, most of them following present international trends. As a result, the new law mostly favours strong patent protection in Brazil, although a few points still need to be reviewed in order to achieve full harmonization with TRIPS.

**Bermudez JA, Epsztein R, Oliveira MA, Hasenclever L. The WTO TRIPS Agreement and patent protection in Brazil: recent changes and implications for local production and access to medicines. Rio de Janeiro, WHO/PAHO Collaborating Center for Pharmaceutical Policies, National School of Public Health, and Oswaldo Cruz Foundation, 2000.**

Brazil signed the Final Act of the Uruguay Round in 1994 and is consequently obliged to abide by the TRIPS Agreement. The industrial property law was passed in 1996 to meet the requirements of the TRIPS Agreement, including the patentability of pharmaceutical products. This report analyses the implications of the implementation of the TRIPS Agreement and the changes in Brazilian legislation in the field of patent protection. The study indicates that recent changes have failed to produce obvious benefits for the domestic pharmaceutical industry. There has been no reduction in drug prices, nor any increase in access of the low-income population to essential drugs. The authors conclude that the greatest beneficiaries of recent changes in Brazilian legislation and the implementation of the TRIPS Agreement are transnational companies with their persistent domination in the market.

**Correa CM. Implementation of the TRIPS Agreement in Latin America and the Caribbean. *European Intellectual Property Review*, 1997, 8, 435-443.**

In accordance with the transitional periods of the TRIPS Agreement, the new minimum standards of protection are being adopted in the various areas of intellectual property in many developing countries at a very different pace. This article describes first the framework for implementation of the TRIPS Agreement and some aspects relating to the incorporation of the Agreement's provisions into national laws. It then discusses interpretation and instrumental problems that have arisen, and some of the problems faced by developing countries in the process of implementation. The main changes introduced in Latin American and Caribbean countries to implement the TRIPS Agreement are then briefly analysed, followed by the main conclusions.

**Correa CM. Reforming the intellectual property rights system in Latin America. *World Economy*, 2000, 851-872.**

During the 1990s, significant changes took place in Latin America in order to comply with the TRIPS Agreement that was adopted as part of the Final Act of the Uruguay Round. This paper reviews the changes in IPR laws in Latin American countries by examining the introduction of substantive amendments, the main problems faced and some implications of the changes. For example, in relation to foreign direct investment, the paper shows that, in some countries where product protection for pharmaceuticals is accepted, a large number of foreign-owned plants for formulating pharmaceuticals have been closed down. This is contrary to the situation in Argentina where patents for pharmaceutical products are not granted, and a significant flow of foreign direct investment has been reported as mainly targeting the acquisition of local firms.

**FIEL. Protection of intellectual property rights: the case of the pharmaceutical industry in Argentina. Buenos Aires, Fundación de Investigaciones Económicas Latinoamericanas, 1990.**

Argentina belonged to the group of developing countries that did not recognize IPR in the pharmaceutical field. Although this situation gave rise to a major legal controversy, from the economic point of view it has provided scarce elements for analysis. The need for a critical revision of the legislation became evident, as Argentina would have to adopt a position regarding relevant international changes and the Uruguay Round. This paper aims to point out the issues that allow for an impartial weighting of the effects of the policy of not recognizing pharmaceutical patents, and to make a contribution to evaluating the economic effects deriving from the adoption of alternative systems.

**Galvao J. Access to antiretroviral drugs in Brazil. *The Lancet*, 7 December 2002, 360(9348): 1862-1865.**

Since 1996, the Brazilian Ministry of Health guarantees free and universal access to antiretroviral treatment for people living with HIV/AIDS. Implementation of this policy has had political, financial and logistical challenges. The author has investigated the history and context of antiretroviral policy in Brazil, the logistics of drug distribution and the Government's strategies for the acquisition of drugs. Many antiretrovirals used in Brazil are produced domestically; the remainder, including some of the most expensive drugs, are purchased from abroad. Although the Brazilian policy of antiretroviral distribution has had notable success, it remains threatened by the high cost of the acquisition of drugs, which has led to disputes with international pharmaceutical companies over prices and patents. Much can be learnt from the Brazilian model of guaranteeing access to antiretroviral treatment for people living with HIV/AIDS.

**Gonzalez E. Juridical action for the protection of collective rights and its legal impact: a case study. *Journal of Law, Medicine and Ethics*, 2002, 30, 644-654.**

The development in 1996 of a new generation of antiretroviral drugs was a major pharmaceutical breakthrough in the struggle against the HIV/AIDS pandemic. Due mainly to their high costs, access to these new drugs was almost impossible for most HIV-positive people. This situation was even more dramatic for people living in developing countries. Many of the organizations struggling for the rights of HIV-positive people have since developed human rights advocacy and legal strategies to try to achieve universal access to treatment. These organizations are also fighting for state compliance with human rights obligations under health-related international human rights treaties and conventions. This paper draws upon the experience gained in Latin America, focusing on the legal strategies that have been explored in Venezuela and the legal consequences for domestic law. The article refers to the main legal cases recently heard by the Venezuela Constitutional Court, the rulings of which have had important consequences for granting access to drugs for important sectors of Venezuela's population.

**Gosain R. Brazil's new patent law. *Patent World*, June/July 1996, 30-34.**

After having been in and out of the limelight for five years, Brazil's new patent law has been approved. This paper focuses on the major changes brought about by the new law as regards patentability and pipeline protection, biotechnology, state of the art legislation, cost reduction of priority claim, filing and examination of application, term of a patent, compulsory licences and working requirements, restrictions on the rights of the patentee, etc.

**Gosain R. Extension of patent term and pipeline route in Brazil. *Patent World*, January 1997, 31-33.**

Although the new Brazilian patent law came into force on 15 May 1997, some issues are still controversial and will need to be clarified by the courts, such as the question of patent term extension for pending Brazilian patent applications and existing patents, and the use of the pipeline provisions.

**Gosain R. Patent law reform in Brazil: an update. *Patent World*, October 1994, 38-41.**

This article develops the essential points of the reform of the Brazilian law on patents, following international pressures: patent protection of microorganisms, chemical and pharmaceutical products, pipeline protection, exhaustion of rights and regulation of compulsory licences.

**Gosain R, Sherrill HK. The effects of GATT/TRIPS on Brazil's patent legislation. *Patent World*, May 1995, 24-26.**

This is an analysis of the reform of the Brazilian patent law: extension of the domain of patentability, duration of protection, compulsory licences, local

working of the patent, and registration of applications for patents on new materials.

**Medina I. Patentability of pharmaceuticals and the new trends in Brazilian legislation. Patent World, November 1990, 33-35.**

This paper focuses on the trend towards harmonizing national patent protection with legislation in developed countries, in particular that which deals with the question of the patentability of pharmaceutical processes and products. It presents the Brazilian legislation prior to the signing of the TRIPS Agreement, and the debate on drug patentability in Brazil.

**Redwood H. Brazil: the future impact of pharmaceutical patents. Felixstowe, UK, Oldwicks Press Ltd, 1995.**

As a strong emerging market for pharmaceuticals and a leader in Latin America's science and technology, Brazil is a signatory of the WTO Agreements, including the TRIPS Agreement, and was consequently committed to introducing pharmaceutical patent protection. This book is based on interviews with those of all shades of opinion on the subject in Brazil, with an extensive study of relevant published sources. It examines the conflict of attitudes over pharmaceutical patent protection in Brazil and considers the prospects. In addition, it evaluates the consequences of eventual patent legislation for the national and multinational pharmaceutical and chemical industries and the trade balance, the pharmaceutical market in Brazil, drug prices and the cost to health care and, finally, R&D in pharmaceuticals and biotechnology.

**Rozanski F. Nueva legislación argentina de patentes de invención. Derechos Intelectuales, vol. 7, Editorial Astrea, 1996.**

The author considers the complex evolution of the regime of invention patents and utility models in Argentina. After having pointed out the main principles governing the TRIPS Agreement, he deals with the most controversial aspects of the new Argentine regime, such as the transitional period for pharmaceutical patents, the filing of revalidation patents, the term of protection, the compulsory licensing regime and the enforcement of IPR. Having identified the ambiguous and controversial aspects of these provisions, the author ends by emphasizing the need for their improvement, so that they respect both the Constitution and the international treaties in force.

**SELA/IDB. The TRIPS Agreement and international trade: effects on Latin America and the Caribbean. Workshop on the application of the TRIPS Agreement, Mexico City, 20-24 May 1994.**

In the context of the Summit of the Americas, the Uruguay Round and the North American Free Trade Agreement (NAFTA), intellectual property is one of the issues proposed for discussion. This document is a contribution to the initial stage of dealing with the issue. It first examines the relationship between trade

and intellectual property, and the relevance of intellectual property as a factor which can help or hinder legitimate trade. It then analyses data about the extent to which international trade is affected by intellectual property. It describes the general characteristics of the TRIPS Agreement and examines specific issues such as trade in counterfeit goods, parallel imports, the control of abuses of IPR and the transfer of technology. Finally, it overviews the consequences of the TRIPS Agreement in Latin America and the Caribbean, with the resulting amendments to legislation, and the regional agreements on intellectual property.

**Tobias G. Patent protection: the Argentinean divide. SCRIP Magazine, November 1992, 26-28.**

Proposals to introduce pharmaceutical patents in Argentina rekindled the debate between national and multinational companies over the benefits of IPP in developing countries. The pricing issue is particularly contentious since both sides tend to gather data most favourable to their own viewpoint. Likewise, the true benefits and/or disadvantages of compulsory licensing may be permanently lost in a fog of partisan wrangling. This article explores the stubborn divisions between the two camps.

**Yamin A. Promoting and protecting the right to health in Latin America: selected experiences from the field. Health and Human Rights, 2000, 5(1): 117-148.**

Through a description of the four major challenges faced by Latin American human rights groups and the strategies that they have adopted to overcome these challenges, this article seeks to incorporate the human rights perspective into the discussion of how to make health a universally recognized human right. The ill-defined normative content of the right to health, the lack of precedents and procedures for enforceability and the lack of consciousness of health as a right have presented major obstacles to the implementation of this right in the Region. Also, it is proposed that Latin American human rights groups move beyond traditional legal methods and expertise to work in an interdisciplinary fashion with health professionals and grass root health groups. The author concludes that, despite the obvious obstacles, Latin American human rights groups cannot afford not to become involved in advocacy and promotion of the right to health.

**Zuccherino DR. Breve panorama de la legislación sobre patentes de invención en la República Argentina. Revista La Información, 1995, 71(786).**

This article first analyses the objective and rationale of the patent system and the social importance of patents. It then discusses the new Argentine patent law, international trends in IPP and the hierarchy between national laws and international treaties.

**Zuccherino DR. Propiedad intelectual y dinámica competitiva. Revista La Información, 1996, 73(797).**

This article examines the relationship between the patent system and competition, the economic perspective and the benefits of patents in stimulating competition and economic development.

## **2.5 Middle East**

**Abouelenein AA. Trade-related aspects of intellectual property rights (TRIPS) and the pharmaceutical industry in Egypt. Cairo, Federation of Egyptian Industry, June 1996.**

This publication presents the view of a member of the Board of the Association of Egyptian Industries on the negative effects of the TRIPS Agreement on the country's pharmaceutical industry. These negative effects not only apply to the national pharmaceutical industry but also extend to economic, social and health aspects in the country.

**Badwan AA. Implications of joining WTO on the Arab pharmaceutical industry. Jordan, 1996 (unpublished paper).**

This paper briefly relates the development of international trade until the WTO was created, with emphasis on the developing countries, and presents the TRIPS Agreement provisions related to pharmaceuticals. It then examines the Arab pharmaceutical industry, pointing out common features, such as patent protection for pharmaceutical processes, but also the different pharmaceutical policy orientations. The author concludes that the reorientation of the Arab industry, by joining the WTO, may have a negative effect on public health with regard to medicines.

**Ghorab MG. Agreement on intellectual property and pharmaceuticals in Egypt. Egypt, 1996 (unpublished paper).**

This is a brief presentation of the drug situation in Egypt followed by an outline of the measures which should accompany the implementation of the TRIPS Agreement, particularly policies on registration and pricing, support to R&D activities and creating strategic alliances. There is also analysis of the advantages accruing from patent protection for the pharmaceutical industry and the Egyptian economy, as well as a discussion on the truths and falsehoods in the drug patents debate.

**Shaarawi NM. Intellectual property rights: Egypt. Glaxo Wellcome Egypt, SAE, 1993.**

This publication presents the view of a multinational's subsidiary on the TRIPS Agreement and the dispute over pharmaceutical patent protection. It first presents the views of the major protagonists: the Government, the national companies and the multinationals. It then discusses the issues of speed and

depth of patent penetration of the Egyptian market, "check and balances" as regards price explosion and pharmaceutical R&D. Finally, the paper defends the motives for strengthening IPP and the options that will shape the end game.

**UN ESCWA. Challenges and opportunities of the new international trade agreements (Uruguay Round) for ESCWA Member Countries in selected sectors: implications of WTO/TRIPS for technology transfer in the pharmaceutical industry. New York, United Nations, 1998.**

This report is part of the study undertaken by the Economic and Social Commission for Western Asia (ESCWA) to assess the implications of the WTO rules and related agreements on selected sectors in the Member Countries. The first part addresses the main implications of WTO rules on trade, investments and technology in the pharmaceutical industry. It briefly describes patent regimes in force in the countries of the Region, reviews the main provisions relating to the protection of IPR, and provides policy recommendations for technology acquisition by the pharmaceutical industry in the Western Asia Region. The second part of the report is more concerned with pharmaceutical production and consumption in Member Countries. Information is given on production, consumption levels, ownership patterns, export ratios and R&D. The implications of WTO rules for technology transfer to the pharmaceutical industry in two countries, Egypt and the Syrian Arab Republic, are further analysed as case studies. The report concludes by claiming that there are two central issues that are among the topmost priorities for industry, government and the science and technology community in the ESCWA Member Countries. These are the acquisition of suitably sophisticated technologies and the enhancement of local R&D capabilities.

## 2.6 North America

**Anderson M, Auld C, Bolton C, Gregory A, McBride J. The economic impact of Bill C-91 on the cost of pharmaceuticals in Canada. Kingston, Canada, Queen's Health Policy Research Unit, Queen's University, January 1997.**

Compulsory licensing for drug patents was introduced in Canada in 1923. However, in 1987, Bill C-22 was passed to provide the patent holding firm with a 7-10 year period of market exclusivity before the entry of generic drug competition. In 1993, after the passage of Bill C-91, the compulsory licensing provision was eliminated and patent protection of brand-name drugs was extended to at least 20 years. This study focuses on the economic impact of Bill C-91 on the cost of pharmaceuticals in Canada. Three different scenarios are modelled using the cases of 7 or 10 years of patent protection from launch date, as provided under Bill C-22, compared to a 5-year extension of current patent protection (total 25 years). The authors conclude that in each model consumers would incur substantial costs because of the extended patent protection on new drugs, estimated at between \$ 3.7 and \$ 9.4 billion.

**Congressional Budget Office. How increased competition from generic drugs has affected prices and returns in the pharmaceutical industry. July 1998. Available on the web at: <http://www.cbo.gov>**

In 1984, the United States Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Act) created an abbreviated approval process for generic drugs and, at the same time, extended patent terms for innovator drugs. This study examines the price competition among manufacturers in the pharmaceutical market, including the impact of the dramatic growth in the generic drug industry since 1984. Such competition comes in three main forms: between brand-name drugs in the same therapeutic class, between brand-name drugs and their generic counterparts, and between different generic versions of the same drug. This study also analyses the changes in patent protection for brand-name drugs as well as supply-side factors that have boosted generic market share, in order to assess how that competition has affected the returns from developing a drug.

**Hunt MI. Prescription drugs and intellectual property protection: finding the right balance between access and innovation. Washington, D.C., National Institute for Health Care Management Research and Educational Foundation, August 2000.**

This report is devoted to the examination of the most important law pieces related to IPP for pharmaceuticals approved in the United States of America during the last two decades, from the 1983 Orphan Drug Act to the 2000 Pipeline Drug Proposals with mention of the Uruguay Round Agreements Act and the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman). It also takes into account the effects of this enhanced protection on technological innovation and the market for prescription drugs. The report asserts the critical impact of current patent laws on the price of prescription drugs and general public health costs. It pays close attention to some of the reported benefits of IPP, such as the support for technological innovation, showing in contrast the major role played by IPP, not only in protecting pharmaceutical industry profits but also in delaying the entry of affordable generic drugs onto the market and shielding brand-name drugs from price competition. The report concludes by asking for greater vigilance on the part of public authorities on the use by private companies of public funds devoted to R&D while signalling that, within the period 2000-2005, some of the most lucrative brand-name drugs will go off patent, leaving the way open for their replacement by generic drugs in prescription schemes.

**Kanavos P. Health policy versus industrial policy in the pharmaceutical sector: the case of Canada. Health Policy, 1997, 41, 241-260.**

All governments face the dilemma of balancing a dual role of encouraging the pharmaceutical industry while at the same time attempting to contain the costs of pharmaceutical products. This paper analyses the trade-off between health policy and industrial policy objectives in the Canadian setting. It provides a brief overview of the Canadian health system and the domestic pharmaceutical industry. It examines pharmaceutical policies at the federal and provincial level,

and discusses the impact of federal health and industrial policies on the provincial objectives for pharmaceutical cost control.

**Prime Institute. The cost of Bill C-91: An economic impact analysis of the elimination of compulsory licensing of pharmaceuticals in Canada. Prime Institute, College of Pharmacy, University of Minnesota, January 1993.**

This study was reported in 1993 before the promulgation of Bill C-91, to show the possible impact if the compulsory licensing of pharmaceuticals were eliminated as the result of this legislation. The author argues that, although the passage of this Bill may have a number of positive effects for some sectors, there would also be major costs in terms of increased pharmaceutical expenditures throughout Canada. The author claims that the magnitude of direct costs due to Bill C-91 over the subsequent 15 to 20 years, \$ 3.6 to \$ 7.3 billion, would far outweigh the direct benefits, \$ 500 million, in increased R&D spending in Canada.

**Rhein R. Patent passions run high in Canada. Scrip Magazine, April 1998, 37-39.**

Since the passage of the controversial Bill C-91, the Canadian generics industry has been campaigning for the repeal of at least some of its provisions, such as the link between a drug's notice of compliance and its patent status. However, the Government revisions have not lived up to the industry's expectations.

**Torremans P. Compulsory licensing of pharmaceutical products in Canada. International Review of Industrial Property and Copyright Law (IIC), 1996, 27(3): 316-331.**

Canada had always stood out for its special policy in relation to pharmaceutical patents until important changes took place at international level with the negotiation of the NAFTA and the TRIPS Agreement. Compulsory licences were at the centre of all these debates and they have attracted attention in Europe. This article investigates what pattern is to be found in all these developments and what are the advantages and disadvantages of the various regimes. It seeks to demonstrate that the new system, while perfectly acceptable in principle, can be improved on a series of points, and that experience under European law can be of assistance.

**Wilcox PR. Pharmaceutical patent litigation in Canada. Patent World, May 1996, 26-30.**

Pharmaceutical patent litigation in Canada is a burgeoning field. Since 1993, when compulsory licences as of right were abolished and the patented medicines (notice of compliance (NOC)) regulations were enacted, the opportunities for pharmaceutical patentees to enforce their rights have dramatically improved. As a result, a number of legal proceedings have been initiated by pharmaceutical patentees since 1993, including actions for patent infringement and court applications pursuant to NOC regulations.



## 3. TRIPS, drugs and human rights

### 3.1 TRIPS and patents

**Bartlett S. Compulsory licences pursuant to TRIPS Article 31 in the light of the Doha Declaration on the TRIPS Agreement and Public Health. *The Journal of World Intellectual Property*, March 2003, 6(2): 283-310.**

With the adoption in November 2001 of The Doha Declaration on the TRIPS Agreement and Public Health, WTO Members stressed the need for the TRIPS Agreement to be part of the wider national and international action to address problems afflicting many developing countries, such as those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. Above all, the Doha Declaration addressed the problem that the instrument of compulsory licensing could become useless for those countries in need that have no production facilities, since Article 31 of the TRIPS Agreement requires that goods manufactured under a compulsory licence shall be “predominantly for the supply of the domestic market of the Member authorizing such use”. In order to find a solution to this problem, a variety of proposals have been made, which are currently being discussed at the WTO TRIPS Council. The crucial point about implementing a solution is how far a compulsory licence for export could be subject to possible abuses, such as the re-exportation of the medicines to markets with higher prices, or the export to other countries which are not facing a public health crisis.

**Bourgeois J, Burns TJ. Implementing paragraph 6 of the Doha Declaration on TRIPS and Public Health: the waiver solution. *The Journal of World Intellectual Property*, November 2002, 5(6): 835-864.**

The magnitude of the HIV/AIDS pandemic in developing countries was not foreseen at the time of the conclusion of the TRIPS Agreement, and was one of the paramount concerns at the origin of the Doha Declaration on the TRIPS Agreement and Public Health. In paragraph 6 of that Declaration, WTO Members recognized that countries with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. Accordingly, they instructed the WTO Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002. In this article, the authors consider the options before the Council for TRIPS and conclude that a waiver under Article IX of the Marrakesh Agreement establishing the WTO is the most workable, transparent, sustainable and legally secure solution to the problem identified in paragraph 6, and will permit this issue to be dealt with as a matter of urgency.

**Correa CM. Implications of the Doha Declaration on the TRIPS Agreement and Public Health. Geneva, WHO, Health Economics and Drugs, EDM Series No. 12, 2002.**

This study analyses the antecedents and consequences of the Doha Declaration on the TRIPS Agreement and Public Health. The author highlights how the Declaration acknowledges the seriousness of public health problems faced by developing countries, such as AIDS, tuberculosis and malaria, while equally taking note of developing countries' concerns about possible implications of the TRIPS Agreement for public health in general. The report considers that the specific wording of protection of public health will be critical for future cases presented to the WTO panels and Appellate Body. The author highlights the Declaration's instruction to the governing body of the WTO to address the issue of use of compulsory licensing in countries with little or no manufacturing capacity or insufficient market demand. According to the report, critical factors for a sustainable IPP framework are, among others, a stable international legal framework, transparency and predictability of the applicable rules in the exporting and importing countries and the facilitation of a multiplicity of potential suppliers of the required medicines. The study considers that the apparent concession for an extension of the transitional period, established by Article 66.1 of the TRIPS Agreement, is deceiving as most developing countries already grant patents for pharmaceuticals. The report concludes by underlining how the Declaration acknowledged that differentiation in patent rules might be necessary to protect public health. The author considers the Declaration to be a strong political statement, which may be used by developing countries to adopt measures to ensure and improve access to health care, while recalling that, as a Ministerial Declaration, it will have legal effects both on administrators of the TRIPS Agreement and WTO bodies.

**Correa CM. Protection of data submitted for the registration of pharmaceuticals. Implementing the standards of the TRIPS Agreement. Geneva, South Centre/WHO, 2002.**

This report is focused on one of the most disputed patent-related issues: the protection of submitted data. As a condition for registering pharmaceutical products, national authorities normally require registrants to submit data relating to drug quality, safety and efficacy. A particularly important issue is the direct or indirect use of the data for subsequent registration of products similar to those originally registered. Article 39.3 of the TRIPS Agreement requires Members to establish protection for submitted test data. But this requirement is in fact narrowly drawn, and countries maintain substantial flexibility in its implementation. Article 39.3 does not require that protection be given to already public data. Protection is required only for new chemical entities. Members have considerable discretion in defining "new" and may exclude applications for second indications, formulations and dosage forms. The pharmaceutical industry and some countries have argued for much broader coverage of Article 39.3, and for a requirement that countries confer exclusive rights on originators of marketing approval data. However, these positions are not well grounded in either the text or negotiating history of TRIPS. TRIPS negotiators specifically considered and rejected language requiring grants of exclusive rights to test data. The author highlights the long-term implications of the so-called "TRIPS-plus" protection schemes for developing countries, illustrating the different choices

that policy-makers have in order to protect the interests of the originators of data without undermining competitiveness.

**Granville B. (editor). *The economics of essential medicines*. London, The Royal Institute of International Affairs, 2002.**

This edited volume highlights the pressing issue of the availability of essential medicines in developing countries. It includes perspectives from developed and developing countries, the public and the private sector, and health service delivery, as well as R&D issues. It is noteworthy to mention that the contributors are representatives of the wide range of interested parties, such as international organizations (UNAIDS), government AIDS departments (Uganda), NGOs (Oxfam) and academic experts, guaranteeing different points of views and a combination of approaches.

**Helfer L. *Adjudicating copyright claims under the TRIPS Agreement: the case for a European human rights analogy*. *Harvard International Law Journal*, Spring 1998, 39(2): 357-441.**

This article focuses on the critical role played by the TRIPS Agreement within the WTO legal framework and attempts to shed light on the interpretation of WTO's dispute settlement procedures. It does so by linking them with the experience of other international and supranational courts and arbitration institutions, such as those established under the European Convention on Human Rights (ECHR). Initially, the author identifies the main weaknesses, contradictions and traits of the TRIPS regime, such as minimum standards, the relative autonomy of states/parties in its implementation or the different available approaches. The author highlights the systemic and structural similarities between the ECHR and the TRIPS Agreement that would allow for the development of a conceptual link between them which could be used by TRIPS jurists. Some of the main ECHR traits such as the nuanced legal doctrines present in the jurisprudence of the European Court or human rights issues are cited as examples of a possible common ground. The article is divided into four parts. Firstly, the author examines the TRIPS Agreement and its problems, establishing a comparison with its historical copyright predecessor, the Berne Convention. It illustrates how the lack of enforcement measures and the absence of meaningful dispute settlement procedures pushed the copyright framework into a period of crisis, accelerating the need for reform. The second part of the article is devoted to an analysis of the TRIPS Agreement, identified as the remedy for the previous crisis while being simultaneously considered as a source of new difficulties. According to the author, the link established between IPR and the WTO dispute settlement system, considered to be one of the main strengths of the new protection regime, is threatened by the danger of non-compliance by states/parties. In the third part of the article, the author identifies the methodological difficulties that TRIPS jurists might face during interpretation of the protection regime, suggesting a *European human rights analogy* that would take into consideration the structural similarities between the ECHR and the TRIPS Agreement and the interpretative methodologies specific to the ECHR. The fourth part of the article is devoted to the development of a comprehensive framework for TRIPS jurists to apply in international copyright disputes, particularly in connection with four types of

situation: absence of national copyright laws, enforcement and copyright piracy issues, disputes about copyrightable material and minimum rights and the need to balance IPR and other societal values. The author concludes that TRIPS jurists might be ready to adopt different levels of deference to national decision makers depending on the type of dispute presented before them: ranging from no deference with those states that fail to modify their national laws to close examination of national legislatures, courts and administrative bodies in cases connected with patent holders exclusive rights. The article acknowledges the need to balance *“copyright protection against other important societal values, including free expression, cultural values and human rights goals.”*

**Panos Institute. Patents, pills and public health. Can TRIPS deliver? London, Panos Institute, December 2002.**

Poverty and lack of access to health care are closely linked. Today, a third of the world's population has no means of obtaining essential medicines; a figure that rises to a half in the poorest countries of Africa and Asia. Ironically, it is in these countries that individuals have to spend the largest proportion of their incomes on health care. Many experts argue that the introduction of patent rules in developing countries will drive up the cost of medicines, especially for the complex drugs needed to treat HIV/AIDS and related illnesses. They also point out that patents prevent other companies from marketing cheaper “generic” versions of a drug, which can radically reduce prices. Supporters of patents reply that they are needed to protect drug company profits that pay for much-needed R&D of new drugs, and that inadequate public health systems, rather than the cost of medicines, are the biggest barrier to health care for the poor. This report examines the pros and cons of the TRIPS Agreement for the developing world. It outlines different ways of ensuring access to essential drugs for all, including the poorest. It also stresses the importance of ensuring a public debate in every country in order to put the issues of patenting, pills and public health under the spotlight.

**TWN. TRIPS, drugs and public health: issues and proposals. Third World Network, Intellectual Property Rights Series No. 2, September 2001.**

Millions of people die each year of diseases that are preventable or treatable and this health problem has reached crisis proportions in developing countries. Most patients in poor countries do not have access to the medicines they require to treat their ailments due to their high prices. These prices are set by producers who enjoy a monopolistic position over the manufacture and distribution of life-saving drugs. Control is granted by the IPR framework, developed under the TRIPS Agreement. This report discusses the policy options permitted by the safeguards, in particular compulsory licensing and parallel importation, in order to secure access to affordable medicines. It equally makes proposals for clarifying these provisions to affirm the right of developing countries to invoke them with full flexibility. The report recommends that TRIPS rules be amended in order to ensure that the TRIPS Agreement does not represent an obstacle for those developing countries that take measures to protect public health and save human lives.

**WHO. Network for monitoring the impact of globalization and TRIPS on access to medicines. Report of a meeting, Thailand, February 2001. Geneva, WHO, Health Economics and Drugs, EDM Series No. 11, 2002.**

At a meeting held in Bangkok, Thailand, in February 2001, WHO, as mandated by resolution WHA52.19, initiated the process to monitor and analyse the impact of trade agreements on access to drugs in partnership with four WHO collaborating centres in Brazil, Spain, Thailand and the United Kingdom. The main emphasis of the meeting was to develop a framework of operations for a nascent network for monitoring the impact of globalization and TRIPS on access to medicines. The meeting established that the network, through the individual and collective work of the Collaborating Centres, would undertake research that shed light on four questions: How is patenting affecting drug pricing? How are patents and enhanced IPP affecting the rate of introduction of generic drugs? Are TRIPS and expanded IPP spurring development of drugs for neglected diseases? Are TRIPS and expanded IPP contributing to an increase or decrease in transfer of technology? The participants developed a harmonized model of selected indicators to be adapted according to the characteristics of different regions. These indicators are intended to offer important information, though of course not definitive answers, regarding the four questions, though they relate more to some of the questions than others (the template is included at the end of this report). This report seeks to explore one element of this stark reality: the lack of R&D into drugs to treat the diseases of the poor. When treatment options do not exist or are inadequate, a disease can be considered “neglected”. The neglect is a result of market failure and public policy failure. Recent initiatives and policies seeking to redress the R&D imbalance are also outlined. Public-private partnerships (PPP) have been successful in mobilizing public and private sector expertise around certain diseases. Yet, to date, none of these provide an adequate strategy for developing drugs for the most neglected diseases. Recommendations for moving forward are presented, including the need for a well-defined and needs-driven research agenda be established at a global level.

### **3.2 Research and development**

**Batson A, Ainsworth M. Private investment in AIDS vaccine development: obstacles and solutions. Bulletin of the World Health Organization: International Journal of Public Health, 2001, 79(8): 721-727.**

The development of vaccines for the prevention of AIDS, malaria, tuberculosis, and other diseases requires both public and private investment. Private investment, however, has been far lower than might have been hoped, given the massive human toll of these diseases, particularly in the poorest countries. With a view to understanding this situation and exploring potential solutions, the World Bank AIDS Vaccine Task Force commissioned a study on the perspectives of the biotechnology, vaccine and pharmaceutical industries regarding investment in R&D work on an AIDS vaccine. It was found that different obstacles to the development of an AIDS vaccine arose during the product development cycle. During the earlier phases, before obtaining proof of product, the principal barriers were scientific. The lack of consensus on which approach was likely to be effective increased uncertainty and the risks associated with

investing in expensive clinical trials. The later phases, which involved adapting, testing, and scaling up production for different populations, were most influenced by market considerations. In order to raise the levels of private R&D on an AIDS vaccine, there will probably have to be a combination of push strategies, which reduce the cost and scientific risk of investment, and pull strategies, which guarantee a market.

**Global Alliance for TB Drug Development. The economics of TB drug development. Global Alliance for TB Drug Development, October 2001.**

This report summarizes the work and projects of the Global Alliance for TB Drug Development, a partnership gathering private companies, international agencies, NGOs and others with the common goal of developing a new, more effective anti-TB drug which would greatly facilitate the treatment and control of the TB epidemic. TB, Malaria and HIV/AIDS are major infectious diseases threatening global health today. TB was reported to affect 8.4 million people in 1999, with 10.2 million cases expected by 2005. This report is divided into five parts. Firstly, it examines TB's epidemiology, stressing how, in countries with high HIV/AIDS infection rates, TB patients are also on the rise. The second part is devoted to the potential market of anti-TB drugs, a global market whose value the report quantifies between 412.5 and 470.5 million dollars per year and this is expected to increase to 670 million dollars in 2010. The report identifies two different kinds of market: a public/tender market composed of government and international donor purchases; and a private one made up of traditional pharmacy and hospital sales. The third part of the report focuses on the possible costs of a new anti-TB drug. It recalls how no new anti-TB drugs have been developed in over 30 years and considers that between 76 and 115 million dollars will be required in order to achieve Phase III clinical trials and regulatory approval. The report stresses the need for greater collaboration between private companies, NGOs and international aid agencies in gathering funds. The fourth part of the report looks into the potential return on investment. From the financial point of view, the internal rate of return of a new anti-TB drug would be between 15 and 32%, depending on a number of factors (most notably the pace of development, the conduction of clinical trials and revenue size); the social benefits of a new anti-TB drug would be represented by a substantial reduction in the per patient treatment costs, improved compliance and a reduction in resistance, transmission, morbidity and mortality. The final part of the report focuses on the options available for conducting and funding a new anti-TB drug. The report explores new partnerships between public and private actors in order to share and balance risks and investment related to the development of any new drug and concludes by recalling that all necessary factors for the development of a new anti-TB drug are, or soon will be, in place.

**IFPMA. Encouraging pharmaceutical R&D in developing countries. Geneva, International Federation of Pharmaceutical Manufacturers Associations, February 2003.**

This report of the IFPMA addresses the issue of innovative pharmaceutical R&D capacities in developing countries. The goal of the report is to identify and analyse those factors that would encourage future development of private sector R&D within a country. It also names those obstacles that would prevent a greater contribution of developing countries in the global R&D effort. The author acknowledges the opportunity and need for more R&D on drugs and vaccines, stating that an increased participation of developing countries in such endeavour would be beneficial not only for those countries but also for the private sector and patients worldwide. The heavy investments needed for pharmaceutical and biotechnological R&D can only be afforded by multinational companies from the private sector, the author considering that alternative approaches would be unlikely to contribute to the innovation of medicines. According to the report, recent developments in science make it extremely difficult for an individual actor or company to cover all areas of research. Fragmentation and the outsourcing of individual components of R&D are seen as critical factors of modern and efficient R&D. This specialisation (product- or illness-based research) could be used by developing countries to foster their own R&D industry. For a national R&D industry to be developed there are several conditions that should be met such as a certain level of structure and resources. The report identifies 23 factors which are of utmost importance for the development of a domestic R&D-based industry; among them the author highlights government support, IPR protection and the existence of public research institutions. As it looks into national initiatives that could contribute to strengthening the domestic R&D-based industry, the report acknowledges the great power of governments to create a pro-innovative business environment by acknowledging (through regulation for example) the essential symbiosis between players involved in the global and domestic R&D effort. Countries such as Brazil, India and the People's Republic of China are considered to be in a position to foster their national pharmaceutical R&D-based industry.

**IFPMA - R&D-based Pharmaceutical Association in China. Accelerating innovative pharmaceutical research and development in China: a case study. Geneva, International Federation of Pharmaceutical Manufacturers Associations, April 2003.**

This report constitutes a case study of a set of factors, which had been outlined in another IFPMA publication (Encouraging pharmaceutical R&D in developing countries), applied to the situation in the People's Republic of China. The author analyses the current situation of the pharmaceutical and biotechnological R&D-based industry in China and its prospects for further development. Five essential components for the development of an R&D-based national industry were identified: government prioritization of R&D, particularly in connection with the modernisation of the generics and traditional Chinese medicine sectors; the existence of public research institutions, which partly compensate the quasi absence of biopharmaceutical research currently undertaken by the small private sector; the establishment of an IPP framework, particularly after the reform of patent laws in 1993 and the accession of China to the WTO in 2002; the already existing industry in China, especially with regard to generics and traditional Chinese medicine; and the important human resource potential offered by the

large number of Chinese science and medicine graduates once brain drain dynamics are reversed. While acknowledging some of the positive conditions that China currently offers for developing a national R&D-based industry, the report expresses some reservations. While critical factors seem to be in place, there is a range of problems and difficulties to which the Chinese authorities should respond in order to develop a national R&D-based industry. As regards public research institutions, the report notes the weak market orientation of their research and, in connection with IPR, the Chinese government is required to reward investment and innovation in biopharmaceutical R&D by effectively enforcing patent laws. The author concludes that the Chinese model of industrial R&D is substantially different from the Western one, where companies are deemed responsible for the entire process of finding and bringing products to the market. Under the Western model, the patent system is precisely the device used to finance company investment in R&D and to bring products to the market. The report considers that the dominant role of the State in China might slow the development of a national R&D-based industry in the country, adding that reforms are necessary, particularly in connection with pricing incentives which, according to the report, should be determined by the market and not the cost of the product.

**Kang M. Trade policy mix under the WTO: protection of TRIPS and R&D subsidies. Korea Institute for International Economic Policy, 2000.**

This article addresses the apparent contradiction between domestic attempts to limit the protection of IPR and the acceptance of R&D subsidies by national authorities. To better understand what could initially be seen as a breach of the basic WTO principle of *fair competition*, the author links such strategic trade policy tools as R&D and IPR. According to the author, a less strict enforcement of IPR at the national level would have a negative impact on future R&D capabilities. This would not be the case if the trade structure reflected an optimal balance where the burdens and costs would be shared between exporting and importing countries. According to this article, the TRIPS Agreement would disproportionately benefit Northern exporting countries to the detriment of Southern importing countries with a smaller R&D capability.

**Kettler H, Towse A. Public-private partnerships for research and development: medicines and vaccines for diseases of poverty. London, Office of Health Economics, 2002.**

This report examines the potential of PPP to encourage the development of therapeutics for those infectious diseases responsible for most deaths in developing countries. The authors looked at four case studies: the Medicines for Malaria Venture, the International AIDS Vaccine Initiative, the Malaria Vaccine Initiative and The Global Alliance for TB Drug Development. The report examines firstly the challenges to which PPP are bound to respond, notably the lack of R&D investment for neglected diseases. Secondly, the authors look closely at the major trends which are transforming the traditional model of pharmaceutical R&D, stressing the necessary collaboration between parties and the increasing presence of biotechnology and specialist genomic technology companies. Thirdly, the authors analyse the PPP models set as case examples,

concluding that substantial progress has been made in all areas except one, namely the ability to create a viable financial model that addresses the R&D funding gap. While the authors consider PPP as a valuable part of a total solution to the necessity of making available new drugs, vaccines and diagnostics to meet the health needs of the populations of less developed countries, they suggest that further international support is needed as, even if PPP are seen as a viable model, they can not achieve their goals in isolation.

**MSF/DND. Fatal imbalance. The crisis in research and development for drugs for neglected diseases. Geneva, Médecins sans Frontières, September 2001.**

In 1999, MSF convened an international body of health experts to study the current state of drug R&D for diseases that affect people in the developing world. This independent body, the Drugs for Neglected Diseases (DND) Working Group, has since undertaken an analysis and made some recommendations for moving forward. When treatment options do not exist or are inadequate, a disease can be considered “neglected”, or even “most neglected” in some cases. The neglect is a result of market and public policy failure. Strategies must be developed to specifically address neglected and most neglected diseases. Recent initiatives and policies seeking to redress the R&D imbalance are outlined. Recommendations for moving forward are presented, among them: that a well-defined and needs-driven research agenda be established at the global level; that governments fulfill their responsibility to become directly and proactively involved in searching for solutions; that funding be increased for research into neglected and most neglected diseases; and that a new not-for-profit enterprise be explored as one way to address the shortage of R&D for the most neglected diseases.

**Scherer FM. The pharmaceutical industry and world intellectual property standards. Vanderbilt Law Review, November 2000, 53(6): 2245-2254.**

This article focuses on the possible link between the enforcement of IPR and the possibilities for private pharmaceutical companies to invent and produce new drugs. One of the declared goals of the IPR framework is to protect companies that have heavily invested in the development of new products. Granting these companies with exclusivity rights for a fixed period of time would allow them to recover previous investment and at the same time provide a stimulus to keep on innovating. This is one of the main arguments justifying the TRIPS Agreement in relation to pharmaceutical products. Developed countries are not only home to all major international pharmaceutical companies, but also represent the biggest market for pharmaceutical products. This market, considered to be secure, has been driving the R&D efforts of pharmaceutical companies, leaving behind the needs of a majority of the population who, living in developing countries, do not represent an interesting market.

**Trouiller P, Olliaro P, Torreele E, Orbinski J, Laing R, Ford N. Drug development for neglected diseases: a deficient market and a public-health policy failure. *The Lancet*, June 2002, 359(9324): 2188-2194.**

There is a lack of effective, safe and affordable pharmaceuticals to control infectious diseases that cause high mortality and morbidity in the developing world. The authors analysed outcomes of pharmaceutical R&D over the past 25 years, and reviewed current public and private initiatives aimed at correcting the imbalance in R&D that leaves diseases that occur predominantly in the developing world largely unaddressed. They compiled data by searches of Medline and databases of the US FDA and the European Agency for the Evaluation of Medicinal Products, and reviewed current public and private initiatives through an analysis of recently published studies. The authors found that, of 1 393 new chemical entities marketed between 1975 and 1999, only 16 were for tropical diseases and tuberculosis. There is a 13-fold greater chance of a drug being brought to market for central nervous system disorders or cancer than for a neglected disease. The pharmaceutical industry argues that R&D is too costly and risky to invest in low-return neglected diseases, and public and private initiatives have tried to overcome this market limitation through incentive packages and PPP. The lack of drug R&D for "non-profitable" infectious diseases will require new strategies. No sustainable solution will result for diseases that predominantly affect poor people in the South without the establishment of an international pharmaceutical policy for all neglected diseases. Private sector research obligations should be explored, and a public sector not-for-profit R&D capacity promoted.

**UNDP/WORLD BANK/WHO Special Programme for Research and Training in Tropical Diseases. Research capacity strengthening: strategy (2002-2005). Geneva, WHO, 2002.**

The Special Programme for Research and Training in Tropical Diseases (TDR) is an independent global programme of scientific collaboration, which over the years has funded about 400 research groups in 80 disease endemic countries, contributing to the formation of a new generation of public health leaders. TDR activities and projects are confronted with the fact that most of the R&D work in neglected diseases is still concentrated in developed countries, while scientists in disease endemic countries are closer to the problems and possible solutions in the field. This document summarizes the TDR strategy for 2002-2005 and identifies the direct involvement of researchers from disease endemic countries as being the best way to achieve the development and future incorporation of new tools and interventions into policy and practice. This new strategy transforms the research capacity strengthening approach in order to adapt itself to the rapidly evolving environment for communicable disease research, due to advances reported in the fields of biotechnology and information and the expanding interaction between private and public partners. This new strategy has two interrelated goals: to increase the involvement of scientists from developing disease endemic countries in all stages of R&D and to optimize the development of more relevant and affordable intervention tools, strategies and policies for disease control. The document sets out the main components of TDR's strategy, notably the expansion and integration of all research capacity strengthening activities within TDR areas and the planning and design of capacity strengthening activities

around expected results (with special emphasis on partnerships, leaderships and sustainability), focusing on least developed countries and fostering greater collaboration and coordination with bilateral and multilateral capacity building and mainstream health system and disease control efforts, such as UN agencies and international NGOs.

**Webber D, Kremer M. Perspectives on stimulating industrial research and development for neglected infectious diseases. *Bulletin of the World Health Organization: International Journal of Public Health*, 2001, 79(8): 735-741.**

This paper summarizes recent thinking on stimulating industrial R&D for neglected infectious diseases and argues that it is critical to enlarge the value of the market for medicines and vaccines through, for example, global purchase funds. The most important economic barriers to R&D are small commercial markets and severely limited individual purchasing power, even though the number of patients may be very large. Since R&D costs for all diseases are high, returns will not cover investment. Various mechanisms have been proposed to address this economic imbalance (accepting that other barriers will also need to be considered). Economic devices which reduce the cost of R&D - push factors - are useful, but this review suggests that high costs do not explain the shortfall in R&D. Economic devices which address the lack of viable markets have been termed pull factors and are designed to create or secure a market, thereby improving the likelihood of a return on investment. The authors identify as a useful pull mechanism the commitment in advance to purchase a product that meets specified criteria, if invented. The purchase pre-commitment approach has a number of attractive features. For example, it only rewards successful outputs rather than supporting research that may not succeed. Pull programmes effectively mimic the market and lead companies to favour lines of attack that they believe will lead to marketable products. Overall, a combination of push and pull mechanisms is likely to represent an attractive approach. This could combine, for example, increased funding for public laboratories, PPP in R&D, purchases of under-utilised existing products, and a pre-commitment to purchase new drugs and vaccines when developed.

### **3.3 Human rights and access to drugs.**

**Cullet P. Patents and medicines: the relationship between TRIPS and the human right to health. *International Affairs*, January 2003, 79(1): 139-160.**

The question of access to drugs in developing countries is at present largely influenced by the TRIPS Agreement. TRIPS compliance in the field of health requires substantial changes in existing patent laws in some countries. These changes must be analysed in the context of the spread of epidemics, such as HIV/AIDS, and in relation to other international obligations that states have, for instance, regarding the human right to health. IPR treaties have a significant impact on the realization of some human rights, such as the right to health. This article examines the extent to which the TRIPS Agreement encompasses flexibility for developing countries to be able to foster greater access to

medicines. The article also examines these issues from the point of view of human rights and considers, in particular, how the relationship between human rights and intellectual property can be addressed in international law.

**Elliot R. TRIPS & rights: international human rights law, access to medicines, and the interpretation of the WTO Agreement on Trade-Related Aspects of IPR. Montreal: Canadian HIV/AIDS Legal Network, 2001.**

Acknowledging the massive impact that the interpretation and application of the TRIPS Agreement could have on millions of people around the world, this report attempts to widen the debate by examining it from a human rights perspective. It aims to set out the basis in international law for demonstrating that the binding legal obligation of states to realize human rights has general primacy in international law and that the TRIPS Agreement should therefore be interpreted in a manner consistent with this obligation. The author first examines the existence, nature and scope of states' obligation under international law to respect, protect and fulfil the right to health. The author then illustrates, by referring to the Vienna Convention on the Law of Treaties and the United Nations Charter, how state obligations under international human rights law have pre-eminence over other international law dispositions (such as trade agreements). The third part of the document is largely devoted to a discussion on how the TRIPS Agreement could be interpreted in a more flexible way and, based upon existing WTO jurisprudence and Articles 8 and 27 of the TRIPS Agreement, in a manner allowing states to satisfy their legal obligations as regards international human rights law. The author supports a major flexibility in the interpretation and implementation of the TRIPS Agreement in developing countries, recalling that if the founding treaty of the WTO states that the Organization itself and economic and trade relations are aimed to raise standards of living and sustainable development, TRIPS should therefore be interpreted accordingly. In conclusion, the report recommends that states formally recognize, within the WTO context, the primacy of their legal obligation to respect, protect and fulfil human rights, including the human right to health. As regards the interpretation of the TRIPS Agreement, the report considers that WTO's Dispute Settlement Body should prefer any reasonable interpretation of the Agreement that is consistent with state obligations under international human rights law. Finally, the report suggests that the TRIPS Agreement be amended in order to include express reference to state obligations under international human rights law, and that a clause be included recognizing the non-binding nature of any obligation under the Agreement that would require a state to act in breach of its obligations under international human rights law.

**Evans T. A human right to health? *Third World Quarterly*, 2002, 23(2): 197-215.**

A right to health is one of a range of socio-economic rights for which states accept an obligation under international law. However, the politics of rights has meant that socio-economic rights are rarely given the same status as liberal freedoms associated with civil and political rights. This article discusses the liberal rationale for rejecting socio-economic claims as rights and examines the basic rights challenge to liberal arguments. Given the dominance of liberalism, the

article concludes with an examination of the potential for promoting a right to health within the context of globalization.

**Gathii JT. Rights, patents, markets and the global AIDS pandemic. *Florida Journal of International Law*, Spring 2002, 263-346.**

This article seeks to provide new arguments for those initiatives which try to provide access to or increase the affordability of drugs and health services, particularly for low-income consumers affected by life-threatening diseases. According to the author, it is possible to combine a market-based approach with a human rights one. Moreover, the use of market-based arguments contributes to expanding the traditional registry of legal and social causes. To illustrate the necessary combination between market-based and other approaches, the article develops three different strategies to achieve the stated goals of access and affordability. The first strategy consists of using social and economic rights clauses in constitutional charters, as in South Africa. The author examines the obstacles and challenges of the rights-based approach characterized by this strategy, particularly in developing countries. The second strategy is derived from a market-based argument, the author attempts to establish the TRIPS consistent possibilities that are available for combining pharmaceutical producers and consumers, especially low-income ones. The article recalls how the TRIPS regime was specifically designed to offer protection both to producers and consumers of intellectual property items. In this sense, the author signals how, within the private property model of the TRIPS Agreement, there are two clashing perceptions of the notion of property: one perceives it as market commodity and the other sees it from a public policy perspective. According to the article, it is possible to combine both approaches while examining the available scope for developing countries for setting their own patent legislation. The third proposed strategy is also related to a market-based argument and is related to the US FDA framework of control which, according to the author, constitutes an important obstacle for the entry of new drugs into the market, particularly generic version of branded drugs or applications which have been approved in other countries. The article considers that the best strategy to overcome a system which was built to benefit big pharmaceutical companies would be a consumer-driven, anti-cartelist strategy to put to an end pharmaceutical industry concentration. In this sense, the author mentions the *Pfizer v. India* case at the US Supreme Court to show how anti-trust and trade laws can be combined. The author perceives competition in the pharmaceutical industry as one of the best ways to ensure access and affordability of drugs for low-income consumers and an effective pricing mechanism. The article concludes that any increase in IPP would have a negative impact on competition. The author finally considers the potential for market-based arguments to advance legal and social cases while demonstrating the feasibility of assimilating diverse intellectual approaches.

**Heywood M. Drug access, patents and global health: " chaffed and waxed sufficient". *Third World Quarterly*, 2002, 23(2): 217-231.**

In July 2000, the UN Committee on Economic, Social and Cultural Rights issued a General Comment on the Right to the Highest Attainable Standard of Health. In

its paragraph 10, the Committee makes the following admission: *“Since the adoption of the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights in 1966 the world health situation has changed dramatically and the notion of health has undergone substantial changes and widened in scope. More determinants are being taken into consideration, such as resource distribution and gender differences. A wider definition of health also takes into account such socially related concerns as violence and armed conflict. Moreover, formerly unknown diseases, such as HIV and AIDS, and others that have become more widespread, such as cancer, as well as the rapid growth of the world population, have created new obstacles for the realization of the right to health which need to be taken into account when interpreting article 12”*. The need to understand why and how *“the notion of health has undergone substantial changes and widened in scope”*, the forces that are contributing to this redefinition, and the implications for governments, multinational pharmaceutical companies and ordinary people is the subject of this article. In particular, global health is assessed according to the extent of global access to life improving-medicines, and the surmountable barriers that prevent this.

**Joseph S. Pharmaceutical corporations and access to drugs: the “fourth wave” of corporate human rights scrutiny. *Human Rights Quarterly*, 2003, 25 , 425-452.**

Access to essential medicines is a human right which is currently compromised by the high prices charged by pharmaceutical corporations, which are facilitated by the global protection afforded to pharmaceutical patents by TRIPS. However, pharmaceutical patents are arguably justified as they promote R&D in the industry. The arguments for and against patents are examined in this article, along with the salient human rights duties of pharmaceutical companies and governments, as well as recent victories in the battle for access to essential drugs in the developing world. Alternative strategies for facilitating access to essential medicines, without compromising R&D, are put forward.

**OHCHR/UNAIDS. HIV/AIDS and human rights. International guidelines. Geneva, United Nations, 1998.**

This is a joint effort by the Joint United Nations Programme on HIV/AIDS and the Office of the United Nations High Commissioner for Human Rights to address and provide assistance to states, NGOs and individuals on human rights issues affecting HIV-positive people, such as discrimination, education or access to drugs. Through 12 clearly formulated guidelines it offers guidance on how to respond to the human rights implications of the AIDS pandemic. Of special significance is Guideline 6 (Regulation of Goods, services and information) which refers to legal and economic obstacles to access to drugs and the necessity to overcome them. This guideline was the object of a specific debate during the Third Consultation on HIV/AIDS and Human Rights (Geneva, July 2002) where it was reformulated into access to prevention, treatment, care and support as a step forward in linking human rights and access to drugs.

**Toebes B. The right to health as a human right in international law. Ed. Antwerp, Intersentia, 1999.**

This book identifies one of the main obstacles to the enforceability of the right to health as its vague formulation and lack of clarity about its real content. Even though the human right to health is present in almost all major international human rights treaties, it has not been clearly established what individuals can expect or what states are obliged to provide for according to those treaties. The author analyses the current implementation practices by treaty monitoring bodies by providing an in depth evaluation of reporting dynamics. Interestingly, the book pays attention to justiciability issue through a detailed description of international and national case law by judicial and quasi judicial bodies. On the basis of these findings, the author finally outlines the content of the right to health, describing at the same time the resulting obligations on the part of states.

**Walker S. The implication of TRIPS: ethics, health and human rights. Journal of Human Development, 1 January 2001, 2, 109-114.**

According to this article, it is only recently that intellectual property is being addressed from a human rights perspective. Yet, the human right to the protection of intellectual property dates back 50 years to the basic human rights text - the Declaration on Human Rights of 1948. This right was included under Article 15 of the International Covenant on Economic, Social and Cultural Rights. The monitoring committee of the Covenant recently began to examine this article as a means of exploring the human rights dimensions of the protection of intellectual property. In order to speak about the human rights implications of IPP of pharmaceuticals, it is necessary to focus on the question of access to HIV treatments. This article develops the three most important questions: why access to anti-HIV treatment should be considered as a human rights issue; what would define a human rights approach to the IPP framework; and can IPP be considered as consistent with state obligations established under international human rights law.

**WHO. 25 questions & answers on health and human rights. Geneva, WHO Health & Human Rights Publication Series, Issue No.1, July 2002.**

This is the first issue of a WHO series specifically focused on a rights-based approach to health topics. This publication seeks to clarify some key concepts and notions critical for a better understanding of the right to health and its implications for policy makers, health workers and patients alike. What are human rights and how health care can be effectively framed within them is one of the questions that find an answer in this publication, which is intended to be used as an education tool and an advocacy resource. It offers brief, concise explanations about each concept providing a non-specialized reader with a comprehensive view of what is implied by a rights-based approach to health. It represents a clear sign of WHO's commitment to the promotion of the human right to health, understood as a fundamental and universal human right.

**Wojahn PL. A conflict of rights: intellectual property under TRIPS, the right to health and AIDS drugs. *UCLA Journal of International Law and Foreign Affairs*, Fall-Winter 2001-2002, 463-497.**

Modelled on the intellectual property laws of the United States of America, the TRIPS Agreement established global standards for stringent protection of patents for new pharmaceutical developments. Stringent IPR, however, are in direct conflict with the international right to health, established by the International Covenant on Economic, Social and Cultural Rights, ratified by over 130 countries. The Covenant specifically states that the right to health requires states-parties to take the necessary steps for the “*prevention, treatment and control of epidemic, endemic, occupational and other diseases*” and “*the creation of conditions which would assure to all medical service and medical attention in the event of sickness*”. Strict protection of IPR raises the price of pharmaceuticals, blocking access to these drugs for many people in developing countries who need them to survive. Certain provisions of the TRIPS Agreement, however, allow countries, in cases of national emergency, to permit private manufacturers to produce generics, subject to certain conditions, through compulsory licensing. In addition, countries can use parallel importation or importation of competing, generic goods from other countries, to provide cheaper access to life-saving drugs. Although there are many uncertainties in TRIPS relating to when and under what conditions compulsory licensing and parallel importation are permitted, the whole framework can be interpreted to allow these strategies in order to provide greater access to, for instance, antiretroviral drugs. This article explores an interpretation of TRIPS which would comply with the right to health, while examining whether the exceptions to strict IPP will adequately address the need of developing countries to provide the medical resources required by the right to health.

## 4. Electronic information

### 4.1 Some useful web sites

<http://www.accessmed-msf.org>

The web site of the Médecins sans Frontières Campaign on access to essential medicines is a valuable source of information for the current debate on access to medicines and includes a selection of press reports on access to medicines and trade agreements from around the world.

<http://www.cptech.org/ip/health/>

The Consumer Project on Technology is active on a number of issues, including intellectual property, telecommunications, privacy and electronic commerce, plus a variety of projects relating to antitrust enforcement and policy. It is also very active on a number of projects involving health care, particularly pricing of intellectual property that relates to medical inventions and compulsory licensing of essential medical technologies in developing countries. This web site is an extensive source of information, providing articles and data on regional trade agreements and TRIPS, patents and drugs, compulsory licensing, parallel imports, health registration data, generic competition and more.

<http://www.dndi.org>

The MSF Drugs for Neglected Diseases initiative, is a not-for-profit initiative that aims to research and develop drugs for millions of people debilitated by neglected diseases by using existing R&D capacity in both rich and poor countries. It also aims to raise awareness of the need for immediate action in this field.

<http://www.ielrc.org>

The web site of the International Environmental Law Research Center, a not-for-profit organization based in Geneva with sections in New Delhi and Nairobi, displays articles, reports and other information on biodiversity, climate change, human rights and intellectual property. The Center is specialized in policy-related academic research relating to the environment in a North-South context, providing assistance and advice to national authorities, NGOs and International Organizations.

<http://www.oxfam.org.uk/cutthecost/>

Oxfam, an international aid agency, has been involved for a long time in international development and cooperation projects. Currently it is actively participating in promotion and advocacy for a fairer implementation of the various WTO agreements, with special attention to the issue of TRIPS and access to drugs. Their web site offers updated reports and articles on the issue as well as information on ongoing campaigns.

<http://www.pih.org/index.html>

Partners in Health is a not-for-profit organization that works on health projects in Latin America, the Caribbean, Russia and the United States of America. It has a research and educational arm in the Institute for Health and Social Justice which examines the impact of poverty and inequalities on health by linking critical scholarly analysis with community-based experience. Seminars are periodically organized, with all contributions available on the web site.

<http://www.southcentre.org/>

The South Centre is an intergovernmental body with 46 developing country members. The Centre, however, works for the benefit of the South as a whole, making efforts to ensure that all developing countries and interested groups and individuals have access to its publications and the results of its work, irrespective of membership. The web site provides interesting bibliographical references and papers.

<http://www.tac.org.za/>

The Treatment Action Campaign is one of the world's most important grass root organizations working for access to treatment for HIV-positive people. Its main objective is to campaign for greater access to treatment for all South Africans, by raising public awareness and understanding about issues surrounding the availability, affordability and use of HIV treatments. Its web site offers extensive information about the AIDS pandemic in South Africa, different judicial cases and current mobilisation and campaigns.

<http://www.twinside.org.sg/>

The Third World Network is an independent not-for-profit international network of organizations and individuals involved in issues relating to development, the Third World and North-South issues. The TWN web site offers articles and position papers on a variety of issues related to developing countries, including trade issues and WTO, health, biotechnology and biosafety.

<http://www.wipo.org/index.html.en>

The web site of the World Intellectual Property Organization provides basic fundamental information related to intellectual property and patents in general (<http://www.wipo.int/patent/en/>) and to international intellectual property treaties managed by WIPO.

<http://www.wto.org/>

The World Trade Organization has a very comprehensive web site and its page on the TRIPS Agreement may be a useful tool ([http://www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/trips_e.htm)).

## 4.2 Interesting discussion groups

The issue of the impact of international trade agreements on access to drugs and the pharmaceutical sector is increasingly debated through two electronic discussion groups.

<http://www.essentialdrugs.org>

E-drug is an electronic conference on essential drugs. E-drug is used by professionals in this field to obtain and discuss current information on essential drugs, including international and national policies, and standard treatment guidelines. Discussions are held in English, French and Spanish.

<http://www.hivnet.ch>

Treatment-Access is an electronic discussion forum created and managed by the Fondation du Présent, a not-for-profit organization which brings together a multisectoral community of more than 12 000 members – half of them in developing countries – to raise and jointly resolve AIDS-related issues through email discussion.

<http://lists.essential.org/mailman/listinfo/ip-health>

Ip-health is an electronic newsletter devoted to the relationship and links between intellectual property and health care. The pharm-policy list is no longer in use and has been integrated into this one as their subjects were overlapping. It is one of the most complete and useful lists to follow the evolution of TRIPS.

**Other documents in the EDM  
Health Economics and Drugs Series**

- No. 1** Alternative drug pricing policies in the Americas
- No. 2** The public and private circuits for the distribution of drugs in the Chilean health system
- No. 3** Global comparative pharmaceutical expenditures
- No. 4** Financing drugs in South-East Asia. Report of the first meeting of the WHO/SEARO Working Group on Drug Financing
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- No. 6** Health reform and drug financing. Selected topics
- No. 7** Globalization and access to drugs. Perspectives on the WTO/TRIPS Agreement
- No. 8** Financing drugs in South-East Asia. Report of the second meeting of the WHO/SEARO Working Group on Drug Financing
- No. 9** Globalization, patents and drugs (1st ed.). An annotated bibliography
- No. 10** Globalization, patents and drugs (2nd ed.). An annotated bibliography
- No. 11** Network for monitoring the impact of globalization and TRIPS on access to medicines. Report of a meeting, February 2001, Bangkok, Thailand
- No. 12** Implications of the Doha Declaration on the TRIPS Agreement and Public Health
- No. 13** Cost-Containment Mechanisms for Essential Medicines, including Antiretrovirals, in China