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Abbreviations and acronyms

CPT	Consumer Project on Technology
ECJ	European Court of Justice
EU	European Union
FDA	Food and Drug Administration
GATT	General Agreement on Tariffs and Trade
HAI	Health Action International
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
IPP	intellectual property protection
IPRs	intellectual property rights
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
R&D	research and development
S&T	science and technology
SEARO	WHO Regional Office for South-East Asia
SADC	Southern African Development Community
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TWN	Third World Network
UNCTAD	United Nations Conference on Trade and Development
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
WTO	World Trade Organization

Introduction

Many WHO Member States have expressed concern about the effects of the TRIPS Agreement on access to pharmaceuticals and, in May 1999, the World Health Assembly mandated WHO “to cooperate with Member States, at their request, and with international organizations in monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements.”¹.

The TRIPS Agreement is one of the most controversial of the Uruguay Round in terms of content, objectives and possible consequences. This is clearly shown by the entries in this bibliography, in which some authors argue that patent protection of pharmaceuticals will lead to:

- an increase in the flow of technology transfer and foreign direct investment to the benefit of developing countries;
- an increase in the resources devoted to R&D of needed new drugs, ensuring a dynamic pharmaceutical industry;
- the end of the “brain drain” from developing to industrialized countries, caused by the absence of patent protection in developing countries.

However, other authors assert that:

- the price of patented drugs will increase with the strengthening and prolongation of the patent holders’ monopoly;
- pharmaceutical production will increasingly be concentrated in industrialized countries and it will be difficult for local manufacturers in developing countries to survive;
- the introduction of patents for pharmaceutical products will certainly not lead to an increase in R&D investment in developing countries.

This annotated bibliography aims to inform people in the health sector, with no particular legal background, about the impact of globalization and trade agreements on access to drugs, and the growing importance of this issue. It directs the reader to key reports, books and articles from technical and scientific journals, both general references and specific country studies. Details of some useful web sites are also given.

¹ Resolution WHA52.19(7).

Some provisions of the TRIPS Agreement (such as the scope of patent protection, compulsory licences and exceptions to patent rights) permit a range of interpretations as to how they are implemented in national laws. These provisions will be interpreted within WTO. However, WHO will help countries to interpret and implement TRIPS and other international trade agreements with public health implications. WHO's mandate, as the UN technical agency promoting public health, is to intervene when health interests are affected by globalization and to propose measures to protect these interests. It is hoped that the bibliography will help countries to make the most appropriate decisions relating to new international trade agreements, bearing in mind that access to essential drugs is a fundamental human right.

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 IPRs holders 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 IPRs holders 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 save 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 OECD countries. 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 IPRs.

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 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has a far-reaching impact on consumers' 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. 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 IPRs, 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 EU Member States as a distortion which is inconsistent with open markets 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.

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 such countries as Argentina, India and the Republic of Korea "an unfortunate grace period, allowing them to exploit consumers".

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 US, 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. Apartheid of pharmacology. Le Monde Diplomatique, January 8-9, 2000.

This article explores the issue of limited access to essential drugs, by providing various examples in the developing world. Inadequate research and development, 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. 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 what 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.

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, supply increase through importation, compulsory licences, reaction to anti-competitive practices in licence contracts and transitional periods.

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 IPRs. The paper presents the main provisions of the Agreement regarding all kinds of IPRs 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. Correa 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 IPRs. 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 that have recently taken place 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. 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 IPRs. 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. (In press).

The cases examined illustrate some of the patenting practices used in the pharmaceutical sector that may be detrimental to competition and, in

particular, affect the early sale of cheaper alternative products to the public. The cases cover a broad range of products of varying medicinal value. Their common factor is the use of the occasionally excessive flexibility of the patents system to set up barriers to legitimate competition. The author states that there is no question that patents are valuable as a means of rewarding genuinely inventive, occasionally costly activity. However, he believes his analysis shows how the system is blighted by accepting patents of dubious worth that make a negligible or non-existent contribution to technology, and whose sole purpose is commercial: to serve as a barrier to legitimate third-party competition. For governments to have a credible and sound patents system, they need to make a concerted effort to define rigorous criteria for patentability, and in particular to apply them in a responsible and consistent manner, the book concludes.

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 WTO 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 IPRs, 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.

Farnsworth S. Tobacco puffery. Multinational Monitor, June 1994, 7-8.

This article discusses proposed legislation in Canada ordering cigarette companies to use plain packaging as a public health measure. This proposal

triggered off a threat by United States trade officials, who argued that it was a violation of international trade agreements.

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

This document 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 consumers' 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 Agreement on Technical Barriers to Trade 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, an NGO's view 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. The 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 IPRs 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 WTO 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 on the TRIPS Agreement. It covers developments concerned with the general provisions, the rules relating to patents, the means of ensuring respect for IPRs, 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 intellectual property protection 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. Genève, Institut Universitaire d'études du développement, Juillet 1999.

(Intellectual property. What are the stakes for developing countries? TRIPS Agreement - Patentability of life - Access to medicines and patents. Report of the Annuaire Suisse-Tiers Monde 1998. Geneva, University Institute of Development Studies, July 1999.)

In this report, the authors focus on the question of intellectual property protection 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 Agreement on Technical Barriers to Trade 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 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.

Lobo F, Velasquez 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 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.

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.

Mackay J, Zatonski W, Chitanondh H, Le Gresley E. Taking on tobacco imperialism: interviews with tobacco control advocates from around the world. *Multinational Monitor*, July/August 1997, 19-32.

J. Mackay is the executive director of the Asian Consultancy on Tobacco Control, a coordinating organization to facilitate sharing of information, experience and expertise on tobacco control among countries in the Asia-Pacific region. W. Zatonski is the head of the department of epidemiology and cancer prevention at the Marie Curie Memorial Cancer Center and Institute of Oncology in Warsaw, Poland. H. Chitanondh is the president of the Thailand Health Promotion Institute of the National Health Foundation, as well as president of the Asian Pacific Association for Control of Tobacco. E. Le Gresley is legal counsel to the Non-Smokers Rights Association, the leading Canadian anti-tobacco industry advocacy group.

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 OTC switches.

Marques MB. Brazil-US 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 IPRs 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 IPRs 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 IPRs 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 IPRs in supporting restrictive conditions in licensing contracts. Finally, it discusses aspects of competition policy that might be used to ensure that stronger IPRs promote dynamic competition rather than foster competitive abuses.

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 harm 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 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".

Ministry of Foreign Affairs, The Netherlands. Medicines for the poor: The World Trade Organization and the developing countries. Report of a public debate held on 16 December 1999.

This report contains speeches and papers delivered during a public debate on Medicines for the Poor, hosted by the Dutch Ministry of Foreign Affairs in December 1999. It covers the presentation of Eveline Herfkens, Minister for Development Cooperation, discussing the complex problem of lack of access to essential drugs, and the need to improve health care in developing countries. She stressed that public and private cooperation can be used to develop and distribute medicines. International rules and agreements must be based on a better balance between private and public interests. Jeffrey Sachs from Harvard University explained his ideas on the significance of health for development and how to mobilise funding and research activities towards the treatment of tropical diseases. Harvey E. Bale Jr. from the International Federation of Pharmaceutical Manufacturers Associations spoke from the industry point of view on the TRIPS Agreement and drug development. He stressed the importance of patent protection for drug development. Finally, the document reports on the speech by Ellen 't Hoen, representing Médecins Sans Frontières, who emphasized the need for balance between the interests of business and those of the public. Several provisions are included in the TRIPS Agreement that provide remedies to the severe adverse affects of patent protection, she said. Compulsory licensing is one of them that can be used to make medicines more widely available.

Moufang R. Methods of medical treatment under patent law. The 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.

NERA, SJ Berwin & Co, YRCR Ltd. Legal issues of intellectual property protection. In: Policy relating to generic medicines in the OECD countries (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 grant 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 IPRs on the development of the generic industry.

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 industrial 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 countries' 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, industrial 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 industrial 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.

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 such matters 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. Oxford, UK, Oxfam, 2001. Available on the web at: <http://www.oxfam.org.uk/cutthecost>

This is the first in a series of papers that will 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 intellectual property protection 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, UK, Oxfam, 2001. Available on the web at: <http://www.oxfam.org.uk/cutthecost>

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 governments' role 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. Patent injustice: how world trade rules threaten the health of the poor. Oxford, UK, Oxfam, 2001. Available on the web at: <http://www.oxfam.org.uk/cutthecost>

In this paper Oxfam argues that by restricting the right of governments to allow the production, marketing and import 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.

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 research and development, 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 importing 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 research and development 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, Berman D, Chirac P, Kaper T, Pécoul B, de Vincenzi I, von Schoen-Angerer T. HIV/AIDS medicines pricing report. Setting objectives: is there a political will? Available on the web at: <http://msf.org/advocacy/accessmed//reports/2000/07/aidspricing/>

The authors stress 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 US price with the price in eight countries, and shows that prices are set differently in different countries. The authors claim 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 productions costs and prices. According to the authors, 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, Malaysia, 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 the light of these, 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 incentives structures to stimulate innovation at the local level; resist any further elevation of international intellectual property standards beyond the TRIPS; 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. *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 Member States 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*, 2000/1. Numéro spécial: Brevets pharmaceutiques, innovations et santé publique, 2000.**

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".

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? *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 intellectual property protection. 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 intellectual property rights 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. The consequences of pharmaceutical product patenting: a critique. *World Competition*, 1993, 16(3): 92-106.

According to the author, the article of Pablo Challu on the consequences of pharmaceutical product patenting "is fatally flawed in its conceptual and empirical analysis". The most severe shortcomings of his article are a misunderstanding of the causes of economic modernization, inaccurate or incomplete data, and inappropriate price comparisons. The author concludes

that protecting intellectual property should be a "public policy goal of developing countries seeking sustained economic growth".

Rozek RP, Tully N. The TRIPS Agreement and access to health care. *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 IPRs 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.

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, 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 implementing legislation and to 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 research and development 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 on the pharmaceutical industry will be published in two parts. The first part provides an overview of the characteristics of the industry and current trends in its growth and structure: production and consumption, employment, research and development, 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. The second part will look at foreign direct investment, inter-firm networks and governmental policies.

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.

Thurrow 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 IPRs 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 IPRs, the decline of public knowledge, the emergence of new technologies and the globalization of the economy. Thus, a new system of IPRs 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 TWN with the objective of bringing together a team of individuals with in-depth knowledge of IPRs 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.

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. This document is downloadable from the WHO or UNAIDS web sites:
<http://www.who/medicines/> or <http://www.unaids.org>

UNAIDS/WHO. Pharmaceuticals and the WTO TRIPS Agreement: questions and answers. March 2000.

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. Some further readings are also recommended. This document is downloadable from the WHO or UNAIDS web sites (see above).

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 IPRs standards stipulated in the TRIPS Agreement. A preliminary section sets out for 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.

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. *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 the analysis of the TRIPS Agreement in relation to drugs. The second part of the book contains presentations at the 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.

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

By bringing IPRs within the context of the GATT/WTO, the exclusivity aspect of IPRs 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 Japan, the EU and the US. 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. The International Review of Industrial Property and Copyright Law (IIC), 1996, 27(3): 331-363.

The operation of the new intellectual property regime has yet to be seen, but given the fact of intense negotiations which accompanied its adoption, a few pertinent questions may be asked about the efficacy of the new regime for developing countries. Patenting in pharmaceuticals is still open to considerable debate in most developing countries. Will the emerging new regime work in the national interest of the developing countries? Will it encourage the transfer of technology to them from developed countries and help them become competitive in world trade? Will 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 WCC on 30 October 1997. Geneva, World Council of Churches, 1997.

According to the report, "The meeting at WCC established that the protectionism promoted by this 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).

Intellectual property protection 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.

2. Country studies by region

2.1 Africa

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 is the subject of legal proceedings (as at March 2001).

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 US. 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.

Love J. Medicines and Related Substances Control Amendment Bill and South African reform of pharmaceutical policies. Comments of the Consumer Project on Technology to the Portfolio Committee on Health Parliament, Cape Town, 6 October 1997. Available on the web at: <http://www.cptech.org/ip/health/sa/>

The main features of this South African legislation would facilitate aggressive marketplace competition for pharmaceutical drugs, through encouraging the use of generic drugs and parallel imports. This paper provides discussions on the issues of parallel imports: their nature, scope, use in other countries and their status in the TRIPS Agreement. The issue of health registration data in South Africa is also discussed.

Monot G. World Trade Organization agreements and their implications for public health and drug access in SADC countries.

The aim of this paper is to inform people in the health sector about the impact of globalization on health care and access to drugs in developing countries. It starts by giving a brief review of GATT, WTO and WTO agreements relating to health. The impacts of WTO and TRIPS on health and health care are then described in terms of advantages and disadvantages. The paper continues by examining the case study of the South Africa dispute with the WTO. Finally, it presents the important steps to be taken to manage potential conflicts regarding TRIPS/the General Agreement on Trade in Services in the SADC region, in terms of public interest, legal, and policy and health systems responses.

Roberts I. South Africa: the rationale for reform. Deeb M. The need for pragmatism. Scrip Magazine, June 1997, 51-54.

The South African Government has drawn up a series of measures, including a National Drug Policy, to reform the country's healthcare system. In this issue, Dr Ian Roberts explains the reasoning behind the proposals and what it is hoped they will achieve, while Mirryena Deeb puts forward the industry's reaction to the draft legislation.

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 intellectual property rights 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 IPRs 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 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 – 37S/200).

In this trade dispute between the United States 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.

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 over-the-counter 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. On 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 provide 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 IPRs 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 to countries with underdeveloped and developing economies.

Mashelkar R.A. Indian S&T in the wake of GATT: the concerns, challenges and opportunities. In: Rajiv Gandhi Institute for Contemporary Studies, eds. Indian S&T after GATT: an agenda for action. New Delhi, RGICS Project No 9.

The impending change in the patent regime will force Indian industry as well as R&D laboratories to move away from the path of reverse engineering. The author analyses changes with regard to the patenting of microorganisms and the protection of plant varieties. Emerging challenges and opportunities for R&D institutions and industry are investigated, as well as ways to enhance patenting skills in India.

Mehta PS. TRIPS and pharmaceuticals: implications for India. Annuaire Suisse-Tiers Monde, 1998.

Since the TRIPS Agreement does not provide for the retrospective patenting of drugs already on the market somewhere in the world, no significant effect can be anticipated until after 2005 because the number of patented drugs on the Indian market will be too small for economic impact. Moreover, balances such as government price control should be considered as a safeguard against price explosion. But Indian firms will be affected to a large extent: the focus of R&D should change into innovation of new processes, development of generic drugs, production of patented drugs under licence and marketing of imported drugs.

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 therefore 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 patents' 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

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 PCT route is being used.

Subbaram NR. Framing of national policy on intellectual property: some suggestions for taking advantage of opportunities in the post-GATT era. In: Rajiv Gandhi Institute for Contemporary Studies, eds. Indian S&T after GATT: an agenda for action. New Delhi, RGICS Project No. 9.

This chapter discusses some important and special issues which require careful consideration while formulating amendments to the Indian Patent Act, and suggests how to frame a national policy on intellectual property for taking advantage of the post-GATT era. The author focuses on the protection of pure compounds, the patenting of microorganisms and the protection of new plant varieties. He also insists on incentives for innovation and modernization of IPRs offices, including training of adequate intellectual property professionals, creation of a good infrastructure and establishment of a patent tribunal.

Subramaniam A & J. Coming of the age. Business India, December 1994, 54-60.

This article describes the performance of the Indian pharmaceutical industry. It demonstrates that, although comprehensively shielded from foreign competition for two decades by high tariffs, restrictions on drug multinationals, price controls and little or no patent protection, the industry is among the most fiercely competitive in the world. Low purchasing power, together with stiff competition among multiple producers for the same drug, has made Indian drugs among the cheapest in the world. However, future growth will have to combine a global presence with innovative research. If Indian companies have historically relied on export of bulk drugs and on developing countries, they may have to move further to developed countries and to formulations. According to the author, Indian companies could well aspire to international leadership in the manufacture and global marketing of bulk drugs for generics.

Supakankunti S et al. Study of the implications of the WTO TRIPS Agreement for the pharmaceutical industry in Thailand, 1999.

The TRIPS patent system is expected to have strong impacts 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 Law, 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. Originator pharmaceutical firms are found to perform better than generic firms after 1989 and the 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 forth 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 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 TRIPS may create uncertainties and some disruption to a *status quo* that Indians believe is working to their advantage.

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 Law that 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 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 health ministries 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. WHO/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/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.

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 traditional medicine. The impacts 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.

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

This article from Médecins Sans Frontières describes the problem of access to HIV/AIDS treatment in Thailand. It alleges that pressure from the US is one important factor that has limited access to affordable treatment for Thai patients. The paper concludes by emphasizing the importance for developing

and least developed countries to understand 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 effects 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 article 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 article proposes to the EU that national and EU laws should be amended in line with the WTO panel decision (WT/DS114/R) of 17 March 2000. This is related 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 the production of samples is compatible with TRIPS. This paper argues that incorporating this development and testing provision in 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 US. It emphasizes the difference between the “repression of unfair competition” and other forms of intellectual property protection. Furthermore, it maintains that the interpretation that Article 39.3 requires data exclusivity is beyond the agreed terms of TRIPS. 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 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. Economics effects of strengthening pharmaceutical patent protection in Italy. The International Review of Industrial Property and Copyright Law (IIC), 1995, 26(6): 1009-1024.

The Italian experience of introducing pharmaceutical patent protection recently 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 research and development 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/default2.htm>

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 opportunity for industry figures to air their views.

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 ECJ's pending judgement in *Merck v. Primecrown* and of Bayer's appeal against the Commission's decision in *Adalat*.

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

The ECJ's judgement in *Merck v. Primecrown* 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. The 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. 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 recent Industrial Property Act 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 transition 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 IPRs 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 will allow for an impartial weighting of the effects caused by the policy of not recognizing pharmaceutical patents, and to make a contribution to evaluating the economic effects deriving from the adoption of alternative systems.

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, biotechnology, state of the art, 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 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 present 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 Agreement, including the TRIPS Agreement, and was consequently committed to introducing pharmaceutical patent protection. According to the author, 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 drug industry, pharmaceutical chemicals 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 IPRs. 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 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 some particular issues such as trade in counterfeit goods, parallel imports, the control of abuses of IPRs 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 have rekindled the debate between national and multinational companies over the benefits of intellectual property protection 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.

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 IP protection 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 question of 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 concerning medicines.

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

This is a brief presentation of the current 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 intellectual property protection 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, a review of the main provisions relating to the protection of IPRs, and 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 has been 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 (CBO). How increased competition from generic drugs has affected prices and returns in the pharmaceutical industry. Available on the web at: <http://www.cbo.gov/showdoc.html>

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 drugs. 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.

Government of Canada. Information – Review of the Patent Act Amendment Act, 1992 (Bill C-91). February 1997. Available on the web at: <http://strategis.ic.gc.ca/pharmf>

This document provides information on the objective and content of Bill C-91, the Patented Medicine Prices Review Board (PMPRB), drug prices/expenditures, the Pharmaceutical Manufacturers Association of Canada commitments, and international obligations and comparisons, as well as a profile of the Canadian pharmaceutical industry.

Hunt MI, Kotis L. Prescription drugs and intellectual property protection: finding the right balance between access and innovation. Washington, D.C., National Institute for Health Care Management Foundation, August 2000. Available on the web at: <http://www.nihcm.org/prescription.pdf>

The expenditure on US prescription medications has increased significantly over the last decade. This study examines the major pieces of legislation that extend the intellectual property protection period for pharmaceuticals and the implications of these extensions. Intellectual property protection is seen as the tool that stimulates both the breakthrough and incremental innovation. This encourages companies to derive new products from compounds or drugs already patented. In the 1990s, 60% of New Drug Applications approved by FDA were for drugs containing existing active ingredients. The extension of protection incurs costs to consumers with limitation of generic competition and increasing pharmaceutical industry profits. The authors argue that increasing intellectual property protection has forced consumers to incur billions of dollars in drug costs that they may not have paid. The effect of protection on the quality as well as the quantity of innovation should be further examined. The authors finally conclude that policy makers must consider the sort of innovation that is in the public interest to reward.

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 policy 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 previous Government passed 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 current Government's revisions have not lived up to the industry's expectations.

Torremans P. Compulsory licensing of pharmaceutical products in Canada. The 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 NAFTA and the WTO 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 P.R. 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) 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 started by

pharmaceutical patentees since 1993, including actions for patent infringement and court applications pursuant to NOC regulations.

3. Electronic information

3.1 Some useful web sites

<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 in 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 the regional trade agreements and TRIPS, patents and drugs, compulsory licensing, parallel imports, health registration data, generic competition and more.

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

The website 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.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.twinside.org.sg/>

The Third World Network is an independent non-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 World Intellectual Property Organization provides basic fundamental information related to intellectual property and patents in general 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.

3.2 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.healthnet.org/programs/edrug.html>

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.

<http://www.hivnet.ch:8000/topics/treatment-access/>

Treatment-Access is an electronic discussion forum created and managed by the Fondation du Présent, a non-profit NGO, 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/pharm-policy>

Pharm-policy covers pharmaceutical policies, particularly those involving intellectual property, technology transfer and pricing. Anything significant happening gets on this discussion group within 24 hours.

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