UTILIZING TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PROTECTION THROUGH SOUTH-SOUTH REGIONAL FRAMEWORKS

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PREFACE

The South Centre is undertaking this study as part of its efforts to promote South-South cooperation and it is a continuation of the Centre's work to help developing countries design public health sensitive intellectual property rules and develop new strategies to ensure better healthcare provision. Already, the Centre has published three studies on intellectual property and public health, namely, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (Carlos Correa; 2000); *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (a joint publication with the Department of Essential Drugs and Medicines Policy of the World Health Organization (WHO) (Carlos Correa; 2002); and *Protection and Promotion of Traditional Medicine: Implications for Public Health in Developing Countries* (also a joint publication with the Department of Essential Drugs and Medicines Policy of WHO (Carlos Correa; 2002) as well as a number of papers under the T.R.A.D.E working papers series.

The study was carried out with the funding support of the Rockefeller Foundation and with the assistance of an expert consultative group (ECG) made up of: Professor Frederick M. Abbott, Florida State University College of Law; Professor Carlos M. Correa, South Centre; J. Michael Finger, American Enterprises Institute; Dr Fawzia Rasheed,WHO; Beryl Leach, Health Action International - Africa; and, Professor Ruth Okediji, University of Minnesota Law School. The administrative and logistical support was provided by a project assistant, Fabienne Stephan. Contributions to the study were also made by Watu Wamae of the Université de la Méditerranée in Aix en Provence, France. The authors are greatly indebted to the members of the ECG and Watu Wamae for their valuable inputs and consistent support and to the project assistant for her tireless efforts to ensure that the various activities and processes proceeded as planned.

A preliminary review of a draft of the study, co-sponsored by the Department of Essential Drugs and Medicines Policy of WHO and the Health Equity Department of the Rockefeller Foundation, took place on 22 July 2003 in New York. The participants in the review meeting were: Francisco Cannabrava, Brazilian Embassy – Mexico; Carlos Correa, University of Buenos Aires; Christopher Garrison, Campaign for Access to Essential Medicines, Medecins Sans Frontieres (MSF); Andrew Farlow, Oxford University; Sakiko Fukuda-Parr, Human Development Report Office, United Nations Development Programme (UNDP); Desmond Johns, UNAIDS, New York; Keith Johnson, Center for Pharmaceutical Management, Managements Sciences of Health (MSH); Jim Keon, The Canadian Generic Pharmaceutical Association; Jamie Love, Consumer Project on Technology; Faris Natour, Calvert Group; Juan Rovira, The World Bank; Eric Sawyer, Health Global Access Project; Anthony So, The Rockefeller Foundation; Jonathan Soverow, The Rockefeller Foundation; German Velasquez, Drug Action Programme, Department of Essential Drugs and Medicines Policy, WHO; and Robert Weissman (Essential Information). The Authors are grateful to the reviewers for their valuable inputs.

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The views expressed in the study are, however, the views of the authors and do not necessarily reflect the views of the South Centre, the Rockefeller Foundation or any of the other institutions to which the authors are affiliated. The authors are solely responsible for this text.

ABBREVIATIONS

ACTRIPS	Advisory Council on Trade-Related Innovation Policies
ADF	African Development Fund
AEC	African Economic Community
AICO	ASEAN Industrial Cooperation
AIDS	Acquired immuno-deficiency syndrome
ARV	Antiretroviral
AZT	Azidothymidine
BMS	Bristol-Myers Squibb
CBO	Community-based organization
CCH	Caribbean Cooperation in Health
ECG	Expert Consultative Group
EDL	Essential Drugs List
EDM	Essential Drugs and Medicines Policy Department, WHO
FORMED	Revolving Fund for Essential Drugs for Central America and Panama
FTAA	Free Trade Area of the Americas
GDP	Gross domestic product
GMP	Good manufacturing practices
HIV	Human immuno-deficiency virus
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICH	International Conference on Harmonization
LAFTA	Latin American Free Trade Association
MSF	Médecins Sans Frontières
MSH	Management Sciences of Health
NIHCM	National Institute of Health Care Research and Educational Foundation
NGO	Non-governmental organization
PPS	Pharmaceutical Procurement Service
R&D	research and development
REC	Regional Economic Community
SEATINI	Southern and Eastern African Trade Information and Negotiations Institute
STG	standard treatment guidelines
TF	Task Force

TRIPS	Trade-Related Aspects of Intellectual Property Rights
TWN	Third World Network
UDHR	Universal Declaration of Human Rights
UK	United Kingdom
USPTO	United States Patent and Trademark Office
USTR	United States Trade Representative

Organizations

ACAME	African Association of Central Medical Stores for Generic Essential Drugs
ADB	African Development Bank
AMU	Arab Maghreb Union
ASEAN	Association of Southeast Asian Nations
ARIPO	African Regional Intellectual Property Organization
AU	African Union
CACM	Central American Common Market
CARICOM	Caribbean Community
CEMAC	Central African Economic and Monetary Community
COMESA	Common Market for Eastern and Southern Africa
CRHCS	Commonwealth Regional Health Community Secretariat
EAC	East African Community
ECDS	Eastern Caribbean Drug Service
ECOWAS	Economic Community of West African States
ESARIPO	Industrial Property Organization for English-speaking Africa
EU	European Union
GCC	Gulf Cooperation Council
MERCOSUR	Common Southern Market
OAMPI	African and Malagasy Office for Industrial Property
OAPI	African Intellectual Property Organization
OAU	Organization of African Unity
OECS	Organization of Eastern Caribbean States
PAHO	Pan-American Health Organization
SAARC	South Asian Association for Regional Cooperation
SACU	South Africa Customs Union
SADC	Southern African Development Community
UEMOA	West African Economic and Monetary Union

UNAIDS	UN Joint Programme on AIDS
UNCTAD	United Nations Conference on Trade and Development
UNIDO	United Nations Industrial and Development Organization
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

Despite the significant scientific and technological developments of the 20th century, there continue to exist unacceptable inequalities in the health status of people as between developed and developing countries as well as within developing countries. It is in this context that efforts have been underway over the last several years to make medical technology work better for developing countries and for poor people. A major component of these efforts has focused on the impact of the expansion of patent protection to pharmaceutical products and processes under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The initial challenge related to the scope and interpretation of the policy flexibilities embodied in the Agreement that could be used to improve availability and access to essential patented medicines. This challenge was resolved by the Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration), which affirmed that public health considerations can and should condition the extent to which patents on pharmaceuticals are enforced and that flexibilities in the TRIPS Agreement should be used to this end.

However, while developing countries have the right to exercise the flexibilities under the TRIPS Agreement, in reality it remains difficult for many of them to make effective use of these flexibilities as a public health policy tool. For example, paragraph six of the Doha Declaration on TRIPS and public health recognized that while developing countries can issue compulsory licences; they nevertheless faced difficulties in making effective use of this policy tool due to lack of or insufficient manufacturing capacity. This is, however, just one of the constraints that developing countries face at the national level in their efforts to use TRIPS flexibilities. Other constraints include: lack of technical expertise effectively to implement the TRIPS flexibilities; insufficient technical and infrastructural ca-

pacities for medicines regulations; bilateral and other pressures not to use the TRIPS flexibilities for public health purposes and/or to adopt TRIPS-plus standards; difficulties in regulating anti-competitive practices and abuse of intellectual property rights; and difficulties in accessing pricing and patent status information. Many of these constraints can be addressed by adopting complimentary policy and legal measures at the regional level.

A regional approach to the use of TRIPS flexibilities will enable similarly situated countries to address their constraints jointly by drawing on each others' expertise and experience and by pooling and sharing resources and information. This approach has several advantages. First, it creates better policy conditions for addressing the challenges of implementing TRIPS flexibilities, which can be daunting for each individual country. Second, a common approach to improve access to essential medicines will enhance the efforts by developing countries to pursue common negotiating positions at the WTO and in other multilateral negotiations such as those on a substantive patent law at the World Intellectual Property Organization (WIPO). In addition, a regional approach coincides with the objective of enhancing South-South cooperation on health and development.

Consequently, if strategically utilized, regional South-South frameworks will significantly help developing countries devise ways by which national constraints in the use of TRIPS flexibilities can be overcome. This study provides the conceptual as well as a strategic basis for further thinking and decision-making on how effectively to use TRIPS flexibilities for public health purposes through regional South-South mechanisms and cooperation. The study should, however, not be seen as the A to Z of regional approaches to the use of TRIPS flexibilities, but rather as a first step. Critical issues with a regional dimension that need to be further explored through empirical research and discussions are identified and explored. In this regard the study recommends, among other things, that:

- Regional economic communities (RECs) and other similar regional bodies should establish regional Advisory Councils on Trade-Related Innovation Policies (ACTRIPS) or

functionally equivalent mechanisms as a central feature of an institutionalized approach to regional research and innovation including essential health research and, in particular, as a focal point for training, research, information exchange and political coordination in the use of TRIPS flexibilities for public health promotion and protection;

- Serious consideration be given to the viability of developing regional pharmaceutical research and manufacturing capacities and that further research be undertaken with respect to the factors necessary for pharmaceutical production in a disaggregated way, that is, the factors relevant for different types of pharmaceutical production be studied. With respect to the WTO's 30 August 2003 Decision, that consideration be given to developing a system for the issue of regional compulsory licences where there are regional patents such as in the African Intellectual Property Organization (OAPI) countries and also developing a system of mutual recognition where REC members can issue their own compulsory licences based on the issuance of a licence in another REC member, where regional patents do not exist;

- Existing South-South RECs in Africa, Asia, Latin America and the Caribbean be utilized to address among other things, challenges in drug registration and post-marketing surveillance, development of essential medicines lists, development of medicines policies, and rules on pharmaceutical advertising and labelling;

- Depending on the level of existing cooperation in health matters in each region, mechanisms be put in place to facilitate the implementation of suitable models of cooperation in pharmaceutical management and procurement. Whenever feasible, developing countries should seek to put in place regional procurement systems where they would jointly conduct tendering through an entity acting

on their behalf and a central purchasing agency managing the purchases on behalf of all the member countries;

- Developing countries use their regional institutions and frameworks in resisting pressures to forgo the use of TRIPS flexibilities for public health as well as TRIPS-plus pressures. In this connection, the establishment of regional NGO and community-based organization (CBO) networks should be facilitated through RECs and other institutions. This effort should be linked to the creation of regional ACTRIPS; and,

- In recognizing that competition enforcement is critical in ensuring a competitive pharmaceutical industry, both in terms of lowering prices and ensuring availability of essential medical products, and the fact that developing countries lack expertise and the necessary economic and political clout, they should utilize RECs to enforce competition rules. There are particularly important benefits to be gained from undertaking joint investigations and information exchange.

I. INTRODUCTION

The technological transformation of the 20th Century has had the effect of advancing the frontiers of science in many technological fields. In the medical and pharmaceutical field, in particular, major technological breakthroughs have been witnessed including the mapping of the human genome, antiretroviral (ARV) therapy for the treatment of HIV/AIDS and second line treatments for tuberculosis and malaria. These dramatic developments have provided increasing hope for the realization of the right to health in the developing world.[1] For the people in these regions, however, the reality on the ground is the stark opposite; treatable and preventable diseases continue to kill millions each year.[2] Today, despite significant scientific and technological developments, there continue to exist unacceptable

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[1] The right to health is today solidly embedded in international, regional and national human rights instruments. At the international level, the starting point is article 25 of the Universal Declaration of Human Rights (UDHR) (General Assembly resolution 217 A (III) of 10 December 1948). It provides *inter alia* that:

> [25(1)] "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

The provisions of this article are further defined and given legal standing in international law by article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). At the regional level, article 11 of the European Social Charter and article 16 of the African Charter on Human and Peoples' Rights, for example, contain the right to health along the lines of the ICESCR.

[2] According to the latest UNAIDS Report, 3 million people died of HIV/AIDS in 2003, a majority of them in the developing world. See UNAIDS (2003).

inequalities in the health status of people between developed and developing countries as well as within developing countries. It is in this context that efforts have been under way over the last several years to make medical technology work better for developing countries and for poor people.

A major component of these efforts has focused on the impact of the expansion of patent protection to pharmaceutical products and processes under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[3] The initial challenge related to the scope and interpretation of the policy flexibilities embodied in the Agreement that could be used to improve availability and access to essential patented medicines. This challenge was resolved by the Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) which affirmed that public health considerations can and should condition the extent to which patents on pharmaceuticals are enforced and that flexibilities in the TRIPS Agreement should be used to this end.[4]

However, at the time of adopting the Doha Declaration, the WTO membership also recognized that for many of them, it remains difficult to make effective use of these flexibilities as a public health policy tool. For example, paragraph six of the Declaration recognized that while developing countries have the right to issue compulsory licences, they nevertheless faced difficulties in making effective use of this policy tool due to lack of or insufficient manufacturing capacity.[5] This is, however, just one of the constraints that develop-

[3] The TRIPS Agreement was adopted as part of the Final Act of the Uruguay Round of Multilateral Trade Negotiations in Marrakech, Morocco on 15 April 1994. For the full text of the Agreement see WTO (1999) pp. 321-353.

[4] The Declaration was adopted at the Fourth Session of the WTO Ministerial Conference in Doha, Qatar on 14 November 2001. See WTO document WT/MIN(01)/DEC/W/2.

[5] Para. 6 provides *inter alia* that:

> "We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties

ing countries face at the national level in their efforts to use TRIPS flexibilities. Other constraints include: lack of technical expertise effectively to implement the TRIPS flexibilities; insufficient technical and infrastructural capacities for medicines regulations; bilateral and other pressures not to use the TRIPS flexibilities for public health purposes; difficulties in regulating anti-competitive practices and abuse of patent rights; and difficulties in accessing pricing and patent status information. Consequently, after Doha, the challenge is to ensure that the policy flexibilities embodied in the TRIPS Agreement are used effectively by developing countries to protect and promote public health. A number of the constraints that individual developing countries face in utilizing the TRIPS flexibilities can be addressed by adopting complementary policy and legal measures at the regional level. A regional approach will enable similarly situated countries (countries trying to use TRIPS flexibilities for public health protection and promotion) to address their constraints jointly by drawing on each others' expertise and experience and by pooling and sharing resources and information.

I.1 The Rationale for and Scope of the Study

The effective use of the TRIPS flexibilities such as compulsory licensing as a public health policy tool, presupposes the existence of certain conditions such as the existence of local research and pharmaceutical manufacturing capacities and the existence of adequate regulatory measures for use of medicines as well as for quality control. While efforts are being made to establish these conditions at the national level, many developing countries find it difficult to do this on their own. It is in this context that South-South frameworks such as regional economic communities (RECs), offer strategic opportuni-

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in making effective use of compulsory licensing under the TRIPS Agreement."

ties for countries to cooperate and make maximum use of the TRIPS flexibilities.

These frameworks, if strategically utilized, will help developing countries devise ways by which national constraints in the use of TRIPS flexibilities can be overcome. This study is aimed at providing the conceptual as well strategic basis for further thinking and decision-making on how to effectively use TRIPS flexibilities for public health purposes through regional mechanisms and cooperation. The study should therefore be seen as a first step and not as the A to Z of regional approaches to the use of TRIPS flexibilities. The study raises critical issues with a regional dimension that need to be further explored through empirical research and discussions. It is noteworthy, however, that a number of the regional approaches considered in this study, such as regional pooled procurement, are already being implemented in the South, albeit not in the context of TRIPS flexibilities.

Policies that are likely to benefit significantly from a regional approach to implementing TRIPS flexibilities include those related to production of pharmaceuticals, regulatory approval of medicines, market surveillance and maintenance of quality standards, border control measures, import rules and competition issues, among others. An additional issue that deserves consideration is the question of research and development and the supply of medicines for neglected diseases. A collective regional approach to the issue of patents and public health has several advantages. First, it creates better policy conditions for addressing the challenges of implementing TRIPS flexibilities, which can be daunting for each individual country. Second, a common approach to improve access to essential medicines will enhance the efforts by developing countries to pursue common negotiating positions at the WTO and in other multilateral negotiations, such as those on a substantive patent law treaty at the World Intellectual Property Organization (WIPO), by providing a solid basis for technical discourse as well as political coordination. In addition, this approach coincides with the objective of enhancing South-South cooperation in dealing with matters of public health and development.

I.2 The Study Process and Methodology

This study was undertaken through a consultative process that spanned over a year. The research was undertaken by a Task Force (TF) consisting of three developing country experts with experience on international law, international intellectual property law and policy, and public health and regional cooperation. The TF also drew on the expertise of medical and health professionals, partner intergovernmental organizations and civil society groups. The TF was assisted in an advisory role by an Expert Consultative Group (ECG) made up of international experts in international law, international intellectual property and technology law and policy, economics and public health.

The first part of the process involved the South Centre identifying the core research team in February 2003. The idea was to identify developing country experts with a demonstrated experience at country, regional and international level on issues of patents and public health. An effort was also made to ensure that the members of the TF included experts based in the regions. After establishing the TF, the second task was to identify the members of the ECG. Here the premise was to identify international experts on the subject and to include both nationals of developing countries and some experts from the North. An effort was made to ensure that there was expertise in the ECG not only on patent issues, but also on medicines and public health issues as well as on economic issues to ensure a multidisciplinary approach to the analysis. After establishing the TF and the ECG, the initial research and determination of the scope of the study began. This initial phase culminated in the first meeting of the TF in April 2003. This first meeting provided an opportunity for the TF to discuss and finalize the outline of the study and to share the results of their initial research.

Following the first meeting of the TF, work on the first draft began. In addition to the research and writing during this phase, the lead author travelled to Africa to meet representatives of RECs in June 2003. These meetings were aimed at enabling the lead author to

have an initial exchange of views and ideas on the study with the REC secretariats. In this regard, the lead author had meetings with the representatives of the Common Market for Eastern and Southern Africa (COMESA), the Southern Africa Development Community (SADC) and the East African Community (EAC). After these meetings, there followed a period of research and writing which resulted in completion of the first draft of the study in July 2003. The draft was then presented and reviewed by an expert group at a meeting in New York on 22 July 2003. The expert review meeting was co-sponsored by the Department of Essential Drugs and Medicines Policy (EDM) of WHO and the Health Equity Department of the Rockefeller Foundation.

On the basis of the first draft and the results of the New York expert review, a working meeting was held in August 2003 of the TF and the ECG in Geneva to discuss the draft and the outcomes of the expert review. This meeting provided an opportunity for the TF and the ECG to engage in an in-depth discussion of the various components of the study and share information and insights. This meeting was followed by a consultative workshop on 12 August 2003 also in Geneva. The consultative workshop provided a forum for discussions and consultations on the first draft of the study with a wider group of stakeholders and experts. The workshop brought together the TF, the ECG, and international experts on intellectual property, public health, pharmaceutical markets and procurement, representatives of a significant number of the permanent missions of developing countries in Geneva and representatives of various RECs from the South including SADC, COMESA, EAC and the Andean Community. Participants also included representatives of international Organizations such as the United Nations Conference on Trade and Development (UNCTAD), the World Health Organization (WHO), the UN Special Programme on AIDS (UNAIDS) and The Global Fund as well as civil society organizations.

Following the consultative workshop, the TF again met to review the outcomes of the workshop and plan for the final phase of research and writing. This final phase was undertaken between September and November 2003 at which time the initial final draft of the

study was produced. This draft was circulated among the ECG and selected experts for further review in December 2003 and, on the basis of their comments, observations and suggestions the final draft was prepared in March 2004. This was followed by a period of editing, formatting and revisions culminating in the publication of the study in April 2004. The conclusions and recommendations in the study have therefore been arrived at through research and a series of meetings and consultations with various stakeholders. In terms of the sources of information and data, the study relies predominantly on secondary sources except in a few cases where questionnaires were used.

I.3 Parts of the Study

The study is divided into four main parts. The first part provides a brief background on the debate about patents and access to medicines in developing countries as well as an overview of the public health-related TRIPS flexibilities. The second part then identifies the constraints that developing countries face in their efforts to use TRIPS flexibilities for the promotion and protection of public health. The third part analyses, assesses and considers various possibilities for utilizing south-south regional frameworks to overcome the identified constraints in the use of TRIPS flexibilities for public health purposes. Finally, the fourth part draws some conclusions and summarizes the various recommendations made in the study on how developing countries can utilize regional cooperation mechanisms in the South to enhance their capacities to use TRIPS flexibilities for public health promotion and protection.

II. Intellectual Property and Access to Essential Medicines in Developing Countries

The substantial gains in life expectancy and unparalleled medical advances of the 20th century, as noted above, have left most of the world's population behind in important ways.[6] In all the developing regions – Africa, Asia, the Caribbean and Latin America – the disease burden remains high. Africa, where millions still die from preventable and treatable diseases, is a particularly telling case. In working to address this heavy disease burden, the countries of the South face new challenges. One important challenge relates to the high costs of essential medicines and related products due to the mandatory requirement under the WTO TRIPS Agreement for patent protection for medicines and for the processes of manufacturing medicines. Before 1994, when the TRIPS Agreement was adopted as part of the Final Act of the Uruguay Round of Multilateral Trade Negotiations, the various countries approached the patenting of pharmaceutical products differently. A large number of countries did not grant patents for medicines so as to keep the cost low and affordable and to ensure their ready availability to their populations at all times.

After TRIPS, problems arose in large measure due to the prohibitive cost of patented ARV medicines as well as for medicines used in the treatment of opportunistic infections. The high prices for these medicines seriously compromised the ability of governments, communities and other players in the health sector in developing countries effectively to manage the HIV/AIDS epidemic. The cost disparity guaranteed, virtually, that most of the sick in these countries would have little or no access to the best available treatments. It is important to remember, however, that the problems of cost go be-

[6] Médecins Sans Frontieres (MSF) Drugs for Neglected Diseases Working Group and Campaign for Access to Essential Medicines (2001), p. 8.

yond HIV/AIDS and other politically visible diseases such as malaria and tuberculosis.

The international debate on the implications of the TRIPS Agreement for access to essential medicines came into the international media limelight in 1997 with the attempts by the United States Government to force the revision of the South Africa's Medicines and Related Substances Amendment Act and the subsequent filing of a legal challenge against that law by the South African Pharmaceutical Manufacturers Association.[7,8] Thereafter, particularly in the period leading up to the Fourth Session of the WTO Ministerial Conference in Doha, developing countries were pitted in a bitter debate against developed countries over the interpretation and scope of TRIPS flexibilities and how these could be utilized to address the public health needs in developing countries.

The Doha Declaration, adopted at the Conference, represents a final agreement between the two groups of countries, that public health considerations condition the extent to which rules on patent protection are implemented. The Trade Ministers of the then 142 Members of the WTO expressed their agreement in the following words:

> "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and in particular, to promote access to medicines for all."[9]

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[7] Act No. 90 of 1997. Among other things, the law provided for parallel importation and generic substitution.

[8] For further discussion on this case and the debates in the WTO, see t'Hoen (2002) and also Sell (2002).

[9] *Supra* note 4.

The Doha Declaration marked a significant achievement for developing countries. It testifies to the need for cooperation among the countries of the South in finding solutions to alleviate the disease burden. It is indisputable that today, the debilitating social, economic, cultural and political consequences of diseases, particularly HIV/AIDS, pose the greatest challenge to sustainable development in the developing world. The gains made in economic development through regional integration and cooperation are being reversed. Access to essential medicines and therapies is therefore an integral part of the socio-economic and other responses needed to manage the enormous disease burden in the South and to improve the living standards of people.

II.1. An Overview of Public Health-related TRIPS Flexibilities

The adoption of the TRIPS minimum standards resulted into a significant loss of policy flexibilities by developing countries in regulating the granting and use of pharmaceutical patents and controlling the cost of medicines. However, the Agreement left some room for countries to take public interest measures including measures to protect public health. The Doha Declaration recognized that the TRIPS Agreement does not prevent Members from taking measures to protect public health. At Doha, WTO Members also reaffirmed the right of each Member to use to the full, the provisions of the Agreement which provide flexibility for protecting public health and, in particular, for promoting access to medicines for all.

There are a number of such flexibilities which developing countries can use to address some of the negative consequences of pharmaceutical patents. The main flexibilities include: compulsory licensing; parallel importation; provisions relating to patentable subject matter; provisions relating to exceptions to patent rights; provisions relating to data protection; and provisions relating to abuse of

rights, competition and the control of anti-competitive practices. The following is an overview of each of these flexibilities.[10]

II.1.1 Compulsory Licensing

A compulsory licence is a licence granted by an administrative or judicial body to a third party to exploit an invention without the authorization of the patent holder. This type of licence is commonly referred to as a non-voluntary licence connoting the lack of consent by the patent holder. The TRIPS rules on compulsory licensing are contained in article 31. The concept of compulsory licensing itself, however, has a long history. One of the earliest legal instruments to incorporate the concept was the United Kingdom (UK) Statute of Monopolies of 1623.[11] At the international level, compulsory licences are recognized and provided for in the Paris Convention of 1883.[12] Indeed, by 1994, when TRIPS was adopted, compulsory licensing provisions had become a typical feature of patent laws around the world.[13]

Article 31 of TRIPS lists detailed conditions which must be complied with when a WTO Member chooses to use compulsory licensing. These include the need to grant licences on a case-by-case basis, evidence of unsuccessful prior request for a voluntary license, non-exclusivity of the licence and the requirement for compensation. There are also conditions governing the termination of licences and

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[10] For a detailed discussion of most of these public health-related TRIPS flexibilities see Correa (2000).

[11] Correa (1999a), p. 1.

[12] See article 5A(2) of the Paris Convention which provides that,

> "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent abuses which might result from the exercise of the exclusive rights conferred by the patent, for example failure to work:"

[13] Correa (1999a), p.2.

restrictions on export and on assignment of licences to third parties. Notwithstanding these conditions, the Agreement still leaves considerable room for flexibility in legislating on compulsory licences.

Compulsory licensing as a policy mechanism can be used to address a number of situations including, among others:

- The high prices of medicines.
- Anti-competitive practices by pharmaceutical companies.
- Failure by pharmaceutical patent holders sufficiently to supply the market with needed medicines.
- Emergency public health situations.
- The need for establishing a pharmaceutical industrial base.

II.1.2 Parallel Imports and Exhaustion of Rights

Parallel importation refers to a situation where a third party, without the authorization of the patent holder, imports a foreign manufactured product put on the market abroad by the patent holder, his licensee or in another legitimate manner in competition with imports or locally manufactured products by the patent holder or his licensee.[14] The practice is based on the principle that the patent holder has been remunerated through the first sale of the product and his further control over the resale of the product would unreasonably restrain trade and stifle competition. In other words, having been remunerated the right holders are said to have exhausted their rights. Under article 6 of the TRIPS Agreement, as confirmed by the Doha Decla-

[14] For further discussion on parallel imports, see Correa (2000). See also Lettington and Musungu (2000) and Abbott (1998).

ration, WTO Members are free to choose their own regime of exhaustion of rights without challenge.[15]

Parallel importation is used as a measure to prevent market division and price discrimination on a regional or international scale.[16] Since pharmaceutical companies set prices for the same products at different levels in different countries, parallel importation enables consumers to gain access to the product without affecting the right of the patent holder to receive remuneration in the country where the product is first sold. While allowing parallel importation in developed countries could be seen as undermining efforts to provide lower prices in developing countries, the same argument can not be made where it is developing countries allowing parallel imports. Even in cases where importation takes place from markets where medicine prices are regulated, it remains true that patent holders will be compensated albeit at a lower rate than where price regulation does not exist.

II.1.3 Limitation on the Grant of New Use Pharmaceutical Patents

New use pharmaceutical patents refer to patents granted for new uses for previously known products. New pharmaceutical uses are either first pharmaceutical use (also referred to as first medical indication) or second pharmaceutical use (second medical indication).[17] The former case relates to a situation where a new pharmaceutical use is discovered for a product with no previously known pharmaceutical use. Under this scenario, the product will be put to use in the pharmaceutical sector for the first time. In the latter case, a product already known to have one or more pharmaceutical uses is discovered to have a further pharmaceutical use although unrelated to the earlier

[15] See para. 5(d) of the Declaration.

[16] Correa (2000), p. 72.

[17] For further discussion see Grubb (1999), pp. 217-218.

known use(s). The classical example of second medical indication is the case of Azidothymidine (AZT).[18]

The general rule on patentable subject matter under article 27 of the TRIPS Agreement is that, subject to the exceptions set out in the TRIPS Agreement, patents shall be available for all inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[19] However, article 27 does not define what an invention means. The effect of not defining an invention under Agreement is that countries have the flexibility to define the scope of the concept of invention under their national laws to exclude new uses from patentability.[20] The proponents of new use patents justify them on the basis that the discovery of a new use may require the same level of investment and creativity as in the case of a new product. However, this applies in very limited cases, if any.

Innovation in the pharmaceutical industry for which patents are claimed varies widely. It ranges from breakthrough discoveries to minor modifications of existing medications. A recent study by the National Institute of Health Care Management Research and Educational Foundation (NIHCM) has shown that in the United States, the market with the largest number of pharmaceutical patents, in the 12 year period from 1889 to 2000 of the 1,035 new drugs approved by the federal regulatory agency only 35 per cent of them contained a new active ingredient.[21] Consequently, highly innovative drugs –

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[18] The drug was first discovered in 1964 at the United States National Cancer Institute Laboratory as a cancer treatment. However, due to problems of toxicity, it was not used and the patent eventually expired. In 1984, the Institute invited companies to submit compounds for testing as possible AIDS drugs and Burroughs Welcome submitted AZT. For a detailed discussion of the AZT case, see Ackiron (1991).

[19] See article 27 of the TRIPS Agreement.

[20] Correa (1999b), p. 228.

[21] NIHCM (2002), p. 3.

medicines which contain new active ingredients and at the same time provide significant clinical improvement- are rare. During the 12 year period only 15 per cent were such medicines.[22] The bulk of new medicines are therefore modified versions of older drugs which, however, command high prices.

Protection of new uses, especially second medical indications, is routinely used for anti-competitive purposes mainly for extending the patent period and blocking generic entry. Patent holding companies have been able to thwart generic entry by modifying the existing drugs and claiming patents on them.[23] In the United States, modifying existing drugs enables companies to extend their patent protection on existing drugs by either patenting new features of old medicine or by obtaining three year exclusivity under the provisions of the so-called Hatch-Waxman Act.[24] This problem can become quite acute in those countries where pharmacy laws do not permit generic substitution and or generic prescribing.

II.1.4 Research and the Early Working Exceptions

Article 30 of the TRIPS Agreement establishes the general bases for exceptions to the exclusive rights envisaged under the Agreement.[25] The rule is that exceptions to the patent rights must be limited; should not unreasonably conflict with the normal exploitation of the

[22] *Idem*.

[23] NIHCM (2002), p. 4.

[24] Under this Act if the federal regulatory agency approves a modified version of the branded drug on the basis of new clinical studies, its manufacturer receives three years of market exclusivity on the new use of the product. New uses encompass not only the new indications but also other changes to the drug including the older drug's dosage form, route of administration and incorporation into a new combination product. For further discussion see NIHCM (2002).

[25] For these rights see article 28 of TRIPS.

patent; and should not unreasonably prejudice the legitimate interests of the patent holder, taking into account the legitimate interests of third parties. Although not explicitly mentioned in the Agreement, the research and experimentation and early working exceptions are the two widely accepted exceptions under article 30 with implications for public health. In some countries, such as the United States, these exceptions have traditionally been judicially determined while in others, such as Japan, they are statutory rights.

The research and experimental use exception is aimed at ensuring that scientific research aimed at generating new knowledge is fostered and is not impeded by patents. It is a longstanding exception which is justified on the basis that one of the main aims of patent laws is to facilitate the dissemination of knowledge, promote innovation and thereby facilitate the advancement of science. The exception is useful in fostering pharmaceutical technological progress by exempting experimentation acts for purposes such inventing around the initial invention, improving on the invention or for the purposes of evaluating the invention and determining if it works.[26]

The early working exception, on the other hand, relates to a situation where a potential competitor uses an invention without the authorization of the patent holder to undertake acts necessary for obtaining regulatory approval and registration of a generic product before the expiry of the patent term. The exception is intended to ensure that generic versions of the product are available on the market immediately or within a reasonable time of the expiry of the patent.[27] The actual implementation of the exception differs from country to country. Under the 1984 United States Drug Price Competition and Patent Term Restoration Act, the United States introduced this type of provision while also allowing patent holders an extended period of protection.[28] Other countries such as Kenya, on the other hand, pro-

[26] See Correa (2000), p. 66.

[27] Lettington and Musungu (2000), p.65.

[28] Ackiron (1991), p. 157.

vide for the early working exception to generic manufacturers without extending the life of the patent.[29]

II.1.5 Limiting the Extent of Test Data Protection

National health authorities generally require, as a condition for registering new pharmaceutical products, the submission of test data relating to the quality, safety and efficacy as well as information on the composition and physical and chemical characteristics of the product.[30] Once the data is submitted by the originator company, however, a significant number of regulatory authorities do not require companies seeking registration of generic versions of the original product to repeat the studies that are carried out by the originator company but instead rely on bioequivalence tests to grant marketing approval.

Consequently, while article 39 of the TRIPS Agreement envisages the protection of test data submitted to governments to meet regulatory approval requirements and, in particular, provides that in ensuring the effective protection against unfair competition as provided for in article 10*bis* of the Paris Convention, "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test data or other data, the origination of which involves a considerable effort, shall protect such data against disclosure",[31] to require generic producers to conduct trials on equivalent compounds imposes additional costs which are passed on to the consumer. It can also be said that such a requirement is socially wasteful.[32]

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[29] See section 21(3) (e) "The Industrial Property Act", Kenya Gazette Supplement No. 60 (Acts No. 3) 3 August 2001.

[30] Correa (2002), p. xi.

[31] See article 39(3) of the TRIPS Agreement.

[32] Abbott (2001), p.29.

In recognition of these factors, among others, article 39 only requires protection of test data relating to new chemical entities and where the origination of the data involved considerable effort and provides for exceptions, such as where disclosure is necessary to protect the public. Article 39 therefore leaves room for each Member to determine how to protect test data. In other words, in so far as generic competition lowers prices and increases availability and access to essential medicines, it is in the public interest to limit the extent of test data protection. The public interest is served as competition is promoted by ensuring that data protection does not become a means of blocking the timely entry of generics into the market.

Test data protection is subject to specific regulations in a number of jurisdictions although the approach differs from jurisdiction to jurisdiction.[33] In some developed countries, such as the United States and in the European Union (EU), the regulations provide for exclusive use of test data by the originator company for a limited period of time, while in other jurisdictions such exclusivity is not established and generic medicines can be registered by relying on test data made available to health authorities by the originator company from the time the data is submitted.

II.1.6 Control of Anti-Competitive Practices and Abuse of Intellectual Property Rights

The TRIPS Agreement envisages a balance between the promotion of technological innovation and the transfer and dissemination of technology, in addition to a balance in the enjoyment of the benefits accruing to the users and producers of technology. These balances are contained in a number of provisions in the Agreement. The basic concept of balance under TRIPS is, however, contained in the objectives and principles of the Agreement. The principles upon which the balance is to be achieved are, first, that Members in formulating or amending their laws may adopt measures necessary for the protec-

[33] Correa (2002), p.57.

tion of public health and nutrition and take measures to promote public interests in sectors of vital importance to their socio-economic and technological development.[34] Second, they may adopt appropriate measures to prevent the abuse of intellectual property rights by rights holders or the resort by them to practices that unreasonably restrain trade or adversely affect the international transfer of technology.[35]

The second principle, in particular, should be read as an interpretive principle in favour of the adoption of measures deemed necessary for the promotion of competition and the prevention of abuse of the monopoly position by patent holders including engaging in anti-competitive licensing arrangements. Article 40 of the TRIPS Agreement specifically establishes a regime for the control of anti-competitive practices in contractual licences. Consequently, apart from the measures aimed at improving competitiveness in the pharmaceutical market that a country may take under article 8(2), countries can also take additional measures to control the licensing practices of pharmaceutical companies. By prohibiting the use of terms such as exclusive grant back clauses, clauses that preclude challenges to validity of the patent and coercive packaging, countries can reduce the concentration of market power and improve competition in the pharmaceutical markets.

Finally, trademark and copyright rules can also be used to block competition in the pharmaceutical markets. For example, on the basis of trademark rules, pharmaceutical companies have attempted to block generic prescription or generic substitution rules.[36] This is, however, inconsistent with article 16 of the TRIPS Agreement which only requires countries to protect trademark holders against use of their marks where there is a likelihood of confusion.

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[34] Article 8.1.

[35] Article 8.2.

[36] For a discussion on how trademarks are used to block generic substitution in the context of the access to essential medicines see Abbott (2001), p.27.

This means that based on article 16, countries can establish a trademark regime that ensures that trademarks do not become a basis for claims of affirmative market access rights.

Attempts have also been made to use copyright laws to block generic entry. For example, pharmaceutical manufacturers have argued that package labels and inserts that contain physician and consumer information are protected by copyright and as such generic producers cannot use similar information.[37] Again, this is a claim that goes beyond the rights conferred for copyright under article 9 of the TRIPS Agreement. In other words, product description, instructions for application or use, dosage recommendations and information about possible contraindications or allergic reactions should be regarded as "facts" not subject to copyright protection under article 9(2) of the TRIPS Agreement.

[37] See Abbott (2001), p.28.

III. Constraints on National Efforts to Implement TRIPS Flexibilities for Public Health Purposes

Incorporating the public health-related TRIPS flexibilities into national law and policy is necessary but not sufficient to deal with the patent-related obstacles to improving access to medicines. There are therefore two levels of constraints that need to be addressed if developing countries are effectively to use TRIPS flexibilities for public health purposes.

The first level relates to constraints associated with the incorporation and general implementation of the TRIPS flexibilities themselves. The second level relates to constraints in the framing and implementation of supporting legal and policy measures such as those concerning local innovation and production of pharmaceuticals. For example, legal and policy measures need to be introduced to guarantee availability of alternative sources of medicines, either through local production or through importation; to assure the quality of the medicines; to ensure expedited registration of essential generics; and to ensure cost effectiveness of the resources spent in the procurement of medical supplies. The constraints in implementing these secondary legal and policy measures at the national level have the effect of inhibiting the effective use of the TRIPS flexibilities.

The main constraints at the second level include the lack of domestic pharmaceutical research and manufacturing capacities; insufficient technical and infrastructural capacities for medicines regulation; difficulties in establishing efficient pharmaceutical management and procurement systems; bilateral and other political pressures against the use of TRIPS flexibilities; lack of capacity to address anti-competitive practices and abuse of patent rights; and difficulties in accessing pricing and patent status information.

III.1 Lack of Technical Expertise to Incorporate and Implement TRIPS Flexibilities in National Law and Policy

The flexibilities afforded by TRIPS can only be utilized if they are incorporated into a country's domestic legislation. This is a first and necessary step in any attempt to use the flexibilities for public health purposes. It is therefore important that countries enact legislations that allow them full flexibility. However, many developing countries have not incorporated the TRIPS flexibilities into their laws for various reasons. What the TRIPS Agreement permits and what countries actually do are two different things. In the end, it is national law and practice that will be decisive, both in terms of providing access to medicines, and in establishing a domestic framework in which TRIPS rules will be interpreted. One major reason many developing countries have not incorporated TRIPS flexibilities into their national laws is lack of technical expertise.

Virtually all national patent systems of developing countries are modelled on European and United States patent laws. These are often based either upon colonial statutes or on laws crafted with the help of technical assistance from WIPO and the patent offices of developed countries.[38] Most of the technical assistance that has gone to these countries, however, is more concerned with compliance with the provisions relating to the rights of the patent holders rather than the application of flexibilities within the multilateral framework to promote and protect public health.[39]

Another problem that exacerbates the lack of technical expertise to implement TRIPS flexibilities in national laws is the inability to access information on best practices. Developing countries are generally not aware of the measures undertaken by their counterparts around the world. As a result, even countries within a region with similar or the same access problems adopt different strategies, with

[38] Love (2001).

[39] Balasubramaniam (2002).

varying degrees of success. More importantly, while most developed countries are quick to provide assistance and to give examples of best practices on how to protect patent rights, there is never a best practice guide or technical assistance, for example, on the extensive use by the United States of compulsory licensing or antitrust legislation to curb abuse of patent rights and serve other public interest purposes.[40]

The lack of expertise has also increased the likelihood that frivolous patents or even patents on excluded subject matter will be issued. Under the TRIPS Agreement, states may, for example, exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals as well as plants and animals other than micro-organisms and new uses of known products. These exceptions are rendered nugatory in the absence of expertise. In the Philippines, for example, patent examiners routinely rely on the issuance of United States or European patents as a precondition to the grant of a Philippine patent, notwithstanding the fact that Philippine patent law excludes certain subject matter that may be allowed under the United States and European patent laws such as business methods and computer programmes.

III.2 Insufficient Domestic Research and Manufacturing Capacities in the Pharmaceutical Sector

In many developing countries, there is insufficient research and pharmaceutical manufacturing capacities. With respect to research, the challenge for these countries is how to enlarge their capacity for research, for example, through increased investment in basic sciences, research and development (R&D) and technological innovation. In the 1990s, the Commission on Health Research for Devel-

[40] For further discussion on the use of compulsory licensing in the United States see Reichman and Hasenzahl (2003).

opment proposed that all governments allocate 2 per cent of health expenditure to research. The South Commission's report, in the same year, also pointed to the critical need for developing countries to increase R&D spending.[41] Lack of resources, however, means that very few developing countries can afford to devote more that 0.5 per cent of national income to health R&D.

As technology develops and becomes an important tool for development increasingly it is also becoming a means of competitive advantage. This raises the question of research standards for pharmaceutical research, manufacturing and quality. In this regard, the International Conference on Harmonisation (ICH) process raises particular difficulties for developing country research. While no one should seek lower quality medicines, diagnostics etc. there is need to guard against protectionist research and quality standard setting. The fiascos around generic HIV/AIDS drugs and quality and the WHO pre-qualification process have also demonstrated the problems that developing country companies face in this area. Developing countries face significant barriers that may block R&D based in developing countries or with the collaboration of developing countries.

Pharmaceutical manufacture includes all operations - purchasing of material, processing, production, packaging, quality control, release and storage of medicinal products and related control.[42] According to the United Nations Industrial and Development Organization (UNIDO) there are various categories of countries with respect to pharmaceutical manufacturing.[43] These include those that: 1) have no manufacturing facilities and are dependent on imported finished medicines; 2) package already formulated medicines and have small-scale local production of sterile or non-sterile formulations such as IV fluids; 3) make formulations of drugs in final dosage

[41] See South Commission (1990).

[42] Kaplan, W., et al. (2003), p. 16.

[43] See Balance, R., J. Pogany and H. Forstner (1992). Also see WTO Secretariat document IP/C/W/345.

form and engage in some production from imported intermediates; 4) engage in production from imported intermediates and manufacture of some intermediates from local materials; and 5) those that engage in production of active substances and processing to produce the required pharmaceutical dosage forms.

The production of pharmaceuticals requires many elements. Kaplan et al. in a recent literature survey identified various factors as general preconditions for economically viable domestic production of pharmaceuticals.[44] First, there should be a high ratio of domestic R&D to gross domestic product (GDP) since production in the pharmaceutical industry is technology-driven. The second factor is the size of the economy. This may enable a pharmaceutical firm to take advantage of domestic economies of scale and also provide an opportunity for product variation and improvement. The third factor relates to the income level in the domestic market. The fourth factor is availability of reliable local infrastructure and amenities at competitive prices. The fifth factor relates to policies that govern local production and their enforceability so as to ensure efficiency and reliability of the market. The final factor relates to the structure of trade barriers in the pharmaceutical industry. For example, a structure of tariff and non-tariff barriers that promotes investment in the local pharmaceutical industry can play an important role.

There is, however, no conclusive evidence that all these factors must exist for a country to produce pharmaceuticals nor is there clarity in the available literature on the relative importance of each of the identified factors or on how these factors change with the type of production in question. For example, different factors are likely to be at play depending on whether the production is low-end manufacture and repackaging or high-end manufacture and whether the production is for raw materials or final products. That said, the lack of

[44] See Kaplan et al. (2003), p. 17. Note, however, that this paper was aimed at identifying gaps in available information on global pharmaceutical manufacturing and consequently, only a research agenda - as opposed to evidence of the necessity of these factors for production - was identified.

manufacturing capacity negatively affects the ability of developing countries to use certain TRIPS flexibilities, such as compulsory licensing, for public health purposes.

III.3 Insufficient Technical and Infrastructural Capacities for Medicines Regulation

Another constraint on the use of TRIPS flexibilities is the insufficiency of technical and infrastructural capacities for the regulation of medicines. For example, countries normally require that all medicines offered for sale in their territories be locally registered. Many developing countries, however, lack the facilities and expertise needed to review the safety, efficacy and quality of drugs destined for their national markets, and remain dependent on foreign authorities to set the necessary standards and do the necessary testing. A 1993 study of 36 African countries conducted by the WHO found that only three had a "limited drug regulatory capacity". Not one African nation had what the WHO called a "comprehensive drug regulatory capacity".[45] One of the major challenges both within countries and within regions in the South therefore relates to medicines registration and regulation.

Regulatory approval processes raise a number of problems which affect the effectiveness with which TRIPS flexibilities can be used to improve availability and access to essential medicines. For example, the speed and efficiency of the procedure for the registration of medicines has important implications for the effectiveness of the early working exception. The slow speed of the registration process denies generic companies the benefits that the early working exception is supposed to provide.

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[45] Status of Drug Regulation and Drug Quality Assurance in WHO African Region and Selected Countries, WHO, March 1999, cited in Love (2001).

Another regulatory issue that arise relates to post-marketing surveillance. Lack of proper post-marketing surveillance, for example, makes it difficult for authorities to prove abusive behaviour by patent holders in the pharmaceutical market, thereby making compulsory licensing on this ground more difficult. Lack of advertising regulations can also be a problem for the use of TRIPS flexibilities. Aggressive misleading promotion and advertising of brands has been reported to have adverse effects as consumers become averse to generics. Efforts to promote generics in some countries such as Pakistan, Nigeria and the Philippines have revealed a poor public perception of lower-priced drugs.[46] Advertising regulations through mechanisms that set and enforce guidelines for drug promotion are thus needed to avoid advertisements that may be false, lacking in fair balance, or are otherwise misleading.

III.4 Difficulties in Establishing Efficient Pharmaceutical Management and Procurement Systems

Another challenge that faces developing countries in their efforts to improve availability and access to essential medicines relates to establishing efficient pharmaceutical management and procurement systems. Putting in place efficient management systems for pharmaceutical procurement can be a costly and complex process requiring vast resources and technical know-how. The problems can be particularly acute for small countries whose average drug prices are generally high due to lack of economies of scale. The cost of taking care of quality and supply chain issues is also high.

The lack of efficient and cost-effective management and procurement systems therefore has an effect on prices, on quality, on rational use of drugs as well as on availability of medicines generally. Consequently, the use of TRIPS flexibilities to improve avail-

[46] See Velasquez and Boulet (1999).

ability and access to medicines faces challenges due to lack of resources and technical expertise to administer efficient pharmaceutical management and procurement systems.

III.5 Bilateral and other TRIPS-plus Pressures

Compounding the problem of limited technical expertise to implement TRIPS flexibilities in many developing countries is the political pressure exerted on these countries to prevent them from using the flexibilities, or worse, to pressure them to enact "TRIPS-plus" legislation and measures. Political pressure can be either internal or external. Internal pressure generally comes from dominant multinational pharmaceutical companies operating in local markets directly or through their agents. These companies generally have vast resources which are used not just to lobby governments but also to conduct massive marketing campaigns aimed at undermining the exercise of TRIPS flexibilities.[47] For example, a statement on the website of the pharmaceutical industry association claims that "independent studies have shown that claims that patents are a barrier to access to medicines are unfounded and inaccurate".[48]

But more often than not, the political pressure is external, emanating from developed country governments, particularly the United States government. Such pressure takes various forms. One form is bilateral trade agreements that have intellectual property components. For example, both Vietnam and Cambodia entered into bilateral trade agreements with the United States that contains intellectual property requirements including compliance with TRIPS

[47] For a flavour of what these companies tell countries see the website of the pharmaceutical industry association whose South African branch had sued the South African government over the use of TRIPS flexibilities http://www.ifpma.org/Issues/issues_intell.aspx.

[48] Idem.

standards when these countries were not members of the WTO.[49] Thus, both Vietnam and Cambodia provide that any compulsory licence issued shall be used predominantly for the domestic market.[50,51] A more recent example is the agreement between the United States and the Central American Countries which, among other things, includes provisions for the extension of patent term to compensate for delays, limits the grounds for revoking patents, and introduces rules for pharmaceutical and agricultural chemicals market exclusivity and test data protection that go way beyond the TRIPS requirements.

The second form of pressure is unilateral trade pressures such as under Section 301 of the United States Trade Act.[52] In the case of medicines, the office of the United States Trade Representative (USTR) bases its assessment and grading on information supplied by the pharmaceutical industry.[53] Countries such as Argentina, Brazil, China, Colombia, Egypt, Hungary and India were on the 2001 Spe-

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[49] Item Nos. 1 and 2, Questionnaire on Intellectual Property Protection in Vietnam and Cambodia, answered by Le and Le Intellectual Property Attorneys, 8 April 2003.

[50] Item 6(d), Questionnaire on Intellectual Property Protection in Vietnam, answered by Le and Le Intellectual Property Attorneys, 8 April 2003.

[51] Items 6(d) and 6(g), Questionnaire on Intellectual Property Protection in Cambodia, answered by Le and Le Intellectual Property Attorneys, 8 April 2003.

[52] Although, the U.S. can not impose sanctions on the basis of this section without a WTO ruling, Special Section 301 provisions deal with the protection of intellectual property rights abroad and provide for a range of country listings, remedies and possible investigations to "persuade" other nations to yield to U.S. demands and views. The range of country listings includes a "Priority Foreign Country List", a "Priority Watch List", a "Watch List" and a "Special-Mention Category", with each listing triggering a particular course of investigation and possible remedies or actions. For further discussion see Vivas-Eugui (2003), p. 7.

[53] Bailey (2001).

cial 301 Priority Watch List for reasons relating to pharmaceuticals and patent protection.[54]

The third form of external pressure is the threat of filing a complaint at the WTO. Argentina and Brazil are the most recent targets of this mode of TRIPS-plus pressure. Although the United States Government subsequently withdrew its WTO complaint against Brazil's "local working" requirement due to adverse public opinion, it has continued to pressure Brazil through bilateral channels. The United States Government uses these mechanisms to push developing countries into enacting TRIPS-plus legislation, or to discontinue the exercise of TRIPS flexibilities. It requires a significant level of political and economic clout for individual governments to resist the pressure.[55]

III.6 Difficulties in Tackling Anti-Competitive Practices and Abuse of Intellectual Property Rights

Lack of competition is central to the problem of access to medicines. Competition regulation is required to curb the unchecked exercise of market power which, in the context of patents, may be defined as attempts to extend exploitation of a patent beyond the boundaries provided by intellectual property rights.[56] Such patent abuses include monopoly pricing which limits access, especially among the poor; non-price predation, whereby intellectual property rights are used to bring bad-faith litigation and opposition proceedings in order to exclude and harass competitors; the acquisition and strategic use of patent portfolios to prevent competition by similar but non-infringing

[54] 2001 Special 301 Report, available at http://www.ustr.gov/reports/2002/special301-report.PDF, visited on 22 September 2003.

[55] See Okediji (2004).

[56] Lahouel and Maskus (1999), p. 23.

products; and the continued blurring of the lines between invention and discovery.[57,58]

Despite the continued increase in patent protection in developing countries, and while article 40 of TRIPS permits countries to use competition measures subject to permitting opportunities for administrative review and bilateral consultations to deal with abusive behaviour, very few developing and least developed countries have adequate competition. Moreover, the prohibitive costs of patent litigation and of administering a patent and competition system present a substantial barrier to obtaining timely and just resolutions of disputes over patent validity or abuses of patent rights. The lack of adequate competition policies and enforcement mechanisms has the effect of undermining the potential for the use of TRIPS flexibilities. This means that developing countries will not be able to use the flexibilities in TRIPS that allow them to use competition law to prevent abuse of patent rights and thereby improve access to essential medicines.

An additional problem closely related to anti-competitive practices and abuse of patent and related rights is that of information asymmetries. While local companies in developing countries with a pharmaceutical manufacturing base can manufacture unpatented products without having to resort to compulsory licensing, there is no ready or easily accessible information on what drugs are patented in which country. This lack of information discourages local companies from manufacturing drugs for fear of lawsuits from patent holders who are generally overzealous in litigating even invalid patents. One illustration of the problems posed by lack of information is the blockage of generic production in Thailand of ddI, a drug for HIV/AIDS. Bristol-Myers Squibb (BMS) was able to obtain patents for formulation claims in Thailand when the same had been rejected by the United States Patent and Trademark Office (USPTO).

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[57] Lahouel and Maskus (1999), p. 25.

[58] Vivas-Eugui (2003), p. 21.

It may also be noted that in small national markets, no substantial financial incentives exist for generic drug companies to challenge bad patents, unlike in the United States, Japan and European markets. It is thus predictable that a considerable number of patents in developing countries will be bad, because the countries or competitors will not have the capacity or economic incentives to evaluate and litigate overreaching patent claims. Lack of information on patent status and pricing information also adversely affects the decisions and effectiveness of procurement agencies.

IV. Overcoming Constraints in the use of TRIPS Flexibilities through South-South Regional Frameworks

The constraints on national efforts to implement the TRIPS flexibilities in a public-health sensitive way demonstrate that developing countries need significant additional resources and technical inputs to take maximum advantage of the flexibilities. An important avenue for providing such support is through regional mechanisms that can complement the national efforts. Public health is a shared concern in all the developing regions of the world and is an area that has been identified as deserving of cooperation in virtually all RECs in the South. A regional approach to use the TRIPS flexibilities is therefore a logical and beneficial approach and can provide creative solutions founded on common purpose, cooperation, collaboration, and collective action. Politically, a collective regional position on matters of public health and access to medicines can provide much needed bargaining leverage for developing countries in their dealings with developed trading partners. Regional collaboration can also facilitate the sharing of information among countries as well as the pooling of resources and expertise for activities such as procurement.

From an economic and public health standpoint, a regional approach can provide incentives for establishing or developing regional pharmaceutical production and help expand research capabilities. In addition, higher effective demand for the same medicines due to climatic conditions and other geographical reasons, as well as cultural aspects, will result in lower consumer drug prices due to increased economies of scale in procurement and distribution. Other important benefits include: the costs associated with adapting medicines to the region may be offset/lowered due to increased economies of scale; stronger local technological capacities/domestic innovation resulting from the pooling of adequate resources including financing, and human capital and physical capital will be stimulated. Finally, a re-

gional approach can also help to improve cross-border disease control.

IV.1 Relevant Regional Frameworks

Regional cooperation among developing countries for public health and other purposes can take various forms ranging from mechanisms that bring together countries within the same geographical region, to models that cut across the various regions. The main form of cooperation, which is evident in all the regions of the South with established institutional structures, relates to regional economic integration schemes and related frameworks. While this is the main framework in which a regional approach to the use of TRIPS flexibilities can be implemented, there are other forms of South-South cooperation mechanisms that might also bring advantages such as regional health organizations. Examples include the Commonwealth Regional Health Community Secretariat in Eastern and Southern Africa, the African Association of Central Medical Stores for Generic Essential Drugs (ACAME) for French-speaking West African Countries and the Organization of Eastern Caribbean States (OECS) in the Caribbean.

Regional economic integration as an idea and means of achieving economic growth and development is common to all the developing regions of the world. In Africa, the region embraced regional integration as a central element of its development strategy from the early days of independence as reflected in the creation of the Organization of African Unity (OAU). The fragmentation of the continent into a large number of nation states with scant economic underpinnings, and the small size and primary production structure of most African economies provided a powerful basis for African countries to pursue mutually beneficial economic cooperation and regional integration. The desire to overcome the economic disadvantages of fragmentation gave rise to the establishment of a large number of

regional groupings with the objective of creating self-reliant development of African countries.

Regional integration was therefore viewed as a vehicle towards industrialization with dynamic neighbourhood effects and regional spillovers.[59] It was also seen as offering opportunities leading to market expansion, economies of scale and diversification of the economic base. Other perceived benefits included efficiency through competition, stronger voice in the international arena, breaking the power of national interest groups and policy credibility. In addition to the economic motivations, aspirations for identity, unity and coherence also influenced the early drives for regional integration in Africa and the desire for regional economic cooperation as the building blocks for continental cooperation and economic development.

However, despite the enthusiasm for and the creation of a large number of regional economic groupings, African economies continued to be constrained by political boundaries, marginalized and un-integrated in the world economy.[60] Responding to the rather poor outcomes of the early integration processes, African countries started showing renewed interest in developing appropriate frameworks for integration in order to realize the benefits of enlarged markets with the attendant opportunities for economic transformation, growth and sustainable development with the signing of the Treaty establishing the African Economic Community (AEC) in 1991.[61]

Current integration initiatives in Africa build on earlier institutions while broadening the objectives of the economic cooperation and regional integration to include and emphasize the coordination and harmonization of macroeconomic policies; the lowering of trade

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[59] See African Development Bank (ADB) and African Development Fund (ADF) (2000).

[60] Idem.

[61] The Treaty was signed on 3 June 1991 in Abuja, Nigeria. For the full text see 30 I.L.M 1241.

tariffs and removal of non-tariff barriers; the facilitation of capital mobility and the free movement of persons. In addition, the new economic integration schemes are paying more attention to cross-cutting development issues such as those related to health and education. Today, there are over ten regional economic communities in Africa with the major ones being: the Common Market for Eastern and Southern Africa (COMESA); the Southern African Development Community (SADC); the Economic Community of West African States (ECOWAS) and the East African Community (EAC).[62] Box 1 below contains an overview of these RECs.

BOX 1
REGIONAL INTEGRATION IN AFRICA

COMESA: This Common Market was created in 1995, succeeding the Preferential Trade Area (PTA) framework that had been established in 1981. Headquartered in Lusaka, Zambia, it consists of 20 countries: Angola, Burundi, Comoros, D.R Congo, Djibouti, Egypt, Eritrea, Ethiopia, Kenya, Madagascar, Malawi, Mauritius, Namibia, Rwanda, Seychelles, Sudan, Swaziland, Uganda, Zambia and Zimbabwe. COMESA was established with five main aims and objectives. These are: to attain sustainable growth and development of Member States by promoting a more balanced and harmonious development of its production and marketing structures; to promote joint development in all fields of economic activity and joint adoption of macroeconomic policies and programmes to raise the standard of living of its people; to cooperate in the creation of an enabling environment for foreign, cross-border and domestic investment including joint promotion of research and adaptation of science and technology for development; to cooperate in the promotion of peace, security and stability in order to enhance economic

[62] Other groupings include: the Central African Economic and Monetary Community (CEMAC); the South Africa Customs Union (SACU); the West African Economic and Monetary Union (UEMOA); and the Arab Maghreb Union (AMU).

development in the region; to cooperate in strengthening the relations between the Common Market and the rest of the world; and to contribute towards the establishment, progress and the realization of the objectives of the AEC.

To achieve these aims, the COMESA Treaty envisages cooperation in six main areas, namely, trade liberalization and customs, transport and communications, industry and energy, monetary affairs and finance, agriculture and in the field of economic and social development. The integration process under COMESA is hoped to result in the lowering or elimination of interregional tariffs, removal of non-tariff barriers, movement towards a common external tariff and rules of origin and cooperation in monetary and financial matters, coordination of macroeconomic policies, free movement of persons, goods, capital and services and towards a common currency.

SADC: SADC succeeded the Southern African Development Coordination Conference in 1992, to bring about economic development and regional integration. The original organization was founded in 1980 by the Frontline States to advance regional cooperation in addition to the objective of putting political pressure on the then apartheid government in South Africa. The SADC Treaty was signed on 17 August 1992 in Windhoek, Namibia. Today the organization has 14 members: Angola, Botswana, D.R. Congo, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe. SADC was created to advance a number of objectives including: to promote sustainable and equitable economic growth and socioeconomic development that will ensure poverty alleviation with the ultimate objective of its eradication, enhance the standard and quality of life of the people of Southern Africa and support the socially disadvantaged through regional integration; to promote common political values, systems and other shared values which are transmitted through institutions which are democratic, legitimate, and effective; to consolidate, defend and maintain democracy, peace, security and stability; and to promote self-sustaining development on the basis of collective self-reliance, and the interdependence of Member States.

ECOWAS: The Treaty establishing ECOWAS was signed in Lagos, Nigeria in 1975. In July 1993 a revised ECOWAS Treaty was signed with the aim of accelerating economic integration and increasing political cooperation. The Member States of ECOWAS are: Benin, Burkina Faso, Cape Verde, Cote d'Ivoire, The Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone and Togo. ECOWAS was established with the aim of promoting cooperation and integration, leading to the establishment of an economic union in West Africa in order to raise the living standards of its peoples, and to maintain and enhance economic stability, foster relations among Member States and contribute to the progress and development of the African Continent.

EAC: The EAC was re-established in 1999, 12 years after the collapse of the original East African Community in 1977. The main reasons contributing to the dissolution of the earlier regional arrangement was the lack of strong political will, lack of participation by the private sector and civil society, the continued disproportionate sharing of benefits of the Community and lack of adequate policies to address the latter problem in particular. The Treaty establishing the EAC was signed on 30 November 1999 in Arusha, Tanzania. The Members of the EAC are Kenya, Tanzania and Uganda. The Treaty sets out the objectives of the EAC as, developing policies and programmes aimed at widening and deepening cooperation among the Partner States in political, economic, social and cultural fields, research and technology, defence, security and legal and judicial affairs for their mutual benefit. In this regard, the Treaty envisions the creation of a customs union, a common market, subsequently a monetary union and ultimately a political federation.

In Latin America and the Caribbean, regional integration has also been a long running theme. During the 1960s, the Latin American Free Trade Association (LAFTA), comprising the South American Countries and Mexico, and the Central American Common Market (CACM) were officially launched. The Andean Group was founded

in 1969 and the Caribbean Community (CARICOM) established in 1973. While these agreements experienced some success, by the second half of the 1970s all of them were in difficulty, falling into open crisis in the 1980s. The original central objective of these agreements, considered today as "old regionalism", was to support the prevailing state-led import substitution industrialization model of development. The basic strategy was based on a model of development that emphasized increasing private and public investment in manufacturing and infrastructure in order to overcome dependence on exports of primary commodities. Trade discrimination had the objective of fostering domestic industrialization. By extending markets and eventually allowing the benefits of economies of scale and specialization to be reaped, regional integration was supposed to provide social development in member countries.

The new preferential trade arrangements in the region, which were relaunched in the 1990s, referred to as "new regionalism"; display a number of distinctive features as compared to the past.[63] The background against which preferential trade arrangements were revived throughout Latin American differed sharply from that of previous decades. In contrast to the goal of protecting domestic markets in order to benefit from economies of scale and specialization, the new focus of preferential liberalization was on improving and securing market access, and upon enhancing the attractiveness of different locations to foreign investment. The central features of 'the new regionalism' therefore include an opening to world markets, promotion of private sector initiative, and reinforcing competition in the international markets. Consequently, in addition to the earlier integration schemes, a new integration process emerged, by way of the Common Southern Market (MERCOSUR) in 1991 between Brazil, Argentina, Paraguay and Uruguay. Today, the main regional economic communities in Latin America and the Caribbean therefore include the Andean Community, MERCOSUR, CARICOM, and CACM. Box 2 below contains an overview of these integration schemes.

[63] See Bouzas and Ros (1994).

BOX 2
REGIONAL INTEGRATION IN LATIN AMERICA AND THE CARIBBEAN

The Andean Community: The Andean Community which came into being with the signing of the Cartagena Agreement in 1969 is one of the oldest RECs in the Western Hemisphere. Its explicit aim has always been the creation of an economic union, and from the beginning, the group has maintained a substantial institutional structure. After some initial success, the Community endured difficult years in the late 1970s and 1980s. The integration process was revitalized and transformed in the 1990s when group members Bolivia, Colombia, Ecuador, Peru and Venezuela reached a greater consensus towards liberal economic policy reforms. Guided by the Strategic Plan for the Reorganization of the Andean Group (1989), the Community established a four-country free trade area in 1993 and a partial customs union between three members (Colombia, Ecuador and Venezuela) two years later. Peru agreed, in 1997, to full integration into the Andean free trade area by 2005. The purpose of the revitalized system is to ensure the effective coordination between the bodies and institutions that compose it, in order to deepen Andean subregional integration, to promote its external presence and to consolidate and strengthen actions related to the integration process.

Under the Cartagena Agreement member countries commit themselves to implementing a Common External Tariff that must provide adequate levels of protection in favour of subregional production, taking into account the Agreement's objective of gradually harmonizing the different economic policies of the Member Countries. The component on 'harmonization of economic policies and coordination of development plans' establishes that member countries shall progressively adopt a strategy for the achievement of the subregional development objectives. They shall coordinate their development plans in specific sectors and will gradually harmonize their economic and social policies, with the objective of achieving an integrated development of the area, through planned actions.

MERCOSUR: The Treaty establishing MERCOSUR, the largest economic group in Latin America and the Caribbean, was signed in March, 1991 by Argentina, Brazil, Paraguay and Uruguay. MERCOSUR constitutes a "deeper" integration between four of the 11 parties of the Latin American Integration Association (LAIA). The integrated market represents around 45 per cent of Latin American population, 60 per cent of total land area, and over 50 per cent of the region's gross domestic product (GDP). As its name implies, the group's ultimate aim is a common market where the free movement of goods, services, capital and people is complemented by a common external tariff and close policy cooperation among its member countries. Beyond developing its internal integration project, MERCOSUR has sought to widen its membership, admitting Chile as an associate member in 1996 and Bolivia in 1997. Agreements with both of these countries are based on pre-existing accords but are relatively far-reaching, involving the virtual elimination of tariffs on trade in goods as well as provisions on issues such as services, investment and double taxation, and sanitary and phytosanitary measures. Free trade negotiations between MERCOSUR and the ANDEAN Community, Mexico, and Peru, are also underway.

The process, as planned, entails five broad steps, namely, the elimination of customs duties and non-tariff barriers to the circulation of goods and services, establishment of a common external tariff and common external trade policy, liberalization of factor movements in the Community, coordination of macroeconomic and sectorial policies of member countries and harmonization of laws in order to strengthen the integration process. The main objective of MERCOSUR is to achieve a free trade area in goods, the first step towards a common market. Consequently, MERCOSUR´s founding treaty established a programme of automatic and across-the-board elimination of import duties between 1991 and 1994. Most tariffs were dismantled, with the majority of intraregional trade facing zero duties since 1995. With the free trade area largely in place, a common external tariff structure ranging from zero to 20 per cent was introduced in January 1995. The simple average MFN tariff for the trade bloc declined from 41 percent in 1986 to just below 13 percent in 1999.

CARICOM: The Caribbean countries consist of very small economies, many of which are microstates, the smallest being Montserrat. The first integration measures, in 1968, took the form of lowering tariffs and quantitative restrictions. In the 1970s, intraregional trade expanded steadily and stimulated interest in moving from a free trade area to a customs union. Consequently, CARICOM was established by the Treaty of Chaguaramas, in 1973. Initial membership included twelve English –speaking countries- Antigua and Barbuda, The Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Jamaica, St. Kitts & Nevis, St. Lucia, St. Vincent & Grenadines, and Trinidad & Tobago- and the dependent territory of Montserrat. Surinam joined CARICOM in 1995 and Haiti in 2000. Despite its large membership, CARICOM is the smallest regional integration scheme in the Western Hemisphere; the group's combined GDP is less than US$ 20 billion, its population just 6 million. Because of their small size, CARICOM Member States are acutely aware of the benefits of regional integration and cooperation, and have shown growing dynamism in recent years in terms of joint policy formulation, coordination and commitment towards their integration project.

CARICOM was established with a three-fold objective: to foster economic integration among its Member States' by creating a common market; to strengthen the region's external position through the coordination of Member States foreign policies; and to pool scarce resources through functional cooperation in a variety of areas related to socio-economic development. The broad objectives of CARICOM are therefore to promote economic development, which was viewed as possible only if the degree of external dependence was reduced and some measure of economic sovereignty was reclaimed. The process of economic development necessarily involved structural transformation by industrialization, which would be made more viable by the increased size of the regional market and the efficiency generated by attaining economies of scale. Like the other integration processes, CARICOM experienced relative stagnation during the 1980s. Since the early 1990s, however, Member States have actively sought to revitalize their regional links, both by deepening their existing integration scheme and by expanding it to include new members.

The Central American Common Market (CACM): CACM was one of four regional economic integration organizations created during the Latin American export boom of the 1960s. It was established by Guatemala, Honduras, El Salvador, and Nicaragua (and later joined by Costa Rica) with the signing of the General Treaty of Central American Economic Integration in Managua on 15 December 1960. In a move unprecedented in Latin America and the Caribbean at the time, 95 per cent of intraregional trade was liberalised within a few years according to an automatic and set schedule, and in the decade that followed an imperfect union was created. The strong initial dynamism of the CACM was undermined, however, by internal imbalances, external debt crisis and the political crisis in the 1980s.

In terms of objectives, the Managua Treaty incorporated the commitment to establish a common market in five years since the signing of the Treaty. The Member States also agreed to create a free trade area and to constitute a custom union through a common external tariff. During the 1960s and 1970s, the CACM had a significant positive impact on trade flows in Central America. In addition to the protection afforded to consumer goods production by the common external tariff on consumer imports, CACM Member States also promoted investment in industry by introducing generous tax incentives and exemptions for new and existing industrial firms. Despite the considerable expansion of intraregional trade and investment in the 1960s, the main objectives of the Managua Treaty were, however, not fulfilled. By the end of the decade, the region had neither achieved the custom union, the common market, nor the balanced industrial growth. In the early 1990s, after a prolonged period of stagnation, Central American countries began a process of reviving their regional integration scheme. In 1993, with the signing of the Protocol of Guatemala modifying the original founding treaty, CACM member countries adopted a new framework for regional cooperation.

Regionalism in Asia, on the other hand, is relatively new as compared to Africa, Latin America and the Caribbean. The concept only gained momentum in the late 20th Century mainly as a result of po-

litical and security considerations.[64] Asian regionalism therefore began from political and security considerations before extending to other areas of cooperation such as economic integration. Its development has been accompanied by a deep ambiguity with respect to questions relating to the territorial reach of "Asia" and varying characterizations thereof (e.g., "Pacific Asia", "East Asia", "Central Asia", "South Asia", "Southeast Asia"), the objective existence of *de facto* economic spaces, and the values (both cultural and economic) and identities embodied in the idea of "Asia".[65] As a result of these debates, and owing to the great diversities in history, religion, ethnicity, culture, language, and values among Asian countries, Asian regional economic integration has developed along a pluralistic line, with the proliferation of rival organizational expressions of regionalism[66] but no single dominant organization across the continent.[67]

Regional organizations in Asia are therefore more loosely institutionalized and have not involved the creation of separate supranational institutions. The provisions of preferential trade agreements are generally implemented on a subregional level in accordance with commonly agreed standards, and dispute settlement mechanisms tend to be based on bilateral negotiations. In addition, notwithstanding the existing Asian regional organizations and preferential trade agreements, there has been a proliferation of bilateral trade agreements between Asian countries and their non-Asian counterparts in recent years. For example, Vietnam and Cambodia have trade agreements with the United States. Other countries such as the Philippines as well as Thailand are currently discussing and or studying proposals on bilateral free trade agreements. In the context of this study, the

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[64] Yang (2002).

[65] Rosamond (2003).

[66] These regional groupings include the ASEAN, SAARC, Asia Pacific Economic Cooperation (APEC), the ASEAN Regional Forum ("ARF"), the East ASEAN Growth Area ("EAGA"), and the Commonwealth of Independent States ("CIS").

[67] Rosamond (2003), p. 128

relevant regional groupings in Asia are the Association of Southeast Asian Nations (ASEAN) and the South Asian Association for Regional Cooperation (SAARC). Box 3 below contains an overview of both organizations.

BOX 3
REGIONAL INTEGRATION IN ASIA

ASEAN: ASEAN consists of ten south-east Asian countries, namely, Brunei, Malaysia, Thailand, Singapore, Indonesia, the Philippines, Vietnam, Cambodia, Laos, and Myanmar. ASEAN has a combined population of approximately 500 million people covering a total area of 4.5 million square kilometres. Established on 8 August 1967 in Bangkok, Thailand with the signing of the "ASEAN Declaration," also known as the "Bangkok Declaration," ASEAN was founded primarily for political and economic reasons. The main aims underlying the creation of the Association under the Bangkok Declaration include to: accelerate the economic growth, social progress and cultural development in the region through joint endeavours in the spirit of equality and partnership in order to strengthen the foundation for a prosperous and peaceful community of south-east Asian nations; and to promote regional peace and stability through abiding respect for justice and the rule of law in the relationship among countries in the region and adherence to the principles of the United Nations Charter.

Other aims include to: promote active collaboration and mutual assistance on matters of common interest in the economic, social, cultural, technical, scientific and administrative fields; provide assistance to each other in the form of training and research facilities in the educational, professional, technical and administrative spheres; collaborate more effectively for the greater utilization of their agriculture and industries, the expansion of their trade, including the study of the problems of international commodity trade, the improvement of their transportation and communications facilities and the raising of the living standards of their peoples; promote south-east Asian studies; and to maintain close and beneficial cooperation with existing international and regional organizations with similar aims and purposes.

ASEAN remained basically inert until political cooperation was formally accepted by the five founding members in 1976 during the Bali Summit, when the Treaty of Amity and Cooperation in Southeast Asia, the Declaration of ASEAN Concord, and the Agreement for the Establishment of the ASEAN Secretariat were signed. The main areas of cooperation are in economic and industrial matters in addition to cooperation in research and development, technology transfer and other economic-related areas.

SAARC: SAARC was established in 1985 with the adoption of its Charter by its seven South Asian member countries, namely, Bangladesh, Bhutan, India, the Maldives, Nepal, Pakistan, and Sri Lanka. SAARC's objectives include the acceleration of economic growth, social progress and cultural development in the region; promotion of active collaboration and mutual assistance in the economic, social, cultural, technical and scientific fields; and strengthening of cooperation among the Member States in international fora on matters of common interest. Of these objectives, economic cooperation is deemed as the inevitable imperative for promoting all-round development of the region, and is the field of cooperation which has gained considerable momentum within the association.

In 1995, the SAARC Preferential Trading Arrangement (SAPTA) formally came into operation. SAPTA reflected the desire of the SAARC member countries to promote and sustain mutual trade and economic cooperation within the SAARC region through exchange of concessions. SAPTA was likewise envisaged to be the first step towards the transition to a South Asian Free Trade Area (SAFTA), to lead subsequently towards a Customs Union, Common Market, and Economic Union.

From the above review of regional frameworks, it is clear that regional economic integration schemes between developing countries in the same region cover much more than trade. For example, the AEC Treaty has as one of its objectives the promotion of cooperation in "all fields of human endeavour" while the 1967 Bangkok Declaration establishing ASEAN provides for "active collaboration and mu-

tual assistance on matters of common interest in economic, social, cultural, technical, scientific and administrative fields".[68] In the context of developing countries, RECs can also be seen as a part of nation building such as the phenomenon of the *Zollverein* in the 19th Century.[69] The RECs, considered together with regional health organizations, in particular, provide a solid institutional and legislative framework for cooperation in matters of health and the use of TRIPS flexibilities.

IV.2 Regional Approaches to Use of TRIPS flexibilities for Public Health

There are a number of measures that can be taken by developing countries at the regional level to overcome the constraints that they face at the national level in using TRIPS flexibilities for public health purposes. These include measures that are aimed at operationalizing the TRIPS flexibilities themselves as well as measures aimed at tackling the challenges in relation to supporting legal and other policy areas.

IV.2.1 Developing Local Technical Expertise on the Use of TRIPS Flexibilities

Regional cooperation in developing local expertise in intellectual property and development matters and in the use of flexibilities, in particular, has an important role to play. Such an approach is promising as it would benefit from pooling of financial, human and other resources that currently exist in each country. For example, the experience of South Africa in dealing with the case against the Government of South Africa by pharmaceutical companies, the pressure

[68] See Article 4(c) of the AEC Treaty, 30 I.L.M 124*;* 1991.

[69] See Venables (2000).

from the United States Government and the recent decision by its competition commission against two pharmaceutical companies on competition grounds could benefit many other countries in the region if it was widely shared. Access to information through sharing of expertise and best practices can empower countries to take a more determined position on public health and access to medicines issues.

There are two possible models of regional cooperation that could be considered as a vehicle for developing local expertise in intellectual property matters generally, health-related research and innovation and, in particular, the use of TRIPS flexibilities. The first approach is where intellectual property issues are dealt with as a component of the broad regional economic integration and related processes. This approach has most commonly been adopted among the RECs in Latin America and the Caribbean region.[70] The best example of this approach where members of a REC have attempted to work together on incorporating TRIPS flexibilities is the Andean Community (See Box 4).

Under this scenario, the REC or other regional body would establish within its secretariat, a division to help the Member countries address matters of intellectual property and, in particular, assist them in training and research and act as a forum for discussion and exchange of information on the best practices on the use of TRIPS flexibilities. The mechanism would also help the Member countries draw on each others expertise and experience in the use of the flexibilities. RECs like COMESA have already been carrying out studies and responding to Member States' requests for assistance on the use of TRIPS flexibilities and on negotiations in the WTO. While there may be a number of such activities ongoing in various RECs there is need to develop a more institutionalized approach.

[70] For example, the Andean Community has adopted various decisions dealing with intellectual property.

BOX 4
THE ANDEAN COMMUNITY'S COMMON APPROACH TO THE USE OF TRIPS FLEXIBILITIES

Decision 486 on Industrial Intellectual Property which covers patents, industrial designs and trademarks provides the legal basis in the Community for dealing with compulsory licences, parallel imports, research exception, patentability and data protection.

A. Compulsory licensing

The Decision is closely modelled on article 31 of the TRIPS Agreement. The relevant provisions include: article 65 (cases of "public interest, emergency or national security"); article 66 (practices that "adversely affect free competition"); article 67 (cases of dependent patents); and, article 68 (conditions for granting compulsory licences). Unlike previous Andean Community law, Decision 486 does not establish a local working obligation. It only provides that a patent may not be subject to a compulsory licence if the protected product is imported "in a manner sufficient to meet the needs of the market." Situations relating to practices that adversely affect free competition are dealt with by allowing the competent national office, after having obtained the consent of the national antitrust authority, to grant compulsory licences where practices are determined to be detrimental to the exercise of free competition. This is especially so in cases where such practices constitute an abuse by the patent holder of a dominant position in the market.

B. Parallel imports and exhaustion of rights

The Decision incorporates the principle of international exhaustion of rights. It is, however, interesting to note that the principle of international exhaustion of rights, as provided for in the Decision, is narrower than under the previous regime which existed before the implementation of the TRIPS Agreement. Under the earlier regime, the rule was that the patent owner could not prevent the importation of a patented product "put into the market in any country, with the consent of the owner of the patent, a licensee or any other person author-

ized therefore") meant that the *consent* of the patent owner was not a condition for the application of the international exhaustion of rights, thereby allowing the parallel importation from a compulsory licensee abroad. Decision 486, on the other hand, adopts "the express consent theory" as the basis of the international exhaustion principle.

The application of the "express consent theory" may go too far and make illegal the parallel importation from even a voluntary licensee if the latter was not authorized by the patent holder, under the licence agreement, to export in general or to particular countries. Decision 486 therefore only presumes the patent holder's consent where the parallel exporter is "economically associated" to the former. Such a literal interpretation of the relevant article, article 54, would seem to exclude the legality of parallel imports from independent compulsory licensees.

C. Research and the early working exceptions

Decision 486 contemplates exceptions where the patent holder may not exercise the rights conferred. This include cases where the relevant acts were: carried out in a private circle and for non-commercial purposes; carried out exclusively to experiment with the subject matter of the patented invention; and carried out exclusively for the purposes of teaching or scientific or academic research. Hence, while Decision 486 includes an explicit research exception, it does not include an explicit "early working exception". It is uncertain the extent to which the experimentation exception could be judicially interpreted to allow the initiation of procedures for the approval of generic drugs before the expiry of the patent.

D. Test data protection

In relation to the protection of test data, the Decision includes, under the rubric of "intellectual property- linked trade practices", some important provisions. Article 261 of the Decision provides that information provided to any authority or disclosed pursuant to legal requirements by the person in lawful possession of it shall not be considered public property if that person supplies the information for the

purpose of obtaining licences, permits, authorizations, registrations, or any other legal purposes. With regard to the information provided as a condition for approving chemical products, the Decision literally incorporates article 39(2) and 39(3) of the TRIPS Agreement.

The Decision therefore only grants protection against "unfair commercial use" of confidential data. This means that a third party could be prevented from using the results of the test undertaken by another company as background for an independent submission for marketing approval, if the data had been acquired through dishonest commercial practices. However, the Decision does permit a national competent authority to rely on data in its possession to assess a second and further application, relating to the same drug, since this would not amount to "unfair commercial use".

The mechanism can be institutionalized through the establishment in the region of a high-level Permanent Advisory Council on Trade-Related Innovation Policies (ACTRIPS) or a functionally equivalent mechanism.[71] The ACTRIPS or its equivalent would become the focal point within the structure of the REC or other regional body for policy-making about the integration into domestic law of TRIPS flexibilities and adapting these flexibilities to evolving international legal standards in the context of a broader innovation policy. The ACTRIPS would not duplicate the activities of national or regional intellectual property offices and would ideally play a supervisory and policy-making role that requires inputs from intellectual property offices but that locates such inputs within a broader policy-making process for the countries of the region.

[71] The original proposal for the ACTRIPS mechanism was first advanced in Reichman, Watal and Okediji (2000). See also Reichman (2003) and Musungu and Dutfield (2003). Note that the ACTRIPS would be about innovation policies and not just intellectual property which is only one part of innovation issues.

This mechanism, apart from coordinating such issues as training, information exchange and other related activities, would also be important in coordinating regional positions on TRIPS flexibilities and other matters of common concern and enabling consensus building on these issues for future intellectual property negotiations. Such a regional structure could also play an oversight and supervisory role for regional intellectual property organizations such as the African Intellectual Property Organization (OAPI) and the African Regional Intellectual Property Organization (ARIPO). Establishing ACTRIPS at the regional level will therefore, if appropriately implemented, empower developing countries to maximize the benefits of intellectual property while reducing the social and economic costs of existing international legal obligations.

This would also help these countries position themselves to contribute to the future development of suitable international legal norms affecting the use of the flexibilities for public health purposes, national innovation systems and policies. Furthermore, the regional mechanism could serve to institutionalize a broad-based coalition from the member countries focusing on both existing and new issues, monitor developments in different fora, including WIPO and the WTO, and serve as a vehicle for rapidly responding to TRIPS-plus pressures in an ongoing and systematic fashion. Finally, the ACTRIPS would make it possible for governments to continue to receive technical assistance from varied sources and process inputs from such assistance in a more systematic fashion ensuring continuity and that such assistance does not undermine the use of TRIPS flexibilities for public health purposes.

As the case of the Andean Community shows, however, this type of mechanism should not be used as a vehicle for harmonizing intellectual property standards generally or with respect to the use of flexibilities. Attempts at complete harmonization in the approach to the use of TRIPS flexibilities may be problematic since different countries in the region could have different needs. Consequently, this mechanism is likely to work better where expertise is developed through training, research, exchange of information and sharing of best practices in the use of flexibilities at the regional level, but each

country is allowed the space to frame the actual flexibilities and their use to suit its specific needs. This coordinated but non-harmonizing approach is also less likely to encounter political and institutional resistance from the individual countries.

The second model of regional cooperation on intellectual property matters is where regional intellectual property organizations are established as independent organizations with no linkage to regional economic and development organizations. This scenario obtains mostly in Africa in the form of OAPI and ARIPO (See Box 5). While this model could help to develop expertise in such matters as patent examination and related issues, it is unlikely to offer a viable forum for developing local expertise on the use of TRIPS flexibilities for public health and related purposes. The main reason for this is the tendency of these types of organizations towards harmonization as opposed to coordination. OAPI which constitutes a single regional patent system, for example, harmonized the rules on compulsory licensing by requiring that no compulsory licence can be issued before the expiry of three years from the date the patent was issued or four years from the date of application.[72] The Agreement (commonly called the Bangui Agreement) also provides that compulsory licences do not extend to acts of importation[73] which defeats the whole purpose, for example, of paragraph six negotiations. This goes beyond the requirements of TRIPS and therefore has the effect of limiting the powers of the Member States to use compulsory licensing.

Another problem with this model of independent intellectual property or patent organizations is that they tend to operate outside the broad policy framework on research, technology development and innovation that should inform intellectual property policy formulation. There is very little policy supervision by economic development bodies in the region with the result that very little expertise on the use of TRIPS flexibilities for public health purposes has so far been developed in these organizations. Finally, the mandates of these

[72] Weissman (2003).

[73] Vandoren and Van Eeckhaute (2003), p. 791.

organizations are mostly limited to matters of patent grants and examination or registration and do not include issues relating to the exercise of patent rights. This will limit the extent to which the organizations can help Member States in the use of TRIPS flexibilities for public health purposes.

BOX 5
AFRICAN REGIONAL INTELLECTUAL PROPERTY ORGANIZATIONS

A. African Organization for Intellectual Property (OAPI)

OAPI came into being on 13 September 1962 when 12 French-speaking African countries decided, by the Libreville Agreement, to set up a common structure, which was to act as national office for industrial property for each of them. The organization was called African and Malagasy Office for Industrial Property (OAMPI). Until 1962, patents were issued by the French National Institute for Industrial Property, which served as national office for states regrouped within the French Union. The basic idea behind the Libreville Agreement was: the adoption of uniform legislation; the creation of a common authority on matters of patents; and the centralization of procedures. With the signing of a new agreement in 1977, the Bangui Agreement, OAMPI became OAPI. The Bangui Agreement was adopted for various reasons including the withdrawal of the Malagasy Republic from the Libreville Agreement, the need to cover all rights items, the need better to involve patent rights in development and the desire for wider integration. Today, OAPI has 16 Member States, namely; Benin, Burkina Faso, Cameroon, The Central African Republic, Chad, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, and Togo.

The issuing of patents in OAPI Member States is regulated by the Bangui Agreement, which has the status of national patent law for all Members. OAPI receives all patent applications and registers regional patents which have a binding effect in all 16 Member States. Once the patents have been issued by OAPI, they are then regulated

at the national level by each respective State. Questions relating to existing patents (e.g. infringement, voluntary or compulsory licences) are settled before the civil courts of each Member State based on the provisions of the Agreement. The Bangui Agreement is therefore the effective law for these countries both in terms of procedural matters and substantive patent law including with respect to the use of TRIPS flexibilities. The Bangui Agreement was revised in 1999 in an attempt to bring it in line with the requirements of the TRIPS Agreement. The revised Bangui Agreement entered into force on 28 February 2002.

B. African Regional Intellectual Property Organization (ARIPO)

ARIPO's formal history goes back to the Lusaka Agreement, which was adopted by a Diplomatic Conference held in Lusaka, Zambia on 9 December 1976 establishing the Industrial Property Organization for English-speaking Africa (ESARIPO). Until 1 June 1981, when ESARIPO established its own secretariat, the United Nations Economic Commission for Africa (UNECA) and WIPO, the two main players behind the establishment of ESARIPO, acted as its joint secretariat. In December 1985, the Lusaka Agreement was amended in order to open up the membership of the Organization to all African states members of UNECA or OAU and changed its name to ARIPO apparently in order to reflect its new panAfrican outlook. There are currently 15 states which are party to the Lusaka Agreement. These are: Botswana, the Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

ARIPO was established to pool together the resources of its member countries in industrial property matters in order to avoid duplication of financial and human resources. Thus the preamble to the Lusaka Agreement states that Member States are "aware of the advantage to be derived by them from the effective and continuous exchange of information and harmonization and co-ordination of their laws and activities in industrial property matters". An additional consideration at the time of establishing ARIPO was that the majority of the countries concerned had dependent industrial property legislations which did not provide for original grant or registration in the countries concerned but could only extend to their territories the effects of industrial property rights obtained in a foreign country.

The main objectives of the organization as set out in article 3 of the Lusaka Agreement include: (a) to promote the harmonization and development of the industrial property laws, and matters related thereto, appropriate to the needs of its members and of the region as a whole; (b) to foster the establishment of a close relationship between its members in matters relating to industrial property; (g) to promote and evolve a common view and approach of its members on industrial property matters; and (h) to assist its members, as appropriate, in the acquisition and development of technology relating to industrial property matters. Cooperation activities in the area of patents are governed by the Harare Protocol, which was adopted by the Administrative Council of ARIPO in December 1982, in Harare, Zimbabwe.

The Protocol empowers the ARIPO Office to receive and process patent and industrial design applications on behalf of states party to the Protocol. The Protocol which entered into force in 1984 currently has 14 Members, namely, Botswana, The Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe. Unlike OAPI, which creates substantive patent standards for its members, the Harare Protocol only governs receipt, examination and provisional grant of patents. Each member therefore retains sovereignty over legislating on substantive patent standards. In addition, ARIPO patent grants do not apply automatically in the Member States and the States retain the right to reject an ARIPO issued patent.

Recommendation:

RECs and other similar regional bodies should establish regional ACTRIPS or functionally equivalent mechanisms as a central feature of an institutionalized approach to regional research and innovation including essential health research and, in particular, as a focal point for training, research, information exchange and political coordination in the use of TRIPS flexibilities for public health promotion and protection. As far as possible, however, developing countries should avoid a harmonization approach or using regional patent or industrial property organizations with no broad economic and

development mandates as a basis for regional cooperation on the use of TRIPS flexibilities in general and for public health in particular.

IV.2.2 Addressing the Problem of Insufficient Research and Manufacturing Capacities in the Pharmaceutical Sector

There are two components that need to be examined in addressing the problem of insufficient manufacturing capacity in developing countries. The first component relates to improving availability and access to medicines from current sources of quality generic medicines through importation. The second component relates to efforts to establish local research and manufacturing capacity in the long-term. The issue of compulsory licensing and its use in the regional context has already been a subject of negotiations at the WTO.

The WTO General Council's Decision of 30 August 2003 to implement paragraph six of the Doha Declaration provides, among other things, that in implementing the Decision, the domestic market may be defined to cover a regional market. Paragraph 6(i) of the Decision provides that:

> "[W]here a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that

> this will not prejudice the territorial nature of the patent rights in question."[74]

Article 31(f) provides that a compulsory licence shall be issued predominantly for the supply of the domestic market of the member issuing the license. However, this obligation is not applicable where the compulsory licence has been issued to remedy a practice determined by a judicial or administrative process to be anti-competitive.[75] Consequently, if the licence issued in the importing country was to remedy anti-competitive practices then the drugs supplied under the system would freely circulate in the region and beyond without the need to take recourse to paragraph 6(i) of the Decision. It is in cases where a licence is issued in the importing country for other reasons that recourse should be taken to the waiver under paragraph 6(i) of the 30 August Decision.

The approach under the Decision could help deal with the problem of many territorial markets in developing countries that are too small to support viable production or importation.[76] One barrier to using this regional approach that has been cited by some commentators relates to the fact that patents rights and related exceptions are territorial.[77] The Decision provides that the waiver does not prejudice any rights that accrue to patent holders due to the territorial nature of patents. This is by no means an insurmountable problem.

One possibility, in cases where there are regional patents such as in OAPI, is the grant of a single regional licence since the territory

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[74] See WTO document WT/L/540, 2 September 2003. Note, however, that based on the U.N. list of LDCs, only RECs in Africa will be able to take advantage of this provision.

[75] See TRIPS article 31(k).

[76] See the proposal by Brazil et al., para. 12. WTO document IP/C/W/355, 24 June 2002.

[77] See Vandoren and Van Eeckhaute (2003), p. 790.

for the patent in this case is the whole regional as opposed to a national patent system where the territory of the patent is limited to the country. Where there are no regional patents an alternative mutual recognition mechanism can be developed in the context of the REC or similar framework. Under this system, members of the REC could grant their own compulsory licences on the basis of a decision(s) of another member(s). This system could be strengthened it terms of transparency, legal security and efficiency by tying it into the ACTRIPS so that the ACTRIPS would advise members when to consider issuing the licences based on the scheme. A system of mutual recognition is preferable in these circumstances as it would not be obligatory, thus avoiding sovereignty issues and challenges by patent holders, while providing a basis for overcoming bureaucratic delays and other problems.

A system of mutual recognition for patent grants is already employed in ARIPO under the Harare protocol and there is no reason why a similar system, with appropriate modifications, cannot be used with respect to compulsory licensing. Since the system is not mandatory and will involve a certain level of national action it would be in conformity with article 4*bis* of the Paris Convention on independence of patents.[78]

With respect to developing research and manufacturing capacity, regional cooperation offers several advantages and can to help establish a number of the factors necessary for local production including enlarging the size of the relevant economy and addressing some of the other barriers that make local production difficult. Again, here most RECs already have a mandate for both science and technology, for creating single markets and for improving investments. Indeed, regional cooperation in manufacturing is in progress in the ASEAN which can serve as a model, with appropriate adjustments, for other regions and with respect to pharmaceutical production in particular.

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[78] Article 4*bis* of the Paris Convention is a TRIPS requirement pursuant to the provisions of article 2(1) of the Agreement.

The Basic Agreement on the ASEAN Industrial Cooperation (AICO) signed on 27 April 1996 and effective from 1 November 1996 has the objective of promoting joint manufacturing activities of companies operating in the region by establishing large-scale ASEAN industrial plants to meet regional requirements of essential commodities. It was designed to encourage technology-based investments in ASEAN. The AICO arrangement enables participating countries and companies to enter into a cooperative arrangement whereby they engage in some form of resource-sharing such as technology-sharing, market-sharing, or consolidated purchases of raw materials. The arrangement consists of a minimum of two participating countries and one participating company in each participating country.[79]

To be eligible to participate in the AICO Scheme, the companies concerned must: (1) be incorporated in and operating in an ASEAN country; (2) have a minimum of 30 per cent ASEAN equity; and (3) undertake resource sharing, industrial complementation or industrial cooperation activities.[80] Once accredited, the participating companies are entitled to various privileges, including: preferential tariff rates of 0-5 per cent on approved AICO products, the actual rate of which shall be determined by each participating country;[81] local content accreditation; and non-tariff incentives offered by the respective national authorities.[82] The ASEAN member countries may introduce additional tariff and non-tariff incentives under the Basic Agreement.[83] The Basic Agreement provides that all products other

[79] Article 1(2), Basic Agreement on the ASEAN Industrial Cooperation Scheme.

[80] Article 3 (1).

[81] It must be noted, however, that the preferential tariff rates cease when the tariff rates of the products concerned reach the final CEPT rate. [Art. 5(1), Basic Agreement on the ASEAN Industrial Cooperation Scheme]

[82] See article 5(1)

[83] See article 5(2).

than those listed as General Exceptions under Article 9 of the ASEAN Free Trade Area-Common Effective Preferential Tariff (AFTA-CEPT) Agreement are eligible for the AICO Scheme.[84,85]

However, by virtue of the conditions imposed, only certain types of products and operations currently benefit from the scheme. Theoretically, the AICO scheme is suitable for companies or products which meet four basic operational conditions in addition to the stipulated AICO criteria. These conditions are: availability of parts and materials; divisibility of labour and processes; principles of economies of scale; and the presence of counterpart companies.[86] Any company or product which can satisfy these conditions would thus be a primary candidate for the AICO Scheme. In 2001, ASEAN approved 77 projects under this scheme.[87]

So far, the automobile and automobile parts industries constitute the largest sector participating in the AICO Scheme, although other industries such as the electrical and electronics industries, agricultural machinery industry, and food industry have also been participating.[88] Although further research is required with respect to the viability of pharmaceutical production in different countries and regions of the world, an approach modelled on the AICO scheme with

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[84] Article 9 of the AFTA-CEPT Agreement states:

> "Nothing in this Agreement shall prevent any Member State from taking action and adopting measures, which it considers necessary for the protection of its national security, the protection of public morals, the protection of human, animal or plant life and health, and the protection of articles of artistic, historic and archaeological value."

[85] See article 4(1)

[86] See www.asean.or.jp/invest/archive/speech/02aic.html, last visited on 11 April 2003.

[87] See www.mot.gov.vn/Confs/2001/AEM33/En/Vankien/press_asean.htm, last visited on 12 April 2003.

[88] See Mansor and Radam, (2000) p. 9.

enhanced research focus and a review of how the AICO scheme has worked, can be adopted with respect to the development of the pharmaceutical industry in the countries of the South.[89]

Regional schemes modelled on AICO with an enhanced research focus can be critical in helping to prioritize investments in pharmaceutical research and production and in evaluating performance to ensure greater public health impact in developing countries. Such a scheme can also help to facilitate and rationalize technology transfer arrangements from other countries of the South such as Brazil, China and India in the case of pharmaceuticals. The starting point could be agreement on determining the priority regional essential health problems.[90] Then, the required essential health solutions need to be defined for the region. This could include matching essential health problems with existing health solutions (which may not be drugs but different types of intervention) and identifying the gaps.

The essential health research agenda then becomes defined. Where drugs, diagnostics and vaccines are required, the gaps become clear. Based on an analysis of public health problems and matching these with the most appropriate existing medicines, an essential medicines list could then be developed to guide public policy in terms of what should be the focus of research and manufacturing activity in the region. This process can also be useful in identifying, for example, areas where to share information on patents or prices and sources of medicines.

Recommendation:

There are a number of steps that can be taken in the regional context to facilitate the enhancement of the pharmaceutical research and

[89] See discussion in section III.2 above.

[90] Priority problems are usually calculated using a combination of estimates of disease burden (impact on morbidity and mortality), population size affected, economic and social impact on the individual and society.

manufacturing capacities of developing countries as well as facilitating the implementation of paragraph 6(i) of the WTO 30 August 2003 Decision. These include:

- *Undertaking further research with respect to the factors necessary for pharmaceutical production in a disaggregated way, that is, the factors relevant for different types of pharmaceutical production. A research agenda on the lines of the Kaplan et al. paper or another method of identifying gaps could form the basis for further work in this regard.*

- *Undertaking a review of the AICO and other similar industrial schemes to determine their viability for regional pharmaceutical production and further research on how such schemes could be improved to include a stronger research focus.*

- *With respect to the 30 August 2003 Decision, developing a system for the issue of regional compulsory licences where there are regional patents such as in OAPI countries and a system of mutual recognition where REC members can issue their own compulsory licences based on the issuance of a licence in another REC member country where there are no regional patents.*

IV.2.3 Developing Technical and Infrastructural Capabilities for Medicines Regulation

Regulatory approval processes raise a number of issues with respect to availability and improved access to essential medicines. Difficulties and constraints at the national level could be addressed in a regional context through coordination of registration and cross-recognition of registrations in other countries. To be able to establish a coordinated regional system of regulatory approval and/or a system of cross-recognition of registrations, however, several actions will

need to be taken by countries. These would include: the coordination of the current lists of drugs registered in each country; the creation of independent and transparent drug regulatory authorities preferably autonomous from the ministries of health; the coordination of national drug policies and guidelines related to rational drug use including the use of national essential medicines lists for drug selection; adherence to interagency guidelines on medicines donations; and the creation of mechanisms to deal with differences in resistance patterns and how to reflect these in drug lists.

Other issues relate to correct labelling, which raises the issue of language; tariffs; inspection procedures; registration of pharmacies and drug vendors and regulation of traditional and herbal medicines. In particular, regulation in advertising through mechanisms that set and enforce guidelines for drug promotion is required to avoid advertisements that may be false, lacking in fair balance, or otherwise misleading. Trademark law could also be used for this purpose. A system could be developed where trademarks that have been abused are nullified. With respect to quality issues a basic requirement, which can be achieved more easily at the regional level, is a well-equipped, well-maintained, well-staffed, quality control laboratory. In this regard, current methods for each country need to be standardized, for example, by following the WHO Good Manufacturing Practices (GMP) criteria. In addition, a coordinated regional warning/drug recalls system could be developed. These steps are also critical in helping to ensure the proper functioning of a regional procurement system as discussed in the next section.

All these steps can be taken through existing regional frameworks and institutions in the South. In Africa, for example, COMESA Member States have committed themselves to cooperate in health matters and on quality assurance through according mutual recognition to drugs registered in the common market. Using the technical committee structure COMESA can, through existing mechanisms, begin to address these issues. SADC has similar aims under its health protocol also and can address the issues of regulation and quality through the health sector coordinating unit, the health sector committee of ministers, the committee of senior official and

the subcommittees.[91] The EAC Member States have also committed to harmonizing drug registration procedures and national health policies and regulations and are already addressing some of these issues under the Social Sector Committee.

In Latin America and the Caribbean, there are also similar aims and objectives with respect to medicines regulations and quality issues. In MERCOSUR, for example, the Commission on Health which deals with matters related to the production and registration of medicines has established harmonized rules on good practices and quality inspection of medicines; requirements for pharmaceutical products registration; good fabrication practices and control in establishments of pharmaceutical industry; information and documents required for pharmaceutical products registration; validity, renovation, cancellation and modification of pharmaceutical products registers; among others. These provisions constitute a significant step towards MERCOSUR integration in this field, because they allow mutual recognition between governmental agencies which authorize medicines for the domestic markets.[92] In CARICOM these matters can be addressed both in the context of the Cooperation in Health Initiative (CCH) and the in the context of the OECS procurement scheme. The CACM also has a commitment towards mutual recognition of medicines and issues related to technical regulations and safety under the Guatemala Protocol.[93]

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[91] See article 4 of the SADC Protocol on Health.

[92] See Inter-American Development Bank, Serie Red Int. (2000).

[93] The concept of the CCH was introduced in 1984 at a meeting of the former CARICOM Conference of Ministers responsible for Health (CMH). The CMH saw this as a mechanism for health development through increasing collaboration and promoting technical cooperation in the Caribbean countries. The initiative, in which seven priority areas were identified, was adopted by the CMH and approved by the Heads of Government in 1986. An evaluation of the Initiative (1992-1994), found that the priorities identified ensured that activities were focused on areas critical to improving health status in the region. Overall it was established that the Initiative was beneficial to Caribbean countries.

In ASEAN, although significant steps have also been taken still more can be done. In the context of the ASEAN Health Declaration and through the ASEAN Ministers of Health technical cooperation plan, significant strides can be made towards achieving the goals of regional cooperation on technical and related matters in medicines regulations.[94] The Pharmaceutical Product Working Group is already undertaking activities related to pharmaceutical regulations. The primary objective of the ASEAN Drug Regulatory Harmonisation project is to strengthen national regulatory authorities in order to ensure improved access to safe, effective quality and good quality pharmaceutical products in all the ASEAN countries.

Recommendation:

Regional coordination on regulatory issues will offer significant benefits to developing countries and help them overcome current constraints in this area. Existing South-South RECs in Africa, Asia, Latin America and the Caribbean offer ready institutional frameworks for this purpose which should be utilized to address among other things, challenges in drug registration and post-marketing surveillance, development of essential medicines lists, development of medicines policies, and rules on pharmaceutical advertising and labelling. Existing regional efforts on these issues should be studied and lessons on good and bad practices shared.

IV.2.4 Establishing Efficient Pharmaceutical Management and Procurement Systems

Significant cost savings, efficiency and other benefits can accrue for developing countries through regional pooled procurement. This is an area that offers a lot of promise to overcome national constraints

[94] More information available at http://www.aseansec.org/8621.htm, last visited on 17 March 2003.

in the use of TRIPS flexibilities as there exist a number of regional pooled procurement schemes that have brought important benefits to the participating countries in terms of prices, quality and overall pharmaceutical management and from which lessons can be learned. Indeed, Management Sciences for Health (MSH) with the funding support of the Rockefeller Foundation has recently undertaken studies to identify specific opportunities for, and barriers to, pursuing a multi-country regional solution for procuring drugs, in particular HIV/AIDS medicines in the South. Two reports have been prepared under the project.[95] The first report describes the operation of the survey, details of the findings of the survey, assesses the feasibility of regional pooled procurement, formulates development plans, and analyses the overall viability of proposed pooled procurement operations.

The second report reviews past and present efforts to establish regional programmes for pooled procurement of drugs in the developing world. It focuses on those procurement programmes in the public sector, with either direct or indirect government support, in which the countries in the group take joint responsibility and accountability for the bulk purchasing activities. The report draws its lessons from a review of eight regional pooled procurement programmes including: the OECS Pharmaceutical Procurement Service (PPS), formerly known as the Eastern Caribbean Drug Service (ECDS); the Pan-American Health Organization (PAHO) Revolving Fund for Vaccine Procurement; the Revolving Fund for Essential Drugs for Central America and Panama (FORMED); and the Gulf Cooperation Council (GCC).

Others are: the Arab Maghreb Union (AMU); the Joint Bulk-Purchasing Scheme for the Pacific Island Countries; ACAME; and SADC. Some of these programmes have been in operation for more than a decade, whereas others are still relatively new. Lessons learned from the more established programmes appear to have influenced the more recent efforts. In all the regional pooled procurement

[95] MSH (2002) and MSH (2003).

programmes reviewed in the report, the main objective of achieving economies of scale was accomplished. However, simply reducing prices is in itself not sufficient. The incentive for reducing prices must also be an incentive for improving other aspects of managing drug supply, cohesion and collaboration between member countries, and financial stability and accountability. The following analysis draws significantly from the findings of these two reports.

A. Regional pooled procurement

There are a number of traditional reasons for and benefits of pooled procurement.[96] The first is the effect of lowering prices. In general, countries participating in a successful bulk procurement scheme have experienced major reductions in unit prices of drugs. For example, at the start of the ECDS, the unit cost of drugs dropped an average of 44 per cent in the first tender cycle, which was sustained in subsequent tenders and has been reported as better than 25 per cent lower than individual country prices for years 2001/2.[97] The second reason is improved quality resulting from improved access to information about drug quality through exchanging information about supplier performance with respect to quality of drugs, coordinating technical aspects of quality assurance through a centralized quality assurance laboratory and coordinating and cost-sharing GMP inspections through a centralized procurement body created specifically for the purpose of pooled procurement.

The third traditional reason for multi-country pooled procurement relates to improved availability. In this regard, the countries that participate in information sharing or centralized purchasing are better able to make decisions when selecting suppliers, which assists in eliminating erratic or rogue suppliers and providing better information on the state of the market and drug availability, particularly with respect to anticipated short-supply or drugs difficult to obtain.

[96] See MSH (2003) p. 1-2.

[97] Burnett (2001).

This allows countries to increase lead time allowances and/or exercise multiple supplier options to obtain secure supply routes and to locate previously unknown sources for orphan and difficult to obtain drugs. The fourth and final reason is improved rational use of drugs as pooled procurement increases the incentive for coordinating drug selection and use, for example, drug medical supply registration procedures, essential drugs lists (EDLs) and standard treatment guidelines (STG).

Many developing countries, however, while generally acknowledging that regional pooled procurement could certainly improve prices, quality assurance, and other factors relating to the procurement of essential drugs by individual countries, have considered the potential efficiencies not so much better than they were already achieving on standard essential drugs: and were "outweighed" by the perceived loss of sovereignty or control; the loss of procuring flexibility; and potential adverse influences on the local pharmaceutical industry.[98] Consequently, although multi-country pooled procurement of essential drugs is considered a good idea, few countries see a clear incentive to take part. Successful multi-country drug procurement initiatives have therefore often been dismissed as exceptions. For example, ACAME which has undertaken some pooled procurement, has member states that all share a common currency and so was considered "unusual" and "not representative" of the actual situation in sub-Saharan Africa.[99] With the advent of the HIV/AIDS pandemic, however, the situation has drastically changed and countries have suddenly to consider buying many more essential drugs, which are expensive and with which they have little previous procurement experience.

In light of the changed market and health situation, regional pooled procurement can offer several distinct additional advantages.[100] In the first instance, added to the fact that pooled procure-

[98] See MSH (2003).

[99] MSH (2003), p. 5.

[100] MSH (2003) pp 3-4.

ment generally brings substantial cost savings, the relatively large quantities of ARVs likely to be required over the next few years,[101] means that pooling can make the difference by bringing greater cost savings and therefore making it possible to treat hundreds or even thousands more people. Moreover, pooling is likely to help individual member countries access the best available pricing competition between brand name and generic manufacturers. The second advantage relates to information exchange and the related spillover effects. While there is no doubt that market intelligence is useful, in the new situation where prices and suppliers are developing almost daily, it has become critical. Information obtained directly, such as where market experiences by one country on new suppliers and sources can be rapidly made available to all in the group and also indirectly through sharing costs of market research, enabling countries obtain up-to-date information at moderate cost, is likely to offer real benefits.

The third benefit in the changed situation is the possibility of sharing quality assurance techniques and costs. In the case of ARVs, in particular, some drugs are so new that quality assurance procedures are not yet well established, adding particular uncertainty in developing procurement specification and monitoring. Pooling is likely to offer rapid dissemination of information on techniques and especially of adaptation of methodologies appropriate to developing-country settings. In addition, pooling will also help in the policing of commodity supply chains which is an expensive exercise. Sharing these costs will offer significant cost savings, in both direct costs and organizational/administrative overheads.

Sharing costs and techniques can also help assure product quality, whether the source is the originator company or a generic company. Finally, there are also benefits associated with the concept of safety in numbers. As more and more countries are expected to

[101] This applies if one assumes that countries through their own means and through international means such as the Global Fund are going to substantially scale-up HIV/AIDS treatment for their infected populations.

buy moderate quantities of expensive drugs in a rapidly changing market place from suppliers who may not feel that they have incentives to perform to the letter of their contracts and supply agreements, errant suppliers may not worry much about the threat of being barred from future supply to a single country, which may be buying only small quantities.[102] However, the possibility of being barred from future supply to an entire region carries much greater weight, both in lost reputation and sales. Further, there are also additional side benefits that can accrue from regional pooled procurement. For example, in the Eastern Caribbean, other benefits of the programme include the provision of a wide range of related training and technical assistance, drug utilization studies, and improvements in quality control.

However, in considering the potential for regional pooled procurement in helping developing countries better to utilize the TRIPS flexibilities, the logistical and political challenges such as loss of sovereignty over drug procurement decisions should be taken into account. In this regard, decisions should take account of the state of integration in the region and the level of cooperation on pharmaceutical issues. There are four possible levels of cooperation that should be considered ranging from informed buying: where member countries share information about prices and suppliers but procure individually; coordinated informed buying, where member countries undertake joint market research, share supplier performance information and monitor prices but they continue to procure individually; group contracting, where, member countries jointly negotiate prices and select suppliers and agree to buy from the selected suppliers although each country eventually purchases individually; to regional pooled procurement, where member countries jointly conduct tendering through an organization acting on their behalf and a central purchasing agency manages the purchases on behalf of all the member countries.[103]

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[102] MSH (2003) p. 4.

[103] Ibid.

Table 1 below contains a detailed description of the various models; identifying regional group roles and responsibilities as well as country roles and responsibilities under each model.

TABLE 1
REGIONAL PHARMACEUTICAL MANAGEMENT AND PROCUREMENT MODELS

	Informed Buying	**Coordinated Informed Buying**	**Group Contracting**	**Regional Pooled Procurement**
Description	Member countries share information about prices and suppliers Countries conduct procurement individually	Member countries undertake joint market research, share supplier performance information, and monitor prices Countries conduct procurement individually	Member countries jointly negotiate prices and select suppliers Member countries agree to purchase from selected suppliers Countries conduct purchasing individually	Member countries jointly conduct tenders and award contracts through an organization acting on their behalf Central buying unit manages the purchase on behalf of countries
Regional group roles and responsibilities	Facilitate the gathering and dissemination of supplier and price information among member countries	Forum for harmonization of information requirements and systems; mechanism for market research, dissemination of	Country delegates meet to jointly conduct price negotiation and supplier selection on behalf of member countries Alternatively, an agency may be	Contracts with a jointly designated central buying unit to conduct and adjudicate tenders

	Informed Buying	**Coordinated Informed Buying**	**Group Contracting**	**Regional Pooled Procurement**
	(clearing-house) Sharing of information	findings among member countries, and potential provision of drug information Focus on coordination of information gathering and sharing	contracted for this purpose	
Country roles and responsibilities	Share procurement information for selected items	Collect information related to pricing and supplier performance based on harmonized requirements; provide resources to conduct joint market research activities for selected items	Provide accurate and reliable quantification of needs for selected items Provide timely payment to suppliers Provide accurate and reliable information on supplier performance and product quality monitoring	Provide accurate and reliable quantification of needs for selected items Provide funds to procurement unit/agency for supplier payment Provide accurate and reliable information on product quality monitoring

Source: Adapted from MSH (2003)

Depending on the state of health cooperation in each region a different model can be chosen. The existence of different possibilities also means that countries can move on to closer cooperation as they gain experience and build confidence. Here again there already exist regional institutional frameworks to facilitate the speedy implementation of whatever model is chosen. It could be done through regional health organizations such as the Commonwealth Regional Health Community Secretariat (CRHCS), regional procurement organizations such as OECS, GCC and ACAME or through the health committees and similar mechanisms in the RECs.

Recommendation:

Regional cooperation in pharmaceutical management and procurement offers undoubted benefits for developing countries. Depending on the level of existing cooperation in health matters, countries should put in place mechanisms to facilitate the implementation of any of the four models of cooperation identified above. Whenever feasible, developing countries should seek to put in place regional procurement systems where they would jointly conduct tendering through an entity acting on their behalf and a central purchasing agency managing the purchases on behalf of all the member countries. The criteria developed by MSH to assess the feasibility of pooled procurement and the 'lessons learned' report, could be a starting point for various RECs and other organizations to assess which model best suits the circumstances of their members.

IV.2.5 Resisting Bilateral and other TRIPS-plus Pressures

A regional approach to the use of TRIPS flexibilities for public health and access to medicines can provide much-needed bargaining leverage for developing countries in their dealings with their developed trading partners and in resisting pressures to forgo the use of TRIPS flexibilities and TRIPS-plus pressures. A major advantage that regional cooperation offers with respect to resisting bilateral and

other TRIPS-plus pressures is that it has the potential of enhancing the political capacities and economic clout of developing countries. Regional cooperation in political matters can be a complex, long-term process that poses many challenges for government, development agencies, private entrepreneurs, and local communities. But such cooperation is necessary if individual developing countries are to withstand political pressure exerted upon them by developed countries and multinational corporations to forgo the use of flexibilities for public health and other socio-economic purposes and or to adopt TRIPS-plus standards.

Regional cooperation in this area has begun to emerge in the South. For example, during the ASEAN Workshop on Increasing Access to HIV/AIDS Drugs and Reagents held in Jakarta, Indonesia in June 2002, it was agreed that ASEAN would focus on the review of TRIPS and patent laws in ASEAN member countries with a view to using appropriate legal mechanisms available in the region such as parallel importation and compulsory licensing.[104] The adoption of such a common understanding on the importance of using the flexibilities for public health purposes across the region can enable member countries to resist bilateral and other pressures. The possibility to achieve results through a regional approach will, however, depend mainly on the political will of policy makers in the South.

A major problem to be faced is the inadequate participation of Ministries of Health in key negotiations and trade-related decisions. Though the situation has slightly improved since the Uruguay Round, public health interests are in general not institutionally represented and are likely to be overlooked when concessions are exchanged. Consequently, in bilateral and other trade negotiations with developed countries, enhanced levels of intellectual property protection (with significant impact on public health interests) have often been traded against short-term advantages obtained in market access

[104] ASEAN Task Force on AIDS and ASEAN Secretariat, (2002-2005), Operational Framework for the ASEAN Work Programme on HIV/AIDS II, p. 7.

or other areas. Effort therefore needs to be made to ensure the effective integration of public health considerations in trade negotiations and related policy-making. Sometimes, the impact of enhanced levels of intellectual property protection is assessed by trade negotiators in terms of their effects on the local industry rather than on patients and public health budgets. A methodology to assess the public health impacts of trade agreements could be instituted more cost effectively in a regional context to help developing countries make reasoned and sound decisions on this matter.

Another important way of helping countries resist bilateral and other TRIPS-plus pressures is through efforts to establish and enhance regional non-governmental organization (NGO) networks. NGOs have played a significant role in recent debates on intellectual property and public health, as illustrated by their active participation in the discussions leading to the Doha Declaration and the implementation of its paragraphs 6 and 7. Regional civil society networks in the South working together with like-minded civil society networks in the North can provide a third force that can help developing countries discuss the issues and develop confidence to resist pressures.

Such networks are also useful in making intellectual property issues become accessible as a topic of the public interest, and of political importance to society at large. An important example of a regional civil society network that has played a critical role in intellectual property and public health as well as other trade and development issues is the Southern and Eastern African Trade Information and Negotiations Institute (SEATINI). It has been at the forefront of promoting regional coordination and in publicizing pressures by developed countries on African Governments. The network has also helped governments with technical support to resist bilateral and other pressures. The participation of civil society groups in the Free Trade Area of the Americas (FTAA) processes also illustrates how regional civil society networks can help a country to resist pressures. Other organizations, although not networks strictly speaking, such as the Third World Network (TWN), which has offices and activities in both Asia and Africa, also play a critical role.

Recommendation:

Developing countries should use their regional institutions and frameworks in resisting pressures to forgo the use of TRIPS flexibilities for public health as well as TRIPS-plus pressures. In this connection, the establishment of regional NGO and community-based organization (CBO) networks should be facilitated through RECs and other institutions. This effort should be linked to creating regional ACTRIPS. The need for enhanced civil society participation in regional and REC processes is already recognized. For example, the EAC Treaty specifically recognizes that one of the reasons the earlier integration process in East Africa failed was the lack of participation by civil society organizations in its processes and engagement in the political process.[105] *On their part, a large number of civil society groups perceive integration as a process that articulates and promotes development, with an integrated approach encompassing political and social aspects.*

IV.2.6 Regional Competition Enforcement Mechanisms

A strong link exists between patent protection and anti-competitive behaviour in the pharmaceutical market since patents grant their holders monopoly privileges. There is a growing body of evidence that competition and, in particular, generic competition has a substantial impact on the prices of medicines.[106] Monopoly prices resulting from patent protection as well as anti-competitive practices therefore need to be regulated for public health purposes. Intervention through regulatory and strong judicial institutions is necessary to curb anti-competitive behaviour due to the large concentration in the pharmaceutical industry where nearly 40 per cent of the estimated

[105] See para. 4 of the EAC Treaty.

[106] Abbott (2002), p. 16. Also see Abbott (2001) Annex A.

worldwide market for pharmaceuticals is held by 10 companies.[107] This has largely been a result of a spate of mergers over the last several years. The mergers have been spurred by two conflicting policies. One is based on the idea that a certain size is required for investment in platform technologies, which can generally be shared across different programme research areas. The other, is based on the idea that it is not possible for one organization to own all the technology and that what is needed are companies that can pick and choose their business relationships by creating a critical mass of talent.

The pricing behaviour of these companies in such a concentrated market is one of the reasons that has fuelled the debate on intellectual property in relation to product patents for pharmaceuticals. More importantly, because of the concentration in the industry, taking action to deal with anti-competitive and other abusive behaviour by companies means that the government is going against very powerful entities. Such an undertaking requires high levels of investigative and negotiating sophistication, economic and political clout and strong judicial institutions. This is very difficult to achieve in small developing countries, which have neither the expertise in competition regulation nor the economic and political clout. Regionally, however, various possibilities exist that would enable such countries to address these challenges.

The existing RECs provide a basis for developing countries to carry out joint investigations into the business practices of pharmaceutical companies generally and their use of their market power. By establishing regional mechanisms for this purpose, countries would have better information through sharing and would also share their expertise. Where training or technical assistance is needed the cost would also be lower. A regional approach would also provide a framework through which countries such as South Africa, which has

[107] See IMS Health World Review (2002), IMS Market Report. Available at www.ims-global.com/insight/report/global/report.htm cited in Kaplan et al. (2003) p.10.

already undertaken competition enforcement action against pharmaceutical companies, could share their experiences.

The various RECs in Africa, Latin America and the Caribbean and Asia have institutional frameworks through which such a mechanism can be operationalized. At the same time, all the major RECs in Africa and Latin America and the Caribbean have regional courts and or regional dispute settlement mechanisms. In Africa, all the four main regional economic communities together with the AEC establish courts of justice or tribunals fairly along the lines of the European Court of Justice. Enforcement action can therefore be undertaken through administrative procedures, and where necessary, through court procedures. Such a mechanism could also be tailored to improve general information sharing in the region in relation to pharmaceutical markets, price and patent status of various pharmaceutical products.

Recommendation:

Competition enforcement is critical in ensuring a competitive pharmaceutical industry both in terms of lowering prices and ensuring availability of essential medical products. Because of lack of expertise and the necessary economic and political clout in individual developing countries, they should utilize RECs to enforce competition rules. There are particularly important benefits to be gained in terms of undertaking joint investigations and information exchange. Existing RECs already have an institutional framework that can be adapted to establish mechanisms for regional competition enforcement.

V. CONCLUSIONS AND RECOMMENDATIONS

The effective use of the TRIPS flexibilities requires expertise in intellectual property law and policy as well as expertise and resources to implement complementary legal and policy measures. While significant efforts are being made to establish these conditions at the national level, many developing countries find it difficult to attain these on their own. Regional mechanisms can significantly help to address these constraints thus helping these countries better to use TRIPS flexibilities for public health purposes. While the role of regional cooperation in the socio-economic, cultural and political development of the countries of the South is well accepted, their role in helping address the impact of intellectual property protection on pharmaceuticals has rarely been examined. This study has demonstrated that regional frameworks, including RECs, have an important role to play in helping developing countries overcome the barriers imposed by patents.

Public health is a common concern and has in fact been identified as a vital area of cooperation in the South, and utilizing the various regional frameworks offers a great opportunity to improve access to essential medicines and related products, services and facilities. A regional approach will empower each developing country to maximise the use of TRIPS flexibilities through sharing resources and expertise. A regional approach will also lead to political unity which is essential in overcoming internal and external pressures to forgo the use of TRIPS flexibilities for public health and other socio-economic purposes or to adopt TRIPS-plus standards. Further, a regional approach can also encourage the creation of a larger market and a regional pharmaceutical industry as well as mechanisms for addressing regulatory issues such as common registration requirements and standards as well as procurement issues.

V.1 Summary of Recommendations

Many of the issues that need to be addressed through regional frameworks such as developing technical expertise on intellectual property and development matters including public health, coordination of drug registration, research and manufacturing issues, however, raise important political and other practical issues that will have to be dealt with and, in some cases, hard decisions need to be made. There are also issues about sharing of benefits and participation by the private sector and civil society in regional initiatives that will have to be addressed. That said, the following is a summary of recommendations, which emerge in this study, which can help developing countries further explore the role of regional approaches to overcoming the constraints that they face in implementing the TRIPS flexibilities effectively at the national level for public health purposes.

1. RECs and other similar regional bodies should establish regional ACTRIPS or functionally equivalent mechanisms as a central feature of an institutionalized approach to regional research and innovation including essential health research and, in particular, as a focal point for training, research, information exchange and political coordination in the use of TRIPS flexibilities for public health promotion and protection. As far as possible, however, developing countries should avoid a harmonization approach or using regional patent or industrial property organizations with no broad economic and development mandates as a basis for regional cooperation on the use of TRIPS flexibilities in general and for public health in particular.

2. There are a number of steps that can be taken in the regional context to facilitate the enhancement of the pharmaceutical research and manufacturing capacities of developing countries as well as facilitating the implementation of paragraph 6(i) of the WTO 30 August 2003 Decision. These include:

- Undertaking further research with respect to the factors necessary for pharmaceutical production in a disaggregated way, that is, the factors relevant for different types of pharmaceutical production. A research agenda on the lines of the Kaplan et al. paper or another method of identifying gaps could form the basis for further work in this regard.

- Undertaking a review of the AICO and other similar industrial schemes to determine their viability for pharmaceutical production and further research on how such schemes could be improved to include a stronger research focus.

- Developing, with respect to the 30 August 2003 Decision, a system for the issue of regional compulsory licences where there are regional patents, such as in OAPI countries, and a system of mutual recognition where REC members can issue their own compulsory licences based on the issuance of a licence in another REC member country where there are no regional patents.

3. Regional coordination on regulatory issues will offer significant benefits to developing countries and help them overcome current constraints in this area. Existing South-South RECs in Africa, Asia, Latin America and the Caribbean offer ready institutional frameworks for this purpose which should be utilized to address among other things, challenges in drug registration and post-marketing surveillance, development of essential medicines lists, development of medicines policies, and rules on pharmaceutical advertising and labelling. Existing regional efforts on these issues should be studied and lessons on good and bad practices shared.

4. Regional cooperation in pharmaceutical management and procurement offers undoubted benefits for developing countries. Depending on the level of existing cooperation in health matters, countries should put in place mechanisms to facilitate the implementation of any of the four models of cooperation identified in this study. Whenever feasible, developing countries should seek to put in place regional procurement systems where they would jointly conduct tendering through an entity acting on their behalf and a central purchasing agency managing the purchases on behalf of all the member countries. The criteria developed by MSH to assess the feasibility of pooled procurement and the 'lessons learned' report, could be a starting point for various RECs and other organizations to assess which model best suits the circumstances of their members.

5. Developing countries should use their regional institutions and frameworks in resisting pressures to forgo the use of TRIPS flexibilities for public health as well as TRIPS-plus pressures. In this connection, the establishment of regional NGO and community-based organization (CBO) networks should be facilitated through RECs and other institutions. This effort should be linked to creating regional AC-TRIPS. The need for enhanced civil society participation in regional and RECs processes is already recognized. For example, the EAC Treaty specifically recognizes that one of the reasons that the earlier integration process in East Africa failed was the lack of participation by civil society organizations in its processes and engagement in the political process. For their part, a large number of civil society groups perceive integration as a process that articulates and promotes development, with an integrated approach encompassing political and social aspects.

6. Competition enforcement is critical in ensuring a competitive pharmaceutical industry both in terms of lowering prices and ensuring availability of essential medical prod-

ucts. Because of lack of expertise and the necessary economic and political clout in individual developing countries, they should utilize RECs to enforce competition rules. There are particularly important benefits realizable in terms of undertaking joint investigations and information exchange. Existing RECs already have an institutional framework that can be adapted to establish mechanisms for regional competition enforcement.

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