

THE USE OF FLEXIBILITIES IN TRIPS  
BY DEVELOPING COUNTRIES:  
Can they Promote  
Access to Medicines?



World Health  
Organization  
Technical Cooperation for  
Essential Drugs and Traditional Medicine

**THE USE OF FLEXIBILITIES IN TRIPS  
BY DEVELOPING COUNTRIES:  
CAN THEY PROMOTE ACCESS TO MEDICINES?**

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## ACRONYMS

ACP	African, Caribbean and Pacific Countries
AIDS	Acquired Immune Deficiency Syndrome
AMTC	Access to Medicine and Treatment Campaign
ARV	Anti-retroviral
CAFTA	Central America Free Trade Agreement
CBD	Convention on Biological Diversity
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
COMESA	Common Market for Eastern and Southern Africa
CSIR	Council for Scientific and Industrial Research
EC	European Community
EMRs	Exclusive Marketing Rights
EPA	Economic Partnership Agreement
EU	European Union
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
HAART	Highly-Active Anti-retroviral Treatment
HIV	Human Immunodeficiency Virus
IFAC-3	Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters
IDMA	Indian Drug Manufacturers Association
IPR Commission	Commission on Intellectual Property Rights
ITAC	Industry Trade Advisory Committee on Intellectual Property Rights
KCAEM	Kenya Coalition for Access to Essential Medicines
LDC	Least-developed country
MCAZ	Medicines Control Authority of Zimbabwe

NIHCM	National Institute of Health Care Management and Educational Foundation
NOIP	National Office of Industrial Property Rights (Viet Nam)
OAPI	African Intellectual Property Organization
R&D	Research and Development
TIFAs	Trade and Investment Framework Agreements
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
USPTO	United States Patents and Trademark Office
USTR	United States Trade Representative
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

## PREFACE

This study is the third in a series published by the South Centre in collaboration with the World Health Organization (WHO). These studies are aimed at assisting countries, especially developing countries, to design public health-sensitive intellectual property rules in the context of the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and other international, regional and bilateral intellectual property agreements. The earlier studies were: *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (Correa; 2002); and *Protection and Promotion of Traditional Medicine: Implications for Public Health in Developing Countries* (Correa; 2002).

This study was originally commissioned by the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) and an electronic version was published on Commissions website. (See: [http://www.who.int/intellectualproperty/studies/TRIPS\\_flexibilities/en/index.html](http://www.who.int/intellectualproperty/studies/TRIPS_flexibilities/en/index.html)) in August 2005. In order to increase the dissemination and impact of the study, the South Centre and WHO decided to publish the study. It is hoped that the publication of the study will make it readily available and accessible to developing country governments and other stakeholders. In this regard, the South Centre and WHO are indebted to the CIPRH for granting permission to publish the study.

The publication of the study has been made possible through the financial support of the French Ministry for Foreign Affairs - Directorate for International Cooperation and Development, through WHO, and the Rockefeller Foundation, through the South Centre.

The first draft of the study was presented and discussed during the CIPRH Study Workshops held in Geneva on 30-31 May 2005, and benefited from the comments of participants of the workshop. The authors also wish to acknowledge and thank Germán Velásquez (WHO); Mrs. Malebona Matsoso (WHO); and Charles Clift (CIPRH) for their valuable

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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, WHO, the CIPIH, the Rockefeller Foundation, or the French Government. The authors are solely responsible for the final text.

## EXECUTIVE SUMMARY

This study was commissioned to: (1) examine the extent to which the flexibilities contained in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) have been incorporated into the legislation of developing countries and the extent of the actual use for public health purposes; (2) review the stated trade policies of major industrialized countries, particularly the United States and the European Union , *vis-à-vis* developing countries, to determine whether they take adequate account of the public health priorities of developing countries; and (3) examine the practical effect and implications of recently concluded bilateral and regional free trade agreements (FTAs) for public health protection in developing countries. The study has been compiled based on existing literature and other available evidence.

Overall, the study finds that the use of TRIPS flexibilities can promote access to medicines in developing countries. Most developing countries whose laws and practices we reviewed had incorporated one or more of the TRIPS flexibilities and there has been increasing usage of these flexibilities such as compulsory licensing for public health purposes. However, there remain important gaps both in terms of incorporation and usage of flexibilities, which will need to be addressed if the TRIPS flexibilities are to be used effectively across the developing world.

With respect to the stated trade policies of the United States and the EU relating to the protection of intellectual property in third countries, especially developing countries, we find that although some concern for the public health needs of developing countries is reflected, in general, the policies fail to adequately take into account the public health priorities of developing country trading partners.

Finally, with respect to FTAs, we find that a number of provisions in recently concluded FTAs between developed countries (essentially the United States) and developing countries, pose a real risk of undermining the effective use of TRIPS flexibilities in developing countries for public health purposes.

The analysis and conclusions in the study regarding the use of TRIPS flexibilities by developing countries, the intellectual property-related trade policies of the United States and the EU and other developed countries and, the implications of FTAs for public health protection in developing countries, are underpinned by a number of public health principles for the implementation of intellectual property in the area of pharmaceuticals. It is in this context that we make a range of recommendations for the consideration of the Commission on how intellectual property regimes could be better implemented, used and/or reformed, nationally and internationally, to facilitate the development and access to medicines in developing countries.

From a public health perspective, developed and developing countries not only have the flexibility to utilize and/or facilitate the utilization of TRIPS flexibilities for public health purposes but, in fact they have an obligation to do so. Consequently, notwithstanding the tentative steps that have been taken in this direction, further guidance and clarity is required to facilitate the incorporation of TRIPS flexibilities and their use to promote access to medicines. This clarity can be assured by defining public health principles and guidelines for implementing intellectual property-related measures in the public health sector.

Policy makers in developing countries and developed countries need to base their implementation of intellectual property rules on these pro-public health and pro-access principles. These principles, in the context of access to medicines, are informed by a range of national legal and policy instruments, from the national constitutions to national drug policies, where they exist, to international legal and policy instruments including the Constitution of the World Health Organization (WHO).

The achievement of public health objectives must be the guiding principle for the implementation of intellectual property rules and policies in the pharmaceutical sector. The implementation of intellectual

property rules and policies should be based on the following key principles and guidelines. The policy and rules in this area should ensure:

- a rapid and effective response to public health needs;
- sustainability of supply of quality medicines and other health products at affordable prices;
- competition through the facilitation of a multiplicity of potential suppliers, both from developed and developing countries; and,
- the provision for a wide range of pharmaceuticals to meet an array of health needs, as well as the need to ensure equality of opportunities for countries in need, irrespective of their level of technological capacity, including countries with insufficient or lack of manufacturing capacity, and irrespective of their membership in the WTO.

## **IMPLEMENTATION OF TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PURPOSES IN DEVELOPING COUNTRIES**

The examples of developing countries' use of the TRIPS flexibilities are not many, but they are growing. In 2002, Zimbabwe issued a declaration of emergency, which empowered the Minister of Justice, Legal and Parliamentary Affairs to authorize any government department or third party to use any patented invention for the service of the state. A local producer was authorized to manufacture and supply anti-retroviral (ARV) medicines to government health institutions under a government use licence. In 2003, the Malaysian government used the provisions of its patent law to allow for the importation of generic ARVs from India for use in public hospitals. In 2004, both Mozambique and Zambia issued compulsory licences for the local production of ARVs. In the same year, the Indonesian President also issued a decree authorizing the government use of patents related to two ARVs, empowering the Minister



of Health to appoint a pharmaceutical company to undertake local production of these medicines.

In South Africa and more recently Kenya, licences have been granted to local manufacturers by patent holding companies for the production of ARVs. In the South African case, the licences were granted based on a settlement in a competition claim which would make these licences technically compulsory licences. In Kenya, the voluntary licences followed concerted pressure from the government, civil society organizations and local manufacturers. Although technically voluntary licences, in that they were negotiated between the patent holding companies and the licensee company, the political and legal context in this case should be noted. It can be argued that in both South Africa and Kenya, the patent holding companies were compelled to enter into voluntary licensing arrangements with local producers, given that national legislation in both countries incorporated a number of the TRIPS flexibilities and, there seemed to be sufficient political impetus for their use.

Below, we summarize our analysis and recommendations with respect to the implementation and use of various TRIPS Flexibilities in developing countries. In particular, the study examined the following flexibilities: (1) transition periods; (2) compulsory licensing; (3) public, non-commercial use of patents; (4) parallel importation; (5) exceptions from patentability; and (6) limits on data protection.

## **Transition Periods**

The TRIPS Agreement provides three transition periods for the implementation of its minimum standards. The first two sets of transition periods, that is those relating to developed countries and developing countries, have lapsed. The expiry of the 2005 deadline has important implications for the future supply and availability of generic versions of patented medicines and, its consequential impact on prices and affordability. Although the impact is not expected immediately, it can be foreseen that generic versions of new medicines may no longer be produced in India, if they come under product patent protection. This not only affects the generic industry in India, but also other countries depending on generic medicines and active ingredients from India. In this scenario, the avail-

ability and use of TRIPS flexibilities in producing countries such as India, as well as Thailand and Brazil, will become even more important.

The third transitional period, that relating to least-developed countries (LDCs), will remain in force for pharmaceutical patents and test data protection at least until 2016 by virtue of the TRIPS Council's Decision of 27 June 2002 (WTO document IP/C/W/25) under Article 66.1 of TRIPS. This Decision was taken to implement paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health. This period could still be extended after 2016. From a public health perspective, this extension of the transition period for LDCs is of significant importance.

The extension is a clear recognition of the implications of patent protection on public health. Thus, it is recommended that all LDCs adopt the necessary measures to use the 2016 transition period in relation to pharmaceutical patents and test data protection. Although there is some uncertainty with respect to patents already granted, it is not questioned that LDCs can prospectively suspend the operation of their patent, test data protection and market exclusivity schemes with respect to medicines until 2016. Whilst the absence of pharmaceutical patents may or may not encourage the development and growth of the local pharmaceutical industry, at the minimum, its absence will ensure that patent rights will not be an obstacle to the supply of generic medicines.

## **Compulsory Licensing**

Virtually all developing countries whose laws and practices we reviewed provided for the granting of compulsory licences, underscoring the critical importance that countries place on this policy tool for public health and other socio-economic purposes. The grounds upon which such licences could be granted however, varies considerably. To ensure the widest possible use of compulsory licensing, developing countries should not only incorporate within their patent laws provisions to enable the granting of compulsory licences but, they should also specify as many of the possible grounds for the issuing of licences in order to avoid ambiguity or uncertainty.

In many cases, the most significant barrier to the use of compulsory licensing is the absence of simple, straightforward legislative and administrative procedures, which establish clear decision-making processes and responsibilities. A multi-agency committee may be set up at the national level, to enable relevant agencies to discuss and take joint decisions. The setting of adequate remuneration or compensation (as required by Article 31(h) of TRIPS), such as the adoption of royalty guidelines, should also be predictable and easy to administer, to reduce uncertainty and to facilitate speedier decision-making.

### **Public, non-commercial use of Patents (Government Use)**

The right of the state to use a patent without the consent of the patent holder for public health purposes is recognized to be an important public health safeguard by many countries. Those developing countries which have not done so should incorporate within their domestic legislation government and non-commercial use provisions that are no less broad than those currently applicable in the United States or the United Kingdom legislation. Although Article 31 of the TRIPS Agreement sets out the conditions governing both government use of patents and compulsory licences, one important difference is that government use of patents may be “fast-tracked” because of the waiver of the requirement for prior negotiations with patent holders.

In this regard, the establishment of a straightforward and simple administrative system of inter-agency decision-making process, as in the case of compulsory licensing, is also paramount. As for compulsory licences, it will also be important to formulate open and transparent decision-making processes and procedures, including the formulation of guidelines for determining adequate remuneration so that it is predictable and easy to administer. A single administrative system could serve the purpose of facilitating decision-making in relation to the granting of compulsory licences and government use authorization.

## **Parallel Importation**

Parallel importing can be an important tool enabling access to affordable medicines because there still are substantial price differences for pharmaceutical products in different markets. Permitting some form of parallel imports provides opportunities to shop for better-priced pharmaceutical products. Developing countries should avail themselves of the widest scope in terms of parallel imports and incorporate explicit provisions to put into effect an international exhaustion regime in their national patent laws. It is important to remember that while this “flexibility” is allowed in the TRIPS Agreement and confirmed by the Doha Declaration, it does not automatically translate into the national regimes, and it will be necessary for specific legal provisions be enacted in national laws.

## **Exceptions to Patent Rights**

Apart from the proviso “that exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner taking into account the legitimate interests of third parties”, Article 30 of the TRIPS Agreement does not define the scope or nature of the permissible exceptions. The result is that countries have considerable freedom in this area. In addition, paragraph 5(a) of the Doha Declarations stresses the importance of the object and purpose of the TRIPS Agreement in the implementation and interpretation the Agreement.

Consequently, exceptions crafted to achieve objectives related to the promotion of the transfer of technology; the prevention of abuse of intellectual property rights and the protection of public health are justifiable and desirable. In particular, the early working (or the Bolar) exception is an important mechanism in facilitating the production of, and accelerating the introduction of generic substitutes on patent expiry. This exception has important implications for developing countries, especially if they are currently or potentially producers of generic medicines. Even where they are not likely to be producers of medicines, the United Kingdom Commission on Intellectual Property Rights (IPR Commission) has recommended that developing countries incorporate a Bolar-type exception within their domestic law, in order to enable the

generic products of a foreign company to gain regulatory approval and to enter the market soon after the expiry of the patent.

### **Exemptions from Patentability**

The TRIPS Agreement only requires that patents be granted to products and processes which are new, involve an inventive step and are industrially applicable. The Agreement does not require the patenting of new uses of known products including pharmaceuticals, and permits countries to deny protection for such uses for lack of novelty, inventive step or industrial applicability. Protection of new uses, particularly second medical indications, is often used for anti-competitive purposes mainly for extending patent protection periods and blocking generic entry.

Therefore, it is prudent for developing countries to exclude new uses of known products or processes from patentability, in order to promote access to medicines. This is the approach recommended by the IPR Commission, which stated that “most developing countries, particularly those without research capabilities, should strictly exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products”.

### **Limits on Data Protection**

In many countries, national health authorities rely on the test data relating to quality, safety and efficacy as well as information on the composition and the physical and chemical characteristics of a product submitted by the originator company, usually, but not always, the patent holder, to register generic substitutes based on bioequivalence. This approach is fully compatible with the provisions of Article 39.3 of the TRIPS Agreement which requires the protection of such data only from unfair commercial use. However, in some jurisdictions, such as in the United States and in the EU, this provision has been implemented by granting a time-limited exclusivity to the originator company, during which period the regulatory authorities can not rely on the test data to register generic substitutes. The TRIPS Agreement does not require the granting of such exclusivity.

On the basis of paragraph 4 of the Doha Declaration which provides that provisions of the Agreement 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”, developing countries should allow drug regulatory authorities to approve equivalent generic substitutes on the basis of reliance on the originator data from the time of its submission. They should implement data protection legislation that is consistent with public health objectives, that is, to facilitate the entry of generic competitors.

### **Implementation of the WTO Decision under Paragraph 6 of the Doha Declaration**

At the WTO Doha Ministerial Conference in 2001, WTO Members in adopting the Doha Declaration on TRIPS and Public Health, recognized in paragraph 6, that although developing countries had the theoretical flexibility to grant compulsory licences, many of them could not effectively use this policy tool for public health purposes due to insufficient or lack of manufacturing capacity in the pharmaceutical sector. Under that paragraph, the Council for TRIPS was tasked with finding an expeditious solution for these countries. A Decision implementing paragraph 6 of the Doha Declaration was adopted on 30 August 2003 by the WTO General Council. For countries to make effective use of the Decision to achieve public health objectives however, it will be important for domestic laws or regulations to reflect the following aspects:

- To provide for a broad range of grounds for the grant of compulsory licences and specific provisions for government use of patents, as already stated above. In this case, grounds for compulsory licence should also specifically include importation.
- There should be a time limitation for negotiations for voluntary licences so that where prior negotiations for a voluntary licence with the patent holder is required, a definite time limit should be set for such negotiations, after which the requirement shall be deemed satisfied, so that the grant of a compulsory licence can proceed without unnecessary delay.

- Provisions in domestic law should not limit the implementation of the Decision to a restricted list of products or diseases, as it is clear that the Decision is applicable without any restrictions on products or diseases. There could also be a clear definition of “pharmaceutical products” for which the Decision can be used. Countries should consider explicitly including diagnostics, vaccines and medical devices used for treatment. Provisions in national legislation should also allow for the compulsory licences or the government use authorization to refer to the product, instead of the patent(s) on that product, as this will facilitate decision making, and reduce the time required to conduct patent searches on all patents in force with respect to each product.
- The Decision also included a waiver for Article 31(h) so the requirement that adequate remuneration be paid to patent holders should be waived in the importing country. A specific provision should be made in domestic law on this waiver.
- Any litigation or appeal by the patent holder should not suspend the implementation of a compulsory licence.

It is also recommended that whenever possible, countries should consider using measures less cumbersome than the system in the WTO Decision. The Decision does not preclude other options available under the TRIPS Agreement and the Doha Declaration, as is clearly stated in Paragraph 9 of the Decision. Thus, where no relevant patent is in force in the exporting country, production and export of the generic version of a medicine patented elsewhere can take place without the need of a compulsory licence. In those countries, notably India, where the 1 January 2005 transition period was employed to delay the provision of patent protection, a number of medicines currently under patent elsewhere are still off-patent. In such cases, there is no need to resort to the use of the Decision.

## INTELLECTUAL PROPERTY-RELATED TRADE POLICIES OF MAJOR DEVELOPED COUNTRIES AND PUBLIC HEALTH IN DEVELOPING COUNTRIES

Major developed countries, especially the United States and the EU, due to their economic, political and military power, have a major influence on how developing countries deal with intellectual property and other policies relating to pharmaceuticals. For this reason, the policies of these developed countries *vis-à-vis* developing countries with respect to intellectual property and access to medicines are a critical factor that determines how the latter address matters relating to intellectual property, innovation and public health. For the study, we reviewed the stated trade policies of the United States and the EU, the two major trading powers, and Canada, Japan and Switzerland with respect to intellectual property, to determine whether these countries take into account public health priorities of developing countries and international commitments such as the Doha Declaration.

### The United States

The current stated United States policy on intellectual property as set out in the Trade Act 2002 and exemplified in the Special 301 Reports, with the main focus being on preserving its unparalleled strength in economic, political and military affairs, raises particular concerns. First, a trade policy framed purely as a foreign trade and security instrument is unlikely to take adequate account of the priorities of developing countries with respect to public health. In particular, the United States policy fails to reflect a clear objective *vis-à-vis* developing countries, nor contributes to the promotion of technological innovation in these countries with respect to the diseases that disproportionately affect them. Furthermore, it does not contribute to the transfer and dissemination of technology, to the mutual advantage of producer's and users of technological knowledge and, in a manner conducive to social and economic welfare.

Secondly, the United States policy, by focusing exclusively on the interests of its export industries, may lead to very restrictive interpreta-



tions of the flexibilities contained in international agreements to the detriment of public health needs in developing countries. Finally, the stated objective for bilateral and multilateral agreements entered into by the United States to reflect a standard of protection similar to that of the United States runs counter to the well accepted principle that the standard of intellectual property protection in each country should reflect the particular economic, social and cultural circumstances and level of development of the country.

For the above reasons, the United States should consider:

- reviewing and revising its trade policy with respect to intellectual property in third countries, especially developing countries, to not only ensure respect for the Doha Declaration but, the wider objectives on innovation and the transfer and dissemination of technology, especially technology related to pharmaceuticals for diseases that disproportionately affect developing countries;
- calibrating its policy on intellectual property in third countries so that it can reflect a better balance between the legitimate interests of its export industries and the need to improve access to medical technologies in the poorest countries;
- explicitly spelling out in its trade policy that provisions of multilateral and bilateral trade agreements governing intellectual property entered into by the United States with developing countries, reflect standards of protection that are in line with the economic, social and cultural development of those developing countries; and
- amending its relevant laws and fully implementing the 30 August 2003 WTO Decision and/or the proposed amendment to the TRIPS Agreement, so as to enable those developing countries with insufficient or no manufacturing capacity in the pharmaceutical sector to issue compulsory licences and import generic medicines from the United States.

## The European Union

The EU trade policy with respect to intellectual property protection in third countries, especially developing countries, is more nuanced and a little more favourable to public health in developing countries. The stated policy, among others, is aimed at ensuring that intellectual property rights are supportive of public health objectives and that accession to international instruments referred to in the TRIPS Agreement is in line with the level of development of developing countries.

However, the EU's policy of ensuring an adequate and effective level of protection of intellectual property rights, and other rights covered by TRIPS *in line with the international standards*, and related policies such as its enforcement strategy, raises concerns. The EU's intellectual property enforcement strategy also seems to be implicitly predominated by market access concerns as opposed to improving availability and access to essential products including medicines. Finally, although the EU has made efforts to implement the 30 August Decision to enable the production and export of pharmaceuticals to developing countries with insufficient or no manufacturing capacity, the EU should take measures to ensure that the conditions imposed on such exports do not lead to disincentives to generic producers.

In this regard, the EU should consider, among others:

- clarifying the meaning of the notion of “ensuring an adequate and effective level of protection of intellectual property, in line with international standards”, in the Cotonou Agreement and, in its enforcement strategy in third countries, so as to ensure that the phrase does not result in the imposition of TRIPS-plus standards negotiated bilaterally, regionally or multilaterally and, that it does not mean that TRIPS flexibilities, such as test data protection, must be interpreted by developing countries in line with the EU interpretation; and,
- reviewing and revising its draft regulation relating to exports under the 30 August Decision, to ensure that no additional conditions which are not required in the WTO Decision, which may discourage potential suppliers are imposed; that

there are precise definitions of other conditions such as those relating to time frames for prior negotiations; that there are instruments to promote the transfer of technology and capacity building in pharmaceuticals in developing countries and, that non-WTO developing countries have the possibility to import products under the system.

### **Japan, Canada and Switzerland**

Japan, Canada and Switzerland are important players in the international discussions on intellectual property and public health and have important interests in the pharmaceutical markets in developing countries. Although their stated policies do not seem to pose as serious a threat to public health in developing countries as the United States and EU policies, there are important concerns. In this regard:

- these countries should consider clearly stating their policies with respect to the protection of intellectual property and access to essential medicines in developing countries, with a view to ensure that their approach to this question is in line with the objectives of developing countries in promoting access to medicines for diseases that disproportionately affect them;
- Japan and Switzerland, as important players in the world pharmaceutical market, should take immediate measures to enact legislation to implement the 30 August Decision and any subsequent amendment to the TRIPS Agreement;
- although Canada's efforts, particularly in implementing the 30 August Decision should be applauded, steps should be taken to ensure that its legislation does not contain provisions which make it difficult to export generics under the Decision.

## **BILATERAL AND REGIONAL FTAs: PRACTICAL IMPLICATIONS FOR ACCESS TO MEDICINES IN DEVELOPING COUNTRIES**

Through the use of TRIPS flexibilities governments, particularly developing country governments, can address problems of lack of access to medicines for diseases that affect their populations, high pharmaceutical prices and restrictions on availability. In particular, they can allow different types of exceptions to the rights conferred by patent rights; they can issue compulsory licences to allow third parties to make generic versions of patented medicines; they can permit parallel imports by adopting an international exhaustion regime; they can take remedial measures against pharmaceutical companies which engage in anti-competitive practices; they could limit the types of subject matter on which pharmaceutical patents can be granted; they can accelerate the introduction of generics into the market by allowing third party testing, manufacturing and export for purposes of meeting regulatory approval requirements and, by not extending patent terms on the basis of regulatory delays in registration of medicines; and they can allow regulatory agencies to rely on test data provided by the originator of the product to register generics.

Recent FTAs between developing and developed countries, particularly FTAs involving the United States, have however, been cited as having a serious potential to undermine the use of the TRIPS flexibilities for public health purposes and, for promoting innovation in respect to diseases that disproportionately affect developing countries' populations. Despite these potentially serious problems, developing countries continue to conclude FTAs with the United States with fairly similar provisions on intellectual property.

It appears that while these countries accept that they are losing TRIPS flexibilities, they seem to consider that overall, there is a net gain for them and the concessions in intellectual property affecting access to medicines are justified. However, this net gains analysis presumes that earnings in agriculture or other sectors due to increased market access for example, would automatically translate into the ability to afford higher priced medicines. Though higher export earnings may lead to better earnings for some parts of the population and therefore better abil-

ity to afford medicine, it is difficult to see how overall, such earnings would improve the ability of citizens to afford higher cost medicines.

In the study, we have examined the potential effects of FTAs as manifested in the relevant provisions on intellectual property of recently concluded FTAs for efforts in promoting access to medicines and, for the various options available under the TRIPS Agreement. The FTAs covered here are mainly the United States FTAs which are the most recent and, have been concluded after the adoption of the Doha Declaration.

### **The Object and Purpose of Intellectual Property Protection and the General Approach to Exceptions**

The object and purpose of intellectual protection and the relationship between the purpose of protection and the promotion of technological innovation and the transfer and dissemination of technology, as well as the promotion of social and economic welfare, are important balancing elements in the TRIPS Agreement. The object and purpose has important implications for the use and interpretation of TRIPS flexibilities for public health. As confirmed by the Doha Declaration, “[E]ach provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.” Most of the recently concluded FTAs do not clearly spell out the object and purpose of the intellectual property protection under the FTAs, nor do they emphasize the importance of technological innovation, transfer of technology and the protection of economic and social welfare.

To ensure that public health flexibilities are fully preserved in FTAs, the FTAs or at least their intellectual property chapters, must clearly spell out the object and purpose of intellectual property with a focus on technological innovation, transfer of technology and the protection of essential sectors of the economy such as public health. This will be important, not only for preserving the flexibilities, but also for assuring a public health-sensitive interpretation of those flexibilities. A clear object and purpose that emphasizes innovation, technology transfer and the protection of essential sectors and socio-economic welfare, including

public health, will also be critical to ensure that the application of non-violation and situation complaints to intellectual property matters under the FTAs, does not undermine the implementation of the flexibilities.

The approach to the related issue of exceptions under Article 30 of TRIPS has been generally consistent with public health objectives and should be applauded. However, care must be taken to ensure that the agreements do not establish restrictive special rules with respect to the actual operation of some of the Article 30 exceptions. This has been particularly the case with respect to the early working exception and the patenting of new uses for pharmaceuticals. Where such rules have been established, developing countries should either seek to amend the FTAs or, at the very least seek confirmation through additional agreements, for example, that these rules do not restrict the use of Article 30 consistent measures.

### **Protection of Test Data and Patent Term Extensions**

As has already been pointed out, there is an obvious public health interest in limiting the scope and nature of test data protection to ensure the timely entry of generic medicines and the use of TRIPS flexibilities, including compulsory licences. The current trend in FTAs is to require the application of a mandatory exclusivity model, where:

- the registration of generics based on evidence of marketing approval or safety and efficacy in third countries is prohibited for five years from the date of approval of the originator in the country, although the regulatory agencies in that country do not require the submission of test data;
- the concept of utilization of new chemical entities is reduced to meaning “one that does not contain a chemical entity that has previously been approved by the Party”;
- TRIPS level protection is required for information disclosed where necessary to protect the public;

- and developing countries are required to introduce patent extensions due to regulatory delays relating to both pharmaceutical registration and patent grant procedures.

This approach has serious negative consequences for public health objectives. The assurance by the United States that test data provisions would not stand in the way of the TRIPS/Health solution does not adequately address these concerns. Consequently:

- the United States and other developed countries should take measures to clarify and where necessary, amend FTA provisions that unduly restrict the use of test data by public health authorities. Furthermore, extensive and complex protections such as those contained in the United States-CAFTA FTA should be avoided in future agreements;
- test data protection provisions should not only not stand in the way of the use of the TRIPS flexibilities and the 30 August 2003 WTO Decision, but also with respect to all measures necessary to assure access to essential generic medicines;
- developing countries that have already entered into FTAs which contain enhanced protections for test data, should seek ways to amend and clarify the FTA provisions relating to test data, to ensure that such protection does not impede the timely entry of generics; and
- developing countries that are currently negotiating FTAs should ensure that all flexibilities contained in the TRIPS Agreement with respect to test data protection are preserved and, that at the national level, clear rules are established to ensure that the operation of the system does not impede the timely entry of generics on the market.

## **Compulsory Licences including Licences under the 30 August 2003 WTO Decision and Government Use**

Compulsory licensing and government use provisions, as already noted, are key features of a public health focused intellectual property regime in any country, developed and developing. The Doha Declaration confirmed that the use of these provisions is a key flexibility and, in particular, determined that each country should have the freedom to determine the grounds for the issue of compulsory licences. Retaining this flexibility, especially the freedom to determine a wide range of grounds, is a key measure.

Although there has been no significant erosion of this key flexibility in FTAs, in the sense that the two cases where restrictions have been imposed so far are somewhat special, care should be taken to ensure that the approach such as that in the United States-Singapore and United States-Jordan FTAs, is not replicated with other developing countries. The WHO and other international bodies should be asked to study the implications of such a restrictive approach for access to medicines in Singapore and Jordan as a basis for evaluating the desirability of such an approach even for middle-income countries.

### **The Early Working Exception**

The early working exception has been confirmed as a permissible practice under the TRIPS Agreement and, its advantages for public health purposes have been amply demonstrated by its practical application in many developing and developed countries such as Canada. In general, recent FTAs have preserved this important flexibility. However, the approach in most of these FTAs has constrained the use of this flexibility in one significant way.

By requiring that exportation under the FTA provision is only permissible for purposes of registration in the country where a third person used the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical, that is in the country where the tests were carried out, the FTAs have introduced an impracticable system. There is no possibil-



ity that generic companies would be able to undertake market approval related research and tests in each country where they seek registration. For this reason, it is difficult to justify such an impractical system from a public health perspective.

To mitigate the clear negative implications, immediate measures need to be taken to either:

- amend the relevant FTA provisions to remove the requirement that the export is only permissible for purposes of registration in the country where the export emanates and, to clarify that export is permissible for purposes of obtaining marketing approval in third countries; or,
- at the very least, to clarify through additional agreements, that the provision would not stand in the way of ensuring the timely entry of generics into the markets of countries where tests for marketing approval can not be carried out and, the use of other TRIPS flexibilities including compulsory licensing.

## **Exemptions from Patentability**

Patentability criteria and exemptions from patentability is an important though often forgotten flexibility with long-term implications for innovation, technology transfer and dissemination of technology in the pharmaceutical sector. This is a general problem but, particularly pernicious with respect to biotechnological inventions which are playing an ever increasing role in the pharmaceutical sector. The notion of substantial and credible utility for example, as opposed to the TRIPS industrial applicability standard, the push for the mandatory patenting of plants and animals and the requirement for patenting new uses of known products under recent FTAs, therefore have very serious implications that need to be immediately addressed.

No public health-related reason seems to justify this approach. Consequently, it is advisable that consideration be given to:

- revising and, as necessary, amending recent FTAs to ensure that there are no long-term negative consequences for pharmaceutical innovation and the transfer of technology arising from a permissive patentability criteria that allows patent claims over information the effect of, and the application of which is unknown, the patenting of plants and animals and the patenting of new uses of known products, especially second medical indications; and,
- advising developing countries currently negotiating FTAs or, that intend to negotiate FTAs in the future, to ensure that they retain and use their TRIPS flexibilities in this area.

### **Parallel Importation**

While there may be a case for developed countries prohibiting parallel importation, the case for developing countries prohibiting parallel imports does not find much support in current literature and existing evidence. Consequently, developing countries should, as far as possible, adopt an international exhaustion regime except where there is evidence that the higher price charges resulting from prohibition on the importation of cheaper products serves a greater economic or social purpose. This is likely to be the case only in exceptional circumstances, because even patients in the United States have found it difficult to live with a national exhaustion scheme resulting in waves of elderly people traveling to Canada to buy prescription drugs.

Countries, such as Morocco, which have already entered into an FTA, should explore ways to revise the national exhaustion provision. For developing countries that are negotiating FTAs, they should ensure that they preserve their flexibility on this issue and, in particular, adopt an international exhaustion regime. It is laudable that a number of developing countries that have entered into FTAs recently, such as Chile, CAFTA countries and Singapore have retained this flexibility.



## I. INTRODUCTION

The current international debate on the implications of intellectual property, especially the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) for access to essential medicines, came into the international media limelight starting in 1997 with the attempts by the United States government to force the revision of South Africa's Medicines and Related Substances Amendment Act<sup>1</sup> and, the subsequent filing of a legal challenge against that law by the South African Pharmaceutical Manufacturers Association. Thereafter, particularly in the run 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 the flexibilities in the Agreement and, the use of these flexibilities to improve access to essential medicines.

This debate culminated in the adoption in Doha of the Declaration on the TRIPS Agreement and Public Health (the Doha Declaration).<sup>2</sup> Therefore, the Doha Declaration represents a final agreement between the two camps that public health considerations condition the extent to which patent protection is implemented. The Ministers of the then 142 Members of the WTO expressed their agreement in the following terms:

“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

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<sup>1</sup> Act No. 90 of 1997.

<sup>2</sup> “Declaration on the TRIPS Agreement and Public Health”, WTO document WT/MIN(01)/DEC/W/2 dated November 20, 2001. Available at <http://www.wto.org>.

Members' rights to protect public health and in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”<sup>3</sup>

However, although the Doha Declaration resolved the issues in the WTO, there remain major challenges for developing countries to interpret and implement the TRIPS Agreement and other intellectual property rules, in a manner supportive of their efforts to protect public health and promote access to medicines for all. Indeed, the interpretation of the Doha Declaration has been a subject of controversy.<sup>4</sup>

At the same time, many developing countries have failed either to incorporate the TRIPS flexibilities into their laws or, have not used such flexibilities for public health purposes for a variety of reasons. New developments and trends in the field of intellectual property also suggest that the existing flexibilities may be eroded especially through bilateral and regional free trade agreements (FTAs) between developed and developing countries or, other multilateral agreements such as treaties currently under negotiation at the World Intellectual Property Organization (WIPO).<sup>5</sup>

Consequently, this study, based on existing literature and available evidence, seeks to:

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<sup>3</sup> See para 4 of the Declaration.

<sup>4</sup> For example, during the subsequent negotiations on the implementation of paragraph 6 of the Declaration, disagreements arose with respect to whether the Declaration applied to all diseases or only to the illustrative epidemics specifically mentioned in paragraph 1 of the Declaration.

<sup>5</sup> For a discussion of the current negotiations at WIPO and their implications for public policy in various sectors including public health, see Musungu and Duffield, (2003); the United Kingdom Commission on Intellectual Property Commission (IPR Commission), (2002); and Correa and Musungu, (2002).

- examine the extent to which TRIPS flexibilities, for example, compulsory licensing, parallel importation, patent exceptions, as well as the 30 August Decision, have been incorporated into national legislation in developing countries;
- analyze the actual use of the flexibilities by developing countries, including the use of compulsory licensing as a credible threat in price negotiations and, identify reasons why such flexibilities may not be used;
- review the policies of developed countries, in particular the United States and the European Union (EU), as well as Canada, Japan, and Switzerland, in respect of the intellectual property components of trade policies, to determine whether they take adequate account of public health priorities in developing countries; and,
- examine the potential effect of bilateral and regional FTAs, identifying in particular, the aspects that may have implications for public health and access to medicine.

Based on this examination, review and analysis, the study makes a number of proposals and recommendations for consideration by the Commission on how intellectual property regimes could be better implemented, used and or reformed, nationally and internationally, to facilitate the development and access to medicines in developing countries.

The study is divided into four main parts. In Part II we examine the extent to which developing countries have incorporated TRIPS flexibilities into their legislations, and analyze the actual use of these flexibilities for promoting access to medicines. In Part III we review the stated policies of developed countries, particularly the United States and the EU as well as Canada, Japan and Switzerland, with respect to the intellectual property components of trade policies, to determine whether they take into account public health priorities of developing countries. In Part IV we examine the potential effects of FTAs on intellectual property related mechanisms for promoting access to medicines. Finally in Part V, we conclude with final remarks on how intellectual property

regimes could be better implemented, used and or reformed, nationally and internationally, to facilitate the development and access to medicines in developing countries.

The analysis and conclusions about the use of TRIPS flexibilities by developing countries, the intellectual property-related trade policies of the United States and the EU and, the implications of FTAs for public health protection in developing countries, have been framed to reflect a number of public health principles that should guide the formulation, implementation and interpretation of intellectual property in the area of pharmaceuticals.

From a public health perspective, developed and developing countries not only have the flexibility to utilize and/or facilitate the utilization of TRIPS flexibilities for public health purposes but, in fact they have an obligation to do so. Consequently, notwithstanding the tentative steps that have been taken in this direction, further guidance and clarity is required to facilitate the incorporation of TRIPS flexibilities and their use to promote access to medicines. This clarity can be assured by defining public health principles and guidelines, which such intellectual property-related measures are intended to meet.

Policy makers in developing countries as well as developed countries need to base their implementation of intellectual property rules on these pro-public health and pro-access principles. These public health principles, in the context of access to medicines, are informed by a range of national legal and policy instruments, from national constitutions to national drug policies where they exist, to international legal and policy instruments, including the Constitution of the World Health Organization (WHO).

The public health principles that should guide the implementation of intellectual property rules and policies include, but are not limited to, the principle that intellectual property rules and policies should ensure:

- a rapid and effective response to public health needs;
- sustainability of supply of quality medicines at affordable prices;

- competition, through the facilitation of multiplicity of potential suppliers, both from developed and developing countries; and,
- the provision for a wide range of pharmaceuticals to meet an array of health needs and, the need to ensure equality of opportunities for countries in need, irrespective of their level of technological capacity, including countries with insufficient or lack of manufacturing capacity, and irrespective of their membership of the WTO.





## **II. IMPLEMENTATION OF TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PURPOSES IN DEVELOPING COUNTRIES**

The objectives of this part are two-fold. The first is to analyze the extent to which developing countries have implemented the so-called TRIPS flexibilities within their national legislation. The second is to review the actual use of these flexibilities for public health purposes. In this regard, two key questions are asked:

- What national legislation is in place in developing countries?
- What needs to be put in place to enable countries to use TRIPS-compliant flexibilities to facilitate access to medicines?

The main focus is on the implementation of the provisions of the TRIPS Agreement as they relate to patent protection, set out in Section 5 of the Agreement. An overview of the key public health-related TRIPS flexibilities that could be incorporated into domestic patent laws is first provided. The prevailing laws in developing countries are then assessed against this range of public health-related flexibilities to determine the extent to which they have incorporated such flexibilities. The patent legislation of 49 developing and least-developed countries were reviewed.<sup>6</sup> The findings of this review are set out in Annex I. Annex II contains a statistical analysis of the review findings. Four case studies of the use of the TRIPS flexibilities are also presented and assessed to

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<sup>6</sup> Data on national legislation was compiled from a review of national patent laws, where these were available. Additional information was sourced from the reports of the WTO TRIPS Council review of implementing legislation. Supplementary sources of information included some unpublished data, including that collected for the WHO Network for Monitoring the Impact of Globalization and TRIPS on Access to medicines.

bring out lessons learnt in the use of TRIPS flexibilities and recommendations or proposals for improvements.

Whilst the TRIPS Agreement has introduced an important multilateral framework for intellectual property rights, and obliges WTO Members to adhere to the minimum standards of intellectual property protection and enforcement, it does not prescribe a universal or harmonized intellectual property regime.<sup>7</sup>

The TRIPS Agreement was the result of intense negotiations. The idea of incorporating intellectual property protection within the WTO was promoted by the group of (mainly developed) countries, which sought to introduce a multilateral framework reflecting the then prevailing standards of intellectual property rights protection in their countries. Although the developing countries were not successful in resisting the introduction of the TRIPS Agreement, they successfully negotiated into the Agreement a degree of policy autonomy for governments in relation to the implementation of the Agreement's obligations. The TRIPS Agreement thus reflects the somewhat uneasy compromise that was eventually struck between these two main groups of countries during the negotiating process. As such, the Agreement contains a degree of built-in flexibility, which trade negotiators from developing countries have been at pains to preserve, so as to allow countries sufficient room to accommodate their own patent and intellectual property systems and developmental needs.<sup>8</sup>

The flexibility in the TRIPS Agreement can be categorized into two types.

The first is time-based, in the form of transition periods, which allow developing and least-developed countries extra time to implement their TRIPS obligations. Three transition periods are provided for in the Agreement: 1) the 1995-2000 period, at the end of which developing countries were obliged to implement the TRIPS Agreement; 2) the

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<sup>7</sup> Correa (2000), p.3.

<sup>8</sup> For a discussion of the negotiating process, see e.g.: Raghavan (1990); Braithwaite and Drahos (2000); and the UNCTAD-ICTSD (2005).

2000-2005 period, which provided an additional period of five years to put in place product patent protection for pharmaceuticals or agrochemicals, for those countries without such protection at the entry into force of the Agreement; and 3) the 1995-2006 period, after which least-developed countries would be required to implement their TRIPS obligations.<sup>9</sup>

In addition to these time-based flexibilities, there are substantive flexibilities in the TRIPS Agreement. This concept of flexibility was much discussed at the height of the debate on TRIPS and access to medicines. The HIV/AIDS pandemic afflicting many developing countries, particularly in sub-Saharan Africa, fuelled the debate, focusing public attention on the manner in which intellectual property protection, as promulgated by the TRIPS Agreement, has an impact on areas of public policy-making, and in particular public health.

In the face of pressures from certain developed countries and pharmaceutical companies which favoured narrow interpretations of the TRIPS provisions and its flexibilities, developing countries in the WTO sought greater recognition for their position that the TRIPS Agreement did provide countries flexibility and discretion. These countries argued that the provisions of the Agreement did not prevent them from adopting measures to ensure access to medicines and to meet other public health needs.<sup>10</sup> Their efforts culminated in the adoption of the Doha Declaration on the TRIPS Agreement and Public Health at the Fourth WTO Ministerial Conference in 2001. Subsequently, the WTO General Council adopted the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, to address the problem of countries with insufficient or no manufacturing capacity to effectively use compulsory licences.<sup>11</sup>

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<sup>9</sup> This transition period has been extended to 2016 with respect to patents on pharmaceutical products and exclusive marketing rights, by TRIPS Council's Decision of 27 June 2002 (WTO document IP/C/W/25) implementing Paragraph 7 of the Doha Declaration.

<sup>10</sup> See TRIPS Council submissions from developing countries and the EC to the TRIPS Council Special Session of 20 June 2001, IP/C/W/296 and IP/C/W/280.

<sup>11</sup> See WTO document WT/L/540

Thus, there are now three pieces of texts that can be said to delineate the WTO legal framework for the protection of intellectual property rights in the context of countries' right to take measures to protect public health including to promote access to medicines. They are: 1) the TRIPS Agreement; 2) the Doha Declaration and 3) the WTO Decision on Paragraph 6.<sup>12</sup>

Although these texts spell out the flexibilities available to countries to overcome intellectual property rights-related barriers to acquiring affordable medicines, they are not self-executing in that, they do not translate automatically into the national regimes. Hence, it will be necessary for specific legal provisions to be enacted in domestic laws to enable countries to make full use of them. This part of the study considers how countries have enacted the TRIPS flexibilities within their domestic laws.

The Doha Declaration re-affirmed the inherent policy flexibility available in the TRIPS Agreement, and clarified that the Agreement does permit governments the ability to consider and implement a range of options that take public health into account when formulating their domestic intellectual property laws and policies. The Declaration referred to several aspects of the Agreement, including the right to grant compulsory licences and the freedom to determine the grounds upon which licences are granted; the right to determine what constitutes a national emergency and circumstances of extreme urgency and, the freedom to establish the regime of exhaustion of intellectual property rights.<sup>13</sup>

Recognizing that the listing of flexibilities was non-exhaustive, the Declaration also clarified how the Agreement should be interpreted and implemented. In Paragraphs 4 and 5(a), the Doha Declaration gives guidance for the overall interpretation and implementation of the TRIPS

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<sup>12</sup> It may be argued that the Chairman's Statement that accompanies the WTO Decision on Paragraph 6 also has legal standing in terms of the interpretation of the Decision. However, WTO Members have expressed differing views on this point, particularly in the context of the current negotiations for the amendment of the TRIPS Agreement.

<sup>13</sup> Paragraph 5 of the Doha Declaration.

provisions. WTO Members, by virtue of the Doha Declaration, have therefore agreed to a rule of interpretation, which will guide future WTO panels and the Appellate Body.<sup>14</sup> Paragraph 4 of the Declaration sets out the fundamental principle, which is that not only can WTO Members implement the TRIPS Agreement in a manner supportive of their rights to protect public health but, that they should do so.<sup>15</sup>

In the light of this rule of interpretation, this part of the study considers the public-health-sensitive options for implementing the provisions of the TRIPS Agreement relating to the following:

- transition periods;
- compulsory licensing;
- public, non-commercial use of patents;
- parallel importation;
- exceptions to patent rights;
- exemptions from patentability;
- limits on data protection.

The study also considers the public-health-sensitive means of implementing the system for import and export adopted by the WTO Decision on Paragraph 6.

The study draws from the wide array of literature on this subject and provides an overview of the flexibilities and the manner by which they can be incorporated within domestic legislation, so that developing countries may use them for the purpose of promoting access to medicines.<sup>16</sup> Analysis of similar provisions in selected developed country legislation also provided useful lessons and examples in optimizing the policy space allowed under the TRIPS Agreement to respond to public interest, in particular public health needs.

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<sup>14</sup> Correa (2002), p.11-12.

<sup>15</sup> Ibid.

<sup>16</sup> Notable references included: Baker (2004), IPR Commission (2002) Correa (2000), World Bank (2004), UNDP (2001), Third World Network (2003), Velasquez & Boulet (1999).

## **II.1 Transition Periods**

As mentioned above, three transition periods are provided for in the TRIPS Agreement.

The end of the 1995-2000 transition period<sup>17</sup> obliged developing countries to implement the TRIPS Agreement and to put into place patent legislation that complied with the minimum standards of intellectual property protection prescribed by the TRIPS Agreement. In terms of patent protection, the critical requirements included the criteria for patentability, the minimum 20-year protection term and, protection for both products and processes in all fields of technology.<sup>18</sup> By the 1 January 2000 deadline, the majority of developing countries already had patent legislation meeting these requirements, although this meant a significant change from their previous patent regimes which allowed for shorter protection terms and differentiated treatment for products or sectors.<sup>19</sup>

The 2000-2005 transition period<sup>20</sup> could be used by those countries which had not provided patent protection for pharmaceuticals or agro-chemical products at the entry into force of the Agreement. They were allowed a further five years to put in place a product patent regime for pharmaceuticals and agro-chemicals. However, the use of this transition period was subject to certain conditions. Developing countries were required to accept patent applications as of 1995, to keep them in a patent queue “mailbox” and, to start processing the applications in 2005.<sup>21</sup> During the mailbox period, developing countries are required to grant exclusive marketing rights for those products for which patents have been filed in the mailbox, where marketing approval of the products had been obtained in the country and, the said product had previously been patented in another country.<sup>22</sup>

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<sup>17</sup> Article 65.2 of the TRIPS Agreement.

<sup>18</sup> Articles 27 and 33 of the TRIPS Agreement.

<sup>19</sup> UNCTAD (1996).

<sup>20</sup> Article 65.4 of the TRIPS Agreement.

<sup>21</sup> Article 70.8 and 70.9 of TRIPS Agreement.

<sup>22</sup> Article 7.8(c) of the TRIPS Agreement.

The 1995-2006 transition period allowed least-developed countries 10 years to implement their obligations under the TRIPS Agreement, in view of their economic, financial and administrative constraints. In addition, this period could still be extended by the TRIPS Council if requested by an LDC Member of the WTO.<sup>23</sup>

### ***II.1.1 Implementation in Developing Countries***

Most developing countries had already put into place some form of patent legislation by the January 2000 deadline. This meant that these countries were obliged to accept patent applications for pharmaceutical products and processes as of the date their patent legislation came into force.

This left two groups of countries with further transition periods. First, there were a number of developing countries that had notified the WTO of their intention to use the 2000-2005 transition, during which they would put in place a product patent regime for pharmaceuticals and agro-chemicals. With the end of this transition period on 1 January 2005, these countries are now obliged to put in place product patent protection and to review the patent applications in their “mailboxes”. Although a total of 13 countries had previously notified the WTO of their use of this transition period, a number of them had put into place product patent protection for pharmaceuticals and agro-chemicals before the end of the 2005 deadline. As of 2003, six Members were still using the transition period - Cuba, Egypt, India, Pakistan, Qatar and the United Arab Emirates. The case of India is a notable example of the use of this flexibility and the effect of the use of this flexibility in India is discussed further in Case Study I, below.

The second group of countries is the LDCs with their 2006 deadline. However, virtually all of the LDC WTO Members provided intellectual property protection regimes well ahead of this deadline. A study for the IPR Commission in 2001 showed that only two LDCs in Africa had yet to provide for intellectual property protection, one of which is not yet a WTO Member.<sup>24</sup> In French-speaking Africa for example, 11

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<sup>23</sup> Article 66.1 of the TRIPS Agreement.

<sup>24</sup> Thorpe (2001)



LDCs by virtue of their membership of the African Intellectual Property Organization (OAPI), the regional patent organization that serves as a common patent authority for the membership, already provide patent protection for pharmaceutical products ahead of their obligations under the TRIPS Agreement.

In Asia, Myanmar - currently engaged in the WTO accession process - is perhaps the only country that has yet to put in place a patent protection regime. Bangladesh, another LDC, is understood to have amended its colonial patent legislation in 1988,<sup>25</sup> but it is not clear if its provisions are enforced.

The transition period for LDCs has been further extended until 2016 but this extension is limited to the obligations under certain provisions in the TRIPS Agreement relating to patents and marketing rights, and data protection for pharmaceutical products.<sup>26</sup> While the TRIPS Council Decision implementing Paragraph 7 of the Doha Declaration extends the transition period for pharmaceutical patents until 2016, LDCs are still obliged to implement the rest of their obligations under the TRIPS Agreement as of 2006.<sup>27</sup> In order to be able to use this flexibility, those LDCs that have already provided patent protection will have to make the necessary changes to their national laws, to provide for this exemption for pharmaceuticals. However, there is some uncertainty in terms of how countries may act to deal with pharmaceutical patents already granted, as the TRIPS Council Decision does not seem to extinguish existing patent holders' rights under national law. While it has been suggested that an LDC may proclaim its intention to suspend patent enforcement pursuant to the Decision, there is a risk of a claim from

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<sup>25</sup> Based on the United Kingdom Patents and Design Act of 1911

<sup>26</sup> Paragraph 7 states that the LDC Members "will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the rights of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement". See also the TRIPS Council Decision of 2002, *supra* note 11.

<sup>27</sup> Unless a further extension of time is granted under the terms of Article 66.1 of the TRIPS Agreement.

a patent holder unless the national law on suspension or non-voluntary use of patents has been properly followed.

Cambodia appears to be the only country that has incorporated the 2016 extension into its patent law to take advantage of this flexibility, with this provision in Article 137 in its Law on the Patents, Utility Model Certificates and Industrial Designs, 2003:

“The pharmaceutical products mentioned in Article 4 of this Law shall be excluded from patent protection until January 01, 2016, according to the declaration of the Ministerial conference in Doha on the TRIPS Agreement and public health dated November 14, 2001.”

Since Cambodia had not provided patent protection prior to this, the problem of existing patents did not arise. On this point, Malawi presents an interesting case. In effecting its anti-retroviral roll-out programme, the Malawian government decided to use the 2016 extension for pharmaceutical patents. Malawi’s roll-out programme is based exclusively on the anti-retroviral fixed-dose combination, Triomune, which is produced by Indian generic manufacturer, Cipla. Since at least two of the components of the fixed-dose combination were under patent protection in Malawi, the Government issued a letter to the United Nations Children’s Fund (UNICEF), which was acting as the procurement agent for its roll-out programme, invoking Paragraph 7. However, the contents of the letter to UNICEF indicate a number of problems. In invoking Paragraph 7 without the necessary changes to the national law, the letter does not address the problem that the pharmaceutical patents in question have already been granted.<sup>28</sup> However, it would also appear that the political and public relations considerations would discourage patent holders from taking action against the Government of Malawi. It is understood that Triomune has already been supplied to Malawi.

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<sup>28</sup> See Lettington & Banda (2004) for a more detailed discussion of the Malawi case.

### **Case study 1** **India's Use of the transition period<sup>29</sup>**

The role of the Indian pharmaceutical industry as a producer of affordable generic medicines and, in particular, anti-retroviral medicines, received wide recognition when the Indian company Cipla, offered its generic version of the anti-retroviral triple therapy at US\$350.00 per patient per year.<sup>30</sup> This offer has been credited with triggering significant reductions in prices of anti-retroviral triple therapy, which had been largely unaffordable for most of the HIV patients in the developing world.

In 1999, the Indian pharmaceutical industry supplied 70% of the bulk drugs (active pharmaceutical ingredients) and 80% of formulations in the country. This would make India one of the few countries, and possibly the only developing country in the world, that has come this close to achieving so-called self-sufficiency in medicines. The availability of lower-cost human resources with specialist technical knowledge, coupled with the large domestic market for pharmaceuticals, provided India with the important pre-conditions for the economic viability of pharmaceutical production.

However, another crucial factor in the development of the technological capability of the Indian pharmaceutical industry has been the existence of an enabling policy and legal environment. A study of the Indian industry for the United Nations Conference on Trade and Development (UNCTAD) posits the view that the development of the pharmaceutical industry in India is the result of successful, active policy interventions by the government.<sup>31</sup> The study identified three critical aspects of the policy initiatives undertaken by the Indian government in the 1970s: the establishment of an incentive scheme for domestic producers, the promotion of research and development and, an enabling patent protection regime.

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<sup>29</sup> Information for this case study was compiled from a number of sources, notably, Dhar & Rao (2002), Chaudhuri (2003) and (2004), Grace (2004) and Keayla (2004).

<sup>30</sup> Reuters: "*Indian Firm Offers AIDS Cocktail for \$1 a Day*", 9 February 2001.

<sup>31</sup> Dhar & Rao (2002).

The incentive scheme included a price control regime aimed both at ensuring the availability of affordable medicines and providing incentives for domestic producers. A local content policy encouraged the production and use of active pharmaceutical ingredients, and controls were placed on the imports of active ingredients and intermediates, so as to foster an increase in downstream capacities. Secondly, research and development was strongly promoted,<sup>32</sup> in particular through public-funded research and development facilities. It encouraged the more knowledge-based and research-intensive production of active pharmaceutical ingredients over that of formulation production. Foreign firms were also required to make minimum capital investments in research and development (R&D) facilities in India and, to re-invest part of their turnover in local R&D facilities. Finally, the domestic patent law was crafted with a view to encouraging innovations in the context of limited technological capabilities and financial resources.

The prevailing intellectual property legislation in India post-independence was the Patents and Design Act of 1911, which was only modified after a long period of debate. The amendments were largely based on the recommendations of two Patent Enquiry Committees which examined the country's patent system and concluded that the country had not derived much benefit from the previous or the then existing systems, and made recommendations designed to make the patent system an effective catalyst of industrial and economic growth.<sup>33</sup>

The resulting Patents Act 1970 (which came into effect in 1972) is considered a landmark in the industrial development of India. It was designed to preserve the continuing interest of the inventor in his creation, the social interest in encouraging research, the consumers' interest in enjoying the fruits of inventions at reasonable cost and, the creation of conditions for the acceleration and promotion of the economic development of the country.<sup>34</sup> Three aspects in the Act affected the pharmaceutical industry: 1) the grant of process patents only; 2) a relatively

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<sup>32</sup> As set out in the New Drug Policy of 1978.

<sup>33</sup> Keayla (2004), p. 21.

<sup>34</sup> For a brief summary of the evolution of the Indian patent system, see for e.g., Keayla (2004), p. 19-23 and Chaudhuri (2003).

short term of protection,<sup>35</sup> and 3) automatic “licences of right” that could be issued three years after the granting of the patent to enable the exploitation of a process patent, on terms mutually agreed between the patent holder and the licensee.

The absence of product patents in the field of pharmaceuticals, food, insecticides and chemicals in India, facilitated reverse engineering and the development of alternative processes for the manufacture of products patented elsewhere. Although the “weak” patent regime may not have encouraged foreign inventors to patent in India - with some implications for foreign investment in the pharmaceutical sector - it allowed Indian firms to find alternative processes for the manufacture and production of pharmaceuticals.<sup>36</sup> Indian firms were also able to progressively shorten the time lag between the introduction of a pharmaceutical product in the global market by the inventor and, the marketing of the same drug in the local market. Within a range of products studied, it was found that Indian firms were able to introduce their generic versions to the local market between one to six years from the introduction by the innovator company to the world market.<sup>37</sup>

The adoption of a process patent regime, as opposed to product patent regime, to encourage the technological advancement and the growth of industries is supported by evidence of the policy and patent regimes adopted by several developed countries when their industries were at a nascent stage. For example, chemical substances and pharmaceutical products remained unpatentable in developed countries, such as Germany, Italy, Japan and Switzerland, until well into the 1970s and, pharmaceutical products were not patentable in Canada and Spain until the 1990s.<sup>38</sup> In taking advantage of the TRIPS transition period and es-

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<sup>35</sup> The term of protection for a process patent was five years from the date of the sealing of the patent or seven years from the date of application, whichever was shorter.

<sup>36</sup> Dhar & Rao (2002), p.6-7.

<sup>37</sup> Ibid. at p.20.

<sup>38</sup> For a discussion of the role of intellectual property rights in economic development and industrialization of developed countries, see e.g. Chang (2003), p.273-298

tablishing the complementary policy environment, India has similarly encouraged the development of its domestic pharmaceuticals sector.

As the Indian economy liberalized in the 1990s, modifications were introduced to the policy regime aimed at de-regulating the industry. Two key elements in the revised policy environment affected the pharmaceutical industry: first, the removal of restrictions on the use of imported active pharmaceutical ingredients and on formulation production; and secondly, narrowing of the scope of price control mechanisms.<sup>39</sup> The other significant change in the policy regime was the end of the transition period on 1 January 2005.

The Patent Act of 1970 had been amended by the Patents (Amendment) Act 1999, and again by the Patents (Second Amendment) Act 2002, in order to fulfil the TRIPS obligations, including the establishment of the mailbox facility and the 20-year patent protection term. Patent amendments in India, after the TRIPS Agreement came into force, can be characterized in three stages,<sup>40</sup> as follows:

1. As required under Article 70.8, India provided the mailbox facility, to allow the filing of pharmaceutical product patent applications during the 10-year period from 1995-2005. During this period, a regime for the granting of exclusive marketing rights (EMRs) was also instituted. EMRs were to be granted to those applications that fulfilled the criteria of having been granted a foreign patent and, having successfully obtained marketing approval in India. In India, it is reported that only two products have been granted EMRs.<sup>41</sup>
2. 1 January 2000 marked the end of the transition period for developing countries in terms of implementation of the TRIPS obligations. In India, notable changes to the patent law with an impact on pharmaceuticals included the establishment of the 20-year patent protection term for all patents and, the

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<sup>39</sup> Price controls would no longer apply to new drugs developed through indigenous R&D.

<sup>40</sup> Chaudhuri (2004), p.4-5.

<sup>41</sup> Grace (2004).

abolition of the licensing of right system. Provisions relating to the granting of compulsory licences were also amended to comply with the conditions for the granting of compulsory licences as set out in Article 31 of the TRIPS Agreement – including the restrictions on export under compulsory licence and, the payment of adequate remuneration in the case of the granting of a compulsory licence.

3. India is now required to provide for full patent protection, both product and process, in all fields of technology including pharmaceuticals as of 1 January 2005. The mailbox applications will now have to be assessed. If an application meets the TRIPS Agreement standards of patentability, as interpreted and implemented under the national law, a patent would be granted for the remainder of the patent term, calculated from the application filing date in India.

The latest amendments to the Patents Act of 1970 are found in the Patents (Amendment) Act 2005, which received Presidential assent on 4 April 2005. The objective of the 2005 Act was intended to bring India into compliance with the TRIPS Agreement after the end of the transition period in 2005 (for those countries without product patent protection) and thus, the majority of the amendments are deemed to have come into force on 1 January 2005.<sup>42</sup>

Since the 2005 Act makes provisions to bring India into full implementation of the TRIPS Agreement, one of the most significant aspects of the Act is the introduction of a product patent regime in India and the provisions relating to the patentability criteria. While the TRIPS Agreement lays down the criteria for patentability; i.e. novelty, inventive step and industrial applicability, it still allows a degree of flexibility for countries to determine how these criteria should be interpreted and applied. The 2005 Act thus contains a number of provisions relating to the patentability of pharmaceutical products.

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<sup>42</sup> Except for provisions in Section 37(ii) (a) and (b), Sections 41, 42 47, 59 to 63 and 74 (largely relating to the revocation and amendment of specification) shall come into force by notification in the Official Gazette.

First, the Act defines a “pharmaceutical substance” that is patentable as one that means “any new entity involving one or more inventive steps”.<sup>43</sup> There has been criticism that this definition is too broad, with critics calling for a narrower definition to be used. In this context, the Minister of Commerce and Industry has established a Technical Expert Group to study this issue. A five-member committee, chaired by Dr. R.A. Mashelkar, Director General of the Council of Scientific and Industrial Research (CSIR), will consider whether it is TRIPS-compatible to limit the granting of patents for pharmaceutical substance to “new chemical entity” or to “new medical entity” involving one or more inventive steps. The Committee is expected to report to the Ministry of Commerce and Industry with recommendations on whether further amendments to the Act are required.<sup>44</sup>

The 2005 Act also substitutes the existing definition of “inventive step” for: “a feature of an invention that involves a technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art”.<sup>45</sup> Whilst this definition specifies that “a technical advance or economic significance” is required to meet the criterion of an inventive step, the use of the word “or” dilutes the criterion for patentability, as it would enable an inventive step to be determined on the basis of economic significance alone.

Another provision<sup>46</sup> provides that the “mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy or the mere discovery of any new property or new use of a known substance or mere use of a known process ... unless such known process results in a new product or employs at least one new reactant”, would not be considered to be a patentable invention. The provision is further explained by a note stating that:

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<sup>43</sup> Section 2(h) of the Patents (Amendment) Act 2005 inserting a new clause Section 2(ta) in the Patents Act 1970

<sup>44</sup> Press Information Bureau, Government of India, 6 April 2005.

<sup>45</sup> Section 2(f) of the Patents (Amendment) Act 2005 substituting Section 2(ja) in the Patents Act 1970.

<sup>46</sup> Section 3 of the Patents (Amendment) Act 2005 substituting Section 3 in the Patents Act 1970.



“For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”

This provision is intended to prevent “evergreening” of patents by not allowing the “mere” discoveries of a new form or a new use of a known substance or mere use of a known process, to be patentable. However, it is not as yet clear how the provision will be interpreted. The use of the word “mere” is ambiguous and may cause difficulties in the interpretation of the provision. In a critique of the amendments, it has been argued that the phrase “unless they differ significantly in properties with regard to efficacy” in the explanatory note, would have the effect of negating the intention of the provision by diluting the inventive step requirement, and thus potentially allowing for “evergreening”.<sup>47</sup>

An obvious concern in the context of the introduction of the product patent regime in India is the future of domestic generic production and export. The 2005 Act contains provisions which relate to the granting of patents for mailbox applications and, the granting of compulsory licences and exports under compulsory licences.

The Act provides that after a patent is granted in respect of an application in the mailbox, no infringement proceedings may be instituted against generic manufacturers who continue to manufacture the product covered under the patent, so long as specified conditions are met. Thus, the production of the generic versions of the now-patented medicine can continue, provided that three conditions are satisfied: 1) that the generic manufacturer had been producing and marketing the product prior to 1 January 2005; 2) that the manufacturer has made significant investment

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<sup>47</sup> “A critical view of the new Indian Patent (Amendment) Act 2005”, by the Access to Medicine and Treatment Campaign (AMTC), Alternative Law Forum and Lawyers’ Collective HIV/AIDS Unit, March 2005, <http://archives.healthdev.net/af-aids/msg01715.html>.

for such production and marketing; and 3) that a reasonable royalty is paid to the patent holder.

This provision, which has been variously referred to as a system of “automatic compulsory licences” or “prior user rights” will in theory, ensure the continued production of currently available generic medicines. However, a number of issues will still require clarification, including the definitions of “significant investment” and “reasonable royalty”. There is concern that the requirement of significant investment may be open to differing interpretations. Similarly, in the case of reasonable royalty, guidelines may be necessary to reduce uncertainty. In this regard, the practice in other countries may be instructive in terms of setting compensation or royalty rates for compulsory licences; for example, the Japanese guidelines for royalty rates which range between 2-8%, and the average 4% and 5% rates normally used in Canada and the United States.

The 2005 Act also modifies the compulsory licensing system in India in several ways. The first modification relates to the requirement that the applicant for a compulsory licence must have made efforts to obtain a licence from the patent holder, which were unsuccessful within a “reasonable period”, before applying for the compulsory licence. The amendment Act now clarifies that the reasonable period “shall not ordinarily exceed six months”. The quantification of the term “reasonable period” can be expected to help hasten the process of an application for a compulsory licence and to prevent unnecessary delays.

Secondly, the Indian law now includes a provision allowing the granting of a compulsory licence to manufacture and export patented pharmaceutical products to any country with insufficient manufacturing capacity. This provision seeks to implement the WTO Decision on Paragraph 6 of the Doha Declaration, which is aimed at facilitating the import and export of generic versions of patented medicines. The provision in the Indian law states that a compulsory licence “shall be available for manufacture and export”, provided that the importing country has either granted a compulsory licence or has, by notification or other means, allowed importation of such products. Although the language of the text would suggest the mandatory grant of a compulsory licence when the conditions are met, it has been pointed out that some questions may yet arise as to whether the procedure for the granting of a compul-

sory licence for domestic supply is the same as that for compulsory licences for export.

Thirdly, the Act also clarifies that where a compulsory licence is granted to remedy anti-competitive practices, the licensee shall also be permitted to export the product. This provision implements Article 31(k) of the TRIPS Agreement, which specifies that where a compulsory licence is granted on anti-competitive grounds, the restriction on exports under compulsory licences do not apply.

Whilst the amendment Act in India adopts a number of the flexibilities allowed under the TRIPS Agreement, it still remains to be seen how the various provisions will be implemented. The passage of the amendment Act had been a contentious process. The Act replaces the Patent Ordinance that was issued by the Indian Parliament in December 2004, which had attracted international debate over its impact on the domestic generic industry and the availability of generic medicines in the world market. The legal process also became headline-making news in India as political parties adopted opposing positions with regard to the proposed amendments. Although there are still divergent views as to the impact of the amendments, the debate has ensured to a large extent that public health concerns had been taken into account in the development and formulation of the amendments. It is hoped that the interpretation and implementation of the Indian law will similarly take public health into account.

It is difficult to predict the exact impact of the changes to the patent regime on the generic industry in India. Estimates vary as to the share of patented medicines in the overall sales of the Indian pharmaceutical industry. The Indian Drug Manufacturers' Association (IDMA) puts the estimate at 21.47% of the total pharmaceutical market (in terms of the value of medicines marketed in India during the period June 1990-July 1991 with a valid United States patent), while another estimate (Redwood, 1994) puts it at a lower level at 11% in 1993, on the basis of the 500 top selling brands for which patents were still effective in Europe.<sup>48</sup>

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<sup>48</sup> See e.g. Grace (2004) on the possible impacts of changes to the intellectual property regime in India.

A product patent regime may also have an impact on research and development, although views differ as to the consequences. The promotion of a research base has been a central focus of government policies but, it is said that the Indian industry has yet to reach the objective. In the typology of the world's pharmaceutical industry as set out in Balance, Pogany and Forstner (1992), only developed countries were deemed to be "countries with a sophisticated pharmaceutical industry and a significant research base".

The second group of countries in which India is included were deemed to be "countries with innovative capabilities"; that is to say, that while they are not active in the discovery of new molecular entities they have the technological capacity to either develop innovative processes or improved formulations of existing drugs. The UNCTAD study details the discoveries of 13 new molecular entities in India during the period 1956-1987, whilst in the late 1990s, a number of new molecules were discovered by private sector firms.<sup>49</sup> An area of success however, has been that of innovations in new drug delivery systems, which involve modifying an existing molecule to develop more user-friendly dosage forms of medicines. A notable case of such delivery systems developed in India includes the new drug delivery system for ciprofloxacin.<sup>50</sup>

However, it seems clear that the introduction of the product patent regime in India will have an impact on the future supply of generic versions of patented medicines. While the granting of patents on mailbox applications will not in theory, affect the production of the generic versions already on the market, the concern now relates to the production and availability of the generic versions of new medicines. Following full implementation of the TRIPS Agreement in India, it will no longer be possible to manufacture generic versions of patented medicines (for which applications were filed after 1 January 2005) unless the production was under licence (either compulsory or voluntary).

This scenario raises obvious concerns that the production of generic versions of patented medicines in India will be hampered, with a

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<sup>49</sup> Dhar & Rao (2002), p.20.

<sup>50</sup> See e.g. Grace (2004) on the development of the new drug delivery systems by Ranbaxy and Dr Reddys.

consequential effect on the availability and affordability of these medicines worldwide. Production of raw materials or active pharmaceutical ingredients may also be affected as new molecules will come under patent. In this context, the use of TRIPS flexibilities such as compulsory licences and government use authorization, will become even more important in the post-2005 environment.

### ***II.1.2 Recommendations***

The case study of India suggests that the absence of product patents - by virtue of the 2000-2005 transition periods - coupled with a conducive policy environment dating back to 1970, encouraged and promoted the development and growth of the domestic pharmaceutical sector. The expiry of the 2005 deadline therefore, has implications for the future supply and availability of generic versions of patented medicines and, the consequential impact on prices and affordability. Although the impact is not expected immediately, it can be foreseen that generic versions of new medicines may no longer be produced in India, if they come under product patent protection. This not only affects the generic industry in India, but also other countries depending on generic medicines from India. In this scenario, the availability and use of TRIPS flexibilities in producing countries like India, as well as Thailand and Brazil will become even more important.

While developing countries are now obliged to implement fully the TRIPS Agreement, LDCs may still avail themselves of extra time to implement the TRIPS Agreement. There is a possibility to further extend the 2006 deadline for general TRIPS implementation. In this case, a LDC may make a “duly-motivated” request to the TRIPS Council for such an extension, as has recently been made by Maldives.<sup>51</sup>

From a public health perspective the extension granted to LDCs by the TRIPS Council pursuant to Paragraph 7 of the Doha Declaration is significant. This is a clear recognition of the implications of patent protection on public health, and LDCs should take the necessary measures to use the 2016 transition period in relation to pharmaceutical pat-

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<sup>51</sup> See WTO document IP/C/W/425.

ents. Notwithstanding the uncertainty with respect to patents already granted, it is not questioned that LDCs can prospectively suspend the operation of their patent and market exclusivity schemes with respect to medicines until 2016 (further extensions are possible by virtue of Article 66.1). It should also be noted that the 2016 extension also covers the rules relating to the protection of data submitted for the purpose of obtaining marketing approval. Whilst the absence of pharmaceutical patents *per se* may, or may not encourage the development and growth of the local pharmaceutical industry, at the minimum, its absence will ensure that patent rights will not be obstacles to the importation of generic medicines.

## **II.2 Compulsory Licensing**

A compulsory licence, also referred to as a non-voluntary licence, is a licence granted by an administrative or judicial body to a third party to exploit a patented invention, without the consent of the patent holder. The TRIPS Agreement allows for such licences. The granting of patent rights enables the patent holder to prevent a third party from exploiting his invention. However, when reasons of public interest justify it, national authorities may allow for the exploitation of the patent by a third party without the patent holder's consent or authorization. In such cases, the public interest of ensuring broader access to the patented invention is deemed to be more important than the interest of the patent holder in retaining his exclusive rights. Compulsory licences can therefore play a crucial role in ensuring that patent laws are able to meet public health needs, and that patent rights do not unnecessarily hinder or prevent access to affordable medicines.<sup>52</sup> Compulsory licences may be granted to enable the production of generic versions of patented medicines or, their importation from foreign producers.

Under the TRIPS Agreement, WTO Members are only limited with regard to the procedure and conditions to be followed in the grant-

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<sup>52</sup> For a more detailed discussion on compulsory licences and public health, see e.g., Velásquez & Boulet (1997) and Correa (2000).

ing of compulsory licences. Article 31 sets out the conditions to be met in the granting of such licences. Although the Agreement refers to some of the possible grounds for compulsory licences; such as in the case of a national emergency or situation of extreme urgency; as a measure to remedy anti-competitive practices; to enable the use of a dependent patent; and public, non-commercial use of patents,<sup>53</sup> it does not limit the use of other grounds. Since the permissible grounds are not explicitly defined in the Agreement, it leaves developing countries wide discretion when determining public health sensitive compulsory licensing policies and law.

This flexibility to determine the grounds was re-affirmed in Paragraph 5(b) of the Doha Declaration on the TRIPS Agreement and Public Health, which states that “each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”.

The following is a list of seven possible grounds for the granting of compulsory licences, based on an analysis of current state practice around the world:

1. Refusal to licence

Where the patent holder has refused, over a reasonable period of time, to enter into a voluntary licensing agreement on the reasonable commercial terms offered by the applicant, the refusal to deal or to license may be a ground for an application for a compulsory licence. The German Patent Law<sup>54</sup> for example, provides for such a ground, as does the Patent Law of the People’s Republic of China.<sup>55</sup>

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<sup>53</sup> Article 31 refers to “public, non-commercial use”, in the context of use of a patent without authorization of the patent holder. Thus, public, non-commercial use may be incorporated as a specific ground for the granting of a compulsory licence. However, public and non-commercial use of a patent can also be in the form of the government’s right to use patents; that is to say, without the need for a compulsory licence. As discussed below, government-use provisions allow for the use of patents to be ‘fast-tracked’, as government rights in terms of public and non-commercial use of patents are often procedurally much simpler.

<sup>54</sup> Section 24-(1), Patent Law (text of 16 December, 1980, amended by the Laws of 16 July and 6 August 1996).

<sup>55</sup> Section 51, Patent Law of PRC, 1992.

## 2. Public interest

A general public interest ground for the granting of a compulsory licence is a standard feature in almost all patent laws. Most patent laws do not define “public interest” or provide a non-exhaustive or illustrative list of what may constitute public interest grounds for the granting of a compulsory licence. While this leaves the competent authority the discretion to determine the ambit of public interest, it may also be expedient to specify a public health ground (see (c) below).

## 3. Public health and nutrition

A compulsory licence may be granted on the grounds that the interests of public health and nutrition, including that of the need to ensure availability and affordability of medicines, require it. The French law provides an example of *ex-officio* licences that may be granted by the responsible Minister “in the event of medicines being made available in insufficient quantity or quality or at abnormally high prices”.<sup>56</sup>

## 4. National emergency or situation of extreme urgency

Most countries provide for the use of patented inventions without the consent of the patent holder in emergency situations, such as war, famine, natural catastrophe, and so on. In the case of compulsory licences for emergencies, the requirement for prior negotiations for a voluntary licence is also waived and it should also be reflected in the domestic law.

## 5. Anti-competitive practices

The need to correct anti-competitive practices is a ground for the issue of a compulsory licence, which is specifically referred to in the TRIPS Agreement. Where a compulsory licence is granted on this basis, the TRIPS Agreement allows for the waiver of certain conditions, including the requirement for prior negotiations for a voluntary licence<sup>57</sup> and the restriction on exports under the compulsory li-

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<sup>56</sup> Article L.613-16, Law No. 92-597 of 1 July 1992 on the Intellectual Property Code (Legislative Part) (last amended by Law No.97-1106 of 18 December 1996).

<sup>57</sup> Article 31(b) states that the prior negotiation requirement is waived where a compulsory licence is granted in the case of an emergency, where it is a public



cence.<sup>58</sup> These waivers should be specifically provided for in the domestic law.

#### 6. Dependent patents

A compulsory licence may be granted on the basis of certain conditions, where a new invention requires the use of a pre-existing patented invention for working. This ground is specifically referred to in the TRIPS Agreement.<sup>59</sup>

#### 7. Failure to exploit or insufficiency of working

If a patent has been granted but the invention is not being exploited in the territory of the country or, is insufficiently exploited, this may constitute a ground for the granting of a compulsory licence. The working of a patent was originally understood to be the execution or exploitation of the patent in the country of registration. Under the Paris Convention, failure to work a patent is clearly a permissible ground for the granting of a compulsory licence.<sup>60</sup> However, Article 27.1 of the TRIPS Agreement has been interpreted by some as to exclude the possibility of requiring the local working of a patented invention.<sup>61</sup> The Brazilian patent law which establishes an obligation for local working of a patented invention, was challenged by

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non-commercial use of the patent or, when it is granted to remedy anti-competitive practices.

<sup>58</sup> Article 31(k) refers to the exemption from the requirement of predominant use of the licence for the domestic market.

<sup>59</sup> Article 31(l).

<sup>60</sup> Article 5A(2) of the Paris Convention provides that: "Union Members 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".

<sup>61</sup> The negotiating history of the TRIPS Agreement indicates widely divergent views amongst the Members on the issue of local working. While several delegations during the negotiations pressed for a clear prohibition against local-working requirements, the TRIPS Agreement does not include such a prohibition. Indeed, nothing in Article 31 suggests that there is a prohibition. Hence, it should be justified for countries to legislate that in sectors of vital importance, if the patent holder does not locally manufacture the product or, is still importing after three years, a compulsory licence could be granted with a view to improving supply to the domestic market or, price conditions.

the United States, as being in violation of the TRIPS Agreement.<sup>62</sup> The United States eventually withdrew its complaint so the dispute was not pursued to its conclusion. It was eventually agreed between the two countries that Brazil would first consult the United States if it intended to make use of the local working provision. Commentators have suggested that the local working provision is a valid ground.<sup>63</sup> The Doha Declaration's affirmation of WTO Members' freedom to determine grounds for the granting of compulsory licences, coupled with the rule of interpretation put forth in Paragraphs 4 and 5(a) of the Declaration, would strengthen this argument.

### ***II.2.1 Implementation in Developing Countries***

Virtually all the patent laws of countries reviewed have provided for some form of compulsory licensing in their patent laws. In the Asian region however, the Sri Lankan patent law did not appear to provide for compulsory licensing. In Brunei, where the patent law has recently been introduced but is not yet in force,<sup>64</sup> it also does not appear to have provided for a compulsory licensing regime. Other country legislation reviewed incorporated compulsory licensing systems but, the grounds on which such licences could be granted varied between countries. However, a number of regional similarities can be discerned.

A general public interest ground featured in most patent legislation of the Asian and Latin American and Caribbean countries. The An-

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<sup>62</sup> The argument against local working is that a compulsory licence for this purpose would contravene the provisions of Article 27.1 of the TRIPS Agreement, which states that patent rights shall be "enjoyable without discrimination ... whether the products are imported or locally produced". This was the basis of the United States complaint in 2000 against Brazil over the local working provision in Brazil's patent law.

<sup>63</sup> See e.g. Correa (1999) and UNCTAD-ICTSD (2005) for further analysis of the local working ground and the relationship between Article 27.1 and 31 of the TRIPS Agreement.

<sup>64</sup> The Emergency (Patents) Order 1999.

dean Community Decision 486 also provides for public interest as a ground for the granting of a compulsory licence. In most cases, the public interest ground is broadly defined, leaving governments with the discretion to determine public interest in the particular circumstances. However, the term “public interest” does not appear to be a common feature in the laws of the African countries nor, is it in the Bangui Agreement of OAPI. In Africa, the commonly found ground adopted language incorporating “failure to exploit” a patent or, the “failure to supply or meet demand on reasonable terms”. The Bangui Agreement 1977, which binds the 16 OAPI member-states, specifically provides for the granting of compulsory licences on this ground, as do the the patent legislation of Botswana, Egypt, Kenya, Nigeria and South Africa.

In those cases where a public interest ground is broadly framed, it may be sufficient to encompass the public health needs in terms of ensuring access to medicines. Where the public interest ground is not available, it would be advisable for countries to review their laws to ensure that the compulsory licensing provisions are not unnecessarily restrictive.

Many of the patent laws reviewed also provided for compulsory licences to remedy anti-competitive practices and to enable the use of dependent patents. Most countries reviewed have provided for a small number of grounds justifying the granting of compulsory licences. This is not unsurprising, and in some cases, patent laws have merely reiterated the grounds specifically referred to in the TRIPS Agreement (in particular, compulsory licences to remedy anti-competitive practices and for dependent patents).

### ***II.2.2 Recommendations***

Analysis of the compulsory licensing provisions in developed countries provided useful lessons, as these countries have a rich experience in the use of compulsory licences. In order to fully use the flexibilities allowed, developing countries should incorporate within their patent laws provisions for compulsory licensing and specify as many of the possible grounds in order to avoid ambiguity or uncertainty.

In the recent post-Doha years, there have been a number of cases of compulsory licences being granted by developing countries on grounds related to public health and access to medicines. Zimbabwe was probably the first country to use its government use provisions (a form of compulsory licensing) in 2002 for the procurement of anti-retroviral medicines after the adoption of the Doha Declaration (see Case Study 2 below). In 2004, Zambia and Mozambique relied on emergency provisions in their domestic patent laws as a ground for the granting of compulsory licences to enable local production of antiretroviral medicines. In all of these cases, existing domestic patent laws already incorporated compulsory licensing provisions.

Existing legal provisions may sometimes be adequate to meet public health needs even if they may not have been developed with a public health perspective. In many cases, the most significant barrier to the use of compulsory licensing is the absence of simple, straightforward legislative and administrative procedures to put the system into effect.<sup>65</sup> This is often as crucial as having suitable legal provisions enacted.

For a start, it will be useful to establish clear decision-making processes, including the determination or designation of the authorities or bodies charged with the responsibility for the various stages of decision-making. In most countries, there will be a situation of overlapping roles and responsibilities in the case of ensuring access to medicines. This was the case in Zimbabwe, and also in Malaysia, (Case Studies 2 and 3, below). Multi-agency involvement will also facilitate informed-decision making. At a minimum, decisions would have to be taken by the following government agencies: the Ministry of Health, in terms of medicines procurement (including the medicines required and the potential sources or suppliers); and the Patent office, in terms of the patent status of the required medicines. It would therefore be helpful to clarify and assign the roles and responsibilities of such agencies. Where this is unclear, delay or inaction may result.

Both the United Nations Development Programme (UNDP) Human Development Report and the IPR Commission report have recom-

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<sup>65</sup> IPR Commission (2002), p. 44.

mended the establishment of quasi-judicial and independent administrative systems for the implementation of compulsory licensing and government use authorizations to address urgent public health needs and concerns.<sup>66</sup> It can be envisaged that a multi-agency committee may be set up at the national level, to enable relevant agencies to discuss and take joint decisions. This approach would also avoid emphasis on litigation, which is an obvious benefit given that the legal systems in most developing countries are already overburdened. The TRIPS Agreement does not prohibit administrative decision-making on compulsory licences and government use of patents.<sup>67</sup>

Key features for such a system, as recommended by the IPR Commission would include straightforward, transparent and fast procedures; clear, easy-to-apply and transparent guidelines for setting royalty rates; and a procedure for appeals that does not suspend the execution of the compulsory licence or government-use provision. It is recommended that developing countries develop and publish regulatory procedures by which compulsory licences and government use will be authorized. A process governed by published regulations or administrative orders which spell out the opportunities to provide evidence and be heard, as well as the existence of an appeals process to a body independent from the one that makes the initial decision, would satisfy the requirements of fairness and transparency.

The setting of adequate remuneration or compensation (as required by Article 31(h) of TRIPS) should also be predictable and easy to administer. For these reasons, the UNDP<sup>68</sup> suggests the adoption of royalty guidelines, to reduce uncertainty and to facilitate speedier decision-making. In addition, the process should place the onus on patent holders to disclose the essential economic data to justify claims of inadequate royalty rate if they appeal against compensation decisions. This would

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<sup>66</sup> See UNDP (2001) and IPR Commission (2002).

<sup>67</sup> Article 31 of TRIPS does not define the nature of the authority that may grant a compulsory licence or determine the level of compensation. Thus, an administrative system for the processing and granting of compulsory licences would be TRIPS-consistent.

<sup>68</sup> UNDP (2001), p.107-108.

help to promote transparency as well as to discourage intimidating and unjustified claims from patent holders.

### **II.3 Public, Non-commercial Use of Patents (Government Use)**

The right of the state or government to use patents without the consent of the patent holder is a standard feature of patent laws in many countries. Such use of patents by the government is viewed in common-law countries as an eminent domain taking of a licence under the patent and thus, not an infringement of the patent.

Although the TRIPS Agreement does not refer specifically to government use of patents, it recognizes such use in its references to the concept of public, non-commercial use and, of patents “used by or for the government”.<sup>69</sup> Analysis of the negotiating history of the TRIPS Agreement reveals that both compulsory licences and government use provisions were envisaged. Hence, Article 31 of the TRIPS Agreement is intended to cover non-voluntary use of patents in the form of both compulsory licences and government use provisions.<sup>70</sup> Many patent regimes provide for government use of patents without the need to grant a compulsory licence. In such cases, a determination by a government agency or Minister is generally required to attest that the government use is justified and is within the terms of the national law. These government rights are usually framed in broad terms and are often subject to less procedural requirements than are compulsory licences.

The distinction between government-use provision and compulsory licence would lie primarily in the nature or purpose of the use of the patent. In the case of government use, it would be limited to “public, non-commercial purposes”, whereas compulsory licences would also cover private and commercial use. However, the precise meaning of “public, non-commercial use” is not defined in the TRIPS Agreement, which would leave developing countries the policy space to interpret the

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<sup>69</sup> Article 31(b) of the TRIPS Agreement.

<sup>70</sup> See e.g. Reichman & Hazendahl (2002) and Love (2001).

term. It seems indisputable that use by a government authority of a patented invention, for example the purchase of anti-retroviral medicines for distribution through public hospitals without commercial profit, would come within the scope of the term.

In addition, there may be further flexibility inherent in the term given that there is nothing in the TRIPS Agreement to prevent different ways of defining the term. In this case, the word “public” could be interpreted as referring to the purpose of the use, so that even a private entity charged with exploiting a patented invention for the benefit of the public would also come within the scope of “public, non-commercial use”.<sup>71</sup> Referring to both government use and compulsory licensing, the World Bank in its technical guide on procurement of ARVs, describes them as “principal means enabling procurement authorities to overcome patent barriers to obtaining lower priced generic medicines and related supplies”.<sup>72</sup>

Whilst conditions set out in the TRIPS Agreement<sup>73</sup> are applicable to government use of patents as they are to compulsory licences, there are important differences that make public and non-commercial use of patents procedurally simpler. A notable difference is the waiver of the requirement for the government or its authorized party to first seek a voluntary licence.<sup>74</sup> This waiver provides a considerable degree of flexibility and allows for speedier action. In other words, it allows for the use of patents to be ‘fast-tracked’, which is of importance when life-saving medicines are required. There is only an obligation to inform the patent holder of the proposed use of the patent, or promptly after such use.

The United States system for example, provides a useful illustration of how public use of patents may be broadly framed. Under section 28 USC 1498 the United States Government may use patents, or authorize a third party to use patents, for virtually any public use. Under this

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<sup>71</sup> See e.g. World Bank (2004) and UNCTAD-ICTSD (2005) for further discussion and analysis of the concept of “public, non-commercial use”.

<sup>72</sup> World Bank (2004), p.90.

<sup>73</sup> In Article 31 of the TRIPS Agreement, generally.

<sup>74</sup> Article 31(b) of the TRIPS Agreement.

statute, the government does not have to seek a licence or negotiate for the use of a patent or copyright.<sup>75</sup> The patent holder is entitled to compensation but, may not have resort to injunctive relief to prevent the use of the patent by the government. The government may only be held liable to the patent owner for payment of the “reasonable and entire compensation” for its non-authorized use of the patent.

A similar approach applies in the United Kingdom with regard to the “Crown use” of a patent, whereby use of a patent “in the services of the Crown” without the prior consent of the patent holder is not considered an infringement of the patent.<sup>76</sup>

### ***II.3.1 Implementation in Developing Countries***

A significant number of the patent laws reviewed for this study incorporated explicit provisions for government or public use patents. The provisions were generally broadly based on public interest grounds. For example, in much of the patent legislation in Asian countries, public interest has been defined to include “in particular national security, nutrition, health and the development of other vital sectors of the economy”, a formulation which reflects the language found in Article 8 of the TRIPS Agreement.

Provisions relating to government rights to use patents in the national laws of Commonwealth countries were generally modelled after the British 1883 Act, which provided for broad powers to the government to “make, use, exercise and vend the patented invention for any purpose for which appears to the government necessary or expedient”.<sup>77</sup>

Where domestic laws provide for government use or public, non-commercial use of patents, the provisions are generally sufficiently broad to provide governments with the flexibility to take necessary

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<sup>75</sup> See Love (2001) and Reichman & Hasenzahl (2002) for discussion on the United States Government use provision, 28 USC 1498 (1997).

<sup>76</sup> United Kingdom Patents Act 1977.

<sup>77</sup> See e.g. Section 65, Singapore Patents Act 1994 (No. 21 of 1994, as amended by the Patents (Amendment) Act 1995).



measures to meet public health needs. However, there may be a need to establish procedures to give rapid effect to such provisions. As mentioned above, the requirement for prior efforts to have been made to obtain a voluntary licence from the patent holder is waived in the case of public, non-commercial use of patents. This should be properly reflected in the provisions, in order to maximize the flexibility afforded by the TRIPS Agreement.

## **Case Study 2**

### **Zimbabwe's Declaration of a period of emergency<sup>78</sup>**

In 2002, the Minister of Justice, Legal and Parliamentary Affairs issued a notice declaring a period of emergency on HIV/AIDS for the purpose of enabling:

“The State or a person authorised in writing by the Minister to make or use any patented drug, including any anti-retroviral drugs, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions; and/or to import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions.”<sup>79</sup>

The declaration was made pursuant to Section 34, read with Section 35 of the Patents Act.<sup>80</sup> Section 34 empowers the Minister to authorize the

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<sup>78</sup> Information on the Zimbabwe case study was largely drawn from a report published by the Common Market for Eastern and Southern Africa (COMESA) Secretariat by Felix Maonera and Tadeous Chifamba in 2003. This was supplemented by information available from the Internet and press reports, including personal communications with Felix Maonera, Director of Multilateral Affairs, Ministry of Foreign Affairs, Zimbabwe and Chris Chitemere, Varichem Pharmaceuticals (Pvt) Ltd.

<sup>79</sup> Declaration of Period of Emergency (HIV/AIDS) Notice 2002, General Notice 240 of 2002.

<sup>80</sup> Section 34 (1) of the Patent Act provides as follows:

use of patented inventions by any government department or third party, for the service of the state, whilst Section 35 clarifies that an authorization by the Minister under Section 34 during a period of emergency “shall include power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient”. Section 34(2) further provides that the uses of inventions are to be on terms and conditions which the Minister and the patent holder may agree upon.

The declaration makes a distinction between production and use of medicines, and their importation, in that it enables production and use of any patented drug, but refers only to the importation of generic drugs. No provision was made for the importation of patented drugs. Two reasons were given to explain this.<sup>81</sup> First, it was a deliberate policy of the

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“Notwithstanding anything in this Act, any department of the State or any person authorized in writing by the Minister may make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State in accordance with this section”,

and Section 35 (1) provides that:

“During any period of emergency the powers exercisable in relation to an invention by a department of the State or a person authorized by the Minister under section thirty-four shall include power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient- (a) for the efficient prosecution of any war in which Zimbabwe may be engaged; or (b) for the maintenance of supplies and services essential to the life of the community; or (c) for securing a sufficiency of supplies and services essential to the well-being of the community; or (d) for promoting the productivity of industry, commerce or agriculture; or (e) for fostering and directing exports and reducing imports or imports of any classes, from all or any countries and for redressing the balance of trade; or (f) generally, for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community; or (g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any part of Zimbabwe or any foreign country that is in grave distress as the result of war; and any reference in that section or in section thirty-six to the service of the State shall be construed as including a reference to the purposes referred to in paragraphs (a) to (g).”

<sup>81</sup> Maonera and Chifamba (2003), p.94.

Ministry of Health to promote the importation of generics, which are considered invariably cheaper than the patented equivalents. Secondly, it assumed that the importation of the patented versions of medicines could take place via parallel import. However, the Zimbabwean patent law does not specifically provide for parallel importation.

The declaration announced an initial period of emergency of six months. The short time frame was apparently due to the concerns of the Ministry of Health and the Medicines Control Authority of Zimbabwe (MCAZ) that the declaration would be challenged by the pharmaceutical companies.<sup>82</sup> When the challenge did not materialize, the declaration was extended to a further period of five years from January 2003 to December 2008.<sup>83</sup>

In April 2003, Varichem Pharmaceuticals [Pvt] Ltd, a Zimbabwean registered company, was granted authority to “make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the purpose of achieving the objectives of Statutory Instrument 32 of 2003”. Under the terms of this authorization, Varichem “shall produce anti-retroviral or HIV/AIDS-related drugs and supply three-quarters of its produced drugs to State-owned health institutions”.<sup>84</sup> According to a Varichem representative, the company produced its first ARV in October 2003, and currently has seven generic versions of ARVs medicines on the market.<sup>85</sup>

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<sup>82</sup> *ibid.*, at p.93-94.

<sup>83</sup> In Statutory Instrument 32 of 2003.

<sup>84</sup> Letter of authorization signed by the Minister of Justice, Legal and Parliamentary Affairs, Patrick Anthony Chinamasa, dated 8 April 2003.

<sup>85</sup> Information from Chris Chitemere of Varichem Pvt Ltd., presented during the African Regional Workshop on the WTO TRIPS Agreement and Access to Medicines, Addis Ababa (1-4 March 2005). The Varichem ARV portfolio is as follows: (a) Varivar tablets 60s at US\$13.95 (this is the generic version of Combivir - the trade name of the double fixed dose combination of zidovudine and lamivudine, produced by GlaxoSmithKline, which holds the relevant patent on Combivir in Zimbabwe); (b) nevirapine 200mg tablets 60s at US\$7.15; (c) Stanalev-40 (fixed dose combination of stavudine 40mg, lamivudine 150mg and nevirapine 200mg) tablets 60s at US\$14.45 (d) Stanalev-30 (as Stanalev-40 except for stavudine 30mg) tablet 60s at US\$14.25; (e) stavudine 30mg cap-

The average monthly cost of anti-retroviral treatment is estimated at between US\$30 and US\$50 a month, putting it beyond the reach of the majority of Zimbabwean patients. Varichem has reportedly agreed to supply the government with its generic version of Combivir at US\$15 per month and, to meet 75% of the government's needs for the drug. According to Varichem, Stanalev-30 and Stanalev-40 are currently being supplied to the Ministry of Health and the Defence Forces, as well as to the private sector. A concern has been the availability of foreign currency to enable the import of active ingredients, and to keep the exchange rates from increasing the final price of the product.

It is understood that two other companies have been authorized to procure ARVs under the declaration. Datlabs, a pharmaceutical manufacturer, has been authorized to import ARVs from Ranbaxy in India. Omahn, an agent for the Indian manufacturer Cipla, has also been authorized to import Cipla products.<sup>86</sup> However, no further information has been available regarding the products to be imported or, the terms and conditions agreed upon by the Minister and the patent holder(s) for the use of the patents under the declaration, including that of the remuneration to be paid to the patent holder(s).

Although the impact of the declaration in terms of local production and import of anti-retroviral medicines cannot yet be properly assessed, it is noted that the prices of patented anti-retroviral medicines have not increased or, in some cases have dropped significantly.<sup>87</sup>

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sules 60s at US\$2.40; (f) stavudine 40mg capsules 60s at US\$3.25; and (g) lamivudine 100mg tablets 60s at US\$5.25.

<sup>86</sup> According to the information presented by Mrs Ropafadzai Hove, Principal Regulatory Officer, Legal Affairs and Narcotics, Medicines Control Authority of Zimbabwe, at the African Regional Workshop on the WTO TRIPS Agreement and Access to Medicines, Addis Ababa, 1-4 March 2005.

<sup>87</sup> It is reported in Maonera & Chifamba (2003) that the price of the anti-retroviral Zerit (stavudine) dropped from Zimbabwe dollars 22,000 per patient per month [US\$400 at the then official exchange rate] in 2001 to Zimbabwe dollars 1,800 per month, [US\$30 ] by 2002. However, the price has been increasing due largely to the exchange rates and is currently Zimbabwe dollars 14,000 a month.

### Case study 3

#### Malaysia - Rights of government to exploit a patented invention<sup>88</sup>

In 2003 the Malaysian government authorized a local company<sup>89</sup> to import three anti-retroviral medicines.<sup>90</sup> In a letter to the company, the Minister of Domestic Trade and Consumer Affairs authorized the company to import generic versions of the medicines from India, for the sole purpose of supplying public hospitals. In the letter, the Minister cited Section 84<sup>91</sup> of the Malaysian Patents Act, which allows the Minister to authorize a government agency or a third person to exploit a patented invention in the case of, *inter alia*, a national emergency or, where the public interest so requires, as the basis for his authorization.

The letter further stipulated that importation of the medicines would be subject to the following terms and conditions:

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<sup>88</sup> Information for this case study was compiled from personal communication with Dato' Mohd Zin Che Awang, Director of Pharmaceutical Services Division, Ministry of Health, Malaysia, and supplemented by information presented by Mr Farid Wong Abdullah, Pharmaceutical Services Division, Ministry of Health, Malaysia at the 2<sup>nd</sup> Asian Regional Workshop on TRIPS and Public Health, Kuala Lumpur (November 2004).

<sup>89</sup> Megah Pharmaceuticals Sdn Bhd. It is understood that the company is a distributing agent for the Indian manufacturer, Cipla.

<sup>90</sup> They were didanosine/ddI, zidovudine and Combivir (lamivudine+zidovudine fixed-dose combination).

<sup>91</sup> Section 84 (1) of Patents Act of 1983, amended as at 15 May 2002 provides that:

“Notwithstanding anything contained in this Act- (a) Where there is national emergency or where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the Government, so requires; or (b) Where a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive, ... The Minister may decide that, even without the agreement of the owner of the patent, a Government agency, or a third person designated by the Minister may exploit a patented invention”.

- the authorization would be valid for two years from 1 November 2003;
- the medicines imported would be in the quantities specified by the Ministry of Health;
- the prices of the medicines should not exceed the ceiling amount specified by the Ministry of Health;
- the imported medicines should be labelled with the words “Ministry of Health, Malaysia”;
- the shape, or colour of the tablets or capsules should be differentiated from the patented product sold in Malaysia; and
- Remuneration would be paid to the patent holder(s) within two months of the importation.

The government use authorization had been prompted by the lack of success in the price negotiations between the Ministry of Health and the patent-holding companies. In July 2001, the Ministry of Health had requested price discounts on a number of anti-retroviral medicines.<sup>92</sup> At the time, the government treatment programme only provided free highly active anti-retroviral treatment (HAART) to a small group of patients – infected mothers and children, health care workers infected in the line of duty, and patients infected through contaminated blood transfusions. Other patients were provided only one free ARV, and were required to purchase the other two, to ensure commitment to treatment. However, civil society organizations in the country had been pressing for free HAART to be made available to all patients.<sup>93</sup> When the negotiations failed to produce the desired price reductions, the Ministry of Health began to consider alternative options. By November 2001, the Doha Declaration had been adopted by the WTO Members. In August 2002, the Ministry of Health organized an inter-Ministry workshop to

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<sup>92</sup> The Ministry of Health of Malaysia asked for price reductions as follows: 10% price reduction for ritonavir, 10-40% reduction for stavudine, didanosine, zidovudine and Combivir/zidovudine+lamivudine, 60-79% reduction for indinavir, efavirenz and nevirapine.

<sup>93</sup> Public pressure on the government to provide affordable anti-retroviral treatment came from civil society organizations, in particular from the Malaysian AIDS Council, which played a key role in promoting comprehensive HIV/AIDS treatment and care in the country.

discuss the implications of the Doha Declaration and the legal options open to the government in terms of accessing affordable anti-retroviral medicines.<sup>94</sup> The Ministry of Health had set out its policy objective of providing free HAART to patients with CD4 counts under 400, with a target of putting 10,000 patients on treatment. The policy incorporated a three-prong strategy of bringing down prices of HIV/AIDS medicines: through price negotiations with patent holders, encouraging local production of HIV/AIDS medicines not under patent, and use of the rights of government provision in the Patents Act.<sup>95</sup> These developments, coupled with pressure from civil society organizations, added to the impetus for the government use authorization.

In November 2002, the Ministry of Health submitted a paper to the Cabinet of Ministers on its plan to import generic versions of anti-retroviral medicines from India, proposing the use of government rights provision in the Patents Act. The Cabinet approved the proposal and acting on this basis, the Ministry of Health officials commenced price negotiations in January 2003 with the Indian generic manufacturer Cipla.

The Cabinet decision prompted offers of price discounts from the affected patent holding originator companies. Up until early 2004, the originator companies began to offer significant discounts. GlaxoSmith-Kline reduced the prices of Combivir by 80%, lamivudine by 67% and zidovudine by 53% of their 2001 prices. Bristol-Myers Squibb also dropped the price of didanosine: the price of the 100mg formulation was reduced by 49% from its 2001 price, and the price of the 25mg formulation was reduced by 82% from its 2001 price. The affected originator companies, GlaxoSmithKline and Bristol-Myers Squibb, also lodged complaints against the decision.<sup>96</sup>

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<sup>94</sup> The Minister of Health, Dato' Chua Jui Meng, invited trade, intellectual property and public health experts – Carlos Correa, James Love, Dr. K. Balasubramaniam and Martin Khor – to brief officials from the Ministries of Health, International Trade and Industry, Domestic Trade and Consumer Affairs, and the Attorney-General's Chambers.

<sup>95</sup> Section 84 of the Patents Act 1983.

<sup>96</sup> The affected originator companies, in meetings between their legal representatives at the Malaysian Embassy in New York and High Commission in London, questioned the legality of the proposed importation, alleging that it would

Possibly as a consequence of these complaints, a number of Ministries raised concerns regarding the TRIPS-compliant nature of the proposal and the possibility of negative implications for investment prospects in the country. After further deliberations over a number of months, the Cabinet eventually authorized the Ministry of Health to proceed with its proposal. The contract for the importation of the generic medicines was finally issued by the Ministry of Health in February 2004.

With the introduction of the generic ARVs, the Ministry of Health reports that the current monthly cost of treatment has seen a significant reduction from 2001. The Combivir+efavirenz regime had cost US\$ 362.63 per month in 2001 but, in 2004 with the introduction of a generic version of Combivir, the monthly cost of the generic Combivir + patented efavirenz was US\$115.14, while the regime which uses patented products still costs US\$136.34 per month.

However, the government use authorization in Malaysia left one issue unresolved – the remuneration to be paid to the patent holder(s). A royalty rate of 4% of the value of the stocks actually delivered (i.e. of the generic medicines) had been proposed. However, the patent holders showed little interest in accepting or negotiating the proposed remuneration. The Ministry of Health officials postulated that this was due to the patent holders' reluctance to indicate their acquiescence of the authorization and to set a precedent for future cases.

The authorization period expired in November 2005, and the Ministry of Health has indicated that it is amenable to either engaging in price negotiations with the pharmaceutical companies which have since become more co-operative or, applying for an extension of the government use authorization. The Ministry of Health has also recently received a proposal from a local producer to manufacture the fixed dose ARV combination of stavudine+lamivudine+nevirapine. It is understood that the proposal is being considered.

The government use authorization in Malaysia had been the culmination of a long process of discussion and debate involving a number

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be a violation of the TRIPS obligations. One company suggested that the proposal would affect their investment decisions in relation to Malaysia.



of different government agencies. The decision-making process had been complicated by the fact that at least three different government Ministries had to be involved in the decision-making process. While the Ministry of Health was responsible for medicines procurement, the administration of intellectual property rights in Malaysia was the responsibility of the Ministry of Domestic Trade and Consumer Affairs. Thus, the implementation of the TRIPS obligations at the domestic level lay with the Domestic Trade Ministry. However, the Ministry of International Trade and Industry is responsible for the negotiation and implementation of the WTO Agreements in general.

### ***II.3.2 Recommendations***

The World Bank recommends that domestic legislation expressly provides the basis for the government use of patents, although it adds that even where such laws are not in place, governments are not prevented from taking action to protect the public interest in a national emergency.<sup>97</sup> Both the IPR Commission and the UNDP have recommended that developing countries incorporate within their domestic legislation, government and non-commercial use provisions that are no less broad than those applicable in the United States or the United Kingdom legislation.<sup>98</sup>

As stated above, the conditions governing government use of patents are the same as those for compulsory licences, with the important difference that government use of patents may be “fast-tracked” because of the waiver of the requirement for prior negotiations with patent holders. In this regard, the recommendations for the establishment of an administrative decision-making process with respect to compulsory licences will similarly apply here. It will be important to formulate open and transparent decision-making processes and procedures, including the formulation of guidelines for determining adequate remuneration, so that it will be predictable and easy to administer. A single administrative system would serve the purpose of facilitating decision-making in rela-

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<sup>97</sup> World Bank (2004), p.89.

<sup>98</sup> See IPR Commission (2002), p.45 and UNDP (2001).

tion to the granting of compulsory licences and government use authorization.

## **II.4 Parallel Imports**

Parallel import is the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent. A patent holder may have the exclusive right to manufacture his product and to put it on the market. But once the product is placed on the market, the principle of exhaustion means that the patent holder has no further right over the product. Thus, a patent holder cannot prevent the subsequent resale of that product since their rights over the product have been exhausted by the act of selling it.<sup>99</sup>

Parallel importation is allowed under the TRIPS Agreement. Article 6 of the TRIPS Agreement provides that matters relating to exhaustion of rights shall not be subject to dispute settlement. They have three main options:

1. Members may adopt the principle of international exhaustion of patent rights. Adoption of this principle in the national patent law would allow any party to import into the national territory a patented product from any other country in which the product was placed on the market by the patent holder or any authorized party.
2. Members may adopt regional exhaustion of rights, where adoption of this principle would allow the possibility of importing into the national territory a patented product originating from any other member state of a regional trade agreement.

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<sup>99</sup> Vélasquez & Boulet (1999).

3. The third option is that of national exhaustion of rights. This principle limits the circulation of products covered by patents in one country to only those put on the market by the patent owner or its authorized agents in that same country. In this case, there can be no parallel importation.

Where a developing country adopts the international exhaustion regime, the first sale by the patent holder in any country will exhaust any parallel intellectual property rights in the importing country; hence the rights may not be used to block importation. Parallel import medicines are typically purchased from a party other than the patent holder; for example, a medicine wholesaler that initially purchased (the first sale) from the patent holder or its authorized representatives.

The Doha Declaration has re-affirmed that each Member is “free to establish its own regime for such exhaustion without challenge”. That this has been clarified in the Doha Declaration is an added reassurance for Members wishing to adopt an international exhaustion principle that is legitimate and consistent with the TRIPS Agreement to do so. Hence, Members may decide how the principle should be applied within their national territories.

#### ***II.4.1 Implementation in Developing Countries***

The legislation review indicated an almost equal number of patent laws that incorporated specific provisions allowing for parallel importation, and those that did not make specific reference to parallel importation or the exhaustion principle. This may be because the legal basis of parallel importation has historically been established through case law.

In many cases, national laws provide for the explicit derogations to the exclusive rights of the patent holder, to allow for parallel imports. In terms of the use of parallel imports for public health purposes, an example is found in South African legislation. Section 15C of the Medicines and Related Substances Control Amendment Act No. 90 of 1997, has a provision enabling the Minister to “prescribe conditions for the supply of more affordable medicines” and, in this context determine that

the patent rights related to a medicine have been exhausted once the said medicine has been put on the market.

Regulations issued under the Act specify the conditions for parallel importation of medicines into South Africa, and provide that “parallel importation” means the importation into South Africa of a medicine protected under patent and/or registered in South Africa, that has been put onto the market outside South Africa by, or with the consent of the patent holder. The regulations and guidelines provide procedures under which a parallel importer must obtain a permit to undertake importation. These procedures are intended to assure that parallel import medicines are duly approved and registered by the Department of Health.

In Kenya, where the drafting of a new Industrial Property Act had generated considerable discussion and debate on the need to incorporate the TRIPS flexibilities aimed at promoting affordability and availability of essential medicines, the incorporation of the international exhaustion principle was a key focus. The previous patent regime had prohibited parallel imports, and the appropriate amendments were made to adopt the international exhaustion regime. The legal process in Kenya is further discussed in Case Study 4, below.

Argentina’s patent law provides for a broad interpretation of the international exhaustion principle by stating that patent rights are exhausted where “the said product has been lawfully placed on the market in any country”. This formulation may be interpreted broadly to cover those products placed on the market by the patent holder (or with his consent) but also for example, those products that have been placed on the market legitimately under a compulsory licence. There are differing views as to the TRIPS-consistency of this approach.

The Andean Community Decision 486 incorporates a specific provision adopting the international exhaustion of rights regime.<sup>100</sup> However, the Bangui Agreement on the other hand, appears to have adopted a rather restrictive provision that suggests a national exhaustion regime, which would prohibit parallel import.<sup>101</sup>

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<sup>100</sup> Article 54, Decision 486.

<sup>101</sup> Article 8.1(a) Bangui Agreement.

#### **Case study 4**

### **Kenya - Incorporating the International Exhaustion Regime<sup>102</sup>**

The Kenyan Parliament passed into law the Industrial Property Act 2001 in June 2001, and the Act came into force by notice on 1 May 2002.<sup>103</sup> A key focus of debate during the drafting of the Act had been the effects of patents on prices of essential medicines and the need to incorporate public health safeguards aimed at promoting affordability and availability of essential medicines in Kenya.

The process attracted considerable public attention both in Kenya and abroad, particularly since it was taking place while WTO Members were engaged at the TRIPS Council in a similar debate over the use of TRIPS flexibilities to ensure access to medicines. Civil society organizations, particularly the Kenya Coalition for Access to Essential Medicines (KCAEM) - a broad coalition of public health, trade and development organizations and individuals - had played a critical role in the legislative process in Kenya, by actively campaigning for the incorporation of public health safeguards in the law.

When the Intellectual Property Bill 2001 came to parliament for debate, the Parliament was unanimous in supporting the public health safeguards proposed by the Kenya Coalition and others. The Kenyan Minister for Trade, who moved the motion to pass the Bill, justified the incorporation of the safeguards on the basis that they were necessary 'to take into account the overriding public interests'.<sup>104</sup> The public health safeguards incorporated in the Intellectual Property Act 2001 include most of the TRIPS flexibilities that were being discussed in the TRIPS Council, and finally affirmed by the Doha Declaration, including parallel importation, compulsory licensing and government use powers. In addition, the Act also makes specific provisions relating to the early

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<sup>102</sup> Information on the Kenya case study was largely drawn from a paper by Musungu (2002) on the Industrial Property Act 2001 and Access to Essential Medicines in Kenya.

<sup>103</sup> See section 1 IP Act 2001 and Legal Notice No. 53 of 2002 of 12 April 2002.

<sup>104</sup> See the Hansard (The official parliamentary record) 12 June 2001, p. 27.

working exception and gives the relevant Minister the power to restrict the patenting of new uses of known pharmaceutical molecules.

With regard to parallel importation, the Intellectual Property Act 2001 adopts the international exhaustion principle, which is a departure from the national exhaustion approach under the Industrial Property Act 1989.<sup>105</sup> Section 58(2) of the 2001 Act on limitation of patent rights now provides that:

“The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.”

The original text of the Intellectual Property Bill 2001 had included the words *‘by the owner of the patent or with his express consent’* at the end of the sentence. These words were eventually left out of the final text. The effect of this omission would appear to make the provision broader in scope.

The text as originally drafted would have restricted parallel imports with the requirement of “express consent” of the patent holder before a patented product is imported. Under the original text, only the importation of products put on the market abroad by the patentee or his voluntary licensee, would have been allowed because of the use of the words *‘express consent’*. The text as it stands in the Act, is therefore broader and contemplates the importation of any products put on the market abroad legitimately, including products put on the market under a compulsory licence.

This interpretation is supported by Regulation 37 of the Intellectual Property Regulations which clarifies that the limitation on the rights under a patent in section 58(2) extends to acts in respect of articles that are imported from a country where the articles were legitimately put on the market. Legitimacy of products in this context only implies compliance with the national laws applicable in those foreign markets.

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<sup>105</sup> Chapter 509 Laws of Kenya (Now repealed).

An argument often raised by the opponents of parallel importation, as it was in Kenya, was that parallel importation would result in an influx of counterfeit medicines. It should be clarified that parallel imports relate only to legitimate products; that is to say, products that are of assured quality. Therefore, there is a very clear distinction between parallel imports and counterfeits.

The issue of counterfeits, which relates to market surveillance, is applicable whether products are locally produced or imported, and whether they are branded or generics. With or without parallel imports, sub-standard and counterfeit drugs may enter the market as long as the system of market surveillance is weak.

In addition, it is also important to note that pharmaceutical products are perhaps the most highly regulated products. Thus, while the issue of parallel imports is a matter for the Intellectual Property Act 2001, other laws and regulations, such as those relating to customs and border controls, import licensing and drug registration, are still applicable to parallel imports. For example, if a medicine is not registered in Kenya, it cannot be imported for sale in Kenya, not because of the Intellectual Property Act 2001, but because of the Pharmacy and Poisons Act.

#### ***II.4.2 Recommendations***

Parallel importing can be an important tool enabling access to affordable medicines, because there are substantial price differences for pharmaceutical products in different markets. The price differences may be due to various factors such as the local market conditions, factors such as differences in intellectual property rules or, prevailing income levels, as well as the degree of competition among producers. Where there is little competition, income levels may not have an influence on the prices charged. Permitting some form of parallel imports provides opportunities to shop for better-priced pharmaceutical products. However, it is sometimes argued that parallel importation is inconsistent with preferential or equity pricing of medicines, in that patent holders – fearing parallel importation of medicines into rich countries – will refrain from supplying the lower priced medicines (or increase the prices so that the price differentials are eliminated). This argument loses strength when

one considers that the rules prohibiting importation of preferentially priced medicines are already in place in almost all developed countries.<sup>106</sup>

Developing countries should therefore avail themselves of the widest scope in terms of parallel imports and incorporate explicit provisions to put into effect the international exhaustion regime. It is important to note in this context that while this “flexibility”, allowed in the TRIPS Agreement and confirmed by the Doha Declaration, does not automatically translate into the national regimes, it will be necessary for specific legal provisions to be enacted in national laws.<sup>107</sup>

Unnecessarily restrictive formulations on parallel imports should be avoided, such as those that require “express consent” of the patent holder before a patented product is imported. If the consent of the patent holder is required for the import of a patented product, the ability to parallel import will be restricted to only those cases where the patent holder has given consent, which is an unlikely prospect. For instance, although the patent owner may grant voluntary licences in a foreign country, he may prohibit his licensees from exporting generally or, to some countries or regions.

## **II.5 Exceptions to Patent Rights**

Virtually all patent laws provide for exceptions to the exclusive rights granted by a patent, although the scope and content of these provisions vary from country to country.<sup>108</sup> Exceptions to patents rights are based on the premise that the rights conferred by patents are not absolute and, in certain circumstances use of a patented invention by third parties is justified, in order to achieve public policy objectives of facilitating the dissemination of knowledge, encouraging innovation, promoting education and protecting other public interests.

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<sup>106</sup> See e.g. World Bank (2004), p.87

<sup>107</sup> Correa (2002), p.18.

<sup>108</sup> Correa (2000), p. 65.



The TRIPS Agreement allows for “limited exceptions” to the exclusive rights conferred by a patent. The Agreement does not define the nature and extent of these exceptions but, it provides a general test to be used to determine their admissibility. Article 30 requires a three-fold test to be satisfied; that the exception does 1) not unreasonably conflict with the normal exploitation of the patent; 2) not unreasonably prejudice the legitimate interests of the patent owner and, 3) take into account the legitimate interests of third parties. Each condition must be satisfied as a separate and independent condition. In addition, the conditions must also be interpreted in relation to each other.<sup>109</sup>

While it is obvious that Article 30 does not permit unreasonable interference with the patent rights, its wording suggests that some impact on patent rights is envisaged.<sup>110</sup> The early working exception for example, has a significant impact on patent rights by speeding up the approval of generic competition by as much as three years. This exception – also generally known as the “Bolar exception” after the United States case on the use of this exception – was introduced in the United States Drug Price Competition and Patent Term Restoration Act (1984), to permit the testing of a medicine for establishing the bio-equivalency of generic products before the expiration of the relevant patent. The TRIPS-compliant nature of this exception was confirmed by a WTO panel decision in 2000, which addressed the legality of the Canadian provision on early working.<sup>111</sup>

One advantage of Article 30 exceptions is that they operate automatically; that is, there is no need for consent by the patent holder nor, is there a requirement to obtain authorization from a court or other au-

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<sup>109</sup> The WTO Panel in the Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R, 17 March 2000.

<sup>110</sup> For further analysis of the negotiating history of Article 30 and possible interpretations of the text, see UNCTAD-ICTSD (2005), p.95-101.

<sup>111</sup> The complaint was brought by the EU against Canada under the WTO dispute settlement mechanism, in which the EU questioned the legality of a Canadian provision allowing not only the testing of medicines prior to patent expiry, but also production and stock-piling of the generic product for immediate release upon patent expiry. The Panel confirmed the early working provision was TRIPS-consistent but, the production and stockpiling was not. See also UNCTAD-ICTSD (2005), p. 102-105 for a fuller discussion on the case.

thority to use the patent or, to compensate the patent holder. Provided an exception is clearly specified in the patent law, any person may benefit from an exception at any time during the life of a patent.

Although a list of exempted acts was considered during the negotiations of the TRIPS Agreement, the final text of Article 30 only incorporated a general rule. However, a comparative analysis of national laws provides guidance in terms of the exceptions that are most commonly provided for in domestic legislation and deemed to be TRIPS-compliant. These include, but are not limited to, the following:

1. The early-working exception. As mentioned above, this exception permits the use of an invention for the purpose of obtaining approval of a generic product before the expiry of the patent. This procedure facilitates the marketing of a generic version promptly after the patent protection of the patented product expires. The exception is available with respect to pharmaceutical patents and may also apply to agrochemical and other products requiring administrative approval prior to commercialization.
2. Exception for research or experimental use of an invention. An exception for experimental use is one of the most widely adopted Article 30-type exceptions in national laws.<sup>112</sup> An exception for research or experimentation should be broad enough to allow the use of a patent in experimentation for both scientific as well as commercial purposes, without the consent of the patent holder. In the European Community Patent Convention, acts done for experimental purposes relating to subject matter of the patented invention are not considered an infringement, even if carried out for commercial purposes, such as to invent around or improve upon the protected invention.<sup>113</sup>
3. Exception for individual prescriptions. This allows the use of patented pharmaceutical products in the preparation of indi-

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<sup>112</sup> WTO Dispute Panel on the EC-Canada Case, paragraph 7.69.

<sup>113</sup> Correa (2000), p. 66 and see also UNCTAD-ICTSD (2005), p.101.

vidual prescriptions. An example of this exception can be found in the EU's Community Patents Agreement 1989.

### ***II.5.1 Implementation in Developing Countries***

The patent law review indicated that most countries incorporated either one of two exceptions to patent rights. The first is the research exception or the exception for experimental use of patents. In nearly all of the country legislation reviewed, an explicit exception has been provided for use of patents for research purposes or the experimental use of patents. National laws reviewed in Latin American and Caribbean countries all contained provisions relating to the research or experimental use exception; in Asia, 85% of the national laws reviewed provided for this exception, although the figure is lower in Africa at 59%.

In the regional organizations, both the Bangui Agreement and the Andean Community Decision have explicit provisions excepting research or experimental use of patented inventions. This approach has been adopted for example, in Botswana, Trinidad and Tobago, Bhutan and Singapore.<sup>114</sup> A number of laws specifically exempted private and non-commercial use of patented inventions (39% of the laws reviewed). However, the language in the provisions does not appear to restrict research or experimental use only to non-commercial purposes. In a few cases, such as Malaysia and Tanzania, exceptions for scientific research are provided for but within the general limitation

The second is the early working or Bolar exception, which has been incorporated into the patent laws of a number of developing countries, but is not as commonly found as the research or experimental use exception. The legislative review found that 61% of the national laws did not make specific provision for the early working exception.

In Latin America, 32% of the national laws reviewed did provide for this exception. However, it is not specifically provided for in the Andean Community Decision 486. In Asia, 31% of the laws reviewed

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<sup>114</sup> See also UNCTAD-ICTSD (2005), p.106.

incorporated specific provisions for the early working exception. Those countries with some production capacity, such India, Thailand and Malaysia, made specific provisions for this exception and, it is understood that China is considering such an exception. In Africa, the majority of country legislation reviewed did not make specific provisions for this exception. Neither did the Bangui Agreement for the OAPI member states. Notable exceptions were Egypt, Kenya and Nigeria.

### ***II.5.2 Recommendations***

In the public health context, the early working (or the “Bolar”-type) exception is an important mechanism in facilitating the production of, and accelerating the introduction of generic substitutes on patent expiry.<sup>115</sup> This exception has important implications for developing countries, especially if they are currently or potentially producers of generic medicines. Even where they are not likely to be producers of medicines, the United Kingdom Commission on Intellectual Property Rights has recommended that developing countries include a Bolar-type exception within their domestic law, in order to enable the products of a foreign company to gain regulatory approval and, to enter the market soon after the expiry of the patent.<sup>116</sup>

Although the patent laws reviewed indicated that developing countries have established different types of exceptions to the patent holder’s exclusive rights, the room left by Article 30 has so far only been used in a limited manner. Since the TRIPS Agreement does not define the scope or nature of the permissible exceptions, countries are left with considerable freedom for doing so. In determining which other exceptions may fall within the ambit of Article 30, Paragraph 5(a) of the Doha Declaration provides guidance for the interpretation and implementation in stressing the importance of the object and purpose of the TRIPS Agreement. In the circumstances, exceptions crafted to achieve objectives related to the promotion of the transfer of technology, the prevention of abuse of intellectual property rights, as well as the protection of public health, may well be justifiable.

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<sup>115</sup> IPR Commission (2002), p. 50.

<sup>116</sup> Ibid.

In this connexion, a group of developing countries in the WTO<sup>117</sup> proposed an authoritative interpretation of Article 30 of TRIPS as a main focus for their solution to the Paragraph 6 problem. The authoritative interpretation would “recognize the right of Members to make, sell and export patented public health related products without consent of the patent holder to address public health needs in another country”. Although this approach was not adopted as the interim solution under the WTO Decision on Paragraph 6, it has been argued that the possibility of framing an exception to facilitate the production and export of pharmaceutical products is still preserved.<sup>118</sup>

## II.6 Exemptions from Patentability

While the debate surrounding pharmaceutical patents and access to medicines has focused on the flexibilities permitted under the TRIPS Agreement to address effects of exclusive patent rights, much less attention has been directed at the issue of the granting of pharmaceutical patents themselves. Yet, it is arguably the aspect of the TRIPS Agreement that will have the most significant impact on the availability and affordability of medicines. Exemptions from patentability should not be confused with exceptions to patent rights, which apply where a patent has been granted. Exemptions from patentability would exclude a subject matter from protection and result in a patent not being granted.

Prior to the TRIPS Agreement, under the Paris Convention for the Protection of Industrial Property (1883), countries were able to exclude certain areas from patentability and to make special rules for certain types of invention. There are numerous examples of how domestic laws defined and applied the patentability criteria, according to the prevailing

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<sup>117</sup> The group of developing countries included Bolivia, Brazil, Cuba, China, the Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela.

<sup>118</sup> See for e.g., Baker (2004) and Correa (2004a), p.5.

technology levels and public policy priorities.<sup>119</sup> At the start of negotiations on the TRIPS Agreement, some 50 countries did not provide patent protection for pharmaceutical products at all, and some also excluded pharmaceutical processes from protection.<sup>120</sup> These general exclusions from patentability of pharmaceutical products, once common in national patent laws, will no longer be permitted when countries are obliged to implement the TRIPS Agreement in full.<sup>121</sup>

Article 27.1 of the TRIPS Agreement now makes it obligatory for WTO Members to make available patent protection to all inventions, in all fields of technology. The Article also sets out the criteria of novelty, inventive step and industrial applicability, which an invention must meet to qualify for a patent. Although there appears to be a general principle of eligibility to be patented where these criteria are satisfied, there is still some degree of flexibility for countries in their national implementation. Since the TRIPS Agreement does not define the terms “novelty, inventiveness and industrial applicability”, WTO Members may determine how these criteria should be interpreted and applied, and hence, the scope of patentability of pharmaceutical inventions.

From a public health perspective, where patentability standards are too lax – the terms “novelty” and “inventive step” are too loosely defined – too many secondary patents may be granted on the various forms of the new chemical entity, such as the formulation, and new combinations and uses, which will have implications for access to medicines. The innovation claimed in pharmaceutical patents range from major “discoveries” to minor modifications of existing medications. New molecules or new innovative medicines are now rare, yet pharmaceutical patents number in the thousands each year. This raises a number of questions as to the number of patents that may be granted for minor

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<sup>119</sup> Such as the exclusion of pharmaceutical and food products, chemical processes, and agricultural methods.

<sup>120</sup> See for example, UNCTAD (1996)

<sup>121</sup> See discussion in A. above on the three transition periods for the implementation of the TRIPS Agreement. Now that the 2000-2005 transition period has ended, only LDCs may be exempt from full implementation of TRIPS by virtue of the 2006 deadline and the Paragraph 7 extension for pharmaceutical products until 2016.

modifications.<sup>122</sup> A related concern is that of the quality of patents granted, given that a number of studies have given rise to a general opinion that the patent offices have been lax in granting certain types of patents, including pharmaceutical patents.<sup>123</sup>

An important interpretative question is whether Article 27.1 obliges Members to protect “uses” as in the case of new uses for known products, in addition to products and processes. “New use” patents arise in one of two circumstances; where a new pharmaceutical use is discovered for a product not previously used as a pharmaceutical product – that is, the first medical indication; and where a product already known to have pharmaceutical use(s) is discovered to have a further pharmaceutical use that is unrelated to the known use(s) – that is, the second medical indication.

A comparative review of laws indicates that national approaches vary on the question of whether a new therapeutic use of a known product is patentable.<sup>124</sup> Discovery of a new purpose of a product would not render the product patentable under the general patentability principles. Where a second medical indication is sought to be patented, it would be equivalent to a method of therapeutic treatment, which may be excluded from patentability under the TRIPS Agreement.<sup>125</sup> However, some patent systems have attempted to accommodate such patents by expanding the scope of protection beyond the ordinary boundaries or, by providing for special rules. Thus, patents for new uses are granted in some countries as product patents, process patents or, as a separate patent category. In the United States, patenting of use inventions depend on whether the purpose of use is novel and non-obvious. Patents on uses in the United States are limited to a particular “method-of-use” and, do not cover pro-

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<sup>122</sup> The National Institute of Health Care Management Research and Educational Foundation (NIHCM) showed that during the 12 year period 1988-2000, only 35% of the 1,035 drugs approved by the FDA contained a new active ingredient (NIHCM 2002). Highly innovative drugs are increasingly rare.

<sup>123</sup> See for example, Correa (2001)

<sup>124</sup> For further discussion, see Correa (2000) and UNCTAD-ICTSD (2005).

<sup>125</sup> Article 27.3(a) of the TRIPS Agreement permits Members to exclude from patentability “diagnostic, therapeutic and surgical methods for the treatment of humans and animals”.

tection of the product as such. In contrast, the patentability of a known product for a new specific purpose is allowed in Europe.

### ***II.6.1 Implementation in Developing Countries***

Most patent laws in developing countries merely restate the three usual patentability criteria, without making explicit provisions on the availability of patents for uses, even in cases where laws have been recently amended or adopted. There is generally no specific reference to the availability of patents for uses, leaving it unclear whether the protection for processes covers “uses” or “methods of use”. In the majority (55%) of the laws reviewed, there was no specific exclusion but, only in three of the patent laws reviewed were new use or second use patents specifically allowed.

In Asia, WHO’s review of the patent legislation of India, Indonesia, Sri Lanka and Thailand, showed that these countries, save India, did not specifically exclude patents on uses.<sup>126</sup> In the case of India, the previous patent law specifically excluded new use patents but, there is some uncertainty as to the effect of the 2005 Act, which appears to allow for the granting of new use patents subject to the condition that it is not a “mere” discovery of any new property or new use for a known product.<sup>127</sup>

In Africa, as with Asia, none of the national laws specifically excluded patents on new use or second use patents, although there appeared to be only one case of a national law that specifically provided for the patenting of new or second use patents. Both the Bangui Agreement and the Harare Protocol also did not provide for such exclusions.

In the Andean Community,<sup>128</sup> products or processes already patented and included in the state of the art may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent. In the Latin American

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<sup>126</sup> Keayla (2004).

<sup>127</sup> Section 3(d) the Indian Patent Act 2005.

<sup>128</sup> Article 21 of Decision 486.



countries, a number of the patent laws reviewed did specifically exclude new use and/or second use patents. These include, for example, Argentina, Chile, the Dominican Republic and Uruguay.

Developing countries with limited capacity in patent infrastructure and expertise will need to guard against problems in the examination, granting and administration of patents. In reality, it is quite common for developing countries not to carry out substantive examinations before granting patents and, to rely to a great extent on the European, United States and Japanese Patent Offices. This is the case in Viet Nam's National Office of Industrial Property Rights (NOIP). The practice in NOIP is to allow claims to a new use of an old drug if it can show efficacy over the use of the drug that has already been known to the public. NOIP follows the guidelines of the European Patent Office, which treats first and second medical indications as a product claim. However, it is not clear whether this is prohibited by the national law, which prohibits patents on medical treatment.

In any case, Patent Offices in a number of developing countries do not have the capacity to examine the patent applications, and they often function as de-facto registration agencies for patents filed and granted in the developed countries. This raises a concern, in that developing countries may effectively be running a patent "registration" system in which it is relatively easy to get patents but relatively harder to challenge them even where there may be concerns regarding their validity.

### ***II.6.2 Recommendations***

Whilst the TRIPS Agreement permits countries to expand patent protection beyond the general principles of patent law, it does not prevent countries from denying the patentability of new uses for lack of novelty, inventive step or industrial applicability.<sup>129</sup> In the case of new uses, countries are free to decide whether or not to allow their patentability. Protection of new uses, particularly second medical indications, is often

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<sup>129</sup> Correa (2000), p. 23.

used for anti-competitive purposes, mainly for extending the patent protection period and blocking generic entry.

It would be sensible for developing countries to exclude new uses from patentability, in order to promote access to medicines. This is the approach recommended by the IPR Commission, in stating that “most developing countries, particularly those without research capabilities, should strictly exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products”.<sup>130</sup>

## **II.7 Limits on Data Protection**

As a condition for permitting the sale or marketing of a pharmaceutical product, drug regulatory authorities usually require pharmaceutical companies to submit test or registration data demonstrating the safety, quality and efficacy of the product (as well as information relating to the products’ physical and chemical characteristics). Such information is generally collectively referred to as test data.

Once the required test data is submitted by the originator company, some drug regulatory authorities may rely on this data to approve subsequent applications for similar products or, to rely on proof of prior approval of a similar product in another country. Generic manufacturers need only to prove that their product is chemically identical to the brand name, the original product and, in some countries, that it is bio-equivalent. This approach was adopted in most countries prior to the TRIPS Agreement and enables swift introduction of generics into the market without extra registration data-related costs.<sup>131</sup> It is simple to administer and, imposes no regulatory burdens on governments.

However, there are different opinions on the scope of the obligation that the TRIPS Agreement places on countries with respect to the protection of test data. Article 39.3 of the TRIPS Agreement requires

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<sup>130</sup> IPR Commission (2002), p. 50.

<sup>131</sup> Correa (2002), p. 11.

Members to provide protection for undisclosed test or other data submitted for the purposes of obtaining marketing approval against “unfair commercial use”. Proponents of higher standards of protection argue for an interpretation of Article 39.3 that grants exclusive rights over the test data. The argument is that the originator of the data deserves a return on the often significant investment in conducting tests. This approach of granting data exclusivity has been adopted in the United States and the European Union. In the United States, the exclusivity period is five years (for new chemical entities),<sup>132</sup> while the EU Directive has been recently amended to increase the exclusivity period from six years to ten.<sup>133</sup> Thus, drug regulatory authorities are not permitted to rely on an originator’s test data to approve other registration applications during this period of exclusivity.

The alternative interpretation contends that WTO Members have considerable discretion to define “unfair commercial use” in the context of national laws. This view argues that the use of data by drug regulatory authorities to assess the efficacy and toxicity of a pharmaceutical or agrochemical product is not a commercial use subject to Article 39.3.<sup>134</sup> In this case, the granting of marketing approval to a second entrant, based on the second product’s similarity to a previously approved first product, is not a proscribed “use” under Article 39.3. For example, a drug regulatory authority in approving an HIV/AIDS medicine for use in the national health care system should not be considered to be making “unfair commercial use” of the originator’s data.<sup>135</sup> It is argued that the obligation to protect test data is met where the national law prohibits the use of data through “misappropriation”; for example, where a competitor derives a commercial advantage by use of the data through fraud, breach of confidence, or other dishonest practices or uses.<sup>136</sup> In this context, countries need not protect test data through the granting of exclu-

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<sup>132</sup> Ibid., p. 8.

<sup>133</sup> See EU Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use (Official Journal of the European Communities No. L. 311/67) as amended by Directive 2004/27/EC in 2004 (Official Journal of the European Union No. L. 136/34).

<sup>134</sup> See e.g., Correa (2002), World Bank (2004)

<sup>135</sup> World Bank (2004), p.92.

<sup>136</sup> Correa (2002), p.25-33.

sive rights; that is, they need not adopt the data exclusivity approach. Analysis of the negotiating history of Article 39.3 provides supporting evidence that TRIPS negotiators had rejected proposed language requiring the provision of data exclusivity.<sup>137</sup>

The obligation to protect test data under Article 39.3 is also subject to a number of conditions. Test data need only be protected against “unfair commercial use” when three conditions are met; that is: 1) where national authorities require the data to be submitted; 2) if the data is undisclosed (and not already public data); and 3) if “considerable effort” was involved in generating the data. In addition, protection is required only for new chemical entities, which means that applications for second indications, formulations and dosage forms may be excluded from protection. It is a common practice in many developing countries for drug regulatory authorities to approve marketing authorization for pharmaceutical products on the basis of prior approval in another country and on published data. In this case, such data would not qualify for protection under the terms of Article 39.3.

### ***II.7.1 Implementation in Developing Countries***

The patent laws reviewed showed that a significant proportion of countries do not have specific provisions relating to data protection. Only 57% of the country legislation reviewed incorporated provisions related to data protection. Many of the countries in the Asian region did specifically provide for protection of test data from unfair commercial use, using language similar to that in Article 39.3 of the TRIPS Agreement. For example, in Thailand, the Trade Secrets Act protects undisclosed test data from being “disclosed, taken away, or unfairly used for commercial purposes”. China and Viet Nam, which are the exceptions, provide for six-year and five-year data exclusivity, respectively. In Cambodia, a draft law is being considered which, it is understood, will provide for a five-year data exclusivity period, which appears to have been a commitment agreed to in Cambodia’s WTO accession agreement.<sup>138</sup>

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<sup>137</sup> Watal (2001), p.204.

<sup>138</sup> See Working Party Report on the Accession of Cambodia, WT/ACC/KHM/21 (15 August 2003).

At the regional level, the Andean Community Decision 486 reproduces the language of Article 39.3, while the Bangui Agreement protects confidential or test data from dishonest use. In both cases, the data exclusivity approach has not been adopted.

In nearly all of the African countries reviewed, no specific provision was made in relation to the protection of test data. In many countries, although there were no specific provisions in the patent law, there were general provisions related to the protection of confidential information or other undisclosed information to be found in other laws, such as the Protection against Unfair Competition Act 2000 in Ghana, and the General Civil Service Act of Morocco. In Egypt however, the patent law provides for the protection of test data from disclosure and unfair commercial use for a period “until it is no longer confidential, or for a period not exceeding five years, whichever comes first”.<sup>139</sup>

In Latin America, the Argentinean patent law protects undisclosed information submitted to the health authority for approval of new chemical entities, where the information is the outcome of significant technical and economic effort. This appears to be the general model on which a number of the national laws in the region are based, including those in Barbados, Trinidad and Tobago, Nicaragua, Costa Rica and the Dominican Republic. However, an analysis of the country responses to questions asked during the TRIPS review of implementing legislation (which was undertaken between 2001 and 2003) indicates that there may be some degree of confusion as to the scope and effect of such provisions.

A number of country responses had suggested that second applicants for marketing approval of pharmaceutical products would have to submit new test data, whereas the provisions in the national laws do not necessarily prohibit the use or reliance by drug regulatory authorities of test data submitted by the originator companies.

While the majority of the country legislation reviewed does not currently provide for the data exclusivity approach, the situation may change with the advent of bilateral trade agreements that require gov-

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<sup>139</sup> Intellectual Property Law 82 of 2002.

ernments to provide for data exclusivity in the national law. For example, the countries party to the Central American Free Trade Agreement, (CAFTA) including Costa Rica, the Dominican Republic, El Salvador, Guatemala and Nicaragua will have to provide for data exclusivity in their national laws. See Part IV below on the impact of test data protection in bilateral trade agreements.

### ***II.7.2 Recommendations***

There is an obvious public health interest in limiting data protection, so that the timely entry of generic competition is not unnecessarily hindered or prevented. Generic manufacturers may not enter the market until they are able to rely on the use of the originators' test data, as it is too time-consuming and expensive for the generic industry to repeat the safety and efficacy testing. There are also significant ethical questions regarding conducting human clinical trials in particular, when data already exists on quality and efficacy. Exclusive rights over test data can provide patent-like protection even where pharmaceuticals are not covered by patents or, do not meet the standards of patentability in a country or, prevent the registration of a product produced under a compulsory licence.<sup>140</sup> In either case, access to the generic medicine is affected.

For developing countries it will be important to clarify the extent to which test data is protected within the domestic law. As with other provisions of the TRIPS Agreement, flexibility is provided in terms of countries' ability to determine the appropriate means of protecting test data.<sup>141</sup> In addition, the rule of interpretation in Paragraph 4 of the Doha Declaration would also dictate that the provision 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*". Thus, it is clear that the TRIPS Agreement does not require data exclusivity; the obligation is to protect against unfair commercial use. Devel-

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<sup>140</sup> Although a compulsory licence may enable the manufacture of the generic version of a patented product, the generic manufacturer may not be able to register the generic product if he is not able to rely on the test data submitted for marketing approval of the patented product.

<sup>141</sup> Correa (2002), p. 25-33.

oping countries should allow drug regulatory authorities to approve equivalent generic substitutes on the basis of reliance on the originator data.<sup>142</sup> They should implement data protection legislation that is consistent with public health objectives, that is, to facilitate the entry of generic competitors.

## **II.8 Implementation of the WTO Decision on the Implementation of Paragraph 6 of the Doha Declaration**

The WTO addressed the problem of countries with insufficient or no manufacturing capacity and their inability to make effective use of compulsory licensing in the so-called Paragraph 6 negotiations. Paragraph 6 of the Doha Declaration instructed WTO Members to find “an expeditious solution” to address this problem, which they eventually did in August 2003.<sup>143</sup> While the Decision is not a TRIPS flexibility in the strict sense, it is the attempt by WTO Members to address the problem of those countries not being able to effectively use a flexibility afforded by the TRIPS Agreement – compulsory licensing.

The Decision allows countries to import generic medicines from a foreign generic producer. Where a medicine is under patent protection in the importing country, the importing country government will have to issue a compulsory licence for the import of the generic version of the patented drug. Where there is no patent in force, the importing country need not issue compulsory licences.<sup>144</sup> In the exporting country, the patent status of the medicine is also relevant – if the medicine is patent protected the generic manufacturer would need a compulsory licence to produce and export.

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<sup>142</sup> See IPR Commission (2002), p. 51.

<sup>143</sup> Although they missed the deadline of December 2002 as set out in the Doha Declaration, WTO Members finally adopted a solution to the Paragraph 6 problem, after intensive negotiations, on August 30, 2003 in Geneva.

<sup>144</sup> This may be the case in some developing and LDCs Members that may not have implemented patent protection for pharmaceuticals until recently. In addition, LDCs need not allow for drug patents until 2016.

The Decision comprises a series of waivers – first, a waiver of the restriction on exports in Article 31(f); second, a waiver of this restriction on re-export in the context of free trade arrangements; and finally, a waiver to the requirement for payment of adequate remuneration to the patent holder in the importing countries under Article 31(h). It should be noted that a waiver in the WTO context means that there shall not be a complaint initiated by a Member against another, if the latter acted in accordance with the terms of the waiver. However, the national law of the Member would have to reflect the terms of the waiver, in order that the provisions of the national law may not be invoked to block action. Therefore, whether countries may export and import generic versions of patented medicines under the system adopted in the WTO Decision will depend on the extent to which the national laws allow for it.<sup>145</sup>

In adopting the Decision, Members also agreed to a statement by the Chair of the WTO General Council. The Statement spells out “key shared understandings” of how the August Decision would be interpreted and implemented, including the understanding that the Decision “should be used in good faith to protect public health ... and not be an instrument to pursue industrial or commercial policy objectives”. It is not clear how this wording may affect the use of compulsory licences nor the grounds on which they may be granted but, commentators and negotiators have expressed the view that this statement does not have legal status, and cannot be read as creating any new conditions.<sup>146</sup>

The August 30 Decision also set forth conditions for the use of the system by the importing country. First, there are the notification requirements, whereby the importing countries are required to inform the WTO of their intention to use the Decision and to grant compulsory licences. This notification can be done in one or two stages. Thus, when

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<sup>145</sup> Correa (2004a), p. 5.

<sup>146</sup> See e.g., Vandoren and Van Eeckhaute (2003). The Chair’s Statement is widely understood to be an attempt to incorporate “comfort language” designed to enable the United States to join the consensus on the solution, when negotiations re-started in 2003 after having stalled in December 2002. Developing countries had initially objected to the statement, concerned that the effect of the statement would prevent or hinder incentives for generic producers to use the Decision, with its emphasis on non-industrial and non-commercial policy objectives.



an importing country intends to grant a compulsory licence, it may inform the WTO TRIPS Council of this intention and proceed to notify the granting of the compulsory licence and, the needed products and quantities specified in the licence. Where the importing country is not an LDC, it will also have to demonstrate its lack of, or insufficient manufacturing capacity, via a self-determining process, in the manner as specified in the Annex of the Decision.<sup>147</sup>

All countries are also required under the Decision, to provide for anti-diversion measures, designed to prevent the diversion of the medicines that have been produced and exported under compulsory licence, to unintended destinations. However, these measures should be reasonable and “proportionate to their administrative capacities and to risk of trade diversion”.

In the potential exporting countries, national laws will also have to be amended, to enable the use of the system, as patent laws do not typically allow for production and export under compulsory licences.

### ***II.8.1 Implementation***

In terms of implementation, a number of initiatives have taken place in potential exporting countries to amend national laws in order to enable the production and export of generic medicines under compulsory licences. Canada was the first country to commence its legislative reform, followed subsequently by Norway. The European Union is currently considering its draft regulation which will set out the framework for the EU member states. India, in its 2005 Patent Act, also included a provision on compulsory licences for production and export.

However, a number of concerns have been expressed that the amendments in the potential exporting countries may not provide sufficient administrative flexibility and economic incentives for generic producers to apply for compulsory licences. In the Norwegian case, it is acknowledged that the initiative was merely a symbolic gesture, as the

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<sup>147</sup> Correa (2004a), p.17 provides an illustration of how this determination may be done.

domestic industry did not produce pharmaceutical products of interest to developing countries. The Canadian C-9 Bill was passed in May 2004, and is due to come into force when implementing regulations are passed. The Canadian law went through an extensive consultation process which highlighted areas of contention, notably the provision on the right of first refusal (which gives the patent holder the option of taking over a contract agreed between the generic manufacturer and the importing country) and, the listing of medicines for which a compulsory licence may be obtained. It was argued that these provisions went beyond the requirements in the Decision and, would reduce incentives for generic manufacturers.

The draft EU regulation is currently in its consultation phase. Some commentators have suggested that the current provisions relating to the requirement for prior negotiations with the patent holder and, for compensation to be paid to the patent holder, do not provide sufficient ease, predictability or incentives for generic manufacturers. The Indian Patent Act has also raised some questions about its provision which enables the granting of a compulsory licence for production and export, subject to a compulsory licence being first issued in the importing country. This requirement seems to suggest that the importing countries where the relevant patents are not in force or, where the patent applications have not been filed, would not be able to import from Indian generic manufacturers.

Although the Decision was adopted more than a year ago - ostensibly to meet an urgent public health need - there has not been any notification by countries to the WTO in respect of their intention to use the system. Nor have there been any reports of potential importing developing countries undertaking legal reform to put into place the system adopted in the Decision, so as to be able to import generic medicines produced under compulsory licences. However, it could be argued that in countries with a compulsory licensing system which does not prohibit importation, they may be able to use the system on the basis of the existing provisions. However, it would be necessary for the waiver of payment of remuneration to be provided for in national law, otherwise the patent holder may still be able to claim for such remuneration for the use of his patent.

## **II.8.2 Recommendations**

For countries to make effective use of the Decision to achieve public health objectives,<sup>148</sup> it will be important for domestic laws or regulations to reflect the following aspects:

1. Provide for a broad range of grounds for the granting of compulsory licences and specific provisions for government use of patents, as stated in Part II.1 above. In this case, grounds for compulsory licences should also specifically include importation.
2. Provide for a time limitation for negotiations for voluntary licences so that where prior negotiations for a voluntary licence with the patent holder is required,<sup>149</sup> a definite time limit is set for such negotiations, after which the requirement shall be deemed satisfied, so that the granting of a compulsory licence can proceed without unnecessary delay.
3. Provisions in domestic law should not limit the implementation of the Decision to a restricted list of products or diseases, as it is clear that the Decision is applicable without any restrictions on products or diseases. There could also be a clear definition of “pharmaceutical products” for which the Decision can be used. Countries should consider explicitly including diagnostics, vaccines and medical devices used for treatment. Provisions in national legislation should also allow for the compulsory licences or the government use authorization to refer to the product, instead of the patent(s) on that product, as this will facilitate decision making, and reduce the time required to conduct patent searches on all patents in force.

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<sup>148</sup> The Decision should be interpreted and implemented in a manner that ensures that the objectives of protecting public health and promoting access to medicines for all can be achieved. See Correa (2004a).

<sup>149</sup> In cases of compulsory licences issued for national emergency, other circumstances of extreme urgency, public non-commercial use/government use, or to remedy anticompetitive behaviour, the requirement for prior negotiation with the patent holder is waived and explicit provisions can be made in domestic law on this exception.

4. The requirement that adequate remuneration be paid to patent holders should be waived in the importing country. A specific provision should be made in domestic law on this waiver.
5. Any litigation or appeal by the patent holder should not suspend the implementation of a compulsory licence under the system.<sup>150</sup>

It is also recommended that whenever possible, countries should consider using measures less cumbersome than the system in the WTO Decision. The Decision does not preclude other options available under the TRIPS Agreement and the Doha Declaration, as is clearly stated in Paragraph 9 of the Decision. Thus, where no relevant patent is in force in the exporting country, production and export of the generic version of a medicine patented elsewhere can take place without the need of a compulsory licence. In those countries, notably India, where the 1 January 2005 transition period was employed to delay the provision of patent protection, a number of medicines currently under patent elsewhere are still off-patent.<sup>151</sup>

In such cases, there is no need to resort to the use of the Decision. As stated above, LDCs should consider amendments to their legislation in order to make use of paragraph 7 of the Doha Declaration, as implemented by the June 2002 TRIPS Council Decision, which allows them to defer the implementation and enforcement of pharmaceutical patents until at least 2016.

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<sup>150</sup> Article 44.2 of the TRIPS Agreement provides that Members are not obliged to provide for injunctive rights in the cases of use of compulsory licences.

<sup>151</sup> In India, for example, the production of generic versions of anti-retroviral medicines is allowed. After the 2005 deadline, product patents will be allowed in India, and patents may be granted on those products for which patents may have been applied for and placed in the mailbox. Until the mailbox patent applications are examined and granted, there is little known about which medicines will be affected. However, it is clear that from now on, all newly -patented medicines will be affected.



### **III. INTELLECTUAL PROPERTY-RELATED POLICIES OF MAJOR DEVELOPED COUNTRIES AND PUBLIC HEALTH IN DEVELOPING COUNTRIES**

Through multilateral, regional and bilateral trade relations, major developed countries especially the United States and the EU have a major influence on how developing countries deal with intellectual property and other policies relating to pharmaceuticals. This is because most developing countries rely heavily on preferential market access to these two markets for their exports. Consequently, the policies of these developed countries *vis-à-vis* developing countries with respect to intellectual property and access to medicines are critical factors that determine how the latter address matters relating to intellectual property, innovation and public health. In this Part we review the stated policies of the United States and the EU, the two major trading powers, as well as Japan, Canada and Switzerland, also important players in the pharmaceutical industry, with respect to intellectual property, in order to determine whether they take into account the public health priorities of developing countries and, international commitments such as the Doha Declaration.

#### **III.1 The United States**

The current policy of the United States on matters of intellectual property in third countries, including developing countries, is most clearly spelled out in the Trade Act of 2002 and, in the main implementation instrument of the ‘Special 301’ provisions of the United States Trade Act of 1974;<sup>152</sup> the Special 301 Reports and follow-up mechanisms.

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<sup>152</sup> “Special 301” is the part of the United States Trade Act that requires the USTR to identify countries that deny adequate protection for intellectual property rights or that deny fair and equitable market access for United States persons who rely on intellectual property rights.

Under the Trade Act 2002, the principal negotiating objectives of the United States on intellectual property are:

- “(A) to further promote adequate and effective protection of intellectual property rights, including through- inter alia;
- i) ensuring accelerated and full implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 USC. 3511(d)(15)), particularly with respect to meeting enforcement obligations under that agreement; and
- ii) ensuring that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law; providing strong protection for new and emerging technologies and new methods of transmitting and distributing products embodying intellectual property;

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Under Special 301, countries that have what the United States considers the most egregious acts, policies, or practices, or whose acts, policies, or practices have the greatest adverse impact (actual or potential) on relevant United States products and are not engaged in good faith negotiations to address these problems, must be identified as “priority foreign countries.” If so identified, such a country could face bilateral United States trade sanctions if changes are not made that address United States concerns. In the 2004 Report, Ukraine, China and Paraguay are listed as Priority Foreign Countries. The USTR has also created a “Priority Watch List” and “Watch List” under Special 301 provisions. Placing a country on the Priority Watch List or Watch List indicates that particular problems exist in that country with respect to intellectual property protection or enforcement or, market access for persons relying on intellectual property. In the 2004 report, the countries on the Priority Watch List included Argentina, Bahamas, Brazil, Egypt, the EU, India, the Republic of Korea, Indonesia, Pakistan and the Philippines. The countries on the Watch List include Bolivia, Canada, Chile, Israel, Mexico and Thailand.

- iii) preventing or eliminating discrimination with respect to matters affecting the availability, acquisition, scope, maintenance, use, and enforcement of intellectual property rights;
  - iv) ensuring that standards of protection and enforcement keep pace with technological developments and, in particular ensuring that right holders have the legal and technological means to control the use of their works through the Internet and other global communication media and to prevent the unauthorized use of their works; and
  - v) providing strong enforcement of intellectual property rights, including through accessible, expeditious, and effective civil, administrative, and criminal enforcement mechanisms;
- (B) to secure fair, equitable, and non-discriminatory market access opportunities for United States persons that rely upon intellectual property protection; and
- (C) to respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001”.<sup>153</sup>

The congressional mandate under the Trade Act 2002 is being implemented through the actual conclusion of trade agreements and through the Special 301 Reports and follow-up mechanisms. In the various notification letters to Congress regarding negotiations of FTAs, the United States Trade Representative (USTR) states the main objective of negotiating FTAs as being ‘to enhance the levels of protection of intellectual property in third countries beyond TRIPS and to have the third countries

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<sup>153</sup> See Section 2102(b) (4).



apply levels of protection that are in line with United States law and practices'.<sup>154</sup> In the 2004 Special 301 Report, the USTR States that:

“The United States is committed to a policy of promoting increased intellectual property protection” and, that through FTAs and trade and investment framework agreements (TIFAs), it is seeking “higher levels of intellectual property protection in a number of areas covered by the TRIPS Agreement”.<sup>155</sup>

Although a number of the provisions in the Trade Act 2002 appear balanced and, there is a specific commitment to respect the Doha Declaration, the actual implementation of the mandate as exemplified in the FTA negotiations and the Special 301 reports is particularly problematic. Seeking higher levels of protection beyond TRIPS and having developing countries apply standards similar to the United States standards suggests that the United States may seek to curtail the use of legitimate flexibilities under TRIPS such as compulsory licensing.<sup>156</sup> Such an approach also proceeds on the assumption that United States law on intellectual property is perfect and or intrinsically superior. However, this assumption is unproven. The United States patent system in particular, and its functioning, has generated intense scholarly as well as political debate about its ability to foster innovation, due to increasing evidence

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<sup>154</sup> See the various letters of notification to Congress on the USTR website at <http://www.ustr.gov>. However, the main focus in each negotiation differs. For example, for Chile the focus was stated as being on Internet service provider liability, patent protection and protection of undisclosed information. For Morocco the main focus was on patent protection and the protection of undisclosed information, while for Singapore the main focus is on Internet service provider liability, optical discs and patent protection and the protection of undisclosed information.

<sup>155</sup> See the 2004 Special 301 Report, p. 2. Available at <http://www.ustr.gov>. It is also important to note that under the ‘Special 301’ provisions, compliance with TRIPS does not amount to adequate and effective intellectual property protection.

<sup>156</sup> For additional discussion of United States policy in FTAs see the World Bank (2004) chapter 5 and Abbott (2004a).

that the system could be harming investment and research based innovation.<sup>157</sup>

Following widespread criticism of the United States approach to the issues of intellectual property and public health in recent FTAs, including from members of the United States Congress, the USTR has responded by indicating in side letters that the obligations of the intellectual property chapters of the FTA:

“[D]o not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.”<sup>158</sup>

While on the face of it the side letters preserve the TRIPS flexibilities as confirmed in the Doha Declaration, a number of issues arise. First, side letters have not accompanied all FTAs. Does that mean that those FTAs not accompanied by side letters do not contain the flexibilities to address public health? Secondly, the side letters, although constituting a formal agreement between the parties, do not appear to be legally capable of overriding specific language in the FTA.<sup>159</sup> In this context, it is not clear why the language in the side letters could not be included in the actual text of the agreements, considering that the Trade Act 2002 specifically mandated that respecting the Doha Declaration would be a principal negotiating objective of the United States.

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<sup>157</sup> See e.g. Lerner and Jaffe (2004). See also Maskus and Reichman (2004) and the Federal Trade Commission (2003).

<sup>158</sup> See the side letters to the United States-Morocco and United States-Bahrain FTAs. Both are available at <http://www.ustr.gov>.

<sup>159</sup> It can be argued that the side letters constitute a subsequent agreement between the parties regarding the interpretation of the treaty and would therefore be taken into account as an interpretive guide under Article 31.3(a) of the Vienna Convention on the Law of Treaties. Indeed, the USTR General Counsel in a letter to a Congressman with respect to the United States-Morocco FTA, says that the side letters constitute a formal agreement between the parties and thus a significant part of the interpretive context for the FTA.

The United States approach also suggests that even where flexibilities are preserved, their interpretation may be construed very narrowly. As we demonstrate in the next Part, FTA provisions entail a significant narrowing of TRIPS flexibilities. This is likely to have important implications for the development and access to medicines in the developing countries that have signed these agreements. It is also notable that beyond the FTAs, the USTR has sometimes read TRIPS rules very restrictively and inconsistently with the negotiating history. For example, in the 2004 Special 301 Report, the USTR asserts that under Article 39.3 “the TRIPS Agreement recognizes that the original applicant should be entitled to a period of exclusivity...During this period of exclusive use, the data cannot be relied upon by regulatory officials to approve similar products.” Article 39.3 of TRIPS does not mandate any exclusivity nor does it prohibit reliance on data by public officials as explained in Part II (G) above.

Therefore, it is quite clear that the United States policy on intellectual property is framed as a foreign trade and security instrument aimed at achieving greater market access and competitive edge in developing country markets, and does not take adequate account of the priorities of developing countries with respect to public health. Indeed, the Trade Act 2002 provides that through various agreements, trade “will create new opportunities for the United States and preserve the unparalleled strength of the United States in economic, political, and military affairs”.<sup>160</sup>

Section 2104 (e) of the Trade Act of 2002 requires that separate advisory committees provide the President, the USTR and Congress with detailed reports, including an advisory opinion as to whether and to what extent, the specific proposed trade agreement promotes the economic interests of the United States. A key committee in this regard is the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3). IFAC-3 is made up of 20 members from industry sector advisory committees and another 20 from private sector areas.<sup>161</sup> Another important committee in the area of intel-

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<sup>160</sup> See Section 2101(b) (2).

<sup>161</sup> For the Charter of IFAC-3 detailing its functions, membership etc. see <http://www.ita.doc.gov/td/icp/Charter-23.html>.

lectual property is the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC).<sup>162</sup> ITAC is made up of approximately 50 representatives from ‘such private sectors as to provide expertise on the subject of intellectual property rights’. Essentially therefore, IFAC-3 and ITAC are made up of business representatives whose interest is primarily, if not wholly, to secure as much profit as possible from other countries including developing country markets.

There are a number of incentives for the USTR and other United States negotiators to give the IFAC-3 and ITAC view greater weight than<sup>163</sup> for example, public interest groups in the United States which might advocate a better balance between United States interests and the interests of developing country trading partners, with respect to development generally or, access to essential medicines, in particular. First is the fact that the United States Trade Act 2002 requires the USTR to seek levels of intellectual property protection similar to those in the United States. Secondly, IFAC-3 in particular, ultimately has to write a report endorsing any agreement as meeting the economic interests of the United States, which means that negative reports would significantly complicate the life of the USTR, if not jeopardize the trade representatives job.<sup>164</sup> Therefore, a detailed review of the operation of IFAC-3 has found that “the standards that the members of IFAC-3 seek are very often the ones they achieve.”<sup>165</sup>

In this context, the Trade Act 2002, although referring to the Doha Declaration, appears to have been conceived without any serious intent to ensure global advancement of science and the sharing of the resulting benefits. It is also notable in this regard that the Trade Act makes no mention of promoting innovation or other basic purposes that

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<sup>162</sup> For information on ITAC and its Charter see <http://www.ita.doc.gov/itac>.

<sup>163</sup> Drahos (2004a), p.417.

<sup>164</sup> For some of the reports on recent FTAs entered into by the United States see e.g., [www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Bahrain\\_FTA/Reports/asset\\_upload\\_file822\\_5528.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Bahrain_FTA/Reports/asset_upload_file822_5528.pdf) on the United States-Bahrain FTA and [www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Australia\\_FTA/Reports/asset\\_upload\\_file813\\_3398.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Australia_FTA/Reports/asset_upload_file813_3398.pdf) on United States-Australia FTA.

<sup>165</sup> *Ibid.*

are used to justify intellectual property protection, as principal negotiating objectives.

Finally, it is also noteworthy, that the United States has taken no steps to implement the WTO 30 August 2003 Decision of the General Council implementing paragraph 6 of the Doha Declaration. Under the Decision, countries with generic manufacturing capacity, such as the United States, were expected to modify their legislation in order to enable the production and export of generic medicines to developing countries.

### ***III.1.1 Recommendations***

Due to its economic and military power, the United States has a major influence on how developing countries implement intellectual property standards and policies generally and, with respect to pharmaceuticals in particular. Because of this power, the United States has an important role to play in ensuring that developing countries can use various tools available under international law, to address the lack of research and/or access to medicines relating to diseases that disproportionately affect these countries. The current stated United States policy on intellectual property, whose main focus is on preserving its unparalleled strength in economic, political and military affairs, therefore raises particular concerns.

First, a trade policy framed purely as a foreign trade and security instrument is unlikely to take adequate account of the priorities of developing countries with respect to public health. In particular, the United States policy fails to reflect a clear objective *vis-à-vis* developing countries, to contribute to the promotion of technological innovation in these countries with respect to the diseases that disproportionately affect them and, to the transfer and dissemination of technology, to the mutual advantage of producer's and users of technological knowledge, in a manner conducive to social and economic welfare and, to the balance of rights and obligations. The mere respect of the Doha Declaration through side letters to the FTAs cannot achieve this purpose.

Secondly, the United States policy, by focusing exclusively on the rights of its export industries, may lead to very restrictive interpretation of the flexibilities contained in international agreements, to the detriment of public health needs in developing countries. Finally, the stated objective for bilateral and multilateral agreements entered into by the United States to reflect a standard of protection similar to that of the United States, runs counter to the well accepted principle that the standard of protection in each country should reflect the particular economic, social and cultural circumstances and level of development of the country. This approach also fails to take into account the shortcomings of the United States patent system, which are widely documented and, the possible negative impacts on pharmaceutical innovation and access to medicines.

For the above reasons, the United States should consider:

- reviewing and revising its trade policy with respect to intellectual property in third countries, especially developing countries, to not only ensure respect for the Doha Declaration but, the wider objectives of innovation and the transfer and dissemination of technology, especially technology related to pharmaceuticals for diseases that disproportionately affect developing countries;
- calibrating its policy on intellectual property in third countries so that it can reflect a better balance between the legitimate interests of its export industries and the need to improve access to medical technologies in the poorest countries;
- explicitly spelling out in its trade policy, that provisions of multilateral and bilateral trade agreements governing intellectual property entered into by the United States with developing countries, reflect standards of protection that are in line with the economic, social and cultural development of those countries; and
- amending its relevant laws and fully implementing the 30 August 2003 WTO decision and/or the proposed amendment to the TRIPS Agreement, so as to enable those developing

countries with insufficient or no manufacturing capacity in the pharmaceutical sector, to issue compulsory licences and import generic medicines from the United States.

### **III.2 The European Union**

The EU policy on intellectual property in third countries, including developing countries, is not quite as clear as in the case of the United States. However, through an examination of a number of documents, one can construct a fairly aggressive policy with respect to intellectual property and public health. According to Directorate General Trade, the policy in the field of intellectual property *inter alia* includes: promoting the implementation of effective standards for intellectual property protection world-wide; promoting adequate enforcement of intellectual property rights world-wide; ensuring that intellectual property rights are supportive of public health objectives; and reaching specific objectives during the new round of negotiations at the WTO.<sup>166</sup>

Under the Cotonou Agreement, on the basis of which the EU is negotiating Economic Partnership Agreements (EPAs) with various African, Caribbean and Pacific (ACP) countries, the parties agreed, with respect to intellectual property, that:

- “1. Without prejudice to the positions of the Parties in multilateral negotiations, the Parties recognize the need to ensure an adequate and effective level of protection of intellectual, industrial and commercial property rights, and other rights covered by TRIPS including protection of geographical indications, in line with the international standards with a view to reducing distortions and impediments to bilateral trade.

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<sup>166</sup> See the website of DG Trade at [http://europa.eu.int/comm/trade/issues.sectoral/intell\\_property/index\\_en.htm](http://europa.eu.int/comm/trade/issues.sectoral/intell_property/index_en.htm). Also see World Bank (2004) for additional discussion of the EU policy in FTAs.

2. They underline the importance, in this context, of adherence to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to the WTO Agreement and the Convention on Biological Diversity (CBD).
3. They also agree on the need to accede to all relevant international conventions on intellectual, industrial and commercial property as referred to in Part I of the TRIPS Agreement, in line with their level of development.
4. The Community, its Member States and the ACP States may consider the conclusion of agreements aimed at protecting trademarks and geographical indications for products of particular interest of either Party.
5. For the purpose of this Agreement, intellectual property includes in particular copyright, including the copyright on computer programmes, and neighbouring rights, including artistic designs, and industrial property which includes utility models, patents including patents for bio-technological inventions and plant varieties or other effective sui generis systems, industrial designs, geographical indications including appellations of origin, trademarks for goods or services, topographies of integrated circuits as well as the legal protection of data bases and the protection against unfair competition as referred to in Article 10a of the Paris Convention for the Protection of Industrial Property and protection of undisclosed confidential information on know-how.
6. The Parties further agree to strengthen their cooperation in this field. Upon request and on mutually agreed terms and conditions cooperation shall inter alia extend to the following areas: the preparation of laws and regulations for the protection and enforcement of intellectual property rights, the prevention of the abuse of such rights by right holders and the infringement of such rights by competitors, the establishment and reinforcement of domestic and regional offices and other agencies including support for regional in-



tellectual property organizations involved in enforcement and protection, including the training of personnel”.<sup>167</sup>

Although there is no specific mention of public health in Article 46 of the Cotonou Agreement, it specifically refers to the need to implement standards based on the level of development and the need to prevent abuse of intellectual property rights. This is good policy. However, it is not entirely clear what is meant by “ensure an adequate and effective level of protection of intellectual, industrial and commercial property rights, and other rights covered by TRIPS including protection of geographical indications, *in line with the international standards*”.<sup>168</sup>

New international standards are continually being established with respect to the areas covered by TRIPS including through FTAs and, the question then is whether under this article, such standards would be the basis for the EPAs. It is also notable that the agreement contemplates patents for biotechnological inventions and the protection of non-original databases. In some instances, the EU has interpreted TRIPS provisions, such as those on test data protection, differently from developing countries. In such cases, ensuring adequate and effective levels of protection of intellectual property may be interpreted as the application of TRIPS rules as interpreted by the EU.

The EU’s approach to intellectual property in third countries, including developing countries, can also be gleaned from the EU *Strategy for the Enforcement of Intellectual Property Rights in Third Countries*. The Strategy provides useful insights into the EU approach. Providing that the EU does not intend to “impose unilateral solutions” to the problem of enforcement or, to “propose a one-size-fits-all approach”,<sup>169</sup> the Strategy seeks, among other things, to identify priority countries and to revisit its approach to intellectual property chapters in bilateral agreements with a view to *inter alia* strengthening enforcement clauses.<sup>170</sup>

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<sup>167</sup> See Article 46 of the Agreement. Available at [http://europa.eu.int/comm/development/body/cotonou/index\\_en.htm](http://europa.eu.int/comm/development/body/cotonou/index_en.htm).

<sup>168</sup> Emphasis added.

<sup>169</sup> European Union, Directorate General for Trade, (2004), Brussels, p. 3.

<sup>170</sup> *Id.*, p.4.

Consequently, although not so explicit, the EU approach to intellectual property in developing countries seems to be also fairly predominated by market access concerns as opposed to improving availability and access to essential products including medicines.

Finally, unlike the United States, the EU has taken measures to implement the 30 August Decision. In addition to action at the European level, individual European countries such as the Netherlands and Norway have enacted legislation. However, the EU's Draft Regulation, aimed at uniformly implementing the 30 August 2003 Decision within the Union, has been criticized for, among other things: establishing additional conditions which are not required in the WTO Decision, which may discourage potential suppliers; imprecisely defining other conditions such as those relating to the time frame for prior negotiations; lacking instruments to promote the transfer of technology and capacity building in pharmaceuticals in developing countries and LDCs; and, excluding non-WTO member countries from the possibility of importing products under the system.<sup>171</sup>

### ***III.2.1 Recommendations***

The EU trade policy with respect to intellectual property protection in third countries, especially developing countries, is much more nuanced and favourable to public health in developing countries than the United States policy. The stated policy, among others, is aimed at ensuring that intellectual property rights are supportive of public health objectives and that accession to international instruments referred to in the TRIPS Agreement is in line with the level of development of developing countries or, at least ACP countries. This is a good policy *vis-à-vis* developing countries. However, the EU's policy of ensuring an adequate and effective level of protection of intellectual property rights, and other rights covered by TRIPS in ACP countries *in line with the international standards*, raises concerns.

The EU intellectual property enforcement strategy which seeks, among other things, to identify priority countries and to revisit its ap-

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<sup>171</sup> Correa (2004c).

proach to intellectual property chapters in bilateral agreements with a view to *inter alia* strengthening enforcement clauses, seems also to be implicitly predominated by market access concerns, as opposed to improving availability and access to essential products including medicines. Finally, although the EU's efforts to implement the 30 August Decision to enable the production and export of pharmaceuticals to developing countries with insufficient or no manufacturing capacity must be applauded, care should be taken to ensure that the conditions imposed on such exports do not lead to disincentives to generic producers.

In this regard, the EU should consider, among other actions:

- clarifying the meaning of the notion of “ensuring an adequate and effective level of protection of intellectual property, in line with international standards”, in the Cotonou Agreement and its enforcement strategy in third countries, so as to ensure that the phrase does not result in the imposition of TRIPS-plus standards and, that it does not mean that TRIPS flexibilities, such as test data protection, must be interpreted by developing countries in line with the EU interpretation; and,
- reviewing and revising its draft regulation relating to exports under the 30 August Decision, to ensure that no additional conditions, which are not required in the WTO Decision, and, which may discourage potential suppliers are imposed; that there are precise definitions of other conditions such as those relating to the time frame for prior negotiations; that there are instruments to promote the transfer of technology and capacity building in pharmaceuticals in developing countries and, that non-WTO developing countries have the possibility to import products under the system.

### **III.3 Japan, Canada and Switzerland**

Although Japan, Canada, and Switzerland do not boast the same economic, military and political clout that the United States and EU com-

mand in international affairs, they are important players in the international trading and development aid systems. In addition, these countries are also important players in the world pharmaceutical market. Consequently, their intellectual property related trade policies *vis-à-vis* developing countries also play an important role with respect to questions of access to medicines. This sub-section briefly reviews their approach to intellectual property and public health in developing countries.

### *Japan*

Japan considers intellectual property as an important component of its foreign trade policy. Its national strategy on these matters is determined by the Strategic Council on Intellectual Property.<sup>172</sup> Japan's law on intellectual property, Law No. 122 of 2002,<sup>173</sup> contains several provisions that are directly related to foreign policy on intellectual property. These include, Article 16(2) which provides that where intellectual property owned by judicial persons and other associations that are established under Japanese laws or by persons who have Japanese nationality, is not properly protected in a foreign country, the State shall take necessary measures, such as achieving proper enforcement of rights under intellectual property-related treaties. The Law also provides in Article 17 that the State shall take necessary measures to develop an environment in which Japanese persons can promptly and certainly obtain or enforce intellectual property rights in countries or regions where an intellectual property protection system has yet to be sufficiently developed.

This approach is expressed in practical terms through Japan's negotiations of FTAs and other bilateral trade agreements. The current policy of Japan with respect to FTAs is contained in the Basic Policy towards further Promotion of Economic Partnership Agreements ap-

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<sup>172</sup> The Council consists of the Prime Minister, the Chief Cabinet Secretary, the Minister of State for Economic and Fiscal Policy and IT Policy, the Minister of State for Science and Technology Policy, the Minister for Public Management, Home Affairs, Posts and Telecommunications, the Minister of Justice, the Minister of Education, Culture, Sports, Science and Technology, the Minister of Health, Labour and Welfare, the Minister of Agriculture, Forestry and Fisheries and the Minister of Economy, Trade and Industry as well as experts. For details see [http://www.kantei.go.jp/foreign/policy/titeki/index\\_e.html](http://www.kantei.go.jp/foreign/policy/titeki/index_e.html).

<sup>173</sup> Available at [http://www.kantei.go.jp/foreign/policy/titeki/hourei/021204kihon\\_e.pdf](http://www.kantei.go.jp/foreign/policy/titeki/hourei/021204kihon_e.pdf).

proved by the Council of Ministers on the Promotion of Economic Partnership on 21 December 2004.”<sup>174</sup> Based on this policy and its predecessors, Japan has concluded EPAs with Singapore and, has reached agreements in principle with the Philippines. There are also on-going negotiations with Thailand, Malaysia, and the Republic of Korea as well as negotiations with the Association of South East Asian Nations (ASEAN) countries which were initiated in 2005.<sup>175</sup> Under the Japan-Singapore Agreement, although there are no detailed rules on intellectual property, the Agreement identifies cooperation in intellectual property as an objective of the Agreement and, includes intellectual property rights in the definition of an investment.

Overall, the Japanese law and stated policy does not give a very good idea on how intellectual property and public health should be dealt with in its relations with developing countries. Therefore, it is difficult to make conclusions as to whether the policy is as aggressive as the United States policy, as nuanced as the EU policy or otherwise. However, one indicator of Japan’s attitude could be its actions with respect to the implementation of the 30 August Decision to enable developing countries with no manufacturing capacity access to generic medicines from Japan. Japan has taken no measures to implement the Decision. Japan’s overall position in international negotiations and discussions on intellectual property, including in the WTO, WIPO and the WHO, has also been seen as a replica of the United States position including that on intellectual property and public health.

### *Canada*

Canada does not have a clearly stated policy regarding intellectual property in third countries, particularly with respect to intellectual property and public health. However, intellectual property protection abroad is mentioned as an important issue within the international policy statement<sup>176</sup> and, there is a formal position on intellectual property with re-

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<sup>174</sup> Available at [www.kantei.go.jp/foreign/policy/index/keizairenkei/041221kettei\\_e.html](http://www.kantei.go.jp/foreign/policy/index/keizairenkei/041221kettei_e.html).

<sup>175</sup> For more information on these developments see <http://www.mofa.go.jp/policy/economy/fta/index.html>.

<sup>176</sup> Available at <http://itcan-cican.gc.ca/ips/menu-en.asp>.

spect to multilateral and bilateral negotiations.<sup>177</sup> Under the Policy Statement it is stated that, “As Canadians trade internationally, they may encounter roadblocks such as ... a lack of respect for intellectual property rights”.<sup>178</sup> Regarding its position on multilateral and bilateral intellectual property protection, it states with respect to the negotiations on a Free Trade Area of the Americas (FTAA) that, “Our immediate priority is to ensure full implementation of the current international rules (i.e. the TRIPS provisions) rather than to seek broadened intellectual property rights.” Apart from the North America Free Trade Agreement (NAFTA), other FTAs involving Canada with developing countries, such as those with Chile and Costa Rica, do not have detailed intellectual property provisions. Under the Canada-Israel Agreement<sup>179</sup> for example, Article 9.1 provides that the rights and obligations of the Parties relating to intellectual property rights shall be governed by the TRIPS Agreement.

Regarding international commitments such as the implementation of the Doha Declaration on the TRIPS Agreement and Public Health, Canada, under its Bill C-9, distinguished itself as the first country to move to implement the 30 August Decision to enable the export of generic medicines from Canada to those developing countries with no or insufficient manufacturing capacity in the pharmaceutical sector.<sup>180</sup> Although there were intense debates regarding the formulation of the provisions and, the law has been criticized for certain flaws, such as the inclusion of a list of products, this was an important step.<sup>181</sup> Time will tell whether the legislation is effective.

From the above, it can be concluded that Canada has made important efforts to take into account the public health interests of developing countries in implementing its foreign trade policy. This approach should

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<sup>177</sup> Available at <http://www.dfait-maeci.gc.ca/tna-nac/other-en.asp>.

<sup>178</sup> Ibid, p. 12.

<sup>179</sup> Available at <http://www.dfait-maeci.gc.ca/tna-nac/cifta-en.asp>.

<sup>180</sup> For details see [http://www.parl.gc.ca/common/Bills\\_ls.asp?Parl=37&Ses=3&ls=C9](http://www.parl.gc.ca/common/Bills_ls.asp?Parl=37&Ses=3&ls=C9).

<sup>181</sup> For a comparative analysis of the Canadian Law see Elliot, R, “Generics for the developing world: a comparison of three approaches to implementing the WTO decision“, *Scrip Magazine*, 24 November 2004. Available at <http://www.aidslaw.ca/Maincontent/issues/cts/Scrip-article-RElliot-241104.pdf>.

be encouraged although there is need for further action, especially to provide more clarity on the intellectual property policy with respect to third countries. Criticisms such as those levelled at Bill C-9 also need to be taken into account in the future and in the further development of the policy.

### *Switzerland*

Switzerland, like Canada and the EU has no stated policy on intellectual property protection in third countries generally or, with respect to intellectual property and public health in particular. However, Switzerland has been an important player in the international debate on intellectual property and public health, pursuing in the main a policy mirroring the demands of its pharmaceutical industry.<sup>182</sup> Switzerland has also concluded numerous Agreements on trade and economic cooperation (TECA) and Free trade Agreements (FTA) with third countries, covering among other disciplines intellectual property.<sup>183</sup> In recent years, Switzerland has been negotiating FTAs together with other European Free Trade Association (EFTA) countries.<sup>184</sup> Negotiations undertaken within this framework include the on-going negotiations with countries of the Southern Africa Customs Union (SACU) and Thailand.<sup>185</sup> Although no clear picture has yet emerged about the Swiss demands on matters relating to intellectual property and public health, its approach in these negotiations has been criticized as having a high potential for imposing TRIPS-plus standards on the developing countries involved including with respect to public health.<sup>186</sup>

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<sup>182</sup> For a flavour of the Swiss position see the minutes of the TRIPS Council especially those relating to the debate before the Doha Declaration in 2001 and with respect to the paragraph 6 negotiations. Available at <http://www.wto.org>

<sup>183</sup> For a listing and details of the various agreements see <http://www.igECh/E/jurinfo/j13001.shtm>

<sup>184</sup> EFTA is made up of the non-EU western European countries, namely, Switzerland, Norway, Liechtenstein and Iceland.

<sup>185</sup> Details including those on concluded agreements are available at <http://secretariat.efta.int/Web/LegalCorner/>

<sup>186</sup> For a critique, see e.g. Berne Declaration "TRIPS-plus" through EFTA's back door -How Free Trade Agreements concluded with EFTA-States impose much stronger rules on Developing Countries for IPRs on life than the WTO", November 2004 (on File with authors).

With respect to the 30 August Decision, it is notable that Switzerland, which hosts both WTO and WHO, has taken no concrete steps and is yet to implement the Decision. These are important omissions which reflect on the seriousness with which Switzerland takes the issues related to intellectual property and public health in developing countries.

### ***III.3.1 Recommendations***

Japan, Canada and Switzerland are important players in the international discussions on intellectual property and public health and, have important interests in the pharmaceutical markets in developing countries based on the interests of their export industries. Although their stated policies do not seem to pose as serious a threat to public health in developing countries as the policies of the United States and the EU, there are important concerns. In this regard:

- these countries should consider clearly stating their policies with respect to the protection of intellectual property and access to essential medicines in developing countries, with a view to ensuring that their approaches to this question are in line with the objectives of developing countries in promoting access to medicines for diseases that disproportionately affect them;
- Japan and Switzerland as important players in the world pharmaceutical market should take immediate measures to enact legislation to implement the 30 August Decision and any subsequent amendments to the TRIPS Agreement;
- although Canada's efforts, particularly in implementing the 30 August Decision should be applauded, steps should be taken to ensure that its legislation does not contain provisions which make it difficult to export generics under the Decision.





#### **IV. BILATERAL AND REGIONAL FTAs: PRACTICAL IMPLICATIONS FOR ACCESS TO MEDICINES IN DEVELOPING COUNTRIES**

The adoption of the TRIPS minimum standards resulted in a significant loss of policy flexibilities, especially for 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 put in place public interest measures including measures to protect public health. At Doha, WTO Members reaffirmed the right of each Member to use to the full, the provisions of the TRIPS Agreement which provide flexibility for protecting public health and, in particular, for promoting access to medicines for all.

Through these flexibilities governments can address problems of lack of innovation for diseases that affect their populations, high pharmaceutical prices and restrictions on availability.<sup>187</sup> In particular, governments can allow different types of exceptions to the rights conferred by patent rights; they can issue compulsory licences to allow third parties to make generic versions of patented medicines; they can permit parallel imports by adopting an international exhaustion regime; they can take remedial measures against pharmaceutical companies which engage in anti-competitive practices; they could limit the types of inventions on which pharmaceutical patents can be granted; they can accelerate the introduction of generics into the market by allowing third party testing, manufacturing and export for purposes of meeting regulatory approval requirements; by not extending patent terms on the basis of regulatory delays in registration of medicines; and they can allow regulatory agencies to rely on test data provided by the originator of the product to register generics.

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<sup>187</sup> See Abbott (2004b), p. 4.

Recent FTAs between developing and developed countries, particularly FTAs involving the United States, have been cited by governments, international organizations, civil society groups and academics as having a serious potential to undermine the use of the TRIPS flexibilities for public health purposes and, for promoting innovation in respect of diseases that disproportionately affect developing countries' populations. The elimination or narrowing of TRIPS flexibilities raises a number of real and potential problems for developing countries. By reducing or otherwise circumscribing their ability to use these flexibilities, FTAs pose a great danger to the production and availability of medicines in developing countries.

Despite these potentially serious problems, developing countries continue to conclude FTAs with the United States with fairly similar provisions on intellectual property. While these countries accept that they are losing TRIPS flexibilities, they seem to consider that overall there is a net gain for them and the concessions on intellectual property affecting medicines regulation are justified.<sup>188</sup> However, the net gains analysis presumes that earnings in agriculture or other sectors due to increased market access would translate into an ability to afford higher priced medicines. Although increased earnings in these sectors may lead to better earnings for the workers and therefore, a better ability to afford medicine, it is difficult to see how overall such earnings would improve the ability of citizens to afford higher cost medicines.

In this Part, we examine the potential practical effects of FTAs as manifested in the relevant provisions on intellectual property chapters of recently concluded FTAs, on efforts to promote access to medicines and for the various options available under the TRIPS Agreement. The FTAs covered here are mainly the United States FTAs, which are the most recent and, have been cited in most of the literature as having the most potential to undermine the use of TRIPS flexibilities to improve access to medicines.

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<sup>188</sup> See Abbott (2004b), p.7. Also see e.g., Roffe (2004).

#### **IV.1 The Object and Purpose of Intellectual Property Protection and the General Approach to Exceptions**

The framers of the TRIPS Agreement agreed that intellectual property protection in the context of international trade should:

“Contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to the balance of rights and obligations.”<sup>189</sup>

To achieve this objective, the Members of WTO agreed that it might be necessary to adopt measures to protect, *inter alia* public health.<sup>190</sup> The Doha Declaration affirmed the importance of keeping in mind the object and purpose of the TRIPS Agreement when interpreting and implementing it. In particular, paragraph 5(a) of the Declaration provides that “[E]ach provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.”

This approach to the object and purpose of intellectual protection under TRIPS, mirrors the approach of the United Nations on these matters as exemplified in the Agreement between the United Nations and WIPO establishing WIPO as a specialized agency.<sup>191</sup> Under Article 1 of the Agreement, the United Nations recognized WIPO as a specialized agency responsible for: “promoting creative intellectual activity and for facilitating the transfer of technology...to the developing countries in order to accelerate economic, social and cultural development”.

In the light of the object and purpose, the general rule on exceptions and limitations under TRIPS is that:

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<sup>189</sup> Article 7 of the TRIPS Agreement.

<sup>190</sup> See article 8 of TRIPS.

<sup>191</sup> WIPO (1975).

“Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner taking into account the legitimate interests of third parties.”<sup>192</sup>

A legal interpretation of the meaning of this clause has already been rendered by a WTO Dispute Settlement Panel in the *Canada-Patent Protection of Pharmaceutical Products* case.<sup>193</sup> With respect to the term ‘legitimate interests’ of the patent holder in particular, the panel concluded that the: “term must be defined in the way that it is often used in legal discourse - as a normative claim calling for protection of interests that are “justifiable” in the sense that they are supported by relevant public policies or other social norms”.

Overall, the recent FTAs between the United States and developing countries have preserved the language of Article 30.<sup>194</sup> However, the object and purpose of intellectual property protection and the balance required with respect to public health and other sectors of vital importance to developing countries, has not been as clearly spelt out in the FTAs except for in the United States-Chile agreement which makes an attempt to maintain the object and purpose of intellectual property protection and, a number of agreements which also preserve the flexibility available with respect to the control of anti-competitive practices.<sup>195</sup>

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<sup>192</sup> See Article 30 of the TRIPS Agreement.

<sup>193</sup> See the Panel’s report document WD/DS 114/R.

<sup>194</sup> See e.g., Articles 17.9(3) of the United States-Chile; 15.9(3) of United States-CAFTA; 15.9(3) of United States-Morocco; and 14.8(3) of United States-Bahrain Agreements. Except in the Jordan Agreement, where a general provisions on exceptions does not appear under the patents section but appears under the copyright section.

<sup>195</sup> See the preamble to Chapter 17 of the United States-Chile agreement. The United States-CAFTA Agreement for example, has a clause on competition, Article 15.15, but this is not stated in affirmative terms. It provides that:

“Nothing in this Chapter shall be construed to prevent a party from adopting measures necessary to prevent anti-competitive practices that may re-

However, the language in the United States-Chile agreement is modified to espouse the absolute value of intellectual property.<sup>196</sup>

The approach to Article 30 of TRIPS in the United States FTAs is generally consistent with public health objectives. However, there are two main concerns. First, while this is a good outcome, there is no certainty that if there was a dispute in the context of an FTA that the interpretation of the provisions would necessarily follow the WTO panel approach, especially since there is no well defined object and purpose in the FTAs, coupled with the application of non-violation claims to intellectual property under the FTAs.<sup>197</sup> Secondly, while the general approach to the exceptions has been preserved, the agreements have in some cases established specific rules with respect to the actual operation of these exceptions. This is particularly the case with respect to the early

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sult from abuse of intellectual property rights set out in this chapter, provided that such measures are consistent with this Chapter”.

See also Article 17.1(13) of United StatesChile.

<sup>196</sup> The preamble in paragraph 6 emphasises that:

“[T]he protection and enforcement of intellectual property rights is a fundamental principle of this Chapter that helps promote technological innovation as well as the transfer and dissemination of technology to the mutual advantage of technology producers and users, and that encourages the development of social and economic well-being”.

Consequently, the agreement seems to state as a fact that intellectual property protection and enforcement inevitably result in the promotion of innovation and technology transfer. This is different to the framing under the TRIPS Agreement which does not presuppose a causal relationship. Some of the FTAs have a non-derogation clause with respect to TRIPS rights and obligations. However, it is not clear that such a clause would override a specific obligation to forgo flexibilities under the FTA.

<sup>197</sup> Non-violation complaints refers to claims established under Article XXIII (b) and (c) of the General Agreement on Tariffs and Trade (GATT) 1994 whereby a WTO Member can challenge measures taken by another Member not on the basis of a violation of a rule but, on the basis that the attainment of the agreement's objectives is being impeded by the application of an otherwise permissible measure. For a detailed discussion of the possible implications of non-violation and situation complaints for public interest flexibilities see Stilwell and Tuerk (2000). Also see WTO document IP/C/W/349/Rev.1 dated 24 November 2004.

working exception and the patenting of new uses for pharmaceuticals. We discuss the implications of defining the rules with respect to these two areas below in subsections IV.4 and IV.5.

#### ***IV.1.1 Recommendations***

The object and purpose of intellectual protection and the relationship between the purpose of protection and the promotion of technological innovation and the transfer and dissemination of technology as well as the promotion of social and economic welfare, is an important balancing element in the TRIPS Agreement. The object and purpose has important implications for the use and interpretation of TRIPS flexibilities for public health. As confirmed by the Doha Declaration, “[E]ach provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.” Most of the recently concluded FTAs do not clearly spell out the object and purpose of the intellectual property chapters, nor do they emphasize the importance of technological innovation, transfer of technology and the protection of economic and social welfare.

To ensure that public health flexibilities are fully preserved in FTAs, the FTAs or at least their intellectual property chapters, must clearly spell out the object and purpose of intellectual property with a focus on technological innovation, transfer of technology and the protection of essential sectors of the economy such as public health. This will be important not only for preserving the flexibilities, but also for assuring a public health-sensitive interpretation of those flexibilities. There are divergent interpretations of some of the TRIPS flexibilities such as the provisions relating to test data protection. Consequently, developing countries which enter into FTAs should insist on retaining the TRIPS language on the object and purpose of intellectual property protection and, on the full implementation of paragraph 5(a) of the Doha Declaration. A clear object and purpose that emphasizes innovation, technology transfer and the protection of essential sectors and socio-economic welfare, including public health, will also be critical to ensure that the application of non-violation and situation complaints does not undermine the implementation of the TRIPS flexibilities.

The approach to Article 30 of TRIPS in the United States FTAs which is generally consistent with public health objectives, should be applauded. However, care must be taken to ensure that the agreements do not establish restrictive special rules with respect to the actual operation of some of the Article 30 exceptions. This has been particularly the case with respect to the early working exception and the patenting of new uses for pharmaceuticals. Where such rules have been established, developing countries should either seek to amend the FTAs or, at the very least seek confirmation through side-letters that these rules do not restrict the use of Article 30 consistent measures.

#### **IV.2 Limits on Test Data Protection and Patent Term Extensions**

All the recent FTAs between the United States and developing countries cover test data protection under provisions relating to “measures related to certain regulated products”. These provisions cover test data relating to pharmaceutical products as well as agrochemical products. This is one of the most problematic areas with respect to FTAs between the United States and developing countries. The subject matter covered is particularly important with respect to the availability of generics. The most extensive of these provisions are found in Article 15.10 of the United States-CAFTA agreement.<sup>198</sup> The agreement provides that:

- “1. (a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided such information, to market a product on the basis of (1) such information or (2) the approval granted to the person who submitted

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<sup>198</sup> Similar, but mostly less extensive, provisions can be found in Articles 17.10 of the United States-Chile; 15.10 of the United States-Morocco; 14.9 of the United States-Bahrain; 16.8 of the United States-Singapore; and 22 of the United States-Jordan FTAs.



such information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party.

- (b) If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in another territory or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in another territory for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date approval was granted in the Party to the person who received authorization in the other territory. In order to receive protection under this subparagraph (b), a Party may require that the person providing the information in the other territory seek approval in the Party within five years after obtaining marketing approval in the other territory.
- (c) For purposes of this Article, a new product is one that does not contain a chemical entity that has been previously approved in the Party.
- (d) For the purposes of this paragraph, each Party shall protect such undisclosed information against disclosure except where necessary to protect the public, and each Party shall not consider information accessible within the public domain as undisclosed data. Notwithstanding the foregoing, if any undis-

closed information concerning safety and efficacy submitted to a government entity, or an entity acting on behalf of the government, for purposes of obtaining marketing approval is disclosed by such entity, each Party is required to protect such information from unfair commercial use in the manner set forth in this Article.

2. With respect to any pharmaceutical product that is subject to a patent, each Party shall make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.
3. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the Party or in another territory, that Party:
  - (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and
  - (b) if the Party permits a third person to request marketing approval of a product during the term of a patent identified as claiming the product or its approved use, it shall provide that the patent owner be informed of such request and the identity of any such other person”.

While Article 39.3 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 ...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.”<sup>199</sup>

Article 15.10 of United States-CAFTA and other similar provisions in other FTAs go far beyond this requirement and introduces layers of complex protections. It is particularly important to note that test data exclusivity is applied to all new medicines irrespective of whether such medicines would qualify for patenting.

Paragraph 1(a) of the Article introduces a mandatory five-year exclusivity period for test data. Article 39.3 of TRIPS, as already discussed in Part II(G) above, only requires the application of unfair competition rules as opposed to exclusivity.<sup>200</sup> The exclusivity approach is justified on the grounds that it would enable the originator companies to recoup their investments. However, the approach raises a number of problems and is likely to deter generic competition. To require generic producers to conduct trials on equivalent compounds not only imposes additional costs which are passed on to the consumer, but also such a requirement is socially wasteful.<sup>201</sup>

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<sup>199</sup> See article 39.3 of the TRIPS Agreement.

<sup>200</sup> Similar provisions can be found in Articles 17.10(1) of United States-Chile; 15.10(1) of United States-Morocco; 14.9(1) (a) of United States-Bahrain; and 16.8(1) of United States-Singapore. For a discussion of the issues that arise with respect to the test data provisions of FTAs, see e.g. Correa (2004c), p.5. Also see Correa (2002) for a detailed discussion of Article 39.3.

<sup>201</sup> Abbott (2001), p.29.

Paragraph 1(b) establishes a prohibition on the registration of generics based on evidence of marketing approval or safety and efficacy in third countries for five years from the date of approval of the originator in the country.<sup>202</sup> The only condition that can be imposed on the originator company is to require marketing approval to be sought within five years of registering the product in the other Party to the FTA. This provision effectively means that even in cases where a developing country registers medicines based on evidence of foreign registration and does not therefore require submission of data from the originator company, it would in any case have to provide marketing exclusivity for five years.<sup>203</sup> This provision can in fact be used to provide exclusivity for up to 9 years, 11 months and 30 days. For example, if the FTA is between country A and B, the originator company need only register the medicine in country A and then it can wait for 4 years, 11 months and 30 days and then submit the marketing approval application in country B and, it would be entitled to five years of exclusivity from that date based on paragraph 1(a).

Article 39.3 of TRIPS contemplates the protection of data only in cases where the pharmaceutical in question utilizes new chemical entities and, where the generation of the data involved considerable effort. Paragraph 1(c) of Article 15.10 of United States-CAFTA and similar provisions in other FTAs eliminate this requirement by requiring data protection with respect to any new product. A new product is defined loosely as “one that does not contain a chemical entity that has previously been approved by the Party.”<sup>204</sup> This means that a first registrant of a new pharmaceutical product may obtain protection even in cases of old and well-known products.<sup>205</sup> It also means that such an entity may

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<sup>202</sup> Similar provisions can be found in Articles 16.8(2) of United States-Singapore; 14.9(1) (b) of United States-Bahrain; and 15.10(2) of United States-Morocco. This provision does not appear in United States-Jordan; and United States-Chile.

<sup>203</sup> For additional discussion see Abbott (2004a), pp. 6-8.

<sup>204</sup> Similar provisions can be found in Articles 15.10(1) of United States-Morocco; and 14.9(1) (c) of United States-Bahrain. There is no similar provision in United States-Chile; United States-Jordan; and United States-Singapore.

<sup>205</sup> Abbott (2004a), p.8. Conducting human clinical trials, and even animal trials, to generate such data also raises critical ethical concerns.

be entitled to such protection irrespective of whether any effort was spent in the generation of the data. The rationale for such unbridled exclusivity is difficult to see.

Paragraph 1(d) admits the TRIPS flexibility which allows WTO Members to disclose information relating to safety and efficacy where it is necessary to protect the public but, effectively takes away that flexibility by requiring TRIPS level protection for information that would otherwise not be protectable under TRIPS.<sup>206</sup> Under Article 39.3 WTO Members are not required to provide any protection for data whose disclosure is necessary to protect the public.

Article 15.10(2) introduces the principle of patent term restoration to compensate for unreasonable curtailment of the effective patent term as a result of a marketing approval process.<sup>207</sup> In addition to the provisions requiring patent term restoration on the ground of regulatory approval delays, recent FTAs also have additional provisions requiring patent term extension based on delay in the granting of the patent. For example, Article 15.9(6) of CAFTA provides that:

“Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than five years from the date of filing of the application in the Party, or three years after a request for examination of the application has been made, whichever is later, provided that periods of time

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<sup>206</sup> There is no similar provision in the other FTAs. It is important to note however, that in the cases of Singapore, Bahrain and Morocco there is also no exception for disclosure where it is necessary for the protection of public health.

<sup>207</sup> Similar provisions can be found in Articles 17.10(2) of United States-Chile; 15.10(3) of United States-Morocco; 23(a) of United States-Jordan; and 16.8(4) (a) of United States-Singapore. There are no similar provisions in United States-Bahrain.

attributable to actions of the patent applicant need not be included in the determination of such delays.”<sup>208</sup>

Some FTAs go even further and require automatic patent term extensions based on an extension in another country. For example, in United States-Bahrain, Article 14.8(7) provides that:

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

The issue of patent term restoration to compensate for time “lost” in regulatory processes in particular, was one of the issues that the EC had raised in the *Canada-Patent Protection of Pharmaceutical Products* case, claiming that patent owners had a legitimate interest in being granted such extension. In that case, the EC argued that patent owners who suffer a reduction of effective market exclusivity from such delays should be entitled to impose the same type of delay in connexion with corresponding regulatory requirements upon the market entry of competing products. In particular, the EC argued that:

“[T]here exists no reason why the research based pharmaceutical enterprise is obliged to accept the economic consequence of patent term erosion because of marketing approval requirements which reduce their effective term of protection to 12-8 years while the copy producer should be entirely compensated for the economic consequence of the need of marketing approval for his generic product, and at the expense of the inventor and patent holder.”<sup>209</sup>

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<sup>208</sup> Similar provisions are contained in Articles 17.9(6) of United States-Chile, 15.9(7) of United States-Morocco, 14.8(6) of United States-Bahrain and 16.7(7) of United States-Singapore.

<sup>209</sup> See the panel report at para 7.74.

However, in response Canada argued that:

“[N]otwithstanding the private economic advantage that would be obtained by doing so, a patentee can have no legitimate interest deriving from patent law in exercising its exclusive use and enforcement rights within the term of protection to achieve, through exploitation of regulatory review laws, a *de facto* extension of that term of protection beyond the prescribed period, thereby unilaterally altering the bargain between the patentee and society. In this respect, the interests of a patentee of a pharmaceutical invention can be no different from those of patentees in other fields of technology.”<sup>210</sup>

After considering both arguments and reviewing the number of countries that provide compensatory patent terms, the Panel came to the conclusion that:

“[T]he interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized that it could be regarded as a “legitimate interest” within the meaning of Article 30 of the TRIPS Agreement.”<sup>211</sup>

In addition to all the requirements related to the protection of test data in its own right, the FTAs go even further and link test data protection to the patent term with the affect that for new products which are also patented, no generic can be registered, except with the consent or acquiescence of the patent owner, during the term of the patent including where the patent term is extended based on marketing approval ‘delays’ as discussed above or, due to delay in issuing the patent as discussed in subsection IV.7 below. Article 15.10(3) of United States-CAFTA embodies this rule which is also contained in Articles 16.8(4) (c) of United States-Singapore, 14.9(4) of United States-Bahrain and 15.10(4) of United

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<sup>210</sup> See para 7.80 of the Panel Report.

<sup>211</sup> See para 7.82 of the Panel Report.

States-Morocco. There are no similar provisions in United States-Jordan and United States-Chile.

Despite all these rules and alterations to the TRIPS rules on test data protection, the USTR has argued that the FTA provisions would not affect the use of other TRIPS flexibilities especially compulsory licensing. According to the USTR:

“[I]f circumstances ever arise in which a drug is produced under a compulsory licence, and it is necessary to approve that drug to protect public health or effectively utilize the TRIPS/health solution, the data protection provision of the FTA would not stand in the way”.<sup>212</sup>

However, even if compulsory licences can still be issued, the restrictive approach to test data protection as shown has its own distinct consequences affecting availability and access to medicines in developing countries. The effects of these provisions on other flexibilities such as compulsory licensing are additional consequences.

#### ***IV.2.1 Recommendations***

There is an obvious public health interest in limiting the extent of test data protection to assure the timely entry of generic medicines and the use of TRIPS flexibilities including compulsory licences. The current trend where: a mandatory exclusivity model is applied; the registration of generics based on evidence of marketing approval or safety and efficacy in third countries is prohibited for five years from the date of approval of the originator in the country, although the regulatory agencies in that country do not require the submission of test data; the concept of utilization of new chemical entities is reduced to meaning “one that does not contain a chemical entity that has previously been approved by the Party”; TRIPS level protection is required for information disclosed

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<sup>212</sup> See the letter of the General Counsel of USTR to Congressman Levin dated 19 July 2004 with respect to the United States-Morocco FTA. Available at *Inside US Trade*.



where necessary to protect the public; and developing countries are required to introduce patent extension's due to regulatory delays despite the clear verdict of the WTO Dispute Settlement panel, has serious negative consequences for public health objectives. The assurance that test data provisions would not stand in the way of the TRIPS/Health solution does not adequately address these concerns.

Consequently:

- the United States and other developed countries should take measures to clarify and, where necessary, amend FTA provisions that unduly restrict the use of test data by public health authorities and furthermore, extensive and complex protections such as those contained in the United States-CAFTA FTA should be avoided in future agreements;
- test data protection provisions should not only not stand in the way of the use of the TRIPS/Health solution but also with respect to all measures necessary to assure access to essential generics;
- developing countries that have already entered into FTAs which contain enhanced protections for test data should seek ways to amend and clarify the FTA provisions relating to test data to ensure that such protection does not impede the timely entry of generics;
- developing countries that are currently negotiating FTAs should ensure that all flexibilities contained in the TRIPS Agreement with respect to test data protection are preserved and, that at the national level clear rules are established to ensure that the operation of the system does not impede the timely entry of generics on the market; and
- as confirmed by the WTO Dispute Settlement panel, the interest claimed on behalf of patent owners on this matter is neither so compelling nor so widely recognized that it could be regarded as a "legitimate interest" within the meaning of Article 30 of the TRIPS Agreement.

### **IV.3 Compulsory Licences including Licences under the 30 August Decision and Government Use**

Compulsory licensing and government use have been recognized as particularly important regulatory tools in dealing with the negative effects of patents in the pharmaceutical sector. Recent FTAs threaten in some cases to restrict the flexibilities available to developing countries and to negate the purpose of the Doha Declaration. These restrictions are at two levels. First, there are indirect restrictions introduced particularly through the test data provisions of the FTAs which we have discussed in sub-section IV.2 above. The second level of restriction which is direct, but which is found in a limited number of FTAs, restricts the grounds on which compulsory licences can be issued negating the Doha Declaration's provision providing that: "Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted".<sup>213</sup>

In particular, the United States-Singapore agreement restricts the grounds for issuing compulsory licensing or exercising government use powers. Article 16.7(6) provides that:

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

- (a) to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (b) in cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that:
  - (i) such use is limited to use by government entities or third parties authorized by the government;
  - (ii) the patent owner is provided with reasonable and entire compensation for such use and manufacture; and

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<sup>213</sup> See paragraph 5(b) of the Doha Declaration.

- (iii) the Party shall not require the patent owner to transfer undisclosed information in technical “know how” related to the patented invention that has been authorized for use without the consent of the patent owner pursuant to this paragraph”.

Similar restrictions also appear in the United States-Jordan agreement. However, the two agreements with these restrictions are somewhat special cases. Singapore for example, was one of the countries which agreed not to use the 30 August Decision except in cases of emergency or other circumstances of extreme urgency. Although the Decision only applies to compulsory licences for import, Singapore has clearly signalled its willingness to restrict its use of compulsory licences to these situations. The United States-Jordan agreement is special in the sense that the FTA was concluded before Jordan became a Member of the WTO and before the adoption of the Doha Declaration.

Notwithstanding the special nature of these two instances where the grounds for the issue of compulsory licences have been circumscribed, a trend in this direction does not bode well for the international commitment to facilitate the sustainable use of these important mechanisms. It is also important to note that in most developed countries, including in the United States, the grounds for the issue of compulsory licences tend to be broader.

#### ***IV.3.1 Recommendations***

Compulsory licensing and government use provisions are key features of a public health focused patent law in any country, developed or developing. The Doha Declaration confirmed that the use of these provisions is a key flexibility and, in particular, determined that each country should have the freedom to determine the grounds for the issue of such licences. Retaining this flexibility, especially the freedom to determine a wide range of grounds, is a key measure. Although there has been no significant erosion of this key flexibility in FTAs in the sense that the two cases so far are somewhat special, care should be taken to ensure

that the restrictive approach in the United States-Singapore and United States-Jordan FTAs is not replicated with other developing countries.

WHO and other international bodies should study the implications of such a restrictive approach for access to medicines in Singapore and Jordan as a basis for evaluating the desirability of such an approach even for middle-income developing countries.

#### **IV.4 -The Early Working Exception**

All the recently concluded FTAs between the United States and developing countries adopt identical language with respect to the early working exception. They provide that:

“If a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical...that Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of that Party other than for purposes related to generating information to meet requirements for approval to market the product once the patent expires, and if the Party permits exportation, the product shall only be exported outside the territory of that party for purposes of marketing approval requirements of that Party.”<sup>214</sup>

On the face of it this provision appears to conform to the decision in the *Canada-Patent Protection of Pharmaceutical Products* case and therefore preserves the flexibility in the TRIPS Agreement under Article 30. The interpretation however, goes further than the Panel’s decision in at least one respect.

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<sup>214</sup> See Article 19.5(3) of the US-CAFTA. Also see Article 17.9 (4) of United States-Chile; Article 15.9(6) of United States-Morocco; and Article 14.8(5) of United States-Bahrain.

Exportation under the provision appears to be only permissible for purposes of registration in that Party meaning that if, for example, a Chilean company wishes to register its generic product abroad, say in Costa Rica or Brazil, it will be prohibited from generating the necessary information and exporting the product for purposes of registration in Costa Rica or Brazil. This provision will definitely restrict the operations of generic companies as it attempts to force all tests and production of quantities necessary for marketing approval to be done country by country. Even multinational pharmaceutical companies with extensive R&D facilities would find it difficult to implement such a system where one would have to establish facilities to undertake marketing approval related tests in every country where registration is sought. The provision may also have significant implications for the use of the system under the 30 August Decision where registration in the importing country is an important consideration.

#### ***IV.4.1 Recommendations***

The early working exception has been confirmed as a permissible practice under the TRIPS Agreement and its advantages for public health purposes amply demonstrated by its practical application in many developing and developed countries such as Canada. It is laudable that the FTAs have in general preserved the TRIPS flexibility. However, the approach in most of these FTAs has constrained the use of this flexibility in one significant way.

Requiring that exportation under the FTA provision is only permissible for purposes of registration in the country where a third person used the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical, that is in the country where the tests were carried out, introduces an impracticable system. There is no possibility that generic companies would be able to undertake market approval related research and tests in each country where they seek registration. This will be the case in most developing countries.

To mitigate the clear negative implications of this system, immediate measures need to be taken to either:

- amend the relevant FTA provisions to remove the requirement that the export is only permissible for purposes of registration in the country where the export emanates and, to clarify that export is permissible for purposes of obtaining marketing approval in third countries; or,
- at the very least to clarify through side letters or additional agreements, that the provision would not stand in the way of ensuring the timely entry of generics into the markets of countries where tests for marketing approval can not be carried out nor, the use of other TRIPS flexibilities including compulsory licensing.

#### **IV.5 Exemptions from Patentability**

Some recent FTAs seek to define the patentability criteria such as utility to conform to the United States standard. For example, a number of FTAs provide that “a claimed invention is industrially applicable if it has specific, substantial and credible utility”.<sup>215</sup> This language, which is based on the ‘Utility Guidelines’ of the United States Patents and Trademark Office (USPTO), may be problematic in the context of biotechnological inventions where patent applicants are known to claim information the effects and application of which they really do not know.<sup>216</sup>

FTAs are also requiring developing countries to provide mandatory patents for plants and animals. For example, the United States-Morocco FTA provides that except where it is necessary to protect *ordre public* or morality, including to protect human, animal, or plant life or health or, to avoid serious prejudice to the environment, “Each Party shall make patents available for the following inventions (a) plants, and

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<sup>215</sup> See e.g., Articles 15.9(11) of United States-CAFTA and 15.9(11) (b) of United States-Morocco.

<sup>216</sup> Drahos (2004b). This was a submission to the Australian Senate Committee.

(b) animals”.<sup>217</sup> Patenting plants and animals is an issue of significant importance in medicine, including in the area of genomics.

A number of FTAs also specifically require that developing countries grant patents for new uses of known pharmaceutical products. The United States-Morocco FTA for example, provides that “the Parties confirm that patents shall be available for any new uses or methods of using known products, including new uses of known products for the treatment of humans and animals”.<sup>218</sup> As already discussed, innovation in the pharmaceutical industry for which patents are claimed varies widely. It ranges from breakthrough discoveries to minor modifications of existing medications with the former being rare. The bulk of new medicines are therefore modified versions of older drugs which however, command high prices.

Protection of new uses will simply encourage this trend with serious implications for innovation for new medicines. The patenting of new uses, which is routinely used for anti-competitive purposes, mainly to block generic entry, serves no useful innovation or access related purpose. This problem can become quite acute in those countries where pharmacy laws do not permit generic substitution and/or generic prescribing.

#### ***IV.5.1 Recommendations***

Patentability criteria and exemptions from patentability are important, though oft forgotten flexibilities with long-term implications for innovation, technology transfer and the dissemination of technology in the pharmaceutical sector. This is a general problem but, particularly pernicious with respect to biotechnological inventions which are playing an

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<sup>217</sup> See Article 15.9(2). Although some agreements such as the United States-CAFTA preserve the flexibilities under Article 27 paras 2 and 3 of TRIPS (See Article 15.9(2) of United States-CAFTA) there is a definite push for patenting plants and animals, since even in the United States-CAFTA each party is required to take all reasonable measures to make patents available for plants and animals.

<sup>218</sup> See Article 15.9(2). Similar provisions are also included in Articles 14.8(2) of United States-Bahrain.

ever increasing role in the pharmaceutical sector. Therefore, the notion of substantial and credible utility as opposed to the TRIPS industrial applicability standard, the push for the mandatory patenting of plants and animals despite the flexibility in Article 27.3(b) of TRIPS and, the requirement for patenting new uses of known products under recent FTAs have very serious implications that need to be addressed immediately.

No public health-related justification seems to support this emerging trend. For this reason it is advisable that consideration be given to:

- revising and, as necessary, amending recent FTAs to ensure that there are no long-term negative consequences for pharmaceutical innovation and the transfer of technology arising from a permissive patentability criteria that allows patent claims over information the effect of, and application of which is unknown, the patenting of plants and animals and the patenting of new uses of known products, especially second medical indications; and
- maintaining the TRIPS flexibilities in this area and advising developing countries currently negotiating FTAs or, that intend to negotiate, to ensure that they retain and use their TRIPS flexibilities in this area.

#### **IV.6 Parallel Importation**

Some FTAs also restrict and/or prohibit parallel importation. Under Article 15.9(4) of United States-Morocco for example, it is provided that:

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



According to the footnote to this provision, the prohibition may be limited to cases where the patent owner has placed restrictions on importation by contract or other means. Notwithstanding the footnote however, the provision effectively prohibits parallel importation. It essentially allows the patent holders, through contract laws, to segment markets and maintain price discrimination.

#### ***IV.6.1 Recommendations***

While there may be a case for a country like the United States to prohibit parallel importation, the case for developing countries prohibiting such imports stands on less firm grounds from a public health perspective. As recommended in Part II (D) developing countries should, as far as possible, adopt an international exhaustion regime, except where there is evidence that the higher price charges resulting from prohibition of the importation of cheaper products serves a greater economic or social purpose. This is likely to be only in exceptional cases, because even patients in the United States have found it difficult to live with a national exhaustion scheme resulting in waves of elderly people travelling to Canada to buy prescription drugs.

Countries such as Morocco which have already entered into an FTA, should explore ways in which to revise the national exhaustion provision. For developing countries that are negotiating FTAs, they should ensure that they preserve their flexibility on this issue and, in particular, adopt an international exhaustion regime. It is laudable that a number of developing countries that have entered into FTAs recently, such as Chile, CAFTA countries and Singapore have retained this flexibility.

## V. CONCLUSIONS

Three international legal texts now define the WTO legal framework for the protection of intellectual property rights in the context of countries' right to take measures to protect public health, including the promotion of access to medicines. The TRIPS Agreement sets out the minimum prescribed standards for the protection of intellectual property rights, within which the means for exercising national discretion and flexibility in its implementation are specified. The Doha Declaration subsequently re-affirmed and clarified a number of these flexibilities, but also provided a general rule or principle for the overall interpretation and implementation of the other TRIPS provisions.

Paragraph 4 of the Declaration, not only confirms the right, but also the obligation of WTO Members to interpret and implement the TRIPS Agreement in a manner supportive of measures to protect public health and, to promote access to medicines for all. Finally, the 30 August Decision sets out a system by which the export limitation under compulsory licensing in TRIPS Agreements is waived so as to allow production and export under compulsory licence, subject to notification and other requirements to prevent diversion of the products to unintended markets. Since these texts are not self-executing, it is important that specific legal provisions be enacted in domestic laws to enable countries to make full use of the flexibilities.

However, as has been shown in the discussion in this study, the majority of developing countries have yet to incorporate the full range of public health-related flexibilities through clear and explicit provisions within domestic legislation. Much has been written and documented about the reasons for developing countries' lack of progress in implementing the TRIPS flexibilities, thus it will suffice for this study to highlight the key ones.

A widespread lack of clarity about the options available, coupled with the lack of local legal and technical expertise to incorporate and implement TRIPS flexibilities in national law and policy, are the obvious and major problems. These countries' experience in implementing TRIPS and its flexibilities is limited and requires effective cooperation between different government agencies and departments, including trade, health and industry, that may have not had to coordinate before in developing common policy. In this regard, apart from addressing these specific problems, it is suggested that there is a need for guidance in implementing a good policy on intellectual property protection in the context of public health. Although it is clearly stated that countries are enabled to take public health measures, it seems less clear what would constitute such measures.

At the same time, the effects of the intellectual property-related policies of developed countries and recent FTAs need to be fully examined and understood. In this context further guidance will be required to facilitate the incorporation of TRIPS flexibilities into FTAs. Clarity can be achieved by defining those public health objectives or principles, which such measures are intended to meet. Policy makers in developing and developed countries need to construe pro-public health and pro-access norms and principles to guide their implementation of the collective legal framework provided by the TRIPS Agreement, the Doha Declaration and the 30 August Decision.

These principles include, but are not limited to, the principle that intellectual property rules and policies should ensure:

- the rapid and effective response to public health needs;
- sustainability of supply of quality medicines at affordable prices;
- competition, through the facilitation of a multiplicity of potential suppliers, both from developed and developing countries; and
- the provision for a wide range of pharmaceuticals to meet an array of health needs, as well as the need to ensure equality of

opportunities for countries in need, irrespective of their level of technological capacity, including countries with insufficient or lack of manufacturing capacity and, irrespective of their membership of the WTO.



# ANNEX I

## PATENT LEGISLATION REVIEW

The review of patent legislation was undertaken on the basis of information compiled from national patent laws, where the laws were available. Additional information was sourced from the reports of the TRIPS Council review of implementing legislation, which are available from the WTO website. Supplementary sources of information included unpublished data, including that collected for the WHO Network for Monitoring the Impact of Globalization and TRIPS on Access to Medicines. A breakdown of the patent laws reviewed, and the sources of information is shown below.

<b>Both patent legislation and WTO responses reviewed</b>	<b>Patent legislation ONLY</b>	<b>WTO responses ONLY</b>	<b>Other source ONLY</b>
China Honduras Indonesia Nicaragua Malaysia Paraguay Singapore Peru Thailand Trinidad and Tobago Argentina Uruguay Barbados Venezuela Belize Kenya Brazil Morocco Bolivia Nigeria Chile South Africa Colombia Tunisia Ecuador Guatemala	Cambodia Viet Nam India Pakistan Egypt Ghana Malawi Mauritius Sudan Swaziland Tanzania Uganda Zambia Zimbabwe	Brunei Philippines Sri Lanka Costa Rica Dominican Republic Jamaica Botswana	Laos Mozambique
26 countries	14 countries	7 countries	2 countries

# **Patent Legislation Review in Asia** **Asia 1: Patentability and patent systems**

Country Sources consulted	Applicable patent law	Provisions/Mechanisms			Other exceptions
		Pharmaceutical products	Patentability exceptions: new use or 2 <sup>nd</sup> use patents	Early working exception	
Brunei WTO review, Other source <sup>o</sup>	Chapter 72 Laws of Brunei  <i>Emergency (Patents) Order 1999 Not yet in force as of 2001.</i>	Yes. Registration of patents granted in United Kingdom, Malaysia and Singapore.		No	Experimental use
Cambodia Patent Law	Law on the Patents, Utility Models Certificates and Industrial Designs 2002	No. Patents excluded until 2016	Not explicitly excluded	No	Experimental purposes
China Patent Law, WTO review	Patent Law of PRC 1992	Yes	2 <sup>nd</sup> use patents allowed	Yes, under Article 13 of the Chinese Regulations on Drug Registration.	Scientific research or experimentation

Country Sources consulted	Applicable patent law	Provisions/Mechanisms			Other exceptions
		Pharmaceutical products	Patentability exceptions: new use or 2 <sup>nd</sup> use patents	Early working exception	
India Patent Law	Patents Act 1970 Patents (Amendment) Act 1999 Patents (Second Amendment) Act 2002 Patents Ordinance 2004	Yes, with mailbox provision	2 <sup>nd</sup> use excluded, but effect of patents ordinance to be clarified	Yes	
Indonesia Patent Law, WTO review	Patents Act, Law no. 14-2001	Yes	Not explicitly excluded	No	Experimental use, use for research, education and analysis
Laos Other source°	Patents, Petty Patents and Industrial Designs Decree <i>New patents law being drafted</i> <i>WTO Accession process</i>	No <i>Yes under draft law</i>			Experimental use
Malaysia Patent Law, WTO review	Patents Act 1983 (Latest amendment 2002)	Yes	2 <sup>nd</sup> use patents allowed	Yes	“The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done only for scientific research.”



Country Sources consulted	Applicable patent law	Provisions/Mechanisms			Other exceptions
		Pharmaceutical products	Patentability exceptions: new use or 2 <sup>nd</sup> use patents	Early working exception	
Philippines WTO review	Intellectual Property Code (Republic Act No. 8293)	Yes	Not excluded  * Specifically permitted for certain new medicinal applications.	No	Private and non-commercial use Scientific research and experiment
Singapore Patent Law, WTO review	Patents Act 1994, amended 1995	Yes	Not excluded	No	Private and non-commercial use “Experimental purposes relating to the subject-matter of the invention.”
Sri Lanka WTO review	Intellectual Property Code 1979 (Last amended 2000)  <i>Intellectual Property Bill 2003, not yet enforced as of 2004</i>	No	Not excluded		Broad provision: Patent owner’s rights “extend only to acts done for industrial or commercial purposes and, in particular, not to acts done only for scientific research.”
Thailand Patent Law, WTO review	Patents Act 1999	Yes	Not excluded	Yes	Broad provision: “Any act for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate

Country Sources consulted	Applicable patent law	Provisions/Mechanisms			Other exceptions
		Pharmaceutical products	Patentability exceptions: new use or 2 <sup>nd</sup> use patents	Early working exception	
					interests of the patent owner.”
Viet Nam Patent Law	Civil Code on Protection of Industrial Property (cif. 1 July 1996) Decree 63/CP 1996, Decree 06/2001, Decree 54/2000	Yes	Not excluded	No	Reverse-engineering of products specifically permitted under Trade Secrets Act 2002. Use for purposes which are not commercial
Pakistan Patent Law	Patents Ordinance 2000 Patents (Amendment) Ordinance, 2002	Yes, post-2005, with mailbox provision.	New and 2 <sup>nd</sup> use both excluded  Mere change in “physical appearance of a chemical product where the chemical formula remains the same” also excluded.	No	Experimental purposes, teaching purposes in educational or research institutions.

## Asia 2: Doha flexibilities – Parallel Imports, Compulsory Licensing and Government Use

Country Sources consulted	Provision/Mechanism			Data protection
	Exhaustion regime	Compulsory licence grounds	Government use	
Brunei WTO review, Other source <sup>o</sup>	No provision under existing law  <i>International, under Emergency Order</i>	No provision  <i>Emergency Order provides for compulsory licensing scheme on grounds of:</i> Failure to work domestically. Demand not met on reasonable terms. Anti-competitive practices.	No.  <i>Yes, under Emergency Order.</i>	No provision (only common law),  Stated in WTO review that data protection measures will be included in new Medicines Act.
Cambodia Patent Law	International	Failure to exploit*  * This ground may only be invoked after three years from grant or four years from filing.	Yes. For public interest including national security, nutrition, health, and finding of anticompetitive practices.  * Patent owner may request Ministry hearing to vary terms of the decision authorizing the exploitation.	No provision, but accession agreement appears to include commitment for five-year data exclusivity.  A separate law on the Protection of Undisclosed Information and Trade Secrets is planned for adoption by the National Assembly in 2004 and promulgation in 2005.

Country Sources consulted	Provision/Mechanism			Data protection
	Exhaustion regime	Compulsory licence grounds	Government use	
China Patent Law, WTO review	National	<p>Public interest Emergency/extraordinary state of affairs Refusal to deal Dependent patents</p> <p>* Under Implementing Regulations, all grounds seem subject to delay of three years after grant.</p> <p>** Patent holder is entitled to judicial review as to “legal validity” of licensing decision within three months of notification. Unclear as to whether this would suspend execution of CL.</p>	No explicit provision	<p>Yes. Data exclusivity of six years, under Implementation Provisions of Drug Administration Law (2002), as follows: “Within six years from the date on which a manufacturer or distributor was granted marketing approval of a pharmaceutical product utilized new chemical entities, if any second applicant applies for market authorization using the said undisclosed data without the permission of the prior applicant, the competent authority for drug administration shall not grant the market authorization, except for that the second applicant submits his own data.”</p>

Country Sources consulted	Provision/Mechanism			Data protection
	Exhaustion regime	Compulsory licence grounds	Government use	
India Patent Law	International	Failure to work domestically.* Public demand not being met on reasonable terms.* Product not supplied to public at “reasonably affordable price.”** Dependent patents.  * These grounds may only be invoked three years from grant or four years from filing.	Yes, for national emergency/ extreme urgency, and for public non-commercial use.	No provision, although discussion underway.
Indonesia Patent Law, WTO review	No explicit provision	Failure to exploit.* Patent implemented in a manner that “contravenes the public interest.” Dependent patents.  * This ground may only be invoked 36 months after date of patent issue, and requires a court hearing.	Yes. For national defence or security, or “an urgent need for the sake of public interest.”.	No provision   * However, WTO response states that data protection will be provided for under the draft Law on Trade Secrets.
Laos Other source °	No explicit provision	Public interest.. Failure to exploit.. Anti-competitive practices Dependent patents Failure to work domestically.*	No Yes, under draft law	No provision
Malaysia Patent Law, WTO review	International	Failure to meet public demand on reasonable terms.* Inter-dependent patents.  * These grounds may be invoked only	Yes. For public interest including national security, nutrition, health, and on finding of anticompetitive practices.	No provision (only common law and Official Secrets Act 1972).

Country Sources consulted	Provision/Mechanism			Data protection
	Exhaustion regime	Compulsory licence grounds	Government use	
		after three years from grant or four years from date of filing.	* Patent owner may request Ministry hearing to vary terms of the decision authorizing the exploitation.	
Philippines WTO review	National	Public interest, including national security, nutrition, or health. National emergency. Failure to exploit, or in cases of “public non-commercial use of the patent by the patentee, without satisfactory reason”. Anti-competitive practices. Refusal to license.	No	Yes, but only under Food, Drug and Cosmetic Act and general business confidentiality regulations.  No specific provision in patent legislation.  * For agricultural chemical products, the Pesticide Regulation provides data exclusivity for 8 years from data of approval. No other applications may be filed during this time-frame.

Country Sources consulted	Provision/Mechanism			Data protection
	Exhaustion regime	Compulsory licence grounds	Government use	
Singapore Patent Law, WTO review	International	Failure to exploit domestically.* Failure to supply on reasonable terms.* Dependent patents.**  *These grounds may only be invoked 3 years from grant or 4 years from filing. ** Requires court hearing.	Yes. For “services of the Government”, national security purposes, public non-commercial use during emergency.	Yes. Data exclusivity office years under Medicines Act 1998 and Control of Plants Act 1998.  * Stated in WTO interview that later applicants must provide new data even after five years.
Sri Lanka WTO review	Unclear: language suggests national exhaustion.	No provision		No. However, draft legislation will include provisions for data protection. As stated in WTO interview, later applicants will be required to submit new data.
Thailand Patent Law, WTO review	Unclear. National exhaustion implied but not specified.	Failure to exploit domestically.* Public demand not being met on reasonable terms.* Dependent patents.*  * These grounds may only be invoked three years from grant or four years from filing.	Yes. For “any service for public consumption”, national defence, environmental preservation, or to “prevent or relieve” severe food shortages.	Yes, under Trade Secrets Act 2002.  No specific provision in patent law.  * Stated in WTO interview that the issue of whether later applicants may rely on previous test data will be determined “on a case by case basis.”
Viet Nam Patent Law	International (incl. products placed on mar-	Failure to exploit. Public interest, including national security, “prevention and treatment of	No	Yes, under Decree no. 54/2000/ND-CP

Country Sources consulted	Provision/Mechanism			Data protection
	Exhaustion regime	Compulsory licence grounds	Government use	
	ket under CL Article 52.1 (b) Decree 63-CP).	diseases", or "other urgent needs of society". Refusal to deal.  * No emergency provisions. ** Under Decree No. 06/2001/ND-CP, CLs may not be applied for until three years from grant or four years from filing.		
Pakistan Patent Law	International	Failure to exploit*  * This ground may only be invoked three years from grant or four years from filing.	Yes. For public interest, including health, nutrition, or national security, and on finding of anticompetitive practices. * Patent owner may request hearing to vary terms of the decision authorizing the exploitation.	Yes, under Trade Marks Ordinance 2001, Rules of Business 1973, Official Secrets Act 1923, Civil Servants Rules 1964.  * According to interpretation stated in WTO interview, later applicants would probably have to provide new data.



## Patent Legislation Review in Latin America and the Caribbean Latin America and the Caribbean 1: Patentability and patent systems

Country Sources consulted	Applicable patent law	Provisions/Mechanisms Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents	Early working exception	Other exceptions
Argentina Patent Law, WTO Review	Law 24.481, 1996	Yes, with mailbox provision	<p>Not excluded</p> <p>* Combinations of known inventions or mixtures of known products excluded unless non-obvious.</p>	<p>Yes, under Undisclosed Information Law No. 24.766, 1996.</p>	<p>Private and non-commercial use, including scientific research, teaching purposes</p> <p>Other uses broadly interpreted by reproduction of Article 30 text which authorizes the provision of "limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent</p>

Country Sources consulted	Applicable patent law	Provisions/Mechanisms Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents	Early working exception	Other exceptions
					and, do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”
Barbados Patent Law, WTO Review	Patent Act no. 18/2001	Yes	Not excluded	No	Scientific research
Belize Patent Law, WTO Review	Patent Act Chapter 253/2000 Patents Bill 2000	Yes	Not excluded	No	Experimental purposes
Brazil Patent Law, WTO Review	Industrial Property Law, No. 9,279, 1996 (amended 2001, Law no. 10.196)	Yes, as of 2004 Mailbox provision * Patents have to be passed by Health Ministry.	Not excluded	Yes	Experimental use, use related to studies, or scientific/technological research. Private and non-commercial use. Use of patented self-reproducing biological material.

Country Sources consulted	Applicable patent law	Provisions/Mechanisms Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents	Early working exception	Other exceptions
Chile Patent Law, WTO Review	Law No 19.039, 1991 <i>New draft law proposed</i>	Yes	New use excluded "except where the qualities of the subject matter are essentially altered or where its use solves a technical problem that did not previously have an equivalent solution."	No	Experimental use, non-commercial use, teaching purposes.
Costa Rica WTO Review	Patent Law No 7979/2000 Law 6867 of 1983 amended 2000	Yes	Not excluded. * Combinations of known inventions or mixtures of known products excluded unless non-obvious.	Yes	Experimental use, private and non-commercial use.
Dominican Republic WTO Review	Law No. 20-00 on Industrial Property, 2000		New use excluded.	Yes	Private and non-commercial use. Teaching purposes. Scientific or academic purposes. Use of patented self-reproducing biological material.
Guatemala Patent Law, WTO Review	Decree 57/2000	Yes	Not excluded.	No	Experimental use. Private and non-commercial use. Educational purpose.

Country Sources consulted	Applicable patent law	Provisions/Mechanisms Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents	Early working exception	Other exceptions
					poses. Scientific or academic research. Use of patented self-reproducing biological material.
Honduras Patent Law, WTO Review	Decree 12-99E Industrial Property Law, 2000	Yes	Not excluded.	No	Experimental use. Scientific research. Private and non-commercial use. Educational use.
Jamaica WTO Review	Draft Patents and Designs Act, 2001	<i>Yes, upon enforcement of draft legislation.</i>			
Nicaragua Patent Law, WTO Review	Law on Patents, Utility Models and Industrial Designs, no. 354 2000	Yes	Not excluded.	No	Private and non-commercial use. Teaching purposes. Scientific or academic research. Use of patented self-reproducing biological material.
Paraguay Patent Law, WTO Review	Patent Law No 1.630/2000	Yes	Not excluded.	Yes, but only within	Exclusively non-commercial experimentation.

Country Sources consulted	Applicable patent law	Provisions/Mechanisms Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents	Early working exception	Other exceptions
				30days before patent expiry.	Teaching purposes. Scientific or academic research.
Trinidad and Tobago Patent Law, WTO Review	Patent Act (Consolidation), 1996 (2000)	Yes	Not excluded.	No	Experimental use Private and non-commercial use
Uruguay Patent Law, WTO Review	Patent Law No 17.164/1999	Yes	New use and 2nd use excluded.	Yes.* * However, must be carried out within one year before patent expiry.	Private and non-commercial use. Educational purposes. Scientific or academic research.
Bolivia Patent Law, WTO Review	Decision 486 of the Andean Community	Yes	New / 2 <sup>nd</sup> use excluded under Decision 486  Article 21 states: “Products or processes already patented and included in the state of the art... may not be the subject of new patents on the sole ground of having been put to a use different form that originally contemplated	No	Experimental use. Private and non-commercial use. Teaching purposes.

Country Sources consulted	Applicable patent law	Provisions/Mechanisms Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents by the initial patent."	Early working exception	Other exceptions
Colombia Patent Law, WTO Review	Decision 486 of the Andean Community	Yes	New / 2 <sup>nd</sup> use excluded under Decision 486	No	Experimental use. Private and non-commercial use. Teaching purposes.
Ecuador Patent Law, WTO Review	Intellectual Property Law, 1998 Decision 486 of the Andean Community	Yes	New / 2 <sup>nd</sup> use excluded under Decision 486	No	Experimental use. Private and non-commercial use. Academic purposes.
Peru Patent Law, WTO Review	Decree No. 823 on Industrial Property, Decision 486 of Andean Community	Yes	New / 2 <sup>nd</sup> use excluded under Decision 486.	No	Experimental use. Private and non-commercial use. Teaching purposes.

Country Sources consulted	Applicable patent law	Provisions/Mechanisms Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents	Early working exception	Other exceptions
Venezuela Patent Law, WTO Review	Industrial Property Law, 1955 Decision 486 of Andean Community	Yes	New / 2 <sup>nd</sup> use excluded under Decision 486.	No	Experimental use. Private and non-commercial use. Teaching purposes. Scientific or academic research.  Use of patented self-reproducing biological material.

## Latin America and the Caribbean 2: Doha flexibilities – Parallel Imports, Compulsory Licensing, Government Use

Country	Provisions/Mechanism			
Sources consulted	Exhaustion regime	Compulsory licence grounds	Government use	Data protection
Argentina Patent Law, WTO Review	International  * Including products placed on market under CL.	Failure to exploit.* Anti- competitive practices, including excessive prices and refusal to supply domestic market on reasonable terms. Dependent patents.  *This ground may only be invoked after three years from grant or four years from filing.	Yes, for national security or health emergency.	Yes, under Undisclosed Information Law No. 24.766, 1996.  No data exclusivity provisions, and according to WTO interview, later applicants may rely on previous test data.
Barbados Patent Law	National	Failure to exploit* Dependent patents*  *These grounds may only be invoked after three years from grant or four years from filing.	Yes, for national security, health, nutrition, other public interests or, on finding of anticompetitive practices.	Yes, under Protection Against Unfair Competition Act ,1998.  According to WTO review later applicants must submit new data.
Belize Patent Law, WTO Review	National	Failure to exploit. Refusal to licence. Dependent patents.	Yes, for public interest including national security, nutrition or health, or on finding of anti-	No provision (common law only).  According to WTO interview, this issue will be



Country	Provisions/Mechanism			
Sources consulted	Exhaustion regime	Compulsory licence grounds	Government use	Data protection
Brazil Patent Law, WTO Review	National	<p>“Abuse of economic power”* Failure to exploit domestically* Demand not met on reasonable terms* Dependent patents Public interest National emergency</p> <p>* These grounds may only be invoked after 3 years from grant of patent.</p>	<p>competitive practices. The Minister must have a hearing with the patent holder before deciding.</p> <p>No explicit provision</p>	<p>addressed in a new draft law.</p> <p>Yes</p> <p>According to WTO interview, the “general rule” is that later applicants may not rely on previous test data.</p>
Chile Patent Law, WTO Review	No explicit provision	“Monopolistic abuse of a patent” (anti-competitive practices)	No explicit provision	Yes, under Health Code, and Law No. 19.653 on administrative probity
Costa Rica WTO Review	International	<p>Failure to exploit* Refusal to license* WTO interview cites the existence of other grounds “according to the criteria set out in Article 31 of the TRIPS Agreement”</p> <p>* These grounds may only be invoked after 3 years from grant</p>		Yes, under Law on Undisclosed Information, No. 7975, 2000

Country	Provisions/Mechanism			
Sources consulted	Exhaustion regime	Compulsory licence grounds	Government use	Data protection
Dominican Republic WTO Review	International	Failure to work Public interest, including national emergency or national security Anti-competitive practices Dependent patents		Yes  According to WTO inter-view, later applicants must submit new test data
Guatemala Patent Law, WTO Review	International	Dependent patents	Yes, For public interest, including national emergency, public health, national security, public non-commercial use, or to remedy anti-competitive practices	Yes  A new law (passed but not yet in force) provides for data exclusivity of 5 years, to meet obligations of CAFTA.
Honduras Patent Law, WTO Review	International	Refusal to license* Dependent patents  * This ground may only be invoked after 3 years from grant or 4 years from filing	Yes, for public interest including national security, public health or nutrition	Yes
Jamaica WTO Review			Yes	No provision (only common law)
Nicaragua Patent Law,	International	Dependent patents	Yes, For public interest,	Yes

Country	Provisions/Mechanism			
Sources consulted	Exhaustion regime	Compulsory licence grounds	Government use	Data protection
WTO Review			national emergency, or to remedy anti-competitive practices	According to WTO inter-view, later applicants may only use same data if the information is “obtained lawfully” or if the applicant “had access be-cause of disclosure else-where in the world”.
Paraguay Patent Law, WTO Review	International	Failure to exploit* Health emergency National defence or security Anti competitive practices, in-cluding excessive prices, or fail-ure to supply local market on reasonable terms Dependent patents  *This ground may only be in-voked after 3 years from grant or 4 years from filing ** Patent owner or other inter-ested parties may request hearing to vary terms of the license	No explicit provision	No provision  <i>Under discussion for inclu-sion in draft law</i>
Trinidad and Tobago Patent Law, WTO Review	National	Failure to work* Demand not met on reasonable terms* Anticompetitive practices	Yes, for public interest	Yes  According to WTO inter-view, data exclusivity

Country	Provisions/Mechanism			
Sources consulted	Exhaustion regime	Compulsory licence grounds	Government use	Data protection
		* These grounds may only be invoked after 3 years from grant or 4 years from filing		extends for a “reasonable period of time” that is “normally not less than 5 years”, subject to judicial review.
Uruguay Patent Law, WTO Review	International	Failure to work* Public interest Anti-competitive practices Dependent patents  * This ground may only be invoked after 3 years from grant or 4 years from filing	Yes, For public utility, national security, public health emergencies	Yes, but only general protection under unfair competition provisions of Decree-Law No. 14.910 of 1979.
Bolivia Patent Law, WTO Review	International	Failure to exploit* Demand not met on reasonable terms* Anti-competitive practices Public interest National emergency National security  * These grounds may only be invoked after 3 years from grant or 4 years from filing	No explicit provision	Yes, under Decision 486  WTO response is unclear regarding use of previous data; states only that all applicants must be treated equal under the law, and that:  an authority “would be able to make internal use of any information available to it.” in determining “whether the later product complied with

Country	Provisions/Mechanism			
Sources consulted	Exhaustion regime	Compulsory licence grounds	Government use	Data protection
				the requirements of the legislation”
Colombia Patent Law, WTO Review	International	Failure to exploit* Demand not met on reasonable terms* Anti-competitive practices Public interest National emergency National security  * These grounds may only be invoked after 3 years from grant or 4 years from filing	No explicit provision	Yes, under Decision 486 and Criminal Code
Ecuador Patent Law, WTO Review	International	Failure to exploit* Demand not met on reasonable terms* Public interest, including national emergency and national security Anti-competitive practices Refusal to license * These grounds may only be invoked after 3 years from grant or 4 years from filing	No explicit provision	Yes, in patent legislation  According to WTO inter-view, later applicants must submit new data

Country	Provisions/Mechanism			
Sources consulted	Exhaustion regime	Compulsory licence grounds	Government use	Data protection
Peru Patent Law, WTO Review	International	Failure to exploit* Demand not met on reasonable terms* Anticompetitive practices Public interest National emergency National security  * These grounds may only be invoked after 3 years from grant or 4 years from filing	No explicit provision	Yes, under Decision 486  According to WTO interview, later applicants may not rely on previous test data
Venezuela Patent Law, WTO Review	International	Failure to exploit* Demand not met on reasonable terms* Anti-competitive practices Public interest National emergency National security  * These grounds may only be invoked after 3 years from grant or 4 years from filing	No explicit provision	Yes, under Decision 486.  Further, databases are specifically protected under Law on Copyright

# Patent Legislation Review in Africa

## Africa 1: Patentability and patent systems

Country Sources consulted	Applicable patent law	Provisions/Mechanisms			Early working exception	Other exceptions
		Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents			
Botswana WTO Review, Other Source °	Intellectual Property Act, 1996	Yes		No	Experimental purposes.	
Egypt Patent Law	Intellectual Property Law 82, 2002	Yes, post-2005 with mailbox provision.	Not excluded	Yes	Scientific research purposes. Other broad exceptions: “Any other acts by third parties, provided that they shall not unreasonably hamper the normal exploitation of the patent, and shall not be unreasonably prejudicial to the legitimate interests of the patent owner, taking into consideration the legitimate interests of others.”  Also: “use of the result of propagation material, by farmers on their own holdings for private propagating purposes.”	

Country Sources consulted	Applicable patent law	Provisions/Mechanisms			Other exceptions
		Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents	Early working exception	
Ghana Patent Law	Patents Act, 2003	Yes		No	Experimental purposes.
Kenya Patent Law, WTO Review	Industrial Property Act, 2001	Yes	Not excluded	Yes	Broad provision: "The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research."
Malawi Patent Law	Patents Act, 1992	Yes	Not excluded. *But inventions "capable of being used as food or medicine" which are "a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients" are specifically excluded.	No	None specified.



Country Sources consulted	Applicable patent law	Provisions/Mechanisms			
		Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents	Early working exception	Other exceptions
Mauritius Patent Law	The Patents, Industrial Designs, and Trademark Act No. 25 of 2002	Yes	Not excluded.	No	Research and experimental purposes.
Morocco Patent Law, WTO Review	Law no. 17-97 on the Protection of Industrial Property, 2000	Yes	Not excluded.	No	Experimental purposes. Private and non-commercial use.
Mozambique Other Source °	Industrial Property Code: Decree No. 18/99, 2004			No	Non-commercial use.
Nigeria Patent Law, WTO Review	Patent Law 1971 Draft Patents and Designs Act 2002	Yes	Not excluded.	Yes	Scientific research, including “experimentation on the invention to test the invention or improve it”. Private and non-commercial use. Teaching purposes.
South Africa Patent Law, WTO Review	Patents Act 1978, amended 1997 Medicines Act 1997	Yes	2 <sup>nd</sup> medical use allowed.	No	No

Country Sources consulted	Applicable patent law	Provisions/Mechanisms			
		Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents	Early working exception	Other exceptions
Sudan Patent Law  <i>Currently in WTO accession process</i>	Patent Act 1971, Patent Regulation 1981  <i>A new draft bill is under consideration.</i>	No  <i>Draft bill will invoke 2016 transition period.</i>	Not excluded.	No	Implied but not specified; patent rights “shall only extend to acts done for industrial or commercial purposes.”
Swaziland Patent Law, WTO notification	Patents, Designs and Trade Marks Act, 1936 (only provides registration for patents filed in UK or South Africa) <i>New draft law: Patents, Utility Models and Industrial Designs Act No. 6 of 1997</i>				

Country Sources consulted	Applicable patent law	Provisions/Mechanisms			
		Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents	Early working exception	Other exceptions
Tanzania Patent Law	Patents Act 1987 (Gif 1994)		Not excluded.	No	Patent rights “shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research.”
Tunisia Patent Law, WTO Review	Law No. 2000-84 on Patents	Yes		Yes, but <i>only</i> for “acts necessary for the manufacture of generic drugs.”.	Private and non-commercial use. Experimental purposes.
Uganda Patent Law	Patents Act, 1993  <i>New draft law: Industrial Property Bill 2004</i>		Not excluded.	No provision in current law.  <i>Yes, in draft law.</i>	Scientific research.  <i>Draft law adds exception for teaching purposes, permits experimental use for commercial purposes, and, provides for exportations to other countries with CL authorizations.</i>

Country Sources consulted	Applicable patent law	Provisions/Mechanisms			Other exceptions
		Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents	Early working exception	
Zambia Patent Law	Patents Act	Yes	Not excluded.  * But specifically excludes any invention which is “capable of being used as food or medicine which is a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients.”	No	None specified.
Zimbabwe Patent Law	Patents Amendment Act, 2002		Not excluded.	Yes. “Test batches” of a patented product may be produced, but not put on the market, six months before patent expiry.	None specified.

## Africa 2: Doha flexibilities – Parallel Imports, Compulsory Licensing and Government Use

Country Sources consulted	Provisions/Mechanism	Compulsory licence grounds	Government use	Data protection
	Exhaustion regime			
Botswana WTO Review, Other Source °	National	Failure to supply on reasonable terms.	Yes	
Egypt Patent Law	International	<p>Public non-commercial interest, including “preservation of national security, health, environment and food safety.”</p> <p>Emergency/extreme urgency.</p> <p>“Support of national efforts in vital sectors for economic, social and technological development”.</p> <p>Inadequate quantity or quality, or prohibitive prices of patented medicines.</p> <p>Medicines “addressing critical cases, or incurable or endemic diseases”, or medicine-related inventions.</p> <p>Refusal to license on reasonable terms.</p> <p>Anti-competitive practices, including “exorbitant prices”, failure to supply local market on reasonable terms.</p> <p>Dependent patents.</p> <p>Failure to exploit domestically.*</p> <p>*This ground may only be in-</p>	<p>Yes.</p> <p>For national defence or emergency.</p>	<p>Yes</p> <p>* Authorities must protect test data in support of pharmaceuticals and food-related agro-chemical products from disclosure and unfair commercial use for a period “until it is no longer confidential or, a period not exceeding five years, whichever comes first.”</p>

Country Sources consulted	Provisions/Mechanism		Government use	Data protection
	Exhaustion regime	Compulsory licence grounds		
		<p>invoked after three years from grant or four years from filing.</p> <p>** Patent owner may appeal decisions awarding CLs to third parties within one month of notification of grant.</p>		
Ghana Patent Law	International	<p>Anti-competitive practices.</p> <p>Refusal to license.</p> <p>Failure to exploit.*</p> <p>Dependent patents.*</p> <p>* These grounds may only be invoked via a request to the courts after three years from grant or four years from application.</p>	<p>Yes.</p> <p>For public interest, including national security, nutrition or health.</p> <p>* Language unclear on whether prior negotiations with patent holders are required for non-emergency government use.</p> <p>Yes-</p>	<p>Yes, under Protection against Unfair Competition Act, 2000.</p> <p>No specific provision in Patents Act.</p>
Kenya Patent Law, WTO review	International	<p>Failure to exploit.*</p> <p>Demand not being met on reasonable terms.*</p> <p>Dependent patents.</p> <p>* These grounds may only be invoked after three years from grant or four years from application.</p>	<p>Yes, under Pharmacy and Poisons Act and the Pest Control Products Act-</p> <p>No time-limit on data exclusivity currently, but an amending provision is under consideration.</p>	

Country Sources consulted	Provisions/Mechanism		Government use	Data protection
	Exhaustion regime	Compulsory licence grounds		
Malawi Patent Law, Other source °	Unclear, possibly international.	Failure to work.* Demand not being met on reasonable terms.* Food- and medicine- related commodities.  *These grounds may only be invoked after three years from grant or four years from application.	Yes, but terms may not be TRIPS-compliant, and may omit authorization for importation or exportation.	No specific provision in patent law.
Mauritius Patent Law	International	Failure to exploit* Dependent patents  *This ground may only be invoked after three years from grant or four years from application.	Yes.* For public interest, including national security, nutrition, health or, on finding of anti-competitive practices.  * A hearing with the patent owner is required before issuing a CL.	Yes, under The Protection Against Unfair Practices Act, 2002.  Data exclusivity for “a reasonable period of time” that is “not less than five years”, subject to Minister’s discretion.
Morocco Patent Law, WTO review	National	Failure to work domestically.* Domestic market demand not met.* Dependent patents.*  *These grounds may only be invoked after three years from grant or four years from application.  **Terms of licence may be	Yes.* For interests of public health where medicine-related inventions are provided in insufficient quality or quantity, or at abnormally high prices.  * Patents may be exploited <i>ex officio</i> only after one year from issue of formal notice	Yes, under various legislation including General Civil Service Act, and Code of Obligations and Contracts.  No specific provision in patent legislation.  According to WTO

Country Sources consulted	Provisions/Mechanism			Data protection
	Exhaustion regime	Compulsory licence grounds amended by court at request of owner or licensee.	Government use to patentee.	
				review: "A second applicant wishing to register the same product as a generic product is permitted to use a simplified procedure, i.e. he is not obliged to repeat all the clinical, pharmacological and toxicological studies, but may refer to the data published in the scientific literature."
Mozambique Other Source °		National emergency/extreme urgency "of either an economic or a social nature." Failure to exploit, demand not being met on reasonable terms. Refusal to license.	Yes	
Nigeria Patent Law, WTO review	National	Failure to work domestically.* Demand not met on reasonable terms.* National security.* Public health and nutrition.* Environmental conservation.* Dependent patents.*  * All grounds may only be invoked after four years from grant of	Yes, for public interest including national security, nutrition, health or environmental protection, and for emergency purposes.	Yes



Country Sources consulted	Provisions/Mechanism		Government use	Data protection
	Exhaustion regime	Compulsory licence grounds		
South Africa Patent Law, WTO review		<p>patent. ** CLs only allowed for imports or locally produced patented products.</p> <p>Failure to work domestically.* Demand not met on reasonable terms. Refusal to license. Dependent patent.</p> <p>*This ground may only be invoked after three years from grant or four years from filing.</p>	<p>Yes.</p> <p>*However, requires hearing with patentee beforehand.</p>	<p>No specific provision in patent law.</p> <p>General confidentiality provisions in common law, Medicines and Related Substance Control Act No. 101 of 1965, and Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act No. 36 of 1947.</p>
Sudan Patent Law	<p>National under current law.</p> <p><i>International, under new draft bill.</i></p>	<p>Failure to work domestically.* Demand not met on reasonable terms.* Refusal to license.* Interdependent patents.</p> <p>*These grounds may only be invoked after three years from grant or four years from filing.</p> <p><b>** Draft bill will redefine conditions considered under national</b></p>	<p>Yes, on grounds of national defence, national economy, and public health.</p> <p>* CLs may be granted for purposes of importation.</p>	<p>No specific provision in patent law.</p>

Country Sources consulted	Provisions/Mechanism		Government use	Data protection
	Exhaustion regime	Compulsory licence grounds		
		<i>emergency to include: public health crises, "lack of pharmaceutical products at affordable prices", and insufficient manufacturing capacity for pharmaceuticals.</i>		
Swaziland Patent Law, WTO notification		Public interest, including national security, nutrition, health.	Yes.	
Tanzania Patent Law	National	<p>Failure to work domestically.* Demand not met on reasonable terms.* Refusal to license.* Dependent patents. Public health or defence.</p> <p>*These grounds may only be invoked after three years from grant or four years from filing. ** All grounds require court proceedings.</p>	<p>Yes.* For vital public interests including national security, health, or development of vital sectors of economy.</p> <p>* "The minister shall take his decision... after a hearing to which the patent owner and any licensee shall be invited". Further, patent owners may appeal, but this "shall not suspend the effects of the decision."</p>	No specific provision in patent law.

Country Sources consulted	Provisions/Mechanism			Data protection
	Exhaustion regime	Compulsory licence grounds	Government use	
Tunisia Patent Law, WTO review	International	<p>Failure to work domestically.* Market demand not sufficiently met.*</p> <p>*These grounds may only be invoked after three years from grant or four years from filing. Court hearing required.</p>	<p>Yes. “To meet the needs of the national economy,” or “to safeguard the environment.”*</p> <p>Public health interests, including remedy inadequate quality or quantity or excessively high price of drugs or products necessary for the production of drugs. National defence or security.</p> <p>* CL on these grounds may only be imposed one year after initial formal notice.</p>	<p>No specific provision in patent law.</p> <p>General protection of undisclosed information is provided by various legislation including Labour Code, Penal Code, and Order of the Minister of Public Health 1996 on the marketing of medicines for human use.</p> <p>According to WTO review, “clinical data pertaining to subject-matter of a second application is not required because the molecule has already been analysed.”</p>
Uganda Patent Law	National under current law. <i>International, under draft law.</i>	<p>Failure to work domestically.* Demand not met on reasonable terms.* Refusal to license.* Anti-competitive practices.</p> <p>*These grounds may only be invoked after three years from grant or four years from filing.</p>	Yes, for vital public interests, including national security, public health, public order and morality.	No specific provision in patent law.

Country Sources consulted	Provisions/Mechanism		Government use	Data protection
	Exhaustion regime	Compulsory licence grounds		
		<p>Court hearing required.</p> <p><i>Draft law waives requirement for patent holder permission in cases of national emergency/ extreme urgency, or for anti-competitive practices.</i></p>		
Zambia Patent Law	No explicit provision.	<p>Failure to work domestically.*</p> <p>Demand not met on reasonable terms.*</p> <p>Refusal to license.*</p> <p>“Unfair conditions attached by the patentee... to the purchase, hire, license or use of the patented article.”*</p> <p>Unlawfully restrictive contract terms, including provisions that are “in restraint of trade” or are “contrary to public policy.”**</p> <p>Food- and medicine- related commodities.</p> <p>*These grounds may only be invoked after three years from grant or four years from filing, and require court hearing.</p>	<p>Yes, for “services of the State”* or during “any period of emergency.”**</p> <p>*Disputes over CL decision for “services of the State” or “terms for the use” of an invention in such service may be referred to the High Court “by any party in the dispute.”</p> <p>** Unclear as to whether dispute proceedings are required during periods of emergency.</p>	No specific provision in patent law.

Country Sources consulted	Provisions/Mechanism		Government use	Data protection
	Exhaustion regime	Compulsory licence grounds		
Zimbabwe Patent Law	International, “if the cost of importing a product “is less than the cost of purchasing from the patentee.”	Abuse or insufficient use of patent rights, including failure to work domestically and demand not met on reasonable terms.* Unlawfully restrictive contract terms, including provisions that are “in restraint of trade” or are “contrary to public policy.”** Food- and medicine- related inventions, or “any invention capable of substantially improving the technological, social, and economic development of the country.” Dependent patents. Anti-competitive practices.  * For these grounds, a CL must be applied for within six months of initial attempt to procure a voluntary licence	Yes. For “service of the State”, * or during “periods of emergency.”  * Use for “service of the State” shall be made “upon such terms and conditions as may be agreed upon between the Minister and the patentee” or as determined by dispute resolution under Patents Tribunal.**  ** This condition seems not to apply during periods of emergency.	No provision in patent legislation.

## Patent Legislation Review: Regional patent organizations

Regional organization	African Intellectual Property Organization (OAPI)	African Regional Intellectual Property Office (ARIPO)	Andean Community
Membership	16 member states: Benin, Burkina Faso, Cameroon, Central African Republic, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad, Togo	15 member states: Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, Zambia	five member states: Bolivia, Colombia, Ecuador, Peru, Venezuela
Applicable treaty instrument	Bangui Agreement 1977, revision of 1999	Harare Protocol, 1982	Andean Community Decision 486
Administration of patent system	Common patent legislation and authority; i.e. single body serving as national patent authority. Filing of application with Organization is equivalent to a national filing in each member state and grant of patent will mean registration of national rights in all members, subject to national legislation.	Filing of one application (designating country in which protection is sought), but no automatic national registration. Members may reject patents granted (six months from date of receipt from ARIPO) on basis they are contrary to national legislation.	Filing and grant, of applications at individual national patent offices.
Pharmaceutical products	Yes.	Yes.	Yes.
Patentability exclusions	No exclusion.	Not explicitly excluded.	New and 2 <sup>nd</sup> use patents excluded.
Opposition system			
Parallel imports	Appears to regional exhaustion? Relevant provision states that patent rights “do not extend to subject matter brought on to the market on the territory of a		International.

Regional organization	African Intellectual Property Organization (OAPI)	African Regional Intellectual Property Office (ARIPO)	Andean Community
	Member state by the patent holder or with his consent” - Art 8.1(a).		
Compulsory licensing	Demand not being met on reasonable terms. 1999 Revision – includes failure to exploit and dependent patents.		Failure to exploit. Public interest. Emergency or national security considerations. Anti-competitive practice.
Limits on export under CL			Yes.
Government use	Yes.		
Early working	Not provided.		Not specifically provided
Patent exceptions – others	Experimental use in the course of scientific and technical research.		Private and non-commercial experimental use. Acts carried out exclusively for teaching or scientific or academic research.
Data protection	Protection dishonest use of confidential test or other data (production of which requires considerable effort) which have been communicated to authorities for the purpose of obtaining market authorization.		Reproduces Article 39.3 wording.

° Further information about “other sources” used:

Brunei: Unpublished data obtained from ASEAN IPR Project

Laos: Unpublished data obtained from ASEAN IPR Project

Botswana: Luke D. Musungu S, Nkrumah Y, Rossi F. “Report on the Mission to Assess Options for Accessing Low Cost Anti-retroviral (ARV) Medicines in Southern Africa”, 2004.

Mozambique: Luke D, Musungu S, Nkrumah Y, Rossi F. "Report on the Mission to Assess Options for Accessing Low Cost Anti-retroviral (ARV) Medicines in Southern Africa", 2004.

Malawi: Lewis-Lettington R, Banda C. "A Survey of Policy and Practice on the Use of Access to Medicines-Related TRIPS Flexibilities in Malawi", DFID Health Systems Resource Centre, Sept. 2004

#### Internet links:

##### ASIA

China Patent Law available at: [http://www.sipo.gov.cn/sipo\\_English/fffg/zlfffg/t20020327\\_33872.htm](http://www.sipo.gov.cn/sipo_English/fffg/zlfffg/t20020327_33872.htm)

China: Implementing Regulations available at: [http://www.sipo.gov.cn/sipo\\_English/fffg/zlfffg/t20020327\\_33871.htm](http://www.sipo.gov.cn/sipo_English/fffg/zlfffg/t20020327_33871.htm)

Indonesia Patents Act 2001 available at: <http://www.dgip.go.id>

Indonesia Patents Act available at: [http://www.wipo.int/clea/docs\\_new/en/sg/sg013en.html](http://www.wipo.int/clea/docs_new/en/sg/sg013en.html)

Singapore Medicines Act available at: [http://www.wipo.int/clea/docs\\_new/en/sg/sg019en.html](http://www.wipo.int/clea/docs_new/en/sg/sg019en.html)

Singapore Control of Plants Act available at: [http://www.wipo.int/clea/docs\\_new/en/sg/sg018en.html](http://www.wipo.int/clea/docs_new/en/sg/sg018en.html)

Thailand Patent Act available at: [http://www.wipo.int/clea/docs\\_new/en/th/th007en.html](http://www.wipo.int/clea/docs_new/en/th/th007en.html)

Thailand Trade Secrets Act, 1992, available at: [http://www.wipo.int/clea/docs\\_new/en/th/th018en.html](http://www.wipo.int/clea/docs_new/en/th/th018en.html)

India Patent Act and amendments available at: <http://ipindia.nic.in/ipr/patent/patents.htm>

##### LATIN AMERICA/ CARIBBEAN

Barbados Patents Act, 2001-18 available at: [http://www.wipo.int/clea/docs\\_new/en/bb/bb016en.html](http://www.wipo.int/clea/docs_new/en/bb/bb016en.html)

Nicaragua Law no. 354, 2000 available at: [http://www.wipo.int/clea/docs\\_new/en/ni/ni011en.html](http://www.wipo.int/clea/docs_new/en/ni/ni011en.html)

Guatemala Decree 57-2000 available (Spanish only) at: [http://www.wipo.int/clea/docs\\_new/es/gt/gt001es.html](http://www.wipo.int/clea/docs_new/es/gt/gt001es.html)

Argentina Law 24,481 available (Spanish only) at: [http://www.wipo.int/clea/docs\\_new/es/ar/ar002es.html](http://www.wipo.int/clea/docs_new/es/ar/ar002es.html)

Belize Patents Bill 2000 available at: [http://www.wipo.int/clea/docs\\_new/en/bz/bz003en.html](http://www.wipo.int/clea/docs_new/en/bz/bz003en.html)

Belize Patents Act available at: [http://www.wipo.int/clea/docs\\_new/en/br/br003en.html](http://www.wipo.int/clea/docs_new/en/br/br003en.html)

Brazil Law no. 10.196 available at: [http://www.wipo.int/clea/docs\\_new/en/br/br035en.html](http://www.wipo.int/clea/docs_new/en/br/br035en.html)

Ecuador Intellectual Property Law 1998 available at: [http://www.wipo.int/clea/docs\\_new/en/ec/ec001en.html](http://www.wipo.int/clea/docs_new/en/ec/ec001en.html)

Guatemala Decree no. 57-2000 available (Spanish only) at: [http://www.wipo.int/clea/docs\\_new/es/gt/gt001es.html](http://www.wipo.int/clea/docs_new/es/gt/gt001es.html)

Honduras Decree 12-99E available (Spanish only) at: [http://www.sice.oas.org/int\\_prop/nat\\_leg/Honduras/indice.asp](http://www.sice.oas.org/int_prop/nat_leg/Honduras/indice.asp)

Nicaragua Law no. 354, 2000 available at: [http://www.wipo.int/clea/docs\\_new/en/ni/ni011en.html](http://www.wipo.int/clea/docs_new/en/ni/ni011en.html)

Paraguay Law No. 1.630/2000 available at: [http://www.mic.gov.py/propiedad\\_intelectual/](http://www.mic.gov.py/propiedad_intelectual/)

Trinidad and Tobago Patent Act available at: [http://www.wipo.int/clea/docs\\_new/en/tt/tt036en.html](http://www.wipo.int/clea/docs_new/en/tt/tt036en.html)

Uruguay Patent Law 17.164 available at: [http://www.sice.oas.org/int\\_prop/nat\\_leg/Uruguay/L17164Be.asp](http://www.sice.oas.org/int_prop/nat_leg/Uruguay/L17164Be.asp)

Venezuela Industrial Property Law, 1955 available at: [http://www.sice.oas.org/int\\_prop/nat\\_leg/Venezuela/lips.asp](http://www.sice.oas.org/int_prop/nat_leg/Venezuela/lips.asp)



Decision 486 of Andean community available at: <http://www.comunidadandina.org/ingles/treaties/dec/D486e.htm>

#### AFRICA

Egypt Intellectual Property Law 82, 2002 available at: [http://www.egypo.gov.eg/inner/english/Laws\\_1.html](http://www.egypo.gov.eg/inner/english/Laws_1.html)

Morocco Law No. 17-97 available at: <http://www.ompic.org.ma/english/presentation/lois.html>

South Africa Patents Act available at: [http://www.wipo.int/clea/docs\\_new/en/za/za026en.html](http://www.wipo.int/clea/docs_new/en/za/za026en.html)

Tunisia Law no. 2000-84 available at: [http://www.wipo.int/clea/docs\\_new/en/tn/tn001en.html](http://www.wipo.int/clea/docs_new/en/tn/tn001en.html)

## ANNEX II

### STATISTICAL ANALYSIS OF PATENT LEGISLATION REVIEW

The tables below indicate the findings of the patent legislation review, in which the patent law of a country is assessed against a number of key public health-related TRIPS flexibilities, in order to show the extent to which countries have incorporated the TRIPS flexibilities. Review asked the following questions:

1. Are pharmaceutical products patentable subject matter?
2. Are new use or 2nd use patents excluded under the patent law?
3. Is the early working exception specifically provided for in the patent law?
4. What other exceptions to exclusive patent rights are provided for in the patent law?
5. Which exhaustion regime is adopted in the patent law?
6. What are the grounds for the grant of compulsory licenses?
7. Is there a provision for government use or public non-commercial use of patents?
8. Is there a provision for data protection in the patent law?

The review is based the current laws in force.

The total number of countries reviewed

Asia	13
Latin America/Caribbean	19
<u>Africa</u>	<u>17</u>
<u>Total</u>	<u>49</u>

1. Are pharmaceutical products patentable subject matter?

Pharmaceutical products	Asia		Latin America Caribbean		Africa		Total	% of Total
Yes	10	(77%)	18	(95%)	11	(65%)	39	80%
No	3	(33%)	0	(0%)	1	(6%)	4	8%
Unknown	0	(0%)	1	(5%)	5	(29%)	6	12%

**2. Are new use or 2<sup>nd</sup> use patents excluded under the patent law?**

Patentability: New use or 2 <sup>nd</sup> use patents	Asia		Latin America Caribbean		Africa		Total	% of Total
Excluded	2	(15%)	8	(42%)	0	(0%)	10	20%
Specifically allowed	2	(15%)	0	(0%)	1	(6%)	3	6%
Not excluded	7	(54%)	10	(53%)	11	(65%)	28	57%
Unknown	2	(15%)	1	(5%)	5	(29%)	8	16%
Allowed plus not excluded	9	(69%)	10	(53%)	12	(71%)	31	63%

3. Is the early working exception specifically provided for in the patent law?

Early working ex-ception	Asia		Latin America Caribbean		Africa		Total	% of Total
Yes	4	(31%)	6	(32%)	5	(29%)	15	31%
No	7	(54%)	12	(63%)	11	(65%)	30	61%
Unknown	2	(15%)	1	(5%)	1	(6%)	4	8%

**4. What other exceptions to exclusive patent rights are provided for in the patent law?**

Other exceptions specified:	Asia		Latin America Caribbean		Africa		Total	% of Total
Broadly worded provision*	3	(23%)	1	(5%)	5	(29%)	9	18%
Experimental/ Scientific research	11	(85%)	19	(100%)	10	(59%)	40	82%
Education/Teaching	3	(23%)	14	(74%)	2	(12%)	19	39%
Private and non-commercial use	2	(15%)	14	(74%)	3	(18%)	19	39%
Use of patented self-reproducing biological material	0	(0%)	5	(26%)	1	(6%)	6	14%
None specified	1	(8%)	0	(0%)	3	(18%)	4	8%
Unknown	0	(0%)	1	(5%)	1	(6%)	2	4%

\*Broadly-worded provisions are those that provide for a limitation of patent rights to “acts done for industrial or commercial purposes”.

**5. Which exhaustion regime is adopted in the patent law?**

Exhaustion regime	Asia		Latin America Caribbean		Africa		Total	% of Total
International	6	(46%)	13	(68%)	7	(41%)	26	53%
National	2	(15%)	4	(21%)	6	(35%)	12	24%
No explicit provision	3	(23%)	1	(5%)	1	(6%)	5	10%
Unclear/ unknown	2	(15%)	1	(5%)	3	(18%)	6	12%

## 6. What are the grounds for the grant of compulsory licenses?

Compulsory license grounds	Asia		Latin America Caribbean		Africa		Total	% of Total
Failure to work/exploit	10	(77%)	14	(74%)	15	(88%)	39	80%
Anti-competitive practice	5	(38%)	14	(74%)	5	(29%)	24	49%
Dependent patents	7	(54%)	10	(53%)	10	(59%)	27	55%
Demand not met on reasonable terms	3	(23%)	6	(32%)	13	(76%)	22	45%
Public interest/ public	10	(77%)	15	(79%)	8	(47%)	33	67%
National emergency/	5	(38%)	11	(58%)	6	(35%)	22	45%
No provision	2	(15%)	0	(0%)	0	(0%)	2	4%
Unknown	0	(0%)	1	(5%)	0	(0%)	1	2%

\* This includes grounds listed under government use

\*\* Statistics on countries requiring delay before CL may be applied for on ground of failure-to-work: (9 Asia) + (13 Latin America/Caribbean) + (13 Africa) = 35 countries

This represents, 71% of all countries, or 88% of countries with failure-to-work provisions.



**6. Is there a provision for government use or public non-commercial use of patents?**

Government use	Asia		Latin America Caribbean		Africa		Total	% of Total
Yes	7	(54%)	9	(47%)	17	(100%)	33	67%
No explicit provision	5	(38%)	8	(42%)	0	(0%)	13	27%
Unknown	1	(8%)	2	(11%)	0	(0%)	3	6%










**8. Is there a provision for data protection in the patent law?**











Data protection	Asia		Latin America Caribbean		Africa		Total	% of Total
Yes	6	(46%)	16	(84%)	6	(35%)	28	57%
No explicit provision	7	(54%)	3	(16%)	8	(47%)	18	37%
Unknown	0	(0%)	0	(0%)	3	(18%)	3	6%










Country response to question in TRIPS Council review of implementing legislation: “May later applicants rely on previous test data?”	Asia		Latin America Caribbean		Africa		Total	% of Total
Yes (or probably)	3	(23%)	4	(21%)	4	(24%)	11	(22%)
No, later applicants must supply “new” data	3	(23%)	5	(26%)	0	(0%)	8	(16%)
Not Answered/Unclear/ No WTO interview	7	(54%)	10	(53%)	13	(76%)	30	(61%)























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