DRAFT NOVEMBER 12, 2004 FOR REVIEW PURPOSED ONLY. NOT FOR DISTRIBUTION.

TRIPS AND PHARMACEUTICAL POLICY: ACHIEVING COHERENCE BETWEEN NATIONAL DRUG POLICIES AND TRIPS COMPLIANT INTELLECTUAL PROPERTY LAW

BY
MICHELE FORZLEY, JD, MPH

NOVEMBER 12 2004

For all comments and questions concerning this paper,
please contact Michele Forzley at mforzley@gphlc.com or 1-301-565-1693.

INTRODUCTION

Developing and least-developed countries are facing the challenge to meet their obligations under The Agreement on Trade Related Aspects of Intellectual Property (TRIPS) and at the same time evolve a national drug policy that meets the universal objective of access to essential medicines to manage national disease burdens. [1]As more than three-quarters of World Trade Organization (WTO) members, of which 30 are least-developed (LDC), have the self-elected the status of "developing countries", a substantial portion of WTO members face this task.[2] The purpose of this paper therefore is to describe how the development of a national pharmaceutical policy can be accomplished in a manner that is consistent with national trade policy in WTO member developing and LDC countries. Though national trade policy encompasses numerous aspects of trade, this paper focuses on how national intellectual property laws and national pharmaceutical policy objectives can be shaped and implemented in a manner to take full advantage of and be consistent with TRIPS.

At the outset it is emphasized that pharmaceuticals are not the only public health topic implicated by the WTO agreements, nor specifically by TRIPS. Indeed other agreements including the General Agreement on Trade in Services, (GATS), Agreement on the Application of Sanitary and Phytosanitary Measures, (SPS) and Technical Barriers to Trade (TBT) have relevance to public health. Moreover, pharmaceuticals are not the only aspect of public health implicated by TRIPS.[3] Traditional medicines, genetic materials, bio-engineered products are also affected by TRIPS. While this article is focused solely on TRIPS and its relevance to pharmaceutical policy, many of the comments are applicable to other aspects of public health.

PART I – PHARMACEUTICAL POLICY AND DRUG ACCESS

PHARMACEUTICAL POLICY

Whether explicitly stated in a document or implicitly understood from actions and procedures, all governments have a national drug policy.[4] The main objectives of a national drug policy are to make effective, safe and low cost drugs available and affordable to meet the needs of the entire population and second to ensure that drugs are of good quality and used rationally.[5] In other words, the goal is to provide access to medicines.[6] To ensure access, four key conditions must be met: (1) rational selection and use of medicines (2) sustainable adequate financing (3) affordable prices and (4) reliable health and supply systems.

Central to a national drug policy is the essential medicines concept. Essential drugs are those that satisfy the health care needs of the majority of the population and should be available at all times in adequate quantity and in the appropriate dosage form. Most countries have a national essential drugs list and if not the WHO Model Essential Drug List is available for countries.[7] One of the measures to evaluate a national

essential medicines list is to compare the availability of drugs on the list with national morbidity and mortality patterns.

An effective national drug policy requires appropriate strategies adapted to national resources and the necessary technical means to achieve the main objectives, which are basically the same for all nations.[8] A panel of 54 international experts has identified seven key components or priorities for a pharmaceutical strategy in developing countries.[9] These are

1. The establishment of appropriate legislation and regulation,
2. The selection of essential drugs and a registration process,
3. The maintenance of a significant drug allocation in the health budget and the development of a financing policy in the public sector,
4. Improvement of the procurement procedures in the private sector,
5. Strengthening of the drug distribution and logistics in the public sector,
6. Establishment of a drug pricing policy in both the public and private sector,
7. And information and continuing education programs to improve drug use.

The implementation of these strategies will intersect with aspects of national trade and intellectual property rights policies. For example if a country were to adopt a strategy of import substitution for all or a portion of an essential drugs list, it is immediately obvious that in the implementation of appropriate legislation and regulation, trade policy and TRIPS obligations will have to be considered to avoid conflicts, provide policy coherence and to optimize the use of trade flexibilities. Thus, in developing national trade and intellectual property rights policy, the key pharmaceutical policy priorities should be taken into account.

What is the state of pharmaceutical policy and drug access globally and in the West Africa region?

In 1997, it was estimated that at least one third of the population of the world lacks access to drugs because they are either unavailable, or too expensive, there are no professionals to prescribe them and or no facilities from which to get them. In poorer areas of Africa or Asia, the rate may be as high as 50% of the population that lacks access to essential drugs.[10] Less than one third of countries have fully functioning drug regulatory authorities.[11] Access to medicines is particularly price sensitive as about 50-90% of drugs in developing world are paid for out of pocket, thus placing heaviest burden on the poor. [12]

The World Bank characterizes the West Africa countries of Senegal, Nigeria, Ghana, Guinea and the Gambia as low-income economies. Nigeria and Gambia and Ghana have reproductive capabilities enabling the manufacture of finished products from imported ingredients only. Senegal and Guinea have no pharmaceutical industry. [13] Senegal and Nigeria have a national drug policy that is less than ten years old, the status of Gambia's policy is unknown and that of Guinea and Ghana is more than ten years old.

Essentially these countries are importers. For example, Senegal has a negotiated a reduced price for two HIV/AIDS drugs in 2000 [14] and Nigeria will spend $248million on AIDS drugs by year end 2005 according to Health Minister Eyitayo Lambo. [15] With regard to traditional medicines only 22 of 46 African countries have policies or laws covering traditional medicine. [16] See Table 1.

Role of intellectual property rights and access to drugs

The role of patents in inspiring research in drug development and their impact on drug access has been the subject of much academic work and global public debate.[17] There is general consensus that patents have been an incentive for research and development of many types of technology and certainly for new drugs, [18] although this has not been the case for drugs to treat tropical diseases or those afflicting the developing world.[19] In the year 2002, 82% of the investment by the global pharmaceutical companies was spent in the US versus 18% elsewhere, including Europe. This is attributed to a strong patent system in a market free of price controls and a legal system in which rights can be enforced with relative certainty.[20] Over 95% of all patent filings in the world are by nationals of OECD member countries.[21]

Studies relate data comparing degrees of patent protection with economic growth and level of development and argue that the overall costs to an economy of failing to protect patents outweighs a short term temporary easy access to drugs. [22] The extension of this argument is that by failing to protect patents on pharmaceuticals, countries risk having fewer new pharmaceutical products and thus ultimately reduced health for citizens, because manufacturers will not export newer drugs to markets where there is no patent protection and local industry will not invest in their development or production under license. This issue is particularly important as some tropical diseases become multi-drug resistant. Drug companies contend that patent protection is necessary to provide a return on R&D investment and to encourage the development of new drugs.

Some argue that patents are a primary impediment to drug access.[23] The argument for the opposite has also been made based on an analysis of patents on the WHO Model Essential Drugs List which determined that only 1.4 % of the drugs on the list have been patented.[24] In order to answer the question whether patents impede access to drugs, some authors have analyzed the status of patents on HIV/AIDS drugs for example in Sub-Saharan Africa and have concluded that as there are few of these drugs patented in these markets other factors fundamentally determine access.[25]

Given the estimate that 50% of the population in the developing world lacks access to essential medicines where the leading causes of death could be readily treated with generic medicines, [26] the precise role of patents is further clouded. Focusing on patents is too simplistic an explanation for lack of access. A fruitful approach would be to examine the marketing decisions of pharmaceutical businesses, which may or may not be patent holders, wherever they may be located as their decisions affects whether a drug will or will not be available in a market. Marketing decisions are based on a variety of factors, patent protection being just one. Moreover, there is no conclusive evidence as to

Comment: The purpose of this paper is to present a view of the development of pharmaceutical policy to achieve the public health objective of providing access to drugs in a manner that is consistent with TRIPS obligations and to offer practical insights into how to achieve these two goals.

the relative contributions or importance of other factors attributed with a role in access to drugs. Pragmatically given that between 2005 and 2016 more than half of the members of the WTO must implement an intellectual property rights regime, it is simply more useful to offer guidance on just how to achieve policy coherence between intellectual property and pharmaceutical policies and achieve pharmaceutical policy objectives. This is not to diminish the importance of earlier debates and analysis that contributed to the interpretations of TRIPS leading to the decision of August 2003.[27]

Factors leading to lack of access to drugs

Many other factors have been cited as actual or possible causes and conditions leading to the lack of access to drugs in much of the world. Elemental to the ability of a country to provide an environment in which drug access can be adequate is a functioning health system with services and infrastructure to manage the disease burden of a country. The pharmaceutical component of a health system must have the capacity to store and distribute medications, monitor patient compliance and conduct testing. It must ensure an adequate supply of all drugs necessary, when needed and in suitable dosages. A functioning system would operate within an established regulatory regime that protects against misuse, counterfeiting, substandard drugs and misappropriation. In addition to providing information and training for health professionals, patients could obtain counseling, testing, and benefit from adherence programs. The country must contain reliable laboratories for monitoring and testing both patients and drugs.

Appropriate domestic and international financing are essential to adequate access as are reduced or eliminated national debt, import tariffs or duties, streamlined customs procedures, and low to no domestic income taxes on pharmaceuticals to ensure price reductions. How pharmaceuticals are marketed is another area where attention can be focused, specifically international pricing mechanisms or preferential pricing. Finding ways to increase current market potential in the developing world will be key to improving access. It may be that regional groupings will be essential to increasing market potential, however this will take time and local capacity building. Last, governments must seek to eliminate corruption, diversion, and increase political will to solve the lack of access problem. These other areas are worthy of in depth study by countries as part of the overall policy planning process to identify which are in need of policy and regulatory intervention or training.

Economically viable domestic pharmaceutical production

In an attempt to understand why to date no countries have taken advantage of the TRIPS flexibilities, there is a developing view that the lack of manufacturing production capacity has a negative affect on the ability of developing countries to use certain TRIPS flexibilities for public health purposes.[28] To fully underscore the complexity of the matter of drug access as the consequence of many factors, not just patents, factors related to the production of pharmaceuticals or the raw materials are reviewed here. A number of factors have been identified although there is no conclusive evidence that all these factors

must exist nor is it known the relative importance of each or how these factors change with the type of production in question. There might be differences for example as to what is important for low-end production, versus repackaging, or the manufacture of raw materials or final products.

The following factors have been identified as general preconditions for viable production: (1) a high ratio of domestic R&D to gross domestic product since production in the pharmaceutical sector is technology driven, (2) a size of economy that permits a manufacturer to take advantage of economies of scale and provides opportunity for product variation and improvement, (3) the income level of the domestic market, (4) availability of reliable local infrastructure and amenities at competitive prices, and (5) policies that govern local production and their enforceability which is thought to ensure efficiency and reliability of the market.[29]

Another factor related to viable production is the lack of technical and infrastructural capacities for medicines regulation such as facilities and expertise to review safety, efficacy and quality of drugs destined for national markets and the speed and efficiency of the procedure for the registration of medicines.[30] A slow speed in the latter effectively denies the generic companies the benefits of the early working exception.

Lack of post-marketing surveillance, which makes it difficult to prove abusive behavior, is one of the possible prerequisites to the use of compulsory licensing and difficulties in establishing efficient pharmaceutical management and procurement systems have also been cited as additional reasons why countries have difficulty in providing access to medicines.[31]

Steps towards developing and implementing a national drug policy

Like other national policies, pharmaceutical policy is generated at the central level or by ministry of health policy makers. Where the policies of one executive department intersect with the jurisdiction of other government departments, as is the case for pharmaceutical and intellectual property rights policies, other relevant ministries must be involved in the policy formulation process. The ministries of trade, foreign affairs, health, drug regulation, intellectual property, finance, customs, and justice would be involved. Generally the steps to developing policy and adopting relevant laws include an assessment, identification of focal points within the government to form a country level working group, drafting of appropriate legislation and designing mechanisms for monitoring outcomes. There is often a need for staff training either in intellectual property rights for ministry of health staff and in health for intellectual property rights staff and others who may not generally be involved with health matters in their daily work.

Figure 1: Steps to developing national drug and intellectual property rights policies and laws.

1. Assessment of situation - what are the laws and regulations in this area, how do they compare with TRIPS obligations?

2. Who should be involved? An intellectual property (IP) point person should be identified within the ministry of health and drug regulatory authority (DRA) and a public health point person should be identified within the ministries of trade, finance, justice and all other participants which do not generally interact with health matters, including the office on intellectual property, the legislative body and staff, the head of state, and other stakeholders including civil society members. Build an inter-ministerial team or working group among these participants. This team will be useful for all trade negotiations as pharmaceutical policy is not the only aspect of public health implicated by trade negotiations.

3. Draft appropriate legislation for IP, DRA and other relevant laws trade and non-trade laws. Obtain reliable specialized legal advice. Invite technical capacity building workshops and training.

4. Mechanism for monitoring the health impact of trade agreements and related domestic legislation. Some basic questions include:
   ⇒Are newer essential drugs more expensive than they would have been if not under patent?
   ⇒Is the introduction of generic drugs being slowed?
   ⇒Are more new drugs for neglected diseases being developed?
   ⇒Are transfer of foreign technology and direct foreign investment in developing countries increasing or decreasing?

PART II - ASPECTS OF TRIPS RELEVANT TO PHARMACEUTICAL POLICY IN COUNTRIES WITH LITTLE TO NO LOCAL DRUG OR RAW MATERIAL MANUFACTURING CAPACITY.

What is TRIPS?

TRIPS is one of the principle agreements, along with the General Agreement on Trade and Tariffs (GATT) and the General Agreement on Trade in Services (GATS) forming the basic structure of the rules of trade and the WTO. It sets out minimum standards for the protection and enforcement of intellectual property rights, including patents, copyrights, trademarks and related rights, geographical indications, industrial designs, layout-designs of integrated circuits, and undisclosed information. All members must give effect to the standards within the time periods established in the Agreement and subsequent WTO Ministerial Conference decisions interpreting the agreements.

When must a country be compliant in with TRIPS with respect to pharmaceutical policy?

Upon accession or formal entry to the WTO, member countries must adopt the legal ground-rules for international commerce within limits established in the WTO agreements. These agreements are essentially contracts and bind governments to their terms. In the case of TRIPS, once a developed country achieves membership, it must apply all the provisions within one year. Developing countries and least developed countries must apply Articles 3, 4, and 5 immediately and the rest of TRIPS by the end of designated transition periods. Articles 3,4 and 5 are the fundamental rules on national treatment and most-favored-nation treatment of foreign nationals.

The transition period ends for developing countries January 1, 2005 and for least developed countries by January 1, 2016. Key for pharmaceutical policy development in the least developed countries is that these countries will not be obliged to apply or implement Sections 5 and 7 of Part II or to enforce rights there under with respect to pharmaceutical patents or other product patents until by January 1, 2016. [32] Least developed countries can request an extension of this time period to the TRIPS Council. See Table 2.

Accordingly, Ghana and Nigeria are likely near to concluding the revision process for intellectual property legislation but have time to also adapt it to conform to pharmaceutical policy. As least developed countries, the Gambia, Guinea and Senegal are still in the transition period and have a few more years to bring their legislation and practices into conformity with TRIPS. Nonetheless, public health problems are here and now, thus as national pharmaceutical policies are reviewed, it would efficient to take into account TRIPS obligations while these are developed.

There are two other exceptions to these rules however in the case of pharmaceutical and agricultural chemical products for which patent applications must be accepted for filing from the beginning of the transitional period, thus preserving the novelty of the invention as of the date of filing the application. [33] Further if authorization for the marketing of the pharmaceutical or agricultural chemical is obtained during the transitional period, developing countries must offer exclusive marketing rights for the product for five years, or until a product patent is granted, whichever is shorter. [34]

All forms of intellectual property are relevant to pharmaceutical policy

All forms of intellectual property are potentially relevant to a pharmaceutical policy, although much attention has been focused on patents, which are covered in a subsequent portion of this paper. Copyrights, trademarks and undisclosed information have particular relevance to public health as follows.

Copyrights

Copyrights extend to expressions such as literary works likes songs, books, and articles, and not to ideas, procedures, methods of operation or mathematical concepts. Copyrights are considered a vital part of a modern society's infrastructure because of the "centrality of the copyright system" in the dissemination and communication of information to the public.[35] TRIPS Article 10.1 provides that computer programs, whether in source or object code, shall be protected as literary works. A computer program may of course be part of drug development.

Copyrights are especially relevant to pharmaceutical research and development. A national drug policy may include provisions as to the conduct of clinical research by domestic or foreign researchers, the results of which are reported to drug regulatory authorities to establish efficacy, safety, dosage levels, etc as part of the registration process for drugs. Or the research results may be reported in public health journals and at conferences so that other researchers can replicate them, a step considered essential to prove a scientific concept. Researchers are keenly aware that their ability to obtain funding is related to the availability of proof of concept, which is made known generally through peer-reviewed publications. Researchers are highly protective of their findings and rely on the availability of copyright protection before releasing their research results to the public.

Trademarks

Trademarks are any sign, or any combination of signs, capable of distinguishing the goods and services of one enterprise from those of another.[36] Such marks must be eligible for registration as a trademark, as long as it is visually perceptible. An owner of a registered trademark is granted the exclusive right to prevent all third parties from using in commerce an identical or similar signs for goods or services, which are identical or similar to the registered trademark when such use would result in a likelihood of confusion. Trademarks are the form of intellectual property most often counterfeited or infringed.[37] It is important to keep in mind also in this discussion that the packaging or labeling of many generic drugs are trademarked making the enforcement of intellectual property rights essential to the drug safety.

Trademarks are especially relevant to the matter of public health and safety inspections by drug regulatory authorities, customs and border officials. During the drug registration process, pharmaceutical policy as manifested in drug regulation can require a pre- approval inspection, intermittent safety inspections of manufacturing operations in the event counterfeit or substandard production is underway or suspected. In addition, when a country establishes an intellectual property law, customs or other border officials may be empowered to seize infringing goods during the import process. During all of these types of inspections the use of visual evidence of the genuine nature of a product is key to the ability of inspectors to conduct their work. Without the ability to rely on trademarks, inspection would be almost impossible as it is simply impractical to conduct chemical analysis of all products subject to inspections.

There is evidence that when inspections are conducted at borders the rates of counterfeit drugs within markets is reduced. [38] Counterfeit drugs are attributed with deaths and injuries on a worldwide basis in adults and children. [39] Of particular concern to the developing and least developed world is drug resistance in tropical diseases such as malaria, a condition attributed in part to counterfeit drugs.[40]

Undisclosed information

The TRIPS Agreement requires that undisclosed information, also known as trade secrets or know-how is to be protected.[41] Information that is secret that has commercial value because it is secret and that has been subject to reasonable steps to keep it secret qualifies for protection. The formula for Coca Cola is one of the most famous trade secrets. TRIPS requires that a person lawfully in control of such information must have the possibility of preventing it from being disclosed to, acquired by, or used by others without consent. In order to prevent unlawful use, a person may use legal concepts of breach contract or confidence and inducement to breach.

A pharmaceutical policy should take into consideration the concept of undisclosed information by protecting such information against unfair commercial use and disclosure when the submission of undisclosed information such as test data and other data is required by governments as a condition of approving the marketing of pharmaceutical or agricultural chemical products. The law may provide an exception to this rule where necessary to protect the public, although the boundaries of this exception are not clear. It is conceivable to imagine a situation such as the outbreak of a highly infectious disease during the processing of a patent for a vaccine. In such a case, the disclosure of test data or other undisclosed information to protect the public might be possible within TRIPS jurisprudence.

In contrast, is the disclosure required as part of a patent application. The grant of a patent is "social contract" which offers the patent holder exclusive rights in exchange for making publicly available important technical information. This information may be of use to others in advancing technology in the area, during the patent term, and certainly, after the expiry of the patent term when the invention falls into the public domain when others have the information to produce the item. Generic drugs are possible because of this required disclosure aspect of a patent application.

Geographical indications

Geographical indications are place names (in some countries also words associated with a place) used to identify the origin and quality, reputation or other characteristics of products (for example, "Champagne", "Tequila" or "Roquefort"). Research has not disclosed an example of a drug named after a geographic indication.

Technology Transfer and Least Developed Countries

Developing countries are obligated to provide incentives for domestic companies to transfer technology to least-developed countries.[42] A pharmaceutical policy can open

opportunities to technology transfer of all essential elements of a local pharmaceutical sector for example. This approach might include ensuring that a country is attractive to foreign investment. Technology transfer need not be limited to patent formulas for drugs. As important are the equipment, skills to operate manufacturing equipment, training in good manufacturing practices for pharmaceuticals, a functional industrial base, transportation, banking institutions, or other assets necessary to build domestic industry.

Patents and Pharmaceutical Policy

Patents are most often the form of intellectual property that comes to mind when considering pharmaceutical policy. It is correct to view patents as particularly important to pharmaceuticals as drugs are made as a result of a process or formula, both of which are suitable for patent protection. Drugs offer a therapeutic, diagnostic or prophylactic benefit, without which the fields of public health and medicine could not succeed. There is no debate over the importance of drugs to health. Thus patents and pharmaceutical policy are inextricably connected.

In countries without a domestic pharmaceutical industry, or one that provides all medicines considered essential to the disease burden of the country, governments are faced with the challenge of how to address this public health responsibility with an appropriate pharmaceutical policy. As sufficient pharmaceutical capacity is not capable of evolution in the short term, a pharmaceutical policy must evolve that combines short, medium and long-term solutions and objectives. The manner in which a country implements TRIPS in national legislation is an essential element of pharmaceutical policy and will influence the outcome of all solutions whatever duration. Figure 3 arrays possible elements of a TRIPS compliant pharmaceutical industry development strategy.

The long term solution of developing a local industry capable of supplying the needs of a country by manufacturing and importing is the simplest to describe, but perhaps the solution which is the most out of reach for many countries. Nonetheless, integrating TRIPS compliant strategies into a strategic plan is both permissible and advisable given that importation will be essential in the near to medium term and importation is an act of international trade.

An intellectual property legal system in and of itself will not foster a local industry to address local disease burdens, however, it is essential to a longer-term pharmaceutical policy. In the absence of functioning institutions defined as the socially organized aspects of life, which are coded in the rule of law and custom of which an intellectual property legal system is one among others no economy will flourish.[43] The absence of a functioning economy will forever preclude the development of sufficient local capacity to provide drug access. Thus intellectual property is essential as an element of the institutions necessary for an economy.

What can be patented?

A patent applies to any invention, whether products or processes, in all fields of

technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. Patents must be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced.[44] TRIPS applies only to drugs patented and placed on the market on and after January 1, 1005. The evolving nature of various therapies means that new drugs are being developed all the time, thus this time limitation may not be very helpful to the developing world. Drugs for both human and animal use could be patented.

A country may legislate three exceptions to patentability, (1) inventions contrary to *ordre public* or morality, such as inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment, (2) diagnostic, therapeutic and surgical methods for the treatment of humans or animals, and (3) plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.[45] Future work is ahead on the matter the patentability or non-patentability of plant and animal inventions, and the protection of plant varieties and the relationship between the TRIPS Agreement and the UN Convention on Biological Diversity, the protection of traditional knowledge and folklore.

What does a patent holder get?

A patent holder receives the right for twenty years to prevent unauthorized persons from using the patented process and making, using, offering for sale, or importing the patented product into a country where the patent is registered or a product obtained directly by the patented process. Product patent holders are granted the same rights.[46] Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts, the latter of which is important for the contract manufacturing of pharmaceuticals.

Patent protection period and pharmaceutical policy

The effective period of patent protection is 20 years, however for new drugs that must be approved by the regulatory authority, this term can be much shorter due to the amount of time needed to complete the regulatory process. A patent only gives an inventor the right to prevent others from using the patented invention. It says nothing about whether the product is safe for consumers and whether it can be supplied to the market. The process to approve drugs generally includes several steps including clinical trials to establish efficacy, safety and quality. Clinical trials can take several years to complete during which time the patent period is expiring. Regulatory approval must be completed before a drug is made available to patients. One solution to this problem is to prolong the period of protection to compensate, at least in part, for this loss of the effective period of protection. TRIPS does not preclude an extension of the patent period, only its shortening. This issue is best addressed when national intellectual property legislation is drafted and is appropriate to be considered as part of a medium or long term strategy.

Exceptions to Patent Exclusivity and TRIPS flexibilities

The rights of patent holders are not exclusive. Limitations on patent rights are permitted. Members may legislate certain exceptions such as parallel imports, compulsory licenses, and government use. TRIPS permits exceptions to patent rights, none of which are required, but all of which do afford the opportunity to develop policy coherence between pharmaceutical and trade policy, particularly in the developing and least developed countries because of their present need to import drugs to meet local needs. Indeed these exclusions are rich sources for strategic solutions to address national essential drug needs, particularly in the short and medium term and in the case of emergencies. What follows is a review of the exception to patent exclusivity, examples of how countries have settled their laws and model language in Appendix A.

Article 30 Exceptions to Rights Conferred [47]

Article 30 is widely understood to mean that experimental uses are permissible as are non- commercial uses. Exceptions such as the Bolar exception, or the so-called pre-marketing testing, which allows generic manufacturers to conduct tests to prepare applications for approval during the term of the patent so they are able to market directly upon expiration of the patent are also allowable. In contrast a stockpiling of generics exception would be a violation as determined in a dispute settlement proceeding against Canada.[48] Countries have legislated Article 30 exceptions in various ways. An example of the law of Argentina is included below.

Argentina: Law No. 24.766, Article 8

"In the case of a product or process protected by patent, any third party may use the invention prior to its patent expiration for experimental purposes and to obtain the information required for the approval of a product or process by the competent authority so that it may be marketed following the patent expiration."

Parallel importing

Parallel importing is a process by which a patented product, not a generic, can be imported without violation of TRIPS and the patent holder's rights. In such cases, a patent holder has marketed a product X to Country A and Country B, but markets X to Country B at a lower price than in Country A. An importer in Country C can import product X from Country B at the lower price. The import to Country C is parallel importing, which TRIPS clearly states is not a matter of dispute resolution. [49] The Doha Declaration on the TRIPS Agreement on Public Health has affirmed Article 6 by stating the each WTO Member is free to establish its own regime for exhaustion without challenge. A model provision is provided in Appendix A.

The international exhaustion doctrine states that once a product is placed on the market anywhere in the world, a patent owner looses any exclusivity with respect to preventing the import of a product or movement of a product anywhere else but where patented. The US applies the national exhaustion principle meaning that a patent owner

can no longer exercise control over the product once it is placed on the domestic market in the US. The patent owner may however exercise his rights with regard to products placed on the market outside the US.

Parallel importing can be applied to any patented product or process, thus it is permissible to parallel import pharmaceuticals and raw chemicals to produce drugs as part of a national pharmaceutical strategy. The advantage of parallel importing are that there is no need to obtain a government use order or compulsory license nor is there a need to pay compensation to the patent holder. This can also be regarded as international price arbitrage. There is debate over whether a patented product that is exported pursuant to a compulsory license can be imported pursuant to a parallel importing provision.

Article 31 "*Other Use Without Authorization of the Right Holder"*

Article 31 is intended to allow for non-authorized use in the form of both compulsory licenses and government-use provisions. Other use refers to use other than that allowed under Article 30. An Article 31 use can be by the government or by a third party authorized by the government. A health care provider such as an insurer providing coverage for government employees or the military could be a third party authorized under Article 31.

The grounds upon which a compulsory license may be granted or authorized are not restricted by TRIPS except in three areas: non-working and dependent patents, and semi-conductor technology- not relevant here. As long as the procedural conditions are met, compulsory licenses are permitted on any grounds including public health, nutrition, national security, food security, etc.

Pursuant to Article 31 no use confers any exclusivity, as is the case for the original patent holder. The use is non-assignable and is of a duration that expires with the ending of the reasons the use was permitted at the outset. The following outlines the basis elements of government use and the compulsory license.

Government use –

A. Non-commercial government use
   i. Adequate remuneration
   ii. No prior negotiations
   iii. Government act only or authorized agents
   iv. Inform patent holder promptly if reason to know without a patent search there is a valid patent

B. National Emergency or other circumstances of extreme urgency
   i. No prior negotiations
   ii. Emergency or extreme emergency as determined by the relevant national authority that an emergency exists.
   iii. Inform patent holder as soon as reasonably practicable

Compulsory Licenses (CL)

A. CL to manufacture a patented product (grounds of non-working or insufficiency of working) Will be necessary as of 1/1/2005

B. CL to export - limited amount to be exported – CL predominately for local market (49%). Prior negotiations and the limitation on exports of products to the domestic market are waived if a compulsory license is authorized to remedy an anti-competitive practice. See Paragraph 6 Solutions on exports as follows.

C. Applicable to all CLs
- Any interested party may obtain a CL
- Must be prior effort to negotiate (Art 31b)- reasonable period of time
- Adequate remuneration based on "circumstances of each case"

France, UK and Singapore have adopted the following provisions to provide other uses without authorization. Model provisions for Article 31 are in Appendix A.

France: Law No. 92-597 of July 1, 1992 on the Intellectual Property Code (Legislative Part) (as last amended by Law No. 97-1106 of December 18, 1996)

Chapter III, Section 1, Article L. 613-16: *"Where the interests of public health demand, patents granted for medicines or for processes for obtaining medicines or for processes for manufacturing such products may be subject to ex officio licenses in accordance with Article L. 613-17 in the event of such medicines being made available to the public in insufficient quantity or quality or at abnormally high prices, by order of the Minister responsible for industrial property, at the request of the Minister responsible for health."*

United Kingdom**:** Patents Act 1977 Chapter 37 (as amended by the Copyright, Designs and Patents Act 1988)

Section 48(3): *"The grounds (for the grant of compulsory licenses) are:*

(a) where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable;
(b) where the patented invention is a product, that a demand for the product in the United Kingdom-
(i) is not being met on reasonable terms, or
(ii) is being met to a substantial extent by importation;
(c) where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked-
(i) where the invention is a product, by the importation of the product

(ii) where the invention is a process, by the importation of the product obtained directly by means of the process or to which the process has been applied …"

Singapore**:** Patents Act 1994 (No. 21 of 1994, as amended by the Patents (Amendment) Act 1995)

Part XII Use of Patented Inventions for Services of Government

Section 65 provides that *"... the powers exercisable in relation to an invention by a Government department or a person authorized by a Government department under section 61 shall include power to make, use, exercise and vend the patented invention for any purpose which appears to the Government necessary or expedient-*
for public non-commercial use".

The Paragraph 6 solution for countries with little to no local manufacturing capacity:

Even though TRIPS is rich with provisions that enable a country to meet drug needs in a manner that is consistent with its obligations, there are still countries for which the goal of supplying drug needs based on provisions in TRIPS is impossible. This is so, because many countries have insufficient or domestic manufacturing capacity. Their ability to take advantage of an Article 31 compulsory license is prevented by the language found in Article 31(f) "produce predominately for the domestic market".

In Paragraph 6 of the Doha Declaration[50], WTO Members directed the TRIPS Council to find a solution to the conflict between the letter and intent of the provisions on compulsory licensing, hereafter referred to as the "Para 6 solution". The TRIPS Council Decision of August 30, 2003[51] provided a solution to the problem until TRIPS is amended. It directed the Council to initiate preparation of such an amendment by the end of 2003 with a view towards adoption by mid 2004. The work has begun, although no amendment has been adopted. [52]

The Para 6 solution essentially permits countries with pharmaceutical manufacturing capacity to produce enough extra pharmaceutical products to export an amount to meet the needs of a qualified importer. By waiving the limitation of Article 31 (f) on the amount produced pursuant to a compulsory licenses and permitting it to be exported, Para 6 permits countries to import medicines to meet their public health needs as defined in a compulsory license. The system Para 6 has designed also provides transparency for the patent holder, the exporter, the importer and the TRIPS Council so that the system can be monitored.

The mechanics and scope of Para 6

The mechanics of Para 6 are designed to amplify the circumstances under which a compulsory license may be used and limit the actions of both importers and exporters. Para 6 waivers apply to pharmaceutical products which include any patented product or product manufactured through a patented process, active ingredients necessary for the

manufacture of a product and diagnostic kits needed for the use of a patented product.

A compulsory license based on a Para 6 solution can be used to address the public health problems as recognized in the Doha Declaration. These are described as those that affect developing and least developed countries, those resulting from HIV/AIDS, TB, and malaria and other epidemics. This description of diseases and public health problems for which the Para 6 solution, although at this time is intended to assist with HIV/AIDS, malaria and TB, is broad and general enough to permit flexibility to countries to meet public health challenges as they arise.

What are the eligibility requirements?

An Eligible Importing Members (EIM) is any least-developed country and any other Member that notifies the TRIPS Council of an intention to use the system as an importer in a whole or in a limited way. Certain countries have noted already that they will not use the system as an importer.[53] And to date no country has notified the TRIPS Council of an intention to use the Para 6 solution system as importer or exporter.[54] A "whole way" would include public health problems and public non-commercial use and a limited manner would include the case of emergencies, epidemics, whether national or other circumstances of extreme urgency. The TRIPS Council has not amplified the meaning of the terms and phrases regarding emergencies.

EIMs can operate as a group to if they are Members of a regional trading group, one or more of which can be the primary importer and re-export to the other EIMs in the trading group. One such regional trading group that may serve for this purpose is the Economic Community of the West African States (ECOWAS), established in 1975 the aim of which is to accelerate economic integration and increase political cooperation. Member States include Benin, Burkina Faso, Cape Verde, Cote d'Ivoire, The Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, and Togo.

An eligible exporting member (EEM) is any Member using the system to produce for export to an eligible importer. Para 6 works by waiving the limitation of Article 31(f) in the case of an export to an EIM that is a limitation on the amount to be produced under a compulsory license to that which is predominately for the local market. This amount is thought to be no more than 49% of the domestic market. This limitation possibly precludes the export of an amount sufficient to meet the needs of a country or countries without domestic manufacturing capacity whether a compulsory license is issued or not and clearly impedes the ability of the manufacturer to harness economies of scale so necessary to keeping prices low.

T*he mechanics of these waivers*

The Decision of August 30 establishes conditions precedent for the waiver of the limitation of Article 31(f). These conditions are notification and specifications for a compulsory license pursuant to the Decision. An EIM or several EIMs must declare in a

notice to the TRIPS Council that each has no or insufficient capacity and that if the pharmaceutical product it intends to import is patented in its territory that is has or will grant a compulsory license in accordance with Art. 31.

The compulsory license must specify that it be only for an amount that is necessary to meet the needs of the EIM and that its entirety (under the CL) shall be exported to EIMs that have notified the Council. The products to be exported shall be identified through specific markings or labeling. The licensee shall post notice on its web site certain information regarding the quantity, the markings, and destination of the products. The EEM shall notify the Council of its grant of a license, naming the conditions attached to it, and the same information as the EIM must supply. This will permit the TRIPS Council to match imports and exports and thus monitor and evaluate the system.

In a further effort to promote price reductions of essential medicines, the Decision slightly tailors Art 31(h), which requires adequate remuneration to a patent holder under a CL. Patent holders are still to be paid, however as they are paid by the exporter, the calculation of the remuneration amount must take into account the economic value to the importer. Further in the event the importer also issues a CL, the Decision states the patent holder is to be paid once and should look to the exporter only for payment. This is the Article 31 (h) waiver.

Last, in order to prevent diversion of product intended for export and import pursuant to this Decision, EIMs are admonished to take reasonable measures to prevent re-exportation. If EIMs are members of a regional trade agreement group and have collectively imported, re-exportation among members of the regional trading group is permitted.[55]

Conclusion:

Coherence can be achieved between national pharmaceutical policies to meet basic drug access objectives of and TRIPS compliant national intellectual property legislation. The obligation to protect public health by providing for access to drugs and private intellectual property rights are not mutually exclusive. Rather substantial flexibility in TRIPS and subsequent WTO Ministerial declarations affirm the right within national intellectual property law and provide a means for nations to protect public health. Moreover provisions within other WTO agreements such as the GATT consistently affirm a global consensus that it is important to protect public health.

TRIPS and national IP law are not an impediment to national drug policy objectives. Though the relative importance of other factors leading to access to drugs is not clear, it is sure that TRIPS compliant national intellectual property law alone is not the determining factor in access. Indeed further study may be able to clarify the relative roles of all factors, however resources, focus and energy are sorely needed to address the access issue immediately. These are better spent on developing national pharmaceutical policies to meet basic objectives that can take advantage of clear strategic options suggested in this paper none of which are in conflict with TRIPS.

[1] Trade-Related Aspects of Intellectual Property, commonly referred to as TRIPS can be found at http://www.wto.int/english/tratop_e/trips_e/trips_e.htm.
[2] WTO Assistance for developing countries. http://www.wto.int/english/tratop_e/devel_e/teccop_e/tct_e.htm. Accessed September 7, 2004. The WTO is the international organization dealing with the rules of trade between nations. Membership in this organization by 147 countries as of April 2004 requires adherence to 18 specific agreements of which one, TRIPS is devoted to intellectual property rights.
[3] Forzley M. *The World Trading Organization and Public Health - What does trade have to do with health?* Global HealthLink, Issue #124, November-December 2003. Global Health Council, White River Junction, VT.
[4] The terms drug, medicines and pharmaceuticals are used interchangeably in this paper.
[5] P.Brudon-Jakobowicz, J.D. Rainhorn, M.R. Reich. Indicators for Monitoring National Drug Policies – A Practical Manual (Second Edition) 1999. WHO/EDM/PAR/99.3.
[6] How to develop and implement a national drug policy. WHO Policy Perspectives on Medicines January 2003.
[7] World Health Organization. www.who.int.
[8] Id at note 5 P.Brudon.
[9] Rainhorn JD, Brudon-Jakobowicz P, Reich MR. Priorities for pharmaceutical policies in developing countries: results of a Delphi survey. Bulletin of the World Health Organization, 1994, 72(2): 257-264.
[10] WHO Essential Drugs and Medicines Policy (at who.int/medicine).
[11] How to develop and implement a national drug policy. WHO Policy Perspectives on Medicines January 2003. WHO.
[12] WHO Essential Drugs and Medicines Policy (at who.int/medicine).
[13] Supra note 9. See also *Status of Drug Regulation and Drug Quality Assurance in WHO African Region and Selected Countries,* WHO, March 1999.
[14] World Bank Press Release, "Senegal Secures Price Reductions for HIV Drugs", 24 October 2000.
[15] Nigeria to Spend $248M to Fight HIV, The Associated Press, 19 August 2004. New York Times. http://www.nytimes.com/aponline/international/AP-Nigeria-AIDS.html.
[16] Traditional medicines must be registered and studied', SciDevNet. GhanaWeb.com http://www.scidev.net/News/index.cfm?fuseaction=printarticle&itemid=1559&language=1. WHO rep says at the first scientific meeting of the Western Africa Network of Natural Products Research Scientists, local pharmacists prefer to import foreign drugs rather than prepare traditional treatments.
[17] Correa CM. *Ownership of knowledge – the role of patents in pharmaceutical R&D*. Round Table Bulletin of the World Health Organization. October 2004,82 (10).
[18] World Health Assembly Resolution WHA52.19. Globalization, TRIPS and access to pharmaceuticals. WHO Policy Perspectives on Medicines No. 3 March 2001. WHO.
[19] *The 10/90 Report on Health Research 2001-2002*, Global Forum for Health Research. See also *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases*, Geneva, 2001; Médecins Sans Frontières, October 2001.
[20] Pharmaceutical Industry Profile 2003.
[21] WIPO, Industrial Property Statistics, Publication A: 2001.
[22] Richard T. Rapp & Richard P. Rozek, Benefits and Costs of Intellectual Property Protection in Developing Countries, J. World Trade 75 (Oct. 1990);
[23] The Guardian: African AIDs drugs trapped in the laboratory. Médecins Sans Frontières, May 21, 2003. http://www.accessmed-msf.org/prod/publications.asp?scntid=21520031434524&contenttype=PARA&. Accessed November 12, 2004.
[24] Attaran A. *How do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?* Health Affairs, Vol. 23, Issue 3, 155-156, 2004.
[25] Patent Protection and Access to HIV/AIDS in Pharmaceuticals in Sub-Saharan Africa. International Intellectual Property Institute 2000. www.iipi.org.
[26] *The Worldwide Role of Generic Pharmaceuticals*, Presentation to International Generic Pharmaceutical Association by Dr. Jonathan Quick, Director of Essential Drugs and Other Medicines, World Health Organization, June 1999. The diseases are diarrheol disease, TB, measles, malaria, tetanus, heart attack and stroke and cancer.

[27] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health WT/L/540, referred to as the Decision of August 2003.
[28] Musungu S F, Villanueva S, Blasetti R. *Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks*. South Center April 2004.
[29] Kaplan, WA, R Laing B, Waning L, Levison and S. Foster, (2003) "*Is Local Production of Pharmaceuticals a Way to Improve Pharmaceutical Access in Developing and Transitional Countries? Setting a Research Agenda*", Boston School of Public Health , mimeo.
[30] Status of Drug Regulation and Drug Quality Assurance in WHO African Region and Selected Countries, World Health Organization. March 1999. www.who.int.
[31] Supra note 28.
[32] World Trade Organization General Council Decision of 8 July 2002, WT/L/478 and TRIPS Council Decision 27 June 2002, IP/C/25.
[33] Id at 32.
[34] TRIPS Art. 70 (9). See also General Council Decision WT/L/478.
[35] Mould-Iddrisu B. A Developing Country's Perspective. International Information Programs, USINFO.STATE.GOV. http://usinfo.state.gov/products/pubs/intel. Accessed September 21, 2004.
[36] TRIPS Articles 15.1, 16.2 and 62.3.
[37] Forzley M. *Counterfeit Goods and the Public's Health and Safety*. International Intellectual Property Institute. 2003. www.iipi.org. See also: Forzley M. *A concept paper on a convention to combat counterfeit drugs* for the WHO Department of Essential Medicines March 2004. On file with author.
[38] *Counterfeit and substandard drugs in Myanmar and Viet Nam*. WHO/EDP/QSM/99.3. http://www.who.int/medicines/library/qsm/who-edm-qsm-99-3/who-edm-qsm-99-3.pdf.
[39] Forzley M supra note 37.
[40] Newton P, Proux S, Green M, et al. *Fake artesunate in Southeast Asia*. Lancet 2001; 357: 1948-9.
[41] TRIPS Article 39.2.
[42] TRIPS Article 66.2.
[43] Rodrik D, Subramanian A, Trebbi F. *Institutions Rule: The Primacy of Institutions over Geography and Integration in Economic Development*. NBER Working Paper # 9305. http://www.nber.org. Sachs, J. *Macroeconomics and Health: Investing in Health for Economic Development*. Report of the Commission on Economics and Health. World Health Organization, 2001.
[44] TRIPS Article 27.1.
[45] TRIPS Articles 27.2, 27.3(a), and 27.3(b).
[46] TRIPS Article 28.
[47] TRIPS Article 30: Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.
[48] Canada – Patent protection of Pharmaceutical Products – Complaint by the European Communities and their member States, Report of the Panel, World Trade Organization, WT/DC114/R, 17 March 2000.
[49] TRIPS article 6 states that "nothing in this agreement shall be used to address the issue of exhaustion of intellectual property rights."
[50] Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN/(01)/DEC/2.
[51] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health WT/L/540.
[52] As of November 12, 2004.
[53] The countries include: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America
[54] TRIPS and health: Dedicated webpage for notifications. http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm. Accessed September 20, 2004.
[55] Supra note 51.

