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An Overview of Progress in the International Regulation of the Pharmaceutical Industry

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Abstract
[Excerpt] "The pharmaceutical industry, a significant source of healthcare throughout the world, has several features that distinguish it from the rest of the health industry. In the last half-century, new technology, better technological know-how, and overall economic growth have led to widespread and rapid growth in the pharmaceutical sector. Advancements in pharmaceutical research and development have led to the production of drugs that can routinely combat afflictions that, only years ago, were untreatable or even fatal. Since 1970, the average share of Gross Domestic Product (GDP) on pharmaceutical goods has increased in most Organization for Economic Cooperation and Development (OECD) countries by approximately 50%, meaning that pharmaceutical expenditure has increased on average 1.5% more per year than GDP growth.

Given that access to health care is fundamental to developed society and that pharmaceutical goods are a significant source of healthcare, drugs should be accessible to everyone across the world. However, universal accessibility to drugs is not an easy feat. As nations work with their pharmaceutical industries to provide the best possible access to drugs, they must do so on limited budgets and while maintaining proper incentives for pharmaceutical companies to continue to innovate. These conflicting objectives are problems unique to the pharmaceutical industry and critical to its successful future.

In the European Union (EU), major steps are being made to balance these objectives through the establishment of a Single Market for Pharmaceuticals. As stated in a Commission Communication on the single market in pharmaceuticals, "The purpose of the completion of the Single Market in Pharmaceuticals is not just to provide an environment which is favorable for pharmaceutical innovation and industrial development, it is also to improve consumer choices in pharmaceuticals of the required quality, safety and efficacy, at an affordable cost."

The aim of this note is to present an overview of the major factors that are currently shaping and effecting international trade in the international pharmaceutical industry, and of how these factors contribute to the EU's progression towards a single market. Through outlining the present status of the industry, we hope to facilitate the making of future decisions to reach a better balance between industry innovation and healthcare accessibility."

Keywords
pharmaceuticals, drugs, healthcare, GAAT, TRIPS, WTO, Doha

Cover Page Footnote
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An Overview of Progress in the International Regulation of the Pharmaceutical Industry*

JOAN COSTA-FONT AND AARON BURAKOFF **

INTRODUCTION

The pharmaceutical industry, a significant source of healthcare throughout the world, has several features that distinguish it from the rest of the health industry. In the last half-century, new technology, better technological know-how, and overall economic growth have led to widespread and rapid growth in the pharmaceutical sector.[1] Advancements in pharmaceutical research and development have led to the production of drugs that can routinely combat afflictions that, only years ago, were untreatable or even fatal. Since 1970, the average share of Gross Domestic Product (GDP) on pharmaceutical goods has increased in most Organization for Economic Cooperation and Development (OECD) countries by approximately 50%, meaning that pharmaceutical expenditure has increased on average 1.5% more per year than GDP growth.[2]

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1. Alfonso Gambardella, Luigi Orsenigo & Fabio Pammolli, *Global Competitiveness in Pharmaceuticals, A European Perspective* <http://europa.eu.int/comm/enterprise/library/enterprisepapers/pdf/enterprise_paper _01_2001.pdf> (Nov. 2000).

2. This rate of increase, though significant in its own right, is consistent with the rise in overall health expenditures. Organization for Economic Cooperation and Development, *OECD Health Data 2002 4th ed.* <http://www.oecd.org /EN/document/0,,EN-document-684-5-no-1-29046-0,00.html> (version Aug. 20, 2002).

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The aim of this note is to present an overview of the major factors that are currently shaping and effecting international trade in the international pharmaceutical industry, and of how these factors contribute to the EU's progression towards a single market. Through outlining the present status of the industry, we hope to facilitate the making of future decisions to reach a better balance between industry innovation and healthcare accessibility.

THE LEGAL FRAMEWORK REGULATING PHARMACEUTICAL TRADE

A Brief History

The General Agreement on Tariffs and Trade (GATT), created in 1944, was the first major set of international trade guidelines established to facilitate the growth of a global economy. The GATT centered on building mutually advantageous agreements to promote international trade and to eliminate discrimination between nations. In order for the GATT to continue to liberalize trade as the economy developed through the years, contracting parties took part in eight rounds of multilateral trade negotiations. The longest lasting and most ambitions of these rounds, the Uruguay Rounds, were completed in 1994 with the establishment of the new World Trade Organization (WTO).

The WTO is the institutional successor to the GATT. The GATT was simply a treaty signed by a group of nations and adhered to depending on the degree to which each nation committed itself. Conversely, the WTO binds all of its Member States to a series of multilateral agreements and provides an optional set of plurilateral agreements. The contents of the GATT, including modifications and revisions, still remain as one of the multilateral agreements within the WTO. Also under the auspices of the WTO, with implications in the healthcare industry, are the General Agree-

3. European Union, *Commission Communication on the Single Market in Pharmaceuticals* <http://europa.eu.int/ comm/enterprise/library/lib-regulation/doc/com-98-588_en.pdf> (Nov. 25, 1998).

ment on Trade in Services (GATS), the Agreement on Technical Barriers to Trade (TBT), the Sanitary and Phytosanitary agreements (SPS), and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement, which signified the first recognition of intellectual property rights as a fully-fledged trade related issue, is the chief method of protection for pharmaceutical innovation and the aspect of the WTO that this article is most concerned with.

The Agreement on Trade-Related Aspects of Intellectual Property Rights

The TRIPS Agreement defines the guidelines that Members must follow in setting up systems to protect intellectual property rights. Unlike the other WTO rules, which describe what countries cannot do, TRIPS is proscriptive. It states what countries must do. Member States must grant patents for a minimum of twenty years to the invention of a pharmaceutical product or process that exhibits novelty, inventiveness, and usefulness. Before TRIPS, many States did not issue patents for pharmaceuticals in their territory, which meant that the inventor had no particular right over his invention in that country, which led to the proliferation of copies of patented drugs in some countries. The lack of adequate protection was the driving force behind the establishment of TRIPS.[4]

It is important to stress the significance that patent protection has on continued pharmaceutical innovation and the creation of new drugs. Developing new drugs is a costly and extremely risky business, for not all new drugs are guaranteed to produce profits. In fact, studies have identified that most drugs fail to recoup their research and development expenses and that a very small amount of so-called "blockbuster" drugs are necessary to repay the losses on the majority of low-payoff products. For this reason, patent protection is essential to recoup the expenses involved in developing new medications. Research and development managers have recognized the importance of maintaining patent protection, identifying it as more important to attaining profits than any other single factor.

Accordingly, all industrialized WTO Member States have recognized the TRIPS Agreement since the start of 1996 and by 2005, all developing nations under TRIPS will have to grant legal protection by patents to

4. South Centre, *Main Provisions of the TRIPS Agreement* <http://www.southcentre.org/publications/trips/ tripsmaintexttrans-02.htm#P282_33352> (accessed Sept. 2002).

5. South Centre, *Implications of the TRIPS Agreement for Developing Countries* <http://www.southcentre.org /publications/trips/tripsmaintexttrans-04.htm#P482_63629> (accessed Sept. 2002).

pharmaceutical products.[5] Nevertheless, we must keep in mind that the protection of intellectual property rights in TRIPS is not an end in itself, but merely part of a set of broader economic objectives. Article 8 (pertaining to public health) of the Agreement reads: "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement." [6] It is with this concept underlying the TRIPS Agreement that Member States can utilize various measures, such as compulsory licensing, parallel imports, and Bolar provisions to increase drug accessibility at lower costs during periods of patent protection.

Compulsory Licensing, Parallel Imports, and Bolar Provisions Under the TRIPS Agreement

By definition, a compulsory license is a license granted by a judicial or administrative authority to a company to produce patented medicines without permission from the holder. Article 31 of the TRIPS Agreement stipulates that companies, after unsuccessfully attempting to receive a voluntary license from a patent holder, may be given a compulsory license to produce patented drugs when the practices of the patent holder are deemed to be anti-competitive or when the intentions of the licensee are for non-public use of the product. According to a report issued by the World Health Organization, compulsory licenses are the most effective method to increase the supply of products because they deter patent holders from arbitrarily reducing supply or artificially increasing prices.

However, interested parties have recognized that WTO Members with insufficient manufacturing capacities could face difficulties in implementing compulsory licenses. Article 31(f) mandates that the license be used only for domestic use, which is not economically feasible in many developing countries. Furthermore, despite its potential to increase drug access, the importance of compulsory licensing seems to be declining as modern firms tend to transfer technology through direct investment, either through joint ventures or fully-owned subsidiaries.

Parallel imports are generally defined as the importation into a country where a patent has been registered for the same product patented and legally marketed in another country. Parallel importing, another method

6. South Centre, *Main Provisions of the TRIPS Agreement* <http://www.southcentre. org/publications /trips/tripsmaintexttrans-02.htm#P279_33310> (accessed Sept. 2002).

compliant with the TRIPS Agreement, works to increase both supply and price competition where patented medicines in one country are imported into another country and then sold in parallel with the same home-patented product. In many places, including the European Community, parallel importing is not only permitted, but national antitrust authorities actively take steps to prevent manufacturers from impending parallel imports. Accordingly, many European countries have significant trade in pharmaceutical parallel imports.

Though parallel imports are a significant source of price competition, their usage implies a conflict between competing EU goals. On one hand, the principle of subsidiarity allows each Member State to set its own pharmaceutical prices (this, in fact, is why there are different prices in different countries and why parallel trading can exist). On the other hand, the principle of free trade permits traders to arbitrage price differentials and reduce revenues earned by the pharmaceutical companies. The fact that most of the profit in parallel trade goes to the arbiter, rather than the health care system or the patient, is an inefficiency cited by critics of parallel trading.

Another flaw in parallel importing is that it works against basic economic theory in recouping research and development costs. Critics argue that pharmaceutical research and development is a global joint cost that benefits consumers world wide, and that price differentiation is the best way to cover the joint costs of the research and development.[7] Since parallel trade erodes the price differences, it undermines the price mechanism that pays for research and development.

In September 1999, a "joint understanding" was reached between the U.S. and South Africa to enable the latter country to provide affordable health care to its citizens. The South African government introduced the Medicines Act that would allow parallel imports and compulsory licensing. The joint understanding concluded that the Act would not impede South Africa from honoring the terms of the TRIPS Agreement. The joint understanding followed after four years of negotiation and lobbying, both between and within the two countries, which notably, was conducted outside of the WTO dispute settlement process.[8]

Nevertheless, parallel trade does exist, and therefore presents several possible scenarios for pharmaceutical manufacturers. Manufacturers must look to avoid launching new drugs in markets where prices are expected to be low. If extensive practice of parallel trade emerges, it is possible that

7. Keith E. Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries* <http://www.wipo.org/about-ip/en/studies/pdf/ssa_maskus_pi.pdf> (accessed Jan. 2003).

8. Gordon Nary, *Sloppy Homework* <http://www.thebody.com/iapac/edit899.html> (August 1999).

manufacturers will choose not to launch their products in certain countries where the prices are too low, or in the most extreme scenario, manufacturers might discontinue research and development in countries where prices are highly regulated and shift activities to countries with high prices. Such an event would lead to over-concentration in countries such as the United Kingdom or Germany.

In the U.S., Canada, Australia, and other countries, experiments and tests required to secure regulatory authorization to market a generic drug can take place and applications for approval can be submitted prior to patent expiry without the consent of the patent. These patent infringement exemptions are termed the Roche-Bolar provisions (or Bolar provisons). Roche-Bolar provisions, so named after the 1984 U.S. case of *Roche Products, Inc. v. Bolar Pharmaceutical Company*,[9] were introduced into U.S. legislation as part of the 1984 Hatch-Waxman Act.[10] The provisions allow generic firms to compete in the post-patent market almost immediately following patent expiry. Bolar provisions allow for the use of a patented invention, before the expiration of the patent, in order to prepare a generic version of the drug to be ready for production and distribution once the patent has expired. Bolar provisions currently exist in the U.S., Canada, Israel, and Australia, where, in exchange for the Bolar provisions, the patent holder is granted an extension on the patent. Though EU countries do not have Bolar provisions, an EU ruling confirmed that early work on a drug is consistent with the TRIPS, but that stockpiling before the expiration of the patent is not.

Bolar provisions facilitate a common global trend to cut costs by encouraging the use of generic medications that are much cheaper to produce than their brand-name predecessors. Indeed, many OECD countries have established a variety of policies and financial incentives to promote generic prescription. Seeing that generic drugs tend to enter the market at whole sale prices only 40-70% of the original patented drug prices, the push towards generics has become and will continue to be an important factor in cutting healthcare costs. Due to the provisions of Article 28, providing that a patent confers on its owner certain exclusive rights, and Article 30, allowing exceptions to the exclusive rights, it is not clear whether Bolar provisions are in compliance with the TRIPS agreement. In particular, what constitutes a legitimate exception is not set out explicitly. This ambiguity favors generic medicine manufacturers in countries where Bolar provisions

9. *Roche Products, Inc. v. Bolar Pharmaceutical Company,* 733 F. 2d 858 (1984).

10. Consumer Project on Technology, *The Hatch-Waxman Act and New Legislation to Close Its Loopholes* <http://www.cptech.org/ip/health/generic/hw.html> (accessed Sept. 2002); see also The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (1984), 1984 Stat. 1538.

do exist, and is a bargaining platform for the generic industry in countries where Bolar provisions are not permitted. That is, the generic industry in these countries may argue that adopting Bolar provisions would not infringe on international regulations for intellectual property.

Taken together, developing countries believe that compulsory licensing, parallel importing, and Bolar provisions are an intrinsic part of the balance in the TRIPS Agreement. Yet, despite the legitimacy of these measures, some Member States that have applied one or more of them have faced the threat of unilateral retaliations or the suspension of aid by developed nations. In developing countries, where there are currently insufficient funds and opportunities for significant pharmaceutical innovation, it will be important to monitor how accessible drugs will be for them, especially after the forced implementation of patent protection in 2005.

Exclusive Marketing Rights

Article 70.9 if the TRIPS agreement establishes the right of a patent holder to obtain exclusive marketing rights. This would allow for patent-holding companies, who have filed an application for a patent in a WTO Member State, to market their product without market competition for a period of five years or until the patent application is decided. Article 70.9 states that pending the grant of a patent, exclusive marketing rights shall be granted during the transitional period to patent recognition, as from the time the invention receives marketing approval. The conditions are that a marketing authorization for that same product must have been obtained in another Member State and a patent for the product must have been granted in that same State. Here, there is a well-known dispute between the U.S. and Argentina. The U.S. alleges that in Argentina, there is an absence of an effective system for providing exclusive marketing rights in pharmaceuticals. The United States contends that the TRIPS Agreement does not permit WTO Members to allow third parties to market products subject to exclusive marketing rights without the consent of the right holder. Also, according to the United States, Argentina's law does not provide a system that conforms to Article 70.9 of the TRIPS Agreement with regard to the grant of exclusive marketing rights.

Reaction to the TRIPS Agreement

Unsurprisingly, overall reaction to TRIPS is mixed. Advocates of the Agreement believe that we will see an increase in the flow of technology transfer and direct foreign investment for the benefit of developing countries. Accordingly, they expect the increase of resources allotted to research and development in developing nations to result in the development

of more drugs suited to their own needs. As stated by Harvey Bale, on behalf of the International Federation of Pharmaceutical Manufacturers Association:

> In the future, TRIPS rules can be expected to spread the application of research more globally and involve local companies and countries which have not been part of the effort to discover new treatments, cures and preventive vaccines. Also, international companies can be expected to increase investment and partnerships with locally-oriented companies, where the lack of patent protection and the prevalence of counterfeiting has hindered such activities until now.[11]

Furthermore, when patent protection is guaranteed in developing nations, TRIPS proponents expect to see an end to the "brain drain" because intelligent and productive workers from developing nations will no longer need to leave their home countries because their work will be protected at home. On the opposing side, critics believe that the strengthening of patents will only increase the prices of patented drugs. These critics expect that the increase in prices will coincide with a concentration of production in industrialized countries, where multinational firms will have the freedom to export finished or semi-finished products rather than transfer their technology directly to the developing countries. They find it hard to believe that the TRIPS provisions will lead to an increase of research and development by enterprises in developing countries because, despite patent protection, these countries will still have to deal with a lack of technical infrastructure and human resources.[12]

Compliance with Implementation of the TRIPS Agreement

The U.S. and the European Community (EC) have filed complaints against India concerning India's implementation of the TRIPS Agreement. An agreement has been reached between India and the U.S. for an implementation period of fifteen months expiring on April 16, 1999. The EC established an agreement for the implementation period to correspond to India's agreement with the U.S. At the dispute settlement board (DSB) meeting on April 28, 1999, India presented its final status report on implementation of this matter, which disclosed the enactment of the relevant legislation to implement the recommendations and rulings of the DSB.

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11. Harvey E. Bale, *Consumption and Trade in Off-Patented Medicines* <http://www.icrier.res.in/pdf/bale65.PDF> (May 2001).

12. Ummy Ally Mwalimu, *Implications of WTO/TRIPS in East Africa- With Special Emphasis on Pharmaceutical Patents* <http://www.esrftz.org/global/output/glob007.pdf> (April 15-16, 2002).

India has also been the subject of complaint by the EC and the U.S. over an alleged absence in India of patent protection for pharmaceutical and agricultural chemical products and the absence of formal systems that permit the filing of patent applications and provide exclusive marketing rights for such products. The EC and the U.S. contend that this is inconsistent with India's obligations under Article 70, paragraphs 8 and 9, of the TRIPS Agreement.[13] The Dispute Settlement Panel found that India has not complied with its obligations under Article 70.8(a) or Article 63(1) and (2) of the TRIPS Agreement by failing to establish a legal basis that adequately preserves novelty and priority in respect to applications for product patents for pharmaceutical and agricultural chemical inventions. India was also not in compliance with Article 70.9 by failing to establish a system for the grant of exclusive marketing rights.

THE DOHA DECLARATION

Recently, in the Doha WTO ministerial 2001, the WTO recognized that the gravity of public health problems (mainly HIV but also tuberculosis and others) afflicting many developing and least-developed countries might require taking an international action, which implies the introduction of the so-called "flexibilities." However, at the same time, these actions involved recognition that they might cause difficulties to the pharmaceutical industry. To this extent, the Council for TRIPS is instructed to find an expeditious solution to this problem and to report to the General Council before the end of 2002. The following flexibilities are under consideration:

a. In applying the customary rules of interpretation of public international law, each 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.

b. Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

13. World Trade Organization, *Agreement Establishing the World Trade Organization, Annex 1C Trade-Related Aspects of Intellectual Property Rights* <http://www.wto.org/english/docs_e/legal_e/27-trips.doc> (Apr. 15, 1994).

d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.[14]

The Declaration later states:

> We also agree that the least-developed country 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 right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement.[15]

THE EU AND RECENT DEVELOPMENTS IN THE PUSH TOWARD A SINGLE MARKET

Though we have already described several elements of the TRIPS Agreement and how they factor into the EU pharmaceutical market, there are other important features to discuss regarding the creation of the EU Single Market for Pharmaceuticals. Specifically, several recent court rulings by the European Court of Justice (ECJ) have significant implications for the free movement of pharmaceutical goods throughout the EU.[16]

The ECJ has made clear through its rulings that it is dedicated to the promotion of the free movement of goods and services. One such ruling by the Court granted patients permission to import over-the-counter medications for their own use from a pharmacy in another country, provided that the product is authorized in their home country. Then, in the Decker Case (*Nicolas Decker v. Caisse de Maladie des Employes Prives*, C-120/95 (European Court of Justice, 1997)), the ECJ ruled that a social security organization's refusal to reimburse goods purchased in another Member State opposed the Treaty of the EU. In *Raymond Kohll v. Union des Caisses de Maladie*, C-158/96 (European Court of Justice, 1998), the Court

14. Doha WTO Ministerial 2001, *Declaration on the TRIPS Agreement and Public Health* <http://www.wto.org/ english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> (Nov. 14, 2001).

15. *Id*.

16. Working Group on "Pharmaceuticals and Public Health" of the High Level Committee on Health, *Pharmaceuticals and Public Health in the EU: Proposals to the High Level Committee on Health for Policies and Actions in the Framework of the Treaty of Amsterdam* <http://europa.eu.int/comm/health/ph/key_doc/ke02_en.pdf> (Mar. 28, 2000).

made a ruling that implied that purely economic aims cannot justify a barrier to the fundamental principle of free movement of services.[17]

In addition to the progress made by the Court rulings, the usage of the Euro, a common currency throughout much of the EU, significantly facilitates the movement of goods across borders. The single monetary union pushes towards price transparency and contributes to easier price comparisons across countries.

There is much to be gained by the completion of a single market for pharmaceuticals in the EU. As stated in the Commission, "The continued differences between European markets lead to excess costs (such as higher marketing costs, higher distribution and administrative costs) and, in some cases, to excess production capacity, that could be off-set by a better operating (single) market." Accordingly, policy makers and the ECJ must continue to facilitate the development of the single market.[18]

CONCLUSION

Many changes in the past decade, including the TRIPS Agreement and several rulings by the ECJ, have significant implications for the future of trade in the international pharmaceutical industry. However, it is important to emphasize that trade regulation is only one of the many aspects to be considered to gain a full understanding of the nature of the pharmaceutical industry. It is expected that trade regulation will be considered by individual countries within the contexts of their own healthcare systems and their own necessities. Proper patent protection, along with some limitations in such forms as compulsory licensing, parallel imports, and Bolar provisions, will contribute to the shaping of a market in which continued innovation and especially increased access to pharmaceutical products can benefit all nations. This has been the motivation of recent changes in the regulation of patent protection worldwide as a result of the Doha declaration by stating that, "International trade can play a major role in the promotion of economic development and the alleviation of poverty."[19]

A potential argument in favor of patent recognition often cited by the multinational pharmaceutical companies is its positive impact on the transfer of technology to the developing world. However, the evidence suggests otherwise. Typically, pharmaceutical plants are dismantled by foreign

17. European Union, *supra* n. 3.

18. Working Group on "Pharmaceuticals and Public Health" of the High Level Committee on Health, *supra* n. 15.

19. Doha WTO Ministerial 2—1, Ministerial Declaration <http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_e.htm> (November 14 2001).

subsidiaries of multinational companies after the introduction of pharmaceutical patents. In these cases, medicines are brought into the country in finished form and subsidiaries act as distribution centers only. However, even when patent protections are not helpful for technology transfer, they might be helpful for fighting disease when pharmaceutical research is focused on the specific health problems of developing countries, as well as the ones of developed countries. An alternative regulation proposal refers to setting up a legal framework that ensures a system of differential pricing that would guarantee access to drugs under patent to those individuals infected by specific diseases. However, international regulation of trade still demands higher development. Current TRIPS regulation setting specific barriers to parallel trade and to implementing a patent policy should be made consistent with providing incentives for pharmaceutical companies to commercialize drugs for "less profitable diseases."