Congress of the United States
House of Representatives
Washington, DC 20515

July 15, 2004

The Honorable Robert B. Zoellick
U. S. Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Zoellick:

We are writing to express our ongoing concern about sections of recently negotiated U.S. free trade agreements (FTAs) that could affect the availability of affordable drugs in developing countries. In particular, we are concerned about the impact of restrictions on parallel imports and about marketing exclusivity requirements for pharmaceuticals included in the Morocco FTA. Our concern relates to two points.

First, it appears that some of the provisions contradict, both explicitly and in spirit, commitments made by the United States in the World Trade Organization in both the November 2001 *Declaration on the TRIPS Agreement and Public Health* (the Doha Declaration) and the September 2003 *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (the Paragraph 6 Decision). Section 2101(b)(4)(C) of the Trade Act of 2002 (Trade Promotion Authority or TPA) directs the Administration to respect the Doha Declaration, necessarily including subsequent agreements related to that Declaration.

Second, we are concerned that the FTA's restrictions on obtaining regulatory approval for drugs, including drugs that are already off-patent, are likely to increase prices in the Moroccan market. These restrictions, described below, could undermine the availability of generic versions of drugs to treat serious health problems, including HIV/AIDS, that are widespread in many, if not most, developing countries. Moreover, any increase in the price of drugs in a developing country like Morocco will be borne by consumers because most developing countries have large rural, uninsured, and poor populations who pay out-of-pocket for drugs.

In discussions with your staff and in recent testimony before the Committee on Ways and Means, we understand that your office is of the view that the FTA does not interfere with a country's efforts to ensure broader access to medicines. We request that you explain that view to us in writing, and in particular, by responding to the questions outlined below. We have focused on Chapter 15 of the U.S.-Morocco FTA, because it may be considered by Congress in the coming weeks.

Restrictions on Parallel Importation

Article 15.9.4 of the U.S.-Morocco FTA requires both countries to recognize the exclusive right of a patent holder to import a patented product, at least where the patent holder has restricted the right to import by contractual means. In practical terms, this provision means that neither Morocco, nor for that matter, the United States, may allow parallel imports of patented pharmaceutical products from the other country, or where a national of the other country owns the patent.[1]

With respect to Morocco, which is a developing country, this provision appears to limit one of the flexibilities identified in the Doha Declaration for increasing access to medicines, and accordingly, it appears to contradict the direction in section 2102(b)(4)(c) of TPA. Specifically, the Doha Declaration reaffirmed that the TRIPS Agreement provides flexibility for WTO Members to take measures to protect public health, including "promot[ing] access to medicines for all." One of the key flexibilities identified in the Doha Declaration is the right of each country to determine for itself whether to allow parallel imports.

- *Does Article 15.9.4 of the Morocco FTA prevent Morocco from allowing parallel imports of a patented pharmaceutical product?*

- *Given that the Doha Declaration explicitly confirms the right of each country to retain flexibility in allowing parallel imports of drugs as one way of meeting the public health needs of its citizens, please explain why the provision was included given that TPA directs the Administration to respect the Doha Declaration?*

- *Which country sought inclusion of this provision?*

- *If Morocco or the United States eliminated the exclusive right of a patent holder to import a patented product, would either be in violation of Article 15.9.4?*

Market Exclusivity and Related Provisions

Article 15.10.1 of the U.S.-Morocco FTA requires that both countries prevent the use of data submitted to support an application for marketing approval (e.g., approval from the Food and Drug Administration (FDA)) for a new pharmaceutical chemical product without the consent

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[1] Parallel imports are not imports of counterfeit products. These are products marketed by the patent owner or with the patent owner's permission in one country and imported into another country without the approval of the patent owner.

of the person submitting such data, for a period of five years from the date of approval.[2] In layman's terms, this means that if a company submits data to meet FDA-type safety and efficacy standards, and obtains marketing approval based on that data, other companies cannot obtain regulatory approval based on those data for five years. Given the cost of generating such data, this provision operates effectively as a grant of market exclusivity in virtually all cases, including in cases where the drug is off patent. Article 15.10.2 appears to allow an additional three years of marketing exclusivity for new uses of an already-approved pharmaceutical product. Article 15.10.3 requires both countries to extend patents where there is a delay in the marketing approval process.

The provisions described above appear to be based on 1984 amendments to U.S. law known as the Hatch-Waxman Act. The objectives of the Hatch-Waxman Act were to accelerate and increase the availability of generic drugs in the United States while balancing the need for continued investment in new drugs. As you are aware, the Hatch-Waxman Act was necessary because prior to 1984, U.S. law made it extremely difficult and expensive to bring a generic version of a pharmaceutical product to market, even after a patent expired. This was because prior to the 1984 changes, a company seeking marketing approval for a copy of an already-approved drug had to generate its own data to support its FDA application. The cost of generating those data effectively precluded second entrants from entering the market. (First entrants were able to offset the cost for generation of the data because they enjoyed patent protection.) The Hatch-Waxman Act allowed second entrants to rely on data submitted by first entrants, thereby reducing costs and speeding introduction of generic versions of drugs to the U.S. market. In exchange for allowing second entrants to "piggy-back" off first entrants, first entrants were given a period of market exclusivity, even for drugs that are off-patent.

- *The Hatch-Waxman Act's provisions on market exclusivity were part of a compromise necessary to ensure that the U.S. regulatory structure was updated to facilitate the entry of generic drugs into the U.S. market. Most developing countries already have robust generic markets, in large part because they already allow producers of generic versions of drugs to obtain regulatory approval based on data submitted by first applicants or based on prior approval. In light of that fact, and given that innovative drug companies largely develop drugs for developed country markets and conduct the necessary tests to get marketing approval in those markets regardless of whether they are given market exclusivity in low-income developing countries, what is the rationale for including these provisions?*

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[2] The FTA requires similar protection for agricultural chemical products (fertilizers).

- *Please describe the circumstances under which the three additional years of marketing exclusivity described in Article 15.10.2 would apply.*

- *Neither Article 15.10.1 or 15.10.2 on marketing exclusivity appear to allow for reliance on previously submitted data or prior approval during the period of market exclusivity absent consent of the first applicant. The Doha Declaration reaffirmed the right of countries to use flexibilities under the TRIPS Agreement, such as compulsory licenses. A compulsory license allows someone other than the patent holder to produce and sell a drug under patent. It is not clear to us why the grant of a compulsory license would override a grant of market exclusivity, as provided in Articles 15.10.1 and 15.10.02. (We note that there is no exception to protect the public.) Please describe how the market exclusivity provisions in Article 15.10.1 and Article 15.10.2 relate to Morocco's ability to issue a compulsory license.*

- *Where a compulsory license has been issued, may a Party automatically deem that the first applicant has consented to reliance on the data or prior approval for the drug produced under the compulsory license?*

- *If the patent and test-data were owned by different entities, does a compulsory license result in legal "consent" by both the patent holder and the data owner for use of the patented material and the test data?*

- *When the drug is off patent, and a Party wishes to permit marketing for a second entrant, what mechanism exists in the FTA to allow for an exception to the provisions on market exclusivity?*

- *Is a grant of market exclusivity pursuant to Articles 15.10.1 and 15.10.2 considered an "investment" with respect to Chapter 10 of the agreement? If so, would an abridgement of the period of market exclusivity constitute a compensable expropriation under Chapter 10?*

- *Article 10.6.5 of the FTA appears to clarify that any act of patent infringement carried out by a Party in the issuance of a compulsory license in accordance with the TRIPS does not constitute a compensable expropriation. Issuance of a compulsory license, however, is only one aspect of the process of getting a drug to market. Does the clarification in Article 10.6.5 also ensure that other measures taken by a government to ensure that a drug on which a compulsory license has been issued can be lawfully marketed (e.g., a grant of marketing approval to a*

generic or second producer before the period of marketing exclusivity has expired) will not constitute compensable expropriations? If not, is there another provision in the agreement that would ensure that such measures do not constitute expropriations?

- *Article 15.10.3 requires that a patent term be extended where there is a delay in the regulatory approval process. The provision does not state whether delays attributable to the applicant (e.g., failure to provide adequate data) mitigate against extension. Article 15.9.8, the comparable provision for extension of a patent term because of a delay in the patent approval process, makes clear that delays attributable to the patent applicant should not be considered in determining whether there is a delay that gives rise to the need for an extension. Why was similar language not included in Article 15.10.3?*

- *Is Morocco, or for that matter the United States, required by the FTA to extend a patent term where there is a delay in the regulatory approval that is attributable to the applicant?*

Bolar-Type Provisions That Limit Export[3]

Article 15.9.6 of the U.S.-Morocco FTA appears to allow a person other than a patent holder to make use of a patent in order to generate data in support of an application for marketing approval of a pharmaceutical product (e.g., approval from the FDA). However, Article 15.9.6 also states that if exportation of the product using the patent is allowed, exportation must be limited to "purposes of meeting marketing approval requirements." This provision appears to preclude Morocco from exporting generic versions of patented pharmaceutical products for any reason other than use in obtaining marketing approval because that is the only exception noted.

If that is the case, the provision would seem to curtail Morocco's ability to act as an exporter of pharmaceutical products to least-developed and other countries under the Paragraph 6 Decision. Specifically, the Paragraph 6 Decision allows countries to export drugs produced under a compulsory license to least-developed countries or to countries that lack pharmaceutical manufacturing capabilities. Were the provisions to constrain Morocco's ability to export under the Paragraph 6 Decision, the United States could be accused of backtracking on commitments that have been made.

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[3] The ability of a generic manufacturer to use a patented pharmaceutical product to obtain marketing approval is known in U.S. law as the Bolar provision, after the court case that gave rise to the need for the amendment.

- *Please explain whether this Article prohibits Morocco from allowing the export of generic versions of patented pharmaceutical products for purposes other than "meeting market approval requirements." If it does not, please explain in detail how you came to that conclusion.*

- *If this provision does in fact limit Morocco's ability to allow the export of generic versions of patented pharmaceutical products, please explain how Morocco could serve as an exporting country to help least-developed and other countries address public health needs under the Paragraph 6 Decision. (Exporters under the Paragraph 6 Decision are exporting to meet the health needs of an importing country, not merely to obtain marketing approval.)*

- *Does Article 15.9.6 allow export of a generic version of a patented drug to get marketing approval in a third country (i.e., other than the United States or Morocco)? (Article 15.9.6 states that "the Party shall provide that the product shall only be exported outside its territory for purposes of meeting marketing approval requirements of that Party.")*

Side Letter to the Agreement

The Morocco FTA includes an exchange of letters dated June 15, 2004, between the Governments of Morocco and the United States. The letters appear intended to clarify the relationship between the intellectual property provisions of the FTA and the ability of Morocco and the United States to take measures to protect the public health.

The letters address two issues. First, the letters state that the intellectual property provisions in the FTA "do not prevent the effective utilization" of the Paragraph 6 Decision. Second, the letters state that if the TRIPS Agreement is amended on issues related to promotion of access to medicines, and that either the United States or Morocco takes action in conformity with such amendments, both countries will "immediately consult in order to adapt [the intellectual property provisions of the FTA] as appropriate in light of the amendment."

- *On the Paragraph 6 Decision, please explain how the statement that the FTA does not "prevent the effective utilization" is not merely rhetorical. Please be specific as to why you believe the provisions in the FTA do not preclude Morocco from acting as an importer or exporter of drugs under the Paragraph 6 Decision, including how the FTA's provisions related to market exclusivity can be waived if Morocco acts in either capacity.*

- *On the issue of consultation, do the letters mean that both Parties agree to amend the FTA as soon as possible to reflect access to medicines amendments to the TRIPS Agreement? Will the United States refrain from enforcing provisions of*

the FTA that contravene the TRIPS Agreement amendments while the FTA is being amended? Is USTR willing to engage in an exchange of letters with the Government of Morocco memorializing such an understanding?

We appreciate your prompt response to these questions.

Sincerely,

Charles B. Rangel
Ranking Democrat
Committee on Ways and Means

Sander M. Levin
Ranking Democrat
Subcommittee on Trade
Committee on Ways and Means

Jim McDermott
Member
Committee on Ways and Means

Henry A. Waxman
Ranking Democrat
Committee on Government Reform