

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE
WASHINGTON, D.C. 20506

The Honorable Sander M. Levin
U.S. House of Representatives
Washington, D.C. 20515

JUL 19 2004

Dear Congressman Levin:

Thank you for your letter of July 15, 2004, regarding certain provisions of the intellectual property chapter of the U.S.-Morocco Free Trade Agreement (FTA).

I have addressed each of your specific questions below. As a general matter, for the reasons also set forth below, the FTA does not conflict with the Doha Declaration on the TRIPS Agreement and Public Health or otherwise adversely affect access to medicines in Morocco. The FTA does not require Morocco to change its policies with respect to any of the flexibilities noted in the Doha Declaration. Furthermore, we believe that this FTA can advance Morocco's ability to address public health problems, both by putting in place incentives to develop and bring new medicines to market quickly and by raising standards of living more broadly.

The experience of Jordan under the U.S.-Jordan FTA is illuminating. The United States and Jordan signed the FTA in 2000, during the prior Administration, and we worked with Congress to enact that agreement in 2001. The U.S.-Jordan FTA contains a strong intellectual property chapter that covers, for example, data protection, one of the issues highlighted in your letter. Jordan has witnessed a substantial increase in pharmaceutical investment, creating new jobs and opportunities. In addition, Jordan has approved 32 new innovative medicines since 2000 -- a substantial increase in the rate of approval of innovative drugs, helping facilitate Jordanian consumers' access to medicines. The Jordanian drug industry has even begun to develop its own innovative medicines. This is an example of how strong intellectual property protection can bring substantial benefits to developing and developed countries together.

Your specific questions with respect to the U.S.-Morocco FTA are addressed below.

Parallel Importation

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

Article 15.9.4 of the FTA reflects current Moroccan law and therefore does not require Morocco to do anything it does not already do. The FTA also reflects existing U.S. law. Both Morocco and the United States already provide patent owners with an exclusive right to import patented products, including pharmaceuticals but also all other types of patented products. Many innovative industries and their employees in the United States -- from the high tech and pharmaceuticals sectors to sectors covering chemicals and agricultural inputs, and on to engineering and manufacturing -- benefit from this long-standing protection in U.S. patent law.

2 *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?*

Providing patent owners with an exclusive import right is consistent with Article 28.1 of the TRIPS Agreement, which states that patent owners have the exclusive right to make, use, sell, offer for sale, and import products covered by their patents. U.S. law, developed through a long line of Supreme Court and lower court cases, has recognized this right for over a hundred years. The TRIPS Agreement more precisely articulated the exclusive import right, and, when implementing TRIPS in the Uruguay Round Agreements Act, Congress amended the patent law by providing for such a right expressly in the statute.

At the same time, however, the TRIPS Agreement also allows countries to choose to permit "international exhaustion" without challenge under WTO dispute settlement. International exhaustion would allow parallel imports. The Doha Declaration affirms this approach, and states that "[t]he 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."

Importantly, neither the TRIPS Agreement nor the Doha Declaration require WTO members to adopt an international exhaustion rule; they merely recognize that countries may do so without challenge. WTO members are free to exercise their sovereign right to choose an alternative policy. As noted, the United States does not permit parallel imports. Morocco also decided in 2000, well before the FTA negotiations, not to permit parallel imports. The fact that the FTA reflects principles already present in both Parties' laws does not in any way lessen our commitment to the Doha Declaration. In fact, in previous FTA negotiations with developing countries that do not have parallel import restrictions in their domestic law (e.g., Central America, Chile, and Bahrain), the final negotiated texts do not contain provisions on parallel importation.

3 *Which country sought inclusion of this provision?*

This provision is a standard component of the U.S. draft text, which USTR staff has presented to Congress for review and comment on numerous occasions. Morocco readily accepted the proposal, without objection, and noted during the negotiations that Moroccan patent law, like U.S. law, already provided patentees with an exclusive importation right.

4 *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?*

It would depend on the details of the particular legislation. A change in U.S. law would, however, affect many other innovative sectors that rely on patents besides the pharmaceutical sector. Many U.S. technology, manufacturing, and other innovative businesses -- as well as

Members of Congress -- urge us regularly to vigorously safeguard U.S. patents and the jobs they help create.

Market Exclusivity

5 *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?*

In negotiating the U.S.-Morocco FTA and other recent FTAs, USTR has been mindful of the guidance provided in the Trade Act of 2002, which directs USTR to seek to "ensur[e] that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the United States reflect[s] a standard of protection similar to that found in United States law." We understand the rationale of this guidance is to help protect and create high-paying jobs in leading American businesses. As a developed economy, it is understandable that U.S. workers will be increasingly employed in higher value (and better paid) innovative and productive jobs. On the basis of Congress' direction, the United States sought to include provisions that reflect U.S. law, including with respect to the protection of data.

The protection of clinical test data has long been a component of trade agreements negotiated by U.S. Administrations with both developed and developing countries. Data protection provisions were included, for example, in many past trade agreements, including the U.S.-Jordan FTA and the U.S.-Vietnam Bilateral Trade Agreement -- both negotiated by the prior Administration after the passage of the law to which you refer. Such provisions were included in NAFTA, too. They are in all recent FTAs, including the U.S.-Singapore FTA and the U.S.-Chile FTA. Data protection provisions have also been included in many bilateral intellectual property agreements.

The TRIPS Agreement itself requires protection of clinical test data against unfair commercial use. While the United States protects data to obtain approval for new chemical entities for five years, other countries provide different terms. The EU, for example, protects such data for 6-10 years.

Implicit in the question, however, appears to be an assumption that data protection is disadvantageous for developing countries like Morocco. Yet, protection of data actually has the potential of facilitating and accelerating access to medicines. As recognized in Chapter 15 of the FTA (footnotes 12 and 13), Morocco does not currently approve generic versions of medicines based on approvals granted in other countries. As a result, today a generic producer wishing to sell pharmaceuticals in Morocco may obtain approval only if an innovative producer first obtains approval in Morocco or if the generic producer invests the significant money and time necessary

to recreate the data itself. After an innovative producer obtains approval in Morocco, a generic producer may rely on such data to obtain approval for its generic product.

Therefore, under existing Moroccan law, generic manufacturers in Morocco cannot obtain marketing approval for a generic drug until an innovator has first obtained approval for the drug in Morocco. Without data protection, innovative producers will be less likely to enter the Moroccan market in the first place because, once they obtain approval, generic producers may capture most of the market. The data exclusivity provisions of the FTA can thus provide an important incentive for innovators to enter the market, which may in turn expand the potential universe of generic drugs in Morocco. As noted above, this is the development we are seeing in Jordan, to the benefit of Jordan consumers.

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

The question seems to imply that the basic five year term of protection for data submitted to obtain approval of new chemical entities may be extended to eight years. This is not correct. There is no circumstance in which the FTA requires that an innovator receive a data protection period longer than five years for new chemical entities.

The three year period of protection reflects a provision in U.S. law, which relates to new information that is submitted after a product is already on the market (for example, because the innovator is seeking approval for a new use of an existing product). In that situation, at least in cases where the origination of this new data involves considerable effort, the FTA requires that the person providing the new data gets three years of protection for that new data relating to that new use. This three year period only applies to the new data for the new use; it is not added to the exclusivity period for any data previously submitted.

For example, if a new chemical entity is given marketing approval, the data supporting that approval is protected for five years. After that time, generic producers may rely on the data to obtain approval for a generic version of the drug for the use supported by the original data. If a new use is subsequently discovered for the chemical entity, and the health authority approves the new use based on new data, then the originator of the new data is entitled to three years of protection for that data. During that time, however, generics can continue to produce and market the drug for the original use.

7. *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 15.10.2. (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*

The Doha Declaration recognizes that the TRIPS Agreement allows countries to issue compulsory licenses to address public health problems. The U.S.-Morocco FTA is fully consistent with this principle. It contains no provisions with respect to compulsory licensing, leaving the flexibilities available under WTO rules unchanged.

In the negotiation of the U.S.-Morocco FTA, both parties recognized the importance of protecting public health. Your questions pertain to whether provisions of Chapter 15 (which is the Intellectual Property Rights chapter) might affect this common interest. To address this type of concern, the United States and Morocco agreed to a side letter on public health in which both Parties stated their understanding that “[t]he obligations of Chapter Fifteen of the Agreement do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.” The Parties also stated that “Chapter Fifteen does not prevent the effective utilization of the TRIPS/health solution” reached in the WTO last year to ensure that developing countries that lack pharmaceutical manufacturing capacity may import drugs. Therefore, if circumstances ever arise in which a drug is produced under a compulsory license, and it is necessary to approve that drug to protect public health or effectively utilize the TRIPS/health solution, the data protection provisions in the FTA would not stand in the way.

8 *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?*

As explained above, if the measure described in the question is necessary to protect public health, then, as explained in the side letter, the FTA would not stand in the way.

9 *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?*

See previous response

10 *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?*

A patent is designed to protect one type of intellectual property work, i.e., an invention. Protection of data is intended to protect a different type of work, i.e., undisclosed test data that required significant time and effort to compile. The fact that one type of intellectual property protection for a product has expired, should not lead as a matter of course to the conclusion that all other intellectual property rights attached to the same product should also expire. The same is true in other areas of intellectual property. For example, a single CD may encompass several intellectual property rights related to the music, the performer and the record company. These rights may expire at different times. The fact that the copyright attached to the sound recording has expired, should not mean that the composer or performer loses the copyright it has. As you

know, this principle is important to a broad range of U.S. creative and innovative industries, including the entertainment sector, America's second largest export business.

However, as indicated in the side letter, if a circumstance arose, such as an epidemic or national emergency, that could only be addressed by granting a second entrant marketing approval notwithstanding the data protection rights of the originator of the data, the FTA would not stand in the way.

11 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?

The definition of an "investment" in the FTA includes, *inter alia*, "intellectual property rights." Whether an abridgement of the data protection obligation gives rise to a compensable expropriation of an "investment" under Chapter Ten is a fact-specific issue that would have to be resolved on the merits of a particular case. It is worth noting, however, that Article 10.6.5 provides that the expropriation provision of Chapter Ten does not apply to the issuance of compulsory licenses or to the limitation of intellectual property rights to the extent that such action is consistent with the intellectual property chapter (Chapter Fifteen). A determination concerning the consistency of an action with Chapter Fifteen would be informed by the side letter.

12. 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?

See response to Question 11.

13 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, 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?

The Parties did not find it necessary to specifically address the issue of how to handle delays attributable to an applicant for marketing approval in the context of data protection. As with numerous other provisions, the Parties retain the flexibility to address such details in their implementation of the FTA, provided that they comply with the basic obligation.

14. *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?*

The FTA preserves flexibility for the Parties to address the issue of delays attributable to an applicant for marketing approval through their domestic laws and regulations

Bolar Provisions

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

No, it does not. The Article dealing with the "Bolar" exception to patent rights only deals with one specific exception. It does not occupy the field of possible exceptions, and thus does not prevent Morocco from allowing the export of generic versions of patented pharmaceutical products for purposes other than "meeting marketing approval requirements" when permitted by other exceptions. For example, Morocco has the right to allow exports where consistent with TRIPS Article 30 and WTO rules on compulsory licensing. Morocco may, for example, allow export of generic versions of patented drugs by issuing a compulsory license in accordance with the TRIPS/health solution agreed last August in the WTO.

16. *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)*

As noted in the response to Question 15, the FTA does not limit Morocco's ability to make use of the TRIPS/health solution agreed last August to export drugs under a compulsory license to developing countries that cannot produce drugs for themselves.

17. *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.")*

Morocco can get marketing approval in a third country to allow export of a generic version through the issuance of a compulsory license for export, consistent with WTO rules. Article 15.9.6 does not interfere with that result.

Side Letter

18. *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

There are no provisions in the FTA related to compulsory licensing, which means that it does not limit in any way Morocco's ability to issue compulsory licenses in accordance with WTO rules, including TRIPS Article 31 and the TRIPS/health solution. With respect to other rules included in Chapter 15, including data protection, the side letter states that the FTA does not "prevent the effective utilization of the TRIPS/health solution." As stated in the side letter, the letter constitutes a formal agreement between the Parties. It is, thus, a significant part of the interpretive context for this agreement and not merely rhetorical. According to Article 31 of the *Vienna Convention on the Law of Treaties*, which reflects customary rules of treaty interpretation in international law, the terms of a treaty must be interpreted "in their context," and that "context" includes "any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty."

19. *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 letter with the Government of Morocco memorializing such an understanding?*

The United States would, of course, work with Morocco to ensure that the FTA is adapted as appropriate if an amendment to the TRIPS Agreement were adopted to ensure access to medicines. The only amendment currently being contemplated with respect to TRIPS involves translating the TRIPS/health solution from last August into a formal amendment. The United States has no intention of using dispute settlement to challenge any country's actions that are in accordance with that solution. In fact, Canada passed legislation recently that would allow it to export drugs in accordance with the TRIPS/health solution. The United States reached an agreement with Canada just last Friday, July 16, to suspend parts of NAFTA to ensure that Canada could implement the solution without running afoul of NAFTA rules.

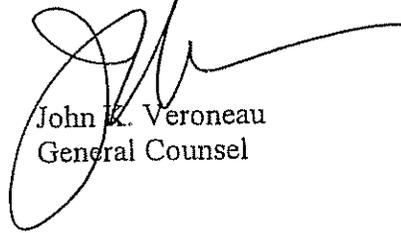
In closing, let me emphasize that we appreciate the importance of the U.S. commitment to the Doha Declaration on the TRIPS Agreement and Public Health and the global effort to ensure access to medicines in developing countries to address acute public health problems, such as AIDS, malaria and tuberculosis. The United States played a leading role in developing these provisions, including enabling poor countries without domestic production capacity to import drugs under compulsory licenses. We also successfully called for giving Least Developed Countries an additional ten years, from 2006 until 2016, to implement TRIPS rules related to pharmaceuticals. These accomplishments offer a significant solution to the conflicts we encountered on taking office in 2001.

At the same time, as Congress has directed us, the Administration has worked on multiple fronts to strengthen the value internationally of America's innovation economy. These efforts have

included stronger intellectual property protection rules and enforcement so as to assist U.S. businesses and workers, and encourage ongoing innovation that benefits U.S. consumers

Our FTAs are but one component of the Administration's broader efforts to achieve these objectives, and complement efforts undertaken in other fora. Our FTAs not only do not conflict with the objectives expressed in the Doha Declaration but reinforce those objectives and facilitate efforts to address public health problems.

Sincerely,

A handwritten signature in black ink, appearing to be 'J. Veroneau', written over the typed name and title.

John K. Veroneau
General Counsel