108TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
108–627

UNITED STATES-MOROCCO FREE TRADE AGREEMENT IMPLEMENTATION ACT

JULY 21, 2004.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. THOMAS, from the Committee on Ways and Means, submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany H.R. 4842]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 4842) to implement the United States-Morocco Free Trade Agreement, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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29–006

I. INTRODUCTION

A. PURPOSE AND SUMMARY

H.R. 4842 would implement the June 15, 2004 Agreement establishing a free trade area between the United States and Morocco.

B. BACKGROUND

The United States-Morocco Free Trade Agreement (FTA) is the fourth trade agreement considered by the Congress under the Trade Promotion Authority (TPA) procedures outlined in the Bipartisan Trade Promotion Authority Act of 2002 signed into law in August 2002 (P.L. 107–210). The United States and Morocco have a strong bilateral relationship. This free trade agreement forms part of the Administration's initiative to establish a Middle East Free Trade Area by 2013. Morocco is a progressive Arab state in terms of democracy and rule of law. The Moroccan government has also undertaken a strong economic and labor reform program.

The United States-Morocco FTA is a 21st century agreement that reflects the modern globalized economy, opens markets, and provides mutual benefits in intellectual property, services, government procurement, and e-commerce.

The Committee believes that the Agreement meets the objectives and priorities set forth in the Bipartisan Trade Promotion Authority Act of 2002. More than 95 percent of bilateral trade in consumer and industrial products will become duty-free immediately upon entry into force of the Agreement, with all remaining tariffs to be eliminated within nine years. According to the Office of the United States Trade Representative (USTR), this is the best market access package of any U.S. free trade agreement that has been signed to date with a developing country. Currently, U.S. exports to Morocco face an average tariff of 20 percent versus a 4 percent average tariff that Moroccan exports face in the U.S. market. U.S. export sectors such as information technology products, construction equipment, and chemicals stand to benefit from the Agreement.

Notwithstanding the outstanding provisions on industrial market access noted above, one sector that warrants special discussion is textiles and apparel. Unlike the practice in most previous FTAs, duties on textile and apparel products satisfying the rule of origin in this FTA are not eliminated upon entry into force of the Agreement. Instead, duties on originating textile and apparel products are phased out over a ten-year period. Ambassador Peter Allgeier, Deputy United States Trade Representative, testified at the Committee's hearing on implementation of the FTA on July 7, 2004, that these provisions were included to respond to a unique situation in which Morocco raised concerns about increased imports from the European Union and that it is not USTR's intention to replicate these provisions in future agreements. The Committee expects that the immediate liberalization for qualifying goods included in these other agreements will be the model for future agreements.

In addition, the Committee believes that maintaining a current short supply list under the FTA is integral to the effective functioning of the rule of origin for textiles and apparel. The Committee expects the President to seek to incorporate all existing and future affirmative short supply determinations from other trade agreements and trade preference programs into the textile and apparel rule of origin for this FTA. Moreover, given that prior short supply designations have already undergone public comment and consultation with domestic parties, the President should apply those designations to this FTA without further public investigation. Finally, the Committee clarifies that the short supply provision included in this FTA, as well as previous FTAs and trade preference programs enacted by Congress, contemplates items only being added to the list of short supply items. In other words, once an item is designated as being in short supply under this FTA, other FTAs, and trade preference programs, the item is permanently designated as such unless otherwise provided for by the statute implementing the FTA or trade preference program.

On agriculture market access, tariffs on most U.S. agricultural exports to Morocco are phased out over the following periods: immediate, five years, eight years, ten years, 12 years, 15 years, and 18 years. Certain sensitive products will have phase out periods of as long as 25 years. U.S. tariffs will be phased out over the following periods: immediate, five years, eight years, ten years, 12 years, 15 years, and 18 years. The Committee notes with particular approval that all agricultural products are included in the FTA and expects that this comprehensiveness will be reflected in future FTAs brought before the Committee. The American Farm Bureau Federation estimates that for every $1 in increased imports from Morocco, U.S. farmers can expect $10 in increased exports to Morocco, tripling our current exports. Because comprehensive liberalization of agricultural trade is included in this FTA and not in the European Union-Morocco Association Agreement, new commercial opportunities for U.S. exporters are very likely.

In services, the Committee is pleased that the Agreement utilizes a trade-enhancing "negative list" approach to ensure maximum market access for services providers. Morocco will accord substantial market access across its entire services regime, offering access in sectors such as audiovisual, express delivery, telecommunications, computer and related services, distribution, and construction and engineering.

The FTA calls for higher standards for protecting intellectual property rights such as copyrights, patents, trademarks, and trade secrets, as well as enhanced means for enforcing those rights. The FTA also requires both Parties to ratify or accede to the World Intellectual Property Organization (WIPO) Copyright Treaty and WIPO Performances and Phonograms Treaty. The Committee also notes that the intellectual property provisions will not affect Morocco's ability to take measures necessary to protect public health. In fact, a side letter to the agreement makes this assurance explicit.

For covered procurements above certain contract values (i.e., thresholds), the FTA ensures that Moroccan government purchasers cannot discriminate against U.S. firms or in favor of Moroccan firms. Strong and transparent disciplines on procurement procedures, such as requiring advance public notice of purchases,

as well as timely and effective bid review procedures, provide U.S. suppliers with not only greater market access opportunity but also increased certainty in the bidding and contracting process. The FTA provides access to procurements by thirty Moroccan central government entities, including the Ministries of Defense, Foreign Affairs, Interior, and the Prime Minister. The FTA also covers procurement by Morocco's provinces and prefectures.

The Committee notes with particular approval that the FTA includes an investor-state dispute resolution mechanism, which has been included in every FTA signed by the United States in the last 15 years with the exception of the recently signed agreement with Australia. The investor-state dispute mechanism provides protection for investment agreements concluded after the FTA goes into effect, although it does not provide protection for existing investment agreements (defined as agreements relating to natural resources or other assets controlled by the foreign government).

The Agreement also contains obligations under which each government commits to enforce its domestic labor and environmental laws, as required by TPA. The Committee understands that the prospect of an FTA with the United States spurred Morocco to update and upgrade its labor law. The Committee notes that Moroccan labor laws comply with core labor standards set forth by the International Labor Organization (ILO). Accordingly, requiring that each government enforce its labor laws is tantamount to an enforceable ILO standard. Similarly, Morocco's environmental laws set a high level of protection.

The Committee notes that the FTA will cover trade with and investment in the territory of Morocco as recognized by the United States, which does not currently include the Western Sahara.

As noted above, this legislation is being considered by Congress under TPA procedures. As such, the Agreement has been negotiated by the President in close consultation with Congress, and it can be approved and implemented through legislation using streamlined procedures. Pursuant to TPA requirements, the President is required to provide written notice to Congress of the President's intention to enter into the negotiations. Throughout the negotiating process and prior to entering into an agreement, the President is required to consult with Congress regarding the ongoing negotiations.

The President must notify the Congress of his intent to enter into a trade agreement at least 90 calendar days before the agreement is signed. Within 60 days after entering into the Agreement, the President must submit to the Congress a description of those changes to existing laws that the President considers would be required in order to bring the United States into compliance with the Agreement. After entering into the Agreement, the President must also submit to the Congress the formal legal text of the agreement, draft implementing legislation, a statement of administrative action proposed to implement the Agreement, and other related supporting information as required under section 2105(a) of TPA. Following submission of these documents, the implementing bill is introduced, by request, by the Majority Leader in each chamber. The House then has up to 60 days to consider implementing legislation for the Agreement (the Senate has up to an additional 30 days). No

amendments to the legislation are allowed under TPA requirements.

C. LEGISLATIVE HISTORY

On October 1, 2002, the President first notified Congress of his intent to negotiate an FTA with Morocco. FTA negotiations between the United States and Morocco began in January 2003 and concluded in March 2004. During and after the negotiations, the President continued his consultations with Congress pursuant to the letter and spirit of the TPA requirements. On March 8, 2004, the President notified Congress of his intent to enter into the United States-Morocco FTA. The text of the United States-Morocco FTA was released to the public on April 2, 2004. Under TPA procedures, the President is able to sign an FTA ninety calendar days after he has notified Congress. Accordingly, the FTA was signed on June 15, 2004, by U.S. Trade Representative Robert B. Zoellick and Moroccan Minister-Delegate of Foreign Affairs and Cooperation Taib Fassi-Fihri.

On July 7, 2004, the Committee on Ways and Means held a hearing on the United States-Morocco FTA. The Committee received testimony supporting the Agreement from the Administration and numerous U.S. private sector companies and organizations. On July 14, 2004, the Committee on Ways and Means considered in an informal markup session draft implementing legislation for the Morocco FTA. The Committee approved the draft implementing legislation by a recorded vote of 23 yeas to 1 nay, with one Member voting present, without amendment.

In accordance with TPA requirements, President Bush submitted to Congress on July 9, 2004 a description of the changes to existing U.S. laws that would be required to bring the United States into compliance with the Agreement.

On July 15, 2004, President Bush formally transmitted to Congress the formal legal text of the United States-Morocco FTA, implementing legislation, a statement of administrative action proposed to implement the Agreement, and other related supporting information as required under section 2105(a) of TPA. Following this transmittal, on July 15, 2004, Majority Leader DeLay introduced, by request, H.R. 4842 to implement the United States-Morocco FTA. The bill was referred to the Committee on Ways and Means.

On July 19, 2004, the Committee on Ways and Means formally met to consider H.R. 4842. The Committee ordered H.R. 4842 favorably reported to the House of Representatives by a recorded vote of 26 yeas to 0 nays, without amendment; under the requirements of TPA, amendments were not permitted.

II. SECTION-BY-SECTION SUMMARY

TITLE I: APPROVAL AND GENERAL PROVISIONS

SECTION 101: APPROVAL AND ENTRY INTO FORCE

Current law

No provision.

Explanation of provision

Section 101 states that Congress approves the Agreement and the Statement of Administrative Action and provides that the Agreement enters into force when the President determines that Morocco is in compliance and has exchanged notes, on or after January 1, 2005.

Reason for change

Approval of the Agreement and the Statement of Administrative Action is required under the procedures of section 2103(b)(3) of the Bipartisan Trade Promotion Authority Act of 2002. The remainder of section 101 provides for entry into force of the Agreement.

SECTION 102: RELATIONSHIP OF THE AGREEMENT TO U.S. AND STATE LAW

Current law

No provision.

Explanation of provision

Section 102 provides that U.S. law is to prevail in a conflict and states that the Agreement does not preempt state rules that do not comply with the Agreement. Only the United States is entitled to bring a court action to resolve a conflict between a state law and the Agreement.

Reason for change

Section 102 is necessary to make clear the relationship between the Agreement and federal and state law, respectively.

SECTION 103: IMPLEMENTING ACTIONS IN ANTICIPATION OF ENTRY INTO FORCE AND INITIAL REGULATIONS

Current law

No provision.

Explanation of provision

Section 103(a) provides that after the date of enactment, the President may proclaim actions and issue regulations as necessary to ensure that any provision of this Act that takes effect on the date that the Agreement is entered into force is appropriately implemented, but not before the date the Agreement enters into force.

Section 103(b) establishes that regulations necessary or appropriate to carrying out the actions proposed in the Statement of Administrative Action shall, to the maximum extent feasible, be issued within one year of entry into force or the effective date of the provision.

Reason for change

Section 103 provides for the issuance of regulations. The Committee strongly believes that regulations should be issued in a timely manner in order to provide maximum clarity to parties claiming benefits under the Agreement. As noted in the Statement of Administrative Action, the regulation-issuing agency will provide a report to Congress not later than thirty days before one year

elapses on any regulation that is going to be issued later than one year.

SECTION 104: CONSULTATION AND LAYOVER FOR PROCLAIMED ACTIONS

Current law

No provision.

Explanation of provision

Section 104 provides that where the President is given proclamation authority subject to consultation and layover, he may proclaim action only after he has: obtained advice from the International Trade Commission and the appropriate private sector advisory committees; submitted a report to the House Ways and Means and Senate Finance Committees concerning the reasons for the action; and consulted with the Committees. The President may proclaim the proposed action after 60 days have elapsed.

Reason for change

The bill gives the President certain proclamation authority but requires extensive consultation with Congress before such authority may be exercised. The Committee believes that such consultation is an essential component of the delegation of authority to the President and expects that such consultations will be conducted in a thorough manner.

SECTION 105: ADMINISTRATION OF DISPUTE SETTLEMENT PROCEEDINGS

Current law

No provision.

Explanation of provision

Section 105 authorizes the President to establish an office within the Commerce Department responsible for providing administrative assistance to any panels that may be established under the Agreement and authorizes appropriations for the office and for payment of the U.S. share of expenses.

Reason for change

The Committee believes that the Commerce Department is the appropriate agency to provide administrative assistance to panels.

SECTION 106: ARBITRATION OF CLAIMS

Current law

No provision.

Explanation of provision

Section 106 authorizes the United States to resolve certain claims covered by the Investor-State Dispute Settlement procedures set forth in the Agreement.

Reason for change

This provision is necessary to meet U.S. obligations under Section B of Chapter 10 of the Agreement.

SECTION 107: EFFECTIVE DATES; EFFECT OF TERMINATION

Current law

No provision.

Explanation of provision

The effective date of this Act is date the Agreement enters into force with respect to the United States except sections 1–3 and Title I take effect upon the date of enactment. The provisions of the Act terminate on the date on which the Agreement terminates.

Reason for change

Section 107 implements U.S. obligations under the Agreement.

TITLE II: CUSTOMS PROVISIONS

SECTION 201: TARIFF MODIFICATIONS

Current law

No provision.

Explanation of provision

Section 201(a) provides the President with the authority to proclaim tariff modifications to carry out the Agreement and requires the President to terminate Morocco's designation as a beneficiary developing country for the purposes of the Generalized System of Preferences program.

Section 201(b) gives the President the authority to proclaim further tariff modifications, subject to consultation and layover, as the President determines to be necessary or appropriate to maintain the general level of reciprocal and mutually advantageous concessions with respect to Morocco provided for by the Agreement.

Section 201(c) allows the President, for any goods for which the base rate is a specific or compound rate of duty, to substitute for the base rate an ad valorem rate to carry out the tariff modifications in subsections (a) and (b).

Reason for change

Section 201(a) is necessary to put the United States in compliance with the market access provisions of the Agreement. Section 201(b) gives the President flexibility to maintain the trade liberalizing nature of the Agreement. The Committee expects the President to comply with the letter and spirit of the consultation and layover provisions of this Act in carrying out this subsection. Section 201(c) allows the President to convert tariffs to ad valorem rates to carry out the tariff modifications in the Agreement.

SECTION 202: ADDITIONAL DUTIES ON CERTAIN AGRICULTURAL GOODS

Current law

No provision.

Explanation of provision

Section 202 of the bill implements the agricultural safeguard provisions of article 3.5 and Annex 3–A of the Agreement. Article 3.5 permits the United States to impose an agricultural safeguard

measure, in the form of additional duties, on imports from Morocco of certain horticultural goods listed in the U.S. schedule to Annex 3–A of the Agreement.

No additional duty may be applied under section 202 if, at the time of entry, the good is subject to import relief under subtitle A of title III of this bill (the general safeguard) or chapter 1 of title II of the Trade Act of 1974 ("section 201" relief). The assessment of an additional duty shall cease to apply to a good on the date on which duty-free treatment must be provided to that good. If an agricultural good is subject to a tariff-rate quota under the Agreement, any additional duty assessed under this section shall be applied only to over-quota imports of the good. The sum of the duties assessed under an agricultural safeguard and the applicable rate of duty in the U.S. schedule may not exceed the lesser of the existing normal trade relation (NTR)/most favored nation (MFN) rate or the NTR/MFN rate imposed when the Agreement entered into force.

Reason for change

Section 202 implements the agriculture safeguard provisions of article 3.5 and Annex 3–A of the Agreement and provides important security to U.S. farmers.

SECTION 203: RULES OF ORIGIN

Current law

No provision.

Explanation of provision

Section 203 codifies the rules of origin set out in chapter 5 of the Agreement. Under the general rules, there are four basic ways for a good of Morocco to qualify as an "originating good" and therefore be eligible for preferential tariff treatment when it is imported into the United States. A good is an originating good if it is imported directly from the territory of Morocco into the territory of the United States and: (1) it is "wholly the growth, product, or manufacture of Morocco, the United States, or both"; (2) it is a new or different good that has been "grown, produced, or manufactured in Morocco, the United States, or both" and the value of the materials produced and the direct cost of processing operations performed in Morocco, the United States, or both is not less than 35 percent of the appraised value of the good; (3) it satisfies certain rules of origin for textile or apparel goods specified in Annex 4–A of the Agreement; or (4) it satisfies certain product-specific rules of origin specified in Annex 5–A of the Agreement.

Under the rules in Article 4.3 and Annex 4–A of the Agreement, an apparel product must generally meet a tariff shift rule that implicitly imposes a "yarn forward" requirement. Thus, to qualify as an originating good imported into the United States from Morocco, an apparel product must have been cut (or knit to shape) and sewn or otherwise assembled in Morocco from yarn, or fabric made from yarn, that originates in Morocco or the United States, or both. However, Article 4.3.11 provides a limited exception to this general rule allowing access for 30 million square meter equivalents of apparel that does not meet the yarn forward rule of origin in the first year of the Agreement, phasing down over a ten-year period. Sec-

tion 203 also includes a de minimis exemption providing that in most cases a textile or apparel good will be considered originating if the total weight of all nonoriginating fibers or yarns is not more than 7 percent of the total weight of the good.

The remainder of section 203 addresses valuation of materials and special definitions.

Reason for change

Rules of origin are needed in order to confine Agreement benefits, such as tariff cuts, to Moroccan goods and to prevent third-country goods from being transshipped through Morocco and claiming benefits under the Agreement. Section 203 puts the United States in compliance with the rules of origin provisions of the agreement. The Committee notes that the exception to the textile and apparel yarn forward rule of origin is phased down over ten years and covers approximately 0.08 percent of U.S. textile and apparel imports by volume.

SECTION 204: ENFORCEMENT RELATING TO TRADE IN TEXTILE AND APPAREL GOODS

Current law

No provision.

Explanation of provision

Section 204 implements the verification provisions of the Agreement at article 4.4 and authorizes the President to take appropriate action while the verification is being conducted. Such appropriate action includes suspending liquidation of the textile or apparel good for which a claim of origin has been made or, in a case where the request for verification was based on a reasonable suspicion of unlawful activity related to such goods, for textile or apparel goods exported or produced by the person subject to a verification. If the Secretary determines that the information obtained from verification is insufficient to make a determination, the President may take appropriate action described in section 204(d), including publishing the name and address of the person subject to the verification and denial of preferential treatment and denial of entry to certain textile and apparel goods produced or exported by the person subject to the verification.

Reason for change

In order to ensure that only qualifying textile and apparel goods receive preferential treatment under the Agreement, special textile enforcement provisions are included in the Agreement. Section 204 is necessary to authorize these enforcement mechanisms for use by U.S. authorities.

SECTION 205: REGULATIONS

Current law

No provision.

Explanation of provision

Section 205 provides that the Secretary of the Treasury shall issue regulations to carry out provisions of this bill related to rules of origin and Customs user fees.

Reason for change

Because the implementing bill involves lengthy and complex implementation procedures by customs officials, section 205 is necessary in order to authorize the Secretary of the Treasury to carry out provisions of the implementing bill through regulations.

TITLE III: RELIEF FROM IMPORTS

Subtitle A: Relief From Imports Benefiting From the Agreement (Sections 311–316)

Current law

No provision.

Explanation of provision

Sections 311–316 authorize the President, after an investigation and affirmative determination by the U.S. International Trade Commission (ITC), to impose specified import relief when, as a result of the reduction or elimination of a duty under the Agreement, a Moroccan product is being imported into the United States in such increased quantities and under such conditions as to be a substantial cause of serious injury or threat of serious injury to the domestic industry.

Section 311(c) defines "substantial cause" and applies factors in making determinations in the same manner as section 201 of the Trade Act of 1974.

Section 311(d) exempts from investigation under this section Moroccan articles for which import relief has been provided under this safeguard since the Agreement entered into force.

Under sections 312(b) and (c), if the ITC makes an affirmative determination, it must find and recommend to the President the amount of import relief that is necessary to remedy or prevent serious injury and to facilitate the efforts of the domestic industry to make a positive adjustment to import competition.

Under section 313(a), the President shall provide import relief to the extent that the President determines is necessary to remedy or prevent the injury found by the ITC and to facilitate the efforts of the domestic industry to make a positive adjustment to import competition.

Under section 313(b), the President is not required to provide import relief if the President determines that the relief will not provide greater economic and social benefits than costs.

Section 313(c) sets forth the nature of the relief that the President may provide as: a suspension of further reductions for the article; or an increase to a level that does not exceed the lesser of the existing NTR/MFN rate or the NTR/MFN rate imposed when the Agreement entered into force. Section 313(c)(1)(C) specifies that if a duty is applied on a seasonal basis, then the NTR/MFN rate corresponds to the immediately preceding season. Section 313(c)(2) states that if the President provides relief for greater than one

year, it must be subject to progressive liberalization at regular intervals over the course of its application.

Section 313(d) states that the import relief that the President is authorized to provide may not exceed three years. If the President determines that import relief continues to be necessary and there is evidence that the industry is making positive adjustment to import competition, then he may extend the relief, but the aggregate period of relief, including extensions, may not exceed five years.

Section 314 provides that no relief may be provided under this subtitle after five years from the date on which the United States must eliminate duties on the good at issue under the Agreement.

Section 315 authorizes the President to provide compensation to Morocco consistent with article 8.5 of the Agreement.

Section 316 provides for the treatment of confidential business information.

Reason for change

The Committee believes that it is important to have in place a temporary, extraordinary mechanism if a U.S. industry experiences injury by reason of increased import competition from Morocco in the future, with the understanding that the President is not required to provide relief if the relief will not provide greater economic or social benefits than costs. The Committee intends that administration of this safeguard be consistent with U.S. obligations under Chapter Eight (Safeguards) of the Agreement.

Subtitle B: Textile and Apparel Safeguard (Sections 321–328)

Current law

No provision.

Explanation of provision

Sections 311–316 authorize the President, after an investigation and affirmative determination by the U.S. International Trade Commission (ITC), to impose specified import relief when, as a result of the reduction or elimination of a duty under the Agreement, a Moroccan product is being imported into the United States in such increased quantities and under such conditions as to be a substantial cause of serious injury or threat of serious injury to the domestic industry.

Section 311(c) defines "substantial cause" and applies factors in making determinations in the same manner as section 201 of the Trade Act of 1974.

Section 311(d) exempts from investigation under this section Moroccan articles for which import relief has been provided under this safeguard since the Agreement entered into force.

Under sections 312(b) and (c), if the ITC makes an affirmative determination, it must find and recommend to the President the amount of import relief that is necessary to remedy or prevent serious injury and to facilitate the efforts of the domestic industry to make a positive adjustment to import competition.

Under section 313(a), the President shall provide import relief to the extent that the President determines is necessary to remedy or prevent the injury found by the ITC and to facilitate the efforts of

the domestic industry to make a positive adjustment to import competition.

Under section 313(b), the President is not required to provide import relief if the President determines that the relief will not provide greater economic and social benefits than costs.

Section 313(c) sets forth the nature of the relief that the President may provide as: a suspension of further reductions for the article; or an increase to a level that does not exceed the lesser of the existing NTR/MFN rate or the NTR/MFN rate imposed when the Agreement entered into force. Section 313(c)(1)(C) specifies that if a duty is applied on a seasonal basis, then the NTR/MFN rate corresponds to the immediately preceding season. Section 313(c)(2) states that if the President provides relief for greater than one year, it must be subject to progressive liberalization at regular intervals over the course of its application.

Section 313(d) states that the import relief that the President is authorized to provide may not exceed three years. If the President determines that import relief continues to be necessary and there is evidence that the industry is making positive adjustment to import competition, then he may extend the relief, but the aggregate period of relief, including extensions, may not exceed five years.

Section 314 provides that no relief may be provided under this subtitle after five years from the date on which the United States must eliminate duties on the good at issue under the Agreement.

Section 315 authorizes the President to provide compensation to Morocco consistent with article 8.5 of the Agreement.

Section 316 provides for the treatment of confidential business information.

Reason for change

The Committee intends that the provisions of subtitle B be administered in a manner that is in compliance with U.S. obligations under Article 4.2 of the Agreement. In particular, the Committee expects that the President will implement a transparent process that will serve as an example to our trading partners. For example, in addition to publishing a summary of the request for safeguard relief, the Committee notes that the President plans to make available the full text of the request, subject to the protection of business confidential data, on the Department of Commerce, International Trade Administration's website. In addition, the Committee encourages the President to issue regulations on procedures for requesting such safeguard measures, for making its determinations under section 322(a), and for providing relief under section 322(b).

III. VOTE OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statements are made concerning the vote of the Committee on Ways and Means in its consideration of the bill, H.R. 4842.

MOTION TO REPORT THE BILL

The bill, H.R. 4842 was ordered favorably reported by a rollcall vote of 26 yeas to 0 nays (with a quorum being present). The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas	√			Mr. Rangel	√		
Mr. Crane	√			Mr. Stark			
Mr. Shaw	√			Mr. Matsui			
Mrs. Johnson	√			Mr. Levin	√		
Mr. Houghton				Mr. Cardin			
Mr. Herger	√			Mr. McDermott			
Mr. McCrery				Mr. Kleczka			
Mr. Camp	√			Mr. Lewis (GA)	√		
Mr. Ramstad	√			Mr. Neal	√		
Mr. Nussle	√			Mr. McNulty			
Mr. Johnson	√			Mr. Jefferson			
Ms. Dunn	√			Mr. Tanner			
Mr. Collins				Mr. Becerra	√		
Mr. Portman	√			Mr. Doggett			
Mr. English	√			Mr. Pomeroy	√		
Mr. Hayworth	√			Mr. Sandlin			
Mr. Weller	√			Ms. Tubbs Jones	√		
Mr. Hulshof	√						
Mr. McInnis							
Mr. Lewis (KY)	√						
Mr. Foley	√						
Mr. Brady	√						
Mr. Ryan							
Mr. Cantor	√						

IV. BUDGET EFFECTS OF THE BILL

A. Committee Estimate of Budgetary Effects

In compliance with clause 3(d)(2) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of this bill, H.R. 4842, as reported: The Committee agrees with the estimate prepared by CBO which is included below.

B. Statement Regarding New Budget Authority and Tax Expenditures

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that enactment of H.R. 4842 would reduce customs duty receipts due to lower tariffs imposed on goods from Morocco.

C. Cost Estimate Prepared by the Congressional Budget Office

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, requiring a cost estimate prepared by the Congressional Budget Office, the following report prepared by CBO is provided.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 21, 2004.

Hon. WILLIAM "BILL" M. THOMAS,
Chairman, Committee on Ways and Means,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 4842, a bill to implement the United States-Morocco Free Trade Agreement.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Annabelle Bartsch.

Sincerely,

DOUGLAS HOLTZ-EAKIN,
Director.

Enclosure.

H.R. 4842—A bill to implement the United States-Morocco Free Trade Agreement

Summary: H.R. 4842 would approve the free trade agreement between the government of the United States and the government of Morocco that was entered into on June 15, 2004. It would provide for tariff reductions and other changes in law related to implementation of the agreement.

The Congressional Budget Office estimates that enacting the bill would reduce revenues by $5 million in 2005, by $52 million over the 2005–2009 period, and by $144 million over the 2005–2014 period, net of income and payroll tax offsets. The bill would not affect federal spending.

CBO has determined that H.R. 4842 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would not affect the budgets of state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 4842 over the 2005–2014 period is shown in the following table.

	By fiscal year, in millions of dollars—									
	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Changes in receipts	−5	−9	−11	−13	−15	−16	−18	−19	−19	−20

Basis of estimate: Under the United States-Morocco agreements, tariffs on U.S. imports from Morocco would be phased out over time. The tariffs would be phased out for individual products at varying rates according to one of several different timetables ranging from immediate elimination on January 1, 2005, to gradual elimination over 18 years. According to the U.S. International Trade Commission, the United States collected $15 million in customs duties in 2003 and $396 million of imports from Morocco. Those imports consist mostly of various types of apparel articles and produce. Based on these data, CBO estimates that phasing out tariff rates as outlined in the U.S.-Morocco agreement would reduce revenues by $5 million in 2005, by $52 million over the 2005–2009 period, and by $144 million over the 2005–2014 period, net of income and payroll tax offsets.

This estimate includes the effects of increased imports from Morocco that would result from the reduced prices of imported products in the United States, reflecting the lower tariff rates. It is likely that some of the increase in U.S. imports from Morocco would displace imports from other countries. In the absence of specific data on the extent of this substitution effect, CBO assumes that an amount equal to one-half of the increase in U.S. imports from Morocco would displace imports from other countries.

Intergovernmental and private-sector impact: The bill contains no intergovernmental or private-sector mandates as defined in UMRA and would not affect the budgets of state, local, or tribal governments.

Estimate prepared by: Federal Revenues: Annabelle Bartsch; Impact on State, Local, and Tribal Governments: Melissa Merrell; and Impact on the Private Sector: Crystal Taylor.

Estimate approved by: G. Thomas Woodward, Assistant Director for Tax Analysis.

V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. Committee Oversight Findings and Recommendations

With respect to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives (relating to oversight findings), the Committee, based on public hearing testimony and information from the Administration, concluded that it is appropriate and timely to consider the bill as reported. In addition, the legislation is governed by procedures of the Bipartisan Trade Promotion Authority Act of 2002.

B. Statement of General Performance Goals and Objectives

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill contains no measure that authorizes funding, so no statement of general performance goals and objectives for which any measure authorizes funding is required.

C. Constitutional Authority Statement

With respect to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, relating to Constitutional Authority, the Committee states that the Committee's action in reporting the bill is derived from Article 1 of the Constitution, Section 8 ("The Congress shall have power to lay and collect taxes, duties, imposts and excises, to pay the debts and to provide for * * * the general Welfare of the United States.")

D. Information Relating to Unfunded Mandates

This information is provided in accordance with section 423 of the Unfunded Mandates Act of 1995 (P.L. 104–4).

The Committee has determined that the bill does not contain Federal mandates on the private sector. The Committee has determined that the bill does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

SECTION 202 OF THE TRADE ACT OF 1974

SEC. 202. INVESTIGATIONS, DETERMINATIONS, AND RECOMMENDATIONS BY COMMISSION.

(a) PETITIONS AND ADJUSTMENT PLANS.—

(1) * * *

* * * * * * *

(8) The procedures concerning the release of confidential business information set forth in section 332(g) of the Tariff Act of 1930 shall apply with respect to information received by the Commission in the course of investigations conducted under this chapter, part 1 of title III of the North American Free Trade Agreement Implementation Act, title II of the United States-Jordan Free Trade Area Implementation Act, title III of the United States-Chile Free Trade Agreement Implementation Act, [and] title III of the United States-Singapore Free Trade Agreement Implementation Act*, and title III of the United States-Morocco Free Trade Agreement Implementation Act*. The Commission may request that parties providing confidential business information furnish nonconfidential summaries thereof or, if such parties indicate that the information in the submission cannot be summarized, the reasons why a summary cannot be provided. If the Commission finds that a request for confidentiality is not warranted and if the party concerned is either unwilling to make the information public or to authorize its disclosure in generalized or summarized form, the Commission may disregard the submission.

* * * * * * *

VII. VIEWS

ADDITIONAL VIEWS

I. LABOR

Had this agreement contained a fully enforceable provision requiring both countries to implement and enforce the five basic International Labor Organization labor standards (rights to associate and bargain collectively, prohibitions on forced labor, discrimination, and child labor), then it would have sailed through both chambers of Congress easily and without delay. Instead, the agreement includes simply an obligation for each country to enforce its own domestic law, regardless of what that law happens to say.

It is ironic that, as the U.S. aggressively pursues provisions on intellectual property rights and other areas reflecting U.S. law—which is among the most stringent in the world on those often contentious issues—that USTR will not seek provisions on labor reflecting even the basic norms that have been endorsed by virtually every country in the world.

The "enforce domestic law" standard continues to be the wrong one. And, when a country's labor laws do not meet the basic international standards, then this approach will be unacceptable.

Unfortunately, the Bush Administration continues to negotiate trade agreements including the "enforce your own law" standard, and we are forced to take an up-or-down vote on what the Bush Administration has negotiated.

While the Bush Administration has shown an ideological rigidity, pursuing the same model regardless of the realities in each country with which it negotiates, it does not make sense for us to take the same cookie-cutter approach. We need to look at the facts on the ground in each country to examine how the provisions in each agreement will operate in practice and to ensure that the trade agreement will not force U.S. workers, farmers and businesses to compete with firms whose competitive advantage is the suppression of labor.

As a result, we were left with the difficult task of closely scrutinizing Morocco's labor laws to see how they match up against the basic ILO standards, and of examining Morocco's commitment to respect the basic rights of its workers. This scrutiny was made more complex by the fact that Morocco just adopted major reforms in July 2003, which went into effect only in June of this year.

We note the following facts:

• There is an active union movement in Morocco, with five major national union federations. Additionally, there is a tradition in Morocco of sector-level collective bargaining.

• These aspects of Morocco's labor situation are attributable in part to the fact that Morocco inherited a socialist-leaning labor law and industrial structure from France. They are also attributable in part to the fact that Morocco's unions played an important role in Morocco's independence movement.
• Prior to July 2003, Moroccan law had notable deficiencies in its law relative to the five basic ILO standards.
• In 2003, Morocco undertook a major "social dialogue" involving the Government of Morocco, representatives from the business community, and representatives from the major Moroccan union federations.
• This "social dialogue" resulted in the adoption of major labor law reforms in July 2003, which reflected a common agreement of and were endorsed by all three groups—government, business and labor. The law came into effect in June 2004.
• There was also a "tripartite agreement" in July 2003, which included a commitment for additional reforms related to the right to strike (also following the government-business labor structure of the "social dialogue").
• The July 2003 reforms constitute a major, not cosmetic, change in Morocco's laws. Many of the reforms were aimed specifically at correcting previously-existing inconsistencies between Morocco's labor laws and the basic ILO standards. Morocco received support from the ILO in crafting these reforms.
• Among numerous other reforms, Morocco made anti-union and other forms of discrimination illegal; provided strong penalties against such conduct; created a legal obligation to engage in collective bargaining; prohibited interference in union activities; eliminated a rule requiring mandatory arbitration that had limited the ability to strike; disciplined the use of temporary contracts, which had previously been used to evade worker rights; and prohibited retaliation by employers against workers engaged in legitimate strikes.
• Morocco's labor ministry and judicial system have played a fairly active and generally constructive role in resolving labor disputes in Morocco.
• Morocco has worked with the ILO on various issues (particularly child labor) for several years now, and has expressed a willingness to work with the ILO on implementation and enforcement of its new labor laws.
• Morocco's independent union movement has come out in support of the FTA.

In the past, Morocco has been criticized for using criminal sanctions (under Article 288 of its Penal Code) against legitimate strikers. We note that Morocco is still working on reforms to the right to strike. The Government of Morocco has committed to reforming Article 288 and to using the same "social dialogue" model on the negotiations over new rules on the right to strike, meaning any changes will receive the endorsement of the labor unions in Morocco. In response to our inquiries, the Government of Morocco also committed in a letter dated July 14, 2004 as follows:

> The government of Morocco is committed to protecting the right to strike in conformance with the International Labor Organization's core principles. In particular, the

> government will not use Article 288 of our penal code against lawful strikers.

The Government of Morocco, to its credit, has shown an up front openness and honesty about the situation in its country and a willingness to work with us to address our concerns. The letter provided by Morocco (which was made a part of the record of the Committee's mark-up proceedings and is attached to these Additional Views) committed to implement provisions of its law consistent with the ILO core labor standards and to seek the ILO's assistance in this regard:

> On the ILO involvement, Morocco has always worked with the ILO. For instance, the ILO assisted Morocco to write the Labor Code of 2003 and the new law on child labor. Morocco, as in the past, will continue to ask the support of ILO and work with this organization in all labor issues such as new laws and will ask its help in providing assistance for the implementation of the current rules.

In light of the major reforms of July 2003—which addressed flaws in Morocco's labor laws relative to the ILO standards, which were negotiated with the full participation and ultimate endorsement of Morocco's independent labor movement, and which were based in many cases on the advice of the ILO; in light of the history and situation in Morocco; in light of Morocco's commitment to implement its laws consistent with ILO core labor standards; we believe that the situation with respect to labor rights in Morocco appears strong enough to implement and assure the internationally-recognized labor standards, leading to fair competition and the steady development of a substantial middle class for the benefit of Morocco and as a market for U.S. goods and services.

II. ACCESS TO MEDICINES

While we support this Agreement, we were concerned about sections of this Agreement (as well as other recently-negotiated U.S. free trade agreements (FTAs)) that affect the availability of affordable drugs in developing countries. In particular, we were concerned about the impact of restrictions on parallel imports and about test data requirements for pharmaceuticals included in the Morocco FTA. At stake are the health needs of Morocco's citizens, and we were determined to explore and clarify whether some of the provisions could undermine, 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). The Doha Declaration re-affirmed that the TRIPS Agreement does not prevent WTO Members from taking measures to protect public health, including measures aimed at promoting the availability of medicines, and identified specific provisions within the TRIPS Agreement that provide flexibility for that purpose. Among the flexibilities identified were the right of countries to issue compulsory licenses to increase access to medicines (and to decide for themselves the grounds on which such licenses could be issued),

and the right of countries to decide whether to allow parallel importation of medicines. Section 2102(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.

We raised concerns in this area with USTR at both the Committee's mock mark-up and official mark-up, as well as in a July 15, 2004 letter to Ambassador Zoellick (the July 15 letter is attached to these Additional Views). USTR's verbal responses, and the July 19 written response to the July 15 letter from four Members (the July 19 USTR letter is attached to these Additional Views), as well as clarifications from the Embassy of the Kingdom of Morocco (the letter from Morocco dated July 19 is attached to these Additional Views), provide helpful clarification on some of the issues raised. For example, in its July 19 response, USTR makes clear that Article 15.9.6 (the "Bolar exception") does not preclude Morocco from exporting generic versions of patented drugs to least developed countries and certain other countries under the Paragraph 6 Decision. USTR also makes clear in its July 19 response that the United States "has no intention" of bringing a dispute settlement case against countries that act in accordance with the Paragraph 6 Decision.

That said, and as discussed in greater detail below, USTR needs to make explicit in future trade agreements with developing countries like Morocco that intellectual property protections for pharmaceutical products (including protections in the investment chapter of such FTAs) can be waived, so long as a country acts to effectuate its right to protect public health. USTR's July 19 letter and answers at both mark-ups seem to suggest that the Morocco Agreement's side letters on public health create such an exception. That clarification is helpful in considering whether to support the Morocco FTA; however, the exception needs to be explicit from the outset and in the basic content of future trade agreements with developing countries.

Remaining Concerns

(1) Restrictions on Parallel Imports

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. (We note that 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.)

With respect to Morocco, the provision appears to limit one of the flexibilities identified in the Doha Declaration, which left it up to each country to determine for itself what policy on parallel imports to adopt. Accordingly, one could argue that this provision in an

FTA with a developing country contradicts the direction in section 2102(b)(4)(c) of TPA to respect the Doha Declaration.

We note that Morocco's domestic law already prohibited parallel imports prior to negotiation of the FTA (as does U.S. law). That fact, however, is not dispositive of whether it is appropriate to include an absolute restriction on parallel importation in an FTA with a developing country. Given that the Doha Declaration recognized parallel imports as potential way for a developing country to address a public health problem, USTR should have allowed Morocco to preserve its flexibility on this point.

The Ambassador of Morocco, in the July 19 letter to Committee Members, indicates that the Government of Morocco believes that it retains sufficient flexibility to address public health issues, even absent recourse to parallel imports. In particular, the Ambassador notes that Morocco has a well developed pharmaceutical industry, and that domestic demand for medicines could be satisfied through compulsory licensing. With this explanation from the Embassy, we believe that the impact of the parallel import restriction, in the case of Morocco, is likely to be minimal. Moreover, we assume that the exception created by the side letters for "necessary measures to protect public health" apply to this restriction as well. (More on this point below.)

That said, we remain concerned about inclusion of such provisions in future trade agreements. In this regard, it is important that in its July 19 letter, USTR indicates that it would not seek such provisions with developing countries that do not already prohibit parallel imports.

(2) Test Data Provisions

Articles 15.10.1, 15.10.2. and 15.10.03 of the FTA require the United States and Morocco to protect certain test data submitted to obtain regulatory marketing approval of a drug. The provisions operate as follows: if a government requires submission of test data in order to obtain marketing approval for a drug (e.g., FDA approval), the government may not allow any other company to use these test data as the basis of obtaining marketing approval for a similar drug for a period of 5 years. The company first submitting the data has the right to prevent anyone else from using those data to enter the market for that period. Test data rights are separate and distinct from patent rights, and can exist for drugs not covered by a patent.

The key issue raised by the test data requirements in the Agreement is whether they can be waived if Morocco wants to approve a producer other than the test data owner to produce and sell a drug in Morocco during the test data protection period. An example may be helpful to illustrate the issue.

> Assume Morocco decides that it needs to increase the supply of HIV/AIDS Drug X in its market. Drug Company A owns the patent on Drug X, and also is the only producer to have obtained marketing approval for Drug X in the Moroccan market. If Morocco is unable to convince Drug Company A to produce more of Drug X at a reasonable price, Morocco could issue a compulsory license to another drug manufacturer, Drug Company B. However, the

compulsory license, which is allowed under the FTA, is an exception only for the patent rights related to Drug X. The compulsory license does not affect Drug Company A's right to prevent any other company from receiving marketing approval for Drug X based on the data it submitted.

(The above analysis applies if Drug X is not covered by a patent. The only difference is that Morocco would not need to issue a compulsory license.)

The Intellectual Property Chapter of the Agreement (Chapter 15) does not include any specific exceptions that would allow Morocco to waive the test data requirements to address a public health need. As such, our concern was that the test data requirements could effectively undermine Morocco's ability to use compulsory licenses. (Morocco could license the drug for production, but not for sale.) As such, we believed that language in the FTA violated at least the spirit of the Doha Declaration, because the key flexibility identified in that Declaration was the ability of developing countries to use compulsory licensing to "protect public health" and "promote access to medicines for all."

In its July 19 letter, USTR responded to our concerns in a way that provides some comfort. Specifically, in its July 19 letter, USTR stated that "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." USTR stated that it based this conclusion on side letters to the FTA. USTR does not explicitly say that the side letters should be read as a blanket exception to the obligations in the Intellectual Property Chapter. That said, their response—"the FTA would not stand in the way"—suggests that it is such an exception. (USTR provides a similar answer where the drug in question is not covered by a patent.) USTR confirmed the view that the side letters create an exception in an answer to a question at the official Committee mark-up. This means that Morocco can waive test data requirements in certain circumstances, based on the side letters.

The portion of the side letters on which USTR relies for this interpretation state, in relevant part, that "[t]he obligations of [the Intellectual Property Chapter] do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all * * * ." We appreciate USTR's clarification as to how this language in the side letters should be interpreted. That said, we continue to believe that the side letters are not sufficiently clear as to whether they provide an exception. To the contrary, absent USTR's July 19 clarification and USTR's answer at the mark-up, the language could have been misinterpreted as a description of the chapter, rather than an exception to the chapter.

To eliminate any ambiguity in the future, USTR must make the exception explicit in the text itself of future agreements.

(3) Test Data Provisions and Investment

We also remain concerned that other provisions in the Agreement appear to make it more complicated and costly for Morocco

to waive the test data requirements. In particular, the Investment Chapter of the FTA (Chapter 10) treats intellectual property, including potentially test data, as an "investment." This means that if Morocco were found to have "expropriated" the intellectual property of a U.S. company, including potentially by waiving test data protections, the U.S. company might be entitled to compensation for the "expropriation." This would significantly increase the cost to Morocco of taking such actions.

In its July 19 response, USTR states that the Investment Chapter has a broad exception for measures related to intellectual property rights that are consistent with the intellectual property provisions of the Agreement. USTR goes on to state that "a determination concerning the consistency of an action with [the intellectual property provisions] would be informed by the side letter." This suggests that waiver of the test data requirements to meet a public health need would fall within that exception.

We believe that the exception in the Investment Chapter should be more explicit for three reasons. First, the Government of Morocco likely faces more "exposure" to potential causes of action under the Investment Chapter than under the Intellectual Property Chapter. Unlike the Intellectual Property Chapter, the Investment Chapter gives private companies the ability to sue the Government of Morocco directly for compensation (i.e., investor-state arbitration). Private cases tend to be more easily brought than cases by a government. Second, investor-state arbitration decisions cannot be appealed (despite direction in TPA for an appellate mechanism). Therefore, if an arbitration panel decided that the side letters do not create a clear exception for measures to protect the public health, and the panel required Morocco to provide compensation for waiver of test data requirements related a drug, nothing could be done to appeal that decision. Third, this threat of liability for compensation could have a chilling impact on Morocco taking action to promote access to medicines.

USTR's clarification that the side letter exception should apply to defend a claim of expropriation of test data consistent with the side letter exception, however, does provide sufficient clarity in the context of this Agreement. That said, the clarification should be explicit in future agreements.

III. WESTERN SAHARA ISSUE

In 1975, Morocco annexed Western Sahara, which it now claims as its own territory. This claim is not considered legitimate by the United Nations or the United States, although the United States recognizes Morocco's administrative control over Western Sahara. The United States is supportive of a 2003 United Nations plan to allow a referendum in Western Sahara, which would allow its inhabitants (the Saharawis) to vote on whether to become part of the sovereign Kingdom of Morocco or become an independent, sovereign state. The Saharawis have agreed to the United Nations proposal but the Moroccan government has not; as such progress on resolving the status of this disputed territory has halted. Although the U.S.-Moroccan Free Trade Agreement does not apply to trade and investment in Western Sahara, we encourage the President to use opportunities created by the Agreement to expeditiously pursue a

settlement of the issue of sovereignty in Western Sahara. In no way should this agreement be used to advance Morocco's legal claim to Western Sahara or deepen its economic engagement in this disputed territory.

SANDER LEVIN.
XAVIER BECERRA.
MAX SANDLIN.
STEPHANIE TUBBS JONES.
JOHN LEWIS.
CHARLES B. RANGEL.
ROBERT T. MATSUI.
JIM MCDERMOTT.
RICHARD NEAL.
EARL POMEROY.

EMBASSY OF THE KINGDOM OF MOROCCO,
Washington, DC, July 14, 2004.

Hon. SANDY LEVIN,
Rayburn House Office Building,
Washington, DC.

DEAR CONGRESSMAN LEVIN: I have deeply appreciated the continuing opportunity to work with you on the U.S. Morocco Free Trade Agreement. In particular, I welcome your interest in our nation's labor law, specifically the comprehensive reforms, passed last year.

I want to address through this letter some of the issues that have been highlighted in conversations with you and your staff. Under Moroccan law, it is illegal to fire an individual because they are a member of a labor organization or have engaged in labor organizing. To fire someone on these grounds would be arbitrary under the 2003 law and would make available the full remedies provided under that law.

Under Moroccan law, it is illegal to refuse to hire an individual because they are a member of a labor organization or have engaged in labor organizing It is also illegal to refuse to rehire or extend the contract of an individual for these reasons.

Section 473 is a provision is the 2003 Labor Law and the provision's intent is to ensure that labor representatives do not undermine the traditional labor organizations. The government intends to implement this provision to achieve that goal consistent with the core provisions of the ILO.

The right to strike is protected in the Moroccan constitution. Further clarification of these rights is underway. The government of Morocco is committed to protecting the right to strike in conformance with the International Labor Organization's core principles. In particular, the government of Morocco will not use Article 288 of our penal code against lawful strikers.

Concerning the questions regarding Labor Representatives, employers have the obligation to organize the elections for the labor representatives. Employers cannot vote in these elections and are not able to choose labor representatives. Only employees can vote and elect freely the labor representatives.

Employees can join freely the Union of their own choice. Unions designate their representatives within the companies.

On the ILO involvement, Morocco has always worked with ILO. For instance, ILO assisted Morocco to write the Labor Code of 2003 and the new law on child labor. Morocco, as in the past, will continue to ask the support of ILO and work with this organization in all labor issues such as new laws and will ask its help in providing assistance for the implementation of the current rules.

I look forward to continuing to work with you on these issues and any others of potential concern. Nevertheless, I wanted to get

back to you in a timely manner on the key issues addressed in this letter.

Sincerely,

AZIZ MEKOUAR,
Ambassador.

CONGRESS OF THE UNITED STATES,
HOUSE OF REPRESENTATIVES,
Washington, DC, July 15, 2004.

Hon. ROBERT B. ZOELLICK,
U.S. Trade Representative,
Washington, DC.

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/ADS, 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 provi-

sion 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 of the person submitting such data, for a period of five years from the date of approval.[2] 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

[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.

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

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 "piggyback" 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?
- 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 clam 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

[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.

under the Paragraph 6 Decision, the United States could be accused of backtracking on commitments that have been made.

• 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.
JIM MCDERMOTT,
Member, Committee on Ways and Means.
SANDER LEVIN
Ranking Democrat, Subcommittee on Trade, Committee on Ways and Means.
HENRY A. WAXMAN,
Ranking Democrat, Committee on Government Reform.

EXECUTIVE OFFICE OF THE PRESIDENT,
OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE,
Washington, DC, July 19, 2004.

Hon. SANDER M. LEVIN,
House of Representatives,
Washington, DC.

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-Taxman 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 provioed in the Trade Act or 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 sup-

ported 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 pat-

ent 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 doe 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 accord-

ance 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,

JOHN K. VERONEAU,
General Counsel.

EMBASSY OF THE KINGDOM OF MOROCCO,
Washington, DC, July 19, 2004.

HON. SANDY LEVIN,
Rayburn House Office Building,
House of Representatives.

DEAR REPRESENTATIVE LEVIN: I deeply appreciate the opportunity to work with you on the U.S. Morocco Free Trade Agreement. In particular, I appreciate the opportunity to talk to you about the pharmaceutical provisions in the Free Trade Agreement, and about how the Government of Morocco is meeting the health needs of its citizens.

The Government of Morocco has a well-developed health system, including a comprehensive public health program. For example, free medical care, including medicines, is available through our hospitals. Morocco's health care policy includes a strong emphasis on generic drugs.

Morocco has not needed to engage in emergency measures such as compulsory licensing or parallel imports. In fact, there is a well-developed domestic pharmaceutical industry in Morocco, producing also generics, and in 2000, well in advance of the Free Trade Agreement and completely independent of it, Morocco decided to bar parallel imports.

In addition, as a separate, but quite important matter, the Government of Morocco is strongly committed to and has agreed to the highest-standard intellectual property rights provisions in the Free Trade Agreement. The Government of Morocco believes that effective intellectual property right protection will play a vital role in the continued economic development of our country.

The pharmaceutical provisions in the Free Trade Agreement were carefully considered in Morocco. They were discussed in detail with all parties. All sectors of our health system were involved, including the pharmaceutical industry. The discussions also included the members of the civil society in Morocco.

The Government of Morocco achieved in this agreement full flexibility to meet our nation's health concerns. In particular, the Government of Morocco believes the agreement fully preserves its right to issue a compulsory license in the event that this should prove necessary.

The Agreement does bar "parallel imports" in 1.5.9.4. However, as described above, the Government of Morocco already bans "parallel imports." In addition, the Government of Morocco believes that in the event that it faced a situation where extraordinary action was required, it could meet the needs of its people through a compulsory license.

The Government of Morocco considered carefully the data exclusivity provisions in the agreement. We do not believe that they present any risk to our ability to meet the health needs of our citizens.

Under the Agreement, a compulsory license does not override obligations to provide data exclusivity under 15.10.1 and 2. The Government of Morocco believes it is unlikely that a situation would ever arise where data exclusivity would be a barrier to the issuance of a compulsory license. If such an event did occur, the Government of Morocco believes that an accommodation could be reached with the owner of the data.

The Government of Morocco supports the Paragraph 6 solution of the Doha Declaration. The Free Trade Agreement does not restrict our ability to export under the Paragraph 6 solution of the Doha Declaration. To the specific, 15.9.6 does not create a barrier to exports under the Paragraph 6 solution of the Doha Declaration.

The June 15, 2004 side letter between our two countries addresses the ability to amend the Free Trade Agreement, responsive to amendments to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights. Under the Agreement, the Government of Morocco believes it can consult immediately to amend the Agreement responsive to any WTO amendments. Under the Agreement, it is not required to wait for there to be an application in dispute of the Agreement.

I look forward to keep working with you.

Sincerely,

AZIZ MEKOUAR,
Ambassador.

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