

September 10, 1997

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC 20436

MEMORANDUM TO THE COMMITTEE ON WAYS AND MEANS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES ON PROPOSED TARIFF LEGISLATION¹

Bill no., sponsor, and sponsor's state: H.R. 2047 (105th Congress), Representative Matsui (CA).

Companion bill: None.

Title as introduced:² To suspend temporarily the duty on the production of anti-HIV/anti-AIDS drugs.

Summary of bill:³

Temporarily suspends the column 1 rate of duty for U.S. imports of (S-(R*,R*))⁻2,3-dihydroxybutanedioic acid through December 31, 2000. The bill would amend subchapter II of chapter 99 of the HTS by adding, in numerical sequence, provision for free entry for imports of this chemical from countries entitled to most-favored-nation (MFN) treatment.

Effective date: 15th day after enactment.

Retroactive effect: None.

Statement of purpose:

Representative Matsui made no statement in the *Congressional Record* at the time this legislation was introduced. However, according to a spokesman for the company requesting this legislation, this chemical intermediate is being considered in the development of a new, more efficient, production route for nelfinavir, a newly-developed HIV protease inhibitor that recently received FDA approval.⁴

¹ Industry analyst: Rob Randall (205-3366); attorney: Leo Webb (205-2599).

² See Technical Comments.

³ See appendix A for definitions of tariff and trade agreement terms.

⁴ Facsimile communication from Robert A. Shapiro, Counsel to Agouron Pharmaceuticals, Inc., July 30, 1997.

Product description and uses:

(S-(R*,R*)))-2,3-dihydroxybutanedioic acid:

This chemical, commonly known as D-tartaric acid, is an isomer of L-tartaric acid which is found in grapes. This intermediate chemical is intended for use in developing a new, more efficient manufacturing route to nelfinavir, a recently approved anti-HIV protease inhibitor drug.

There is confusion in chemical nomenclature and identity surrounding isomers of tartaric acid. For example, D-tartaric acid is also known as l-tartaric acid, while L-tartaric acid is also known as d-tartaric acid. The USITC's search of the Beilstein database turned up 5 CAS registry numbers in addition to 147-71-7. Tracing those additional CAS numbers through the Chemical Abstracts database turned up 2 additional numbers. The Merck Index, Eighth Edition, indicates that what is sold commercially in the United States as D-tartaric acid is invariably actually L-tartaric acid.

Tariff treatment:⁵

<u>Product</u>	<u>HTS subheading</u>	<u>Col. 1-general rate of duty</u>
(S-(R*,R*)))-2,3-dihydroxybutanedioic acid	2918.12.00 ⁶	Free

Structure of domestic industry (including competing products):

(S-(R*,R*)))-2,3-dihydroxybutanedioic acid:

There is no known domestic production of this chemical; therefore all necessary quantities must be imported.

Protease inhibitors are a new class of anti-HIV/anti-AIDS drugs that are generally used in conjunction with other drugs for a more effective therapeutic package. Producers of protease inhibitors, other than Agouron, include Merck (indinavir, sold under the trade name Crixivan), Abbott Laboratories (ritonavir, sold under the trade name Norvir), and Hoffmann-LaRoche (saquinavir).

Private-sector views:

⁵ See appendix B for column 1-special and column 2 duty rates.

⁶ See Technical Comments.

The Commission contacted three companies that produce protease inhibitors (the product category made from the subject chemical intermediate).⁷ No written responses had been received by the Commission at the time of preparation of this report.

U.S. consumption:

(S-(R*,R*)))-2,3-dihydroxybutanedioic acid: ⁸	<u>1994</u>	<u>1995</u>	<u>1996</u>
U.S. production.....	0	0	0
U.S. imports.....	0	0	0
U.S. exports.....	0	0	0
Apparent U.S. consumption.....	0	0	0

Principal import sources: Japan.
Principal export markets: None.

Effect on customs revenue:⁹

Future (1998-2000) effect: The product already being duty-free under HTS 2918.12.00, there would be no loss of revenue from imports in future years.
Retroactive effect: None.

Technical comments:

The title of the legislation should be modified to reflect the temporary suspension of the duty on a chemical intermediate intended to be used to produce the finished therapeutic agent. A suggested title would be: "To suspend temporarily the duty on a chemical intermediate intended to be used in the production of anti-HIV/anti-AIDS drugs."

Inasmuch as Customs has ruled that (S-(R*,R*)))-2,3-dihydroxybutanedioic acid is classified in HTS 2918.12.00, which is already duty-free, this legislation would appear to be unnecessary.

⁷ Staff telephone conversations August 1, 1997, with Rosemary Hobbs, Abbott Laboratories; Linda Distilrath, Merck; and Ed Desmond, Hoffmann-LaRoche.

⁸ All information in this section was provided by the proponent of this legislation.

⁹ Actual revenue loss may be understated in the event of a significant increase in imports over the duty suspension period. The proponent is seeking inclusion of this chemical in the Pharmaceutical Appendix from 1999. If successful, this would reduce the revenue loss to zero in 1999 and thereafter. The estimates in this section are based on information provided by the proponent.

APPENDIX A

TARIFF AND TRADE AGREEMENT TERMS

In the **Harmonized Tariff Schedule of the United States** (HTS), chapters 1 through 97 cover all goods in trade and incorporate in the tariff nomenclature the internationally adopted Harmonized Commodity Description and Coding System through the 6-digit level of product description. Subordinate 8-digit product subdivisions, either enacted by Congress or proclaimed by the President, allow more narrowly applicable duty rates; 10-digit administrative statistical reporting numbers provide data of national interest. Chapters 98 and 99 contain special U.S. classifications and temporary rate provisions, respectively. The HTS replaced the **Tariff Schedules of the United States** (TSUS) effective January 1, 1989.

Duty rates in the **general** subcolumn of HTS column 1 are most-favored-nation (MFN) rates, many of which have been eliminated or are being reduced as concessions resulting from the Uruguay Round of Multilateral Trade Negotiations. Column 1-general duty rates apply to all countries except those enumerated in HTS general note 3(b) (Afghanistan, Cuba, Laos, North Korea, and Vietnam), which are subject to the statutory rates set forth in **column 2**. Specified goods from designated MFN-eligible countries may be eligible for reduced rates of duty or for duty-free entry under one or more preferential tariff programs. Such tariff treatment is set forth in the **special** subcolumn of HTS rate of duty column 1 or in the general notes. If eligibility for special tariff rates is not claimed or established, goods are dutiable at column 1-general rates. The HTS does not enumerate those countries as to which a total or partial embargo has been declared.

The **Generalized System of Preferences** (GSP) affords nonreciprocal tariff preferences to developing countries to aid their economic development and to diversify and expand their production and exports. The U.S. GSP, enacted in title V of the Trade Act of 1974 for 10 years and extended several times thereafter, applies to merchandise imported on or after January 1, 1976 and before the close of June 30, 1998. Indicated by the symbol "A", "A*", or "A+" in the special subcolumn, the GSP provides duty-free entry to eligible articles the product of and imported directly from designated beneficiary developing countries, as set forth in general note 4 to the HTS.

The **Caribbean Basin Economic Recovery Act** (CBERA) affords nonreciprocal tariff preferences to developing countries in the Caribbean Basin area to aid their economic development and to diversify and expand their production and exports. The CBERA, enacted in title II of Public Law 98-67, implemented by Presidential Proclamation 5133 of November 30, 1983, and amended by the Customs and Trade Act of 1990, applies to merchandise entered, or withdrawn from warehouse for consumption, on or after January 1, 1984. Indicated by the symbol "E" or "E*" in the special subcolumn, the CBERA provides duty-free entry to eligible articles, and reduced-duty treatment to certain other articles, which are the product of and imported directly from designated countries, as set forth in general note 7 to the HTS.

Free rates of duty in the special subcolumn followed by the symbol "IL" are applicable to products of Israel under the **United States-Israel Free Trade Area Implementation Act** of 1985 (IFTA), as provided in general note 8 to the HTS.

Preferential nonreciprocal duty-free or reduced-duty treatment in the special subcolumn followed by the symbol "J" or "J*" in parentheses is afforded to eligible articles the product of designated beneficiary countries under the **Andean Trade Preference Act** (ATPA), enacted as title II of Public Law 102-182 and implemented by Presidential Proclamation 6455 of July 2, 1992 (effective July 22, 1992), as set forth in general note 11 to the HTS.

Preferential or free rates of duty in the special subcolumn followed by the symbol "CA" are applicable to eligible goods of Canada, and rates followed by the symbol "MX" are applicable to eligible goods of Mexico, under the **North American Free Trade Agreement**, as provided in general note 12 to the HTS and implemented effective January 1, 1994 by Presidential Proclamation 6641 of December 15, 1993. Goods must originate in the NAFTA region under rules set forth in general note 12(t) and meet other requirements of the note and applicable regulations.

Other special tariff treatment applies to particular **products of insular possessions** (general note 3(a)(iv)), **products of the West Bank and Gaza Strip** (general note 3(a)(v)), goods covered by the **Automotive Products Trade Act (APTA)** (general note 5) and the **Agreement on Trade in Civil Aircraft (ATCA)** (general note 6), **articles imported from freely associated states** (general note 10), **pharmaceutical products** (general note 13), and **intermediate chemicals for dyes** (general note 14).

The **General Agreement on Tariffs and Trade 1994** (GATT 1994), pursuant to the Agreement Establishing the World Trade Organization, is based upon the earlier GATT 1947 (61 Stat. (pt. 5) A58; 8 UST (pt. 2) 1786) as the primary multilateral system of disciplines and principles governing international trade. Signatories' obligations under both the 1994 and 1947 agreements focus upon most-favored-nation treatment, the maintenance of scheduled concession rates of duty, and national treatment for imported products; the GATT also provides the legal framework for customs valuation standards, "escape clause" (emergency) actions, antidumping and countervailing duties, dispute settlement, and other measures. The results of the Uruguay Round of multilateral tariff negotiations are set forth by way of separate schedules of concessions for each participating contracting party, with the U.S. schedule designated as Schedule XX.

Pursuant to the **Agreement on Textiles and Clothing (ATC)** of the GATT 1994, member countries are phasing out restrictions on imports under the prior "Arrangement Regarding International Trade in Textiles" (known as the **Multifiber Arrangement (MFA)**). Under the MFA, which was a departure from GATT 1947 provisions, importing and exporting countries negotiated bilateral agreements limiting textile and apparel shipments, and importing countries could take unilateral action in the absence or violation of an agreement. Quantitative limits had been established on imported textiles and apparel of cotton, other vegetable fibers, wool, man-made fibers or silk blends in an effort to prevent or limit market disruption in the importing countries. The ATC establishes notification and safeguard procedures, along with other rules concerning the customs treatment of textile and apparel shipments, and calls for the eventual complete integration of this sector into the GATT 1994 over a ten-year period, or by Jan. 1, 2005.

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APPENDIX B

**SELECTED PORTIONS OF THE
HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES**

(Appendix not included in the electronic version of this report.)

105TH CONGRESS
1ST SESSION

H. R. 2047

To suspend temporarily the duty on the production of anti-HIV/anti-AIDS drugs.

IN THE HOUSE OF REPRESENTATIVES

JUNE 25, 1997

Mr. MATSUI introduced the following bill; which was referred to the Committee on Ways and Means

A BILL

To suspend temporarily the duty on the production of anti-HIV/anti-AIDS drugs.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. TEMPORARY SUSPENSION OF DUTY.**

4 (a) IN GENERAL.—Subchapter II of chapter 99 of
5 the Harmonized Tariff Schedule of the United States is
6 amended by inserting in numerical sequence the following
7 new heading:

“	9902.32.23	[S-(R*,R*)]- 2,3-dihydroxy- Butanedioic acid (CAS No. 147-71- 7)(provided for in subheading 2918.19.90)	Free	No change	No change	On or before 12/31/2000	”.
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1 (b) EFFECTIVE DATE.—The amendment made by
2 this section applies with respect to goods entered, or with-
3 drawn from warehouse for consumption, on or after 15th
4 day after the date of the enactment of this Act.

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