

September 2, 1998

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC 20436

MEMORANDUM TO THE COMMITTEE ON FINANCE OF THE UNITED STATES
SENATE ON PROPOSED TARIFF LEGISLATION¹

Bill no., sponsor, and sponsor's state: S. 2399 (105th Congress), Senator Moseley-Braun (IL).

Companion bill: None.

Title as introduced:

To suspend temporarily the duty on certain drug substances used as an HIV antiviral drug.

Summary of bill:^{2,3}

The bill would temporarily suspend the column 1-general rate of duty on U.S. imports of four chemicals entered or withdrawn from warehouse for consumption, on or before June 30, 1999.

Effective date: 15th day after enactment.

Retroactive effect: None.

Statement of purpose:

Senator Moseley-Braun stated in the *Congressional Record* that she introduced this bill because the subject chemicals are used in the production of protease inhibitors, which are important components of a "cocktail" treatment for the HIV virus. She noted that by eliminating the duty on imports of the precursor chemicals for protease inhibitors, the cost of the drug therapy would be lowered; this is particularly important given the high dosages of these drugs that are required for effective treatment of AIDS patients.⁴

¹ Industry analyst: Elizabeth Howlett (205-3365); attorney: Leo Webb (205-2599).

² See appendix A for definitions of tariff and trade agreement terms.

³ See technical comments.

⁴ Statement of Senator Moseley-Braun, *Congressional Record*, July 31, 1998, pp. S-9560.

Product description and uses:

(S)-N-tert-Butyl-
1,2,3,4-tetrahydro-
isoquinoline-

3-carboxamide: This synthetic organic chemical, abbreviated TIC-C, is used in the production of two pharmaceutical products, Saquinavir® and Nelfinavir®, which are protease inhibitors used in the treatment of AIDS.

(S)-N-tert-Butyl-
1,2,3,4-tetrahydro-
isoquinoline-
3-carboxamide hydro-

chloride salt: This synthetic organic chemical, the hydrochloride salt of TIC-C, is used in the production of two pharmaceutical products, Saquinavir® and Nelfinavir®, which are protease inhibitors used in the treatment of AIDS.

(S)-N-tert-Butyl-1,2,3,4-
tetrahydroisoquinoline-3-
carboxamide

sulfate salt: This synthetic organic chemical, the sulfate salt of TIC-C, is used in the production of two pharmaceutical products, Saquinavir® and Nelfinavir®, which are protease inhibitors used in the treatment of AIDS.

(3S)-1,2,3,4-Tetrahydro-
isoquinoline-3-

carboxylic acid: This synthetic organic chemical, abbreviated TIC-A, is used in the production of three pharmaceutical products, Saquinavir®, Quinapril®, and Nelfinavir®, which are protease inhibitors used in the treatment of AIDS.

Tariff treatment:⁵

<u>Product</u>	<u>HTS subheading</u>	<u>Col. 1-general rate of duty</u>
(S)-N-tert-Butyl-1,2,3,4-tetrahydro- isoquinoline-3-carboxamide.....	2933.40.60	Free. ⁶
(S)-N-tert-Butyl-1,2,3,4-tetrahydroisoquinoline- 3-carboxamide hydrochloride salt.....	2933.40.60	10.7% ad valorem.
(S)-N-tert-Butyl-1,2,3,4-tetrahydroisoquinoline- 3-carboxamide sulfate salt.....	2933.40.60	10.7% ad valorem.

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

⁶ This product is currently listed on Table 3 of the Pharmaceutical Appendix to the HTS and therefore may be imported free of duty under the “K” rate of duty; i.e., under the Agreement on Trade in Pharmaceutical Products.

(3S)-1,2,3,4-Tetrahydroisoquinoline-3-carboxylic acid..... 2933.40.60 10.7% ad valorem.

Structure of domestic industry (including competing products):

All chemicals: During 1995-97, there were no known domestic producers of commercial quantities of these four chemicals. However, there are domestic producers of other protease inhibitors used to treat AIDS which may be considered by the producing companies to be in competition with the finished pharmaceutical products manufactured with the subject chemicals.

Private-sector views:

Most pharmaceutical chemicals, including finished products, active ingredients, and intermediates used solely in the production of drug products, are afforded duty-free entry to the United States under the WTO Pharmaceutical Agreement. Three of the subject chemicals are currently being considered for inclusion on the list of approved items covered by this agreement, also referred to as the Pharmaceutical Appendix; however, a decision on these three chemicals is not expected to become effective until mid-1999.⁷ The list of proposed additions to the Pharmaceutical Appendix has been circulated among domestic chemical companies for their review. According to industry sources,⁸ at this time there has been no objection to the proposed elimination of duties on these products.

U.S. consumption:

All chemicals:	<u>1995</u>	<u>1996</u>	<u>1997</u>
	-----(\$million)-----		
U.S. production.....	(1)	(1)	(1)
U.S. imports.....	(1)	(1)	(1)
U.S. exports.....	(1)	(1)	(1)
Apparent U.S. consumption.....	(1)	(1)	(1)

¹Not available.

Principal import sources: India.
Principal export markets: Not available.

⁷ The fourth chemical is already listed in the Pharmaceutical Appendix to the HTS.
⁸ A conversation with a representative of the Pharmaceutical Researchers and Manufacturers of America (PhRMA) on April 15, 1998.

Effect on customs revenue:⁹

Future (1998-99) effect: The projected average annual revenue loss for three¹⁰ of these four chemicals is anticipated to be less than \$450,000 during the period covered by this bill.¹¹

Retroactive effect: None.

Technical comments:

The recommended names for the subject chemicals are:

(S)-N-tert-butyl-1,2,3,4-tetrahydroisoquinoline-3-carboxamide (CAS No. 149182-72-9);

(S)-N-tert-butyl-1,2,3,4-tetrahydroisoquinoline-3-carboxamide hydrochloride salt (CAS No. 149057-17-0); and

(S)-N-tert-butyl-1,2,3,4- tetrahydroisoquinoline-3-carboxamide sulfate salt (CAS No. 186537-30-4).

Because (S)-N-tert-butyl-1,2,3,4-tetrahydroisoquinoline-3-carboxamide is currently on Table 3 of the Pharmaceutical Appendix to the HTS, it may enter duty-free if it is imported under the special rate of duty "K" of HTS subheading 2933.40.60.

⁹ Actual revenue loss may be understated if a significant increase in imports occurs during the duty suspension period.

¹⁰ There is no revenue loss for (S)-N-tert-Butyl-1,2,3,4-tetrahydroisoquinoline-3-carboxamide because it is already eligible for duty-free treatment.

¹¹ Based on information provided on August 19, 1998, by Pamela Graves-Moore of Monsanto, the proponent company.

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
2D SESSION

S. 2399

To suspend temporarily the duty on certain drug substances used as an HIV antiviral drug.

IN THE SENATE OF THE UNITED STATES

JULY 31, 1998

Ms. MOSELEY-BRAUN introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To suspend temporarily the duty on certain drug substances used as an HIV antiviral drug.

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 DUTY SUSPENSIONS ON CERTAIN**

4 **HIV DRUG SUBSTANCES.**

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

“	9902.32.14	(S)-N-tert-butyl-1,2,3,4-tetrahydro-3-isoquinoline carboxamide (CAS No. 149182-72-9)(provided for in subheading 2933.40.60)	Free	No change	No change	On or before 6/30/99	
	9902.32.16	(S)-N-tert-butyl-1,2,3,4-tetrahydro-3-isoquinoline carboxamide hydrochloride salt (CAS No. 149057-17-0)(provided for in subheading 2933.40.60)	Free	No change	No change	On or before 6/30/99	
	9902.32.18	(S)-N-tert-butyl-1,2,3,4-tetrahydro-3-isoquinoline carboxamide sulfate salt (CAS No. 186537-30-4)(provided for in subheading 2933.40.60)	Free	No change	No change	On or before 6/30/99	
	9902.32.20	(3S)-1,2,3,4-tetrahydroisoquinoline-3-carboxylic acid (CAS No. 74163-81-8)(provided for in subheading 2933.40.60)	Free	No change	No change	On or before 6/30/99	”.

1 (b) EFFECTIVE DATE.—The amendment made by
2 subsection (a) applies with respect to goods entered, or
3 withdrawn from warehouse for consumption, on or after
4 the date that is 15 days after the date of enactment of
5 this Act.

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