September 9, 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 LEGISLATION[1]

Bill no., sponsor, and sponsor's state: H.R. 2041 (105th Congress), Representative Matsui (CA).

Companion bill: None.

Title as introduced: To suspend temporarily the duty on the production of anti-cancer drugs.

Summary of bill:[2]

Temporarily suspends the column 1 rate of duty for the subject chemical, which is used in the production of a newly-discovered anti-cancer drug. The bill would amend subheading 2930.90.90 of chapter 29 of the HTS to add the subject chemical by name with free entry during 1998-2000 for imports 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 that this legislation was introduced. However, in a letter to Commission staff, Mr. Robert A. Shapiro of Barnes, Richardson and Colburn, counsel to Agouron Pharmaceuticals, Inc., the firm that imports or intends to import the subject chemical, stated:

> Agouron is seeking a temporary tariff suspension for certain chemicals used in the production of three newly-developed anti-cancer drugs which are currently still undergoing testing. The compound referred to in this bill is used to make a GARFT inhibitor and is also in clinical trials and is directed toward advanced cancer.
>
> Agouron is also seeking duty free treatment for these chemicals under the WTO pharmaceutical zero-for-zero update negotiations, which are to become effective in 1999. In the interim, however, a substantial duty cost will be incurred in obtaining critical components from foreign suppliers which significantly adds to the costs of development.

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[1] Industry analyst: Aimison Jonnard (205-3350); attorney: Leo Webb (205-2599).
[2] See appendix A for definition of tariff and trade agreement terms.

The temporary suspension of duty on these products will allow consumers to have access to these anti-cancer drugs as cost effectively as possible.

Product description and uses:

(S)-N-{[5-{2-(2-Amino-4,6,7,8-tetrahydro-4-oxo-1H-pyrimido(5,4-b)(1,4)thiazin-6-yl)ethyl}-2-thienyl]carbonyl}-L-glutamic acid, diethyl ester: The subject chemical is a synthetic organic chemical intermediate that will be used in the production of anti-cancer drugs. The latter products have not yet been approved for use in the United States.

Tariff treatment:[3]

Product	HTS subheading	Col. 1-general rate of duty
(S)-N-{[5-(2-(2-Amino-4,6,7,8-tetrahydro-4-oxo-1H-pyrimido(5,4-b)(1,4) thiazin-6-yl)ethyl}-2-thienyl]carbonyl}-L-glutamic acid diethyl ester	2930.90.90	3.7%

Structure of domestic industry (including competing products):

(S)-N-{[5-{2-(2-Amino-4,6,7,8-tetrahydro-4-oxo-1H-pyrimido(5,4-b)(1,4)thiazin-6-yl)ethyl}-2-thienyl]carbonyl}-L-glutamic acid, diethyl ester: According to Commission records and industry sources, there was no significant domestic production of this chemical during the past 5 years. Drugs produced by other pharmaceutical companies for the treatment of cancer are similarly derived from organic chemical intermediates, but different in composition from the subject chemical.

Private-sector views:

Absent appreciable domestic production of the subject chemical, the Commission contacted four pharmaceutical companies that produce or are developing drugs for the treatment of cancer.[4] None of the companies had submitted written comments as of August 1, 1997.

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[3] See appendix B for column 1-special and column 2 duty rates.

[4] Merck & Co., Inc.; Eli Lilly & Co.; Pfizer, Inc.; and SmithKline Beecham Pharmaceuticals were contacted about this proposed legislation on July 23, 1997.

U.S. consumption:

(S)-N-{[5-{2-(2-Amino-4,6,7,8-tetrahydro-4-oxo-1H-pyrimido(5,4-b)(1,4)thiazin-6-yl)ethyl}-2-thienyl]carbonyl}-L-glutamic acid, diethyl ester:	1994	1995	1996
U.S. production[1]	0	0	0
U.S. imports[1]	0	0	0
U.S. exports	0	0	0
Apparent U.S. consumption	0	0	0

[1]Production and/or imports in these years was only to support research and clinical testing and was negligible in commercial terms.
Source: Based on official statistics of the U.S. Department of Commerce and estimates provided by industry sources.

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

Effect on customs revenue:[5]

Future (1998-2000) effect: $240,000 x .037 = $8,900 per year (based on industry estimates).

Retroactive effect: None.

Technical comments:

In the title of the bill, the words "the production of" should be replaced by the words "imports of chemical intermediates used to produce."

The name of the chemical in this bill should be corrected by capitalizing "amino."

[5] Actual revenue loss may be understated in the event of a significant increase in imports over the duty suspension period should the anti-cancer drugs be approved for use in the United States. Industry sources expect, however, that these intermediates will be added to the Pharmaceutical Appendix of the HTS during the second review of the pharmaceutical agreement enacted as a result of the Uruguay Round Agreement negotiations. If this happens, the imports of these products would enter the United States free of duty (possibly as early as 1999).

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.

APPENDIX B

SELECTED PORTIONS OF THE
HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

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

I

105TH CONGRESS
1ST SESSION

H. R. 2041

To suspend temporarily the duty on the production of anti-cancer 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

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A BILL

To suspend temporarily the duty on the production of anti-cancer drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. TEMPORARY SUSPENSION OF DUTY.

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

“	9902.32.16	(S)-N-[[5-[2-(2-amino-4,6,7,8-tetra-hydro-4-oxo-1H-pyrimido[5,4-b] [1,4]thiazin-6-yl)ethyl]-2-thieny-l]carbonyl]-L-glutamic acid diethyl ester (CAS No. 177575–19–8) (Provided for in sub-heading 2930.90.90)	Free	No change	No change	On or before 12/31/2000	”.

(b) EFFECTIVE DATE.—The amendment made by this section applies with respect to goods entered, or withdrawn from warehouse for consumption, on or after the 15th day after the date of the enactment of this Act.

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