June 22, 1998

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC 20436

MEMORANDUM TO THE COMMITTEE ON FINANCE OF THE UNITED STATES SENATE ON PROPOSED TARIFF LEGISLATION[1]

Bill no., sponsor, and sponsor's state: S. 1936 (105th Congress), Senator Feinstein[2] (CA).

Companion bill: H.R. 2041 (105th Congress), Representative Matsui (CA).

Title as introduced: To suspend temporarily the duty on certain chemicals used in the formulation of anti-cancer drugs.

Summary of bill:[3]

The most-favored-nation (MFN) rate of duty is temporarily suspended through December 31, 1999.

Effective date: 15th day after enactment.

Retroactive effect: None.

Statement of purpose:

Senator Feinstein stated in the *Congressional Record:*[4]

"Mr. President, together with my California colleague, Senator Barbara Boxer, I rise today to introduce legislation to eliminate tariffs for twenty-one chemical compounds. These compounds are components of certain AIDS and cancer drugs. . . .

The AIDS and cancer drug chemical compounds will be entitled to receive a zero tariff when a revised international agreement eliminating tariffs for pharmaceutical products goes into effect in January 2000.

Until then, however, the compounds could face a tariff of between six and twelve percent, raising costs for patients and their families and discouraging the manufacturing of the pharmaceutical

---

[1] Industry analyst: Aimison Jonnard (205-3350); attorney: Leo Webb (205-2599).
[2] For herself and Senator Boxer (CA).
[3] See appendix A for definition of tariff and trade agreement terms.
[4] *Congressional Record,* vol. 144, p. S3219, Apr. 3, 1998.

products in this country. The legislation we introduce today would eliminate the tariff, providing the same zero tariff provided by the WTO agreement.

The list of specific pharmaceutical products which are entitled to receive the zero tariff is only updated every three years through the WTO negotiations. Drugs which are not approved by an agency of a federal government, like the FDA in the United States, cannot be included in the negotiations. Without formal federal approval by one of the governments, the drug cannot be included in the negotiations until the next round of negotiations, perhaps as much as three years later. This is unfair for those pharmaceutical products experiencing delays in the FDA process or whose approval does not match up with the negotiating time line.

The international community, through the World Trade Organization, committed to eliminate tariffs for pharmaceutical products. This agreement will help ensure that individuals around the world get the medicine they need, reducing drug costs by eliminating the tariff. Otherwise, the pharmaceutical products would be subject to a 6-12% tariff before they could be brought into the United States. . . .

Last year, the administration completed negotiations for the update round, revising the list of drugs eligible to claim the zero tariff. The administration agreed to incorporate twenty-one chemical compounds, which are constituents of an AIDS or cancer drugs, into agreement. As a result, these chemical compounds will receive a zero tariff when the WTO agreement goes into effect in January 2000. Until then, however, the AIDS and cancer chemicals remain subject to U.S. tariffs.

The legislation we introduce would suspend the tariff until the international agreement goes into effect in 2000. These chemical compounds have been added to the zero tariff international agreement, but we should take off the tariff now to speed up the development of the AIDS and cancer drugs.

These chemicals are not available in the United States from domestic manufacturers and are not used for other products. Consequently, the zero tariff does not undermine domestic chemical manufacturers. In fact, these chemicals eligibility for the zero tariff has been reviewed and approved by the chemical industry advisory committee, which advises the administration on trade policy.

This legislation only reduces the tariff for these chemical compounds that will receive a zero tariff under the international agreement. The zero tariff for these chemical compounds has, literally, been approved by both the United States and the international negotiators."

<u>Product description and uses</u>:

(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 an intermediate that will be used in the production of anti-cancer drugs; specifically it is used to make a GARFT

inhibitor.[5] (The GARFT inhibitor made from the subject chemical is currently in phase I clinical trials, directed toward advanced cancer.)[6]

Tariff treatment:[7,8]

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[9]	2934.90.90[10]	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.[11] None of the companies had submitted any written comments as of the date of preparation of this report.

---

[5] Glycinamide ribonucleotide formyl transferase (GARFT) is an enzyme inhibitor for cancer.

[6] Letter to Commission staff from counsel to Agouron Pharmaceuticals, May 22, 1998.

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

[8] See technical comments section.

[9] Chemical Abstracts Service Registry No. 177575-19-8.

[10] According to a binding ruling issued by the U.S. Customs Service (Customs Ruling NYRL B89017), this HTS subheading is the appropriate classification for U.S. imports of this product.

[11] Merck & Co., Inc.; Eli Lilly & Co.; Pfizer, Inc.; and SmithKline Beecham Pharmaceuticals were contacted about this proposed legislation in 1997, following the introduction of the companion bill.

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:	1995	1996	1997
U.S. production[1]	0	0	0
U.S. imports[1]	0	0	0
U.S. exports	0	0	0
Apparent U.S. consumption[1]	0	0	0

[1]According to a representative of Agouron, 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:[12]

Future (1998-99) effect: The estimated average annual revenue loss in 1998-99 will be $30,000.[13]

Retroactive effect: None.

Technical comments:

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

[12] 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).

[13] Letter to Commission staff from Mr. Matthew T. McGrath and Mr. Robert A. Shapiro, counsel to Agouron Pharmaceuticals, May 22, 1998.

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.)

105TH CONGRESS
2D SESSION

S. 1936

To suspend temporarily the duty on certain chemicals used in the formulation of anti-cancer drugs.

IN THE SENATE OF THE UNITED STATES

APRIL 3, 1998

Mrs. FEINSTEIN (for herself and Mrs. BOXER) introduced the following bill; which was read twice and referred to the Committee on Finance

---

A BILL

To suspend temporarily the duty on certain chemicals used in the formulation 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-tetrahydro-4-oxo-1H-pyrimido[5,4-b] [1,4]thiazin-6-yl)ethyl]-2-thienyl]carbonyl]-L-glutamic acid diethyl ester (CAS No. 177575–19–8) (provided for in subheading 2934.90.90) ...	Free	No change	No change	On or before 12/31/1999	".

(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 enactment of this Act.

○