UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC 20436

MEMORANDUM ON PROPOSED TARIFF LEGISLATION of the 110th Congress [1]

[Date approved: October 6, 2008][2]

Bill No. and sponsor: H.R. 5304 (Mr. Bill Pascrell, Jr. of New Jersey).

Proponent name,[3] location: Bayer HealthCare Pharmaceuticals, Wayne, NJ.

Other bills on product (110th Congress only): None.

Nature of bill: Extension of temporary duty suspension through December 31, 2011.

Retroactive effect: None.

Suggested article description(s) for enactment (including appropriate HTS subheading(s)):

4-(4-{3-[4-Chloro-3-(trifluoromethyl) phenyl]ureido}phenoxy)-N-2-methylpyridine-2-carboxamide 4-methylbenzenesulfonate (Sorafenib tosylate) (CAS No. 475207-59-1) (provided for in subheading 2933.39.41)

Check one: X Same as that in bill as introduced.
___ Different from that in bill as introduced (see Technical comments section).

Product information, including uses/applications and source(s) of imports:

The subject product is the active ingredient that is used to manufacture Nexavar®, an anti-cancer medicine to treat adults with advanced renal cell carcinoma. The proponent indicates that the product is undergoing clinical trials for use in treating hepatocellular cancer, lung cancer, breast cancer, and melanoma. The product is imported from Germany.

[1] Industry analyst preparing report: Elizabeth Nesbitt (202-205-3355); Tariff Affairs contact: David G. Michels (202-205-3440).
[2] Access to an electronic copy of this memorandum is available at http://www.usitc.gov/tata/hts/other/rel_doc/bill_reports/.
[3] The sponsor/proponent did not identify any additional beneficiaries of this bill.

Estimated effect on customs revenue:

HTS subheading: 2933.39.41					
	2009	2010	2011	2012	2013
Col. 1-General rate of duty	6.5%	6.5%	6.5%	6.5%	6.5%
Estimated value ***dutiable*** imports	$250	$250	$250	$250	$250
Customs revenue loss 1/	$0	$16	$16	$16	$16

1/ There is an existing duty suspension under HTS heading 9902.22.02 that expires on December 31, 2009. Therefore, there will be no customs revenue loss related to this bill in 2009. Additionally, imports of this product, if claimed, are eligible to enter free of duty as of January 2007 under the Pharmaceutical Appendix to the HTS.[4]

Source of estimated dutiable import data: U.S. industry estimates.

Contacts with domestic firms/organizations (including the proponent):

Name of firm/organization	Date contacted	Claim US makes same or competing product(s)?	Submission attached?	Opposition noted?
		(Yes/No)		
Bayer HealthCare Pharmaceuticals (Proponent) Karen Niedermeyer, karen.niedermeyer.b@bayer.com	05/31/2008	No	No	No
Archimica USA Andrew Zamoyski, az@azamoyski.com	06/01/2008	No	No	No
Abbott Laboratories Claude Burcky, pclaude.burcky@abbott.com	06/01/2008	No	No	No
Bristol-Myers Squibb David Warr, David.Warr@BMS.com	06/03/2008	No	No	No
CIBA Specialty Chemicals Michelle Forte, Michelle.forte@cibasc.com	06/01/2008	No	No	No
Clariant Corporation Andrew Zamoyski, az@azamoyski.com	06/01/2008	No	No	No
Dow Chemical Max Turnipseed, mctint@att.net	06/01/2008	No	No	No
DuPont Helen McMahon, Helen.C.McMahon@USA.dupont.com	06/01/2008	No	No	No

[4] Representative of U.S. Customs and Border Protection, e-mail message to Commission staff June 2, 2008.

Name of firm/organization	Date contacted	Claim US makes same or competing product(s)?	Submission attached?	Opposition noted?
		(Yes/No)		
Eli Lilly Desiree Filippone, Filippone_D@Lilly.com	06/03/2008	No	No	No
Fanwood Chemical Jim DeLisi, JdeLisi@fanwoodchemical.com	06/01/2008	No	No	No
Gilead Sciences Government Affairs Department	06/03/2008	No	No	No
GlaxoSmithKline William Schuyler, William.J.Schuyler@gsk.com	06/03/2008	No	No	No
Lonza, Inc. Sheri Donno, Sheri.Donno@lonza.com	06/032008	No	No	No
Merck & Co. Thomas Bombelles, thomas_bombelles@merck.com	06/01/2008	No	No	No
Monsanto Michael Parrish, Michael.Parrish@monsanto.com	06/03/2008	No	No	No
Novartis Tracy Haller, tracy.haller@novartis.com	06/01/2008	No	No	No
Pfizer Anthony Barone, Anthony.Barone@pfizer.com	06/02/2008	No	No	No
Procter & Gamble Jim McCarthy, McCarthy.JR@pg.com	06/03/2008	No	No	No
Rhodia Dominick Cangiano, Dominick.Cangiano@us.rhodia.com	06/02/2008	No	No	No
Schering-Plough Rob Lively, robert.lively@spcorp.com	06/01/2008	No	No	No
Watson Pharmaceuticals Sara Swee, Sara.Swee@watson.com	06/03/2008	No	No	No

Technical comments:[5]

The Commission staff notes that the subject product is eligible for duty-free treatment according to the allowable combinations available in the Pharmaceuticals Appendix to the Harmonized Tariff Schedule.

[5] The Commission may express an opinion on the HTS classification of a product to facilitate consideration of the bill. However, by law, only the U.S. Customs Service is authorized to issue a binding ruling on this matter. The Commission believes that the U.S. Customs Service should be consulted prior to enactment of the bill.

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110TH CONGRESS
2D SESSION

H. R. 5304

To extend the temporary suspension of duty on Sorafenib tosylate.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 7, 2008

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

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A BILL

To extend the temporary suspension of duty on Sorafenib tosylate.

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

SECTION 1. SORAFENIB TOSYLATE.

(a) IN GENERAL.—Heading 9902.22.02 of the Harmonized Tariff Schedule of the United States (relating to Sorafenib tosylate) is amended by striking ''12/31/2009'' and inserting ''12/31/2011''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) applies 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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