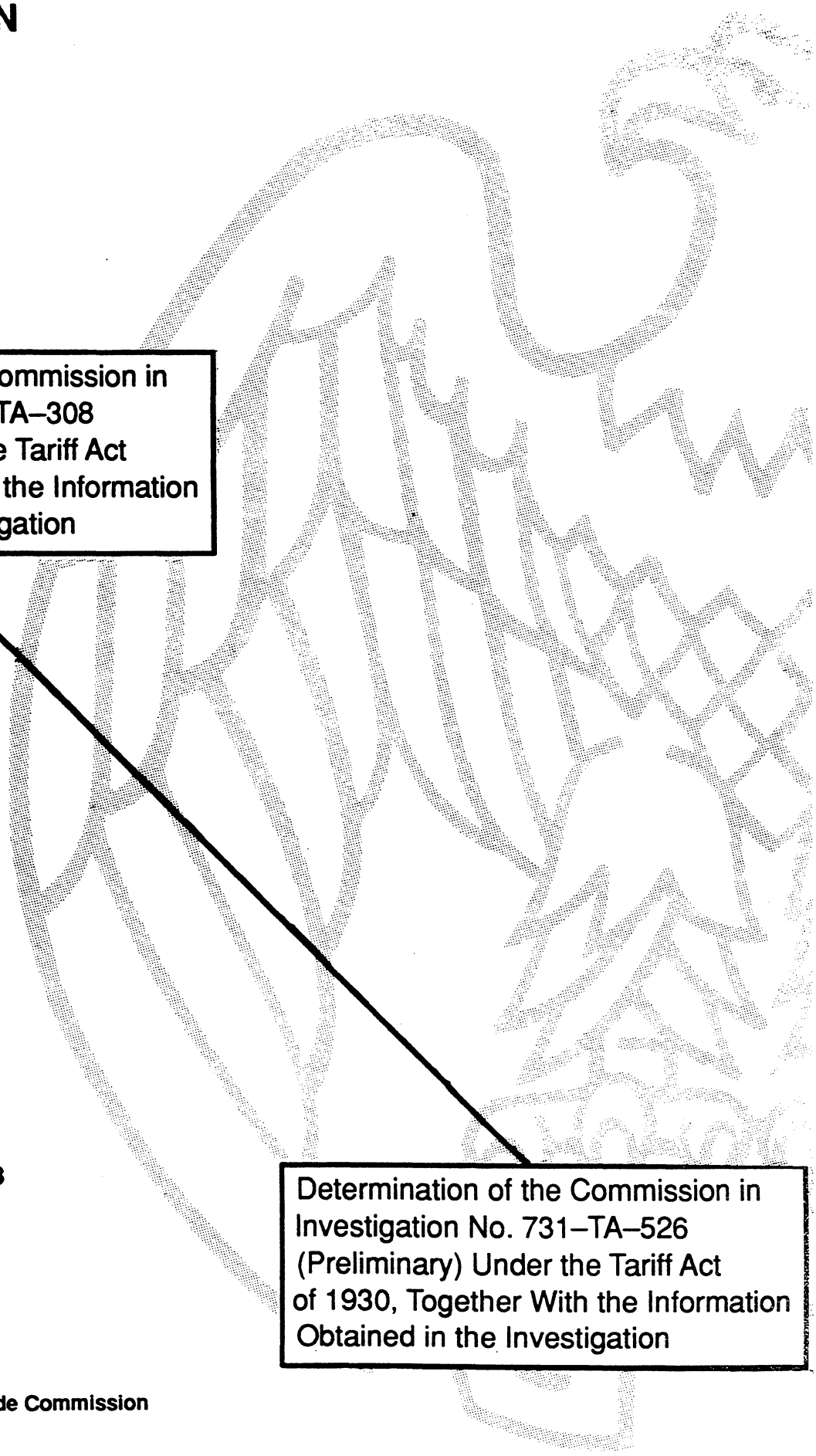
BULK IBUPROFEN FROM INDIA

Determination of the Commission in Investigation No. 701–TA–308 (Preliminary) Under the Tariff Act of 1930, Together With the Information Obtained in the Investigation



Determination of the Commission in Investigation No. 731–TA–526 (Preliminary) Under the Tariff Act of 1930, Together With the Information Obtained in the Investigation

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United States International Trade Commission
Washington, DC 20436

UNITED STATES INTERNATIONAL TRADE COMMISSION

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Note.--Information that would reveal the confidential business information of individual firms may not be published and therefore has been deleted from this report. Deletions are indicated by asterisks.

UNITED STATES INTERNATIONAL TRADE COMMISSION

Investigations Nos. 701-TA-308 (Preliminary)
and 731-TA-526 (Preliminary)

BULK IBUPROFEN FROM INDIA

Determinations

On the basis of the record[1] developed in the subject investigations, the Commission determines, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. §§ 1671b(a) and 1673b(a)), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports from India of ibuprofen in bulk form, provided for in subheading 2916.39.15 of the Harmonized Tariff Schedule of the United States, that are alleged to be subsidized by the Government of India and sold in the United States at less than fair value (LTFV).

Background

On July 31, 1991, a petition was filed with the Commission and the Department of Commerce by Ethyl Corporation, Richmond, VA, alleging that an industry in the United States is materially injured by reason of subsidized and LTFV imports of bulk ibuprofen from India. Accordingly, effective July 31, 1991, the Commission instituted countervailing duty investigation No. 701-TA-308 (Preliminary) and antidumping investigation No. 731-TA-526 (Preliminary).

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[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR § 207.2(f)).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the Federal Register of August 7, 1991 (56 F.R. 37571). The conference was held in Washington, DC, on August 21, 1991, and all persons who requested the opportunity were permitted to appear in person or by counsel.

VIEWS OF THE COMMISSION

Based on the information obtained in these preliminary investigations, we determine that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of bulk ibuprofen from India that allegedly are subsidized and sold at less than fair value (LTFV).

I. The Legal Standard in Preliminary Investigations

The legal standard in preliminary countervailing duty and antidumping investigations is set forth in sections 703(a) and 733(a) of the Tariff Act of 1930, as amended.[1] Those sections require the Commission to determine whether, based on the best information available at the time of the preliminary determination, there is a reasonable indication of material injury to a domestic industry, or threat thereof, or material retardation of establishment of an industry, by reason of the imports under investigation.[2]

In American Lamb Co. v. United States,[3] the United States Court of Appeals for the Federal Circuit addressed the standard for preliminary determinations. The Court held that the reasonable indication standard requires more than a finding that there is a possibility of material injury or threat thereof, and that the Commission is to determine if the evidence obtained demonstrates that a reasonable indication exists. The Commission may render a negative preliminary determination only if: "(1) the record as a whole contains clear and convincing evidence that there is no material injury

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[1] 19 U.S.C. §§ 1671b(a), 1673b(a).

[2] Maverick Tube Corp. v. United States, 687 F. Supp. 1569, 1573 (Ct. Int'l Trade 1988). Material retardation of the establishment of an industry is not an issue in this investigation and will not be discussed further.

[3] 785 F.2d 994 (Fed. Cir. 1986).

or threat of such injury; and (2) no likelihood exists that contrary evidence will arise in a final investigation."[4]

II. Like Product

A. Background

In determining whether there is a reasonable indication of material injury or threat thereof to a domestic industry, the Commission must make threshold factual determinations with respect to "like product" and "domestic industry." Section 771(4)(A) of the Tariff Act of 1930 defines the term "industry" as "the domestic producers as a whole of a like product, or those producers whose collective output of the like product constitutes a major proportion of the total domestic production of that product. . . ."[5] "Like product" is defined as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation . . . ."[6]

The Department of Commerce (Commerce) defines the imported merchandise that is subject to the investigation, and the Commission determines the domestic products "like" the imports.

In the initiation notice, Commerce defined the product under investigation as follows:

> The product covered by this investigation is bulk ibuprofen from India. Bulk ibuprofen, a white powder, is a non-steroidal anti-inflammatory agent which also has analgesic and antipyretic activity. It is used in the symptomatic treatment of acute and chronic rheumatoid arthritis, osteoarthritis, primary dysmenorrhea and for the relief of mild to moderate pain. The chemical description of bulk ibuprofen is 2-(4-isobutylphenyl) propionic acid, C_{13} H_{18} O_2. The product covered by this investigation does

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[4] Id. at 1001.

[5] 19 U.S.C. § 1677(4)(A).

[6] 19 U.S.C. § 1677(10).

> not include ibuprofen sold in tablet, capsule or similar forms for direct human consumption. . . .[7]

Each producer of bulk ibuprofen uses a slightly different chemical reaction process to produce the product. Petitioner, Ethyl Corporation (Ethyl) employs a seven-step process using two raw materials, isobutyl benzene and acetyl chloride. This process is explained in the Commission Report.[8]

The bulk ibuprofen is purchased by pharmaceutical companies, which add inert and active ingredients to formulate ibuprofen tablets as well as products containing both ibuprofen and other pharmaceutical ingredients (e.g., cold medication). Over the counter ibuprofen tablets in 200 milligram dosages and prescription ibuprofen tablets in 300, 400, 600, and 800 milligram dosages are sold under both trade and generic labels.

The sale of tableted ibuprofen in the U.S. market entails two levels of approval by the Food and Drug Administration (FDA).[9] First, the bulk producer must receive FDA approval as a qualified producer. This process begins with the filing of a Drug Master File (DMF), which is reviewed only after a U.S. tableter applies to the FDA for approval to use that bulk producer's product. Upon receipt of such application, the FDA inspects the facilities of the bulk producer, after which the FDA may approve the company as a qualified producer.

In addition to approval of the bulk producer, sale of ibuprofen tablets requires FDA approval of the finished product which the tableter intends to sell. To receive this approval, the tableter conducts required tests of each dosage strength of the product, and submits its data to the FDA. If the FDA is satisfied with the results, it then grants approval to market tablets

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[7] 56 Fed. Reg. 42026 (August 26, 1991).

[8] Report at A-4.

[9] See Report at A-5.

containing the manufacturer's bulk ibuprofen. Each dosage strength produced by the manufacturer must be approved separately by the FDA, even if the source of the bulk is the same.[10]

There are two like product issues raised in this investigation, both of which address the possible broadening of the like product beyond Commerce's scope determination. The first question is whether the like product should include "downstream" oral dosage forms of ibuprofen, such as tablets, caplets or liquids. The second question is whether the like product should include other analgesics, particularly aspirin and acetaminophen.

The Commission's decision regarding the appropriate like product or products in an investigation is essentially a factual determination, and the Commission has applied the statutory standard of "like" or "most similar in characteristics and uses" on a case-by-case basis.[11] In analyzing like product issues, the Commission generally considers a number of factors including: (1) physical characteristics; (2) end uses; (3) interchangeability of the products; (4) channels of distribution; (5) production processes; (6) customer or producer perceptions of the products; (7) the use of common

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[10] Under the Drug Price Competition and Patent Term Restoration Act of 1984, applicants seeking approval of generic versions of post-1962 drugs can file Abbreviated New Drug Applications (ANDAs), which excuse the applicant from repeating the safety and efficacy tests required in New Drug Applications. Transcript of Conference (August 21, 1991) (Tr.) at 69-70. See Generic Cephalexin Capsules from Canada, Inv. No. 731-TA-423 (Final), USITC Pub. 2211 at 15 (1989). However, because of recent problems involving the manufacture of some generic drugs, the FDA has tightened up the process of reviewing ANDAs, and may take up to two years to approve an ANDA. Report at A-5.

[11] Asociacion Columbiana de Exportadores de Flores, et al. v. United States ("ASOCOFLORES"), 693 F.Supp. 1165, 1169 (Ct. Int'l Trade 1988).

manufacturing facilities and production employees; and (8) price.[12] No single factor is dispositive, and the Commission may consider other factors that it deems relevant based upon the facts of a given investigation.

B. Inclusion of oral dosage forms in the like product

Petitioner argues that the like product should include only bulk ibuprofen and should not be expanded to cover oral dosage forms. Respondents disagree and urge that oral dosage forms be included in the like product definition.

Based on an application of our usual like product criteria, we determine that oral dosage forms of ibuprofen should not be included in the like product. The physical characteristics of bulk and processed ibuprofen are different in that the former is an easily-compressible powder not soluble in water whereas the latter is a tablet, caplet, or liquid that is hard to compress and soluble in water. Bulk ibuprofen is not interchangeable with the dosage forms and is not approved by FDA as a drug product, whereas the dosage forms must be so approved before they can be sold.[13] Bulk ibuprofen is not sold to pharmacies or to the ultimate consumers (e.g., patients) of the product.

Because the "customers" of bulk and oral dosage forms are different, it follows that their perceptions are different. The consumers of bulk ibuprofen are the pharmaceutical firms that purchase bulk ibuprofen and then process it

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[12] See, e.g., Sweaters Wholly or in Chief Weight of Manmade Fibers from Hong Kong, the Republic of Korea, and Taiwan, Invs. Nos. 731-TA-448-450 (Final), USITC Pub. 2312 (Sept. 1990) ("Sweaters") at 4-5; Certain Steel Pails from Mexico, Inv. No. 731-TA-435 (Final), USITC Pub. 2277 (May 1990) at 4.

[13] As discussed above and in the Commission Report, the bulk producer must be approved by the FDA as a qualified producer, but the bulk product itself does not receive independent FDA approval.

into dosage forms. Plainly, they do not perceive the bulk product and the processed product as interchangeable. Bulk ibuprofen is not even offered for sale to the purchasers and end users of oral dosage forms. Further, only by purchasing a processed form of ibuprofen can the retailer or consumer ascertain exact dosage strengths.

There is no overlap in distribution channels of bulk and oral dosage forms. Bulk ibuprofen is sold only to dosage manufacturers who have been approved by the FDA. Ibuprofen dosage forms are sold directly to distributors, hospitals, or stores.

There is not a commonality of manufacturing processes, facilities, or employees. There are no domestic manufacturers of both bulk and oral dosage ibuprofen. As such, there are no common manufacturing facilities or employees. In addition, the manufacturing processes differ substantially. Bulk ibuprofen is manufactured through a multi-step chemical process that requires the use of organic solvents, acids, bases, catalysts in large reaction vessels, and distillation columns. Dosage forms are processed using small blenders, fluid bed granulators and dryers, tablet pressers, coaters, and packaging machinery. The processing of bulk ibuprofen into oral dosage forms adds an additional 50-100 percent to the value of the product.[14]

Finally, there is a significant price difference between bulk and oral dosage ibuprofen. Bulk ibuprofen sells in the range of $15.00-$25.00 per kilogram.[15] Dosage forms retail at many times that amount, with the exact

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[14] Tr. 64 (anywhere from 50 to 75 percent of the total cost to make one tablet is the cost of bulk ibuprofen). Compare with Cephalexin at 8-9 (Ninety percent of the finished product was bulk cephalexin, and the processing required to achieve the finished product was "not extensive.")

[15] Report at A-6.

price depending on the form, strength, and label under which the product sells.

In two previous Title VII investigations, the Commission has addressed similar like product questions. In Certain Acetylsalicylic Acid (Aspirin) from Turkey ("Aspirin")[16] the product under investigation was bulk aspirin, and the Commission found the like product to consist of bulk aspirin.[17] In Generic Cephalexin Capsules from Canada ("Cephalexin"), the Commission broadened the like product definition to include "upstream" bulk cephalexin as well as oral dosage form, including tablets and oral suspension powders.[18]

Respondents contend that Cephalexin is "controlling" here,[19] whereas petitioner relies on the determination in Aspirin. We find that this investigation is most like the Aspirin investigation, in that the product under investigation is the upstream bulk version of the substance rather than the processed downstream tableted form. Moreover, we recently have stated our reluctance to broaden the like product to include products downstream from the product under investigation.[20]

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[16] Invs. Nos. 701-TA-283 and 731-TA-364 (Final), USITC Pub. 2001 (1987).

[17] It should be noted, however, that in Aspirin, the issue of including the aspirin tablets in the like product was not expressly raised or discussed in either the Commission's Report or Decision.

[18] USITC Pub. 2211 at 7-9.

[19] Respondents' postconference brief at 3. We note that a previous like product determination, especially one involving a different product under investigation, is not "controlling." The Commission determines like product on a sui generis basis in each investigation, although it may look at previous determinations for guidance and must explain departures from like product definitions involving identical products. See Citrosuco Paulista S.A. v. United States, 704 F. Supp. 1075, 1088 (Ct. Int'l Trade 1988).

[20] See e.g., Tungsten Ore Concentrates from the People's Republic of China, Inv. No. 731-TA-497 (Preliminary), USITC Pub. 2367 at 7 (March 1991).

As the Commission noted in Tungsten Ore, broadening the definition of a like product, and hence the definition of the domestic industry, to include products which result from further processing of the article subject to investigation, has the effect of including within the domestic "industry" producers of a product, whose interest, as consumers, may be contrary to that of the producers of the bulk product corresponding directly to the product subject to investigation.[21] This is so in this investigation. The only current (Ethyl) or anticipated (Boots-Hoechst-Celanese or BHC) domestic producers of bulk ibuprofen do not produce oral dosage forms of ibuprofen in the United States.[22] Rather, they sell the bulk product to any of approximately 27 purchasers, who then further process it into oral dosage forms for sale to distributors, hospitals, or retailers. Indeed, inclusion of the tableters in the domestic industry would lead to the unwarranted result in this case of including within the industry all of the tableters who purchase the allegedly LTFV imports as the base ingredient used in their domestically produced finished tablets.

Moreover, the Commission's determination to broaden the like product in Cephalexin was based on an application of its "semi-finished" criteria traditionally applied to evaluate whether semifinished or component products are like the finished products subject to investigation. As noted in Tungsten Ore, the Commission generally has applied these criteria only in instances in which the finished, or further processed product, is included within the

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[21] USITC Pub. 2367 at 9.

[22] Ethyl does not produce tablets or any other processed ibuprofen product. A company related to BHC (Boots PLI) produces both bulk and tablets in the United Kingdom, but BHC does not intend to produce both in the United States.

article subject to investigation. It has not been the Commission's practice to apply its "semi-finished" criteria to include a finished product in the like product when the scope of the investigation covers only a lesser-processed input.[23]

C. Inclusion of Aspirin and Acetaminophen in the Like Product

Petitioner argues that the like product should be limited to bulk ibuprofen and should not include any other analgesics in any form. Respondents, in addition to arguing that the like product should include oral dosage forms, urge that the Commission expand the like product to include aspirin and acetaminophen. In Aspirin, the Commission considered whether bulk ibuprofen and bulk acetaminophen were "like" the bulk aspirin under investigation and determined that they were not.[24] Respondents suggest that the determination in Aspirin was merely "dicta" and was not based upon a thorough investigation of the relevant information because the parties did not dispute the issue.

Respondents' characterization aside, an application of the like product criteria supports a definition similar to that found in Aspirin, i.e, that the like product should not include aspirin or acetaminophen.[25] With regard to physical characteristics, respondents agree with petitioner that the three products differ in their chemical compositions. In addition, according to

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[23] Tungsten Ore, USITC Pub. 2367 at 8.

[24] We note, however, that two of the four voting Commissioners either expressed reservations about not including other analgesics in the like product or indicated that the issue was moot in part because the Commission had not obtained data on the firms producing acetaminophen and ibuprofen. USITC Pub. 2001 at 12-13 (dissenting views of Chairman Liebler) and 27-28 (dissenting views of Vice Chairman Brunsdale).

[25] For discussion of her views on this issue, see Additional Views of Acting Chairman Anne E. Brunsdale, infra.

petitioner, the three substances also have different chemical properties, such as melting points and chemical stability.[26]

Broadly speaking, the three substances serve the same essential end use, i.e. relief of pain. However, there are some particular symptoms for which each may be the preferred drug.[27] Aspirin and ibuprofen have anti-inflammatory properties, whereas acetaminophen does not. Aspirin is often used for treatment of cardiovascular problems; ibuprofen is more effective against arthritic pain; and acetaminophen is a more effective fever reducer. The Commission previously has declined to group into one like product various types of medicines solely because they share a common therapeutic purpose.[28]

The bulk forms of the products are not interchangeable. The bulk forms of each can be used only to make the oral dosage form of the corresponding prescription or over-the-counter medication. In addition, bulk acetaminophen can also be used to make nondrug products such as photographic chemicals and azo dyes.

Although the channels of distribution are similar for all three types of products, i.e., direct sales of the bulk product from its producer to pharmaceutical companies which have been approved to manufacture the drug products made with that bulk drug substance,[29] customer perceptions differ. The bulk producers' customers, i.e., the pharmaceutical companies which

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[26] Petitioner's postconference brief at 4.

[27] See Report at A-5, n. 10; Tr. 52.

[28] Cephalexin at 9-10 (like product not broadened to include non-cephalexin cephalosporin or other antibiotics.)

[29] Petition at 6; Petitioner's postconference brief at 5; Respondents' postconference brief at 9.

purchase and process the bulk products, do not perceive the bulk products as interchangeable.[30]

Petitioner Ethyl is the only current manufacturer of bulk ibuprofen, and it does not manufacture either aspirin or acetaminophen in any form. BHC is building a domestic facility for the production of bulk ibuprofen at a site in Bishop, Texas, where one of its owners (Hoechst Celanese) is also building an acetaminophen plant. However, BHC has represented that the ibuprofen facility will be operated independently from the acetaminophen plant and that there will be no sharing of production employees.[31] The information obtained regarding comparisons of machinery and processes used for producing the three different substances is very general. Respondents focus on similarities in some equipment used to process bulk substances into oral dosage forms,[32] which is not the appropriate focus in light of our definition of a like product limited to the bulk product. Confidential, albeit general, information that was received concerning comparisons between production of bulk ibuprofen and bulk forms of other analgesics suggests that the manufacturing equipment is dissimilar.

There is a substantial difference in the prices of the bulk products. Bulk ibuprofen ranges from $15.00-25.00 per kilogram, as compared to $1.00-$2.00 per kilogram for aspirin and $5.00-$7.00 per kilogram for acetaminophen.

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[30] The end users of the pain relief products may view the finished tablets as largely interchangeable for pain relief. There is some evidence obtained in the investigation that increased sales of one type of analgesic can correspond to decreases in sales of the other types. Respondents' postconference brief, Exhibits 3 & 4; Tr. 56.

[31] BHC's submission at 6. BHC did not appear as a party in the investigation, but filed a nonparty submission pursuant to Commission Rule 207.15.

[32] Respondents' postconference brief at 10.

E. Conclusions Regarding Like Product

For the purposes of these preliminary investigations, we find one like product coextensive with the scope of the investigation. This product is defined as bulk ibuprofen and does not include other analgesics.

III. Domestic Industry

Section 771(4)(A) of the Tariff Act of 1930 defines domestic industry as:

> . . . the domestic producers as a whole of a like product, or those producers whose collective output of the like product constitutes a major proportion of the total domestic production of that product.[33]

Concomitant with the recommended like product definition, the domestic industry consists of the domestic producers of bulk ibuprofen. During the period of investigation, Ethyl has been the only producer in this domestic industry. Respondents, however, have suggested that BHC, which is in the process of building a facility in Texas for the production of bulk ibuprofen, should be included in the domestic industry. Petitioner, Ethyl, argues against inclusion of BHC. BHC has filed a nonparty submission, but has not expressed a view as to whether it is part of the domestic industry.

In previous investigations, the Commission generally has not included in the domestic industry companies which have not begun commercial production of the like product.[34] Likewise, it does not seem appropriate to include BHC in the domestic industry producing bulk ibuprofen, at least for the purposes of

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[33] 19 U.S.C. § 1677(4)(A).

[34] E.g., 3.5" Microdisks and Media Thereof from Japan, Inv. No. 731-TA-389 (Preliminary), USITC Pub. 2076 at 18, n. 41. (1988). In Fresh and Chilled Atlantic Salmon from Norway, Invs. Nos. 701-TA-302 and 731-TA-454 (Preliminary), USITC Pub. 2272 (1990), the Commission included in the domestic industry firms which, although they had not yet begun commercial sales, were engaged in the 18-month process of growing harvestable salmon from smolt.

the preliminary investigations. BHC has not begun commercial production. The production of samples necessary for its customers to receive FDA approval of the finished product does not rise to the level of commercial production that would warrant inclusion in the existing domestic industry. These samples are not sold and have been produced only on a small scale in insignificant overall quantities at a separate research and development laboratory maintained by one of the parent companies.[35]

Accordingly, we find for purposes of these preliminary investigations that BHC is not part of the domestic industry producing bulk ibuprofen.

IV. Condition of the Domestic Industry[36]

In assessing the condition of the domestic industry, the Commission considers, among other factors, domestic consumption, production, capacity, capacity utilization, shipments, inventories, employment, financial performance, capital investment, and research and development efforts.[37] We must evaluate these factors within the context of the business cycle and conditions of competition that are distinctive to the affected industry.[38] For the purposes of these preliminary investigations, the Commission collected data bearing on the condition of the domestic industry for the period 1988 through 1990, as well as interim data for the first six months of 1990 and 1991.

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[35] Report at A-9 & n. 24.

[36] Acting Chairman Brunsdale does not join in the remainder of this opinion. The reasons for her determination that there is a reasonable indication that the subject imports have caused material injury to a domestic industry are discussed in her additional views, infra.

[37] 19 U.S.C. § 1677(7)(C)(iii).

[38] See id.

Because there presently is only one domestic producer of bulk ibuprofen, information concerning the condition of the domestic industry is business proprietary and can be discussed only in very general terms. The indicia of industry performance are mixed, with little change in some factors from the beginning to the end of the investigatory period.

The financial trends provide a reasonable indication of present material injury. For example, as illustrated by a public exhibit introduced by Ethyl at the conference, the industry's profitability (as measured by the profit-to-sales ratio) declined substantially from the beginning to the end of the investigatory period, despite an increase in 1989 from the 1988 level.[39]

Confidential information concerning other factors, such as apparent domestic consumption and market share, further provide a reasonable indication of present injury. Accordingly, on the basis of the information gathered in these preliminary investigations, we find a reasonable indication of material injury to the domestic industry producing bulk ibuprofen.

V. Reasonable Indication of Material Injury By Reason of the Subject Imports

In these preliminary investigations, the Commission must determine whether there is a reasonable indication of material injury or the threat thereof to the domestic industry "by reason of" the imports under investigation.[40] The Commission considers the volume of imports, their effect on prices for the like product, and their impact on domestic producers.[41] In doing so, the Commission examines whether import volumes or increases in volume are significant, whether there has been significant underselling by

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[39] Exhibit 1, Tr. 16.

[40] 19 U.S.C. §§ 1971b(a), 1673b(a).

[41] 19 U.S.C. § 1677(7)(B)(i).

imports, whether imports significantly depress or suppress prices for the like product, and such factors as domestic production, sales, capacity utilization, inventories, employment, and profits.[42] The Commission may in its discretion examine additional economic factors.[43]

The Commission may consider alternative causes of injury, but it is not to weigh causes.[44] The Commission need not determine that imports are the principal or a substantial cause of material injury.[45] Rather, as the Court of International Trade has held, the Commission is to determine whether imports are a cause of material injury.[46]

Petitioner asserts that the domestic industry has experienced serious financial harm as a result of "dramatic" and increasing rises in the market share and volume of Indian imports.[47] While the precise import data collected

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[42] 19 U.S.C. § 1677(7)(C).

[43] 19 U.S.C. § 1677(7)(B)(ii).

[44] Citrosuco Paulista S.A. v. United States, 704 F. Supp. 1075, 1101 (Ct. Int'l Trade 1988). Alternative causes may include:

> the volume and prices of imports sold at fair value, contraction in demand or changes in patterns of consumption, trade, restrictive practices of and competition between the foreign and domestic producers, developments in technology, and the export performance and productivity of the domestic industry.

S. Rep. No. 249, 96th Cong., 1st Sess. 74 (1979). Similar language is contained in the House Report. H.R. Rep. 317, 96th Cong., 1st Sess. 47 (1979).

[45] "Any such requirement has the undesirable result of making relief more difficult to obtain for industries facing difficulties from a variety of sources; industries that are often the most vulnerable to less-than-fair-value imports." S. Rep. No. 249, at 74-75.

[46] LMI-La Metalli Industriale, S.p.A. v. United States, 712 F. Supp. 959, 971 (Ct. Int'l Trade 1989), citing, British Steel Corp. v. United States, 593 F. Supp. 405, 413 (Ct. Int'l Trade 1984); Hercules, Inc. v. United States, 673 F. Supp. 454, 481 (Ct. Int'l Trade 1987). See also, Maine Potato Council v. United States, 613 F. Supp. 1237, 1244 (Ct. Int'l Trade 1985) (The Commission must reach an affirmative determination if it finds that imports are more than a "de minimis" cause of injury.)

[47] Petitioner's postconference brief at 18.

from questionnaire responses is business proprietary, we note that the imports of bulk ibuprofen imports from India rose over the investigatory period, both in terms of quantity and value.[48] The Indian imports also gained market share steadily throughout the period, by both quantity and value.[49]

The confidential pricing information shows falling prices, with some evidence of underselling by the Indian imports.[50] There is also some evidence that, even in instances in which the domestic products and imports do not compete directly for sales to the same tableter, alleged unfairly traded Indian imports may still ultimately affect domestic prices by forcing Ethyl's tableter-customers, who compete with tableters using the subject imports, to insist that Ethyl lower or at least not raise its prices so that the prices of the finished tablets can remain competitive.[51]

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[48] Report at A-24, Table 14. See also Petitioner's Exhibit 1, introduced at the conference, Tr. 16.

[49] Report at A-25, Table 15. See also Petitioner's Exhibit 1, introduced at the conference, Tr. 16.

[50] Report at A-27.

[51] See Exhibits 2 & 3 to petitioner's postconference brief. Respondents suggest that it is inappropriate to compare prices to brand name customers (which they allege account for the majority of Ethyl's customers) with prices to generic customers (which account for all of Flavine's sales). In this regard, respondents allege that Ethyl's brand name customers pay higher prices for bulk ibuprofen than do Flavine's generic tablet customers, because the former are able to command a "premium" for their end product. Respondents' postconference brief at 44; Tr. 137. We note, however, that Ethyl sells bulk ibuprofen to producers of generic as well as brand name tableters. Ethyl states that it charges the same prices to all its customers, and that price distinctions based on whether the tableter produces brand name or generic tablets are prohibited by the Robinson-Patman Price Discrimination Act (15 U.S.C. § 13(a)). See Tr. 72. We may explore this issue further in any final investigations.

VI. Conclusion

For the foregoing reasons, we find that there is a reasonable indication that the domestic industry producing bulk ibuprofen is materially injured by reason of allegedly subsidized and LTFV imports of bulk ibuprofen from India.

ADDITIONAL VIEWS OF ACTING CHAIRMAN ANNE E. BRUNSDALE

Bulk Ibuprofen from India
Invs. Nos. 701-TA-308 and 731-TA-526 (Preliminary)

I agree with my colleagues that there is a reasonable indication that an industry in the United States has been materially injured by reason of imports of bulk ibuprofen from India that are allegedly dumped and subsidized. Because the information assembled by staff in these preliminary investigations covers only domestic producers of bulk ibuprofen, I accept for our purposes here that the like product consists only of bulk ibuprofen and that the domestic industry consists only of the Ethyl Corporation, the only domestic firm that produced bulk ibuprofen during the period of investigation.

In these additional views I discuss two issues. First, I address respondents' argument that a properly defined like product would include the analgesics aspirin and acetaminophen, as well as ibuprofen. While a lack of data precludes my using such a definition in these preliminary investigations, I find the argument quite persuasive and may well broaden my definition of the like product in any final investigations. Second, I discuss the evidence that leads me to find a reasonable indication of material injury in these preliminary investigations.

Like Product

Respondents argued that the like product should consist of ibuprofen, aspirin, and acetaminophen both in bulk and oral dosage forms.[1] This raises two issues. First, should oral dosages should be included along with the bulk products? On this issue, I have little to add to the discussion in the Commission's opinion. I note that producers of oral dosages are purchasers of the bulk ibuprofen that is the subject of the current investigations. As such, they are unlikely to have been injured by any dumping or subsidization of bulk ibuprofen. Indeed, they may have benefited from a reduction in the price of an important input into their production process. Including such purchasers in the domestic industry, which would be the obvious result of including their product in the like product, could mask the extent of any injury to producers who actually compete with the subject. Such an approach is not consistent with the meaning of the statute.

The second issue raised by respondents is whether aspirin and acetaminophen should be included in the like product or whether the like product consists solely of bulk ibuprofen. In thinking about this issue, I find it useful to employ the reasoning I recently set forth regarding like product

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[1] Respondents' Post-Conference Brief at 1.

definition.[2] There, I sought to focus our attention on whether dumping would induce significant substitution among the potential like products by either producers or consumers. By examining substitutability among domestic products, I can identify the types of products that will be significantly affected by any dumping or subsidization of the articles subject to investigation.

The question of whether to include aspirin and acetaminophen in the like product appears to involve the issue of substitution by consumers.[3] Specifically, respondents pointed to considerable evidence that all three products are useful in reducing fever and in relieving the same types of pain and discomfort. The labels for the three products cite their effectiveness for the same ailments, as do several experts cited by respondents.[4] Further, market research and advertising appear to treat all three as competitors of each other.[5] This evidence would seem to suggest

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[2] See Polyethylene Terephthalate Film, Sheet, and Strip from Japan and the Republic of Korea, Invs. Nos. 731-TA-458 and 459 (Final), USITC Pub. 2383 (May 1991) at 31-43 (Dissenting Views of Acting Chairman Anne E. Brunsdale).

[3] Given our current knowledge, there does not appear to be any issue of production substitutability. However, I would be interested in any additional information on this issue in any final investigations.

[4] See Respondents' Post-Conference Brief at 5-6 and the sources cited there.

[5] For example, respondents provide two studies of the analgesics market which show changes in the market shares of the three drugs within the overall analgesics grouping. (See Respondents' Post-Conference Brief at Exhibit 4.)

that any suppression or depression of the price of ibuprofen caused by dumping or subsidies would lead some consumers to purchase ibuprofen rather than aspirin or acetaminophen. As a result, producers of these products, as well as producers of ibuprofen, would be affected by any unfair pricing of imported ibuprofen.

Of course, the question is not whether any consumers would respond to the price change, but how many consumers would respond. If only a small percentage of consumers would shift in response to a price change, then there would be no significant effects on producers of aspirin and acetaminophen, and those products should not be included in the like product. However, if a large percentage of consumers would change their purchasing patterns in response to a modest change in relative prices, then all three products should be included in the like product. I would be most interested, in the event of any final investigations, in any studies or other evidence on the extent to which consumer demand for aspirin or acetaminophen products are affected by changes in the price of ibuprofen.[6]

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[6] I note that to the extent there is competition among ibuprofen, aspirin, and acetaminophen, it is at the final consumer level, not where the bulk product is purchased. For example, a tablet producer, the immediate purchaser of the three products in bulk form, must purchase bulk aspirin to fill an order for aspirin tablets; he may not substitute bulk ibuprofen. This does not seem to create any significant problems for treating the three analgesic products as being the same like product in this case, at least in part because essentially all bulk aspirin, acetaminophen, and ibuprofen are used to produce oral doses of

(continued...)

Reasonable Indication of Material Injury by Reason of Unfair Imports[7]

While the record in a preliminary antidumping investigation is less developed than in a final investigation, I am required to answer the same basic question in both instances. I therefore find it useful to employ in preliminaries the same simple tools of economic analysis I utilize in final investigations. By using economic analysis, one can examine directly -- as our governing statute requires -- the impact of the imports in question on the domestic industry, the nature of any such impact, and finally whether that impact constitutes material injury.[8,9]

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[6](...continued)
the three products and the bulk products clearly impart the essential characteristic to the resulting oral doses. However, the competition is certainly somewhat different from what the Commission considers in the average case. I would therefore also be interested in the views of the parties concerning any problems created by this approach.

[7] The above discussion strongly suggests that the appropriate like product in these investigations includes bulk aspirin and acetaminophen in addition to bulk ibuprofen. However, as noted previously, the lack of data on aspirin and acetaminophen precludes me from employing this definition for purposes of these preliminary investigations. Therefore, my discussion of material injury is based on the assumption that the like product consists of only bulk ibuprofen.

[8] In addition, I have examined the information on the condition of the domestic industry as reported in the Staff Report and find it useful in determining whether the injury resulting from any dumping and subsidization is material. Because there is only one domestic producer of bulk ibuprofen, this information is confidential and cannot be discussed in any detail in a public report.

Three factors are particularly significant in my evaluation of the likelihood of material injury in the present investigation. First, it appears that the subject imports are quite substitutable for the ibuprofen produced by domestic firms. While different firms use slightly different processes in producing bulk ibuprofen,[10] each firm making ibuprofen tablets must obtain FDA approval of the bulk ibuprofen it wishes to use in its tablets.[11] As a result, ibuprofen from any approved source is likely to be highly substitutable for ibuprofen from any other approved source. The high degree of substitutability makes it more likely that an industry will be materially injured if substantial quantities of imports are sold at less than fair value.

Second, the alleged dumping and subsidy margins in these investigations are quite high. Petitioner alleges that the Indian ibuprofen producer benefits from a variety of countervailable subsidy programs and estimates the total effect

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[9](...continued)
[9] A more thorough discussion of the economic analysis I use in my approach to causation analysis is contained in Internal Combustion Forklift Trucks from Japan, Inv. No. 731-TA-377 (Final), USITC Pub. 2082, at 66-83 (May 1988) (Additional Views of Vice Chairman Anne E. Brunsdale); see also Certain Steel Pails from Mexico, Inv. No. 731-TA-435 (Final), USITC Pub. 2277, at 24-28 (March 1990) (Additional Views of Chairman Anne E. Brunsdale) and Certain Residential Door Locks and Parts Thereof From Taiwan, Inv. No. 731-TA-433 (Final), USITC Pub. 2253, at 33-36 (January 1990) (Additional Views of Chairman Anne E. Brunsdale).

[10] Report at A-4.

[11] Report at A-10 and A-29.

of these programs is a net subsidy margin that may exceed 76 percent.[12] Based on petitioner's data, Commerce has calculated alleged dumping margins ranging from 3.0 to 7.55 percent.[13] While these margins are little more than petitioner's claims, they are the best information currently available concerning the level of the subsidies and dumping and suggest that the price of Indian ibuprofen may be significantly below "fair" levels.

Finally, the share of the U.S. ibuprofen market accounted for by the Indian imports is not small enough, when combined with the other factors, to ensure that there is no material injury by reason of the "unfair" imports. Imports of bulk ibuprofen from India increased from [***] percent of consumption in 1988 to [***] percent in the first half of 1991, measured by quantity, and rose from [***] percent of U.S. apparent consumption in 1988 to [***] in the first half of 1991, measured by value.[14]

Taken together, these factors support a finding of a reasonable indication that an industry in the United States is materially injured by reason of imports of ibuprofen from India. While the market share is not particularly high, the alleged dumping and subsidy margins suggest that prices of the subject imports may be considerably below "fair" levels. Further, imported ibuprofen is a good substitute for that produced

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[12] Petition at 17.

[13] Report at A-7.

[14] Report at A-25, Table 15.

domestically so that any lowering of the subject import price is likely to affect the demand for domestic ibuprofen.

Therefore, based on the evidence available to us in this preliminary investigation, I find that there is a reasonable indication of material injury to domestic producers of bulk ibuprofen by reason of imports of bulk ibuprofen from India that is allegedly subsidized or sold at less than fair value.

INFORMATION OBTAINED IN THE INVESTIGATIONS

INTRODUCTION

On July 31, 1991, a petition was filed with the U.S. International Trade Commission (Commission) and the U.S. Department of Commerce (Commerce) by counsel for Ethyl Corporation (Ethyl), Richmond, VA, alleging that an industry in the United States is materially injured and threatened with further material injury by reason of imports from India of bulk ibuprofen[1] that are alleged to be subsidized by the Government of India and to be sold in the United States at less than fair value (LTFV).

Accordingly, effective July 31, 1991, the Commission instituted investigations Nos. 701-TA-308 (Preliminary) and 731-TA-526 (Preliminary) under sections 703(a) and 733(a) of the Tariff Act of 1930, respectively, to determine whether there is a reasonable indication that an industry in the United States is materially injured, or is threatened with material injury, or that the establishment of an industry in the United States is materially retarded, by reason of the allegedly subsidized and LTFV imports of bulk ibuprofen into the United States.

Notice of the institution of these investigations and of a conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the Federal Register of August 7, 1991 (56 F.R. 37571). Commerce published its notices of initiation in the Federal Register of August 26, 1991 (56 F.R. 42026).[2] The conference was held on August 21, 1991,[3] and the Commission's vote was September 11, 1991. The statute directs that the Commission make its determinations in these investigations within 45 days after receipt of the petition, or by September 16, 1991.

THE PRODUCT

Description and Uses

Bulk ibuprofen is a nonsteroidal anti-inflammatory agent that is also used to control pain and fever. The chemical description of bulk ibuprofen is 2-(4-isobutylphenyl) propionic acid, $C_{13}H_{18}O_2$. It comes in a white free-flowing crystalline form, which is easily compressed and not soluble in water.

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[1] For purposes of these investigations, the subject product is ibuprofen in bulk form. A white powder, it is defined as a nonsteroidal anti-inflammatory agent which also has analgesic and antipyretic activity. It is used in the symptomatic treatment of acute and chronic rheumatoid arthritis, osteoarthritis, and primary dysmenorrhea, and for the relief of mild to moderate pain. The chemical description of bulk ibuprofen is 2-(4-isobutylphenyl) propionic acid, $C_{13}H_{18}O_2$. The product covered by these investigations does not include ibuprofen in tablet, capsule, or similar forms for sale or direct human consumption. Bulk ibuprofen is classified in subheading 2916.39.15 of the Harmonized Tariff Schedule of the United States (HTS).

[2] Copies of the Commission's and Commerce's notices are shown in app. A.

[3] A list of witnesses appearing at the conference is presented in app. B.

Its sole use is in the manufacture of dosage forms for human consumption, for example, tablets, caplets, or liquid suspensions. Dosage forms are used in the symptomatic treatment of acute and chronic rheumatoid arthritis, osteoarthritis, and primary dysmenorrhea, and for the relief of mild to moderate pain. Ibuprofen tablets are sold over-the-counter in 200 milligram dosages under the trade names Nuprin, Advil, Mediprin, Ibuprin, Motrin IB, Trendar, Haltran, Midol 200, and Doans and under many private labels. Prescription ibuprofen tablets (300, 400, 600, and 800 milligram dosages) are sold under such trade names as Motrin and Rufen, and under numerous generic labels.[4]

Manufacturing Process

Ethyl, the Indian producers, and Boots Company PLC,[5] all use a slightly different series of chemical reactions to produce the product. Ethyl makes its bulk ibuprofen in a seven-step process using two key ingredients, isobutyl benzene (IBB) and acetyl chloride.[6] IBB is converted to bulk ibuprofen through a series of chemical reactions. The result of each reaction in turn reacts with other chemicals to provide a new chemical compound. Many of the reactions are conducted in glass-lined equipment. All raw material must be tested and approved before use. Isolated intermediates are tested and must meet certain specifications before use in subsequent steps. Bulk ibuprofen is isolated from the organic solvent by a crystallization process where the solution containing ibuprofen is cooled at a carefully controlled rate until precipitation occurs. The ibuprofen is then centrifuged, washed, and dried.

Ethyl's production is on a batch-by-batch basis, as opposed to a continuous process.[7] Each batch takes *** days to produce. The process has numerous recycle streams to minimize waste and to achieve efficient operation. The plant includes its own solvent-recovery process, aqueous waste-treatment facilities, and vent incinerator. A dedicated analytical laboratory performs raw material and intermediate product analysis as well as final product qualification. Ethyl maintains and retests individual batch samples for *** years and subjects each batch to multiple analyses before release for shipment.

At Ethyl, the bulk ibuprofen is screened and packaged into fiber drums lined with two polyethylene bags. The drums are sealed and covered with tamper-proof tape to insure product integrity. Packaging is conducted in a clean-room environment. Pharmaceutical companies are the only purchasers of bulk ibuprofen. They further process the bulk ibuprofen by first adding inert ingredients. The mixture is then baked, granulated, lubricated, compressed into tablets, coated, and packaged.

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[4] Petition, p. 4. The various dosage strengths simply reflect the amount of contained ibuprofen. Bulk ibuprofen itself is not differentiated by either strengths or grades.

[5] Boots Company PLC (Boots PLC) of Nottingham, United Kingdom, invented ibuprofen in 1960 and is the largest producer of bulk ibuprofen in the world.

[6] Petition, p. 2.

[7] Ethyl produces primarily ***-kilogram batches, but can also produce ***-kilogram batches.

The ability of a tableter to use a source's bulk ibuprofen is contingent on FDA approval of its own drug product and FDA approval of the facilities and manufacturing practices used in making the drug product. Tableters indirectly obtain FDA approval for their bulk suppliers' facilities and manufacturing practices as part of obtaining FDA approval for each of the tableters' dosage forms. A producer of bulk ibuprofen who wishes to become qualified to sell to U.S. tableters submits a Drug Master File (DMF) to the FDA. The DMF is not reviewed by the FDA unless it receives an application by a U.S. tableter to use that company's product.

After a tableter has identified a bulk ibuprofen producer in its application, and the FDA has found the bulk producer's DMF satisfactory, the FDA will schedule an inspection of the bulk producer's plant. Once any problems are resolved, the manufacturer is considered an acceptable source of the bulk substance. The next phase of the review begins when the FDA examines the data submitted by the tableter.[8] If the FDA is eventually satisfied with the test results, it will grant approval for the dosage manufacturer to use the supplier's bulk ibuprofen. Each dosage strength produced by the tableter must be approved separately by the FDA, even if the source of the bulk is the same. The FDA approval process can take from 6 months to 2 years.

There are no quality differences between FDA-approved bulk ibuprofen from different sources; they have the same chemical and molecular structure, the same pharmacological effect, the same uses, and therefore are interchangeable.[9]

Substitute Products

Bulk ibuprofen is the only FDA-approved substance used to make ibuprofen drug products. However, bulk ibuprofen is not by itself approved by the FDA for use as a drug product and is not interchangeable with dosage forms. In dosage form, two other analgesics, aspirin and acetaminophen, are also commonly used for the relief of mild to moderate pain. Though they differ in their effectiveness, all three can reduce fever and relieve headache, muscle ache, menstrual pain, toothache, and similar discomfort.[10] Bulk aspirin and bulk acetaminophen are produced in separate facilities, and have a different chemical and molecular composition than ibuprofen. The manufacturing processes and facilities of neither bulk aspirin nor bulk acetaminophen are interchangeable with those for bulk ibuprofen.[11] There is also a significant

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[8] Test batches usually consist of 100,000 tablets per dosage. They are subjected to a 3-month accelerated stability study to ensure that the tablet will be stable and effective throughout its shelf life.

[9] Transcript of conference, p. 9.

[10] Aspirin has more gastrointestinal side effects than acetaminophen or ibuprofen. Acetaminophen has little anti-inflammatory effects. Both aspirin and acetaminophen are more effective at reducing fever than ibuprofen.

[11] Of the 4 U.S. producers of bulk aspirin, Dow Chemical Co., Rhone Poulenc, Sterling Drug, Inc., and Norwich Easton, two, Sterling Drug and Rhone Poulenc, also produce bulk acetaminophen. Mallinckrodt, Inc. is a third producer of acetaminophen. Monsanto Co., a former producer of both bulk

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price difference between the three products. Bulk ibuprofen sells for $15.00-25.00 per kilogram, bulk aspirin for $1.00-2.00 per kilogram, and bulk acetaminophen for $5.00-7.00 per kilogram.[12]

The analgesic market as a whole is highly competitive. There are approximately 20 analgesics, a majority of which contain narcotics or other central nervous system depressants and are available in the United States only in prescription forms. The three major analgesics that are not narcotics--aspirin, acetaminophen, and ibuprofen--comprise a majority of the total analgesic market and come both in prescription and over-the-counter dosages.

U.S. Tariff Treatment

Ibuprofen in bulk form is provided for in HTS subheading 2916.39.15, for which the column 1-general rate of duty is 6.8 percent ad valorem and the column 2 rate of duty is 15.4 cents per kilogram plus 47.5 percent ad valorem. Bulk ibuprofen may be entered free of duty under the Generalized System of Preferences (GSP); however, imports of bulk ibuprofen from India are not eligible for GSP treatment.[13]

Ibuprofen in tablet or other dosage form is provided for in HTS subheading 3004.90.60, bearing a column 1-general rate of duty of 6.3 percent ad valorem and a column 2 rate of duty of 30 percent ad valorem.

NATURE AND EXTENT OF ALLEGED SUBSIDIES AND SALES AT LTFV

Alleged Subsidies

Petitioner listed a number of practices by the Government of India that allegedly confer subsidies on producers or exporters of bulk ibuprofen in India. Commerce is initiating an investigation of the following programs: import replenishment licenses; rebates under the cash compensatory support program; excessive drawback of import duties; grants under the market development assistance program; diesel oil subsidies; preferential export financing through export packing credits; income tax deductions for exporters; preferential post-shipment financing; import duty exemptions available through advance licenses; sales of additional licenses; grants received under the central investment subsidy scheme; transportation subsidies; extension of free trade zones; import duty exemptions available to 100 percent export-oriented units; and preferential waste disposal rates.

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[11] (...continued)
aspirin and bulk acetaminophen, recently sold its bulk analgesics facilities to Rhone Poulenc. Ethyl, the sole producer of bulk ibuprofen, does not produce either bulk aspirin or bulk acetaminophen.

[12] Dorsey & Whitney, postconference brief, p. 6.

[13] GSP treatment for bulk ibuprofen from India was withdrawn effective July 1, 1991, as a result of a petition filed by Ethyl with the United States Trade Representative in the 1990 annual review of the operation of the GSP program.

Alleged Sales at LTFV

In order to obtain estimated dumping margins for bulk ibuprofen imported from India, the petitioner compared the United States price (USP) to foreign market value (FMV). The petitioner based the USP on customs data for imports of bulk ibuprofen from India. Adjustments were made, where appropriate, for foreign inland freight, foreign inland insurance, foreign brokerage, drug export clearance charges, port charges, and credit expenses. These adjustments were based on information contained in a marketing research study and petitioner's own experience. Petitioner's estimate of FMV is based on domestic prices of bulk ibuprofen published on a monthly basis in the Indian Chemical Weekly. The prices were adjusted for inland freight, insurance, packing costs, and credit expenses. Based on a comparison of USP and FMV, petitioner has alleged dumping margins ranging from 33.69 to 39.12 percent. As estimated by Commerce, dumping margins range from 3.00 percent to 7.55 percent.

U.S. MARKET

Ibuprofen was discovered in 1960 by Boots PLC while conducting anti-rheumatic medical research. Boots PLC received a U.S. patent on ibuprofen in 1968. In 1974, Upjohn Corporation (Upjohn) of Kalamazoo, MI, became Boots PLC's exclusive licensee in the United States. Under a manufacturing agreement with Upjohn, Ethyl began producing bulk ibuprofen in 1978. When ibuprofen was approved for sale over-the-counter in May 1984, Upjohn licensed Bristol-Myers to market Nuprin, and Boots PLC licensed American Home Products to market Advil. The U.S. patent on bulk ibuprofen expired in May 1985.[14]

The analgesic market is highly competitive. Media advertising spending for the industry is estimated at more than $300 million annually, with the five leading brands accounting for more than 75 percent of this expenditure.[15] It is estimated that ibuprofen in dosage form holds about 21 percent of the $2.4 billion U.S. over-the-counter analgesics market, and is expected to expand its share to 33 percent.[16]

The pharmaceutical industry has changed in recent years due to the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Waxman-Hatch Act. This act made the pharmaceutical market more accessible to new entrants by creating the Abbreviated New Drug Applications (ANDAs) process for FDA approval of generic versions of post-1962 drugs. Because of the simplification of the application process and the cost savings, many generic competitors have entered the market.[17]

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[14] Transcript, p. 58.

[15] Aducci, Mastriani, Meeks & Schill, postconference brief, p. 8.

[16] "BHC Starts 'Countdown' to U.S. Ibuprofen Facility," Chemical Marketing Reporter, Apr. 22, 1991.

[17] Aducci, Mastriani, Meeks & Schill, postconference brief, p. 41.

U.S. Producers

ETHYL

The petitioner, Ethyl, is the sole U.S. manufacturer of bulk ibuprofen. Ethyl is headquartered in Richmond, VA, and has four chemical manufacturing locations in the United States. Bulk ibuprofen is only produced at Ethyl's Orangeburg, SC, facility. This 300-acre facility employs 500 people directly, with another 100 or more on the payrolls of contractors working on the site. The Orangeburg plant manufactures 16 basic chemical products and another 57 in either blended formulations or limited-production runs. These are all "intermediates" that require additional processing by customers to manufacture finished products. In addition to ibuprofen, products manufactured at the Orangeburg plant include additives used in gasoline and diesel fuels; antioxidants used in plastics and lubricants; agricultural intermediates used in compounds for protecting corn, cotton, and rice; aluminum alkyls used as catalysts in chemical reactions; and specialty polymers for specialty chemical intermediates. Bulk ibuprofen is the only pharmaceutical intermediate produced by Ethyl.

As mentioned, Ethyl began producing bulk ibuprofen in 1978 under an agreement with Upjohn. When Upjohn had trouble keeping up with U.S. demand for ibuprofen products, it approached Ethyl to produce the key ingredient for bulk ibuprofen, isobutyl benzene. Ethyl and UpJohn realized that Ethyl, as a chemical company, could produce bulk ibuprofen more efficiently than Upjohn, a pharmaceutical company. An agreement was made under which Ethyl would produce the bulk ibuprofen for UpJohn, which in turn would tablet it. Ethyl is now the ***.

In 1989, Ethyl invested *** in its bulk ibuprofen facility, changing the manufacturing process, expanding capacity, and adding significant environmental-control facilities. The investment was largely aimed at cost reduction. By eliminating 2 steps in the manufacturing process, it is estimated that Ethyl will save *** year, or *** per kilogram.[18] After Ethyl changed its manufacturing process, each of its customers had to obtain FDA approval to use the bulk ibuprofen produced by the new method.

BOOTS HOECHST CELANESE

In April 1988, Boots Manufacturing, Inc.[19] (BMI) and Hoecel Corp.[20] (HC) announced a joint venture to build a ***-metric ton capacity bulk ibuprofen plant in the United States. The joint venture, called Boots Hoechst Celanese (BHC), was legally formed in ***. This venture is 50-percent owned by BMI and 50-percent owned by HC. An engineering contractor was selected in *** and engineering began in ***. The U.S. market for bulk ibuprofen ***. Bishop,

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[18] Telephone conversation with ***.

[19] Boots Manufacturing, Inc. is wholly owned by the Boots Company (USA), Inc., which in turn is owned by Boots PLC.

[20] Hoecel is wholly owned by Hoechst Celanese Corporation, an importer of bulk ibuprofen, which is owned by Hoechst Corp., a Delaware corporation. Hoechst Corp. is in turn wholly owned by Hoechst AG, of Frankfurt, Germany.

TX, was selected as the site of BHC's plant in the third quarter of 1990. Construction was begun in *** 1990 and is currently *** percent complete.[21] BHC expects the plant to be mechanically complete in ***. Commercial production and sales will not be initiated until *** and full capacity is not expected to be reached until ***.[22] The plant will be located on *** acres with the facility occupying approximately *** of the area. BHC projects employment of *** workers. Hoechst Celanese, the parent company of HC, is building an acetaminophen plant directly adjacent to the BHC plant. This plant is solely owned by Hoechst Celanese and will not share employees with BHC's bulk ibuprofen facility.

BHC entered into an exclusive distribution agreement with Boots PLC in *** whereby BHC distributes Boots PLC's bulk ibuprofen in the United States. Once most potential customers receive FDA approval to use BHC's bulk ibuprofen, BHC intends ***.[23] In an effort to speed the FDA approval process, two Hoechst Celanese employees in a pilot plant in Corpus Christi, TX, can produce samples for customers for FDA testing and qualification purposes.[24] [25] BHC has not made any sales of bulk ibuprofen produced in the United States. BHC is ***.[26]

U.S. Importers

Questionnaires were sent to *** firms identified by the U.S. Customs Service as having imported bulk ibuprofen during the period of investigation. Of the *** recipients of the Commission's questionnaire, imports of bulk ibuprofen were reported by eight firms, one of which reported imports of bulk ibuprofen from India. *** firms reported that they did not import bulk ibuprofen during the investigation period. Data from the eight importers of bulk ibuprofen are believed to account for virtually all imports of bulk ibuprofen.

Flavine International, Inc. (Flavine), of Closter, NJ, accounted for all known imports of bulk ibuprofen from India during the period of investigation. As the sole authorized U.S. distributor of bulk ibuprofen from Cheminor Drugs (an Indian producer and exporter) since 1987, Flavine sells bulk ibuprofen to three domestic tablet formulators for generic, over-the-counter tablet production.[27] Flavine is an importer and wholesaler of bulk fine

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[21] Baker & Hostetler submission, p. 3.

[22] Baker & Hostetler submission, p. 7.

[23] At that time, ***.

[24] The pilot plant is part of a Hoechst Celanese research and development technical facility. ***.

[25] Since test batches produced at the pilot plant are made using the same chemical process that will be used at the Bishop facility, tableters can use these samples to produce test batches of tablets. However, once the Bishop facility is completed, it will have to receive FDA approval on its manufacturing facility and practices. Telephone conversation with ***.

[26] Baker & Hostetler submission, p. 2.

[27] Five customers of Flavine are FDA approved to buy bulk ibuprofen from Cheminor for use in the production of dosage forms: ***.

pharmaceuticals and vitamins for both human and animal consumption.[28] It sells approximately 70-80 different products and bulk ibuprofen represented *** of its sales in 1990.[29]

Roussel Corporation, the U.S. agent for Shasun Drugs (another Indian bulk ibuprofen producer), is currently quoting prices for bulk ibuprofen to U.S. tablet formulators contingent upon FDA approval. The FDA inspected Shasun Drugs' facilities on September 17 and 18, 1990.[30] Presently, no U.S. tableter has included Shasun's ibuprofen in an ANDA submission or has supplemented their ANDA with Shasun's ibuprofen. The Roussel Corporation does not expect to be able to sell commercial quantities of bulk ibuprofen in the United States until 1993.[31]

Other current importers and their sources of bulk ibuprofen are Boots Pharmaceutical, Inc., Shreveport, LA (Boots PLC, United Kingdom); Hoechst Celanese Corporation, Dallas, TX (Boots PLC, United Kingdom); Interchem Corporation, Paramus, NJ (Francis, S.P.A., Italy); and Whitehall Laboratories, New York, NY (Boots PLC, United Kingdom). Gyma Laboratories of America, Inc., Garden City, NY, and Mitsubishi International Corporation, New York, NY, imported bulk ibuprofen from Spain (Inquimes) and Japan (Hamani), respectively, during 1988, but have since ceased all imports of bulk ibuprofen.

Channels of Distribution

Ethyl and Flavine, the only U.S. importer of bulk ibuprofen from India, sell all of their bulk ibuprofen to pharmaceutical companies, which formulate the bulk ibuprofen into tablets, caplets, or liquid suspensions. With the exception of Boots Pharmaceuticals and Whitehall Laboratories, a majority of the remaining U.S. importers similarly sell to pharmaceutical companies. Both Boots and Whitehall, ***, import bulk ibuprofen from the United Kingdom and prepare dosage forms of ibuprofen in their own facilities in the United States. However, once the BHC plant begins commercial production in Bishop, TX, Boots plans ***.

There are approximately 27 tablet formulators of bulk ibuprofen in the U.S. market. These tableters sell dosage forms to distributors, wholesalers, chain stores, mass merchandisers, independent pharmacies, and hospitals. Based on questionnaire responses, Ethyl sells *** percent of its bulk ibuprofen to generic pharmaceutical companies which formulate generic tablets in both prescription and over-the-counter dosages. The remaining *** percent of Ethyl's sales are to pharmaceutical companies which formulate and sell brand-name tablets in both prescription and over-the-counter dosages. In contrast, Flavine sells *** percent of its bulk ibuprofen from India to generic pharmaceutical companies. Only five U.S. tableters are FDA approved to use the bulk ibuprofen produced by Cheminor (see footnote 27), whereas a

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[28] Transcript, p. 82.
[29] Postconference brief of respondents, app. A.
[30] Telephone conversation with ***.
[31] Letter dated ***.

majority of the 27 are approved to use the bulk ibuprofen produced by Ethyl and Boots PLC.

Domestically produced bulk ibuprofen is sold nationwide. Flavine's sales currently ***. ***.[32]

Apparent U.S. Consumption

Data on apparent U.S. consumption of bulk ibuprofen were compiled from information submitted in response to Commission questionnaires. These data, presented in table 1, are composed of the sum of shipments of the U.S. producer and importers.

The quantity and value of apparent U.S. consumption of bulk ibuprofen *** by *** percent and *** percent, respectively, between 1988 and 1990. From January-June 1990 to January-June 1991, quantity and value *** by *** percent and *** percent, respectively. U.S. demand for bulk ibuprofen was the highest ever in 1989 due to three factors: Whitehall was in the process of bringing on stream its new tableting facility in Puerto Rico; three new ibuprofen products were being introduced in the U.S. market (CoAdvil and two forms of liquid ibuprofen for children); and the cold season was very intense and longer than usual.[33]

CONSIDERATION OF ALLEGED MATERIAL INJURY TO AN INDUSTRY IN THE UNITED STATES

The information in this section of the report is based on data received from Ethyl, the only U.S. producer of bulk ibuprofen, representing 100 percent of U.S. production for the period covered by the investigation.

U.S. Producer's Capacity, Production, and Capacity Utilization

Data for U.S. production, capacity, and capacity utilization are summarized in table 2. Ethyl's capacity to produce bulk ibuprofen *** by *** percent from 1988 to 1990, and by *** percent during the interim periods. In 1989, Ethyl began to convert from its original production process to a more efficient one and at the same time increased its capacity. U.S. production *** by *** percent from 1988 to 1990, *** by *** percent during the interim periods. It should be noted that Ethyl's production *** in 1989 with a ***-percent *** from 1988.

Capacity utilization *** from *** percent in 1988 to *** percent in 1990, *** from *** percent to *** percent during the interim periods. Ethyl reported capacity based on *** hours per week, *** weeks per year.

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[32] Telephone conversation, Aug. 22, 1991.
[33] Transcript, p. 55.

Table 1
Bulk ibuprofen: U.S. producer's and importers' shipments and apparent U.S. consumption,[1] 1988-90, January-June 1990, and January-June 1991

Item	1988	1989	1990	January-June-- 1990	1991
	*	*	*	*	*

[1] There are discrepancies between data received from Commission questionnaires and official statistics of the U.S. Department of Commerce. The official statistics appear to be overstated (particularly in 1988 and 1989) as a result of the misclassification of imports of ibuprofen tablets from the United Kingdom under the subheading for bulk ibuprofen. Apparent consumption based on quantity as calculated from official statistics, would be *** thousand kilograms in 1988, *** thousand in 1989, *** thousand in 1990, *** thousand in January-June 1990, and *** thousand in January-June 1991. Apparent consumption based on value would be *** thousand dollars in 1988, *** thousand in 1989, *** thousand in 1990, *** thousand in January-June 1990, and *** thousand in January-June 1991.

Note.--Because of rounding, figures may not add to the totals shown.

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

Table 2
Bulk ibuprofen: U.S. capacity, production, and capacity utilization, 1988-90, January-June 1990, and January-June 1991

Item	1988	1989	1990	January-June-- 1990	1991
	*	*	*	*	*

Note.--Capacity utilization computed from the unrounded figures.

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

U.S. Producer's Shipments[34]

Ethyl's domestic and export shipments of bulk ibuprofen are presented in table 3.

DOMESTIC SHIPMENTS

The U.S. producer's domestic shipments of bulk ibuprofen *** by *** percent from 1988 to 1990, and *** by *** percent from January-June 1990 to January-June 1991. Similarly, the value of these shipments *** by *** percent from 1988 to 1990, and *** by *** percent from January-June 1990 to January-June 1991. The average unit value of Ethyl's U.S. shipments of bulk ibuprofen *** from *** per kilogram in 1988 to *** in 1990. ***, the average unit value *** from *** to *** during the interim periods.

Included in Ethyl's domestic shipment numbers are free sample shipments. Small quantities of free samples are sent to U.S. tableters on a one-time basis for testing and FDA qualification purposes. These samples are usually *** kilograms in size. During the period of investigation they approximated no more *** kilograms in a given year.

EXPORT SHIPMENTS

Export shipments *** by *** percent from 1988 to 1990, and *** by *** percent during the interim periods. Ethyl's principal export markets for bulk ibuprofen are ***. The quantity of Ethyl's export shipments ranged from *** to *** percent of its total shipments throughout the period of investigation except for January-June 1991, when they were *** percent. The unit values of these exports were *** than the unit values of domestic shipments throughout the period.

TOTAL SHIPMENTS

Total U.S. producer's shipments of domestically produced bulk ibuprofen *** by *** percent from 1988 to 1990, and *** by *** percent during the interim periods. *** the value of such shipments *** by *** percent from 1988 to 1990, and *** by *** percent during the interim periods.

U.S. Producer's Inventories

Ethyl's end-of-period inventories of bulk ibuprofen are presented in table 4. These inventories *** by *** percent from 1988 to 1990, and by *** percent from January-June 1990 to January-June 1991. The ratio of inventories to Ethyl's total shipments *** from *** percent in 1988 to *** percent in 1990, and similarly *** from *** percent in January-June 1990 to *** percent in January-June 1991. Packed in air-tight drum containers, bulk ibuprofen has

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[34] Since Ethyl is not an ibuprofen tableter, it does not consume internally any of the bulk ibuprofen that it produces.

Table 3
Bulk ibuprofen: Shipments by the U.S. producer, by types, 1988-90, January-June 1990, and January-June 1991

Item	1988	1989	1990	January-June-- 1990	1991
*	*	*	*	*	*	*

Note.--Unit values computed from the unrounded figures.

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

Table 4
Bulk ibuprofen: End-of-period inventories of the U.S. producer, 1988-90, January-June 1990, and January-June 1991

Item	1988	1989	1990	January-June-- 1990	1991
*	*	*	*	*	*	*

Note.--Ratios are calculated from the unrounded data; partial year ratios are calculated using annualized shipments.

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

a shelf-life of at least 4 years; therefore, the maintenance of large inventories is not harmful to the product.

U.S. Employment, Wages, and Productivity

Data on employment and productivity are shown in table 5. Ethyl runs *** shifts each day with approximately *** workers on each shift. Ethyl's bulk ibuprofen production and related workers are ***.

The number of workers producing bulk ibuprofen and hours worked *** by *** percent from 1988 to 1990, and by *** percent from January-June 1990 to January-June 1991. Wages and total compensation paid to workers producing

Table 5
Average number of production and related workers producing bulk ibuprofen, hours worked, wages and total compensation paid to such employees, and hourly wages, productivity, and unit labor costs,[1] 1988-90, January-June 1990, and January-June 1991

Item	1988	1989	1990	January-June-- 1990	1991
*	*	*	*	*	*	*

[1] On the basis of total compensation paid.

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

bulk ibuprofen *** by *** percent and *** percent, respectively, from 1988 to 1990, and by *** percent and *** percent, respectively, during the interim periods. Hourly wages and hourly total compensation paid to workers *** by *** percent and *** percent respectively, from 1988 to 1990, and by *** percent and *** percent, respectively, during the interim periods.

Productivity *** by *** percent from 1988 to 1990, and *** by *** percent during the interim periods. Unit labor costs (per kilogram) *** by *** percent from 1988 to 1990, and *** by *** during the interim periods.

Financial Experience of the U.S. Producer

Ethyl submitted financial data on the establishment[35] in which bulk ibuprofen is produced and on its bulk ibuprofen operations.

OVERALL ESTABLISHMENT OPERATIONS

Income-and-loss data of Ethyl on its overall establishment operations in which bulk ibuprofen is produced are shown in table 6. Net sales on overall establishment operations *** percent from *** in 1988 to *** in 1989, and *** percent to *** in 1990.[36] Operating *** was *** in 1988, *** in 1989, and *** in 1990. Operating *** as a share of sales was *** percent in 1988, *** percent in 1989, and *** percent in 1990. Net sales of *** for the

[35] Ethyl produces bulk ibuprofen in its Orangeburg Chemical Facility in Orangeburg, SC. Bulk ibuprofen accounted for approximately *** percent of the total production of the Orangeburg facility in 1990.
[36] Ethyl's fiscal yearend is ***.

Table 6
Income-and-loss experience of Ethyl on the overall operations of its establishment in which bulk ibuprofen is produced, calendar years 1988-90, January-June 1990, and January-June 1991

Item	1988	1989	1990	January-June-- 1990	1991
*	*	*	*	*	*	*

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

6-month period ended June 30, 1991, were *** percent *** the net sales of *** for the 6-month period ended June 30, 1990. Operating *** was *** in the 1991 interim period compared to *** in interim 1990. The operating *** margin *** percent in interim 1990 and *** percent in interim 1991.

OPERATIONS ON BULK IBUPROFEN

Income-and-loss data for Ethyl on its bulk ibuprofen operations are shown in table 7. Net sales of bulk ibuprofen *** percent from *** in 1988 to *** in 1990. Operating *** was *** in 1988, *** in 1989, and *** in 1990. Operating *** margins were *** percent in 1988, *** percent in 1989, and *** percent in 1990.

Net sales of *** for the 6-month period ended June 30, 1991, were *** percent *** than the net sales of *** for the 6-month period ended June 30, 1990. Operating *** was *** in the 1991 interim period compared to *** in interim 1990. The operating *** margin as a percent of sales was *** percent in interim 1990 and *** percent in interim 1991.

Mr. Turnipseed, Director, International Trade, ***. He further stated that the plant ***.[37]

Mr. Turnipseed stated[38] that ***. He believes that ***. *** for the interim period of 1991 includes ***. If the cost of ***. ***.

Ethyl's income-and-loss experience on an average per-kilogram basis is presented in table 8. The sales value *** percent *** in 1988 *** in 1990. Operating *** per kilogram was *** in 1988, *** in 1989, and *** in 1990. The sales value *** percent from *** in interim 1990 to *** in interim 1991. Operating *** was *** per kilogram in interim 1990 and *** in interim 1991.

[37] Telephone conversation, Aug. 26, 1991.
[38] Telephone conversation, Aug. 22, 1991.

Table 7
Income-and-loss experience of Ethyl on its operations producing bulk ibuprofen, calendar years 1988-90, January-June 1990, and January-June 1991

Item	1988	1989	1990	January-June-- 1990	1991
*	*	*	*	*	*	*

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

Table 8
Income-and-loss experience (on a per-kilogram basis) of Ethyl on its operations producing bulk ibuprofen, calendar years 1988-90, January-June 1990, and January-June 1991

Item	1988	1989	1990	January-June-- 1990	1991
*	*	*	*	*	*	*

Note.--Because of rounding, figures may not add to totals shown.

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

The variance analysis[39] indicates *** price variances from *** caused by *** sales prices in each succeeding period. However, the price variance was *** when comparing the *** period to the *** period because of *** sales prices. The sales volume variance was *** from *** due to *** quantities sold. However, the sales volume variance was *** from *** because ***.

Two key raw materials, isobutyl benzene (IBB) and acetyl chloride (ACCL), used to produce bulk ibuprofen are produced by Ethyl at the Orangeburg facility. Mr. Turnipseed stated ***.[40]

[39] The variance analysis (submitted to the Commission as a separate memorandum) assists in the assessment of the causes of changes in profitability and identifies the relationships between price, cost, and volume.

[40] Mr. Turnipseed also stated that Ethyl's ***.

CAPITAL EXPENDITURES

Capital expenditures of Ethyl for its establishment in which bulk ibuprofen is produced and for its operations on bulk ibuprofen are shown in table 9. Capital expenditures for bulk ibuprofen were *** in 1988 and *** in 1990. However, capital expenditures for the interim period ending June 30, 1991, of *** were *** the *** for the interim period ending June 30, 1990. This *** presented in appendix C. ***.

INVESTMENT IN PRODUCTIVE FACILITIES

Ethyl's investment in productive facilities and its annual return on total assets are presented in table 10 for its overall establishment and bulk ibuprofen operations. The return on total assets was *** for ibuprofen than for establishment operations. However, ***, the return on ibuprofen was *** percent, approximately *** percent return on overall establishment operations.

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses for Ethyl's overall establishment and bulk ibuprofen operations are presented in table 11. Ethyl's research and development expenditures for bulk ibuprofen *** percent from *** in 1988 *** in 1990. Research and development expenses of *** in the interim period of 1991 were *** percent *** than the *** in the interim period of 1990.

IMPACT OF IMPORTS ON CAPITAL AND INVESTMENT

The Commission requested the U.S. producer to describe any actual or potential negative effects of imports of bulk ibuprofen from India on its growth, development and production efforts, investment, and ability to raise capital (including efforts to develop a derivative or improved version of its product). Ethyl's comments are presented in appendix C.

Consideration of the Question of Threat of Material Injury

Section 771(7)(F)(i) of the Tariff Act of 1930 (19 U.S.C. § 1677(7)(F)(i)) provides that--

> In determining whether an industry in the United States is threatened with material injury by reason of imports (or sales for importation) of any merchandise, the Commission shall consider, among other relevant factors[41]--

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[41] Section 771(7)(F)(ii) of the act (19 U.S.C. § 1677(7)(F)(ii)) provides that "Any determination by the Commission under this title that an industry in the United States is threatened with material injury shall be made on the basis of evidence that the threat of material injury is real and that actual injury is imminent. Such a determination may not be made on the basis of mere conjecture or supposition."

Table 9
Capital expenditures by Ethyl on its overall establishment and bulk ibuprofen operations, calendar years 1988-90, January-June 1990, and January-June 1991

(In thousands of dollars)

Item	1988	1989	1990	January-June-- 1990	1991

* * * * * * *

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

Table 10
Value of assets and return on assets of Ethyl for its overall establishment and bulk ibuprofen operations, calendar years 1988-90, January-June 1990, and January-June 1991

Item	As of December 31-- 1988	1989	1990	As of June 30-- 1990	1991

* * * * * * *

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

Table 11
Research and development expenses of Ethyl's overall and bulk ibuprofen operations, calendar years 1988-90, January-June 1990, and January-June 1991

(In thousands of dollars)

Item	1988	1989	1990	January-June-- 1990	1991

* * * * * * *

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

(I) If a subsidy is involved, such information as may be presented to it by the administering authority as to the nature of the subsidy (particularly as to whether the subsidy is an export subsidy inconsistent with the Agreement),

(II) any increase in production capacity or existing unused capacity in the exporting country likely to result in a significant increase in imports of the merchandise to the United States,

(III) any rapid increase in United States market penetration and the likelihood that the penetration will increase to an injurious level,

(IV) the probability that imports of the merchandise will enter the United States at prices that will have a depressing or suppressing effect on domestic prices of the merchandise,

(V) any substantial increase in inventories of the merchandise in the United States,

(VI) the presence of underutilized capacity for producing the merchandise in the exporting country,

(VII) any other demonstrable adverse trends that indicate the probability that the importation (or sale for importation) of the merchandise (whether or not it is actually being imported at the time) will be the cause of actual injury,

(VIII) the potential for product-shifting if production facilities owned or controlled by the foreign manufacturers, which can be used to produce products subject to investigation(s) under section 701 or 731 or to final orders under section 736, are also used to produce the merchandise under investigation,

(IX) in any investigation under this title which involves imports of both a raw agricultural product (within the meaning of paragraph (4)(E)(iv)) and any product processed from such raw agricultural product, the likelihood that there will be increased imports, by reason of product shifting, if there is an affirmative determination by the Commission under section 705(b)(1) or 735(b)(1) with respect to either the raw agricultural product or the processed agricultural product (but not both), and

(X) the actual and potential negative effects on the existing development and production efforts of the domestic industry, including efforts to develop a derivative or more advanced version of the like product.[42]

The available information on the nature of the subsidies found by the Department of Commerce (item (I) above) is presented in the section of this report entitled "Alleged subsidies;" information on the volume, U.S. market penetration, and pricing of imports of the subject merchandise (items (III) and (IV) above) is presented in the section entitled "Consideration of the causal relationship between imports of the subject merchandise and the alleged material injury;" and information on the effects of imports of the subject merchandise on U.S. producers' existing development and production efforts (item (X)) is presented in the section entitled "Consideration of alleged material injury to an industry in the United States." Available information on U.S. inventories of the subject products (item (V)); foreign producers' operations, including the potential for "product-shifting" (items (II), (VI), (VIII) and (IX) above); any other threat indicators, if applicable (item (VII) above); and any dumping in third-country markets, follows. Other threat indicators have not been alleged or are otherwise not applicable.

U.S. Importers' Inventories

Table 12 presents the end-of-period inventories of bulk ibuprofen held by Flavine. The end-of-period inventories of bulk ibuprofen from India, on the basis of quantity, ***. Inventories *** in interim 1991, *** percent compared to interim 1990. End-of-period inventories of imports from all other sources *** percent from 1988 to 1990, *** percent in interim 1991 compared to interim 1990.

End-of-period inventories as a share of total shipments of imports from India *** percent in 1988 to *** percent in 1990. Inventories as a share of imports shipments *** percent in January-June 1991 compared to *** percent in the corresponding period of 1990.

Ability of Foreign Producers to Generate Exports and the Availability of Export Markets Other than the United States

The Commission requested information regarding Indian manufacturers producing bulk ibuprofen. Two firms provided a response to this request; Cheminor Drugs, Ltd., the current exporter to the United States, and Shasun Drugs, an ibuprofen manufacturer which has indicated plans to export to the

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[42] Section 771(7)(F)(iii) of the act (19 U.S.C. § 1677(7)(F)(iii)) further provides that, in antidumping investigations, ". . . the Commission shall consider whether dumping in the markets of foreign countries (as evidenced by dumping findings or antidumping remedies in other GATT member markets against the same class or kind of merchandise manufactured or exported by the same party as under investigation) suggests a threat of material injury to the domestic industry."

Table 12
Bulk ibuprofen from India: End-of-period inventories of U.S. importers, 1988-90, January-June 1990, and January-June 1991

Item	1988	1989	1990	January-June-- 1990	1991
*	*	*	*	*	*	*

Note.--Ratios are calculated using data of firms supplying both numerator and denominator information. Partial year ratios are computed using annualized shipments.

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

United States contingent on FDA approval. Data received by the Commission are presented in table 13 and are estimated to represent virtually all Indian exports of bulk ibuprofen to the United States during the period of investigation.

Cheminor was established in 1984 and is currently one of the largest manufacturers of bulk pharmaceuticals in India. Cheminor produces ibuprofen, diltiazem, and certain related intermediates at its Hyderabad facilities. Cheminor reported that *** percent of the firm's sales in its most recent fiscal year were represented by sales of bulk ibuprofen. Approximately 65-70 percent of its production of bulk ibuprofen is exported to Europe, Asia, the USSR, and the United States.[43]

Reported capacity for the two firms *** from 1988 to 1990, while levels of production *** percent, from *** kilograms in 1988 to *** kilograms in 1990. Cheminor which operated at *** percent of capacity in 1990, has indicated that it has ***. In a written statement to the Commission, *** explained that Cheminor had planned to expand its ibuprofen production in a proposed plant to be constructed in Vishakhapatman. In 1990, the plans for production were cancelled and the proposed plant was redesigned and reconfigured for the exclusive production of chloramphenicol and its intermediates and salts. The facility has already commenced pre-production of these products and commercial production is planned for the fall of 1991.[44]

Cheminor's shipments of bulk ibuprofen to the United States *** in 1988 to *** in 1990. Compared to interim 1990, shipments to the United States *** in interim 1991. As indicated earlier, ibuprofen manufactured at Shasun Drugs is not FDA approved, thus the small amount of exports noted from Shasun are sample batches sent to U.S. tableters for ANDA submission. However, no U.S. company has yet included Shasun's ibuprofen in an ANDA submission.

[43] Transcript, p. 81.
[44] Transcript, p. 99.

Table 13
Bulk ibuprofen: Indian production capacity, production, shipments and end-of-period inventories, 1988-90, January-June 1990, January-June 1991, and projected 1991-92

(In 1,000 kilograms)

Item	1988	1989	1990	Jan.-June-- 1990	Jan.-June-- 1991	Projected 1991	Projected 1992
*	*	*	*	*	*	*	

Note.--Because of rounding, figures may not add to the totals shown.

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

End-of-period inventories of *** kilograms and *** kilograms were reported by the two firms in 1990 and in interim 1991, respectively. The ratio of end-of-period inventories to total shipments was *** percent in 1990 and *** percent in interim 1991.

According to the U.S. Embassy in New Delhi, the European Community has begun a countervailing duty/antidumping investigation on Indian ibuprofen, but the results of the investigation have not yet been determined.[45]

CONSIDERATION OF THE CAUSAL RELATIONSHIP BETWEEN IMPORTS OF THE SUBJECT MERCHANDISE AND THE ALLEGED MATERIAL INJURY

U.S. Imports

Data from the eight responding importers of bulk ibuprofen are believed to account for virtually all imports of bulk ibuprofen. As indicated in table 14, imports of bulk ibuprofen from India, in terms of quantity, *** percent during 1988-90 and *** percent in January-June 1991 compared with the corresponding period of 1990. The value of imports *** percent during 1988-90 and *** percent in interim 1991 compared with interim 1990. India's share of total imports, in terms of quantity, *** percent in 1988 to *** percent in 1990. India's share of total imports *** percent in January-June 1991.

Flavine occasionally provides its potential customers with bulk ibuprofen in relatively small amounts so that they may produce a sample of tablets, submit them to the FDA, and gain approval to produce tablets with

[45] U.S. Department of State telegram from the U.S. Embassy, New Delhi, in response to the Commission's request for information.

Table 14
Bulk ibuprofen: U.S. imports, by sources, 1988-90, January-June 1990, and January-June 1991

Item	1988	1989	1990	January-June-- 1990	1991
*	*	*	*	*	*	*

Note.--Because of rounding, figures may not add to the totals shown. Unit values are calculated from the unrounded figures, using data of firms supplying both quantity and value information.

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

Indian bulk ibuprofen purchased from Flavine.[46] ***.[47] ***. The FDA requires purchasers of the product to test and retain a sample from each batch that is shipped. ***. Consequently, ***. ***.[48]

Imports of bulk ibuprofen from all other countries, in terms of quantity, *** percent during 1988-90, *** percent in January-June 1991 compared with the corresponding period of 1990. In terms of value, bulk ibuprofen imported from all other countries *** percent from 1988 to 1990, *** percent in January-June 1991 compared with the corresponding period of 1990.

The unit value for imports from India *** from *** per kilogram in 1988 to *** per kilogram in 1990, then *** in interim 1991 to *** per kilogram. In comparison, the average unit values of imports from other sources *** from *** per kilogram in 1988 to *** per kilogram in 1990, but *** from *** per kilogram in interim 1990 to *** per kilogram in interim 1991.

Market Penetration by the Allegedly Subsidized and LTFV Imports

As indicated in table 15, India's share of apparent U.S. consumption of bulk ibuprofen *** from *** percent in 1988 to *** percent in 1990. Compared to a ***-percent market share in interim 1990, India's share of apparent U.S. consumption *** to *** percent in interim 1991. In terms of value, the *** was from *** percent in 1988 to *** percent in 1990 and from *** percent in interim 1990 to *** percent in interim 1991.

[46] Reported customers, dates, and quantities provided over the investigation period are as follows: ***.
[47] ***.
[48] ***.

Table 15
Bulk ibuprofen: Share of apparent U.S. consumption[1] supplied by the domestic producer, and importers from India and all other countries, 1988-90, January-June 1990, and January-June 1991

(In percent)

Item	1988	1989	1990	January-June-- 1990	1991
*	*	*	*	*	*	*

[1] There are discrepancies between data received from Commission questionnaires and official statistics of the U.S. Department of Commerce (particularly in 1988 and 1989). The official statistics appear to be overstated as a result of the misclassification of imports of ibuprofen tablets from the United Kingdom under the subheading for bulk ibuprofen. If official statistics are used, the Indian market penetration, based on quantity, would be *** percent in 1988, *** percent in 1989, *** percent in 1990, *** percent in January-June 1990, and *** percent in January-June 1991. Market penetration, based on value, would be *** percent in 1988, *** percent in 1989, *** percent in 1990, *** percent in January-June 1990, and *** percent in January-June 1991.

Note.--Shares are calculated from unrounded figures.

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

The share of the market held by Ethyl *** from *** percent in 1988 to *** percent in 1990, *** from *** percent in interim 1990, to *** percent in interim 1991. By value, the Ethyl's market share *** from *** percent in 1988 to *** percent in 1990, *** from *** percent in interim 1990 to *** percent in interim 1991.

Prices

MARKET CHARACTERISTICS

Ethyl sells all of its bulk ibuprofen on an f.o.b. basis from its production facility located in Orangeburg, SC. In some cases Ethyl arranges and prepays inland shipping charges for delivery of the product to its customers, but these charges are always billed to the customers. Ethyl publishes and distributes price lists which quote a price per kilogram for bulk ibuprofen packed in 70-kilogram drums. Standard terms of sale are most often net 30 days, although Ethyl reports that in order to remain competitive

with Cheminor it has frequently been forced to extend the terms of sale to as long as 90 days.[49]

List prices are usually quoted to customers requiring spot purchases of bulk ibuprofen, although this price is frequently adjusted in order to meet competitive situations.[50] Most customers and potential customers that purchase bulk ibuprofen from Ethyl on a spot basis are awaiting FDA approval to use the product in the production of ibuprofen tablets. These customers usually expect to gain FDA approval to use Ethyl's bulk ibuprofen, and purchase relatively small amounts on a spot basis to get equipment and procedures ready for mass production once approval is received. Reported quantities sold on a spot basis during the investigation period range from *** to *** kilograms. Typically when a customer gains FDA approval to use Ethyl's bulk ibuprofen in the production of tablets, the spot sales are replaced by a contract or sales agreement.

Supply contracts between Ethyl and its customers ***.[51] The contract usually specifies a price per kilogram and a total quantity that will be shipped over the duration of the contract. Ethyl ***. ***.[52] Most contracts or sales agreements also contain a "meet-or-release" clause in which Ethyl agrees to meet a lower price offered by a competitor or release the customer from the obligation to purchase all or a portion of the quantity previously agreed to. Because of very strict FDA regulations, Ethyl's sales agreements never contain provisions for a customer to return unused bulk ibuprofen to Ethyl. Careful documentation verifying the integrity of the product would be necessary before it could be sent back to the producer for repackaging or resale, so bulk ibuprofen is generally not returnable if it is not used by the purchaser.

Flavine, the importer of Indian bulk ibuprofen, follows practices similar, but not identical, to Ethyl. Flavine does not publish price lists and instead ***. ***. The product is imported from India in 50-kilogram drums and is resold to pharmaceutical companies for tablet formulation in the same drums without repackaging or any additional processing.[53]

Inland delivery costs were estimated at *** percent of the total delivered value of the product at the customer's location. Flavine's sales of bulk ibuprofen are made to pharmaceutical companies that produce tablets sold only under generic labels. Respondents argue that prices for bulk ibuprofen sold to these generic companies are naturally 10-15 percent below prices to

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[49] Transcript, p. 15.

[50] Ethyl, in its questionnaire response, ***.

[51] ***.

[52] According to Charles Weidig, Product Manager, Ethyl, different prices are not quoted to pharmaceutical companies based on whether they produce generic or national brand name tablets. Transcript, p. 72.

[53] The difference in volume between the 70-kilogram containers used by the domestic manufacturer and the 50-kilogram containers used by the Indian manufacturers does not appear to constitute an advantage or a market niche for either country's bulk ibuprofen. According to representatives for both Ethyl and Flavine, purchasers have never expressed a preference for either size of packaging over the other. Transcript, pp. 73, 140.

companies producing national brand name tablets because the generic end product is sold for a price substantially below that of the product sold under a national brand-name label.[54]

Flavine generally ***. ***. As with Ethyl, Flavine also includes a meet-or-release clause in its contracts which allows its customers to purchase bulk ibuprofen from a competitor offering a price that Flavine cannot meet. In addition, because of the strict FDA requirements, return provisions are also never included in the contracts which Flavine arranges with its customers.[55]

PRICE TRENDS AND PRICE COMPARISONS

Ethyl and Flavine were requested to provide the quantity and the net f.o.b. price per kilogram for their largest single spot and contract sale of bulk ibuprofen to an unrelated U.S. pharmaceutical company in each quarter during the period January 1988 through June 1991. Each firm was also requested to provide the total quantity and total net f.o.b. value shipped for all sales to U.S. pharmaceutical companies during each quarter over the investigation period.[56]

Ethyl provided pricing data for both spot and contract sales, while Flavine provided pricing data only for contract sales (table 16 and figure 1).[57] [58] For contract sales, Ethyl reported price and quantity data for total shipments of bulk ibuprofen to its largest single customer in each quarter of the investigation period.[59] ***. Ethyl's prices for contract sales *** from *** per kilogram during *** to *** per kilogram during ***. Prices ***.[60] Flavine reported pricing for its largest single shipment of bulk ibuprofen to a contract customer during the investigation period. Prices *** from *** per kilogram in *** to *** per kilogram in ***. Reported prices *** per kilogram ***. During ***, prices *** per kilogram and ***.

Bulk ibuprofen imported from India was priced *** the domestic product during *** in which price comparisons were possible. ***.

Exchange Rates

Quarterly data reported by the International Monetary Fund indicates that during January 1988-June 1991 the nominal value of the Indian rupee steadily decreased, ending the period 36.5 percent below its initial value

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[54] Transcript, pp. 113, 137-38.

[55] Conversation with ***.

[56] In the instances in which Flavine sold its bulk ibuprofen on a delivered basis, company representatives calculated net f.o.b. prices by subtracting out the known delivery charges for each shipment.

[57] Flavine ***.

[58] Prices for Ethyl's spot sales ***.

[59] According to ***.

[60] The contract selling price ***.

Table 16
Bulk ibuprofen: Weighted-average net f.o.b. prices for contract sales to pharmaceutical companies reported by Ethyl and Flavine and margins of underselling (overselling), by quarters, January 1988-June 1991

Period	United States[1]		India		
	Price	Total Quantity	Price	Total Quantity	Margin
	*	*	*	*	*

[1] Prices reported are for total sales to the largest single contract customer in each quarter. ***.

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

Figure 1
Contract sales: Net f.o.b. price trends and price comparisons for Ethyl and Flavine, by quarters, January 1988-June 1991

* * * * * * *

Source: Compiled from data submitted in response to questionnaires of the U.S. International Trade Commission.

(table 17).[61] Adjusting for the movements in producer price indexes in the United States and India, the real value of the Indian rupee showed an overall depreciation of 23.9 percent during the investigation period.

Lost Sales and Lost Revenues

Ethyl alleged *** instances of lost sales to *** different customers for a total of *** kilograms of bulk ibuprofen valued at *** and *** instances of lost revenues to *** different customers for a total of ***. The Commission was able to contact ***.

Ethyl alleged ***. ***, a sale of *** kilograms of bulk ibuprofen offered at a delivered price of *** per kilogram was ***. ***.

* * * * * * *

[61] International Financial Statistics, August 1991.

Table 17
Exchange rates:[1] Indexes of nominal and real exchange rates of the Indian rupee, and indexes of producer prices in the United States and India,[2] by quarters, January 1988-June 1991

Period	U.S. producer price index	Indian producer price index	Nominal exchange rate index	Real exchange rate index[3]
1988:				
January-March	100.0	100.0	100.0	100.0
April-June	101.6	102.0	97.1	97.6
July-September	103.1	105.0	91.4	93.1
October-December	103.5	105.6	87.4	89.2
1989:				
January-March	105.8	106.5	85.4	86.0
April-June	107.7	110.1	81.0	82.8
July-September	107.3	113.7	78.5	83.2
October-December	107.7	115.0	77.1	82.3
1990:				
January-March	109.3	115.7	76.6	81.1
April-June	109.1	119.9	75.2	82.7
July-September	111.0	123.8	74.3	82.9
October-December	114.4	127.1	72.1	80.2
1991:				
January-March	112.0	130.6	69.3	80.9
April-June	110.9[4]	132.9[4]	63.5	76.1[4]

[1] Exchange rates expressed in U.S. dollars per Indian rupee.
[2] Producer price indexes are intended to measure final product prices and are based on period-average quarterly indexes presented in line 63 of the International Financial Statistics.
[3] The real exchange rate is derived from the nominal rate adjusted for relative movements in producer prices in the United States and India.
[4] Derived from price data reported for April and May 1991 only.

Note: January-March 1988 = 100.

Source: International Monetary Fund, International Financial Statistics, August 1991.

***. Since the end of ***, *** bulk ibuprofen. *** believes that ***. *** has experienced problems with ***.

Ethyl alleged ***. The specific allegations include ***. ***.

* * * * * * *

APPENDIX A

FEDERAL REGISTER NOTICES

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 701-TA-308 (Preliminary) and 731-TA-526 (Preliminary)]

Bulk Ibuprofen From India

AGENCY: United States International Trade Commission.

ACTION: Institution and scheduling of preliminary countervailing duty and antidumping investigations.

SUMMARY: The Commission hereby gives notice of the institution of preliminary countervailing duty investigation No. 701-TA-308 (Preliminary) under section 703(a)) of the Tariff Act of 1930 [19 U.S.C. 1671b(a) and of preliminary antidumping investigation No. 731-TA-526 (Preliminary) under section 733(a) of the Tariff Act of 1930 [19 U.S.C. 1673b(a)) to determine whether there is a reasonable indication that an industry in the United States is materially injured, or is threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from India of ibuprofen in bulk form, provided for in subheading 2916.15 of the Harmonized Tariff Schedule of the United States, that are alleged to be subsidized by the Government of India and to be sold in the United States at less than fair value. The Commission must complete preliminary countervailing duty and antidumping investigations in 45 days, or in these cases by September 16, 1991.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E [19 CFR part 201], and part 207, subparts A and B [19 CFR part 207].

EFFECTIVE DATE: July 31, 1991.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Haines (202-205-3206), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000.

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted in response to a petition filed on July 31, 1991, by Ethyl Corporation, Richmond, VA.

Participation in the investigations and public service list.—Persons [other than petitioners] wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven (7) days after publication of this notice in the Federal Register. The Secretary

will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these preliminary investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made not later than seven (7) days after the publication of this notice in the Federal Register. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Commission's Director of Operations has scheduled a conference in connection with these investigations for 9:30 a.m. on August 21, 1991, at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC. Parties wishing to participate in the conference should contact Elizabeth A. Haines (202–205–3200) not later than August 16, 1991 to arrange for their appearance. Parties in support of the imposition of countervailing and antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before August 26, 1991, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference no later than three (3) days before the conference. If briefs of written testimony contain BPI, they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to § 207.12 of the Commission's rules.

Issued: August 2, 1991.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 91–18742 Filed 8–6–91; 8:45 am]

BILLING CODE 7020-02-M

International Trade Administration

[A-533-803]

Initiation of Antidumping Duty Investigation: Bulk Ibuprofen From India

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: August 26, 1991.

FOR FURTHER INFORMATION CONTACT: Tracey Oakes, Office of Countervailing Duty Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, room B099, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 377-3174.

Initiation

The Petition

On July 31, 1991, the Ethyl Corporation filed with the Department of Commerce (the Department) an antidumping duty petition on behalf of the United States industry producing bulk ibuprofen (ibuprofen). In accordance with 19 CFR 353.12, the petitioner alleges that imports of ibuprofen from India are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Tariff Act of 1930, as amended (the Act), and that these imports are materially injuring, or threaten material injury to, domestic producers of ibuprofen. The petitioner has stated that it has standing to file the petition because it is an interested party, as defined in 19 CFR 353.2(k), and because it has filed the petition on behalf of the U.S. industry producing ibuprofen. If any interested party, as described in 19 CFR 353.2(k) (3), (4), (5), or (6), wishes to register support for, or opposition to, this investigation, please file written notification with the Assistant Secretary for Import Administration.

United States Price and Foreign Market Value

Petitioner based U.S. price (USP) on Customs IM 145 data for imports of ibuprofen from India. Petitioner alleges that sales of ibuprofen to the United States are made by an Indian producer through an unrelated exclusive agent/distributor in the United States.

Petitioner calculated USP pursuant to the purchase price (PP) methodology (19 CFR 353.41(b)). Adjustments were made, where appropriate, for foreign inland freight, foreign inland insurance, foreign brokerage, drug export clearance charges, port charges and credit expenses. These adjustments were based on information contained in a marketing research study and petitioner's own experience.

Petitioner's estimate of Foreign Market Value (FMV) is based on domestic prices of ibuprofen published on a monthly basis in the Indian Chemical Weekly. The prices represent delivered prices offered to certain customers referred to as dealers. Petitioner contends that larger quantities of the subject merchandise also are sold directly to tablet formulators at prices comparable to those published in the Chemical Weekly. The prices were adjusted for inland freight, insurance, packing costs, and credit expenses. Based on a comparison of USP and FMV, petitioner has alleged dumping margins ranging from 33.69 percent to 39.12 percent.

In accordance with our purchase price methodology, we have recalculated credit as a circumstance of sale adjustment to FMV. Also, in the companion countervailing duty case, petitioner alleged that Indian ibuprofen producers benefit from excessive duty drawback. Petitioner did not, however, add uncollected or refunded duties to USP. Pursuant to section 722(d)(1)(B), we have done so for the non-excessive portion of duty drawback. Based on a comparison of FMV to USP, as estimated by the Department, the alleged margins range from 3.00 percent to 7.55 percent.

Initiation of Investigation

Under 19 CFR 353.13(a), the Department must determine, within 20 days after a petition is filed, whether the petition properly alleges the basis on which an antidumping duty may be imposed under section 731 of the Act, and whether the petition contains information reasonably available to the petitioner supporting the allegations. We have examined the petition on ibuprofen from India and find that it meets the requirements of 19 CFR 353.13(a). Therefore, we are initiating an antidumping duty investigation to

determine whether imports of ibuprofen from India are being, or are likely to be, sold in the United States at less than fair value.

In accordance with 19 CFR 353.13(b) we are notifying the International Trade Commission (ITC) of this action.

Any producer or reseller seeking exclusion from a potential antidumping duty order must submit its request for exclusion within 30 days of the date of the publication of this notice. The procedures and requirements regarding the filing of such requests are contained in 19 CFR 353.14.

Scope of Investigation

The product covered by this investigation is all bulk ibuprofen from India. Bulk ibuprofen, a white powder, is a non-steroidal anti-inflammatory agent which also has analgesic and antipyretic activity. It is used in the symptomatic treatment of acute and chronic rheumatoid arthritis, osteoarthritis, primary dysmenorrhea and for the relief of mild to moderate pain. The chemical description of bulk ibuprofen is 2-(4-isobutylphenyl) propionic acid C13 H18 02. The product covered by this investigation does not include ibuprofen sold in tablet, capsule or similar forms for direct human consumption. Bulk ibuprofen is provided for in the Harmonized Tariff Schedule (HTS) subheading 2916.39.15. Although the HTS subheading is provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Preliminary Determination by ITC

The ITC will determine by September 16, 1991, whether there is a reasonable indication that imports of ibuprofen from India are materially injuring, or threaten material injury to, a U.S. industry. If its determination is negative, the investigation will be terminated. If affirmative, the Department will make its preliminary determination on or before January 7, 1992, unless the investigation is terminated pursuant to 19 CFR 353.17 or the preliminary determination is extended pursuant to 19 CFR 353.15.

This notice is published pursuant to section 732(c)(2) of the Act and 19 CFR 353.13(b).

Dated: August 20, 1991.

Marjorie A. Chorlins,

Acting Assistant Secretary for Import Administration.

[FR Doc. 91-20430 Filed 8-23-91; 8:45 am]

BILLING CODE 3510-DS-M

[C-533-804]

Initiation of Countervailing Duty Investigation: Bulk Ibuprofen From India

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: August 26, 1991.

FOR FURTHER INFORMATION CONTACT: Tracey E. Oakes or Paulo Mendes, Office of Countervailing Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, room B099, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 377-3174 and (202) 377-5050, respectively.

SUPPLEMENTARY INFORMATION:

The Petition

On July 31, 1991, the Ethyl Corporation filed with the Department of Commerce (the Department) a countervailing duty petition on behalf of the United States industry producing bulk ibuprofen (ibuprofen). In accordance with 19 CFR 355.12, the petitioner alleges that producers and exporters of ibuprofen in India receive subsidies within the meaning of section 701 of the Tariff Act of 1930, as amended (the Act).

Since India is a "country under the Agreement" within the meaning of section 701(b) of the Act, title VII of the Act applies to this investigation, and the International Trade Commission (ITC) is required to determine whether imports of the subject merchandise from India materially injure, or threaten material injury to, the U.S. industry.

The petitioner has stated that it has standing to file the petition because it is an interested party as defined in 19 CFR 355.2(i), and because it has filed the petition on behalf of the U.S. industry producing ibuprofen. If any interested party, as described in 19 CFR 355.2(i) (3), (4), (5), or (6), wishes to register support for, or opposition to, this petition, please file written notification with the Assistant Secretary for Import Administration.

Allegations of Subsidies

Petitioner lists a number of practices by the Government of India which allegedly confer subsidies on producers or exporters of ibuprofen in India. We are initiating an investigation of the following programs:

1. Import Replenishment (REP) Licenses
2. Rebates under the Cash Compensatory Support Program (CCS)
3. Excessive Drawback of Import Duties
4. Grants Under the Market Development Assistance (MDA) Program
5. Diesel Oil Subsidies
6. Preferential Export Financing Through Export Packing Credits
7. Income Tax Deductions for Exporters (Section 80HHC)
8. Preferential Post-Shipment Financing
9. Import Duty Exemptions available through Advance Licenses
10. Sales of Additional Licenses
11. Grants Received Under the Central Investment Subsidy Scheme (CISS)
12. Transportation Subsidies
13. Extension of Free Trade Zones
14. Import Duty Exemptions Available to 100 Percent Export Oriented Units
15. Preferential Waste Disposal Rates

Initiation of Investigation

Under 19 CFR 355.13(a), the Department must determine, within 20 days after a petition is filed, whether the petition properly alleges the bases on which a countervailing duty may be imposed under section 705 of the Act, and whether the petition contains information reasonably available to the petitioner supporting the allegations. We have examined the petition on ibuprofen from India and find that it meets the requirements of 19 CFR 355.13(a). Therefore, we are initiating a countervailing duty investigation to determine whether Indian producers or exporters of ibuprofen receive subsidies.

In accordance with 19 CFR 355.13(b) we are notifying the ITC of this action.

Any producer or reseller seeking exclusion from a potential countervailing duty order must submit its request for exclusion within 30 days of the date of the publication of this notice. The procedures and requirements regarding the filing of such requests are contained in 19 CFR 355.14.

Scope of Investigation

The product covered by this investigation is all bulk ibuprofen from India. Bulk ibuprofen, a white powder, is a non-steroidal anti-inflammatory agent which also has analgesic and antipyretic activity. It is used in the symptomatic treatment of acute and chronic rheumatoid arthritis, osteoarthritis, primary dysmenorrhea and for the relief of mild to moderate pain. The chemical description of bulk ibuprofen is 2-(4-isobutylphenyl) propionic acid, $C_{13}H_{18}O_2$. The product covered by this investigation does not include ibuprofen sold in tablet, capsule or similar forms for direct human consumption. Bulk ibuprofen is provided for in the Harmonized Tariff Schedule (HTS) subheading 2916.39.15. Although the HTS subheading is provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

ITC Notification

Section 702(d) of the Act requires us to notify the ITC of this action and to provide it with the information we used to arrive at this determination. We will notify the ITC and make available to it all non-privileged and non-proprietary information. We will also allow the ITC access to all privileged and business proprietary information in the Department's files, provided the ITC

confirms in writing that it will not disclose such information, either publicly or under administrative protective order, without the written consent of the Deputy Assistant Secretary for Investigations, Import Administration.

Preliminary Determination by the ITC

The ITC will determine by September 16, 1991, whether there is a reasonable indication that imports of ibuprofen from India are materially injuring, or threaten material injury to, a U.S. industry. If its determination is negative, the investigation will be terminated. If affirmative, the Department will make its preliminary determination on or before October 24, 1991, unless the investigation is terminated pursuant to 19 CFR 355.17 or the preliminary determination is extended pursuant to 19 CFR 355.15.

This notice is published pursuant to section 702(c)(2) of the Act.

Dated: August 20, 1991.

Marjorie A. Chorlins,

Acting Assistant Secretary for Import Administration.

[FR Doc. 91-20431 Filed 8-23-91; 8:45 am]

BILLING CODE 3510-DS-M

APPENDIX B

LIST OF WITNESSES

CALENDAR OF PUBLIC CONFERENCE

Those listed below appeared at the United States International Trade Commission's conference:

Subject: BULK IBUPROFEN FROM INDIA

Investigations Nos: 701-TA-308 and 731-TA-526 (Preliminary)

Date and Time: August 21, 1991 - 9:30 a.m.

Sessions were held in connection with the investigations in Main Hearing Room 101 of the United States International Trade Commission, 500 E Street SW., Washington, DC.

In Support of the Imposition of Countervailing and Antidumping Duties:

Dorsey & Whitney
Washington, D.C.
on behalf of

Ethyl Corporation

Max Turnipseed, Director, International Trade and Regulatory Affairs

Dr. Charles F. Weidig, Product Manager, Pharmaceuticals Intermediates, Performance Products Division

Will E. Leonard)--OF COUNSEL
Jonathan H. Glazier)

In Opposition to the Imposition of Countervailing and Antidumping Duties:

Adduci, Mastriani, Meeks & Schill
Washington, D.C.
on behalf of

Cheminor Drugs Limited

Flavine International, Inc.

Ron Schiavello, Vice President of Sales

John P. Milhard, Manager of Traffic & Operations

Louis S. Mastriani)--OF COUNSEL
Barbara A. Murphy)

APPENDIX C

COMMENTS RECEIVED FROM ETHYL ON THE IMPACT OF IMPORTS OF BULK IBUPROFEN FROM INDIA ON ITS GROWTH, INVESTMENT, ABILITY TO RAISE CAPITAL, AND DEVELOPMENT AND PRODUCTION EFFORTS

COMMENTS RECEIVED FROM ETHYL ON THE IMPACT OF IMPORTS OF BULK IBUPROFEN FROM INDIA ON ITS GROWTH, INVESTMENT, ABILITY TO RAISE CAPITAL, AND DEVELOPMENT AND PRODUCTION EFFORTS

The Commission requested the U.S. producer to describe and explain the actual and potential negative effects, if any, of imports of bulk ibuprofen from India on its growth, investment, ability to raise capital, and development and production efforts (including efforts to develop a derivative or improved version of its product). Ethyl's responses are shown below.

Actual Negative Effects

* * * * * * *

Anticipated Negative Effects

* * * * * * *

Influence of Imports on Capital Investment

* * * * * * *