

GENERIC CEPHALEXIN CAPSULES FROM CANADA

Determination of the Commission in
Investigation No. 731-TA-423
(Final) 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Note.--Information that would reveal confidential business operations of individual firms may not be published and therefore has been deleted from this report.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

Investigation No. 731-TA-423 (Final)

GENERIC CEPHALEXIN CAPSULES FROM CANADA

Determination

On the basis of the record 1/ developed in the subject investigation, the Commission determines, pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. § 1673d(b)) (the act), that an industry in the United States is not materially injured or threatened with material injury, and the establishment of an industry in the United States is not materially retarded, by reason of imports from Canada of generic cephalexin capsules, 2/ provided for in subheading 3004.20.00 of the Harmonized Tariff Schedule of the United States (previously item 411.76 of the Tariff Schedules of the United States), that have been found by the Department of Commerce to be sold in the United States at less than fair value (LTFV).

Background

The Commission instituted this investigation effective April 12, 1989, following a preliminary determination by the Department of Commerce that imports of generic cephalexin capsules from Canada were being sold at LTFV within the meaning of section 731 of the act (19 U.S.C. § 1673). Notice of the institution of the Commission's investigation and of a public hearing to be

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

2/ The imported products covered by this investigation are generic cephalexin capsules from Canada. Generic cephalexin capsules are cephalexin monohydrate in capsule form. Cephalexin monohydrate is a semisynthetic cephalosporin antibiotic intended for oral administration. Its chemical formula is $C_{16}H_{17}N_3O_4S \cdot H_2O$. Generic cephalexin capsules contain not less than 90 percent and not more than 120 percent of the labeled amount of cephalexin monohydrate. The capsule is made of a water soluble gelatin, designed to facilitate swallowing and a phased release of the drug into the user's digestive system.

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 May 4, 1989 (54 F.R.
19251). The hearing was held in Washington, DC, on June 28, 1989, and all
persons who requested the opportunity were permitted to appear in person or by
counsel.

VIEWS OF THE COMMISSION

We unanimously determine that a domestic industry in the United States is not materially injured, or threatened with material injury, by reason of imports of generic cephalixin capsules from Canada that are sold at less than fair value. 1/

Like Product

To determine whether material injury or threat of material injury to a domestic industry exists, the Commission must first determine the like product corresponding to the imported merchandise under investigation. Section 771(10) of the Trade Act of 1930 defines the term "like product" 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" 2/

The Department of Commerce made a final determination of sales at LTFV on the imported product subject to this investigation. These imports were defined as:

. . . generic cephalixin capsules from Canada. Generic cephalixin capsules are cephalixin monohydrate in capsule form. Cephalixin monohydrate is a semi-synthetic cephalosporin antibiotic intended for oral administration. Its chemical formula is $C_{16}H_{17}N_3O_4S \cdot H_2O$. Generic cephalixin capsules contain the equivalent of not less than 90 percent and not more than 120 percent of the labelled amount of cephalixin monohydrate. The capsule is made of a water soluble gelatin, designed to facilitate swallowing and a phased release of the drug into the user's digestive system. 3/

1/ Material retardation was not an issue in this investigation and will not be discussed further.

2/ 19 U.S.C. § 1677(10).

3/ 54 Fed. Reg. 26821 (June 26, 1989). This merchandise is currently classifiable under HTS subheading 3004.20.00. Id.

The Commission's decision regarding like product is essentially a factual determination made on a case-by-case basis. 4/ The Commission generally considers a number of factors when determining whether a domestic like product is "like" the product subject to investigation. 5/ These factors have included: (1) physical characteristics and uses, (2) interchangeability, (3) channels of distribution, (4) common manufacturing facilities and production employees, (5) customer or producer perceptions, and (6) price. 6/ No single factor is dispositive, and the Commission may consider other factors it deems relevant based on the facts of a given investigation. The Commission looks for clear dividing lines between like products; 7/ minor distinctions are an insufficient basis for finding separate like products. 8/

As described more fully in the investigation report, cephalexin is a first generation semisynthetic cephalosporin antibiotic used in the treatment of serious respiratory tract, skin and skin structure, and urinary

4/ Asociacion Colombiana de Exportadores de Flores v. United States, 12 CIT ___, 693 F. Supp. 1165, 1169 (like product issue essentially one to be based on the unique facts of each case) (hereinafter ASOCOFLORES I).

5/ Vice Chairman Cass treats these factors as interrelated parts of his analysis of the market in which the imported product competes with potential domestic like products. See Additional Views of Vice Chairman Cass, infra.

6/ See, e.g., Certain All-Terrain Vehicles from Japan, Inv. No. 731-TA-388 (Final), USITC Pub. No. 2163 (March 1989) at 4; ASOCOFLORES I, 693 F. Supp. at 1170 n.8.

7/ See, e.g., Antifriction Bearings (Other than Tapered Roller Bearings) and Parts Thereof from the Federal Republic of Germany, France, Italy, Japan, Rumania, Singapore, Sweden, Thailand, and the United Kingdom, Invs. Nos. 303-TA-19 and 20, 731-TA-391-399 (Final), USITC Pub. 2185 (May 1989) at 11. See also Additional Views of Chairman Brunsdale, infra.

8/ ASOCOFLORES I, 693 F. Supp. at 1168-69; S. Rep. No. 249, 96th Cong., 1st Sess. 90-91 (1979).

tract infections in humans and animals. It is intended for oral administration and is currently produced in two versions, cephalixin monohydrate and cephalixin hydrochloride monohydrate. 9/

In its preliminary determination, the Commission defined the like product to be "cephalexin, whether brand name or generic, in all oral dosage forms" and noted the possibility of including bulk cephalixin and Keftab within the like product in any final investigation. 10/

In this final investigation petitioner continued to urge the Commission to limit its like product definition to generic cephalixin monohydrate in capsule dosage form. 11/ Respondent contended that the like product should be broadened to include cephalixin hydrochloride monohydrate, a patented product sold under the brand name Keftab by Eli Lilly, as well as other first generation cephalosporins including cefaclor, cephradine, and cefadroxil. 12/

In this final investigation, we define the like product to be all oral

9/ See Report at A-2.

10/ Generic Cephalixin Capsules from Canada, Inv. No. 731-TA-423 (Preliminary), USITC Pub. 2143 (Dec. 1988) at 5 and 8 n.23. In our preliminary determination the term "cephalexin" meant cephalixin monohydrate. In this final determination "cephalexin" means both cephalixin monohydrate and cephalixin hydrochloride monohydrate. Further, "brand name" cephalixin refers to cephalixin that has been given a trade name. Eli Lilly markets its cephalixin monohydrate capsules under the brand name Keflex. Lilly held a patent on cephalixin monohydrate that expired in April 1987, at which time generic forms of cephalixin monohydrate entered the market. Lilly also markets cephalixin monohydrate tablets under the brand names Keflet and Keflex. Lilly still holds the Keflet patent. See Report at A-3 and A-12.

11/ Petitioner's prehearing brief at 2-20.

12/ Respondent's prehearing brief at 7-22.

dosage forms of cephalexin monohydrate, whether brand name or generic, as well as cephalexin hydrochloride monohydrate and bulk cephalexin. 13/

As we found in our preliminary determination, the like product includes all oral dosage forms of brand name and generic cephalexin monohydrate. The identical characteristics and uses of generic and brand name cephalexin monohydrate, the evident similarity in production processes of the brand name and generic forms, and the fact that the generic product seems to be substituting for the brand name product to a large and increasing degree in the marketplace, indicate that brand name as well as generic cephalexin monohydrate constitute part of the like product in this investigation. 14/ We include all oral dosage forms of cephalexin monohydrate (capsules, tablets, and powder for oral suspension) within the like product because the essential characteristics and uses of all three oral dosage forms are similar if not identical, and all three forms are, or

13/ While Vice Chairman Cass does not disagree with the Commission's treatment of the substantive like product issues leading to this definition, he does not join in this definition for the reasons stated in his Additional Views, infra.

14/ See Report at A-9--A-10, A-12--A-13, A-19--A-20; petitioner's prehearing brief at 17; respondent's prehearing brief at 11. Although there are some differences in channels of distribution between generic and brand name forms of cephalexin, and similarities or differences in channels of distribution have been one factor considered by the Commission in defining like products, the Commission has rejected arguments in other cases that different distribution systems or different end users using the product for the same purpose are sufficient bases alone to make a like product definition. See Yuasa-General Battery Corp., 661 F. Supp. at 1217 (Commission rejected arguments that identical batteries sold in the original equipment and replacement markets, respectively, should not both be considered part of the like product); Bicycles from Taiwan, Inv. No. 731-TA-111 (Final), USITC Pub. 1417 (August 1983) at 6, n.8 ("the different channels of distribution and the different level of service provided by the two channels do not provide a basis for finding more than one like product").

could be, manufactured by cephalexin producers at the same facility by the same employees. 15/

In this final investigation we also find it appropriate to define the like product to include Keftab. Keftab is cephalexin hydrochloride monohydrate marketed by Eli Lilly in tablet form. It is a different salt formulation of cephalexin monohydrate that was approved by the FDA in October 1987, and is still under patent. 16/ The record indicates that cephalexin monohydrate and cephalexin hydrochloride monohydrate have comparable bioavailability. 17/ The production process for Keftab is similar to that described for cephalexin monohydrate tablets above. Like Lilly's other brand name products, it is distributed through Lilly's Dista Division. 18/ Accordingly, similarities between the characteristics and uses, production process, and channels of distribution of Keftab and those of cephalexin monohydrate lead us to include Keftab in the like product. 19/

We also find it appropriate to define the like product to include bulk

15/ See Report at A-6--A-7; Generic Cephalexin from Canada, Inv. No. 731-TA-423 (Preliminary), USITC Pub. 2143 (December 1989) at 8.

16/ The fact that Keftab is still under patent does not preclude us from including Keftab within our like product definition.

17/ Bioavailability refers to the rate and extent of absorption into general circulation in the body; bioequivalence means that the generic drug shows the same bioavailability as the reference drug. See Report at A-9 n.3.

18/ See Report at appendix D and A-19.

19/ Chairman Brunsdale does not join the determination regarding Keftab. See Additional Views of Chairman Brunsdale, infra.

cephalexin as well. 20/ 21/ When considering whether intermediate or semi-finished products such as bulk cephalexin are like finished products, the Commission considers such factors as:

- (1) whether the intermediate product imparts or contributes to an essential characteristic, either physical or functional, of the finished product;
- (2) the type and extent of further processing required to transform the intermediate product into the finished product;
- (3) whether the component has an independent use or is dedicated to use in the finished product;
- (4) the extent to which the intermediate and finished products are sold through the same channels of distribution; and
- (5) the degree of interchangeability of the articles at different stages of production. 22/

Bulk cephalexin is the active ingredient used to produce oral dosage forms of cephalexin, be they capsule, tablet, or powder for oral suspension. Approximately ninety percent of the finished oral dosage form is bulk cephalexin, the remainder being inert ingredients, sugar, or

20/ No related parties issue is presented by the fact that generic cephalexin processors import the bulk cephalexin used to produce oral dosage forms of cephalexin because they do not import "generic cephalexin capsules," the only allegedly dumped merchandise involved in this investigation. See 19 U.S.C. § 1677(4)(B).

21/ Commissioner Rohr does not join in this discussion of bulk cephalexin for two reasons. First, as he pointed out in 64K Dynamic Random Access Memory Components from Japan, Inv. No. 731-TA-270 (Final), USITC Pub. 1862 (June 1986) at n.15 & n.21, the issues relating to semifinished (upstream) inputs in investigations involving finished (downstream) goods can be more appropriately considered in the context of a "domestic industry" analysis rather than a "like product" analysis. On the other hand, in investigations involving semifinished goods, issues relating to finished goods may be more appropriately handled in the traditional manner.

Second, inclusion or exclusion of "bulk cephalexin" in this case is a distinction that makes no difference. For example, the additional data gained by inclusion (because all other data must remain the same to avoid double counting bulk which is processed into dosage form, or because of the way companies were able to present data to the Commission) are certain minor exports of the bulk product. These exports are, in the context of this case, immaterial. The bulk cephalexin issue is therefore irrelevant.

22/ Certain Granite from Italy and Spain, Invs. Nos. 701-TA-289, 731-TA-381 (Final), USITC Pub. No. 2110 (August 1988) at 8.

flavorings. Business proprietary information shows that the channels of distribution for bulk cephalexin differ from those of the finished oral dosage forms, with most of the bulk cephalexin being consumed internally. 23/ Thus, the only use for domestically produced bulk cephalexin is in the production of cephalexin in oral dosage form. Although bulk cephalexin and its finished dosage forms are not interchangeable, bulk cephalexin contributes the essential therapeutic characteristic of the finished dosage forms of cephalexin, the processing required to achieve the finished product is not extensive, and the bulk product is dedicated solely to finished dosage forms of cephalexin. Therefore, we include it within the like product. 24/

We do not believe the information on cephalosporins available in this investigation supports a like product definition which includes any cephalosporin beyond cephalexin. Numerous antibiotics may be used to treat any given infection. The exact antibiotic prescribed will depend on several factors, including its efficacy against the targeted infection, the patient's sensitivity to the antibiotic, and the patient's concurrent consumption of other medications. 25/ Consequently, once the focus on like product moves beyond cephalexin to other cephalosporins, or even further to

23/ Until 1989, Lilly was the only manufacturer of bulk cephalexin in the United States. Lilly uses its own bulk cephalexin in the production of its brand name cephalexin products Keflex, Keflet, and Keftab. SquibbMark began commercial production using its own bulk cephalexin in November 1988. Petitioner began commercial production of bulk cephalexin in June 1989, but still relies primarily on the foreign-sourced bulk product. Other domestic processors of cephalexin products import their bulk cephalexin from abroad. See Report at A-14--A18; A-21.

24/ See Report at A-2, A-6--A-8.

25/ See Report at A-3.

other antibiotics, there is no clear line which distinguishes the characteristics and uses of the nineteen different cephalosporins.

We therefore define the like product to include all oral dosage forms of cephalexin, whether brand name, generic, monohydrate, or hydrochloride monohydrate, and bulk cephalexin.

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." 26/ There are two domestic industry issues that warrant discussion in this final investigation.

In our preliminary determination, we found that "producers of cephalexin in dosage forms who import the bulk cephalexin used to manufacture their products are engaged in sufficient production-related activity to be considered part of the domestic industry." 27/ Information collected by the Commission staff during our final investigation has caused us to reexamine this finding.

In deciding whether a firm is a domestic producer, the Commission has examined: (1) the overall nature of production-related activities in the United States, including the extent and source of a firm's capital investment, (2) the technical expertise involved in production activity in the United States, (3) the value added to the product in the United States,

26/ 19 U.S.C. § 1677(4)(A).

27/ Generic Cephalexin Capsules from Canada, Inv. No. 731-TA-423 (Preliminary), USITC Pub. 2143 (December 1988) at 10.

(4) employment levels, (5) the quantity and type of parts sourced in the United States, and (6) any other costs and activities in the United States directly leading to production of the like product. 28/ No single factor is determinative, and the Commission's analysis should consider any other factors that are deemed relevant in light of the specific facts of the investigation. 29/

As stated in our preliminary determination, there is no question that Eli Lilly, which produces bulk cephalexin as well as the dosage forms of the drug, is a domestic producer. 30/ Similarly, SquibbMark is also clearly a domestic producer because it too has a completely integrated cephalexin production process. 31/

More problematic is the treatment of those firms that import bulk cephalexin and process it into oral dosage forms in the United States. Including these firms in the definition of the domestic cephalexin industry is troublesome because the value these U.S. firms add during the production process to the cephalexin product they sell is extremely low. 32/ However,

28/ See, e.g., Certain All Terrain Vehicles from Japan, 731-TA-338(Final), USITC Pub. 2163 (March 1989) at 12; Erasable Programmable Read Only Memories from Japan, 731-TA-288 (Final), USITC Pub. 1927 (Dec. 1986) at 11; Low-Fuming Brazing Copper Wire and Rod from New Zealand, Inv. No. 731-TA-246 (Final) USITC Pub. 1779 (November 1985) at 6.

29/ Id.

30/ Generic Cephalexin Capsules from Canada, Inv. No. 731-TA-423 (Preliminary), USITC Pub. 2143 (December 1988) at 9.

31/ Petitioner began commercial production of bulk cephalexin in June 1989, but still relies primarily on foreign sourced bulk product. See Report at A-15.

32/ See Report at A-25.

these firms have expended a significant amount of capital in order to initiate production of dosage forms of generic cephalixin. 33/

Further, the creation of oral dosage form cephalixin from bulk cephalixin involves considerable effort and expertise. First, the generic drug firms must demonstrate to the Food and Drug Administration (FDA) that their generic product is bioequivalent to the "innovative" drug (usually a patented drug). This process may take up to two years. 34/ Second, facilities processing the oral dosage forms of cephalixin for the U.S. market must comply with the manufacturing requirements of the FDA. 35/ Accordingly, we reaffirm our preliminary determination and find that processing bulk cephalixin into oral dosage forms is sufficient activity to qualify as a domestic industry. 36/

In the preliminary determination, we also considered producers located in the U.S. Virgin Islands to be producers in the "United States" for the purpose of that determination. 37/ Petitioner agreed with this decision 38/ and respondent did not contest the point. 39/ Our analysis of this issue has not changed since our preliminary determination, so we

33/ See Report at A-26.

34/ See Report at appendix F.

35/ See Report at A-7.

36/ Vice Chairman Cass addresses the definition of the domestic industry in light of his definition of like product. See Additional Views of Vice Chairman Cass, infra.

37/ Generic Cephalixin Capsules from Canada, Inv. No. 731-TA-423 (Preliminary), USITC Pub. 2143 (December 1988) at 11.

38/ Petitioner's prehearing brief at 20.

39/ Hearing Transcript at 147 (response of Mr. Norrell).

continue to consider producers located in the U.S. Virgin Islands to be producers in the "United States" for the purpose of this final determination.

Accordingly, we define the domestic industry to be U.S. producers of generic and brand name cephalixin, whether monohydrate or monohydrate hydrochloride, in bulk and all oral dosage forms. 40/

Condition of the Domestic Industry 41/

In determining the condition of the domestic industry, the Commission considers, among other factors, U.S. consumption, production, capacity, capacity utilization, shipments, inventories, employment, financial performance and existing development and production efforts, within the context of the business cycle and conditions of competition that are distinctive to the domestic industry. 42/ For purposes of this final investigation, the Commission considered questionnaire data for the period 1986 through 1988, and the first quarter of 1989 (the interim period) supplemented by relevant information gathered during the period between

40/ Chairman Brunsdale, Commissioners Eckes, Lodwick, and Newquist note that a strong case could be made to exclude from the domestic industry producing the like product those firms that import and process bulk cephalixin. From a cost basis, the value added is extremely low. This fact is consistent with our finding that bulk cephalixin is sufficiently "like" the oral dosage forms of cephalixin. A finding to exclude the importers of bulk cephalixin may have some precedent. See Certain Radio Paging and Alerting Devices from Japan, Inv. 731-TA-102 (Final), USITC Pub. 1410 (August 1983) at 11. Had we decided to exclude the processors, it would not have changed our no injury determination.

41/ On July 12, 1989, Biocraft filed two antidumping petitions concerning generic cephalixin capsules from Israel and Portugal thereby raising the issue of cumulation of imports in this investigation. Biocraft withdrew these petitions on August 1, 1989 thereby mooted the issue of cumulation.

42/ 19 U.S.C. § 1677(7)(C)(iii).

March 31, 1989 and the Commission's vote on August 3, 1989. 43/ Until April 1987 the only domestic producer of cephalexin in any form was Eli Lilly, the patent holder. Upon expiration of one of Lilly's cephalexin monohydrate patents in April 1987, generic cephalexin producers and importers entered the cephalexin market.

In our preliminary determination, we did not find even a reasonable indication of material injury to a U.S. industry, because, among other indicators, the available financial data described an industry that was very profitable. 44/ Based on our evaluation of the record now before us, we again find that the domestic cephalexin industry is not suffering material injury in this final investigation. The strong profitability of the cephalexin industry in spite of the change from a patented monopoly market to a more competitive market upon the entry of the generic producers precludes a finding of material injury in this instance. 45/

43/ We note that Title VII of the Trade Act of 1930 does not expressly direct the Commission to examine a particular period of time when making its injury determinations. Our reviewing court has held that we have broad discretion to determine the appropriate period of investigation. *Wieland Werke A.G. v. United States*, 13 CIT ___, Slip op. 898-96 (July 12, 1989) at 12; see also *Kenda Rubber Co. V. United States*, 10 CIT 120, 126, 630 F. Supp. 354, 359 (1986).

44/ *Generic Cephalexin Capsules from Canada*, Inv. No. 731-TA-423 (Preliminary), USITC Pub. 2143 (December 1988) at 11.

45/ Commissioner Rohr wishes to make clear that while the profitability of this industry was an important consideration, it was only one of many leading to his determination. It was the overall performance of the industry including production-related, employment-related, and financial performance indicators, viewed in the context of what the record indicates would be an injured or an uninjured cephalexin-producing industry that lead him to conclude that the industry is not currently experiencing material injury. No one factor, even as important a factor as profitability, is sufficient for this determination.

As noted above, the Commission is to consider the impact of the Canadian cephalexin capsules on the domestic industry in the context of the conditions of competition unique to the domestic cephalexin industry. 46/ The pharmaceutical industry as a whole, and with it the cephalexin industry, has been changing in recent years. Most significantly, for this investigation, competition has increased as a result of the Drug Price Competition and Patent Term Restoration Act of 1984. This Act opened up the pharmaceutical market by creating the Abbreviated New Drug Application (ANDA) process for FDA approval of generic versions of post-1962 drugs. Instead of having to repeat the safety and efficacy tests required in New Drug Applications, the ANDA applicant need only prove that the generic copy of an innovative drug is equivalent to that innovative drug in terms of bioavailability and bioequivalence. This application process significantly reduces product-development costs. Consequently, entry into the market is easier and feasible even at relatively low sales volumes, thus inviting more generic competitors to enter the market. 47/

Generic producers initiate ANDA's early and may even take sales orders before the patent expiration date. In this way, generic producers are often prepared to enter the market on the day that the patent on the brand name drug expires. 48/ When Lilly's patent for Keflex (cephalexin

46/ 19 U.S.C. § 1677(7)(C)(iii). This amendment to the antidumping statute by the Omnibus Trade and Competitiveness Act of 1988 codified a Congressional concern that first appeared in the Trade Act of 1979. See S. Rep. 249, 96th Cong., 1st Sess. 88 (1979) ("It is expected that . . . the Commission will continue to focus on the condition of trade, competition, and development regarding the industry concerned.")

47/ See Report at A-8--A-9.

48/ See Report at A-11.

monohydrate) expired, the generic cephalixin producers moved quickly to capture market share and take advantage of the product life cycle or "window of opportunity". The "window of opportunity" is the short period of time during which the first producers of any generic drug may realize unusually high profits by introducing the generic drug at a price substantially below that of the brand name drug but also substantially above cost. 49/ This high-profit period within the product life cycle of a generic drug averages three to nine months. 50/ In the case of cephalixin, the "window of opportunity" opened on April 21, 1987, when Lilly's patent expired. 51/

The competition among generic producers of cephalixin has been particularly intense. Lilly's Keflex was an enormously popular drug prior to the expiration of its patent, and many generic producers of cephalixin were eagerly anticipating access to the cephalixin market. 52/ Within sixty days of the patent's expiration seven domestic producers and importers were competing against one another and Lilly for a share of this lucrative market. Lilly's share of the cephalixin monohydrate market declined dramatically from 1986 to 1988. 53/ The data gathered by the Commission staff in this investigation encompass this period of drastic

49/ See Report at A-11; Hearing Transcript, June 19, 1989 at 35-36 (testimony of Dr. Samuel M. Rosenblatt for petitioner).

50/ See Report at A-12 n.2.

51/ See Hearing Transcript at 37.

52/ See Report at A-12.

53/ See Report at B-35. If cephalixin hydrochloride monohydrate is included, Lilly's share of the market was eroded to a slightly lesser extent.

change in the cephalixin industry. We must analyze trends in the data while recognizing that these trends reflect the metamorphosis of the domestic industry from a single patent holder at the beginning of 1986 to a much more competitive industry consisting of a number of domestic producers by mid-1987.

Apparent U.S. consumption of cephalixin rose significantly from 1986 to 1987 and then declined somewhat from 1987 to 1988. Consumption rose again in interim period 1989 when compared with interim period 1988. 54/ The decline in apparent consumption between 1987 and 1988 likely occurred because abnormally large shipments of the generic product entered the market during the months immediately following the patent expiration when the demand for the generic product was unusually high. 55/

Although domestic production of cephalixin fell from 1987 to 1988, it rose in interim period 1989 as compared with interim period 1988. Capacity to produce cephalixin rose astronomically between 1986 and 1988, due to the capacity added by generic producers after the expiration of Lilly's patent in April 1987, and decreased slightly from interim period 1988 to interim period 1989. 56/ Capacity utilization decreased substantially from 1986 to 1988 because of the capacity added by the generic producers after April 1987. Capacity utilization figures rose slightly in interim period 1989 when compared with interim period 1988. 57/

54/ See Report at A-22, Table 3.

55/ See Report at A-22, Table 3.

56/ See Report at A-21, Table 2.

57/ We note that none of the domestic producers has ever produced at the capacity levels reported to the Commission. See Report at A-21.

Domestic shipments of cephalexin increased from 1986 to 1987, declined from 1987 to 1988, and increased in interim period 1989 as compared to interim period 1988. 58/ As stated above, this decline in shipments between 1987 and 1988 is predictable given the events occurring in the cephalexin market in 1987. 59/ U.S. producers' inventories of cephalexin fluctuated during the period of investigation, but generally remained stable. 60/

The average number of employees rose dramatically from 1986 to 1987 and then declined somewhat from 1987 to 1988. 61/ The number of hours worked rose from 1986 to 1987, and then declined in the following year. Average hourly wages declined from 1986 to 1987, but then rose significantly from 1987 to 1988. 62/

Financial data gathered by the Commission staff indicate that the domestic industry is highly profitable. 63/ We place little weight on the declines in net sales, operating profits, and net income in this investigation because such declines logically follow from decreased consumption in 1988 and the decreased prices at which cephalexin is sold in

58/ See Report at A-22, Table 3.

59/ See Report at A-22, Table 3.

60/ See Report at A-22, Table 4.

61/ See Report at A-23, Table 5. Some of the data reported on employment, wages, and productivity are based on allocations and may not present an accurate picture of the domestic industry. Trends relating to these factors may, therefore, be unreliable. Id. Accordingly, we give these data less weight.

62/ See Report at A-23, Table 5.

63/ See Report at A-24, Table 7.

the more competitive post-patent-protected market. 64/ The decline in some industry indicators is a natural result of this transformation process and does not indicate material injury. 65/

Based largely upon the strong profit position of the domestic cephalixin industry, and our consideration of the conditions of competition unique to the cephalixin industry, we conclude that the domestic cephalixin industry is not experiencing material injury and therefore find it

64/ Commissioner Rohr notes that in analyzing the financial performance of this, or any other industry, he is always very cautious about giving any weight to absolute changes in the raw financial indicators of net sales, cost of good sold, income, etc. Any time the Commission deals with a multicompany industry, such indicators can be misleading. It is much more important to look at the ratio of the financial indicators to net sales, what the Commission calls the financial "margins." In this case, these margins are extremely high. While high income margins appear to be characteristic of the generic pharmaceutical industry, the margins he sees for the cephalixin industry as a whole, as well as those margins for the generic portion of that industry, do not appear to be below what the record of the investigation reveals would be normal for an uninjured industry.

65/ We note that petitioner recognized that the price of a generic drug declines rapidly in a post-patent drug market in hearing testimony:

We introduced cephalixin in 1987 at 50 percent of the price it had been offered by Lilly. We expected that over 9 to 18 months, the price would drop to less than 25 percent of Lilly's. That is the kind of experience we had with ampicillin.

Hearing Transcript at 23 (testimony of Mr. Harold Snyder, President, Biocraft Laboratories).

unnecessary to make a determination as to whether any present material injury is by reason of the LTFV imports. 66/ 67/ 68/ 69/ 70/

66/ See American Spring Wire Corp. v. United States, 8 CIT 20, 590 F. Supp. 1273 (1984), aff'd sub nom., Armco, Inc. v. United States, 760 F.2d 2149 (Fed. Cir. 1985); National Association of Mirror Manufacturers v. United States, 12 CIT ___, 696 F. Supp. 642, 647 (1988).

67/ See Additional Views of Chairman Brunsdale, infra.

68/ Vice Chairman Cass does not join this statement, but does join the discussion of the industry's condition. He believes that the statute under which the Commission conducts title VII investigations does not contemplate any decision based solely on the condition of the domestic industry. While he believes that the condition of the domestic industry is relevant to assessing whether the effect of the allegedly LTFV imports has been "material," that information has statutory relevance only in assessing material injury by reason of the allegedly LTFV imports. See Digital Readout Systems and Subassemblies Thereof from Japan, Inv. No. 731-TA-390 (Final), USITC Pub. 2150 (January 1989) at 95-113 (Concurring and Dissenting Views of Commissioner Cass). See Additional Views of Vice Chairman Cass, infra.

69/ Commissioners Eckes and Rohr note that the Commission has a long-standing practice of omitting the analysis of causation when a determination is made that the domestic industry is not materially injured. Causation factors such as import volume and penetration are addressed in the subsequent analysis of the possible threat of injury by reason of unfair imports. This practice has a history longer than the 1979 Act under which the Commission currently operates. It has been reviewed and approved by the Commission's reviewing courts on numerous occasions. See, e.g., American Spring Wire Corp. v. United States, 8 CIT 20, 590 F. Supp. 1273, 1276 (1984), aff'd sub nom. Armco Inc. United States, 760 F.2d 249 (Fed. Cir. 1985) (aff'd explicitly on the basis of the CIT opinion); Nat'l Ass'n of Mirror Mfrs v. United States, 12 CIT ___, 696 F. Supp. 642 (1988). Congress was aware of this practice when it made two major revisions to the trade statutes in 1984 and 1988, but did not criticize it on either occasion. Therefore, the Commissioners believe that this course of action is deemed appropriate under the statute. They have yet to see any method that better implements the language of the trade laws and the Congressional intent embodied in those laws.

70/ Commissioner Newquist notes that the sharp declines in capacity utilization, net sales, and domestic prices may properly be accorded less weight, and thus be considered not to constitute "material" injury, in the context of the conditions of competition within the cephalixin market--i.e., the generic drug life cycle. Alternatively, it would be reasonable to conclude in a causation analysis that such declines are solely attributable to market conditions "other than the less-than-fair-value

(continued...)

No Threat of Material Injury by Reason of LTFV Imports. 71/

Section 771(7)(F) of the Tariff Act of 1930 directs the Commission to determine whether a U.S. industry is threatened with material injury by reason of imports "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." 72/ The ten statutory factors the Commission must consider are:

(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,

70/(...continued)

imports." Compare 19 U.S.C. § 1677(7)(C)(ii) with S. Rep. No. 249, 96th Cong. 1st Sess. 75. Both analyses are supported by substantial evidence in the record of this investigation. The volume and price effect considerations associated with a causation analysis are subsumed in our threat analysis, particularly in regard to the somewhat limited incidence of underselling and the modest market penetration levels by the subject imports.

71/ Vice Chairman Cass joins the Commission's discussion of threat, but has additional views on the appropriate approach to the threat analysis. See Additional Views of Vice Chairman Cass, infra.

72/ 19 U.S.C. § 1677(7)(F)(ii).

(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 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 1671 or 1673 of this title or to final orders under section 1671e or 1673e of this title, are also used to produce the merchandise under investigation,

(IX) in any investigation under this title which involves imports of both raw agricultural product (within the meaning of paragraph (4)(E)(iv) and any product processed from such raw agricultural product, the likelihood 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. 73/

In addition, we must consider whether dumping findings or antidumping remedies in markets of foreign countries against the same class of merchandise suggest a threat of material injury to the domestic industry. 74/ We consider these factors in turn.

There is no subsidy alleged in this antidumping investigation.

The Canadian exporter's capacity to produce cephalexin increased between 1986 and 1987. 75/ This increase occurred because production of

73/ 19 U.S.C. § 1677(7)(F)(i), as amended by 1988 Act §§ 1326(b), 1329.

74/ See 19 U.S.C. § 1677(7)(F)(iii), as amended by 1988 Act § 1329.

75/ Respondent is the sole exporter and importer of the Canadian product. Therefore, data collected under administrative protective order during this investigation pertaining to its operations may not be publicly discussed

(continued...)

cephalexin was transferred to a separately dedicated plant, a move prompted by FDA requirements that cephalosporins be produced in a dedicated facility separate from the manufacture of other antibiotic products. However, the exporter's capacity to produce cephalexin remained unchanged from 1987 to 1988. 76/ Moreover, the Canadian exporter's capacity utilization is significantly higher than that of the domestic industry. 77/ In addition, other business proprietary information leads us to believe that the Canadian exporter will be downsizing its practical production capacity. 78/ Although the United States is the primary export market for the Canadian exporter, 79/ we believe there is little incentive for the Canadian exporter to increase capacity at the current low U.S. price levels. 80/

In terms of volume of the subject imports, the Canadian exporter increased its penetration of the U.S. cephalexin market significantly from 1987 to 1988. Such an increase is not surprising given the dynamics of a newly opened generic market. Import penetration rose slightly from interim period 1988 to interim period 1989. In terms of value, the Canadian exporter also increased its penetration of the U.S. cephalexin market from

75/(...continued)

absent a waiver. The Commission has obtained written permission from the respondent to characterize the trends of the business proprietary information it submitted to the Commission under an administrative protective order. Without such permission, the Commission would not have discussed the information in this manner.

76/ See Report at A-30, Table 13.

77/ These higher capacity utilization rates are due in part to different methods of calculating capacity. Compare Report at A-21 with A-30.

78/ See Report at A-30.

79/ See Report at A-31.

80/ See price discussion, infra.

1987 to 1988, but its exports represented a much smaller share of the U.S. market than if measured in terms of volume. 81/

Despite this increase in market penetration during the period of investigation, we find it unlikely that such penetration will increase to an injurious level. Pricing data collected by the Commission staff indicate that prices in the generic segment of the domestic cephalexin market are generally lower than those of the imported Canadian capsules, even though both domestic and Canadian generic cephalexin must meet the same quality standards set by the FDA. 82/ Almost all the instances of underselling by the Canadian product occurred in 1987, in all generic product categories. In fact, the trends in 1988 indicate increasing margins of overselling in several product categories. Given the mixed underselling data, and the strong predominance of overselling in the last fifteen months, we find there is insufficient evidence on the record that the Canadian imports will have a price depressive or suppressive effect on domestic prices in the generic segment of the U.S. cephalexin market, the most significant segment of the market, in the foreseeable future. 83/

81/ See Report at A-34, Table 18.

82/ See Report at A-41, Table 26; A-41--A-43. In our preliminary determination we were concerned that our pricing data might understate the degree of underselling because certain of the Canadian prices were not adjusted for all rebates and discounts. In this determination the Canadian data have been adjusted but the prices reported for U.S. produced cephalexin capsules were not adjusted for all discounts and rebates. Therefore, we note that the pricing data collected by the Commission staff may understate the extent to which the Canadian cephalexin capsule imports are overselling the domestic product. See id. at A-40.

83/ In considering the generic segment of the cephalexin market, we are focusing on that segment of the cephalexin market where the price competition is the most intense. In any event, the generic market segment accounts for a large majority of the cephalexin market. See Report at B-35.
(continued...)

Inventories of Canadian generic cephalixin capsules in the United States increased steadily during the period of investigation. 84/ This increase in inventories appears to be due to a failure to predict seasonal demand accurately and to FDA testing requirements. Although current U.S. inventories of the Canadian imports represent a not insignificant share of current apparent domestic consumption, in view of our conclusion that it is unlikely that the Canadian imports will be sold at depressive or suppressive prices, we see little likelihood that the sale of these Canadian import inventories will have an injurious effect on the domestic cephalixin industry.

As explained more fully above, we believe there is little incentive for the Canadian exporter to expand its generic cephalixin capacity to levels that would be injurious to the domestic market. We find no other demonstrable adverse trends that indicate the probability that importation of generic cephalixin capsules from Canada will be the cause of material injury to the U.S. cephalixin industry.

With regard to product shifting, there is no evidence that the production facilities owned or controlled by the Canadian exporter may be used to produce products subject to antidumping or countervailing duty

83/(...continued)

Our reviewing court has held that we may consider whether imports are having a greater or lesser effect on certain segments of the market, even where there is competition between the imports and the domestic like product generally. See, e.g., Gifford-Hill Cement Co. v. United States, 9 CIT 357, 363, 615 F. Supp. 577, 582 (1985) (price trends in geographic submarkets). See also Internal Combustion Engine Forklift Trucks from Japan, Inv. No. 731-TA-377 (Final), USITC Pub. 2082 (May 1988) at 26 (focusing on pricing data where "competition between imported and domestic products was the most vigorous") (Views of Commissioners Eckes, Lodwick, and Rohr).

84/ See Report at A-29, Table 12.

investigations or to final orders under section 706 of the Tariff Act of 1930.

As stated in our preliminary determination, imports of generic cephalixin from Canada appear to have had little effect on research and development in the domestic cephalixin industry. 85/ The original patent holder of cephalixin has already paid for the research and development needed to develop oral dosage forms of cephalixin. The generic producers rely on this research when seeking approval from the FDA to produce a generic cephalixin product. We find no meaningful evidence of any actual or potential negative effects on efforts to develop a derivative or more advanced version of the like product. Finally, there are no dumping findings or antidumping orders in effect in third countries with respect to cephalixin capsule imports from Canada. 86/

Based upon the foregoing analysis, we find that the domestic cephalixin industry is not faced with a real and imminent threat of material injury by reason of imports of generic cephalixin capsules from Canada: we foresee no significant increase in Canadian capsule production capacity, the Canadian exporter's capacity utilization figures are relatively high, and it appears that the prices of the Canadian capsule imports are not likely to have a depressive or suppressive effect on prices in the domestic cephalixin market.

85/ Generic Cephalixin Capsules from Canada, Inv. No. 731-TA-423 (Preliminary), USITC Pub. 2143 (December 1988) at 16.

86/ See Report at A-32.

Conclusion

For all the reasons set forth above, we determine that the U.S. cephalalexin industry is not materially injured nor threatened with material injury by reason of imports from Canada of generic cephalalexin capsules. 87/

87/ We note that our determination was not affected by the recently enacted U.S.-Canada Free Trade Agreement. Article 1902 of the FTA allows each country to retain the right to apply its antidumping and countervailing duty laws to goods imported from the territory of the other party. United States-Canada Free Trade Agreement, art. 1902, H.R. Doc. No. 216, 100th Cong., 2d Sess. 512 (1988); U.S.-Canada Free Trade Agreement, Implementing Act, H.R. Doc. No. 216, 100th Cong., 2d Sess. 47 (1988).

ADDITIONAL VIEWS OF CHAIRMAN ANNE E. BRUNSDALE

Generic Cephalexin Capsules from Canada
Inv. No. 731-TA-423 (Final)

August 10, 1989

Like my colleagues, I conclude that an industry in the United States is neither materially injured nor threatened with material injury by reason of dumped imports of generic cephalexin capsules from Canada.^{1/} I incorporate herein my observations in the preliminary investigation, in which I determined that there was no reasonable indication of material injury or threat thereof to a domestic industry.^{2/} The additional information compiled during the final investigation confirms and buttresses my initial determination. I write these additional views to address several of the arguments raised by the parties during the final investigation and to comment on additional data collected by the Commission.

Like Product and Domestic Industry

This case raises two difficult issues regarding the nature of the domestic industry producing the relevant like product. First, the parties contest whether products like Keflex (the Eli Lilly & Co. version of cephalexin which is a formerly patented product), Keftab (Lilly's new,

1/ Petitioner did not contend that the establishment of an industry in the United States was materially retarded, and I do not discuss that matter further.

2/ See Generic Cephalexin Capsules from Canada, Inv. No. 731-TA-423 (Preliminary), USITC Pub. 2143 (December 1988) at 19-37 (Dissenting Views of Acting Chairman Anne E. Brunsdale). To the extent that the Views of the Commission, supra, elaborate further on the issue of threat, I join those views.

patented cephalosporin product), and bulk cephalixin should be included in the definition of like product. Second, the Commission must decide whether the process of processing bulk cephalixin into dosage form, which process accounts for a relatively small percentage of the value of the final product, constitutes domestic production within the meaning of the statute. In my view, the majority adequately addresses the second issue in its views, which I therefore adopt. The parties' contentions regarding the relevant like product deserve greater attention, especially in light of my particular approach to like-product issues.

Commission Practice. I outlined in a recent decision^{3/} my approach to the definition of like product. I noted that, while the Commission's standard approach to like-product issues focuses on differences between product categories devised by the parties, the real import of the like-product provision is "to segregate the industry that will be the focus of our investigation from all other industries in the United States." Different product characteristics vel non are not relevant to this inquiry.

I stated:

In our standard discussion of like products, however, we often neglect to mention that our purpose is not to define separate products, but to identify separate industries. The critical issue, therefore, is not whether two products are comfortably differentiated, but rather whether those products are traded in separate markets inhabited by separate industries. If an economic event, like the onset of dumping, is likely to have a simultaneous impact on production and sales of two physically different articles, then we can comfortably conclude that the producers in

^{3/} Industrial Belts from Israel . . . , and West Germany, Inv. Nos. 701-TA-293 and 731-TA-412-419, USITC Pub. 2194 (May 1989) at 53.

those markets comprise one industry producing one like product. ^{4/}

I reiterated this view more succinctly in a subsequent decision in which I commented that "references to 'product variations' not grounded in the context of markets in which those products are produced and sold are irrelevant."^{5/} This approach to like-product decisions stems from my understanding that the Commission should make certain "to ensure that [its] determination regarding the definition of like product and the domestic industry focus on distinctions between products and producers that have real economic consequences."^{6/} In sum, product differences are relevant to our determination only if the market in which they are sold deems them so.

One of my colleagues has commented on my views regarding the like product inquiry. He agreed with me that the "domestic industry provision establishes the group of domestic producers against whose operations the impact of imports will be assessed, in the course of the Commission's investigation."^{7/} He concluded, however, that the

definitions are not market based, but rather are based on statutory criteria, and any product variations relating to these criteria may be relevant. The factors traditionally used by the Commission, which relate to the characteristics and uses of the product, as opposed to the market, have

^{4/} Id.

^{5/} Certain Steel Pails from Mexico, Inv. No. 731-TA-435 (Preliminary), USITC Pub. 2205 (July 1989) at 7 n.14.

^{6/} Internal Combustion Engine Forklift Trucks from Japan, Inv. No. 731-TA-377 (Final), USITC Pub. 2082 (May 1988) at 59 (Views of Vice Chairman Brunsdale).

^{7/} Steel Pails, supra, USITC Pub. 2205 at 7 n.15.

been approved on numerous occasions by the Commission's reviewing courts. ^{8/}

I disagree with my colleague's premise and his conclusion. The traditional factors employed by the Commission are designed to provide an appropriate description of the product market, and hence allow the Commission to identify the domestic firms that occupy that market. Channels of distribution, customer perception, product interchangeability, commonality of manufacturing facilities and employees, and price all are characteristics of the market in which a product is sold. Physical appearance is important only if the product's customers, i.e., the market, make it so.^{9/}

Furthermore, the only way to explain prior Commission decisions regarding like products is to view them as efforts to isolate relevant markets. As one scholar has noted, citing Commission precedent:

A galvanized carbon steel sheet is not "like" an ungalvanized carbon steel sheet, but a galvanized carbon steel wire nail is "like" an ungalvanized carbon steel wire nail.

Carbon steel wire rope and stainless steel wire rope are like products, as are galvanized and ungalvanized wire rope, but a porcelain-coated carbon steel cooking pan is not "like" a stainless steel cooking pan -- yet all stainless steel pans are "like products", even though they may be combined with other products such as copper or aluminum. Carbon steel wire rod and stainless steel wire rod, however, apparently are not "like products."

^{8/} Id. (emphasis in original).

^{9/} For example, the color of a product --orange versus green-- may be immaterial in some markets (like cars) but very important in other markets (like basketballs) where one color has traditionally prevailed over another or where the appearance is otherwise commercially significant.

Pipe that is welded is not "like" pipe that is seamless, unless the pipe is used for the oil industry. ^{10/}

Looking at this evidence and reviewing the cases on which it is based, I am hard-pressed to explain how the differences in the products, for example galvanization, warranted different treatment unless the various markets treated them differently — i.e., galvanization is a critical distinction between products in the sheet steel market but not in the steel nail market. If, in fact, the decisions were based on a view of the law that the factors addressed by the Commission "relate to the characteristics and uses of the product, as opposed to the market," then these decisions are flawed.

In my opinion, these cases in the main were correctly decided because the Commission focused on the relevant markets for the products under investigation. Commission tradition thus is to take a market-based, rather than a product-based, approach to like product/domestic industry determinations. We should renew our focus on this aspect of our decisions.

Petitioner's Contentions. Petitioner in this case properly focused its arguments on like product and domestic industry on identifying the proper market on which to base our injury determination. Petitioner extended this exercise one step further, however, and directed our attention to the methods developed for identifying and segregating relevant markets in antitrust cases. Drawing on precedent from that area, particularly the recent court of appeals' decision in United States v. Archer-Daniels-

^{10/} Palmeter, Injury Determinations in Antidumping and Countervailing Duty Cases — A Commentary on U.S. Practice, 21 Journal of World Trade Law 123, 131 (1987) (citations omitted).

Midland Co.,^{11/} petitioner urges that generic cephalixin capsules be treated as a separate like product from the previously patented Keflex in light of the persistently large price difference between the two products.

While those arguments are intriguing and, in fact, make valid points regarding the Commission's use of the price factor in like-product determinations, I believe that petitioner's antitrust focus is too narrow even in these circumstances to form the basis of a like-product decision under the trade laws. Furthermore, I do not read Archer-Daniels-Midland as support for petitioner's view that Keflex should be treated as a separate like product.

As our reviewing court has pointed out, concepts applicable to the antitrust laws are not necessarily relevant to a Commission determination under the dumping laws.^{12/} This is especially true with regard to like-product matters. Market delineations in antitrust cases --at least in the line of cases cited by petitioner-- focus primarily on whether two products are interchangeable to the degree that they should be treated as occupying one market. While interchangeability by consumers is a factor traditionally considered by the Commission, "If one has to choose a single basis upon which to make a like product determination, consumer preference would seem to be a poor choice."^{13/} Similarly, price differential, which

^{11/} 866 F.2d 242 (8th Cir. 1988).

^{12/} See USX Corp. v. United States, 682 F. Supp. 60, 64-68 (Ct. Int'l Trade 1988).

^{13/} Asociacion Colombiana de Exportadores de Flores v. United States, 693 F. Supp. 1165, 1168 (Ct. Int'l Trade 1988).

is the reflection of consumer preference and interchangeability, is also a poor choice as a sole factor to consider.

Because the like-product determination is inextricably linked with the identification of the relevant domestic industry, we must take into account not only the terms on which the products are bought, but the means by which they are produced and sold. "Industries whose products are made in different types of facilities and travel through different streams of commerce to the end user will not react the same way to an onslaught of unfair imports."^{14/} The antitrust analysis propounded by petitioner is therefore incomplete because it addresses only the consumer side of the like-product issue; while antitrust cases may provide useful guidance for the treatment of the price and interchangeability factors, they do not address the production and sales factors the Commission must also take into account.

Turning to the merits of petitioner's contention that Keflex should be treated as a separate like product, one finds that virtually none of the factors underlying like-product analysis supports separate treatment for Keflex. Keflex and generic cephalexin are, and under Food and Drug Administration regulations must be, produced in substantially identical, federally approved facilities. Both forms of the drug travel through similar channels of distribution to the pharmacist and ultimately to the patient. While state laws may differ on the means by which a druggist is

^{14/} Industrial Belts, supra, USITC Pub. 2194 at 54 (Views of Chairman Brunsdale).

permitted to substitute Keflex for a generic brand,^{15/} the evidence indicates that these laws have not prevented the generics from competing with Keflex and taking a substantial share of the cephalixin market.

From the consumer perspective, Keflex and the generics are bioequivalents, i.e., complete medical substitutes. But, as petitioner points out, the price difference between the two is substantial and persistent. Citing Archer-Daniels-Midland, petitioner argues that this price differential segregates the market for Keflex and generic cephalixin.

Archer-Daniels-Midland, however, is not precisely on point. In that case, the court determined that high fructose corn syrup (HFCS) and sugar are completely interchangeable, but that the two occupied separate markets in light of the statutory quota on sugar imports that artificially inflates the price of domestic sugar. "As long as an effective price support program is in existence, a monopolist of HFCS will be able to raise the price of HFCS to just below the supported price of sugar. . . . In other words, the HFCS monopolist is able to exercise excess market power [and thus HFCS occupies a separate market]."^{16/} Significantly, the court noted that elimination of the sugar quota would require the reexamination of that decision.^{17/}

When Keflex was protected by a patent and its price was "inflated" by virtue of Lilly's monopoly on cephalixin, it certainly occupied a market

^{15/} In some states, substitution is permitted unless expressly forbidden by the physician. In other states, substitution is permitted only if the physician so indicates.

^{16/} Archer-Daniels-Midland, *supra*, 866 F.2d at 246.

^{17/} *Id.*

unto itself.^{18/} During that time, purchasers learned to associate cephalexin with Keflex, to deal with Lilly as a supplier, and to trust the product. Thus, even after the patent expired, Lilly has been able to maintain some market share at a higher price than that offered by the generics. While this may put Lilly in an advantageous position with respect to its ability to compete with generic cephalexin and the unfair imports, the record is clear that the domestic, generic version of cephalexin and the unfair imports compete with Lilly's product. This is not de jure market separation as petitioner maintains. It is more like the case alluded to by the court of appeals in Archer-Daniels-Midland that might arise upon the expiration of the sugar quota. Because the evidence on the record suggests that the firms producing Keflex and generic cephalexin inhabit one unified market, competing both with each other and with the Canadian imports, I conclude that they are one like product.

In contrast, Lilly's currently patented version of cephalexin, Keftab, occupies its own market niche. Keftab has a different chemical formula from Keflex and generic cephalexin; while it is produced from the same bulk cephalexin as other generic cephalexin drugs, it is manufactured by an additional process that adds a chloride to its chemical structure. Lilly markets Keftab for specific types of infections.^{19/} Keftab stands in relation to other cephalexin products in the same position as other

^{18/} As discussed below, I do find the existence of patent protection to be germane to the question whether Keftab, a drug similar to cephalexin and used to treat many of the same diseases, is a separate like product. I find that it is, and therefore do include it within the scope of the investigation.

^{19/} Staff Report, Appendix D.

antibiotics that could be used to treat the same infections —that is, they may all be more or less adequate substitutes for each other, but they are not part of the same market. While this is a close call, I believe that the additional production process, the special marketing effort, and the patent protection segregates the market for Keftab from the other cephalaxins.

Two additional like-product issues have been raised by the parties. The first concerns the treatment of bulk cephalaxin and the second concerns other oral dosage forms of the drug besides capsules (tablets and powder preparations). These matters are treated in the Views of the Commission, and I concur in the results. In sum, I conclude that there is one like product in this investigation consisting of bulk cephalaxin and generic and brand-name cephalaxin (but excluding Keftab) in all oral dosage forms.

Material Injury by Reason of Canadian Imports

Condition of the Industry. As I stated in a previous investigation,

ascertaining the state of the domestic industry and its performance over the period of investigation is an important part of my analysis. It allows me to place in some context the impact of the imports under investigation, and particularly to assess the interaction between the dynamics of the market for the product and the imports under investigation. 20/

This simply recognizes that industries with different histories and

20/ Certain Light-Walled Rectangular Pipes and Tubes from Taiwan, Inv. No. 731-TA-410 (Final), USITC Pub. 2169 (March 1989) at 10 (Views of Chairman Brunsdale and Vice Chairman Cass — Chairman Brunsdale's discussion of causation). I cited as an example of this approach my dissenting views in the preliminary phase of this investigation. Id. at 10 n.19.

characteristics will react differently to the introduction of dumped imports.

The dynamics of the generic cephalixin market are critical to petitioner's case. Petitioner cited a "window of opportunity" for generic cephalixin producers that begins immediately upon the expiration of the patent for the branded product.

Therefore, being first on the market with a new drug soon after patent expiration is important, since pricing flexibility disappears rapidly once a number of competitors market a product. It is fair to say that the initial price in the market may be the highest a company ever sees. 21/

By generating sufficient revenue during this "window of opportunity," the generic drug manufacturers can more easily withstand the hyper-competition that develops when other producers enter the market and devote the requisite capital to preparation (including FDA approval) of manufacturing facilities for the next drug to come off patent (or even to research, test, and patent a new drug on its own).^{22/} One cannot discount the possibility in the drug industry that today's moneymaker will fall prey to the miracle cure of the future.^{23/}

In this type of market, it would be especially perilous to determine whether the industry is materially injured separate and apart from the impact of the subject imports. The determination would necessarily depend on the timing of the petition, i.e., whether the industry was on the upward

21/ Petitioner's Prehearing Brief, quoting Swergold, Chefitz, Inc., Health Care Research at 24 (January 10, 1989).

22/ Id. at 1.

23/ "Over time, unlike their branded competitors, individual generic drug products revenues tend to decrease, requiring new products to augment revenues." Id.

or downward sloping portion of its cycle. This seems to me a particularly quixotic basis for a decision. Finally, and to my mind most important, the industry might appear to be very healthy but still be injured because the revenues it generates are insufficient to ensure its long-term viability as tomorrow's wonder drugs replace today's. An industry in that position is entitled to the protection of the statute, no matter how outstanding the profits may appear to be to the members of this panel. On the other hand, if a decline in the industry's fortune is solely attributable to expected product cycles, then import relief is not warranted. In sum, a mere description of this industry in terms of financial, employment, or production data says nothing about the entitlement of petitioner and other firms in the domestic industry to an affirmative determination.

Injury by Reason of Dumped Imports in This Case. The Views of the Commission in this final investigation in large measure track my dissenting, negative views in the preliminary investigation. In essence, I pointed out that the presence of Canadian imports had no material impact on the domestic cephalexin market. Rather, "prices and profits in this domestic industry were affected adversely not by unfairly traded imports, but by the normal, and expected, competitive pressures found in the generic drug market."^{24/} The Commission now recognizes that the industry underwent a metamorphosis upon the expiration of Lilly's patent that did not result from the Canadian imports.

While the Commission therefore concludes that the domestic industry is not "injured" because its profits are still high, I find the issue more

^{24/} USITC Pub. 2143 at 32.

properly addressed as a matter of causation. I do not see how the Commission can examine industry trends over the course of its business cycle and determine simply that the industry is not "injured"; any such analysis must relate to causation, i.e., whether the imports affected the course of that business cycle. Indeed, in this case, the price of generic cephalexin (not including Keflex) has dropped markedly since the product was introduced in April 1987. Although the industry's profits are still high, they are certainly lower than they were both before and immediately after April 1987. The issue therefore is not whether the industry is doing well, but whether the imports had a role in exacerbating the declines. The Commission majority, in my view, provides the right answer to the wrong question.

My conclusion in the preliminary investigation is buttressed by the low dumping margin calculated by the Commerce Department in this case -- 7.5 percent.^{25/} Given the low market penetration of the Canadian imports^{26/} as compared with the tremendous drop in the unit values of cephalexin following the expiration of Lilly's patent, it is highly unlikely that the imports had any appreciable impact on the domestic market. Further, given that nine other foreign and domestic producers of cephalexin entered the market at approximately the same time as petitioner and the Canadian importer, it is difficult to lay responsibility for the industry's performance at the Canadian's door.

^{25/} 54 F.R. 26,820 (June 29, 1989).

^{26/} Because only one Canadian cephalexin producer exports to the United States, the exact import penetration figures are confidential.

Furthermore, the evidence suggests that, even absent Canadian imports, the domestic industry would not have obtained sales equal to the Canadian product's penetration into the domestic market. The demand for cephalexin is somewhat elastic, meaning that a drop in the price of the drug will increase domestic demand (typically by drawing away users of other, more expensive antibiotics).^{27/} Thus, the volume effect of the Canadian imports was even smaller than their import penetration —itself small— would suggest.

Despite these negative indications of injury, petitioner attempted to rest its entitlement to relief on the ground that the Canadian imports injured the domestic industry by leading the price of cephalexin down. Petitioner pointed to the high substitutability of cephalexin products sold in the United States and instances of underselling by the Canadian product.^{28/} As petitioner's president testified, however, his own firm itself led the price competition:

We introduced cephalexin in 1987 at 50 percent of the price at which it had been offered by Lilly. We expected that over 9 to 18 months, the price would drop to less than 25 percent of Lilly's. That's the kind of experience we had with ampicillin. ^{29/}

^{27/} The staff estimates a demand elasticity of between $-.5$ and -1.5 , meaning that demand for cephalexin will increase between .5 percent and 1.5 percent for every 1 percent drop in its price. Given that apparent U.S. consumption of cephalexin rose dramatically in 1987, the year Lilly's patent expired and the cheaper generic product became available, and remained high in 1988 (Staff Report at A-14), I conclude that the demand elasticity is at the high end of this range.

^{28/} Indeed, because of FDA regulations governing the manufacture and marketing of cephalexin, products sold legally in the U.S. market are generally substitutable.

^{29/} Tr. at 23 (Testimony of Howard Snyder).

Petitioner contended that, despite its own efforts to undercut Lilly, it was undercut by unfairly priced Canadian imports. In support, it attributed two early lost sales to the unfair Canadian pricing.

The pricing data in this investigation do not support petitioner's case. The weight to be placed on the price information collected by the Commission will inevitably vary with the facts of each case. In all cases, however, one must recognize the limits of this information. The price data collected by the Commission often represent a relatively sparse sampling of all transactions.^{30/} In such cases, the price data must be recognized as being isolated numbers rather than facts. There is no guarantee that a collection of numbers such as the prices of the largest sale of each producer in each quarter^{31/} is representative of all transactions or is comparable to any other randomly selected set. In some markets, competition will force prices into tight bands; in others, prices will vary widely across producers, customers, and terms of sale. The largest sales of each producer in each quarter, which the Commission generally treats as comparable statistics, may themselves vary significantly. Taking these factors into account, the Commission must assess carefully the comparability of the price data it collects to guard against any unwarranted characterization of general conditions based on narrow observations.

^{30/} In some cases, particularly where the product is sold by means of a few, large contracts, the Commission can collect much more complete data.

^{31/} In cases involving a large number of sales of the like product, this is the data set normally set out in the Commission report.

Given the high degree of interchangeability of cephalexin manufactured by different firms and the low dumping margins calculated by the Department of Commerce, differences in price between the domestic and imported product are driven by such factors as imperfect information, long-term relationships between suppliers and customers involving cephalexin and/or other products, or differences in the transaction size. In this particular case, the Canadian importer offered cephalexin terms of sale markedly different from those offered by the domestic generic cephalexin producers.^{32/} The different terms of sale largely explain the lost sales that petitioner cited.

Furthermore, the Commission staff's analysis of the pricing data reveals that Canadian imports were not the price leaders.^{33/} The information on the largest-sale price collected by the Commission does not support petitioner's argument that the subject imports led the price in the domestic market. This is generally true for all types of customers including generic drug distributors, pharmaceutical companies, and full-line drug wholesalers. Detailed information on low and high transaction prices and quantities covering 1988 suggest generally that both domestic and foreign producers offered their lowest prices to their largest customers. Quantity data show that these transactions typically involved larger quantities than those in other channels. Furthermore, reported high prices in small-quantity transactions is an additional indication of the

^{32/} Staff Report at A-35.

^{33/} In this investigation, information developed by the staff and reported in Office of Economics Memorandum EC-M-278, was particularly helpful.

inverse relationship between price and quantity.^{34/}

The pricing data thus provide no indication of a causal link between the subject imports and prices received by domestic producers. In particular, these data show that the price level of the Canadian imports has been consistent with the domestic price given the same terms of sale.

Petitioner's suggestion that the Canadian imports were the price leaders in this market must therefore be rejected.

Conclusion

For the foregoing reasons, I conclude that an industry in the United States has not been materially injured or threatened with material injury by reason of dumped imports of Canadian cephalexin tablets.

^{34/} Discrepancies in these patterns can be explained by the downward trend in the price of cephalexin following the expiration of Lilly's patent. Data on prices of smaller shipments from the end of a quarter will inevitably reflect the decline in prices during that quarter and thus might be lower than a larger sale three months earlier. This does not, however, negate the general inverse correlation between the size of the sale and the price.

ADDITIONAL VIEWS OF VICE CHAIRMAN RONALD A. CASS

Generic Cephalexin Capsules from Canada
Inv. No. 731-TA-423
(Final)

I concur with the Commission's determination in this investigation that the domestic industry is not suffering material injury or threat of material injury by reason of less than fair value ("LTFV") imports of Cephalexin capsules from Canada. I join the Commission's evaluation of the threat of injury to the domestic industry and generally concur in the Commission's description of the domestic industry's condition. I do not, however, believe that the Commission's description of the condition of the domestic industry obviates the need for consideration of material injury by reason of unfairly traded imports. I offer additional views regarding the like product and industry definitions in this case and on the analysis appropriate to disposition of Petitioner's claim that the domestic industry has been materially injured by reason of LTFV imports.

I. DOMESTIC LIKE PRODUCT AND DOMESTIC INDUSTRY

A. Like Product

In final investigations under the antidumping laws^{1/} the Commission must assess the effects of LTFV imports on the

^{1/} Tariff Act of 1930, ch, 497, title VII, § 735, as added by the Trade Agreements Act of 1979, Pub. L. No. 96-39, title I, § 101, 93 Stat. 150, 169 (codified as amended at 19 U.S.C. § 1673d(b)).

industry in the United States comprised of "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."2/ The term "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."3/

In the preliminary investigation in this case the Commission majority found a single like product consisting of the oral dosage forms of Cephalexin, including capsules, tablets and powder for oral suspension.4/ In contrast, I used a like product definition limited to cephalexin capsules, which more closely tracked the definition requested by Petitioner.5/ I did not accept the Petitioner's contention that only generic capsules (excluding Eli Lilly's branded product, Keflex) should be included, finding the evidence against such a restricted like product determination conclusive.6/

2/ 19 U.S.C. § 1677(4).

3/ 19 U.S.C. § 1677(10).

4/ Generic Cephalexin Capsules From Canada, Inv. No. 731-TA-423 (Preliminary), USITC Pub: 2143 (December 1988) at 5, 23 (herein after "Cephalexin Preliminary"). Chairman Brunsdale, while dissenting from the disposition of the investigation, nonetheless concurred in the like product determination.

5/ Id. at 47.

6/ Id.

Arguments of the Parties

In this final investigation Petitioner has again argued that the domestic like product and industry should consist only of generic cephalexin capsules and their producers.^{7/} Although Petitioner recognizes that the Commission looks at a variety of factors in determining like product, Petitioner urges the Commission to place special emphasis in this case on the price disparity between branded and generic cephalexin and on the absence of any correspondence in the price movements of the two products.^{8/} Petitioner argues that while Keflex and the generics produce the same therapeutic effects, the enormous * * * price differential between them indicates that they are not commercially interchangeable in the marketplace.^{9/} Petitioner urges us to adopt an approach to like product definition that has been developed in antitrust law to define product markets, and argues that under this approach generic cephalexin capsules alone comprise the relevant product market and, hence, the appropriate like product for this investigation. Petitioner also makes a number of factual assertions in support of this contention.

According to Petitioner, the pharmaceutical industry is not like other industries in which physically identical products compete directly. Petitioner asserts that the ultimate consumer

^{7/} Petitioner's Prehearing Brief, dated June 23, 1989 ("Petitioner's Brief") at 2.

^{8/} Id. at 4, 17.

^{9/} Id. at 17.

in this market is not the decision maker who chooses which drug to prescribe, and may not even be able to stipulate the form of the drug purchased.^{10/} Rather, doctors, hospitals and sometimes third-party payors make these choices, including the choice between branded and generic drugs. Petitioner contends that these decision makers have different sensitivities to the prices of drug products based on their own perspectives and concerns.^{11/} Petitioner argues that the actual decision makers in this market divide between those who will demand a generic product and those who will demand a branded product; the two groups of decision makers differ, and demand for the two types of pharmaceutical products differs.

Petitioner observes that generic drugs are prescribed by large health-care institutions such as hospitals and HMOs, or are required by third-party payors; these entities usually are high-volume, price-sensitive purchasers (direct or indirect) of pharmaceuticals.^{12/} Hospitals, HMOs and retail drugstores that stock generics buy through wholesale distributors and buying groups that gather extensive cost data on the competing generics in order to obtain the lowest possible price.^{13/} Petitioner believes that in turn, the patients who receive drugs through

^{10/} Id. at 5-6.

^{11/} Id. at 6.

^{12/} Id.

^{13/} Id. at 12.

these channels also tend to be more price sensitive, if only because their insurers require them to be so.^{14/}

Conversely, Petitioner argues that branded drugs, such as Keflex, are prescribed by doctors who have become loyal to the brand-name product over the patent period.^{15/} Drug companies initially foster this loyalty, and then prolong it after the patent expires, through extensive advertising intended to distinguish the brand-name drug in the individual physician's mind from the myriad other competing drugs.^{16/} Through repeated use of the brand-name drug the physician develops confidence in the product and thereafter may hesitate to prescribe a generic out of habit or fear of malpractice liability.^{17/} Petitioner cites evidence that doctors usually are unaware of the brand-name product's cost and argues that doctors have no incentive to obtain price information regarding lower cost alternatives.^{18/}

Pharmacies, which stock both the brand and generic forms of a drug, dispense whichever generates the largest return in the absence of specific directions from the doctor, patient or insurer.^{19/} In states that require pharmacies to pass generic

^{14/} Id. at 6, 13.

^{15/} Id. at 7-8.

^{16/} Id. at 7-12.

^{17/} Id.

^{18/} Id. at 9.

^{19/} Id. at 9.

drug savings to customers, the brand-name product may be the greater source of revenue.^{20/}

Petitioner argues that the different price sensitivities among drug purchasers result in separate markets for branded and generic drugs once the branded product goes off-patent.^{21/} Keflex's recent loss of market share to the generics, Petitioner contends, is simply the natural division of these markets and represents no ongoing competition between Keflex and the generics. Petitioner asserts that this is evidenced by Keflex's * * * during this time and still retain substantial sales volumes.^{22/} Finally, Petitioner argues that the laws enacted by state legislatures to encourage physicians to use generics are further evidence that Keflex and the generics do not compete directly because of barriers to entry into the market created by Eli Lilly during the patent term of the drug.^{23/}

With respect to the other forms of cephalexin that could be considered like products, Petitioner argues that bulk cephalexin should be excluded because it can not be used without further processing. Tablets and powder likewise should be excluded because they are different forms of cephalexin from the capsules that form the class of imports defined by the Department of

^{20/} Id.

^{21/} Id. at 13.

^{22/} Id. at 14.

^{23/} Id. at 16.

Commerce, they are produced differently from cephalixin capsules and they do not share the commercial acceptance of capsules.24/

Respondent rejects Petitioner's segregation of the market for cephalixin capsules into generic and brand-name submarkets and urges the Commission to expand the like product definition to include all oral dosage forms of cephalixin, including brand-name and generic capsules, tablets and powder for oral suspension, cephalixin hydrochloride, and all dosage forms of other orally-administered first generation cephalosporins.25/ Respondent argues that Petitioner's effort to distinguish the markets for generic and brand-name cephalixin capsules is aimed solely at avoiding weaknesses in its case that arise if Eli Lilly is included in the domestic industry.26/ Respondent contends that not only is this result-oriented choice of like product contrary to the intent of Congress, the Commission has refused to treat differences in marketing and demand between potential like products as dispositive factors in its traditional like product analysis.27/ The antitrust cases cited by Petitioner to support its argument therefore are simply inapposite.28/

24/ Id. at 19.

25/ Respondent's Prehearing Brief, dated June 23, 1989 ("Respondent's Brief") at 9.

26/ Id. at 10-11.

27/ Id. at 11-12.

28/ Id.

Respondent argues further that "the Commission's primary focus in identifying the 'like products' that compete with imported merchandise has consistently been on the 'characteristics and uses' of the domestic and imported merchandise...."29/ Various factors the Commission considers, such as commercial substitutability, common production processes, channels of distribution, physical appearance, and customer and producer perceptions, are seen by Respondent as informing the decision regarding whether the products have similar characteristics and uses.30/

Respondent points out that Keflex and the generics are chemically identical and asserts that this indicates an identity of characteristics and uses. They are produced in essentially the same way, look the same, have the same biological effect and are distributed through many of the same channels to the same purchasers.31/ Moreover, according to Respondent, the generics clearly compete directly with Keflex in the marketplace. Although Keflex accounted for all U.S. sales of cephalexin capsules through the first quarter of 1987, by the first quarter of 1989 generic production and domestic shipments were * * * those of Keflex and * * * percent of all cephalexin prescriptions were filled with a generic product.32/ Respondent notes that

29/ Id. at 8.

30/ Id. at 8, 14.

31/ Id. at 11.

32/ Id. at 16.

these sales of generics * * * . In that regard Respondent observes that Eli Lilly's extensive marketing campaign to promote Keflex is a response to competition from the generics,^{33/} and that state laws facilitating the use of generics have increased this competition.^{34/}

Respondent uses essentially the same reasoning in arguing that the like product should include all oral dosage forms of cephalexin, cephalexin hydrochloride and other orally administered forms of first generation cephalosporins. These drugs are medically interchangeable with capsules, are perceived as such by prescribing physicians and compete for customers in the same market.^{35/} They may even be produced in the same manufacturing facilities on the same equipment as capsules.^{36/}

Like Product Definition

The Commission has rejected the arguments advanced by Petitioner and has defined the like product under investigation to include all of the forms of cephalexin urged by Respondent to be like cephalexin capsules. Moreover, reaching a point not advanced by Respondent, the Commission has decided to include bulk cephalexin, from which the various forms of cephalexin products sold to ultimate consumers are made, within the like product definition.

^{33/} Id. at 16.

^{34/} Id. at 17.

^{35/} Id. at 18-22.

^{36/} Id. at 22.

I do not offer separate views on like product definition here out of disagreement with the Commission's treatment of the substantive issues presented in this investigation. Indeed, I believe that the weight of the evidence supports all of the choices made by the Commission on these issues. I do not, however, believe that the broad product definition chosen by the Commission is well-advised for reasons that do not go to the substance of that definition.

The essence of my disagreement is that, with the exception of the inclusion or exclusion of the branded product Keflex, I do not believe that any of the like product issues framed by arguments of the parties or by the Commission's analysis has any bearing on the outcome of this investigation. While we plainly should not choose a given like product definition with an eye on its effect on disposition of the investigation before us, that does not mean that we should reach difficult legal issues that have no conceivable bearing on the ultimate issue in the investigation, the actual or threatened material injury to a domestic industry.

In this investigation, any product definition, with the possible exception only of Petitioner's proposed definition limited to generic capsules alone, will produce the same outcome under any interpretation of Title VII. That said, I see no point to tackling the additional issues raised by some of the like product choices the Commission addresses. Notably, the most problematic issue -- whether there is sufficient activity in

producing the goods within the like product category to constitute an existing domestic industry -- is raised by the Commission sua sponte, and arises only because of the decision, again taken without urging by either party, to include bulk cephalexin within the like product. I am not asserting that the Commission has overstepped its authority or defined the product category irrationally; I only question the wisdom of proceeding with these issues. Moreover, in this context, I see no reason to deny Petitioner an explanation of why, on the arguably proper like product definition that is closest to that proposed in support of the Petition, a negative determination is required by the record before us.

The one issue raised by the parties that does require attention is the relationship of generic and branded cephalexin capsules. On this issue, I find that the Respondent has by far the more persuasive argument. In this regard, however, given the amount of effort and number of arguments directed to this issue, it is important to emphasize what does, and what does not, underlie my conclusion. First, although I do not believe that Petitioner has adequately demonstrated the basis for eschewing the Commission's traditional approach to like product analysis, I also do not believe that the Petitioner's arguments based in antitrust law are irrelevant. Petitioner contends that economic principles used in the antitrust cases to define markets based on the degree of competition between products is equally appropriate to like product definition under the trade law. Petitioner

claims that under these principles price is the "fundamental indication" of product similarity and that products with disparate and unrelated prices cannot be deemed to compete in the same market for antitrust or trade law purposes.^{37/}

It is not sufficient response to these arguments to observe that Petitioner has drawn on a body of law other than the law this Commission applies. Nor is it sufficient to note, as the Commission's reviewing courts have, that the goals and underlying suppositions of the trade laws administered by the Commission differ from those of the antitrust statutes in many respects.^{38/} Although any economic analysis employed by the Commission must flow from and be consistent with the particular statutory directives we implement, that does not suggest any necessary inconsistency between those directives and principles intended to answer cognate questions in antitrust enforcement. Disinterested commentary on the legal framework embodied in the Tariff Act of 1930 has suggested applicability of antitrust market definition principles to the very issue before us.^{39/} Adherence to these principles, so far as they accord with Title VII, might well assist us to achieve a degree of consistency and predictability

^{37/} Id. at 4.

^{38/} See Maverick Tube Corp. v. United States, 687 F. Supp. 1569, 1573-74 (Ct. Int'l Trade 1988); USX Corp. v. United States, 682 F. Supp. 60, 65-68 (Ct. Int'l Trade 1988).

^{39/} See, e.g., Note, Economically Meaningful Markets: An Alternative Approach to Defining "Like Product" and "Domestic Industry" Under the Trade Agreements Act of 1979, 73 Virginia Law Review 1459 (1987).

in our determinations that would benefit all parties (and potential parties) to our investigations.

Exploration of the relation between antitrust product market analysis and Title VII like product analysis, however, is not of any moment to the disposition of this investigation. Whether we use principles from antitrust or the Commission's traditional like product analysis, the Petitioner's contention regarding exclusion of Keflex from the market definition cannot withstand scrutiny.

That brings me to the second point deserving of emphasis. Although the price difference between Keflex and generic cephalixin capsules is not dispositive here, Petitioner surely is correct that the prices paid for goods often can yield considerable information about consumers' evaluations of their similarity or dissimilarity. Petitioner is undoubtedly correct in observing that significant price differentials and unrelated price movements generally indicate that, even if products seem similar in various ways, they do not compete in the same markets, for the same consumers, or on the same terms.^{40/} Even though generic and branded cephalixin are medically interchangeable and share similar methods of production and distribution, the price

^{40/} Normally, differences in the prices between goods that belong to the same general product category, such as cars, exist because there are at least perceived differences in the design and performance of the product. Though BMWs and Yugos are both cars, they offer the consumer very different levels of performance, comfort and styling. Purchasers in the market for either do not view these two cars as interchangeable, and for the Yugo purchaser at least, price may be a significant impediment to the purchase of a BMW.

difference between them would, in a stable market for cephalexin capsules, strongly suggest some significant difference in these products. The evidence submitted by Respondent and collected by the Commission staff, however, demonstrates that during the period when LTFV sales were found to have occurred direct competition has existed between Keflex and the generics.^{41/} The data indicate that the rapid growth in sales of generic capsules has been almost entirely at the expense of Keflex sales.^{42/} Further, the record contains anecdotal evidence of direct competition between Keflex and the generics for the allegiance of individual prescribing physicians and derivatively for purchases by their patients.^{43/} In time, the branded drug may sell in a residual market separate from that for the generic products. The evidence of record in this investigation, however, does not indicate that separate markets for the two products have developed.

B. Domestic Industry

In light of the like product definition, I believe that the appropriate industry definition for analysis of actual injury would include the five domestic firms producing generic cephalexin capsules in the United States during the period in which Commerce found sales at LTFV and for analysis of threat of injury would include the six firms now engaged in such

^{41/} Report at A-10, n.5, A-35.

^{42/} Id. at A-10, n.5; A-14, Table 1; A-35.

^{43/} Id.

production. Petitioner's arguments for exclusion of Eli Lilly and Company, which produces only the Keflex branded capsules, are discussed above. Although several issues respecting the scope of the domestic industry would be raised by inclusion of bulk cephalixin along with other oral dosage forms of cephalixin in the like product definition, no such issues are presented under the like product definition adopted here. Neither party makes a case for exclusion of producers of the like product from the domestic industry. All of these producers perform the activities necessary to produce cephalixin capsules from bulk cephalixin and their inclusion appears at least arguably appropriate. There is no basis for exclusion of domestic firms with production facilities located in the U.S. Virgin Islands in the domestic industry for the reasons expressed in the Views of the Commission.

II. MATERIAL INJURY BY REASON OF LTFV IMPORTS

A. Statutory Meaning

My principal difference with the majority of my colleagues concerns the meaning of Title VII's command to determine whether a domestic industry in the United States is suffering material injury by reason of imports sold at LTFV. In this investigation, as in a number of other investigations over the past several years, the majority divides the question posed by Title VII into two independent inquiries. This bifurcated approach asks first whether the domestic industry's financial health is poor. In

some investigations, this may be assessed in relation to the financial performance of other industries in the United States, although the Commission has not, to my knowledge, ever gathered, much less carefully evaluated, information on other industries with which systematically to compare the particular domestic industry before us. I can find no such evidence in the record of this investigation. In other investigations, this first inquiry refers not to the absolute state of an industry's financial health but to that health relative to some earlier period. The question, in other words, is whether the industry has suffered some adversity over the period examined in our proceeding. If the industry's health is deemed to be poor or declining, the adherents to this approach conclude that "material injury" exists. In such cases, they then attempt to ascertain whether unfairly traded imports contributed to that "injury." Where, as in this investigation, the industry is deemed to be in good health, the bifurcated approach does not address the effect of imports on the domestic industry.

Petitioner in the instant investigation objects to the bifurcated approach as inconsistent with the statute that governs our decisions. I believe Petitioner is correct, and that the majority errs in stopping its analysis after concluding that the industry is too profitable to be injured. The notion is akin to asserting that a profitable company cannot be injured by embezzlement; if it were injured, how could it be profitable?

In other opinions, I have spelled out at length my reasons for concluding that the bifurcated approach is not consistent with, and certainly is not the preferable interpretation of, Title VII.^{44/} Nothing in the language of the statute or in its legislative history prohibits the Commission from granting relief to a domestic industry solely because we deem it healthy.^{45/} Nor does the imposition of such a threshold requirement find support in Commission practice until fairly recently. It also is inconsistent with the logic of the judicial decision routinely relied on to demonstrate its acceptance by the courts and more recently in fact relied on by a judge on one of our reviewing courts.^{46/} Finally, denial of relief to industries based on the satisfactory level of industry performance at the present time or on positive industry trends over the period selected by the Commission (without statutory basis) for examination cannot easily be squared with the recently added statutory directive that the Commission take into account business cycles and other

^{44/} See Certain All-Terrain Vehicles from Japan, Inv. No. 731-TA-388 (Final), USITC Pub. 2163 (Mar. 1989) (Additional Views of Commissioner Cass); Digital Readout Systems and Subassemblies Thereof from Japan, Inv. No. 731-TA-390 (Final), USITC Pub. 2150 (Jan. 1989) (Concurring and Dissenting Views of Commissioner Cass) 98-108 ("Digital Readout Systems"); 3.5" Microdisks and Media Therefor from Japan, Inv. No. 731-TA-389 (Preliminary), USITC Pub. 2076 (April 1988) (Additional Views of Commissioner Ronald A. Cass).

^{45/} See Sewn Cloth Headwear From the People's Republic of China, Inv. No. 731-TA-405 (Final), USITC Pub. 2183 (May 1989) (Additional Views of Vice Chairman Ronald A. Cass) at 27.

^{46/} See discussion of American Spring Wire in Digital Readout Systems at 112-117.

effects on industry performance.^{47/} I will not recapitulate the discussion of these points in full, but I do think it important to restate briefly one argument against the reading of the statute adopted by the majority here and to restate the basis for my belief that judicial precedent does not support such a reading.

The simplest and most important argument is that the text of the statute cannot be made consistent with the threshold "health" test so long as the text is read in accordance with basic precepts of the English language. The statute instructs the Commission to determine whether "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" determined by the Department of Commerce to have been sold at less than fair value.^{48/} The instruction is a single sentence asking us to determine if there was material injury by reason of the subject imports, not two sentences asking for separate determinations on the health of the industry and the effect of LTFV imports. The term "injury" is commonly understood to mean a change for the worse consequent to a specific causal event. Dictionaries define injury not as "ill health" but as "an act that damages, harms, or hurts; a violation of another's rights . . . compare TORT."^{49/}

^{47/} 19 U.S.C. § 1677(C)(11).

^{48/} 19 U.S.C. § 1673d(b)(1).

^{49/} Merriam-Webster's Third Unabridged Dictionary 1164 (1961).

Title VII does not speak of injury as an abstract concept but asks us to assess injury in relation both to a causal subject (the imports found or alleged to have been sold at LTFV) and an object (an industry in the United States), further indicating that this term was used in accord with its plain meaning.

It is an accepted rule of statutory interpretation that, at least in the absence of compelling evidence to the contrary, a statute should be interpreted in accord with its plain meaning when one can be derived from the text. Here, there is no compelling basis for doing otherwise. Indeed, far from qualifying the initial textual instruction in a manner that raises doubt about its meaning, other relevant provisions support the construction of Title VII as framing a unitary inquiry, not a threshold test of ill health and a secondary examination of cause. The definitions section of Title VII does not separately define meanings for "material injury" and "by reason of" the LTFV imports but instead, under the title of "Material Injury," details factors that might be relevant to determining the connection between industry performance and the imports subject to investigation. These provisions clearly evidence an understanding of the term "injury" as comprehending something other than an absolute decline in industry performance and also as necessarily the product of some particular source of injury. For example, the statute does not direct the Commission to consider absolute changes in prices but instead directs the Commission to consider "the effect of imports of such merchandise

[the LTFV imports] on prices in the United States for like products."^{50/} More pointedly, the statute instructs the Commission to consider whether sale of LTFV imports "prevents price increases which otherwise would have occurred."^{51/} Such language is very difficult to square with a notion of injury as incorporating a freestanding requirement that industry profits be "unhealthy" or that industry financial trends decline in absolute terms. Instead, it appears fully to support a reading of the statute as comprehending a single inquiry into the effect of the LTFV imports on the domestic industry.

The second point respecting the healthy industry test that should be noted concerns judicial authority. The Court of International Trade recently accepted the Commission's argument that such a test is consistent with the statute,^{52/} relying on its earlier decision in American Spring Wire Corp. v. United States.^{53/} Although the recent decision is authority for the proposition that not all judges would find the test inconsistent with the dictates of Title VII, American Spring Wire itself is not such authority. The decision does, however, contain language that has been read out of context often over the past several years.

^{50/} 19 U.S.C. § 1677(7)(B)(ii).

^{51/} 19 U.S.C. § 1677(7)(C)(ii)(II).

^{52/} Nat'l Ass'n of Mirror Mfrs. v. United States, 696 F. Supp. 642 (Ct. Int'l Trade 1988).

^{53/} 590 F. Supp. 1273 (Ct. Int'l Trade 1984), aff'd sub nom., Armco, Inc. v. United States, 760 F.2d 249 (Fed. Cir. 1985).

In that decision, the court stated that the "Commission must make an affirmative finding only when it finds both (1) present material injury...and (2) that the material injury is 'by reason of' the subject imports".^{54/} While, standing alone, this statement's meaning is open to differing interpretations, viewed in the particular factual and legal context in which American Spring Wire was decided, that statement hardly can be characterized as clear support for a healthy industry test.

In the determinations that were reviewed in that case, the Commission declared that "[e]ven assuming that [the posited] injury meets the standard of 'material injury', our analysis of the effects of [the subject] imports...from France during that six month period demonstrates that any such injury is not by reason of the subject imports".^{55/} On appeal of these determinations to the Court of International Trade, petitioners argued that the Commission's decision was not supported by substantial evidence because the Commission had suggested that "material injury" had been shown on the record; petitioners therefore urged that an affirmative determination was required. Counsel for the Commission, on the other hand, argued that the statute required, in addition to a showing of "injury," evidence of a causal link between that injury and the unfairly traded imports. Counsel for the Commission also argued that the

^{54/} 590 F. Supp. at 1276.

^{55/} Prestressed Concrete Steel Wire Strand from France, Inv. No. 701-TA-153 (Final), USITC Pub. 1325 (Dec. 1982) (footnote omitted) at 6.

Commission implicitly determined that no material injury existed; accordingly, there was no need to consider causation other than in the alternative. Counsel further argued that causation was, in any event, lacking.

The court accepted the argument that both material injury and causation must be present to support an affirmative determination, but it did not suggest that these two elements need be considered in the disjunctive. The court agreed that the statute requires a causal connection between the injury to the domestic industry and the subject imports, and it found that the Commission had, as counsel for the Commission suggested, implicitly found that the domestic industry was not materially injured.^{56/}

The court thus simply pointed out that the statutory requirement of injury by reason of less-than-fair value imports means not only that an industry must be suffering some harm, such as might be claimed by any declining industry, but also that there must be a showing that LTFV imports were a cause of that harm. Just as the commonplace notion of injury requires the infliction of harm to someone by something or someone, so the statutory injury requirement mandates something more than an independent evaluation of the condition of a domestic industry.

Hence, the essential insight underlying American Spring Wire's affirmance of the Commission's determination rested on the conclusion that whatever fate had befallen the domestic industry

^{56/} 590 F. Supp. at 277.

could not have constituted injury by reason of the unfairly traded imports because, as the unitary approach explicitly affirms, that concept necessarily requires a nexus between the imports and the change in condition. The court agreed. It held that a change in the condition of the domestic industry cannot satisfy the statutory standard independent of such a nexus. It manifestly was not asked to decide and did not hold that the law requires a determination, independent of the causal reasons, that the industry's condition was too good to allow relief against LTFV imports or that the industry's condition had over a given period (not related to evidence of LTFV sales) changed for the worse.

Furthermore, it should be noted that, while the reading of American Spring Wire challenged here has been accepted by one judge of the Court of International Trade, another judge of the same court has taken a position strongly at odds with the requirement of a healthy industry test. In Republic Steel Corp. v. United States,^{57/} the court stated that:

[T]he ITC should not be engaged in a determination of whether an industry is 'healthy'. A 'healthy' industry can be experiencing injury from importations and an 'unhealthy' industry can be unaffected by importations. The purpose of the ITC's investigation is to determine whether imports are a cause of any effect on an industry which amount to "material injury."

The case was later voluntarily dismissed pursuant to a motion filed by petitioners, and certain aspects of the court's decision

^{57/} 591 F. Supp. 640, 649 (Ct. Int'l Trade 1985), reh'g denied, 9 Ct. Int'l Trade 100 (1985), dismissed (Order of August 13, 1985).

in Republic Steel may properly be questioned in light of the Federal Circuit's subsequent opinion in American Lamb Co. v. United States.^{58/} However, to date, the Federal Circuit has not squarely addressed the particular issue discussed by the court in the portion of its opinion that is quoted above.^{59/}

Although I agree with Petitioner that the statute should not be read to preclude relief simply because the industry is profitable, the record in this investigation convincingly establishes that the LTFV imports had only a negligible effect on the domestic industry producing cephalexin capsules. The approach I use in evaluating the record has been described extensively in other investigations.^{60/} This "unitary" or "comparative" approach specifically addresses the three factors to which the statute directs our attention in assessing possible existence of injury to the domestic industry by reason of LTFV imports. First, we are to examine the volume of imports of the merchandise under investigation. The absolute volumes of imports, their magnitude relative to domestic sales of the competing "like product" and the extent to which import volumes changed as a result of dumping are all relevant to assessing

^{58/} 785 F.2d 994 (Fed.Cir. 1986).

^{59/} The fact that the decision in American Spring Wire was affirmed on the basis of the opinion filed by the Court of International Trade in that case does not, in my view, by any means constitute acceptance of a healthy industry test for the reasons given above.

^{60/} New Steel Rails from Canada, Inv. No. 731-TA-422 and 701-TA-297 (Preliminary), USITC Pub. 2135 (Nov. 1988) (Additional Views of Vice Chairman Cass) at 35-37.

the effect of LTFV imports on the domestic industry. The change in import volumes brought about by LTFV sales (or "dumping"), in turn, will be closely related to, and in large part a function of, changes in the prices of the imports that occurred as a result of dumping. Second, we must determine how the LTFV imports affected prices, and concomitantly sales, of the domestic like product. Finally, we must evaluate the extent to which the changes in demand for the domestic like product caused by dumping affected the financial performance and condition of the domestic industry with respect to such indicators as return on investment, employment, and compensation. Each of these factors must be considered within the context of the dynamics of the relevant industries and markets,^{61/} and the Commission must then evaluate whether the evidence as a whole leads to the conclusion that imports have had a "material" effect on the U.S. industry within the meaning of the statute. On this ultimate issue, we may consider the health of the industry as relevant to the materiality of the effect of LTFV imports, though that alone will not be dispositive of that issue.^{62/}

B. Effects of LTFV Imports on the Domestic Industry

1. Volumes and Prices of LTFV Imports

Imports of cephalexin capsules from Canada entered the U.S. market in April of 1987. Total 1987 imports of the Canadian

^{61/} 19 U.S.C. § 1677(C)(iii).

^{62/} New Steel Rails, supra, at note 61.

capsules were * * * kilograms, valued at approximately \$* * *.63/ Total imports in 1988, which encompasses the period (May-October 1988) during which the Department of Commerce found dumping, were * * * kilograms, valued at \$* * * million.64/ Imports for the first quarter of 1989 were * * * kilograms, valued at \$* * * .65/

The share of U.S cephalixin capsule consumption held by imports of cephalixin capsules from Canada was * * * percent by volume and * * * percent by value in 1987, * * * percent by volume and * * * percent by value in 1988, which encompasses the period (May-October 1988) during which the Department of Commerce found dumping, and * * * percent by volume and * * * percent by value during the first quarter of 1989.66/

The Commerce Department calculated average dumping margins for the Canadian producer at 7.5 percent based on a comparison of ex factory prices for sales in Canada and the United States. The record evidence indicates that dumping caused the prices of the subject imports to decline by only minuscule amounts.

In cases in which dumping margins reflect a finding by Commerce that the foreign exporter has charged a lower price for its product in sales to the United States market than it has in sales to its home market, the actual decrease in the U.S. price of the subject imports (compared to what that price would have

63/ Report at A-33, Table 16.

64/ Id.

65/ Id.

66/ Id. at A-34, Table 18.

been absent dumping) will not be equivalent to the full percentage of the dumping margin. The extent to which the dumping margin results in decreased prices for sales to the U.S. is in large measure a function of the importance of each market (home and U.S.) to the foreign producer; an accessible indicator of relative importance is the proportion of its total sales in both of these markets that the producer makes in its home market.^{67/}

In this case, the Canadian producer sells over * * * percent of the capsules it produces in the U.S. market.^{68/} Accordingly, the maximum decrease in the price of the imported capsules that occurred consequent to dumping was at most a percentage representing a very small amount of the dumping margin calculated by Commerce. The effect of dumping on the import price appears to be extraordinarily small.^{69/}

^{67/} See, e.g., Certain All-Terrain Vehicles from Japan, Inv. No. 731-TA-388 (Final), USITC Pub. 2163 (March 1989), (Additional Views of Commissioner Cass) at 58-60.

In reality, an estimate of the decrease in the price of the dumped product that is derived in this fashion will be somewhat overstated as it represents an approximate upper bound of that decrease. For a thorough explication of this subject, see R. Boltuck, Office of Economics, Assessing the Effects on the Domestic Industry of Price Dumping, USITC Memorandum EC-L-149 at 1, n. 1, 13, 19-21 (May 10, 1988). A more accurate statement of the effects of dumping on import prices also may require some adjustment to reflect the fact that dumping margins are calculated on an ex-factory, rather than final sales price, basis. This adjustment almost inevitable will reflect a reduced effect from that calculated here.

^{68/} Report at A-31.

^{69/} Respondent's Posthearing Brief at Attached Memorandum From Economic Consulting Services Inc. at 5; Memorandum to Commissioner Eckes from the Office of Economics, EC-M-273, dated August 1, 1989.

These small price effects most likely had a correspondingly small impact on the volume of imports sold in the United States. That point is explored further in the following section.

2. Prices and Sales of the Domestic Like Product

The record strongly suggests that the subject imports did not materially affect either the prices or the sales of the domestic like product. As noted above, the market penetration of the subject imports, while not de minimis, was quite low throughout the period of investigation. In addition, the record contains evidence that the Canadian producer did not price the subject imports at the low end of the market, and in fact during 1988 and 1989 * * *, although well below the price charged for Lilly's branded product Keflex.^{70/}

Two additional factors are normally of special importance in the inquiry into the impact of imports on domestic sales and revenues. These are the extent to which consumers view the domestic and imported product as similar (the substitutability of the subject imports and the domestic like product), and the degree to which consumers change their purchasing decisions with respect to these products (as a class) based on variations in these products' prices.

Generally, imports have the greatest impact on domestic like product sales and revenues when consumers are unwilling to purchase more of the category of goods to which imports and the

^{70/} Id. at A-39-A-41.

like product belong as the prices of these goods go down, and when, in addition, consumers view the imported and like products as close substitutes. In this situation a decrease in the price of the import will most likely result in direct substitution of the import for the domestic like product, rather than increased overall purchases of the product.

In the investigation before us, consumers are only moderately responsive to changes in the price of cephalexin capsules, and they seem to view domestic and imported generic cephalexin capsules as largely the same.^{71/} Again, Keflex, while competing with the generic capsules, including imports, appears to be viewed as less than fully substitutable. These facts increased the effect that imports had on prices and sales of the domestic like product. The magnitude of that effect, however, is severely constrained by the imports' low penetration of the U.S. market (which is consistent with direct evidence respecting Respondent's prices) and by the limited price effect of LTFV sales noted above. Overall, LTFV Canadian imports appear to have reduced the sales volumes, prices and revenues of the domestic like product over the period of investigation by very small amounts well below those that ordinarily are consistent with an affirmative determination.^{72/}

^{71/} Memorandum to the Commission from the Office of Economics, EC-M-274, dated August 1, 1989, at 13, 16.

^{72/} Memorandum to Commissioner Eckes, EC-M-273, dated August 1, 1989 at 3-5; Respondent's Posthearing Brief, dated July 5, 1989, at Attached Memorandum From Economic Consulting Services Inc. at 5.

3. Investment and Employment

As indicated in the Views of the Commission, the financial indicators for the domestic industry remain strong despite declines in production and shipments between 1987 and 1988.^{73/} The number of industry employees and hours worked have not varied dramatically, and hourly wages have also remained stable after a decline between 1986 and 1987.^{74/}

Due to incomplete data the Commission staff was unable to calculate returns on investment.^{75/} However, given the widely varying degrees of initial investment by the members of the domestic industry and the limited ongoing investment required to maintain production of a particular generic drug,^{76/} neither the rate of return on capital investment nor the annual industry capital or research and development investment figures are good indicators of industry health in the generic drug industry.

Petitioner has argued that the real harm from unfairly traded Canadian imports has been to deprive domestic producers of the revenues needed for future investments in producing new generic drugs once they come off patent.^{77/} In light of the minimal effects of these imports on domestic revenues, however, any inadequacy in the ability of current revenues to sustain

^{73/} Report at A-14 and A-21.

^{74/} Id. at A-23, Table 5.

^{75/} Id. at A-27.

^{76/} Id. at A-26-A-27.

^{77/} Petitioner's Prehearing Brief at 33.

future investment was not caused by imports from Canada. Moreover, the evidence before the Commission indicates that despite strong competition resulting in falling prices for generic capsules, the domestic industry remains very profitable.^{78/}

III. THREAT OF MATERIAL INJURY

I join the Commission's discussion of threat. In doing so, I want to underscore my view that the threat factors contained in the statute require the same sort of integrated analysis as is appropriate to analysis of the actual injury from allegedly LTFV imports experienced by the domestic industry. The statutory factors respecting threat analysis are not a checklist of criteria that should be evaluated on a disaggregated basis, with a negative threat finding ensuing if a majority of statutory factors do not indicate a threat. Rather, the factors suggest where we should look to see whether probable events over the near term will produce the sorts of effects on the domestic industry's prices and sales, and ultimately on its financial returns and employment, that would constitute material injury. Where, as here, the factors almost uniformly move in a single direction, any analysis that refers to them -- even on a factor-by-factor basis -- should produce a sensible result. Where, however, the factors produce a less consistent picture, careful inspection of that information becomes critical.

^{78/} Report at A-24.

Conclusion

The reasons stated above, I conclude that the domestic industry is not materially injured by reason of LTFV imports of cephalalexin capsules. For reasons substantially given in the Views of the Commission, I also conclude that the domestic industry is not threatened with such injury.

INFORMATION OBTAINED IN THE INVESTIGATION

Introduction

Following a preliminary determination by the U.S. Department of Commerce (Commerce) that imports of generic cephalixin capsules 1/ from Canada are being, or are likely to be, sold in the United States at less than fair value (LTFV), the U.S. International Trade Commission (Commission), effective April 12, 1989, instituted investigation No. 731-TA-423 (Final) under section 735(b) of the Tariff Act of 1930 (U.S.C. 1673d(b)) (the act) to determine whether an industry in the United States is materially injured or threatened with material injury, or whether the establishment of an industry in the United States is materially retarded, by reason of such imports. Notice of the institution of this investigation and of a hearing 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 May 4, 1989 (54 F.R. 19251). 2/ The hearing was held in Washington D.C. on June 28, 1989. 3/

In its final determination, published in the Federal Register of June 26, 1989 (54 F.R. 26820), Commerce determined that imports of generic cephalixin capsules from Canada are being, or are likely to be, sold in the United States at LTFV. 4/ The applicable statute directs that the Commission make its final injury determination within 45 days after the final determination by Commerce, or in this case by August 10, 1989. The Commission's vote on this investigation was held August 3, 1989.

1/ The imported products covered by this investigation are generic cephalixin capsules from Canada. Generic cephalixin capsules are cephalixin monohydrate in capsule form. Cephalixin monohydrate is a semisynthetic cephalosporin antibiotic intended for oral administration. Its chemical formula is $C_{16}H_{17}N_3O_4S \cdot H_2O$. Generic cephalixin capsules contain not less than 90 percent and not more than 120 percent of the labeled amount of cephalixin monohydrate. The capsule is made of a water-soluble gelatin, designed to facilitate swallowing and a phased release of the drug into the user's digestive system. The product is currently classifiable under Harmonized Tariff Schedule (HTS) subheading 3004.20.00 (previously in item 411.76 of the Tariff Schedules of the United States (TSUS)).

The term generic cephalixin in this investigation refers to a product approved by the U.S. Food and Drug Administration (FDA) through an abbreviated new drug application (ANDA) because the product is sufficiently similar to the pioneer product (the product originally approved by the FDA, i.e., Keflex, originally patented by Eli Lilly & Co.). "Generic" is defined as "nonproprietary; denoting a drug name not protected by a trademark," in the Dorland's Pocket Medical Dictionary, 22nd ed., 1977, p. 292.

2/ A copy of the Commission's Federal Register notice is presented in app. A.

3/ A list of participants in the hearing is presented in app. B.

4/ A copy of Commerce's notice of final determination is presented in app. C.

Background

This investigation results from a petition filed on October 27, 1988, by Biocraft Laboratories, Inc., Elmwood Park, NJ, alleging that an industry in the United States is materially injured by reason of LTFV imports of generic cephalixin capsules from Canada. In response to this petition, the Commission instituted investigation No. 731-TA-423 (Preliminary) on October 27, 1988, under section 733(a) of the Act (19 U.S.C. 1673b(a)) and, on December 12, 1988, determined that there is a reasonable indication that an industry in the United States is threatened with material injury by reason of such imports. 1/

Following the receipt of a petition from Biocraft on July 12, 1989, alleging that an industry in the United States is materially injured, or threatened with material injury, by reason of allegedly LTFV imports of generic cephalixin capsules from Israel and Portugal, the Commission instituted investigations Nos. 731-TA-436 and 437 (Preliminary), Generic Cephalixin Capsules from Israel and Portugal. However, the petition was withdrawn on August 1, 1989, and the Commission's investigations were terminated.

The Product

Description and uses

The imported product subject to this investigation is generic cephalixin monohydrate (cephalexin) 2/ in capsule form. Cephalixin is a first generation semisynthetic broad-spectrum cephalosporin antibiotic, used in the treatment of serious respiratory tract, skin and skin structure, and urinary tract infections in humans and animals.

Cephalixin in bulk form is the raw material used to manufacture the various dosage formulations. 3/ It is not used in the United States for any purpose other than the manufacture of finished dosage forms of cephalixin. It appears that no independent market exists for bulk cephalixin outside of pharmaceutical manufacturers. 4/

1/ Generic Cephalixin Capsules from Canada, USITC Publication 2143, Dec. 1988.

2/ For the purposes of this report, cephalexin will be used to mean cephalixin monohydrate. There is another version of cephalixin, available from Eli Lilly and Co., known as cephalixin hydrochloride monohydrate and marketed under the trade name Keftab. Keftab is still protected by patent. Like cephalixin, it is intended for oral administration.

The molecular formula of cephalixin is $C_{16}H_{17}N_3O_4S$. The formula of cephalixin monohydrate is $C_{16}H_{17}N_3O_4S \cdot H_2O$, while the formula of cephalixin hydrochloride is $C_{16}H_{17}N_3O_4S \cdot HCl \cdot H_2O$. Additional information on cephalixin hydrochloride is presented in app. D.

3/ Cephalixin is a fluffy powder and can be difficult to work with. To make manufacture easier, bulk cephalixin can be purchased in a compacted form, where the particle size of the product has been mechanically altered by means of hydraulic pressure. Compacted bulk is used primarily in the manufacture of capsules and tablets, aiding in the efficiency of production, while non-compacted bulk is used for oral suspension. However, the need for compacted bulk is dependent upon the machinery used to produce the capsules or tablets. Not all machinery requires the use of compacted bulk cephalixin.

4/ In a supplement to the questionnaire used in this investigation, the Commission asked the seven producers and six importers of cephalixin products whether there were any uses for bulk cephalixin other than to manufacture dosage

Cephalexin is used in three dosage forms for medical treatments: capsules, tablets, and oral suspension. The capsules are by far the most popular formulations used in the United States, comprising approximately 87 percent of consumption of the drug in 1988. They can be prescribed in 250 mg or 500 mg dosages. The capsules are formed by mixing powdered cephalexin with inert substances and then encapsulating the mixture into a gelatin capsule (see the section entitled Manufacturing processes below).

Cephalexin tablets, like capsules, are prescribed in 250 mg and 500 mg dosages. Eli Lilly and Company (Lilly) markets its 250 mg and 500 mg tablets under the trade name Keflet, 1/ and the company produces a 1-gram tablet as well, marketed under the Keflex name. 2/

Cephalexin prescribed in oral suspension form is shipped from the manufacturer as a powder and then reconstituted by the pharmacist into the proper dosage amount. This formulation is a flavored liquid mixture designed to be taken orally. Generally, cephalexin in oral suspension form is prescribed for children and older persons who might have difficulty swallowing a capsule or tablet. Once reconstituted, the mixture must be refrigerated and has a shelf life of about two weeks.

Lilly produces cephalexin hydrochloride monohydrate in tablet form under the trade name Keftab. The product has a slightly different chemical composition and is maintained under a separate patent, but it interacts in the body in a manner nearly identical to that of cephalexin. For more information on Keftab, see appendix D.

Product substitutability

Substitution among available antibiotics.---The antibiotic market as a whole is highly competitive. Often there are numerous pharmaceutical preparations that can be used to treat any given infection. In theory, many of the antibiotics and most of the cephalosporins can be substituted for one another. In practice, the decision to prescribe one particular drug over another is made by the physician on a case-by-case basis. Therapeutic treatment depends on a combination of factors: the efficacy of the product against the organism responsible for the infection, the patient's sensitivity to a particular product, and the patient's concurrent consumption of other medications. For

forms of the drug, and whether there is an independent market for bulk cephalexin outside of pharmaceutical manufacturers. Of the four producers and four importers who responded to that particular question in the supplement, none was aware of uses for bulk cephalexin other than to produce dosage forms of the drug, and none was aware of an independent market for bulk cephalexin outside of pharmaceutical manufacturers.

1/ Keflet is cephalexin monohydrate in tablet form. The product is identical to other cephalexin tablets in terms of its therapeutic use. Its manufacturing process is somewhat different, however, in that Lilly has patented a process in which the same amount of active ingredient can be presented in a tablet that is much smaller than the conventional tablet.

2/ American Hospital Formulary Service, Drug Information 89, 1989, p. 138. Lilly reports that demand * * *.

this reason, the range of products that might substitute for cephalexin is situational and clear dividing lines are difficult to establish. 1/

Within the cephalosporin classification of antibiotics, there are 19 different drugs loosely categorized as first, second, or third generation. 2/ In general, cephalosporins are active in vitro 3/ against many gram-positive aerobic bacteria, some gram-negative aerobic bacteria, and some anerobic bacteria. 4/ It is possible to substitute among generations for some applications; however, there are substantial differences among the cephalosporins in spectra of activity as well as levels of activity against susceptible bacteria. 5/ More information on cephalosporins is provided in appendix E.

Cephalosporins and penicillins are structurally and chemically related beta-lactam antibiotics. Cephalexin is derived from penicillin V, a natural penicillin (see section entitled Manufacturing processes below). Cephalosporins and penicillins can, in some cases, substitute for one another; however, beta-lactam antibiotics vary substantially in their rate and efficiency of bactericidal action. 6/ Patients who are allergic to penicillin have frequently exhibited hypersensitive reactions to cephalosporins.

Cephalexin, as with other cephalosporins, is potentially physically and/or chemically incompatible with some drugs, including aminoglycosides, but the compatibility depends on a combination of factors, including drug concentrations.

Substitution among dosage forms.--Regardless of the antibiotic prescribed, it is not possible for a pharmacist or patient to substitute among dosage forms

1/ For example, * * * identified the following antibiotic drugs that compete with Keflex when the physician or hospital formulary are deciding which drugs to administer or carry: Cleocine/Cleindamycin, Amoxyl/Amoxycillin, Prostaphlin/Oxycillin, Doxycycline/Vibramycin, Veloceph/Cephadrine, Duracef/Cefadroxil, Anspor, all types of penicillin, and generic cephalexin. (Telephone conversations with Commission staff on June 5 and 6, 1989.) Responses to Commission questionnaires on the substitution issue yielded no consensus on which products, if any, could substitute for cephalexin in a therapeutic context.

2/ The most accepted practice is to classify cephalosporins by generations based upon the spectrum of activity of each individual cephalosporin. Generally, second generation cephalosporins have a broader spectrum activity than first generation cephalosporins. Third generation cephalosporins are generally less active in vitro against susceptible staphylococci than first generation cephalosporins, but have an expanded spectrum of activity against gram-negative bacteria compared with first and second generations.

This classification method is imprecise and somewhat arbitrary. For example, there is disagreement among clinicians over whether cefaclor is first or second generation. Similar disagreement exists regarding whether cefotetan is properly classified in the second or third generation.

3/ In vitro is defined as "in an artificial environment;" that is, in a cultivation glass. By contrast, in vivo is defined as "in the living body."

4/ "Gram-negative" and "gram-positive" are classifications of bacteria. The name is derived from the gram stain process which reveals fundamental differences in cell wall structure.

5/ American Hospital Formulary Service Drug Information 89, p. 82.

6/ Ibid., p. 193.

after the prescribing physician has written the prescription. Despite this barrier, there appears to be no therapeutic distinction between the various oral dosage forms of a given drug except for ease of administration and rate of absorption into the body. There does, however, appear to be a division between oral and injectable applications of antibiotics: Oral antibiotics are prescribed for the less ill, home-based patient, but injectables are reserved mainly for treatment of the seriously ill, usually hospitalized, patient.

Cephalexin is not available in an injectable form. Therefore, a patient requiring a dosage level higher than that available or practical for oral administration would be treated with an antibiotic other than cephalexin, even if the infection were one of the type that might normally be treated with cephalexin under other circumstances. 1/

Substitution of generic preparations for brand-name drugs.--Substitution of the generic for the brand-name product can be made at two levels: by the prescribing physician or at the pharmacy. 2/ Laws vary from state to state. In 19 states, a two-line prescription form is required, so that the physician must specifically state on the prescription form that generic substitution is permissible. In 26 states and the District of Columbia, a one-line prescription form is used, so that unless the physician writes "dispense as written" or some equivalent, the pharmacist is allowed to offer the patient the generic version of the product. In five states, either form may be used. Of the states that have adopted the one-line form, 17 (and the District) require a handwritten phrase by the physician to rule out substitution, while 9 other states allow various combinations of preprinted boxes or abbreviations. 3/

Along with the two-line prescription form, the other two most significant barriers to generic substitution are the authority of independent state formulary commissions 4/ and state provisions mandating a full percentage savings pass-through to consumers. However, these barriers are the targets of intensive lobbying by pro-generic forces, such as the American Association of Retired Persons (AARP). 5/ In 1991, the generic drug producers will benefit from implementation of the Medicare Catastrophic Coverage Act of 1988, which will require all U.S. pharmacies to dispense generic drugs to Medicare patients unless a physician specifically indicates "brand medically necessary" on prescription forms. 6/

1/ There is evidence that the division between oral and injectable antibiotics is lessening. A new category of antibiotics, called quinolones, is being aggressively marketed by several pharmaceutical companies and could garner 10 percent of the antibiotic market within 3 to 5 years. The attractiveness of quinolones is the combination of strength and oral administration, thus reducing the costs associated with the hospitalization required for intravenous treatment. A new, third generation cephalosporin, ceftazidime, is expected to offer quinolones heavy competition, even though it must be administered intravenously. At the same time, quinolones are expected to erode the position of a number of antibiotics, including cephalexin and cefaclor, first and second generation cephalosporins, respectively. (Chemical Business, May 1988, pp. 38-41.)

2/ Lilly * * *.

3/ Petitioner's postconference brief, pp. 10-14.

4/ State boards that set pharmaceutical equivalency and substitutability standards.

5/ F-D-C Reports, Feb. 1, 1988. Provided in petitioner's postconference brief.

6/ Business Week, Dec. 5, 1988, p. 172.

Manufacturing processes

Bulk cephalalexin.--Bulk cephalalexin is the raw material 1/ used to produce cephalalexin in dosage form. It is also the starting point for the production of cephalalexin hydrochloride. Bulk cephalalexin is the raw material that imparts the essential therapeutic characteristic to the dosage formulations. 2/

Bulk cephalalexin is produced by the chemical modification of a microbial product derived from the fermentation of Cephalosporium acremonium. 3/ 4/ The material is prepared from penicillin V sulfoxide by a series of chemical reactions specifically designed to preserve the integrity of certain functional groups of the cephalxin molecule. After a specific chemical protecting agent is removed, cephalalexin monohydrate can be recovered from the solution through crystallization. 5/ The manufacturing procedure for bulk cephalalexin requires highly trained workers. 6/

Dosage forms of cephalalexin.--Although the procedure described below applies to dosage forms of cephalalexin, * * * U.S. producers (* * *) indicated on their questionnaire responses 7/ that other cephalosporins 8/ are, or could be, produced on the same equipment after a cleaning and sterilization process.

Petitioner describes the production and quality control procedures used in the production of cephalalexin in dosage form at its cephalosporin facility in appendix A of the petition. This procedure is essentially the same for all producers, and is summarized in the paragraphs below.

When the bulk cephalalexin is received at the company facility, each drum is verified for content, lot number, and physical condition, then transferred to a

1/ Bulk cephalalexin can refer, depending on the context, either to the compound cephalalexin monohydrate or to anhydrous cephalalexin. The bulk product is ordinarily sold commercially in the form of cephalalexin monohydrate. The active ingredient in that compound is anhydrous cephalalexin, which constitutes approximately 90 percent of the compound and is used to denote the strength of the finished dosage forms. (Letter from counsel for Novopharm to Commission staff dated June 13, 1989.)

2/ FDA regulations and U.S. pharmacopeia permit a range of bulk cephalalexin content in finished cephalalexin products of between 90 and 120 percent of the amount of active ingredient labeled.

3/ Cephalosporium acremonium, the first source of the cephalosporins, was isolated in 1948 from the sea near a sewer outlet off the Sardinian coast. Crude filtrates from cultures of this fungus were found to inhibit the in vitro growth of staph. aureus and to cure staphylococcal infections and typhoid fever. Culture fluids in which the Sardinian fungus was cultivated were found to contain three distinct antibiotics, which were named cephalosporin P, N, and C. With the isolation of the active nucleus of cephalosporin C and with the addition of side chains, it became possible to produce semisynthetic compounds with antibacterial activity much greater than that of the parent substance.

(Goodman & Gilman, The Pharmacological Basis of Therapeutics, 7th ed. 1985, p. 11.

4/ Kirk-Othmer, Encyclopedia of Chemical Technology, third edition, vol. 2, pp. 889-95.

5/ Specifically, * * *.

6/ Telephone conversation between Commission staff and * * *, Dec. 1, 1988.

7/ * * *.

8/ Cephadrine, cefadroxil, and cefaclor.

quarantined holding area. The raw material is sampled and tested for potency and purity, then released for use in production.

In order to facilitate the processing of the bulk cephalexin into finished (dosage) form, certain inert additives, such as starch, must be mixed with the bulk product. The ingredients are rechecked and weighed, sifted, and loaded into mixers. * * * hours are required to mix a capsule batch properly; * * * hours are required to mix powder for oral suspension because of the greater number of inert ingredients (sugar, flavorings, etc.).

The mixture is then metered into dosage formulations. Capsule-filling machines are used to produce capsules. Filled capsules are passed through machines that individually weigh and sort the product and reject any capsules that are not within specifications. 1/

The finished capsules are screened rigorously for quality assurance and then polished. Each batch takes approximately * * * hours to encapsulate, * * * hours to inspect, and * * * hours to polish. According to industry sources, the encapsulation process used in the United States is similar to that used worldwide, both in terms of the actual process and in terms of cost. Capsule batches are bottled on a high-speed packaging line, a process requiring approximately * * * hours.

The mixture of active and inactive ingredients for tablets is the same as for capsules. To form tablets, the mixture is tightly compressed and often coated with a light film. 2/

Powder for oral suspension, after mixing, is packaged on a high-speed bottle filling line. The process requires approximately * * * hours to complete one batch.

All labeling materials are strictly controlled. Labels and brochures are quarantined until they are proofread against a master label and verified for accuracy. Inventory records regarding the receipt, issuance, and return of labeling materials are maintained.

Product samples are gathered and tested at each stage of the manufacturing process. Samples of the finished product are tested for moisture content, assay, dissolution, and weight variation. Additional samples are gathered for retention and stability purposes as per the FDA good manufacturing processes (GMPs). 3/

Imported cephalexin capsules are comparable in quality to those produced domestically and, as such, can be used interchangeably. FDA regulations and U.S. pharmacopeia standards require that all medicinal chemicals consumed in the United States, including cephalexin and other cephalosporins, meet certain criteria regarding purity and efficacy. In addition, facilities producing these products domestically and abroad must be approved by the FDA and must comply with the FDA's GMPs. Antibiotics, for example, must be manufactured in separate equipment and facilities from other medicinal chemicals to prevent cross

1/ In its questionnaire response, Biocraft * * *.

2/ Telephone conversation between Commission staff and officials at * * *, Nov. 23, 1988.

3/ Regulations put forward by the FDA regarding manufacturing procedures, to which producers must adhere.

contamination. 1/ Products produced in another country, such as Canada, can be exported to the United States only if the producing facility is FDA approved. (See appendix F for a summary of FDA regulations.)

The drug approval process in Canada for drugs manufactured in that country is similar to that of the United States. 2/ Certain agreements have been reached between the two countries that reaffirm this. One such agreement permits Canadian inspectors to perform the initial inspection that the FDA requires on products for which a new drug evaluation has been filed with the FDA (i.e., those products intended for export to the United States).

A Canadian company would, however, still experience varying degrees of difficulty in obtaining FDA approval to export a particular product to the United States, generally for reasons other than product quality. For example, a drug that is approved in Canada for two therapeutic applications will probably need additional approval in the United States if it is targeted for three such applications. Labeling standards could be different, requiring new equipment or increased capital expenditures.

The U.S. market

The U.S. pharmaceutical industry and generic drugs.--In addition to U.S. sales, the prosperity of the U.S. pharmaceutical industry as a whole is measured by the number of new products it develops, the value of its exports, the cash flow it generates, and the level of its profits. Many changes have taken place in the industry over the last decade, with product liability, protection of intellectual property rights abroad, and the high cost of research and development becoming important issues.

Opportunities for growth in the industry are presented by international sales, especially in developing countries, diversification of products and enhancement of productivity through computerization, 3/ and particularly by an aging population. 4/ While the prescription drug market continues to support one of the most profitable industries in the United States, the continual introduction of new (though not always more effective) prescription drugs tends to slow sales of the older ones. Development of these new drugs is expensive: the industry spent a record \$5.4 billion on research and development (R&D) in 1987, with an estimated \$6 billion spent in 1988. The number of new drugs entering the market has not necessarily increased, however. In 1987, the FDA approved 21 new drugs, compared with 30 in 1985. The review time for a new drug

1/ Although Biocraft President Harold Snyder stated at the hearing that Biocraft was "required" to build a greenfield facility to produce cephalixin (tr. at 22), the FDA requires only a separately dedicated facility.

2/ According to a staff telephone conversation with a representative of FDA, Nov. 23, 1988.

3/ Some pharmaceutical companies, especially the larger companies with extensive R&D programs, use computer-aided design and testing programs to develop new drugs, much like CAD-CAM trends in heavier manufacturing sectors. (Telephone conversation between Commission staff and * * *, July 24, 1989.)

4/ By the year 2000, 20 percent of the U.S. population will be over the age of 65, and health care for this group will account for 50 percent of total U.S. health care expenditures. (U.S. Industrial Outlook 1989, p. 16-1.)

application can run 5 to 7 years. By contrast, the median review time for a generic drug is 17 months. 1/

Competition in the industry has increased dramatically and will continue to increase as companies identify new markets for existing products and/or identify new products for existing markets. 2/ One growing market is the field of off-patent drugs, which includes both brand-name drugs and generic drugs. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Waxman-Hatch Act, opened up this market by creating the Abbreviated New Drug Application (ANDA) process for generic versions of post-1962 drugs. The ANDA eliminated the costly safety and efficacy tests mandated in New Drug Applications (NDAs), requiring the applicant to prove only that the generic copy is equivalent in terms of bioavailability and bioequivalence. 3/ The bill also gave market exclusivity extensions for drugs given NDA approval between January 1, 1982, and September 24, 1984.

One effect of the Waxman-Hatch Act has been to lower the sales volume threshold at which a drug becomes suitable for generic competition, thereby contributing to the expansion that has taken place in the industry since the law was passed. An unusually large number of high-volume drugs lost patent exclusivity between 1985 and 1987, in addition to a backlog of available drugs that had accumulated over the years. 4/

Two other factors have boosted growth in the generic drug industry: passage of the Medicare Catastrophic Coverage Act of 1988, which takes effect in 1991 and requires pharmacists to dispense generic drugs to Medicare patients unless the prescribing physician specifically requests the brand-name product, 5/ and the cost containment measures employed by many third-party payment programs, which often require generic substitution.

The effect of these three factors has been a dramatic improvement in industry fortunes since 1984, with generic drug manufacturers being dubbed "darlings among the Wall Street set." 6/ Nine out of ten of the most widely used prescription drugs are now available generically. Out of \$23.3 billion in total retail prescription drug sales in 1988, \$3.3 billion, or 14 percent, went to generic drug producers. Generic drugs were used to fill 429 million prescriptions in 1988, or 27 percent of the 1.59 billion worth of prescriptions dispensed at retail in that year. In the antibiotic class, 44 percent of new prescriptions were filled with a generic drug in 1988, compared with 32 percent in 1987. 7/ Sales of off-patent drugs are expected to continue to increase by

1/ Telephone conversation between Commission staff and * * *, July 19, 1989.

2/ U.S. Industrial Outlook 1988, p. 18-5.

3/ Bioavailability refers to the rate and extent of absorption into general circulation in the body; bioequivalence means that the generic drug must show the same bioavailability as the reference (or patented) drug. If a generic company actually improves upon an existing drug, it must file a NDA, not an ANDA.

4/ Swergold, Chefitz Incorporated, Health Care Research, Jan. 10, 1989, p. 8. Submitted with respondent's prehearing brief as app. 4.

5/ The Generic Pharmaceutical Industry Association predicts that Medicare will boost the usage rate of generic drugs from 40-50 percent to 80-90 percent. (Chain Drug Review, Jan. 16, 1989, p. 9)

6/ Chain Drug Review, Jan. 16, 1989, p. 9. Submitted with respondent's prehearing brief as app. 2, attachment D.

7/ Ibid., Jan. 16, 1989, p. 9.

approximately 20-25 percent per year, reaching \$8 billion in 1990, when nearly all of the patents on the top 200 ethical products are expected to have expired. ^{1/} It is predicted that the market for generic drugs could double by 1992. ^{2/}

Generic drugs are almost always lower in price than the brand-name product, primarily because of the lack of the high overhead costs of R&D and clinical testing. The R&D costs associated with innovative products were estimated to account for 15 percent of the sales revenues of innovative firms in 1987. The average overall cost of developing an innovative drug, including R&D, clinical testing, and FDA approval, was estimated to be well over \$1 million in 1987. ^{3/} In comparison, the cost of preparing a generic product was estimated to be \$250,000 to \$1 million. ^{4/}

However, competition is an important factor in setting a lower price for generic drugs, and fierce price competition in the industry has become the norm. ^{5/} When an innovative drug goes off-patent, the innovator loses its monopoly market, along with its monopoly profits, but generic producers are presented with what is often referred to as the crucial "window of opportunity." The first generic producer into the market can expect to reap tremendous profits by introducing the generic substitute at a price substantially below the brand-name drug, but still substantially above cost. In addition, early entrants can build a customer base that helps protect market share against later competition. Since 1984, the usual trend in the generic industry has been for the product to be introduced by the first generic producer at a price approximately one-half the price of the brand-name product. After the initial introduction the price is expected to fall at a rate that is dependent on demand and the number of other producers entering the market. ^{6/ 7/} Late entrants into the market are at a considerable disadvantage and seek to establish market share through price distinctions. ^{8/}

1/ The Economist, Feb. 7, 1987.

2/ U.S. Industrial Outlook 1988, pp. 18-5 and 18-6.

3/ Pharmaceutical Manufacturers Association, Statistical Fact Book, 1988, p. 20.

4/ Medical Advertising News, Sept. 15, 1988.

5/ Vitarine Pharmaceuticals describes competition in the generic drug industry as "intense," stating that the company's manufacturing operations compete with generic drug manufacturers, brand-name pharmaceutical companies which manufacture generic drugs, the original manufacturers of brand-name drugs which continue to be produced after patent expirations, and manufacturers of newly-developed drugs that compete with the company's generic drugs. (Securities and Exchange Commission Form S-1, Registration Statement of Vitarine Pharmaceuticals, Inc., p. 26.)

6/ Statement of Leslie Dan, Novopharm, Ltd., at the staff conference held Nov. 16, 1988. See transcript, p. 176.

7/ Statement of Jerry Moskowitz, Biocraft Laboratories, at the staff conference held Nov. 16, 1988. See transcript, p. 68.

8/ Delay of even a month or two in entering the market can have a significant adverse effect on a generic producer. The FDA's Division of Generic Drugs is currently being investigated by the House Energy and Commerce Subcommittee on Oversight and Investigations on charges that division employees accepted bribes to expedite the ANDAs of certain companies, thus ensuring them a portion, if not all, of the extraordinarily high profits of the immediate post-patent period.

* * *. At the request of Frank E. Young, FDA Commissioner, the inspector general of the Department of Health and Human Services has begun an investigation of the generic drug division. The investigation should be

For these reasons, generic producers watch the FDA patent expiration schedule carefully, and initiate ANDAs early. Multiple generic versions of the patented product can be approved by the FDA before the patent expires. The generic producer can even take sales orders before the expiration date, as long as no generic product is actually sold or manufactured while the patent is still in effect. 1/ As a result, many generic producers are often prepared to enter the market on the very day that the patent on a popular drug expires.

The generic drug producers depend upon this "window of opportunity" to sustain their overall level of profitability. The generic drug industry is essentially driven by the FDA patent-expiration schedule. The short life-cycle and rapid price erosion characteristic of generic drugs mean that a constant supply of new products is necessary to maintain profit margins. 2/ Generic producers must move quickly and aggressively to capture market share, since the window of opportunity is the time a generic drug producer hopes to earn sufficient profits to allow it to have the resources to take advantage of the next "window" when it comes along. 3/

The lower cost of generic drugs is appealing to the customer, the pharmacist, and many insurance companies. For the pharmacist, sales of lower priced product can result in higher profit margins. Many medical insurance companies have lowered reimbursement amounts to customers, favoring the lower priced products. Companies with brand-name products have at times responded to increased sales of generic drugs by instituting price hikes and increasing advertising that emphasizes the perceptions of quality and security that are generally associated with brand-name products. These companies have also developed active trademark registration and enforcement policies, as well as alternative formulations of the brand-name products. 4/ However, there is some evidence that the trend is for major pharmaceutical companies to "abandon" a product to the generic market once its patent expires, and concentrate instead on developing and promoting a patented substitute. 5/

After its rapid growth during the 1980s, however, the generic drug industry appears to be maturing. With more generic companies jockeying for position, the business cycle may now be moving faster and the "window of opportunity" for generic drugs may be growing smaller, particularly for drugs where the patented

completed by October. (Washington Post, Health Section, July 18, 1989, p. 6.)

1/ Commission staff conversation with * * *, May 24, 1989. Under Waxman-Hatch, a generic company filing an ANDA on a product with an existing patent must inform the patent holder. However, if a generic company successfully challenges a patent, the company receives 180 days of market exclusivity protection from other generic competition.

2/ Swergold, Chefitz Incorporated, Health Care Research, Jan. 10, 1989, p. 2. Submitted with respondent's prehearing brief as app. 4.

3/ Testimony of Dr. Samuel M. Rosenblatt for Petitioner. Tr. at 35-36.

4/ Industrial Minerals, Aug. 1988, p. 43.

5/ Information gathered in this investigation suggests that this has been the strategy of Eli Lilly. The company obtained a separate patent on cephalexin hydrochloride, to be marketed under the trade name Keftab. Keftab was introduced in November 1987, 7 months after the expiration of the patent on Keflex. In its 1988 Annual Report, Lilly describes Keftab as "posting strong sales gains," while sales of Keflex "declined due to strong domestic competition resulting in widespread generic substitution since its U.S. patent expiration."

* * *. For more information on Keftab, see app. D.

version, like Keflex, was a popular item. 1/ 2/ Intensified competition among producers and increasing costs of quality assurance may serve to temper the growth of the generic drug industry in the near future. 3/ In fact, the industry has recently been described as experiencing a "shakeout." Competitive pressures are forcing generic drug producers to distinguish themselves in the marketplace through product line, service, name identification, technology, or through patented products of their own, rather than through price slashing alone. This may prove to be a difficult task. In the near future, large generic manufacturers may find it attractive to expand by purchasing smaller companies whose product lines or distribution network complement their own. 4/

Cephalexin.--The experience of the generic cephalexin producers in the United States in many ways mirrors the experience of the pharmaceutical industry overall. Prior to the expiration of the U.S. patent on cephalexin in April 1987, the patent holder, Eli Lilly, was the only domestic company that could lawfully produce the chemical in bulk and then market it domestically in finished form. Keflex, and to a lesser extent Keflet, were enormously popular drugs. At one time, Keflex was the best selling drug in its class of oral antibiotics. 5/

In the 12 months immediately following expiration of the Keflex patent, however, five domestic producers and six importers entered the marketplace for cephalexin products, in addition to the original producer Lilly. 6/ Competition for price and market share in the cephalexin market since April 1987 has been, by all accounts, merciless. 7/ The petitioner and the respondent were the first two generic firms to enter the market, followed closely by Vitarine, Barr, Zenith, and importers from Switzerland, India, Israel, Japan, and Portugal (in that order). During the period of investigation, the price of domestically-produced generic cephalexin capsules * * * from * * * percent of the Keflex price to * * * percent, 8/ * * *. 9/

1/ Telephone conversation between Commission staff and * * *, Nov. 15, 1988.

2/ The "product life cycle" (window of opportunity) of the generic drug industry is "ultra-short:" 3-9 months, on average. In the case of several products (generic Diabenese and Nalfon), pricing was decimated before any generic product entered the market. (Swergold, Chefitz Incorporated, Health Care Research, Jan. 10, 1989, p. 24. Submitted with respondent's prehearing brief as app. 4.)

3/ U.S. Industrial Outlook 1989, p. 16-4.

4/ Swergold, Chefitz Incorporated, Health Care Research, Jan. 10, 1989. Submitted with respondent's prehearing brief as app. 4.

5/ Sales of Keflex were eclipsed in 1988 by Ceclor, Lilly's patented version of cefaclor. (Eli Lilly and Co. 1988 Annual Report, p. 5) According to * * *. Submitted with respondent's prehearing brief.

6/ Since mid-1988, * * *.

7/ Generic drug distributors reportedly will switch suppliers for price differences of pennies per bottle.

8/ Prices are weighted-average selling prices of U.S.-produced Keflex and generic 250 mg capsules in 100-capsule bottles, sold to * * *, during the periods Apr.-June 1987 and Jan.-Mar. 1989. For more complete price comparisons, see app. I.

9/ The question of the "window of opportunity" for cephalexin has been at issue in this investigation. At the hearing, Biocraft could not provide a definitive answer regarding whether the window of opportunity was still open (transcript of hearing at pp. 70-74). However, in its questionnaire response, Biocraft writes * * *. (Questionnaire response of Biocraft, response to section V-D, demand and supply factors.)

Something of a shakeout appears to be occurring in the cephalexin market, as well. The joint venture, LyphoMed/Novopharm Inc., through which Canadian generic cephalexin capsules are imported and distributed, was dissolved in June 1989. Two other importers, * * *, dropped out of the market in 1988, citing cost competition (see section entitled U.S. importers). One producer, Vitarine Pharmaceuticals, was forced by the FDA to close its cephalosporin production facility in May 1989 (see section entitled U.S. producers). Its continued viability in the U.S. cephalexin market is unclear.

U.S. tariff treatment

U.S. imports of cephalexin capsules are currently provided for in subheading 3004.20.00 of the HTS of the United States as medicaments, put up in measured doses or in forms or packings for retail sale, containing antibiotics other than penicillins for human use. 1/ The rate of duty applicable to cephalexin from Canada under the United States-Canada Free Trade Agreement is 3.3 percent ad valorem. The most-favored-nation (column 1) rate of duty 2/ is 3.7 percent ad valorem. Cephalexin is not eligible for duty-free entry under the Generalized System of Preferences (GSP); 3/ however, it is eligible for duty-free entry under the Caribbean Basin Economic Recovery Act (CBERA), 4/ and under the United States-Israel Free Trade Area Implementation Act of 1985.

Nature and Extent of Sales at LTFV

On June 26, 1989, Commerce published in the Federal Register its final determination that generic capsules from Canada are being, or are likely to be, sold in the United States at less than fair value (54 F.R. 26820). Commerce also determined that, despite the existence of massive imports of the subject merchandise over a relatively short period of time, critical circumstances do not exist with respect to imports of generic cephalexin capsules from Canada.

1/ Previously provided for in item 411.76 of the Tariff Schedules of the United States (TSUS) as "Antibiotics other than penicillin obtained, derived, or manufactured in whole or in part from any product provided for in subpart A or B of part 1C of schedule 4." TSUS items 437.30-.32 were originally considered by the petitioner to be the TSUS number under which U.S. imports of cephalexin capsules entered. There was also originally some confusion among U.S. Customs import specialists regarding the proper classification for cephalexin capsules, and some importers did import capsules under the wrong tariff item for a short period of time. In order to avoid understatement of imports in this investigation, however, the Commission requested in its questionnaires that cephalexin products imported under any TSUS classification be reported.

2/ The most-favored-nation (MFN) rates of duty in rate col. 1 of the HTS generally represent the final stage of the reductions granted in the Tokyo Round of the Multilateral Trade Negotiations.

3/ The Generalized System of Preferences (GSP) affords nonreciprocal tariff preferences to developing countries to aid their economic development and to diversify and expand their production and exports.

4/ The Caribbean Basin Economic Recovery Act (CBERA) affords nonreciprocal tariff preferences to developing countries in the Caribbean Basin area to aid their economic development and to diversify and expand their production and exports.

The value of the sales examined during the period of Commerce's investigation (May 1, 1988, through October 31, 1988) amounted to * * * units ^{1/} valued at \$* * *. The sales found to be at LTFV amounted to * * * units valued at \$* * *. LTFV margins ranged from * * * to * * *. The final weighted-average margin is 7.5 percent. All sales examined by Commerce were those of Novopharm, Ltd., which accounts for all sales of generic cephalixin capsules from Canada to the United States.

The petition filed in connection with investigations Nos. 731-TA-436 and 437 (Preliminary), Generic Cephalixin Capsules from Israel and Portugal, alleged LTFV margins of between * * * percent and * * * percent for Israel and * * * percent and * * * percent for Portugal. As noted, that petition was withdrawn on August 1, 1989.

The Domestic Market

Apparent U.S. consumption

Data on apparent consumption of cephalixin were compiled from information submitted in response to questionnaires of the U.S. International Trade Commission. Table 1 shows apparent consumption of all dosage forms of cephalixin.

Consumption of cephalixin in all dosage forms (excluding Keftab) rose * * * percent between 1986 and 1987, then declined * * * percent between 1987 and 1988. Consumption rose * * * in January-March 1989 when compared with the corresponding period of 1988. There is some evidence that consumption rose * * * in 1987 when the patent on Keflex expired and many vendors purchased the new generic product in addition to the brand-name product. Apparent consumption of bulk cephalixin is not shown because the product is not shipped domestically.

Table 1

Cephalixin and Keftab: Domestic shipments of U.S.-produced and imported product and apparent U.S. consumption, by products, 1986-88, January-March 1988, and January-March 1989

* * * * *

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

U.S. producers

There are six U.S. producers of generic cephalixin in dosage form: Biocraft Laboratories Inc., Elmwood Park, NJ; Vitarine Pharmaceuticals, Inc., Springfield Gardens, NY; Barr Laboratories, Northvale, NJ; Zenith Laboratories, Ramsey, NJ; SquibbMark, Princeton, NJ; and Jerome Stevens Pharmaceuticals, Bohemia, NY. There is one producer of the originally patented cephalixin dosage formulation, Keflex: Eli Lilly and Company, Indianapolis, IN. Three companies (Lilly, Biocraft, and SquibbMark) manufacture bulk cephalixin.

^{1/} A unit is a bottle or box of generic cephalixin capsules.

Biocraft Laboratories, Inc.--Biocraft Laboratories, Inc. (Biocraft) has been a producer of generic pharmaceuticals since 1964. Biocraft is headquartered in Elmwood Park, NJ, and has been the * * * producer of cephalexin products, brand-name or generic, since 1988. 1/ The company has been listed on the New York Stock Exchange since 1985 and is a leading manufacturer of generic pharmaceuticals in bulk and dosage form. Although its principal focus is on penicillins and cephalosporins, the company's product line also includes non-antibiotic generic drugs.

In February 1987, Biocraft received FDA approval to manufacture dosage forms of generic cephalexin and generic cephradine, both first generation cephalosporins, in its state-of-the-art cephalosporin plant in Fairfield, NJ. Production of cephalexin began in April 1987. In March 1989, Biocraft introduced generic cefadroxil monohydrate. 2/ The company also has an agreement with American Cyanamid Company's Lederle Laboratories to begin manufacture of dosage forms of cefixime, a third generation cephalosporin, sometime in 1989. Under that agreement, Biocraft will be Lederle's exclusive supplier of cefixime for at least the first three years of commercial production. 3/

* * *. 4/ On June 1, 1989, Biocraft commenced production of bulk cephalexin in its Waldwick, NJ, facility. The company is building a new facility in Mexico, MO, which it plans to have on-line in fiscal 1991. 5/ * * *. The company believes that its production of the raw material will help reduce its manufacturing costs and increase profit margins.

Barr Laboratories, Inc.--Founded in 1980, Barr Laboratories, Inc. (Barr) manufactures and sells approximately 70 prescription pharmaceutical products, under generic names, in 177 dosage forms. At the time of publication of its 1988 Annual Report (September 1988), Barr was awaiting FDA approval to market 46 dosage forms and strengths of 19 additional generic drugs. Principal products manufactured by the company include analgesics, anti-hypertensives, anti-infectives, cardiovasculars, psychotherapeutics, and antibiotics.

Barr received FDA approval to produce and market generic cephalexin capsules in April 1987 (500 mg dosage) and June 1987 (250 mg dosage). In addition, the company received approval to produce and market cephalexin tablets in 250 mg and 500 mg dosages, as well as powder for oral suspension in 125 mg and 250 mg bases, in August 1987. Barr manufactures its cephalexin products in a new cephalosporin facility located in Pomona, NY. The complex includes a completely segregated cephalosporin manufacturing building, sales and distribution center, and shipping department. The company claims its new facility is one of only two such generic facilities located in the United States.

Barr is * * *. The company is publicly held. Barr was the * * * producer of generic cephalexin in 1988 * * * and is the * * * such producer in 1989.

1/ Biocraft * * *.

2/ Biocraft believes that introduction of generic cefadroxil contributed to making March 1989 the most successful month in its history. 1989 Annual Report, p. 2.

3/ 1989 Annual Report, pp. 2-3.

4/ * * *.

5/ Biocraft 1989 Annual Report, p. 2.

Jerome Stevens Pharmaceuticals, Inc.--Jerome Stevens Pharmaceuticals (JSP) is the * * * generic producer to enter the market. JSP received FDA approval to produce and market generic cephalexin in March 1988. * * *.

JSP initially refused to supply information in connection with this investigation and was served with a subpoena to compel disclosure. Even then, data received from JSP were incomplete and represented only estimates. JSP, established in 1976, is privately held and is located in Bohemia, NY.

Vitarine Pharmaceuticals, Inc.--Vitarine Pharmaceuticals, Inc. (Vitarine) has been a producer of generic pharmaceuticals since 1983. The company was organized under the name Phoenix Pharmaceuticals, Inc. to acquire certain assets of two other companies engaged in generic drug manufacturing. In 1985, Phoenix Pharmaceuticals was recapitalized and reorganized under the name Vitarine Pharmaceuticals. The new management consolidated and upgraded the company's manufacturing facilities and production operations and focused the company's business on the development of new generic drugs, increasing research and development expenses fourfold between 1985 and 1988. 1/

The company received FDA approval to produce generic cephalexin capsules in 1987 and began production in April of that year. Approval to produce oral suspension forms of cephalexin was received in December 1987, and production began in 1988. Additionally, the company received FDA approval to produce tablets in August 1988 * * *. While Vitarine produces other antibiotics, cephalexin is one of its five best selling high-margin products (19 percent of net sales in fiscal 1987). 2/ Vitarine * * *. 3/

Vitarine manufactures its generic cephalexin at a 20,000-square foot facility dedicated to the production of cephalosporin dosage forms in St. Croix, U.S. Virgin Islands. The bulk cephalexin is imported from * * * to St. Croix, where it is processed into finished products and bottled. The bottles are then shipped to Vitarine's facility in Springfield Gardens, NY, where they are labeled and distributed to the U.S. market.

* * * * *

Vitarine was the * * * producer of generic cephalexin capsules in 1988, and was the * * * such producer in January-March 1989. In April 1989, however, operations at the St. Croix facility were suspended, pending an investigation into allegations that the company used fraudulent data to obtain FDA approvals of various drugs. 4/ In addition, Vitarine has suspended distribution of all drugs approved since 1986, and postponed its initial public stock offering. Its continued participation in the cephalexin market is unclear at this time. The company is headquartered in Springfield Gardens, NY.

1/ Securities and Exchange Commission Form S-1, Registration Statement of Vitarine Pharmaceuticals, Inc. p. 3.

2/ Ibid., p. 6.

3/ Vitarine questionnaire response, p. 46B.

4/ Conversation with * * *, May 24, 1989. Specifically, during an audit of Vitarine's production records, it was discovered that certain batches of drug product used to generate data relied upon by the FDA for approval of Vitarine ANDAs were not as large as were reported to the FDA. Vitarine is alleged to have used brand-name product to obtain these approvals, claiming their competitors' products as their own.

Zenith Laboratories Inc.--Zenith Laboratories (Zenith) was the * * * generic cephalixin producer in 1988, and the * * * in January-March 1989. 1/ The company was incorporated in 1956 and is engaged in the manufacture, sale, and distribution of a wide range of generic pharmaceutical products. As of December 1988, Zenith was producing 45 products in 85 dosage forms (tablets and capsules). Like Vitarine, Zenith produces its cephalixin products in the U.S. Virgin Islands and then ships the finished dosage forms to the United States for distribution. * * *.

Zenith filed a petition for reorganization under chapter 11 of the bankruptcy laws on May 4, 1988. Public reports attributed the reorganization to difficulties brought on by practices that caused the company to temporarily recall 33 of its drugs from the market. 2/ Zenith's 1987 Annual Report describes declines in the company's sales in 1986 and 1987 pending FDA reapprovals of certain products and cites an inability of the company to recover market share following the 1986 problems with the FDA. * * *. 3/ Officials at the company confirm that their financial troubles predate the onset of imports. 4/ Zenith is headquartered in Northvale, NJ. The company is publicly held.

SquibbMark--SquibbMark, an unincorporated division of E.R. Squibb and Sons, is located in Princeton, NJ, and is the most recent generic producer to enter the market. SquibbMark is active in the development, marketing, and sales of a range of multisource (generic) prescription and consumer health care product lines in the United States. The company carries both oral and injectable forms of cephalosporin and penicillin antibiotics. SquibbMark was approved to manufacture bulk cephalixin in 1988. The company began production of capsules in * * *.

Eli Lilly and Co.--Eli Lilly and Company (Lilly) was the original patent holder for Keflex, which is marketed through Lilly's Dista division. The company's U.S. patent on the product expired in April 1987, and in fact has expired worldwide. 5/ Lilly's * * *. 6/ In addition to cephalixin, Lilly produces some 400 other pharmaceutical products.

Lilly received FDA approval in October 1987 to produce and market cephalixin hydrochloride in tablet form, a patented product with the trade name Keftab. Although Keftab has a slightly different chemical formulation than that of cephalixin monohydrate, the two drugs are considered the same by the FDA for the purposes of safety and therapeutic application. 7/ Lilly also produces other cephalosporins, notably Ceclor, the still-patented version of cefaclor,

1/ Zenith's * * *.

2/ Business Week, December 5, 1988, p. 176.

3/ In its questionnaire response, Zenith * * *.

4/ Telephone conversation between Commission staff and * * * on June 22, 1989.

5/ Telephone conversation between Commission staff and * * * Dec. 1, 1988.

6/ Ibid.

7/ Telephone conversation between Commission staff and * * *, Dec. 1, 1988.

Lilly notes that the FDA's Orange Book does not list any other product as being therapeutically equivalent. However, the American Hospital Formulary Service Drug Information 89 maintains that there is no clinical difference between cephalixin monohydrate and cephalixin hydrochloride monohydrate. See also app. D.

generally considered a second generation cephalosporin. 1/ Lilly's 1987 Annual Report notes that Ceclor is the world's largest selling product in its therapeutic class. 2/

Lilly objected to providing information in this investigation and was eventually served with a subpoena to compel disclosure of financial information. Company officials caution that * * *.

The following tabulation shows the U.S. producers of cephalexin in all dosage forms, brand-name and generic, their approximate share of production during 1988, and their position on the petition:

<u>Producers</u>	<u>Position on the petition</u>	<u>Share of the quantity of U.S. production in 1988-- 1/</u>
Biocraft.....	Supports	***
Barr.....	***	***
JSP.....	***	***
Vitarine.....	***	***
Zenith.....	***	***
SquibbMark.....	***	***
Eli Lilly.....	***	***

1/ Due to rounding, totals may not add to 100.

U.S. importers

One U.S. importer accounted for all known imports of generic cephalexin capsules or other cephalexin products from Canada during the period covered by this investigation. The importer, LyphoMed/Novopharm Pharmaceutical Company (LyphoMed), Rosemont, IL, is a joint venture owned by LyphoMed Ventures, Inc. of Rosemont, IL, and Novopharm, Inc. of Scarborough, Ontario, Canada. * * * of the joint venture.

LyphoMed Ventures, Inc., is a wholly owned subsidiary of LyphoMed, Inc. of Rosemont, IL, a leading supplier of critical care injectable pharmaceuticals. Novopharm, Inc. is a wholly owned subsidiary of Novopharm, Ltd. (Novopharm) of Scarborough, Ontario, Canada, a manufacturer and marketer of oral pharmaceutical products. Novopharm, Ltd. was established in 1965 and is one of Canada's largest generic manufacturers, marketing oral dosage form products to retail, hospital, government, and export markets.

The joint venture was created to permit LyphoMed to sell Novopharm's oral drugs in the United States. A similar joint venture was established in Canada for the purpose of selling LyphoMed, Inc.'s line of injectable products to the Canadian hospital market.

LyphoMed began importing and marketing generic cephalexin capsules in the United States in April 1987, and began importing and marketing generic

1/ Some clinicians classify cefaclor as a first generation cephalosporin because it is less effective against certain bacteria than other currently available second generation cephalosporins. (American Hospital Formulary Service, Drug Information 88, 1988, p. 91.

2/ Eli Lilly and Company, 1987 Annual Report, p. 2.

cephalexin in oral suspension form in July 1987. The joint venture does not import or market bulk cephalexin or cephalexin tablets.

Novopharm has been the supplier to LyphoMed since the inception of the joint venture. The company received its FDA approval to produce generic cephalexin capsules in April 1987, and its approval to produce generic cephalexin in oral suspension in June 1987. LyphoMed * * *.

On June 8, 1989, Novopharm, Ltd. and LyphoMed, Inc. announced their decision to dissolve the LyphoMed/Novopharm Joint Venture. Novopharm will continue its U.S. operations through Novopharm, Inc. According to the firm's posthearing brief, * * *.

Other current importers and their sources of cephalexin in dosage form are * * *. 1/ * * *. All importers responded to the Commission questionnaire, accounting for 100 percent of known imports of cephalexin capsules from all known sources. Countries exporting cephalexin in dosage form, in addition to Canada, are India, Israel, Japan, Portugal, and Switzerland. Bulk cephalexin is generally imported from either Italy or Spain. There are no reported imports of bulk cephalexin from Canada.

Channels of distribution

There are four primary channels of distribution in the pharmaceutical market: full-line drug wholesalers, retail drug store chains, pharmaceutical companies, and generic drug distributors. 2/ U.S. producers and importers of generic cephalexin capsules sell a majority of their capsules in the U.S. market to generic drug distributors and pharmaceutical companies. The remainder is sold to retail drug store chains and full-line drug wholesalers. 3/

The generic drug distributors, pharmaceutical companies, and the full-line drug wholesalers sell to the same types of customers at both the wholesale and retail levels of the pharmaceutical distribution chain. The generic drug distributors, as the name implies, sell almost exclusively generic drugs. The pharmaceutical companies are producers of mostly brand-name drugs, and purchase generic drugs to complement their product lines. Full-line drug wholesalers sell both generic and brand-name drugs, as well as other pharmaceutical supplies.

* * *. The tabulation below, calculated from information submitted in Commission questionnaires, shows the proportion of generic and brand-name cephalexin capsules sold between April 1987 and March 1989 by U.S. producers and

1/ * * *.

2/ The respondent argues that there actually are seven channels of distribution: private label distributors, regular distributors of house-label product, retail wholesalers, chain drug stores, hospitals and wholesalers serving hospitals, retail level suppliers who purchase from manufacturers, and miscellaneous small suppliers, such as nursing home supply houses.

For the purposes of this investigation, various subcategories were combined to arrive at the four major channels of distribution described in this section. The four major categories were determined as a result of staff conversations with producers and distributors in the industry.

3/ The category of full-line drug wholesalers also includes some direct sales to hospitals and a limited amount of sales to other retail accounts.

the Canadian importer to each of the four categories of customers (in percent, based on value):

Type of purchaser	U.S. produced cephalexin capsules		Imported Canadian cephalexin capsules
	Generic	Keflex	Generic
Generic drug distributors.....	***	***	***
Pharmaceutical companies.....	***	***	***
Retail drug store chains.....	***	***	***
Full-line drug wholesalers <u>1/</u> ..	***	***	***
Total.....	100	100	100

1/ Includes some direct sales to hospitals and to small retail customers.

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

The proportions shown in the above tabulation are in percentage terms, based on the value of sales of the specified types of cephalexin capsules sold during the period of investigation as reported in the price section of the Commission questionnaires. Although not shown, non-capsule formulations of the domestic and imported Canadian cephalexin are generally sold in the same manner as the capsule form. 1/

Generic drug distributors and pharmaceutical companies accounted for similar shares of the domestic and imported Canadian generic cephalexin capsules sold during the period of investigation. Combined, these two categories of customers accounted for * * * percent of the domestic generic capsules and * * * percent of the imported generic capsules. The remaining sales of domestic generic capsules were to retail drug store chains (* * * percent) and to full-line drug wholesalers (* * * percent). All of the remaining sales of the imported products (* * * percent) were to * * *. These latter sales reflect the Canadian importer's greater proportion of sales to * * *. 2/

Consideration of Material Injury to an Industry in the United States

In order to evaluate the condition of the U.S. industry producing cephalexin, the Commission sent questionnaires to the seven known manufacturers of the product in the United States. These firms and their respective roles in the U.S. market are discussed in the U.S. industry section of this report. Pursuant to the Commission's decision in the preliminary investigation not to distinguish between generic and brand-name cephalexin for the purposes of applying the statutory definition of the like product, the industry data presented herein are aggregates of generic and brand-name data. For reference, salient generic and brand-name data are provided separately in appendix G.

1/ * * *.

2/ LyphoMed * * *.

U.S. production, capacity, and capacity utilization

U.S. production of generic cephalexin capsules commenced in April 1987, after the expiration of Lilly's patent on Keflex. Capacity to produce cephalexin in all dosage forms rose * * * percent between 1986 and 1988 (table 2). This was due to the introduction of generic cephalexin production in 1987. Two generic producers, * * *, opened new cephalosporin manufacturing facilities in 1987, and * * * retooled an existing facility for cephalosporin production.

For three reporting firms (* * *), capacity is calculated on the basis of a work week of considerably more than 40 hours. * * * based practical capacity on work weeks of approximately 40 hours. * * * did not provide a basis for calculating practical capacity. * * * has ever produced at the capacity levels cited. ^{1/} The capacity for cephalexin can be diverted to produce other cephalosporins. Because of the large theoretical capacity figure, capacity utilization rates are low.

The following tabulation lists the U.S. producers of cephalexin and the dosage forms produced by each:

<u>Firm</u>	<u>Capsules</u>	<u>Tablets</u>	<u>Powder</u>	<u>Bulk</u>
Biocraft.....	***	***	***	***
Vitarine.....	***	***	***	***
Lilly.....	***	***	***	***
Zenith.....	***	***	***	***
Barr.....	***	***	***	***
JSP.....	***	***	***	***
SquibbMark.....	***	***	***	***

Table 2

Cephalexin and Keftab: U.S. capacity, production, and capacity utilization, by products, 1986-88, January-March 1988, and January-March 1989

* * * * *

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

U.S. producers' shipments

Domestic shipments of cephalexin in dosage form, in terms of quantity, * * * percent between 1987 and 1988, and * * * in January-March 1989 when compared with the same period in 1988. Table 3 summarizes shipments of cephalexin in all dosage forms.

To avoid double counting, only bulk cephalexin that was not used for further processing has been included. Bulk cephalexin is not shipped domestically; all bulk cephalexin produced in the United States is further processed or exported by the same firms, and * * *.

^{1/} * * *.

Table 3

Cephalexin and Keftab: Shipments of U.S. producers, by types and by products, 1986-88, January-March 1988, and January-March 1989

* * * * *

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

Of the six domestic producers of cephalexin products, only * * *. 1/
* * *.

Unit values presented in table 3 should be viewed with caution in that both brand-name and generic cephalexin is included. Unit values of brand-name and generic cephalexin can be seen separately in appendix G.

U.S. producers' end-of-period inventories

Inventories of cephalexin in dosage form declined * * * between 1986 and 1988, then increased * * * percent in January-March 1989 when compared with the corresponding period in the previous year. Inventories of bulk cephalexin increased * * * between 1986 and 1988, then declined * * * in January-March 1989 when compared with the corresponding period in 1988. U.S. producers' end-of-period inventories are summarized in table 4.

Table 4

Cephalexin and Keftab: U.S. producers' inventories, by products, as of Dec. 31 of 1986-88, and as of Mar. 31 of 1988 and 1989

* * * * *

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

U.S. employment, wages, and productivity

Employment and hours worked for dosage form cephalexin fluctuated during the period of the investigation, hitting a peak in 1987 with * * * production and related workers and * * * hours worked (table 5). Hourly wages dropped * * * between 1986 and 1987, then rose * * * percent between 1987 and 1988. Wages rose * * * in January-March 1989, a * * * percent increase when compared with the same time period in 1988.

Three companies, * * *, reported that their workers are represented by labor unions: the Oil, Chemical & Atomic Workers International Union, the International Brotherhood of Teamsters, and the United Industrial Workers of North America, respectively.

* * * * *

1/ Staff conversation with * * *, Nov. 2, 1988.

Table 5

Total establishment employment and average number of production and related workers producing cephalexin and Keftab, hours worked, wages and total compensation paid to such employees, and labor productivity, hourly compensation, and unit labor production costs, 1986-88, January-March 1988, and January-March 1989

* * * * *

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

Financial experience of U.S. producers

Three producers, * * *, accounting for * * * percent of reported U.S. production of all cephalexin capsules in 1988, provided usable income-and-loss data on the overall operations of their establishments within which cephalexin capsules are produced, in addition to income-and-loss data on their cephalexin operations. * * *.

Recent verification of the data of Biocraft, which accounted for approximately * * * percent of U.S. production of cephalexin capsules in 1988, resulted in revisions and additions to the questionnaire data.

Overall establishment operations.--Aggregate income-and-loss data are presented in table 6. Overall establishment sales of the reporting firms * * *. ^{1/} Interim sales * * *. Operating income followed a similar trend: * * *. The operating margins were * * *.

Table 6

Income-and-loss experience of U.S. producers on the overall operations of their establishments within which all cephalexin is produced, accounting years 1986-88 and interim periods ended March 31, 1988, and March 31, 1989

* * * * *

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

Cephalexin operations. ^{2/}--Aggregate income-and-loss data are presented in table 7. Net sales decreased * * *. Apparently, the wide swings in the generic market are not unexpected, according to the 1988 Annual Report of Biocraft:

. . . Our introduction of Cephadrine in late fiscal 1987, was closely followed in early 1988 by our first sales of Cephalexin.

^{1/} One producer reported data for 1986, two producers for 1987, and three producers for 1988.

^{2/} Includes cephalexin capsules, tablets, powder for oral suspension, and Keftab.

Sales of these products comprised about one half of net sales for the year. As expected with generic products, the sales trend went from the explosive level at the beginning of the year to the more moderate level later in the year as increased competition resulted in price erosion. . .

The impact of what is often a wide swing in the prices of a generic product as it matures has long been a concern in the generic industry. . . 1/

Operating income followed a similar trend, falling * * *. Although there was also a * * * decrease in the interim periods, operating margins remained relatively high throughout the period * * *.

Table 7

Income-and-loss experience of U.S. producers on their cephalixin operations, accounting years 1986-88 and interim periods ended March 31, 1988, and March 31, 1989

* * * * *

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

Because of Lilly's unique position as the patent holder in 1986, and its continued * * * presence in the market after expiration of the patent in 1987, a tabulation of selected key financial results, individually and in total, for Lilly and the generic producers is presented below (in thousands of dollars, except where noted):

* * * * *

Cephalexin capsule operations.--Aggregate income-and-loss data are presented table 8. Cephalexin capsule sales of the reporting firms declined * * * during 1986-88 and in the interim periods. The decline was from \$* * * million in 1986 to \$* * * million in 1988, or a decrease of * * * percent, and a further decline of * * * percent was experienced from \$* * * million in interim 1988 to \$* * * million in interim 1989. Operating income, although suffering * * * declines during the period from \$* * * million in 1986 to \$* * * million in 1988, and from \$* * * million in interim 1988 to \$* * * million in interim 1989, remained relatively high as a percent of sales. The margins were * * * percent, * * * percent, * * * percent, * * * percent, and * * * percent in 1986, 1987, 1988, interim 1988, and interim 1989, respectively.

1/ Biocraft 1988 Annual Report, pp. 2-3.

Table 8

Income-and-loss experience of U.S. producers on their cephalixin capsule operations, accounting years 1986-88 and interim periods ended March 31, 1988, and March 31, 1989

* * * * *

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

On a per kilogram basis, Lilly's sales values are approximately * * *. Lilly's unit price is * * *. Notwithstanding Lilly's * * *. Although Biocraft's rate * * *. The per kilogram income-and-loss results by firm are presented in table 9.

Table 9

Income-and-loss experience (on a per kilogram basis) of U.S. producers on their cephalixin capsule operations, accounting years 1986-88 and interim periods ended March 31, 1988, and March 31, 1989

* * * * *

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

A tabulation of selected key financial results, individually and in total, for Lilly and the generic producers is presented below (in thousands of dollars, except where noted):

* * * * *

Conversion costs for the generic producers, ^{1/} i.e., direct labor and factory overhead costs which contribute to the physical changes of the product, were * * * percent, * * * percent, * * * percent, and * * * percent of cost of goods sold in fiscal 1987, 1988, interim 1988, and interim 1989, respectively. Accordingly, the raw material costs were * * * percent, * * * percent, * * * percent, and * * * percent of cost of goods sold in the respective periods. The relatively high raw material costs and low conversion costs indicate that the transformation from input to finished goods is not as significant to the generic drug producers as that in typical manufacturing processes. If GS&A is considered to add value to the product, the value added as a percent of total operating expenses, i.e., cost of goods sold plus GS&A, was * * * percent, * * * percent, * * * percent, and * * * percent in 1987, 1988, interim 1988, and interim 1989, respectively.

Value added as a percent of cost of goods sold and total operating expenses for the producers of generic cephalixin capsule operations is presented in the following tabulation:

* * * * *

^{1/} Lilly did not provide data on its conversion costs.

Cephalexin tablet operations and powder for oral suspension operations.--
Aggregate income-and-loss data of U.S. producers on their cephalexin tablet operations are reported in table 10, and aggregate income-and-loss data of U.S. producers on their operations producing powder for oral suspension are reported in table 11.

Table 10

Income-and-loss experience of U.S. producers on their cephalexin tablet operations, accounting years 1986-88 and interim periods ended March 31, 1988, and March 31, 1989

* * * * * * *

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

Table 11

Income-and-loss experience of U.S. producers on their operations producing cephalexin powder for oral suspension, accounting years 1986-88 and interim periods ended March 31, 1988, and March 31, 1989

* * * * * * *

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

Value of plant, property, and equipment.--The data provided by the producers on their end-of-period investment in productive facilities in which cephalexin products are produced are shown in the following tabulation (in thousands of dollars):

* * * * * * *

Data presented here on asset valuations and capital expenditures are not comparable because some producers did not report, nor allocate to cephalexin, assets or capital expenditures for those years in which there was no cephalexin production. 1/

Capital expenditures.--The data the producers provided relative to their capital expenditures in total for land, buildings, and machinery and equipment used in the production of cephalexin products are shown in the following tabulation (in thousands of dollars):

* * * * * * *

1/ In general, annual changes in the level of plant, property, and equipment often do not equate to the amount of capital expenditures due to the sale or acquisition of assets that would change asset valuation figures independently of the level of capital expenditures.

Expenditures by the separate categories of land, buildings, and equipment are not presented since * * * furnished data in total only.

Capital expenditures varied considerably between the generic producers. On one hand, * * *.

Research and development expenses.--Whereas R&D expenses conventionally are aimed at developing new products or processes, or modifying existing products or processes, these expenses for the generic producers are incurred primarily for patent research and fulfilling governmental testing and documentation requirements. Since the generic product is chemically identical to the patented drug, R&D expenses in this market are essentially to replicate an existing product. Research and development expenses relating to cephalexin products for the producers are shown in the following tabulation (in thousands of dollars):

R&D expenses 1/	1986	1987	1988	Interim period ended March 31--	
				1988	1989
All establishment products...	***	***	***	***	***
All cephalexin.....	***	***	***	***	***
Cephalexin capsules.....	***	***	***	***	***
Cephalexin tablets.....	***	***	***	***	***
Cephalexin powder for oral suspension.....	***	***	***	***	***

1/ The amounts are understated since * * * did not provide any of its R&D expenses and * * * did not provide its overall establishment amounts.

Rates of return.--Only * * * provided sufficient data for rates-of-return analysis on total assets; however, apparent misallocation of assets by at least * * * for the various product groups renders rates-of-return analysis questionable. Accordingly, the rate of return on total assets is not presented. The profits as a ratio to sales for all respondents and industry results in the broad drug category are shown in the following tabulation (in percent):

* * * * *

Capital and investment.--The Commission requested U.S. producers to describe the actual and potential negative effects of imports from Canada of generic cephalexin capsules on their firm's growth, development and production efforts, investment, and ability to raise capital. Their replies are presented in appendix H.

Consideration of Threat of Material Injury to an Industry in the United States

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 1/--

- (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

1/ 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."

efforts to develop a derivative or more advanced version of the like product. 1/

With regard to item (I) above, no subsidies are involved in this investigation; 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 sold at LTFV and the alleged material injury or threat thereof;" 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 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.

U.S. importers' inventories of cephalexin

As stated previously in this report, there is only one importer of cephalexin capsules from Canada. Likewise, there is only one from Israel, and one from Portugal. All imports are of generic product. Imports from any source were first reported in 1987. Inventories of cephalexin capsules from Canada * * * during the period of this investigation, * * * percent in January-March 1989 when compared with the same period in 1988 (table 12). LyphoMed explains that * * *. One reason is * * *. LyphoMed reports that * * *.

A second reason involves * * *. Since this requirement * * *. LyphoMed cites the FDA requirement * * *. 2/

Inventories of imports from Israel * * *. Inventories of imports from Portugal * * *.

Table 12

Cephalexin: Importers' inventories of imported products, by sources, 1986-88, January-March 1988, and January-March 1989

* * * * *

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

1/ 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."

2/ LyphoMed reports that * * *. (Letter from counsel to Commission staff dated July 5, 1989.)

The generic cephalixin industry in Canada and its ability to generate exports

Capacity, production, and capacity utilization.--There is only one producer of generic cephalixin in Canada approved by the FDA to export its product to the United States: Novopharm, Ltd. Other producers of cephalixin products in Canada are Eli Lilly and Glaxo Pharmaceuticals, although these firms do not have FDA approval to export to the United States. * * *. 1/ 2/

Data on Novopharm's capacity and production are presented in table 13. The company's capacity to produce generic cephalixin in dosage form * * *. Production of cephalixin capsules * * * percent between 1987 and 1988, and * * * in January-March 1989 when compared with the corresponding period in the previous year.

Table 13

Cephalixin: End-of-period capacity, production, and capacity utilization in Canada, 1986-88, January-March 1988, and January-March 1989

* * * * *

Source: Compiled from data submitted by counsel for Novopharm Ltd.

Novopharm now produces cephalixin products * * *. In conformance with FDA requirements, the Lexin plant is dedicated to the production of cephalixin. Novopharm reports * * *. 3/ Novopharm does not produce its own bulk cephalixin but instead imports the raw material from * * *.

Novopharm also points out a distinction between capsules produced for the U.S. market and those produced for the Canadian market. Because of differences between the capsules approved in the United States and Canada, capsules produced for the Canadian market cannot be exported to the United States. Specifically, the proportions of inactive ingredients in the bulk cephalixin powder used to fill Canadian capsules differ from those required in Novopharm's ANDA for U.S. capsules. The color and shape of the two types of capsules differ as well. 4/

Novopharm calculates practical capacity based on * * *. The company provided a summary of hours of operation between April 1, 1988, and June 9, 1989, to support this assumption. In addition, Novopharm maintains that

1/ Telephone conversation between Commission staff and * * *, Nov. 29, 1988.

2/ According to Novopharm, patent holders in Canada do not enjoy the same type of product exclusivity that exists in the United States. Canada's "compulsory licensing" law grants a Canadian patentee a period of exclusivity ranging from 7 to 10 years. Toward the end of the exclusivity period, other manufacturers may apply for license rights with the Canadian Patent Office. The Patent Commissioner reviews applications and may select one or more manufacturers to whom the patentee is required to grant a license. The royalty rate is determined by the Commissioner and is usually 4 percent. Novopharm received the right to manufacture cephalixin products in Canada under the compulsory licensing system in 1979. (Letter from counsel for Novopharm to Commission staff, July 6, 1989.)

3/ Respondent's prehearing brief, app. 10, p. 3.

4/ Letter from counsel to Commission staff dated July 21, 1989.

its capacity is limited by the equipment currently available to produce capsules * * *. 1/

Novopharm explains in its prehearing brief that the company * * *. 2/

In light of the changed circumstances of * * *. The company * * *. Additionally, Novopharm * * *. 3/

With regard to future cephalexin operations, Novopharm notes that as long as the Lexin facility continues to produce for the U.S. market, it cannot be used to produce any other product in Novopharm's product line, such as ampicillin, amoxicillin, cloxicillin, tetracycline, and other products scheduled for introduction. Demand for amoxicillin * * *. Finally, Novopharm points out that its fixed assets and fixed manufacturing costs at the Lexin plant * * *. 4/

Shipments.--Novopharm reports that its shipments of cephalexin capsules for the Canadian domestic market have been * * * for the last several years. The company claims to supply approximately * * * percent of the Canadian market for this dosage form. Novopharm historically has supplied * * * percent, by volume, of the Canadian market for cephalexin tablets. According to Novopharm, * * *. The market for cephalexin powder for oral suspension is mostly supplied by * * *, with * * *. 5/

Novopharm did not export cephalexin products to the United States in 1986 (table 14). U.S. shipments of capsules for 1987, the first year that export was possible, equalled * * * kilograms; they * * * percent to * * * kilograms in 1988. In January-March 1989, shipments of capsules to the United States * * * percent over those in the corresponding period of 1988. 6/ Novopharm has never filed an ANDA to manufacture and sell generic cephalexin tablets in the United States, and for this reason the company cannot export tablets to the United States. 7/ Reported U.S. shipments may not reconcile directly with imports reported by LyphoMed due to delay times in clearing U.S. customs.

Novopharm characterizes its export shipments to countries other than the United States as * * *. 8/ The company cites * * *.

Table 14

Cephalexin: Shipments of the Canadian producer, 1986-88, January-March 1988, January-March 1989, and projections for 1989 and 1990

* * * * *

Source: Compiled from data submitted by counsel for Novopharm, Ltd.

1/ The company * * *. Respondent's prehearing brief, app. 10, pp. 3-4.

2/ Respondent's prehearing brief, app. 10, p. 8.

3/ Respondent's prehearing brief, pp. 47-48.

4/ Letter from counsel for Novopharm to Commission staff, July 6, 1989.

5/ Letter from counsel for Novopharm, Ltd. dated July 5, 1989.

6/ Novopharm reports that * * *. (Letter from counsel to Commission staff, July 5, 1989.)

7/ Letter from counsel for Novopharm to Commission staff, July 21, 1989.

8/ Ibid.

Ability to generate exports: The effect of the Canadian formulary system.--The petitioner in this case has maintained that the Canadian formulary system sets the lowest amount for which a listed drug product can be purchased in Canada for wholesale or retail trade in the particular province. Since consumers covered by provincial health maintenance and care programs are reimbursed for the cost of prescription drugs only if they purchase such drugs at pharmacies that charge the approved price, the petitioner maintains that this system provides an incentive for export.

At the request of the Commission, Novopharm addressed the function of the Canadian formulary system and its effect on the company's export decisions in its posthearing brief. Novopharm explains that the provincial formularies, with the exception of Ontario, are not mandatory, and do not govern sales to hospitals and government agencies, * * *. In that regard, Novopharm claims, the * * *. 1/

Inventories of the Canadian producer.--Inventories of the Canadian producer Novopharm are presented in table 15. Its inventories of capsules * * * percent between January-March 1988 and January-March 1989, from * * * kilograms to * * * kilograms. Of the * * * kilograms reported in inventory as of March 31, 1989, Novopharm explains that only * * * kilograms represent manufactured capsules destined for the U.S. market. The remainder represents scrap, partially mixed bulk cephalixin, and capsules destined for the Canadian market.

Table 15

Cephalexin: End-of-period inventories of the Canadian producer, by products, 1986-88, January-March 1988, and January-March 1989

* * * * *

Source: Compiled from data submitted by counsel for Novopharm, Ltd.

There is no past history of dumping of generic cephalixin capsules or of dumping of cephalixin products of any kind from Canada or from any other country. Additionally, there is no evidence of any product shifting.

Consideration of the Causal Relationship Between Imports Sold at LTFV and the Alleged Material Injury or Threat Thereof

U.S. imports

Imports of generic cephalixin capsules from Canada * * * percent between 1987 and 1988 in terms of quantity, but * * * percent in terms of value (table 16). Imports of the product * * * percent in terms of quantity in January-March 1989 when compared with the corresponding period in 1988, but * * * percent in terms of value. There have been no imports of brand-name products.

The data in table 16 represent 100 percent of imports from all known sources for the time period of this investigation. There are no imports of generic cephalixin tablets from any source.

1/ Respondent's posthearing brief.

There were * * * imports of generic cephalixin capsules from Israel or Portugal in 1987. In 1988, imports from Israel totalled * * * kilograms and imports from Portugal amounted to * * * kilograms. Other sources of generic cephalixin capsules in 1987 and 1988 were India, Japan, and Switzerland. By 1989, imports from * * * had ceased, reportedly because those products were priced too high.

Table 16

Cephalexin: U.S. imports for consumption, by products and by source, 1986-88, January-March 1988, and January-March 1989

* * * * *

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

LyphoMed's monthly imports from Canada are shown in the tabulation below (in kilograms): 1/

* * * * *

Monthly imports from Israel are shown in the tabulation below (in kilograms): 2/

* * * * *

Monthly imports from Portugal are shown in the tabulation below (in kilograms): 3/

* * * * *

U.S. importers' domestic shipments are shown in table 17. Shipments of imports of generic cephalixin capsules from Canada * * * percent between 1987 and 1988, and * * * percent in January-March 1989 when compared with the same time period in the previous year. Shipments of imports of generic cephalixin capsules from Israel * * * kilograms in January-March 1988 to * * * kilograms in January-March 1989, a * * * percent * * *. There were * * * shipments of imports of generic cephalixin capsules from Portugal in January-March 1988, but * * * kilograms were shipped in January-March 1989.

Table 17

Cephalexin: Importers' domestic shipments of imported products, by sources, 1986-88, January-March 1988, and January-March 1989

* * * * *

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

1/ Supplied by counsel for LyphoMed in response to Commission request dated May 15, 1989.

2/ Supplied by * * * in response to Commission request dated May 15, 1989.

3/ Supplied by * * * in response to Commission request dated May 15, 1989.

U.S. market penetration by imports

As a percent of apparent U.S. consumption of cephalixin in dosage form (brand-name and generic), imports of generic cephalixin capsules from Canada showed a market penetration level of * * * percent in 1987 and * * * percent in 1988, based on quantity (table 18). For January-March 1989, the market penetration level was * * * percent, compared with * * * percent for the same time period in 1988, again based on quantity.

As a percent of apparent U.S. consumption of cephalixin in dosage form, imports of generic cephalixin capsules from Israel showed a market penetration level of * * * percent in 1987 and * * * percent in 1988. For January-March 1989, the market penetration level was * * * percent, compared with * * * percent for the same period in 1988.

As a percent of apparent U.S. consumption of cephalixin in dosage form, imports of generic cephalixin capsules from Portugal showed a market penetration level of * * * percent in 1987 and * * * percent in 1988. For January-March 1989, the market penetration level was * * * percent, compared with * * * percent for the same period in the previous year.

Table 18

Cephalixin and Keftab: Market penetration of subject imports, by products and by sources, 1986-88, January-March 1988, and January-March 1989

* * * * *

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

Prices

Market characteristics.--U.S. producers and the Canadian importer sell comparable-quality generic cephalixin products in the same formulations, dosages, and types of packaging. More than 85 percent of the domestic and imported Canadian generic cephalixin in dosage form, by weight or value, is sold in capsules. The remainder of the generic cephalixin is sold as oral suspension, mostly as a powder, and as tablets. The majority of the generic cephalixin capsules sold in the U.S. market are priced in bottles of 250 mg and 500 mg dosages containing 100 and 500 capsules per bottle. 1/ Prices reflect the dosage and number of capsules in the bottle, with discounts available for larger volume purchases.

U.S. producers and the Canadian importer of generic cephalixin capsules are relatively small firms that lack the name recognition and extensive marketing resources of many of their customers. As a result, these suppliers typically sell to larger companies, mostly generic drug distributors and pharmaceutical companies, at the wholesale level of the market for subsequent resale, reflecting the marketing advantages of these large-volume purchasers. Generic drug distributors and pharmaceutical companies are generally well known pharmaceutical suppliers that inventory, advertise, and market generic cephalixin capsules and other products at both wholesale and retail levels throughout the United States. These products frequently carry the private label of the wholesale customer. 2/

Prices of Keflex capsules, the brand-name cephalixin produced in the United States exclusively by Eli Lilly, 3/ have been * * * the price level of domestic or imported Canadian generic cephalixin capsules since April 1987, the period the generic drug has been sold in the U.S. market. 4/ During this period, however, Lilly's average net selling prices of Keflex capsules have * * * prior to the expiration of its patent. * * *. Lilly reported in its questionnaire response that * * *. 5/

Based on questionnaire responses of U.S. producers, sales of domestic generic cephalixin are generally on a * * * basis whereas sales of the imported Canadian generic cephalixin and Lilly's sales of its branded cephalixin are typically on a * * * basis. Contracts generally extend for about 1 year and for the generic cephalixin usually involve private-label sales. These contracts usually stipulate the volume expected to be purchased over the contract period, the price level for the contract period, payment terms, the length of time between issuing purchase orders and delivery of the capsules, and * * * any production and packaging/labelling requirements of the customer.

U.S. producers and the importer issue price lists showing discounts based on the volume purchased. Questionnaire responses indicate that such price lists are revised frequently or are a starting point for negotiating prices on both spot and contract sales. The domestic producers and the importer offer

1/ A limited number of the subject generic cephalixin capsules in both the 250 mg and 500 mg dosages are * * *.

2/ * * *.

3/ * * *.

4/ * * *. For a more complete discussion of price comparisons between Keflex and generic cephalixin, see appendix I.

5/ Market share data shown earlier in this report indicate that U.S. producers of generic cephalixin * * *.

* * *. Most sales of the domestic and imported Canadian generic cephalixin capsules are shipped * * *. A more complete discussion of transportation costs is provided later in this report.

Rebate practices.--The changing market for cephalixin since the patent expired in April 1987 has resulted in frequent adjustments to spot and contract prices. 1/ These adjustments include rebates on previous shipments as well as lower prices on current shipments. Two common rebate practices-- * * *--were reported in U.S. producer questionnaire responses, whereas the importer reported * * *. Falling prices at the wholesale level of the market caught some purchasers with relatively high-priced inventories that were purchased at a time when prices were higher. As a result, U.S. producers and the importer of cephalixin have * * *. 2/

During the preliminary investigation, LyphoMed also reported * * *. 3/

A second type of rebate * * * is based on a customer's total drug purchases from the supplying firm for a month or quarter and ranges from * * * percent of the total value of all drugs purchased by the customer during that period. * * *.

Charge-backs.--Another type of price adjustment * * * is a charge-back. This is typically paid to full-line drug wholesalers that sell cephalixin to customers like drug store chains, buyers' groups, HMOs, etc., at prices that the wholesalers' customers have previously negotiated * * *; the negotiated prices are generally below prices normally paid by the wholesaler for cephalixin. Customers that negotiate the purchase price of cephalixin * * * often do not wish to warehouse the entire quantity purchased, so they arrange with a particular wholesaler to service the purchase. The wholesaler then sells cephalixin to these customers at the negotiated price plus an amount to cover the service cost. After selling cephalixin at the negotiated price, the wholesaler sends copies of invoices documenting such sales to * * * and receives a charge-back for the difference between its purchase price of the cephalixin and the price negotiated between its customer and * * *. 4/

Questionnaire price data.--The Commission requested net U.S. delivered selling prices and quantities for two cephalixin capsule products plus a cephalixin powder and a tablet product, identified by generic or brand-name products, from U.S. producers, and the two generic cephalixin capsule products from the importer of the Canadian cephalixin. 5/ The price data were requested for the largest sale and for total sales of the products reported to each of

1/ Although no explicit "meet or release" conditions are included in the typical contract, the very competitive nature of the U.S. cephalixin market has forced suppliers to adjust prices during the contract period. Transcript of the conference, pp. 199-200.

2/ The U.S. producer may * * *.

3/ * * *. For a more complete discussion concerning * * * sourcing of generic cephalixin, see the "lost sales" section of this report.

4/ The charge-back is either credited to the wholesaler's account or paid directly to the wholesaler.

5/ Based on conversations with representatives of * * * during the preliminary and final investigations, the requested products were identified as large-volume products representative of competition between the domestic and imported Canadian cephalixin capsules.

four specified customer categories, 1/ by quarters, during April 1987-March 1989 for the generic drug and during January 1986-March 1989 for Keflex. The four types of customers were generic drug distributors, pharmaceutical companies, retail drug store chains, and full-line drug wholesalers. The four cephalixin products for which the price data were requested are shown below.

- PRODUCT 1: 250 mg capsules in 100- and 500-capsule bottles.
- PRODUCT 2: 500 mg capsules in 100- and 500-capsule bottles.
- PRODUCT 3: 250 mg oral suspension powder in 200 ml bottles.
- PRODUCT 4: 250 mg tablets in 100-tablet bottles.

Five U.S. producers of generic cephalixin, the single U.S. producer of the brand-name cephalixin, and the single importer of the Canadian generic cephalixin provided the requested price data, but not necessarily for every product or period. The five responding U.S. producers of generic cephalixin--Barr, Biocraft, JSP, Vitarine, and Zenith--plus the U.S. producer of the brand-name cephalixin, Eli Lilly, accounted for more than * * * percent of the total value of U.S. producers' domestic shipments of all cephalixin capsules, as well as all cephalixin oral suspension powder and tablets during April 1987-March 1989. Prior to April 1987, Lilly was the only supplier of cephalixin products, including cephalixin capsules, in the U.S. market. The responding U.S. importer, Lyphomed, accounted for 100 percent of the total value of U.S. imports of cephalixin from Canada, all of which were generic, during April 1987-March 1989.

Sales of cephalixin by all the firms normally follow a seasonal pattern of high and rising sales from September through February followed by falling sales from March through August. 2/ * * * indicated, however, that abnormally high sales of the generic cephalixin were made during the first two quarters following the introduction of this drug in April 1987. Reportedly, their customers were building inventories of the generic drug and at the same time trying to fill a rush of orders for the cheaper alternative to Keflex. During the final investigation * * * indicated that the demand for generic cephalixin has fallen somewhat over the last 14 months in response to competing drugs that have more recently become available in generic form. Two competing drugs cited were cefadroxil and cephradine, also first generation cephalosporins. 3/ As mentioned earlier in this report, Lilly also identified several antibiotics that competed with the generic cephalixin.

Purchasers.--The Commission also requested prices from purchasers for the four cephalixin products. The Commission sent purchaser questionnaires to 60 companies encompassing generic drug distributors, pharmaceutical companies, retail drug store chains, and full-line drug wholesalers. The specific purchasers are large buyers of the domestic and imported Canadian generic cephalixin products and were identified in the preliminary investigation by the responding U.S. producers and the importer. Delivered prices and quantities were requested for the largest purchase in each quarter of the specified products during January 1987-March 1989.

Twelve purchasers reported delivered price data, but not necessarily for every product and period. Of the 12 purchasers, 5 were generic drug

1/ * * *.

2/ Based on Commission staff telephone conversations with the responding firms during the preliminary investigation.

3/ Telephone conversation with * * * and the Commission staff on June 2, 1989.

distributors, 2 were pharmaceutical companies, 2 were retail drug store chains, and 3 were full-line drug wholesalers. Five of the twelve purchasers reported net pricing data for the imported Canadian cephalexin; two of the latter firms were generic drug distributors and two were full-line drug wholesalers. 1/

Price trends.--Price trends for the domestic and imported Canadian generic cephalexin are based on the * * *. 2/ The quarterly selling prices of the domestic generic cephalexin were based on delivered selling prices of the largest sale in the quarter weighted by total sales of the specified product to the requested types of customers. 3/ The quarterly selling prices of the * * *. 4/ * * *. The total quantities, weighted-average prices, and indexes of the weighted-average prices of the domestic cephalexin products are shown in tables 19-21 for the generic drug and tables 22-23 for Keflex. 5/

Table 19

U.S.-produced generic cephalexin 250 mg capsules in 100- and 500-capsule bottles: U.S. sales quantities, weighted-average delivered selling prices, and price indexes by, types of customers and by quarters, April 1987-March 1989

* * * * *

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

1/ * * *.

2/ Of the four types of customers specified, Lilly reported * * *.

3/ Of the five responding U.S. producers, * * * reported net selling prices, whereas * * * was not able to deduct all discounts, rebates, etc. * * * has not clearly indicated whether the prices it reported are net of all discounts, rebates, shelf-stock adjustments, chargebacks, and any other price adjustments. The Commission staff requested * * * on June 16 to explain in writing how it calculated its reported price data, but did not receive a reply despite repeated follow-up telephone requests.

4/ * * *. (Telephone conversations with Commission staff on June 5 and 6, 1989).

5/ The reported price data of the specified U.S.-produced generic cephalexin capsule products were based on sales values that accounted for about * * * percent of the total reported value of domestic generic cephalexin capsules shipped in the U.S. market during April 1987-March 1989. The total value of reported U.S. shipments of the specified Keflex capsules during January 1986-March 1989 for which price data were requested accounted for about * * * percent of the total reported value of all Keflex capsules shipped in the United States during this latter period. The total sales value of all generic and branded domestic cephalexin capsules for which price data were reported accounted for about * * * percent of the total reported value of all domestic dosage cephalexin shipped in the U.S. market during January 1987-March 1989.

Table 20

U.S.-produced generic cephalixin 500 mg capsules in 100- and 500-capsule bottles: U.S. sales quantities, weighted-average delivered selling prices, and price indexes, by types of customers and by quarters, April 1987-March 1989

* * * * *

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

Table 21

U.S.-produced generic cephalixin 250 mg oral suspension powder in 200 ml bottles and 250 mg tablets in 100-tablet bottles: U.S. sales quantities, weighted-average delivered selling prices, and price indexes, by types of customers and by quarters, April 1987-March 1989

* * * * *

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

Table 22

U.S.-produced Keflex capsules in 100-capsule bottles sold to * * *: U.S. sales quantities, weighted-average net delivered selling prices and price indexes, by capsule dosage, and by quarters, January 1986-March 1989

* * * * *

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

Table 23

U.S.-produced Keflex 250 mg oral suspension powder in 200 ml bottles and 250 mg tablets (Keflet) in 100-tablet bottles sold to * * *: U.S. sales quantities, weighted-average net delivered selling prices and price indexes, by quarters, January 1986-March 1989

* * * * *

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

The quarterly selling prices of the imported Canadian generic cephalixin capsules were based on net delivered selling prices of the largest sale in the quarter of the specified product to * * *. ^{1/} The importer indicated that the firm * * *. Price data for the imported Canadian generic cephalixin capsules are shown in tables 24 and 25. ^{2/}

^{1/} LyphoMed indicated that * * *.

^{2/} The reported price data of the specified * * *.

Table 24

Imported Canadian generic cephalexin 250 mg capsules in 100- and 500-capsule bottles: U.S. sales quantities, weighted-average net delivered selling prices, and price indexes, by types of customers and by quarters, April 1987-March 1989

* * * * *

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

Table 25

Imported Canadian generic cephalexin 500 mg capsules in 100- and 500-capsule bottles: U.S. sales quantities, weighted-average net delivered selling prices, and price indexes, by types of customers and by quarters, April 1987-March 1989

* * * * *

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

Reported prices of the U.S.-produced and imported Canadian generic cephalexin capsules generally * * * during the periods reported, whereas prices of the Keflex capsules generally * * *. The reported prices of the domestically produced generic cephalexin capsules * * *. Because several new suppliers of the generic cephalexin have recently entered the U.S. market, competition among several firms makes it difficult to determine if any firms are price leaders. More recent entrants, however, may temporarily exert downward pressure on prices to establish themselves in the market. 1/ Selling price data for major domestic and imported Canadian generic cephalexin capsule products reported by the individual U.S. producers and the importer are shown in appendix J.

U.S. producers' prices.--Quarterly delivered selling prices of the specified domestic generic cephalexin capsules * * * during April 1987-March 1989, typically ending the period * * * the prices at the beginning of the period (tables 19 and 20). On the other hand, prices of the domestic generic cephalexin oral suspension and tablet products * * * during the periods reported, and where prices * * * they * * * (table 21). Fewer firms supply the generic cephalexin oral suspension powder and tablets than supply the capsules and, 2/ according to * * *, this has resulted in less price competition for suppliers of the powder and tablets. 3/

Quarterly net delivered selling prices of the Keflex capsule and oral suspension powder products sold to * * * during January 1986 through June 1987. Prices of these brand-name cephalexin products * * * during April 1987-March

1/ Prehearing brief of LyphoMed/Novopharm.

2/ All five responding U.S. producers and the importer of generic cephalexin reported selling the generic capsules. Three U.S. producers and Lyphomed reported supplying domestic and the imported Canadian generic cephalexin oral suspension in powder form and two U.S. producers reported selling the generic cephalexin tablets. No Canadian-produced generic cephalexin tablets are exported to the United States.

3/ Telephone conversation between * * * and Commission staff on June 6, 1989.

1989 but * * * than in the earlier period (tables 22-23). Quarterly net selling prices of the brand name cephalexin tablet product (Keflet) sold to * * * were reported for a shorter period, October 1986-March 1989, but * * * in subsequent periods (table 23).

Prices of imports from Canada.--Quarterly net delivered selling prices of the specified imported Canadian generic cephalexin capsules * * * during April 1987-March 1989, with prices of some of the imported products ending the period * * * prices at the beginning of the period (tables 24 and 25). ^{1/} Quarterly selling prices of the imported 250 mg and 500 mg capsules in 100-capsule bottles * * * during April 1987-March 1989. Prices of these imported products to * * *. Reported sales of the imported 500 mg capsules in 500-capsule bottles were * * *.

Price comparisons.--Price comparisons between U.S.-produced and imported Canadian cephalexin capsules are based on the quarterly delivered selling prices of the specified generic and Keflex products reported by U.S. producers and the importer to specified types of customers during April 1987-March 1989. * * *. Table 26 shows the weighted-average selling prices of the domestic and imported Canadian generic cephalexin capsules in 250 mg and 500 mg dosages sold to * * * during April 1987-March 1989. Table 27 shows prices of these capsules sold to * * * and table 28 shows the prices of these capsules sold to * * * during this period. Tables 26-28 also show any price differences between the domestic and foreign products during April 1987-March 1989.

Table 26

Generic cephalexin capsules: Weighted-average net selling prices of generic cephalexin capsules produced in the United States and imported from Canada and sold to * * *, and margins of under/(over)selling, by dosage amounts, by bottle sizes, and by quarters, April 1987-March 1989

* * * * *

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

Table 27

Generic cephalexin capsules in 100-capsule bottles: Weighted-average net selling prices of generic cephalexin capsules produced in the United States and imported from Canada and sold to * * *, and margins of under/(over)selling, by dosage amounts and by quarters, April 1987-March 1989

* * * * *

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

^{1/} LyphoMed reported prices on sales of the imported cephalexin to * * *.

Table 28

Generic cephalixin capsules: Weighted-average net selling prices of generic cephalixin capsules produced in the United States and imported from Canada and sold to * * *, and margins of under/(over)selling, by dosage amounts, by bottle sizes, and by quarters, April 1987-March 1989

* * * * *

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

In addition, 12 purchasers returned questionnaires and reported usable net delivered price data, which were generally based on total quarterly purchases of the specified product. Price comparisons between the domestic and imported Canadian cephalixin based on purchaser questionnaires were possible for * * * and * * *; no delivered purchase price data were reported for the imported cephalixin sold to * * * or * * *. ^{1/} Because of limited responses * * * price comparisons between the domestic and imported Canadian generic cephalixin capsules based on purchaser questionnaires may not be as reliable as price comparisons based on U.S. producer and importer questionnaires. The price comparisons based on purchaser questionnaires are not presented in tables but will be discussed briefly in the text.

Price comparisons based on questionnaire responses of U.S. producers and the importer show that the U.S.-produced generic cephalixin capsule products are * * *. ^{2/} In several product categories * * *. The price comparison data also show that both the domestic and imported generic cephalixin capsules are consistently priced substantially below the Keflex capsules. In addition, domestically produced generic cephalixin oral suspension powder and tablets are priced significantly below prices of the Keflex products. Price comparisons between the domestic and imported Canadian generic cephalixin products are discussed below. Price comparisons between Keflex and generic cephalixin are discussed in appendix I.

Based on selling prices of the largest quarterly sale reported by U.S. producers and the importer, the reported price data resulted in 67 quarterly price comparisons between the domestic and imported Canadian generic cephalixin capsules. ^{3/} * * * of the 67 price comparisons showed that the imported capsules were priced * * * the domestic capsules by an average of about * * *

^{1/} Only * * * and * * * reported the requested price data for the domestic and imported generic cephalixin; * * * provided a majority of the price data for the imported products purchased by * * *. In addition, LyphoMed reported * * *.

^{2/} Based on purchaser questionnaire price data, price comparisons involving * * * also indicate that the U.S.-produced generic cephalixin was generally * * * imported Canadian cephalixin. Purchaser price comparisons involving * * * show the imported Canadian cephalixin to be * * * the domestic products in many instances. The purchaser response was very limited, whereas questionnaire price data from U.S. producers and the importer accounted for a significant share of total sales.

^{3/} Some U.S. producers were not able to report selling prices net of all rebates. As a result, comparisons of the weighted-average selling prices of domestic cephalixin capsule products with the reported net selling prices of the imported Canadian products may overstate any * * * by the foreign products.

percent; * * * of these * * * price comparisons occurred during 1987. The remaining * * * price comparisons showed that prices of the imported Canadian capsules were * * * than prices of domestic capsules, averaging almost * * * percent * * * than prices of the domestic products.

Generic drug distributors.--Based on selling prices reported by U.S. producers and importers, * * * quarterly price comparisons were possible between U.S.-produced and imported Canadian generic cephalexin capsule products sold to generic drug distributors during April 1987-March 1989 (table 26). The products were 250 mg and 500 mg capsules in 100- and 500-capsule bottles. * * * of the * * * price comparisons showed the imported products were priced * * * the U.S.-produced products by margins ranging from * * * to * * * percent, averaging about * * * percent. * * * of the * * * price comparisons showing * * * were in 1987. * * * price comparisons showed that the imported cephalexin capsules were priced * * * the domestic products by margins averaging almost * * * percent. 1/

Pharmaceutical companies.--Selling prices reported by U.S. producers and the importer resulted in * * * quarterly price comparisons between the domestic and imported Canadian generic cephalexin 250 mg and 500 mg capsules in 100-capsule bottles sold to * * * during April 1987-March 1989 (table 27). * * * of the * * * price comparisons showed that the imported generic products were priced * * * the domestic generic products by margins ranging from * * * to * * * percent, or averaging almost * * * percent * * * prices of the U.S. products. * * * of the * * * price comparisons that showed * * * took place in 1987, * * * occurred in 1988, and * * * in January-March 1989. * * * of the * * * price comparisons showed the imported products to be * * * than the domestic products, by margins averaging about * * * percent.

Full-line drug wholesalers.--Selling prices reported by U.S. producers and the importer resulted in * * * quarterly price comparisons between the domestic and imported Canadian generic cephalexin 250 mg capsules in 100- and 500-capsule bottles and 500 mg capsules in 100-capsule bottles sold to full-line drug wholesalers during April 1987-March 1989 (table 28). * * * of the * * * price comparisons showed that the imported generic products were priced * * * the domestic generic products by margins of * * * and * * * percent, or averaging almost * * * percent * * * prices of the U.S. products. * * * instances of * * * occurred in April-June 1987. * * * of the * * * price

1/ Net delivered purchase price data reported by the * * * responding generic drug distributors resulted in * * * quarterly price comparisons between the domestic and imported Canadian generic cephalexin 250 mg and 500 mg capsules in 100- and 500-capsule bottles purchased during April 1987-March 1989. * * * of the * * * comparisons showed that the imported products were priced * * * than the domestic products by margins averaging about * * * percent. * * * price comparisons showed that the imported products were priced * * * the domestic products by an average margin of almost * * * percent. In addition, the * * * distributors reported net prices that resulted in * * * price comparisons between the domestic and imported Canadian generic cephalexin 250 mg oral suspension powder in 200 ml bottles purchased during July 1987-March 1989. * * * of the * * * comparisons showed that the imported product was priced * * * the domestic product by margins averaging about * * * percent. * * * price comparisons showed that the imported products were priced * * * the domestic products by an average margin of almost * * * percent.

comparisons showed the imported products to be priced * * * the domestic products, by margins averaging about * * * percent. 1/

Transportation factors

Biocraft and Vitarine, U.S. producers of generic cephalexin capsules, Lilly (the U.S. producer of Keflex), and LyphoMed (the U.S. importer of the imported Canadian generic cephalexin capsules) responded to questions on transportation factors in the questionnaire. * * *. 2/ * * *.

* * * * *

Exchange rates

Quarterly data reported by the International Monetary Fund indicate that the nominal value of the Canadian dollar increased relative to the U.S. dollar by approximately 18 percent during January 1986-March 1989 (table 29). Similar rates of inflation in Canada and the United States during this period, of approximately 8 and 9 percent, respectively, resulted in a similar rate of appreciation of the Canadian dollar in real terms compared to nominal terms. In real terms, the Canadian dollar appreciated against the U.S. dollar during January 1986-March 1989 by almost 17 percent.

1/ Net delivered purchase price data reported by the * * * responding full-line drug wholesalers resulted in * * * quarterly price comparisons between the domestic and imported Canadian generic cephalexin 250 mg capsules in 100- and 500-capsule bottles and 500 mg capsules in 100-capsule bottles purchased during January 1988-March 1989. * * * of the * * * comparisons showed that the imported products were * * * than the domestic products by margins averaging almost * * * percent. * * * price comparisons showed that the imported products were priced * * * the domestic products by an average margin of almost * * * percent. In addition, the responding firms reported net prices that resulted in * * * price comparisons between the domestic and imported Canadian generic cephalexin 250 mg oral suspension powder in 200 ml bottles purchased during October 1988-March 1989. * * * comparisons showed that the imported product was priced * * * the domestic product, by margins of * * * and * * * percent.

2/ * * *. (Telephone conversation with Commission staff on November 15, 1988.)

Table 29

U.S.-Canadian exchange rates: 1/ Indexes of the nominal and real exchange rates between the U.S. and Canadian dollars, and indexes of producer prices in the United States and Canada, 2/ by quarters, January 1986-March 1989

Period	Nominal exchange- rate index	Real exchange- rate index 3/	Canadian Producer Price index	U.S. Producer Price Index
1986:				
January-March.....	100.0	100.0	100.0	100.0
April-June.....	101.4	101.8	98.5	98.2
July-September.....	101.3	102.5	98.7	97.7
October-December....	101.4	102.8	99.3	98.1
1987:				
January-March.....	104.9	105.6	99.8	99.2
April-June.....	105.3	105.7	101.1	100.8
July-September.....	106.2	106.8	102.5	101.9
October-December....	107.1	108.4	103.6	102.3
1988:				
January-March.....	110.8	112.0	104.0	102.9
April-June.....	114.1	114.6	105.1	104.8
July-September.....	115.1	115.2	106.3	106.2
October-December....	116.4	116.9	107.2	106.7
1989:				
January-March.....	117.8	116.7	108.1 4/	109.0

1/ Based on exchange rates expressed in U.S. dollars per Canadian dollar.

2/ The producer price indexes are aggregate measures of inflation at the wholesale level in the United States and Canada. Quarterly producer prices in the United States fluctuated but rose by 9 percent during January 1986-March 1989, while producer prices in Canada rose by 8.1 percent.

3/ The real value of a currency is the nominal value adjusted for the difference between inflation rates as measured by the producer price indexes in the United States and Canada.

4/ January only.

Source: International Monetary Fund, International Financial Statistics, June 1989.

Note: January-March 1986=100.

Lost sales

In the final investigation, * * *. 1/ Staff telephone conversations with the purchasers cited are discussed below.

* * * * *

Lost revenues

* * * * *

1/ During the preliminary investigation, Biocraft provided * * *, but indicated at the conference that it meets low price competition rather than lose the sale (transcript of the conference, pp. 25-26).

APPENDIX A

NOTICE OF THE COMMISSION'S INSTITUTION
OF A FINAL ANTIDUMPING INVESTIGATION

(LTFV). Unless the investigation is extended, Commerce will make its final LTFV determination on or before June 19, 1989, and the Commission will make its final injury determination by August 10, 1989, (see sections 735(a) and 735(b) of the act (19 U.S.C. 1673d(a) and 1673(b))).

For further information concerning the conduct of this investigation, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 207, subparts A and C (19 CFR part 207, as amended, 53 FR 33041 *et. seq.* (August 29, 1988) and 54 FR 5220 *et. seq.* (February 2, 1989)), and part 201, subparts A through E (19 CFR part 201).
EFFECTIVE DATE: April 12, 1989.

FOR FURTHER INFORMATION CONTACT: Lisa Zanetti (202-252-1189), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-252-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-252-1000.

SUPPLEMENTARY INFORMATION:

Background.—This investigation is being instituted as a result of an affirmative preliminary determination by the Department of Commerce that imports of generic cephalixin capsules from Canada are being sold in the United States at less than fair value within the meaning of section 731 of the act (19 U.S.C. 1673). The investigation was requested in a petition filed on October 27, 1988, by Biocraft Laboratories, Inc., Elmwood Park, NJ. In response to that petition the Commission conducted a preliminary antidumping investigation and, on the basis of information developed during the course of that investigation, determined that there was a reasonable indication that an industry in the United States was threatened with material injury by reason of imports of the subject merchandise (53 FR 51327, December 21, 1988).

Participation in the investigation.—Persons wishing to participate in this investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules (19 CFR 201.11), not later than twenty-one (21) days after the publication of this notice in the Federal Register. Any entry of appearance filed after this date will

[Investigation No. 731-TA-423 (Final)]

Generic Cephalixin Capsules From Canada

AGENCY: United States International Trade Commission.

ACTION: Institution of a final antidumping investigation and scheduling of a hearing to be held in connection with the investigation.

SUMMARY: The Commission hereby gives notice of the institution of a final antidumping investigation No. 731-TA-423 (Final) under section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the act) to determine whether 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 Canada of generic cephalixin capsules, provided for under subheading 3004.20.00 of the Harmonized Tariff Schedule of the United States (formerly provided for in item 411.76 of the Tariff Schedules of the United States). That have been found by the Department of Commerce, in a preliminary determination, to be sold in the United States at less than fair value

be referred to the Chairman, who will determine whether to accept the late entry for good cause shown by the person desiring to file the entry.

Public service list.—Pursuant to § 201.11(d) of the Commission's rules (19 CFR 201.11(d)), the Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance. In accordance with § 201.16(c) and 207.3 of the rules, as amended, (19 CFR 201.16(c) and 207.3, as amended), each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by the public service list), and a certificate of service must accompany the document. The Secretary will not accept a document for filing without a certificate of service.

Limited disclosure of business proprietary information under a protective order and business proprietary information service list.—Pursuant to section 207.7(a) of the Commission's rules (19 CFR 207.7(a), as amended), the Secretary will make available business proprietary information gathered in this final investigation to authorized applicants under a protective order, provided that the application be made not later than twenty-one (21) 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 business proprietary information under a protective order. The Secretary will not accept any submission by parties containing business proprietary information without a certificate of service indicating that it has been served on all parties that are authorized to receive such information under a protective order.

Staff report.—The prehearing staff report in this investigation will be placed in the nonpublic record on June 13, 1989, and a public version will be issued thereafter, pursuant to section 207.21 of the Commission's rules (19 CFR 207.21).

Hearing.—The Commission will hold a hearing in connection with this investigation beginning at 9:30 a.m. on June 28, 1989, at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission not later than the close of business (5:15 p.m.) on June 19, 1989. All persons desiring to appear at the hearing and make oral presentations should file prehearing briefs and attend

a prehearing conference to be held at 9:30 a.m. on June 23, 1989, at the U.S. International Trade Commission Building. The deadline for filing prehearing briefs is June 23, 1989.

Testimony at the public hearing is governed by section 207.23 of the Commission's rules (19 CFR 207.23). This rule requires that testimony be limited to a nonbusiness proprietary summary and analysis of material contained in prehearing briefs and to information not available at the time the prehearing brief was submitted. Any written materials submitted at the hearing must be filed in accordance with the procedures described below and any business proprietary materials must be submitted at least three (3) working days prior to the hearing (see § 201.6(b)(2) of the Commission's rules (19 CFR 201.6(b)(2))).

Written submissions.—All legal arguments, economic analyses, and factual materials relevant to the public hearing should be included in prehearing briefs in accordance with § 207.22 of the Commission's rules (19 CFR 207.22). Posthearing briefs must conform with the provisions of § 207.24 (19 CFR 207.24) and must be submitted not later than the close of business on July 5, 1989. In addition, any person who has not entered an appearance as a party to the investigation may submit a written statement of information pertinent to the subject of the investigation on or before July 5, 1989.

A signed original and fourteen (14) copies of each submission must be filed with the Secretary to the Commission in accordance with section 201.8 of the Commission's rules (19 CFR 201.8). All written submissions except for business proprietary data will be available for public inspection during regular business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary to the Commission.

Any information for which business proprietary treatment is desired must be submitted separately. The envelope and all pages of such submissions must be clearly labeled "Business Proprietary Information." Business proprietary submissions and requests for business proprietary treatment must conform with the requirements of § 201.6 and 207.7 of the Commission's rules (19 CFR 201.6, as amended, 54 FR 13677 (April 5, 1989) and 207.7, as amended).

Parties which obtain disclosure of business proprietary information pursuant to § 207.7(a) of the Commission's rules (19 CFR 207.7(a), as amended) may comment on such information in their prehearing and posthearing briefs, and may also file additional written comments on such

information no later than July 10, 1989. Such additional comments must be limited to comments on business proprietary information received in or after the posthearing briefs.

Authority.—This investigation is being conducted under authority of the Tariff Act of 1930, title VII. This notice published pursuant to § 207.20 of the Commission's rules (19 CFR 207.20).

By order of the Commission.

Kenneth R. Mason,

Secretary.

Issued: April 26, 1989.

[FR Doc. 89-10639 Filed 5-3-89; 8:45 am]

BILLING CODE 7020-02-M

APPENDIX B

LIST OF WITNESSES APPEARING AT THE COMMISSION'S HEARING

CALENDAR OF PUBLIC HEARING

Those listed below appeared as witnesses at the United States International Trade Commission's hearing:

Subject : Generic Cephalexin Capsules from Canada

Inv. No. : 731-TA-423 (Final)

Date and Time : June 28, 1989 - 9:30 a.m.

Sessions were held in connection with the investigation in the Main Hearing Room 101 of the United States International Trade Commission, 500 E Street, S.W., in Washington.

In Support of the Imposition of
Antidumping Duties:

Bryan, Cave, McPheeters & McRoberts
Washington, D.C.
on behalf of

Biocraft Laboratories, Inc.
Elmwood Park, New Jersey

Harold Snyder, President, Biocraft Laboratories, Inc.

Dr. Samuel M. Rosenblatt, Economic Consultant

Peter D. Ehrenhaft)
) —OF COUNSEL
Daniel C. Schwartz)

OTHER PARTY:

Bishop, Cook, Purcell & Reynolds
Washington, D.C.
on behalf of

Barr Laboratories, Inc.

Amy M. Jones)—OF COUNSEL

- more -

In Opposition to the Imposition of
Antidumping duties:

Kirkland & Ellis
Washington, D.C.
on behalf of

Novopharm Ltd.

LyphoMed/Novopharm Pharmaceutical Company

LyphoMed., Inc.

Leslie Dan, President, Novopharm Ltd.

Edward MacCormick, Chief Financial Officer and
Vice President, Novopharm Ltd.
(In attendance but did not testify)

Allan Gottlieb, Canadian Law Firm
Stikeman & Elliott, Counsel to Novopharm Ltd.

Robert Gunter, Vice President and General Manager,
LyphoMed/Novopharm Pharmaceutical Company

Christiana C. Kleitz)—Economic Consulting Services
(In attendance but did not testify)

David G. Norrell)
Robert C. Sexton)—OF COUNSEL
Christine M. Thomson)

APPENDIX C

NOTICE OF THE DEPARTMENT OF COMMERCE'S
FINAL DETERMINATION

determination and have directed the U.S. Customs Service to continue to suspend liquidation of all entries of generic cephalexin capsules from Canada, as described in the "Continuation of Suspension of Liquidation" section of this notice. The ITC will determine, within 45 days of the publication of this notice, whether these imports are materially injuring, or threaten material injury to, a United States industry. We also determine that critical circumstances do not exist with respect to imports of generic cephalexin capsules from Canada.

EFFECTIVE DATE: June 26, 1989.

FOR FURTHER INFORMATION:

Contact Karim Leiman or Louis Apple, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; (202) 377-8371, (202) 377-1769.

SUPPLEMENTARY INFORMATION:

Final Determination

We determine that generic cephalexin capsules from Canada are being, or are likely to be, sold in the United States at less than fair value, as provided for in section 735 of the Tariff Act of 1930, as amended (19 U.S.C. 1673d(a)) ("the Act"). The estimated weighted-average margins are shown in the "Continuation of Suspension of Liquidation" section of this notice. We also determine that critical circumstances do not exist with respect to generic cephalexin capsules from Canada.

Case History

On April 7, 1989, we made an affirmative preliminary determination (54 FR 14669, April 12, 1989). The following events have occurred since the publication of that notice.

On April 12, 1989, a disclosure conference was held with the respondent, Novopharm, Ltd. ("Novopharm"), to explain the methodology used in the Department's preliminary determination. A disclosure conference was held with the petitioner, Biocraft Laboratories, Inc., on April 13, 1989. The petitioner submitted comments pursuant to the disclosure conference on April 17, 1989.

Novopharm's response to the Department's second deficiency letter (dated April 4, 1989) was submitted in two parts. Appendices A and B were received on April 18, 1989, and the balance of the response, including two computer tapes, was received on April 19, 1989. Two corrected tapes were filed on April 20, 1989.

International Trade Administration
(A-122-806)

Final Determination of Sales at Less Than Fair Value; Generic Cephalexin Capsules From Canada

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

ACTION: Notice.

SUMMARY: We determine that generic cephalexin capsules from Canada are being, or are likely to be, sold in the United States at less than fair value. We have notified the U.S. International Trade Commission (ITC) of our

The Department received a request from respondent on April 21, 1989, for a public hearing to comment on the preliminary determination. A request for a public hearing was received from petitioner on April 24, 1989.

The Department's verification at the Novopharm facility in Scarborough, Ontario, Canada took place from April 24 through April 28, 1989. Verification took place at the headquarters of LyphoMed/Novopharm Pharmaceutical Company ("the joint venture") and LyphoMed, Inc. ("LyphoMed") in Rosemont, Illinois from May 1 through May 5, 1989.

Case briefs were submitted by both the petitioner and the respondent on May 31, 1989. On June 5, both parties submitted rebuttal briefs. The public hearing was held on June 7, at which counsel for both parties were present.

On June 9, 1989, the Department received post-hearing comments from the petitioner.

Scope of Investigation

The United States has developed a system of tariff classification based on the international harmonized system of customs nomenclature. On January 1, 1989, the U.S. tariff schedules were fully converted to the *Harmonized Tariff Schedule* (HTS), as provided for in section 1201 *et seq.* of the Omnibus Trade and Competitiveness Act of 1988. All merchandise entered, or withdrawn from warehouse, for consumption on or after that date is now classified solely according to the appropriate HTS subheading(s). The HTS numbers are provided for convenience and Customs purposes. The written description remains dispositive.

The products covered by this investigation are generic cephalixin capsules from Canada. Generic cephalixin capsules are cephalixin monohydrate in capsule form. Cephalixin monohydrate is a semi-synthetic cephalosporin antibiotic intended for oral administration. Its chemical formula is $C_{16}H_{17}N_3O_4S \cdot H_2O$. Generic cephalixin capsules contain not less than 90 percent and not more than 120 percent of the labelled amount of cephalixin monohydrate. The capsule is made of a water soluble gelatin, designed to facilitate swallowing and a phased release of the drug into the user's digestive system.

Prior to January 1, 1989, such merchandise was classifiable under item 411.7600 of the *Tariff Schedules of the United States Annotated* (TSUSA). This merchandise is currently classifiable under HTS subheading 3004.20.00.

Period of Investigation

The period of investigation is May 1, 1988, through October 31, 1988.

Fair Value Comparisons

To determine whether sales of generic cephalixin capsules from Canada to the United States were made at less than fair value, we compared the United States price to the foreign market value ("FMV"), as specified below.

United States Price

We based United States price on exporter's sales price ("ESP"), in accordance with section 772(c) of the Act, since the first sale to an unrelated customer was made after importation of the subject merchandise. We analyzed sales by the joint venture and by LyphoMed. To calculate ESP, we used the packed, ex-warehouse or delivered, duty-paid prices to unrelated purchasers in the United States. We made deductions, where appropriate, for foreign inland freight, U.S. inland freight, U.S. and foreign brokerage and handling charges, insurance, and U.S. duty, in accordance with section 772(d)(2) of the Act. We made further deductions, where appropriate, for discounts, rebates, and price protection payments.

In accordance with section 772(e)(2), we made additional deductions, where appropriate, for credit expenses, commissions, royalties, and indirect selling expenses, including: Pre-sale warehousing, inventory carrying costs, advertising, and other indirect selling expenses. The total of the U.S. indirect selling expenses formed the cap for the allowable home market indirect selling expenses offset under § 353.56(b) of the Department's new regulations (54 FR 12742, March 28, 1989) (to be codified at 19 CFR).

Pursuant to section 772(d)(1) of the Act, we added duty drawback paid by the Canadian government to respondent as a rebate of duties paid on imports of raw cephalixin.

Foreign Market Value

In accordance with section 773(a) of the Act, we calculated foreign market value based on the packed, delivered home market prices to unrelated purchasers. We made deductions, where appropriate, for freight to warehouse, inland insurance, discounts, rebates, credit expenses, royalties, warranty expenses, and commissions. We also deducted indirect selling expenses, including: inventory carrying costs, advertising, warehousing expenses, and other indirect selling expenses. These expenses were capped by the amount of indirect selling expenses incurred on

sales in the U.S. market, in accordance with § 353.41 of our new regulations.

In order to adjust for differences in packing between the two markets, we deducted Canadian home market packing costs from foreign market value and added U.S. packing costs.

Pursuant to section 773(a)(4)(C) of the Act, we made further adjustments to the home market price to account for differences in merchandise. In calculating the difference in merchandise adjustment, we used only those cost differences related to physical differences in the merchandise.

Currency Conversion

We used the official exchange rates in effect on the dates of sale, in accordance with section 773(a)(1) of the Act. All currency conversions were made at the rates certified by the Federal Reserve Bank of New York in accordance with § 353.60 of the Department's new regulations.

Verification

We verified the information used in making our final determination in this investigation in accordance with section 776(b) of the Act. We used standard verification procedures, including examination of relevant accounting records and original source documents provided by the respondent.

Critical Circumstances

Petitioner alleges that "critical circumstances" exist with respect to imports of the subject merchandise from Canada. Section 735(a)(3) of the Act provides that critical circumstances exist if we determine that:

(A) (i) there is a history of dumping in the United States or elsewhere of the class or kind of merchandise which is the subject of the investigation; or

(ii) the person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the merchandise which is the subject of the investigation at less than its fair value; and

(B) there have been massive imports of the class or kind of merchandise which is the subject of the investigation over a relatively short period.

Pursuant to section 735(a)(3)(B), we generally consider the following factors in determining whether imports have been massive over a relatively short period of time: (1) The volume and value of the imports; (2) seasonal trends (if applicable); and (3) the share of domestic consumption accounted for by imports.

Because the Department's import data pertaining to the subject merchandise are based on basket TSUSA categories,

we requested specific data on shipments of the subject merchandise as the most appropriate basis for our determinations of critical circumstances.

Based on our analysis of the monthly shipment data submitted by the respondent, we have found that imports of the subject merchandise have been massive over a relatively short period of time because they increased by more than 15% in the period following the Department's initiation. While some of this increase may have been due to seasonal fluctuations in the demand for the subject merchandise, we were presented with insufficient data to determine the extent of any seasonality. Therefore, we find that the requirements of section 735(a)(3)(B) are met.

We have examined antidumping duty measures undertaken by foreign countries as reported through the GATT Committee on Antidumping Practices. We found no record of antidumping orders on generic cephalixin capsules from Canada. Therefore, we find that the requirements of section 735(a)(3)(A)(i) are not met. As for section 735(a)(3)(A)(ii), it is our standard practice to impute knowledge of dumping when the estimated margins in our determinations are of such a magnitude that the importer should realize that dumping exists with regard to the subject merchandise.

The estimated margins found in this determination are not sufficiently high to impute knowledge of dumping. Therefore, despite the existence of massive imports, we conclude that critical circumstances do not exist with respect to imports of generic cephalixin capsules from Canada.

Interested Party Comments

Comment 1: Respondent requests that the Department make an allowance for quantity discounts pursuant to § 353.55 of the Department's new regulations by comparing the highest volume sales in the United States with the highest volume sales in the home market. Respondent claims that it is eligible for a quantity discount adjustment under both § 353.55(b)(1) and (b)(2). It claims that it granted quantity discounts on more than 20 percent of its home market sales during the period of investigation ("POI"). It also claims that its U.S. quantity discounts are attributable to production cost savings.

Petitioner argues that the Department should not make an allowance for quantity discounts. Petitioner claims that respondent has not satisfied the requirements of section 353.55 because it did not grant comparable quantity discounts on at least 20% of its home market sales, nor has it shown that the

discounts it offers in either the home market or the United States are related to economies of scale associated with the production of larger quantities of cephalixin capsules.

DOC Position: In order to make the most reasonable comparison, the Department has compared sales to buying groups and government agencies in the home market with sales to purchasers of large quantities in the United States. Similarly, we have compared sales to purchasers other than buying groups and government agencies in the United States.

Because of this, we have not applied a quantity discount adjustment to foreign market value, as provided for under § 353.55(b)(1) or (b)(2). Moreover, respondent's claim for such an adjustment was not adequately supported.

Comment 2: Petitioner argues that the Department should exclude variable factory overhead and direct labor costs from the adjustment for physical differences in merchandise. Further, the cost data excluded from the adjustment for physical differences in merchandise should not be allowed as a quantity adjustment.

Respondent argues that all costs (factory overhead, labor, and materials) associated with producing physically different merchandise should be included in the adjustment for physical difference in merchandise. Should the Department exclude these costs from the adjustment for physical differences in merchandise, respondent maintains that the costs should be used to adjust the FMV in accordance with § 353.55(b)(2).

DOC Position: To the extent that physical differences exist between the merchandise sold in the U.S. and home markets, the Department adjusts the observed FMV by the net differences in variable costs associated with those differences, in accordance with § 353.57. In this instance, respondent was unable to show that differences in variable factory overhead and direct labor costs are associated with physical differences in the merchandise. The Department therefore did not adjust the FMV by the net difference in these costs. Respondent did demonstrate that differences in the costs of materials for the products sold in the two markets were associated with physical differences in the merchandise. Therefore, we adjusted FMV for the difference in material costs.

Further, as explained in Comment 1 above, the Department did not adjust the FMV by the net difference in manufacturing costs pursuant to § 353.55(b)(2).

Comment 3: Petitioner argues that due to Canadian government dominance of the home market, sales to government agencies and hospitals should be excluded from the FMV because these sales are not made under "free market conditions. Petitioner asserts that sales are as "state controlled" as sales in Poland or Hungary.

DOC Position: We disagree and have included sales to government agencies and hospitals in the home market in the weighted-average FMV. There is no foundation in the statute, regulations, or in Departmental practice for finding "state control" of only certain sales to certain purchasers in a market economy.

Comment 4: Respondent asserts that date of sale for all sales in both the U.S. and home markets is the date of shipment. The terms of the sales are subject to change up to the time of shipment of the merchandise.

DOC Position: We agree. We recognize a sale when all terms, including price and quantity, are fixed. We have reviewed numerous examples of respondent's contracts in both the U.S. and home markets. We determined that the terms of sale, including price and quantity, are subject to change until the shipment date.

Comment 5: Petitioner argues that the magnitude of the difference between the packing costs reported for U.S. sales and packing costs reported for Canadian sales raises doubts about the accuracy of the information.

Doc Position: We disagree. We examined packing costs for both markets at verification and found the reported costs to be accurate.

Comment 6: Petitioner argues that due to the frequency of erroneous data discovered by the Department at verification, the Department should adjust all reported values in a given category to reflect the average differential between the reported values and the verified values.

Doc Position: In making our final determination, we used only verified information. We did not adjust all reported values as petitioner has suggested. In certain instances, we used respondent's revised figures, which reflect the correction of errors found at verification. We did not make deductions for home market freight costs to customers or for cash discounts because of pervasive errors in the reported data.

Comment 7: Petitioner agrees with the Department's preliminary determination finding evidence of "massive" imports by respondent after the Department's initiation, but disagrees with the Department's conclusion that the

importer did not know of sales at less than fair value. Petitioner argues that the price differential between the U.S. and home markets was large enough to impute knowledge of dumping by the importer because there is a close corporate relationship between the exporter and importer. This relationship permitted the parties to know that the goods were selling in the United States at less than fair value. Petitioner asks that the Department conclude that critical circumstances exist.

Respondent agrees with the Department's preliminary determination finding that no critical circumstances exist and argues that the estimated margins are not sufficiently high to impute knowledge of dumping. Respondent states that its exports of the subject merchandise were not "massive." Rather, it contends that it was filling pre-investigation contracts that were made when "seasonal" orders were high. Respondent states that despite the relationship between the companies, the Department's analysis is sufficiently complex and the margins sufficiently low that it was not possible to know that sales were made at less than fair value.

DOC Position: The Department has determined that critical circumstances do not exist with respect to imports of the subject merchandise, as explained in the "Critical Circumstances" section of this notice.

Comment 8: Respondent argues that the Department should treat advertisements by the joint venture as indirect selling expenses, and not as direct selling expenses, because the advertisements were directed at customers of the joint venture, and not to customers of these customers.

Petitioner argues that the wording of the promotional flier can be construed as directed either at customers of the joint venture or at the customer's customers. Hence, the joint venture's advertising should be deducted directly from the U.S. price.

DOC Position: We agree with respondent. We examined the joint venture's advertising at verification and found that these advertisements were directed at first level purchasers and not at the customer's customer.

Comment 9: Respondent argues that the Department should use the interest rate on LyphoMed's convertible subordinated debentures issued in the United States in March, 1987, in its calculation of credit and inventory carrying costs for U.S. sales. Respondent argues that while the actual interest paid may fall below generally available rates of interest during the period, the Department should follow its

established policy of using actual costs rather than imputing hypothetical credit costs.

Petitioner argues that the rate paid to holders of the debentures does not accurately reflect respondent's costs of financing its operations in the United States. The interest rate paid on the debentures omits the cost to respondent of the outstanding equity rights enjoyed by the debenture holders.

DOC Position: We agree with petitioner. We recalculated U.S. inventory carrying costs and credit costs using the prime rate in effect during the period of investigation. The outstanding debentures contain a stock convertibility option. This option represents a real, though unquantifiable, cost to respondent over and above the cost of the interest payments to the debenture holders. In the absence of actual quantifiable short-term borrowing costs, the Department uses the prime rate as the best information available.

Comment 10: Respondent argues that advertising expenses incurred by LyphoMed on the sales of its products sold under the LyphoMed name should not be deducted as a circumstance of sale adjustment nor included in the ESP cap. Respondent claims that advertising for LyphoMed products bears no relationship to the sale of products, including cephalixin capsules, bearing the "LyphoMed/Novopharm" name.

Petitioner argues that LyphoMed's advertising benefits LyphoMed/Novopharm products as well as LyphoMed products and that an allocated portion should be deducted from the U.S. price.

DOC Position: We agree with respondent and did not include LyphoMed's advertising in our calculation of U.S. price. LyphoMed, while one of the partners in the joint venture, is an independent corporate entity producing products other than the subject merchandise. There is no evidence that advertising for LyphoMed brandname products, which do not include generic cephalixin capsules, has any relation to U.S. sales of generic cephalixin capsules.

Comment 11: Respondent argues that the Department should not deduct from U.S. price, inventory carrying costs incurred between date of production and date of export. Respondent further argues that if the Department does deduct these costs, it should calculate these costs using Novopharm's actual borrowing rate during the POI.

DOC Position: It is the Department's practice to make an adjustment to U.S. price in ESP situations for inventory carrying costs incurred from the date of production to the date of export to the

United States because merchandise is held in inventory for this time period and this calculation thus more accurately reflects the cost to the manufacturer in an ESP situation. We calculated this adjustment using Novopharm's actual short-term borrowing cost. *See, Final Determination of Sales at Less than Fair Value: Industrial Phosphoric Acid from Belgium*, 52 FR 25436 (July 7, 1987); *Final Determination of Sales at Less Than Fair Value: Industrial Forklift From Japan*, 53 FR 12552 (April 15, 1988).

Comment 12: Respondent believes that sales of "short-dated" merchandise in the United States should be excluded from the Department's fair value comparisons because they involved second quality merchandise. Respondent states that this merchandise was of lesser quality because the product was approaching the end of its shelf life and that a small amount of this merchandise was sold at reduced prices to a small group of customers during the period of investigation.

DOC Position: We agree with respondents. We excluded sales of short-dated merchandise from our value comparisons. At verification, we found that these sales accounted for an insignificant portion of total sales to the United States.

Comment 13: Respondent argues that the Department should accept its method of discounting to present value the post-sale payments for chargebacks and commissions in the United States. Respondent states that credit expense is distorted because it is calculated based on invoice gross unit price rather than the actual value of these sales, which is the invoice gross unit price less chargebacks and commissions. Respondent argues that by discounting to present value these post-sale adjustments it is compensating for the distortion of credit expenses.

DOC Position: We disagree with respondents. Imputed credit costs represent the costs of financing receivables, which are generally booked on the basis of invoice price. While post sale expenses, such as commissions and chargebacks, affect the actual amount received by the seller, they do not affect the dollar value in receivables that is actually financed.

Comment 14: Respondent argues that its payments to a distributor in the home market are not commissions as originally reported, but are more properly categorized as rebates. Novopharm grants these post-sale price reductions regardless of whether the merchandise is resold. Respondent

argues that purchasers cannot receive a "commission" for their own purchases.

Petitioner argues that these payments should be treated as commissions because they are the distributor's sole compensation for selling Novopharm's products and the distributor makes these purchases for resale, not for its own use.

DOC Position: We agree with respondent. The payment to the distributor is a fixed percentage of the original invoice price and is made regardless of whether the merchandise is resold. The Department considers payments of this type to be rebates, not commissions. See, e.g., *Final Determination of Sales at Less Than Fair Value, Portland Hydraulic Cement From Japan*, 48 FR 41059, 41061 (Sept. 13, 1983).

Respondent reported commissions paid to its own employees, in both the home market and the United States. We treated these commissions to salesman to salesmen and order takers as direct selling expenses. It is the Department's practice to account for commissions of this type with a circumstance of sale adjustment when the commissions are directly related to specific sales. In this case, the company made payments equal to a specified percentage of the selling price. The respondent incurred the commission expense only if a sale was made. See, e.g., *Final Determination of Sales at Less Than Fair Value, Egg Filler Flats From Canada*, 50 FR 24009, 24010, (June 7, 1985); *Final Determination of Sales at Less Than Fair Value, Iron Construction Castings From Canada*, 51 FR 2412, 2414, (Jan. 16, 1986).

Comment 15: Respondent contends that the Department should deduct home market inventory carrying costs from foreign market value as a direct expense. Respondent states that because it tracks the time in inventory for each "lot" of cephalixin produced, it can compute the time in inventory for each capsule produced within each lot. Respondent argues that because it has tied inventory carrying costs to specific sales under investigation, these costs should be treated as direct selling expenses.

Petitioner argues that inventory carrying costs should be treated as an indirect selling expense. Petitioner argues that, even though respondent has the capability to track a batch of chemicals from mixing bowl to bottle, these costs are not incurred directly for the benefit of individual customers.

DOC Position: We agree with the petitioner. The ability to calculate inventory carrying costs for specific sales does not mean that these costs are

directly related to those sales. These costs are incurred regardless of whether the merchandise is sold and are, therefore, properly treated as indirect expenses.

Comment 16: Respondent contends that the Department should deduct warranty expenses from foreign market value as a circumstance of sale adjustment. Respondent states that it has identified the actual warranty expenses incurred during the period of investigation and it has shown that these expenses are directly related to sales under investigation.

Petitioner argues that respondent has not justified the difference between warranty expenses associated with sales in the United States and in Canada and, consequently, is not entitled to any adjustment. Petitioner further argues that if there are no warranty expenses in the United States, no adjustment should be made.

DOC Position: We agree with respondent. We examined warranty expenses at verification and found that the reported expenses were directly related to the sales under investigation.

Comment 17: Respondent contends that the Department should not impute post-sale payments for chargebacks and commissions for certain sales in the United States. Respondent states that its methodology for reporting these payments does not understate the actual expenses incurred on the sales under investigation.

Petitioner contends that the Department should impute post-sale payments for chargebacks and commissions on certain sales in the United States. Petitioner argues that, even though the expenses were not yet incurred, the expenses are understated because they will likely be incurred in the future.

DOC Position: We agree with respondent. At verification, we examined respondent's method for reporting these expenses and found it to be reasonable. We did not find that these expenses were understated.

Comment 18: Respondent maintains that the Department should make a circumstance of sale adjustment for quality control expenses. Respondent argues that the quality control expenses it incurred for products sold in the United States are different than quality control expenses incurred for products sold in Canada due to differing regulatory requirements in the two countries. Respondent further argues that these expenses relate directly to the sales under investigation and should be treated as direct selling expenses. Respondent states that if the Department does not treat these

expenses as direct, then these expenses should be treated as indirect selling expenses.

Petitioner argues that these expenses should be treated as indirect selling expenses because they are only indirectly related to the sales under investigation.

DOC Position: We agree with petitioner. These expenses are incurred regardless of whether a sale is made and are properly treated as an indirect selling expense.

Comment 19: Respondents argue that the expenses reported as "home market direct selling expenses" should be treated as direct selling expenses.

Petitioner argues that these expenses should be treated as indirect selling expenses because they are indirectly related to the sales under investigation.

DOC Position: We agree with petitioner. We examined the components of the reported "home market direct selling expenses," which included such items as salaries and training, and found that these expenses did not bear a direct relationship to the sales under investigation.

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1) of the Act, we are directing the U.S. Customs Service to continue to suspend liquidation of all entries of generic cephalixin from Canada, as defined in the "Scope of Investigation" section of this notice, that are entered, or withdrawn from warehouse for consumption, on or after April 12, 1989, the date of publication of the preliminary determination in the Federal Register. The U.S. Customs Service shall continue to require a cash deposit or posting of bond equal to the estimated amounts by which the foreign market value of the merchandise subject to this investigation exceeds the United States price, as shown below. This suspension of liquidation will remain in effect until further notice.

The weighted-average margins are as follows:

Manufacturer/producer/exporter	Weighted-average margin percentage
Novopharm, Ltd.....	7.5
All others	7.5

ITC Notification

In accordance with section 735(c) of the Act, we have notified the ITC of our determination. In addition, we are

making available to the ITC all nonprivileged and nonproprietary information relating to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under administrative protective order, without the written consent of the Assistant Secretary for Import Administration. The ITC has 45 days from this final determination to determine whether or not material injury exists, or if threat of material injury exists. If the ITC determines that material injury, or threat of material injury, does not exist, the proceeding will be terminated and all securities posted as a result of the suspension of liquidation will be refunded or cancelled. However, if the ITC determines that material injury does exist, the Department will issue an antidumping duty order directing Customs officials to assess antidumping duties on generic cephalixin from Canada entered, or withdrawn from warehouse, for consumption, on or after the effective date of the suspension of liquidation, equal to the amount by which the foreign market value exceeds the United States price.

This determination is published pursuant to section 735(d) of the Act (19 U.S.C. 1673(d)).

June 19, 1989.

Eric I. Garfinkel,

Assistant Secretary for Import Administration.

[FR Doc. 89-14956 Filed 6-23-89; 8:45 am]

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Corrections

Federal Register

Vol. 54, No. 127

Wednesday, July 5, 1989

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

International Trade Administration

[A-122-806]

Final Determination of Sales at Less Than Fair Value; Generic Cephalixin Capsules From Canada

Correction

In notice document 89-14956 beginning on page 26820 in the issue of Monday, June 26, 1989, make the following correction:

On page 26822, in the second column, in the first complete paragraph, in the ninth line, after "agencies" insert "in the home market with sales to purchasers of small quantities".

BILLING CODE 1505-01-0

APPENDIX D

CEPHALEXIN HYDROCHLORIDE MONOHYDRATE (KEFTAB)

Cephalexin Hydrochloride Monohydrate (Keftab)

Cephalexin hydrochloride monohydrate (Keftab), like cephalexin monohydrate (Keflex), is a first generation semisynthetic cephalosporin antibiotic intended for oral administration. It is a different salt formulation of basic cephalexin. Dosage formulations of both Keftab and Keflex receive their strength based on the amount of active ingredient cephalexin.

In applying for FDA approval of Keftab, Eli Lilly conducted bioequivalence studies between Keflex and Keftab, and demonstrated that the two compounds are bioequivalent. Clinical trials were conducted later. During development, it was thought that the hydrochloride formulation would have better bioavailability and thus possibly be superior to the marketed monohydrate. 1/ However, human volunteer studies showed that the drugs were comparable. It was the conclusion of the FDA during the approval process that Keflex and Keftab can essentially be considered one and the same drug from the standpoint of safety. 2/

From a therapeutic standpoint, both drugs treat essentially the same types of infections, have the same contraindications, and issue the same precautions. Package inserts for both drugs are nearly identical. 3/

To manufacture Keftab, * * *.

* * * * *

Table D-1

Keftab: Certain salient data, 1986-88, January-March 1988, and January-March 1989

* * * * *

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

1/ According to the American Hospital Formulary Service Drug Information 89, both cephalexin and cephalexin hydrochloride are acid-stable and rapidly absorbed from the GI tract. The hydrochloride may be absorbed more rapidly because cephalexin must first be converted to the hydrochloride in the stomach prior to absorption. However, the extent of absorption appears to be similar, and differences in the rate of absorption do not appear to be clinically important (p. 138).

2/ It should be noted that in the FDA's Orange Book, Keftab appears as a single source drug with no other form of cephalexin listed as being therapeutically equivalent.

3/ In Lilly's request for FDA approval of the package insert, * * *.

APPENDIX E
CEPHALOSPORINS

Cephalosporins

General.--Cephalosporins are semisynthetic antibiotic derivatives of cephalosporin C, a substance produced by the fungus cephalosporium acremonium. The drugs are beta-lactam antibiotics structurally and pharmacologically related to penicillins, 1-oxa-beta-lactams, and cephamycins. All commercially available cephalosporins contain the 7-aminocephalosporanic acid (7-ACA) nucleus which is composed of a beta-lactam ring fused with a 6-membered dihydrothiazine ring instead of the 5-membered thiazolidine ring of penicillins. Cephalosporins are used in the treatment of serious respiratory tract, skin and skin structure, urinary tract, and bone and joint infections.

History.--Cephalosporium acremonium was first isolated in 1948 from the sea near a sewer outlet off the Sardinian coast. Crude filtrates of this fungus were found to inhibit the in vitro growth of staph. aureus and to cure staphylococcal infections and typhoid fever. Culture fluids in which the Sardinian fungus was cultivated were found to contain three distinct antibiotics, which were named cephalosporin P, N, and C. With the isolation of the active nucleus of cephalosporin C, and with the addition of side chains, it became possible to produce semisynthetic compounds with antibacterial activity significantly greater than that of the parent substance. 1/

Chemistry.--Cephalosporin C contains a side chain derived from d-a-aminoadipic acid which is condensed with a dihydrothiazine beta-lactam ring system (7-ACA). Compounds containing 7-ACA are relatively stable in dilute acid and highly resistant to penicillinase, regardless of the nature of their side chains and their affinity for the enzyme. 2/

Cephalosporin C can be hydrolyzed by acid to 7-ACA. This compound has been subsequently modified by the addition of different side chains to create a whole family of cephalosporin antibiotics. It appears that modifications at position 7 of the beta-lactam ring are associated with alteration in antibacterial activity and that substitutions at position 3 of the dihydrothiazine ring are associated with changes in the metabolism and the pharmacokinetic properties of the drugs. 3/ The cephamycins are similar to the cephalosporins, but have a methoxy group at position 7 of the beta-lactam ring of the 7-ACA nucleus.

Classification.--Although cephalosporins can be classified by their chemical structure, clinical pharmacology, resistance to beta-lactamase, 4/ or antimicrobial spectrum, the most accepted classification is based on general features of antimicrobial activity. 5/ In general, second generation

1/ Goodman and Gilman, The Pharmacological Basis of Therapeutics, 7th ed., 1985, p. 1137.

2/ Ibid.

3/ Ibid.

4/ Beta-lactamases (or cephalosporinases) are enzymes produced by bacteria that disrupt the beta-lactam ring and render the cephalosporin inactive.

5/ Goodman and Gilman, The Pharmacological Basis of Therapeutics, 7th ed., 1985, p. 1137. These classifications are imprecise, however, and the divisions somewhat arbitrary. Individual cephalosporins will frequently exhibit characteristics of generations other than the one in which they are generally

cephalosporins are active against organisms susceptible to first generation cephalosporins, and show greater activity against organisms resistant to first generation cephalosporins. Third generation cephalosporins are generally less active in vitro against susceptible staphylococci than first generation cephalosporins; however, the third generation drugs have an expanded spectrum of activity against gram-negative bacteria compared with the first and second generation drugs. Closely related beta-lactam antibiotics are also classified in these groups because of their similar spectra of activity.

The three generations of cephalosporin are detailed below, according to the classifications found in the American Hospital Formulary Service Drug Information 89. Other sources may group the generations somewhat differently.

First generation cephalosporins--(cefadroxil, cefazolin, cephalixin, cephalothin, cephalpirin, and cephadrine) are usually active in vitro against gram-positive cocci, group B streptococci, and streptococcus pneumoniae. These cephalosporins have limited activity against gram-negative bacteria, although some strains may be inhibited in vitro by the drugs.

Second generation cephalosporins--(cefaclor, cefamandole, cefonicid, ceforanide, cefotetan (a cephamycin), cefoxitin (a cephamycin), and cefuroxime) are usually active in vitro against organisms susceptible to first generation cephalosporins. In addition, second generation drugs are active in vitro against most strains of haemophilus influenzae (including ampicillin-resistant strains). Although the specific spectra of activity differ, second generation cephalosporins are generally more active against gram-negative bacteria than first generation cephalosporins. The second generation drugs (except cefaclor) may be active against some strains of bacteria that are resistant to the first generation cephalosporins.

Third generation cephalosporins--(cefoperazone, cefotaxime, ceftazidime, ceftizoxime, ceftriaxome, and moxalactam (a 1-oxa-beta-lactam)) are usually less active against susceptible staphylococci than first generation drugs; however, the third generation drugs have an expanded spectrum of activity against gram-negative bacteria compared with the first and second generations. The third generation drugs are generally active against the same bacteria susceptible to the first and second generation drugs, and are also active against other strains of bacteria that may be resistant to the first two generations.

Mechanisms of action.--Resistance to individual cephalosporins may be related to the inability of the antibiotic to reach the site of action, or may be caused by alterations in the antibiotic-binding proteins so that interaction does not take place. Bacteria have the ability to produce enzymes--beta-lactamases or cephalosporinases--that disrupt the beta-lactam ring and render the cephalosporin inactive. The cephalosporins have variable susceptibility to beta-lactamase.

A first generation cephalosporin is generally preferred when a cephalosporin is used for the treatment of infections caused by susceptible

classified. Disagreements exist among clinicians as to the proper classification of some cephalosporins; for example, cefaclor is variously classified in the first and second generations, and cefotetan is classified in the second and third.

gram-positive bacteria. Although oral cephalosporins are generally effective in the treatment of mild to moderate infections caused by susceptible staphylococci or streptococci, they are not usually the drugs of choice for the treatment of these infections. Some clinicians suggest that an oral penicillin or an erythromycin may be more effective than an oral cephalosporin in the treatment of mutually-susceptible organisms. Cephalosporins are inactive against fungi and viruses. 1/

1/ American Hospital Formulary Service Drug Information 89, p. 85.

APPENDIX F

A SUMMARY OF THE U.S. FOOD AND DRUG ADMINISTRATION
GENERIC DRUG APPROVAL PROCESS

A Summary of the U.S. Food and Drug Administration
Generic Drug Approval Process

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, also known as the Waxman-Hatch Amendments, designed to make available high quality, therapeutically equivalent generic versions of previously single source drugs. In enacting this legislation, Congress eliminated the need for costly animal and human clinical studies to support the safety and efficacy of duplicate versions of drugs approved since 1962 by allowing companies to apply for an Abbreviated New Drug Application (ANDA).

One of the key components of ANDA approval is the submission of adequate information to demonstrate bioequivalence of the generic version of the pioneer or innovator drug (usually a patented drug). The requirement of bioequivalence to gain approval for a generic drug product was not a novel concept; the FDA had accepted bioequivalence testing, in lieu of clinical testing in patients, between 1970 and 1984 for the purpose of approving generic versions of drugs first approved before 1962. The 1984 law extended this requirement to cover approval of generic versions of drugs approved after 1962, for which the ANDA procedure was not available, and for which costly, duplicative safety and effectiveness studies were mandatory.

The reasoning behind this change lay in the fact that the safety and efficacy of active ingredients in brand-name drug products had been amply demonstrated by adequate and well-controlled studies by the pioneer manufacturer, by the acceptance of the findings by the medical community, and by the widespread use of these drug entities in patient therapy over several years. Repetition of clinical studies for generic versions of brand name drug products tied up valuable and scarce scientific and economic resources without any new contribution to the body of knowledge regarding the safety and efficacy of the drug.

A generic drug producer wishing to prove bioequivalence of the generic drug must demonstrate that the test product offers equivalent bioavailability to the reference product; that is, the generic drug must have the equivalent (though not identical) ^{1/} rate and extent of absorption into general circulation in the body, where it becomes available to the tissues of the body. Rate of entry is important when rapidity of action is a major concern. If a drug is injected directly into the systemic circulation, it is immediately and completely bioavailable. Since many drugs are administered orally, however, partial absorption of the drug can lead to bioavailability problems. In those cases, bioequivalence is usually determined by measuring the concentration of the drug in plasma or serum. The plasma concentrations of drugs exist in some

^{1/} Some major pharmaceutical companies have argued that the FDA's review process does not ensure therapeutic equivalence, and that wide disparities in bioavailability between various generic versions could cause problems for a patient. To date, however, the FDA has not found that any inequivalencies represent anything more significant than the normal lot by lot variations found in any pharmaceutical product. (Swergold, Chefitz Inc., Health Care Research, January 10, 1989, pp. 8-9, submitted as app. 4 to respondent's prehearing brief.)

form of equilibrium with the target tissue and represent a valid indication of potential desired clinical action.

In order to ensure that adequate and appropriate bioequivalence testing is conducted by generic manufacturers and to provide guidance as to proper bioequivalence study procedures, the FDA has developed guidelines for conducting in vivo bioequivalence testing and in vitro dissolution testing for specific products.

The basis for submitting an ANDA for a generic drug is simply that there must be a previously approved drug which is the "same" as the proposed drug. The product must have the same active ingredient(s), route(s) of administration, dosage form, and strength. All approved products appear in a document entitled Approved Drug Products with Therapeutic Equivalence Evaluations. It is possible that proposed products can be different, within defined limits, from previously approved products and still be acceptable for submission as ANDAs. The substitution of one ingredient for another may only be considered for a multiple ingredient product. In these instances, the new ingredient must be of the same pharmacological or therapeutic class as that contained in the listed drug and is expected to have the same therapeutic effect when administered to patients. The substitution of one active ingredient for another in single ingredient products is not authorized under Section 505 (j)(2)(c) of the 1984 Act.

When reviewing a petition for ANDA suitability, the FDA requires the following information:

1. Identification of the proposed drug product, including the active ingredient(s), strength, dosage form, route(s) of administration, conditions of use, bioequivalence data, and labeling.
2. Patent certification. Petitioner must certify that one of four conditions holds true for each patent that claims the listed drug or which claims a use for the listed drug for which the applicant seeks approval: (1) patent information has not been filed, (2) the patent has expired, (3) the patent will expire on this date, or (4) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug.
3. Statement regarding prescription and/or over-the-counter status.
4. Specifications and tests for active ingredient(s), inactive ingredient(s), container/closure system, and finished dosage form.
5. Stability profile, including stability data.
6. Manufacturing procedures, controls, and certification of conformance with current Good Manufacturing Practices (GMPs).
7. Description of all facilities used in the manufacturing, processing, testing and packaging of the drug.
8. Samples statement.
9. Environmental impact assessment.

Once an ANDA has been granted, the applicant must file an annual report each year within 60 days of the anniversary date of approval. Each annual report must contain: (1) a summary of significant new information about the drug, (2) distribution data, (3) copies of all current package labeling, including all distributor labeling, (4) manufacturing or controls changes, (5) non-clinical laboratory studies, (6) clinical data, and (7) status reports concerning postmarketing studies and, at the applicant's discretion, a list of any pending regulatory business with the FDA concerning the application.

Source: Division of Generic Drugs, Center for Drugs and Biologics, U.S. Food and Drug Administration, Rockville, MD.

APPENDIX G

U.S. PRODUCERS' SALIENT DATA,
GENERIC AND BRAND-NAME CEPHALEXIN

Presented in the table below are U.S. producers' salient data on generic and brand name cephalixin, aggregated for all dosage forms.

Table G-1

Cephalexin: U.S. producers' salient data, generic and brand-name products, 1986-88, January-March 1988, and January-March 1989

* * * * *

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

Lilly's market share of cephalixin products is presented in the tabulation below (in percent, based on quantity):

* * * * *

APPENDIX H

U.S. CEPHALEXIN PRODUCERS' DESCRIPTIONS OF
THE ACTUAL AND POTENTIAL NEGATIVE EFFECTS OF
IMPORTS OF GENERIC CEPHALEXIN CAPSULES FROM CANADA
ON THEIR GROWTH, DEVELOPMENT AND PRODUCTION EFFORTS,
INVESTMENT, AND ABILITY TO RAISE CAPITAL

The following statements were provided by U.S. producers of cephalexin in response to questionnaires of the U.S. International Trade Commission regarding actual and potential negative effects of imports of generic cephalexin capsules from Canada on their growth, investment, and ability to raise capital:

* * * * *

APPENDIX I

COMPARISONS OF SELLING PRICES OF KEFLEX AND GENERIC CEPHALEXIN

Comparisons of Selling Prices of Keflex and Generic Cephalixin

* * * * * * *

Table I-1

Cephalixin capsules in 100-capsule bottles: Weighted-average selling prices of U.S.-produced Keflex capsules sold to * * *, selling prices of U.S.-produced and imported Canadian generic cephalixin capsules sold to * * *, and price differences between Keflex and the domestic and imported generic drug, by capsule dosages and by quarters, April 1987-March 1989

* * * * * * *

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

Table I-2

U.S.-produced cephalixin 250 mg oral suspension in 200 ml bottles and 250 mg tablets in 100-tablet bottles: Weighted-average selling prices of U.S.-produced Keflex capsules and generic capsules sold to * * *, and price differences between Keflex and the domestic generic drug, by quarters, October 1987-March 1989

* * * * * * *

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

* * * * * * *

APPENDIX J

NET DELIVERED SELLING PRICES OF DOMESTIC AND
IMPORTED CANADIAN GENERIC CEPHALEXIN CAPSULES
BY INDIVIDUAL RESPONDING U.S. PRODUCERS
AND BY THE IMPORTER

Net Delivered Selling Prices of Domestic and Imported Canadian Generic
Cephalexin Capsules by Individual Responding U.S. Producers and by the Importer

* * * * *

Table J-1

Generic cephalexin capsules in 100-capsule bottles: Net delivered selling
prices of U.S.-produced and imported Canadian cephalexin capsules sold to * * *,
by responding firms, by capsule dosages, and by quarters, April 1987-March 1989

* * * * *

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

Table J-2

Generic cephalexin capsules in 500-capsule bottles: Net delivered selling
prices of U.S.-produced and imported Canadian cephalexin capsules sold to * * *,
by responding firms, by capsule dosages, and by quarters, April 1987-March 1989

* * * * *

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

Table J-3

Generic cephalexin capsules in 100-capsule bottles: Net delivered selling
prices of U.S.-produced and imported Canadian cephalexin capsules sold to * * *,
by responding firms, by capsule dosages, and by quarters, April 1987-March 1989

* * * * *

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

