

# GENERIC CEPHALEXIN CAPSULES FROM CANADA

etermination of the Commission in  
vestigation No. 731-TA-423  
Preliminary) Under the Tariff Act  
f 1930, Together With the  
formation Obtained in the  
vestigation



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**UNITED STATES INTERNATIONAL TRADE COMMISSION**

**COMMISSIONERS**

**Anne E. Brunsdale, Acting Chairman**

**Alfred E. Eckes**

**Seeley G. Lodwick**

**David B. Rohr**

**Ronald A. Cass**

**Don E. Newquist**

*Staff assigned:*

Lisa Zanetti, Office of Investigations

Elizabeth Nesbitt, Office of Industries

Gerry Benedick, Office of Economics

Marshall Wade, Office of Investigations

Edwin Madaj, Office of the General Counsel

Frances Marshall, Office of the General Counsel

Vera Libeau, Office of Investigations

**Address all communications to  
Kenneth R. Mason, Secretary to the Commission  
United States International Trade Commission  
Washington, DC 20436**

## CONTENTS

	<u>Page</u>
Determination.....	1
Views of the Commission.....	3
Dissenting views of Acting Chairman Anne E. Brunsdale.....	19
Dissenting views of Commissioner Ronald A. Cass.....	39
Information obtained in the investigation.....	A-1
Introduction.....	A-1
The product:	
Description and uses.....	A-1
Product substitutability.....	A-2
Manufacturing processes.....	A-4
The U.S. market.....	A-6
U.S. tariff treatment.....	A-7
Nature and extent of alleged sales at LTFV.....	A-9
The U.S. industry.....	A-10
U.S. importers.....	A-12
The domestic market.....	A-12
Apparent U.S. consumption.....	A-12
Channels of distribution.....	A-14
Consideration of material injury to an industry	
in the United States.....	A-15
U.S. production, capacity, and capacity utilization.....	A-15
U.S. producers' domestic shipments.....	A-16
U.S. producers' export shipments.....	A-17
U.S. producers' end-of-period inventories.....	A-17
U.S. employment, wages, and productivity.....	A-18
Financial experience of U.S. producers.....	A-19
Overall establishment operations.....	A-19
Cephalexin operations.....	A-20
Generic cephalexin capsule operations.....	A-21
Other cephalexin operations.....	A-22
Value of plant, property, and equipment.....	A-22
Capital expenditures.....	A-22
Research and development expenses.....	A-22
Return on total assets.....	A-22
Capital and investment.....	A-23
Consideration of threat of material injury to an	
industry in the United States.....	A-23
U.S. inventories of cephalexin from Canada.....	A-25
The generic cephalexin industry in Canada and its	
ability to generate exports.....	A-25
Inventories of the Canadian producer.....	A-27
Consideration of the causal relationship between imports	
of the subject merchandise and alleged material injury.....	A-27
U.S. imports.....	A-27
U.S. market penetration by imports.....	A-28
U.S. market shares of U.S. producers and imports, by country.....	A-28
Prices.....	A-29
Market characteristics.....	A-29
Questionnaire price data.....	A-30
Price trends.....	A-31
U.S. producers' prices.....	A-31
Prices of imports from Canada.....	A-33
Price comparisons.....	A-34
Transportation factors.....	A-37
Exchange rates.....	A-37

## CONTENTS--Continued

Lost sales.....	A-39
Price supression/depression.....	A-39
Appendices:	
Appendix A - Federal Register Notices.....	B-1
Appendix B - Calendar of the Public Conference.....	B-7
Appendix C - Cephalosporins.....	B-9
Appendix D - A Summary of the U.S. Food and Drug Administration Generic Drug Approval Process.....	B-14
Tables	
1. Cephalexin capsules: Apparent U.S. consumption, branded and generic, domestically produced and imported, 1985-87, January- September 1987 and January-September 1988.....	A-13
2. Cephalexin capsules: Apparent U.S. consumption, by firms and by countries of origin, 1985-87, January-September 1987, and January- September 1988.....	A-13
3. Cephalexin, dosage forms other than capsules: Apparent U.S. consumption, by firms and countries of origin, 1985-87, January- September 1987 and January-September 1988.....	A-13
4. Cephalexin capsules: U.S. production, capacity, and capacity utilization, by firms, 1985-87, January-September 1987, and January- September 1988.....	A-15
5. Cephalexin, dosage forms other than capsules: U.S. production, capacity, and capacity utilization, by firms, 1985-87, January- September 1987, and January-September 1988.....	A-16
6. Cephalexin: U.S. producers' domestic shipments, branded and generic, by dosage types, 1985-87, January-September 1987, and January-September 1988.....	A-17
7. Cephalexin: U.S. producers' domestic shipments, by firms and by dosage types, 1985-87, January-September 1987, and January- September 1988.....	A-17
8. Cephalexin: U.S. producers' end-of-period inventories, branded and generic, by dosage form, 1985-87, January-September 1987, and January-September 1988.....	A-18
9. Cephalexin: U.S. producers' end-of-period inventories, by firms and by dosage type, 1985-87, January-September 1987 and January-September 1988.....	A-18
10. Generic cephalixin: Average number of production and related workers, hours worked, wages paid, total compensation, productivity, and unit labor costs, 1985-87, January-September 1987, and January-September 1988.....	A-19
11. Branded cephalixin: Average number of production and related workers, hours worked, wages paid, total compensation, productivity, and unit labor costs, 1985-87, January-September 1987, and January-September 1988.....	A-19
12. Income-and-loss experience of U.S. producers on the overall operations of their establishments within which generic cephalixin capsules are produced, accounting years 1985-87 and interim periods ended September 30, 1987, and September 30, 1988.....	A-20
13. Income-and-loss experience of U.S. producers on their cephalixin operations within which generic cephalixin capsules are produced, accounting years 1985-87 and interim periods ended September 30, 1987, and September 30, 1988.....	A-20

## CONTENTS

## Tables--Continued

14.	Income-and-loss experience of U.S. producers on their generic cephalixin capsule operations, accounting years 1985-87 and interim periods ended September 30, 1987, and September 30, 1988.....	A-21
15.	Income-and-loss experience of U.S. producers on their other cephalixin operations, accounting years 1985-87 and interim periods ended September 30, 1987, and September 30, 1988.....	A-22
16.	Generic cephalixin: U.S. end-of-period inventories of imports from Canada, 1985-87, January-September 1987 and January-September 1988.....	A-25
17.	Generic cephalixin: Production, end-of-period capacity, and capacity utilization in Canada, 1985-87, January-September 1987 and January-September 1988.....	A-26
18.	Generic cephalixin: Shipments of Canadian producer, 1985-87, January-September 1987 and January-September 1988, with projected data for October-December 1988 and 1989.....	A-27
19.	Generic cephalixin: Inventories of Canadian producer, 1985-88.....	A-27
20.	Cephalixin: Imports from Canada and from all other sources, by dosage type, 1985-87, January-September 1987, and January-September 1988.....	A-28
21.	Cephalixin capsules: Market penetration of imported Canadian generic cephalixin capsules, expressed as a percent of U.S. consumption, 1985-87, January-September 1987, and January-September 1988.....	A-28
22.	U.S.-produced generic cephalixin 250mg capsules in 100-capsule bottles: Sales quantities, weighted-average net f.o.b. selling prices, and price indexes of U.S. producers' domestically-produced generic cephalixin 250mg capsules, by types of customer and by quarters, April 1987-September 1988.....	A-32
23.	U.S.-produced generic cephalixin 500mg capsules in 100-capsule bottles: Sales quantities, weighted-average net f.o.b. selling prices, and price indexes of U.S. producers' domestically-produced generic cephalixin 500mg capsules, by types of customer and by quarters, April 1987-September 1988.....	A-32
24.	U.S.-produced Keflex capsules in 100-capsule bottles: U.S. sales quantities, weighted-average net f.o.b. selling prices, and price indexes of domestically-produced Keflex capsules, ***, by capsule dosages and by quarters, January 1985-September 1988.....	A-32
25.	Imported Canadian generic cephalixin capsules in 100-capsule bottles: U.S. sales quantities, weighted-average net f.o.b. selling prices, and price indexes of generic cephalixin capsules imported from Canada and sold to *** and to ***, by types of customer, by capsule dosages, and by quarters, April 1987-September 1988.....	A-33
26.	Imported Canadian generic cephalixin capsules in 100-capsule bottles: U.S. sales quantities, weighted-average f.o.b. selling prices, and price indexes of generic cephalixin capsules imported from Canada and sold to *** and to ***, by types of customer, by capsule dosages, and by quarters, April 1987-September 1988...	A-34

## CONTENTS

## Tables--Continued

- |     |   |      |
|-----|---|------|
| 27. | Generic cephalixin capsules in 100-capsule bottles: Weighted-average net f.o.b. selling prices of generic cephalixin capsules produced in the United States and imported from Canada and sold to *** and to *** companies, and margins of under/(over) selling, by capsule dosage, and by quarters, April 1987-September 1988.....                              | A-35 |
| 28. | Generic cephalixin capsules in 100-capsule bottles: Weighted-average net f.o.b. selling prices of generic cephalixin capsules produced in the United States and imported from Canada and sold to *** and to ***, and margins of under/(over) selling, by capsule dosage, and by quarters, April 1987-September 1988.....  | A-35 |
| 29. | Cephalixin capsules in 100-capsule bottles: Weighted-average selling prices of U.S.-produced Keflex capsules sold to *** and the selling prices of imported-Canadian generic cephalixin capsules sold to *** and to ***, and price differences between Keflex and the imported generic drug, by capsule dosage, and by quarters, April 1987-September 1988..... | A-36 |
| 30. | U.S.-produced Cephalixin capsules in 100-capsule 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 capsule dosage, and by quarters, April 1987-September 1988.....   | A-37 |
| 31. | U.S.-Canadian exchange rates: 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, by quarters, January 1985-June 1988.....  | A-38 |

UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, DC

Investigation No. 731-TA-423 (Preliminary)

GENERIC CEPHALEXIN CAPSULES FROM CANADA

Determination

On the basis of the record 1/ developed in the subject investigation, the Commission determines, 2/ pursuant to section 733(a) of the Tariff Act of 1930 (19 U.S.C. § 1673b(a)), that there is a reasonable indication that an industry in the United States is threatened with material injury by reason of imports from Canada of generic cephalexin capsules, provided for in item 411.76 of the Tariff Schedules of the United States (subheading 3004.20.00 of the Harmonized Tariff Schedule of the United States), that are alleged to be sold in the United States at less than fair value (LTFV).

Background

On October 27, 1988, a petition was filed with the Commission and the Department of Commerce 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 cephalexin capsules from Canada. Accordingly, effective October 27, 1988, the Commission instituted preliminary antidumping investigation No. 731-TA-423 (Preliminary).

Notice of the institution of the Commission's investigation and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the Federal

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

2/ Acting Chairman Brunsdale and Commissioner Cass determine that there is no reasonable indication that an industry in the United States is materially injured or threatened with material injury, or that the establishment of an industry in the United States is materially retarded, by reason of imports from Canada of generic cephalexin capsules that are alleged to be sold in the United States at less than fair value.

Register of November 4, 1988 (53 F.R. 44676). The conference was held in Washington, DC, on November 16, 1988, and all persons who requested the opportunity were permitted to appear in person or by counsel.



## VIEWS OF COMMISSIONERS ECKES, LODWICK, ROHR AND NEWQUIST

We determine that there is a reasonable indication that an industry in the United States is threatened with material injury by reason of imports from Canada of generic cephalexin capsules which are alleged to be sold at LTFV. 1/

Like Product and Domestic Injury.

To determine whether there exists a "reasonable indication of material injury or threat of material injury" the Commission must first determine the "like product" corresponding to the imported merchandise under investigation. Like product is defined in section 771(10) of the Tariff Act of 1930 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 Commission's decision regarding like product is essentially a factual determination, made on a case-by-case basis. 3/ The Commission usually considers a number of factors when determining whether a domestic like product is "like" the product subject to investigation. 4/ These

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1/ Material retardation of the establishment of an industry is not an issue and will not be discussed further.

2/ 19 U.S.C. § 1677(10).

3/ *Asociacion Colombiana de Exportadores de Flores v. United States*, 12 CIT \_\_\_, 693 F. Supp. 1165, 1169 (1988) (hereinafter "ASCOFLORES").

4/ Petitioner in this investigation has argued that in enacting the Omnibus Trade and Competitiveness Act of 1988 ("the 1988 Act"), the Congress intended to require the Commission to change its analysis of the like product definition, to one "similar to those that characterize current antitrust analysis." Petition at 13. This assertion is unfounded. The antidumping and countervailing duty laws are not antitrust statutes. See *Maverick Tube Corp. v. United States*, 12 CIT---, 687 F. Supp. 1569, 1573-74 (1988); *USX Corp. v. United States*, 12 CIT ---, 682 F. Supp. 60, 65-68

(continued...)

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. 5/ 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 6/ because minor distinctions are an insufficient basis for finding separate like products. 7/

Petitioner argues that the like product in this investigation should be limited to the scope of the Department of Commerce's investigation, 8/

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4/(...continued)

(1988); 125 Cong. Rec. S 10312 (July 23, 1979). That fact was not changed by the 1988 Act, nor did the Congress make any changes to the definitions of like product or industry in the statute.

5/ See, e.g., Certain All-Terrain Vehicles from Japan, Inv. No. 731-TA-388 (Preliminary), USITC Pub. 2071 (March 1988) at 6; ASCOFLORES, 693 F. Supp. at 1170 n.8.

6/ See, e.g., Operators for Jalousie and Awning Windows from El Salvador, Invs. Nos. 701-TA-272 and 731-TA-319 (Final), USITC Pub. 1934 (Jan. 1987) at 4, n.4.

7/ ASCOFLORES, 693 F. Supp. at 1168-1169. S. Rep. No. 249, 96th Cong., 1st Sess. 90-91 (1979).

8/ In making its like product determination, the Commission may define the domestic like product and industry more broadly than the scope of Commerce's investigation. See ASCOFLORES, 693 F. Supp. at 1168 n.4; Shock Absorbers and Parts, Components, and Subassemblies Thereof from Brazil, Inv. 731-TA-421 (Preliminary), USITC Pub. 2128 (Sept. 1988) at 7. See also Industrial Belts from Israel, Italy, Japan, Singapore, South Korea, Taiwan, The United Kingdom, and West Germany, Invs. Nos. 701-TA-293-295 and 731-TA-412-419, (Preliminary), USITC Pub. 2113 (Aug. 1988) at 6-8 (like product not limited to scope of investigation).

generic cephalixin monohydrate in capsule form. 9/ Respondent contends that the like product includes both generic and brand name cephalixin capsules 10/ and suggests that the like product could include other oral dosage forms of cephalixin, i.e., tablets and powder for oral suspension, as well as capsules. 11/

We define the like product to be cephalixin, whether brand name or generic, in all oral dosage forms. We see no basis in this investigation for distinguishing between generic and brand name cephalixin for purposes of applying the statutory definition of like product. The record in this investigation 12/ establishes that generic and brand name cephalixin

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9/ Petition at 4-18; petitioner's postconference statement at 4-24.

The Department of Commerce defined the imported products subject to this investigation as:

...generic cephalixin capsules from Canada, as provided for in item 411.7600 of the Tariff Schedules of the United States Annotated (TSUSA) and currently classifiable under Harmonized System (HTS) item number 3004.20.00. 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<sub>16</sub>H<sub>17</sub>N<sub>3</sub>O<sub>4</sub>S.H<sub>2</sub>O. 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.

53 Fed. Reg. 47563 (November 23, 1988).

10/ "Brand name" cephalixin refers to cephalixin that has been given a trade name. Cephalixin is marketed under the brand name "Keflex" by Eli Lilly & Co. Lilly held a patent on cephalixin monohydrate which expired in April 1987. Lilly now also markets cephalixin monohydrate tablets under the trade name "Keflet", as well as under the "Keflex" trade name. We understand that the "Keflet" tablet is still under patent. E.g., Report at A-11.

11/ Respondent's postconference statement at 3-6.

12/ Much of the data gathered in this investigation consists of business proprietary information. We are thus unable to discuss fully some aspects of our determination in this opinion.

capsules are identical and bioequivalent. 13/ Thus, as far as characteristics and uses are concerned, there seems to be no significant basis for distinguishing the products on the grounds that one is marketed under a brand name and the other is not. 14/ Further, there do not appear to be any appreciable differences in production processes between generic and brand name cephalexin. 15/

The branded and generic forms of cephalexin are viewed as substantially interchangeable in the marketplace. Among certain physicians there is some resistance to substitution of bioequivalent generic drugs for brand name drugs, and certain states' laws make such substitution more difficult than in others. However, resistance to such substitution resulting from good will generated during the life of the patent, extensive and costly promotional activities, and legal barriers to substitution are declining as hospitals, HMOs, and consumers search for ways to contain the cost of medical care. 16/ When a drug goes "off-patent" and generic producers then

13/ E.g., Petition at 7, 13, Tr. at 44, 58, 117; Respondent's postconference brief at 5.

14/ See, e.g., *Yuasa-General Battery Corp. v. United States*, 11 CIT \_\_\_, 661 F. Supp. 1214, 1217 (1987) (the 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); *EC 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").

15/ We note that the Food and Drug Administration must approve all production processes for manufacture of cephalexin. See, e.g., Report at A-5.

16/ Respondent's postconference statement, attachment A; Tr. at 152-153. Novopharm stated at the conference that the Canadian product competes in all segments of the market with the U.S. product, including Lilly's product. Tr. at 183-85. We note that the state prescription laws referred to by petitioner do not bar physicians from prescribing the generic instead of the

(continued...)

enter the market, it is expected that the former patent holder will lose market share to the new generic competitors. Consistent with this expectation, the record in this investigation indicates that generic cephalixin, from whatever source, has taken market share from the branded product. 17/ Despite the resistance of individual physicians and the fact that substitution of a generic drug for a branded drug is more difficult in some states than others, it is evident that generic cephalixin is substituting for brand name cephalixin.

There are some differences in the channels of distribution of brand name and generic cephalixin capsules, although the initial purchasers of cephalixin from producers and importers all sell to the same types of end-users. 18/ There is also a substantial difference in the price of the branded product versus the generic product. 19/ However, we find that the identical characteristics and uses of the generic and brand name capsules, the evident similarity in production processes, 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 the branded as

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16/(...continued)  
brand name drug. Certain states' laws may hinder pharmacists and/or patients from substituting a generic drug for a brand name drug when the physician prescribes the brand name drug.

17/ E.g., Report at A-6--A-7; A-13; A-28.

18/ See Report at A-14.

19/ See Report at A-36.

well as the generic forms of cephalexin are the like product in this investigation. 20/

We also find it to be appropriate in this preliminary investigation to define the like product to include cephalexin capsules, tablets, and powder for oral suspension. 21/ The products are simply different dosage forms of the same drug, 22/ and their essential characteristics and uses are similar if not identical. Further, the evidence gathered in this investigation indicates that all three forms are or could be manufactured by producers of capsules at the same facilities. 23/ 24/

The domestic industry is defined in section 771(4)(A) of the Tariff Act of 1930 as:

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20/ Further, while similarities or differences in channels of distribution have been one factor considered by the Commission in defining like products, the Commission has rejected arguments 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 (the 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, USITC Pub. 1417 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").

21/ Commissioner Lodwick intends to consider this question more fully in any final investigation.

22/ In particular, cephalexin tablets contain the same mixture of active and inactive ingredients as capsules. See Report at A-4.

23/ We intend to consider further this like product definition in any final investigation, in particular, whether bulk cephalexin should also be included in the like product. We also intend to consider whether Keftab, a form of cephalexin hydrochloride manufactured under patent by Eli Lilly, should be included in the like product in any final investigation, and will seek more extensive data on this product.

24/ Commissioner Rohr notes that there is a strong case to be made for including bulk cephalexin in the like product. He did not do so in this preliminary investigation largely due to the scarcity of data on bulk cephalexin production.

... 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. 25/

Accordingly, we define the industry to be the U.S. producers of cephalexin in oral dosage form.

One issue in this investigation is whether processing bulk cephalexin into oral dosage forms such as capsules is sufficient production-related activity to be considered "domestic production" or whether such firms are more appropriately considered importers or "packagers" rather than producers. Eli Lilly & Co. produces bulk cephalexin as well as the dosage form of the drug, and there is thus no question that it is a producer. However, other producers of dosage form cephalexin import bulk cephalexin which is then processed into dosage form. The Commission must thus consider whether such processing firms should be included in the industry.

Factors considered by the Commission in prior investigations in deciding whether a firm is a producer have included the extent and source of a firm's capital investment, the technical expertise involved in production activity in the United States, the value added to the product in the United States, employment levels, the quantity and type of parts sourced in the United States, and any other costs and activities in the United States directly leading to production of the like product. 26/

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25/ 19 U.S.C. § 1677(4)(A).

26/ See, e.g., Certain All-Terrain Vehicles from Japan, Inv. No. 731-TA-388 (Preliminary), USITC Pub. 2071 (March 1988) at 10-11; Erasable Programmable Read Only Memories from Japan, Inv. No. 731-TA-288 (Final), USITC Pub. 1927 (December 1986) at 11 & n.23; Low-Fuming Brazing Copper Wire and Rod from New Zealand, Inv. No. 731-TA-246 (Final), USITC Pub. 1779 (November 1985) at 6.

Although value added by processing bulk cephalexin is low, 27/ and employment levels are not high, 28/ a not insignificant amount of capital was expended by the producers for which the Commission has information. 29/ Further, production of dosage form cephalexin appears to involve considerable technical expertise. 30/ Accordingly, we determine 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 industry. 31/ 32/

A further question presented by the definition of the industry is whether producers with production facilities located in the U.S. Virgin Islands are considered part of the industry "in the United States." "United States" is not defined in the antidumping or countervailing duty laws. For purposes of this preliminary determination, we include producers located in the U.S. Virgin Islands in the industry. Although the U.S. Virgin Islands are outside the customs territory of the United States, 33/ we are directed to make our determination as to whether there is a reasonable indication of material injury to a domestic industry "in the United States," 34/ not in

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27/ See Report at A-21.

28/ See Report at A-18--A-19.

29/ See Report at A-22.

30/ See Report at A-4--A-5.

31/ Commissioner Rohr notes that this was a close decision.

32/ Commissioners Lodwick and Newquist intend to consider further these producers engaged in sufficient production-related activity in any final investigation

33/ See 19 U.S.C. § 1202, Headnote 2.

34/ 19 U.S.C. § 1673b(a).



the "customs territory of the United States." 35/ We have previously considered a producer located in a foreign trade zone (thus outside the customs territory of the United States) to be a producer in the United States. 36/ We, therefore, have considered producers located in the U.S. Virgin Islands to be producers in the "United States" for the purpose of this determination.

Reasonable Indication of Threat of Material Injury.

We have made our affirmative preliminary determination on the basis of a reasonable indication of a threat of material injury rather than material injury. 37/ We did not make our determination based on present material injury because, considering the information available, there does not appear to be even a reasonable indication of material injury. Available financial data indicate an industry that is [ \*\*\* ], 38/ While a number of industry indicators have declined since Lilly's patent expired, such a decline is not indicative of material injury for this industry, because such a decline may be expected in the situation when a monopoly market suddenly becomes

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35/ "[A] patent distinction is drawn between the boundaries delineating the geographic territory of the United States and the customs territory of the United States." Hawaiian Independent Refinery v. United States, 460 F.Supp. 1249 (Cust. Ct. 1978).

36/ See Certain All-Terrain Vehicles from Japan, Inv. No. 731-TA-388 (Preliminary), USITC Pub. 2071 (March 1988) at 10-11 (including Kawasaki Motors Manufacturing Corp. in the U.S. industry), A-5 (Kawasaki production facilities located in foreign trade zones).

37/ Although petitioner indicated that the Commission need not address the issue of threat of material injury because it viewed the investigation as focusing solely on present material injury, the statute requires that we consider threat of material injury. See 19 U.S.C. § 1673b(a). See also Budd Company Railway Division v. United States, 1 CIT 67, 74, 507 F. Supp. 997, 1003 (1980) reh'g denied, 1 CIT 156 (1981).

38/ See Report at A-20.

subject to competitive pressures. 39/ Indeed, it is expected that when a drug goes "off-patent" those generic producers who enter the market immediately will reap higher prices and profits than are possible at a later date when increasing competition results in lower prices and profit margins. 40/

Accordingly, we find the data supporting a reasonable indication of threat of material injury to be more persuasive than the case for a preliminary present material injury determination. 41/

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." 42/ The ten 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,

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39/ With respect to cephalexin capsules, which accounted for 80 percent of demand in 1987, five producers and six importers from a number of countries have entered the marketplace since April 1987. See Report at A-7.

40/ See Report at A-7; A-20.

41/ We note that our affirmative preliminary determination was based in part on the fact that we cannot find that there is no likelihood that contrary evidence would be developed in any final investigation.

42/ 19 U.S.C. § 1677(7)(F)(ii).

(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 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. 43/

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. 44/

We consider these factors in turn:

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43/ 19 U.S.C. § 1677(7)(F)(i), as amended by 1988 Act §§ 1326(b), 1329.

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

There is no subsidy alleged in this antidumping investigation.

The Canadian exporter's capacity to produce cephalexin increased between 1986 and 1987. This increase occurred because production of cephalexin was transferred to a separately dedicated plant, a move prompted by Food & Drug Administration requirements that cephalosporins be produced in a dedicated facility separate from the manufacture of other antibiotic products. 45/ [ \*\*\* ]. 46/ [ \*\*\* ], 47/ there is the potential for a significant increase of exports to the United States. 48/ 49/ Respondent [ \*\*\* ]. 50/ 51/ 52/

45/ Report at A-25; A-26, Table 17.

46/ While reported capacity utilization for the Canadian exporter [ \*\*\* ]. Compare Report at A-15--A-16 with A-26.

47/ See Report at A-27.

48/ We examine only the imports that are alleged to be sold at LTFV, generic cephalexin capsules. However, in assessing threat of material injury, the ability of the Canadian producer to divert other cephalexin production to capsule production may be a relevant factor for our consideration. We note, however, that production of other forms of cephalexin is primarily shipped within Canada, [ \*\*\* ]. Report at A-27.

49/ Commissioners Rohr and Newquist intend to explore in any final investigation whether the price of drugs in Canada is controlled by the national or provincial governments, and whether any such price controls may create an incentive for increased exports to the United States. See generally Tr. at 170.

50/ See Report at A-28.

51/ We note that [ \*\*\* ] if, in any final investigation, the import figures are examined on a monthly, instead of a quarterly, basis. The interim period examined by the Commission includes the first quarter of 1987, when Lilly's patent was still in effect. This may skew a comparison of market penetration between the first three quarters of 1988 and the first three quarters of 1987. In addition, to the extent that the Commission did not receive complete data, market penetration levels are overstated.

52/ Commissioner Newquist notes that, measured in terms of value, the imports from Canada achieved a much lower market share than if measured in terms of volume. [ \*\*\* ]. See Report at A-28.

The effect of Canadian generic cephalixin capsules on prices in the United States for the like product is unclear. The cephalixin market is very price competitive. 53/ Despite the competitive nature of this environment, sharply declining prices in the generic segment of the market, 54/ 55/ and an apparent decline in demand 56/ our data indicate that the respondent has [ \*\*\* ] during the period covered by this investigation. There are no evident quality differences between the domestic and imported product and, thus, [ \*\*\* ]. However, underselling data are ambiguous on this point, 57/ and we intend to revisit this question in any final investigation.

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53/ See Report at A-7.

54/ See Report at A-31. Such declining prices, however, may be unrelated to the presence of the Canadian imports, as sharply declining prices are expected when competition increases after a drug goes off-patent. See Report at A-7.

55/ While branded cephalixin is part of the like product, branded cephalixin prices have fluctuated at a much higher level than prices of the generic product. See Report at A-70--A-76. 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); 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") (Eckes, Lodwick, Rohr).

56/ We note that the apparent decline in demand for cephalixin between the first three quarters of 1987 and the first three quarters of 1988 may be due to factors related to the startup of generic cephalixin production. See Report at A-12, n.1.

57/ While there appear to be few instances of underselling between the imported product and the generic product, our pricing data understates the degree of underselling because certain of the Canadian prices obtained were not adjusted for all rebates and discounts. See Report at A-31.

There has not been an increase in inventories of Canadian generic cephalixin capsules in the United States. [ \*\*\* ]. 58/

The discussion of underutilized capacity required by factor six is subsumed in the discussion of factor two above.

We find no other demonstrable adverse trends that indicate the probability that importation of the merchandise will be the cause of actual injury.

There is no evidence of product shifting in this investigation as described in factor eight because there are no known antidumping or countervailing duty investigations or orders that apply to Canadian production facilities that can be used to produce cephalixin capsules.

Cephalixin capsules are not a raw agricultural product nor a product processed from such a raw agricultural product. There is no likelihood of increased imports by reason of shifting production from a raw agricultural product to cephalixin capsules.

Imports of generic cephalixin from Canada appear to have had little effect on research and development in the domestic cephalixin industry. The original patent holder of cephalixin has already paid for the research and development needed to develop an oral dosage form of cephalixin. The generic producers rely on this research when seeking approval from the Food and Drug Administration 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 do not appear to be any dumping findings or antidumping

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58/ See Report at A-25.

orders in effect in third countries with respect to cephalexin capsule imports from Canada. 59/

Our determination of a reasonable indication of threat of material injury is based upon the [ \*\*\* ] of the alleged LTFV imports from Canada while U.S. cephalexin consumption has declined, the [ \*\*\* ] of the Canadian exporter of the allegedly LTFV product, and incomplete pricing data that suggests that the Canadian imports may have obtained their [ \*\*\* ] share of the market by price underselling. 60/ The decline in a number of industry indicators, [ \*\*\* ] 61/ suggest that the domestic industry may be vulnerable to increasing imports from Canada.

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59/ See Tr. at 104; 185.

60/ Commissioner Newquist notes that the record in this investigation barely supports an affirmative preliminary determination.

61/ Report at A-15-A-16; A-20.





## DISSENTING VIEWS OF ACTING CHAIRMAN ANNE E. BRUNSDALE

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

December 12, 1988

In this investigation, I disagree with the majority of my colleagues and determine that there is no reasonable indication that the domestic industry producing cephalexin is being materially injured by unfair imports from Canada, nor is there any reasonable indication that the domestic industry is threatened with material injury by reason of these imports.<sup>1/</sup> I offer these views to explain my analysis in this case.

Legal Standard in Preliminary Investigations

The Commission has in recent opinions offered quite a bit of explanation on the analytical framework in preliminary Commission investigations.<sup>2/</sup> As I stated in my views in Steel Rails from Canada, I believe that a negative determination, resulting from no reasonable indication of material injury or threat of material injury, might occur on one of two bases. First, Petitioner may offer no evidence or

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<sup>1/</sup> Material retardation of the domestic industry is not an issue in this investigation and will not be discussed further.

<sup>2/</sup> See e.g., New Steel Rails from Canada, Inv. No. 701-TA-297, 731-TA-422 (Preliminary), USITC Pub. 2135 (Additional Views of Commissioner Alfred Eckes, Additional Views of Commissioner Ronald A. Cass, Views of Acting Chairman Anne E. Brunsdale) (November 1988).

an insignificant amount of evidence in support of its position. Second, evidence collected by staff and that presented by the Respondent in favor of a negative determination might outweigh the evidence presented by the Petitioner.<sup>3/</sup> In both cases, there must be no likelihood that contrary evidence central to the negative determination will arise in a final investigation.<sup>4/</sup> This investigation is one in which the latter basis for a negative is present: I believe the evidence favoring a negative determination far outweighs the evidence of material injury presented by the Petitioner in this case.<sup>5/</sup> Therefore, I make a negative determination in this preliminary investigation.

#### Like Product and the Domestic Industry

The Commission's threshold inquiry in Title VII investigations is the determination of the appropriate like product and domestic industry. The statute defines like product as the product "like, or in the absence of like, most similar in characteristics and uses with, the article subject

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<sup>3/</sup> Id. at 68. Using either formulation, the evidence is clear and convincing that there is no reasonable indication of material injury.

<sup>4/</sup> See American Lamb v. United States, 785 F.2d 994, 1001 (Fed. Cir. 1986).

<sup>5/</sup> In addition, I believe that the available evidence is complete and that no contrary evidence would arise in any final investigation.

to investigation."6/ The domestic industry under investigation consists of all domestic producers of the like product.7/ In this case, I believe the like product consists of brand name and generic cephalexin capsules, tablets, and powder for oral suspension.

Respondent and Petitioner differ on whether brand name and generic cephalexin are the same like product.8/ Both parties agree that brand name and generic cephalexin are bioequivalent and identical in physical characteristics. In addition, both agree that brand name and generic capsules are produced using the same manufacturing process.9/ Also, while there is some evidence that brand name and generic cephalexin are sold to different middlemen in the chain of distribution, that evidence is mixed.10/

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6/ See 19 U.S.C. 1677(10). The Commission traditionally has examined a number of factors in its like-product analysis, including (1) physical characteristics and uses, (2) interchangeability, (3) channels of distribution, (4) common manufacturing facilities and employees, and (5) customer or producer perceptions. I agree with the Petitioner's assertion that these five inquiries act as proxies for two questions -- how substitutable are the products under scrutiny from the perspective of the manufacturer and from the perspective of the consumer? I believe that these five areas of inquiry are among those the Commission can use to gather evidence on the two questions of substitutability that are at the heart of the like-product determination.

7/ See 19 U.S.C. 1677(4)(A).

8/ See, e.g., Respondent's Post Conference Brief at 5, Petitioner's Post Conference Brief at 10-15.

9/ See Report at A-4.

10/ See Report at A-29, Tr. at 183-85.

Petitioner argues that, in practice, brand name and generic cephalixin are not substitutable for a number of reasons, including extensive advertising for brand name cephalixin, physicians' habit of only prescribing brand name medicines, and physicians' fear of malpractice claims resulting from prescribing generic drugs.<sup>11/</sup> These arguments, however, are starkly refuted by market share data, which indicate a [\*\*\*\*\*  
 \*\*\*\*\*  
 \*\*\*\*\*].<sup>12/</sup> Clearly, consumers believe the two are substitutable, and are increasingly choosing the cheaper generic version over the more costly brand name variety wherever possible.

Another factor allowing increased substitution of generic for brand name cephalixin are state laws designed to promote the use of generic drugs. In 26 states, the prescription form used by doctors is designed to allow pharmacists to substitute generic for brand name drugs unless the physician expressly forbids the substitution.<sup>13/</sup> This provides further evidence that generic and brand name

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<sup>11/</sup> See Petitioner's Post Conference Brief at 10.

<sup>12/</sup> See Report at A-28.

<sup>13/</sup> See Report at A-3. Nineteen states use a two-line form that forces physicians to specifically state that generic substitution is permissible, a factor that favors brand name over generic drugs. In five states, either prescription form is permissible. Id.

cephalexin are substitutable and should be considered the same like product.

Thus, based on the similarity in physical characteristics, manufacturing processes, and consumer perceptions, I conclude that brand name and generic cephalexin should be considered the same like product in this investigation. I also believe that the like product should include cephalexin capsules, tablets, and powder for oral suspension. The essential characteristics of all three forms are similar and the uses for all three are also nearly identical.<sup>14/</sup>

The domestic industry in this case therefore consists of the six domestic producers that manufacture brand name or generic cephalexin capsules, tablets, and oral suspension -- Eli Lilly & Co., Biocraft Laboratories, Inc., Vitarine Pharmaceutical, Barr Laboratories, Zenith Laboratories, and Jerome Stevens Pharmaceuticals.<sup>15/</sup>

#### Condition of the Domestic Industry

The production and financial data for this industry are mixed, indicating a slight decline over the three-year period of investigation and an industry that remained in good health

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<sup>14/</sup> As reported by the staff, the physical composition of all three forms are very similar. See Report at A-5-7.

<sup>15/</sup> See id. at A-10-11.

throughout.<sup>16/</sup> As demonstrated below, changes in the condition of the domestic industry can be linked to the emergence of generic cephalexin from all sources in 1987, and not to the introduction of Canadian cephalexin into the market.

Capacity to produce cephalexin in all dosage forms skyrocketed in 1987, the year generic producers entered the market. Capacity rose from [\*\*\*\*\*] kilograms in 1985 and [\*\*\*\*\*] kilograms in 1986 to [\*\*\*\*\*] kilograms in 1987.<sup>17/</sup> Production remained steady over the three-year period, with [\*\*\*\*\*] kilograms produced in 1985, [\*\*\*\*\*] kilograms in 1986, and [\*\*\*\*\*] in 1987. Thus, capacity utilization fell dramatically with the advent of generic drug capacity in 1987.<sup>18/</sup>

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<sup>16/</sup> Most of the information made available to the Commission in this investigation is confidential because of the structure of the domestic industry and the presence of only one Canadian producer and importer under investigation. Thus, individual firm data and some aggregate data are confidential in this case. The information in this section comes from the [\*\*\*\*\*] domestic producers -- [\*\*\*\*\*].

<sup>17/</sup> See Report at A-15 (Table 4), A-16 (Table 5). In the first nine months of 1987, capacity stood at [\*\*\*\*\*] kilograms, compared with [\*\*\*\*\*] kilograms in the same period of 1988. Id.

<sup>18/</sup> Average capacity utilization for capsule manufacturing operations was [\*\*] percent in 1985, [\*\*] percent in 1986, [\*\*] in 1987, [\*\*] percent for three quarters of 1987 and [\*\*] percent for the first three quarters of 1988. Id. at A-15 (Table 4). Average capacity utilization for tablet and oral suspension operations was [\*\*] percent in 1985, [\*\*] percent in 1986, [\*\*] percent in 1987, [\*\*] percent for the first three quarters of 1987, and [\*] percent for the first three quarters of 1988. Id. at A-16 (Table 5).

The volume of domestic shipments increased for the first three years of the investigation, but turned down in the first nine months of 1988. The volume increased from [\*\*\*\*\*] kilograms in 1985 to [\*\*\*\*\*] kilograms in 1986 and [\*\*\*\*\*] kilograms in 1987.<sup>19/</sup> Comparing interim periods, volume declined from [\*\*\*\*\*] kilograms to [\*\*\*\*\*] kilograms between 1987 and 1988.<sup>20/</sup> The value of domestic shipments peaked in 1986 and declined in 1987 and 1988. Shipments totalled [\*\*\*\*\*] million in 1985, [\*\*\*\*\*] million in 1986, [\*\*\*\*\*] million in 1987,<sup>21/</sup> and thereafter [\*\*\*\*\*] from [\*\*\*\*\*] million in interim 1987 to [\*\*\*\*\*] million in interim 1988.<sup>22/</sup> The drop in value over the course of the investigation was much more pronounced than the drop in volume.

Inventories of domestic producers showed no clear trends. They stood at [\*\*\*\*\*] kilograms in 1985, [\*\*\*\*\*] kilograms in 1986, and [\*\*\*\*\*] kilograms in 1987.<sup>23/</sup>

Employment and total compensation increased sharply in 1987 with the entry of generic producers into the market. Employment was [\*\*] in 1985, [\*\*] in 1986, and [\*\*\*] in

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<sup>19/</sup> See Report at A-17 (Table 6).

<sup>20/</sup> Id.

<sup>21/</sup> Id.

<sup>22/</sup> Id.

<sup>23/</sup> Id. Inventory levels stood at [\*\*\*\*\*] kilograms in the first three quarters of 1987 and [\*\*\*\*\*] kilograms for the first nine months of 1988. Id.

1987,<sup>24/</sup> but fell slightly in the interim periods to [\*\*\*] in 1987 and [\*\*\*] in 1988.<sup>25/</sup> Total compensation was [\*\*\*\*] million in 1985, [\*\*\*\*] million in 1986, and [\*\*\*\*] million in 1987,<sup>26/</sup> and rose slightly from [\*\*\*\*] million in interim 1987 to [\*\*\*\*] million in interim 1988.<sup>27/</sup>

The available financial data indicate that while the industry's condition declined somewhat during the investigation, it continues to be profitable.<sup>28/</sup> Net sales were [\*\*\*\*\*] million in 1987, [\*\*\*\*\*] million in the first three quarters of 1987, and [\*\*\*\*\*] million in the first three quarters of 1988.<sup>29/</sup> The cost of goods sold also declined, but not as rapidly as net sales, so that the cost of goods sold as a percentage of net sales increased from [\*\*] percent for all of 1987 to [\*\*] percent in the first three quarters of 1988.<sup>30/</sup> This indicates that downward market pressures are forcing producers to cut prices more deeply than they can cut their costs. Another indication of

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<sup>24/</sup> Id. at A-19 (Table 10).

<sup>25/</sup> Id.

<sup>26/</sup> Id.

<sup>27/</sup> Id.

<sup>28/</sup> Only [\*\*\*] of the six producers, accounting for [\*\*] percent of all generic cephalixin production, were able to supply financial data -- [\*\*\*\*\*].

<sup>29/</sup> See id. at A-20 (Table 13).

<sup>30/</sup> Id. The cost of goods sold as a percentage of net sales was [\*\*] percent for the first three quarters of 1987. Id.



this is the fall in operating income from [\*\*\*\*\*] million in the first three quarters of 1987 to [\*\*\*\*] million in the first three quarters of 1988.<sup>31/</sup> Despite this decline, operating income in this industry is still significantly higher than operating income for the drug industry as a whole.<sup>32/</sup>

The above information depicts an industry that went through a period of rapid expansion and high profitability and is now retreating from that point. The available information does not, however, indicate to me that the industry is materially injured. It is still profitable, and its production factors are relatively stable. Under these conditions, I believe the impact of unfair imports would have to be significant and quite clear before I could conclude that this industry was suffering material injury that had been caused by imports. In this case, the effect of the unfair imports is clearly not that significant, and any downturn in the industry's performance is explained by other factors.

Any Injury Suffered by the Domestic Cephalexin Industry in This Case Was Not Caused by Canadian Imports

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<sup>31/</sup> Id. Operating income for all of 1987 was [\*\*\*\*\*] million, indicating that the profits had already begun to decline by the fourth quarter of 1987. Id.

<sup>32/</sup> See id. at A-23.

In this case, the imported product and the product manufactured by the domestic industry are highly substitutable. Cephalexin from any source must meet FDA standards governing the drug's composition and manufacturing process if it is to be sold in the United States.<sup>33/</sup> We have no evidence that consumers perceive differences between imported and domestic cephalexin.<sup>34/</sup> Therefore, sales of Canadian cephalexin will directly affect the fortunes of the domestic industry.

In addition, the Petitioner alleges that the margin of dumping in this case ranges from 18.4 to 39.7 percent.<sup>35/</sup> These margins are fairly high, so that, in some cases, if the Canadians were forced to increase their prices by the full amount of these margins, they would be priced out of the domestic cephalexin market.<sup>36/</sup>

Despite these factors, Canadian imports have only made minimal inroads into the domestic cephalexin market. The volume of imports from Canada has been consistently low over

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<sup>33/</sup> See Report at A-5.

<sup>34/</sup> See *id.* at A-5 (pharmacists see no difference between the two).

<sup>35/</sup> See *id.* at A-9. The margins are based on actual sales prices in Canada and the United States, and are the best information available at this stage of the investigation.

<sup>36/</sup> In my analysis, I assume that if the foreign producer were found to be dumping and duties were imposed, an amount equal to the entire margin of dumping would be passed along from the foreign manufacturer to the customer in the form of a price increase. In this case, that translates into price increases of 18 to 40 percent by Canadian producers.

that portion of the period of investigation in which generic drugs were available.<sup>37/</sup> Imports started in April 1987 when the market was opened to generic cephalixin. By volume, they reached [\*\*\*\*\*] kilograms in the April-September 1987 period,<sup>38/</sup> [\*\*\*\*\*] kilograms in the last quarter of 1987,<sup>39/</sup> and [\*\*\*\*\*] kilograms in the first three quarters of 1988.<sup>40/</sup> The value of the Canadian imports [\*\*\*\*\*] over the period of investigation. Thus, measured by value, the unfair imports totalled [\*\*\*\*] million for the last nine months of 1987, compared with [\*\*\*\*] million for the first three quarters of 1988.<sup>41/</sup>

By volume, market penetration was [\*] percent in 1987 and [\*] percent for the first three quarters of 1988.<sup>42/</sup> By value, market penetration was [\*] percent in 1987 and [\*] percent in the first three quarters of 1988.<sup>43/</sup> These figures for import volume, value, and market share indicate

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<sup>37/</sup> Only generic cephalixin was imported from Canada during this investigation.

<sup>38/</sup> See Report at A-28 (Table 20).

<sup>39/</sup> Id.

<sup>40/</sup> Id. Arguably, if you compare the two three-quarter periods, [\*\*\*\*\*].

<sup>41/</sup> Id.

<sup>42/</sup> Id. at A-28 (Table 21).

<sup>43/</sup> Id.

that the Canadian presence in the U.S. market is not very significant.

The pricing data also present no clear evidence that the Canadian product is injuring U.S. sales.<sup>44/</sup> In most cases, the price evidence revealed overselling by the Canadian product, not underselling.<sup>45/</sup> Therefore, despite the high degree of substitutability, the Canadian imports are unlikely to be the factor responsible for the downward drift of domestic industry indicators.

A much more plausible explanation is the nature of the prescription drug industry and the effect of introducing generic drugs into the marketplace. Encouraged by a number of factors, the sale of generic drugs has increased dramatically in the U.S. market and is expected to continue this course.<sup>46/</sup> Experience in markets where generic drugs

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<sup>44/</sup> Not all of the Canadian prices were properly adjusted for all rebates and discounts. See Report at A-30, A-33. This factor limit the usefulness of this information. However, it is clear that, at best, the pricing evidence is mixed, revealing neither a consistent trend of overselling nor underselling.

<sup>45/</sup> However, if all instances in which the Canadian prices were not properly adjusted were removed from consideration, the instances of underselling and overselling would be roughly even. See Report at A-85-86 (Tables 27 and 28). In addition, it appears that [\*\*\*\*\*] in this industry is more responsible for price trends than sales of Canadian imports.

<sup>46/</sup> The leading factor encouraging the use of generics is the nationwide effort to reduce the costs of medical care. See Report at A-6. Generic drugs also offer the opportunity for higher profits for pharmacists, and their approval has been speeded by the FDA. *Id.* Some experts expect that the market for generic drugs could double by 1992. *Id.* at A-6.

have been introduced reveals that introducing of generics substantially increases competition, and reduces the sales and profits of the brand-name drug manufacturers.<sup>47/</sup>

Normally, the generic producers that enter a market first after the expiration of the brand name drug's patent are the generic producers that make the greatest profits. Over time, as the FDA approves the sale of the generic drug by a number of other producers, the profitability of generic sales drops. The speed of the drop in profitability normally depends on the number of generic producers entering the market and the popularity of the brand name drug.<sup>48/</sup> Parties explained to the Commission that the normal pricing practice with generic drugs is to introduce the generic drug at half the price of the brand name drug.<sup>49/</sup> In this investigation, both these factors mitigated against the ability of domestic producers to earn sustained high profits.

At present, there are six domestic and six foreign producers that manufacture cephalexin for sale in the United States, eleven of which entered the market after April 1987.<sup>50/</sup> Cephalexin is a popular drug, recommended for a

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<sup>47/</sup> Id. at A-6.

<sup>48/</sup> Id.

<sup>49/</sup> Id. The price drops from that point, by an amount and at a rate that depends on the competitive conditions of that market.

<sup>50/</sup> Id.

number of serious bacterial infections.<sup>51/</sup> The market for the drug was strong enough to encourage all eleven firms to enter, and it appears that the first generic firms to enter the market made large profits because of their early entry. In fact, Biocraft stated in its 1988 annual report:

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.<sup>52/</sup>

As Biocraft itself recognized, prices and profits in this initially lucrative market were affected adversely not by unfairly traded imports, but by the normal, and expected, competitive pressures found in the generic drug market.<sup>53/</sup> Thus, the downward trends present in this domestic industry can all be adequately explained by the nature of the market for generic drugs, and have nothing to do with the presence of unfair imports from Canada. I conclude that the requisite causal link is therefore not present in this case, and I therefore determine that there is no reasonable indication

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<sup>51/</sup> Id. at A-1.

<sup>52/</sup> Id. at A-20, quoting the Biocraft Annual Report at 2-3. Biocraft was one of the first firms to enter the generic cephalixin market.

<sup>53/</sup> Experts at the FDA also note and expect this trend in the generic drug market -- high initial profits, followed by strong competition, and decreases in prices and profits. If anything, according to FDA experts, the generic drug marketplace is growing more competitive and the window for high profits and limited competition may be disappearing, especially when the brand name drug is popular, like cephalixin. Id.

that the domestic cephalixin industry is injured by reason of unfair imports from Canada.

No Threat of Material Injury

An analysis of the factors the Commission is to consider in evaluating the threat of material injury in its investigations leads me to conclude that no reasonable indication of threat of material injury is present in this case.<sup>54/</sup>

Canadian Capacity. The production capacity of the Canadian firm exporting to the United States [\*\*\*\*\*] in 1987, the year generic producers could begin legally producing cephalixin for sale in the United States, and [\*\*\*\*\*]. Capacity for capsules was [\*\*\*\*\*] kilograms in 1985, [\*\*\*\*\*] kilograms in 1986, and

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<sup>54/</sup> The factors the Commission must consider in threat cases are an increase in capacity or existing unused capacity, or the presence of underutilized capacity, a rapid increase in market penetration and the likelihood it will increase to injurious levels, the probability that imported merchandise will enter the United States at prices causing price suppression or depression, substantial increases in inventories, the potential for product shifting, the actual and potential negative effects on the existing development and production efforts of the domestic industry, and any other demonstrable adverse trends. In this case, there are no allegations of subsidization, so consideration of the nature of the subsidy is not a relevant inquiry. See 19 U.S.C. 1677(7)(F)(i). The Commission's determinations in this area are not to be based on "mere conjecture or supposition." 19 U.S.C. 1677(7)(F)(ii). In addition, there are no third country dumping findings or remedies in place for cephalixin, so that factor need not be considered in this investigation. See 19 U.S.C. 1677(7)(F)(iii).

[\*\*\*\*\*] kilograms in 1987.<sup>55/</sup> Capacity in interim 1987 was [\*\*\*\*\*] kilograms, [\*\*\*\*\*]. Capsule capacity utilization was [\*\*\*\*\*] percent in 1985 to [\*\*\*] percent in 1986, [\*\*] percent in 1987, [\*\*] percent in interim 1987, and [\*\*] percent in interim 1988.<sup>56/</sup>

Capacity for tablets and oral suspension followed a similar trend. Capacity was [\*\*\*\*\*] kilograms in 1985, [\*\*\*\*\*] kilograms in 1986, [\*\*\*\*\*] kilograms in 1987, [\*\*\*\*\*] kilograms in interim 1987 and [\*\*\*\*\*] kilograms in interim 1988.<sup>57/</sup> Capacity utilization was [\*\*\*\*\*] percent in 1985, [\*\*] percent in 1986, [\*\*] percent in 1987, [\*\*] percent in interim 1987, and [\*\*] percent in interim 1988.<sup>58/</sup>

These figures indicate some unused capacity in the Canadian industry, although there is no sign of any increase in capacity.<sup>59/</sup> Thus, the evidence on this point is mixed.

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<sup>55/</sup> Report at A-26 (Table 17).

<sup>56/</sup> Id.

<sup>57/</sup> Id.

<sup>58/</sup> Id.

<sup>59/</sup> It appears that all firms in this industry [\*\*\*\*\*]. I am therefore not persuaded that these figures should be accorded a great deal of significance.



**Market Penetration.** The market penetration of Canadian imports remained low throughout the period of investigation and showed little likelihood of rising to injurious levels. Measured by value, market penetration was [\*] percent in 1985 and 1986, [\*] percent in 1987, and [\*] percent in the first three quarters of 1988.<sup>60/</sup> Measured by volume, market penetration was [\*] percent in 1985 and 1986, [\*] percent in 1987, and [\*] percent for the first three quarters of 1988.<sup>61/</sup> These numbers indicate neither a rapid increase nor an increase to injurious levels in the future.

**Price Suppression or Depression.** As stated earlier,<sup>62/</sup> the available pricing evidence suggests that overselling by Canadian imports is at least as prevalent as underselling in this market. Although there is some question about the reliability of this pricing evidence, even if only the "reliable" evidence were to be considered,<sup>63/</sup> overselling would still be as prevalent as underselling. Therefore, I conclude that this factor supports a negative determination.

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<sup>60/</sup> See Report at A-28 (Table 21).

<sup>61/</sup> Id.

<sup>62/</sup> See supra notes 44 to 45 and accompanying text.

<sup>63/</sup> That is, the Canadian prices that were adjusted for discounts and rebates.

Increase in Inventories. As noted earlier, inventories of U.S. producers did not reveal a steady pattern of increases or decreases.<sup>64/</sup> Canadian importers' inventories [\*\*\*\*\*  
\*\*\*\*\*] from [\*\*\*] kilograms for the first three quarters of 1987 to [\*\*\*] kilograms for the first three quarters of 1988.<sup>65/</sup> While these numbers indicate \*\*  
\*\*\*\*\*, when compared to the level of Canadian imports or to domestic consumption, I would not term them "substantial." Thus, I believe this factor also supports a negative determination.

Potential for Product Shifting. No potential for product shifting, as defined by the statute, exists in this case.<sup>66/</sup> This factor therefore supports a negative determination.

#### Negative Effects on Development and Production Efforts.

Expenditures on research and development appear to be tied closely to the introduction of generic cephalexin, and bear no relation to the activity of Canadian producers in the domestic market. Research and development expenses for [\*\*\*\*\*] were comparable in [\*\*\*\*\*], with spending at [\*\*\*\*\*] and [\*\*\*\*\*] in 1987.<sup>67/</sup>

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<sup>64/</sup> See supra note 23 and accompanying text.

<sup>65/</sup> See Report at A-25, A-25 (Table 16).

<sup>66/</sup> See id. at A-27-28.

<sup>67/</sup> Id. at A-22.

In 1986, the year prior to the introduction of generic cephalixin, expenses increased greatly to [\*\*\*\*\*].<sup>68/</sup> There is no evidence to support the contention that unfair imports had a negative effect on research and development in this industry.

Taken together, the factors we are required to consider in threat cases convincingly point to a negative threat determination. I therefore determine that there is no reasonable indication of a threat of material injury to the domestic cephalixin industry in this case.

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<sup>68/</sup> Id.



DISSENTING VIEWS OF COMMISSIONER RONALD A. CASS

Generic Cephalexin Capsules from Canada  
Inv. No. 731-TA-433  
(Preliminary)

I dissent from the Commission's affirmative determination in this preliminary investigation. On the basis of the record before us, I do not believe that there is a reasonable indication that an industry in the United States has been materially injured by reason of cephalexin capsules from Canada traded at less than fair value, or is threatened with such injury.<sup>1/</sup>

I. LEGAL STANDARD GOVERNING DISPOSITION OF  
PRELIMINARY INVESTIGATIONS

Under the statutory standard that governs Title VII preliminary investigations such as the one now before us, the Commission is required to determine whether there is a "reasonable indication" that an industry in the United States has been materially injured, or is threatened with such injury, by reason of imports that have allegedly been dumped or subsidized.<sup>2/</sup> In another recent preliminary investigation, New

<sup>1/</sup> Given the manner in which I have defined the domestic industry in this case (see discussion, infra, at 47-58), material retardation of a domestic industry is not an issue; a domestic industry consisting of the producers of cephalexin capsules is well-established, and has been for quite some time.

<sup>2/</sup> 19 U.S.C. Sections 1671b(a), 1673b(a). The statute also contemplates that the Commission will, where appropriate, reach an affirmative determination in a preliminary investigation if there is a reasonable indication that the development of a domestic industry has been materially retarded by reason of

Steel Rails from Canada, I described my understanding of the manner in which the Commission has interpreted this standard.<sup>3/</sup> I will not discuss that issue at length again here, but I believe a brief reprise important to disposition of this investigation. Indeed, although as a dissenting commissioner I will not see the majority's views until they are released to the public,<sup>4/</sup> I suspect that the majority's decision in this investigation may rest in substantial measure on a misapprehension of the governing legal standard.

Two aspects of the "reasonable indication" standard have been sources of disagreement, and I believe of misunderstanding. The first concerns the quantum of evidence necessary to sustain an affirmative preliminary determination. The Commission, affirmed by our reviewing courts in American Lamb and other cases, has plainly recognized the direction in which the reasonable indication standard inclines our preliminary determinations. The standard signals Congress' intent to "weight the scales in favor

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imports that have allegedly been unfairly traded. For the purposes of this discussion, such "material retardation" is subsumed under the concept of "material injury".

<sup>3/</sup> Inv. No. 731-TA-422 (Preliminary), USITC Pub. 2135 (November 1988) ("Steel Rails") (Additional Views of Commissioner Cass) at 19-31.

<sup>4/</sup> The only portion of the majority's views that have been made available to me is the section relating to the question whether production facilities in the Virgin Islands should be regarded as part of the domestic industry, and the question whether encapsulation activities constitute domestic production.

of affirmative and against negative determinations".<sup>5/</sup> The preponderance of the evidence need not be in favor of a petitioner in a preliminary investigation before an affirmative determination may be reached.<sup>6/</sup> Put another way, the evidence need not rise to a level that makes it more probable than not that a final investigation will be decided in the affirmative; less than a fifty percent probability of such a final determination will constitute a reasonable indication of injury by reason of unfairly traded imports.

This does not, however, suggest that any evidence will suffice to support an affirmative preliminary decision. If Congress did not indicate with precision the minimum probability of ultimate success necessary to constitute a reasonable indication, it did employ language that plainly requires more than de minimis evidence of injury from the allegedly dumped or subsidized imports. Congress plainly did not believe that a "reasonable indication" of such injury can exist where the likelihood of an affirmative final determination is very small. The purpose for mandating a preliminary determination was to weed out those cases in which the probability of an affirmative final determination does not merit the investment of the parties' time and money and the disruption of markets attendant to these

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<sup>5/</sup> American Lamb Co. v. United States, 785 F.2d 994, 1001 (Fed Cir. 1986) ("American Lamb"); see also Yuasa-General Battery Corp. v. United States, slip op. 88-89 (Ct. Int'l Trade, July 12, 1988), at 5.

<sup>6/</sup> Steel Rails, supra, at 21.

investigations.7/ This purpose would be frustrated if those of us who implement that standard read it in a manner that effectively precludes negative determinations in all but the most patently unmeritorious case.8/ Such a reading would render preliminary investigations a meaningless, but expensive, exercise.

The construction of the reasonable indication standard in some Commission opinions, however, threatens to produce just such a result. Our opinions at times seem to confuse an evidentiary standard -- for evaluating evidence that conflicts with other evidence supporting a finding of injury from unfair imports -- with the standard for decision. Plainly, evidence of such injury should be credited unless contradicted by evidence that is both clear and convincing.9/ However, this evidentiary principle does not require that affirmative determinations be reached, regardless of the nature of the affirmative evidence, unless there is clear and convincing proof that the subject imports did not materially injure a domestic industry.10/ Some

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7/ See S. Rep. No. 93-1298, 93rd Cong., 2d Sess. 170-71 (1974). See also Steel Rails, supra, at 22-23.

8/ See id. at 21-22, 30.

9/ See Shock Absorbers and Parts, Components and Subassemblies Thereof from Brazil, Inv. No. 731-TA-421 (Preliminary), USITC Pub. 2128 (September 1988) ("Shock Absorbers") (Views of Acting Chairman Brunsdale and Commissioners Liebeler, Lodwick and Cass); Welded Steel Fabric for Concrete Reinforcement from Italy, Mexico and Venezuela, Inv. No. 731-TA-289(A)-291(A) (Preliminary), USITC Pub. 1795 (January 1986).

10/ Steel Rails, supra, at 29-31.



interpretations of the reasonable indication standard nonetheless appear to embrace just such a requirement.<sup>11/</sup>

The second problematic aspect of the reasonable indication standard, factoring the consideration of evidentiary gaps into our evaluation of the evidence before us, may be a cause of more serious confusion. As the Court of Appeals for the Federal Circuit and the Court of International Trade have noted, whether the evidence of record reveals a reasonable indication of injury from unfairly traded imports depends in part on the evidence that is likely to be gathered in a final investigation.<sup>12/</sup> Because Congress intended the reasonable indication standard to be applied so as to terminate investigations that were not reasonably likely to produce an affirmative final determination, the evidence before us in a preliminary investigation must be assessed in relation to the evidence expected in a final investigation. Both the Commission's prior practice and the test articulated by the Federal Circuit in American Lamb recognize that the Commission should not reach a negative determination when evidence that might be expected in a final investigation would, together with the evidence of record in the preliminary,

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<sup>11/</sup> See, e.g., Shock Absorbers, supra (Views of Commissioner Eckes) at 33; Steel Rails, supra (Additional Views of Commissioner Eckes) at 17-18.

<sup>12/</sup> See, e.g., American Lamb, supra, at 1001; Maverick Tube Corp. v. United States, 687 F. Supp. 1569, 1575 (Ct. Int'l Trade 1988).

support an affirmative final determination.<sup>13/</sup> Surely, however, the Commission cannot reach an affirmative judgment solely because its record in the preliminary investigation is incomplete.<sup>14/</sup>

The Commission's actual practice in preliminary investigations generally has been consistent with the understanding of Congressional intent given in American Lamb. Specifically, the Commission has determined that a negative determination in a preliminary investigation is warranted when the evidence presented in support of a petition does not, standing alone, amount to a reasonable indication of injury or threat of injury from unfair imports, or when the contrary evidence is so clear and convincing that the evidence supporting the petition cannot on the record as a whole be said to provide a reasonable indication of injury from unfairly traded imports.<sup>15/</sup> In making such determinations, the Commission has also considered the likelihood that a final investigation might produce evidence supporting an affirmative finding of actual or threatened injury.<sup>16/</sup> Increasingly, however, Commission decisions have

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<sup>13/</sup> See Electrolytic Manganese Dioxide from Greece, Ireland and Japan, Inv. No. 731-TA-406 (Preliminary), USITC Pub. 2097 (July 1988) ("Manganese Dioxide") (Additional Views of Vice Chairman Brunsdale and Commissioners Liebeler and Cass) at 23-25; American Lamb, supra, at 1001.

<sup>14/</sup> See Manganese Dioxide, supra (Additional Views of Vice Chairman Brunsdale and Commissioners Liebeler and Cass) at 23-25.

<sup>15/</sup> Steel Rails, supra, at 30.

<sup>16/</sup> Id. at 27-28.

intimated that the mere possibility of additional information will suffice to justify an affirmative determination in a preliminary investigation.<sup>17/</sup> This development would undermine the Congressional purpose for preliminary investigations, especially where threatened injury, for which evidence is necessarily incomplete, is the basis for decision.

This investigation illustrates that concern. The evidence that is at odds with the petition clearly and convincingly refutes the scant evidence presented in support of the petition that might otherwise justify an affirmative determination. Further, there is no reasonable likelihood that a final investigation would lead to a contrary conclusion. The record evidence that leads me to these conclusions is discussed in detail in the succeeding sections of these Dissenting Views.

## II. DOMESTIC LIKE PRODUCT AND INDUSTRY

In this case, we have been presented with a number of close and complex questions concerning the appropriate definition of the domestic like product and the domestic industry that produces that product. The issue that was the subject of the most intense discussion by the parties is whether Keflex, the brand-name product produced by Eli Lilly, should be included, along with generic cephalixin capsules, as part of a single domestic like

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<sup>17/</sup> See, e.g., Industrial Belts from Israel, Italy, Japan, Singapore, South Korea, Taiwan, the United Kingdom, and West Germany, Inv. No. 701-TA-293-295 (Preliminary), USITC Pub. 2113 (August 1988) (Additional Views of Commissioner Rohr).

product. Petitioner argued that it should not be included;<sup>18/</sup> Respondents contended that it should be.<sup>19/</sup> This, however, is not the only like-product issue raised by the factual record before us; there are various other possible like-product questions, most of which have been addressed only in passing, if at all, by the parties. For example, there are other forms of cephalexin in dosage form used for medical treatment, specifically cephalexin tablets and oral suspension.<sup>20/</sup> All forms of cephalexin in dosage form, in turn, are produced from a raw material that is commonly referred to as "bulk cephalexin".<sup>21/</sup> Moreover, cephalexin is but one of many products in the family of "cephalosporin" drugs.<sup>22/</sup> For the most part, Petitioner and Respondents have taken opposing positions with respect to the items not specifically the subject of Petitioner's unfair trading allegations -- Keflex, cephalexin tablets and powder for oral suspension, bulk cephalexin and other

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<sup>18/</sup> Petitioner's Post-Conference Statement ("Petitioner's Postconference Brief") at 4.

<sup>19/</sup> Comments by Novopharm, Ltd., Lyphomed/Novopharm Pharmaceutical Company, and Lyphomed, Inc. ("Respondents' Postconference Brief") at 2-14.

<sup>20/</sup> Report at A-2.

<sup>21/</sup> Id.

<sup>22/</sup> Id. at A-2.

cephalosporin drugs -- Respondents urging and Petitioner resisting their inclusion in the domestic like product.<sup>23/</sup>

For the purposes of this preliminary investigation, I have, with one notable exception, used the like-product definition proposed by Petitioner, although, as explained below, the Respondents have more accurately characterized the considerations apposite to like product determinations and well may have the better argument on each of the items in dispute. Were this a case in which the choice among competing like-product definitions were critical to disposition of the investigation, I would be less inclined to cast the like-product definition so much in Petitioner's favor. The one exception to my use of Petitioner's suggested like-product definition involves the inclusion of Keflex in the domestic like product. On this issue, in my view, Respondents so plainly have the better of the argument that even generosity cannot justify exclusion of Keflex from the like-product definition.

Petitioner's argument for excluding Keflex from the domestic like product is premised, in large measure, upon an economic analysis that contends that Keflex simply does not compete with generic cephalexin capsules in the domestic marketplace. According to Petitioner,<sup>24/</sup> economic analysis of the like product issue is required because Section 1328 of the Omnibus Trade and

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<sup>23/</sup> All of these issues were not explicitly addressed by both parties.

<sup>24/</sup> See Petitioner's Postconference Brief at 18.

Competitiveness Act of 1988 ("the 1988 Trade Act")<sup>25/</sup> directed the Commission, when assessing the existence of material injury, to

evaluate all economic factors . . . within the context of the conditions of competition that are distinctive to the affected industry.

Petitioner asserts that this amendment to Title VII was intended to require the Commission to change its approach to like-product issues.<sup>26/</sup> Petitioner also argues, however, that the criteria that the Commission has traditionally considered in analyzing these issues -- product characteristics and uses, product interchangeability, channels of distribution, common manufacturing facilities and production employees, and customer or producer perceptions<sup>27/</sup> -- simply provide different terminology for evaluation of the economic criteria that Petitioner urges the Commission to consider: cross-elasticity of demand and of supply.<sup>28/</sup>

In making its economic argument, Petitioner relies heavily on the fact that the price of Keflex in the domestic market is approximately six times higher than the generic product.<sup>29/</sup>

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<sup>25/</sup> Pub. L. No. 100-418, 102 Stat. 1107.

<sup>26/</sup> Petitioner's Postconference Brief at 19-20.

<sup>27/</sup> See, e.g., Certain All-Terrain Vehicles from Japan, Inv. No. 731-TA-388 (Preliminary), USITC Pub. 2071 (March 1988) at 6; Certain Fabricated Structural Steel from Canada, Inv. No. 731-TA-387 (Preliminary), USITC Pub. 2062 (February 1988) at 5, n. 10.

<sup>28/</sup> Petitioner's Post-Conference Brief at 22.

<sup>29/</sup> Id. at 22-23.

Petitioner notes, too, that the price of Keflex did not change significantly, and did not in any event fall, after the generic product was introduced, or after, or contemporaneous with, the subsequent substantial decreases in the price of the generic product.<sup>30/</sup> Petitioner ascribes this phenomenon to the fact that a large number of physicians have persisted in prescribing brand-name, rather than generic, products, even in the face of changes in state laws and policies designed to facilitate greater use of generic drugs, which, Petitioner argues, evidences the medical profession's distinction of Keflex from generic cephalexin.<sup>31/</sup>

Petitioner also argues that an analysis of the criteria traditionally considered by the Commission in its like-product determinations also argues in favor of excluding Keflex from the domestic like product, again referring to evidence suggesting that many physicians perceive generic and brand-name drugs differently.<sup>32/</sup> In addition, Petitioner asserts that the methods used to distribute Keflex and generic cephalexin capsules are quite different as Keflex, unlike the generic product, is promoted through extensive advertising and other marketing efforts.<sup>33/</sup>

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<sup>30/</sup> Id.

<sup>31/</sup> Id. at 16-23.

<sup>32/</sup> Id. at 7-8.

<sup>33/</sup> Id. at 15-16.

Respondents, on the other hand, take the position that the application of the Commission's traditional like-product criteria to the facts presented in this case plainly indicates that Keflex and generic cephalexin capsules should be included in a single like product. Respondents emphasize that the characteristics and uses of the two types of capsules are in fact identical in that they have the same chemical composition, and treat the same infections.<sup>34/</sup> They assert that the channels of distribution for the two types of capsules are "similar" and note the absence of any evidence that the two types of capsules are produced by different processes, leading the Respondents to conclude that the two products "presumably" are produced in the same manner.<sup>35/</sup> Respondents also contend that the majority of purchasers perceive the two types of products as interchangeable.<sup>36/</sup>

Respondents argue that there is no basis for Petitioner's claim that the 1988 Trade Act amendment to Title VII cited by Petitioner was in any way intended to require the Commission to modify its approach to like-product questions. They note that the amendment in question relates only to the manner in which the Commission evaluates the issue of material injury.<sup>37/</sup> Respondents also assert that Petitioner's economic arguments are in any

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<sup>34/</sup> Respondents' Postconference Brief at 5-6, 11.

<sup>35/</sup> Id. at 5.

<sup>36/</sup> Id. at 5-6.

<sup>37/</sup> Id. at 10.



event misguided. In that context, they point to certain evidence that, in their view, indicates that Keflex and generic cephalixin capsules compete directly with one another. Among other things, Respondents argue that the steady and substantial decline in the market share of Keflex that has been experienced since the introduction of generic capsules shows that the two types of capsules compete for substantially the same market.<sup>38/</sup>

Respondents contend that Lilly's continued aggressive marketing of Keflex indicates that Lilly is aware of this competition, and is responding to it.<sup>39/</sup> Respondents also claim that there are certain classes of customers -- such as hospitals -- for whom there is direct evidence of head-to-head competition between Keflex and generic cephalixin capsules.<sup>40/</sup> Finally, Respondents dispute the significance of the continuing disparity in the price of Keflex and generic capsules, arguing that the high price of Keflex is merely an "attempt, typical of brand-name manufacturers, to maximize profits before losing their remaining market share to the generics".<sup>41/</sup>

Respondents' arguments are persuasive. I do not believe that the 1988 Trade Act was in any way intended to alter our approach to like-product issues. There is simply no evidence in

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<sup>38/</sup> Id. at 12-13.

<sup>39/</sup> Id. at 12.

<sup>40/</sup> Id. at 13, Attachment A.

<sup>41/</sup> Id. at 13.

either the language or legislative history of the Act to support such an argument. At the same time, however, this question is, in large part, irrelevant to the issue at hand. As I have stated in other opinions, I believe that the Commission's traditional like-product criteria not only are consistent with an economic approach to like-product issues, but in fact represent the appropriate means by which to carry out such an analysis.<sup>42/</sup>

In this case, consideration of these criteria -- in particular, product characteristics and uses -- leads me to the conclusion that Keflex and generic cephalexin capsules are part of the same like product. There is no question that the characteristics of the two types of cephalexin capsules are identical. Further, there is compelling evidence that the two types of capsules are used for exactly the same purposes and are not distinguishable from the standpoint of the ultimate consumer.

The economic evidence of record buttresses the conclusion that these form a single like product. Petitioner is correct in stating that price disparities generally will evidence product differences and also in observing that such disparities have been part of our traditional like product consideration.<sup>43/</sup> In this case, however, other evidence suggests that this price difference

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<sup>42/</sup> 3.5" Microdisks and Media Therefor from Japan, Inv. No. 731-TA-389 (Preliminary), USITC Pub. 2076 (April 1988) (Additional Views of Commissioner Cass) ("Microdisks") at 47-48.

<sup>43/</sup> See, e.g., Certain All-Terrain Vehicles from Japan, Inv. No. 731-TA-388 (Preliminary), USITC Pub. 2071 (March 1988); *Asociacion Columbiana de Exportadores de Flores v. United States*, 693 F. Supp. 1165, 1170, n. 8 (Ct. Int'l Trade 1988).

does not reflect intrinsic product differences and is not likely to be sustainable over time. The evidence does not suggest any reason to suppose it is coincidence that, since the time the generic product was introduced, sales and production of Keflex have fallen [ \* \* ]. Using 1986 as the base period, Keflex production appears to have fallen, on an annualized basis, by roughly [ \* ]%.<sup>44/</sup> By contrast, domestic consumption of cephalexin capsules from all sources, domestic and imported, is now at approximately the same level as it was in 1986.<sup>45/</sup> Sales of generic cephalexin capsules thus appear to have been made almost entirely at the expense of Keflex.

Under these circumstances, the disparity in the price of Keflex and generic cephalexin capsules does not support a conclusion that there is no effective competition between the two types of capsules. The record evidence is instead more consistent with the interpretation placed upon it by Respondents -- that the price of Keflex has been kept high because its producer, Lilly, has decided that such a strategy is profit-maximizing, notwithstanding the substantial erosion in market share that may be associated with such a strategy.

In sum, then, the record evidence as a whole strongly supports the conclusion that Keflex and generic cephalexin capsules compete with each other for substantially the same

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<sup>44/</sup> Report at A-15, Table 4.

<sup>45/</sup> Id. at A-13, Table 1. Consumption actually [ \* \* \* \* ] in the first nine months of 1988. Id. \* \* \* \*

market. Accordingly, I have concluded that they should be considered part of the same domestic like product.

The remaining like-product issues pose more difficult questions. The record does not contain information sufficient to enable me to determine with any degree of confidence whether other forms of dosage cephalexin, bulk cephalexin, or other cephalosporin drugs should also be included in the domestic like product. There is, for example, no evidence indicating whether there are any differences between cephalexin capsules and cephalexin tablets that might be significant for our purposes. At an intuitive level, it seems quite doubtful that such differences exist. So far as the record reveals, there is no reason to expect the different forms of cephalexin to have significantly different properties and uses. Indeed, the various forms of cephalexin would seem most likely to be close substitutes one for another. Nevertheless, I have excluded other forms of cephalexin from the domestic like product because expansion of the like product by inclusion of these other products would resolve to the detriment of Petitioner any doubts that I have on this issue. Given the general weakness of the arguments for Petitioner's substantive position in this investigation, as well as the Congressional directive to incline preliminary determinations somewhat in petitioners' favor, it seems appropriate to give the Petitioner the benefit of every possible doubt.

For the same reasons, I have likewise excluded bulk cephalalexin and other cephalosporin drugs. Unlike the case with other forms of cephalalexin, however, the limited record evidence developed on these issues in this investigation provides some ground for excluding these products from consideration. From the standpoint of both consumer and producer substitutability, both of these products may be sufficiently different from cephalalexin capsules to preclude their inclusion in the domestic like product. However, the record evidence on this point is quite fragmentary. Although the record is, therefore, insufficiently developed to allow me to reach any definitive conclusions as to whether bulk cephalalexin and other cephalosporin drugs should be included in the domestic like product, I have excluded these products solely in order to resolve in favor of Petitioner any doubts that I have at this juncture.

In analyzing this case, therefore, I have assessed the question of material injury, or the threat thereof, from unfairly traded imports by considering the impact of the subject imports on the domestic industry producing cephalalexin capsules, including the brand-name product, Keflex. I have also concluded that this domestic industry includes production facilities that are located in the Virgin Islands, and is not confined to those domestic firms that produce the bulk cephalalexin that is used in the production of cephalalexin capsules. I understand that the Commission is unanimous on these issues and expect that the

reasons for our conclusions will be explained adequately in the Views of the Commission majority.

III. CAUSATION OF MATERIAL INJURY:  
GENERIC CEPHALEXIN CAPSULES FROM CANADA

In assessing whether there is a reasonable indication that the domestic industry has suffered material injury by reason of the subject imports, I have conducted the three-part inquiry suggested by the statute under which we conduct Title VII investigations. Using this approach, I have evaluated the possible existence of material injury by comparing the conditions experienced by the domestic industry to the conditions that would have obtained had there been no less than fair value ("LTFV") imports. The three parts of the inquiry needed to carry out this analysis are as follows. First, conclusions must be reached respecting the extent to which the prices and sales of the subject imports were affected by the dumping that is alleged to have taken place. Second, it is necessary to draw inferences concerning the effect of these apparent changes in the market for the subject imports on prices and sales of the domestic like product. Third and finally, the impact of these changes in prices and sales of the domestic like product on employment and investment in the domestic industry must be considered. These questions are addressed separately below.

Before turning to a discussion of these issues, I note that the 1988 Trade Act requires Commissioners to address specifically

three factors that are set forth in the statute and also requires explanation of other, unlisted factors that a Commissioner considers relevant. In this regard, I should emphasize that the three-part inquiry that I have outlined is designed to analyze the particular statutory factors that we are required to consider in Title VII investigations.

The first statutory factor is the volume of imports of the merchandise under investigation. The volume of allegedly unfair imports, and the effect of the unfair practice on the volume of such imports, are central to the first part of the Title VII inquiry, which evaluates the extent to which the sales and prices of these imports changed as a consequence of the alleged unfair trade practices under investigation; this inquiry necessarily entails full consideration of the actual volume of the subject imports during the period covered by the investigation.

The second statutory factor, the effect of the subject imports on prices in the United States for like products, is the principal focus of the second part of the three-part inquiry. Examination of the relation between the imports and domestic like product, and the nature of the markets for the production and consumption of the domestic like product, is essential to evaluation of the effect of the allegedly unfair imports on the prices of the domestic like product. As the effect on prices is integrally related to effects on sales of the domestic product, the latter effects also are considered in the second part of the inquiry undertaken here.

The third part of the inquiry explicitly focuses on the third statutory factor, the impact of the subject imports on domestic producers of like products, including explicit attention to the various indicia of such impact listed in Title VII as subsidiary factors pertinent to this determination.

Certain other relevant economic factors, such as data pertaining to the volume of sales made by Respondent producers in their home markets or the dumping margins (the relative amounts by which ex-factory prices for sales of the subject product in the exporters' home market exceed comparable prices for sales to the United States), are also considered in carrying out this three-part inquiry. Their relevance is explained in the pertinent following subsections of this opinion.

A. LTFV Imports

In this investigation, Petitioner has alleged that the subject imports were sold at prices reflecting significant margins of dumping. Specifically, Petitioner claims that the dumping margins for those sales ranged from a low of 18.42% to a high of 39.73%, depending upon the specific dosage of the cephalexin capsules that are alleged to have been dumped.<sup>46/</sup> The decline in the price of the dumped imports that occurs as a result of dumping, while related to the facts subsumed within the dumping margin, will in general be less than the full amount of the dumping margin.

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<sup>46/</sup> See Petition, as amended by filing dated November 14, 1988, at 10-11.



As I have explained elsewhere, assessment of the change in price consequent to dumping is informed by the nature of dumping, which is statutorily defined as simply a disparity in price between a (higher-priced) foreign market and the (lower-priced) U.S. market. While in this investigation the nature of the dumping, and the consequent implications for its effect on the prices of the allegedly dumped imports, is plain, the price differences that constitute dumping need not always have a single cause. Dumping may reflect, for instance, the desire to capture the value of an established brand name in a market where that name is known but not to add a premium for that name when its goods are introduced into a new market.<sup>47/</sup> This is hardly likely to have been the explanation for any dumping that has taken place in connection with the sale of the subject imports, for the Canadian producer is a recently-created joint venture of a U.S. company, LyphoMed Ventures, Inc., and a Canadian firm, Novopharm, Ltd.<sup>48/</sup> Their product is sold as a generic good. The Respondents apparently do not have any brand name on which to capitalize in the Canadian market. So, too, predation, which never need be demonstrated and is, in all events, a most improbable explanation for dumping,<sup>49/</sup> is a thoroughly unlikely

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<sup>47/</sup> Microdisks, supra, at 77.

<sup>48/</sup> Report at A-12.

<sup>49/</sup> The Supreme Court in Matsushita Electric Industries Co. v. Zenith Radio Corp., 475 U.S. 574, 589 (1986) recognized that "predatory pricing schemes are rarely tried, and even more rarely successful".

explanation for the dumping in which Respondents are alleged to have engaged, since Respondents have only a small share of the U.S. market<sup>50/</sup> and cannot realistically expect, or have expected, to achieve a dominant position in that market. The most likely explanation for the alleged dumping is the one that explains most instances of dumping -- that is, the foreign producer has charged different prices in the U.S. and Canadian markets because the producer enjoys more market power in the Canadian market than in the U.S. market and seeks to increase its overall profitability by charging more where the producer is able to and less where he faces more competition.<sup>51/</sup>

In any case where such differential pricing has occurred, the actual decrease in the price of the subject imports that occurred consequent to dumping, as a percentage of the dumping margin, will be, in large measure, a function of the proportion of the sales of the subject foreign producer(s) in their combined U.S. and (respective) home market that is accounted for by sales in their (respective) home market.<sup>52/</sup> In reality, an estimate of

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<sup>50/</sup> See discussion, *infra*, at 64.

<sup>51/</sup> Commentators who have studied differential pricing in international markets have long believed that this is the best explanation for most instances of dumping. See, e.g., G. von Haberler, *The Theory of International Trade with its Application to Commercial Policy* 296-317 (1936).

<sup>52/</sup> See, e.g., *Granular Polytetrafluoroethylene Resin from Japan*, Inv. No. 731-TA-385 (Final), USITC Pub. 2112 (August 1988) (Additional Views of Commissioner Cass) at 74; *Certain Bimetallic Cylinders from Japan*, Inv. No. 731-TA-383 (Final), USITC Pub. 2080 (May 1988) (Additional Views of Commissioner Cass) at 44.

the decrease in the price of the dumped product that is derived in this fashion will somewhat overstate the price decrease as it represents an approximate upper bound of that decrease.<sup>53/</sup> However, this approximation suffices for purposes of this investigation because it is, if anything, overstated in a manner that can only be favorable to Petitioner.

In this case, Respondents' sales in their home market, Canada, accounted for [ \* \* \* \* \* ] of their total sales in the combined U.S./Canadian market. During the first nine months of this year, which covers the period when dumping is alleged to have occurred, Respondents' sales in Canada accounted for only [ \* ] of their sales in that combined market.<sup>54/</sup> Accordingly, even accepting the upper bound of the dumping margins alleged by Petitioner, as I have for the purposes of this preliminary investigation, the alleged dumping could have caused the price of the subject imports to decline, at most, by a very small percentage of the dumping margin (a portion of the dumping margin approximately equivalent to the proportion of sales in the home market).<sup>55/</sup> This in turn would have produced

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<sup>53/</sup> For a thorough explication of this subject, see USITC Memorandum EC-L-149, Assessing the Effects on the Domestic Industry of Price Dumping, Part I (May 10, 1988) from the Office of Economics at 1, n. 1, 13, 19-21.

<sup>54/</sup> See Report at A-27, Table 18.

<sup>55/</sup> Microdisks, supra, at 82, n. 100. For a full explanation of the technical basis for this calculation, see USITC Memorandum EC-L-149, supra. This memorandum has been made publicly available, as have simulation models incorporating this calculation.

an even smaller change in the actual price of the Respondents' product, approximately proportional to the product of the fraction just described multiplied by the fractional margin of dumping; the resulting fractional change in Respondents' prices would at most range from about [ \* ]% to [ \* ]%.

As discussed further below, this minimal price decrease could not have produced more than a very small increase in sales of the subject imports. It is unlikely that this increase amounted to more than a trivial percentage of the sales actually made by Respondent producers in the United States during the relevant period.

B. Domestic Prices and Sales

In this investigation, the record evidence indicates that the minor changes in the market for the subject imports that could have resulted from the alleged dumping would have produced correspondingly insignificant changes in the price and sales of the domestic like product. The U.S. market penetration of the subject imports during the period covered by the investigation was, and continues to be, low. The subject imports, measured on the basis of value, accounted for, at most, [ \* ]% of total U.S. consumption of cephalexin capsules in 1987 and [ \* ]% in the first nine months of 1988.<sup>56/</sup> By volume, U.S. sales of subject imports amounted, at most, to [ \* ]% of U.S. consumption of cephalexin capsules in 1987 and [ \* ]% in the first nine months

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<sup>56/</sup> Report at A-28, Table 21.

of 1988.<sup>57/</sup> These figures are, to some extent, overstated because the Commission did not receive shipment or other data from [ \* ] domestic producers of cephalexin capsules;<sup>58/</sup> total domestic consumption of cephalexin capsules was therefore higher, and Canadian market penetration was therefore lower, than the figures compiled by the Commission might, at first blush, suggest. In any event, the market penetration data, standing alone, suggest that the impact of the subject imports on sales of the domestic like product was limited. Certainly, in view of the small market share captured by Respondents' product and the very small price and volume difference that followed from the asserted unfair trade practice, the change in these data consequent to dumping must have been quite small indeed.

The record strongly suggests that the price of the domestic like product was not significantly affected by the changes in the market for the subject imports that may have occurred consequent to the alleged dumping. The magnitude of these changes is itself so small as to suggest that this was the case, even though record evidence indicates that the domestic like product and imported Canadian product are highly substitutable.<sup>59/</sup> Any significant impact is particularly unlikely given the small market share held

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<sup>57/</sup> Id.

<sup>58/</sup> Id. at A-12.

<sup>59/</sup> In particular, we have found that "[i]mported cephalexin capsules are generally comparable in quality to those produced domestically and, as such, can be used interchangeably". Id. at A-5.

by Respondents and the relatively great disparity between generic cephalixin capsule prices, including Respondents', and prices for Keflex capsules.

The price data collected by the Commission do not provide any basis for a contrary conclusion. The price of generic cephalixin capsules sold in the U.S. market declined significantly over the period covered by the investigation.<sup>60/</sup> However, as Respondents argue<sup>61/</sup> and Petitioner essentially acknowledges,<sup>62/</sup> this price trend does not differ from what would be expected in the absence of imports, dumped or otherwise: it is normal for prices of generic drugs to decline following the expiration of the patent on the original, brand-name product, as other producers of the generic drug enter the market. In short, the record evidence does not support an inference that the subject imports were responsible for the decline in the price of the generic product. Furthermore, the price data compiled by the Commission likewise contain little, if any, evidence that the Canadian producers have been competing with the domestic industry principally on the basis of price.<sup>63/</sup> These data are admittedly incomplete in that [ \* \* \* \* \* ]

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<sup>60/</sup> Id. at A-31-A-32. As previously noted, the price of Keflex has remained at more or less the same level. Id. at A-32-33.

<sup>61/</sup> Respondents' Postconference Brief at 14-15, 21; Transcript of 11/17/88 Conference ("Tr.") at 136.

<sup>62/</sup> Petition at 36.

<sup>63/</sup> See Report at A-34-A-37.

\* \* \* \* \*  
\* \* \* \* \*  
\* \* ].64/ However, even if these adjustments

were made, in the course of a final investigation or otherwise, there is, in my view, no likelihood that the adjusted data would suffice to support an affirmative determination.

C. Investment and Employment

The data relating to employment and investment in the domestic industry that have been collected by the Commission also provide no basis for an inference that the alleged dumping has caused material injury to that industry. Various measures indicate that employment in the industry has not suffered. Employment figures appear congruent with what one would expect of an industry evolving from a monopoly, brand-drug market into a competitive, generic market. During the first nine months of this year, total employment of production workers involved in the production of cephalexin capsules was in fact slightly higher than it was in the comparable period in 1987.65/ Over the same period, the total hours worked by such employees was slightly lower, but the total compensation paid to them was more or less

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64/ See id. at A-34.

65/ Id. at A-19, Tables 10-11.

the same.<sup>66/</sup> The hourly wages paid to such workers actually appears to have increased during that time.<sup>67/</sup>

The financial data are more difficult to interpret. The domestic firms producing generic cephalixin capsules are quite profitable, although substantially less so than they were in 1987, when the generic drug was introduced.<sup>68/</sup> However, given the pricing pattern normally to be expected after the introduction of generic drugs into the marketplace -- i.e., significant price decreases normally occur as other generic producers enter the market<sup>69/</sup> -- this development is not surprising. There is no record evidence that even remotely suggests that the subject imports, accounting for only a small share of the U.S. market, could have been responsible for any significant portion of the reported change in the profitability of the generic producers. To the contrary, for the reasons previously discussed, the record evidence indicates that it is quite implausible that the subject imports could have caused, or significantly contributed to, a material decline in the profitability of domestic firms.

Finally, I note that the producer of Keflex, Eli Lilly,

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<sup>66/</sup> Id.

<sup>67/</sup> Id.

<sup>68/</sup> Id. at A-21, Table 14.

<sup>69/</sup> See discussion, supra, at 66.



[ \* \* \* \* \* ] 70/

The possibility that such data [ \* \* ] in a final investigation does not provide a basis for an affirmative determination in this investigation. For one thing, it is readily apparent that Lilly's Keflex operations are quite profitable. Given the substantial amount by which the price of Keflex exceeds the price of the generic product, it is obvious that Lilly must be covering the cost of its Keflex operations by a very substantial margin. Even assuming Lilly were to produce data indicating that the profitability of these operations has declined significantly during the past two years, the Commission would not have a rational basis for attributing this decrease to the subject imports. The obvious explanation for any decline in the profitability of Keflex is the expiration of the Keflex patent and consequent opening of the cephalexin capsule market to competition from generic products.71/ While an erosion in the profitability of Lilly's Keflex operations would doubtless emerge, it is extraordinarily unlikely that Petitioner could link evidence of such a change to the subject imports. In short, there is no realistic likelihood that the [ \* \* ] of Lilly's Keflex financial data would support an affirmative determination in a final investigation.

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70/ Report at A-19.

71/ It should also be noted that Petitioner, by requesting the Commission to adopt a like-product definition that excludes Keflex, has already essentially admitted that the subject imports have not materially impaired the profitability of Keflex.

IV. THREAT OF MATERIAL INJURY

In the Commission's recent decision in Shock Absorbers and Parts, Components and Subassemblies Thereof from Brazil,<sup>72/</sup> we had occasion to discuss at some length the circumstances under which the Commission may make an affirmative determination in a preliminary investigation based upon a finding that material injury is threatened. In that case, we found that no such threat existed for reasons that I believe apply with equal force in this proceeding.

The starting point in any analysis of the issue of threat is the statutory command that the Commission make an affirmative determination only "on the basis of evidence that the threat of material injury is real and that actual injury is imminent".<sup>73/</sup> Furthermore, while analysis of nonobservable events invariably is required, such a determination may not be made on the basis of mere conjecture or supposition.<sup>74/</sup> In a preliminary investigation, a reasonable indication of threat of material injury will, of course, suffice. Still, Congress has made clear that, even in that context, we are to make affirmative determinations only when we are presented with concrete evidence that imminent injury is threatened.<sup>75/</sup>

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<sup>72/</sup> Inv. No. 731-TA-421, USITC Pub. 2128 (September 1988).

<sup>73/</sup> 19 U.S.C. Section 1677(7)(F)(ii).

<sup>74/</sup> Id.

<sup>75/</sup> See 19 U.S.C. Section 1677(7)(F)(ii).

Title VII, as amended by the 1988 Trade Act, directs the Commission to consider a number of specifically enumerated factors in assessing whether there is a sufficient threat of material injury. The listed factors that are relevant, or potentially relevant,<sup>76/</sup> for our purposes are the following:

- (1) the ability and likelihood of the foreign producers to increase the level of exports to the United States due to increased production capacity or unused capacity;
- (2) any rapid increase in penetration of the U.S. market by imports and the likelihood that the penetration will increase to injurious levels;
- (3) the probability that imports will enter the United States at prices that will have a depressing or suppressing effect on domestic prices of the merchandise;
- (4) any substantial increase in inventories of the merchandise in the United States;
- (5) underutilized capacity for producing the merchandise in the exporting country;
- (6) 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;
- (7) any other demonstrable adverse trends that indicate that importation of the merchandise will be the cause of actual injury.<sup>77/</sup>

In this investigation, I believe that there is no conceivable basis -- other than speculation of the kind in which

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<sup>76/</sup> Certain other statutory factors are not relevant because they relate to facts not presented in this case, e.g., cases where subsidy allegations are made.

<sup>77/</sup> See 19 U.S.C. Section 1677(7)(F)(i).

we are prohibited from engaging -- upon which we might find that any of these factors indicates that there is a reasonable indication of threat of material injury to the domestic industry. Indeed, Petitioner appears to have recognized as much: Petitioner has explicitly disavowed any claim that the domestic industry is threatened with material injury.<sup>78/</sup> I will, nonetheless, consider the statutory criteria, guarding against the remote possibility that the Petitioner has not recognized its own best argument.

To begin, there is no indication in the record that the sole Canadian producer exporting to the United States is expanding production capacity. It appears that the Canadian producer does have a certain amount of unused production capacity -- its capacity utilization rate during the first nine months of this year was [ \* ]<sup>79/</sup> -- but the record is devoid of any indication that this unused capacity is likely to be used to increase exports to the United States.

Similarly, there has been no rapid increase in the market penetration of the subject imports. At first blush, the data compiled by the Commission might appear to suggest that the market penetration of this product during the first nine months of this year was [ \* \* ] the level experienced during the

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<sup>78/</sup> Tr. 51.

<sup>79/</sup> Report at A-26, Table 17.

comparable period in 1987.<sup>80/</sup> However, this increase is almost entirely illusory. During the first four months of 1987, when the Keflex patent was still in effect, generic cephalexin capsules, including the subject imports, were not allowed in the domestic marketplace. If this is taken into account, it is clear that the subject imports have not been entering the U.S. market this year at a significantly greater rate than last year.

There also is no evidence before us suggesting a probability that the subject imports might have a depressing or suppressing effect on prices of the domestic like product. To the contrary, as previously discussed, the evidence that does exist indicates that those imports to date have had no significant effect of that kind. We have not been presented with any evidence indicating that this is likely to change.

Nor do inventories of imported cephalexin capsules support a finding of threatened injury from dumping. U.S. inventories of the subject imports [ \* \* ]. Indeed, they have [ \* \* ] [ \* \* ] during the first nine months of this year relative to the comparable period in 1987.<sup>81/</sup>

The sixth threat factor likewise provides no support for an affirmative determination on this ground. There is no reason to believe that the subject imports have had, or potentially will have, negative effects on any existing development and production

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<sup>80/</sup> See *id.* at A-28, Table 21.

<sup>81/</sup> *Id.* at A-25.

efforts by the domestic industry. The record is essentially bereft of evidence relating to this issue. The limited evidence that is in the record demonstrates that Petitioner is apparently prepared to proceed with its investment in a bulk cephalosporin production facility, notwithstanding the presence of the Canadian producers in the domestic market.<sup>82/</sup>

As with the preceding factors, the final statutory factor does not add any basis for an affirmative determination. There is no other evidence before us of any demonstrable adverse trends indicating that the subject imports imminently will become the cause of actual injury to the domestic industry. As discussed in Part III of these Views, the subject imports have a very small share of the highly competitive U.S. cephalosporin capsule market and, for reasons explained above, dumping cannot appreciably advance their competitive position in that market.

In sum, then, the record before us not only does not contain any reasonable indication that the domestic industry is threatened with material injury within the meaning of the statute. Indeed, it contains no indication whatever that a real and imminent threat exists.

#### Conclusion

For the foregoing reasons, I find that there is no reasonable indication of material injury, or threat of such

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<sup>82/</sup> Id. at A-5.

injury, to the domestic industry. I dissent from the contrary determination of my colleagues.





## INFORMATION OBTAINED IN THE INVESTIGATION

## Introduction

On October 27, 1988, a petition was filed with the U.S. International Trade Commission and the U.S. Department of Commerce by counsel on behalf of Biocraft Laboratories, Inc., Elmwood Park, NJ. The petition alleges that an industry in the United States is materially injured by reason of imports from Canada of generic cephalixin capsules <sup>1/</sup> that are being sold at less than fair value (LTFV). Accordingly, effective October 27, 1988, the Commission instituted investigation No. 731-TA-423 (Preliminary) under section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)) to determine whether or not there is a reasonable indication that an industry in the United States is materially injured, or is threatened with material injury, or the establishment of an industry is materially retarded, by reason of such imports.

Notice of the institution of this investigation and of a conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing a notice in the Federal Register of November 4, 1988 (53 F.R. 44676). <sup>2/</sup> The conference was held in Washington, DC on November 16, 1988. <sup>3/</sup> On November 23, 1988, the U.S. Department of Commerce initiated an antidumping investigation to determine whether the subject merchandise is being, or is likely to be, sold in the United States at LTFV (53 F.R. 47563).

The Commission's briefing and vote in this investigation was held on December 7, 1988. The statute directs the Commission to make its determination within 45 days after receipt of the petition, or in this case by December 12, 1988. There have been no previous Commission investigations of cephalixin capsules.

## The Product

Description and uses

The product subject to the petitioner's complaint is generic cephalixin in capsule form. Cephalixin is a first generation semisynthetic broad-spectrum cephalosporin antibiotic. It is 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. It is not used in the United States for any

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<sup>1/</sup> Cephalixin is a semisynthetic cephalosporin antibiotic, considered a first-generation cephalosporin on the basis of its spectrum of activity, commercially available as the monohydrate for oral administration, as provided for in item 411.76 of the Tariff Schedules of the United States Annotated (1987) (TSUSA) (subheading 3004.20.00 of the Harmonized Tariff Schedule). The chemical formula is C<sub>16</sub>H<sub>17</sub>N<sub>3</sub>O<sub>4</sub>S. The term generic cephalixin in this investigation refers to a product approved by the 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). "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.

<sup>2/</sup> Copies of cited Federal Register notices are presented in app. A.

<sup>3/</sup> A list of witnesses who appeared at the conference is presented in app. B.

purpose other than the manufacture of finished dosage forms of cephalexin. Bulk cephalexin can be purchased in compacted and noncompacted forms. In compacted bulk cephalexin, 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 noncompacted 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 compacted bulk cephalexin.

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 80 percent of demand for the drug in 1987, and can be prescribed in 250mg or 500mg dosages. The pills are formed by mixing powdered cephalexin with inert substances and then encapsulating the mixture into a gelatin capsule (see section entitled Manufacturing processes below). Tablets are also prescribed in 250mg and 500mg dosages, and Eli Lilly and Co. (Lilly) produces a 1 gram tablet as well. 1/

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, as the name implies. 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.

#### Product substitutability

The antibiotic market as a whole is highly competitive. In general, many of the antibiotics and most of the cephalosporins can be substituted for one another on a case-by-case basis, at the physician's discretion, after considering the broad spectrum of action of the individual products. Therapeutic treatment with cephalexin, as with other antibiotics, depends primarily on a combination of factors--the efficacy of the product against the organism responsible for the infection (which is determined on the basis of a culture) and the patient's sensitivity to a particular product, taking into consideration the patient's concurrent consumption of other medications. Patients who are allergic to penicillin, for example, 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.

Within the cephalosporin classification of antibiotics, there are 19 different drugs categorized by first, second, or third generation. In general, each generation of cephalosporin has a narrower spectrum of activity, so that the antibiotics with the broadest uses are in the first generation and those with the narrowest uses are in the third generation. It is possible to substitute between generations for some applications. More information on cephalosporins is provided in app. C.

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

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1/ American Hospital Formulary Service, Drug Information 88, 1988, p. 145.

physician has written the prescription. There also appears to be a division between oral and injectable applications of antibiotics: oral antibiotics are prescribed for the less-ill, home-based patient, whereas injectables are reserved 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 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 the generic for the branded product can be made at two levels, by the prescribing physician or at the pharmacy, and the 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, 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 5 states, either form may be used. Of the states that have adopted the one-line form, 17 require a handwritten phrase by the physician to rule out substitution, while 9 other states allow various combinations of preprinted boxes or abbreviations. 2/

Along with the two-line prescription form, the other two most significant barriers to generic substitution are the authority of independent state formulary commissions 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). 3/ 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. 4/

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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/ Petitioner's postconference statement, pp. 10-14.

3/ F-D-C Reports, Feb. 1, 1988. Provided in Petitioner's postconference statement.

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

Manufacturing processes

Bulk cephalixin is the active ingredient used in the capsules under investigation. This product is produced by the chemical modification of a microbial product derived from the fermentation of Cephalosporium acremonium. 1/

It should be noted that although the procedure described below applies to cephalixin products, \*\*\* indicated on their questionnaire responses that other cephalosporins could be produced on the same equipment.

Petitioner describes the production and quality control procedures used in the production of cephalixin in dosage form at their cephalosporin facility in Appendix A of the petition. This procedure is essentially the same for all producers, and is summarized in the following paragraphs. It should be noted that the manufacturing procedure for bulk cephalixin is substantially different, requiring a fermentation process and highly trained workers. 2/

When the bulk cephalixin is received at the company facility, each drum is verified for content, lot number, and physical condition, and then transferred to a 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 cephalixin 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. \*\*\* are required to mix a capsule batch properly; \*\*\* are required to mix powder for oral suspension, due to 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.

The finished capsules are screened rigorously for quality assurance and then polished. Each batch takes approximately \*\*\* to encapsulate, \*\*\* to inspect, and \*\*\* 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 \*\*\*.

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

Although \*\*\*, other industry sources indicate that the mixture of active and inactive ingredients is the same as for capsules. To form tablets, the mixture is tightly compressed and often coated with a light film. 3/

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

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

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

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's Good Manufacturing Processes (GMPs).

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 and then market it domestically in finished form. As of the end of 1987, Eli Lilly was still the only domestic manufacturer of bulk cephalexin, marketing the chemical in capsule, tablet, and oral suspension forms under the trade, or brand name, Keflex. Lilly also has a patent on a tablet of cephalexin monohydrate called Keflet.

Since April 1987, however, five other domestic producers have entered the market with generic versions of cephalexin in dosage form. Additionally, Biocraft Laboratories and \*\*\* recently received FDA approval to manufacture bulk cephalexin domestically. Production for both companies is expected to start sometime in early 1989.

Imported cephalexin capsules are generally comparable in quality with 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, must 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 GMPs. Antibiotics, for example, must be manufactured in separate equipment from other medicinal chemicals to prevent cross contamination. Products produced in another country, such as Canada, can only be exported to the United States if the producing facility is FDA approved. (See app. D for a summary of FDA regulations.)

The drug approval process in Canada for drugs manufactured in that country is fairly similar to that of the United States. 1/ 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 applications will probably need additional approval in the United States if it is targeted for three applications. Labeling standards could be different, requiring new equipment or increased capital expenditures.

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

The U.S. market

Many changes have taken place in the U.S. pharmaceutical industry over the last decade. While the prescription drug market continues to be one of the most profitable industries in the United States, the industry has experienced little recent growth, and the availability of new prescription drugs tends to slow sales of the older ones. 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. 1/

Sales of off-patent drugs, which include both brand name drugs and generic drugs, totaled approximately \$7 billion in 1987, or approximately 20 percent of the U.S. market, compared with 10 percent in 1983. Generic drugs accounted for about 30 percent of the off-patent sales, or about \$2 billion. 2/ Sales of generic drugs are estimated to be increasing by about \$400 million yearly. Drugs are prescribed during 60 percent of office visits to practitioners, and an estimated 20 percent of prescriptions are written generically. Nine out of 10 of the most widely used prescription drugs are now available generically. It is predicted that the market for generic drugs could double by 1992, as patent protection is lifted on another 35 prescription drugs, adding an estimated \$3.5 billion to generic sales. 3/ Several factors have favored the increased sales of generic products, including the relative speed with which they can be approved in the United States, and the strong economic and political pressures for reductions in medical costs.

In 1987, the FDA approved 21 new drugs compared with 20 in 1986. The average review time for the new drugs was 32 months. 4/ Although this was two months shorter than that in 1986, it was still longer than the estimated one year for a generic product. 5/

Generics are generally lower in price than the branded product, primarily because of the lack of the high overhead costs of research and development (R&D) and clinical testing, but also because competition grows stronger as more generic producers enter the market. 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 over \$1 million in 1987. 6/ In comparison, the cost of preparing a generic product was estimated to be \$150,000. 7/

The lower cost of generics is appealing to the customer and the pharmacist. In the latter case, sales of lower-priced product can result in higher profit margins. In addition, many medical insurance companies have lowered reimbursement amounts to customers, favoring the lower-priced products. Sales of off-patent drugs are expected to continue to increase by approximately 20 to 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. 8/

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

2/ The Economist, Feb. 7, 1987, pp. 3-14.

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

4/ Statistical Fact Book, 1988, pp. 20-26; The Economist, Feb. 7, 1987.

5/ The Economist, Feb. 7, 1987.

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

7/ The Economist, Feb. 7, 1987.

8/ The Economist, Feb. 7, 1987.

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 branded products. These companies have also developed active trademark registration and enforcement policies, as well as alternative formulations of the branded products. 1/ 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.

The experience of the generic cephalexin producers in the United States in many ways mirrors the experience of the pharmaceutical industry overall. In the 17 months since the patent on Keflex expired, five domestic producers and six importers have entered the marketplace for cephalexin products, in addition to the original producer Lilly. The normal trend for the generic industry is for the product to be introduced by the first generic producer at a price approximately one-half the price of the branded product, and for the price to fall after that point, depending on demand and the number of other producers entering the market. 2/ Industry sources confirm that this is indeed the case, and in fact state that this cycle may be moving faster and the "window of profitability" for generic drugs may be growing smaller, particularly for drugs where the patented version, like Keflex, was a popular item. 3/ The number of generic producers entering the market also influences the rate of price decline for generic products. 4/

#### U.S. tariff treatment

U.S. imports of cephalexin capsules are presently 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". 5/ The duty rate for most-favored-nation (col. 1) countries is 6.6 percent ad valorem. 6/ The column 2 duty rate is 7 cents per pound plus 45 percent ad valorem. This classification includes all cephalexin, whether or not in dosage

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1/ Industrial Minerals, August 1988, p. 43.

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

3/ Telephone conversation between Commission staff and staff of the U.S. Food and Drug Administration, Nov. 15, 1988.

4/ Statement of Leslie Dan, Novopharm, Ltd. at conference. See transcript, p. 176.

5/ According to information provided by the National Import Specialist for this product at the U.S. Customs Service.

6/ The rates of duty in col. 1 of the TSUS are most-favored-nation (MFN) rates and in general represent the final stage of the reductions granted in the Tokyo Round of the Multilateral Trade Negotiations. Column 1 duty rates are applicable to imported products from all countries except those Communist countries and areas enumerated in general headnote 3(d) to the TSUS, whose products are dutied at the rates set forth in col. 2; the People's Republic of China, Hungary, Poland, and Yugoslavia are the only Communist countries eligible for MFN treatment. Among articles dutiable at column 1 rates, particular products of enumerated countries may be eligible for reduced rates of duty or for duty-free treatment under one or more preferential tariff programs. Such tariff treatment is set forth in the special rates of duty column.

form. It also covers all imports of antibiotics, other than penicillins, that are either benzenoid in structure or derived from benzenoid sources. Examples of other products that would be classified in TSUS item 411.76 include chloramphenicol, moxalactam, and imipenem. Other antibiotics (i.e., non-benzenoid) imported in bulk are provided for in TSUS items 437.30-.32. 1/

Cephalexin is not eligible for duty-free entry under the Generalized System of Preferences (GSP); 2/ however, it is eligible for duty-free entry under the Caribbean Basin Economic Recovery Act (CBERA), 3/ and under the United States-Israel Free Trade Area Implementation Act of 1985 as indicated in the special column. 4/ The proposed rate of duty for goods originating in the territory of Canada will be 3.3 percent ad valorem, if the U.S.-Canada Free Trade Agreement is implemented.

Under the Harmonized Tariff Schedule of the United States (HTS), which becomes effective January 1, 1989, this chemical is classified in subheading 3004.20.00 as medicaments, put up in measured doses or in forms or packings for retail sale, containing antibiotics other than penicillins for human use. 5/

1/ The latter tariff item was 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, however, the Commission requested in its questionnaires that imports of cephalexin products under any TSUS classification be reported.

2/ The Generalized System of Preferences (GSP) affords nonreciprocal tariff preferences to developing countries to aid their economic development and to diversify and expand their production and exports. The U.S. GSP, enacted in title V of the Trade Act of 1974 and renewed in the Trade and Tariff Act of 1984, applies to merchandise imported on or after January 1, 1976 and before July 4, 1993. Indicated by the symbol "A" or "A\*" in the special rates column, the GSP provides duty-free entry to eligible articles the product of and imported directly from designated beneficiary developing countries.

3/ The Caribbean Basin Economic Recovery Act (CBERA) affords nonreciprocal tariff preferences to developing countries in the Caribbean Basin area to aid their economic development and to diversify and expand their production and exports. The CBERA, enacted in title II of Public Law 98-67 and implemented by Presidential Proclamation 5133 of November 30, 1983, applies to merchandise entered, or withdrawn from warehouse, for consumption on or after January 1, 1984; it is scheduled to remain in effect until September 30, 1995. Indicated by the symbol "E" or "E\*" in the special rates column, the CBERA provides duty-free entry to eligible articles the product of and imported directly from designated Basin countries.

4/ Preferential rates of duty in the special rates column followed by the code "I" are applicable to products of Israel under the United States-Israel Free Trade Area Implementation Act of 1985, as provided in general headnote 3(e)(viii) of the TSUS. Where no rate of duty is provided for products of Israel in the special rates column for a particular tariff item, the rate of duty in column 1 applies.

5/ The Harmonized Commodity Description and Coding System, known as the Harmonized System or HS, is intended to serve as the single modern product nomenclature for use in classifying products for customs tariff, statistical, and transport documentation purposes. Based on the Customs Cooperation Council Nomenclature, the HS is a detailed classification structure containing approximately 5,000 headings and subheadings describing articles in trade. The provisions are organized in 96 chapters arranged in 20 sections which, along with the interpretative rules and the legal notes to the chapters and sections, form the legal text of the system. Parties to the HS Convention agree to base



The column 1 general rate of duty (the MFN rate) will be 3.7 percent ad valorem. 1/ This category covers all antibiotics, not elsewhere enumerated, that are imported in dosage form, regardless of how they are derived.

#### Nature and Extent of Alleged Sales at LTFV

The petitioner alleges that imports of generic cephalexin capsules from Canada are being sold in the United States at LTFV margins ranging from 18.4 to 39.7 percent. These alleged dumping margins were calculated by comparing Canadian home market prices for generic cephalexin capsules with export prices to the United States based on bids by the importer to first unrelated customers. Home market prices are taken from the Drug Benefit Formularies (April and July 1987, January and July 1988) published by the Ministries of Health of Ontario and Saskatchewan, Canada. 2/ The period covered by the LTFV analysis is the 10-month period from December 1987 through September 1988.

Additionally, the petitioner alleges the existence of "critical circumstances," 3/ i.e., that the importer knew, or should have known, that the exporter was selling at LTFV, since the importer, Lyphomed/Novopharm Pharmaceutical Co., is the U.S. side of a joint venture between Lyphomed, Inc., a U.S. manufacturer of critical care injectable pharmaceuticals, and Novopharm, Ltd., a Canadian manufacturer of oral pharmaceuticals. Through this joint venture, each manufacturer is allowed to import and market the other's products in the importer's country. Petitioner alleges that, considering the extent of the relationship and the sophistication of both parties, awareness of both Novopharm's production costs and home market prices can be attributed to the venture, as well as knowledge of the fact that its U.S. prices for the imported merchandise were or became priced at less than "fair value," if not below Novopharm's cost of production.

Petitioner further alleges that the injury caused by sales at LTFV is difficult to repair and was caused by reason of massive imports of the subject product over a relatively short period of time. Petitioner cited more than 180 price cuts, made to existing customers for products already ordered or on open invoice, which were specifically required in order to prevent the customers from canceling the orders and purchasing the imported merchandise. These price cuts are believed to be primarily attributable to competition from the subject imports, and ranged from \*\*\* to \*\*\* percent of the originally invoiced price.

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Legislation to replace the TSUS with an HS-based tariff schedule known as the Harmonized Tariff Schedule of the United States was passed by the U.S. Congress and the HS is scheduled to go into effect January 1, 1989.

1/ Source: Harmonized Tariff Schedule of the United States, supp. 2 to USITC Pub. No. 2030.

2/ According to petitioner, prices listed in the Drug Benefit Formularies represent the lowest, not average, amount for which a listed drug product of the particular dosage indicated can be purchased in Canada for wholesale or retail trade in the particular province. Respondent differed with this interpretation at the conference, explaining that the Canadian formulary system actually allows for a certain margin above or below the formulary price. Transcript at pp. 169-173.

3/ Section 733(e)(1) of the Tariff Act of 1930.

## The U.S. Industry

There are five U.S. producers of generic cephalixin capsules: Biocraft Laboratories, Inc., Elmwood Park, NJ; Vitarine Pharmaceuticals, Inc., Springfield Gardens, NY; Barr Laboratories, Northvale, NJ; Zenith Laboratories, Ramsey, NJ; and Jerome Stevens Pharmaceuticals, Bohemia, NY. In addition, there is one producer of the originally patented cephalixin capsule: Eli Lilly and Co., Indianapolis, IN.

Biocraft Laboratories, Inc.--Biocraft Laboratories, Inc. (Biocraft) has been a producer of generic pharmaceuticals since 1963. Biocraft is headquartered in Elmwood Park, NJ and was the \*\*\* producer of generic cephalixin products in 1988. The company is listed on the New York Stock Exchange 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 nonantibiotic generic drugs.

In February 1987, Biocraft received FDA approval to manufacture dosage forms of generic cephalixin and generic cephradine, both first generation cephalosporins, in its cephalosporin plant in Fairfield, NJ. The company also has an agreement with American Cyanamid Co.'s Lederle Laboratories to begin manufacture of dosage forms of cefixime, a third generation cephalosporin, sometime in 1989. In 1989 Biocraft will also commence production of bulk cephalixin in its Warwick, NJ, facility. It will be the only U.S. generic drug manufacturer with the capacity to do so. Currently, all U.S. generic drug manufacturers import or purchase from importers the bulk cephalixin used in the production of dosage forms of the medication. Biocraft originally sourced the bulk cephalixin from \*\*\*.

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 cephalixin capsules in April 1987 (500mg dosage) and June 1987 (250mg dosage). In addition, the company received approval to produce and market cephalixin tablets in 250mg and 500mg dosages, as well as powder for oral suspension in 125mg and 250mg bases, in August 1987. Barr manufactures its cephalixin 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 is the \*\*\* producer of generic cephalixin in 1988.

Jerome Stevens Pharmaceuticals, Inc.--Jerome Stevens Pharmaceuticals (JSP) is the \*\*\* most recent domestic generic producer to enter the market. JSP received FDA approval to produce and market generic cephalixin in March 1988. The company is located in Bohemia, NY.

JSP was not identified as a producer in the petition. During the course of the investigation, the Commission identified JSP as a producer \*\*\*. 1/

Vitarine Pharmaceuticals, Inc.--Vitarine Pharmaceuticals, Inc. (Vitarine) has been a producer of generic pharmaceuticals since 1983. 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, \*\*\*. Although Vitarine produces other antibiotics, \*\*\*. Vitarine \*\*\*.

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. The company is headquartered in Springfield Gardens, NY.

Zenith Laboratories Inc.--Zenith Laboratories (Zenith) is the \*\*\* producer of generic cephalexin in the United States. \*\*\*. 2/

Eli Lilly and Co.--Eli Lilly and Co. (Lilly) was the original patent holder for Keflex, which is marketed through Lilly's Dista division. The company's patent on the product expired in April 1987, and in fact has expired worldwide. 3/ Lilly's \*\*\* U.S. cephalexin production facilities are located at \*\*\*. The company also \*\*\*. 4/ In addition to its cephalexin line, Lilly produces some 400 other pharmaceutical products.

Although the patent on Keflex capsules and powder for oral suspension has expired, Lilly retains a patent on its film-coated cephalexin tablet, which sells under the trade name Keflet. Lilly also received FDA approval in October 1987 to produce and market a cephalexin hydrochloride in tablet form, a patented product with the trade name Keftab. Although Keftab has a slightly different chemical formulation than cephalexin monohydrate, and may interact somewhat differently in solutions, the two products are considered clinical equivalents. 5/

Lilly also produces other cephalosporins, notably Ceclor, the still-patented version of cefaclor, generally considered a second generation

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1/ Telephone conversations between Commission staff and \*\*\*, Nov. 21 and 29, 1988.

2/ \*\*\*.

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

4/ Ibid.

5/ Telephone conversation between Commission staff and an official of the U.S. Food and Drug Administration, Dec. 1, 1988.

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

#### 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. LyphoMed/Novopharm Pharmaceutical Company (LyphoMed) is a joint venture owned by LyphoMed Ventures, Inc., of Rosemont, IL and Novopharm Inc. of Scarborough, Ontario, Canada. \*\*\*. LyphoMed Ventures, Inc. is a wholly owned subsidiary of LyphoMed, Inc., of Rosemont, IL, and Novopharm Inc. is a wholly owned subsidiary of Novopharm, Ltd. (Novopharm) of Scarborough, Ontario, Canada.

LyphoMed began importing and marketing generic cephalexin capsules in April 1987, and began importing and marketing generic cephalexin in oral suspension form in July 1987. 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.

Other importers of cephalexin in dosage form are \*\*\*. 3/ Countries exporting cephalexin in dosage form, in addition to Canada, are \*\*\*. Bulk cephalexin is generally imported from \*\*\*.

#### The Domestic Market

##### Apparent U.S. consumption

Data on apparent consumption of cephalexin were compiled from information submitted in response to questionnaires of the U.S. International Trade Commission. Table 1 shows apparent consumption of cephalexin capsules, branded and generic, domestically produced and imported, by quantity and by value. Table 2 shows apparent consumption, by firms and countries of origin, in terms of quantity and value. Table 3 shows apparent consumption of cephalexin in other dosage forms, by firms and countries of origin. Apparent consumption figures are compiled from data submitted on shipments of domestically produced and imported product. To the extent that the Commission did not receive data from \*\*\*, consumption figures are understated.

During 1985-87, apparent consumption of all cephalexin capsules \*\*\* from \*\*\* kilograms in 1985 to \*\*\* kilograms in 1987, \*\*\*, the year that generic capsules entered the market. 4/ Apparent consumption of branded cephalexin capsules \*\*\* percent in terms of quantity between January-September 1987 and January-September 1988, the interim periods used in this investigation. During that same time, consumption of domestically-produced generic capsules \*\*\* percent, from \*\*\* kilograms to \*\*\* kilograms. Consumption

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.

3/ \*\*\*.

4/ This \*\*\* in consumption may be partially accounted for by the fact that \*\*\*.

of imports from Canada \*\*\* percent during the interim periods, from \*\*\* kilograms to \*\*\* kilograms, and overall consumption of cephalexin capsules, regardless of brand or country of origin, \*\*\* percent, from \*\*\* kilograms to \*\*\* kilograms for January-September 1987 when compared to the corresponding period of 1988.

Table 1

Cephalexin capsules: Apparent U.S. consumption, branded and generic, domestically produced and imported, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

1/ \*\*\*.

2/ \*\*\*.

3/ Not applicable.

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

Table 2

Cephalexin capsules: Apparent U.S. consumption, by firms and by countries of origin, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

1/ Imports from \*\*\* were reported.

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

Table 3

Cephalexin, dosage forms other than capsules: 1/ Apparent U.S. consumption, by firms and by countries of origin, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

1/ Tablets and powder for oral suspension.

2/ \*\*\*.

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

Channels of distribution

U.S. producers of generic cephalixin capsules and the U.S. importer of the Canadian generic cephalixin capsules sell a majority of their capsules in the U.S. market to \*\*\*. The remainder is sold to \*\*\*. 1/

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, and other pharmaceutical supplies.

\*\*\*, Lilly sells its Keflex capsules \*\*\*. For 1987, the proportion of generic and brand name cephalixin capsules sold by U.S. producers and the Canadian importer to each of the four categories of customers are shown in terms of percentages, based on the value of sales of the specified types of cephalixin capsules sold during 1987, in the following tabulation:

<u>Type of purchaser</u>	<u>U.S.-produced cephalexin capsules</u>		<u>Imported Canadian cephalexin capsules</u>	
	<u>Generic</u>	<u>Keflex</u>	<u>Generic</u>	<u>Keflex</u>
	*	*	*	*

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

Although not shown, non-capsule formulations of the domestic and imported Canadian cephalixin are generally sold in the same manner as the capsule form. 2/

Generic drug distributors and pharmaceutical companies accounted for similar shares of the \*\*\*. Combined, these two categories of customers accounted for \*\*\* percent of the domestic generic capsules and \*\*\* percent of the imported generic capsules. Most of the remaining sales of domestic generic capsules were to \*\*\* and the remainder \*\*\*. All of the remaining sales of the imported products \*\*\* were to \*\*\*. These latter sales reflect \*\*\*.

1/ \*\*\*.

2/ Non-capsule forms of the domestic and imported-Canadian cephalixin account for less than \*\*\* percent of total U.S. sales of all forms of cephalixin. The only difference in sales patterns between capsule and non-capsule forms involves the U.S.-produced generic cephalixin \*\*\*

Consideration of Material Injury to an  
Industry in the United States

In order to evaluate the condition of the U.S. industry producing generic cephalixin capsules, the Commission sent questionnaires to the five known manufacturers of the product in the United States, as well as to the one producer of branded cephalixin capsules. These firms and their respective roles in the U.S. market are discussed in the U.S. industry section of this report. Information on these firms is presented separately throughout the material injury section of this report. Jerome Stevens Pharmaceuticals was not identified in the petition and was subsequently identified as a producer by Commission staff during the course of the investigation. \*\*\*.

U.S. production, capacity, and capacity utilization

U.S. production of generic cephalixin capsules commenced in April 1987 after the expiration of the patent on Lilly's Keflex. Between January-September 1987 and January-September 1988, production of generic cephalixin capsules \*\*\* percent, from \*\*\* kilograms to \*\*\* kilograms (table 4). During that same period, production of the branded capsule \*\*\* percent from \*\*\* kilograms to \*\*\* kilograms after having \*\*\* percent between 1986 and 1987.

Capacity to produce generic cephalixin capsules is substantial and \*\*\* percent during the interim periods of this investigation. \*\*\*. In 1987, capacity to produce generic cephalixin capsules was \*\*\*, and capacity of all firms to produce cephalixin capsules was \*\*\*. \*\*\*, and, theoretically, the capacity for cephalixin can be diverted to produce other cephalosporins.

\*\*\*. Capacity utilization for the generic capsule producers was \*\*\* percent in interim 1987 and \*\*\* percent in interim 1988. Lilly's capacity utilization \*\*\* percent in interim 1987 to \*\*\* percent in interim 1988. For Lilly, \*\*\* (table 5).

Table 4  
Cephalixin capsules: U.S. production, capacity, and capacity utilization, by firms, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

- 1/ \*\*\*.
- 2/ \*\*\*.
- 3/ \*\*\*.
- 4/ \*\*\*.
- 5/ Not applicable.

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

Table 5

Cephalexin, dosage forms other than capsules: U.S. production, capacity, and capacity utilization, by firms, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

- 1/ \*\*\*.  
 2/ \*\*\*.  
 3/ \*\*\*.  
 4/ \*\*\*.  
 5/ Not applicable.

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

Lilly's capacity, production, and capacity utilization for the production of bulk cephalexin is shown in the following tabulation:

\* \* \* \* \*

- 1/ \*\*\*.

Between January-September 1987 and the corresponding period in 1988, the unit value of bulk cephalexin decreased significantly, a trend primarily due to increased competition from European suppliers. Petitioner noted at the staff conference that this decline in price allowed generic producers' "break even point" to decline as well, explaining in part companies' ability to decrease prices of the finished cephalexin products in response to competition. <sup>1/</sup>

Bulk cephalexin: Purchases of imported bulk cephalexin by U.S. generic producers, by firms, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

U.S. producers' domestic shipments

Domestic shipments of generic cephalexin capsules, in terms of quantity, \*\*\* percent between January-September 1987 and January-September 1988, from \*\*\* kilograms to \*\*\* kilograms. The value of the shipments \*\*\* percent during that time, \*\*\* million to \*\*\* million. Shipments of Keflex \*\*\* in terms of both quantity and value, from \*\*\* kilograms at \*\*\* million to \*\*\* kilograms at \*\*\* million.

Table 6 summarizes shipments of generic and branded cephalexin capsules, by quantity and value, during January 1985-September 1988. Table 7 provides a breakout of shipments by firms, in terms of quantity and value, for the same time periods.

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<sup>1/</sup> See transcript at pp. 55-56, 69-70.



Table 6

Cephalexin: U.S. producers' domestic shipments, branded and generic, by dosage types, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

1/ Tablets and powder for oral suspension.

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

Table 7

Cephalexin: U.S. producers' domestic shipments, by firms and by dosage types, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

1/ Tablets and powder for oral suspension.

2/ \*\*\*.

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

U.S. producers' export shipments

Of the six domestic producers of cephalexin products, both branded and generic, \*\*\* reported export shipments. \*\*\*. 1/ \*\*\*.

Exports \*\*\* throughout the period of the investigation, after \*\*\*. \*\*\* export shipments of \*\*\* are summarized in the following tabulation (in kilograms):

\* \* \* \* \*

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

Inventories of branded cephalexin products \*\*\* kilograms in 1985 to \*\*\* kilograms in 1986, then \*\*\* kilograms in 1987. Inventories of Keflex capsules showed a \*\*\* percent from \*\*\* kilograms to \*\*\* kilograms. Inventories of Keflex capsules \*\*\* between January-September 1987 and the corresponding period of 1988, \*\*\* percent from \*\*\* kilograms to \*\*\* kilograms.

Inventories of generic cephalexin capsules \*\*\* percent between January-September 1987 and the corresponding period of 1988. Inventories of all cephalexin products, including bulk, \*\*\* percent during that time. Bulk cephalexin purchased from importers is held in inventory by generic producers.

U.S. producers' end-of-period inventories are summarized in table 8. Table 9 provides a breakout of end-of-period inventories, by firms.

---

1/ Staff conversation with \*\*\*, Nov. 22, 1988.

Table 8

Cephalexin: U.S. producers' end-of-period inventories, branded and generic, by types, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

- 1/ Tablets and powder for oral suspension.  
 2/ Ratios are based on shipments by those firms reporting inventory data. Ratios for interim periods are based on annualized data. \*\*\*.  
 3/ Not applicable.

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

Table 9

Cephalexin: U.S. producers' end-of-period inventories, by firms and by types, 1985-87, January-September 1987 and January-September 1988

\* \* \* \* \*

- 1/ Tablets and powder for oral suspension.  
 2/ \*\*\*.  
 3/ For internal consumption only. Bulk is purchased from importers, not manufactured, by generic producers.  
 4/ \*\*\*.

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

#### U.S. employment, wages, and productivity

Employment for generic cephalexin producers \*\*\* throughout the period of the investigation, \*\*\* from \*\*\* production and related workers in January-September 1987 to \*\*\* in the corresponding period for 1988. Hours worked \*\*\* in this time, from \*\*\* to \*\*\* hours. Hourly wages \*\*\* percent, from \*\*\* to \*\*\*, and productivity \*\*\* percent, from \*\*\* kilograms \*\*\* per hour to \*\*\* kilograms \*\*\* per hour.

\*\*\*.

\*\*\*. \*\*\*. 1/

Tables 10 and 11 provide employment and wage data for the generic and branded producers of cephalexin products, respectively.

---

1/ Staff conversation with \*\*\*, Nov. 22, 1988.

Table 10

Generic cephalixin: Average number of production and related workers, hours worked, wages paid, total compensation, productivity, and unit labor costs, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

1/ \*\*\*.

2/ Tablets and powder for oral suspension.

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

Table 11

Branded cephalixin: Average number of production and related workers, hours worked, wages paid, total compensation, productivity, and unit labor costs, 1985-87, January-September 1987, and January-September 1988 1/

\* \* \* \* \*

1/ \*\*\*.

2/ \*\*\*.

3/ \*\*\*.

4/ Tablets and powder for oral suspension.

5/ \*\*\*.

6/ \*\*\*.

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

#### Financial experience of U.S. producers

\*\*\*, accounting for \*\*\* percent of reported U.S. production of generic cephalixin capsules in 1987, provided usable income-and-loss data on the overall operations of their establishments within which generic cephalixin capsules are produced, in addition to income-and-loss data on their cephalixin operations. Generic cephalixin operations on the basis of respective sales value were \*\*\* percent of overall establishment operations in 1987. The generic cephalixin producers reported only for the year 1987 and the interim periods ending September 30, 1987 and September 30, 1988, since they did not begin operations until 1987. \*\*\*. 1/

Overall establishment operations.--Aggregate income-and-loss data are presented in table 12. Overall establishment sales of the reporting firms were \*\*\* million in 1987. Sales during the interim periods \*\*\* from \*\*\* million in 1987 to \*\*\* million in 1988, or by \*\*\* percent. Operating income followed \*\*\* trend: income of \*\*\* was experienced in 1987, then there was \*\*\* from \*\*\* million in interim 1987 to \*\*\* million in interim 1988, or \*\*\* of \*\*\* percent. The operating margins, however, \*\*\* percent in 1987, interim 1987, and interim 1988, respectively.

Table 12

Income-and-loss experience of U.S. producers 1/ on the overall operations of their establishments within which generic cephalixin capsules are produced, accounting years 1985-87 and interim periods ended Sept. 30, 1987, and Sept. 30, 1988

\* \* \* \* \*

1/ \*\*\*.

2/ No generic sales because brand name patent was in effect.

3/ \*\*\*.

4/ Cash flow is defined as net income or loss plus depreciation and amortization.

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

Cephalexin operations.--Aggregate income-and-loss data are presented in table 13. Cephalexin sales of the reporting firms were \*\*\* million in 1987. Sales \*\*\* million in 1987 to \*\*\* million in interim 1988, or by \*\*\* percent. Apparently, wide swings in sales are not unexpected in the generic market, 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. 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 \*\*\* trend; income of \*\*\* million was experienced in 1987, then there was \*\*\* million in interim 1987 to \*\*\* million in interim 1988, or \*\*\* percent. The operating margins \*\*\* percent in 1987, interim 1987, and interim 1988, respectively.

Table 13

Income-and-loss experience of U.S. producers 1/ on their cephalixin operations, accounting years 1985-87 and interim periods ended Sept. 30, 1987, and Sept. 30, 1988

\* \* \* \* \*

1/ \*\*\*.

2/ No generic sales because brand name patent was in effect.

3/ \*\*\*.

4/ Cash flow is defined as net income or loss plus depreciation and amortization.

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

Generic cephalixin capsule operations.--Aggregate income-and-loss data are presented in table 14. Generic cephalixin capsule sales of the reporting firms were \*\*\* million in 1987. Sales \*\*\* from \*\*\* million in 1987 to \*\*\* million in interim 1988, or by \*\*\* percent. Operating income followed \*\*\* trend; income of \*\*\* million was experienced in 1987, then there was \*\*\* from \*\*\* million in interim 1987 to \*\*\* million in interim 1988, or \*\*\* percent. The operating margins \*\*\* percent in 1987, interim 1987, and interim 1988, respectively.

Conversion costs, i.e., direct labor and factory overhead, which includes all other factory expenses except raw materials, were \*\*\* percent of cost of goods sold in 1987. The raw material cost was \*\*\* percent of cost of goods sold in that year. The relatively high raw material costs and low conversion costs indicates that the transformation from input to finished goods is not as significant to the generic drug producers as that in typical manufacturing processes. The conversion and raw material costs for each of the generic producers for cephalixin capsules are shown in the following tabulation (as a percent of cost of goods sold):

<u>Item</u>	<u>1987</u>
***	***

The ratios were essentially identical on all cephalixin products for these generic producers.

The aggregate amounts of the three major components of the cost-of-goods-sold plus general, selling, and administrative (G,S,&A) expenses are shown in the following tabulation (in thousands of dollars except where noted):

<u>Item</u>	<u>1987</u>	
	<u>Amount</u>	<u>Percent</u>
***	***	***

Total operating expenses excluding raw materials are \*\*\* million, or the value added as a percent of total operating expenses is \*\*\* percent.

Table 14

Income-and-loss experience of U.S. producers 1/ on their generic cephalixin capsule operations, accounting years 1985-87 and interim periods ended Sept. 30, 1987, and Sept. 30, 1988

\* \* \* \* \*

1/ \*\*\*.

2/ No generic sales because brand name patent was in effect.

3/ \*\*\*.

4/ Cash flow is defined as net income or loss plus depreciation and amortization.

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

Other cephalixin operations.--Aggregate other cephalixin income-and-loss data are presented in table 15. Other cephalixin sales of the reporting firms were \*\*\* million in 1987. Sales \*\*\* from \*\*\* million in 1987 to \*\*\* million in interim 1988, or by \*\*\* percent. Operating income followed a similar trend: \*\*\* million was experienced in 1987, then there was \*\*\* from \*\*\* million in interim 1987 to \*\*\* in interim 1988, or \*\*\* percent. The operating margins \*\*\* percent in 1987, interim 1987, and interim 1988, respectively.

Table 15  
Income-and-loss experience of U.S. producers 1/ on their other cephalixin operations, accounting years 1985-87 and interim periods ended Sept. 30, 1987, and Sept. 30, 1988

\* \* \* \* \*

- 1/ \*\*\*.
- 2/ No generic sales because brand name patent was in effect.
- 3/ \*\*\*.
- 4/ Cash flow is defined as net income or loss plus depreciation and amortization.

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 generic cephalixin capsules are produced are shown in the following tabulation (in thousands of dollars):

\* \* \* \* \*

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

\* \* \* \* \*

Research and development expenses.--Research and development expenses relating to cephalixin products for the U.S. producers are shown in the following tabulation (in thousands of dollars):

\* \* \* \* \*

Return on total assets.--Net-income-before-tax return on total assets 1/ in 1987 for each of the generic cephalixin capsule producers is shown in the following tabulation (as a percent of product assets):

\* \* \* \* \*

1/ Total establishment assets are apportioned to the product groups on the basis of respective book value of property, plant, and equipment.

These producers compare quite favorably with the drug industry as a whole on operating profits before tax, as shown in the following tabulation (as a percent of net sales):

	1987			
	1st Q	2nd Q	3rd Q	4th Q
Industry 1/.....	20.9	18.0	18.4	5.9
Average.....		15.8		
***.....	***	***	***	***

1/ Quarterly Financial Report, Chemicals and Allied Products--Drugs, 1987.

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, investment, and ability to raise capital. Their replies are presented below.

"\*\*\*."

"\*\*\*."

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,

---

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."

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

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

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

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

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

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

(X) the actual and potential negative effects on the existing development and production efforts of the domestic industry, including efforts to develop a derivative or more advanced version of the like product. <sup>1/</sup>

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 of the subject merchandise and the alleged material injury;" and information on the effects of imports of the subject merchandise on U.S. producers' existing development and production efforts (item (X)) is presented in the section entitled "Consideration of material injury to an industry in the United States." Item (IX), involving agricultural products, does not apply in this case. Available information on U.S. inventories of the subject products (item (V)); foreign producers' operations, including the potential for "product-shifting" (items (II), (VI), and (VIII) above); any other threat indicators, if applicable (item (VII) above); and any dumping in third-country markets, follows.

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<sup>1/</sup> 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."



U.S. inventories of cephalexin from Canada

As stated previously in this report, there is only one importer of generic cephalexin capsules from Canada. Imports were first reported in 1987. Inventories of generic capsules \*\*\* percent between January-September 1987 and the corresponding period of 1988, the only periods for which comparison is possible. \*\*\* inventories of other forms of cephalexin (tablets and powder for oral suspension) \*\*\* during this time, from \*\*\* kilograms in 1987 to \*\*\* kilograms in 1988. Inventories of all cephalexin products \*\*\* percent during this time, from \*\*\* kilograms to \*\*\* kilograms (table 16).

Table 16

Generic cephalexin: U.S. end-of-period inventories of imports from Canada, 1985-87, January-September 1987, and January-September 1988 1/

\* \* \* \* \*

1/ \*\*\*.

2/ \*\*\*.

3/ \*\*\*.

4/ Not applicable.

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

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

There is only one producer of generic cephalexin in Canada that is approved by the FDA to export its product to the United States: Novopharm, Ltd. Other producers of cephalexin products in Canada are \*\*\*, firms that do not have FDA approval to export to the United States. \*\*\*. 1/

Data on Novopharm's capacity and production are presented in table 17. The company's capacity to produce generic cephalexin in dosage form \*\*\* between 1986 and 1987 because in April 1987, production of cephalexin was transferred to a separately dedicated plant, a move that was prompted by U.S. FDA requirements that cephalosporins be produced in a dedicated facility separate from the manufacture of other antibiotic products. Novopharm does not have any other facilities in Canada that produce or export cephalexin to the United States, and the company does not produce any other cephalosporins. 2/ Novopharm does not produce its own bulk cephalexin but instead imports the raw material from \*\*\*.

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

2/ Telephone conversation between Commission staff and \*\*\*, Nov. 28, 1988.

Table 17

Generic cephalixin: Production, end-of-period capacity, and capacity utilization in Canada, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

1/ Tablets and powder for oral suspension.

2/ \*\*\*.

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

Novopharm's domestic shipments of generic capsules \*\*\* between 1985 and 1986 (table 18). Between 1986 and 1987, capsule shipments \*\*\* percent, from \*\*\* kilograms to \*\*\* kilograms. During the interim periods January-September 1987 and January-September 1988, shipments of capsules \*\*\*. Combining January-September 1988 data with projected October-December shipments results in anticipated domestic shipments of capsules of \*\*\* kilograms, representing a \*\*\* percent \*\*\* 1987. Projected 1989 shipments are \*\*\* kilograms, \*\*\* of \*\*\* percent from 1988 and \*\*\* percent \*\*\* 1987 (table 18).

For other dosage forms of cephalixin, specifically powder for oral suspension, domestic shipments \*\*\* percent between 1985 and 1986, then \*\*\* percent between 1986 and 1987. Between interim periods, shipments \*\*\* percent. Projected full-year 1988 totals are \*\*\* kilograms, representing \*\*\* percent \*\*\* \*\*\* 1987. Projected 1989 shipments are \*\*\* kilograms, \*\*\* percent \*\*\* 1988 and \*\*\* percent \*\*\* 1987. The differences in shipment quantity between capsules and other dosage forms of cephalixin can be attributed to the fact that the preferred dosage form in Canada is tablets, as opposed to capsules in the United States. 1/

Novopharm did not export cephalixin products to the United States in 1985 or 1986. Shipments of capsules in 1987, the first year that export was possible, totaled \*\*\* kilograms. Capsule exports \*\*\* percent between interim 1987 and interim 1988, from \*\*\* kilograms to \*\*\* kilograms. Exports in 1988 are projected to total \*\*\* kilograms, \*\*\* percent \*\*\* 1987. Projected capsule exports in 1989 are \*\*\* kilograms, \*\*\* percent from the 1988 projection and \*\*\* than actual shipments for 1987.

The company's exports of cephalixin in tablet and powder form \*\*\* in 1987, the year of their introduction. Interim 1988 shipments were \*\*\* kilograms, or \*\*\* percent \*\*\* than shipments during interim 1987. Projected 1988 export figures are \*\*\* kilograms, or \*\*\* percent \*\*\* than in 1987. Projected exports of tablets and powder for oral suspension in 1989 are \*\*\* kilograms, \*\*\* percent \*\*\* than projected 1988 and \*\*\* percent \*\*\* than 1987.

Novopharm exports \*\*\*. Exports of capsules \*\*\* during January-September 1988 at \*\*\* kilograms, with \*\*\* exports projected for 1989. Exports of tablets and powder for oral suspension \*\*\* in 1985 with \*\*\* kilograms, \*\*\* since that year, with \*\*\* exports projected for 1989. Novopharm's principal export market outside the United States is \*\*\*.

---

1/ Statement of Leslie Dan, Novopharm Ltd., at conference. See transcript, p. 145.

Table 18

Generic cephalixin: Shipments of the Canadian producer, 1985-87, January-September 1987, and January-September 1988, with projected data for October-December 1988 and 1989

\* \* \* \* \*

1/ \*\*\*.

2/ \*\*\*.

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

Inventories of the Canadian producer.--Inventories of Novopharm are presented in table 19. Its inventories of capsules \*\*\* percent between January-September 1987 and January-September 1988, from \*\*\* kilograms to \*\*\* kilograms. At the same time, inventories of bulk cephalixin \*\*\* percent. Inventories of all cephalixin \*\*\* percent, from \*\*\* kilograms to \*\*\* kilograms.

Table 19

Generic cephalixin: End-of-period inventories of the Canadian producer, by types, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

1/ \*\*\*.

2/ \*\*\*.

3/ \*\*\*.

4/ \*\*\*.

5/ \*\*\*.

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 of the Subject Merchandise and the Alleged Material Injury

##### U.S. imports

Between January-September 1987 and the corresponding period for 1988, imports of generic cephalixin capsules from Canada \*\*\* percent, from \*\*\* kilograms to \*\*\* kilograms. Imports of generic cephalixin capsules from all sources \*\*\* percent during that time, from \*\*\* kilograms to \*\*\* kilograms. Imports of all other forms of cephalixin from Canada \*\*\*, from \*\*\* kilograms to \*\*\* kilograms. There were \*\*\* imports of other forms of cephalixin from any other country.

Table 20 summarizes imports of cephalixin products from Canada and from all other sources. The data include all known imports from all known sources for the time period of this investigation.

Table 20

Cephalexin: Imports from Canada and from all other sources, by dosage types, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

1/ \*\*\*.

2/ Not applicable.

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

U.S. market penetration by imports.

Measured in terms of quantity, imports of Canadian generic cephalixin capsules accounted for \*\*\* percent of U.S. consumption of all generic capsules during January-September 1987, and \*\*\* percent during the corresponding period of 1988. The Canadian generic cephalixin capsules accounted for \*\*\* percent of U.S. consumption of all cephalixin capsules, branded and generic, in January-September 1987 and \*\*\* percent of the same market segment for the corresponding period of 1988.

Table 21 shows U.S. market penetration by imports of generic cephalixin capsules from Canada, expressed in terms of both quantity and value. The calculations are based on shipment data gathered by the Commission.

Table 21

Cephalexin capsules: Market penetration of imported Canadian generic cephalixin capsules, 1985-87, January-September 1987, and January-September 1988 1/

\* \* \* \* \*

1/ \*\*\*.

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

U.S. market shares of U.S. producers and imports, by country

Market shares of U.S. producers of cephalixin capsules, brand-name and generic, are shown in the following tabulation (in percent).

\* \* \* \* \*

1/ Totals may not add precisely due to rounding.

2/ Less than 0.05 percent.

Data were compiled from information on shipments received in response to Commission questionnaires.

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. The majority of the subject generic cephalixin capsules sold in the U.S. market are priced in bottles of 250 and 500 milligram capsule dosages containing 100 and 500 capsules per bottle. 1/ Prices reflect the dosage and quantity of the 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 supplying firms typically sell to a few large companies, mostly at the wholesale level of the market. Discounted sales of generic cephalixin capsules are concentrated in shipments to generic-drug distributors and pharmaceutical companies, reflecting the marketing power advantages of these large-volume purchasers. Generic-drug distributors and pharmaceutical companies are generally well known wholesale suppliers of drugs and other pharmaceutical materials that inventory, advertise, and market large quantities of generic cephalixin capsules at both the wholesale and retail levels of the distribution chain throughout the United States. Generic cephalixin capsules sold to generic-drug distributors and pharmaceutical companies 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 during the period the generic drug has been sold in the U.S. market \*\*\*. 4/ During this period Lilly's average net f.o.b. selling prices of the specified Keflex capsule products have \*\*\* prior to the expiration of its patent. Although there have been \*\*\*, sales of Keflex have \*\*\* during the 18-month period since the Keflex patent expired and lower-priced generic equivalents have been available. Lilly reports in its questionnaire response that \*\*\*. 5/ Market share data shown earlier in this report indicate that U.S. producers of generic cephalixin, \*\*\*.

Sales of the domestic and imported Canadian generic cephalixin capsules are made on a contract and a spot basis. Contracts generally extend for about one year and typically involve private-label customers. These contracts usually stipulate any production and packaging and labeling requirements of

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

2/ \*\*\*.

3/ \*\*\*.

4/ \*\*\*. For a more complete discussion of prices of Keflex and generic cephalixin capsules, see tables 24, 29, and 30 and the discussion of such prices later in this section of the report.

5/ As advertising and promotion of the generic drug increase and the price disparity between the generic drug and Keflex widens, the quantity of Keflex sold will \*\*\*. In addition, continuing pressure from consumers and third party reimbursables (HMO's, Medicare/Medicaid, health insurance plans, etc.) to hold down medical costs will tend to offset efforts by brand-name drug producers to differentiate their products, such as Keflex, from generic equivalents. (Post Conference Brief of LyphoMed/Novopharm, pp. 11-13).

the customer, the volume expected to be purchased over the contract period, the price level for the contract period, payment terms, and the length of time between issuing purchase orders and delivery of the capsules. The volatile market for cephalexin during the last 18 months has resulted in frequent adjustments to contract and spot prices. 1/

U.S. producers and the importer issue price lists, showing discounts based on the volume purchased. Questionnaire responses indicate that such price lists have not generally been adhered to but are a starting point for negotiated prices on both spot and contract sales. Both U.S. producers and importers typically quote prices f.o.b. their U.S. plants and/or warehouses and offer \*\*\*. Most sales of the domestic and imported Canadian generic cephalexin capsules are shipped on a \*\*\*. For a more complete discussion of transportation costs, see the discussion on transportation factors later in this report.

Questionnaire price data.--The Commission requested net U.S. f.o.b. selling prices and quantities for two generic cephalexin capsule products and two Keflex capsule products from U.S. producers and importers of the subject cephalexin. 2/ The price data were requested for the largest sale and for total sales of the products reported to each of four specified customer categories, by quarters, during April 1987-September 1988 for the generic drug and during January 1985-September 1988 for Keflex. The four types of customers were generic-drug distributors, pharmaceutical companies, retail drug-store chains, and full-line drug wholesalers. The four products for which the price data were requested are shown below:

- PRODUCT 1: GENERIC CEPHALEXIN--250mg capsules in 100-capsule bottles.
- PRODUCT 2: GENERIC CEPHALEXIN--500mg capsules in 100-capsule bottles.
- PRODUCT 3: KEFLEX--250mg capsules in 100-capsule bottles.
- PRODUCT 4: KEFLEX--500mg capsules in 100-capsule bottles.

\*\*\* reported the requested price data, but not necessarily for every product or period. 3/ Based on Commission staff telephone conversations with the responding firms, sales of cephalexin 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. \*\*\* indicated, however, that abnormally high sales of the generic cephalexin were made during the first two quarters following the introduction of this drug in April 1987. Their customers were reportedly \*\*\*.

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

2/ Based on conversations with representatives of \*\*\*, the requested products were identified as large-volume products representative of competition between the domestic and imported Canadian cephalexin capsules. (Telephone conversations with Commission staff on Oct. 18, 29 and 31, 1988.)

3/ \*\*\* responding U.S. producers of generic cephalexin and Lilly are believed to account for \*\*\* of the total value of U.S. producers' domestic shipments of cephalexin capsules during April 1987-September 1988. During the same period, the responding U.S. importer is believed to account for 100 percent of the total value of U.S. imports of cephalexin capsules from Canada--all of which were generic. Prior to April 1987, Lilly was the only supplier of cephalexin capsules (marketed as Keflex) in the U.S. market.

Price trends.--Price trends for the domestic and imported Canadian cephalixin capsules are based on the reported selling prices by types of customers during April 1987-September 1988 for the generic cephalixin, and to \*\*\* during January 1985-September 1988 for Keflex. 1/ The quarterly selling prices of the domestic generic capsules were based on net f.o.b. selling prices of the largest sale in the quarter weighted by total sales of the specified product to each of the four types of customers. The quarterly selling prices of the U.S.-produced Keflex capsules were based on total quarterly net sales values and quantities of the specified products sold to \*\*\*. Lilly \*\*\*. The total quantities, weighted-average prices, and indexes of the weighted-average prices of the domestic cephalixin products are shown in tables 22 and 23 for the generic drug and table 24 for Keflex. 2/

The quarterly selling prices of the imported Canadian generic capsules were based on net f.o.b. selling prices of the largest sale in the quarter of the specified product to \*\*\*. In several periods, however, reported prices of the imported products to these customers were not adjusted for all rebates and discounts--the following price discussion notes these exceptions. Trends in prices of the subject imported generic products are also shown for sales to \*\*\* based on f.o.b. selling prices of the largest sale in each quarter. \*\*\*. 3/4/ \*\*\*. Price data for the imported Canadian generic cephalixin capsules are shown in tables 25 and 26. 5/

U.S. producers' prices.--Quarterly selling prices of the specified domestic generic cephalixin capsules \*\*\* during April 1987-September 1988 (tables 22 and 23). Selling prices of the 250mg capsules in bottles of 100 capsules \*\*\* (table 22). Selling prices of the 250mg capsules \*\*\*.

Quarterly selling prices of the 500mg generic capsules in bottles of 100 capsules \*\*\* (table 23). Selling prices of the 500mg capsules \*\*\*.

1/ \*\*\* during the period of the investigation.

2/ The reported price data of the specified U.S.-produced generic cephalixin capsule products were based on sales values that accounted for approximately \*\*\* percent of the total value of reported U.S. shipments of all domestic generic cephalixin capsules during April 1987-September 1988. The total value of reported U.S. shipments of the specified Keflex capsules during January 1987-September 1988, for which price data were requested, accounted for about \*\*\* percent of the total reported value of shipments of \*\*\* during this latter period.

3/ LyphoMed officials explained at the conference that the firm negotiates discounted prices to hospitals for large-volume sales and the hospitals purchase a certain amount of the cephalixin from the full-line drug wholesalers at the price negotiated with LyphoMed. The importer then remits to the wholesaler the difference between LyphoMed's price to the wholesaler and the negotiated price to the hospital plus an amount for the wholesaler's profit. (Transcript of the conference, pp. 190-192.)

4/ Representatives of LyphoMed indicated that the reported net prices to \*\*\* approximate its net selling prices to \*\*\*, but may understate somewhat LyphoMed's weighted-average net prices based on its total sales to this type of customer. (Telephone conversation with Commission staff on November 23, 1988.)

5/ The reported price data of the specified imported-Canadian cephalixin capsule products were based on sales values that accounted for approximately \*\*\* percent of the total value of reported U.S. imports of all Canadian generic cephalixin capsules during April 1987-September 1988.

Table 22

U.S.-produced generic cephalexin 250mg capsules in 100-capsule bottles: Sales quantities, weighted-average net f.o.b. selling prices, and price indexes of U.S. producers' domestically produced product, by types of customer and by quarters, April 1987-September 1988 1/

\* \* \* \* \*

1/ The quantities represent total sales of all responding U.S. producers of the specified product to each type of customer during the quarters requested. Prices are the net f.o.b. selling prices of their largest quarterly sale weighted by their total sales quantity in that period.

2/ April-June 1987=100.

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

Table 23

U.S.-produced generic cephalexin 500mg capsules in 100-capsule bottles: Sales quantities, weighted-average net f.o.b. selling prices, and price indexes of U.S. producers' domestically-produced product, by types of customer and by quarters, April 1987-September 1988 1/

\* \* \* \* \*

1/ The quantities represent total sales of all responding U.S. producers of the specified product to each type of customer during the quarters requested. Prices are the net f.o.b. selling prices of their largest quarterly sale weighted by their total sales quantity in that period.

2/ April-June 1987=100.

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

Quarterly selling prices of the specified U.S.-produced Keflex capsules \*\*\* (table 24). Prices of the 250mg Keflex capsules \*\*\*. Prices of the 250mg capsules then \*\*\*. Prices of the 500mg Keflex capsules \*\*\*. Thereafter, prices of the 500mg capsules generally \*\*\*.

Table 24

U.S.-produced Keflex capsules in 100-capsule bottles: U.S. sales quantities, weighted-average net f.o.b. selling prices, and price indexes of domestically produced Keflex capsules, \*\*\*, by capsule dosage and by quarters, January 1985-September 1988 1/

\* \* \* \* \*

1/ \*\*\*.

2/ January-March 1985=100.

3/ April-June 1987=100.

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



Prices of imports from Canada.--Quarterly f.o.b. selling prices of the specified imported Canadian generic cephalixin capsules \*\*\* (table 25). \*\*\*. Quarterly selling prices of the imported 250mg capsules in 100-capsule bottles sold to generic-drug distributors \*\*\*. Selling prices of the imported 500mg capsules sold to this type of customer \*\*\*. On sales to pharmaceutical companies, quarterly selling prices of the 250mg capsules in 100-capsule bottles \*\*\*. Selling prices of the 500mg capsules sold to pharmaceutical companies \*\*\*.

Reported f.o.b. prices of the imported Canadian cephalixin capsules sold to \*\*\*, which were not adjusted for discounts and rebates for any of the quarters reported, \*\*\* (table 26). Price trends based on these unadjusted prices should be viewed cautiously, because the later period prices in particular may not adequately reflect increasing price competition in the U.S. market for cephalixin capsules. Quarterly selling prices of the imported 250mg capsules in 100-capsule bottles (product 1) \*\*\*. Selling prices of the imported 500mg capsules (product 2) \*\*\*.

Reported quarterly f.o.b. selling prices of the imported-Canadian products sold to hospitals, based on net prices adjusted for discounts and rebates for all quarters reported, \*\*\* (table 26). These net selling prices may be a better basis than unadjusted prices for showing actual price trends, especially when prices reportedly were \*\*\*. Quarterly net selling prices of the imported 250mg capsules in 100-capsule bottles sold to \*\*\*. Selling prices of the imported 500mg capsules sold to this type of customer \*\*\*.

Table 25

Imported Canadian generic cephalixin capsules in 100-capsule bottles: U.S. sales quantities, weighted-average net f.o.b. selling prices, and price indexes of generic cephalixin capsules imported from Canada and sold to \*\*\* and to \*\*\*, by types of customer, by capsule dosages, and by quarters, April 1987-September 1988 1/

\* \* \* \* \*

1/ The quantities represent total sales of the single U.S. importer of the specified generic cephalixin products imported from Canada and sold to each type of customer during the quarters requested. Prices are the U.S. f.o.b. selling prices of the largest quarterly sales, net of discounts and allowances except where otherwise noted.

2/ April-June 1987=100.

3/ No sales data reported for this period.

4/ \*\*\*.

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

Table 26

Imported Canadian generic cephalexin capsules in 100-capsule bottles: U.S. sales quantities, weighted-average f.o.b. selling prices, and price indexes of generic cephalexin capsules imported from Canada and sold to \*\*\*, and to \*\*\*, by types of customer, by capsule dosages, and by quarters, April 1987-September 1988 1/

\* \* \* \* \*

1/ The quantities represent total sales of the single U.S. importer of the specified generic cephalexin products imported from Canada and sold to each type of customer during the quarters requested. Prices to \*\*\* are U.S. f.o.b. selling prices of the largest quarterly sales without any adjustments for discounts and rebates. Prices to hospitals are based on the total U.S. sales values, net of discounts and allowances, of the specified product sold to hospitals during each quarter.

2/ April-June 1987=100.

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

Price comparisons.--Price comparisons between the U.S.-produced and imported Canadian cephalexin capsules are based on the quarterly f.o.b. selling prices of the specified generic and Keflex products sold to specified types of customers during April 1987-September 1988. Comparisons of f.o.b. prices may be appropriate in this investigation. All the responding U.S. producers and the U.S. importer reported in their questionnaire responses that U.S. freight costs did not exceed 1 percent of the f.o.b. price and were not a significant factor in competition between the domestic and the subject imported cephalexin capsules.

Generic cephalexin capsules.--Table 27 shows the weighted-average selling prices of the domestic and imported Canadian generic products 1 and 2 sold to \*\*\*, and any price differences between the domestic and foreign products during April 1987-September 1988. Table 28 shows the price comparisons between the domestic and imported generic products on sales to \*\*\* and to \*\*\* during this period.

Based on net f.o.b. selling prices of the largest quarterly sale, the reported price data resulted in 12 quarterly price comparisons between the domestic and imported products 1 (250mg capsules) and 2 (500mg capsules) sold to \*\*\*, and 11 quarterly price comparisons on sales to \*\*\* (table 27). Four of the 12 price comparisons involving sales to \*\*\* showed that \*\*\*. Four of the 11 price comparisons involving sales to \*\*\* showed that \*\*\*. Eight of the 12 price comparisons involving sales to \*\*\* and 7 of the 11 price comparisons involving sales to \*\*\* showed \*\*\*. But 9 of these 15 price comparisons \*\*\*.

Reported selling prices involving sales of the domestic and imported Canadian generic cephalexin capsules to full-line drug wholesalers resulted in 12 quarterly price comparisons between the domestic and imported products (table 28). Prices of the U.S.-produced and imported products were both based on prices of the largest quarterly sale, but \*\*\*.

Price comparisons between domestic generic cephalixin capsules sold to \*\*\* and the imported generic capsules sold to \*\*\* resulted in 12 quarterly price comparisons between the domestic and imported products (table 28). The importer indicated that its net sales prices to \*\*\*. On sales to the wholesalers, U.S. producers reported net f.o.b. selling prices based on the largest quarterly sale.

Table 27

Generic cephalixin capsules in 100-capsule bottles: Weighted-average net f.o.b. selling prices of generic cephalixin capsules produced in the United States and imported from Canada and sold to \*\*\* and to \*\*\*, and margins of under/(over) selling, 1/ by capsule dosages and by quarters, April 1987-September 1988 2/

\* \* \* \* \*

1/ Any figures in parentheses indicate that the price of the domestic product was less than the price of the imported Canadian product. Price differences between the U.S. and imported Canadian products were calculated as ratios of the U.S. producers' prices.

2/ The prices of the subject domestic and imported capsules shown in this table were based on net f.o.b. selling prices of the largest sale in the quarter weighted by total sales of the specified product to these types of customers.

3/ No sales data reported for this period.

4/ \*\*\*.

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

Table 28

Generic cephalixin capsules in 100-capsule bottles: Weighted-average net f.o.b. selling prices of generic cephalixin capsules produced in the United States and imported from Canada and sold to \*\*\* and to \*\*\*, and margins of under/(over) selling, 1/ by capsule dosages and by quarters, April 1987-September 1988 2/

\* \* \* \* \*

1/ Any figures in parentheses indicate that the price of the domestic product was less than the price of the imported Canadian product. Price differences between the U.S. and imported Canadian products were calculated as ratios of the U.S. producers' prices.

2/ The prices of the U.S.-produced capsules sold to \*\*\* were based on net f.o.b. selling prices of the largest sale in the quarter weighted by total sales of the specified product to this type of customer.

3/ The reported prices of the imported products sold to \*\*\* were based on f.o.b. selling prices, unadjusted for discounts and rebates, of the largest quarterly sale.

4/ \*\*\*.

5/ \*\*\*.

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

Keflex and generic cephalixin capsules.--Lilly indicated in its questionnaire response that \*\*\*, Table 29 shows the weighted-average selling prices of Keflex capsules, the imported Canadian generic cephalixin capsule products 1 and 2 sold to \*\*\*, and the imported products sold to \*\*\* during April 1987-September 1988. 1/ In addition, table 29 shows price differences between Keflex and the imported generic products. Table 30 shows the weighted-average selling prices of Keflex capsules and the domestic generic cephalixin capsule products 1 and 2 sold to \*\*\*, and price differences between the domestic brand-name and generic products during April 1987-September 1988. \*\*\*, 2/ \*\*\*, 3/ \*\*\*.

The reported f.o.b. selling prices to \*\*\* resulted in 12 price comparisons between the Keflex capsule products and the imported Canadian generic capsule products (table 29). Prices of the imported capsules ranged from \*\*\*. Selling prices of the Keflex capsules were on a net basis, but reported prices of the imported products \*\*\* were not adjusted for discounts and rebates. As a result, such price comparisons most likely \*\*\*. \*\*\* the domestic brand name capsules and imported generic capsules were reported on a net-sales basis. The 12 price comparisons between the Keflex capsules sold to \*\*\*, showed the imported products \*\*\* (table 29).

The reported net f.o.b. selling prices of the U.S.-produced Keflex and generic cephalixin capsule products sold to \*\*\* resulted in 12 price comparisons between these domestic products (table 30). The domestic generic capsules were priced from \*\*\*. On a net f.o.b. selling price basis, the domestic generic capsules \*\*\*. \*\*\*.

Table 29

Cephalixin capsules in 100-capsule bottles: Weighted-average selling prices of U.S.-produced Keflex capsules sold to \*\*\* and the selling prices of imported Canadian generic cephalixin capsules sold to \*\*\* and to \*\*\*, and price differences between Keflex and the imported generic drug, 1/ by capsule dosages and by quarters, April 1987-September 1988

\* \* \* \* \*

1/ Price differences shown above indicate the degree to which the imported generic cephalixin capsules were priced less than the Keflex capsules. Price differences between the imported generic capsules and Keflex were calculated as ratios of the U.S. Keflex prices.

2/ \*\*\*.

3/ \*\*\*.

4/ \*\*\*.

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

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1/ \*\*\*.

2/ \*\*\*.

3/ \*\*\*.

Table 30

U.S.-produced cephalexin capsules in 100-capsule 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, 1/ by capsule dosages and by quarters, April 1987-September 1988

\* \* \* \* \*

1/ Price differences shown above indicate the degree to which the \*\*\*. Price differences between the generic capsules and Keflex were calculated as ratios of the U.S. Keflex prices.

2/ \*\*\*.

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

#### Transportation factors

Two U.S. producers of generic cephalexin capsules \*\*\* and \*\*\* responded to questions on transportation factors in the questionnaire. \*\*\*. 1/ \*\*\*. \*\*\*. In comparison with the three U.S. producers, the importer reported selling \*\*\*. The U.S. producers reported shipping generic cephalexin capsules and Keflex capsules to their U.S. customers almost entirely by truck, whereas the importer reported shipping about \*\*\*. \*\*\*. All four responding firms reported that \*\*\* the transportation costs did not significantly affect price competition between the U.S.-produced and imported Canadian cephalexin capsules.

#### 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 7 percent during January 1985-March 1988--the latest period comparisons with real exchange rates were available (table 31). An approximately 6-percent inflation rate in Canada compared with about 1 percent inflation in the United States during this period resulted in more appreciation of the Canadian dollar in real terms compared with nominal terms. In real terms, the Canadian dollar appreciated against the U.S. dollar during January 1985-March 1988 by approximately 12 percent, or 5 percentage points more than the appreciation in nominal terms. 2/

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1/ \*\*\*. Telephone conversation with Commission staff on Nov. 15, 1988.

2/ The real appreciation of the Canadian dollar against the U.S. dollar indicates the amount that a Canadian producer would have to increase its U.S.-dollar prices of the foreign cephalexin capsule products in the U.S. market without decreasing its profit margins, assuming that foreign costs had not changed and were not denominated in U.S. dollars. To protect their market share, however, Canadian producers may limit the rise of any such U.S. dollar-price increase by reducing their Canadian dollar-denominated costs and/or accepting lower profit margins. Costs of the Canadian producers would be further reduced with an appreciating Canadian dollar if any of their inputs were priced in U.S. dollars.

Table 31

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 1985-June 1988

Period	Nominal- exchange rate index	Real- exchange rate index <u>3/</u>	Canadian Producer Price Index	U.S. Producer Price Index
1985:				
January-March.....	100.0	100.0	100.0	100.0
April-June.....	98.8	99.3	100.5	100.1
July-September.....	99.5	100.7	100.5	99.4
October-December....	98.1	99.4	101.3	100.0
1986:				
January-March.....	96.4	100.2	102.3	98.5
April-June.....	97.8	102.0	100.8	96.6
July-September.....	97.7	102.6	101.0	96.2
October-December....	97.7	102.9	101.6	96.5
1987:				
January-March.....	101.2	105.8	102.1	97.7
April-June.....	101.5	105.8	103.4	99.2
July-September.....	102.4	107.0	104.9	100.3
October-December....	103.2	108.6	106.0	100.8
1988:				
January-March.....	106.8	112.2	106.4	101.2
April-June.....	110.1	<u>4/</u>	<u>4/</u>	102.5

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 slightly, by 1.2 percent, during January 1985-March 1988, while producer prices in Canada rose by 6.4 percent. During April-June 1988, producer prices in the United States jumped by 1.2 percent from the previous quarter--producer price data from Canada, however, were not available during this latter period.

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/ Not available.

Note--January-March 1985=100.

Source: International Monetary Fund, International Financial Statistics, October 1988.

Lost sales

\*\*\*, a U.S. producer of the generic cephalexin capsules, stated in its questionnaire response that \*\*\*. Biocraft, in its questionnaire response, \*\*\*, but indicated at the conference that it meets low price competition rather than lose the sale. 1/ Eli Lilly indicated in its questionnaire response that \*\*\*. Lilly \*\*\*.

Price suppression/depression

\*\*\*. 2/ Staff telephone conversations with the companies cited are discussed below.

\*\*\*, in lost revenue allegations involving 250mg and 500mg generic cephalexin capsules in 100- and 500-capsule bottles. The allegations specified the initial dates price reductions were made and the quantities that were sold at the reduced prices. Initial-period price reductions occurred during December 1987-April 1988 and involved almost \*\*\* bottles of the generic cephalexin capsules. The price reductions allegedly ranged from \*\*\* percent below the initial price offers, resulting in total reported lost revenues of about \*\*\* on sales to \*\*\*. \*\*\*. 3/ \*\*\*. 4/ \*\*\*.

\*\*\* also named \*\*\*, \*\*\*, in lost revenue allegations involving 250mg generic cephalexin capsules in 100- and 500-capsule bottles. The allegations specified the initial dates price reductions were made and the quantities that were sold at the reduced prices. Initial-period price reductions occurred during April-June 1988 and involved about \*\*\* bottles of the generic cephalexin capsules. \*\*\* allegedly reduced its initial price offers by about \*\*\* to obtain the sale, resulting in total reported lost revenues of about \*\*\* on sales to \*\*\*. \*\*\*.

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1/ Transcript of the conference, pp. 25-26.

2/ \*\*\*.

3/ \*\*\*.

4/ \*\*\*.





APPENDIX A  
FEDERAL REGISTER NOTICES

**INTERNATIONAL TRADE  
COMMISSION**

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

**Generic Cephalixin Capsules From  
Canada; Import Investigation**

**AGENCY:** United States International  
Trade Commission.

**ACTION:** Institution of a preliminary  
antidumping investigation and  
scheduling of a conference to be held  
in connection with the investigation.

**SUMMARY:** The Commission hereby gives  
notice of the institution of preliminary  
antidumping investigation No. 731-TA-  
423 (Preliminary) under section 733(a)  
of the Tariff Act of 1930 (19 U.S.C.  
1673b(a)) to determine whether there is  
a reasonable indication that an industry  
in the United States is materially  
injured, or is threatened with material  
injury, or the establishment of an  
industry in the United States is  
materially retarded, by reason of  
imports from Canada of Generic  
Cephalixin Capsules, provided for in  
item 411.76 of the Tariff Schedules of the  
United States (subheading 3004.20.00 of  
the Harmonized Tariff Schedule of the  
United States), that are alleged to be  
sold in the United States at less than fair  
value. As provided in section 733(a), the  
Commission must complete preliminary  
antidumping investigations in 45 days,  
or in this case by December 12, 1988.

For further information concerning the  
conduct of this investigation and rules of  
general application, consult the  
Commission's Rules of Practice and  
Procedure, part 207, subparts A and B  
(19 CFR part 207) (see Commission  
interim rules (53 FR 33034 (August 29,  
1988)), and part 201, subparts A through  
E (19 CFR part 201).

**EFFECTIVE DATE:** October 27, 1988.

**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-

**SUPPLEMENTARY INFORMATION:****Background**

This investigation is being instituted  
in response to a petition filed on

October 27, 1988, by Biocraft Laboratories, Inc., Elmwood Park, NJ.

#### 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 seven (7) days after publication of this notice in the Federal Register. Any entry of appearance filed after this date will 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.

#### Service List

Pursuant to § 201.11(d) of the Commission's rules (19 CFR 201.11(d)), the Secretary will prepare a 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 (19 CFR 201.16(c) and 207.3), each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by the 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

Pursuant to § 207.7(a) of the Commission's rules (19 CFR 207.7(a) as amended, 53 FR 33034 (August 29, 1988)), the Secretary will make available business proprietary information gathered in this preliminary investigation to authorized applicants under a protective order, provided that the application be made not later than seven (7) days after the publication of this notice in the Federal Register. A separate service list will be maintained by the Secretary for those parties authorized to receive 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 the parties that are authorized to receive such information under a protective order.

#### Conference

The Director of Operations of the Commission has scheduled a conference in connection with this investigation for

9:30 a.m. on November 16, 1988, at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC. Parties wishing to participate in the conference should contact Lisa Zanetti (202-252-1189) not later than November 14, 1988, to arrange for their appearance. Parties in support of the imposition of antidumping duties in this investigation and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference.

#### Written Submissions

Any person may submit to the Commission on or before November 18, 1988, a written brief containing information and arguments pertinent to the subject matter of the investigation, as provided in section 207.15 of the Commission's rules (19 CFR 207.15). A signed original and fourteen (14) copies of each submission must be filed with the Secretary to the Commission in accordance with § 201.8 of the 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 and 207.7).

Parties which obtains disclosure of business proprietary information pursuant to § 207.7(a) of the Commission's rules (19 CFR 207.7(a)) may comment on such information in their written brief, and may also file additional written comments on such information no later than November 22, 1988. Such additional comments must be limited to comments on business proprietary information received in or after the written briefs.

**Authority:** This investigation is being conducted under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to § 207.12 of the Commission's rules (19 CFR 207.12).

By order of the Commission.

Issued: November 2, 1988.

**Kenneth R. Mason,**  
Secretary.

[FR Doc. 88-25707 Filed 11-3-88; 8:45 am]

BILLING CODE 7020-02-M

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**International Trade Administration**

[A-122-806]

**Initiation of Antidumping Duty  
Investigation; Generic Cephalexin  
Capsules from Canada**

**AGENCY:** Import Administration,  
International Trade Administration,  
Commerce.

**ACTION:** Notice.

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**SUMMARY:** On the basis of a petition filed in proper form with the U.S. Department of Commerce, we are initiating an antidumping duty investigation to determine whether imports of generic cephalexin capsules from Canada are being, or are likely to be, sold in the United States at less than fair value. We are notifying the U.S. International Trade Commission (ITC) of this action so that it may determine whether imports of this product materially injure, or threaten material injury to, a U.S. industry. If this investigation proceeds normally, the ITC will make its preliminary determination on or before December 12, 1988, and we will make our preliminary determination

**EFFECTIVE DATE:** November 23, 1988.

**FOR FURTHER INFORMATION CONTACT:** Debra Conner 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, telephone (202) 377-1778 or (202) 377-1769.

**SUPPLEMENTARY INFORMATION:**

**The Petition**

On October 27, 1988, we received a petition filed in proper form by Biocraft Laboratories, Inc., on behalf of the industry in the United States which manufactures generic cephalixin capsules. In compliance with the filing requirements of § 353.36 of the Commerce Regulations (19 CFR 353.36), the petitioner alleges that imports of generic cephalixin capsules from Canada are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Tariff Act of 1930, as amended (the Act), and that these imports materially injure, or threaten material injury to, a U.S. industry.

The petitioner has alleged that it has standing to file the petition. Specifically, petitioner has alleged that it is an interested party as defined under section 771(9)(C) of the Act, and that it has filed the petition on behalf of the U.S. industry manufacturing the product that is subject to this investigation.

If any interested party as described under paragraphs (C), (D), (E), or (F) of section 771(9) of the Act wishes to register support of or opposition to this petition, please file written notification with the Commerce official cited in the "FOR FURTHER INFORMATION CONTACT" section of this notice.

**United States Price and Foreign Market Value**

Petitioner's estimate of United States price was based on an average of known Canadian prices it must use to meet the competition. Petitioner listed these prices (competitively met prices) for several customers.

Petitioner based foreign market value on prices published in *Drug Benefit Formularies*, by the Ministries of Health of Ontario and Saskatchewan, Canada. Petitioner states that these prices represent the lowest amount for which a listed drug product can be purchased in those provinces in Canada.

Based on a comparison of United States price and foreign market value, petitioner alleges dumping margins ranging from 18.42 to 39.73 percent.

Petitioner also alleges that "critical circumstances" exist with respect to imports of generic cephalixin capsules from Canada.

**Initiation of Investigation**

Under section 732(c) of the Act, we must determine, within 20 days after a petition is filed, whether it contains information reasonably available to the petitioner supporting the allegations.

We examined the petition on generic cephalixin capsules from Canada and found that it meets the requirements of section 732(b) of the Act. Therefore, in accordance with section 732 of the Act, we are initiating an antidumping duty investigation to determine whether imports of generic cephalixin capsules from Canada are being, or are likely to be, sold in the United States at less than fair value. If our investigation proceeds normally, we will make our preliminary determination by April 5, 1989.

**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 will be fully converted to this *Harmonized Tariff Schedule (HTS)* and all merchandise entered or withdrawn from warehouse for consumption on or after this date will be classified solely according to the appropriate HTS item number(s). Until that time, however, the Department will be providing both the appropriate *Tariff Schedules of the United States Annotated (TSUSA)* item number(s) and the appropriate HTS item number(s) with its product descriptions. As with the TSUSA, the HTS item numbers are provided for convenience and customs purposes. The written description remains dispositive as to the scope of the product coverage.

We are requesting petitioners to include the appropriate HTS item number(s) as well as the TSUSA item number(s) in all petitions filed with the Department through the end of this year. A reference copy of the HTS is available for consultation in the Central Records Unit, Room B-099, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230. Additionally, all U.S. Customs offices have reference copies, and petitioners may contact the import specialist at their local customs office to consult the schedule.

The products covered in this investigation are generic cephalixin capsules from Canada, as provided for in item 411.7600 of the *Tariff Schedules of the United States Annotated (TSUSA)* and currently classifiable under

Harmonized System (HTS) item number 3004.20.00. 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<sub>16</sub>H<sub>17</sub>N<sub>3</sub>O<sub>4</sub>S.H<sub>2</sub>O. 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.

We are tentatively excluding from the scope of this investigation certain proprietary brand-name cephalixin capsules which petitioner alleges differ from the generic product. Such differences allegedly include different consumer expectations, different promotional activities, and significantly different prices. While the Department does not normally consider proprietary brand-names in defining the scope of an investigation, we have done so in this particular instance because the differences alleged by petitioner between branded and generic pharmaceutical products appear to be far greater than would normally be the case for other types of products. We will continue to examine this issue, however, during the investigation and will consider any comments on this issue. Any comments should be addressed as noted in the "FOR FURTHER INFORMATION CONTACT" section of this notice.

**Notification of ITC**

Section 732(d) of the Act requires us to notify the ITC of this action and to provide it with the information we used to arrive at this determination. We will notify the ITC and make available to it all nonprivileged and nonproprietary information. We will also allow the ITC access to all privileged and business proprietary information in our files, provided it confirms in writing that it will not disclose such information either publicly or under an administrative protective order without the written consent of the Assistant Secretary for Import Administration.

**Preliminary Determination by the ITC**

The ITC will determine by December 12, 1988, whether there is a reasonable indication that imports of generic cephalixin capsules from Canada materially injure, or threaten material injury to, a U.S. industry. If its determination is negative, this investigation will terminate; otherwise it

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will proceed according to statutory and regulatory procedures.

This notice is published pursuant to section 732(c)(2) of the Act.

November 16, 1988.

Jan W. Mares,

*Assistant Secretary for Import Administration.*

[FR Doc. 88-27048 Filed 11-22-88; 8:45 am]

BILLING CODE 3510-DS-M

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APPENDIX B

CALENDAR OF THE PUBLIC CONFERENCE

CALENDAR OF THE PUBLIC CONFERENCE

Investigation No. 731-TA-423 (Preliminary)

GENERIC CEPHALEXIN CAPSULES FROM CANADA

Those persons listed below appeared at the United States International Trade Commission's conference held in connection with the subject investigation on November 16, 1988, in Courtroom 111B of the U.S. International Trade Commission, 500 E. Street, SW, Washington, D.C.

In support of the imposition of antidumping duties

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

Biocraft Laboratories, Inc.

Gerald Moskowitz  
Vice President, Sales, Biocraft Laboratories, Inc.

Beryl Synder  
General Counsel, Biocraft Laboratories, Inc.

Peter Ehrenhaft )--OF COUNSEL  
Daniel C. Schwartz )--OF COUNSEL

In opposition to the imposition of antidumping duties

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

LyphoMed/Novopharm Pharmaceutical Co.  
Novopharm, Inc.

Leslie Dan  
President, Novopharm, Inc.  
Robert Gunter  
Vice President and General Manager  
LyphoMed/Novopharm Pharmaceutical Co.

David Norrell )--OF COUNSEL



APPENDIX C  
CEPHALOSPORINS

## Cephalosporins

### Background

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.

In general, cephalosporins are active in vitro against many gram-positive aerobic bacteria, some gram-negative aerobic bacteria, and some anaerobic bacteria. However, there are substantial differences among the cephalosporins in spectra of activity as well as levels of activity against susceptible bacteria. Cephalosporins are inactive against fungi and viruses.

Currently available cephalosporins are generally divided into three groups based on their spectra of activity. 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.

First generation cephalosporins--(cefadroxil, cefazolin, cephalixin, cephalothin, cephapirin, and cephradine) 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.

Cephalosporins are used in the treatment of serious respiratory tract, skin and skin structure, urinary tract, and bone and joint infections. A first generation cephalosporin is generally preferred when a cephalosporin is used for the treatment of infections caused by susceptible 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.

U.S. producers

The Commission sent questionnaires to 43 firms thought to be producing some form of cephalosporin, including cephalixin. Of these, 27 reported that they did not produce any form of cephalosporin in the United States, 7 reported that they did produce cephalosporins, and 9 did not respond to the Commission's questionnaire.

Of the seven firms reporting cephalosporin production, \*\*\*. Of the \*\*\* firms reporting production of cephalixin and at least one other cephalosporin \*\*\* provided no data on cephalosporin operations other than cephalixin. Of the \*\*\* firms reporting production of cephalosporins other than cephalixin, \*\*\* was unable to provide information other than sales volume. Summaries of the questionnaire data are presented below.

Bulk cephalosporins.--\*\*\* reported production of bulk cephalosporins. \*\*\* did not provide the Commission with data on its cephalosporin operations.

Cephalosporin in capsule form.--\*\*\* firms \*\*\* reported production of cephalosporin in capsule form. Only \*\*\* reported operations in the calendar years 1985 and 1986. Operations for the \*\*\* firms are summarized in tables C-1 through C-5.

Table C-1  
Cephalosporin in capsule form: U.S. producers' capacity, production, and capacity utilization, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

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

Table C-2  
Cephalosporin in capsule form: U.S. producers' end-of-period inventories, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

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

Table C-3

Cephalosporin in capsule form: U.S. producers' shipments, domestic and exports  
1/, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

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

Table C-4

Cephalosporin in capsule form: U.S. production and related workers, 1985-87,  
January-September 1987, and January-September 1988

\* \* \* \* \*

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

Table C-5

Cephalosporin in capsule form: U.S. producers' net sales; cost of goods sold;  
gross profit/loss; general, selling, and administrative expenses; and net  
operating profit, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

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

All other forms of cephalosporin.--\*\*\* companies reported production of cephalosporin in dosage forms other than capsules: \*\*\*. Only \*\*\* reported data for calendar years 1985 and 1986. \*\*\*. The data are summarized in the tables C-6 through C-11.

Table C-6

Cephalosporin in dosage forms other than capsules: U.S. producers' capacity,  
production, and capacity utilization, 1985-87, January-September 1987, and  
January-September 1988

\* \* \* \* \*

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

Table C-7

Cephalosporin in dosage form other than capsules: U.S. producers' end-of-period inventories, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

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

Table C-8

Cephalosporin in dosage forms other than capsules: U.S. producers' shipments, domestic and exports, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

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

Table C-9

Cephalosporin in dosage forms other than capsules: U.S. producers' imports 1/, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

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

Table C-10

Cephalosporin in dosage forms other than capsules: U.S. production and related workers, 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

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

Table C-11

Cephalosporin in dosage forms other than capsules: U.S. producers' net sales; cost of goods sold; gross profit/loss; general, selling, and administrative expenses; and net operating profit; 1/ 1985-87, January-September 1987, and January-September 1988

\* \* \* \* \*

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



**APPENDIX D**

**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 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 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) 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.

701

Source: Division of Generic Drugs, Center for Drugs and Biologics, U.S. Food and Drug Administration, Rockville, MD.

