

UNITED STATES TARIFF COMMISSION

PROCAINE AND SALTS AND COMPOUNDS THEREOF

**Report on Escape-Clause Investigation No. 7-106
Under the Provisions of Section 7 of the
Trade Agreements Extension Act of 1951, As Amended**



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U. S. TARIFF COMMISSION

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PROCAINE AND SALTS AND COMPOUNDS THEREOF

U.S. Tariff Commission
Washington, November 2, 1961

Introduction

This report, published pursuant to section 7(d) of the Trade Agreements Extension Act of 1951, as amended (U.S.C. 1364(d)), sets forth the finding and conclusion of the U.S. Tariff Commission in connection with its investigation No. 7-106 under section 7 of the Trade Agreements Extension Act of 1951, as amended, with respect to procaine and salts and compounds thereof (except procaine penicillin). The purpose of the investigation was to determine whether these products, which are provided for in paragraph 28 of the Tariff Act of 1930, are, as a result, in whole or in part, of the duty or other customs treatment reflecting concessions granted thereon under the General Agreement on Tariffs and Trade, being imported in such increased quantities, either actual or relative to domestic production, as to cause or threaten serious injury to the domestic industry producing like or directly competitive products.

This investigation was instituted on June 1, 1961, upon applications of B. L. Lemke & Co., Inc., Lodi, N.J., filed May 4, 1961, and Abbott Laboratories, North Chicago, Ill., filed May 21, 1961. Public notice of the institution of the investigation and of a public hearing to be held in connection therewith was duly given by posting copies of the notice at the office of the Commission in Washington, D.C., and at its office in New York City, and by publishing it in the Federal Register (26 F.R. 5102) and in the June 8, 1961, issue of Treasury Decisions.

The public hearing in this investigation was duly held on August 15, 1961, and all interested parties were given an opportunity to be present, to produce evidence, and to be heard. In addition to the information obtained at the hearing, data were obtained from the Commission's files, from responses to questionnaires sent to domestic producers and importers, and through fieldwork by members of the Commission's staff.

Finding and Conclusion of the Commission

On the basis of this investigation, including the hearing, the Tariff Commission finds ^{1/} that procaine and salts and compounds thereof are not being imported into the United States in such increased quantities, either actual or relative to domestic production, as to cause or threaten serious injury to the domestic industry producing like or directly competitive products. Accordingly, in the judgment of the Commission, no sufficient reason exists for a recommendation to the President under the provisions of section 7 of the Trade Agreements Extension Act of 1951, as amended.

Considerations Bearing on the Commission's Finding and Conclusion

The finding and conclusion stated above are based principally upon the following considerations.

U.S. customs treatment

Procaine and salts and compounds thereof are dutiable under paragraph 28(a) of the Tariff Act of 1930, as modified, as medicinals obtained, derived, or manufactured in whole or in part from any product

^{1/} Commissioners Talbot and Overton were not present at the hearing in this investigation and did not participate in the decision.

provided for in paragraph 27 or paragraph 1651. As originally provided for in the act, the rate of duty was 7 cents per pound plus 45 percent ad valorem. Pursuant to a concession granted in the General Agreement on Tariffs and Trade (Torquay), the rate of duty was reduced to 3-1/2 cents a pound and 25 percent ad valorem, effective June 6, 1951. As for all articles dutiable under paragraph 28(a) for which there is "competitive" domestic production, the ad valorem portion of the duty is based on the American selling price of the similar competitive domestic product. ^{1/}

The rates of duty and their average ad valorem equivalents in relation to the average foreign invoice value and the U.S. dutiable values of imports in 1960 are as follows:

Authority	Rate of duty	Average ad valorem equivalent based on--	
		Foreign invoice value in 1960 ^{1/}	American selling price in 1960
		Percent	Percent
Act of 1930-----	7¢ lb. + 45% ad val. ^{2/}	73.6	48.2
GATT (effective June 6, 1951).	3½¢ lb. + 25% ad val. ^{2/}	40.6	26.6

^{1/} The ad valorem equivalent, based on foreign invoice value, is the approximate rate that would apply to procaine hydrochloride if it were imported on the same basis as the majority of items under the Tariff Act of 1930.

^{2/} Based on the American selling price.

Description and uses

Procaine (or procaine base), the chemical name of which is 2-diethyl-aminoethyl p-aminobenzoate, is a coal-tar medicinal obtained from

^{1/} Defined in sec. 402(e) of the Tariff Act of 1930, as added by sec. 2 of the Customs Simplification Act of 1956.

2-diethylaminoethanol and p-nitrobenzoic acid. The reaction is usually carried out in an acid medium and the procaine is isolated as procaine hydrochloride. The hydrochloride, in turn, may be neutralized to obtain procaine base, from which various procaine salts and compounds can be derived through reaction with appropriate acids.

Of the procaine products covered by this investigation, procaine hydrochloride is commercially by far the most important compound. Most of the domestic output consists of procaine hydrochloride sold as such in bulk in the form of small white crystals. Lesser amounts are marketed in dosage forms either as powder or in solution, and the relatively small remainder is sold in the form of procaine base or procaine compounds such as procaine acetate and procaine isobutyrate.

Procaine and its salts and compounds are important medicinals used chiefly as anesthetics and in antibiotics. As an anesthetic, procaine hydrochloride is widely known also by the proprietary name of Novocain. The most important use of procaine hydrochloride is in the production of the antibiotic procaine penicillin. In recent years as much as 85 percent of the total domestic consumption of procaine hydrochloride has been used in the manufacture of procaine penicillin. When penicillin is given in combination with procaine hydrochloride, the latter causes a slow release of penicillin into the blood stream so that one daily treatment usually suffices, whereas, to be fully effective, most other forms of penicillin must be injected in frequent small doses.

Procaine hydrochloride competes, as a local anesthetic, with Xylocaine, Butacaine, and Tetracaine. It also competes with several other compounds which can be used with penicillin for the prolonged release of the antibiotic.

U.S. industry

During 1956-60 procaine hydrochloride was produced in 1 or more years by six concerns. Two of them stopped producing procaine hydrochloride before imports began to be significant in 1959. A third company manufactured procaine hydrochloride for only a few months in 1959 on a trial basis for the purpose of determining the feasibility of producing it on a commercial scale. Of the remaining three producers, one ceased manufacture of the material in the early part of 1960. At present the two applicants are the only domestic producers of procaine hydrochloride; one is located in Illinois and the other in New Jersey.

Both producers of procaine hydrochloride also manufacture in the plants where procaine is produced a variety of other chemicals and pharmaceuticals. For the larger of the two the value of sales of procaine hydrochloride represented less than 1 percent of the sales of all products of the plant in which procaine hydrochloride is produced in each of the years 1956-60. For the other producer the corresponding ratio was in most years less than 30 percent.

U.S. production, sales, and inventories

Production.--Procaine hydrochloride was first produced about 1905 by the German corporation Farbwerke vorm. Meister Lucius & Bruning. When imports of procaine from Germany became unobtainable during World War I, three domestic companies, one of which was Abbott Laboratories, were licensed to manufacture procaine hydrochloride under section 10 of the "Trading with the enemy Act" of October 6, 1917.^{1/} Other companies later produced procaine hydrochloride, but the annual domestic output

^{1/} 40 Stat. 420.

did not exceed 15,000 pounds until World War II. During World War II, U.S. production of procaine hydrochloride increased to a peak up to that time of 92,000 pounds in 1943, but declined again after the war. With the development of procaine penicillin, the output for the first time exceeded 100,000 pounds in 1948 and has been above that figure in every year since then.

Domestic production of procaine hydrochloride in 1956-60, shown in Table 1, in the appendix, includes both production for sale and that for use by the producing companies in the manufacture of procaine compounds. Production reached a peak of 624,000 pounds in 1958. It declined to 314,000 pounds the following year, but rose to 376,000 pounds in 1960. The two companies that still produce procaine hydrochloride accounted for the bulk of the domestic output of this chemical in the years 1956-60.

Producers' sales.--The bulk of the domestic output of procaine hydrochloride is sold to pharmaceutical houses mostly for the production of procaine penicillin. During 1956-60 such sales accounted for about 95 percent of total sales, the remainder having been sold by the producing companies in the form of procaine medicinals, such as procaine penicillin and procaine isobutyrate.

Sales of procaine hydrochloride as such ^{1/} by the domestic producers of that chemical amounted to approximately 556,000 pounds in 1956; annual sales declined steadily thereafter until in 1960 they amounted to 352,000 pounds. Because of a downward trend in the price of procaine hydrochloride,

^{1/} I.e., not including procaine hydrochloride used in procaine medicinals.

sales declined in value more than in quantity. The value of sales declined steadily from \$1.5 million in 1956 to \$766,000 in 1960.

Producers' inventories.--The Commission obtained information on yearend inventory positions from three domestic producers. Except for 1958 when they were exceptionally high, inventories have fluctuated within relatively narrow limits and in most years were equal to about 20 percent of total sales.

U.S. exports of domestic merchandise

Exports of procaine hydrochloride as such are not separately reported in official statistics. However, the Commission received data on export sales from three domestic producers. There may have been export sales by nonproducers, but information on such exports is not available.

Producers' export sales were fairly substantial only in 1958. In all other years during 1956-60 such sales have been either small or negligible.

However, quantities of procaine hydrochloride much larger than those exported as such by domestic producers have been exported by domestic pharmaceutical manufacturers in the form of procaine penicillin. The Commission obtained data on exports of procaine penicillin from seven domestic producers which account for the entire domestic production of that compound. The procaine penicillin exported by these producers and its estimated procaine hydrochloride equivalent have been as follows:

<u>Year</u>	<u>Procaine penicillin (pounds)</u>	<u>Estimated procaine hydrochloride equivalent (pounds)</u>
1956-----	162,400	87,273
1957-----	191,904	101,782
1958-----	77,725	40,600
1959-----	131,365	68,115
1960-----	115,923	60,295

U.S. imports

Imports of procaine hydrochloride amounted to 5 pounds in 1958, to 13,033 pounds in 1959, and to 66,180 pounds in 1960. ^{1/} These statistics, however, do not correctly reflect or even suggest the extent of the competition afforded domestic producers by the imports. Information obtained by the Commission indicates that virtually all the imports of procaine hydrochloride in 1958-60 entered for the accounts of domestic pharmaceutical concerns for use in the production of procaine penicillin for export with benefit of drawback of the duty. Such imports of procaine hydrochloride would not be directly competitive with procaine hydrochloride produced in the United States. ^{2/} The net or competitive imports of procaine hydrochloride (i.e., the total imports less the quantities used in making procaine penicillin for export) were equal to less than one-half of 1 percent of domestic production in the 3 years 1958-60. It is obvious that the small imports destined for ultimate consumption in the United States could have no significant competitive impact upon the domestic industry producing procaine hydrochloride.

The pharmaceutical concerns that use virtually all of the imported procaine hydrochloride in the manufacture of procaine penicillin for export, have advised the Commission that they expect to collect the full amount of drawback to which they are entitled. They will, therefore,

^{1/} West Germany and Sweden have been the only sources of imports, with West Germany having been by far the larger supplier.

^{2/} That the imports of a product used in making another product that is subsequently exported with benefit of drawback are not considered to be competitive by the Congress is evidenced by the fact that dumping duties imposed under the Antidumping Act may be refunded under the drawback law (Antidumping Act, 1921, sec. 211).

collect 99 percent of the duty paid on the imported procaine hydrochloride that has been or will be incorporated in articles for export. ^{1/} It is obvious that the duty on procaine hydrochloride imposed under paragraph 28(a) could have had no discernible bearing on the volume of imports of that product, since, for all practicable purposes, virtually all the procaine hydrochloride has been imported duty free by virtue of the drawback provision of the Tariff Act of 1930. Inasmuch as the drawback provision is not the subject of a trade-agreement concession, the virtual duty-free importation of procaine hydrochloride may not be considered as U.S. customs treatment reflecting a trade-agreement concession. ^{2/}

U.S. consumption

The Commission has calculated domestic consumption of procaine hydrochloride, but such data may not be published as to do so would disclose the operations of individual producers. U.S. consumption (sales by domestic producers plus net imports less domestic exports) declined by about one-third between 1956 and 1960, but this decline cannot be

^{1/} Under the provisions of sec. 313 of the Tariff Act of 1930. The "drawback" principle, which was first recognized in the U.S. tariff laws as early as 1789, has been progressively liberalized and expanded as an integral part of the tariff policy of this country. As stated by the Supreme Court in Tide Water Oil Co. v. United States, 171 U.S. 210, 216 (1898) the object of the drawback law-- ". . . was evidently not only to build up an export trade, but to encourage manufactures in this country, where such manufactures are intended for exportation, by granting a rebate of duties upon the raw or prepared materials imported, and thus enabling the manufacturer to compete in foreign markets with the same articles manufactured in other countries."

^{2/} Under sec. 7, the increased imports must be due, at least in part, to the "duty or other customs treatment reflecting" a trade agreement concession.

attributed to imports. As already observed, the bulk of procaine hydrochloride is used in the manufacture of procaine penicillin. Between 1956 and 1959, total domestic output of procaine penicillin decreased by about 25 percent; production increased somewhat in 1960 but was still about 20 percent lower in that year than in 1956.

The decline in the total output of procaine penicillin resulted almost entirely from a decrease in the production of the grade of procaine penicillin used as a medicinal for both human beings and animals, as distinct from that used as an animal-feed supplement. Effective August 12, 1957, the Food and Drug Administration limited the medicinal use of procaine penicillin for infusion into a cow's udder to 100,000 units for each application. Furthermore, the order provided that the animal could not be used for commercial milk production for 72 hours following an injection. Previously, there had been no limits on either the dosage or the length of time a cow was to be withheld from commercial milk production. The drop in the production of procaine penicillin, therefore, to a large extent, reflects a decline in the consumption of procaine penicillin for veterinary use resulting from the order by the Food and Drug Administration. The substantial decline in the production (and consumption) of procaine penicillin, in turn, accounted for most, if not all, of the decrease in the domestic production and consumption of procaine hydrochloride. These developments were in no way caused by imports.

Conclusion

The Commission concludes that such of the imports of procaine hydrochloride as have been or will be exported with benefit of drawback

are not competitive with procaine hydrochloride produced in the United States; that such imports were not imported under customs treatment reflecting a trade-agreement concession; that such imports have accounted for all but negligible quantities of the procaine hydrochloride imported into this country; and that the residual competitive imports of the product that have entered have been so negligible that they could not have contributed substantially toward causing any financial or other difficulties the domestic producers may be experiencing.

STATISTICAL APPENDIX

Table 1.--Procaine hydrochloride: U.S. production and sales, 1956-60

Period	Production	Sales ^{1/}		
		Quantity	Value	Unit value
	<u>Pounds</u>	<u>Pounds</u>	<u>1,000 dollars</u>	<u>Per pound</u>
1956-----	589,321	556,260	1,543	\$2.77
1957-----	584,032	535,698	1,462	2.73
1958-----	624,156	<u>2/</u>	<u>2/</u>	2.56
1959-----	314,175	421,419	975	2.31
1960-----	376,430	352,085	766	2.18

^{1/} Exclusive of producers' sales of procaine hydrochloride in the form of procaine medicinals, such as procaine penicillin and procaine isobutyrate.

^{2/} Data may not be published as to do so would disclose the operations of individual producers.

Source: Compiled from data submitted to the U.S. Tariff Commission by the producers.