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UNITED STATES TARIFF COMMISSION

FURAZOLIDONE

Investigation No. 337-21
Under the Provisions of
Section 337 of Title III of the
Tariff Act of 1930, as Amended



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UNITED STATES TARIFF COMMISSION

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UNITED STATES TARIFF COMMISSION
Washington

In the matter of an investigation
with regard to the importation and
domestic sale of furazolidone

Docket No. 21

Section 337

Tariff Act of 1930, as amended

INTRODUCTION

On March 19, 1968, the Norwich Pharmacal Company of Norwich, New York 1/ filed a complaint with the Tariff Commission requesting relief under section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), alleging unfair methods of competition and unfair acts in the importation and sale of the drug, furazolidone. Complainant has alleged that Claim 2 of its United States Letters Patent No. 2,742,462 specifically covers furazolidone, and that the importation and sale of the drug by numerous respondents have the effect or tendency to destroy or substantially injure an efficiently and economically operated industry in the United States.

The Commission conducted a preliminary inquiry to determine whether a full investigation was warranted, and, if so, whether to recommend to the President that a temporary exclusion order be issued. Notice of the receipt of the complaint and the initiation of a preliminary inquiry was published in the Federal Register (33 F.R. 5481). A copy of such notice, together with a copy of the complaint, was sent to a substantial number of the respondents alleged to be engaged in unfair methods or acts.

1/ Early in 1969, the Norwich Pharmacal Co. and Morton International, Inc., merged. The new parent company is known as Morton-Norwich Products, Inc.

Upon conclusion of its preliminary inquiry the Tariff Commission, on July 19, 1968, ordered a full investigation and scheduled a hearing on the matter for September 10, 1968, which was subsequently postponed to September 30, 1968. Due notice of the investigation and hearing and of the postponement of the hearing was given in the Federal Register (33 F.R. 11192 and 33 F.R. 12798-9). Copies of the complaint and of the notice of investigation and hearing were served on any persons known to be associated with the importation, sale or use of the imported furazolidone.

At the conclusion of the preliminary inquiry the Commission was equally divided on the question of whether to recommend to the President that he issue a temporary exclusion order to forbid entry of furazolidone in accordance with the provisions of 19 U.S.C. 1337(f). On August 28, 1968, President Johnson requested the Secretary of the Treasury to exclude furazolidone in accordance with the provisions of the statute, until a full investigation was completed. The Department of the Treasury immediately gave notice of this restriction on importation, in the Federal Register (33 F.R. 12680).

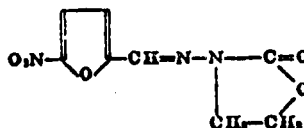
The scheduled public hearing was held September 30 through October 4, 1968. Appearances of record were made by the complainant, Norwich Pharmaceutical Company, and respondents: C. L. Jones, Inc. and Excell Poultry Co. both of Trussville, Alabama, and the Veterinary Corporation of Georgia from Athens, Georgia. Briefs were submitted by attorneys for Norwich Pharmaceutical Company and C. L. Jones, Inc. The hearing was reopened on September 5, 1969, for the purpose of receiving additional relevant information to complete the public record.

ALLEGED UNFAIR METHODS OF COMPETITION
AND UNFAIR ACTS

Alleged Patent Violation

The patent under consideration is U.S. Patent No. 2,742,462 ^{1/} issued on April 17, 1956, to Norwich Pharmacal Company, as assignee of Gabriel Gever (a research scientist in Norwich's employ). Complainant, Norwich, alleges that claim 2 of this patent specifically covers furazolidone and is being infringed by the importation into, and sale in, the United States of furazolidone. Claim two of the patent is stated as follows: ^{2/}

N - (5-nitro-2-furfurylidene)-3-amino-2-oxazolidone
represented by the formula:



This patent has been involved in 56 infringement suits in the past 5 years, ^{3/} all instituted by Norwich. No decision in any of the suits terminated to date has impugned the validity of the patent. There have been 51 consent and default judgments, 11 temporary restraining orders and preliminary injunctions enjoining further acts of alleged infringement, one permanent injunction, ^{4/} and 2 cases are still pending judgment. The suits have been brought in 17 different States. Norwich states in its complaint (p. 12) that "the investigation and litigation

^{1/} A "composition of matter" patent under 35 U.S.C. Sec. 101 (1964), which expires in 17 years: April 1973.

^{2/} The structural formula shown in claim 2 of the patent is the formula for furazolidone, as shown in the furazolidone monograph on page 172 of *The National Formulary*, Twelfth Edition.

^{3/} For a summary of litigation see the listing in Appendix A which includes actions brought since the filing date of the 337 complaint.

^{4/} *Norwich Pharmacal Co. v. Chilton*, Doc. No. 67-225-F (D.C., C.D., Cal., July 31, 1967).

required for the enforcement of patent 2,742,462 is proliferating and becoming very burdensome and expensive. Relief under section 337 of the Tariff Act now appears to be the only appropriate remedy."

Two respondents, who made an appearance at the Commission's hearing, are involved in pending litigation of this patent with complainant in the federal district courts. These cases are still pending in Georgia and Alabama where preliminary injunctions have been entered enjoining respondents in both actions. ^{1/} These respondents stated before the Commission the possibility of existence of tying arrangements between some products of the Norwich Company and Hess & Clark. ^{2/} Another contention of respondents, that of possible misuse of the patent, was initially raised with the Commission by the Justice Department's Anti-trust Division.

^{1/} The Commission has obtained the district court records in both the Alabama litigation involving respondent C. L. Jones, Inc., and the Georgia case of respondent Veterinary Corp. of Georgia. Arguments primarily relating to patent validity were made by respondent in the Georgia action which involved multiple briefs and counter motions prior to the court's granting of complainant's motion for a preliminary injunction. C. L. Jones, Inc., of Alabama has argued validity questions in litigation as well as issues pertaining to Norwich's business activities and patents within the United States, the company's manner of research, and relationship with its subsidiaries, especially the Eaton Laboratories Division. This respondent's particular questioning in a recent deposition pertained to the possibility of tying arrangements between products of the Hess & Clark Company and the Norwich Company or its Eaton Division.

^{2/} Hess & Clark is a division of Richardson-Merrell, Inc., and is Norwich's exclusive licensee and U.S. distributor of furazolidone for use as a poultry feed additive. Prior to 1960, RMI was known as the Vick Chemical Company.

The patent misuse question involving Norwich was not in issue until after the issuance of the temporary exclusion order by the President. On September 30, 1968, the Justice Department addressed a letter to the Tariff Commission indicating possible patent misuse violations by Norwich. The Commission was informed that the Justice Department was investigating possible patent misuse by Norwich to determine what enforcement action, if any, would be appropriate. Justice felt that Norwich had misused its patent by dividing the market uses of the patent product between itself and its licensee as well as creating mutual royalty-free grant-backs of improvements between itself and its licensee.

The Commission received from the Justice Department a further letter of April 15, 1969, concerning the misuse issue. Justice informed the Commission that their investigation confirmed their original belief that the market division of Norwich and its licensee was in violation of the Sherman Act and a misuse of Norwich's furazolidone patent, but that they did not intend to seek any legal action against Norwich owing to the short time remaining before the expiration of the licensing agreement. Although Justice is not pursuing separate action against complainant, they expressed the view that a finding of patent misuse by the Tariff Commission should preclude its recommending to the President the issuance of an exclusion order, since a patentee who misuses its patent is prevented from gaining relief in the federal courts against infringement. Justice expressed the view that a patentee

should not be permitted to invoke section 337 to protect its market position when it would not be permitted to enforce its patent in the courts.

The letters of September 30, 1968 and April 15, 1969, from the Department of Justice are attached in Appendix B.

Other Alleged Unfair Methods of Competition and Unfair Acts

In addition to the patent question, other alleged unfair methods of competition and unfair acts considered by the Commission include smuggling, fraudulent and false invoicing (invoicing the goods to fictitious addressees and addresses), mislabeling, deceptive advertising, conspiracies to import the product fraudulently, "passing off" of the imported product as that of the complainant, disparagement of the patentee's goods and business methods, and wanton and malicious interference and annoyance.

FINDINGS AND RECOMMENDATION OF
THE COMMISSION 1/

The Commission finds unfair methods of competition and unfair acts in the importation and sale of furazolidone manufactured in accordance with the claims and specifications of U.S. Patent No. 2,742,462, and of products containing furazolidone, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, in violation of section 337(a) of the Tariff Act of 1930.

Accordingly, the Commission recommends that, in accordance with section 337(e) of the Tariff Act of 1930, the President direct the Secretary of the Treasury to instruct customs officers to exclude from entry into the United States through April 17, 1973 (the date of expiration of U.S. Patent No. 2,742,462), all foreign-produced furazolidone made in accordance with the claims and specifications of U.S. Patent No. 2,742,462, and all products containing such furazolidone.

1/ Commissioner Thunberg dissents from the findings and recommendation of the majority. Commissioner Leonard did not participate in this investigation for the reason that the investigation had been substantially completed prior to his becoming a member of the Commission.

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CONSIDERATIONS IN SUPPORT OF THE AFFIRMATIVE
FINDINGS OF THE COMMISSION

Statement of Chairman Sutton and Commissioner Newsom

On the basis of the facts obtained in the Commission's full investigation, we conclude that a showing of violation of section 337 has been established. The relevant provision of section 337(a) of the Tariff Act declares as being unlawful --

Unfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States. . . .

In conformity with the requirements of the above-quoted language the text which follows identifies (a) the unfair methods and acts which are involved in the importation and sale of furazolidone, (b) the domestic industry and its efficient and economical operation, and (c) the effect or tendency of the unfair methods and acts to substantially injure the domestic industry.

Unfair Methods and Acts

Furazolidone, the product of concern, is a drug used in combating infectious diseases, primarily in poultry. Its development was through the research initiative of the complainant, particularly the efforts of a chemist in their employ. Some years of testing were given by the complainant company to establishing the safety and uses for the chemical in conformity with Federal statutory and agency requirements.

In 1956, United States Letters Patent No. 2,742,462 was issued to Norwich Pharmacal Company granting it exclusive rights to manufacture, use, and sell the products described in the patent claims, for 17 years, in accord with the Constitution ^{1/} and Federal statutory provisions. ^{2/}

Violation of patent

Complainant, Norwich, alleges that claim 2 of this patent specifically covers furazolidone and is being infringed by the importation into, and sale in, the United States of furazolidone. The importation and domestic sale of a product, which is comparable to that made under valid U.S. patent rights, have been considered by the court as an unfair method or act within the meaning of section 337. In re Von Clemm, 229 F. 2d 441, 444-45 (1955).

The imported drug has been frequently tested by the Customs Service and the Food and Drug Administration laboratories and found to have the same chemical formula as that stated in claim 2 of the complainant's patent No. 2,742,462, which is the formula for the chemical, furazolidone, that is now listed in the National Formulary, an official compendium.

Since the imports are identical in formula to claim 2 of the patent, the question of patent validity could arise. However, in cases under section 337 involving a patented article or process,

^{1/} U.S. Const. art. I, § 8, cl. 8.

^{2/} 35 U.S.C. 154; 35 U.S.C. 271 (1964).

the United States Court of Customs and Patent Appeals has repeatedly held that the validity of the patent may not be questioned by the Tariff Commission and that a regularly issued unexpired patent must be considered valid unless and until a court of competent jurisdiction has held otherwise. ^{1/} This view is supported by 35 U.S.C. 282 (1964) which provides that a "patent shall be presumed valid".

In the past five years, Norwich has brought more than 56 suits under this patent in some 17 States. In none of these suits has there been a decision impugning the patent's validity. Fifty-one of the cases have resulted in consent judgments, and one resulted in a permanent injunction ^{2/} upholding the patent's validity.

Thus, a showing has been made of violation of valid patent rights, which, as noted above, constitutes an unfair method or act under section 337.

^{1/} Frischer & Co., Inc. v. Bakelite Corp., 39 F.2d 247 (1930), cert. denied, 282 U.S. 852 (1930); In re Orion Co., 71 F.2d 458 (1934); In re Northern Pigment Co., 71 F.2d 447 (1934); In re Von Clemm, 229 F.2d 441, 444-45 (1955). The court in the Von Clemm case rejected the contention that the Tariff Commission should question the validity of the patent or patents, but rather concluded that a regularly issued patent must be considered valid unless and until a court of competent jurisdiction has held otherwise. The court, in dismissing respondent's request to delay the investigation until a proper court determined patent validity, said there is "no statute which would justify, much less require, this court to ignore the provisions of section 337, supra, which we must necessarily regard as requiring timely disposition of appeals arising thereunder."

^{2/} Norwich Pharmacal Co. v. Chilton, Civil Action No. 67-225-F (C.D. California, July 31, 1967). In this case, Norwich's motion for summary judgment against patent infringement was granted. The court concluded that the patent was valid, although defendant had not questioned its validity.

Patent misuse

Since the imports in question conform with the valid Norwich patent, the next question to be considered is the relevancy of patent misuse to proceedings under section 337. The question is one of first impression for the Commission. Upon review of the case law on the subject of patent misuse, it is our opinion that, as suggested by the Department of Justice, this doctrine is relevant to section 337 patent-based proceedings. However, after a careful examination of the contract between Norwich and its licensee and of the facts in the public record of this investigation, we are satisfied that viable patent misuse on the part of Norwich or its licensee is not established.

The concept of patent misuse, principally designed to promote fair play in the market place, was first invoked by courts of equity. A patentee asserting his patent claims against a possible infringer was denied his rights if he did not come into court with "clean hands". Morton Salt Co. v. G. S. Suppiger Co., 314 U.S. 488 (1942); B. B. Chemical Co. v. Ellis, 314 U.S. 495 (1942). The defense of misuse is available to defeat the patentee's rights unless and until he purges himself of such misuse. United States v. Nat'l Gypsum Co., 352 U.S. 457 (1957). With the advent of the Sherman Act, and later Federal statutes having broad application in the field of unfair competition, the doctrine of misuse has become entrenched as a principle invoked by the courts in the public interest. Morton Salt Co. v. G. S. Suppiger Co., 314 U.S. 488, 494 (1942).

The Commission, in its investigatory proceedings under section 337, is operating in the public interest to assist the President in unburdening the import trade of the United States of unfair methods of competition and unfair practices. The doctrine of patent misuse is identified with the law of unfair competition, and, as such, is clearly within its competency. It would seem to follow that the Commission should be prepared to invoke it in appropriate situations which may arise in proceedings under section 337.

Two situations come to mind where the Commission might appropriately find the patent misuse issue relevant to proceedings under section 337. One possible situation would be where patent misuse by a foreign patentee, with or without the aid of the domestic importers, might be regarded as an unfair method or unfair act which would be the basis for a complainant seeking to invoke section 337 against a foreign patentee. In this situation, the public interest would be protected against those who over-extend their patent monopolies through misuse.

A second situation would be one such as that arising in the present investigation where the complainant, patentee, may be misusing his patent. This jurisdiction--which declares as an "unfair" method or act the importation into the United States or sale of articles made in accordance with the claims of a duly issued U.S. patent--is well and firmly established having received both judicial and legislative approval. In a practical, if not a legal sense, an

exclusion order issued by the President under section 337 provides for a patentee interested in pursuing the domestic exploitation of his patent an additional remedy ^{1/} against "infringing" imports, a remedy more effective than any other remedy available to private litigants under the patent laws. The form of relief is equitable in nature and of benefit only to those who exploit the patent in the United States, i.e., the patentee or his licensee. An exclusion order is a type of permanent injunction against foreign "infringers". It would seem that the public interest would not be served by invoking sanctions which directly aid a patentee who is misusing his patent.

Prior to Justice Department involvement in the investigation, the Commission was not aware of the existence of the patent misuse issue. However, Justice's letter of September 30, 1968, indicated their interest in the proceedings and a desire to conduct an independent investigation to determine whether Norwich was guilty of any antitrust violations. Justice sent to the Commission a copy of the 1955 Norwich-Vick contract emphasizing particular provisions which they believed indicated patent misuse. Also, Justice presented case law to the Commission indicating the judicial disposition of the patent misuse issue. Justice agreed to come forward with the results of its investigation and any additional information which the Commission would need in disposing of the misuse problem.

^{1/} The only remedy in the case of process patents.

On April 15, 1969, the Commission was informed that Justice would not separately pursue the Norwich agreement, their reasons being the early termination of the agreement and the unlikelihood of its renewal. Justice, however, expressed the firm conclusion that Norwich was guilty of patent misuse but furnished no corroborating facts, such as might have been obtained in their investigation, nor did they furnish adequate legal support for their conclusion. Justice, apparently, rested their conclusion solely on the basis of the Norwich-Vick contract of 1955.

Turning now to the agreement between Norwich and its licensee, it is said to involve patent misuse in that it contains: (1) Provisions for a division of market uses whereby the proprietary veterinary field is exclusively granted to the licensee while the patentee retains the market use in prescriptive veterinary preparations and human uses of furazolidone and related nitrofurans products; (2) Provision for royalty-free grant-back of exclusive licensing to Norwich of improvements in nitrofurans products in Norwich's fields of market use, i.e., all fields of use, excluding the proprietary veterinary field; (3) A provision for royalty-free grant-back from Norwich to Vick of exclusive use of new nitrofurans products in the proprietary veterinary field. This latter grant allows Vick to accept or reject the new product from Norwich. However, if Vick rejects the new product, Norwich agrees to withhold the product

from the market. Each of these three areas of possible patent misuse will now be examined.

Division of Market Uses.--The Justice Department has asserted that division of market uses is an example of patent misuse. Although the courts have said that the patent monopoly does not include: Extension of the patent monopoly to the patentee beyond the manufacture, sale, or use of the patent by the licensee, Adams v. Burke, 84 U.S. (17 Wall.) 453 (1873); tying clauses, Baldwin-Lima Hamilton Corp. v. Tatnall Measuring System Co., 169 F. Supp. 1 (E.D. Penn. 1958), aff'd. 268 F.2d 395 (3d. Cir. 1959), cert.denied, 361 U.S. 894 (1959); price-fixing devices, United States v. Univis Lens Co., Inc., 316 U.S. 241 (1942); and price-fixing through refusing to sell to certain classes, United States v. Ethyl Gasoline Corp., 27 F. Supp. 959 (S.D.N.Y. 1939), aff'd., 309 U.S. 436 (1940); the courts have given the patentee a right to adopt reasonable restrictions upon his licensees. United States v. General Electric Co., 272 U.S. 476 (1926).

In the leading case on market divisions, the Supreme Court has interpreted market divisions to be a reasonable restriction by the patentee upon the licensee. General Talking Pictures Corp. v. Western Electric Corp., 305 U.S. 124 (1938). General Talking Pictures, has been followed by subsequent courts as a reasonable restriction by the patentee upon the licensee. Hazeltine Res. v. Admiral Corp.,

183 F.2d 953 (7th Cir.), cert. denied, 340 U.S. 896 (1950); Sperry Prods., Inc. v. Aluminum Co. of America, 171 F. Supp. 901 (N.D. Ohio 1959), rev'd. in part but aff'd. on this issue, 285 F. 2d 911, 927 (6th Cir. 1960).

Despite Justice Department's assertion that market divisions is a form of patent misuse, we are inclined to the view that under existing case law market division is not a patent misuse.

Grant-Back Provisions of Agreement.--The courts have also upheld patent improvement grant-backs as long as they are not anti-competitive and do not stifle the incentive for research and improvement in the patent area. Transparent-Wrap Mach. Corp. v. Stokes & Smith Co., 329 U.S. 637 (1947). If either condition results from the grant-back, the court will consider the grant-back a patent misuse. It makes no difference whether the grant-back is one which benefits the patentee or the licensee. If the results of the grant-back are anti-competitive or stifle research, the courts regard such provisions as being a type of patent misuse.

Inasmuch as the courts have not regarded grant-back provisions as per se violations, it would seem that a finding of misuse must be grounded upon facts showing that such provisions in a given case have operated anti-competitively or so as to stifle research. As previously indicated, the Commission has before it only the bare provisions of the Norwich-Vick agreement, with little or no facts regarding its operation in practice. Although the grant-back from

Norwich to Vick appears on its face to raise possible anti-competitive impact in operation in that it obliges Norwich in certain situations to withhold nitrofurans products from the market, it is not possible at this time to arrive at a firm conclusion in regard to the practices involved under either of the grant-back provisions. Moreover, further investigative effort at this time is not warranted since, in our opinion, the issue has been rendered moot by the impending termination of the agreement on December 31, 1969.

Other unfair methods and acts

In addition, evidence was obtained in the investigation indicating the existence of other unfair methods of competition and unfair acts, which go hand in hand with the patent violations because of their design to evade, or at least impede, prosecutions for patent infringement. These unfair methods or acts include: Smuggling, fraudulent and false invoicing (invoicing the goods to fictitious addressees and addresses), mislabeling, deceptive advertising, conspiracies to fraudulently import the product, "passing off" of the imported product as that of the complainant, disparagement of the patentee's goods and business methods, and wanton and malicious interference and annoyance.

Investigations by the Bureau of Customs of violations in the importation of furazolidone are summarized in Appendix C.

The Domestic Industry

The Norwich Company is the sole U.S. manufacturer of furazolidone, and has contracted for its further processing and exclusive marketing nationally as a poultry feed additive by the Hess & Clark Division, which is familiar with, and has a product line and trained sales force in veterinary medicinal products. These facilities for manufacture and distribution of furazolidone and products containing furazolidone constitute the domestic industry. ^{1/}

The investigation discloses that this industry is economically and efficiently operated. Modern manufacturing equipment and processing methods are used, with sales being made through personal servicing of the accounts as well as advertising promotions. Both firms are highly reputable in their fields. The forward-looking research and development of the drug and the commercial success in marketing it for poultry are evident from the multi-million dollar sales level obtained in its initial year on the market and in succeeding years.

Effect or Tendency of Unfair Methods and Acts to Injure Industry

The effect or tendency of the unfair methods and acts to substantially injure an industry is indicated from a loss of sales and

^{1/} The court in In re Von Clemm, *supra*, at 444 while holding that a single company patent owner could be considered an industry, further stated that, "there is nothing in the statute which requires that an industry must be of any particular size, or that more than one company must be involved before the protection provided by the statute may be invoked".

goodwill, undue harrassment and expense, the inadequacy of other available remedies leading to the proliferation of suits, and the extreme measures required to be taken to compete effectively with the low-priced imports.

Although the data on imports are incomplete--owing primarily to the clandestine nature of a large number of the relevant import transactions--they do indicate the entry of substantial quantities of furazolidone imports; the verified imports alone amounting to the equivalent of 948,000 pounds of 11 percent pre-mix, from 1961 to August 1968. The magnitude of the imports was greatest in the two fiscal years (1964-65 and 1967-68) when Hess & Clark's sales of the pre-mix were at their lowest levels. In the months January through August 1968 sales of domestic furazolidone were at their lowest ebb while imports attained a record high level.

The exclusive distributor of furazolidone, Hess & Clark Division, has not only lost sales--which are felt again through the resulting loss to Norwich in its sales to Hess & Clark--but Hess & Clark also is experiencing an excessive turnover of sales personnel. Moreover, it has felt compelled to undertake advertising and promotional campaigns specifically aimed at the low-priced imports, and to make two 20 percent price reductions (in 1963 and July 1968) on its pre-mix, resulting in part from import competition.

The number of importers and sellers of the drug are many, as indicated by the multiplicity of suits ^{1/} brought by Norwich. The various deceptive practices associated with the importation and sale of furazolidone, such as the naming of dummy corporations and fictitious people in the records of entry, have contributed to the difficulty of bringing suit against the perpetrators of the unfair acts. Once brought to suit, some individuals have merely changed their business names and resumed importing. The economic incentive present in the sale of imported furazolidone at prices that undersell the domestic producer by as much as half, understandably resulted in a constant addition of new importers and their usurpation of the markets.

^{1/} The court in Frischer & Co., Inc. v. Bakelite Corp., *supra*, at 260, stated, in effect, that one of the purposes of section 316 (which is the predecessor to section 337), was to provide an adequate remedy where none existed under the patent laws:

When . . . merchandise is delivered from customs custody it may be, and frequently is, distributed throughout the United States. The difficulties which confront a patentee seeking to enforce his rights through the courts are practically insurmountable. He is required to proceed against each individual dealer selling the infringing articles, which, of course, would lead to a multiplicity of suits with little likelihood that all infringing dealers could be reached. The cost of the numerous suits with the small amount of damages which may be recovered in any one suit discourages resort to the courts. Moreover, a decree obtained against one dealer would have no binding effect upon others, and by the simple expedient of changing the consignees the effect of a decree when secured would be nullified. Unless, therefore, section 316 may be invoked to reach the foreign articles at the time and place of importation by forbidding entry into the United States of those articles which upon the facts in a particular case are found to violate rights of domestic manufacturers', such domestic manufacturers have no adequate remedy.

Conclusion

In the foregoing paragraphs, we have shown the basis for our finding that a violation of section 337 has been established. Having so found, it follows that we must recommend to the President that he direct the Secretary of the Treasury to exclude from entry furazolidone and articles containing furazolidone during the period which terminates at the close of April 17, 1973, the date of the expiration of U.S. Letters Patent No. 2,742,462.

Statement of Commissioners Clubb and Moore

We concur in the conclusion reached by Chairman Sutton and Commissioner Newsom that a violation of section 337 of the Tariff Act of 1930 has been established in this case and that an exclusion order should be issued. However, we do not agree with their ancillary proposition that patent misuse is relevant to Section 337 patent-based proceedings. Moreover, while we agree with the remainder of our colleagues' statement, we believe certain of respondent's contentions merit a somewhat more detailed comment.

The facts in this case are clear and are well stated in the companion opinion. They reveal that the drug furazolidone, which is patented in the United States, is being produced abroad and imported into the United States without license from the patentee, the Norwich Pharmacal Company (now Morton-Norwich Products, Inc., and hereinafter referred to as the complainant). Since the unlicensed foreign producers have no research costs to recover, they are able for this reason alone to sell at a much lower price than the complainant, whose research staff worked from 1939 to 1956 to develop furazolidone. ^{1/}

^{1/} Information supplied by the Patent Office indicates that other trading nations protect their patent holders against unlicensed imports of the patented article. Among these countries are Norway, Denmark, Sweden

After bringing many patent infringement actions against importers of furazolidone without halting the illicit trade, complainant has petitioned the Tariff Commission to recommend to the President that all unlicensed furazolidone be refused entry into the United States pursuant to section 337 of the Tariff Act. This blanket remedy is obviously much more effective than that available in the courts where multitudinous patent suits would be required to accomplish the same result.

1/ Continued:

Finland, France, Germany, The Netherlands, Japan, and Great Britain. Moreover, a recent decision of the Court of Justice of the EEC has held that such restrictions on imports do not violate the Treaty of Rome (Parke Davis & Co. v. Probel Reise, et al., Ct. of Justice, EEC, No. 24/67 (Feb. 1968), CCH Common Mkt. Reporter § 8054). In that case the Advocate General stated that unless such imports could be prohibited

. . . Little would be left of the legal utilization monopoly which is designed to give the inventor an opportunity for equitable compensation since unauthorized persons could without any difficulty supply the entire Common Market from a country without patent protection, under conditions more favorable than those available to the inventor himself since they would not have to bear the same extraordinary development costs as the patent holder or his licensee. The effects on the economy and on patent law would be incalculable.

In the United States section 337 of the Tariff Act is the most effective remedy in cases involving product patents (see cases cited in Note 3, infra), and the only remedy in cases involving process patents. In re Amtorg Trading Co., 75 F.2d 826 (1935), cert. denied, 296 U.S. 576; 19 U.S.T.C. Ann. Rept. 12-14 (1935); H.R. Rep. No. 1781, 76th Cong., 3rd Sess. (1940); S. Rep. No. 1903, 76th Cong., 3rd Sess (1940); Pub. L. No. 710, 76th Cong., 3rd Sess. (July 2, 1940); 19 U.S.C. 1337(a) (1964).

Complainant is entitled to the relief requested if the requirements of section 337 have been met. In pertinent part section 337 declares unlawful any unfair method of competition or unfair act in the import trade, which has a tendency to substantially injure an efficiently and economically operated domestic industry. ^{2/} The interpretation of this Act set out in earlier decisions of the Courts and the Commission indicate that all requirements have been met in this case, ^{3/} but respondent-importers contend that:

(1) The Commission should suspend its section 337 proceedings until all federal court litigation relating to patents has been concluded;

2/ Section 337 reads as follows:

Unfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to prevent the establishment of such an industry, or to restrain or monopolize trade and commerce in the United States, are declared unlawful, and when found by the President to exist shall be dealt with, in addition to any other provisions of law, as hereinafter provided. 19 U.S.C. § 1337a (1964).

3/ In re Von Clemm, 229 F.2d 441 (C.C.P.A. 1955); In re Orion, 71 F.2d 458 (C.C.P.A. 1934); In re Northern Pigment Co., 71 F.2d 447 (C.C.P.A. 1934); Frischer & Co. v. Bakelite Corp., 39 F.2d 247 (1930).

(2) Patent infringement alone is not an unfair method of competition and therefore section 337 has not been violated;

(3) Norwich has not been injured to the degree required by the statute;

(4) Even if Norwich otherwise qualifies for relief, the proceedings should be dismissed because Norwich has unclean hands, having used its patent in a scheme which violates the antitrust laws. In this latter contention the respondents are joined by the Department of Justice.

Each of these points is discussed below. ^{4/}

^{4/} Respondent has made two other contentions which do not merit extended treatment. Thus it argues that Norwich by itself does not constitute an "industry" for purposes of section 337. However, the Commission has long held that in patent cases the "industry" involved is "the industry legally entitled to manufacture and sell" the patented article. Self-Closing Containers (Squeeze-Type Coin Purses), U.S.T.C. Inv. No. 337-18 at 8 (1962). Normally this confines the "industry" to the patent holder or that portion of the patent holder's operations devoted to the production of the patented product.

In addition, respondent contends that complainant Norwich is not "efficiently and economically operated," and therefore does not qualify for relief under section 337. The thrust of respondent's argument in this respect is that, capitalizing on its monopoly, Norwich charges prices for furazolidone considerably in excess of the cost of production. Respondent argues that Norwich accordingly is not "efficiently and economically operated" from the standpoint of the consumer. This argument also is not new, having been rejected several times in the past. See, In re Northern Pigment Co., 71 F.2d 447 (C.C.P.A. 1934), and Drive Springs, U.S.T.C. Inv. No. 337-7 at 6 (1934).

Suspension of Proceedings

Respondent first argues that the Commission should suspend its section 337 proceeding until the validity of complainant's patent has been determined by the federal courts. ^{5/} This argument has frequently been made in the past, and at one time appears to have been adopted by the Commission. ^{6/} The Congress ^{7/} and the courts ^{8/} implicitly disapproved

^{5/} Brief for Respondents at 13-4 (September 9, 1968).

^{6/} For example, in the section of the Commission's Annual Report for 1937 which discusses section 337 cases, the Commission said:

Patent infringement was the principal ground of complaint and in practically all cases neither the validity nor the scope of the patents had been adjudicated. In such cases the Commission has declined to order formal investigations under section 337, and in two cases principally involving patents . . . it has dismissed investigations which had been previously ordered. 21 U.S.T.C. Ann. Rep. 36 (1937).

^{7/} In reporting on a 1940 amendment to section 337, the Senate Patent Committee indicated that unadjudicated patents should be covered when it stated

In the use of the wording "valid United States letters patent" it is not the intention of the committee to mean that necessarily the patent should have been declared by the court to have been valid previously but that it should be an unexpired patent, and should not be an invalid patent. S. Rep. No. 1903, 76th Cong., 3rd Sess. 4 (1940).

^{8/} The C.C.P.A. has uniformly held that unexpired patents are to be treated as valid unless they have been held invalid by a court. In re Orion Co., 71 F.2d 458, 464-5 (1934); Frischer & Co. v. Bakelite Corp., 39 F.2d 247, 258 (1930).

of the practice, but the Commission appears to have continued it anyway. ^{9/}

Finally, in 1955 the matter was squarely put to our reviewing court, the United States Court of Customs and Patent Appeals, in In re Von Clemm.

The Court ruled that such suspensions were not justified, stating,

It is urged by Von Clemm that the Tariff Commission should have refrained from acting in this case and that this court should also refrain from acting since the questions of validity of Linde's patent and infringement thereof by Von Clemm's stones are involved in a suit now pending between appellant and Linde in the United States District Court for the Southern District of New York. We are aware of no statute, however, which would justify, much less require, this court to ignore the provisions of section 337, supra, which we must necessarily regard as requiring timely disposition of appeals arising thereunder.

As pointed out in In re Orion Co., supra, any order which may be issued by the President may be corrected in the event of a subsequent holding of invalidity of a patent. Moreover, under section 337, supra, the President may, in his discretion, provide for entry of the disputed merchandise under bond pending, inter alia, final determination of the issues of validity and infringement. In re Von Clemm, 229 F.2d 441, 445 (C.C.P.A. 1955).

The wisdom of the Court's ruling is revealed by the record in the present case. Complainant has already brought 56 suits in which its patent has withstood attack, and resourceful lawyers for importers could no doubt force many more. If the Commission were to suspend its proceedings until

^{9/} 40 U.S.T.C. Ann. Rep. 17-8 (1956) and 42 U.S.T.C. Ann. Rep. 30 (1958).

all such suits had been concluded, the patent would no doubt expire before the Commission got a round to acting.

Accordingly, respondent's request to suspend must be denied.

Patent Infringement as an Unfair Method of Competition

Secondly, respondent contends that patent infringement alone does not amount to a violation of section 337, and therefore section 337 is not applicable. ^{10/}

Respondent is not the first to make this argument. Others, noting that patent infringement alone is neither "unfair competition" at common law ^{11/} nor, apparently, an "unfair method of competition" under the Federal Trade Commission Act ^{12/} have argued that the same result should obtain under section 337. ^{13/}

^{10/} Brief for Respondents at 6-11 (Sept. 9, 1968); and 2d Brief for Respondents at 17-21 (November 22, 1968).

^{11/} At first, common law unfair competition applied only to the palming off of goods of one manufacturer for those of another, thus excluding patent infringement where no deception is involved. Unit Const. Co. v. Huskey Mfg. Co., 241 F. 129 (E.D. Pa., 1917). Later the concept of common law unfair competition was broadened so that it covers practices other than palming off, but patent infringement is still excluded, apparently because there is a more specific remedy provided by the patent laws. R. R. Donnelley & Sons Co. v. Haber, 43 F. Supp. 456 (E.D. N.Y. 1942).

^{12/} This point was noted by the dissent in Synthetic Star Sapphires, U.S.T.C. Inv. No. 337-13 at 35 (1954).

We cannot overlook the very important fact that, in the nearly 40 years that the Federal Trade Commission has been

From its very earliest cases to the present, however, this Commission has uniformly held that patent infringement by itself is an unfair method of competition under section 337 despite the fact that a different result might be reached under statutes governing trade within the United States. ^{14/} Until relatively recent times it was argued by some respondents (and a Commission minority) that this Commission position had never been approved by the courts and, therefore, was still open to question in the Commission. The issue was finally settled, however, in

12/ Continued:

administering statutes dealing with unfair methods of competition, to our knowledge, that agency has never held "patent infringement" to be an unfair method of competition. There can be no doubt that, in all these years, numerous cases must have arisen in which the Federal Trade Commission would have had to assert its jurisdiction if patent infringement were deemed to be an unfair method of competition.

^{13/} Id. at 34-37 (dissenting opinion); In re Von Clemm, 229 F.2d 441, 445 (C.C.P.A. 1955) (dissenting opinion).

^{14/} Synthetic Phenolic Resin, U.S.T.C. Inv. No. 316-4 (1927); Coilable Metal Rules and Holders, U.S.T.C. Inv. No. 337-8 (1935). In this latter case the Commission said:

The unlicensed imports into the United States of articles produced according to the terms of United States patents constitutes an unfair method of competition in violation of section 337.

Synthetic Star Sapphires, U.S.T.C. Inv. No. 337-13 (1954), aff'd. sub nom, In re Von Clemm, 229 F.2d 441 (C.C.P.A. 1955), ^{15/} where both the Commission majority and the C.C.P.A. majority (on appeal) refused to adopt the position that something more than patent infringement is required despite vigorous dissents in both the Commission and the C.C.P.A. Since then the Commission has uniformly held (without dissent on this issue) that patent infringement alone is enough. ^{16/}

^{15/} See casenote 45 Geo. L.J. 113 (1956).

^{16/} In Self-Closing Containers (Squeeze-Type Coin Purses), U.S.T.C. Inv. No. 337-18 (1962), the Commission stated:

If an article manufactured in a foreign country is made in accordance with, embodies, employs, or contains the invention disclosed in a current United States patent that has not been held invalid by a court of competent jurisdiction, it is an unfair method of competition or unfair act, within the meaning of section 337 of the Tariff Act of 1930, to import such article into the United States or sell it domestically without license from the registered owner of the patent. This determination is in accord with the applicable decisions of the United States Court of Customs and Patent Appeals. See, In re Von Clemm, 229 F. 2d 441, 443 (1955); In re Orion Co., 71 F.2d 458, 465 (1934); and In re Northern Pigment Co., 71 F.2d 447, 455 (1934). See also, Frischer & Co., Inc. v. Bakelite Corp., 39 F.2d 247 (1930).

The reason for treating patent infringement as an unfair method of competition under section 337, although it is not so regarded under statutes governing domestic trade, is that, under United States patent law, the practical circumstances of competition are vastly different when the infringing producer is foreign rather than domestic. The patent holder can stop domestic infringing production of his product by bringing an infringement action against the unlicensed domestic producer. He cannot stop similar unlicensed production abroad, however, because United States courts have no jurisdiction over the foreign producer. Unable to stop the foreign production at its source, the U. S. patentee must instead find and bring suit against each importer in order to protect his patent rights. That this remedy provided by the patent laws is inadequate is well illustrated by the instant case where the complainant patent holder has brought 56 suits against different importers, and the end is not in sight. ^{17/}

In order to provide an effective remedy the Commission and the courts have held patent infringement to be an unfair method of competition for purposes of section 337, despite the fact that it might not be characterized

^{17/} Moreover, even this inadequate remedy is unavailable to a process patent holder. See note 1, supra.

as such under statutes governing domestic commerce where other adequate remedies are available. No doubt our reviewing court had this thought in mind when it stated in Von Clemm that the statutory language of section 337

I's broad and inclusive and should not be held to be limited to acts coming within the technical definition of unfair methods of competition as applied in some decisions. The importation of articles may involve questions which differ materially from any arising in purely domestic competition, and it is evident from the language used that Congress intended to allow wide discretion in determining what practices are to be regarded as fair. 229 F.2d 441, 444 (C.C.P.A. 1955).

Accordingly, it is clear that respondent's contention that patent infringement is not an unfair method of competition under section 337 must be rejected.

Injury

Thirdly, respondent argues that complainant Norwich has not been injured to the degree required by section 337, and that therefore no exclusion order should issue. Section 337 declares that unfair methods of competition in the import trade are unlawful if they have, inter alia, "the effect or tendency . . . to destroy or substantially injure an industry . . . in the United States. . . ." Respondent and the dissent herein,

relying on various minority opinions of this Commission and the C.C.P.A. ^{18/} argue that the words "substantially injure" require an injury of such severity as to destroy the industry. Respondent correctly notes that if his view of the statute is adopted, it would be fatal to complainant's case here, because Norwich's furazolidone operations (the "industry" involved here) is nowhere near being destroyed. Rather, as noted in the dissenting opinion, it continues to make profits despite widespread infringement of the patent by importers.

With all due respect to our dissenting colleague, it is clear to us that this issue was settled long ago, and is no longer open to question at the Commission level. The rule, supported in substance by the overwhelming weight of authority in Commission opinions and implicitly affirmed by the C.C.P.A., is that the term "tendency . . . to . . . substantially injure" in section 337 is satisfied if the unfair method of competition involved threatens to interfere in any significant way with the ability of the domestic industry to carry on its business.

^{18/} Self-Closing Containers (Squeeze-Type Coin Purses), U.S.T.C. Inv. No. 337-18, at 23 (1962). This view also received tacit support from two members of an equally divided Commission in In-the-Ear Hearing Aids, U.S.T.C. Inv. No. 337-20, at 29 (1966), and in In re Von Clemm, 229 F.2d 441, 447 (1955) (dissent), where the dissenting judge said:

From the context, coupled as the phrase is with "to destroy," it would seem that Congress contemplated a crippling injury, one which verged on the brink of destruction, rather than, as here indicated, a mere competitive nuisance.

This rule was applied by the Commission in early cases such as Manila Rope and Bolt Rope, ^{19/} where the Commission found that low quality imported rope was being sold in the United States as "manila" in violation of a recognized United States market practice. The record contained several instances of inability of the domestic producers to compete with the mislabelled lower priced imported rope, and this was sufficient to satisfy the injury requirement because:

I/t is impossible to escape the conclusion that the importation and sale in this country under the name of "manila" of rope composed in part of such cheaper material will work an injury to the domestic manufacturers who adhere to the trade practice established in the United States. ^{20/}

Similarly, the Commission has held that sufficient injury has been shown where it was a "widespread practice" to offer infringing goods for sale under the domestic producer's trade name. With reference to this practice the Commission said:

It is obvious that such practice cannot but have the effect substantially to injure the good will of the domestic manufacturer. Synthetic Phenolic Resin, U.S.T.C. Inv. No. 316-4, at 13 (1927). ^{21/}

^{19/} Manila Rope and Bolt Rope, U.S.T.C. Inv. No. 316-5 (1927)

^{20/} Id. at 5.

^{21/} See also, Cigar Lighters, U.S.T.C. Inv. No. 337-6 at 6 (1933), where the Commission said:

In none of these cases did the Commission require the complainant to show that it was on the brink of destruction. Rather, the injury requirement was met by a showing that the unfair act had a harmful tendency.

The injury test urged by respondent and by the dissent herein has been implicitly disapproved by our reviewing court in In re Von Clemm, and that ruling is binding on the Commission. The point was vigorously argued by dissenting Commissioners (Synthetic Star Sapphires and Synthetic Rubies, U.S.T.C. Inv. No. 337-13 (1954)), and by the dissenting judge when that case was appealed (In re Von Clemm, 229 F.2d 441, 447 (C.C.P.A. 1955)), but it did not prevail in either forum. Accordingly, the matter having been settled by our reviewing court, it is no longer open to question at the Commission level.

21/ Continued:

Due to the nature of the imported article concerned the Commission has been unable to ascertain the extent of imports, but the record does justify a finding that imported lighters infringing complainant's patent have been offered for sale and sold at retail in the United States, and that Japanese manufacturers and exporters have solicited trade in the United States. The natural and probable effect or tendency of these solicitations and sales is to render substantial injury to the business of complainant and the Commission formally so finds.

But the Commission should not adopt such a restrictive injury test even if it were free to do so. It would be repugnant to both law and reason to hold that a method of competition is unfair, but that it should be permitted to continue because, despite the injury it is causing the victim, he is still able to survive. If such a rule were adopted, it is doubtful that relief could ever be granted under section 337 because rarely will a single unfair act (e.g., patent infringement, product simulation, trade name appropriation, etc.) have the effect of destroying an industry. Domestic producers would, in effect, be denied a remedy for the unfair acts of foreign producers and importers. The Commission has wisely avoided such a result.

Patent Misuse

Finally, respondent argues that even if the complaint in this case otherwise meets the requirements of section 337, relief should be denied because complainant has "unclean hands." The thrust of this argument is that complainant has misused its patent by employing it in a way which violates the antitrust laws. Respondent and the Justice Department allege that enforcement of the patent would be denied in a federal court, and that relief under section 337 should similarly be denied by the Commission.

With all due respect to Chairman Sutton and Commissioner Newsom, who hold a contrary view, it seems to us that whatever the merits the clean hands doctrine might have in a patent case in the federal courts, it clearly has no place in a section 337 proceeding before the Tariff Commission. There are several reasons for this.

First, Tariff Commission jurisdiction under section 337 is limited to unfair methods of competition in the import trade. The Commission has no jurisdiction to rule directly on internal antitrust matters (such as patent misuse) or other issues unconnected with the import trade, and it seems to us that it has no competence to make determinations on such issues when they are raised as matters of defense. Persuasive on this point is the Court of Customs and Patent Appeals' holding that the Commission cannot rule on the validity of a patent when that issue is raised as a defense in a section 337 proceeding because jurisdiction to determine the validity of patents is lodged in the federal courts. ^{22/} A simple extension of this rule requires that the Commission refuse to consider other matters such as domestic antitrust violations

^{22/} Frischer & Co. v. Bakelite, 39 F.2d 247 (C.C.P.A. 1930). See also, In re Orion Co. 71 F.2d 458 (C.C.P.A. 1934), and In re Northern Pigment Co., 71 F.2d 447 (C.C.P.A. 1934).

amounting to patent misuse when they are raised as a defense because jurisdiction over these matters is similarly lodged elsewhere. As in the case of patent validity, a respondent here will not be denied an opportunity to prove his allegations. Rather, he will merely be referred to a forum which has jurisdiction over them.

Second, we question whether patent misuse or other "clean hands" defenses are applicable in a public proceeding in any event.^{23/} We are not the first agency to face this question. In Republic Steel Corporation v. NLRB, 107 F.2d 472 (3d Cir. 1939), an employer charged with an unfair labor practice was ordered to reinstate certain union member employees. The employer resisted, arguing that the union members did not come into court with clean hands and, therefore, should not be reinstated. The court

^{23/} The Commission has sometimes pointed out that the proceedings under section 337 are not private contests between individual litigants as in a suit at law, but instead are public proceedings designed to establish and enforce rules of fair competition in the marketplace. Accordingly, the scope of the full investigation is governed, not by the complaint, but by the Commission's notice of investigation. Synthetic Phenolic Resin, U.S.T.C. Inv. No. 337-4 (1927). Nonetheless, the Commission proceedings are quasi-adversary in the sense that contending parties with antagonistic positions appear before the Commission, and, accordingly, some of the trappings of an adversary proceeding have been adopted. For example, the complaint and answers are circulated to the parties, and cross-examination is normally permitted at the hearing. Such adversary type procedures are permitted only to the extent that the Commission feels that they may bring out useful information, however; they have not been accorded as a matter of right.

ruled, however, that the clean hands doctrine is not applicable in a public proceeding, stating:

Equally untenable is the contention that the strikers are not entitled to reinstatement because they have not come into court with clean hands. This principle is not applicable to a proceeding in which a governmental agency is seeking enforcement of its order in the public interest. Republic Steel Corporation v. NLRB, 107 F.2d 472, 479 (3d Cir. 1939). 24/

Accordingly, until otherwise instructed by the Congress or by Court decision, the Commission, in our judgment, should not consider clean hands defenses in section 337 proceedings.

Conclusion

In view of the foregoing, we conclude that all of the requirements of section 337 have been met--indeed a clearer case could not be found--and therefore we recommend that the President issue an appropriate exclusion order.

24/ To the same effect see NLRB v. Plumbers Union of Nassau County, Local 457, 299 F.2d 497 (2d Cir. 1962); NLRB v. Pease Oil Co., 279 F.2d 135 (2d Cir. 1960); Eichleay Corp. v. NLRB, 206 F.2d 799 (3d Cir. 1953); NLRB v. Remington Rand, Inc., 94 F.2d 862 (2d Cir. 1938); NLRB v. Carlisle Lumber Co., 99 F.2d 533 (9th Cir. 1938); NLRB v. Hearst, 102 F.2d 658 (9th Cir. 1939); Schaffler v. Brewery and Beer Distrib. Drivers, Helpers and Platform Men, Local 830, 162 F. Supp. 1 (E.D. Pa. 1958).

CONSIDERATIONS IN SUPPORT OF THE NEGATIVE
FINDINGS OF COMMISSIONER THUNBERG

In the past various opinions arising from cases under Section 337 of the Tariff Act of 1930 have stated the criteria required for 'unfair methods of competition' and 'unfair acts in the importation of articles' in the United States, 'the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to prevent the establishment of such an industry' to be declared unlawful. In the section 337 In-The-Ear Hearing Aids case, for example (Investigation No. 337-20, T.C. Publication 182, July 1966), participating in a joint decision I set forth two requirements stating the conditions that I believe must be met before the Commission can recommend exclusionary action:

'According to the clear language of the statute, the existence of 'unfair methods of competition and unfair acts' alone is not sufficient to warrant excluding the patent-violating imports from the U.S. market. These acts must in addition cause--or must in addition be likely to cause--injury so substantial that

the danger of the destruction of a domestic industry is present." ^{1/} The record in the present case contains no evidence of any such danger or any such injury.

This investigation of a complaint filed by the Norwich Pharmacal Company has failed to disclose that any unfair trade practice has had the effect or tendency of injuring substantially the Norwich Pharmacal Company, the sole producer in the United States of, and the holder of a U.S. patent upon, furazolidone. Indeed the investigation has disclosed that far from being "substantially injured," the Norwich Pharmacal Company, on the basis of its own profit and loss statements and other data furnished, has been and continues to be an exceedingly profitable and successful enterprise in all of its activities, including its chemical division.

Whether a broad or narrow definition of industry is chosen in this case, there is no evidence of substantial injury or threat thereof. The domestic industry with which we are concerned here may be considered to be as broad as the

^{1/} In-The-Ear Hearing Aids, Inv. No. 337-20 (1966), Statement of Commissioners Sutton and Thunberg, p. 28; see also Self Closing Containers, Inves. No. 337-18 (1962), dissenting opinion of Chairman Dorfman, pp. 29-30; and Synthetic Star Sapphires and Synthetic Rubies, Inv. No. 337-13 (1954), dissenting opinion of Commissioners Ryder and Edminster, pp. 41-42.

Norwich Pharmacal Company, the complainant and the owner of the patent at issue, or it may be confined to the one operation in that company that is concerned with the patent--the chemical division. ^{1/}

A company, operated as a whole, develops a product through revenue derived from other company sources, and in turn the successfully patented item supplies funds for other company uses; thus, the industry can justifiably be viewed as the whole operation of the patent owner, in this case the Norwich Pharmacal Company. The industry encompassing the entire Norwich Pharmacal Company has been and continues to be an exceedingly profitable and a successful enterprise in its aggregate activities, including the chemical division. Indeed, the company's net income before taxes has increased in each year since 1963. Overall company sales and profits increased in each of the past five years, as has the ratio of net income to sales for 1962-67.

If the definition of industry should be confined to the chemical division, where the bulk of the sales results from

^{1/} In re Von Clemm 229 F 2d 441 at 444 wherein it is stated: "There is nothing in the statute which requires that an industry must be of any particular size. . . ."

furazolidone production, conclusions as to injury would remain the same. The chemical division experienced an upswing in profitability in 1966 and 1967, the last two complete years for which data are available. ^{1/} Employment indicators for Norwich's production of furazolidone show an increased output in 1965-67 among the small number of workers engaged in the manufacture of the drug. Net income increased in 1966 and 1967 as did the ratio of net income to sales, and net profits per pound of furazolidone sold to Hess & Clark, the major customer of Norwich. Sales of furazolidone increased in 1966 and 1967 and, although a decrease was shown in 1968 furazolidone sales, it was comparable to the trend in domestic consumption of the drug.

The Norwich Company in its complaint cited as evidence of injury the increasing expense of litigation necessary to protect its patent rights. These expenses have indeed multiplied over the past five years. In the most recent period for which data are available such expenses amounted to about one-tenth of one percent of net income of the company's domestic

^{1/} The partial 1968 figures that are available to the Commission are not appropriate for use due to a 3-month strike in the first quarter of the year.

operations and to about 1 percent of the net income of the chemical division.

Data available to the Commission indicate that between each of the periods 1960-63 and 1964-68 the average price of furazolidone sold by Norwich to Hess & Clark declined by less than 25 percent; over the same interval the average unit value of imports of furazolidone declined by about 50 percent. These data further indicate that Norwich's price to Hess & Clark for the past three or four years has been several times higher than average import values. The data thus suggest that the increasing price differential between domestic and foreign sources of supply has become sufficiently sizable to make the costs of importing, including the risk of smuggling penalties, worthwhile. Further, the difference between prices charged by Norwich in the domestic market and the average unit value of its exports has also expanded in recent years, making the re-import of Norwich exports a highly profitable operation. For the entire period 1961-September 1968 known imports of furazolidone amounted to less than 40 percent of exports. For the period 1964-68, however, known imports exceeded exports

(omitting the year 1967--an unusual year in the French market).

The conclusion is thus inescapable that through its pricing policies for furazolidone the Norwich Company is providing a substantial stimulus to imports. This conclusion further raises a question as to whether the Norwich Company, in its furazolidone pricing policies, is an 'efficiently and economically operated industry.'

Notwithstanding a resolution of the injury issue, I find that the Commission's use of its discretionary jurisdiction under section 337 ^{1/} is inappropriate at this time in view of the fact that the validity of the patent at issue is being litigated in a district court proceeding. Additionally, the patent misuse issue which was not fully exposed at the time of the issuance of the

^{1/} 19 U.S.C. 1337(b) & (c), Section 337 (b) states in part as follows: 'the Commission is thereby authorized to investigate any violation thereof on complaint . . .'. Thus, it is stated that the Commission is authorized, not directed; the statute does not command that the Commission shall hold investigations. The investigatory power is purely discretionary, and failure to exercise it results in no infringement of legal rights. Thus on a case by case basis the Commission must discern if the facts warrant the acceptance of a case or the suspension of it during its proceedings. In this instance, the Commission discovered during its investigation the existence of two actively litigated patent proceedings and the possibility of a Federal suit on the issue of patent misuse.

temporary exclusion order, has been found by the Department of Justice to be of sufficient concern to induce them to advocate against the issuance of any exclusion order that would grant market protection to the patented drug. ^{1/}

During this furazolidone investigation there have been pending court actions in Georgia and Alabama where the validity of this patent is in contention. This was not known at the time of the temporary exclusion order findings. The Commission could have ^{2/} and, in my view, should have suspended its full investigation and awaited a Court's decision on this issue of validity, even though it is not statutorily required to, as stated in the Von Clemm decision. ^{3/} Thus it is my view that, before Tariff Commission or especially Presidential action is taken, the issue of validity should be resolved.

Further, this agency has an obligation not to aid in enforcing a patent, even if valid, when the question of the misuse of

^{1/} See letter of April 15, 1969, to the Commission from Richard W. McLaren, Assistant Attorney General, Antitrust Division, Justice Department, contained in Appendix B.

^{2/} Under its Rules of Procedure, 19 C.F.R. 201.4b, the Commission may suspend any rule which is not a statutory requirement if there is good and sufficient reason therefor. See also footnote 1 supra.

^{3/} In re Von Clemm 229 F 2^d 441 (1955).

the patent is at issue. Subsequent to the Commission's determination with respect to a temporary exclusion order and full investigation, the Department of Justice informed the Commission of an investigation pending in its Antitrust Division and pertaining to a contract agreement between complainant, Norwich, and the Richardson-Merrell Company ^{1/} encompassing the patent product, furazolidone. In its last communication to the Commission in reference to this matter the Department of Justice related:

Our investigation has verified our initial impression that the restrictions in the agreement have been enforced to maintain the allocation of fields set forth therein. Moreover, counsel from Norwich and Richardson-Merrell do not appear to dispute such fact. On the basis of our investigation, it is our belief that the agreement between Norwich and Richardson-Merrell constitutes a violation of the Sherman Act and a misuse of Norwich's furazolidone patent. . . . (citations) The fact that the . . . practices constitute patent misuse which would normally preclude equitable relief against infringement in the district courts . . . (citations) supports denial of the similar relief sought under the Tariff Act. ^{2/}

While the Department of Justice is not instituting a suit due to the short length of time remaining in the agreement and the

^{1/} Richardson-Merrell, Inc. is the parent firm of Norwich's exclusive distributor of furazolidone, Hess & Clark Division.

^{2/} Supra footnote 1 on page 47.

possible nonrenewal of it, it is obvious that the Commission should not proceed with a recommendation for an exclusion order on a product whose patent is still tainted with possible misuse and possible antitrust violations.

Whether the domestic industry is "efficiently and economically operated"--a requisite for a finding of violation of section 337--is thus on this ground also thrown into question. The concept of efficient operation certainly does not encompass patent misuse as a buttress to successful competition. A complainant whose domestic market position rests in part upon unlawful restrictive trade practices can in no way be deemed to be efficiently and economically operated.

In the above discussion I have concluded that there is no "effect or tendency to destroy or substantially injure" the Norwich Pharmacal Company. Based on its own profit figures, as well as other economic indicators, neither the company as a whole nor the chemical division shows any evidence of injury in the meaning of the statute. Additionally, since both the issues of patent misuse and patent validity are currently pending in court litigation, any Presidential action excluding

imports of furazolidone would be inappropriate at this time.

Thus, I find that no exclusion order is warranted and I recommend against the issuance of such an order.

SUMMARY OF INFORMATION OBTAINED
IN THE INVESTIGATION 1/

Description and Uses

Furazolidone, a bright yellow crystalline substance, is the accepted nonproprietary (generic) name for 3-(5-nitro-2-furfurylideneamino)-2-oxazolidinone, 2/ one of a well-defined group of anti-infective drugs, the nitrofurans. As a class, the nitrofurans are effective against a broad range of pathogenic organisms. They leave little or no residue in the tissues and are bactericidal at low concentrations; unlike many of the antibiotics, they do not seem to induce the development of resistant strains of bacteria.

The Norwich Pharmacal Co. produces furazolidone in two grades: a practical grade for use in animal feeds and a medicinal grade for use in pharmaceutical products. Both grades are sufficiently pure to meet the standards of the National Formulary, but the medicinal grade is a higher quality product.

By far the most important use of furazolidone is in the prevention and treatment of certain bacterial and protozoan diseases in poultry. It is the drug of choice for the treatment of salmonella infections and chronic respiratory disease. For these uses no equally effective substitute is available, although neomycin and, to a lesser extent, some of the other antibiotics may be used. It is also effective in the treatment

1/ Much of the information obtained by the Commission in this investigation was received in confidence. Inasmuch as publication of such information would result in the disclosure of the operations of individual firms, it has not been included in this report.

2/ This is the Chemical Abstracts index name, for which the name used in Patent No. 2,742,462, N-(5-nitro-2-furfurylidene)-3-amino-2-oxazolidone, is synonymous.

of other poultry diseases, including blackhead, coccidiosis, and hexamitiasis; however, it is not the drug of choice to treat these diseases individually because cheaper and possibly better drugs are available in each instance. Furazolidone is widely used because of its broad spectrum of activity in cases where the exact nature of the disease has not been established and where a "shotgun" approach is therefore indicated. Its only effective competitors as a broad-spectrum anti-infective agent are the tetracycline antibiotics, chlortetracycline and oxytetracycline.

Medication for animals is generally administered mixed in with the feed. To treat an outbreak of disease in a poultry flock, furazolidone may be given at a dosage level of 100 to 200 grams per ton of feed, depending on the nature of the disease. To prevent an outbreak during a period of disturbing environmental changes, it may be given at a dosage level of 50 to 100 grams per ton. As a routine preventive measure and for the purpose of stimulating growth and increasing egg production, furazolidone may be given one week out of every four or continuously at a reduced rate of 7.5 to 25 grams per ton.

Furazolidone is also used for the prevention and treatment of intestinal diseases in swine, and, to a much lesser extent, for disease prevention in rabbits. In certain foreign countries it is used to treat calves and hatchery trout.

In comparison with its use as an animal feed additive, the total use of furazolidone in pharmaceutical preparations for human use is quite small. For the treatment of Trichomonas vaginalis infections it is used as a powder or in the form of suppositories. Furazolidone also is used,

either in tablets or suspended in a kaolin-pectin mixture, for the treatment of intestinal infections.

U.S. Producer

The Norwich Pharmacal Company, sole domestic producer of furazolidone, manufactures about 300 products, primarily chemotherapeutic compounds for human and veterinary medicinal uses. The company is especially well known for its pioneer efforts in the research and development of nitrofurans including furazolidone.

The company's chemical research laboratories and production facilities are located near Norwich, N. Y.; the general offices and pharmaceutical production facilities are in the town itself. Directly, or through subsidiaries, Norwich also operates plants in other cities. The chemical production facilities consist of a group of buildings which house the chemical reactors and other specialized equipment used for the production of aspirin, nitrofurfural diacetate, a basic intermediate used in the production of all nitrofurans, hydrazinoethanol, an intermediate used in the production of furazolidone, and the actual nitrofurans group of drugs including nitrofurazone and furazolidone. The structures are comparatively new (none older than 12 years) and the equipment quite modern. Most of the buildings have a steel framework containing walls of asbestos panels designed to blow outward in the event of explosion.

The company employs modern chemical technology and whenever possible takes advantage of the economy of continuous-flow processes. Aspirin, nitrofurfural diacetate, and hydrazinoethanol are produced by continuous-flow

processes. The nitrofurans, including furazolidone, are produced by batch process in standard chemical reactors which are readily adaptable to the manufacture of other products.

Domestic Production and Sales

Data on U.S. production and sales of furazolidone in 1960-68 were furnished to the Commission in confidence by Norwich. Production declined from 1960 to 1965, increased in 1966 and 1967, and then declined in 1968. The increased output in 1967 was accounted for principally by a planned increase in inventory in anticipation of a labor dispute, and an increase in exports to France, where the company was engaged in a price war with unlicensed producers. The decline in output in 1968 resulted primarily from a three-and-half month stoppage. The bulk of Norwich's production of furazolidone during the period under consideration was sold to Hess & Clark (its exclusive distributor). Comparatively small amounts were exported, and still smaller amounts were used by Norwich in the manufacture of other products. Practically all of the furazolidone production has consisted of the practical grade.

The Hess & Clark Company, a division of Richardson-Merrell, Inc., is Norwich's exclusive U.S. distributor of furazolidone for use as a poultry feed additive. All shipments from Norwich to Hess & Clark are in bulk. Hess & Clark manufactures and distributes nationally a line of animal feed premixes and other veterinary products. The firm's manufacturing facilities and animal research farm are located in Ashland, Ohio. Bulk furazolidone purchased from Norwich is incorporated in a number of premixes and other

animal health products. A large selling premix and a significant product in Hess & Clark's line is "nf-180 Concentrate", which consists of 11 percent furazolidone in degerminated corn meal with soybean oil and lecithin added. A major share of the furazolidone purchased by Hess & Clark from Norwich during the past 8 years has been sold as the active ingredient in "nf-180 Concentrate." The contract between the two companies provides for an exchange of scientific and technical information on furazolidone, although this exchange is now being phased out as the expiration date (December 31, 1969) of the contract draws near.

Norwich's annual sales of furazolidone to Hess & Clark increased from 1960 to 1961, declined in 1962-65, increased in 1966 and 1967, and declined again in 1968. The work stoppage at Norwich during the first quarter of 1968 did not affect its ability to meet Hess & Clark's requirements.

As noted above, most of the furazolidone purchased by Hess & Clark is incorporated in the product, nf-180 Concentrate. Sales figures of nf-180 Concentrate were furnished to the Commission in confidence. Such sales followed approximately the same trend as Norwich's sales of furazolidone to Hess & Clark.

With respect to allegations of possible tying arrangements between some products of Norwich and Hess & Clark, the Commission's investigation, through contacts with various purchasers of furazolidone products, revealed no evidence of such arrangements.

U.S. Imports

Origin, quantity, and type of imports

U.S. imports of furazolidone are not reported separately in official statistics. The imports, consisting principally of pure furazolidone crystals but including some 11-percent premix, have been entered under various "basket" categories, which include thousands of miscellaneous products. Many of the entries of furazolidone are not identified as such on the entry documents, so that analysis of the documents alone does not reveal the full extent of the imports. The Commission has explored all available sources of information and has compiled data for 1961-68 on all entries known to have consisted of furazolidone and mixtures thereof. These data, hereinafter referred to as "known" imports, are shown below:

<u>Year</u>	<u>Number of entries</u>	<u>Quantity of known imports</u> 1/ (pounds)	<u>Furazolidone content of known imports</u> (pounds)	<u>Equivalent of known imports in terms of 11% premix</u> (pounds)
1961---	18	11,126	11,126	101,145
1962---	10	6,969	6,969	63,355
1963---	3	1,399	1,399	12,718
1964---	16	20,664	20,272	184,291
1965---	9	8,651	8,099	73,627
1966---	33	16,061	10,747	97,700
1967---	19	53,184	18,585	168,955
1968 (Jan.- Aug.)	18	50,252	2/ 27,112	246,473
	<u>126</u>	<u>168,306</u>	<u>104,309</u>	<u>948,264</u>

1/ The data shown were compiled from the statistical copy of Consumption Entry Forms furnished by the Census Bureau, from invoice analysis cards in the possession of the Commission, from information in the investigative files furnished by the Bureau of Customs, from Forms 6531, copies of which are routinely furnished to the Commission by the Bureau of Customs, and from letters to the Norwich Pharmacal Co. by the Customs Districts concerned. The data shown for the years 1966-68 are based

footnote.--continued

principally on a thorough analysis of Consumption Entry Forms covering 11 different TSUSA numbers, but are nevertheless known to be incomplete. There are some entries of which Norwich was notified by Customs for which no record could be found, either because they were informal entries, or because they were classified in TSUSA numbers not analyzed, or because the entry papers were not in file, or because the description of the product was inaccurate or false. In many instances furazolidone has been invoiced as "other drugs, n.e.s.", "other animal feeds", "poultry feed additive", or as "nitrofurazone". There may be some such entries which, in the absence of information from other sources, the Commission has failed to recognize as furazolidone. There may also have been many small informal entries for which Consumption Entry Forms are not required. In addition, there has been some smuggling of furazolidone, the exact extent of which can never be known.

The data shown for the years prior to 1966 are based principally on routine invoice analyses conducted by the Commission's staff. They are believed to be less accurate and less complete than the data shown for later years, because fewer TSUSA (and USIDA) numbers were covered, because many of the invoice analysis cards fail to give any description of the product or fail to show net weight or the name of the importer, and because the information shown is sometimes inaccurate. The quantities of 8 entries made in 1961 and of all entries made in 1962 and 1963 were estimated, because the invoice analysis cards failed to show net weight.

In summary, the data shown for the years 1966-68 are as complete and accurate as the available information permits, but are nevertheless known to be incomplete. The data shown for the years 1961-65 are less complete and less accurate than those shown for 1966-68. The only accurate statement that can be made about imports of furazolidone in the years 1961-68 is that they amounted to at least the quantities shown; the actual quantities imported were almost certainly higher than those shown.

2/ Since issuance of the temporary exclusion order in August, 1968, the Commission has been notified by the Bureau of Customs of only one legal entry, consisting of 800 pounds of 11 percent premix, made in July, 1969. For information concerning recent smuggling activity, see Appendix B.

Most, if not all, of the imports are sold for use as a poultry feed additive, and are therefore in direct competition with the domestically produced furazolidone sold by Hess & Clark. There is no significant difference, so far as the Commission is aware, between imported bulk furazolidone and the practical grade of the domestic product. Hess & Clark reports, however, that tests conducted by the firm on samples of the imported 11-percent premix show that the furazolidone content is sometimes as low as 9 percent.

The 126 known importations of furazolidone, which have come principally from Italy, Canada, and Israel, have been entered through many customs districts of the United States. The port of entry, however, has not necessarily been the area in which distribution has been made; for example, truck shipments from Canada have crossed the border into Vermont destined for delivery in Atlanta. The Atlantic and Gulf Coast ports of entry have been used extensively; more recently New York and Chicago have been major ports of entry.

Numerous firms and individuals have entered, and withdrawn from, the business of importing furazolidone in recent years. The importers include poultry and feed producers, veterinarians, individual businessmen, corporations set up for the purpose of importing furazolidone, and others of undetermined description. No known importations of a consistent and substantial nature have been made by well-established importers in the United States. When the product is entered in the pure form, it is converted to an 11-percent premix by the importer or by his distributors. The premix, whether imported directly or prepared in the United States from the imported

furazolidone, is sold to feed manufacturers, integrated poultry and feed producers, distributors, and jobbers in competition with nf-180 Concentrate sold by Hess & Clark. The known imports during the period from January 1961 through August 1968 were equivalent to 948,000 pounds of 11-percent premix.

Excluding 1967 when exports to France were unusually large, exports of furazolidone since 1963 have somewhat exceeded known imports.

Effect of imports on domestic
furazolidone sales

Hess & Clark officials attribute the decline in their sales of nf-180 Concentrate principally to competition from lower-priced imported furazolidone. In addition to the direct loss of sales occasioned by furazolidone imports, they contend that they have been injured by loss of goodwill with resulting loss of sales to customers who have purchased the imported product and were subsequently placed under injunction, and by excessive turnover in their sales force resulting in loss of sales and the additional expense of recruiting and training new salesmen. ^{1/} They also cite the cost of special advertising campaigns and two 20-percent price reductions, one in 1963 and another in 1968, as efforts made to meet import competition.

Interviews with knowledgeable persons in the poultry, feed, and animal health fields, including a number of former users of imported furazolidone, confirm the existence of customer ill will generated by legal actions against infringers and by the knowledge that cheaper furazolidone is available abroad. One informant stated that "Norwich is gouging the U.S. poultry

^{1/} Hess & Clark relates that it is selective in recruiting and training its sales force because it emphasizes the salesman's responsibility to provide scientific and technical information to the customers.

industry" and that since Norwich brought action against him, he has used as little furazolidone as possible. Another informant understood that the Canadian premix which he had purchased contained furazolidone made in the United States by Norwich, and was indignant at what he took to be a fact, related by an importer, that Norwich was selling for one price in the United States while exporting to Canada and selling at a much lower price there. The informants were generally aware that furazolidone premix is available at a lower price in Canada, and several of them volunteered the opinion that the price for furazolidone in the United States is too high.

Consumption

Exact data on U.S. consumption of furazolidone are not available because of a lack of complete information on imports. Incomplete data on consumption, which consist of Norwich's sales to Hess & Clark and their domestic intra-company transfers, plus the furazolidone content of the known imports, indicates that the consumption declined irregularly in 1961-65, increased in 1966-67, and declined in 1968. 1/

According to many informants, there has been a relative decline in the demand for drugs by the poultry industry in the past few years because of better management, nutrition, breeding, sanitation procedures, and a reduction of one week in the average time required to raise broilers. This relative decline in demand, however, appears to have been offset by increased poultry production. Annual production of broilers, which is the class of

1/ The data available to the Commission cannot be published because publication would reveal information received in confidence.

poultry product which accounts for much of the demand for furazolidone, has increased steadily from 1961 to 1967 and was 32 percent larger in 1967 than in 1961. There have also been smaller increases in production of other classes of poultry.

In general, furazolidone continues to be widely used both for prevention and treatment of certain specific diseases and as a broad-spectrum anti-infective agent. For some specific uses, according to informants, it remains the drug of choice and has no effective substitute; for other specific uses it encounters competition from other drugs, some of which are cheaper, and possibly more effective. Among its competitors as a coccidiostat, for example, is Norwich's buquinolate, a relatively new product marketed as a premix under the trade name, Bonaid. As a broad-spectrum drug, its principal competitors are the tetracycline antibiotics. Some informants indicated that the competition between furazolidone and the tetracyclines has not changed appreciably in the last 8 years. A few informants stated, however, that since the price of these antibiotics dropped several years ago, the price differential is so great that they can save money by using antibiotics. These informants said that they could use or sell substantially greater quantities of furazolidone if the price were lower.

Norwich's Exports and Foreign Operations

Exports

All exports of domestically produced furazolidone have been made by the Norwich Pharmacal Company. Norwich exports both furazolidone crystals

and "nf-180" premix, containing furazolidone. Exports go to foreign subsidiaries, licensees, and wholesale distributors. The crystals are shipped chiefly to industrial countries and the premix is shipped chiefly to less-developed countries.

Business-confidential data indicate that Norwich's combined exports of furazolidone crystals, and of nf-180 (reported on the basis of furazolidone content), generally varied considerably from one year to the next in 1960-67. Data for the first 9 months of 1968 indicate that for the full year, exports were larger than in most years for which data are available, but were smaller than the peak year, 1967.

Generally, Norwich's exports have constituted a small percentage of its sales and intra-company transfers. Among other factors, the volume and composition of Norwich's exports have been influenced by the extent to which its foreign subsidiaries and licensees have become vertically integrated in production, by the subsidiaries' and licensees' degree of success in developing export business of their own, and by competition from unlicensed producers.

Foreign operations

Norwich's foreign subsidiaries and licensees, in some instances, purchase furazolidone crystals manufactured by the parent company or by another subsidiary or licensee and process them into animal feed premixes or ethical pharmaceutical products; in other instances, they make the finished products from furazolidone crystals of their own manufacture.

In addition to marketing furazolidone crystals through its foreign subsidiaries and licensees, Norwich also markets nf-180 Concentrate both through the subsidiaries and licensees and also through its wholesale distributors. These distributors, who are generally located in the less-developed countries, purchase nf-180 either from the parent company or from one of the foreign subsidiaries or licensees.

Norwich has furnished price data for 40 countries. They are the prices charged by Norwich, or by its foreign subsidiaries, licensees, or distributors in foreign countries. These data are business confidential except for the price of nf-180 made by a Canadian subsidiary, which is \$0.85 per pound. This price is low in comparison to other prices at which the premix is sold by Norwich or its licensees in other countries.

Employment

In all years for which the Commission has data, Norwich's domestic employment of production workers, engaged solely or primarily in the production of furazolidone or its intermediate products, was small.

During 1961-65, man-hours declined. In each of the years 1966-67, however, they were larger than in most previous years. In 1961-67, output per man-hour increased irregularly.

During most of 1968, Norwich's production experiences, and its employment practices, were not typical for that company, primarily due to a 15-week strike in the first half of 1968.

Prices

As previously indicated, most of the furazolidone produced by Norwich is sold to Hess & Clark under an exclusive sales-purchase contract between the two firms. Norwich's prices to Hess & Clark for furazolidone crystals, and Hess & Clark's prices for its nf-180 premixes containing furazolidone, have been submitted to the Commission in confidence. Hess & Clark's selling prices for nf-180 Concentrate have been and are higher than the prices U.S. importers charged for similar premixes.

Data are not available on the prices of imported bulk furazolidone. Invoice values (presumably representing foreign export values) of known imports ranged between \$6 and \$11 per pound in 1961-63; invoice values for entries in 1964-68 were substantially lower than in earlier years, generally ranging between \$2.50 and \$4 per pound, although some were higher than \$4 and a few were lower than \$2.50. Some of the invoice values have been found by Customs to be fraudulently understated. ^{1/}

With respect to the prices of imported furazolidone premix in the past years, information furnished by Hess & Clark, and that furnished by certain respondents, appear to be in harmony. Hess & Clark has reported that most imported 11-percent furazolidone premix, sold in competition with its nf-180 Concentrate, is priced between \$1.90 and \$2.85 per pound, and that the most common range is \$2.25-\$2.50 per pound. Price information given to the Commission's staff by some of the respondents, indicates that foreign-made furazolidone premix was sold to them at prices (inclusive of importers' markups and duty) that were from \$1.00 per pound to \$1.80 per pound lower than the prices of Hess & Clark's nf-180 Concentrate. Invoice

^{1/} See Appendix C which summarizes the violations investigated by the Bureau of Customs, particularly with reference to importers designated by the letters A, B, F, G, and H.

values of the imported furazolidone premix furnished to Customs are not reliable, as some of the entries have been found to be fraudulently under-valued. Small quantities of 11-percent premix, imported in 1965, were invoiced at \$2.80 and \$3.50 per pound (foreign export value). Larger quantities, imported during 1966-68, were invoiced at values generally between 60 cents and \$1.00.

Profit-and-Loss Experience of the Domestic Producer

Available public information discloses the profitability of the Norwich Pharmacal Company and subsidiaries to be as follows:

<u>Year</u>	<u>Net sales</u>	<u>Net income before income taxes</u>	<u>Ratio of net income before income taxes to net sales</u>
	<u>1,000 dollars</u>	<u>1,000 dollars</u>	<u>Percent</u>
1960-----	45,165	11,815	26.2
1961-----	48,226	12,784	26.5
1962-----	51,363	13,076	25.5
1963-----	53,025	13,300	25.1
1964-----	59,694	15,560	26.1
1965-----	63,724	16,873	26.5
1966-----	70,127	19,662	28.0
1967 <u>1</u> /-----	114,859	23,076	20.1
1968:			
Jan.-Oct. <u>1</u> /---	110,170	23,790	21.6

1/ Includes Texize Chemicals, Inc., acquired 11-30-67.

Confidential information submitted by the Norwich Pharmacal Company shows that the net sales of its Chemical Division were a small percentage of the overall net sales shown above. However, the bulk of the sales reported for the Chemical Division consists of furazolidone. The years

1966-1967 were the best two years of the Chemical Division's operation since 1961-1962.

Litigation Costs

Since 1963 complainant has actively sought out the alleged infringers of U.S. Patent 2,742,462. Where the alleged infringer has refused voluntarily to halt commerce in, or use of, imported furazolidone, complainant has filed an infringement suit in a district court. To date, 56 suits have been filed, for which the litigation and investigation expenses have been considerably higher than the recoveries of \$27,550 for the approximately six-year period. The expenses include fees for outside counsel, private investigators, Bureau of Customs patent surveys, and travel expenses for the Norwich patent counsel in investigating and making court appearances. Recoveries are payments received from defendants as partial reimbursement for litigation expenses.

LIST OF ALL SUITS FILED FOR INFRINGEMENT OF
UNITED STATES PATENT NO. 2,742,462

<u>Date Filed</u>	<u>Parties</u>	<u>Court</u>	<u>Doc. No.</u>
(1) Sept. 5, 1963	The Norwich Pharmacal Company vs. Portex, Inc. E. Holzer, Inc. Erich Holzer	D.C., S.D. N.Y.	63/2632
	(Consent judgment; defendants enjoined Feb. 16, 1965)		
(2) Mar. 3, 1965	The Norwich Pharmacal Company vs. Joseph O'Connor John Gearing Bio-Chemo Veterinary Supply Co.	D.C., N.D. Ga. (Atlanta)	9351
	(Consent judgment; Temporary Restraining Order granted by Judge Hooper on Mar. 3 and extended by consent until defendants enjoined Mar. 17, 1965)		
(3) Mar. 3, 1965	The Norwich Pharmacal Company vs. Fred Ellis Woodruff Freda Parks Woodruff American Laboratories a/k/a Amerlabs Anannis, Inc. The Southern Cross Trading Co. Northwest Chemicals, S.A. Chemical Solvents & Research Corp.	D.C., N.D. Ga. (Atlanta)	9352
	(Consent judgment; defendants enjoined Mar. 17, 1965)		
(4) Mar. 20, 1965	The Norwich Pharmacal Company vs. Tyson's Foods, Inc. Tyson's Feeds, Inc.	D.C., W.D. Ark. (Fort Smith)	546
	(Consent Judgment; defendants enjoined July 29, 1965)		
(5) Mar. 20, 1965	The Norwich Pharmacal Company vs. Service and Research, Inc. Kenneth Harmon	D.C., W.D. Ark. (Fort Smith)	547
	(Consent judgment; defendants enjoined July 29, 1965)		
(6) Apr. 5, 1965	The Norwich Pharmacal Company vs. Glysson Lawrence Mitchell Pete James Brown L-M Company, Inc. G. L. Enterprises, Inc. Welland, Inc. Northeast Animal Hospital	D.C., N.D. Ga. (Atlanta)	CA9396
	(Motion by defendants for Summary Judgment asserting patent invalidity denied by Judge Morgan on Jan. 10, 1966; Consent judgment; defendants enjoined May 24, 1966)		

<u>Date Filed</u>	<u>Parties</u>	<u>Court</u>	<u>Doc. No.</u>
(7) June 3, 1965	The Norwich Pharmacal Company vs. V.C. Lovell	D.C., N.D. Ga. (Gainesville)	1070
	(Consent judgment; defendant enjoined August 25, 1965)		
(8) June 7, 1965	The Norwich Pharmacal Company vs. J-M Poultry Packing Co., Inc. Farmers Feed & Supply	D.C., W.D. La. (Shreveport)	11,156-S
	(Consent judgment; defendant enjoined Oct. 27, 1965)		
(9) June 8, 1965	The Norwich Pharmacal Company vs. McGehee Feed Store, Inc. Lucius D. McGehee	D.C., W.D. La. (Shreveport)	11,158
	(Case initiated prior to any use by defendant and withdrawn without prejudice upon surrender of substantial quantities of infringing material Oct. 17, 1966)		
(10) June 21, 1965	The Norwich Pharmacal Company vs. Dixie Grain Co., Inc.	D.C., N.D. Ala. (Birmingham)	65-422
	(Consent judgment; defendants enjoined Sept. 27, 1965)		
(11) Aug. 23, 1965	The Norwich Pharmacal Company vs. Tri-State Sales John H. Blackwell	D.C., N.D. Miss. (Aberdeen)	EC 6563
	(Temporary Restraining Order granted by Judge Clayton on Aug. 23 and extended indefinitely by court order on implied consent until final judgment; default judgment; defendants enjoined, material destroyed with damages and attorneys' fees awarded Apr. 15, 1966)		
(12) Sept. 30, 1965	The Norwich Pharmacal Company vs. E. L. Turner	D.C., N.D. Ala. (Birmingham)	65-628
	(Consent judgment; defendant enjoined June 3, 1966)		
(13) Oct 1, 1965	The Norwich Pharmacal Company vs. Morris S. Gatewood, Sr.	D.C., E.D. Tex. (Tyler)	4498
	(Motion by defendant for Summary Judgment asserting patent invalidity denied by Judge Sheehy on Nov. 17, 1965; consent judgment; defendant enjoined June 1966)		

<u>Date Filed</u>	<u>Parties</u>	<u>Court</u>	<u>Doc. No.</u>
(14) Dec. 17, 1965	The Norwich Pharmacal Company vs. Leland C. Winter	D.C., D. Utah (Salt Lake City)	C251-65
	(Consent judgment; defendant enjoined Mar. 25, 1966)		
(15) Mar. 28, 1966	The Norwich Pharmacal Company vs. J. F. McIntosh Universal Agencies, Ltd.	D.C., W.D. Wash.	6711
	(Default judgment; defendants enjoined April 26, 1968)		
(16) May 6, 1966	The Norwich Pharmacal Company vs. Julius Rytman T & T Poultry Company Rytman Feed Company Julius Egg Farms, Inc.	D.C., D. Conn. (Hartford)	11,423
	(Order to Show Cause re Preliminary Injunction entered May 6; Preliminary Injunction entered at hearing thereon May 11 continuing until final judgment; consent judgment; defendant enjoined July 22, 1966)		
(17) Aug. 20, 1966	The Norwich Pharmacal Company vs. Patrick D. Ryan Buffalo Merchandise Warehouse, Inc.	D.C., W.D. N.Y. (Buffalo)	CA1966-71
	(Ryan service quashed, then re-served; Buffalo Warehouse motion for summary judgment submitted but agreed to abide by Temporary Restraining Order in case #27 below; consent judgment enjoining defendants entered October 23, 1967)		
(18) Oct. 6, 1966	The Norwich Pharmacal Company vs. Rycam Limited	D.C., W.D. N.Y. (Buffalo)	CA1966-124
	(Motion to quash service granted, then re-served, preliminary-injunction motion submitted but agreed to abide by Temporary Restraining Order entered in case #27 below; consent judgment enjoining defendants entered Oct. 23, 1967)		
(19) Nov. 20, 1966	The Norwich Pharmacal Company vs. Herbert W. Beaverstone	D.C., W.D. Wash. (Seattle)	6969
	(Default judgment; defendant enjoined April 26, 1968)		
(20) Dec. 6, 1966	The Norwich Pharmacal Company vs. Julius Goldman's Egg City	D.C., C.D. Cal. (Los Angeles)	66-1947-F
	(Temporary restraining order entered Dec. 20, 1966; preliminary injunction entered at hearing thereon Jan. 4, 1967; consent judgment enjoining defendants entered Mar. 7, 1967)		

<u>Date Filed</u>	<u>Parties</u>	<u>Court</u>	<u>Doc. No.</u>
(21) Dec. 6, 1966	The Norwich Pharmacal Company vs. Ryckebosch & Sons	D.C., C.D. Cal. (Los Angeles)	166-1948-F
(22) Dec. 13, 1966	The Norwich Pharmacal Company vs. Hayre's Egg Farms (Temporary restraining order entered Dec. 13, 1966, and extended by agreement; consent judgment enjoining defendant entered May 1, 1967)	D.C., E. D. Cal. (Fresno)	F-66-30 Civ.
(23) Dec. 22, 1966	The Norwich Pharmacal Company vs. Franklin R. McCants McCants Poultry Farms (Consent judgment; defendant enjoined Apr. 17, 1967)	D.C., M.D. Ga. (Columbus)	1213
(24) Jan. 16, 1967	The Norwich Pharmacal Company vs. Veterinary Service, Inc. Willis D. Woodward Donald W. Rosenberg Archie E. Kline Veterinary Service & Supply Co. (Consent judgment; defendants enjoined Apr. 18, 1967)	D.C., E.D. Cal. (San Francisco)	S-176
(25) Feb. 17, 1967	The Norwich Pharmacal Company vs. Barlas Feed Company (Consent judgment; defendant enjoined April 18, 1967)	D.C., E.D. Cal. (San Francisco)	46486
(26) Feb. 22, 1967	The Norwich Pharmacal Company vs. Jay W. Chilton (Norwich's motion for summary judgment that patent is valid and infringed granted on July 31, 1967 and judgment entered enjoining the defendant July 31, 1967)	D.C., C. D. Cal. (Los Angeles)	67-255-F
(27) Feb. 27, 1967	The Norwich Pharmacal Company vs. P.D. Feeds, Inc. (Temporary Restraining Order entered Feb. 27, 1967 and continued in effect by consent until consent judgment enjoining defendants entered October 23, 1967)	D.C., W.D., N.Y. (Buffalo)	1967-82
(28) Mar. 30, 1967	The Norwich Pharmacal Company vs. Peterson-Biddick Company (Consent judgment; defendant enjoined Apr. 14, 1967)	D.C., D. Minn. (Minneapolis)	4-67 CIV 83

<u>Date Filed</u>	<u>Parties</u>	<u>Court</u>	<u>Doc. No.</u>
(29) Mar. 31, 1967	The Norwich Pharmacal Company vs. Kenneth Friedrich Alvin Friedrich Robert D. Friedrich, Individuals d/b/a Union Mills	D.C., D. Oregon (Portland)	67-165
	(Consent judgment; defendant enjoined Sept. 26, 1967)		
(30) Mar. 31, 1967	The Norwich Pharmacal Company vs. William A. Hansen Kenneth Hansen, Individuals d/b/a Vetecon, Inc.	D.C., D. Oregon (Portland)	67-164
	(Consent judgment; defendant enjoined Aug. 18, 1967)		
(31) Apr. 25, 1967	The Norwich Pharmacal Company vs. Samuel Lipman & Son (Inc.)	D.C., D. Maine (Portland)	9-170
	(Consent judgment; defendant enjoined June 2, 1967)		
(32) Apr. 25, 1967	The Norwich Pharmacal Company vs. Maine Milling and Manufacturing Company, (Inc.)	D.C., D. Maine (Portland)	9-171
	(Consent judgment; defendant enjoined June 26, 1967)		
(33) May 1, 1967	The Norwich Pharmacal Company vs. P. D. Feeds, Ltd.	D.C., W.D. N.Y. (Buffalo)	1967-171
	(Consent judgment enjoining defendant entered Oct. 23, 1967)		
(34) June 22, 1967	The Norwich Pharmacal Company vs. Pelmyra Trading Company John J. Dunn Terence H. Gonsalves	D.C., N.D. N.Y. (Utica)	67-CV-216
	(Consent judgment enjoining defendants entered June 9, 1969)		
(35) July 18, 1967	The Norwich Pharmacal Company vs. International Brokers, Inc.	D.C., N.D. Ga. (Atlanta)	11066
	(Preliminary injunction granted and entered Nov. 28, 1967, court's opinion published 159 USPO 417, motion to stay preliminary injunction and to post supersedeas bond during pendency of appeal denied. Dec. 29, 1967; consent judgment, defendant enjoined Oct. 18, 1968)		

<u>Date Filed</u>	<u>Parties</u>	<u>Court</u>	<u>Doc. No.</u>
(36) Aug. 9, 1967	The Norwich Pharmacal Company vs. Haskell E. Willingham Earle-Chesterfield Mill Company	D.C., W.D. N. Car. (Asheville)	2267
	(Consent judgment; defendant enjoined January 31, 1968)		
(37) Aug. 9, 1967	The Norwich Pharmacal Company vs. Banner Roller Mills, Inc.	D.C., W.D. N.Car. (Asheville)	2268
	(Consent judgment defendant enjoined Oct. 16, 1967)		
(38) Aug. 9, 1967	The Norwich Pharmacal Company vs. Threadgills Veterinarian Supply, Inc.	D.C., W.D. N.Car. (Asheville)	2269
	(Consent judgment; defendant enjoined Oct. 6, 1967)		
(39) Aug. 9, 1967	The Norwich Pharmacal Company vs. Walley Milling Co., Inc.	D.C., N.D. Ala. (Birmingham)	CA 67-454
	(Consent judgment; defendant enjoined Oct. 30, 1968)		
(40) Aug. 9, 1967	The Norwich Pharmacal Company vs. Goldsboro Milling Company, Inc.	D.C., E.D. N.Car. (Raleigh)	1042
	(Consent judgment; defendant enjoined Oct. 23, 1967)		
(41) Aug. 15, 1967	The Norwich Pharmacal Company vs. Aycock Milling Company, Inc.	D.C., E.D. N.Car. (Wilmington)	1226
	(Consent judgment; defendant enjoined Oct. 27, 1967)		
(42) Aug. 18, 1967	The Norwich Pharmacal Company vs. Stone Bros., Inc.	D.C., E.D. N.Car. (Fayetteville)	CA 825
	(Default judgment: defendant enjoined Feb. 8, 1968)		
(43) Sept. 11, 1967	The Norwich Pharmacal Company vs. A.P.A., Inc., & P.V.U., Inc.	D.C., N.D. N.Y. (Utica)	67-CV-294
	(Pending-motion to dismiss for lack of personal jurisdiction argued Nov. 6, 1967 and granted Aug. 13, 1968 - appeal filed)		
(44) Oct. 17, 1967	The Norwich Pharmacal Company vs. C. L. Jones, Inc.	D.C., N.D. Ala. (Birmingham)	CA 67-549
	(Pending preliminary injunction; enjoining defendants entered April 12, 1968)		

<u>Date Filed</u>	<u>Parties</u>	<u>Court</u>	<u>Doc. No.</u>
(45) Oct. 19, 1967	The Norwich Pharmacal Company vs. Fors Hatchery & Breeding Farms, Inc. and Ernest W. Fors	D.C., W.D. Wash. (Seattle)	3643
	(Consent Judgment; defendants enjoined Dec. 29, 1967)		
(46) Nov. 30, 1967	The Norwich Pharmacal Company vs. South Georgia Broilers, Inc.	D.C., So. D. Ga. (Waycross)	633
	(Default Judgment - defendant enjoined Feb. 1, 1968)		
(47) Jan 22, 1968	The Norwich Pharmacal Company vs. Luther Martin d/b/a Lu-Mar Laboratories	D.C., W.D. Ark. (Fort Smith)	7720
	(Consent judgment enjoining defendants entered may 24, 1968)		
(48) Jan 26, 1968	The Norwich Pharmacal Company vs. Veterinary and Poultry Supply Co., Inc.	D.C., No.D. Ind. (South Bend)	4144
	(Consent Judgment enjoining defendant entered February 28, 1968)		
(49) Feb. 16, 1968	Norwich Pharmacal Company vs. Upchruch Milling and Storage Co.	D.C., D. N. Car. (Rockingham)	C-20-R-68
	(Consent judgment enjoining defendants entered October 24, 1968)		
(50) Feb. 19, 1968	The Norwich Pharmacal Company vs. Henderson Poultry Supply	D.C., So.D. Miss. (Jacksonville)	4259
	(Consent judgment enjoining defendants entered May 22, 1968)		
(51) May 27, 1968	The Norwich Pharmacal Company vs. Veterinary Corporation of America Veterinary Corporation of Georgia	D.C. M.D. Ga. (Athens)	CA692
	(Pending preliminary injunction enjoining defendants entered October 15, 1968 - Court's opinion published 159 USPQ 758)		
(52) May 28, 1968	The Norwich Pharmacal Company vs. E & W Distributing Co.	D.C.C.D. Cal. (Los Angeles)	68-904 WPa
	(Consent judgment enjoining defendant entered June 25, 1968)		

<u>Date Filed</u>	<u>Parties</u>	<u>Court</u>	<u>Doc. No.</u>
(53) September 1968	The Norwich Pharmacal Company vs. Robert M. Peterson	D.C. D. Minn. (Minneapolis)	CA 4-68-297
	(Consent judgment enjoining defendants entered April 17, 1969)		
(54) September 1968	The Norwich Pharmacal Company vs. Richard Hanson	D.C. D. Minn. (Minneapolis)	CA 4-68-296
	(Consent Judgment enjoining defendants entered April 17, 1969)		
(55) October 10, 1968	The Norwich Pharmacal Company vs. Harrington Industries, Inc.	D.C. S.D. Fla. (Miami)	681171-CIV-CF
	(Consent Judgment enjoining defendant entered April 21, 1969)		
(56) June 24, 1969	The Norwich Pharmacal Company vs. The Joe N. Pless Company	D.C., W.D. Ark. (Fort Smith)	FS-69-C-72
	(Consent Judgment enjoining defendant entered July 31, 1969)		

75-76

APPENDIX B

LETTERS FROM DEPARTMENT OF JUSTICE

Department of Justice
Washington, D.C. 20530

RECEIVED

SEP 30 1968

OFFICE OF THE SECRETARY

Mr. Donn N. Bent
Secretary
United States Tariff Commission
Washington, D. C. 20436

SEP 30 1968

Re: Docket No. 337-21

Dear Mr. Bent:

It has come to the attention of the Department of Justice that The Norwich Pharmacal Company, which has petitioned the Commission for an order under Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), excluding the importation of furazolidone to the United States, may be engaged in antitrust violations in connection with the licensing and distribution of that product in the domestic market. Since this may have a bearing on the propriety of granting the proposed exclusion order, and in order that the Commission may be fully apprised of the facts relevant to making an informed determination in the matter, the Department of Justice wishes to bring to the Commission's attention the following information.

We are lodging with the Commission a copy of an agreement entered into more than ten years ago by Norwich and the predecessor of Richardson-Merrell Inc. As we interpret this agreement, its effect is to divide markets in the sale and distribution of furazolidone and related nitrofurans products between the two firms, with the "proprietary veterinary preparations" field (feed supplements and other nonprescription animal health products) allocated to Richardson-Merrell, and the prescription veterinary field and human field allocated to Norwich.

Under the agreement Norwich sells furazolidone to Richardson-Merrell for resale only in "proprietary veterinary preparations," and Richardson-Merrell may not otherwise resell or dispose of the product. The agreement further provides that Norwich will give Richardson-Merrell the first option to sell as a "proprietary veterinary preparation" any new nitro-furan product that Norwich develops. If Richardson-Merrell rejects the new product for the reason it is "evaluated as having about the same therapeutic or nutritional effect on poultry and animals" as a nitro-furan product already marketed by Richardson-Merrell, then Norwich must not market the new product itself nor sell it to a competitor of Richardson-Merrell. If Richardson-Merrell discovers any new improvements, it is to grant Norwich a royalty-free, exclusive license outside the field of "proprietary veterinary preparations," and Richardson-Merrell will retain exclusive rights within that field.

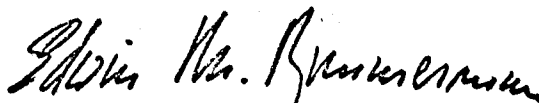
The foregoing agreement raises serious questions under the antitrust laws, for it appears to effectuate a division of markets between two substantial factors in the domestic pharmaceutical products industry. A similar practice has been recently challenged by the Department of Justice. United States v. Farbenfabriken Bayer A.G., et al., Civ. No. 586-68, D.D.C. Related restrictions have been recently challenged in United States v. Glaxo Group Ltd., et al., Civ. No. 558-68, D.D.C. See, also, Hartford-Empire Co. v. United States, 323 U.S. 386 (1945); United States v. Arnold, Schwinn & Co., 388 U.S. 365 (1967). We are, therefore, investigating the arrangement between Norwich and Richardson-Merrell. The Department is diligently pursuing this matter and hopes to complete its investigation in the near future, and to determine what enforcement action, if any, would be appropriate.

The matter under investigation by the Department would appear to be relevant to the Commission's disposition of this proceeding. If the arrangements between Norwich and Richardson-Merrell are indeed illegal, such misuse of patent rights could disable the patentee from enforcing its patent should that be required, as it may well be, to purge the market of the adverse economic effects of the misuse. B.B. Chemical Company v. Ellis, 314 U.S. 495, 498 (1942); Morton Salt Co. v. Suppiger Co., 314 U.S. 488, 493, 494 (1942). Under those circumstances, it would be anomalous to permit a patentee to invoke Section 337 to protect its market position when it would not be permitted to enforce its patent in the courts against domestic or foreign infringers.

Furthermore, such illegality, if found, would appear properly to be considered under Section 337. The statute is directed at "unfair methods of competition and unfair acts" which substantially injure an "efficiently and economically operated" domestic industry. In our view, this standard would not support an exclusion order granted in favor of an applicant engaged in unlawfully restrictive trade practices.

We believe that the Commission should take the foregoing considerations into account in this proceeding. The Department will advise the Commission of the results of its investigation, with adequate notice to the applicant companies, and will cooperate with the Commission in any procedures which it deems appropriate.

Sincerely yours,



EDWIN M. ZIMMERMAN
Assistant Attorney General
Antitrust Division

ASSISTANT ATTORNEY GENERAL
ANTITRUST DIVISION

DO NOT

Department of Justice
Washington, D.C. 20530

APR 15 1969

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APR 16 1969

Mr. Donn N. Bent
Secretary
United States Tariff Commission
Washington, D. C. 20436

OFFICE OF THE SECRETARY

Re: Docket No. 337-21

Copies to:
Comm. (6)
see (5)
McDonald
Chemicals

Dear Mr. Bent:

Reference is made to the September 30, 1968 letter from my predecessor, Edwin M. Zimmerman, indicating that the agreement between Norwich Pharmacal Co. ("Norwich") and Richardson-Merrill, Inc. ("RMI") appeared to raise antitrust and patent misuse questions.

As Mr. Zimmerman stated, Norwich sells furazolidone to RMI for resale only in "proprietary veterinary preparations," and Richardson-Merrill may not otherwise resell or dispose of the product. Norwich reserves for itself the human and the prescription veterinary fields. Our investigation has verified our initial impression that the restrictions in the agreement have been enforced to maintain the allocation of fields set forth therein. Moreover, counsel from Norwich and RMI do not appear to dispute such fact. On the basis of our investigation, it is our belief that the agreement between Norwich and RMI constitutes a violation of the Sherman Act and a misuse of Norwich's furazolidone patent.

It seems clear that sale of a patented product exhausts the statutory monopoly and that restrictions may not be imposed upon the fields in which the products may be used or resold. Hensley Equipment Co. v. Esco Corp., 383 F. 2d 252 (C.A. 5); Baldwin-Lima-Hamilton Corp. v. Tatnall Measuring Systems Co., 196 F. Supp. 1 (E.D. Pa.), affirmed, 268 F. 2d 395 (C.A. 3), certiorari denied, 361 U.S. 894; United States v. Consolidated Car-Heating Co., 1950 Trade Cases ¶62,658 (S.D.N.Y.); see Adams v. Burke, 17 Wall. 453, 456.

However, despite this conclusion, the Department does not presently intend to seek an injunction against Norwich or RMI, since the present agreement, by its terms, will expire in approximately nine months--considerably less time than required to prepare and try an antitrust case in a district court, not to mention any appellate proceedings. Moreover, Norwich has represented to us that the likelihood of its renewing the agreement is extremely remote. If the agreement is renewed with the same restriction, the Department's present intention is to institute such action as may be necessary to eliminate such restrictive practices.

As indicated in our previous letter of September 30, 1968, the apparent existence of an antitrust violation in Norwich's license agreement is pertinent to the Commission's determination in the pending proceeding. Section 337 of the Tariff Act is directed at "unfair methods of competition and unfair acts" which substantially injure an "efficiently and economically operated" domestic industry. We suggest that this standard should not support an exclusionary order in favor of an applicant whose domestic market position rested in part upon unlawful restrictive trade practices. In addition, the fact that the latter practices constitute patent misuse which would normally preclude equitable relief against infringement in the district courts (Morton Salt Co. v. G. S. Suppiger, 314 U.S. 488, 492-494; Hensley Equip. Co. v. Esco Corp., 383 F. 2d, at 260-266 (C.A. 5)), supports denial of the similar relief sought under the Tariff Act.

Sincerely yours,

Richard W. McLaren
 RICHARD W. McLAREN
 Assistant Attorney General
 Antitrust Division

cc: Philip T. Seymour, Esq.
 Hancock, Ryan, Shove & Hust
 One Mony Plaza
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APPENDIX C

INVESTIGATIONS BY THE BUREAU OF CUSTOMS
WITH RESPECT TO THE IMPORTATION OF FURAZOLIDONE

The records of the Bureau of Customs reveal considerable investigative activity by customs agents throughout the United States to cope with widespread practices involving violations of the customs laws by many of the persons importing furazolidone. These practices have included false invoicing 1/--manifested by under-valuation, false consignees, false names and addresses, and false descriptions of the commodity--and, in addition, mislabeling of the imported product, 2/ smuggling, 3/ false statements to customs officers, 4/ and conspiracies to import fraudulently. 5/ In some instances, the shipment of the imported drug has been seized and, in one instance, the vehicle used in smuggling the drug was also seized. Penalties have been assessed and a number of cases of violation closed; certain of the more recent cases are still pending.

Information pertaining to the Customs investigations are summarized below. Certain information regarded by the Bureau of Customs as being of a confidential nature has been omitted at the request of that agency.

Seven entries from Israel made by Importer A were invoiced as nitrofurazone but were subsequently identified by the Customs Laboratory as

1/ 19 U.S.C. 1481 (1964) (contents of invoice); 19 U.S.C. 1483 (1964) (consignee as owner); 19 U.S.C. 1484 (1964) (entry of merchandise); 19 U.S.C. 1485 (1964) (truth in declaration); 19 U.S.C. 1592 (1964) (penalty against goods, and attempt to enter goods falsely).

2/ 18 U.S.C. 542 (1964). Criminal Statute dealing with "Entry of goods by means of false statements."

3/ 18 U.S.C. 545 (1964). Criminal Statute dealing with smuggling.

4/ 18 U.S.C. 1001 (1964). Criminal Statute dealing with "Statements or entries generally."

5/ 18 U.S.C. 542 (1964); Prosser on Torts 260 (3rd ed. 1964).

furazolidone. Penalties or liquidated damages have been assessed against Importer A, his customs broker, and others. Importer A is now a dissolved firm and the case has been closed for technical legal reasons.

Two entries from Italy by Importer B were invoiced as nitrofurazone but were subsequently found by the Customs Laboratory to be a mixture consisting of 50 percent furazolidone and 50 percent nitrofurazone. Importer B, whose only known address was a post office box, stated in writing in response to a written inquiry from Customs that he was testing nitrofurazone for possible use in areas other than the drug, or veterinary field. Attempts by Customs and by Norwich to locate and identify Importer B have been unsuccessful. Further investigation by Customs disclosed that while the Italian shipper had prepared true and correct invoices for use in the exportation of the merchandise from Italy, the firm also had prepared and mailed separately to Importer B, at his request, a set of invoices falsely identifying the merchandise as nitrofurazone valued at \$2.50 per kilogram instead of 50 percent furazolidone and 50 percent nitrofurazone valued at \$5.00 per kilogram. The false invoices were found through customs investigation to be used in making entry into the United States for the express purpose of evading the Customs survey of imports infringing Norwich's furazolidone patent. A third shipment of this material was seized by Customs before entry was made. This case has not yet been resolved.

Importer C had ordered a shipment of 11-percent furazolidone premix from Canada but was placed under injunction by Norwich before it could make entry. A telegram purporting to come from the Canadian supplier, but

actually originating in a U.S. city, instructed the customhouse broker to make entry in the name of Importer D instead of Importer C, and the entry was so made. Investigation disclosed that Importer D has not been in business for several years and that the Internal Revenue Service 9-digit employment identification number shown in the entry papers, apart from having one zero too many, is the number assigned to Importer E who was a customer of Importer C and was being sued by Norwich at the time this entry was made. When the shipment subsequently was released from Customs, it was broken up into five smaller shipments to five different consignees; the name of the shipper was shown as Importer D, but the trucker was furnished a telephone number which proved to be that of Importer E, and the consignees were billed by and made payment to Importer E. No basis was found for assessing customs penalties or taking other action against these importers.

A shipment of furazolidone from Israel to Importer F was seized by Customs for false invoicing. The entry papers showed Importer F as the purchaser, while in actuality Importer F had purchased the material for Importer G, who had previously ordered it from the Israeli manufacturer through Importer A. Certain shipments invoiced to importer G were seized and forfeited for false description of the merchandise.

Importer H, a Canadian national operating through two different corporations, offered by direct mail solicitation to sell 11-percent furazolidone premix in lots of 1,000 pounds or more at \$2.60 per pound with all freight charges prepaid. His literature promoted furazolidone for use in cattle--

a use which has not been approved by the Food and Drug Administration-- and stated that he could make delivery from warehouse facilities in principal centers across the country. Through a non-existent company he purchased furazolidone premix from the Canadian manufacturer for \$0.80 per pound and, after receiving orders from U.S. purchasers at prices ranging from \$2.00 to \$2.95 per pound, he exported it to one or the other of his two corporations in care of a public warehouse in a U.S. city located near the Canadian border. The value of this merchandise was shown as \$0.85 per pound on all entries except two, on which the value was shown as \$1.25 per pound. On orders from Importer H, the warehouse operator then shipped the merchandise to the U.S. purchaser C.O.D. One shipment by Importer H was seized by Customs because of falsification of the name and address of the purchaser or consignee and failure to show the true selling price. Penalties or liquidated damages were subsequently assessed against Importer H, and this case is still pending.

Importer J and another individual, both of whom have felony records in Canada, circulated throughout an entire region of the United States personally soliciting orders for 11-percent furazolidone premix of Canadian origin. Subsequent orders were taken by telephone. Importer J and his partner, using late model cars, made delivery in person to customers located near the Canadian border and to an auto freight forwarder on the U.S. side of the border for shipment to customers located some distance away. Customs officials indicate that they have sales invoices obtained from Importer J's customers proving that he and his partner sold more than 30,000 pounds of furazolidone premix in excess of any possible legal entries.

On one occasion the unidentified driver of a car registered in the name of Importer J was observed removing 50-pound bags from the trunk and from under the hood of his car and delivering them to a freight forwarder on consignment to a firm located in another State. After reaching its destination, this shipment was sampled by FDA and determined to consist of 11-percent furazolidone in corn meal. At the time of the FDA sampling, the bags were unmarked as to contents or origin; but at the time of a later inspection by Customs agents, "glue-on" labels had been attached by the consignee identifying the contents as furazolidone of Canadian origin. The consignee stated that the shipment had been ordered by phone from a company in Canada and that the labels had been mailed separately by the same source. The shipment was seized pending the outcome of the investigation.

On a subsequent occasion border points were alerted to catch Importer J in the act of smuggling furazolidone premix across the border from Canada, but he eluded the border lookout by using a different car which he had purchased a few days earlier. He was later taken into custody and his car and its contents were seized at the point of delivery. He admitted under interrogation that he had just crossed the border from Canada but claimed that he had picked up the furazolidone at a bus depot on the U.S. side of the border. (This claim was subsequently disproved.) He stated that his partner was associated with Importer H and that the merchandise in his possession had been imported by Importer H at another point of entry. Importer J was released for legal reasons at the time, and has not been heard from since.

During the month of July, 1969, Customs seized three shipments of smuggled furazolidone, amounting to 14 tons of 11 percent premix, and arrested a total of six persons (three Americans and three Canadians). The seized materials entered one of the North Central States from Canada via back roads, completely by-passing Customs. Further investigation disclosed that furazolidone premix smuggled from Canada has been sold extensively in some of the South Central States, where 224 50-pound bags of 11 percent premix were seized by Customs in the latter part of July, making a total of 39,200 pounds of 11 percent premix seized during the month. The purchasers of the seized material stated that they had been told that they were buying premix which had been legally imported by posting bond, and they identified the sellers as Importer E, already mentioned, and Importer K, one of three Americans arrested for smuggling.

Other customs cases against various other importers and brokers have either been closed with forfeiture of the goods and penalties assessed, or are pending, or have been closed for lack of evidence.