In the Matter of

DOXYCYCLINE

Investigation No. 337-TA-3

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United States International Trade Commission / Washington, D.C. 20436

UNITED STATES INTERNATIONAL TRADE COMMISSION

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the matter of DOXYCYCLINE	Investigation No. 337-TA-3

COMMISSION DETERMINATION AND ORDER AND COMMISSIONERS' OPINIONS IN SUPPORT OF COMMISSION ACTION

The United States International Trade Commission conducted an investigation under the authority of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) ("section 337") of unfair methods of competition and unfair acts in the unauthorized importation into the United States of doxycycline covered by the claims of United States Letters Patents No. 3,200,149, or in its 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. On March 27, 1979, the Commission determined that there is a violation of section 337 and ordered that doxycycline falling within Claim 10 of United States Letters Patent No. 3,200,149 be excluded from entry into the United States for the term of that patent (until August 10, 1982) unless the importation is licensed by the patent owner.

The purpose of this Commission determination and order, and Commissioners' opinions is to provide for the final disposition of the Commission's doxycycline investigation. The Commission's determination and

order immediately follows and is itself followed by the Commissioners' opinions in support of Commission action.

Determination

Having reviewed the evidentiary record in this matter including (1) the submissions filed by the parties, particularly including the motion of Pfizer for summary determination on all issues and the response of Commission investigative attorney thereto, (2) the pleadings, depositions, admissions and affidavits in this proceeding, (3) the recommended determination of the presiding officer, and (4) the public hearing before the Commission on February 6, 1979, the Commission, on March 27, 1979, determined:

1. That there is a violation of section 337 of the Tariff Act of 1930, as amended, in the importation into the United States of doxycycline falling within claim 10 of complainant's United States Letters Patent No. 3,200,149, or in its sale by its owners, importers, consignees, or agents of either, in the United States, the effect or tendency of which is to substantially injure an industry, efficiently and economically operated, in the United States, 1/

2. That the appropriate remedy for such a violation is to direct that doxycycline falling within claim 10 of United States Letters Patent No.

1/ Commissioners George M. Moore and Paula Stern determined that there are violations of section 337 (1) in the importation of infringing doxycycline into the United States and (2) in the sale of infringing imported doxycycline by the owner, importer, consignee, or agent of either, in the United States.

3,200,149 be excluded from entry into the United States for the term of said patent, except under license of the patent owner; 2/

3. That, after considering the effect of such relief upon the public health and welfare, competitive conditions in the U.S. economy, the production of like or directly competitive articles in the United States, and U.S. consumers, such relief should be imposed; and

4. That the bond provided for in subsection (g)(3) of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337(g)(3)) be in the amount of $600.00 per kilogram of imported bulk doxycycline hyclate.

Order

Accordingly, it is hereby ordered that:

1. Complainant's motion for summary determination as to all issues in this investigation (Motion Docket No. 3-16) is granted;

2. Complainant's motion for summary determination that Danbury Pharmacal is committing unfair acts in the import trade (Motion Docket No. 3-13) is dismissed as being moot;

2/ Commissioners George M. Moore and Paula Stern determined that the issuance of this exclusion order is the appropriate means to remedy the violation of 19 U.S.C. 1337 which they found to exist in the importation of infringing doxycycline into the United States. However, Commissioners Moore and Stern further determined that the issuance of an order requiring International Rectifier Corporation to cease and desist from selling infringing imported doxycycline in the United States which it has imported since May 2, 1973, is the appropriate means to remedy the violation of 19 U.S.C. 1337 which they found to exist in the sale of infringing imported doxycycline by the owner, importer, consignee, or agent of either, in the United States.

3. Complainant's motion for summary determination that the domestic industry is economically and efficiently operated (Motion Docket No. 3-12) is dismissed as being moot;

4. Complainant's motion for imposition of sanctions against respondent International Rectifier Corporation and for a recommended order pursuant to section 337(f) (Motion Docket No. 3-10) is granted insofar as complainant moved the Commission for the imposition of evidentiary sanctions under section 210.36(b) of the rules, and is denied insofar as complainant moved the Commission for an order pursuant to section 337(f); 3/

5. Doxycycline falling within claim 10 of United States Letters Patent No. 3,200,149 is excluded from entry into the United States for the term of said patent except where such importation is licensed by the owner of said patent;

6. Doxycycline ordered to be excluded from entry is entitled to entry into the United States under bond in the amount of $600.00 per kilogram of imported bulk doxycycline hyclate from the day after the day this order is received by the President pursuant to section 337(g) of the Tariff Act of 1930, as amended, until such time as the President notifies the Commission that he approves this action or disapproves this action, but, in any event, not later than sixty (60) days after such day of receipt;

7. That this order will be published in the Federal Register and served upon each party of record in this investigation and upon the U.S.

3/ Commissioners George M. Moore and Paula Stern would also grant that part of complainant's Motion Docket No. 3-10 for an order pursuant to section 337(f).

Department of Health, Education and Welfare, the U.S. Department of Justice, the Federal Trade Commission, and the Secretary of the Treasury; and

8. That the United States International Trade Commission may amend this order at any time.

By order of the Commission:

Kenneth R. Mason

KENNETH R. MASON
Secretary

Issued: April 12, 1979.

Opinion of Chairman Joseph O. Parker and
Commissioner Catherine Bedell

The present proceeding was instituted on May 16, 1974, in response to a complaint filed by Pfizer on April 13, 1973, alleging that respondents International Rectifier Corp. (Rectifier) and USV Pharmaceutical Corp. (USV) were in violation of section 337 by reason of the unauthorized importation or sale of doxycycline which infringes complainant's patent.

Because of concurrent litigation between complainant and respondents in the Federal courts, the proceeding before the Commission has at times been suspended. It was reactivated on February 21, 1978, following a decision by the U.S. Circuit Court of Appeals, which reversed a summary judgment granted by the district court (538 F.2d 180 (8th Cir., 1976)), certiorari denied (429 U.S. 1040 (1977)).

On April 21, 1978, the Commission granted Pfizer's motion to substitute its revised amended complaint of March 10, 1978, for its original complaint. The revised complaint added Danbury Pharmacal (Danbury) as a new party respondent and limited Pfizer's infringement allegation to claim 10 of its patent. USV was dismissed as a party respondent following a stipulation and agreement of settlement and discontinuance of alleged violations between the parties.

Rectifier filed no response to either the original or amended complaint by Pfizer and did not attend any of the four preliminary conferences held by the presiding officer. Danbury responded to Pfizer's amended complaint of May 8, 1978, and attended two of the four conferences referred to above.

Following a series of procedural and other motions, Pfizer, on September 11, 1978, moved for a summary determination of all issues (Motion Docket No. 3-16) in this investigation, including a motion that

respondent Danbury violated section 337 of the Tariff Act of 1930, as amended. This motion was supported by the Commission investigative attorney.

On October 16, 1978, Judge Duvall, the presiding officer, recommended to the Commission that Pfizer's motion for a summary determination with respect to all issues be granted and that it be determined that respondents Rectifier and Danbury be adjudged in violation of section 337.

On February 6, 1979, the Commission, following public notice, conducted an oral hearing on the questions of relief, bonding, and public interest matters.

On March 27, 1979, the Commission, by a 5-0 vote, determined that Rectifier and Danbury were in violation of section 337 of the Tariff Act of 1930, as amended, and by the same vote determined that doxycycline which infringes complainant's patent should be excluded from entry into the United States. 1/

The principal matter of substance which remained for Commission determination was with respect to remedy. The question of violation was determined pursuant to our rules concerning summary determination and the substantive evidentiary showing made by complainant, which satisfactorily supported a determination of violation.

Our determination on the question of violation is in accord with the findings and recommendations of the presiding officer in which he found that the requirements of section 210.50 for a summary determination had been met and that there is no genuine issue as to any material fact. Counsel for Rectifier appeared at the oral hearing and argument before the Commission and stated that his appearance was "to present argument

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1/ Two Commissioners determined that, in addition, an order should be issued ordering respondent Rectifier to cease and desist from selling any doxycycline which it has imported since May 2, 1973. This determination

on the nature of the remedy which would flow from default . . . ." He did not offer any arguments on the question of violation. By settlement agreement between Pfizer and Danbury entered in the U.S. District Court of the District of Connecticut on August 17, 1978, Danbury admitted that the suit patent is valid and enforceable and that it has infringed claim 10 thereof (Pfizer, Inc. v. Danbury Pharmacal, Inc., Civil Action No. B-77-171).

A consideration of the question of remedy necessitates a brief review and understanding of the statute and what is authorized. The Commission has only powers which are delegated to it by the statute. It has no broad, general, equity powers to fashion any remedy it thinks best irrespective of how one may perceive the merits. Since the Commission can only direct as a remedy what is authorized by the statute, we should examine the applicable statutory provisions.

The pertinent statutory provisions concerning remedy are found in sections 337(d), (e), and (f). Section 337(d) provides:

> If the Commission determines . . . that there is a violation it shall direct that the articles concerned . . . be excluded from entry into the United States.

This action is in rem and is applicable to all infringing imports irrespective of the importation.

Section 337(e) relates to exclusion of articles from entry during pendency of the investigation. It provides:

> If, during the course of an investigation under this section, the Commission determines that there is reason to believe that there is a violation of this section, it may direct that the articles concerned . . . be excluded from entry into the United States . . . .

The statute, however, specifically authorizes entry of such articles under bond.

Section 337(f) provides:

> In lieu of taking action under subsections (d) or (e), the Commission may issue . . . an order directing such person to cease and desist from engaging in the unfair methods or acts involved . . . . The Commission may . . . modify or revoke such order, and . . . may take action under subsections (d) or (e), as the case may be.

Complainant urges the Commission to issue an in rem exclusion order under section 337(d) and, in addition, a cease and desist order against specific respondents under section 337(f).

Complainant argues that this is a better and more all-inclusive remedy and that its alleged need thereby requires an interpretation of the statute to give the Commission the power to take such action. This contention, in our opinion, would require a complete distortion of the clear words and plain meaning of the statute and would, in effect, be tantamount to the Commission's legislating a complete rewrite of the statute. It would, in effect, have the Commission delete the words in section 337(f), "In lieu of taking action under subsections (d) or (e)" and substitute therefor the words "In addition to the actions under subsection (d) or (e) the Commission may . . . ."

It is understandable that a patent holder having a legal monopoly as a result of his patent is desirous of having every lawful act taken in furtherance and support of its legal monopoly. That is the very essence of our patent laws and the stimulation to inventiveness provided by patents. But neither the desire of the patent owner nor the underlying policy of patent law affords any basis for a legal interpretation of section 337 which distorts the clear and plain meaning of the statute and to do so would result in administrative usurpation of the legislative power of Congress by an administrative agency.

Not only would the construction of the statute urged by complainant,

and, we might point out, supported by the Commission investigative attorney, do violence to the clear language of the statute, but it would also fly directly in the face of the legislative will, as disclosed by the statutory language and legislative history.

Commission counsel and complainant's counsel attempt to seize upon a single sentence in a Senate committee report. The sentence is, "The power to issue cease and desist orders would add needed flexibility." They would then attempt to give the word "flexibility" an entirely different thrust and meaning than those given to it by the committee and, as a result, would defeat, rather than further, the will of Congress.

It is clear that what we have is a situation of applying the law as it is written and not as we might like it to read.

It should also be noted that complainant has additional remedies available. Section 337(e) authorizes, where justified, interim exclusion orders and bonded entry pending completion of the investigation. The exercise of this power was not appropriately or effectively sought by complainant. Complainant also has legal remedies of injunctions and damages, which are available, if justified, in any legal forum which has jurisdiction including the forum in which complainant initially sought relief before initiating action before the Commission. The remedy of damages also is available to complainant if it ultimately prevails in its litigation.

With respect to the public health and welfare issues and the production of like or directly competitive articles, there is ample evidence in the record that complainant has the capability to supply without delay any medical need for doxycycline in the United States. No submissions were filed by the Department of Health, Education, and Welfare regarding the

public health and welfare issues in this investigation.

The record does not disclose that there would be any adverse impact on competitive conditions in the U.S. economy as a result of the issuance of an exclusion order beyond that contemplated and permitted under applicable provisions of law. We have considered the effect of the proposed exclusion order on U.S. consumers. No public interest group responded to our invitation to present information or to argue that the proposed exclusion order would adversely affect consumer interests and the record does not disclose that such interests of consumers would be adversely affected by an exclusion order.

The legislative history of section 337 states that a bond should be chosen "which would offset any competitive advantage resulting from the unfair method of competition or unfair act enjoyed by persons benefiting from the importation of the article." (S. Rept. No. 93-1298 (93d Cong., 2d sess.), 1979, p. 198.) The bond we have chosen represents our estimate of the amount of bond which would offset any competitive advantage resulting from unfair competition in this investigation.

Concurring Opinion of Vice Chairman Alberger

I concur with my fellow Commissioners in finding that there is a violation of section 337. I also agree that the Commission should order exclusion of the offending products. However, I think it important to explain the grounds on which these determinations were made, and to review the public interest considerations as well. In particular, I feel there are important questions of statutory interpretation and legislative intent which explain my refusal to grant certain relief requested by complainant.

Violation of Section 337

Section 210.50 of the Commission's rules provides that a complainant's motion for summary determination should be granted if the pleadings, depositions, admissions and affidavits on file show that there is no genuine issue as to any material fact and that the moving party is entitled to summary determination as a matter of law. I agree with the presiding officer that the requirements of section 210.50 have been satisfied by Pfizer, and, accordingly, I would grant Motion Docket No. 3-16 1/ as to all issues and

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1/ Pfizer's motion for summary determination on all issues incorporated Pfizers' motion of July 7, 1978 for the imposition of sanctions against respondent International Rectifier Corporation ("Rectifier") (Motion Docket No. 3-10) as well as the appendices attached thereto. In addition, Pfizer's motions of July 21 and July 26, 1978, respectively, for summary determination (1) as to the efficient and economic operation of the domestic industry (Motion Docket No. 3-12) and (2) as to the Commission by respondent Danbury Pharmacal of unfair acts in the import trade (Motion Docket No. 3-13) were not withdrawn by Pfizer. I have considered Motion Docket Nos. 3-16, 3-13, 3-12, and 3-10, and all supporting appendices, affidavits, admissions, depositions, and pleadings on file in determining whether Pfizer is entitled to summary determination as a matter of law as to all issues in this investigation (presiding officer's recommendation of October 16, 1978, page 3).

determine that there is a violation of section 337 in the unauthorized importation and sale in the United States of doxycycline infringing claim 10 of U.S. Letters Patent No. 3,200,149. 2/

In the instant case we were presented with the clear, undisputed default by Rectifier which failed to file a response to the complaint and to the Commission's notice of investigation as is required by section 210.21(a) of the Commission's rules. This constitutes a waiver of the right to contest allegations in the complaint. Furthermore, it authorizes the presiding officer to find the facts as alleged in the complaint. 3/ However, the Commission has recently held that the procedural effect of default is not to eliminate the need for the Commission to base its finding of violation upon sufficient, reliable, and probative evidence. 4/ Hence, the parties, and particularly the Commission investigative attorney, are obligated to present the Commission with facts which demonstrate a violation.

In the present case, complainant submitted affidavits and other documents in support of its motion for summary determination. The evidence is

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2/ United States Letters Patent No. 3,200,149 has not been declared invalid by a court of law, is valid by statutory presumption as a matter of law (35 U.S.C. 282), has not expired, and remains in force until August 10, 1982 (35 U.S.C. 154) in the absence of a finding by any tribunal of invalidity or unenforceability. In addition, one of the consequences of International Rectifier's failure to participate in the Commission's proceedings is that it did not meet its statutory burden of establishing patent invalidity (35 U.S.C. 282).

In this respect, the Eighth Circuit reversed a prior federal district court judgment of patent invalidity on a motion for partial summary judgment (538 F.2d 180 (8th Cir., 1976)) and the Supreme Court denied certiorari (429 U.S. 1040 (1977)).

3/ 19 C.F.R. Section 210.21(d).

4/ Certain Electric Slow Cookers, Investigation No. 337-TA-42, Opinion in Support of Order Remanding for Further Proceedings, March 14, 1979.

clearly sufficient to establish a violation. The essential elements of violation -- patent validity, infringement, economic and efficient operation of the domestic industry, and injury -- were amply demonstrated. 5/ It is clear from the record that respondents are committing unfair acts which have the effect or tendency of injuring the domestic doxycycline industry. I therefore adopt the findings of fact and conclusions of law of the presiding officer and determine that there is a violation of section 337 by Rectifier and Danbury. 6/

Furthermore, it should be noted that during our February 6, 1979, hearing on relief, bonding and the public interest factors enumerated in subsections (d) and (f) of section 337, counsel for Rectifier clearly conceded a section 337 violation as follows:

> We are here today to present argument on the nature of a remedy which would flow from default on an investigation pursuant to 337. We are not here to re-argue a 337a violation. We had our chance. We did not take it and I think that the unfair competition pursuant to that would have to be found under any proper legal procedure. . . (official transcript of proceedings before the United States International Trade Commission in the matter of Doxycycline, February 6, 1979, pages 82-83, as revised by respondent Rectifier on February 22, 1979).

5/ Recommended Determination, pp. 27-30.

6/ In light of the fact that the Comission has granted Pfizer's motion for summary determination as to all issues (Motion Docket No. 3-16, it would be redundant for us to grant Pfizer's motion for summary determination that Danbury has committed unfair acts in the import trade (Motion Docket No. 3-13); likewise, it would be redundant for us to grant Pfizer's motion for summary determination that the domestic industry is efficiently and economically operated (Motion Docket No. 3-12). Accordingly, Motion Docket Nos. 3-13 and 3-12 should be dismissed as being moot.

Remedy

Complainant has requested that the Commission issue both an exclusion order with respect to future imports under section 337(d) and a cease and desist order under section 337(f) barring the sale of doxycycline which was imported during the period of this investigation. Complainant contents both remedies are necessary to adequately protect it from respondents' importations.

It cannot be denied that a complainant in a section 337 proceeding may suffer some injury during an investigation as a result of importations which are subsequently found to be unlawful and subject to a cease and desist or to an exclusion order. However desirable it might be to take action with respect to such imports, the Commission's ability to fashion appropriate relief is dependent upon the scope and purpose of the statute itself. The legislative history of Section 337 suggests that Congress intended the Commission's power to revolve around the ability to prohibit imports or control the conditions under which importation is permitted. Section 337 was not designed to permit a broad exercise of equitable jurisdiction over goods in the domestic stream of commerce, and, absent some extraordinary circumstances, prospective relief against imports will usually be sufficient to achieve the purpose of the statute.

The amendments to section 337 in the Trade Act of 1974 indicate no clear intent to expand our jurisdiction into the field of domestic sales. Prior to 1974, the Commission forwarded its findings and recommendations to the President, who then determined whether unfair methods or acts existed, and whether to direct that the offending articles be excluded. At that time, the President had no other remedy available to him.

The Trade Act of 1974 made significant changes with respect to relief under this section. Pursuant to subsection (d), if the Commission determines that there is a violation of section 337, it can direct that the offending articles be excluded from entry. Under subsection (g)(2), the President may, however, disapprove the Commission's determination for "policy reasons" and the Commission's exclusion order has no force or effect. The Trade Act of 1974 made another significant change with respect to the remedy for a violation of section 337, under subsection (f):

> In lieu of taking action under subsection (d) or (e), the Commission may issue and cause to be served on any person violating this section, or believed to be violating this section, as the case may be, an order directing such person to cease and desist from engaging in the unfair methods or acts involved, . . .

In commenting on this new section the Senate Finance Committee states:

> Section 337(f) of the Act, as amended by this bill, would be a new provision authorizing the Commission to issue cease and desist orders, in lieu of excluding articles, against any persons violating, or believed to be violating, section 337. Such an order could be modified or revoked at any time, and when revoked, could be replaced by an exclusion order. It is clear to your committee that the existing statute, which is so extreme or inappropriate in some cases that it is often likely to result in the Commission not finding a violation of this section, thus reducing the effectiveness of section 337 for the purposes intended.
>
> The power to issue cease and desist orders would add needed flexibility. Any cease and desist order issued by the Commission would, as with directions to exclude from entry, be effective upon issuance, but articles subject to the order are entitled to entry under bond, determined by the Commission and prescribed by the Secretary of the Treasury in order to permit the President to exercise his authority under section 337(g). Also, as in sections 337(d) and (e), the Commission would have to consider the impact of any cease and desist order it would issue on the various interests described in such sections.

While this additional remedy was intended to give the Commission "flexibility," the legislative history also establishes that it was to be less

"extreme" than the exclusion order. An order prohibiting respondents from selling goods already entered as well as from importing the offending articles is obviously more extreme than the sole remedy of exclusion. This is one indication that the intent behind section 337(f) was more limited than that which complainant's position implies. In fact, the Finance Committee report states:

> No change has been made in the substance of the jurisdiction conferred under section 337(a) with respect to unfair methods of competition or unfair acts in the import trade.

Thus, there is no indication in the legislative history that the mere addition of the cease and desist remedy mandates the Commission to reach back and exercise expanded jurisdiction over articles previously entered in the United States.

It is also clear from the structure of section 337 that the relief available under subsections (d) and (f) was intended to apply to importations rather than domestic sales. Pursuant to subsection (g)(3) of section 337:

> . . .articles directed to be excluded from entry under subsection (d) or subject to a cease and desist order under subsection (f) shall be entitled to entry under bond until the President takes action.

Thus, section 337 permits the importation of the goods subject to a cease and desist order during the period in which the President can take action. Such entry is permitted only under bond, to ensure that, if the President does not disapprove the Commission's action, then complainant will not be injured by continued importation. Nothing in the statute authorizes the collection of such bond except upon entry of the goods subject to the order. Thus, if the Commission were to order Rectifier to cease and desist from selling

doxycycline which has already been imported, the act provides no means, similar to entry under bond, for protecting Rectifier's interests during the period of Presidential consideration. This indicates that the statute is to be administered through customs procedures, rather than through control of domestic markets.

Additionally, section 337(f) provides:

> The Commission may at any time, upon such notice and in such manner as it deems proper, modify or revoke any such order, and, in the case of a revocation, may take action under subvsection (d) or (e), as the case may be.

If a Commission cease and desist order is not complied with, the normal sanction is for the Commission to exclude the offending articles. The Commission has no independent power beyond that of exclusion. While 19 U.S.C. Section 1333(c) allows the Commission to seek judicial enforcement of its orders, our ability to compel compliance would depend on time consuming court proceedings. Since Section 337 was designed to afford speedy relief, exclusion is generally the only practical means of enforcement. The possibility of court enforcement may mean that under certain circumstances the Commission could address its cease and desist orders to domestic sales. For example, if a respondent violated an outstanding cease and desist order aimed at importations, the Commission might want to issue a subsequent order prohibiting sale of those particular goods. But since the statute was not designed to operate in that fashion, I would only support such an order in exceptional cases. Clearly the present case does not present such circumstances.

For the reasons stated above, I consider it inappropriate for the Commission to issue a cease and desist order with respect to goods already

entered into the United States during the period of this investigation. I therefore determine that in this investigation the appropriate remedy is an order directing the exclusion of the subject goods from importation into the United States.

It is worth noting that complainant is not without alternative remedies. The relief provided by section 337 is in addition to that provided under any other provision of law. Thus, complainant may have relief available to it including damages for prior imports, if it prevails in other proceedings in the District Court. Exclusion of the infringing products may not render complainant entirely whole from the effects of the usurpation of its patent rights, but this is not the purpose of section 337. Rather, the statute is designed to assure that efficiently and economically operated domestic industries are not rendered incapable of competing because of unfair trade. In my view, exclusion of future imports will adequately serve this purpose.

Public Interest

The Commission is required to consider before ordering any exclusion of entry or issuing any cease and desist order, the impact of such action on various interests, including public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers. The Commission has found that these public interest considerations do not preclude the exclusion of infringing doxycycline from entry into the United States.

With respect to the public health and welfare and the production of like or directly competitive articles, there is ample evidence of record that

Pfizer has the capability to supply without delay any medical need for doxycycline in the United States (FF 24, 26, 28, 30, 31). Although there were submissions from other government agencies, there were no submissions filed by the Department of Health, Education, and Welfare regarding the public health and welfare in this investigation. Furthermore, there is ample evidence of substitutability of a broad spectrum of antibiotics for doxycycline. Accordingly, there is nothing to demonstrate that our issuance of an exclusion order would be contrary to the public health or welfare considerations.

Furthermore, there would be no adverse impact upon competitive conditions in the United States economy through the issuance of our exclusion order. Doxycycline is produced in accordance with the claims of a United States patent which has not been declared invalid or unenforceable by a court of law. To the extent that the patent laws as established by Congress would grant a patentee a limited monopoly, competition may be limited; however, the Constitution is clear that such policy is authorized "to promote the Progress of Science and useful Arts." (Article I, Section 8). There is no sufficient indication in the record that complainant has engaged in anticompetitive acts which would preclude us from issuing this order.

The Commission must also consider the effect of the proposed exclusion order upon United States consumers. Pfizer has indicated its intent to comply with the President's anti-inflation program and the President's price deceleration standard, and that it will not raise prices on doxycycline during 1979 and only modestly raise prices, if at all through 1981. 1/ No

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1/ It is noted that the patent will expire on August 10, 1982.

public interest group responded to our invitation to present arguments on behalf of the consumers at our February 6, 1979, hearing. Therefore, it appears that the interests of consumers would not be adversely affected by the issuance of our exclusion order.

Bonding

With respect to the amount of the bond under subsection (g)(3) of the Tariff Act of 1930, the legislative history of section 337 is clear that a bond should be chosen "which would offset any competitive advantage resulting from the unfair method of competition or unfair act enjoyed by persons benefiting from the importation of the article." (S. Rep. No. 93-1298, 23d Cong., 2d sess. 108 (1974)). The bond I have chosen is equivalent to a reasonable royalty for a drug-related patent and represents an estimate of that amount of bond which would offset any competitive advantage resulting from unfair competition in this investigation. According to the presiding officer's recommendation of October 16, 1978, Rectifier currently sells doxycycline at an average list price of $0.006 per miligram, or $6,000 per kilogram. (FF 52) Applying a 10 percent royalty figure to this figure yields a fixed amount bond of $600.00 per kilogram of imported bulk doxycycline which would offset the competitive advantage enjoyed by Rectifier. (Additional Statement of Commission Investigative Attorney regarding Bonding, February 21, 1979, pages 1-2).

Opinion of Commissioners George M. Moore and Paula Stern, Concurring in Part and Dissenting in Part

We concur with our fellow Commissioners that section 337 has been violated for the reasons stated in their opinions and we adopt the findings of fact and conclusions of law of the administrative law judge. However, unlike our fellow Commissioners, we determined that there are violations of section 337 in both (a) the importation of infringing doxycycline into the United States and (b) the sale of infringing imported doxycycline by the owner, importer, consignee, or agent of either, the effect or tendency of which is to substantially injure an industry, efficiently and economically operated, in the United States. Therefore, with respect to our colleagues' choice of remedy, we dissent in part. In our opinion, the majority remedy is inadequate to address the circumstances existing in this investigation.

We are compelled to register this dissent in light of the administrative law judge's findings of fact that even the exclusion of all future importation of doxycycline until the patent expires would not prevent the sale of large quantities of imported infringing doxycycline in the United States. The administrative law judge found that International Rectifier Corporation has assembled a substantial inventory of imported infringing doxycycline which it is ready to resell (FF 52). He further found that sale of imported infringing doxycycline from this inventory threatens to substantially injure the domestic doxycycline industry (FF 53).

In this investigation, we are confronted with International Rectifier Corporation's substantial stockpiling of an infringing imported product during the period of the Commission's investigation. The imported infringing doxycycline has a shelf life of three years after the date the batches are first certified by the Food and Drug Administration (Transcript of Commission hearing of February 6, 1979, concerning appropriate relief, bonding, and the public interest, pages 114-115). Therefore, infringing imported doxycycline can be sold by International Rectifier Corporation throughout the remaining effective period of complainant's patent, a period during which the majority had intended to protect complainant's patent rights.

Accordingly, the majority's exclusion order, standing alone, cannot redress the unfair acts which exist in this investigation. Therefore, unlike our fellow Commissioners, we made a further determination that issuance of an order requiring International Rectifier Corporation to cease and desist from selling in the United States any doxycycline which it has imported since the initiation of the Commission's investigation is the appropriate means to remedy the violation of section 337 which we found to exist in the sale of infringing imported doxycycline by International Rectifier Corporation.

In our opinion, the remedy chosen by the majority cannot be said to advance the public policy objectives enunciated by the Congress in section 337. The Congress gave the Commission cease and desist powers in 1974 to provide greater remedial flexibility to promote the effectiveness of section 337. (S. Rep. No. 93-1298, 93d Cong., 2d Sess., 198 (1974)). Our remedy would make effective use of this flexibility entrusted to us by the Congress

to make section 337 a meaningful response to unfair trade practices. The majority remedy, by contrast, effectively deprives the complainant of remedial justice.

In fact, the majority, perhaps unwittingly, has given International Rectifier Corporation, as a violator of the law, an incentive to nullify thoroughly the efficacy of the majority's remedy. Indeed, in the absence of the cease and desist order which we would have issued in conjunction with the majority's exclusion order, it is in International Rectifier Corporation's interest to import as much infringing doxycycline as it wishes to fulfill its needs through August 10, 1982, the expiration date of complainant's patent, from the date of our determinations (March 27, 1979) until the date our determination and order is published in the Federal Register and thereby becomes effective (April 16, 1979). The Commission's bond will not discourage such an anomaly since it, too, only becomes effective upon publication in the Federal Register. While our remedy would have largely closed this loophole in the statute, the majority's leaves it wide open.

The only alternate remedy would have been to prevent the stockpiling and its adverse effect upon the complainant at an earlier stage of this proceeding by the Commission's issuing a temporary exclusion order (TEO) under section 337(e). In fact, the complainant had requested a TEO prior to the 1974 revisions of section 337, but the Commission denied that request (Minutes of Commission meeting of May 16, 1974, page 6912). Accordingly, after the 1974 amendments to section 337, which, among other things, gave the Commission flexible cease and desist powers, complainant opted to request cease and

desist relief under section 337(f) in lieu of TEO relief under section 337(e), as authorized by the statute.

We believe there may be certain instances where practical difficulties and inequities inherent in a TEO under section 337(e) may make the issuance of a cease and desist order under section 337(f) the preferable approach to remedy unfair trade practices involving sales from the stockpiles of imported infringing products. 1/ We hold this belief for two primary reasons.

First, the one-year time limit for concluding section 337 investigations, introduced in the 1974 amendments, has rendered the TEO an unworkable enforcement tool. Discovery and hearing on the ultimate issues in a section 337 investigation must inexorably proceed on a tight schedule before the administrative law judge; time expended on a TEO proceeding is time subtracted from the development of an adequate evidentiary record with regard to the ultimate issues in a section 337 investigation.

Second, a TEO is issued by the Commission prior to a determination on the record that section 337 in fact has been violated by any respondent. For this reason, the Commission has required complainants to meet the high standard of proof of immediate and substantial harm to obtain a TEO, a standard which no complainant has met since the 1974 amendments to section 337. 2/ It is clear, therefore, that cease and desist relief under section 337(f) in lieu of a TEO

1/ The Commission's use of the TEO as a remedial tool has declined dramatically in recent years; not one TEO has been issued by the Commission since the effective date of the 1974 amendments to section 337 (April 3, 1975). The last TEO under section 337 was issued on May 2, 1974, in Convertible Game Tables and Components Thereof, investigation No. 337-TA-2.

2/ See, e.g., Chicory Root, investigation No. 337-TA-27; Certain Luggage Products, investigation No. 337-TA-39.

under section 337(e) may be the more equitable approach among the parties where unfair trade practices involving sales from the stockpiles of imported infringing products are concerned, since a cease and desist order under section 337(f) is issued after a determination on the record that section 337 in fact has been violated. Indeed, where the importation of an important article is concerned, the issuance of a TEO under section 337(e) prior to a determination of violation may be antithetical to the public interest.

If unfair trade practices involving sales from the stockpile of an imported infringing product are found to exist, then they should be dealt with by the Commission under either section 337(e) or (f), as is appropriate in the specific case at hand. We see no valid reason why our fellow Commissioners should limit the remedial flexibility of this Commission in dealing with unfair trade practices involving sales from the stockpiles of imported infringing products.

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