

**PUBLIC VERSION**

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, D.C.**

**In the Matter of**

**CERTAIN SILDENAFIL OR ANY  
PHARMACEUTICALLY ACCEPTABLE  
SALT THEREOF, SUCH AS SILDENAFIL  
CITRATE, AND PRODUCTS  
CONTAINING SAME**

**Inv. No. 337-TA-489**

**COMMISSION OPINION ON REMEDY, THE PUBLIC INTEREST, AND BONDING**

**Introduction**

The Commission instituted this investigation on March 6, 2003, based on a complaint filed by Pfizer, Inc. ("Pfizer") of New York, New York. 68 *Fed. Reg.* 10749 (March 6, 2003). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930 in the importation into the United States, sale for importation, and sale within the United States after importation of certain sildenafil or any pharmaceutically acceptable salt thereof, such as sildenafil citrate, and products containing same by reason of infringement of claims 1-5 of Pfizer's U.S. Patent No. 5,250,534 ("the '534 patent").

Fifteen respondents were named in the Commission's notice of investigation. Thirteen of these were successfully served with the complaint and notice of investigation.<sup>1</sup> One respondent

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<sup>1</sup> The two respondents which were not found to have been served with the complaint and notice of investigation are Investment and Future Development Corp., SA and Jiangxi Jilin Chemical Corp., Ltd. Order No. 12 (May 13, 2003). Neither has appeared or otherwise participated in the investigation.

## **PUBLIC VERSION**

has been terminated from the investigation on the basis of a settlement agreement.<sup>2</sup>

Eleven respondents were found to be in default, including respondent #1 Aabaaca Viagra LLC (“Aabaaca”).<sup>3</sup> On October 6, 2003, Pfizer filed a motion pursuant to Commission rule 210.18 (19 C.F.R. § 210.18) for summary determination on the issues of the existence of a domestic industry and violation of section 337. Pfizer’s motion sought a general exclusion order and also a cease and desist order against respondent Aabaaca. On October 27, 2003, the presiding administrative law judge (“ALJ”) issued an initial determination (ID) (Order No. 19) finding that Pfizer had demonstrated by “substantial, reliable, and probative evidence” that there is a violation of section 337 by reason of the defaulting respondents’ importation and sale of sildenafil, sildenafil salts, or sildenafil products that infringe one or more of claims 1-5 of the ‘534 patent. He also found that Pfizer had established the existence of a domestic industry, as required by section 337(a)(2)-(3). He recommended the issuance of a general exclusion order, but did not recommend the issuance of a cease and desist order against respondent Aabaaca. He also recommended that the bond permitting temporary importation during the Presidential review period be set at 100 per cent of entered value. On November 24, 2003, the Commission issued

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<sup>2</sup> The terminated respondent is Ezee Soulnature Healthcare Pvt. Ltd. (“Ezee”). Order No. 16 (June 30, 2003). The Commission affirmed this part of Order No. 16.

<sup>3</sup> The 11 respondents found to be in default are: Planet Pharmacy; LTMC, Ltd.; Aleppo Pharmaceutical Industries; #1 Aabaaca Viagra LLC; Zhejiang Medicines & Health Products Import & Export Co., Ltd.; Tianjin Shuaike Chemical Co., Ltd.; Sino Health Care Company of Sichuan; China Jiangsu International; Yiho Export & Import Co., Ltd.; Lianyungang Foreign Trade Co.; and EBC Corporation. Order No. 14 (June 10, 2003) and Order No. 15 (June 25, 2003). The Commission declined to review either of these initial determinations and thus they became the Commission’s determinations.

## **PUBLIC VERSION**

notice that it had determined not to review the ALJ's ID and set a schedule for written submissions on remedy, the public interest, and bonding. Both Pfizer and the Commission investigative attorney ("IA") timely filed written submissions on those questions. The IA filed a reply submission.

For the reasons discussed below, we have determined that the appropriate remedy in this case is a general exclusion order issued under section 337(d)(2). We have also determined that the issuance of the general exclusion order is not precluded by consideration of the public interest factors set out in section 337(d) and that the amount of the temporary importation bond in effect during the Presidential review period shall be 100 percent of the entered value of the articles covered by the general exclusion order.<sup>4</sup>

### **Remedy**

In recommending the issuance of a general exclusion order, the ALJ found that the proper legal framework for his decision was section 337(g)(2), not section 337(d)(2), as alternatively argued by Pfizer and the IA.

Section 337(d)(2) provides:

(2) The authority of the Commission to order an exclusion from entry of articles shall be limited to persons determined by the Commission to be violating this section unless the Commission determines that –

(A) a general exclusion from entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named persons;

or

(B) there is a pattern of violation of this section and it is difficult to identify the source of infringing products.

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<sup>4</sup> We have also determined not to review Order No. 22, issued by the ALJ on January 6, 2004, terminating respondent Biovea on the basis of a settlement agreement.

## PUBLIC VERSION

Section 337(g)(2) provides:

(2) In addition to the authority of the Commission to issue a general exclusion from entry of articles when a respondent appears to contest an investigation concerning a violation of the provisions of this section, a general exclusion from entry of articles, regardless of the source or importer of the articles, may be issued if --

- (A) no person appears to contest an investigation concerning a violation of the provisions of this section,
- (B) such a violation is established by substantial, reliable, and probative evidence, and
- (C) the requirements of subsection (d)(2) are met.

We find that the issuance of a general exclusion order in the circumstances of this case is not governed by section 337(g)(2), since that provision expressly requires that no respondent appear to contest the investigation and it is clear that respondents Ezee and Biovea did. That no discovery may have been taken from those two respondents prior to action on their termination from the investigation does not change the fact of their appearance to contest the investigation. Section 337(g)(2) therefore cannot apply, and the proper legal framework is section 337(d)(2). However, the non-applicability of section 337(g)(2) does not affect the standard for finding a violation of section 337. This is because the adjudicative provisions of the Administrative Procedure Act, which apply to section 337 investigations, provide that a sanction or order may not be issued unless supported by “reliable, probative, and substantial evidence.” 5 U.S.C. §556. Thus, a violation of section 337 may not be found unless supported by “reliable, probative, and substantial evidence.” We see no difference between this standard and the “substantial, reliable, and probative evidence” standard of section 337(g)(2).<sup>5</sup> The additional criteria of section

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<sup>5</sup> Exceptionally, section 337(g)(1) permits relief directed against specific defaulting respondents based on the facts alleged in the complaint, as opposed to “substantial, reliable, and

## PUBLIC VERSION

337(d)(2) for issuance of a general exclusion order apply in both instances. The Commission's rules have long provided for summary determination, including summary determination of violation of section 337. In this case, the ALJ found that the summary determination record supported a finding that the eleven defaulting respondents had violated section 337 and that a domestic industry existed. The Commission determined not to review the ALJ's ID and it became the Commission's determination.

The ALJ found that the requirements of section 337(d)(2) were met, analyzing those factors in terms of the factors set out in *Certain Airless Paint Spray Pumps and Components Thereof*, Inv. No. 337-TA-90, USITC Pub. No. 1199, 216 U.S.P.Q. 465 (U.S.I.T.C., November, 1981)(“*Spray Pumps*”). The Commission has noted that the criteria of section 337(d)(2) “do not differ significantly” from the factors in *Spray Pumps*. See, *Certain Neodymium-Iron-Boron Magnets, Magnet Alloys, and Articles Containing Same*, Inv. No. 337-TA-372, USITC Pub. No. 2694, 1996 WL 1056324 (U.S.I.T.C., May 1996).

In *Spray Pumps*, the Commission held that a complainant seeking a general exclusion order must show both (1) a widespread pattern of unauthorized use of its patented invention and (2) certain business conditions from which one might reasonably infer that foreign manufacturers other than the respondents to the investigation may attempt to enter the U.S. market with infringing articles. *Spray Pumps*, 216 U.S.P.Q. 465, 473. The Commission stated that among the evidence which might be presented to prove a “widespread pattern of unauthorized use of the patented invention” would be:

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probative evidence.”

## PUBLIC VERSION

- (1) a Commission determination of unauthorized importation into the United States of infringing articles by numerous foreign manufacturers; or
- (2) the pendency of foreign infringement suits based upon foreign patents which correspond to the domestic patent in issue;
- (3) other evidence which demonstrates a history of unauthorized use of the patented invention.

*Spray Pumps*, 216 U.S.P.Q. 465, 473.

Among the evidence which might be presented to prove the “business conditions” referred to would be:

- (1) an established demand for the patented product in the U.S. market and conditions of the world market;
- (2) the availability of marketing and distribution networks in the United States for potential foreign manufacturers;
- (3) the cost to foreign entrepreneurs of building a facility capable of producing the patented article;
- (4) the number of foreign manufacturers whose facilities could be retooled to produce the patented articles; or
- (5) the cost to foreign manufacturers of retooling their facility to produce the patented articles.

*Spray Pumps*, 216 U.S.P.Q. 465, 473.

The ALJ found that Pfizer and the IA agree that (1) there is a “widespread pattern of unauthorized use” by numerous entities in India, China, and possibly Thailand that manufacture sildenafil citrate, and (2) infringing sildenafil citrate is widely available on the Internet and through unsolicited bulk e-mail. ID 15-16. He noted Pfizer’s assertion that the Bureau of Customs and Border Protection (Customs) and the Food and Drug Administration (FDA) have

## PUBLIC VERSION

been overwhelmed by massive shipments of pharmaceutical products resulting in improper importation of sildenafil citrate. ID 16. As to the “business conditions” requirement, the ALJ stated that Pfizer and the IA agree that Pfizer’s sildenafil product, known as Viagra, is a popular drug, that infringers sell their sildenafil products at lower prices than Pfizer, often without a prescription, and that it is not difficult for foreign entities to gain access to the U.S. market. ID 16. Regarding the possibility of circumvention (referred to expressly in section 337(d)(2)(A)), the ALJ stated that Pfizer and the IA agree that identifying and shutting down individual suppliers is difficult and that infringers operating through Internet websites offer very little contact information, making it difficult to take action against them specifically. ID 17.

The ALJ concluded that the *Spray Pumps* factors have been satisfied and recommended the issuance of a general exclusion order. In their written submissions on remedy, the public interest, and bonding, Pfizer and the IA argue for the issuance of a general exclusion order.<sup>6</sup>

We determine that a general exclusion order should issue in this case. Addressing first the language of section 337(d)(2), Pfizer has presented evidence that a general exclusion order is necessary to prevent circumvention of an exclusion order limited to the products of named persons. Specifically, Pfizer has demonstrated that suppliers of infringing products could readily mask their identity or be replaced by other suppliers. Further, Pfizer has shown that there is a pattern of violation of section 337 and that it is difficult to identify the source of infringing

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<sup>6</sup> In his recommended determination, the ALJ recommended that a cease and desist order not be issued against respondent Aabaaca Viagra LLC. Pfizer, which had initially requested the issuance of such an order, did not pursue that remedy in its written submission on remedy, the public interest, and bonding.

## PUBLIC VERSION

products. As Pfizer has noted, eleven defaulting respondents have been found to be in violation of section 337. Pfizer has also shown that it is difficult to identify the source of infringing products, many of whom deal directly with U.S. customers over the Internet and can readily mask or change their identity.

Viewing the case from the point of the factors set out in *Spray Pumps*, Pfizer has shown that a widespread pattern of unauthorized use exists, pointing, *inter alia*, to the Commission's determination of unauthorized importation or sale by eleven respondents. Pfizer has also shown that the requisite business conditions exist. There is no doubt that Pfizer's product has an established market, and Pfizer has presented evidence showing that numerous entities are capable of manufacturing infringing products or exporting them to the United States. Further, Pfizer has demonstrated that foreign manufacturers and sources have available to them marketing and distribution networks in the United States. Indeed, it appears that foreign sources can readily market infringing products directly to U.S. customers over the Internet.

We therefore determine that a general exclusion order should issue in this case. Our order applies only to imports for consumption, as Pfizer has not requested exclusion of imports under other types of entry. *See, Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, Comm. Opinion at 7-10, USITC Pub. 2843 (Dec. 1994).<sup>7</sup>

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<sup>7</sup> Pfizer has suggested certain additional provisions to the order. However, we have found these provisions superfluous and they have not been included in the order.



## **PUBLIC VERSION**

### **Public Interest**

Section 337(d) provides that on finding a violation of section 337, the Commission will issue an exclusion order

...unless, after considering the effect of such exclusion upon the 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, it finds that such articles should not be excluded from entry.

Neither Pfizer, nor the IA, nor any other person have argued that issuance of the general exclusion order is precluded because it would adversely affect the public interest. Indeed, Pfizer and the IA argue that issuance of the order is in the public interest.<sup>8</sup> We therefore determine that issuance of a general exclusion order is not precluded by consideration of the public interest factors set out in section 337(d).

### **Bonding**

During the Presidential review period, imported articles otherwise subject to a remedial order are entitled to conditional entry under bond, pursuant to section 337(j)(3). 19 U.S.C. § 1337(j)(3). The amount of the bond is specified by the Commission and must be an amount sufficient to protect the complainant from any injury. *Id.* As the ALJ noted, when sufficient information is available, the Commission sets the amount of the bond based on the price differential between the complainant's product and the infringing imports. However, he found such information insufficient here, and recommended a bond of 100 percent of entered value,

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<sup>8</sup> Pfizer notes a statement by the ALJ questioning whether Customs will be more effective in enforcing a general exclusion than in enforcing FDA detention notices, but states that any problem with the latter lies with FDA procedures, not Customs, and that it should not be denied relief because of any potential difficulties in enforcing relief.

## **PUBLIC VERSION**

noting that this is the bond amount the Commission has set in the past when confronted with inadequate pricing information. ID 19-20, citing *Certain Oscillating Sprinklers, Sprinkler Components, and Nozzles*, Inv. No. 337-TA-448, USITC Pub. 3498 (Mar. 2002).

Both Pfizer and the IA agree with the ALJ's recommendation with respect to bonding.

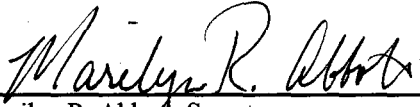
For the reasons stated by the ALJ, we determine that the amount of the temporary importation bond provided for by section 337(j)(3) shall be 100 percent of the entered value of the articles covered by the general exclusion order.

**CERTAIN SILDENAFIL OF ANY PHARMACEUTICALLY  
ACCEPTABLE SALE THEREOF, SUCH AS SILDENAFIL CITRATE  
AND PRODUCTS CONTAINING SAME**

337-TA-489

**CERTIFICATE OF SERVICE**

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF COMMISSION OPINION ON REMEDY, THE PUBLIC INTEREST, AND BONDING**, was served upon all parties via first class mail and air mail where necessary on July 26, 2004.

  
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Marilyn R. Abbott, Secretary  
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**ON BEHALF OF COMPLAINANT PFIZER  
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