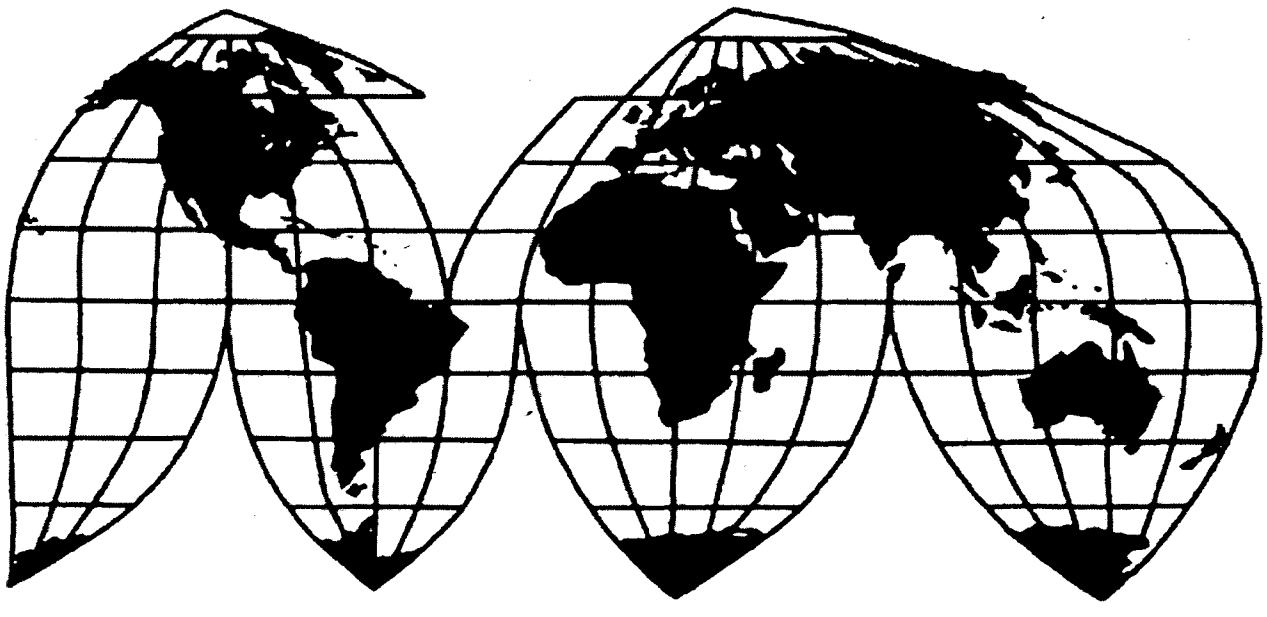
In the Matter of

Certain Tadalafil or any Salt or Solvate Thereof and Products Containing Same

Investigation No. 337-TA-539

Publication 3992 **May 2008**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

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*Commissioner Marcia E. Miller, whose term ended on September 6, 2005, participated in the decision to institute the investigation. Commissioner Shara L. Aranoff, whose term commenced on September 6, 2005, participated in all subsequent phases of the investigation. Commissioner Irving A. Williamson was sworn in on February 7, 2007, and Commissioner Dean A. Pinkert was sworn in on February 26, 2007; they did not participate in this investigation. Commissioner Stephen Koplan, whose term ended on February 6, 2007, and Commissioner Jennifer A. Hillman, whose term ended on February 23, 2007, did participate in this investigation.

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Washington, DC 20436

U.S. International Trade Commission

Washington, DC 20436
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UNITED STATES INTERNATIONAL TRADE COMMISSION
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In the Matter of	)	
CERTAIN TADALAFIL OR ANY SALT OR SOLVATE THEREOF AND PRODUCTS CONTAINING SAME	)	Inv. No. 337-TA-539

NOTICE OF COMMISSION ISSUANCE OF GENERAL EXCLUSION ORDER; DECISION TO GRANT MOTION TO FILE A SURREPLY; TERMINATION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, and has issued a general exclusion order under section 337(g)(2), 19 U.S.C. § 1337(g)(2), and terminated the investigation. The Commission has decided to grant complainant's motion to file a surreply.

FOR FURTHER INFORMATION CONTACT: Jean Jackson, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3104. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted by the Commission based on a complaint filed by Lilly ICOS LLC ("Lilly") of Wilmington, Delaware, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. 70 *Fed. Reg.* 25601 (May 13, 2005). The complainant alleged violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain tadalafil or any salt or solvate thereof, and products containing same by reason of infringement of claims 1-4, 6-8, 12, and 13 of U.S. Patent No. 5,859,006 ("the '006 patent"). The complaint and

notice of investigation named ten respondents.

On September 12, 2005, the Commission issued a notice indicating that it had determined not to review an initial determination ("ID") (Order No. 5) finding respondents Santovittorio Holdings Ltd. d/b/a Inhousepharmacy.co.uk of El Dorado, Panama; Stop4Rx of Port-au-Prince, Haiti, Rx Mex-Com, S.A. de C.V. of Colonia Las Brisas, Mexico; and www.Nudewfds.info of New Orleans, Louisiana; in default. The ID further found that respondent Express Generic had not been properly served with the complaint.

On November 17, 2005, the Commission issued a notice that it had determined not to review an ID (Order No. 9) finding an additional five of the originally named respondents in default. The additional five respondents are Budget Medicines Pty Ltd., of Sydney, Australia; Generic Cialis Pharmacy of Managua, Nicaragua; Cutprice Pills of Scottsdale, Arizona; Allpills.us of Beverly Hills, California; and Pharmacy4u.us of New York, New York.

On October 28, 2005, Lilly filed a motion for summary determination on the issues of the existence of a domestic industry and violation of section 337 by reason of patent infringement with respect to the nine respondents that were found in default. On November 14, 2005, the Commission investigative attorney ("IA") filed a response in support of Lilly's motion.

On December 6, 2005, the presiding administrative law judge ("ALJ") issued an ID (Order No. 10) granting Lilly's motion for a summary determination of violation of section 337. At the same time the ALJ made his recommendations on remedy and the amount of bond to be imposed during the Presidential period of review provided for in section 337(j), 19 U.S.C. § 1337(j). No party petitioned for review of the ID. On January 4, 2006, the Commission determined not to review the ID, thereby allowing it to become the Commission's final determination on violation. 71 *Fed. Reg.* 1452 (Jan. 9, 2006). With respect to remedy, the ALJ recommended the issuance of a general exclusion order under section 337(g)(2), 19 U.S.C. § 1337(g)(2). The ALJ also recommended that the bond permitting importation during the Presidential review period be set at 100 percent of the value of the infringing imported products.

Pursuant to the Commission's notice, Lilly and the IA submitted main briefs on the issues of remedy, the public interest, and bonding on January 17, 2006, with draft general exclusion orders attached. The IA filed a reply submission on January 24, 2006. Lilly filed a motion to file a surreply with surreply attached on February 9, 2006. The Commission has determined to grant Lilly's motion to file a surreply.

Having reviewed the record in this investigation, including the recommended determination of the ALJ and the written submissions of the parties, the Commission has determined that the public interest factors listed in section 337(d)(2) do not preclude issuance of a general exclusion order that prohibits the unlicensed entry for consumption of tadalafil salt or solvate thereof and products containing same that infringe one or more of claims 1-4, 6-8, 12, and 13 of the '006 patent during the term of that patent. The Commission has further determined

that the appropriate bond during the period of Presidential review pursuant to section 337(j) should be set at 100 percent of the value of the infringing products. The Commission's general exclusion order was delivered on the date of its issuance to the President and to the United States Trade Representative, pursuant to the Presidential Memorandum of July 21, 2005. 70 *Fed. Reg.* 43251 (July 26, 2005).

This action is taken under authority of section 337 of the Tariff Act of 1930, 19 U.S.C. §1337, and sections 210.41, 210.49, and 210.50 of the Commission's Rules of Practice and Procedure, 19 C.F.R. §§ 210.41, 210.49, and 210.50.

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: June 13, 2006

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN TADALAFIL OR ANY SALT OR SOLVATE THEREOF AND PRODUCTS CONTAINING SAME	)	**Inv. No. 337-TA-539**

GENERAL EXCLUSION ORDER

The Commission has determined that there is a violation of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, in the unlawful importation and sale of certain tadalafil or any salt or solvate thereof and products containing same that infringe one or more of claims 1-4, 6-8, 12, and 13 of U.S. Patent No. 5,859,006 ("the '006 patent").

Having reviewed the record in this investigation, including the recommended determination of the presiding administrative law judge and the written submissions of the parties, the Commission has made its determinations on the issues of remedy, the public interest, and bonding. The Commission has determined that the appropriate form of relief is a general exclusion order issued under section 337(g)(2), 19 U.S.C. § 1337(g)(2), prohibiting the unlicensed importation of tadalafil or any salt or solvate thereof, and products containing same, covered by one or more of claims 1-4, 6-8, 12, and 13 of the '006 patent.

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude issuance of the general exclusion order, and that the bond during the Presidential review period should be in the amount of 100 percent of the entered value

of the products subject to this order. Accordingly, the Commission hereby **ORDERS THAT :**

1. Tadalafil or any salt or solvate thereof and products containing same covered by one or more of claims 1-4, 6-8, 12, and 13 of U.S. Patent No. 5,859,006 are excluded from entry for consumption into the United States, entry for consumption from a foreign trade zone, and withdrawal from a warehouse for consumption, for the remaining term of the patent, except under license of the patent owner or as provided by law.

2. Notwithstanding paragraph 1 of this Order, the aforesaid tadalafil or any salt or solvate thereof and products containing same are entitled to entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, under bond in the amount of 100 percent of entered value of such products, pursuant to subsection (j) of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(j), from the day after this Order is received by the United States Trade Representative, as delegated by the President, 70 *Fed. Reg.* 43251 (July 21, 2005), and until such time as the United States Trade Representative notifies the Commission that this Order is approved or disapproved but, in any event, not later than sixty (60) days after the date of receipt of this Order by the United States Trade Representative.

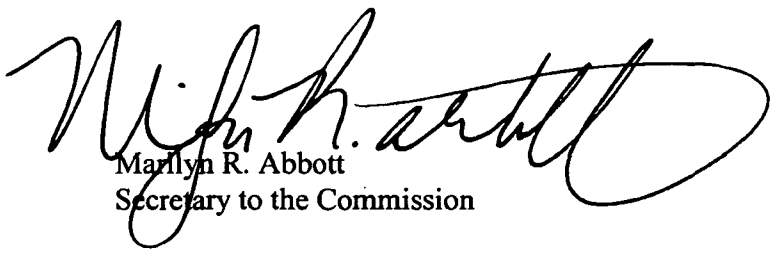
3. In accordance with 19 U.S.C. § 1337(l), the provisions of this Order shall not apply to products otherwise covered by this Order that are imported by and for the use of the United States, or imported for, and to be used for, the United States with the authorization or consent of the Government.

4. The Commission may modify this Order in accordance with the procedures described in section 210.76 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.76.

5. The Secretary to the Commission shall serve copies of this Order upon each party of record in this investigation and upon the Department of Health and Human Services, the Department of Justice, the Federal Trade Commission, and the Bureau of Customs and Border Protection.

6. Notice of this Order shall be published in the *Federal Register* pursuant to section 337(j)(1)(A) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(j)(1)(A) and section 210.49(b) of the Commission's rules of Practice and Procedure (19 C.F.R. § 210.49(b)).

By Order of the Commission.



Marilyn R. Abbott
Secretary to the Commission

Issued: June 13, 2006

CERTAIN TADALAFIL OF ANY SALTS OR SOLVATES THEREOF, AND PRODUCTS CONTAINING SAME **337-TA-539**

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF COMMISSION ISSUANCE OF GENERAL EXCLUSION ORDER; DECISION TO GRANT MOTION TO FILE A SURREPLY; TERMINATION OF INVESTIGATION AND GENERAL EXCLUSION ORDER** has been served on upon all parties and Commission Investigative Attorney, Jay Reiziss, Esq., via first class mail or certified mail on June 13, 2006.

Marilyn R. Abbott

Marilyn R. Abbott, Secretary
U.S. International Trade Commission
500 E Street, S.W.
Washington, D.C. 20436

ON BEHALF OF COMPLAINANT LILLY ISCOS LLC:

Bert W. Rein, Esq.
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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN TADALAFIL OR ANY SALT OR SOLVATE THEREOF AND PRODUCTS CONTAINING SAME	)	**Inv. No. 337-TA-539**

COMMISSION OPINION

INTRODUCTION

This investigation is before the Commission for final disposition, including determinations on remedy, the public interest, and bonding.

PROCEDURAL BACKGROUND

The Commission instituted this investigation based on a complaint filed by Lilly ICOS LLC ("Lilly") of Wilmington, Delaware, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. 70 *Fed. Reg.* 25601 (May 13, 2005). The complaint, as supplemented, alleged violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain tadalafil or any salt or solvate thereof, and products containing same by reason of infringement of claims 1-4, 6-8, 12, and 13 of U.S. Patent No. 5,859,006. Tadalafil is a pharmaceutical composition used for the treatment of erectile dysfunction. Lilly markets its tadalafil composition under the trade name Cialis®.

The complaint and notice of investigation named ten respondents. On September 12,

2005, the Commission issued a notice indicating that it had determined not to review an initial determination ("ID") (Order No. 5) finding four respondents, *viz.*, Santovittorio Holdings Ltd. d/b/a Inhousepharmacy.co.uk of El Dorado, Panama; Stop4Rx of Port-au-Prince, Haiti; Rx Mex-Com, S.A. de C.V. of Colonia Las Brisas, Mexico; and www.Nudewfds.info of New Orleans, Louisiana in default. The presiding administrative law judge ("ALJ")also found that respondent Express Generic had not been properly served with the complaint. Order No. 5 was not reviewed by the Commission.

On November 17, 2005, the Commission issued a notice that it had determined not to review an ID (Order No. 9) finding an additional five of the originally named respondents in default. The additional five respondents were Budget Medicines Pty Ltd., of Sydney, Australia; Generic Cialis Pharmacy of Managua, Nicaragua; Cutprice Pills of Scottsdale, Arizona; Allpills.us of Beverly Hills, California; and Pharmacy4u.us of New York, New York.

On October 28, 2005, Lilly filed a motion for summary determination on the issues of domestic industry and violation of section 337 by reason of patent infringement with respect to the nine respondents that were found in default. On November 14, 2005, the Commission investigative attorney ("IA") filed a response in support of the motion.

On December 6, 2005, the ALJ issued an ID (Order No. 10) granting Lilly's motion for a summary determination of a violation of section 337 with respect to the nine defaulting respondents. At the same time, the ALJ recommended issuance of a general exclusion order under section 337(g)(2), 19 U.S.C. § 1337(g)(2). The ALJ also recommended that the bond permitting importation during the period of Presidential review be set at 100 percent of the value

of the infringing imported products. No party petitioned for review of the ID, and the Commission declined to review it. The ID finding a violation of section 337 became the Commission's final determination on January 4, 2006. 71 *Fed. Reg.* 1452 (Jan. 9, 2006).

Pursuant to the Commission's notice, Lilly and the IA submitted main briefs on the issues of remedy, the public interest, and bonding on January 17, 2006, with draft general exclusion orders attached. The IA filed a reply submission on January 24, 2006. Lilly filed a motion to file a surreply with its surreply attached on February 9, 2006.

DISCUSSION

A. Remedy

1. The RD

The ALJ found that the issuance of a general exclusion order in this investigation case is authorized by section 337(g)(2), which provides:

> In addition to the authority of the Commission to issue a general exclusion order 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.

19 U.S.C. §1337(g)(2)(A)-(C). Section 337(d)(2), referred to in section 337(g)(2)(C), provides:

> 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 the infringing product.

19 U.S.C. §1337(d)(2)(A)-(B)

The ALJ determined that section 337(g)(2) authorized the issuance of a general exclusion order in this investigation because no party appeared to contest the investigation. He noted that of the nine entities who were served with the complaint and notice of investigation, nine were found in default. [1] The tenth entity, Express Generic, was not properly served and, therefore, not found in default.[2] Regarding the nine entities who were properly served, the ALJ found that Lilly has "amply established by 'substantial, reliable, and probative evidence' that a violation has occurred and continues to occur."[3] The Commission determined not to review the ID's finding of violation, thereby allowing it to become the Commission's final determination. 71 *Fed. Reg.* 1452 (Jan. 9, 2006).

Turning to his recommendation on remedy, the ALJ further found that the conditions for

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[1] Santovittorio Holdings Ltd d/b/a Inhousepharmacy.co.uk; Stop4Rx; Rx Mex-Com, S.A. de C.V.; www.Nudewfds.info; Budget Medicines Pty Ltd.; Generic Cialis Pharmacy; Cutprice Pills; Allpills.us; and Pharmacy4Us.us. *See* ALJ Order No.10 at 2.

[2] ALJ Order No. 10 at 2.

[3] *Id.* at 3.

issuing a general exclusion order set forth in section 337(d)(2) and in *Certain Airless Paint Spray Pumps and Components Thereof*, Inv. No. 337-TA-90, Comm'n Opinion (Nov. 1981) ("*Spray Pumps*") were present in this case.[4] In particular, he noted the positions of Lilly and the IA that Cialis is a popular drug; infringers offer tadalafil compositions over the Internet at significantly lower prices than Lilly, often not requiring a prescription; and it is not difficult for foreign entities to gain access to the U.S. market through Internet sales.[5] Concerning circumvention, the ALJ noted that infringers operate through the Internet with little contact information, making it difficult to take effective action against individual suppliers.[6] The ALJ concluded that the considerations in this investigation are similar to those found in *Certain Sildenafil or Any Pharmaceutically Acceptable Salt Thereof, such as Sildenafil Citrate and Products Containing Same*, Inv. No. 337-TA-489, where the Commission found a general exclusion order to be appropriate.[7] Based on these considerations, he found that the *Spray Pumps* factors were satisfied and that a general exclusion order was warranted. [8]

2. Lilly's Position Before the Commission

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[4] *Id.* The Commission has determined that the statutory standards in section 337(d)(2) do not differ significantly from the standards that the Commission set forth in *Spray Pumps*. *Certain Neodymium-Iron-Boron Magnets, Magnet Alloys, and Articles Containing Same,* Inv. No. 337-TA-372, Commission Opinion on Remedy, the Public Interest, and Bonding at 5 (USITC Pub. No. 2964 (1996)).

[5] Order No. 10 at 9.

[6] *Id.*

[7] *Id.*

[8] *Id.*

Lilly argues that a general exclusion order is the appropriate remedy in this case, noting that the Commission has the authority to issue a general exclusion order under section 337(g)(2), where, as here, no person appears to contest the investigation.[9] Lilly argues that a general exclusion order is appropriate under the two factors set forth in *Spray Pumps, i.e.*: (1) "a widespread pattern of unauthorized use of the patented invention, and (2) certain business conditions from which one might reasonably infer that foreign manufacturers other than respondents to the investigation may attempt to enter the U.S. market with infringing articles."[10]

Lilly notes that the Commission has found the following two factors relevant to showing a "widespread pattern of unauthorized use:" (1) "a determination of unauthorized importation into the United States of infringing articles by numerous foreign manufacturers; and (2) other evidence which demonstrates a history of unauthorized foreign use of the patented invention."[11] In this investigation, Lilly argues that "a number of entities in India manufacture tadalafil,"[12] and provides Exhibit No. 28 illustrating that fact. Moreover, Lilly argues that "a cursory search of the internet" reveals the widespread availability of infringing tadalafil, and, consequently, there is a widespread pattern of unauthorized use.[13]

Next, Lilly maintains that the second prong of the *Spray Pumps* test - "certain business

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[9] Lilly Br. at 5.

[10] *Id.* (quoting *Spray Pumps* at 17-18).

[11] *Id.*, citing *Spray Pumps* at 18-19.

[12] *Id.* at 7.

[13] *Id.* at 8.

conditions" - is also satisfied. Lilly notes that this prong includes consideration of factors such as: (1) an established market for the patented product in the U.S. market and conditions of the world market; and (2) the availability of marketing and distribution networks in the United States for potential foreign manufacturers.[14] Regarding the "established market" prong, Lilly maintains that as many as one-third to one-half of men aged 40 and older suffer from some sort of erectile dysfunction.[15] Lilly states that its global sales of Cialis® were approximately $203.3 million in 2003, and approximately $552.3 million in 2004. Thus, Lilly maintains that Cialis® is "fast becoming one of the most recognized pharmaceutical brands in the world."[16]

Lilly states that because defaulting respondents (and other infringing entities) do not bear the same research and development costs as Lilly does, those entities can offer copies of Cialis® at significantly lower prices.[17] Moreover, Lilly states that the defaulting respondents have easy access to the United States market via the Internet, making it difficult to identify and shut down these infringing suppliers.[18] Thus, Lilly maintains that a general exclusion order is necessary to prevent infringement of its patent.[19]

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[14] *Id.* at 7 citing *Spray Pumps*, at 19.

[15] *Id.* at 8. Lilly maintains that approximately 30 million male adults in the U.S. suffer from some degree of erectile dysfunction. *Id.*

[16] *Id.*

[17] *Id.* at 8-9.

[18] *Id.* at 9-10. For example, Lilly states that it could not serve the non-defaulting respondent in this case because it could not obtain a valid address for the company. Lilly submits that it is unclear whether that respondent still imports infringing products into the US. *Id.* at 10.

[19] *Id.* at 10.

Lilly proposes that several novel provisions should be added to the Commission's standard general exclusion order.[20] These provisions are summarized below:

1. Lilly will make reasonable efforts to monitor and periodically provide the Commission with reports identifying entities it believes to be engaged in the importation, sale for importation, or sale in the United States after importation of the infringing products, based upon evidence that such entities have (1) offered such products for sale on an Internet website either specifically for import into the United States or without geographical restrictions; and (2) accepted orders for such products via the Internet for shipping to addresses in the United States. Lilly, however, will not be required to provide any information regarding any website, company, or persons that Lilly is aware of, or believes to be, the subject of a separate, non-public law enforcement investigation.

2. Upon receipt of such information from Lilly, the Commission will send the identified parties a letter providing specific notification of the general exclusion order and requesting that, to facilitate U.S. Customs enforcement of the order, the identified party post within seven days a recommended disclaimer in a conspicuous location on their website in close proximity to where the tadalafil product is being advertised, offered, or sold, stating that it is unlawful to import products containing tadalafil to the United States. Under this provision, failure to post the disclaimer may be deemed by Customs to be a reasonable indication of an attempt to foster importation of articles excluded under the terms of the general exclusion order.

3. The Commission will provide copies of its letter to any third party payment facilitator (*e.g.*, Visa, MasterCard, American Express, Discover, Paypal) specifically appearing on the identified party's website, to Lilly ICOS, and to the U.S. Bureau of Customs and Border Protection (Customs), the Food & Drug Administration, and the Department of Justice.[21]

Lilly argues that the additional provisions are necessary to encourage voluntary compliance with

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[20] *See Id.* at 12-13.

[21] *See also* Lilly Proposed Order at 2-3.

the general exclusion order and to facilitate monitoring of the order by Customs and Lilly.[22]

3. The IA's Position before the Commission

Although the IA agrees that a general exclusion order is the appropriate remedy in this investigation, he recommends against the inclusion of Lilly's proposed additional provisions and contends that the Commission's standard general exclusion order provisions are sufficient to protect Lilly. The IA recommends against the inclusion of Lilly's novel provisions for several reasons. First, he argues that the additional provisions might interfere with Customs' authority and discretion in enforcing the general exclusion order.[23] He notes that Customs has the responsibility to enforce section 337 general exclusion orders, and the Commission's exclusion orders normally do not establish specific procedures for that enforcement.[24] Indeed, he noted that the Commission has repeatedly stated that enforcement of a general exclusion order is the responsibility of Customs. *See Certain Lens-Fitted Film Packages* at 11 (find that "an exclusion order is an *in rem* order, which is interpreted and enforced by the US Customs Service . . . ."); *Certain Agricultural Tractors, Lawn Tractors, Riding Lawnmowers, and Components Thereof*, Inv. No. 337-TA-486, USITC Pub. No. 3625, Comm'n Op. at 12 (August 2003) ("the enforcement of section 337 exclusion orders [is] the responsibility of Customs" . . .).[25]

Second, he argues that it would be more efficient if Lilly or Customs directly notified any

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[22] Lilly Br. at 13.

[23] IA Reply Br. at 4.

[24] *Id.*

[25] *Id.*

retailer that Lilly believes is in noncompliance with the general exclusion order. He believes that having the Commission undertake such notification would add unnecessary complexity to the enforcement of the exclusion order. The IA also believes that the novel provisions proposed by Lilly would strain the Commission's already stretched resources. The IA submits that Lilly is free to solicit the voluntary support of credit card companies and other payment services to aid in enforcement of the general exclusion order.[26]

Third, the IA points out that Lilly contended in arguing for a general exclusion order that "the entities involved in the sale of infringing tadalafil into the U.S. are typically not legitimate business operations but rather "fly-by-night entities that would have no qualms about changing or obscuring their identities in order to evade a limited exclusion order." [27] The IA reasons that such "fly-by-night entities" would be no more likely to comply with a letter from the Commission than with a notification from Customs.[28]

Finally, the IA is troubled by the provision that a failure to post a disclaimer within seven days after receipt of a Commission letter would give rise to a presumption that the entity intended to foster importation of infringing articles. In the IA's view such a presumption may raise due

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[26] *Id.* at 6. The IA supports his statement by citing Exhibit 5 to Lilly's brief, Written Statement of Mark MacCarthy on Behalf of Visa, U.S.A. Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives (December 13, 2005) at 3 ("When alerted that specific Internet pharmacies may be accepting Visa cards for illicit transactions, Visa has worked with its member financial institutions to investigate these pharmacies and to terminate the acceptance of Visa cards for illicit activities.")

[27] IA's Reply brief at 7, citing Lilly's brief at 9-10.

[28] IA's Reply brief at 7-8.

process issues.

4. Lilly's Surreply

In its surreply, Lilly argues that because the IA raised new objections to several provisions in Lilly's proposed order, its surreply should be accepted by the Commission even though the Commission's notice did not provide for such surreplies. Lilly's surreply addresses the IA's statement that one of Lilly's provisions may raise due process concerns, and Lilly's disagreement with the IA's contentions that the additional measures would be both ineffective and unduly burdensome for the Commission and Customs to administer. We grant the motion to file the surreply. However, as discussed below, we do not find Lilly's arguments persuasive.

4. Analysis

We agree with the ALJ that a general exclusion order is the appropriate remedy in this investigation and that the same considerations apply here that applied in the *Sildenafil* investigation. We also agree with the IA that Lilly's novel provisions should not be included in the Commission's order. Lilly's novel provisions call for Lilly to notify the Commission when Lilly believes that defaulting respondents or other entities are violating the general exclusion order. The Commission would then in turn notify each website of the general exclusion order and notify Customs about the offending website. We agree with the IA that such a procedure is neither "necessary [n]or appropriate" to secure compliance with the general exclusion order.[29] If Lilly believes that a particular entity has circumvented the general exclusion order, Lilly itself could notify Customs and/or the particular entity. There is no basis for Commission involvement

[29] *Id.* at 5.

at this level of the enforcement process. Commission involvement in this manner would unnecessarily add an additional party to the procedure and interfere with Customs' enforcement process. Moreover, because enforcement of a general exclusion order is the responsibility of Customs, any concerns regarding enforcement should be directed to Customs in the first instance.

We also agree with the IA that it is unclear how the additional provisions would facilitate the enforcement process.[30] There is no reason to assume that a letter from the Commission would be more effective than a notification from Customs in preventing violations of the general exclusion order. Finally, we agree with the IA that the novel provisions proposed by Lilly would be unduly burdensome for the Commission.

The Commission has broad discretion in fashioning remedies under section 337. *Viscofan, S.A. v. United States Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir.1986)("the Commission has broad discretion in selecting the form, scope, and extent of the remedy, and judicial review of its choice of remedy necessarily is limited."). In our view, there are sufficient reasons to decline to adopt Lilly's novel provisions without considering the due process issues raised by the IA.

B. Bonding

The ALJ recommended that bond provided for during the period of Presidential review, 19 U.S.C. § 1337(j), be set in the amount of 100 percent of entered value. The ALJ found that there was only limited evidence of the prices charged by defaulting respondents because they did not participate in the investigation. He further found that the evidence that did exist

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[30] *See Id.* at 7.

demonstrated a wide range of prices charged by the respondents, and that respondents' prices generally were well below the retail price charged for Lilly's Cialis® product. He found that under *Certain Oscillating Sprinklers, Sprinkler Components, and Nozzles*, Inv. No. 337-TA-448 (Limited Exclusion Order March 2002), the appropriate bond in such circumstances is 100 percent of entered value.

The IA and Lilly support the ALJ's bond recommendation, and we see no reason to reject it. Accordingly, we set the bond during the period of Presidential review at 100 percent of entered value.

C. The Public Interest

Prior to issuing relief pursuant to section 337, the Commission is required to consider the effect of such relief on "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 United States consumers." 19 U.S.C. § 1337(d).

Lilly argues that protection of intellectual property rights is an important public interest. It also maintains that it can meet the domestic consumer demand for tadalafil if infringing imports disappear from the U.S. market. Moreover, Lilly argues that a general exclusion is actually in the public interest because unapproved tadalafil products pose a potential risk to the public health, whereas Lilly's product has been proven to be safe and effective and is produced only in facilities that are approved by the Food and Drug Administration. The IA makes essentially the same arguments. We agree that there are no public interest considerations here

that would prevent the issuance of a general exclusion order in this investigation.[31]

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: June 16, 2006

[31] The Commission has denied relief based on its consideration of the public interest factors in only three case, *i.e.*, *Automatic Crankpin Grinders*, Inv. No. 337-TA-60 (1978); *Inclined Field Acceleration Tubes*, Inv. No. 337-TA-67 (1980); and *Fluidized Supporting Apparatus*, Inv. No. 337-TA-182/188 (1984). In all of these cases, the domestic industry could not adequately supply the U.S. market.

CERTAIN TADALAFIL OF ANY SALTS OR SOLVATES THEREOF, AND PRODUCTS CONTAINING SAME **337-TA-539**

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **COMMISSION OPINION** has been served on upon all parties and Commission Investigative Attorney, Jay Reiziss, Esq., via first class mail or certified mail on June 16, 2006.

Marilyn R. Abbott, Secretary
U.S. International Trade Commission
500 E Street, S.W.
Washington, D.C. 20436

ON BEHALF OF COMPLAINANT LILLY ISCOS LLC:

Bert W. Rein, Esq.
WILEY REIN & FIELDING LLP
1776 K Street, N.W.
Washington, D.C. 20006
P-202-719-7000
F-202-719-7049

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN TADALAFIL OR ANY SALT OR SOLVATE THEREOF AND PRODUCTS CONTAINING SAME	)	Inv. No. 337-TA-539

NOTICE OF COMMISSION DECISION NOT TO REVIEW AN INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337; SCHEDULE FOR WRITTEN SUBMISSIONS ON REMEDY, PUBLIC INTEREST, AND BONDING

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination ("ID") (Order No. 10) issued by the presiding administrative law judge ("ALJ") finding a violation of section 337 in the subject investigation.

FOR FURTHER INFORMATION CONTACT: Steven Crabb, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-5432. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted by the Commission based on a complaint filed by Lilly ICOS LLC ("Lilly") of Wilmington, DE under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. 70 *Fed. Reg.* 25601 (May 13, 2005). The complainant alleged violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain tadalafil or any salt or solvate thereof, and products containing same by reason of infringement of claims 1-4, 6-8, 12, and 13 of U.S. Patent No. 5,859,006. The complaint and notice of investigation named ten respondents.

On September 12, 2005, the Commission issued a notice indicating that it had determined not to review an ID (Order No. 5) finding respondents Santovittorio Holdings Ltd. d/b/a Inhousepharmacy.co.uk of El Dorado, Panama, Stop4Rx of Port-au-Prince, Haiti, Rx Mex-Com, S.A. de C.V. of Colonia Las Brisas, Mexico, and www.Nudewfds.info of New Orleans, LA, in default. The ALJ also found that respondent Express Generic had not been properly served with the complaint.

On November 17, 2005, the Commission issued a notice that it had determined not to review an ID (Order No. 9) finding an additional five of the originally named respondents in default. The additional five respondents were Budget Medicines Pty Ltd., of Sydney, Australia, Generic Cialis Pharmacy of Managua, Nicaragua, Cutprice Pills of Scottsdale, AZ, Allpills.us of Beverly Hills, CA, and Pharmacy4u.us of New York, NY.

On October 28, 2005, Lilly filed a motion for summary determination on the issues of the existence of a domestic industry and violation of section 337 with respect to the nine respondents that were found in default. On November 14, 2005, the Commission Investigative Attorney ("IA") filed a response to Lilly's motion.

On December 6, 2005, the ALJ issued the subject ID (Order No. 10) granting Lilly's motion for a summary determination of a violation of section 337. With respect to the remedy, the ALJ recommended the issuance of a general exclusion order under section 337(g)(2), 19 U.S.C. § 1337(g)(2). The ALJ also recommended that the bond permitting importation during the Presidential review period be set at 100 percent of the value of the infringing imported products. No party petitioned for review of the subject ID. The Commission has determined not to review this ID with respect to the finding of a violation of section 337, and to request written submissions with respect to remedy, bonding, and the public interest.

In connection with the final disposition of this investigation, the Commission may issue an order that could result in the exclusion of the subject articles from entry into the United States. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, it should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *In the Matter of Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

When the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider in this investigation include the effect that an exclusion order would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

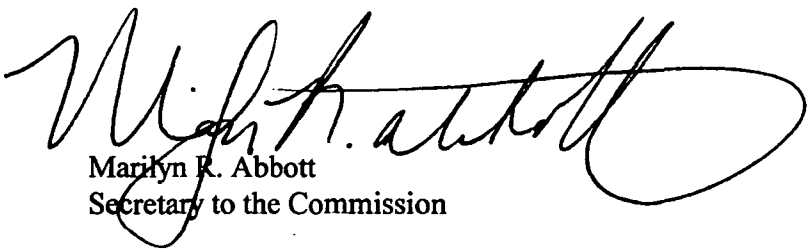
If the Commission orders some form of remedy, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under a bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed.

WRITTEN SUBMISSIONS: The parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on remedy, bonding, and the public interest. Such submissions should address the December 6, 2005, recommended determination (Order No. 10) by the ALJ on remedy and bonding. Complainants and the Commission's investigative attorney are also requested to submit proposed orders for the Commission's consideration. Complainants are further requested to state the expiration date of the patent at issue and the HTSUS numbers under which the infringing goods are imported. Main written submissions and proposed orders must be filed no later than close of business on January 17, 2006. Reply submissions, if any, must be filed no later than the close of business on January 24, 2006. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file with the Office of the Secretary the original document and 14 true copies thereof on or before the deadlines stated above. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons that the Commission should grant such treatment. *See* section 201.6 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 201.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in section 210.42 and 210.50 of the Commission's Rules of Practice and Procedure (19 C.F.R. §§ 210.42 and 210.50).

By order of the Commission.



Marilyn R. Abbott
Secretary to the Commission

Issued: January 4, 2006

CERTAIN TADALAFIL OF ANY SALTS OR SOLVATES THEREOF, AND PRODUCTS CONTAINING SAME **337-TA-539**

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF COMMISSION DECISION NOT TO REVIEW AN INITIAL DETERMINATION FINDING A VIOLTATION OF SECTION 337; SCHEDULE FOR WRITTEN SUBMISSIONS ON REMEDY, PUBLIC INTEREST, AND BONDING** has been served on upon all parties and Commission Investigative Attorney, Jay Reiziss, Esq., via first class mail or certified mail on January 5, 2006.

Marilyn R. Abbott

Marilyn R. Abbott, Secretary
U.S. Int . Trade Commission
500 E Street, S.W.
Washington, D.C. 20436

ON BEHALF OF COMPLAINANT LILLY ISCOS LLC:

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PROPOSED RESPONDENTS:

EXPRESS GENERIC
c/o JNC Worldwide, Inc.
246 West 38th Street
New York, NY 10018

JNC WORLDWIDE, INC.
246 West 38th Street
New York, NY 10018

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of	
CERTAIN TADALAFIL OR ANY SALT OR SOLVATE THEREOF AND PRODUCTS CONTAINING SAME	Inv. No. 337-TA-539

ORDER NO. 10: INITIAL DETERMINATION GRANTING COMPLAINANT'S MOTION FOR SUMMARY DETERMINATION AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

(December 6, 2005)

I. Background

On October 28, 2005, Complainant Lilly ICOS LLC ("Lilly") filed a motion [539-005] pursuant to 19 C.F.R. § 210.18 for summary determination on the issues of the existence of a domestic industry and violation of Section 337. On November 14, 2005, the Commission Investigative Staff ("Staff") filed a response in support of Lilly's motion. No other responses to the motion were filed. On November 30, 2005, Lilly filed an affidavit in support of its motion.

On April 8, 2005 Lilly filed of a complaint with the Commission pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. Lilly's complaint alleged violations of Section 337 by all named respondents in connection with the importation, sale for importation, and sale within the United States after importation of certain tadalafil or any salt or solvate thereof and products containing same, by reason of infringement of Claims 1-4, 6-8 and 12-13 of U.S. Patent No. 5,859,006 ("the '006 patent"). On May 9, 2005, the Commission issued a Notice of Investigation that

was subsequently published in the Federal Register on May 13, 2005.[1] The Notice of Investigation listed ten entities as respondents. Of these, nine were found to be in default.[2] One more was never found to have been served with the complaint and notice of investigation, and did not otherwise participate in the investigation.[3] Thus, none of the named respondents have contested Lilly's allegations that they have violated and continue to violate Section 337. Lilly's motion seeks, in addition to a summary determination of a Section 337 violation and the existence of a domestic industry, the entry of a general exclusion order against all infringing imports of accused tadalafil products.[4]

II. Relevant Law

The standards for granting a motion for summary determination under 19 C.F.R. § 210.18(a) are well-recognized and need no repetition here.[5] It is useful to note that the Commission's Rules require an appropriate, properly supported, unopposed motion for summary determination to be

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1 *See* Notice of Investigation, 70 Fed. Reg. 25601 (May 13, 2005).

2 The nine defaulting respondents are as follows: Santovittorio Holdings Ltd d/b/a/ Inhousepharmacy.co.uk; Stop4Rx; Rx Mex-Com, S.A. de C.V.; www.Nudewfds.info; Budget Medicines Pty Ltd.; Generic Cialis Pharmacy; Cutprice Pills; Allpills.us; and Pharmacy4Us.us. *See* Unreviewed Initial Determinations, Order Nos. 5 (August 22, 2005) and 9 (October 17, 2005).

3 The one respondent that was never found to have been formally served was Express Generic. *See* Lilly Memorandum at 1, n. 1; Staff Response at 3, n. 2.

4 *See* Lilly Memorandum at 1, 11.

5 *See* 19 C.F.R. § 210.18(b); *see also Anchor Wall Systems, Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1306 (Fed. Cir. 2003) ("*Anchor*").

granted.[6] In addition, as detailed in the *Sildenafil*[7] case, given that none of the Respondents have entered an appearance or contested any of the allegations against them, Lilly must come forward with "substantial, reliable, and probative evidence" as required by Section 337(g)(2)(B) to show that a general exclusion order is warranted, and must also meet the *Spray Pumps*[8] factors of Section 337(d) as required by Section 337(g)(2)(C).

III. Discussion

As discussed in further detail below, Lilly has amply established by "substantial, reliable, and probative evidence" that a violation has occurred and continues to occur, and that the *Spray Pumps* conditions for issuing a general exclusion order are present in this case.

A. Importation

Lilly contends that its Complaint includes detailed allegations of importation by each of the nine Respondents that were served with the Complaint.[9] Specifically, the [ ] declaration attached to the complaint demonstrates that each of the defaulting Respondents has imported accused

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[6] *See* 19 C.F.R. § 210.18(c) ("If the opposing party does not so respond, a summary determination, if appropriate, *shall* be rendered against the opposing party." (emphasis added)).

[7] *Certain sildenafil or any pharmaceutically acceptable salt thereof, such as sildenafil citrate, and products containing same*, Inv. No. 337-TA-489, Order No. 19: Initial Determination (October 27, 2003) (unreviewed by Commission) (*"Sildenafil"*).

[8] *Certain Airless Paint Spray Pumps and Components Thereof*, Inv. No. 337-TA-90, USITC Pub. No. 1199, Commission Opinion, 216 U.S.P.Q. 465 (U.S.I.T.C., November 1981).

[9] *See* Lilly Memorandum at 9-10.

tadalafil products into the United States.[10] The Staff concurs with these findings.[11] Accordingly, the undersigned finds that there is a sufficient factual showing to establish importation of the accused products.

B. Infringement of the '006 Patent

Concerning violation of Section 337, Lilly's motion establishes, and the Staff concurs, that there is a violation by reason of the Respondents' importation into the United States, sale for importation in the United States, or sale within the United States after importation, of certain tadalafil or any salt or solvate thereof and products containing same, by reason of infringement of Claims 1-4, 6-8 and 12-13 of the '006 patent.[12] Lilly's complaint includes a declaration of Dr. David Reed, a Lilly research advisor, which identifies the chemical analysis of each product tested demonstrating that the products imported into the United States by the Respondents contain tadalafil and therefore infringe the '006 patent.[13] Dr. Reed's declaration includes detailed chemical analysis reports prepared by Lilly that show the presence of tadalafil in each defaulting respondent's

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[10] [ ] is a private investigation that was retained by Lilly to purchase the accused products from the Respondents. *See* Complaint, Appendix C ([ ]Declaration & accompanying exhibits).

[11] *See* Staff Response at 6-7. The Staff clarifies two points, however. First, with respect to the tablets sold by Express Generic, they were branded as "Tadalis," which is associated with the Indian manufacturer Ajanta Pharma. *See* Exhibits 26 & 32 to Complaint; [ ] Declaration at ¶ 15. Second, the tablets sold by www.nudewfds.info indicated that they were manufactured by Richie Laboratories Ltd., an Indian manufacturer. *See* Exhibits 26 & 33 to Complaint; [ ] Declaration at ¶ 46.

[12] *See* Lilly Memorandum at 10; Staff Response at 7-8.

[13] Complaint, Exhibit 26 (Reed Declaration at ¶¶ 16-21).

product.[14] Additionally, the Reed declaration includes a claim chart demonstrating that the tadalafil present in Respondents' products is covered by claims 1-4, 6-8 and 12-13 of the '006 patent.[15] Accordingly, Lilly has met its burden that there are no genuine issues of material fact in dispute that the accused products infringe the asserted claims of the '006 patent.

C. Domestic Industry

Lilly's motion, with Staff concurrence, also demonstrates that a domestic industry exists that practices the '006 patent in accordance with Section 337(a)(2) and (3).[16] Under Section 337(a)(3), a domestic industry exists: (1) if the domestic articles are "protected by the patent . . . concerned," *i.e.*, practice one or more of the claims of the patent; and (2) if there exist in the United States with respect to those articles one or more of the following:

1. Significant investment in plant and equipment;
2. Significant employment of labor or capital; or
3. Substantial investment in the exploitation of the patent, including engineering, research and development, or licensing.[17]

Lilly's motion satisfies both the first, so-called "technical prong" and the second, so-called "economic prong" of the domestic industry requirements.

Regarding the technical prong, documents attached to the Complaint, along with Lilly's interrogatory responses and production of documents in response to the Staff's discovery requests,

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[14] Reed Declaration ¶¶ 6-14.

[15] *See* Reed Declaration, Appendix C; Lilly Memorandum at 10; Staff Response at 9.

[16] *See* 19 U.S.C. §§ 1337(a)(2) and (a)(3); Lilly Memorandum at 5; Staff Response at 9-10.

[17] *See* 19 U.S.C. § 1337(a)(3).

show that the technical prong has been met. Attached to the Complaint is the declaration of Dr. Reed,[18] which shows that each of the asserted claims of the '006 patent embraces tadalafil or any salt or solvate thereof. Tadalafil is the active ingredient in Cialis®, Lilly's domestic drug for the treatment of erectile dysfunction.[19] The Staff concurs with Lilly's assertions.[20] Accordingly, Lilly has met its burden that there are no genuine issues of material fact remaining in dispute that Lilly's products satisfy the technical prong of the domestic industry requirement with respect to the '006 patent.

With regard to the economic prong, Lilly has submitted an affidavit of Lilly employee Donald L. Corneglio, stating that Cialis® is manufactured at [ ] Lilly facilities in the United States.[21] The facilities are located in [ ][22] The total combined size of the [ ] plants is [ ] square feet, [ ] of which is dedicated to the production of Cialis®.[23] Lilly estimates that its total investment in plant and equipment used in the production of Cialis® for the past three years is [ ] million.[24] In addition, Lilly employs approximately [ ] employees in the United States who are involved in activities relating to Cialis's®

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18 Complaint, Exhibit 26 (Reed Declaration).

19 *See* Lilly Memorandum at 5-6; Staff Response at 1, n. 1; 9; Reed Declaration at ¶ 5; Appendix A.

20 *See* Staff Response at 9.

21 *See* Corneglio Declaration at ¶ 3; Lilly Memorandum at 6-7.

22 *See* Corneglio Declaration at ¶ 3.

23 *See* Corneglio Declaration at ¶ 3.

24 *See* Corneglio Declaration at ¶ 3.

annual labor costs of approximately [ ] million.[25] In addition, Lilly asserts that its investment in research and development in connection with Cialis® was $63.6 million in 2003 and $67.3 million 2004.[26] The Staff concurs with these statements.[27] Accordingly, Lilly has met its burden that there are no genuine issues of material fact remaining in dispute that Lilly satisfies the economic prong of the domestic industry requirement with respect to the '006 patent.

D. Validity of the '006 Patent

As for the validity of the '006 patent, its validity is presumed by law and has not been challenged in this proceeding by the Staff or by any Respondent.[28]

E. Conclusion on Violation of Section 337

In accordance with the foregoing reasons, Lilly has demonstrated by "substantial, reliable, and probative evidence," with the concurrence of the Staff, that there is a violation of Section 337 by reason of the defaulting Respondents' importation into the United States, sale for importation, and sale within the United States after importation, of certain tadalafil , that infringe Claims 1-4, 6-8 and 12-13 of the '006 patent.

IV. Recommended Determination on Remedy and Bonding

A. General Exclusion Order

Following the issuance of an initial determination on violation of Section 337, the administrative law judge must also issue a recommended determination concerning the appropriate

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25 *See* Corneglio Declaration at ¶ 4.

26 *See* Lilly Memorandum at 7.

27 *See* Staff Response at 10.

28 *See* 35 U.S.C.. § 282; Lilly Memorandum at 9; Staff Response at 7.

remedy in the event that the Commission finds a violation of Section 337 and the amount of the bond to be posted by the respondents during the 60-day period of Presidential review of the Commission's action under Section 337(j).[29]

In the case of a finding of violation of Section 337 by defaulting respondents under Section 337(g)(2), a general exclusion order may issue if the requirements of Section 337 (d)(2) are met.[30] As mentioned earlier, these are the *Spray Pumps* factors, under which a general exclusion order is warranted if: "(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."[31] Under *Spray Pumps*, a two-pronged test must be satisfied for issuance of a general exclusion order. There must be (1) "a widespread pattern of unauthorized use of [the] patented invention;" and (2) "certain business conditions from which one might reasonably infer that foreign manufacturers other than respondents to the investigation may attempt to enter the U.S. market with infringing articles."[32] The following factors are considered relevant to demonstrating a widespread pattern of unauthorized use:

1. Commission determination of unauthorized importation into the United States of infringing articles by numerous foreign manufacturers; and

2. other evidence which demonstrates a history of unauthorized foreign use of the patented invention.[33]

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29 *See* 19 C.F.R. § 210.42(a)(1)(ii).

30 *See* 19 U.S.C. § 1337(g)(2)(C).

31 *See* 19 U.S.C. § 1337(d)(2).

32 *Spray Pumps, supra*, 216 U.S.P.Q. at 473.

33 *Id.*

The Commission has also identified a number of factors relevant to showing "certain business conditions," including:

1. an established market for the patented product in the U.S. market and conditions of the world market; and

2. the availability of marketing and distribution networks in the United States for potential foreign manufacturers.[34]

Both Lilly and the Staff agree that there is a "widespread pattern of unauthorized use" in that numerous entities in India manufacture tadalafil.[35] They also agree that infringing tadalafil is widely available on the Internet and through unsolicited bulk e-mail (also known colloquially as "spam").[36]

Concerning the presence of "business conditions" influencing such unfair imports, Lilly and the Staff agree that Cialis® is a popular drug, sales of which were in excess of $207 million in 2004.[37] Infringers offer their versions of Cialis® over the Internet at significantly lower prices than Lilly, often without requiring a prescription.[38] It is not difficult for foreign entities to gain access to the U.S. market, Lilly notes, citing numerous foreign manufacturers of infringing tadalafil products and ready access to the market through Internet sales.[39]

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34 *Id.*

35 Lilly Memorandum at 14; Staff Response at 13.

36 *See* Lilly Memorandum at 14; Staff Response at 13-14; Complaint, Exhibit 30.

37 *See* Lilly Memorandum at 15; Exhibit 3 to Lilly Memorandum; Staff Response at 14.

38 *See* Lilly Memorandum at 15.

39 *See* Lilly Memorandum at 15-16.

Concerning the possibility of circumvention, Lilly and the Staff note the difficulty of identifying and shutting down individual suppliers.[40] Both note that infringers operating through Internet web sites typically offer very limited contact information, making it difficult to take effective action against individual suppliers.[41]

Many of the considerations in this case are similar to those found in the *Sildenafil* case,[42] where a general exclusion order was found to be appropriate. Based on these considerations, it is readily apparent that the *Spray Pumps* factors have been satisfied by Lilly in this case and that a general exclusion order is, therefore, warranted.

B. Bond

In accordance with Section 337(j), the accused products are entitled to entry under bond during the 60-day period of Presidential review.[43] To the extent possible, the bond should be an amount that would be sufficient to protect the complainant from any injury.[44] Although the Commission frequently sets the bond on the basis of a difference in sales prices between the patented domestic product and the infringing product,[45] there is only limited evidence here of prices charged by the defaulting Respondents because they did not participate in the investigation. As Lilly and the

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40 *See* Lilly Memorandum at 16; Staff Response at 14-15.

41 *See* Lilly Memorandum at 16.

42 *Sildenafil, supra.*

43 19 U.S.C. § 1337(j).

44 19 C.F.R. § 210.50(a)(3).

45 *See Certain Microsphere Adhesives, Process for Making Same, and Products Containing Same, Including Self-stick Repositionable Notes*, Inv. No. 337-TA-366, USITC Pub. No. 2949, Commission Opinion at 24-25, 1996 WL 1056298 (January 1996).

Staff both point out, the evidence that does exist is based on Lilly's investigation and demonstrates a wide range of prices charged by the Respondents, generally well below the retail price charged for Lilly's Cialis® product.[46]

Where it has been difficult or impossible to calculate a bond based upon price differentials, and particularly where the respondents fail to provide discovery, the Commission has set the bond at 100 percent of the entered value of the infringing imported product.[47] Lilly and Staff concur, and the undersigned recommends as appropriate, that the bond in this instance should be set at 100 percent of the entered value of Respondents' accused products during the Presidential review period.

Accordingly, Motion No. 539-005 is granted. Pursuant to 19 C.F.R. § 210.38(d), the Administrative Law Judge hereby CERTIFIES to the Commission the record in this investigation. Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination or certain issues therein.

In accordance with 19 C.F.R. § 210.18(e), the undersigned hereby finds the following material facts in this investigation to be "without substantial controversy" and thus established:

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[46] *See* Lilly Memorandum at 18-19; Staff Response at 16.

[47] *See Certain Oscillating Sprinklers, Sprinkler Components, and Nozzles*, Inv. No. 337-TA-448, Limited Exclusion Order at 4-5 (March 2002) (setting bond at 100% of entered value with respect to the products of a defaulting respondent).

1. Lilly ICOS is a joint venture formed in 1998 between Eli Lilly and Company[48] and ICOS Corporation,[49] to develop and globally commercialize phosphodiesterase type 5 (PDE5) inhibitors for human therapeutic use including as oral therapeutic agents for the treatment of male erectile dysfunction. Lilly ICOS developed tadalafil for the treatment of erectile dysfunction. Tadalafil is the active ingredient in Cialis®, the erectile dysfunction drug produced by Lilly ICOS. Lilly ICOS has entered into a Marketing and Sales Service Agreement with Eli Lilly and Company and ICOS Corporation to, inter alia, co-promote Cialis® in the United States on behalf of Lilly ICOS, the exclusive licensee of the U.S. '006 patent.

2. Lilly ICOS has entered into a Toll Manufacturing Agreement with Eli Lilly and Company ("Eli Lilly") to manufacture the worldwide requirements for Cialis®, including quality control, storage and packaging. Pursuant to this agreement, Eli Lilly manufactures Cialis® at a number of plants in the United States. Eli Lilly has made substantial investments in plant and equipment used for Cialis® production in the United States on behalf of Lilly

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[48] Eli Lilly and Company is an Indiana corporation with a principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly and Company is a leading, innovation-driven corporation committed to developing a growing portfolio of best-in-class and first-in-class pharmaceutical products that help people live longer, healthier and more active lives. Lilly products treat depression, schizophrenia, attention-deficit hyperactivity disorder, diabetes, osteoporosis and many other conditions.

[49] ICOS Corporation is a Delaware corporation with a principal place of business at 22021 20th Avenue SE, Bothell, WA 98021. ICOS is a biotechnology company dedicated to bringing innovative therapeutics to patients. ICOS combines its capabilities in molecular, cellular and structural biology, high throughput drug screening, medicinal chemistry and gene expression profiling to develop highly innovative products expected to have significant commercial potential.

ICOS, and employs a significant amount of labor in the United States in the production of Cialis® on behalf of Lilly ICOS.[50]

3. Eli Lilly, on behalf of Lilly ICOS, is the sole producer of Cialis® in the United States. No Abbreviated New Drug Application ("ANDA") has been filed with or approved by the Food and Drug Administration ("FDA") with respect to generic tadalafil or generic tadalafil products. There is thus no approved production of generic tadalafil or generic tadalafil products in the United States. Further, after due investigation, Lilly ICOS has not discovered any production of unapproved tadalafil or unapproved tadalafil products in the United States.

4. Lilly ICOS has conducted significant research and development in the United States relating to its lawful exploitation of the '006 patent. To ensure the safety and efficacy of Cialis®, as well as to satisfy U.S. regulatory requirements, Lilly ICOS conducted extensive pre-market clinical testing of Cialis® in the United States. Since the approval of Cialis® by the FDA on November 21, 2003, Lilly ICOS has conducted, and continues to conduct, numerous additional clinical trials of Cialis® throughout the United States.

5. Lilly ICOS is the exclusive licensee of the '006 patent entitled "Tetracyclic derivatives; process of preparation and use." The patent was issued on January 12, 1999, based on Application No. 669389, filed by Alain Claude Marie Daugan, on behalf of Laboratoire Glaxo Wellcome S.A., on January 19, 1995.[51] ICOS Corporation is now the owner by assignment of the '006 patent from Laboratoire Glaxo Wellcome S.A. dated June 12, 1997,[52]

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[50] Complaint at Exhibit 1.

[51] Complaint at Appendices A and B.

[52] Complaint at Exhibit 25.

and ICOS Corporation exclusively licensed the patent in the United States to Lilly ICOS LLC on September 30, 1998.[53]

6. No evidence has been presented to rebut the statutory presumption that the '006 Patent is valid and enforceable.

7. Cialis® contains as its active ingredient, tadalafil, which is (6R,12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione. Claims 1-4, 6-8, and 12-13 of the '006 patent claim tadalafil at varying levels of generality. The approved product contains tadalafil in the form of a free base, which is described at column 36, lines 50-67, continuing to column 37, lines 1-14, in the '006 patent. Most specifically, tadalafil, the active ingredient in the approved product, is recited by its unique chemical name in claim 13 as (6R,12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)-pyrazino [2',1':6,1]pyrido[3,4-b]indole-1,4-dione. Accordingly, claims 1-4, 6-8, and 12-13 all read on tadalafil and the approved product, Cialis®.[54]

8. Each of the named respondents in this investigation has imported, sold for import into the United States, or sold in the United States after import, the product at issue in this investigation.[55]

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[53] Complaint at Exhibit 24.

[54] *See* Declaration of David E. Reed, Ph.D., Research Advisor with Eli Lilly and Co. (the "Reed Declaration"), Complaint at Exhibit 26

[55] Evidence of specific instances of importation by Respondents of products containing infringing tadalafil is provided in Lilly ICOS's Complaint and the accompanying Investigator's Declaration. Evidence with respect to each Respondent can be found as follows: **Pharmacy4U.us:** Complaint at ¶¶ 7, 36, and Exhibit 3, Investigator Declaration at ¶¶ 5-8 and accompanying exhibits, Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 1; **Santovittorio Holdings d/b/a Inhousepharmacy.co.uk:** Complaint at ¶¶ 8, 37-38, and Exhibit 5, Investigator Declaration at ¶¶ 9-12 and accompanying exhibits, Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 2; **Express Generic:** Complaint at ¶¶ 9, 39-40, and Exhibit 7, Investigator Declaration at ¶¶ 13-16

9. The products sold by Respondents contain tadalafil and therefore infringe claims 1-4, 6-8, and 12-13 of the '006 patent.[56]

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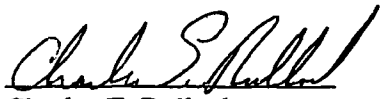
and accompanying exhibits, Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 3; **Cutprice Pills:** Complaint at ¶¶ 11, 41-42, and Exhibits 9-10, Investigator Declaration at ¶¶ 17-20 and accompanying exhibits, Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab; **Stop4Rx:** Complaint at ¶¶ 12, 43-44, and Exhibits 10 and 12, Investigator Declaration at ¶¶ 21-24 and accompanying exhibits, Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 5; **Allpills.us:** Complaint at ¶¶ 13, 45-46, and Exhibit 14, Investigator Declaration at ¶¶ 25-30 and accompanying exhibits, Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 6; **Generic Cialis Pharmacy:** Complaint at ¶¶ 14, 47-48, and Exhibit 16, Investigator Declaration at ¶¶ 31-35 and accompanying exhibits, Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 7; **Rx Mex-Com S.A. de C.V.:** Complaint at ¶¶ 15, 49-50, and Exhibit 18, Investigator Declaration at ¶¶ 36-39 and accompanying exhibits, Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 8; **Budget Medicines Pty Ltd:** Complaint at ¶¶ 16, 51-52, and Exhibit 20, Investigator Declaration at ¶¶ 40-43 and accompanying exhibits, Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 9; **Nudewfds.info:** Complaint at ¶¶ 17, 53, Investigator Declaration at ¶¶ 44-47 and accompanying exhibits, Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 10

[56] **Pharmacy4U.us:** Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 1; **Santovittorio Holdings d/b/a Inhousepharmacy.co.uk:** Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 2; **Express Generic:** Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 3; **Cutprice Pills:** Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 4; **Stop4Rx:** Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 5; **Allpills.us:** Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 6; **Generic Cialis Pharmacy:** Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 7; **Rx Mex-Com S.A. de C.V.:** Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 8; **Budget Medicines Pty Ltd:** Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 9; **Nudewfds.info:** Reed Declaration at ¶¶ 5-21, Appendix C, and Appendix D, Tab 10.

Within seven days of the date of this document, each party shall submit to the office of the administrative law judge a statement as to whether or not it seeks to have any portion of this document deleted from the public version to be issued shortly thereafter. The parties' submissions may be made by facsimile and/or hard copy by the aforementioned date.

Any party seeking to have any portion of this document deleted from the public version thereof must submit to this office a copy of this document with red brackets indicating any portion asserted to contain confidential business information. The parties' submissions concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.



Charles E. Bullock
Administrative Law Judge

IN THE MATTER OF TADALAFIL OR ANY SALTS OR SOLVATES THEREOF, AND PRODUCTS CONTAINING SAME **337-TA-539**

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **ORDER** was served upon, Jay H. Reiziss, Esq., Commission Investigative Attorney, and the following parties via first class mail and air mail where necessary on December 14, 2005.

Marilyn R. Abbott

Marilyn R. Abbott, Secretary
U.S. International Trade Commission
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Washington, D.C. 20436

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PROPOSED RESPONDENTS:

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Rel Mald (W)
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CUTPRICE PILLS
c/o V. Parab
Naoli Pada, Mr. Runwai
Samosa Chewi
Thane (E), India

IN THE MATTER OF TADALAFIL OR ANY SALTS OR SOLVATES THEREOF, AND PRODUCTS CONTAINING SAME **337-TA-539**

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