

**CERTIFIED MAIL - RETURN RECEIPT REQUESTED**

Elan Pharmaceuticals, Inc.  
800 Gateway Boulevard  
South San Francisco, CA 94080

Attn: Ginger Levy  
Vice President, Legal, R&D

Dear Ms. Levy:

The Bureau of Industry and Security, United States Department of Commerce ("BIS") has reason to believe that on eight occasions, Elan Pharmaceuticals, Inc. ("Elan") violated the Export Administration Regulations (the "Regulations"),<sup>1</sup> which are issued under the authority of the Export Administration Act of 1979 (the "Act").<sup>2</sup> Specifically, BIS charges that Elan committed the following violations:

**Charges 1-4 15 C.F.R. §764.2(a) - Unlicensed exports of toxins**

On four occasions from in or about May 2000 through in or about April 2002, Elan caused the export of items subject to the EAR (conotoxin -- Export Control Classification Number 1C351.d.3) from the United States to Belgium without the license required by Section 742.2 of the Regulations. These violations are further described in the attached Schedule A, which is incorporated by reference herein. In so doing, Elan committed four violations of Section 764.2(a) of the Regulations.

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<sup>1</sup> The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2004). The violations charged occurred from 2000 to 2002. The Regulations governing the violations at issue are found in the 2000 to 2002 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (2000-2002)). The 2004 Regulations establish the procedures that apply to this matter.

<sup>2</sup> From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which had been extended by successive Presidential Notices, the last of which was August 3, 2000 (3 C.F.R., 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 - 1706 (2000)) ("IEEPA"). On November 13, 2000, the Act was reauthorized and it remained in effect through August 20, 2001. Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), as extended by the Notice of August 6, 2004 (69 *Fed. Reg.* 48763, August 10, 2004), has continued the Regulations in effect under the IEEPA.

**Charges 5 - 8            15 C.F.R. § 764.2(e) - Exports of Conotoxin With Knowledge or Reason to Know That Violations Would Occur**

In exporting the items described in Charges One through Four above, Elan transferred those items with knowledge or reason to know that violations of the Regulations would occur. Specifically, Elan had knowledge or reason to know that Department of Commerce licenses were required to export the items to Belgium and Elan transferred the items with knowledge that Department of Commerce licenses would not be obtained. These violations are further described in the attached Schedule A, which is incorporated by reference herein. In so doing, Elan committed four violations of Section 764.2(e) of the Regulations.

Accordingly, Elan is hereby notified that an administrative proceeding is instituted against it pursuant to Section 13(c) of the Act and Part 766 of the Regulations for the purpose of obtaining an order imposing administrative sanctions, including any or all of the following:

The maximum civil penalty allowed by law of \$11,000;<sup>3</sup>

Denial of export privileges; and/or

Exclusion from practice before BIS.

If Elan fails to answer the charges contained in this letter within 30 days after being served with notice of issuance of this letter, that failure will be treated as a default. (Regulations, Sections 766.6 and 766.7). If Elan defaults, the Administrative Law Judge may find the charges alleged in this letter are true without hearing or further notice to Elan. The Under Secretary of Commerce for Industry and Security may then impose up to the maximum penalty on each charge in this letter.

Elan is further notified that it is entitled to an agency hearing on the record if Elan files a written demand for one with its answer. (Regulations, Section 766.6). Elan is also entitled to be represented by counsel or other authorized representative who has power of attorney to represent it. (Regulations, Sections 766.3(a) and 766.4).

The Regulations provide for settlement without a hearing. (Regulations, Section 766.18). Should Elan have a proposal to settle this case, Elan or its representative should transmit the offer to me through the attorney representing BIS named below.

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<sup>3</sup> See 15 C.F.R. § 6.4(a)(2).

Elan  
Proposed Charging Letter  
Page 3

The U.S. Coast Guard is providing administrative law judge services in connection with the matters set forth in this letter. Accordingly, Elan's answer must be filed in accordance with the instructions in Section 766.5(a) of the Regulations with:

U.S. Coast Guard ALJ Docketing Center  
40 S. Gay Street  
Baltimore, Maryland 21202-4022

In addition, a copy of Elan's answer must be served on BIS at the following address:

Office of Chief Counsel for Industry and Security  
Attention: Philip Ankel  
Room H-3839  
United States Department of Commerce  
14th Street and Constitution Avenue, N.W.  
Washington, D.C. 20230

Philip Ankel is the attorney representing BIS in this case. Any communications that Elan may wish to have concerning this matter should occur through him. He may be contacted by telephone at (202) 482-5301.

Sincerely,

Michael D. Turner  
Director  
Office of Export Enforcement

Enclosure

**ELAN, INC.**  
**SCHEDULE OF VIOLATIONS**

DATE (on or about)	Violations	COMMODITY	ECCN	DESTINATION
5/22/00	15 C.F.R. 764(a), (e)	Conotoxin	1C351.d.3	Belgium
2/14/01	15 C.F.R. 764(a), (e)	Conotoxin	1C351.d.3	Belgium
11/27/01	15 C.F.R. 764(a), (e)	Conotoxin	1C351.d.3	Belgium
4/22/02	15 C.F.R. 764(a), (e)	Conotoxin	1C351.d.3	Belgium

UNITED STATES DEPARTMENT OF COMMERCE  
BUREAU OF INDUSTRY AND SECURITY  
WASHINGTON, D.C. 20230

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In the Matter of: )  
 )  
Elan Pharmaceuticals, Inc. )  
800 Gateway Boulevard )  
South San Francisco, CA 94080 )  
 )  
Respondent. )  
.....

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made by and between Elan Pharmaceuticals, Inc. ("Elan"), and the Bureau of Industry and Security, U.S. Department of Commerce ("BIS") (collectively referred to as "Parties"), pursuant to Section 766.18(a) of the Export Administration Regulations (currently codified at 15 C.F.R. Parts 730-774 (2005)) ("Regulations"),<sup>1</sup> issued pursuant to the Export Administration Act of 1979, as amended (50 U.S.C. app. §§ 2401-2420 (2000)) ("Act"),<sup>2</sup>

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<sup>1</sup> The violations charged occurred from 2000 to 2002. The Regulations governing the violations at issue are found in the 2000 to 2002 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (2000-2002)). The 2005 Regulations establish the procedures that apply to this matter.

<sup>2</sup> From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which had been extended by successive Presidential Notices, the last of which was August 3, 2000 (3 C.F.R., 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 - 1706 (2000)) ("IEEPA"). On November 13, 2000, the Act was reauthorized and it remained in effect through August 20, 2001. Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), as extended by the Notice of August 6, 2004 (69 Fed. Reg. 48763, August 10, 2004), has continued the Regulations in effect under the IEEPA.

WHEREAS, Elan filed a voluntary self-disclosure with BIS's Office of Export Enforcement in accordance with Section 764.5 of the Regulations concerning the transactions at issue herein;

WHEREAS, BIS has notified Elan of its intention to initiate an administrative proceeding against Elan, pursuant to the Act and the Regulations;

WHEREAS, BIS has issued a proposed charging letter to Elan that alleged that Elan committed eight violations of the Regulations, specifically

1. *Four Violations of 15 C.F.R. §764.2(a) - Unlicensed exports of toxins:* On four occasions from in or about May 2000 through in or about April 2002, Elan caused the export of items subject to the EAR (conotoxin -- Export Control Classification Number 1C351.d.3) from the United States to Belgium without the licenses required by Section 742.2 of the Regulations.
2. *Four Violations of 15 C.F.R. § 764.2(e) - Exports of Conotoxin With Knowledge or Reason to Know That Violations Would Occur:* In exporting the items described in above, Elan transferred those items with knowledge or reason to know that violations of the Regulations would occur. Specifically, Elan had knowledge or reason to know that Department of Commerce licenses were required to export the items to Belgium and Elan transferred the items with knowledge that Department of Commerce licenses would not be obtained.

WHEREAS, Elan has reviewed the proposed charging letter and is aware of the allegations made against it and the administrative sanctions which could be imposed against it if the allegations are found to be true;

WHEREAS, Elan fully understands the terms of this Agreement and the Order ("Order") that the Assistant Secretary of Commerce for Export Enforcement will issue if she approves this Agreement as the final resolution of this matter;

WHEREAS, Elan enters into this Agreement voluntarily and with full knowledge of its rights;

WHEREAS, Elan states that no promises or representations have been made to it other than the agreements and considerations herein expressed;

WHEREAS, Elan neither admits nor denies the allegations contained in the proposed charging letter;

WHEREAS, Elan wishes to settle and dispose of all matters alleged in the proposed charging letter by entering into this Agreement; and

WHEREAS, Elan agrees to be bound by the Order, if entered;

NOW THEREFORE, the Parties hereby agree as follows:

1. BIS has jurisdiction over Elan, under the Regulations, in connection with the matters alleged in the proposed charging letter.

2. The following sanction shall be imposed against Elan in complete settlement of the violations of the Regulations relating to the transactions specifically detailed in the voluntary self-disclosure and the proposed charging letter:

- a. Elan shall be assessed a civil penalty in the amount of \$31,000, which shall be paid to the U.S. Department of Commerce within 30 days from the date of entry of the Order. Payment shall be made in the manner specified in the attached instructions.
- b. The timely payment of the civil penalty agreed to in paragraph 2.a. is hereby made a condition to the granting, restoration, or continuing validity of any export license, License Exception, permission, or privilege granted, or to be granted, to Elan. Failure to make timely payment of the civil penalty set forth above may result in the denial of all of Elan's export privileges for a period of one year from the date of imposition of the penalty.
- c. Elan shall perform an audit of its internal compliance program not less than 12 months from the date of entry of the Order. Said audit shall be in substantial compliance with the Export Management Systems audit module, which is available from the BIS web site at: <http://www.bis.doc.gov/exportmanagementsystems/default.htm> which is incorporated by reference. A copy of said audit shall be transmitted to the Office of Export Enforcement, 96 North Third Street, San Jose CA 95112, not later than 13 months from the date of the entry of the Order.

3. Subject to the approval of this Agreement pursuant to paragraph 8 hereof, Elan hereby waives all rights to further procedural steps in this matter (except with respect to any alleged violations of this Agreement or the Order, if entered), including, without limitation, any right to: (a) an administrative hearing regarding the allegations in any charging letter; (b) request a refund



of any civil penalty paid pursuant to this Agreement and the Order, if entered; (c) request any relief from the Order, if entered, including without limitation relief from the terms of a denial order under 15 C.F.R. § 764.3(a)(2); and (d) seek judicial review or otherwise contest the validity of this Agreement or the Order, if entered.

4. Upon entry of the Order and timely payment of the \$31,000 civil penalty, BIS will not initiate any further administrative proceeding against Elan in connection with any violation of the Act or the Regulations arising out of the transactions specifically detailed in the voluntary self-disclosure and the proposed charging letter.

5. BIS will make the proposed charging letter, this Agreement, and the Order, if entered, available to the public.

6. This Agreement is for settlement purposes only. Therefore, if this Agreement is not accepted and the Order is not issued by the Assistant Secretary of Commerce for Export Enforcement pursuant to Section 766.18(a) of the Regulations, no Party may use this Agreement in any administrative or judicial proceeding and the Parties shall not be bound by the terms contained in this Agreement in any subsequent administrative or judicial proceeding.

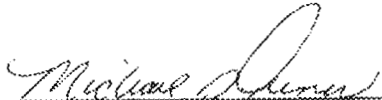
7. No agreement, understanding, representation or interpretation not contained in this Agreement may be used to vary or otherwise affect the terms of this Agreement or the Order, if entered, nor shall this Agreement serve to bind, constrain, or otherwise limit any action by any other agency or department of the U.S. Government with respect to the facts and circumstances addressed herein.

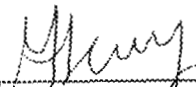
8. This Agreement shall become binding on BIS only if the Assistant Secretary of Commerce for Export Enforcement approves it by entering the Order, which will have the same force and effect as a decision and order issued after a full administrative hearing on the record.

9. Each signatory affirms that he or she has authority to enter into this Settlement Agreement and to bind his or her respective party to the terms and conditions set forth herein.

BUREAU OF INDUSTRY AND SECURITY  
U.S. DEPARTMENT OF COMMERCE

ELAN PHARMACEUTICALS, INC.

  
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Michael D. Turner  
Director  
Office of Export Enforcement

  
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Ginger Levy  
Vice President, Legal

Date: 06/20/2005

Date: 6/14/05

UNITED STATES DEPARTMENT OF COMMERCE  
BUREAU OF INDUSTRY AND SECURITY  
WASHINGTON, D.C. 20230

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In the Matter of: )  
)  
Elan Pharmaceuticals, Inc. )  
800 Gateway Boulevard )  
South San Francisco, CA 94080 )  
)  
Respondent. )  
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ORDER RELATING TO ELAN PHARMACEUTICALS, INC.

The Bureau of Industry and Security, U.S. Department of Commerce ("BIS") having notified Elan Pharmaceuticals, Inc. ("Elan") of its intention to initiate an administrative proceeding against Elan pursuant to Section 766.3 of the Export Administration Regulations (currently codified at 15 C.F.R. Parts 730-774 (2005) ("Regulations"),<sup>1</sup> and Section 13(c) of the Export Administration Act of 1979, as amended (50 U.S.C. app. §§ 2401-2420 (2000)) ("Act"),<sup>2</sup> by issuing a proposed charging letter issued to Elan that alleged that Elan committed eight violations of the Regulations. Specifically, the charges are:

.....  
<sup>1</sup> The violations charged occurred from 2000 to 2002. The Regulations governing the violations at issue are found in the 2000 to 2002 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (2000-2002)). The 2005 Regulations establish the procedures that apply to this matter.

<sup>2</sup> From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which had been extended by successive Presidential Notices, the last of which was August 3, 2000 (3 C.F.R., 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 - 1706 (2000)) ("IEEPA"). On November 13, 2000, the Act was reauthorized and it remained in effect through August 20, 2001. Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), as extended by the Notice of August 6, 2004 (69 *Fed. Reg.* 48763, August 10, 2004), has continued the Regulations in effect under the IEEPA.

1. *Four Violations of 15 C.F.R. §764.2(a) - Unlicensed exports of toxins:* On four occasions from in or about May 2000 through in or about April 2002, Elan caused the export of items subject to the EAR (conotoxin – Export Control Classification Number 1C351.d.3) from the United States to Belgium without the license required by Section 742.2 of the Regulations.
2. *Four Violations of 15 C.F.R. § 764.2(e) - Exports of Conotoxin With Knowledge or Reason to Know That Violations Would Occur:* In exporting the items described above, Elan transferred those items with knowledge or reason to know that violations of the Regulations would occur. Specifically, Elan had knowledge or reason to know that Department of Commerce licenses were required to export the items to Belgium and Elan transferred the items with knowledge that Department of Commerce licenses would not be obtained.

WHEREAS, BIS and Elan have entered into a Settlement Agreement pursuant to Section 766.18(a) of the Regulations whereby they agreed to settle this matter in accordance with the terms and conditions set forth therein, and

WHEREAS, I have approved of the terms of such Settlement Agreement;

IT IS THEREFORE ORDERED:

FIRST, that a civil penalty of \$31,000 which shall be paid to the U.S. Department of Commerce within 30 days from the date of entry of this Order. Payment shall be made in the manner specified in the attached instructions.

SECOND, that, pursuant to the Debt Collection Act of 1982, as amended (31 U.S.C. §§ 3701-3720E (2000)), the civil penalty owed under this Order accrues interest as more fully described in the attached Notice, and, if payment is not made by the due date specified herein,

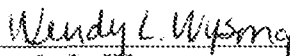
Elan will be assessed, in addition to the full amount of the civil penalty and interest, a penalty charge and an administrative charge, as more fully described in the attached Notice.

THIRD, that the timely payment of the civil penalty set forth above is hereby made a condition to the granting, restoration, or continuing validity of any export license, license exception, permission, or privilege granted, or to be granted, to Elan. Accordingly, if Elan should fail to pay the civil penalty in a timely manner, the undersigned may enter an Order denying all of Elan's export privileges for a period of one year from the date of entry of this Order.

FOURTH, Elan shall perform an audit of its internal compliance program not less than 12 months from the date of entry of the Order. Said audit shall be in substantial compliance with the Export Management Systems audit module, which is available from the BIS web site at: <http://www.bis.doc.gov/exportmanagementsystems/default.htm> which is incorporated by reference. A copy of said audit shall be transmitted to the Office of Export Enforcement, 96 North Third Street, San Jose CA 95112, not later than 13 months from the date of entry of this Order.

FIFTH, that the proposed charging letter, the Settlement Agreement, and this Order shall be made available to the public.

This Order, which constitutes the final agency action in this matter, is effective immediately.

  
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Wendy L. Wysong  
Acting Assistant Secretary of  
Commerce for Export Enforcement

Entered this 21st day of June 2005.