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

In the Matter of:

Alcon Pharmaceuticals Ltd.
Rue Louis d'Affry 6
1701 Fribourg
Switzerland

and

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134

Respondents

ORDER RELATING TO ALCON PHARMACEUTICALS LTD. AND ALCON LABORATORIES, INC.

The Bureau of Industry and Security, U.S. Department of Commerce ("BIS"), has notified Alcon Pharmaceuticals Ltd., of Fribourg, Switzerland ("Alcon Pharmaceuticals"), and Alcon Laboratories, Inc., of Fort Worth, Texas ("Alcon Labs"), of its intention to initiate an administrative proceeding against Alcon Pharmaceuticals and Alcon Labs pursuant to Section 766.3 of the Export Administration Regulations (the "Regulations"),[1] and Section 13(c) of the Export Administration Act of 1979, as amended (the "Act"),[2] through the issuance of Proposed Charging Letters to Alcon Pharmaceuticals and Alcon

[1] The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2016). The charged violations occurred in 2008-2012. The Regulations governing the violations at issue are found in the 2008-2012 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774). The 2016 Regulations set forth the procedures that apply to this matter.

[2] 50 U.S.C. §§ 4601-4623 (Supp. III 2015) (available at https://uscode.house.gov). Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13,222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 7, 2015 (80 Fed. Reg. 48,233 (Aug. 11, 2015)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. § 1701, et seq. (2006 & Supp. IV 2010)).

Labs that allege, respectively, that Alcon Pharmaceuticals committed one hundred forty-five (145) violations and Alcon Labs committed forty-three (43) violations of the Regulations. Specifically, the charges are:

As to Respondent Alcon Pharmaceuticals:

Charges 1-100 15 C.F.R. § 764.2(e) – Acting with Knowledge of a Violation

On at least 100 occasions between on or about July 21, 2008, and on or about September 30, 2011, Alcon Pharmaceuticals ordered various types of U.S-origin medical devices and equipment from the United States ("the items") and then transferred and/or forwarded the items to Iran, via third countries, including, but not limited to, Switzerland, with knowledge that a violation of the Regulations had occurred, was occurring, or was about to occur in connection with the items. The items are subject to the Regulations and were valued at approximately $8,106,260. The items are also subject to the Iranian Transactions Regulations ("ITR").[3]

Pursuant to Section 746.7 of the Regulations, no person may export or reexport an item subject to both the Regulations and the ITR without prior authorization by the U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC"). Under Section 560.204 of the ITR,[4] the exportation, reexportation, sale or supply, directly or indirectly, from the United States of any goods to Iran was prohibited at all times pertinent hereto, including the exportation, reexportation, sale or supply of items from the United States to a third country undertaken with knowledge or reason to know that the items were intended for supply, transshipment, or reexportation, directly or indirectly, to Iran.

At the time Alcon Pharmaceuticals ordered the items at issue from its U.S. sister company, Alcon Laboratories, Inc. ("Alcon Labs"), which manufactured the items in and exported them from the United States, it knew that the items were intended to fulfill orders from Iranian customers. Alcon Pharmaceuticals also knew of the long-standing and well-known U.S. embargo against Iran and the prohibition on exporting U.S.-origin items to Iran without U.S. Government authorization, including knowledge obtained from or through Alcon Labs. However, Alcon Pharmaceuticals sent orders and invoices to Alcon Labs that did not list or disclose that the end-users were located in Iran. Instead, Alcon Pharmaceuticals provided instructions that the items be shipped to warehouse/ distribution centers that it used in various countries, including, but not limited to,

[3] 31 C.F.R. Part 560 (2008-2011).

[4] Administered by OFAC, the ITR were renamed the Iranian Transactions and Sanctions Regulations ("ITSR") and reissued in their entirety by OFAC on October 22, 2012. See 77 Fed. Reg. 64.664 (Oct. 22, 2012). Section 560.204 remains unchanged in pertinent part. See 31 C.F.R. § 560.204 (2008-2011 and 2015).

Switzerland. These facilities did not retain stock or inventory of the items at issue. After the items were received from the United States, Alcon Pharmaceuticals transferred and/or forwarded the items to Iran without the required U.S. Government authorization.

Notwithstanding the need for U.S. Government authorization for exports to Iran, including via transshipments through third countries, no such authorization was sought or obtained for any of the 100 transactions alleged herein, as Alcon Pharmaceuticals knew or had reason to know.

In so doing, Alcon Pharmaceuticals committed 100 violations of Section 764.2(e) of the Regulations.

Charges 101-145 15 C.F.R. § 764.2(a) – Unlicensed Reexports to Syria

On at least 45 occasions between on or about August 7, 2008, and on or about April 10, 2012, Alcon Pharmaceuticals engaged in conduct prohibited by the Regulations by reexporting U.S.-origin medical devices and equipment, items subject to the Regulations and valued at approximately $72,927, from warehouse/distribution centers that it used, including the European Service Center located in France, to Syria without the required BIS license.

Under the long-standing and well-known U.S. trade embargo against Syria, no item subject to the Regulations may be exported or reexported to Syria without a BIS license, with the exception of certain medicines and food, as set forth at all times pertinent hereto in General Order No. 2, codified in Supplement No. 1 to Part 736 of the Regulations and Section 746.9 of the Regulations.[5] No BIS license was sought or obtained for any of the reexports to Syria alleged herein.

In so doing, Alcon Pharmaceuticals committed 45 violations of Section 764.2(a) of the Regulations.

As to Respondent Alcon Labs:

Charges 1-43 15 C.F.R. § 764.2(a) – Unlicensed Exports to Iran

On at least 43 occasions between on or about April 9, 2010, and on or about September 30, 2011, Alcon Labs engaged in conduct prohibited by the Regulations by exporting

[5] General Order No. 2 was issued pursuant to the Syria Accountability and Lebanese Sovereignty Restoration Act of 2003. On December 12, 2011, the controls on exports and reexports to Syria were moved to Section 746.9 of the Regulations. The licensing requirements continued unchanged. *See* 76 Fed. Reg. 77,115 (Dec. 12, 2011).

medical devices and equipment, items subject to the Regulations[6] and valued at approximately $3,652,378, from the United States to Iran, via third countries, without the required U.S. Government authorization. The items are also subject to the Iranian Transactions Regulations ("ITR").[7]

Pursuant to Section 746.7 of the Regulations, no person may export or reexport an item subject to both the Regulations and the ITR without prior authorization by the U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC"). Under Section 560.204 of the ITR,[8] the exportation, reexportation, sale or supply, directly or indirectly, from the United States of any goods to Iran was prohibited at all times pertinent hereto, including the exportation, reexportation, sale or supply of items from the United States to a third country undertaken with knowledge or reason to know that the items were intended for supply, transshipment, or reexportation, directly or indirectly, to Iran.

Alcon Labs was aware of the prohibitions on trade activities under the long-standing and well-known U.S. embargo against Iran, including the prohibition on exporting U.S.-origin items to Iran without U.S. Government authorization, and had on previous occasions applied for and received authorization from OFAC for the export of the same or similar types of items to Iran. Additionally, in or about March 2010, Alcon Labs was alerted by a European freight forwarder that a warehouse/distribution center in Switzerland to which Alcon Labs had been shipping the U.S.-origin items since 2008 to fulfill sales orders by a Swiss affiliate, Alcon Pharmaceuticals Ltd. ("Alcon Pharmaceuticals"), did not retain stock or inventory of the items. Rather, the items had been ordered by Iranian customers and were being transshipped by or at the direction of Alcon Pharmaceuticals to Iran without the required U.S. Government authorization.

Nonetheless, on 43 occasions after March 2010, Alcon Labs continued to export U.S.-origin items to fulfill Alcon Pharmaceuticals' sales orders, albeit shipping the items to one or more other warehouse/distribution centers. Alcon Labs failed to determine the end user or ultimate destination of the items, which continued to be transshipped to Iran. Notwithstanding the need for export licenses, no U.S. Government authorization was sought or obtained for any of these 43 transactions.

In so doing, Alcon Labs committed 43 violations of Section 764.2(a) of the Regulations.

---

[6] The items were designated as EAR99 under the Regulations, which is a designation for items subject to the Regulations but not listed on the Commerce Control List. 15 C.F.R. § 772.1 (2010-2011).

[7] 31 C.F.R. Part 560 (2010-2011).

[8] Administered by OFAC, the ITR were renamed the Iranian Transactions and Sanctions Regulations ("ITSR") and reissued in their entirety by OFAC on October 22, 2012. See 77 Fed. Reg. 64.664 (Oct. 22, 2012). Section 560.204 remains unchanged in pertinent part. See 31 C.F.R. §560.204 (2010-2011 and 2015).

WHEREAS, BIS, Alcon Pharmaceuticals and Alcon Labs 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;

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

WHEREAS, in doing so, I have taken into consideration the settlement agreement that Alcon Pharmaceuticals and Alcon Labs have entered into with the U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC Settlement Agreement").

IT IS THEREFORE ORDERED:

FIRST, Alcon Pharmaceuticals and Alcon Labs shall be assessed a civil penalty in the amount of $8,100,000, the payment of which shall be made to the U.S. Department of Commerce within 30 days of the date of this Order. Alcon Pharmaceuticals and Alcon Labs are jointly and severally liable for the payment of this civil penalty.

SECOND, 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, Alcon Pharmaceuticals and Alcon Labs 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, the full and timely payment of the civil penalty as set forth above and compliance with the OFAC Settlement Agreement are hereby made conditions to the granting, restoration, or continuing validity of any export license, license exception, permission, or privilege granted, or to be granted, to Alcon Pharmaceuticals and Alcon Labs. Accordingly, if Alcon Pharmaceuticals and Alcon Labs should fail to pay the civil

penalty in a full and timely manner, the undersigned may issue an order denying all of Alcon Pharmaceuticals' and Alcon Labs' export privileges under the Regulations for a period of one year from the date of the failure to make such payment. Additionally, the failure by Alcon Pharmaceuticals and Alcon Labs to comply in full with the OFAC Settlement Agreement may result in the denial of all of Alcon Pharmaceuticals' and Alcon Labs' export privileges under the Regulations for a period of one year from the date on which it is determined that a violation of the OFAC Settlement Agreement has occurred.

FOURTH, Alcon Pharmaceuticals and Alcon Labs shall not take any action or make or permit to be made any public statement, directly or indirectly, denying the allegations in the Proposed Charging Letters or this Order. The foregoing does not affect Alcon Pharmaceuticals' or Alcon Labs' testimonial obligations in any proceeding, nor does it affect its right to take legal or factual positions in civil or administrative litigation or other civil or administrative proceedings in which the U.S. Department of Commerce is not a party.

FIFTH, the Proposed Charging Letters, 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.[9]

Richard R. Majauskas
Deputy Assistant Secretary of Commerce
for Export Enforcement

Issued this 30th day of June, 2016.

[9] Review and consideration of this matter has been delegated to the Deputy Assistant Secretary of Commerce for Export Enforcement.

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

In the Matter of:

Alcon Pharmaceuticals Ltd.
Rue Louis d'Affry 6
1701 Fribourg
Switzerland

and

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134

Respondents

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made by and among Alcon Pharmaceuticals Ltd., of Fribourg, Switzerland ("Alcon Pharmaceuticals"), Alcon Laboratories Inc., of Fort Worth, Texas ("Alcon Labs"), and the Bureau of Industry and Security, U.S. Department of Commerce ("BIS") (collectively, the "Parties"), pursuant to Section 766.18(a) of the Export Administration Regulations (the "Regulations"),[1] issued pursuant to the Export Administration Act of 1979, as amended (the "Act").[2]

[1] The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2016). The charged violations occurred in 2008-2012. The Regulations governing the violations at issue are found in the 2008-2012 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774). The 2016 Regulations set forth the procedures that apply to this matter.

[2] 50 U.S.C. §§ 4601-4623 (Supp. III 2015) (available at https://uscode.house.gov). Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13,222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 7, 2015 (80 Fed. Reg. 48,233 (Aug. 11, 2015)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. § 1701, et seq. (2006 & Supp. IV 2010)).

WHEREAS, BIS has notified Alcon Pharmaceuticals and Alcon Labs of its intentions to initiate an administrative proceeding against them pursuant to the Act and the Regulations;

WHEREAS, BIS has issued Proposed Charging Letters to Alcon Pharmaceuticals and Alcon Labs that allege that Alcon Pharmaceuticals committed one hundred forty-five (145) violations and Alcon Labs committed forty-three (43) violations of the Regulations, specifically:

As to Respondent Alcon Pharmaceuticals:

Charges 1-100 15 C.F.R. § 764.2(e) – Acting with Knowledge of a Violation

On at least 100 occasions between on or about July 21, 2008, and on or about September 30, 2011, Alcon Pharmaceuticals ordered various types of U.S-origin medical devices and equipment from the United States ("the items") and then transferred and/or forwarded the items to Iran, via third countries, including, but not limited to, Switzerland, with knowledge that a violation of the Regulations had occurred, was occurring, or was about to occur in connection with the items. The items are subject to the Regulations and were valued at approximately $8,106,260. The items are also subject to the Iranian Transactions Regulations ("ITR").[3]

Pursuant to Section 746.7 of the Regulations, no person may export or reexport an item subject to both the Regulations and the ITR without prior authorization by the U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC"). Under Section 560.204 of the ITR,[4] the exportation, reexportation, sale or supply, directly or indirectly, from the United States of any goods to Iran was prohibited at all times pertinent hereto, including the exportation, reexportation, sale or supply of items from the United States to a third country undertaken with knowledge or reason to know that the items were intended for supply, transshipment, or reexportation, directly or indirectly, to Iran.

At the time Alcon Pharmaceuticals ordered the items at issue from its U.S. sister company, Alcon Laboratories, Inc. ("Alcon Labs"), which manufactured the items in and

[3] 31 C.F.R. Part 560 (2008-2011).

[4] Administered by OFAC, the ITR were renamed the Iranian Transactions and Sanctions Regulations ("ITSR") and reissued in their entirety by OFAC on October 22, 2012. See 77 Fed. Reg. 64.664 (Oct. 22, 2012). Section 560.204 remains unchanged in pertinent part. See 31 C.F.R. §560.204 (2008-2011 and 2015).

exported them from the United States, it knew that the items were intended to fulfill orders from Iranian customers. Alcon Pharmaceuticals also knew of the long-standing and well-known U.S. embargo against Iran and the prohibition on exporting U.S.-origin items to Iran without U.S. Government authorization, including knowledge obtained from or through Alcon Labs. However, Alcon Pharmaceuticals sent orders and invoices to Alcon Labs that did not list or disclose that the end-users were located in Iran. Instead, Alcon Pharmaceuticals provided instructions that the items be shipped to warehouse/distribution centers that it used in various countries, including, but not limited to, Switzerland. These facilities did not retain stock or inventory of the items at issue. After the items were received from the United States, Alcon Pharmaceuticals transferred and/or forwarded the items to Iran without the required U.S. Government authorization.

Notwithstanding the need for U.S. Government authorization for exports to Iran, including via transshipments through third countries, no such authorization was sought or obtained for any of the 100 transactions alleged herein, as Alcon Pharmaceuticals knew or had reason to know.

In so doing, Alcon Pharmaceuticals committed 100 violations of Section 764.2(e) of the Regulations.

Charges 101-145 15 C.F.R. § 764.2(a) – Unlicensed Reexports to Syria

On at least 45 occasions between on or about August 7, 2008, and on or about April 10, 2012, Alcon Pharmaceuticals engaged in conduct prohibited by the Regulations by reexporting U.S.-origin medical devices and equipment, items subject to the Regulations and valued at approximately $72,927, from warehouse/distribution centers that it used, including the European Service Center located in France, to Syria without the required BIS license.

Under the long-standing and well-known U.S. trade embargo against Syria, no item subject to the Regulations may be exported or reexported to Syria without a BIS license, with the exception of certain medicines and food, as set forth at all times pertinent hereto in General Order No. 2, codified in Supplement No. 1 to Part 736 of the Regulations and Section 746.9 of the Regulations.[5] No BIS license was sought or obtained for any of the reexports to Syria alleged herein.

In so doing, Alcon Pharmaceuticals committed 45 violations of Section 764.2(a) of the Regulations.

[5] General Order No. 2 was issued pursuant to the Syria Accountability and Lebanese Sovereignty Restoration Act of 2003. On December 12, 2011, the controls on exports and reexports to Syria were moved to Section 746.9 of the Regulations. The licensing requirements continued unchanged. *See* 76 Fed. Reg. 77,115 (Dec. 12, 2011).

As to Respondent Alcon Labs:

Charges 1-43 15 C.F.R. § 764.2(a) – Unlicensed Exports to Iran

On at least 43 occasions between on or about April 9, 2010, and on or about September 30, 2011, Alcon Labs engaged in conduct prohibited by the Regulations by exporting medical devices and equipment, items subject to the Regulations[6] and valued at approximately $3,652,378, from the United States to Iran, via third countries, without the required U.S. Government authorization. The items are also subject to the Iranian Transactions Regulations ("ITR").[7]

Pursuant to Section 746.7 of the Regulations, no person may export or reexport an item subject to both the Regulations and the ITR without prior authorization by the U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC"). Under Section 560.204 of the ITR,[8] the exportation, reexportation, sale or supply, directly or indirectly, from the United States of any goods to Iran was prohibited at all times pertinent hereto, including the exportation, reexportation, sale or supply of items from the United States to a third country undertaken with knowledge or reason to know that the items were intended for supply, transshipment, or reexportation, directly or indirectly, to Iran.

Alcon Labs was aware of the prohibitions on trade activities under the long-standing and well-known U.S. embargo against Iran, including the prohibition on exporting U.S.-origin items to Iran without U.S. Government authorization, and had on previous occasions applied for and received authorization from OFAC for the export of the same or similar types of items to Iran. Additionally, in or about March 2010, Alcon Labs was alerted by a European freight forwarder that a warehouse/distribution center in Switzerland to which Alcon Labs had been shipping the U.S.-origin items since 2008 to fulfill sales orders by a Swiss affiliate, Alcon Pharmaceuticals Ltd. ("Alcon Pharmaceuticals"), did not retain stock or inventory of the items. Rather, the items had been ordered by Iranian customers and were being transshipped by or at the direction of Alcon Pharmaceuticals to Iran without the required U.S. Government authorization.

---

[6] The items were designated as EAR99 under the Regulations, which is a designation for items subject to the Regulations but not listed on the Commerce Control List. 15 C.F.R. § 772.1 (2010-2011).

[7] 31 C.F.R. Part 560 (2010-2011).

[8] Administered by OFAC, the ITR were renamed the Iranian Transactions and Sanctions Regulations ("ITSR") and reissued in their entirety by OFAC on October 22, 2012. See 77 Fed. Reg. 64.664 (Oct. 22, 2012). Section 560.204 remains unchanged in pertinent part. See 31 C.F.R. §560.204 (2010-2011 and 2015).

Nonetheless, on 43 occasions after March 2010, Alcon Labs continued to export U.S.-origin items to fulfill Alcon Pharmaceuticals' sales orders, albeit shipping the items to one or more other warehouse/distribution centers. Alcon Labs failed to determine the end user or ultimate destination of the items, which continued to be transshipped to Iran. Notwithstanding the need for export licenses, no U.S. Government authorization was sought or obtained for any of these 43 transactions.

In so doing, Alcon Labs committed 43 violations of Section 764.2(a) of the Regulations.

WHEREAS, Alcon Pharmaceuticals and Alcon Labs have reviewed the Proposed Charging Letters and are aware of the allegations made against them and the administrative sanctions that could be imposed against them if the allegations are found to be true;

WHEREAS, Alcon Pharmaceuticals and Alcon Labs fully understand the terms of this Agreement and the Order ("Order") that the Assistant Secretary of Commerce for Export Enforcement will issue if he approves this Agreement as the final resolution of this matter;

WHEREAS, Alcon Pharmaceuticals and Alcon Labs enter into this Agreement voluntarily and with full knowledge of their rights, after having consulted with counsel;

WHEREAS, the Parties enter into this Agreement having taken into consideration the settlement agreement that Alcon Pharmaceuticals and Alcon Labs have entered into with the U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC Settlement Agreement");

WHEREAS, Alcon Pharmaceuticals and Alcon Labs state that no promises or representations have been made to them other than the agreements and considerations herein expressed;

WHEREAS, Alcon Pharmaceuticals and Alcon Labs neither admit nor deny the allegations contained in the Proposed Charging Letters; and

WHEREAS, Alcon Pharmaceuticals and Alcon Labs agree to be bound by the Order, if issued;

NOW THEREFORE, the Parties hereby agree, for purposes of this Settlement Agreement, as follows:

1. BIS has jurisdiction over Alcon Pharmaceuticals and Alcon Labs, under the Regulations, in connection with the matters alleged in the Proposed Charging Letters.

2. The following sanction shall be imposed against Alcon Pharmaceuticals and Alcon Labs in complete settlement of the alleged violations of the Regulations relating to the transactions specifically detailed in the Proposed Charging Letters:

a. Alcon Pharmaceuticals and Alcon Labs shall be assessed a civil penalty in the amount of $8,100,000, the payment of which shall be made to the U.S. Department of Commerce within 30 days of the date of the Order. Alcon Pharmaceuticals and Alcon Labs are jointly and severally liable for the payment of the civil penalty. Payment shall be made in the manner specified in the attached instructions.

b. The full and timely payment of the civil penalty agreed to in Paragraph 2.a and compliance with the OFAC Settlement Agreement are hereby made conditions to the granting, restoration, or continuing validity of any export license, license exception, permission, or privilege granted, or to be granted, to Alcon Pharmaceuticals or Alcon Labs. Failure to make full and timely payment of the civil penalty may result in the denial of all of Alcon Pharmaceuticals' and

Alcon Labs' export privileges under the Regulations for a period of one year from the date of the failure to make such payment. Additionally, failure by Alcon Pharmaceuticals and Alcon Labs to comply in full with the OFAC Settlement Agreement may result in the denial of all of Alcon Pharmaceuticals' and Alcon Labs' export privileges under the Regulations for a period of one year from the date on which it is determined that a violation of the OFAC Settlement Agreement has occurred.

3. Subject to the approval of this Agreement pursuant to Paragraph 8 hereof, Alcon Pharmaceuticals and Alcon Labs hereby waive all rights to further procedural steps in this matter (except with respect to any alleged violations of this Agreement or the Order, if issued), including, without limitation, any right to: (a) receive 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 issued; and (c) seek judicial review or otherwise contest the validity of this Agreement or the Order, if issued. Alcon Pharmaceuticals and Alcon Labs also waive and will not assert any Statute of Limitations defense, and the Statute of Limitations will be tolled, in connection with any violation of the Act or the Regulations arising out of the transactions identified in the Proposed Charging Letters or in connection with collection of the civil penalty or enforcement of this Agreement and the Order, if issued, from the date of the Order until the later of the date Alcon Pharmaceuticals and Alcon Labs pay in full the civil penalty agreed to in Paragraph 2.a of this Agreement or Alcon Pharmaceuticals and Alcon Labs comply with the terms of the OFAC Settlement Agreement.

4. Alcon Pharmaceuticals and Alcon Labs shall not take any action or make or permit to be made any public statement, directly or indirectly, denying the allegations in the Proposed Charging Letters or the Order. The foregoing does not affect Alcon Pharmaceuticals' or Alcon Labs' testimonial obligations in any proceeding, nor does it affect its right to take legal or factual positions in civil or administrative litigation or other civil or administrative proceedings in which the U.S. Department of Commerce is not a party.

5. BIS agrees that upon full and timely payment of the civil penalty as set forth in Paragraph 2.a above and compliance with the OFAC Settlement Agreement, BIS will not initiate any further administrative proceeding against Alcon Pharmaceuticals or Alcon Labs in connection with any violation of the Act or the Regulations arising out of the transactions specifically detailed in the Proposed Charging Letters.

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 issued; 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 the Parties only if the Assistant Secretary of Commerce for Export Enforcement approves it by issuing 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. If the Order issues, BIS will make the Proposed Charging Letters, this Agreement, and the Order available to the public.

///

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

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

Douglas R. Hassebrock
Director
Office of Export Enforcement

Date: June 29, 2016

ALCON PHARMACEUTICALS LTD.

Philippe Deecke
Chief Financial Officer
Alcon Europe, Middle East and Africa
Authorized Signatory for
Alcon Pharmaceuticals Ltd.

Date: June 24, 2016

Sandrine Auffret
Head of Legal and Compliance
Alcon Europe, Middle East and Africa
Authorized Signatory for
Alcon Pharmaceuticals Ltd.

Date: June 24, 2016

ALCON LABORATORIES, INC.

Sergio Duplan
President
United States and Canada
Alcon Laboratories, Inc.

Date: June_____, 2016

Reviewed and approved by:

Amy Conway-Hatcher, Esq.
Baker Botts LLP

Date: June_____, 2016

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

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

Douglas R. Hassebrock
Director
Office of Export Enforcement

Date: June_____, 2016

ALCON PHARMACEUTICALS LTD.

Philippe Deecke
Chief Financial Officer
Alcon Europe, Middle East and Africa
Authorized Signatory for
Alcon Pharmaceuticals Ltd.

Date: June_____, 2016

Sandrine Auffret
Head of Legal and Compliance
Alcon Europe, Middle East and Africa
Authorized Signatory for
Alcon Pharmaceuticals Ltd.

Date: June_____, 2016

ALCON LABORATORIES, INC.

Sergio Duplan
President
United States and Canada
Alcon Laboratories, Inc.

Date: June 24, 2016

Reviewed and approved by:

Amy Conway-Hatcher, Esq.
Baker Botts LLP

Date: June 28, 2016

PROPOSED CHARGING LETTER
BY REGISTERED MAIL – RETURN RECEIPT REQUESTED

Alcon Pharmaceuticals Ltd.
Rue Louis d'Affry 6
1701 Fribourg
Switzerland

Attention: Philippe Deecke
Chief Financial Officer
Alcon Europe, Middle East and Africa
for Alcon Pharmaceuticals Ltd.

Dear Mr. Deecke,

The Bureau of Industry and Security, U.S. Department of Commerce ("BIS"), has reason to believe that Alcon Pharmaceuticals Ltd. ("Alcon Pharmaceuticals"), of Fribourg, Switzerland, has committed one hundred forty-five (145) violations of the Export Administration Regulations (the "Regulations"),[1] which issued under the authority of the Export Administration Act of 1979, as amended (the "Act").[2] Specifically, BIS alleges that Alcon Pharmaceuticals committed the following violations:

Charges 1-100 15 C.F.R. § 764.2(e) – Acting with Knowledge of a Violation

As described in greater detail in the attached Schedule of Violations, which is incorporated herein, on at least 100 occasions between on or about July 21, 2008, and on or about September 30, 2011, Alcon Pharmaceuticals ordered various types of U.S-origin medical devices and equipment from the United States ("the items") and then transferred and/or forwarded the items to Iran, via third countries, including, but not limited to, Switzerland, with knowledge that a violation of the Regulations had occurred, was occurring, or was about to occur in connection with the items. The items are subject to the Regulations and were valued at approximately $8,106,260. The items are also subject to the Iranian Transactions Regulations ("ITR").[3]

---

[1] The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2016). The violations alleged occurred between 2008 and 2012. The Regulations governing the violations at issue are found in the 2008-2012 versions of the Code of Federal Regulations, 15 C.F.R. Parts 730-774 (2008-2012). The 2016 Regulations govern the procedural aspects of this case.

[2] 50 U.S.C. §§ 4601-4623 (Supp. III 2015) (available at http://uscode.house.gov). 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)), which has been extended by successive Presidential Notices, the most recent being that of August 7, 2015 (80 Fed. Reg. 48,233 (Aug. 11, 2015)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. § 1701, et seq. (2006 & Supp. IV 2010)).

[3] 31 C.F.R. Part 560 (2008-2011).

Pursuant to Section 746.7 of the Regulations, no person may export or reexport an item subject to both the Regulations and the ITR without prior authorization by the U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC"). Under Section 560.204 of the ITR,[4] the exportation, reexportation, sale or supply, directly or indirectly, from the United States of any goods to Iran was prohibited at all times pertinent hereto, including the exportation, reexportation, sale or supply of items from the United States to a third country undertaken with knowledge or reason to know that the items were intended for supply, transshipment, or reexportation, directly or indirectly, to Iran.

At the time Alcon Pharmaceuticals ordered the items at issue from its U.S. sister company, Alcon Laboratories, Inc. ("Alcon Labs"), which manufactured the items in and exported them from the United States, it knew that the items were intended to fulfill orders from Iranian customers. Alcon Pharmaceuticals also knew of the long-standing and well-known U.S. embargo against Iran and the prohibition on exporting U.S.-origin items to Iran without U.S. Government authorization, including knowledge obtained from or through Alcon Labs. However, Alcon Pharmaceuticals sent orders and invoices to Alcon Labs that did not list or disclose that the end-users were located in Iran. Instead, Alcon Pharmaceuticals provided instructions that the items be shipped to warehouse/distribution centers that it used in various countries, including, but not limited to, Switzerland. These facilities did not retain stock or inventory of the items at issue. After the items were received from the United States, Alcon Pharmaceuticals transferred and/or forwarded the items to Iran without the required U.S. Government authorization.

Notwithstanding the need for U.S. Government authorization for exports to Iran, including via transshipments through third countries, no such authorization was sought or obtained for any of the 100 transactions alleged herein, as Alcon Pharmaceuticals knew or had reason to know.

In so doing, Alcon Pharmaceuticals committed 100 violations of Section 764.2(e) of the Regulations.

Charges 101-145 15 C.F.R. § 764.2(a) – Unlicensed Reexports to Syria

As described in greater detail in the attached Schedule of Violations, which is incorporated herein, on at least 45 occasions between on or about August 7, 2008, and on or about April 10, 2012, Alcon Pharmaceuticals engaged in conduct prohibited by the Regulations by reexporting U.S.-origin medical devices and equipment, items subject to the Regulations and valued at approximately $72,927, from warehouse/distribution centers that it used, including the European Service Center located in France, to Syria without the required BIS license.

[4] Administered by OFAC, the ITR were renamed the Iranian Transactions and Sanctions Regulations ("ITSR") and reissued in their entirety by OFAC on October 22, 2012. See 77 Fed. Reg. 64.664 (Oct. 22, 2012). Section 560.204 remains unchanged in pertinent part. See 31 C.F.R. §560.204 (2008-2011 and 2015).

Under the long-standing and well-known U.S. trade embargo against Syria, no item subject to the Regulations may be exported or reexported to Syria without a BIS license, with the exception of certain medicines and food, as set forth at all times pertinent hereto in General Order No. 2, codified in Supplement No. 1 to Part 736 of the Regulations and Section 746.9 of the Regulations.[5] No BIS license was sought or obtained for any of the reexports to Syria alleged herein.

In so doing, Alcon Pharmaceuticals committed 45 violations of Section 764.2(a) of the Regulations.

* * * * * *

Accordingly, Alcon Pharmaceuticals is hereby notified that an administrative proceeding is instituted against them 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 up to $250,000 per violation[6] or twice the value of the transaction that is the basis of the violation;[7]
- Denial of export privileges;
- Exclusion from practice before BIS; and/or
- Any other liability, sanction, or penalty available under law.

If Alcon Pharmaceuticals 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. *See* 15 C.F.R. §§ 766.6 and 766.7. If Alcon Pharmaceuticals defaults, the Administrative Law Judge may find the charges alleged in this letter are true without a hearing or further notice to Alcon Pharmaceuticals. The Under Secretary of Commerce for Industry and Security may then impose up to the maximum penalty for the charges in this letter.

Alcon Pharmaceuticals is further notified that they are entitled to an agency hearing on the record if it files a written demand for one with its answer. *See* C.F.R. § 766.6(c). Alcon Pharmaceuticals is also entitled to be represented by counsel or other authorized representative who has power of attorney to represent them. *See* 15 C.F.R. §§ 766.3(a) and 766.4.

---

[5] General Order No. 2 was issued pursuant to the Syria Accountability and Lebanese Sovereignty Restoration Act of 2003. On December 12, 2011, the controls on exports and reexports to Syria were moved to Section 746.9 of the Regulations. The licensing requirements continued unchanged. *See* 76 Fed. Reg. 77,115 (Dec. 12, 2011).

[6] This amount is subject to increase pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Sec. 701 of Public Law 114-74, enacted on November 2, 2015.

[7] *See* International Emergency Economic Powers Enhancement Act of 2007, Pub. L. No. 110-96, 121 Stat. 1011 (2007).

The Regulations provide for settlement without a hearing. *See* 15 C.F.R. § 766.18. Should Alcon Pharmaceuticals have a proposal to settle this case, Alcon Pharmaceuticals' representative should transmit it to the attorney representing BIS named below.

Alcon Pharmaceuticals is further notified that under the Small Business Regulatory Enforcement Flexibility Act, Alcon Pharmaceuticals may be eligible for assistance from the Office of the National Ombudsman of the Small Business Administration in this matter. To determine eligibility and get more information, please see: http://www.sba.gov/ombudsman/.

The U.S. Coast Guard is providing administrative law judge services in connection with the matters set forth in this letter. Accordingly, Alcon Pharmaceuticals' 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 Alcon Pharmaceuticals' answer must be served on BIS at the following address:

Chief Counsel for Industry and Security
Attention: Gregory Michelsen Esq.
Room H-3839
14th Street and Constitution Avenue, N.W.
Washington, D.C. 20230

Gregory Michelsen is the attorney representing BIS in this case; any communications that Alcon Pharmaceuticals may wish to have concerning this matter should occur through him. Mr. Michelsen may be contacted by telephone at (202) 482-5301.

Sincerely,

Douglas R. Hassebrock
Director
Office of Export Enforcement

Schedule of Violations
Alcon Pharmaceuticals Ltd.

Charge	Date of Export	Ultimate Destination	Commodity	ECCN	Total Value	Violation
1	21-Jul-08	Iran	Medical Equipment and Supplies	EAR99	$32,006.00	15 C.F.R. §764.2(e)
2	25-Jul-08	Iran	Medical Equipment and Supplies	EAR99	$63,183.00	15 C.F.R. §764.2(e)
3	31-Jul-08	Iran	Medical Equipment and Supplies	EAR99	$59,941.00	15 C.F.R. §764.2(e)
4	22-Aug-08	Iran	Medical Equipment and Supplies	EAR99	$21,038.00	15 C.F.R. §764.2(e)
5	05-Sep-08	Iran	Medical Equipment and Supplies	EAR99	$229,230.00	15 C.F.R. §764.2(e)
6	30-Sep-08	Iran	Medical Equipment and Supplies	EAR99	$21,905.00	15 C.F.R. §764.2(e)
7	30-Sep-08	Iran	Medical Equipment and Supplies	EAR99	$16,429.00	15 C.F.R. §764.2(e)
8	02-Oct-08	Iran	Medical Equipment and Supplies	EAR99	$148,249.00	15 C.F.R. §764.2(e)
9	07-Oct-08	Iran	Medical Equipment and Supplies	EAR99	$208,749.00	15 C.F.R. §764.2(e)
10	16-Oct-08	Iran	Medical Equipment and Supplies	EAR99	$361,092.00	15 C.F.R. §764.2(e)
11	16-Oct-08	Iran	Medical Equipment and Supplies	EAR99	$83,798.00	15 C.F.R. §764.2(e)
12	16-Oct-08	Iran	Medical Equipment and Supplies	EAR99	$14,870.00	15 C.F.R. §764.2(e)
13	24-Oct-08	Iran	Medical Equipment and Supplies	EAR99	$138,287.00	15 C.F.R. §764.2(e)
14	26-Nov-08	Iran	Medical Equipment and Supplies	EAR99	$16,067.00	15 C.F.R. §764.2(e)
15	05-Dec-08	Iran	Medical Equipment and Supplies	EAR99	$53,182.00	15 C.F.R. §764.2(e)
16	16-Dec-08	Iran	Medical Equipment and Supplies	EAR99	$116,811.00	15 C.F.R. §764.2(e)
17	02-Jan-09	Iran	Medical Equipment and Supplies	EAR99	$115,229.00	15 C.F.R. §764.2(e)
18	06-Jan-09	Iran	Medical Equipment and Supplies	EAR99	$22,684.00	15 C.F.R. §764.2(e)
19	08-Jan-09	Iran	Medical Equipment and Supplies	EAR99	$41,382.00	15 C.F.R. §764.2(e)
20	30-Jan-09	Iran	Medical Equipment and Supplies	EAR99	$62,038.00	15 C.F.R. §764.2(e)
21	30-Jan-09	Iran	Medical Equipment and Supplies	EAR99	$61,738.00	15 C.F.R. §764.2(e)
22	17-Feb-09	Iran	Medical Equipment and Supplies	EAR99	$51,620.00	15 C.F.R. §764.2(e)
23	11-Mar-09	Iran	Medical Equipment and Supplies	EAR99	$92,676.00	15 C.F.R. §764.2(e)
24	18-Mar-09	Iran	Medical Equipment and Supplies	EAR99	$43,671.00	15 C.F.R. §764.2(e)
25	24-Mar-09	Iran	Medical Equipment and Supplies	EAR99	$161,697.00	15 C.F.R. §764.2(e)
26	25-Mar-09	Iran	Medical Equipment and Supplies	EAR99	$105,145.00	15 C.F.R. §764.2(e)
27	26-Mar-09	Iran	Medical Equipment and Supplies	EAR99	$25,810.00	15 C.F.R. §764.2(e)
28	09-Apr-09	Iran	Medical Equipment and Supplies	EAR99	$41,761.00	15 C.F.R. §764.2(e)

Schedule of Violations
Alcon Pharmaceuticals Ltd.

Charge	Date of Export	Ultimate Destination	Commodity	ECCN	Total Value	Violation
29	25-May-09	Iran	Medical Equipment and Supplies	EAR99	$138,639.00	15 C.F.R. §764.2(e)
30	03-Jun-09	Iran	Medical Equipment and Supplies	EAR99	$27,931.00	15 C.F.R. §764.2(e)
31	03-Jun-09	Iran	Medical Equipment and Supplies	EAR99	$21,722.00	15 C.F.R. §764.2(e)
32	09-Jun-09	Iran	Medical Equipment and Supplies	EAR99	$25,810.00	15 C.F.R. §764.2(e)
33	08-Jul-09	Iran	Medical Equipment and Supplies	EAR99	$38,513.00	15 C.F.R. §764.2(e)
34	15-Jul-09	Iran	Medical Equipment and Supplies	EAR99	$224,742.00	15 C.F.R. §764.2(e)
35	15-Jul-09	Iran	Medical Equipment and Supplies	EAR99	$17,424.00	15 C.F.R. §764.2(e)
36	28-Jul-09	Iran	Medical Equipment and Supplies	EAR99	$14,087.00	15 C.F.R. §764.2(e)
37	06-Aug-09	Iran	Medical Equipment and Supplies	EAR99	$204,811.00	15 C.F.R. §764.2(e)
38	20-Aug-09	Iran	Medical Equipment and Supplies	EAR99	$38,715.00	15 C.F.R. §764.2(e)
39	03-Sep-09	Iran	Medical Equipment and Supplies	EAR99	$85,221.00	15 C.F.R. §764.2(e)
40	04-Sep-09	Iran	Medical Equipment and Supplies	EAR99	$278,865.00	15 C.F.R. §764.2(e)
41	21-Sep-09	Iran	Medical Equipment and Supplies	EAR99	$43,156.00	15 C.F.R. §764.2(e)
42	13-Oct-09	Iran	Medical Equipment and Supplies	EAR99	$221,777.00	15 C.F.R. §764.2(e)
43	26-Oct-09	Iran	Medical Equipment and Supplies	EAR99	$22,684.00	15 C.F.R. §764.2(e)
44	03-Dec-09	Iran	Medical Equipment and Supplies	EAR99	$23,385.00	15 C.F.R. §764.2(e)
45	10-Dec-09	Iran	Medical Equipment and Supplies	EAR99	$14,054.00	15 C.F.R. §764.2(e)
46	05-Jan-10	Iran	Medical Equipment and Supplies	EAR99	$18,440.00	15 C.F.R. §764.2(e)
47	09-Feb-10	Iran	Medical Equipment and Supplies	EAR99	$101,763.00	15 C.F.R. §764.2(e)
48	16-Feb-10	Iran	Medical Equipment and Supplies	EAR99	$45,659.00	15 C.F.R. §764.2(e)
49	18-Feb-10	Iran	Medical Equipment and Supplies	EAR99	$14,460.00	15 C.F.R. §764.2(e)
50	19-Feb-10	Iran	Medical Equipment and Supplies	EAR99	$40,077.00	15 C.F.R. §764.2(e)
51	25-Feb-10	Iran	Medical Equipment and Supplies	EAR99	$16,327.00	15 C.F.R. §764.2(e)
52	05-Mar-10	Iran	Medical Equipment and Supplies	EAR99	$109,089.00	15 C.F.R. §764.2(e)
53	19-Mar-10	Iran	Medical Equipment and Supplies	EAR99	$22,020.00	15 C.F.R. §764.2(e)
54	22-Mar-10	Iran	Medical Equipment and Supplies	EAR99	$146,092.00	15 C.F.R. §764.2(e)
55	22-Mar-10	Iran	Medical Equipment and Supplies	EAR99	$22,020.00	15 C.F.R. §764.2(e)
56	24-Mar-10	Iran	Medical Equipment and Supplies	EAR99	$22,020.00	15 C.F.R. §764.2(e)

Schedule of Violations
Alcon Pharmaceuticals Ltd.

Charge	Date of Export	Ultimate Destination	Commodity	ECCN	Total Value	Violation
57	29-Mar-10	Iran	Medical Equipment and Supplies	EAR99	$44,041.00	15 C.F.R. §764.2(e)
58	09-Apr-10	Iran	Medical Equipment and Supplies	EAR99	$129,418.00	15 C.F.R. §764.2(e)
59	09-Apr-10	Iran	Medical Equipment and Supplies	EAR99	$14,214.00	15 C.F.R. §764.2(e)
60	21-Apr-10	Iran	Medical Equipment and Supplies	EAR99	$21,306.00	15 C.F.R. §764.2(e)
61	26-Apr-10	Iran	Medical Equipment and Supplies	EAR99	$102,244.00	15 C.F.R. §764.2(e)
62	26-Apr-10	Iran	Medical Equipment and Supplies	EAR99	$71,644.00	15 C.F.R. §764.2(e)
63	07-May-10	Iran	Medical Equipment and Supplies	EAR99	$44,041.00	15 C.F.R. §764.2(e)
64	14-Jun-10	Iran	Medical Equipment and Supplies	EAR99	$16,088.00	15 C.F.R. §764.2(e)
65	17-Jun-10	Iran	Medical Equipment and Supplies	EAR99	$348,252.00	15 C.F.R. §764.2(e)
66	22-Jun-10	Iran	Medical Equipment and Supplies	EAR99	$112,864.00	15 C.F.R. §764.2(e)
67	15-Jul-10	Iran	Medical Equipment and Supplies	EAR99	$301,030.00	15 C.F.R. §764.2(e)
68	07-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$20,157.00	15 C.F.R. §764.2(e)
69	08-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$196,340.00	15 C.F.R. §764.2(e)
70	08-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$65,872.00	15 C.F.R. §764.2(e)
71	08-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$21,290.00	15 C.F.R. §764.2(e)
72	13-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$40,499.00	15 C.F.R. §764.2(e)
73	21-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$18,529.00	15 C.F.R. §764.2(e)
74	29-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$28,937.00	15 C.F.R. §764.2(e)
75	12-Oct-10	Iran	Medical Equipment and Supplies	EAR99	$40,315.00	15 C.F.R. §764.2(e)
76	13-Oct-10	Iran	Medical Equipment and Supplies	EAR99	$20,157.00	15 C.F.R. §764.2(e)
77	26-Oct-10	Iran	Medical Equipment and Supplies	EAR99	$13,939.00	15 C.F.R. §764.2(e)
78	04-Nov-10	Iran	Medical Equipment and Supplies	EAR99	$41,475.00	15 C.F.R. §764.2(e)
79	04-Nov-10	Iran	Medical Equipment and Supplies	EAR99	$28,163.00	15 C.F.R. §764.2(e)
80	25-Nov-10	Iran	Medical Equipment and Supplies	EAR99	$26,098.00	15 C.F.R. §764.2(e)
81	02-Dec-10	Iran	Medical Equipment and Supplies	EAR99	$44,777.00	15 C.F.R. §764.2(e)
82	10-Dec-10	Iran	Medical Equipment and Supplies	EAR99	$44,697.00	15 C.F.R. §764.2(e)
83	12-Jan-11	Iran	Medical Equipment and Supplies	EAR99	$26,874.00	15 C.F.R. §764.2(e)
84	25-Jan-11	Iran	Medical Equipment and Supplies	EAR99	$44,947.00	15 C.F.R. §764.2(e)

Schedule of Violations
Alcon Pharmaceuticals Ltd.

Charge	Date of Export	Ultimate Destination	Commodity	ECCN	Total Value	Violation
85	09-Feb-11	Iran	Medical Equipment and Supplies	EAR99	$14,557.00	15 C.F.R. §764.2(e)
86	21-Mar-11	Iran	Medical Equipment and Supplies	EAR99	$320,895.00	15 C.F.R. §764.2(e)
87	21-Mar-11	Iran	Medical Equipment and Supplies	EAR99	$140,836.00	15 C.F.R. §764.2(e)
88	21-Mar-11	Iran	Medical Equipment and Supplies	EAR99	$40,888.00	15 C.F.R. §764.2(e)
89	06-Apr-11	Iran	Medical Equipment and Supplies	EAR99	$537,811.00	15 C.F.R. §764.2(e)
90	17-May-11	Iran	Medical Equipment and Supplies	EAR99	$44,060.00	15 C.F.R. §764.2(e)
91	17-May-11	Iran	Medical Equipment and Supplies	EAR99	$44,060.00	15 C.F.R. §764.2(e)
92	23-May-11	Iran	Medical Equipment and Supplies	EAR99	$49,304.00	15 C.F.R. §764.2(e)
93	20-Jun-11	Iran	Medical Equipment and Supplies	EAR99	$114,309.00	15 C.F.R. §764.2(e)
94	22-Jun-11	Iran	Medical Equipment and Supplies	EAR99	$31,633.00	15 C.F.R. §764.2(e)
95	13-Jul-11	Iran	Medical Equipment and Supplies	EAR99	$74,960.00	15 C.F.R. §764.2(e)
96	19-Aug-11	Iran	Medical Equipment and Supplies	EAR99	$113,294.00	15 C.F.R. §764.2(e)
97	24-Aug-11	Iran	Medical Equipment and Supplies	EAR99	$46,186.00	15 C.F.R. §764.2(e)
98	26-Sep-11	Iran	Medical Equipment and Supplies	EAR99	$74,616.00	15 C.F.R. §764.2(e)
99	26-Sep-11	Iran	Medical Equipment and Supplies	EAR99	$74,616.00	15 C.F.R. §764.2(e)
100	30-Sep-11	Iran	Medical Equipment and Supplies	EAR99	$46,186.00	15 C.F.R. §764.2(e)
SubTotal for Iran					**$8,106,210.00**	
101	07-Aug-08	Syria	Medical Equipment and Supplies	EAR99	$71.04	15 C.F.R. §764.2(a)
102	26-Aug-08	Syria	Medical Equipment and Supplies	EAR99	$644.55	15 C.F.R. §764.2(a)
103	01-Sep-08	Syria	Medical Equipment and Supplies	EAR99	$1,204.95	15 C.F.R. §764.2(a)
104	08-Sep-08	Syria	Medical Equipment and Supplies	EAR99	$1,411.18	15 C.F.R. §764.2(a)
105	24-Sep-08	Syria	Medical Equipment and Supplies	EAR99	$3,037.42	15 C.F.R. §764.2(a)
106	25-Sep-08	Syria	Medical Equipment and Supplies	EAR99	$2,926.81	15 C.F.R. §764.2(a)
107	28-Oct-08	Syria	Medical Equipment and Supplies	EAR99	$160.91	15 C.F.R. §764.2(a)
108	08-Jan-09	Syria	Medical Equipment and Supplies	EAR99	$116.56	15 C.F.R. §764.2(a)
109	23-Jan-09	Syria	Medical Equipment and Supplies	EAR99	$268.66	15 C.F.R. §764.2(a)
110	05-Feb-09	Syria	Medical Equipment and Supplies	EAR99	$309.97	15 C.F.R. §764.2(a)
111	05-Feb-09	Syria	Medical Equipment and Supplies	EAR99	$537.32	15 C.F.R. §764.2(a)

Schedule of Violations
Alcon Pharmaceuticals Ltd.

Charge	Date of Export	Ultimate Destination	Commodity	ECCN	Total Value	Violation
112	25-Mar-09	Syria	Medical Equipment and Supplies	EAR99	$3,113.39	15 C.F.R. §764.2(a)
113	29-Jun-09	Syria	Medical Equipment and Supplies	EAR99	$2,092.12	15 C.F.R. §764.2(a)
114	17-Jul-09	Syria	Medical Equipment and Supplies	EAR99	$362.42	15 C.F.R. §764.2(a)
115	05-Aug-09	Syria	Medical Equipment and Supplies	EAR99	$1,434.29	15 C.F.R. §764.2(a)
116	27-Aug-09	Syria	Medical Equipment and Supplies	EAR99	$440.70	15 C.F.R. §764.2(a)
117	16-Sep-09	Syria	Medical Equipment and Supplies	EAR99	$3,725.59	15 C.F.R. §764.2(a)
118	20-Nov-09	Syria	Medical Equipment and Supplies	EAR99	$592.12	15 C.F.R. §764.2(a)
119	16-Dec-09	Syria	Medical Equipment and Supplies	EAR99	$2,077.36	15 C.F.R. §764.2(a)
120	18-Jan-10	Syria	Medical Equipment and Supplies	EAR99	$764.64	15 C.F.R. §764.2(a)
121	25-Jan-10	Syria	Medical Equipment and Supplies	EAR99	$346.48	15 C.F.R. §764.2(a)
122	05-Feb-10	Syria	Medical Equipment and Supplies	EAR99	$719.51	15 C.F.R. §764.2(a)
123	05-Feb-10	Syria	Medical Equipment and Supplies	EAR99	$14,115.45	15 C.F.R. §764.2(a)
124	03-Mar-10	Syria	Medical Equipment and Supplies	EAR99	$594.72	15 C.F.R. §764.2(a)
125	26-Apr-10	Syria	Medical Equipment and Supplies	EAR99	$468.61	15 C.F.R. §764.2(a)
126	12-Aug-10	Syria	Medical Equipment and Supplies	EAR99	$171.25	15 C.F.R. §764.2(a)
127	16-Sep-10	Syria	Medical Equipment and Supplies	EAR99	$1,472.20	15 C.F.R. §764.2(a)
128	20-Oct-10	Syria	Medical Equipment and Supplies	EAR99	$2,739.96	15 C.F.R. §764.2(a)
129	20-Oct-10	Syria	Medical Equipment and Supplies	EAR99	$2,473.14	15 C.F.R. §764.2(a)
130	03-Nov-10	Syria	Medical Equipment and Supplies	EAR99	$523.04	15 C.F.R. §764.2(a)
131	03-Nov-10	Syria	Medical Equipment and Supplies	EAR99	$131.42	15 C.F.R. §764.2(a)
132	04-Nov-10	Syria	Medical Equipment and Supplies	EAR99	$484.36	15 C.F.R. §764.2(a)
133	15-Dec-10	Syria	Medical Equipment and Supplies	EAR99	$959.78	15 C.F.R. §764.2(a)
134	13-Jan-11	Syria	Medical Equipment and Supplies	EAR99	$2,316.95	15 C.F.R. §764.2(a)
135	14-Mar-11	Syria	Medical Equipment and Supplies	EAR99	$1,832.40	15 C.F.R. §764.2(a)
136	17-Mar-11	Syria	Medical Equipment and Supplies	EAR99	$426.07	15 C.F.R. §764.2(a)
137	28-Mar-11	Syria	Medical Equipment and Supplies	EAR99	$1,594.71	15 C.F.R. §764.2(a)
138	28-Mar-11	Syria	Medical Equipment and Supplies	EAR99	$3,751.12	15 C.F.R. §764.2(a)
139	14-Apr-11	Syria	Medical Equipment and Supplies	EAR99	$1,832.40	15 C.F.R. §764.2(a)

Schedule of Violations
Alcon Pharmaceuticals Ltd.

Charge	Date of Export	Ultimate Destination	Commodity	ECCN	Total Value	Violation
140	14-Apr-11	Syria	Medical Equipment and Supplies	EAR99	$1,164.05	15 C.F.R. §764.2(a)
141	2-May-11	Syria	Medical Equipment and Supplies	EAR99	$1,077.72	15 C.F.R. §764.2(a)
142	10-Oct-11	Syria	Medical Equipment and Supplies	EAR99	$2,855.81	15 C.F.R. §764.2(a)
143	28-Nov-11	Syria	Medical Equipment and Supplies	EAR99	$3,533.91	15 C.F.R. §764.2(a)
144	26-Mar-12	Syria	Medical Equipment and Supplies	EAR99	$348.45	15 C.F.R. §764.2(a)
145	10-Apr-12	Syria	Medical Equipment and Supplies	EAR99	$1,702.40	15 C.F.R. §764.2(a)
SubTotal for Syria					**$72,927.91**	
Grand Total					**$8,179,137.91**	

PROPOSED CHARGING LETTER
BY CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134

Attention: Sergio Duplan
President, United States and Canada

Dear Mr. Duplan,

The Bureau of Industry and Security, U.S. Department of Commerce ("BIS"), has reason to believe that Alcon Laboratories, Inc. ("Alcon Labs"), of Fort Worth, Texas, has committed forty-three (43) violations of the Export Administration Regulations (the "Regulations"),[1] which issued under the authority of the Export Administration Act of 1979, as amended (the "Act").[2] Specifically, BIS alleges that Alcon Labs committed the following violations:

Charges 1-43 15 C.F.R. § 764.2(a) – Unlicensed Exports to Iran

As described in greater detail in the attached Schedule of Violations, which is incorporated herein, on at least 43 occasions between on or about April 9, 2010, and on or about September 30, 2011, Alcon Labs engaged in conduct prohibited by the Regulations by exporting medical devices and equipment, items subject to the Regulations[3] and valued at approximately $3,652,378, from the United States to Iran, via third countries, without the required U.S. Government authorization. The items are also subject to the Iranian Transactions Regulations ("ITR").[4]

Pursuant to Section 746.7 of the Regulations, no person may export or reexport an item subject to both the Regulations and the ITR without prior authorization by the U.S. Department of the

[1] The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2016). The violations alleged occurred between 2010 and 2011. The Regulations governing the violations at issue are found in the 2010-2011 versions of the Code of Federal Regulations, 15 C.F.R. Parts 730-774 (2010-2011). The 2016 Regulations govern the procedural aspects of this case.

[2] 50 U.S.C. §§ 4601-4623 (Supp. III 2015) (available at http://uscode.house.gov). 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)), which has been extended by successive Presidential Notices, the most recent being that of August 7, 2015 (80 Fed. Reg. 48,233 (Aug. 11, 2015)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. § 1701, et seq. (2006 & Supp. IV 2010)).

[3] The items were designated as EAR99 under the Regulations, which is a designation for items subject to the Regulations but not listed on the Commerce Control List. 15 C.F.R. § 772.1 (2010-2011).

[4] 31 C.F.R. Part 560 (2010-2011).

Treasury's Office of Foreign Assets Control ("OFAC"). Under Section 560.204 of the ITR,[5] the exportation, reexportation, sale or supply, directly or indirectly, from the United States of any goods to Iran was prohibited at all times pertinent hereto, including the exportation, reexportation, sale or supply of items from the United States to a third country undertaken with knowledge or reason to know that the items were intended for supply, transshipment, or reexportation, directly or indirectly, to Iran.

Alcon Labs was aware of the prohibitions on trade activities under the long-standing and well-known U.S. embargo against Iran, including the prohibition on exporting U.S.-origin items to Iran without U.S. Government authorization, and had on previous occasions applied for and received authorization from OFAC for the export of the same or similar types of items to Iran. Additionally, in or about March 2010, Alcon Labs was alerted by a European freight forwarder that a warehouse/distribution center in Switzerland to which Alcon Labs had been shipping the U.S.-origin items since 2008 to fulfill sales orders by a Swiss affiliate, Alcon Pharmaceuticals Ltd. ("Alcon Pharmaceuticals"), did not retain stock or inventory of the items. Rather, the items had been ordered by Iranian customers and were being transshipped by or at the direction of Alcon Pharmaceuticals to Iran without the required U.S. Government authorization.

Nonetheless, on 43 occasions after March 2010, Alcon Labs continued to export U.S.-origin items to fulfill Alcon Pharmaceuticals' sales orders, albeit shipping the items to one or more other warehouse/distribution centers. Alcon Labs failed to determine the end user or ultimate destination of the items, which continued to be transshipped to Iran. Notwithstanding the need for export licenses, no U.S. Government authorization was sought or obtained for any of these 43 transactions.

In so doing, Alcon Labs committed 43 violations of Section 764.2(a) of the Regulations.

* * * * * *

Accordingly, Alcon Labs is hereby notified that an administrative proceeding is instituted against them 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 up to $250,000 per violation[6] or twice the value of the transaction that is the basis of the violation;[7]
- Denial of export privileges;

---

[5] Administered by OFAC, the ITR were renamed the Iranian Transactions and Sanctions Regulations ("ITSR") and reissued in their entirety by OFAC on October 22, 2012. See 77 Fed. Reg. 64.664 (Oct. 22, 2012). Section 560.204 remains unchanged in pertinent part. See 31 C.F.R. §560.204 (2010-2011 and 2015).

[6] This amount is subject to increase pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Sec. 701 of Public Law 114-74, enacted on November 2, 2015.

[7] *See* International Emergency Economic Powers Enhancement Act of 2007, Pub. L. No. 110-96, 121 Stat. 1011 (2007).

- Exclusion from practice before BIS; and/or
- Any other liability, sanction, or penalty available under law.

If Alcon Labs 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. *See* 15 C.F.R. §§ 766.6 and 766.7. If Alcon Labs defaults, the Administrative Law Judge may find the charges alleged in this letter are true without a hearing or further notice to Alcon Labs. The Under Secretary of Commerce for Industry and Security may then impose up to the maximum penalty for the charges in this letter.

Alcon Labs is further notified that they are entitled to an agency hearing on the record if it files a written demand for one with its answer. *See* C.F.R. § 766.6(c). Alcon Labs is also entitled to be represented by counsel or other authorized representative who has power of attorney to represent them. *See* 15 C.F.R. §§ 766.3(a) and 766.4.

The Regulations provide for settlement without a hearing. *See* 15 C.F.R. § 766.18. Should Alcon Labs have a proposal to settle this case, Alcon Labs' representative should transmit it to the attorney representing BIS named below.

Alcon Labs is further notified that under the Small Business Regulatory Enforcement Flexibility Act, Alcon Labs may be eligible for assistance from the Office of the National Ombudsman of the Small Business Administration in this matter. To determine eligibility and get more information, please see: http://www.sba.gov/ombudsman/.

The U.S. Coast Guard is providing administrative law judge services in connection with the matters set forth in this letter. Accordingly, Alcon Labs' 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 Alcon Labs' answer must be served on BIS at the following address:

Chief Counsel for Industry and Security
Attention: Gregory Michelsen Esq.
Room H-3839
14th Street and Constitution Avenue, N.W.
Washington, D.C. 20230

Gregory Michelsen is the attorney representing BIS in this case; any communications that Alcon Labs may wish to have concerning this matter should occur through him. Mr. Michelsen may be contacted by telephone at (202) 482-5301.

Sincerely,

Douglas R. Hassebrock
Director
Office of Export Enforcement

Schedule of Violations
Alcon Laboratories, Inc.

Charge	Date of Export	Ultimate Destination	Commodity	ECCN	Total Value	Violation
1	09-Apr-10	Iran	Medical Equipment and Supplies	EAR99	$129,418.00	15 C.F.R. §764.2(a)
2	09-Apr-10	Iran	Medical Equipment and Supplies	EAR99	$14,214.00	15 C.F.R. §764.2(a)
3	21-Apr-10	Iran	Medical Equipment and Supplies	EAR99	$21,306.00	15 C.F.R. §764.2(a)
4	26-Apr-10	Iran	Medical Equipment and Supplies	EAR99	$102,244.00	15 C.F.R. §764.2(a)
5	26-Apr-10	Iran	Medical Equipment and Supplies	EAR99	$71,644.00	15 C.F.R. §764.2(a)
6	07-May-10	Iran	Medical Equipment and Supplies	EAR99	$44,041.00	15 C.F.R. §764.2(a)
7	14-Jun-10	Iran	Medical Equipment and Supplies	EAR99	$16,088.00	15 C.F.R. §764.2(a)
8	17-Jun-10	Iran	Medical Equipment and Supplies	EAR99	$348,252.00	15 C.F.R. §764.2(a)
9	22-Jun-10	Iran	Medical Equipment and Supplies	EAR99	$112,864.00	15 C.F.R. §764.2(a)
10	15-Jul-10	Iran	Medical Equipment and Supplies	EAR99	$301,030.00	15 C.F.R. §764.2(a)
11	07-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$20,157.00	15 C.F.R. §764.2(a)
12	08-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$196,340.00	15 C.F.R. §764.2(a)
13	08-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$65,872.00	15 C.F.R. §764.2(a)
14	08-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$21,290.00	15 C.F.R. §764.2(a)
15	13-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$40,499.00	15 C.F.R. §764.2(a)
16	21-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$18,529.00	15 C.F.R. §764.2(a)
17	29-Sep-10	Iran	Medical Equipment and Supplies	EAR99	$28,937.00	15 C.F.R. §764.2(a)
18	12-Oct-10	Iran	Medical Equipment and Supplies	EAR99	$40,315.00	15 C.F.R. §764.2(a)
19	13-Oct-10	Iran	Medical Equipment and Supplies	EAR99	$20,157.00	15 C.F.R. §764.2(a)
20	26-Oct-10	Iran	Medical Equipment and Supplies	EAR99	$13,939.00	15 C.F.R. §764.2(a)
21	04-Nov-10	Iran	Medical Equipment and Supplies	EAR99	$41,475.00	15 C.F.R. §764.2(a)
22	04-Nov-10	Iran	Medical Equipment and Supplies	EAR99	$28,163.00	15 C.F.R. §764.2(a)
23	25-Nov-10	Iran	Medical Equipment and Supplies	EAR99	$26,098.00	15 C.F.R. §764.2(a)
24	02-Dec-10	Iran	Medical Equipment and Supplies	EAR99	$44,777.00	15 C.F.R. §764.2(a)
25	10-Dec-10	Iran	Medical Equipment and Supplies	EAR99	$44,697.00	15 C.F.R. §764.2(a)
26	12-Jan-11	Iran	Medical Equipment and Supplies	EAR99	$26,874.00	15 C.F.R. §764.2(a)
27	25-Jan-11	Iran	Medical Equipment and Supplies	EAR99	$44,947.00	15 C.F.R. §764.2(a)
28	09-Feb-11	Iran	Medical Equipment and Supplies	EAR99	$14,557.00	15 C.F.R. §764.2(a)

Schedule of Violations
Alcon Laboratories, Inc.

Charge	Date of Export	Ultimate Destination	Commodity	ECCN	Total Value	Violation
29	21-Mar-11	Iran	Medical Equipment and Supplies	EAR99	$320,895.00	15 C.F.R. §764.2(a)
30	21-Mar-11	Iran	Medical Equipment and Supplies	EAR99	$140,836.00	15 C.F.R. §764.2(a)
31	21-Mar-11	Iran	Medical Equipment and Supplies	EAR99	$40,888.00	15 C.F.R. §764.2(a)
32	06-Apr-11	Iran	Medical Equipment and Supplies	EAR99	$537,811.00	15 C.F.R. §764.2(a)
33	17-May-11	Iran	Medical Equipment and Supplies	EAR99	$44,060.00	15 C.F.R. §764.2(a)
34	17-May-11	Iran	Medical Equipment and Supplies	EAR99	$44,060.00	15 C.F.R. §764.2(a)
35	23-May-11	Iran	Medical Equipment and Supplies	EAR99	$49,304.00	15 C.F.R. §764.2(a)
36	20-Jun-11	Iran	Medical Equipment and Supplies	EAR99	$114,309.00	15 C.F.R. §764.2(a)
37	22-Jun-11	Iran	Medical Equipment and Supplies	EAR99	$31,633.00	15 C.F.R. §764.2(a)
38	13-Jul-11	Iran	Medical Equipment and Supplies	EAR99	$74,960.00	15 C.F.R. §764.2(a)
39	19-Aug-11	Iran	Medical Equipment and Supplies	EAR99	$113,294.00	15 C.F.R. §764.2(a)
40	24-Aug-11	Iran	Medical Equipment and Supplies	EAR99	$46,186.00	15 C.F.R. §764.2(a)
41	26-Sep-11	Iran	Medical Equipment and Supplies	EAR99	$74,616.00	15 C.F.R. §764.2(a)
42	26-Sep-11	Iran	Medical Equipment and Supplies	EAR99	$74,616.00	15 C.F.R. §764.2(a)
43	30-Sep-11	Iran	Medical Equipment and Supplies	EAR99	$46,186.00	15 C.F.R. §764.2(a)
Total					**$3,652,378.00**	