

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

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In the Matter of: )  
 )  
GE Healthcare Bioscience BioProcess Corp. )  
800 Centennial Ave )  
P.O. Box 1327 )  
Piscataway NJ 08854 )  
 )  
 )  
 )  
Respondent )  
\_\_\_\_\_

ORDER RELATING TO GE HEALTHCARE BIOSCIENCE BIOPROCESS CORP., AS  
SUCCESSOR TO WAVE BIOTECH, LLC

The Bureau of Industry and Security, U.S. Department of Commerce (“BIS”) has notified GE Healthcare Bioscience BioProcess Corp. (“GE Bioscience”) of its intention to initiate an administrative proceeding against GE Bioscience pursuant to Section 766.3 of the Export Administration Regulations (the “Regulations”),<sup>1</sup> and Section 13(c) of the Export Administration Act of 1979, as amended (the “Act”),<sup>2</sup> through the issuance of a proposed charging letter to GE Bioscience that alleged that GE Bioscience, as the successor corporation to Wave Biotech, LLC, is liable for nine violations of the Regulations. Specifically, these charges are:

<sup>1</sup> The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2009). The charged violations occurred between 2004 and 2007. The Regulations governing the violations at issue are found in the 2004 through 2007 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (2004 - 2007)). The 2009 Regulations set forth the procedures that apply to this matter.

<sup>2</sup> 50 U.S.C. app. §§ 2401-2420 (2000). 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 13, 2009 (74 Fed. Reg. 41,325 (Aug. 14, 2009)), continues the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. § 1701, *et. seq.*).

**Charges 1-8                    15 C.F.R. § 764.2(a) - Engaging in Prohibited Conduct by Exporting  
Bioreactor Kits Without the Required Licenses**

On eight occasions between on or about August 18, 2004 and on or about March 27, 2007, GE Bioscience/Wave Biotech<sup>3</sup> engaged in conduct prohibited by the Regulations by exporting bioreactor kits, items classified under Export Control Classification Number (“ECCN”) 2B352 and controlled for chemical and biological weapons proliferation reasons, from the United States to India, Mexico, the People’s Republic of China, Singapore and Taiwan without the Department of Commerce licenses required by Section 742.2 of the Regulations. In so doing, GE Bioscience/Wave Biotech committed eight violations of Section 764.2(a) of the Regulations.

**Charge 9                        15 C.F.R. § 764.2(a) - Engaging in Prohibited Conduct by  
Reexporting to Israel Bioreactor Kits Without the Required License**

On or about March 9, 2006, GE Bioscience/Wave Biotech<sup>4</sup> engaged in conduct prohibited by the Regulations by reexporting a bioreactor kit, an item subject to the Regulations, classified under ECCN 2B352, and controlled for chemical and biological weapons proliferation reasons, from Ireland to Israel without the Department of Commerce license required by Section 742.2 of the Regulations. In so doing, GE Bioscience/Wave Biotech committed one violation of Section 764.2(a) of the Regulations.

WHEREAS, BIS and GE Bioscience 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, GE Bioscience shall be assessed a civil penalty in the amount of \$126,000, the payment of which shall be made to the U.S. Department of Commerce within 30 days of the date of this Order. Payment shall be made in the manner specified in the attached instructions.

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<sup>3</sup> The alleged violations were committed between August 2004 and March 2007, prior to GE Bioscience’s acquisition of Wave Biotech on April 16, 2007. The charges attribute the described pre-acquisition actions to GE Bioscience because it is liable for the alleged violations as successor to Wave Biotech.

<sup>4</sup> See note 3, *supra*.

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, GE Bioscience 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 GE Bioscience. Accordingly, if GE Bioscience should fail to pay the civil penalty in a timely manner, the undersigned may enter an Order denying all of GE Bioscience's export privileges under the Regulations for a period of one year from the date of this Order.

FOURTH, 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.



David W. Mills  
Assistant Secretary of Commerce  
for Export Enforcement

Issued this 5 day of May, 2010.

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

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In the Matter of: )  
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GE Healthcare Bioscience BioProcess Corp. )  
800 Centennial Ave )  
P.O. Box 1327 )  
Piscataway NJ 08854 )  
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Respondent )  
\_\_\_\_\_

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is made by and between GE Healthcare Bioscience BioProcess Corp. (“GE Bioscience”) 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”),<sup>1</sup> issued pursuant to the Export Administration Act of 1979, as amended (the “Act”).<sup>2</sup>

WHEREAS, GE Bioscience filed a voluntary self-disclosure with BIS’s Office of Export Enforcement;

<sup>1</sup> The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2009). The charged violations occurred between 2004 and 2007. The Regulations governing the violations at issue are found in the 2004 through 2007 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (2004 - 2007)). The 2009 Regulations set forth the procedures that apply to this matter.

<sup>2</sup> 50 U.S.C. app. §§ 2401-2420 (2000). 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 13, 2009 (74 Fed. Reg. 41,325 (Aug. 14, 2009)), continues the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. § 1701, *et. seq.*).

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

WHEREAS, BIS has issued a Proposed Charging Letter to GE Bioscience that alleged that GE Bioscience, as the successor corporation to Wave Biotech, LLC (“Wave Biotech”), is liable for nine violations of the Export Administration Regulations, specifically:

**Charges 1-8                    15 C.F.R. § 764.2(a) - Engaging in Prohibited Conduct by Exporting Bioreactor Kits Without the Required Licenses**

On eight occasions between on or about August 18, 2004 and on or about March 27, 2007, GE Bioscience/Wave Biotech<sup>3</sup> engaged in conduct prohibited by the Regulations by exporting bioreactor kits, items classified under Export Control Classification Number (“ECCN”) 2B352 and controlled for chemical and biological weapons proliferation reasons, from the United States to India, Mexico, the People’s Republic of China, Singapore and Taiwan without the Department of Commerce licenses required by Section 742.2 of the Regulations. In so doing, GE Bioscience/Wave Biotech committed eight violations of Section 764.2(a) of the Regulations.

**Charge 9                    15 C.F.R. § 764.2(a) - Engaging in Prohibited Conduct by Reexporting to Israel Bioreactor Kits Without the Required License**

On or about March 9, 2006, GE Bioscience/Wave Biotech<sup>4</sup> engaged in conduct prohibited by the Regulations by reexporting a bioreactor kit, an item subject to the Regulations, classified under ECCN 2B352, and controlled for chemical and biological weapons proliferation reasons, from Ireland to Israel without the Department of Commerce license required by Section 742.2 of the Regulations. In so doing, GE Bioscience/Wave Biotech committed one violation of Section 764.2(a) of the Regulations.

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<sup>3</sup> The alleged violations were committed between August 2004 and March 2007, prior to GE Bioscience’s acquisition of Wave Biotech on April 16, 2007. The charges attribute the described pre-acquisition actions to GE Bioscience because it is liable for the alleged violations as successor to Wave Biotech.

<sup>4</sup> See note 3, *supra*.

WHEREAS, GE Bioscience 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, GE Bioscience fully understands 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, GE Bioscience enters into this Agreement voluntarily and with full knowledge of its rights;

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

WHEREAS, GE Bioscience neither admits nor denies the allegations contained in the Proposed Charging Letter;

WHEREAS, GE Bioscience wishes to settle and dispose of all matters alleged in the Proposed Charging Letter by entering into this Agreement; and

WHEREAS, GE Bioscience agrees to be bound by the Order, if issued;

NOW THEREFORE, the Parties hereby agree as follows:

1. BIS has jurisdiction under the Regulations in connection with the matters alleged in the Proposed Charging Letter.

2. The following sanction shall be imposed against GE Bioscience in complete settlement of the alleged violations of the Regulations relating to the transactions specifically detailed in the Proposed Charging Letter:

a. GE Bioscience shall be assessed a civil penalty in the amount of \$126,000, the payment of which shall be made to the U.S. Department of

Commerce within 30 days of the date 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, permission, or privilege granted, or to be granted, to GE Bioscience. Failure to make timely payment of the civil penalty set forth above may result in the denial of all of GE Bioscience's export privileges for a period of one year from the date of imposition of the penalty.

3. Subject to the approval of this Agreement pursuant to paragraph 8 hereof, GE Bioscience 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 issued), 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; and (c) seek judicial review or otherwise contest the validity of this Agreement or the Order, if issued.

4. Upon entry of the Order, BIS will not initiate any further administrative proceedings against GE Bioscience in connection with any violation of the Act or the Regulations arising out of the transactions specifically detailed in the Proposed Charging Letter.

5. BIS will make the Proposed Charging Letter, this Agreement, and the Order, if issued, 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 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. Each signatory affirms that he has authority to enter into this Settlement Agreement and to bind it respective party to the terms and conditions set forth herein.

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



John Sonderman  
Acting Director  
Office of Export Enforcement

Date: 4/29/2010

GE HEALTHCARE BIOSCIENCE  
BIOPROCESS CORP.



Eric Roman  
President  
GE Healthcare Bioscience BioProcess Corp.

Date: April 22, 2010



PROPOSED CHARGING LETTER

REGISTERED MAIL - RETURN RECEIPT REQUESTED

GE Healthcare Bioscience BioProcess Corp.  
800 Centennial Ave  
P.O. Box 1327  
Piscataway NJ 08854

Attn: *Eric Roman*  
President

Dear Mr. Roman:

The Bureau of Industry and Security, U.S. Department of Commerce (“BIS”), has reason to believe that GE Healthcare Bioscience BioProcess Corp., of Piscataway, New Jersey (“GE Bioscience”), as the successor corporation to Wave Biotech, LLC (“Wave Biotech”), is liable for nine violations of the Export Administration Regulations (the “Regulations”),<sup>1</sup> which are issued under the authority of the Export Administration Act of 1979, as amended (the “Act”).<sup>2</sup> Specifically, BIS charges that GE Bioscience is liable for the following violations:

**Charges 1-8                    15 C.F.R. § 764.2(a) - Engaging in Prohibited Conduct by Exporting Bioreactor Kits Without the Required Licenses**

As described in greater detail in the attached Schedule of Violations, which is incorporated herein by reference, on eight occasions between on or about August 18, 2004 and on or about March 27, 2007, GE Bioscience/Wave Biotech<sup>3</sup> engaged in conduct prohibited by the Regulations by exporting bioreactor kits, items classified under Export Control Classification

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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 (2009). The charged violations occurred between 2004 and 2007. The Regulations governing the violations at issue are found in the 2004-2007 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (2004-2007)). The 2009 Regulations set forth the procedures that apply to this matter.

<sup>2</sup> 50 U.S.C. app. §§ 2401-2420 (2000). 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)), as extended most recently by the Notice of August 13, 2009 (74 Fed. Reg. 41,325 (Aug. 14, 2009)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. § 1701, et seq.).

<sup>3</sup> The alleged violations were committed between August 2004 and March 2007, prior to GE Bioscience’s acquisition of Wave Biotech on April 16, 2007. The charges attribute the described pre-acquisition actions to GE Bioscience because it is liable for the alleged violations as successor to Wave Biotech.

Number (“ECCN”) 2B352 and controlled for chemical and biological weapons proliferation reasons, from the United States to India, Mexico, the People’s Republic of China, Singapore and Taiwan without the Department of Commerce licenses required by Section 742.2 of the Regulations. In so doing, GE Bioscience/Wave Biotech committed eight violations of Section 764.2(a) of the Regulations.

**Charge 9                      15 C.F.R. § 764.2(a) - Engaging in Prohibited Conduct by  
Reexporting to Israel Bioreactor Kits Without the Required License**

As described in greater detail in the attached Schedule of Violations, which is incorporated herein by reference, on or about March 9, 2006, GE Bioscience/Wave Biotech<sup>4</sup> engaged in conduct prohibited by the Regulations by reexporting a bioreactor kit, an item subject to the Regulations, classified under ECCN 2B352, and controlled for chemical and biological weapons proliferation reasons, from Ireland to Israel without the Department of Commerce license required by Section 742.2 of the Regulations. In so doing, GE Bioscience/Wave Biotech committed one violation of Section 764.2(a) of the Regulations.

\* \* \* \* \*

Accordingly, GE Bioscience 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 up to the greater of \$250,000 per violation or twice the value of the transaction that is the basis of the violation;<sup>5</sup>
- Denial of export privileges; and/or
- Exclusion from practice before BIS.

If GE Bioscience 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 GE Bioscience defaults, the Administrative Law Judge may find the charges alleged in this letter are true without a hearing or further notice to GE Bioscience. The Under Secretary of Commerce for Industry and Security may then impose up to the maximum penalty for the charges in this letter.

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

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<sup>4</sup> *See* note 3, *supra*.

<sup>5</sup> *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 GE Bioscience have a proposal to settle this case, GE Bioscience or its representative should transmit it to the attorney representing BIS named below.

GE Bioscience is further notified that under the Small Business Regulatory Enforcement Flexibility Act, GE Bioscience 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, GE Bioscience'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 GE Bioscience's answer must be served on BIS at the following address:

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

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

Sincerely,

John Sonderman  
Acting Director  
Office of Export Enforcement

<b>GE Healthcare Bioscience BioProcess Corp.</b> <b>Proposed Charging Letter</b> <b>Schedule of Violations</b>							
<b>Charge No.</b>	<b>Date of Export or Reexport</b>	<b>Destination</b>	<b>ECCN</b>	<b>Description of Commodity</b>	<b>Quantity</b>	<b>Value</b>	<b>Violation</b>
1	8/18/2004	Taiwan	2B352	KIT50EH (25 Liter Working Volume)	1	\$2,000	15 C.F.R §764.2(a)
2	3/10/2005	Singapore	2B352	KIT50EH (25 Liter Working Volume)	1	\$2,500	15 C.F.R §764.2(a)
3	3/25/2005	Singapore	2B352	KIT50EH (25 Liter Working Volume)	1	\$2,500	15 C.F.R §764.2(a)
4	5/12/2005	PRC	2B352	KIT50EH (25 Liter Working Volume)	2	\$5,000	15 C.F.R §764.2(a)
5	1/31/2006	Mexico	2B352	KIT50EH (25 Liter Working Volume)	2	\$5,000	15 C.F.R §764.2(a)
6	3/31/2006	India	2B352	KIT50EH (25 Liter Working Volume)	2	\$5,000	15 C.F.R §764.2(a)
7	12/1/2006	Taiwan	2B352	KIT50EH (25 Liter Working Volume)	3	\$6,000	15 C.F.R §764.2(a)
8	3/27/2007	PRC	2B352	KIT50EH (25 Liter Working Volume)	1	\$2,125	15 C.F.R §764.2(a)
9	3/9/2006	Israel (from Ireland)	2B352	KIT50EH (25 Liter Working Volume)	1	\$1,750	15 C.F.R §764.2(a)