

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Bristol-Myers Squibb Medical Imaging, Inc.
331 Treble Cove Road
North Billerica, MA 01862

Attn: Cory Zwerling
President

Dear Mr. Zwerling:

The Bureau of Industry and Security, United States Department of Commerce (“BIS”), has reason to believe that DuPont Merck Pharmaceutical Company of North Billerica, Massachusetts, (“DuPont Merck”) has committed three violations of the Export Administration Regulations (the “Regulations”),¹ which are issued under the authority of the Export Administration Act of 1979 (the “Act”).² BIS believes that Bristol-Myers Squibb Medical Imaging, Inc. (“Respondent” or “Bristol-Myers”), as the successor to DuPont Merck, is liable for the violations. Specifically, BIS charges that DuPont Merck committed the following violations:

Charge 1 15 C.F.R. § 764.2(a) - Unlicensed export to Entity List organization

On or about January 6, 1999, DuPont Merck engaged in conduct prohibited by the Regulations by exporting Cobalt-57, an item subject to the Regulations, to the Department of

¹ The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2004). The charged violations occurred in 1999. The Regulations governing the violations at issue are found in the 1999 version of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (1999)). The 2004 Regulations establish the procedures that apply to this matter.

² 50 U.S.C. app. §§ 2401- 2420 (2000). 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., p. 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 by Pub. L. No. 106-508 (114 Stat. 2360 (2000)) and it remained in effect through August 20, 2001. Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp., p. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 6, 2004 (69 *Fed. Reg.* 48763 (August 10, 2004)), continues the Regulations in effect under IEEPA.

Atomic Energy, Directorate of Purchase and Stores, in India (“DAE”) without the Department of Commerce license required by then Section 744.11 of the Regulations. At all times relevant hereto, DAE was an organization listed on the Entity List set forth at Supplement No. 4 to Part 744 of the Regulations (“Entity List”). In so doing, DuPont Merck committed one violation of Section 764.2(a) of the Regulations.

Charge 2 15 C.F.R. § 764.2(c) - Attempted unlicensed export to a Entity List organization

On or about January 16, 1999, DuPont Merck attempted a violation of the Regulations by trying to export Cobalt-57, iron foil, and potassium ferrocyanide, items subject to the Regulations, to DAE without the Department of Commerce license required by then Section 744.11 of the Regulations. At all times relevant hereto, DAE was an organization listed on the Entity List. In so doing, DuPont Merck committed one violation of Section 764.2(c) of the Regulations.

Charge 3 15 C.F.R. § 764.2(e) - Transferring an item to a Entity List organization with Knowledge that a violation of the Regulations was about to occur

On or about January 16, 1999, in connection with the attempted export referenced in Charge 2 above, DuPont Merck transferred Cobalt-57, an item subject to the Regulations, with knowledge that a violation of the Regulations was about to occur. At all times relevant hereto, DuPont Merck knew or should have known that a Department of Commerce license was required to export the Cobalt-57 to DAE and that the required license had not been obtained. In so doing, DuPont Merck committed one violation of section 764.2(e) of the Regulations.

Accordingly, Bristol-Myers is hereby notified that an administrative proceeding is instituted against it pursuant to 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 per violation;³

Denial of export privileges; and/or

Exclusion from practice before BIS.

If Bristol-Myers 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.

³ See 15 C.F.R. § 6.4(a)(2).

§§ 766.6 and 766.7. If Bristol-Myers defaults, the Administrative Law Judge may find the charges alleged in this letter are true without a hearing or further notice to Bristol-Myers. *See id.* The Under Secretary for Industry and Security may then impose up to the maximum penalty on the charges in this letter. *See id.*

Bristol-Myers is further notified that it is entitled to an agency hearing on the record if Bristol-Myers files a written demand for one with its answer. *See* 15 C.F.R. § 766.6. Bristol-Myers 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.

The Regulations provide for settlement without a hearing. *See* 15 C.F.R. § 766.18. Should Bristol-Myers have a proposal to settle this case, Bristol-Myers or its representative should transmit it to me through the attorney representing BIS named below.

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

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

Melissa B. Mannino is the attorney representing BIS in this case. Any communications that Bristol-Myers may wish to have concerning this matter should occur through her. She may be contacted by telephone at (202) 482-5301.

Sincerely,

Acting Director
Office of Export Enforcement

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

In the Matter of:)
)
Bristol-Myers Squibb Medical Imaging, Inc.)
331 Treble Cove Road)
North Billerica, MA 01862)
)
Respondent.)
)

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is made by and between Respondent, Bristol-Myers Squibb Medical Imaging, Inc. (“Bristol-Myers”), as the successor to DuPont Merck Pharmaceutical Company (“DuPont Merck”), and the Bureau of Industry and Security, United States 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 (2004)) (“Regulations”)¹ issued pursuant to the Export Administration Act of 1979, as amended (50 U.S.C. app. §§ 2401-2420 (2000)) (“Act”),²

¹ The violations charged occurred in 1999. The Regulations governing the violations at issue are found in the 1999 version of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (1999)). The 2004 Regulations establish the procedures that apply to this matter.

² 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, BIS has notified Bristol-Myers of its intention to initiate an administrative proceeding against Bristol-Myers, pursuant to the Act and the Regulations;

WHEREAS, BIS has issued a proposed charging letter to Bristol-Myers that alleged that DuPont Merck, a predecessor corporation to Bristol-Myers, committed three violations of the Regulations, specifically:

1. *One Violation of 15 C.F.R. § 764.2(a) - Unlicensed Export to Entity List*

Organization: On or about January 6, 1999, DuPont Merck engaged in conduct prohibited by the Regulations by exporting Cobalt-57, an item subject to the Regulations, to the Department of Atomic Energy, Directorate of Purchase and Stores, in India (“DAE”) without the Department of Commerce license required by then Section 744.11 of the Regulations. At all times relevant hereto, DAE was an organization listed on the Entity List set forth at Supplement No. 4 to Part 744 of the Regulations (“Entity List”).

2. *One Violation of 15 C.F.R. § 764.2(c) - Attempted Unlicensed Export to a Entity List Organization*

Organization: On or about January 16, 1999, DuPont Merck attempted a violation of the Regulations by trying to export Cobalt-57, iron foil, and potassium ferrocyanide, items subject to the Regulations, to DAE without the Department of Commerce license required by then Section 744.11 of the Regulations. At all times relevant hereto, DAE was an organization listed on the Entity List.

3. *One Violation of 15 C.F.R. § 764.2(e) - Transferring an Item to an Entity List*

Organization with Knowledge that a Violation of the Regulations would Occur:

On or about January 16, 1999, in connection with the attempted export referenced in paragraph 2 above, DuPont Merck transferred Cobalt-57, an item subject to the Regulations, with knowledge that a violation of the Regulations was about to occur. At all times relevant hereto, DuPont Merck knew or should have known that a Department of Commerce license was required to export the Cobalt-57 to DAE and that the required license had not been obtained.

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

WHEREAS, Bristol-Myers fully understand 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, Bristol-Myers enters into this Agreement voluntarily and with full knowledge of its rights;

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

WHEREAS, Bristol-Myers neither admits nor denies the allegations contained in the proposed charging letter;

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

WHEREAS, Bristol-Myers agrees to be bound by the Order, if entered;

NOW THEREFORE, the Parties hereby agree as follows:

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

2. The following sanctions shall be imposed against Bristol-Myers in complete settlement of the violations of the Regulations set forth in the proposed charging letter:

- a. Bristol-Myers shall be assessed a civil penalty in the amount of \$16,200 which shall be paid to the U.S. Department of Commerce within 30 days from the date of entry of the Order.
- 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 Bristol-Myers. Failure to make timely payment of the civil penalty set forth above may result in the denial of all of Bristol-Myers'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, Bristol-Myers 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 the proposed 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 \$16,200 civil penalty, BIS will not initiate any further administrative proceeding against Bristol-Myers in connection with any violation of the Act or the Regulations arising out of the transactions identified in 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.

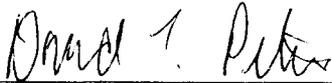
7. No agreement, understanding, representation or interpretation not contained in this Agreement may be used to vary or otherwise affect the terms of this Agreement or the Order, if entered, nor shall this Agreement serve to bind, constrain, or otherwise limit any action by any other agency or department of the United States 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 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.

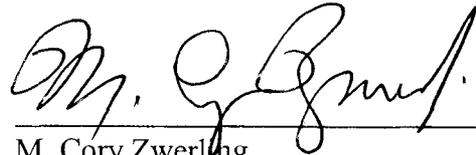
9. Each signatory affirms his authority to enter into this Settlement Agreement and to bind his respective party to the terms and conditions set forth herein.

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

BRISTOL-MYERS SQUIBB MEDICAL INC.
IMAGING, INC.



Acting Director
Office of Export Enforcement



M. Cory Zwerling
President

Date: 11/10/04

Date: 11/2/04

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

In the Matter of:)
)
Bristol-Myers Squibb Medical Imaging, Inc.)
331 Treble Cove Road)
North Billerica, MA 01862)
)
Respondent.)
)

ORDER

The Bureau of Industry and Security, United States Department of Commerce (“BIS”) has notified Bristol-Myers Squibb Medical Imaging, Inc. (“Bristol-Myers”), as the successor to DuPont Merck Pharmaceutical Company (“DuPont Merck”), of its intention to initiate an administrative proceeding against Bristol-Myers pursuant to Section 766.3 of the Export Administration Regulations (currently codified at 15 C.F.R. Parts 730-774 (2004)) (“Regulations”)¹ and Section 13(c) of the Export Administration Act of 1979, as amended (50 U.S.C. app. §§ 2401-2420 (2000)) (“Act”),² based on the proposed charging letter issued to

¹ The violations charged occurred in 1999. The Regulations governing the violations at issue are found in the 1999 version of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (1999)). The 2004 Regulations establish the procedures that apply to this matter.

² 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.

Bristol-Myers that alleged that DuPont Merck, a predecessor corporation to Bristol-Myers, committed three violations of the Regulations. Specifically, the charges are:

1. *One Violation of 15 C.F.R. § 764.2(a) - Unlicensed Export to Entity List*
Organization: On or about January 6, 1999, DuPont Merck engaged in conduct prohibited by the Regulations by exporting Cobalt-57, an item subject to the Regulations, to the Department of Atomic Energy, Directorate of Purchase and Stores, in India (“DAE”) without the Department of Commerce license required by then Section 744.11 of the Regulations. At all times relevant hereto, DAE was an organization listed on the Entity List set forth at Supplement No. 4 to Part 744 of the Regulations (“Entity List”).
2. *One Violation of 15 C.F.R. § 764.2(c) - Attempted Unlicensed Export to a Entity List Organization:* On or about January 16, 1999, DuPont Merck attempted a violation of the Regulations by trying to export Cobalt-57, iron foil, and potassium ferrocyanide, items subject to the Regulations, to DAE without the Department of Commerce license required by then Section 744.11 of the Regulations. At all times relevant hereto, DAE was an organization listed on the Entity List.
3. *One Violation of 15 C.F.R. § 764.2(e) -Transferring an Item to an Entity List Organization with Knowledge that a Violation of the Regulations would Occur:*
On or about January 16, 1999, in connection with the attempted export referenced in paragraph 2 above, DuPont Merck transferred Cobalt-57, an item subject to the Regulations, with knowledge that a violation of the Regulations was about to occur. At all times relevant hereto, DuPont Merck knew or should have known

that a Department of Commerce license was required to export the Cobalt-57 to DAE and that the required license had not been obtained.

BIS and Bristol-Myers having 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 the terms of the Settlement Agreement having been approved by me;

IT IS THEREFORE ORDERED:

FIRST, that a civil penalty of \$16,200 is assessed against Bristol-Myers, 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, Bristol-Myers 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 Bristol-Myers. Accordingly, if Bristol-Myers should fail to pay the civil penalty in a timely manner, the undersigned may enter an Order denying all of Bristol-Myers's export privileges for a period of one year from the date of entry 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.


Julie L. Myers
Assistant Secretary of Commerce
for Export Enforcement

Entered this 12th day of November 2004.