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

In the Matter of **CERTAIN SLEEP-DISORDERED BREATHING TREATMENT SYSTEMS AND COMPONENTS THEREOF**	Investigation No. 337-TA-890

LIMITED EXCLUSION ORDER

The United States International Trade Commission ("Commission") has determined that there is a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in the unlawful importation, sale for importation, or sale within the United States after importation by Respondents BMC Medical Co., Ltd., 3B Medical, Inc. and 3B Products L.L.C. (collectively "Respondents") of certain sleep-disordered breathing treatment systems and components thereof covered by one or more of claims of 1, 9, 32, 89, and 92 of U.S. Patent No. 7,178,527 ("the '527 patent"); claims 19, 21, 29, 32, and 36 of U.S. Patent No. 7,950,392 ("the '392 patent"); claims 32, 33, 34, and 53 of U.S. Patent No. 7,997,267 ("the '267 patent"); claims 30, 37, and 38 of U.S. Patent No. 7,341,060 ("the '060 patent"); and claims 1, 3, 5, 11, 28, 30, 31, and 56 of U.S. Patent No. 8,312,883 ("the '883 patent").

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission has made its determination on the issues of remedy, public interest, and bonding. The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting the unlicensed entry of covered sleep-disordered breathing treatment systems and components thereof manufactured by or on behalf of the Respondents or any of their

affiliate companies, parents, subsidiaries, licensees, or other related business entities, or their successors or assigns.

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude the issuance of the limited exclusion order, and that the bond during the Presidential review period shall be in the amount of 65 percent of the entered value for the covered products.

Accordingly, the Commission hereby **ORDERS** that:

1. Sleep-disordered breathing treatment systems and components thereof that infringe one or more of claims 1, 9, 32, 89, and 92 of the '527 patent; claims 19, 21, 29, 32, and 36 of the '392 patent; claims 32, 33, 34, and 53 of the '267 patent; claims 30, 37, and 38 of the '060 patent; and claims 1, 3, 5, 11, 28, 30, 31, and 56 of the '883 patent that are manufactured by, or on behalf of, or are imported by or on behalf of BMC Medical Co., Ltd., 3B Medical, Inc., or 3B Products L.L.C. or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns, are excluded from entry for consumption into the United States, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, for the remaining term of the patents, except under license of the patent owner or as provided by law, and except for sleep-disordered breathing treatment masks and components thereof imported for use as service or replacement parts for products imported into the United States prior to the Commission's determination becoming final within the meaning of 19 U.S.C. § 1337(j)(4).

2. Notwithstanding paragraph 1 of this Order, the aforesaid sleep-disordered breathing treatment systems and components thereof are entitled to entry into the United States for consumption, entry for consumption from a foreign trade zone, or withdrawal from a

warehouse for consumption, under bond in the amount of 65 percent of the entered value of imported sleep-disordered breathing treatment systems and components thereof pursuant to subsection (j) of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337(j)), and the Presidential Memorandum for the United States Trade Representative of July 21, 2005 (70 *Fed. Reg.* 43,251), from the day after this Order is received by the United States Trade Representative, and until such time as the United States Trade Representative notifies the Commission that this action is approved or disapproved but, in any event, not later than 60 days after the issuance of receipt of this Order.

3. At the discretion of U.S. Customs and Border Protection ("CBP") and pursuant to the procedures it establishes, persons seeking to import sleep-disordered breathing treatment systems and components thereof that are potentially subject to this Order may be required to certify that they are familiar with the terms of this Order, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under paragraph 1 of this Order. At its discretion, CBP may require persons who have provided the certification described in this paragraph to furnish such records or analyses as are necessary to substantiate this certification.

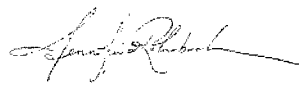
4. In accordance with 19 U.S.C. § 1337 (l), the provisions of this Order shall not apply to infringing sleep-disordered breathing treatment systems and components thereof same that are imported by or for the use of the United States, or imported for and to be used for, the United States with the authorization or consent of the Government.

5. The Commission may modify this Order in accordance with the procedures described in Rule 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

6. The Secretary shall serve copies of this Order upon each party of record in this Investigation and upon the Department of Health and Human Services, the Department of Justice, the Federal Trade Commission, and U.S. Customs and Border Protection.

7. Notice of this Order shall be published in the *Federal Register*.

By order of the Commission.



Jennifer Rohrbach
Supervisory Attorney

Issued: December 23, 2014

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

In the Matter of **CERTAIN SLEEP DISORDERED BREATHING TREATMENT SYSTEMS AND COMPONENTS THEREOF**	Investigation No. 337-TA-890

CEASE AND DESIST ORDER AGAINST
RESPONDENT 3B MEDICAL, INC.

IT IS HEREBY ORDERED THAT RESPONDENT 3B Medical, Inc., 21301 U.S. Highway 27, Lake Wales, Florida 33859 ("3B Medical" or "Respondent") cease and desist from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, transferring (except for exportation), and soliciting U.S. agents or distributors for, sleep-disordered breathing treatment systems and components thereof covered by one or more of claims 1, 9, 32, 89, and 92 of United States Patent No. 7,178,527; claims 19, 21, 29, 32, and 36 of United States Patent No. 7,950,392; claims 32, 33, 34, and 53 of United States Patent No. 7,997,267; claims 30, 37, and 38 of United States Patent No. 7,341,060; and claims 1, 3, 5, 11, 28, 30, 31, and 56 of United States Patent No. 8,312,883. (collectively, "the Asserted Patents") in violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

I. Definitions

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainants" shall mean ResMed Corp. and ResMed, Inc. of San Diego, California and ResMed Ltd of Bella Vista, Australia.

(C) "Respondent" shall mean 3B Medical, Inc., of Lake Wales, Florida.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean sleep-disordered breathing treatment systems and components thereof covered by certain claims of the Asserted Patents. Covered products shall not include articles for which a provision of law or license avoids liability for infringement of certain claims of the Asserted Patents.

II. Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

III. Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining terms of the Asserted Patents, the Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, sell, or otherwise transfer (except for exportation), in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products.

IV. Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this order shall be permitted if:

(A) in a written instrument, the owner of the relevant Asserted Patents authorizes or licenses such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States; or

(B) the conduct is limited to the provision of service and replacement parts for customers that purchased their covered products prior to the date this Order becomes final.

V. Reporting

For purposes of this requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. The first report required under this section shall cover the period from the date of issuance of this order through December 31, 2015. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no inventory of covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and

(b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period.

When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above and submit eight (8) true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-890") in a prominent place on the cover pages and/or the first page. (See Handbook for Electronic Filing Procedures, http:/ /www.usitc.gov/secretary/fed_reg_ notices/ rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainant's counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI. Record-Keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary

[1] Complainants must file a letter with the Secretary identifying the attorney to receive reports associated with this order. The designated attorney must be on the protective order entered in the investigation.

course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

VII. Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen days after the effective date of this order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products in the United States;

(B) Serve, within fifteen days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the last expiration date of the Asserted Patents.

VIII. Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to section V-VI of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX. Enforcement

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.P.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X. Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI. Bonding

The conduct prohibited by Section III of this order may be continued during the sixty-day period in which this order is under review by the United States Trade Representative, as delegated by the President (70 *Fed. Reg.* 43,251 (Jul. 21, 2005)) subject to the Respondent's

posting of a bond in the amount of 65 percent of the entered value of the covered products. This bond provision does not apply to conduct that is otherwise permitted by section IV of this order. Covered products imported on or after the date of issuance of this order are subject to the entry bond set forth in the exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders. (See 19 C.F.R. § 210.68). The bond and any accompanying documentation are to be provided to and approved by the Commission prior to the commencement of conduct that is otherwise prohibited by section III of this order. Upon the Secretary's acceptance of the bond, (a) the Secretary will serve an acceptance letter on all parties, and (b) Respondent must serve a copy of the bond and any accompanying documentation on Complainants' counsel.[2]

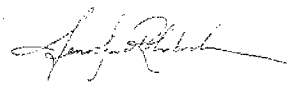
The bond is to be forfeited in the event that the United States Trade Representative approves this order (or does not disapprove it within the review period), unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondent on appeal, or unless Respondent exports or destroys the products subject to this bond and provides certification to that effect that is satisfactory to the Commission.

The bond is to be released in the event the United States Trade Representative disapproves this order and no subsequent order is issued by the Commission and approved (or not disapproved) by the United States Trade Representative, upon service on Respondent of an order

[2] *See* Footnote 1.

issued by the Commission based upon application therefore made by Respondent to the Commission.

By order of the Commission.



Jennifer Rohrbach
Supervisory Attorney

Issued: December 23, 2014

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

In the Matter of **CERTAIN SLEEP DISORDERED BREATHING TREATMENT SYSTEMS AND COMPONENTS THEREOF**	Investigation No. 337-TA-890

CEASE AND DESIST ORDER AGAINST
RESPONDENT 3B PRODUCTS, L.L.C.

IT IS HEREBY ORDERED THAT RESPONDENT 3B Products, L.L.C., 21301 U.S. Highway 27, Lake Wales, Florida 33859 ("3B Products " or "Respondent") cease and desist from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, transferring (except for exportation), and soliciting U.S. agents or distributors for, sleep-disordered breathing treatment systems and components thereof covered by one or more of claims 1, 9, 32, 89, and 92 of United States Patent No. 7,178,527; claims 19, 21, 29, 32, and 36 of United States Patent No. 7,950,392; claims 32, 33, 34, and 53 of United States Patent No. 7,997,267; claims 30, 37, and 38 of United States Patent No. 7,341,060; and claims 1, 3, 5, 11, 28, 30, 31, and 56 of United States Patent No. 8,312,883. (collectively, "the Asserted Patents") in violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

I. Definitions

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainants" shall mean ResMed Corp. and ResMed, Inc. of San Diego, California and ResMed Ltd of Bella Vista, Australia.

(C) "Respondent" shall mean 3B Products, L.L.C., of Lake Wales, Florida.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean sleep-disordered breathing treatment systems and components thereof covered by certain claims of the Asserted Patents. Covered products shall not include articles for which a provision of law or license avoids liability for infringement of certain claims of the Asserted Patents.

II. Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

III. Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining terms of the Asserted Patents, the Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, sell, or otherwise transfer (except for exportation), in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products.

IV. Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this order shall be permitted if:

(A) in a written instrument, the owner of the relevant Asserted Patents authorizes or licenses such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States; or

(B) the conduct is limited to the provision of service and replacement parts for customers that purchased their covered products prior to the date this Order becomes final.

V. Reporting

For purposes of this requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. The first report required under this section shall cover the period from the date of issuance of this order through December 31, 2015. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no inventory of covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and

(b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period.

When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above and submit eight (8) true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-890") in a prominent place on the cover pages and/or the first page. (*See* Handbook for Electronic Filing Procedures, http:/ /www.usitc.gov/secretary/fed_reg_ notices/ rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainant's counsel.[3]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI. Record-Keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary

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course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

VII. Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen days after the effective date of this order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products in the United States;

(B) Serve, within fifteen days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the last expiration date of the Asserted Patents.

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X. Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI. Bonding

The conduct prohibited by Section III of this order may be continued during the sixty-day period in which this order is under review by the United States Trade Representative, as delegated by the President (70 *Fed. Reg.* 43,251 (Jul. 21, 2005)) subject to the Respondent's

posting of a bond in the amount of 65 percent of the entered value of the covered products. This bond provision does not apply to conduct that is otherwise permitted by section IV of this order. Covered products imported on or after the date of issuance of this order are subject to the entry bond set forth in the exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders. (*See* 19 C.F.R. § 210.68). The bond and any accompanying documentation are to be provided to and approved by the Commission prior to the commencement of conduct that is otherwise prohibited by section III of this order. Upon the Secretary's acceptance of the bond, (a) the Secretary will serve an acceptance letter on all parties, and (b) Respondent must serve a copy of the bond and any accompanying documentation on Complainants' counsel.[4]

The bond is to be forfeited in the event that the United States Trade Representative approves this order (or does not disapprove it within the review period), unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondent on appeal, or unless Respondent exports or destroys the products subject to this bond and provides certification to that effect that is satisfactory to the Commission.

The bond is to be released in the event the United States Trade Representative disapproves this order and no subsequent order is issued by the Commission and approved (or not disapproved) by the United States Trade Representative, upon service on Respondent of an order

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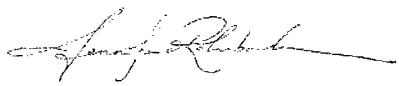
issued by the Commission based upon application therefore made by Respondent to the Commission.

By order of the Commission.



Jennifer Rohrbach
Supervisory Attorney

Issued: December 23, 2014

CERTAIN SLEEP-DISORDERED BREATHING TREATMENT SYSTEMS AND COMPONENTS THEREOF **Inv. No. 337-TA-890**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, Lisa M. Kattan, Esq., and the following parties as indicated, on **December 23, 2014.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants ResMed Corporation, ResMed Incorporated, and ResMed Limited:

Thomas S. Fusco, Esq.
FISH & RICHARDSON P.C.
1425 K Street, NW, 11th Floor
Washington, DC 20005

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

On Behalf of Respondents BMC Medical Co., Ltd., 3B Medical, Inc., and 3B Products, LLC:

Gary M. Hnath, Esq.
MAYER BROWN LLP
1999 K Street, NW
Washington, DC 20006

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____