

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

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In the Matter of

Investigation

No. 337-TA-\_\_\_\_\_

CERTAIN THERMAL SUPPORT  
DEVICES FOR INFANTS, INFANT  
INCUBATORS, INFANT WARMERS,  
AND COMPONENTS THEREOF

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**COMPLAINT UNDER SECTION 337 OF  
THE TARIFF ACT OF 1930, AS AMENDED**

**Complainant:**

Draeger Medical Systems, Inc.  
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Telford, PA 18969  
Tel. (215) 723-5935

**Proposed Respondent:**

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## LIST OF EXHIBITS AND APPENDICES

### LIST OF NON-CONFIDENTIAL EXHIBITS

No.	Description
1	Certified copy of U.S. Patent No. 6,483,080
2	Certified copy of U.S. Patent No. 7,335,157
3	Assignment of '080 patent from inventors to Hill-Rom Services, Inc.
4	Assignment of '080 patent from Hill-Rom Services, Inc. to Draeger Medical Infant Care, Inc.
5	Assignment of '080 patent from Draeger Medical Infant Care, Inc. to Draeger Medical, Inc.
6	Assignment of '080 patent from Draeger Medical, Inc. to Draeger Medical Systems, Inc.
7	Assignment of '157 patent from inventors to Hill-Rom Services, Inc.
8	Assignment of '157 patent from Hill-Rom Services, Inc. to Draeger Medical Infant Care, Inc.
9	Assignment of '157 patent from Draeger Medical Infant Care, Inc. to Draeger Medical, Inc.
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22	Declaration of Scott Blackburn describing the display of Atom products within the United States
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27B	<b>CONFIDENTIAL:</b> Claim chart re: Draeger Medical Systems, Inc.'s practice of representative claims of '157 patent and attachments referenced therein
28	<b>CONFIDENTIAL:</b> Summary of Draeger Medical Systems, Inc.'s investments in plant, equipment, and labor to manufacture products that practice the asserted patents
29	<b>CONFIDENTIAL:</b> Details of Draeger Medical Systems, Inc.'s investments in plant, equipment, and labor with respect to the asserted patents

30	<b>CONFIDENTIAL:</b> Declaration of Peter O'Sullivan detailing Draeger Medical Systems, Inc.'s investments in plant, equipment, and labor
31	<b>CONFIDENTIAL:</b> Declaration of William P. Liptrot detailing Draeger Medical Systems, Inc.'s engineering and research and development efforts
32	<b>CONFIDENTIAL:</b> Details of Draeger Medical Systems, Inc.'s investments in engineering and research and development with respect to the asserted patents

### LIST OF NON-CONFIDENTIAL APPENDICES

No.	Description
A	One (1) certified copy and three (3) duplicate copies of the prosecution history for U.S. Patent No. 6,483,080 ( <i>see</i> Rule 210.12(c)(1))
B	Four (4) copies of each patent and technical reference mentioned in the prosecution history for U.S. Patent No. 6,483,080 ( <i>see</i> Rule 210.12(c)(2))
C	One (1) certified copy and three (3) duplicate copies of the prosecution history for U.S. Patent No. 7,335,157 ( <i>see</i> Rule 210.12(c)(1))
D	Four (4) copies of each patent and technical reference mentioned in the prosecution history for U.S. Patent No. 7,335,157 ( <i>see</i> Rule 210.12(c)(2))

## I. INTRODUCTION

1.1 This Complaint is filed by Draeger Medical Systems, Inc. (“DMSI” or “Complainant”) pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“Section 337”). DMSI is a medical technology and manufacturing company.

1.2 DMSI brings this action to remedy violations of Section 337 arising from the unlawful and unauthorized importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain thermal support devices, infant incubators, infant warmers, and components thereof that directly infringe one or more claims of U.S. Patent Nos. 6,483,080 (claims 1 and 11); and 7,335,157 (claims 9 and 25) (collectively, the “asserted patents”). Certified copies of the asserted patents are attached as Exhibits 1-2 in accordance with Rule 210.12(a)(9)(i). The asserted patents are valid and enforceable patents owned by Draeger Medical Systems, Inc. Certified copies of each of the recorded assignments are attached as Exhibits 3-10. DMSI hereby requests that the United States International Trade Commission institute an investigation into violations of Section 337 of the Tariff Act, as amended, 19 U.S.C. § 1337.

1.3 The proposed respondent is Atom Medical International, Inc. (“Atom” or “Respondent”).

1.4 An industry in the United States exists relating to articles covered by the asserted patents.

1.5 DMSI seeks, as relief, a permanent limited exclusion order barring from entry into the United States certain thermal support devices, infant incubators, infant

warmers, and components thereof that infringe the asserted claims. DMSI also seeks as relief cease and desist orders prohibiting the importation, sale, offer for sale, advertising, or the soliciting of the sale of certain thermal support devices, infant incubators, infant warmers, and components thereof (hereinafter collectively referred to as the “accused products”) that infringe the asserted claims. Further, DMSI requests that the Commission impose a bond upon the Respondent’s importation of the infringing products during the 60-day Presidential review period pursuant to 19 U.S. C. § 1337(j) to prevent further injury to DMSI’s domestic industry related to the ‘080 and ‘157 patents.

## **II. COMPLAINANT DRAEGER MEDICAL SYSTEMS, INC.**

2.1 Complainant Draeger Medical Systems, Inc. (“DMSI”) is a Delaware corporation located in Andover, Massachusetts and Telford, Pennsylvania. The principal place of business for DMSI’s incubator technology and manufacturing unit is at 3135 Quarry Road, Telford, Pennsylvania 18969.

2.2 DMSI is a wholly owned subsidiary of Dräger Medical AG & Co. KG, a corporation organized under the laws of Germany. Dräger Medical AG & Co. KG is itself a wholly owned subsidiary of Drägerwerk AG, a corporation organized under the laws of Germany. DMSI owns Draeger Medical, Inc., a corporation with a principal place of business in Telford, Pennsylvania. Draeger Medical, Inc. is the sales and training division of DMSI.

2.3 DMSI is a medical development and manufacturing company that designs, produces, and sells infant incubators and thermal support devices, and employs approximately 65 people within the U.S. who have research and development,

engineering or manufacturing responsibilities directly related to DMSI's incubator products. DMSI owns numerous patents, two of which are at-issue in this investigation, and invests approximately \$5 million annually in its plant, equipment, and personnel to manufacture infant incubators that practice its patented technology. DMSI is a leader in developing and manufacturing medical technology and devices, including neonatal warming therapy devices such as incubators and infant warming tables.

2.4 DMSI is the sole medical device R&D, manufacturing and sales entity in the United States for the German technology company known as "Dräger." Dräger designs and manufactures two main product lines via two separate entities: Dräger Medical and Dräger Safety. Dräger Medical primarily designs and manufactures medical equipment for hospitals and other healthcare facilities. Some of these devices are designed and manufactured in the United States, including neonatal warming therapy devices, which are designed and manufactured by DMSI at its facilities in Telford, Pennsylvania. Approximately 50% of the incubators and infant warming tables manufactured at DMSI's Telford facility practice the technology asserted in the '080 and/or '157 patents.

### **III. PROPOSED RESPONDENT**

3.1 Atom Medical International, Inc. ("Atom") is a corporation organized under the laws of Japan with a principal place of business at 3-18-16 Hongo, Bunkyo-ku, Tokyo, Japan 113-0033. On information and belief, Atom manufactures thermal support devices, including neonatal incubators and warmers, among other things, that are sold in the United States. On information and belief, the infringing infant incubators and

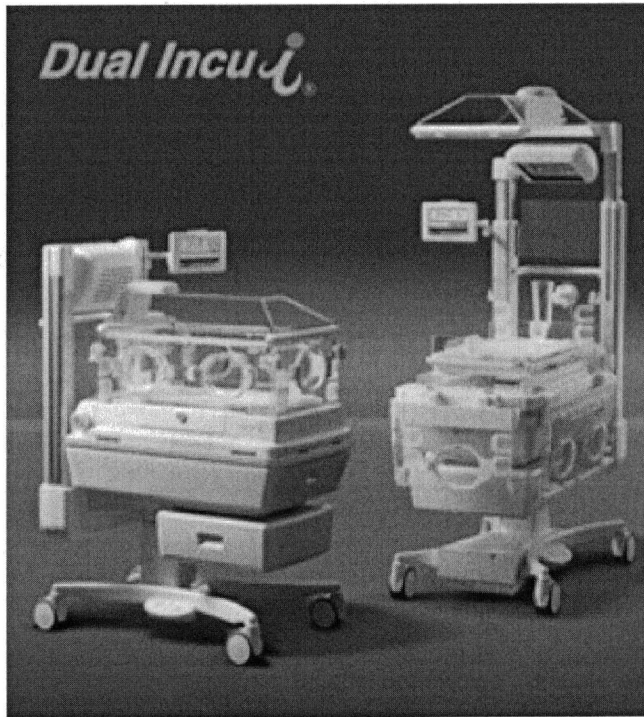
warmers at issue in this Complaint are manufactured by or on behalf of Atom in Japan and are imported into the United States, sold for importation, and/or sold within the United States after importation by a distributor and/or agent of Atom's, namely Philips Electronics North America Corp. (d/b/a Philips Healthcare) ("Philips"). On information and belief, Atom entered into an agreement with Philips in 2010 that makes Philips the exclusive distributor of the accused products within the United States.

#### **IV. THE PRODUCTS AT ISSUE**

4.1 The products at issue are thermal support devices, parts, and components thereof used in the treatment of infants, including incubators and warming devices. Generally, thermal support devices such as incubators and warming devices provide for thermoregulation of patients, often premature infants. Proposed Respondent Atom manufactures such incubators, warming devices, parts and components thereof. On information and belief, Atom manufactures incubators, warming devices, parts and components thereof and then provides them to its distributor, Philips Electronics North America Corp. (d/b/a Philips Healthcare), who sells these products in the United States.

4.2 The infant incubators and infant warmers manufactured by Atom include a variety of features and capabilities that infringe one or more claims of the asserted patents. These infringing devices contain humidification capabilities which allow for the supply of humidified air to patients within the thermal support device. These infringing devices also feature air circulation systems which allow for the control of air temperature and flow within the thermal support device. The air circulation system has the capability to sound an alarm or shut down automatically if its temperature reaches a predetermined

threshold. Pictured below is an example of a thermal support device, in this case the Atom Dual Incu i, that possesses these capabilities and is manufactured by Respondent Atom and sold within the United States.



4.3 The end-users of these infringing devices usually include hospitals and medical facilities and healthcare personnel within these facilities who are involved with patient care.

## V. THE ASSERTED PATENTS

### a. Non-technical description of the asserted patents

5.1 At issue in this investigation is Atom's infringement of two United States patents. The asserted patents are United States Patent Nos. 6,483,080 and 7,335,157. Each patent discloses and claims various features or components that may be included in a thermal support device. The '080 patent generally relates to infant thermal support

devices which have air circulation systems that include air warmers or heaters, and in particular, to a fail safe component in the air warmer or heater that prevents the system from overheating. The '157 patent concerns a humidifier module for use in thermal support devices. Each of these patents is described in more detail below.

5.2 The '080 patent discloses a system for air circulation and warming within a thermal support device, such as an incubator or infant warmer, that contains a fail safe feature. The air circulation system controls the environment within the thermal support device by heating and controlling air flow. The system contains a heater element and a radiator that warm the air. The system also includes a sensing element that detects temperature. The sensing element serves as a fail safe component and may sound an alarm or shut down the system if a certain threshold temperature is reached to avoid injury to the infant.

5.3 The '157 patent discloses a system for supplying humidified air within a thermal support device, such as an incubator or infant warmer. The system includes a humidifier module with at least two interior chambers, one which holds fluid and one in which the fluid is vaporized. The system also includes a heat source to heat the fluid within the humidifier module. The humidifier module is intended to be used with thermal support devices, but can also be removed from the thermal support devices for various purposes, such as cleaning or filling with additional fluid.

**b. Background of the asserted patents**



**i. The '080 patent**

5.4 On November 19, 2002, United States Letters Patent No. 6,483,080 B2, entitled "Fail Safe Device For Incubator Air Warmer," was duly and legally issued to John H. Richards and Robert M. McDonough. The '080 patent issued from U.S. Patent Application Serial No. 09/838,789, which was filed on April 20, 2001. The '080 patent claims priority from Provisional Application No. 60/199,103, filed on April 21, 2000. A certified copy of the '080 patent is attached to the Compliant as Exhibit 1. The '080 patent is valid, enforceable, and is currently in full force and effect.

5.5 Pursuant to Commission Rule 210.12(c), a certified copy of the '080 patent's U.S. Patent and Trademark Office ("USPTO") prosecution history and three additional copies thereof accompany this Complaint as Appendix A, and four copies of each patent and technical reference mentioned in the prosecution history accompany this Complaint as Appendix B.

5.6 The named inventors assigned all right, title, and interest in the '080 patent to Hill-Rom Services, Inc. A certified copy of this executed assignment is attached as Exhibit 3. In 2006, Hill-Rom Services, Inc. assigned all right, title, and interest in the '080 patent to Draeger Medical Infant Care, Inc. A certified copy of this executed assignment is attached as Exhibit 4. Draeger Medical Infant Care, Inc. later merged with Draeger Medical, Inc., assigning all right, title, and interest in the '080 patent to Draeger Medical, Inc. A certified copy of this executed assignment is attached as Exhibit 5. Draeger Medical, Inc. then assigned all right, title, and interest in the '080 patent to

Draeger Medical Systems, Inc. A certified copy of this executed assignment is attached as Exhibit 6.

5.7 Draeger Medical Systems, Inc. currently owns all right, title, and interest in the '080 patent.

5.8 The '080 patent has no foreign counterparts, and no foreign counterpart applications have been filed, rejected, withdrawn, or abandoned with respect to the '080 patent.

**ii. The '157 patent**

5.9 On February 26, 2008, United States Letters Patent No. 7,335,157, entitled "Humidifier Module," was duly and legally issued to Ted W. Czupich and Felix J. Gryn. The '157 patent issued from U.S. Patent Application Serial No. 10/493,168, filed on April 20, 2004. A certified copy of the '157 patent is attached to the Complaint as Exhibit 2. The '157 patent claims priority from Provisional Application No. 60/336,066, filed on November 15, 2001. The '157 patent is valid, enforceable, and is currently in full force and effect.

5.10 Pursuant to Commission Rule 210.12(c), a certified copy of the '157 patent's USPTO prosecution history and three additional copies thereof accompany this Complaint as Appendix C, and four copies of each patent and technical reference mentioned in the prosecution history accompany this Complaint as Appendix D.

5.11 The named inventors assigned all right, title, and interest in the '157 patent to Hill-Rom Services, Inc. A certified copy of this executed assignment is attached as Exhibit 7. In 2006, Hill-Rom Services, Inc. assigned all right, title, and interest in the

'157 patent to Draeger Medical Infant Care, Inc. A certified copy of this executed assignment is attached as Exhibit 8. Draeger Medical Infant Care, Inc. later merged with Draeger Medical, Inc., assigning all right, title, and interest in the '157 patent to Draeger Medical, Inc. A certified copy of this executed assignment is attached as Exhibit 9. Draeger Medical, Inc. then assigned all right, title, and interest in the '157 patent to Draeger Medical Systems, Inc. A certified copy of this executed assignment is attached as Exhibit 10.

5.12 Draeger Medical Systems, Inc. currently owns all right, title, and interest in the '157 patent.

5.13 The foreign counterparts to the '157 patent are identified in Exhibit 13. No other foreign applications other than those identified in Exhibit 13 have been filed, and no other foreign counterpart applications have been rejected, withdrawn, or abandoned.

**iii. Licenses under the asserted patents**

5.14 Draeger Medical Systems, Inc. has not licensed the asserted patents.

**VI. UNFAIR ACTS OF THE RESPONDENT UNDER SECTION 337 – PATENT INFRINGEMENT**

6.1 The unfair acts of the Respondent involve the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain thermal support devices for infants, infant incubators, infant warmers, and components thereof, that infringe the asserted patents. Atom has been aware of DMSI's asserted patents since at least early September 2012 as a result of the filing of a Complaint for patent infringement against Atom in the Middle District of Florida on September 17, 2012. Atom has been aware of DMSI and its incubator and thermal

support products for decades, at least because both companies exhibit their products at gatherings like the *Association of Women's Health, Obstetric and Neonatal Nurses* annual convention in the United States, the *Annual Congress of the European Society of Paediatric and Neonatal Intensive Care* in Europe, and similar conferences and conventions around the world.

6.2 Atom directly infringes claims 1 and 11 of the '080 patent with certain thermal support devices manufactured, imported, used, sold for importation, and/or sold after importation, including but not limited to, Atom incubators and warmers having air circulation systems with a fail safe component, which include but are not limited to, the following exemplary Atom products: Dual Incu i Infant Incubator and Warmer Model 100 and Incu i Infant Incubator Model 101 (collectively "the Accused Products"). More specifically, the Accused Products include a system for air circulation and warming that contains a fail safe feature. The air circulation system within the Accused Products contains a heater element and a radiator that warm the air. The system in the Accused products also includes a sensing element that detects temperature and serves as a fail safe component.

6.3 Atom directly infringes claims 9 and 25 of the '157 patent. More specifically, the Accused Products include a humidifier module for supplying humidified air. The humidifier module within the Accused Products has two interior chambers, one which holds fluid and one in which the fluid is vaporized. The Accused Products also include a heat source to heat the fluid within the humidifier module.

6.4 Claim charts applying the asserted claims of the '080 and '157 patents to exemplary Atom accused products are attached as Exhibits 11-12. Further discovery may reveal that additional claims of the asserted patents are infringed by these accused products and that other Atom products infringe claims of the asserted patents.

## **VII. UNLAWFUL IMPORTATION AND SALE**

7.1 On information and belief, Atom develops, designs, and/or manufactures the accused products that infringe the asserted patents, and Atom imports into the United States, sells for importation into the United States, and/or sells within the United States after importation the accused products and components thereof.

7.2 On information and belief, an Atom Dual Incu i Infant Incubator and Warmer Model 100 was displayed and demonstrated at the 26th Annual Gravens Conference on the Physical and Developmental Environment of the High Risk Infant in Clearwater Beach, Florida, on or around February 27, 2013 – March 3, 2013. *See* Ex. 22, Declaration of Scott Blackburn. On information and belief, Atom imported into the United States and/or sold for importation into the United States the Atom Dual Incu i Infant Incubator and Warmer Model 100 that was displayed and demonstrated by its exclusive distributor, Philips. *Id.* Exhibit 22 is a Declaration from Scott Blackburn, who observed the Atom Dual Incu i Infant Incubator and Warmer Model 100 on display at the conference, and attached to Exhibit 22 is a photograph of the Atom Dual Incu i Infant Incubator and Warmer Model 100 as observed at the conference.

7.3 On information and belief, an Atom Dual Incu i Infant Incubator and Warmer Model 100 was displayed and demonstrated at the 2013 NICU Leadership

Forum in Scottsdale, Arizona, on or around April 9-13, 2013. *See* Ex. 23, Declaration of Ali Pourrad. On information and belief, Atom imported into the United States and/or sold for importation into the United States the Atom Dual Incu i Infant Incubator and Warmer Model 100 that was displayed and demonstrated by its exclusive distributor, Philips. *Id.* Exhibit 23 is a Declaration from Ali Pourrad, who observed the Atom Dual Incu i Infant Incubator and Warmer Model 100 on display at the forum.

7.4 On information and belief, an Atom Dual Incu i Infant Incubator and Warmer was displayed and demonstrated at the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) Annual Convention in Nashville, Tennessee, on or around June 15-19, 2013. *See* Exs. 24-26, Declarations of Denise Homan-Blume, Karen Vandeven, and Lorna Kane. On information and belief, Atom imported into the United States and/or sold for importation into the United States the Dual Incu i Infant Incubator and Warmer that was displayed and demonstrated by its exclusive distributor, Philips. *Id.* Exhibits 24-26 are declarations from several individuals who observed the Dual Incu i Infant Incubator and Warmer on display at the convention.

7.5 On information and belief, Atom notified the United States Department of Health and Human Services ("HHS") of its intention to market the Incu i Infant Incubator Model 101 within the United States on or around July 30, 2010. *See* Ex. 14, 501(k) Summary for Atom Incu i Infant Incubator Model 101 at 2. On information and belief, Atom submitted a summary of 501(k) safety and effectiveness information to HHS indicating its intent to introduce the Incu i Infant Incubator Model 101 to the United States market. *Id.* at 2-4.

7.6 On information and belief, Atom notified the United States Department of Health and Human Services (“HHS”) of its intention to market the Dual Incu i Infant Incubator and Warmer Model 100 within the United States on or around July 30, 2010. *See* Ex. 15, 501(k) Summary for Atom Dual Incu i Infant Incubator and Warmer Model 100 at 2. On information and belief, Atom submitted a summary of 501(k) safety and effectiveness information to HHS indicating its intent to introduce the Dual Incu i Infant Incubator and Warmer Model 100 to the United States market. *Id.* at 2-4.

7.7 On information and belief, Atom entered into an exclusive distribution agreement with Philips Electronics North America Corp. (d/b/a Philips Healthcare) (“Philips”) to distribute the Incu i Infant Incubator Model 101 and Dual Incu i Infant Incubator and Warmer Model 100 within the United States on or around November 18, 2010. *See* Ex. 16, Excerpt from Atom Medical Website (“2010 – A distribution agreement was made with Philips Healthcare to provide (*sic*) Atom products and services in the U.S. and three countries in Europe.”); Ex. 17, Philips Press Release.

7.8 On information and belief, Atom received permission from HHS to market the Incu i Infant Incubator Model 101 in the United States on or around December 29, 2010. *See* Ex. 14, 501(k) Summary for Atom Incu i Infant Incubator Model 101 at 5.

7.9 On information and belief, Atom received permission from HHS to market the Dual Incu i Infant Incubator and Warmer Model 100 in the United States on or around January 4, 2011. *See* Ex. 15, 501(k) Summary for Atom Dual Incu i Infant Incubator and Warmer Model 100 at 5.

7.10 On information and belief, the Incu i Infant Incubator Model 101 and Dual Incu i Infant Incubator and Warmer Model 100 have been imported into the United States, sold for importation, and/or sold within the United States after importation by Atom and/or a distributor and/or agent of Atom's since at least January 2011.

7.11 On information and belief, Atom initiated a voluntary recall of Atom products imported into the United States, sold for importation, and/or sold within the United States after importation by a distributor and/or agent of Atom's, including, among others, the Incu i Infant Incubator Model 101 and Dual Incu i Infant Incubator and Warmer Model 100, on or around August 18, 2011. *See* Ex. 18, Atom Medical Field Safety Notice dated Aug. 18, 2011. On information and belief, the United States Food and Drug Administration ("FDA") published a notification of this recall on or around December 28, 2011 in its Enforcement Report. *See* Ex. 19, FDA Enforcement Report of Dec. 28, 2011 at 22-23. The Enforcement Report indicates the Incu i Infant Incubator Model 101 and Dual Incu i Infant Incubator and Warmer Model 100 are distributed "nationwide" and the volume of products in commerce is "453 units." *Id.* at 23.

7.12 On information and belief, Atom initiated a voluntary recall of Atom Dual Incu i Infant Incubator and Warmer Model 100 units imported into the United States, sold for importation, and/or sold within the United States after importation by a distributor and/or agent of Atom's on or around May 1, 2012. *See* Ex. 20, Atom Medical Field Safety Notice dated May 12, 2012. On information and belief, the United States Food and Drug Administration ("FDA") published a notification of this recall on or around July 18, 2012 in its Enforcement Report. *See* Ex. 21, FDA Enforcement Report of July



18, 2012. The Enforcement Report indicates the Dual Incu i Infant Incubator and Warmer Model 100 is distributed “nationwide” and the volume of products in commerce is “377 units.” *Id.*

7.13 DMSI alleges that the Atom infringing products are assigned a U.S. Harmonized Tariff Schedule number under Chapter 90 of the 2013 Harmonized Tariff Schedule (“HTS”). Specifically, DMSI believes that the unlawful importations occur under at least one of the following subheadings: 9018.90.75 – (Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments; parts and accessories thereof: Other instruments and appliances and parts and accessories thereof: Other); 9018.19.55 (Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments: Electro-diagnostic apparatus (including apparatus for functional exploratory examination or for checking physiological parameters); parts and accessories thereof: Other: Patient monitoring systems); 9018.90.80 (Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments: Other instruments and appliances and parts and accessories thereof: Other). These HTS identifications are exemplary classifications for illustrative purposes only and may not be exhaustive. These classifications are not intended to limit the scope of the Investigation, nor are they intended to restrict the scope of any exclusion order or other remedy ordered by the Commission.

## VIII. DRAEGER MEDICAL SYSTEMS, INC.'S DOMESTIC INDUSTRY

8.1 A domestic industry as defined by 19 U.S.C. § 1337 (a)(3)(A), (B), & (C) exists with respect to DMSI's activities in the United States that exploit each of the asserted patents. DMSI has a significant investment in plant and equipment, a significant employment of labor and capital, and a substantial investment in the exploitation of the asserted patents through engineering and research and development.

**a. A domestic industry exists based upon DMSI's own use of the asserted patents**

8.2 A domestic industry as defined by 19 U.S.C. § 1337(a)(3) exists with respect to DMSI's activities in the United States that exploit the '080 and '157 patents. Specifically, a domestic industry exists in the United States by virtue of DMSI's significant investment in plant and equipment, significant employment of labor and capital, and substantial investment in engineering, research and development in the United States in connection with the exploitation of the asserted patents, which includes the manufacturing and sale of thermal support devices and infant incubators. DMSI designs, manufactures, and produces products, known as the Isolette C2000 and Isolette 8000, at its facility in Telford, Pennsylvania that practice and exploit the '080 and '157 patents. Details of DMSI's significant investment in plant and equipment, significant employment of labor and capital, and substantial investment in engineering, research and development associated with the production of products that practice the asserted patents are contained in Confidential Exhibits 28 - 32.

**i. Technical prong**

8.3 Certain thermal support devices and infant incubators developed and manufactured by DMSI in the United States practice one or more claims of the two asserted patents: the '080 and '157 patents. DMSI designs and manufactures the Isolette C2000 and Isolette 8000 products at its facilities in Telford, Pennsylvania. These products are sold throughout the world to hospitals, clinics, and physicians. A claim chart demonstrating how the Isolette C2000 and the Isolette 8000 practice representative claims of the '080 patent is attached as Exhibit 27A. A claim chart demonstrating how the Isolette 8000 practices representative claims of the '157 patent is attached as Confidential Exhibit 27B.

**ii. Economic prong**

8.4 A domestic industry exists in the United States by virtue of DMSI's (1) significant investment in plant and equipment in the United States; (2) significant employment of labor and capital in the United States; and (3) substantial investment in engineering and research and development in the United States in connection with infant incubators designed and manufactured by DMSI that practice the asserted patents. DMSI's Isolette C2000 and 8000 products are manufactured in the United States. DMSI has established a manufacturing plant in Telford, Pennsylvania and invested in equipment to aid in the manufacture of products that employ and exploit the technology of the '080 and '157 patents. The Isolette C2000 and Isolette 8000 products manufactured at the Telford facility are sold throughout the world, including within the United States. Confidential Exhibits 28-32 set forth DMSI's domestic industry expenditures in plant and

equipment in connection with its thermal support devices and infant incubators, including the Isolette C2000 product (which incorporates the patented technology of the '080 and '157 patents) and the Isolette 8000 product (which incorporates the patented technology of the '157 patent).

8.5 DMSI employs 57 individuals with manufacturing responsibilities associated with the Isolette products. Moreover, DMSI employs 12 individuals who have engineering, development, or technical responsibilities associated with the Isolette products. For example, these individuals develop new product features, maintain the current products by providing lifecycle engineering support, and support production and field quality control issues. Details of the expenses associated with the labor provided by these individuals are contained in Confidential Exhibits 28-32. In addition, Confidential Exhibit 31 describes the responsibilities and tasks performed by those employees involved with the design of the Isolette products.

8.6 DMSI also invests in the research and development of the Isolette products. Details concerning DMSI's investment in research and development concerning the Isolette products is described in Confidential Exhibits 31-32.

8.7 DMSI continues to make significant investments in plant and equipment associated with the exploitation of the asserted patents; continues to employ individuals dedicated to manufacturing, engineering, and research and development associated with the products that practice the asserted patents; and continues to invest capital in product support and development associated with the products that practice the asserted patents.

Details of the continuing expenses associated with DMSI's investment in the exploitation of its patents are contained in Confidential Exhibits 28 and 30-31.

## **IX. RELATED LITIGATION**

9.1 On September 17, 2012, DMSI filed a complaint for patent infringement against Atom Medical International, Inc. and Philips Electronics North America Corp. in the United States District Court for the Middle District of Florida (Civil Action No. 2:12-cv-512) (hereinafter the "District Court Action"). DMSI alleges infringement of the following U.S. patents in the District Court Action: 6,296,606; 6,345,402; 6,540,660; 6,761,683; and 6,483,080. One of these patents is also being asserted in the present complaint.

9.2 On March 15, 2013, DMSI filed an amended complaint for patent infringement against Atom Medical International, Inc. and Philips Electronics North America Corp. in the District Court Action, alleging additional counts of patent infringement against Atom and Philips for the following U.S. Patents: 6,746,394 and 7,335,157. One of these patents is also being asserted in the present complaint.

9.3 There have been no court or agency proceedings related to the asserted patents other than those listed in this section.

## **X. REQUEST FOR RELIEF**

WHEREFORE, by reason of the foregoing, Complainant Draeger Medical Systems, Inc. requests that the United States International Trade Commission:

a) Institute an immediate investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to violations of that section

based on the importation into the United States, sale for importation, and/or the sale within the United States after importation, of the proposed Respondent's thermal support products, parts, and components having features and capabilities that are covered by or infringing one or more claims of U.S. Patent Nos. 6,483,080 and 7,335,157;

b) Schedule and conduct a hearing pursuant to Section 337(c) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, for purposes of receiving evidence and hearing argument concerning whether there has been a violation of Section 337, and following the hearing, to determine that there has been a violation of Section 337;

c) Issue a permanent limited exclusion order pursuant to Section 337(d) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, excluding entry into the United States of certain thermal support devices, infant incubators, infant warmers, and components thereof that are covered by or infringing one or more claims of U.S. Patent Nos. 6,483,080 and 7,335,157;

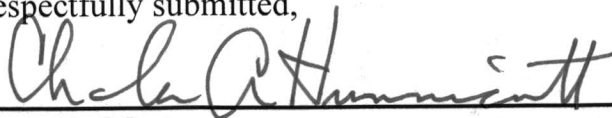
d) Issue permanent cease-and-desist orders pursuant to Section 337(f) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, prohibiting the proposed Respondent and its successors or assigns from engaging in the importation, sale for importation, marketing (including via the Internet or electronic mail), offering for sale (including via the Internet or electronic mail), distribution, the sale after importation (or otherwise transferring within the United States), and providing or offering marketing, sales, or any engineering or technical support services related to all unlicensed products, parts, and components having features and capabilities that are covered by or infringing one or more claims of U.S. Patent Nos. 6,483,080 and 7,335,157;

e) Impose a bond upon Respondent should it continue to import infringing articles during the 60-day Presidential review period per 19 U.S.C. § 1337(j); and

f) Issue such other and further relief as the Commission deems just and proper under the law, based upon the facts determined by the investigation and the authority of the Commission.

Dated: August 29, 2013

Respectfully submitted,



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