

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

In the Matter of

**CERTAIN BIRTHING SIMULATORS
AND ASSOCIATED SYSTEMS**

Investigation No. 337-TA-____

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

COMPLAINANT

Gaumard Scientific Company, Inc.
14700 SW 136 Street
Miami, FL 33196 - U.S.A.

PROPOSED RESPONDENTS

Shanghai Honglian Medical Instrument
Development Co., Ltd.
(d/b/a General Doctor)
Floor 5, No.1 Aijia Bldg, 288# Wuhua Rd.
Shanghai China 200086

Shanghai Evenk International Trading Co.,
Ltd.
Floor 5, No.1 Aijia Bldg, 288# Wuhua Rd.
Shanghai China 200086

COUNSEL FOR COMPLAINANT

Steven M. Levitan
HAYNES AND BOONE LLP
2033 Gateway Place, Suite 400
San Jose, CA 95110
Phone: (408) 660-4120
Fax: (408) 660-4121

Edward M. Lebow
Michael M. Shen
Scott Cunning
HAYNES AND BOONE LLP
1615 L Street, NW, Suite 800
Washington, DC 20036-5610
Phone: (202) 654-4500
Fax: (202) 654-4501

David L. McCombs
Gregory P. Webb
HAYNES AND BOONE LLP
2505 N. Plano Road, Suite 4000
Richardson, TX 75082
Phone: (972) 739-6900
Fax: (972) 680-7551

Index of Non-Confidential Exhibits

| Exhibit Number | Item |
|-----------------------|--|
| 1 | Certified copy of U.S. Patent No. 6,503,087 |
| 2 | Certified copy of U.S. Patent No. 7,114,954 |
| 3 | Certified Assignment Documents for U.S. Patent No. 6,503,087 |
| 4 | Certified Assignment Documents for U.S. Patent No. 7,114,954 |
| 5 | Claim chart applying asserted independent claims of '087 Patent to Honglian GD/F55 simulator |
| 6 | Claim chart applying asserted independent claims of '954 Patent to Honglian GD/F55 simulator |
| 7 | Declaration of David Broussard |
| 8 | Claim chart applying exemplary claim of '087 Patent to exemplary Gaumard NOELLE® Simulator |
| 9 | Claim chart applying exemplary claim of '954 Patent to exemplary Gaumard NOELLE® Simulator |
| 10 | Gaumard NOELLE® Instruction Manual for NOELLE® S550 |
| 11 | Gaumard NOELLE® Instruction Manual for NOELLE® S575 |
| 12 | Excerpts from Gaumard NOELLE® Instructor and Student Guide |
| 13 | Photographs of exemplary Gaumard NOELLE® Simulator |
| 14 | Selections from Honglian website |
| 15 | DHL Shipping Receipt for Honglian GD/F55 simulator |
| 16 | Photographs of Honglian GD/F55 simulator |
| 17 | Excerpts from Honglian 2010 Products Catalog concerning GD/F53 and GD/F55 simulators |
| 18 | Selections from Shanghai Evenk International Trading websites |
| 19 | Public version of Confidential Exhibit 1 |

Index of Confidential Exhibits

| Exhibit Number | Item |
|-----------------------|--|
| 1 | Confidential: Declaration of John S. Eggert |

Index of Appendices

| Appendix | Item |
|-----------------|--|
| A | Certified copy and three additional copies of the prosecution history of the '087 Patent |
| B | Certified copy and three additional copies of the prosecution history of the '954 Patent |
| C | References cited in the prosecution history of the '087 Patent |
| D | References cited in the prosecution history of the '954 Patent |

TABLE OF CONTENTS

| | Page |
|---|-----------|
| I. INTRODUCTION..... | 1 |
| II. COMPLAINANT | 1 |
| III. PROPOSED RESPONDENTS | 4 |
| IV. THE TECHNOLOGY AND PRODUCTS AT ISSUE | 6 |
| V. THE PATENTS AT ISSUE | 7 |
| VI. UNLAWFUL AND UNFAIR ACTS OF THE RESPONDENTS..... | 9 |
| VII. SPECIFIC INSTANCES OF IMPORTATION AND SALE..... | 10 |
| VIII. THE DOMESTIC INDUSTRY | 12 |
| IX. RELATED LITIGATION..... | 15 |
| X. RELIEF..... | 15 |
| XI. PUBLIC INTEREST | 17 |

I. INTRODUCTION

1.1 This Complaint is filed by Gaumard Scientific Company, Inc. (“Gaumard” or “Complainant”) pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based upon the unlawful importation into the United States, the sale for importation, and the sale within the United States after importation, of certain birthing simulators and associated systems, including, without limitation, simulators designated as the GD/F55 Advanced Delivery and Maternal and Neonatal Emergency Simulator and the GD/F53 Advanced Maternal and Neonatal Delivery Model (collectively “Accused Simulator Products”). The Accused Simulator Products are made by or for and/or sold by or for the proposed Respondents Shanghai Honglian Medical Instrument Development Co., Ltd. (d/b/a General Doctor) and Shanghai Evenk International Trading Co., Ltd. (collectively “Honglian”). The Accused Simulator Products infringe at least claims 16-20, 22-23, 25-28, 30-31, 33-34, and 36-38 of U.S. Patent No. 6,503,087 (“the ’087 Patent”) and at least claims 1, 2, 6-7, and 10 of U.S. Patent No. 7,114,954 (“the ’954 Patent”) (collectively “Gaumard’s Asserted Patents”).

1.2 Gaumard seeks, as relief for the unfair acts of Honglian, an investigation into the violations by Honglian, a public hearing, a permanent exclusion order barring from entry into the United States Honglian’s birthing simulators and associated systems that infringe the claims of Gaumard’s Asserted Patents, a permanent cease and desist order prohibiting the importation, sale, sale for importation, offer for sale, promoting, marketing, advertising, or the soliciting of the sale in the United States of Honglian’s birthing simulators and associated systems that infringe the claims of Gaumard’s Asserted Patents, and such other relief as the Commission deems proper.

II. COMPLAINANT

2.1 Complainant Gaumard is a corporation organized and existing under the laws

of Florida with its corporate headquarters and principal place of business at 14700 SW 136 Street Miami, Florida 33196. Gaumard is associated with two other companies, Formatek, Inc. (whose employees manufacture Gaumard products at Gaumard's facilities) and Gaumard Sales Company, Inc. (whose employees market and sell Gaumard products), both also located in Miami, Florida.

2.2 Gaumard, a family owned and operated private company, is in the business of supplying medical training simulators and associated systems for use by the health care community. The particular products at issue, childbirthing simulators including maternal, fetal, and neonatal simulators, are products that Gaumard pioneered in the late 1990s using novel electro-mechanical designs. Gaumard's philosophy and mission is to provide innovative teaching simulators to benefit and improve medical training and help medical professionals save lives, and to provide such simulators at an affordable price. Gaumard designs, develops and manufactures all of its simulators in the United States.

2.3 Gaumard traces its history to 1946 when its founder, a World War II trauma physician, recognized how polymers used in reconstructive and battlefield surgery could be used to create simulators for health care education. The first product was a synthetic human skeleton. In 1949, Gaumard introduced a childbirth simulator, designed at the request of the international health community, to improve the clinical competence of village midwives to reduce maternal and infant mortality and morbidity. Gaumard was incorporated in the State of Florida in 1961 as Scientific Models, Inc. In 1966, Scientific Models, Inc. became Gaumard Scientific Models, Inc. when it merged with Gaumard Company, Inc. The company name was subsequently changed to Gaumard Scientific Company, Inc. in 1983. Over the past half century, Gaumard has dedicated its resources to the continued development of innovative teaching simulators in nursing care,

emergency care and OB/GYN.

2.4 During the late 1990s, Gaumard developed and introduced interactivity and computer integrated manikins for adult, pediatric, and neonatal advanced life support training. In 2000, Gaumard introduced a full-sized birthing simulator system, which was given the name NOELLE®. The NOELLE® birthing simulator system includes a full-sized maternal simulator, a fetal simulator that is received within and birthed from the maternal simulator, and a neonatal or newborn simulator that can replace the fetal simulator in post-birth training scenarios. The NOELLE® simulator system utilizes an electro-mechanical birthing mechanism that is highly controllable and, therefore, produces repeatable results. This repeatability is important when attempting to train someone to master birthing techniques. To enhance the realism of the birthing simulation, the electro-mechanical birthing mechanism is built into a full-sized maternal simulator that also includes the ability to train users on both Basic Life Support (“BLS”) and Advanced Life Support (“ALS”) techniques. Similarly, the newborn simulator also incorporates BLS and ALS features so that students can face situations where both the mother and newborn simultaneously suffer life threatening issues following delivery, such as the simultaneous onset of maternal post-partum hemorrhage and a profound newborn hypoxic event. Quick action by an obstetrics team and a neonatal team is needed within a few minutes to avoid death or lifelong physical/mental impairments. The NOELLE® simulator system addresses not only the individual skills associated with deliveries, it also addresses the interactions of teams within hospitals during truly complicated deliveries, for example during the transition from an obstetrics team to an operating team. Team handoffs are where many errors occur. NOELLE® provides not just for individual skill training, not just team training but, also team handoffs. In short, Gaumard’s objective and accomplishment was a system whereby health care providers,

individually and as teams, can train, and correct mistakes, on a birthing simulator before they provide care to real patients.

2.5 Gaumard introduced the first NOELLE® simulator models in 2000 as part of a worldwide initiative by the international health community to promote “safe motherhood.” At that time it was estimated that more than 500,000 women worldwide died each year during childbirth and many such deaths were believed to be preventable. Gaumard first introduced its NOELLE® models S550, S551, S552, and S560, followed by the S550.100, S555, S565 models, and then the more advanced S574, S575, and S576 models. Presently there are 10 NOELLE® models. Gaumard also published the NOELLE® Instructor and Student Guide in 2002-2003, with a more advanced version published in 2009-2010. See Exhibit 12.

2.6 More than 5000 NOELLE® simulators have been sold worldwide. Gaumard owns 10 U.S. patents, a number of which cover the NOELLE® simulators, including the two Gaumard Asserted Patents.

III. PROPOSED RESPONDENTS

3.1 On information and belief, the proposed Respondents Shanghai Honglian Medical Instrument Development Co., Ltd. and Shanghai Evenk International Trading Co., Ltd. (collectively “Honglian”) are corporations organized and existing under the laws of China, with the same principal place of business located at Floor 5, No.1 Aijia Bldg, 288# Wuhua Rd. Shanghai, China 200086. On information and belief, the proposed Respondents manufacture and import medical training simulators and associated systems, including the GD/F55 Advanced Delivery and Maternal and Neonatal Emergency Simulator and the GD/F53 Advanced Maternal and Neonatal Delivery Model. On information and belief, the proposed Respondents collaborate to manufacture, sell for importation and import the Accused Simulator Products.

3.2 Shanghai Honglian Medical Instrument Development Co.'s website,

<http://en.honglian8.com>, states:

Shanghai Honglian Medical Instrument Dev. Co., Ltd. was established in 1993. She has nearly 15 years history, now she is a leading manufacture made Medical Model in China. Meanwhile she has the most items all over the world which is including First Aid Equipment and Facility,. CPR Training Man. Clinic Skill Training Mankin and all kinds of Human Anatomical Model.

There are more than 320 employees for technology, production, management and sales. The amount for sales volume in local market reached RMB 80,000,000.00 in 2007 and meanwhile, she exported to nearly 57 countries which are UK. USA. LIBIA. GERMANY. BRAZIL. INDIA. PAKISTAN. VIETMAN. Nepal. PHILLIPINES. EGYPT. JORDAN and so on. The export amount reached USD3,000,000.00 in 2007. Further, it is in fast developing on increasing on 40% amount every year.

Selections from Shanghai Honglian Medical Instrument Development Co.'s website are attached as Exhibit 14.

3.3 Shanghai Honglian Medical Instrument Development Co.'s website also contains a 2010 "Products Catalog." See Exhibit 14.

3.4 Shanghai Honglian Medical Instrument Development Co.'s 2010 "Products Catalog" contains a page largely devoted to the GD/F53 Accused Simulator Product, as well as a page devoted to the GD/F55 Accused Simulator Product. See Exhibit 17.

3.5 Using nearly identical language to Shanghai Honglian Medical Instrument Development Co.'s website, one of Shanghai Evenk International Trading Co., Ltd.'s websites, http://zhengqianvivian.en.busytrade.com/about_us.html, states:

Shanghai evenk international trading Co., Ltd. was established in 1993. She has nearly 15 years history, now she is a leading manufacture made Medical Model in China. Meanwhile she has the most items all over the world which is including First Aid Equipment and Facility, . CPR

Training Man. Clinic Skill Training Mankin and all kinds of Human Anatomical Model.

There are more than 320 employees for technology, production, management and sales. The amount for sales volume in local market reached RMB 80, 000, 000.00 in 2007 and meanwhile, she exported to nearly 57 countries which are UK. USA. LIBIA. Germany. Brazil. India. Pakistan. VIETMAN. Nepal. PHILLIPINES. Egypt. Jordan and so on. The export amount reached USD3, 000, 000.00 in 2007. Further, it is in fast developing on increasing on 40% amount every year, . Especially, she has strong empoldering ability to meet all kinds of requires from different customers.

As shown on another Shanghai Evenk International Trading Co., Ltd. website, <http://evenk.en.ecplaza.net/>, Shanghai Evenk International Trading Co., Ltd. appears to offer for sale and sell the same products as Shanghai Honglian Medical Instrument Development Co., Ltd., including the GD/F55 Accused Simulator Product. Selections from these Shanghai Evenk International Trading Co. websites are attached as Exhibit 18.

IV. THE TECHNOLOGY AND PRODUCTS AT ISSUE

4.1 The technology at issue involves medical training interactive education systems for teaching patient care, and more particularly child birthing simulator systems. These simulators allow for hands-on practice by individual medical professionals and trainees, as well as within and between teams of medical professionals and trainees.

4.2 A historical problem in patient care education is that the patient simulators used for teaching a user are generally passive. For example, in a child birthing simulation a user must position the simulated fetus in a simulated maternal pelvis, move it down the birth canal, birth the fetus's head, rotate the fetus approximately 90 degrees to birth the shoulders, and finally, pull out the fetus, now referred to as a neonate. While replicating the sequence of events in a real delivery, the lack of verisimilitude resulting from physical manipulation of the fetus by

the user undermines an appreciation for the difficulties of providing patient care. In a real delivery, the fetus is inaccessible, and most activity is obscured from view, and thus prior simulators failed to address the most challenging conditions of providing patient care during child birthing.

4.3 The birthing simulators and systems at issue herein provide a more realistic birthing simulation by employing an electromechanical mechanism to accurately and repeatedly simulate the child birthing process and problems that may arise during that process. The electromechanical mechanism translates and rotates the fetal simulator through the maternal simulator without the need for physical manipulation of the fetus by the user as it moves through the birth canal.

4.4 The Accused Simulator Products are birthing simulators and systems made, sold, and imported by Honglian. The Honglian Accused Simulator Products are copies of Gaumard's patented NOELLE® simulators, including precisely the same electro-mechanical mechanisms included in the NOELLE® simulators being copied.

4.5 Upon information and belief, the tariff classification which may cover importation of the Accused Simulator Products is No. 9023.00.00 00 of the Harmonized Tariff Schedule ("HTS") of the United States. This HTS number is intended for illustration only and is not intended to be restrictive of the products accused.

V. THE PATENTS AT ISSUE

5.1 Pursuant to Commission Rule 210.12(a) and (c), this Complaint is accompanied by certified copies of Gaumard's Asserted Patents as Exhibits 1 and 2, and certified copies of the assignment of ownership of these patents as Exhibits 3 and 4. Additionally, Appendices A and B contain certified copies and three additional copies of the prosecution

histories of Gaumard's Asserted Patents. Four copies of each reference identified in the prosecution history of each Gaumard Asserted Patent are also included in Appendices C and D.

5.2 U.S. Patent No. 6,503,087 (Ex. 1), entitled "Interactive Education System For Teaching Patient Care," issued to Gaumard Scientific, Inc. (as assignee of the named inventors John S. Eggert, Michael S. Eggert, and Phillip Vallejo) on January 7, 2003. The '087 Patent remains in full force and effect and Gaumard continues to own it. The '087 Patent has 45 claims. Claims 1, 16, 25, and 39 are independent and claims 2-15, 17-24, 26-38, and 40-45 are dependent. At least claims 16-20, 22-23, 25-28, 30-31, 33-34, and 36-38 are infringed by Honglian's Accused Simulator Products.

5.3 U.S. Patent No. 7,114,954 (Ex. 2), entitled "Interactive Education System For Teaching Patient Care," issued to Gaumard Scientific Company, Inc. (as assignee of the named inventors John S. Eggert, Michael S. Eggert, and Phillip Vallejo) on October 3, 2006. The '954 patent is a continuation of U.S. Patent No. 6,758,676, which is a continuation of the '087 patent. The '954 Patent remains in full force and effect and Gaumard continues to own it. The '954 Patent has 10 claims. Claims 1 and 6 are independent and claims 2-5, and 7-10 are dependent. At least claims 1, 2, 6-7, and 10 are infringed by Honglian's Accused Simulator Products.

5.4 A PCT patent application (PCT/US01/42512) was filed based on the '087 patent. Foreign patent protection was sought in Japan and Europe based off of the PCT application. In Japan, two patents have issued (JP 3930429 and JP 4584906), a divisional application (JP 2009-143583) is pending, and a divisional application (JP 2005-333165) was abandoned. In Europe, the originally filed application (EP 01977908.1) is pending. There are no other foreign patents or patent applications corresponding to the '087 and '954 patents.

5.5 Non-Technical Description of the '087 and '954 Patents: The '087 and '954 patents are generally directed to systems and methods for teaching patient care. Some embodiments of the '087 and '954 patents are particularly directed to teaching patient care in the context of child birthing. For example, in one embodiment, a birthing simulator system includes a maternal manikin and an associated fetal manikin. The fetal manikin is automatically delivered from the maternal manikin to simulate a child birth. A birthing mechanism positioned within the maternal manikin causes the fetal manikin to translate and rotate in a manner simulating a natural child birth. In some instances, a ram of the birthing mechanism attaches to the fetal manikin and causes the fetal manikin to move along a track positioned within the maternal manikin. The track guides the path of the fetal manikin in a manner that simulates a natural child birth. In some instances, the birthing simulator system further includes a larger neonatal simulator for replacing the fetal simulator in post-birth simulations.

5.6 There have been no license agreements under the '087 and '954 patents.

VI. UNLAWFUL AND UNFAIR ACTS OF THE RESPONDENTS

6.1 On information and belief, Honglian unlawfully sells for importation, imports, or sells after importation into the United States birthing simulators and systems, including without limitation the GD/F55 Advanced Delivery and Maternal and Neonatal Emergency Simulator and the GD/F53 Advanced Maternal and Neonatal Delivery Model, that infringe claims of the Gaumard Asserted Patents. Photographs of a sample of the Honglian GD/F55 Accused Simulator Product is submitted with this Complaint as Exhibit 16. A claim chart that applies independent claims 16 and 25 of the '087 Patent to the Honglian GD/F55 Accused Simulator Product is attached hereto as Exhibit 5. A claim chart that applies independent claims 1 and 6 of the '954 Patent to the Honglian GD/F55 Accused Simulator Product is attached hereto as Exhibit 6.

6.2 The claim charts in Exhibits 5 and 6 show infringement of exemplary claims by an exemplary Accused Simulator Product. Further discovery may reveal that additional claims of the Gaumard Asserted Patents are infringed by the Accused Simulator Products.

6.3 On information and belief, Honglian imminently will sell for importation, import or sell after importation into the United States the GD/F56 birthing simulator system. See Exhibit 7. Honglian has stated that the GD/F56 will be available in March 2011, and Honglian already is promoting the GD/F56 for sale in the United States. See Exhibit 7. On information and belief, pursuant to Honglian's representations, the GD/F56 birthing simulator system is based on the GD/F55 birthing simulator system, and thus also is subject to this investigation. See Exhibit 7. Further discovery also may reveal that other Honglian products infringe claims of the Gaumard Asserted Patents.

VII. SPECIFIC INSTANCES OF IMPORTATION AND SALE

7.1 On information and belief, Honglian imports into the United States, sells for importation into the United States, and/or sells after importation into the United States the infringing Accused Simulator Products. The specific instance of importation and sale of an infringing GD/F55 simulator product set forth is a representative example of the unlawful importation of the infringing product.

7.2 As described in Exhibit 7, the Declaration of David Broussard, a representative sample of Honglian's GD/F55 simulator product, photos of which are attached as Exhibit 16, was purchased in the United States. On information and belief, the simulator product shown in Exhibit 16 was manufactured by Honglian or an affiliate in China, sold by Honglian for importation into the United States, and imported into the United States by Honglian for sale to a United States customer. The infringing GD/F55 simulator product shown in Exhibit 16 contains a label on the outside of the shipping box that says that the GD/F55 is "Made in China."

Similarly, a label on the motor inside the GD/F55 simulator product as shown in Exhibit 16 says “Made in China.” The infringing GD/F55 simulator product shown in Exhibit 16 contains a label on the “One Year Limited Warranty” document included inside of the shipping box that says that the GD/F55 is “Made in China.” The infringing GD/F55 simulator product shown in Exhibit 16 was received with a DHL shipping receipt that indicates that the product was shipped from Shanghai, China. See Exhibit 15.

7.3 The infringing GD/F55 simulator product shown in Exhibit 16 was purchased through communications with Shanghai Honglian Medical Instrument Development Co., Ltd. See Exhibit 7. The DHL shipping receipt for the product indicates that the shipper was Shanghai Honglian Medical Instrument Development Co., Ltd. See Exhibit 15. However, the “Proforma Invoice” for the product was transmitted on Shanghai Evenk International Trading Co., Ltd. letterhead, with instructions that payment for the product was to be made (and was made) to Shanghai Evenk International Trading Co., Ltd. See Exhibit 7. The “Packing List” for the product also was transmitted on Shanghai Evenk International Trading Co., Ltd. letterhead. See Exhibit 7. The Shanghai Evenk International Trading Co., Ltd. letterhead lists a website, <http://en.honglian8.com>, which purports to be the website of Shanghai Honglian Medical Instrument Development Co., Ltd. See Exhibit 7.

7.4 The continuing sale for importation, importation, and/or sale after importation of the Accused Simulator Products is further demonstrated by the listing of the GD/F55 as an available product for sale on Shanghai Honglian Medical Instrument Development Co.’s website, along with Honglian’s admission on the website that it manufactures its products in China and exports its products to the United States. See Exhibit 14. Additionally, Shanghai Honglian Medical Instrument Development Co.’s 2010 “Products Catalog,” included inside of

the shipping box for the infringing GD/F55 simulator product shown in Exhibit 16, contains pages devoted to both the GD/F55 and GD/F53 Accused Simulator Products. See Exhibit 17.

VIII. THE DOMESTIC INDUSTRY

8.1 In accordance with Section 337(a)(2)-(3), an industry in the United States exists for products protected by the '087 and '954 Patents. Gaumard has made significant investments in plant and equipment, significant employment of labor and capital, and significant investments in its exploitation of the '087 and '954 Patents in the United States, including research and development, technical and customer support, and marketing. These investments are all tied, at least in part, to the '087 and '954 Patents. Confidential Exhibit 1 is a declaration regarding Gaumard's domestic industry, detailing Gaumard's significant investments in plant and equipment, significant employment of labor and capital, and significant investments in its exploitation of the '087 and '954 Patents in the United States.

8.2 Technical Prong: All of Gaumard's 10 NOELLE® simulator models ("domestic industry products"), which are developed, manufactured, sold, and supported in the United States, including the S550 and S575 (which are representative of Gaumard's NOELLE® simulator products with respect to the patented technology at issue), practice at least one or more claims of the '087 and '954 Patents. Exhibit 8 is a claim chart demonstrating that the NOELLE® S550 and S575 models practice at least one independent claim of the '087 Patent. Exhibit 9 is a claim chart demonstrating that the NOELLE® S550 and S575 models practice at least one independent claim of the '954 Patent. The Instruction Manuals for the NOELLE® S550 and S575 models are attached as Exhibits 10 and 11, respectively. The Gaumard NOELLE® Instructor and Student Guides, excerpts attached as Exhibit 12, provide further evidence that the representative NOELLE® products practice at least one claim of each of the

Gaumard Asserted Patents. Photographs of the Gaumard NOELLE® simulator are attached as Exhibit 13.

8.3 Economic Prong: Gaumard is a Florida corporation with its principal place of business in Miami, Florida. Several examples establish that an industry related to Gaumard's birthing simulators and systems exists in the United States.

8.4 Gaumard has made significant investments in its plant and in its equipment in the United States related to its domestic industry products. All of Gaumard's design, development and manufacturing takes place in Miami, Florida. The domestic industry products are manufactured by employees of Formatek, Inc. in Gaumard's factory located at 14700 SW 136 Street Miami, FL 33196, and at 14740 SW 136 Street Miami, FL 33196. 14700 SW 136 Street houses administration and molding, and the adjacent building at 14740 SW 136 Street houses engineering as well as mechanical and electronic assembly. Gaumard owns the two parcels of land at 14700 and 14740 SW 136 Street and paid for the construction of the facilities at each location. Gaumard, Formatek, and Gaumard Sales are the sole occupants of these facilities. Major pieces of equipment, including machinery and computers, were purchased by Gaumard and are used by employees of Gaumard and Formatek in the design and manufacture of the domestic industry products at the two Miami facilities. Further details concerning Gaumard's U.S. investments in plant and equipment are set forth in Confidential Exhibit 1.

8.5 Gaumard has made significant investments in the employment of labor and capital in the United States related to its domestic industry products. Gaumard's employees engage in administrative and engineering activities related to Gaumard products, including the domestic industry products. Formatek's employees engage in manufacturing operations at Gaumard's Miami factory. Because Formatek's employees perform work solely in connection

with Gaumard products (including the domestic industry products), Gaumard compensates Formatek for the cost of Formatek's employee labor. In addition, employees of Gaumard Sales Company, Inc., another company associated with Gaumard, engage in marketing and sales of Gaumard products, including the domestic industry products. Because Gaumard Sales' employees perform work solely in connection with Gaumard designed or distributed products, Gaumard compensates Gaumard Sales for the cost of Gaumard Sales' employee labor. The employees of Gaumard, Formatek, and Gaumard Sales are all based in the United States, and most of these employees conduct activities related to the domestic industry products. Confidential Exhibit 1 contains further details of these employees' activities.

8.6 Gaumard has made significant investments in its exploitation of the '087 and '954 Patents in the United States, for example through engineering and research and development ("R&D") of the domestic industry products in the United States. Engineers employed by Gaumard and Formatek conduct engineering and research and development related to the domestic industry products. Most of these activities are conducted at Gaumard's facilities in Miami, but Gaumard also sponsors research at U.S. universities. Confidential Exhibit 1 contains further details of Gaumard's domestic engineering and R&D expenditures.

8.7 Gaumard and Gaumard Sales engage in significant domestic marketing activities for the domestic industry products. Such activities include www.gaumard.com; a monthly newsletter; at least one comprehensive product catalog a year; numerous product flyers; numerous DVDs; the production of texts and DVDs, including four NOELLE® Instructor and Student Guides; and one Surgical NOELLE® text with videos. Each year employees of Gaumard and Gaumard Sales participate in numerous medical conventions and product shows. Confidential Exhibit 1 contains further details of Gaumard's domestic marketing activities.

8.8 Extensive technical support is provided to Gaumard's U.S. customers of the domestic industry products. Currently, a traveling field staff and additional staff located at the Miami home office are dedicated to these activities. Employees of Gaumard Sales also provide occasional customer support for the domestic industry products. Confidential Exhibit 1 contains further details of Gaumard's domestic technical and customer support activities.

8.9 The technology claimed in Gaumard's Asserted Patents was created and developed in the United States. Confidential Exhibit 1 contains other facts not publicly known that further establish Gaumard's domestic industry with respect to Gaumard's Asserted Patents.

IX. RELATED LITIGATION

9.1 To the best of Gaumard's knowledge, there has been no previous or pending domestic or foreign court or agency litigation concerning any of Gaumard's Asserted Patents or between Gaumard and Honglian.

X. RELIEF

10.1 The proposed Respondents Shanghai Honglian Medical Instrument Development Co., Ltd. (d/b/a General Doctor) and Shanghai Evenk International Trading Co., Ltd. (collectively "Honglian") have infringed and will continue to infringe Gaumard's Asserted Patents unless the Commission prohibits the importation and sale in the United States of Honglian's Accused Simulator Products.

10.2 Gaumard respectfully requests that the United States International Trade Commission:

- (a) institute an immediate investigation pursuant to Section 337(b)(1) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, into the violations by the proposed Respondents of Section 337 arising from the sale for importation into the United States, importation, and/or sale within the United States after importation of the

proposed Respondents' birthing simulators and associated systems, including without limitation the GD/F55 Advanced Delivery and Maternal and Neonatal Emergency Simulator and the GD/F53 Advanced Maternal and Neonatal Delivery Model, that infringe one or more claims of U.S. Patent Nos. 6,503,087 and 7,114,954.

(b) schedule and conduct a hearing, pursuant to Section 337(c), for purposes of receiving evidence and hearing argument concerning whether there has been a violation of Section 337 and, following the hearing, determine that there has been a violation of Section 337.

(c) issue a permanent exclusion order, pursuant to Section 337(d) and (f)(1), excluding from entry into the United States proposed Respondents' birthing simulators and associated systems, including without limitation the GD/F55 Advanced Delivery and Maternal and Neonatal Emergency Simulator and the GD/F53 Advanced Maternal and Neonatal Delivery Model, that infringe one or more claims of U.S. Patent Nos. 6,503,087 and 7,114,954.

(d) issue a permanent order, pursuant to Section 337(f), directing the Proposed Respondents to cease and desist from importing, selling, selling for importation, offering for sale, using, demonstrating, promoting, marketing, and/or advertising in the United States the proposed Respondents' birthing simulators and associated systems, including without limitation the GD/F55 Advanced Delivery and Maternal and Neonatal Emergency Simulator and the GD/F53 Advanced Maternal and Neonatal Delivery Model, that infringe one or more claims of U.S. Patent Nos. 6,503,087 and 7,114,954.

(e) grant all such other and further relief as it deems appropriate under the law, based upon the facts complained of herein as determined by the investigation.

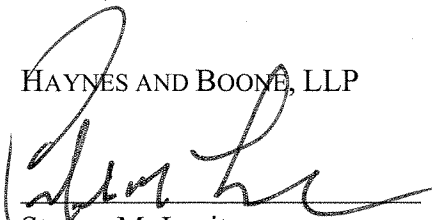
XI. PUBLIC INTEREST

11.1 Exclusion of the Accused Simulator Products will have no negative or deleterious effect on public health and welfare in the United States, on competitive conditions in the United States economy, on the production of like or directly competitive articles in the United States, or on United States consumers.

- (a) There are no public health, safety, or welfare concerns in the United States relating to the potential exclusion order against the infringing products or relating to proposed cease and desist orders against Respondents and their distributors.
- (b) Gaumard's products are widely available in the United States.
- (c) Gaumard is able to meet all current and conceivable demand for its products.

Dated: December 30, 2010

HAYNES AND BOONE, LLP



Steven M. Levitan
2033 Gateway Place, Suite 400
San Jose, CA 95110
Phone: (408) 660-4120
Fax: (408) 660-4121

Edward M. Lebow
Michael M. Shen
Scott Cunning
1615 L Street, NW, Suite 800
Washington, DC 20036-5610
Phone: (202) 654-4500
Fax: (202) 654-4501

David L. McCombs
Gregory P. Webb
2505 N. Plano Road, Suite 4000

Richardson, TX 75082
Phone: (972) 739-6900
Fax: (972) 680-7551

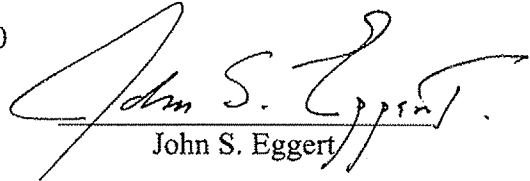
*Attorneys for Complainant
Gaumard Scientific Company, Inc.*

VERIFICATION OF COMPLAINT

I, John S. Eggert, Vice President and Chief Financial Officer of Gaumard Scientific Company, Inc., declare, in accordance with 19 C.F.R. §§ 210.4 and 210.12(a), under penalty of perjury, that the following statements are true:

1. I am duly authorized to sign this Complaint on behalf of Gaumard Scientific Company, Inc. ("Gaumard");
2. I began doing work for Gaumard in 1986 and have been employed by Gaumard fulltime since 1992. I hold a Bachelor of Science degree, a Master of Science degree and a Master of Business Administration degree;
3. I have read the foregoing Complaint and am familiar with the allegations and statements contained therein;
4. To the best of my knowledge, information, and belief, based upon reasonable inquiry, the foregoing Complaint is well founded in fact and is warranted by existing law or by a non-frivolous argument for the extension, modification, or reversal of existing law or the establishment of new law;
5. The allegations and other factual contentions have evidentiary support or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and
6. The foregoing Complaint is not being filed for an improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

Executed this 29th day of December, 2010


John S. Eggert