

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

**In the Matter of**

**CERTAIN BIRTHING SIMULATORS  
AND ASSOCIATED SYSTEMS**

**Investigation No. 337-TA-759**

**ISSUANCE OF A LIMITED EXCLUSION ORDER AND A CEASE AND  
DESIST ORDER; TERMINATION OF THE INVESTIGATION**

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has issued a limited exclusion order and a cease and desist order in the above-captioned investigation directed against products of respondents Shanghai Honglian Medical Instruments of China and Shanghai Evenk International Trading Co., Ltd. of China. The investigation is terminated.

**FOR FURTHER INFORMATION CONTACT:** Michelle Klancnik, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at <http://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted this investigation on February 7, 2011, based on a complaint filed by Gaumard Scientific Company, Inc. of Miami, Florida. 76 *Fed. Reg.* 6632 (Feb. 7, 2011). The complaint, as amended, alleged violations of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the 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 by reason of infringement of various claims of United States Patent Nos. 6,503,087 ("the '087 patent") and 7,114,954 ("the '954 patent"). The complaint named Shanghai Honglian Medical Instruments of China and Shanghai Evenk International Trading Co., Ltd. of China as respondents. The complaint and Notice of Investigation were served on respondents on February 1, 2011. No responses were received.

On March 4, 2011, the ALJ issued an order requiring respondents to show cause why they should not be held in default and judgment rendered against them for failing to respond to the complaint and notice of investigation. Respondents did not respond. On March 30, 2011, the ALJ issued an ID, finding both respondents in default pursuant to Commission Rule 210.16 (19 C.F.R. § 210.16) and terminating the above-referenced investigation. None of the parties petitioned for review of the ID. On May 2, 2011, the Commission determined not to review the ID.

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, the public interest, and bonding. The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting the unlicensed entry of birthing simulators covered by one or more of claims 16-20, 22-23, 25-28, 30-31, 33-34, and 36-38 of the '087 patent and claims 1, 2, 6, 7, and 10 of the '954 patent and that are manufactured by or on behalf of Shanghai Honglian and Shanghai Evenk, their affiliated companies, parents, subsidiaries, licensees, contractors, or other related business entities, or successors or assigns. The Commission has also determined to issue a cease and desist order that prohibits importing, selling for importation, marketing, advertising, distributing, offering for sale, selling, transferring (except for exportation), advertising, and soliciting United States agents or distributors for birthing simulators that are covered by one or more of the asserted claims.

The Commission further determined that the public interest factors enumerated in section 337(d)(1) (19 U.S.C. § 1337(d)(1)) do not preclude issuance of the limited exclusion order. Finally, the Commission determined that the amount of bond to permit temporary importation during the Presidential review period (19 U.S.C. § 1337(j)) shall be in the amount of 100 percent of the entered value of Shanghai Honglian's and Shanghai Evenk's birthing simulators that are subject to the order. The Commission's orders were delivered to the President and the United States Trade Representative on the day of their issuance.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in section 210.50 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.50).

By order of the Commission.

  
James R. Holbein  
Secretary to the Commission

Issued: August 29, 2011

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

**In the Matter of**

**CERTAIN BIRTHING SIMULATORS  
AND ASSOCIATED SYSTEMS**

**Inv. No. 337-TA-759**

**LIMITED EXCLUSION ORDER**

The Commission has previously found Respondents Shanghai Honglian Medical Instrument Development Co., Ltd. (d/b/a General Doctor) and Shanghai Evenk International Trading Co. Ltd. (collectively "Respondents") of China in default for failing to respond to the Notice of Investigation and the Complaint that alleged 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, and sale after importation of certain birthing simulators and associated systems by reason of infringement of 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 claims 1, 2, 6-7, and 10 of U.S. Patent No. 7,114,954 ("the '954 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, the public interest, and bonding. The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting the unlicensed entry of birthing simulators and associated systems that are covered by one or more of claims 16-20, 22-23, 25-28, 30-31, 33-34, and 36-38 the '087 patent and claims 1, 2, 6-7, and 10 of the '954 patent, and that are manufactured abroad by or on behalf of, or imported by or on behalf of Respondents.

The Commission has further determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude issuance of the limited exclusion order, and that a bond in the amount of 100% of the articles in question shall be required during the Presidential review period.

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

1. Birthing simulators and associated systems that infringe one or more of claims 16-20, 22-23, 25-28, 30-31, 33-34, and 36-38 the '087 patent and claims 1, 2, 6-7, and 10 of the '954 patent, that are manufactured abroad by or on behalf of, or imported by or on behalf of, Respondents or any of their affiliated companies, parents, subsidiaries, successors, assigns, or other related business entities, 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 patents' owner or as provided by law.

2. Notwithstanding paragraph 1 of this Order, the aforesaid products are entitled to entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, under bond in the amount of 100% of entered value of such articles 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.* 43251), from the day after this Order is received by the United States Trade Representative 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 date of receipt of this action.

3. At the discretion of U.S. Customs and Border Protection ("CBP") and pursuant to procedures it establishes, persons seeking to import birthing simulators and associated systems 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 the certification.

4. In accordance with 19 U.S.C. § 1337(l), the provisions of this Order shall not apply to birthing simulators and associated systems that are imported by and 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 section 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 CBP.

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

By Order of the Commission.



James R. Holbein  
Secretary to the Commission

Issued: August 29, 2011

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

**In the Matter of**

**CERTAIN BIRTHING SIMULATORS  
AND ASSOCIATED SYSTEMS**

**Inv. No. 337-TA-759**

**ORDER TO CEASE AND DESIST**

IT IS HEREBY ORDERED THAT Shanghai Honglian Medical Instrument Development Co., Ltd. (d/b/a General Doctor), Floor 5, No.1 Aijia Bldg, 288# Wuhua Rd. Shanghai, China 200086, and Shanghai Evenk International Trading Co., Ltd., Floor 5, No.1 Aijia Bldg, 288# Wuhua Rd. Shanghai, China 200086, cease and desist from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, offering for sale, transferring (except for exportation), and soliciting U.S. agents or distributors for birthing simulators and associated systems that infringe 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 claims 1, 2, 6-7, and 10 of U.S. Patent No. 7,114,954 ("the '954 patent") 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) "Complainant" shall mean Gaumard Scientific Company, Inc., 14700 SW 136 Street Miami, Florida 33196.
- (C) "Respondents" refers, collectively, to "Respondent" Shanghai Honglian Medical Instrument Development Co., Ltd. (d/b/a General Doctor), whose address is believed to be Floor 5, No. 1 Aijia Bldg, 288# Wuhua Rd. Shanghai, China 200086, and "Respondent" Shanghai Evenk International Trading Co., Ltd., whose address is believed to be Floor 5, No.1 Aijia Bldg, 288# Wuhua Rd. Shanghai, China 200086.
- (D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity or its majority owned or controlled subsidiaries, or their 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 birthing simulators and associated systems that infringe claims 16-20, 22-23, 25-28, 30-31, 33-34, and 36-38 of the ‘087 patent and claims 1, 2, 6-7, and 10 of the ‘954 patent.

## **II. APPLICABILITY**

The provisions of this Cease and Desist Order shall apply to the Respondents and to any of their 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, the Respondents.

## **III. CONDUCT PROHIBITED**

The following conduct of the Respondents in the United States is prohibited by the Order. For the remaining term of the ‘087 patent and the ‘954 patent, Respondents shall not:

- (A) import or sell for importation into the United States covered products;
- (B) market, distribute, offer for sale, 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, in a written instrument, the owner of the ‘087 patent and the ‘954 patent licenses or authorizes such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States.

## **V. REPORTING**

For purposes of this reporting requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. However, the first report required under this section shall cover the period from the date of issuance of this Order through December 31, 2012. This reporting requirement shall continue in force until such time as Respondents will have truthfully reported, in two consecutive timely filed reports, that they have no inventory of covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondents shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that each Respondent 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, Respondents shall file the original document and two copies with the Office of the Secretary of the Commission. A Respondent desiring to submit a document to the Commission in confidence must file the original and a public version of the original with the Office of the Secretary and serve a copy of the confidential version on Complainant's counsel.<sup>1</sup>

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

## **VII. SERVICE OF CEASE AND DESIST ORDER**

Respondents are ordered and directed to:

(A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of their 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;

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<sup>1</sup> Complainant must file a letter with the Secretary identifying the attorney to receive the reports. The designated attorney must be on the protective order entered in the investigation.

(B) Serve, within fifteen (15) days after the succession of any persons referred to in the preceding paragraph, a copy of this 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 (B) of this Order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and (C) shall remain in effect until the date of expiration of the '087 patent and the '954 patent.

### **VIII. CONFIDENTIALITY**

Any request for confidential treatment of information obtained by the Commission pursuant to Sections V and VI of this Order should be in accordance with Commission Rule 201.6, 19 C.F.R. § 201.6. For all reports for which confidential treatment is sought, Respondents 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 Rules of Practice and Procedure (19 C.F.R. § 210.75), including an action for civil penalties in accordance with section 337(f) of the Tariff Act of 1930, as amended (19 U.S.C. § 1337(f)), and any other action as the Commission may deem appropriate. In determining whether a Respondent is in violation of this Order, the Commission may infer facts adverse to a Respondent if Respondent 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 (60) day period in which this Order is under review by the United States Trade Representative pursuant to section 337(j) of the Tariff Act of 1930, 19 U.S.C. § 1337(j), and the Presidential Memorandum for the United States Trade Representative of July 21, 2005 (70 *Fed. Reg.* 43251), subject to Respondents posting a bond of 100 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 beginning the day after the date of issuance of this

order are subject to the entry bond as set forth in the limited 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* Commission Rule 210.68, 19 C.F.R. § 210.68. The bond and any accompanying documentation is to be provided to and approved by the Commission prior to the commencement of conduct which is otherwise prohibited by Section III of this Order. Upon acceptance of the bond by the Secretary: (a) the Secretary will serve an acceptance letter on all parties; and (b) the Respondent must serve a copy of the bond and any accompanying documentation on Complainant's counsel.<sup>2</sup>

The bond is to be forfeited in the event that the United States Trade Representative approves, or does not disapprove within the Presidential review period, this Order, unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondents on appeal, or unless Respondents export the products subject to this bond or destroys them and provides certification to that effect 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 Respondents of an order issued by the Commission based upon application therefore made by Respondents to the Commission.

By Order of the Commission.



James R. Holbein  
Secretary to the Commission

Issued: August 29, 2011

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<sup>2</sup> Complainant must file a letter with the Secretary identifying the attorney to receive the bond information. The designated attorney must be on the protective order entered in the investigation.

**CERTAIN BIRTHING SIMULATORS AND ASSOCIATED SYSTEMS**

**337-TA-759**

**CERTIFICATE OF SERVICE**

I, James R. Holbein, hereby certify that the attached **ISSUANCE OF A LIMITED EXCLUSIVO ORDER AND A CEASE AND DESIST ORDER; TERMINATION OF THE INVESTIGATION** has been served by hand upon the Commission Investigative Attorney Aarti Shah, Esq. and the following parties as indicated, on August 29, 2011.

  
James R. Holbein  
Secretary to the Commission  
U.S. International Trade Commission  
500 E Street, SW  
Washington, DC 20436

**On Behalf of Complainants:**

Michael M. Shen, Esq.  
**HAYNES AND BOONE LLP**  
1615 L St., N.W.  
Suite 800  
Washington, DC 20006-5610

- Via Hand Delivery
- Via Overnight Mail
- Via First Class Mail
- Other: \_\_\_\_\_

**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

- Via Hand Delivery
- Via Overnight Mail
- Via First Class Mail
- INTERNATIONAL

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

- Via Hand Delivery
- Via Overnight Mail
- Via First Class Mail
- INTERNATIONAL