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

| **In the Matter of**<br><br>**CERTAIN CLIDINIUM BROMIDE AND PRODUCTS CONTAINING SAME** | **Inv. No. 337-TA-1109** |
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## NOTICE OF INSTITUTION OF INVESTIGATION

Institution of Investigation Pursuant to 19 U.S.C.1337

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

**ACTION:** Notice

**SUMMARY:** Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on February 20, 2018, under section 337 of the Tariff Act of 1930, as amended, on behalf of Valeant Pharmaceuticals North America LLC of Bridgewater, New Jersey and Valeant Pharmaceuticals International, Inc. of Canada. An amended complaint was filed on March 20, 2018. The complaint, as amended, alleges violations of section 337 based upon the importation into the United States or the sale after importation of certain clidinium bromide and products containing same by reason of unfair acts or methods of competition, the threat or effect of which is to destroy or substantially injure an industry in the United States.

The complainants request that the Commission institute an investigation and, after the investigation, issue a general exclusion order, in the alternative a limited exclusion order, and cease and desist orders.

**ADDRESSES:** The amended complaint, except for any confidential information contained therein, is 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., Room 112, Washington, D.C. 20436, telephone (202) 205-2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at https://www.usitc.gov. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov.

**FOR FURTHER INFORMATION CONTACT:** Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2560.

**SUPPLEMENTARY INFORMATION:**

**AUTHORITY:** The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10 (2017).

**SCOPE OF INVESTIGATION:** Having considered the complaint, the U.S. International Trade Commission, on April 17, 2018, **ORDERED THAT** –

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(A) of section 337 in the importation into the United States or the sale after importation of certain clidinium bromide and products containing same by reason of false advertising and unfair competition under the Lanham Act, 15 U.S.C. 1125(a), the threat or effect of which is to destroy or substantially injure an industry in the United States;

(2) Notwithstanding any Commission Rules that would otherwise apply, the presiding Administrative Law Judge shall hold an early evidentiary hearing, find facts, and issue an early decision, as to whether the complainants have demonstrated an injury or threat of injury to an industry in the United States. Any such decision shall be in the form of an initial determination (ID). Petitions for review of such an ID shall be due five calendar days after service of the ID; any replies shall be due three business days after service of a petition. The ID will become the Commission's final determination 30 days after the date of service of the ID unless the Commission determines to review the ID. Any such review will be conducted in accordance with Commission Rules 210.43, 210.44, and 210.45, 19 C.F.R. §§ 210.43, 210.44, and 210.45. The Commission expects the issuance of an early ID relating to the requirement of an injury to an industry in the United States within 100 days of institution, except that the presiding ALJ may grant an extension of the ID of up to 50 days for good cause shown. The issuance of an early ID finding that complainants failed to demonstrate an injury or threat of injury to an industry in the United States shall stay the investigation unless the Commission orders otherwise; any other decision shall not stay the investigation or delay the issuance of a final ID covering the other issues of the investigation;

(3) Pursuant to Commission Rule 210.50(b)(1), 19 C.F.R. § 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties and other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. §§ 1337(d)(1), (f)(1), (g)(1);

(4) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Valeant Pharmaceuticals North America LLC
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807

Valeant Pharmaceuticals International, Inc.
2150 St Elzéar Boulevard West
Laval, Quebec, Canada H7L4A8

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the amended complaint is to be served:

Bi-Coastal Pharma International LLC
1161 Broad Street, Suite 216
Shrewsbury, NJ 07702

Bi-Coastal Pharmaceutical Corporation
1161 Broad Street, Suite 216
Shrewsbury, NJ 07702

ECI Pharmaceuticals LLC
5311 NW 35th Terrace
Fort Lauderdale, FL 33309

Virtus Pharmaceuticals LLC
2649 Causeway Center Drive
Tampa, FL 33619

Virtus Pharmaceuticals OPCO II LLC
1321 Murfreesboro Pike
Nashville, TN 37217-2626

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, S.W., Suite 401, Washington, D.C. 20436; and

(5) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the amended complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.13. Pursuant to 19 C.F.R. 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the amended complaint and the notice of investigation. Extensions of time for submitting responses to the amended complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the amended complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the amended complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: April 18, 2018