UNITED STATES INTERNATIONAL TRADE COMMISSION Washington, D.C.

In the Matter of

CERTAIN SELECTIVE THYROID HORMONE RECEPTOR-BETA AGONISTS, PROCESSES FOR MANUFACTURING OR RELATING TO SAME, AND PRODUCTS CONTAINING SAME

Inv. No. 337-TA-1352

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 December 29, 2022, under section 337 of the Tariff Act of 1930, as amended, on behalf of Viking Therapeutics, Inc. of San Diego, California. A supplement was filed on January 13, 2023. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States of certain selective thyroid hormone receptorbeta agonists, processes for manufacturing or relating to same, and products containing same by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure a domestic industry or prevent the establishment of a domestic industry.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. For help accessing EDIS, please email EDIS3Help@usitc.gov. 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.

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 (2022).

SCOPE OF INVESTIGATION: Having considered the complaint, the U.S. International Trade Commission, on February 3, 2023, 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 of certain products identified in paragraph (2) by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure a domestic industry in the United States or prevent the establishment of an industry in the United States;
- (2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is "drug products and drug substances that are selective thyroid hormone receptor-beta agonists for the treatment of metabolic disorders and liver diseases";
- (3) Pursuant to section 210.10(b)(3) of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10(b)(3), the presiding Administrative Law Judge shall hold an early evidentiary hearing, find facts, and issue an early decision, within 100 days of institution except for good cause shown, as to whether complainant can show that the threat or effect of the alleged unfair acts is to (i) to destroy or substantially injure an industry in the United States, or (ii) to prevent the establishment of such an industry. Notwithstanding any Commission Rules to the contrary, which are hereby waived, any such decision should be issued in the form of an initial determination (ID) under Commission Rule 210.42(a)(3), 19 C.F.R. 210.42(a)(3). 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 issuance of an early ID finding that complainant failed to demonstrate that the threat or effect of the alleged unfair acts is (i) to destroy or substantially injure an industry in the United States, or (ii) to prevent the establishment of such an industry 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. Commissioner Schmidtlein does not support the use of a 100-day proceeding in this investigation. See concurrently filed Memorandum No. C086-VV-002 (February 3, 2023);
- (4) Pursuant to Commission Rule 210.50(b)(l), 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 or 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)(l), (f)(1), (g)(1);

- (5) 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 complainant is:

Viking Therapeutics, Inc. 9920 Pacific Heights Blvd., Suite 350 San Diego, CA 92121

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

Ascletis Pharma Inc. 12/F, Building D, 198 Qidi Road, HIPARK Xiaoshan District, Hangzhou Zhejiang Province, China 312000

Ascletis Pharmaceuticals Co. Ltd. No.1, Yunhai Road Lihai Town, Binhai New Town Shaoxing Zhejiang Province, China 312000

Ascletis Bioscience Co., Ltd. 12F, Building D, 198 Qidi Road, HIPARK Xiaoshan District, Hangzhou, Zhejiang Province, China 311200

Gannex Pharma Co., Ltd. 3F, No. 665 Zhangjiang Road Pilot Free Trade Zone Shanghai, China 200000

Jinzi Jason Wu 3413 E. Pine Street Seattle, WA 98122

- (c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, S.W., Suite 401, Washington, D.C. 20436; and
- (6) 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 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), as amended in 85 Fed. Reg. 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of investigation. Extensions of time for submitting responses to the 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 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 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.

Katherine M. Hiner

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Acting Secretary to the Commission

Issued: February 3, 2023