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**	**Investigation No. 337-TA-1352**

NOTICE OF REQUEST FOR SUPPLEMENTAL SUBMISSIONS FROM THE PARTIES; EXTENSION OF THE TARGET DATE

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("the Commission") is requesting supplemental submissions from the parties with respect to whether complainant Viking Therapeutics, Inc. ("Viking" or "Complainant") has shown the required injury to a domestic industry, including whether the alleged unfair acts have caused substantial actual or threatened injury to Complainant's domestic industry and/or prevented the establishment of such an industry. The Commission has also determined to extend the target date for completion of the investigation until May 13, 2025.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone (202) 708-4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.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 9, 2023, based on a complaint, as supplemented, filed by Viking of San Diego, California. 88 FR 8455-56 (Feb. 9, 2023). The complaint alleges a violation of section 337 the Tariff Act, as amended, 19 U.S.C. 1337 ("section 337"), by way of the importation into the United States of certain selective thyroid hormone receptor-beta 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. *Id.* The notice of investigation named the following respondents: Ascletis Pharma Inc. of Hangzhou, Zhejiang Province, China;

Ascletis Pharmaceuticals Co. of Shaoxing, Zhejiang Province, China; Ascletis Bioscience Co. of Hangzhou, Zhejiang Province, China; and Gannex Pharma Co. of Shanghai, China (collectively, Ascletis); and Jinzi Jason Wu ("Dr. Wu") of Seattle, Washington (collectively, "Respondents"). *Id.* The Office of Unfair Import Investigation ("OUII") is also participating in the investigation. *Id.*

On September 22, 2023, the Commission granted a motion to intervene filed by Foster, Murphy, Altman & Nickel, PC for the "limited purpose of defending Foster Murphy and its attorneys' interests in response to Complainant Viking Therapeutics, Inc.'s Omnibus Motion for Sanctions." *See* Order No. 37 (Aug. 28, 2023), *unreviewed by* Comm'n Notice (Sept. 22, 2023). Respondents' former counsel, Rimon PC, also filed a motion to intervene on February 7, 2024, and the Chief Administrative Law Judge ("Chief ALJ") granted that motion in part, allowing Rimon PC to participate as an intervenor to address the Chief ALJ's sanctions decisions.

The Chief ALJ held an evidentiary hearing from November 13 to 16, 2023.

On October 3, 2024, the Chief ALJ issued a final initial determination ("FID") finding a violation of section 337. Specifically, the FID finds that: (1) the Commission has statutory authority to conduct this investigation; (2) the asserted trade secrets are protectable; (3) Respondents misappropriated the asserted trade secrets; (4) Complainant has demonstrated both that a domestic industry exists and is in the process of being established; and (5) Respondents' unfair acts have caused actual and threatened injury to Viking's domestic industry and/or prevented the establishment of such an industry. The FID also grants Complainant's motion for sanctions under Commission Rule 210.33 (19 CFR 210.33) and imposes certain non-monetary and monetary sanctions against Respondents and/or their former counsel, Rimon PC.

The Chief ALJ also issued a recommended determination ("RD") recommending, should the Commission find a violation of section 337, that the Commission issue: (1) a seven-year limited exclusion order against certain selective thyroid hormone receptor-beta agonists, processes for manufacturing or relating to same, and products containing same that are imported by or on behalf of Respondents; and (2) a cease and desist order against each of Respondents. The RD also recommends that the Commission impose a 100 percent (100%) bond against covered articles imported by or on behalf of the Respondents during the period of Presidential review. Regarding the public interest, the RD finds that the statutory public interest factors do not weigh against the issuance of remedial orders.

On November 4, 2024, Complainant filed a statement on the public interest pursuant to Commission Rule 210.50 (19 CFR 210.50). Respondents did not submit a statement on the public interest pursuant to Commission Rule 210.50. In addition, the Commission did not receive any submissions from the public in response to its post-RD *Federal Register* notice. *See* 89 FR 82256-57 (Oct. 10, 2024).

On November 8, 2024, Respondents, Rimon PC, and OUII petitioned for Commission review of the FID. On the same day, Complainant filed a contingent petition for review of the

FID. More specifically, Respondents requested Commission review of the FID's findings with respect to: (1) the Commission's statutory authority over Dr. Wu, who is the Chief Executive Officer or President of each of the Corporate Respondents; (2) sanctions against Respondents and their former counsel, Rimon PC; (3) misappropriation of trade secrets; and (4) injury to a domestic industry. Rimon PC also petitioned for Commission review of the sanctions order against Respondents and their former counsel. Additionally, OUII petitioned for review of: (1) the Chief ALJ's failure to issue an ID at the conclusion of the 100-day proceeding; (2) the FID's findings regarding the existence and misappropriation of trade secrets; and (3) the FID's findings regarding the existence and injury to a domestic industry. Lastly, Complainant contingently petitioned for review of the FID's findings with respect to: (1) misappropriation of trade secrets; (2) existence of a domestic industry and injury thereto; and (3) sanctions against Respondents and their former counsel. On November 27, 2024, the parties filed responses to the petitions.

On February 12, 2025, the Commission issued a notice determining to review the FID in its entirety. *See* 90 FR 9910-13 (Feb. 19, 2025) ("the WTR Notice"). The WTR Notice also requested written submissions from the parties, interested government agencies, and any other interested parties on issues of remedy, the public interest, and bonding. *See id.* Additionally, the notice requested responses to certain public interest questions. *See id.*

As directed in the WTR Notice, the parties filed written submissions concerning the issues of remedy, the public interest, and bonding on February 28, 2025, and replies thereto on March 7, 2025. The Commission did not receive any submissions from the public in response to the WTR Notice.

In connection with its review, particularly with respect to the required injury to a domestic industry, the Commission requests that the parties brief their positions on the following questions with reference to the applicable law and citations to the existing evidentiary record:

1. Please explain whether and how Viking has satisfied the injury requirement under section 337(a)(1)(A)(i) and (ii) and Commission precedent and, more particularly, under each of the indicia outlined in *Certain Rubber Resins and Processes for Manufacturing Same*, Inv. No. 337-TA-849, Comm'n Op., 2014 WL 7497801 (Feb. 26, 2014). The submissions should specify each type of injury asserted in this investigation, including an analysis of whether Respondents' unfair acts have caused substantial actual or threatened injury to Complainant's domestic industry and/or prevented the establishment of such an industry. The submissions should further address injury in the context of each type of domestic industry, *i.e.*, an existing domestic industry and an industry in the process of being established as applicable. To the extent any party relies upon record evidence after the time of the complaint, identify the evidence and whether it represents "a significant and unusual development" such that it should be evaluated in this investigation. *Certain Television Sets, Television Receivers, Television Tuners, &*

Components Thereof, Inv. No. 337-TA-910, Comm'n Op., 2015 WL 6755093, *32 (Oct. 30, 2015).

2. Please explain whether and how the alleged injury takes into account selective thyroid hormone receptor-beta agonists from companies other than Viking and Ascletis, including drug candidates in more advanced stages of development than the accused products, as well as resmetirom, which has been approved by the U.S. Food and Drug Administration. Additionally, please explain whether and how these third-party drug products affect the required nexus between Respondents' unfair acts and Complainant's alleged injury to its domestic industry.

3. Please address the impact that the FDA approval of resmetirom in 2024 has on the ability of Viking and Ascletis to enter the market as an alternative treatment for NASH. Explain the need, if any, for alternative treatments for NASH. Does the evidence of record in this investigation take into account the impact of resmetirom's FDA approval and market entry on the domestic industry and injury?

In answering the additional briefing questions, the parties should specifically point to where in their arguments before the ALJ and in their petition for review these issues were addressed and the corresponding record evidence discussed. In seeking briefing on these issues, the Commission will not excuse any party's noncompliance with Commission rules and the ALJ's procedural requirements, including requirements to present issues and arguments in submissions to the ALJ and/or in petitions for Commission review. Any such attempts will be regarded as waived.

The Commission has also determined to extend the target date for completion of the investigation until May 13, 2025.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues identified in this Notice. The parties' initial written submissions must be filed no later than close of business on **April 11, 2025**. The parties' reply submissions must be filed no later than the close of business on **April 18, 2025**. Initial written submissions may not exceed 30 pages in length, exclusive of any exhibits, while reply submissions may not exceed 15 pages in length, exclusive of any exhibits. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above pursuant to 19 CFR 210.4(f). Submissions should refer to the investigation number (**Inv. No. 337-TA-1352**) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission's vote for this determination took place on April 3, 2025.

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 Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: April 3, 2025