INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1352]

Certain Selective Thyroid Hormone Receptor-Beta Agonists, Processes for Manufacturing or Relating to Same, and Products Containing Same; Notice of a Commission Determination to Review a Final Initial Determination Finding a Violation of Section 337; Request for Written Submissions on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined to review a final initial determination ("FID") issued by the presiding Chief Administrative Law Judge ("Chief ALJ"), finding a violation of section 337 of the Tariff Act of 1930, as amended. The Commission requests written submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

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 Therapeutics, Inc. ("Viking" or "Complainant") 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, by way of the importation, sale for importation, or sale in the United States after importation 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 as 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; Gannex Pharma Co. of Shanghai, China; and Jinzi Jason 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).

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

On October 3, 2024, the Chief ALJ issued the 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. 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) jointly and severally.

The ALJ's recommended determination ("RD") recommends, 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 bond against accused articles imported 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 8, 2024, Respondents, Rimon PC (Respondents' former counsel), 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 request 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 petitions for Commission review of the sanctions order against Respondents and their former counsel. Additionally, OUII petitions 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 petitions 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 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).

Having reviewed the record of the investigation, including the final ID, the parties' submissions to the Chief ALJ, and the parties' submissions to the Commission, the Commission has determined to review the FID in its entirety.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia,* (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, *see Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.[1] In particular, there is interest in responses to the following public interest questions:

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1 Commissioner Johanson does not join Commission questions 2 and 3 to the extent they seek briefing related to the FDA "safe harbor" provision of 35 U.S.C. 271(e)(1) because it is not the basis of the alleged violation in this investigation.

1. Please address with support from the evidentiary record to what extent do the statutory public interest factors set forth in 19 U.S.C. 1337(c), especially that related to public health and welfare, weigh against the issuance of an exclusion order for a violation under 19 U.S.C. 1337(a)(1)(A) directed to the accused drug candidates in this investigation. In answering this question, identify how many people in the United States have been diagnosed with non-alcoholic steatohepatitis ("NASH"), the health implications of NASH (including the extent to which that condition can be life-threatening or raise other serious health concerns), and available treatment options.

2. Please explain with support from the evidentiary record if and how the Commission can tailor its remedy to minimize harm to the public interest. In particular, address whether the importation of accused products found in violation of 19 U.S.C. 1337(a)(1)(A) should nonetheless be permitted for purposes of ongoing or planned clinical trials. *Cf.* 35 U.S.C. 271(e)(1); *Amgen Inc. v. Int'l Trade Comm'n*, 565 F.3d 846, 848 (Fed. Cir. 2009). If an exemption is made to allow importation for purposes of clinical trials, please propose specific language in the Commission's remedial orders reflecting such an exemption and the scope/duration of such exception.

3. Please address how a finding of violation based on the alleged trade secret misappropriation in this case might raise different public interest issues than the policy considerations underlying the FDA "safe harbor" provision of 35 U.S.C. 271(e)(1).

4. Please address with support from the evidentiary record the extent to which Madrigal Pharmaceuticals' resmetirom product, which has been approved by the FDA for treatment of NASH, is effective for the treatment of NASH and the extent to which Viking's VK2809 drug candidate or Ascletis's ASC41 and

ASC43F drug candidates (the accused products) are likely to offer more effective treatment for NASH. In answering this question, explain the extent to which the patient population undergoing treatment for NASH with resmetirom overlaps with the potential patient populations for Viking's VK2809 drug candidate or Ascletis's ASC41 and ASC43F drug candidates.

5. Please address the extent to which resmetirom is available to meet demand for treatment of NASH. Please address the extent to which resmetirom together with Viking's VK2809 drug candidate if approved would be available to meet demand for treatment of NASH. Would there be a shortfall in the availability to meet demand if Ascletis's ASC41 and ASC43F drug candidates are excluded?

6. Please address with support from the evidentiary record how many patients in the United States are currently enrolled in or are expected to be enrolled in clinical trials for Viking's VK2809 drug candidate during the next seven years. Please identify the current status of each clinical trial involving Viking's VK2809 drug candidate, including when each clinical trial began (or is expected to begin), how many patients are enrolled in each trial, and when each clinical trial will end (or is expected to end). Would this answer change depending on whether Ascletis's products are excluded?

7. Please address with support from the evidentiary record how many patients in the United States are currently enrolled in or are expected to be enrolled in clinical trials for Ascletis's ASC41 and ASC43F drug candidates during the next seven years assuming the absence of an exclusion order? Please identify the current status of each clinical trial involving Ascletis's ASC41 and ASC43F drug candidates, including when each clinical trial began (or is expected to begin), how many patients are enrolled in each trial, and when each clinical trial will end (or is expected to end).

8. Please address with support from the evidentiary record what impact an exclusion of the accused products will have on patients with NASH that are currently or later enrolled in clinical trials involving Ascletis's ASC41 and ASC43F drug candidates. Explain the extent to which patients currently or later enrolled in clinical trials involving Ascletis's ASC41 and ASC43F drug candidates can switch to Viking's VK2809 drug candidate, resmetirom, or any other clinical treatment for NASH.

9. To the extent the information requested above does not exist in the evidentiary record or emerged after the close of the evidentiary record, please provide such information with a citation to the source of that information.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the Chief ALJ on remedy, bonding, and the public interest.

In its initial submission, Complainant is also requested to identify the remedy sought and Complainant and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and

proposed remedial orders must be filed no later than close of business on February 28, 2025. Reply submissions must be filed no later than the close of business on March 7, 2025. No further submissions on 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. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). 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. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. 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 vote for this determination took place on February 12, 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.

Issued: February 12, 2025.

Lisa Barton,

Secretary to the Commission.

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