

APPENDIX

Table of Contents

	<u>Page</u>
Order of the U.S. Court of Appeals for the Federal Circuit Dismissing Cross-Appeal (July 14, 2026).....	1a
Opinion of the U.S. International Trade Commission (May 29, 2025) (public version dated June 26, 2025).....	4a
Final Initial Determination of the Chief Administrative Law Judge (Oct. 3, 2024) (public version)	93a

NOTE: This order is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

VIKING THERAPEUTICS, INC.,
Appellant

v.

INTERNATIONAL TRADE COMMISSION,
Appellee

**ASCLETIS PHARMA INC., ASCLETIS
PHARMACEUTICALS CO. LTD., ASCLETIS
BIOSCIENCE CO., LTD., GANNEX PHARMA CO.,
LTD., JINZI JASON WU,**
Intervenors

2025-2162

Appeal from the United States International Trade
Commission in Investigation No. 337-TA-1352.

**ASCLETIS PHARMA INC., ASCLETIS
PHARMACEUTICALS CO. LTD., ASCLETIS
BIOSCIENCE CO., LTD., GANNEX PHARMA CO.,
LTD.,**
Appellants

v.

INTERNATIONAL TRADE COMMISSION,
Appellee

VIKING THERAPEUTICS, INC.
Intervenor

2025-2164

Appeal from the United States International Trade
Commission in Investigation No. 337-TA-1352.

ON MOTION

Before PROST, MAYER, and STOLL, *Circuit Judges*.
MAYER, *Circuit Judge*.

O R D E R

The International Trade Commission moves to dismiss Viking Therapeutics, Inc.’s cross-appeal, No. 2025-2162. The Commission states that Ascletis Pharma Inc. et al. (collectively, “Ascletis”) and Jinzi Jason Wu support the motion. The Commission indicates that Viking does not oppose the motion and “agrees that a panel of this Court would properly dismiss Viking’s cross-appeal,” but that Viking purportedly “reserves all rights to challenge the dismissal of the cross-appeal in future proceedings.” ECF No. 21 at 2.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The motion to dismiss Appeal No. 2025-2162 is granted. Appeal No. 2025-2162 is deconsolidated and

ASCLETIS PHARMA INC. v. ITC

3

dismissed. The revised official captions are reflected in this order.

(2) Costs in Appeal No. 2025-2162 are taxed against the appellant.

(3) The Clerk of Court shall transmit a copy of this order to the merits panel assigned to Appeal No. 2025-2164.

FOR THE COURT



Jarrett B. Perlow
Clerk of Court

July 14, 2026
Date

ISSUED AS A MANDATE (as to Appeal No. 2025-2162 only): July 14, 2026

PUBLIC VERSION

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

COMMISSION OPINION

PUBLIC VERSION

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND	2
	A. Procedural History	2
	B. Domestic Industry Products	7
	C. Accused Products	8
	D. Asserted Trade Secrets	8
III.	LEGAL STANDARDS	9
	A. Commission Review of the FID	9
	B. Order Concerning Sanctions	9
	C. Misappropriation of Trade Secrets	10
	D. Domestic Industry and Injury Thereto	12
	1. Domestic Industry	13
	2. Injury to the Domestic Industry	14
IV.	DISCUSSION	15
	A. 100-Day Early Disposition	16
	B. Importation and Statutory Authority	17
	C. Order Concerning Sanctions	20
	1. FID’s Findings and Parties’ Arguments	20
	2. Analysis	24
	D. Misappropriation of Trade Secrets	26
	1. FID’s Findings and Parties’ Arguments	27
	2. Analysis	30
	E. Domestic Industry and Injury Thereto	37
	1. Domestic Industry	37
	2. Injury to the Domestic Industry	43
V.	REMEDY, PUBLIC INTEREST, AND BONDING	71
	A. Remedy and Bonding	71
	1. Limited Exclusion Order	71
	2. Cease and Desist Orders	78
	3. Bonding	80
	B. Public Interest	81
	1. Public Health and Welfare	83
	2. Competitive Conditions in the United States Economy	85
	3. Production of Like or Directly Competitive Articles	86
	4. United States Consumers	86
VI.	CONCLUSION	87

I. INTRODUCTION

On February 12, 2025, the Commission determined to review in its entirety the final initial determination (“FID”) issued by the Chief Administrative Law Judge Cheney (“Chief ALJ”) on October 3, 2024. On review, the Commission has determined that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“section 337”), based on the misappropriation of certain trade secrets owned by complainant Viking Therapeutics, Inc. (“Viking” or “Complainant”), the threat of which is to destroy or substantially injure a domestic industry. *See* 19 U.S.C. § 1337(a)(1)(A). The Commission takes no position on the FID’s findings that Respondents’ unfair acts have caused actual injury to Viking’s domestic industry or prevented the establishment of such an industry.

More specifically, the Commission has determined to affirm in part and reverse in part the FID’s finding of a violation of section 337. The Commission affirms with modification the FID’s finding of a violation of section 337 by the corporate respondents and adopts the Chief ALJ’s sanctions order against those respondents and their former counsel, Rimon PC.¹ As to the individual respondent, Dr. Wu, the Commission reverses the FID’s finding of a violation of section 337 and vacates the sanctions order against that respondent.²

The Commission has determined that the appropriate remedy is a seven-year limited exclusion order (“LEO”) against certain selective thyroid hormone receptor-beta agonists, processes for manufacturing or relating to same, and products containing same, imported by or

¹ The corporate respondents include: Ascleitis Pharma Inc. of Hangzhou, China; Ascleitis Pharmaceuticals Co. Ltd. of Shaoxing, China; Ascleitis Bioscience Co., Ltd. of Hangzhou, China; and Gannex Pharma Co., Ltd. of Shanghai, China (collectively, “the corporate respondents” or “Ascleitis”).

² The individual respondent is Jinzi Jason Wu of Seattle, Washington (“the individual respondent” or “Dr. Wu”), who is the Chief Executive Officer (“CEO”) or president of each of the corporate respondents.

on behalf of the corporate respondents, and cease and desist orders (“CDOs”) against each of the corporate respondents. The Commission has also determined that the public interest factors enumerated in section 337(d)(1) and (f)(1) (19 U.S.C. § 1337(d)(1), (f)(1)) do not preclude the issuance of the LEO and CDOs. The Commission has further determined to set a bond during the period of Presidential review (19 U.S.C. § 1337(j)) in the amount of one hundred percent (100%) of the entered value of the covered articles.

This opinion sets forth the Commission’s reasoning in support of its determinations. The Commission affirms all other findings in the FID that are not inconsistent with this opinion.

II. BACKGROUND

A. Procedural History

The Commission instituted this investigation on February 9, 2023, based on a complaint, as supplemented, filed by complainant Viking of San Diego, California. 88 Fed. Reg. 8455-57 (Feb. 9, 2023). The complaint alleges a violation of section 337 in the importation into the United States of certain selective thyroid hormone receptor-beta agonists,³ processes for manufacturing or relating to same, and products containing same by reason of misappropriation of Viking’s 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.* at 8455-56. The notice of investigation names the following Respondents: the Ascletis corporate respondents and their CEO or president, Dr. Wu (collectively, “Respondents”). *See id.* at 8456. The Office of Unfair Import Investigations (“OUII”) is also a party to this investigation. *See id.*

³ Thyroid hormone receptor-beta or TR-β agonists are compounds that target thyroid hormone receptors in the liver (beta receptor subtype) for the treatment of certain metabolic disorders and liver diseases.

PUBLIC VERSION

The Commission directed the presiding ALJ to “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 actual or threatened injury to a domestic industry under section 337(a)(1)(A). *Id.* On April 13 and 14, 2023, as directed by the Commission, the Chief ALJ held an evidentiary hearing on the issue of injury (hereinafter, “100-Day Tr.”). On May 11, 2023, the Chief ALJ issued an order finding good cause to continue the investigation beyond the 100-day proceeding. *See* Order No. 22 (May 11, 2023).

On August 28, 2023, the Chief ALJ 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.” Order No. 37 (Aug. 28, 2023), *unreviewed by* Comm’n Notice (Sept. 22, 2023). Rimon PC, Respondents’ former counsel, also filed a motion to intervene on February 7, 2024, and the Chief ALJ granted that motion in part finding that “Rimon may participate in the investigation as an intervenor to address the sanctions decisions, but Rimon must do so based on the existing record of the investigation.” FID at 45.⁴

The Chief ALJ held an evidentiary hearing from November 13 to 16, 2023 (hereinafter, “Hr’g Tr.”). 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

⁴ The Commission does not disturb and therefore affirms the FID’s findings with respect to Rimon PC’s request for intervention.

PUBLIC VERSION

that it is in the process of being established⁵; and (5) Respondents' unfair acts have caused actual and threatened injury to both Viking's existing and future domestic industries. The FID also grants Complainant's motion for sanctions under Commission Rule 210.33 (19 C.F.R. § 210.33) and imposes certain non-monetary (adverse inferences) and monetary (\$567,059.85) sanctions against Respondents and/or their former counsel, Rimon PC.

The FID further includes a recommended determination ("RD") which recommends, should the Commission find a violation of section 337, that the Commission issue: (1) a seven-year LEO 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) CDOs against each of the Respondents. The RD also recommends that the Commission impose a 100 percent bond against covered articles imported during the period of Presidential review.

On November 4, 2024, Complainant filed a statement on the public interest pursuant to Commission Rule 210.50 (19 C.F.R. § 210.50).⁶ Respondents did not file a public interest statement. The Commission did not receive any submissions from the public in response to its post-RD *Federal Register* notice. *See* 89 Fed. Reg. 82256-57 (Oct. 10, 2024).

⁵ The FID finds that Complainant has demonstrated: (1) an existing domestic industry relating to Viking's "research, development, engineering, and testing to commercialize VK2809"; and (2) a domestic industry in the process of being established based on Viking's "investments in Phase III clinical trials, further investments [in] the FDA approval process, and the future commercialization of VK2809 tablets with a strategic partner." FID at 181-89.

⁶ *See* Complainant Viking Therapeutics Inc.'s Statement on the Public Interest (Nov. 4, 2024) ("Complainant's PI Statement").

PUBLIC VERSION

On November 8, 2024, Respondents, Rimon PC, and OUII petitioned for Commission review of some of FID’s findings.⁷ On the same day, Complainant filed a contingent petition for review of the FID.⁸ On November 27, 2024, the parties filed responses to the petitions.⁹ More specifically, Respondents requested Commission review of the FID’s findings with respect to: (1) the Commission’s statutory authority over Dr. Wu; (2) the sanctions order against Respondents and Rimon PC; (3) misappropriation of trade secrets; and (4) injury or threat of injury to a domestic industry. Rimon PC also petitioned for Commission review of the sanctions order against itself and against Respondents. Additionally, OUII petitioned for review of: (1) the Chief ALJ’s failure to issue an initial determination (“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 or threat of injury to a domestic industry. Lastly, Complainant contingently petitioned for review of the FID’s findings

⁷ Respondents’ Petition for Review of the Initial Determination of Violation of Section 337 (Nov. 8, 2024) (“Respondents’ Pet.”); Petition of Rimon PC to United States International Trade Commission to Vacate Sanctions against Rimon PC (Nov. 8, 2024) (“Rimon’s Pet.”); Petition of the Office of Unfair Import Investigations for Review of the Initial Determination on Violation of Section 337 (Nov. 8, 2024) (“OUII’s Pet.”).

⁸ Complainant Viking Therapeutics Inc.’s Contingent Petition and Petition for Review of the Final Initial Determination Finding a Violation of Section 337 and Sanctions (Nov. 8, 2024) (“Complainant’s Pet.”).

⁹ Complainant Viking Therapeutics Inc.’s Combined Response to Respondents’ and Staff’s Petitions for Review of the Final Initial Determination of Violation and Intervenor Rimon PC’s Petition to Vacate Sanctions against Rimon PC (Nov. 27, 2024) (“Complainant’s Pet. Resp.”); Respondents’ Response to Complainant’s Contingent Petition for Review of the Final Initial Determination Finding a Violation of Section 337 (Nov. 27, 2024) (“Respondents’ Pet. Resp.”); Response of Rimon PC to Complainant Viking Therapeutics Inc.’s Contingent Petition and Petition for Review of the Final Initial Determination Finding a Violation of Section 337 and Sanctions (Nov. 27, 2024) (“Rimon’s Pet. Resp.”); Response of the Office of Unfair Import Investigations to the Private Parties’ Petitions for Review of the Initial Determination on Violation of Section 337 (Nov. 27, 2024) (“OUII’s Pet. Resp.”).

PUBLIC VERSION

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, Rimon PC.

On February 12, 2025, the Commission issued a notice determining to review the FID in its entirety. 90 Fed. Reg. 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. *Id.* Additionally, the notice requested responses to certain questions focused on public interest considerations. *Id.* As directed in the notice, the parties filed written submissions¹⁰ concerning the issues of remedy, the public interest, and bonding on February 28, 2025, and replies¹¹ thereto on March 7, 2025. The Commission did not receive any submissions from the public in response to the WTR Notice.

On April 3, 2025, the Commission issued a notice requesting supplemental briefing on 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

¹⁰ See Complainant Viking Therapeutics Inc.’s Response to Commission’s Request For Written Submissions on Remedy, Public Interest and Bonding (Feb. 28, 2025) (“Complainant’s Remedy Br.”); Respondents’ Response to Commission’s Request for Written Submissions on Remedy, the Public Interest, and Bonding (Feb. 28, 2025) (“Respondents’ Remedy Br.”); Response of the Office of Unfair Import Investigations to the Commission’s Request for Written Submissions on Remedy, the Public Interest, and Bonding (Feb. 28, 2025) (“OUII’s Remedy Br.”).

¹¹ See Complainant Viking Therapeutics Inc.’s Combined Reply to Respondents’ and Staff’s Briefs in Response to the Commission’s Request for Written Submissions on Remedy, Public Interest, and Bond (Mar. 7, 2025) (“Complainant’s Remedy Reply”); Respondents’ Reply to Complainant’s and OUII’s Responses to the Commission’s Request for Submissions on Remedy, the Public Interest, and Bond (Mar. 7, 2025) (“Respondents’ Remedy Reply”); Reply Brief of the Office of Unfair Import Investigations on Remedy, the Public Interest, and Bonding (Mar. 7, 2025) (“OUII’s Remedy Reply”).

(“Supplemental Notice”). As directed in the Supplemental Notice, the parties filed initial submissions¹² on April 11, 2025, and replies¹³ thereto on April 18, 2025.

B. Domestic Industry Products

Viking’s domestic industry product is VK2809,¹⁴ an orally available drug product which includes an active pharmaceutical ingredient (“API”) formulated in either a capsule or tablet form with excipients, which are inactive ingredients to ensure sufficient bioavailability, *i.e.*, absorption by the human body. FID at 13-15. The API in VK2809 is a small molecule with the chemical formula $C_{28}H_{32}ClO_5P$, namely a selective thyroid hormone receptor-beta (“TR- β ”) agonist for the treatment of lipid and metabolic disorders, such as non-alcoholic steatohepatitis (“NASH”), which is an advanced form of non-alcoholic fatty liver disease (“NAFLD”).¹⁵ *Id.*

¹² See Complainant Viking Therapeutics Inc.’s Response to the Commission’s Request for Supplemental Submissions (Apr. 11, 2025) (“Complainant’s Suppl. Br.”); Respondents’ Response to the Commission’s Request for Supplemental Submission on Whether Complainant Has Shown the Required Injury to a Protectable Domestic Industry (Apr. 11, 2025) (“Respondents’ Suppl. Br.”); Response of the Office of Unfair Import Investigations to the Commission’s Request for Supplemental Briefing (Apr. 11, 2025) (“OUII’s Suppl. Br.”).

¹³ See Complainant Viking Therapeutics Inc.’s Combined Response to Respondents’ and Staff’s Responses to the Commission’s Request for Supplemental Submissions (Apr. 18, 2025) (“Complainant’s Suppl. Reply”); Respondents’ Reply to Complainant’s and OUII’s Responses to the Commission’s Request for Supplemental Submission on Whether Complainant Has Shown the Required Injury to a Protectable Domestic Industry (Apr. 18, 2025) (“Respondents’ Suppl. Reply”); Reply of the Office of Unfair Import Investigations to the Parties’ Submissions to Commission’s Request for Supplemental Briefing (Apr. 18, 2025) (“OUII’s Suppl. Reply”).

¹⁴ On May 21, 2014, Viking became the exclusive licensee of multiple assets developed by Metabasis Therapeutics Inc. (“Metabasis”) and Ligand Pharmaceuticals Inc. (“Ligand”), including the rights to research, develop, manufacture, have manufactured, use, and commercialize VK2809. FID at 14. Ligand acquired Metabasis in 2010. *Id.* at 14 n.6.

¹⁵ The FID notes that during the pendency of this investigation, non-party Madrigal Pharmaceuticals obtained approval from the U.S. Food and Drug Administration (“FDA”) for Rezdiffra (resmetirom) for the treatment of NASH. FID at 10.

C. Accused Products

The notice of investigation states that “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.’” *See* 88 Fed. Reg. at 8456.

Viking asserts that the accused products include Respondents’ ASC41 and ASC43F drug products, and that the accused products use Viking’s trade secrets and/or are made from or processed using those trade secrets. FID at 16. ASC41 is also a selective thyroid hormone receptor-beta agonist with the same API as VK2809. ASC43F is a combination therapy that includes ASC41, as well as ASC42, which involves a second and different API, namely, a Farnesoid X Receptor (“FXR”) agonist. *Id.* Viking also asserts that the accused products have substantially injured and/or threaten to substantially injure Viking’s domestic industry or to prevent the establishment of such an industry. *Id.* at 192.

D. Asserted Trade Secrets

Viking asserts that its trade secrets (“TS”) include: (1) the capsule or tablet formulations of VK2809 with certain excipients; (2) the manufacturing and preparation of the VK2809 formulation; (3) techniques for storing the VK2809 formulation; (4) certain attributes of the VK2809 formulation, including its stability, solubility, and bioavailability of the API; (5) pre-clinical and clinical trial information and data necessary for commercialization; and (6) the combination of the above-recited trade secrets. FID at 17, 21-29. The asserted trade secrets are generally categorized into three groups: (1) the formulation trade secrets which relate to the drug formulation (TS Nos. 4-11, 34-36, 44, and 111); (2) the preclinical trade secrets which relate to preclinical research and development testing (TS Nos. 16-18, 20-28, 37, 58-60, 100, 102, 104, and 109-10); and (3) the clinical trade secrets which relate to clinical research and development

trials (TS Nos. 12-15, 31-33, 38-39, 41-42, and 112). *Id.* Clinical research means that the studies are done in humans while preclinical research relates to studies done *in vitro* or *in vivo* (e.g., animal testing). *Id.* at 10-11.

III. LEGAL STANDARDS

A. Commission Review of the FID

When the Commission reviews an initial determination, in whole or in part, it reviews the determination *de novo*. *Certain Electronic Stud Finders, Metal Detectors and Electrical Scanners*, Inv. No. 337-TA-1221, Comm’n Op. at 9 (Feb. 15, 2022) (citations omitted), *aff’d*, *Zircon Corp. v. ITC*, 101 F.4th 817 (Fed. Cir. 2024). Upon review, the “Commission has ‘all the powers which it would have in making the initial determination,’ except where the issues are limited on notice or by rule.” *Certain Electronic Devices, Including Streaming Players, Televisions, Set Top Boxes, Remote Controllers, and Components Thereof*, Inv. No. 337-TA-1200, Comm’n Op. at 7 (Nov. 10, 2021), *aff’d*, *Roku, Inc. v. ITC*, 90 F.4th 1367 (Fed. Cir. 2024) (citations omitted).

With respect to the issues under review, “the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge.” 19 C.F.R. § 210.45(c). The Commission also “may take no position on specific issues or portions of the initial determination,” and “may make any finding or conclusions that in its judgment are proper based on the record in the proceeding.” *Id.*; *see also* *Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984).

B. Order Concerning Sanctions

Under Commission Rule 210.25(d), an order granting sanctions pursuant to 19 C.F.R. § 210.33 and issued concurrently with an initial determination on violation of section 337 “may be appealed by filing a petition meeting the requirements of § 210.43(b).” 19 C.F.R.

§ 210.25(d). When considering the sanctions order, the Commission “determine[s] whether to adopt the order after disposition of the initial determination concerning violation of section 337 or termination of the investigation.” *Id.*

C. Misappropriation of Trade Secrets

A claim of misappropriation of trade secrets requires a prerequisite showing that a trade secret exists. The Commission looks to the Uniform Trade Secrets Act (“UTSA”), which defines a “trade secret” as information that “(i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.” UTSA § 1(4). The Commission considers six factors in determining whether a trade secret exists:

- (1) the extent to which the information is known outside of complainant’s business;
- (2) the extent to which it is known by employees and others involved in complainant’s business;
- (3) the extent of measures taken by complainant to guard the secrecy of the information;
- (4) the value of the information to complainant and to his competitors;
- (5) the amount of effort or money expended by complainant in developing the information; and
- (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Certain Botulinum Toxin Prods., Processes for Mfg. or Relating to Same & Certain Prods.

Containing Same, Inv. No. 337-TA-1145, Comm’n Op., 2021 WL 141507, *6 (Jan. 13, 2021)

(citing *Certain Processes for the Manufacture of Skinless Sausage Casings & Resulting Prod.*,

Inv. No. 337-TA-148/169, Initial Determination, 1984 WL 273789, *94 (July 31, 1984),

PUBLIC VERSION

unreviewed by Comm’n Op., 1984 WL 273970, at *2 (Jan. 1, 1984); Restatement of Torts § 757, comment b). These factors are not individually dispositive; rather, they are “instructive guidelines for ascertaining whether a trade secret exists.” *Id.* (citing *Learning Curve Toys, Inc. v. PlayWood Toys, Inc.*, 342 F.3d 714, 722 (7th Cir. 2003)).

As to a showing of misappropriation, the Federal Circuit in *TianRui* held that “a single federal standard, rather than the law of a particular state, should determine what constitutes a misappropriation of trade secrets sufficient to establish an ‘unfair method of competition’ under section 337.” *TianRui Grp. Co. v. ITC*, 661 F.3d 1322, 1327 (Fed. Cir. 2011). Sources of applicable federal law include the UTSA, the Restatement (Third) of Unfair Competition, the Restatement of Torts, the Defend Trade Secrets Act of 2016 (18 U.S.C. §§ 1831-39) (“DTSA”), and federal common law. *See Botulinum Toxin Prods.*, 2021 WL 141507, at *7.

The Commission previously held that complainants must satisfy the following elements to establish an unfair act under section 337(a)(1)(A) based on misappropriation of trade secrets:

- (1) a protectable trade secret exists;
- (2) the complainant is the owner of the trade secret;
- (3) the complainant disclosed the trade secret to respondent while in a confidential relationship or the respondent wrongfully took the trade secret by unfair means; and
- (4) the respondent has used or disclosed the trade secret causing injury to the complainant.

Certain Crawler Cranes & Components Thereof, Inv. No. 337-TA-887, Comm’n Op., 2015 WL 13817116, *22 (May 6, 2015) (citing UTSA, § 1(4)). As noted by the Commission, under the UTSA and the Restatement, a claim of trade secret misappropriation does not itself require a separate injury showing, but rather that type of injury is effectively satisfied when the trade secret is used or disclosed. *See Botulinum Toxin Prods.*, 2021 WL 141507, at *8 (citing UTSA

§ 1(2); Restatement (Third) of Unfair Competition § 40; Restatement of Torts § 757; Milgrim on Trade Secrets § 7.07[1]). The injury requirement of section 337(a)(1)(A) is a separate and distinct injury, and it requires a showing that the unfair act caused or contributed to substantial actual or threatened injury to a domestic industry or prevented the establishment of such an industry. 19 U.S.C. § 1337(a)(1)(A); *see also infra* at section III.D.2.

Complainants bear the burden to establish a *prima facie* case of misappropriation but once they make that showing, the burden shifts to Respondents to show independent development. *Sausage Casings*, 1984 WL 273789, at *95 (“When respondent asserts that his use of the secret process is the product of independent development, respondent bears a heavy burden of persuasion to show that independent development.”); *see also Pioneer Hi-Bred Int’l v. Holden Found. Seeds, Inc.*, 35 F.3d 1226, 1241 (8th Cir. 1994) (“[O]nce [plaintiff] produced convincing evidence of misappropriation, [defendant] was obligated to provide persuasive evidence of lawful derivation.”).

D. Domestic Industry and Injury or Threat of Injury Thereto

To establish a violation of section 337 based on a trade secrets misappropriation claim under section 337(a)(1)(A)(i) or (ii), a complainant must prove that respondent’s unfair acts have caused actual or threatened substantial injury to a domestic industry or prevented the establishment of a domestic industry. 19 U.S.C. § 1337(a)(1)(A). “A complainant has the burden to show by a preponderance of the evidence every element of a violation of section 337.” *Certain Replacement Automotive Lamps*, Inv. No. 337-TA-1291, Comm’n Op., 2024 WL 1298906, *6 (Mar. 7, 2024).

More specifically, section 337(a)(1)(A) declares unlawful:

Unfair methods of competition and unfair acts in the importation of articles . . . into the United States, or in the sale of such articles by the owner, importer, or consignee, the threat or effect of which is—

PUBLIC VERSION

- (i) to destroy or substantially injure an industry in the United States;
- (ii) to prevent the establishment of such an industry; or
- (iii) to restrain or monopolize trade and commerce in the United States.

19 U.S.C. § 1337(a)(1)(A). Thus, a complainant must show that it has “an industry in the United States” (19 U.S.C. § 1337(a)(1)(A)(i)) or that “the establishment of such an industry” is being prevented (19 U.S.C. § 1337(a)(1)(A)(ii)), and that the industry has suffered actual substantial injury, or threat of substantial injury. *See Botulinum Toxin Prods.*, 2021 WL 141507, at *9 (citing *Certain Rubber Resins & Processes for Mfg. Same*, Inv. No. 337-TA-849, Comm’n Op., 2014 WL 7497801, *5 (Feb. 26, 2014) (“Therefore, there is a requirement not only that the complainant demonstrate the existence of a domestic industry, but also that there be actual substantial injury or the threat of substantial injury to a domestic industry.”)).

1. Domestic Industry

In addressing whether an “industry . . . in the United States” exists under section 337(a)(1)(A), the Commission considers the “nature and significance” of the complainant’s activities that allegedly form the domestic industry. *See Botulinum Toxin Prods.*, 2021 WL 141507, at *9 (citations omitted). A complainant may also satisfy the domestic industry requirement by demonstrating that a domestic industry is in the process of being established and that respondent’s unfair acts “prevent[ed] the establishment of such an industry.” *See* 19 U.S.C. § 1337(a)(1)(A)(ii).

Additionally, domestic activities under section 337(a)(1)(A) are not limited to the categories listed in section 337(a)(3). *See Certain Hand Dryers & Housings for Hand Dryers*, Inv. No. 337-TA-1015, Comm’n Op., 2017 WL 11566887, *3 (Oct. 30, 2017) (citing *TianRui*, 661 F.3d at 1335-37 (explaining that “an industry in the United States” under section

337(a)(1)(A)(i) is not limited to the domestic industry definition for statutory IP rights under section 337(a)(2) and (a)(3)).

2. Injury or Threat of Injury to the Domestic Industry

Under section 337(a)(1)(A)(i), “the complainant [must also] demonstrate . . . that there [is] actual substantial injury or the threat of substantial injury to a domestic industry.” *See Botulinum Toxin Prods.*, 2021 WL 141507, at *11 (citing *Rubber Resins*, 2014 WL 7497801, at *5); *see also* 19 C.F.R. § 210.12(a)(8) (requiring that the complaint “state a specific theory and provide corroborating data to support the allegation(s) in the complaint concerning the existence of a threat or effect to destroy or substantially injure a domestic industry, to prevent the establishment of a domestic industry, or to restrain or monopolize trade and commerce in the United States” for claims under section 337(a)(1)(A)). Under section 337(a)(1)(A)(ii), the complainant may show an industry in the process of being established and that respondent’s unfair acts “prevent[ed] the establishment of such an industry.” 19 U.S.C. § 1337(a)(1)(A)(ii).

In assessing actual injury, the Commission considers “a broad range of indicia, including: the volume of imports and their degree of penetration, complainant’s lost sales, underselling by respondents, reductions in complainant’s declining production, profitability and sales, and harm to complainant’s good will or reputation.” *Rubber Resins*, 2014 WL 7497801, at *30.

In determining whether a threatened injury exists, the Commission considers the following non-exclusive list of exemplary indicia:

- 1) substantial foreign manufacturing capacity;
- 2) ability of imported product to undersell the domestic product;
- 3) explicit intention to enter into the U.S. market;
- 4) the inability of the domestic industry to compete with the foreign products because of vastly lower foreign costs of production and lower prices; and

5) the significant negative impact this would have on the domestic industry.

Id. at *32.

In addition, “[w]hen the complainant alleges actual injury, there must be a causal nexus between the unfair acts of the respondents and the injury.” *Botulinum Toxin Prods.*, 2021 WL 141507, at *11 (citing *Rubber Resins*, 2014 WL 7497801, at *30). Similarly, when the complainant alleges a threatened injury, such “injury must [] be ‘substantive and clearly foreseen,’ with a causal connection between the action of the respondents and the threatened injury.” *Id.* (citing *Rubber Resins*, 2014 WL 7497801, at *32).

IV. DISCUSSION

For the reasons set forth below, the Commission has determined to affirm in part and reverse in part the FID’s finding of a violation of section 337. The Commission affirms with modification the FID’s finding of a violation of section 337 by the corporate respondents. As to the individual respondent, Dr. Wu, the Commission reverses the FID and finds no violation of section 337 by that respondent. More specifically, the Commission: (1) finds that it has statutory authority over this investigation including with respect to Dr. Wu, but finds insufficient evidence to establish liability by Dr. Wu in his personal capacity; (2) adopts the sanctions order against the corporate respondents and Rimon PC, but vacates with respect to the individual respondent, Dr. Wu; (3) affirms with modification the FID’s findings as to misappropriation of trade secrets by the corporate respondents; and (4) affirms with modification the FID’s findings as to the domestic industry requirement and threat of injury thereto. The Commission takes no position on the FID’s findings that Respondents’ unfair acts have caused actual injury to Viking’s domestic industry or prevented the establishment of such an industry.

A. 100-Day Early Disposition

The notice of investigation directed the presiding ALJ to “hold an early evidentiary hearing, find facts, and issue an early decision, within 100 days of institution except for good cause shown” with respect to any injury to a domestic industry. 88 Fed. Reg. at 8456. The presiding Chief ALJ declined to issue an ID setting forth his early decision on injury to a domestic industry and instead issued an order finding good cause to “continue this investigation beyond the 100-day proceeding without issuing an early decision.” *See* Order No. 22 at 5. The Chief ALJ stated there was good cause to continue the investigation because Respondents delayed producing relevant documents thereby prejudicing Complainant and preventing the early resolution of the injury issue. *Id.*

OUII petitioned for review arguing that the Chief ALJ erred in failing to issue an early decision and failing to certify for interlocutory appeal the order continuing the investigation beyond 100 days. *See* OUII’s Pet. at 25. OUII reasons that the notice of investigation authorizes the presiding ALJ to extend the 100-day deadline for good cause, but that the good cause provision does not authorize the presiding ALJ to continue the investigation without issuing an ID with respect to the potentially dispositive issue identified in the notice of investigation. *Id.* at 26-30. OUII notes that Commission Rule 210.42(a)(3) requires the presiding ALJ to issue an ID in accordance with Commission Rule 210.10(b)(3) “within 100 days of institution, or as extended for good cause shown.” *Id.* at 30 (citing 19 C.F.R. § 210.42(a)(3); 19 C.F.R. § 210.10(b)(3)). This, according to OUII, demonstrates that good cause applies only to an extension beyond 100 days for issuing the ID. *Id.*

The Commission finds no error in the Chief ALJ’s decision not to issue an early decision in the circumstances of the present investigation. OUII does not dispute that there was good cause under Commission Rule 210.43(a)(3) to extend the issuance of the 100-day ID beyond 100

days, including Respondents' discovery failures and the resulting prejudice to Complainant. The Chief ALJ's continuance was thus a proper extension of the 100-day deadline because the disputed injury issue required further discovery and litigation.

Accordingly, while the issuance of an ID at the conclusion of a 100-day proceeding is required (absent good cause shown to extend), the Commission finds that under the specific facts of the present investigation, where Respondents delayed the production of relevant injury-related discovery, the Chief ALJ did not err in declining to issue an early decision and to continue the investigation through final disposition of the proceeding before him. Additionally, any delay to the injury determination did not negatively impact the outcome of this investigation. In the FID, the Chief ALJ ultimately determined that Complainant satisfied the injury requirement, and this determination required adjudication of the other elements of a violation of section 337.

B. Importation and Statutory Authority

The FID finds that "the accused ASC41 and ASC43F tablets have been imported into the United States," and that "[n]o party disputes the Commission's statutory authority to issue a remedy against imported accused products in accordance with 19 U.S.C. § 1337 if there is a violation of that statute." FID at 61. Specifically, the FID relied upon respondent Gannex Pharma's admission that it imported ASC41 and ASC43F for purposes of certain clinical trials that took place in the United States. *Id.* at 62. The FID further finds that "[n]o party has contested the Commission's statutory authority over the private parties." *Id.* at 61.

Respondents argue that the Commission lacks statutory authority over Dr. Wu. Respondents' Pet. at 26-30. Respondents contend that "Dr. Wu at all times acted as a corporate representative for Ascleitis, a publicly listed company, and should not be individually subject to liability." *Id.* at 26. Respondents further argue that the FID "makes no attempt to undertake the detailed analysis required to pierce the corporate veil, which is necessary to 'enable the

PUBLIC VERSION

Commission to hold an individual liable for acts done in the course of his employment or to hold a shareholder liable for acts done by a corporation.” *Id.* at 27 (citing *Rubber Resins*, 2014 WL 7497801, at *38). Nor did Dr. Wu, according to Respondents, ever “personally direct the importation of the Accused Products.” *Id.* at 27-28 (citing Hr’g Tr. (Wu) at 617:18-24).

Complainant argues that Dr. Wu was personally involved in both the misappropriation and the importation of the accused products. *Id.* at 77-78. OUII further argues that “it was not necessary to determine whether the corporate veil should be pierced” given Dr. Wu’s involvement in the misappropriation and the importation. OUII’s Pet. Resp. at 48 (citing *Certain Balanced Armature Devices, Prods. Containing Same, & Components Thereof*, Inv. No. 337-TA-1186, Comm’n Op., 2021 WL 5104810, *9 n.10 (Oct. 29, 2021)).

The Commission has statutory authority to investigate a potential violation of section 337 based on the factual allegations in a complaint under oath. 19 U.S.C. § 1337(a)(1) (“[T]he following [unfair acts] are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section.”), (b)(1) (“The Commission shall investigate any alleged violation of this section on complaint under oath[.]”). The Commission may find a violation of section 337(a)(1)(A) and/or issue a remedy for “[u]nfair methods of competition and unfair acts in the importation of articles . . . into the United States, or in the sale of such articles by the *owner, importer, or consignee.*” 19 U.S.C. § 1337(a)(1)(A) (emphasis added).

Here, Complainant failed to establish that Dr. Wu is an owner, importer, or consignee of the accused articles, or that he misappropriated the asserted trade secrets, *in his personal capacity*. Complainant’s Pet. Resp. at 75-78. Additionally, the FID does not include “a ‘piercing the veil’ analysis,” which would “enable the Commission to hold an individual liable

PUBLIC VERSION

for acts done in the course of his employment or to hold a shareholder liable for acts done by a corporation.” *Rubber Resins*, 2014 WL 7497801, at *38. The FID makes no distinction between Dr. Wu’s actions in his personal capacity and his actions as CEO of the corporate respondents. At most, the FID states in the remedy recommendation that Dr. Wu was personally involved in importing the accused products and reviewing the trade secrets, but the cited testimony does not support that Dr. Wu was involved in his personal capacity in either the importation or the misappropriation. FID at 223-24 (citing Hr’g Tr. (Wu) at 668:6-671:14); *see also* Respondents’ Pet. at 28-29. Rather, Dr. Wu expressly denied that he was involved in importation and the evidence shows that Dr. Wu’s involvement in directing importation and misappropriation was done in his capacity as CEO. *See* Hr’g Tr. (Wu) at 668:6-671:14 (denying involvement in importation); *see also* Respondents’ Pet. at (citing Hr’g Tr. (Wu) at 615:23-616:9 (testifying that he makes recommendations to the five-member board), 617:18-24 (denying that he was involved in the importation of the accused products)).

OUII relies on the Commission’s opinion in *Balanced Armature Devices*, OUII’s Pet. Resp. at 48, but the present facts are distinguishable from that opinion.¹⁶ Indeed, in *Balanced Armature Devices*, the Commission found that it was not necessary to pierce the corporate veil because the CEO’s “actions in stealing and using [the asserted] trade secrets started well before he joined [the corporate respondents] and continued after he obtained an 85% ownership interest in [the corporate respondents].” *Balanced Armature Devices*, 2021 WL 5104810, at *9. Unlike the present investigation, the Commission in *Balanced Armature Devices* explained that the

¹⁶ *Lubby Holdings*, cited by OUII, is also distinguishable because there is no evidence of a violation of section 337 by Dr. Wu. *See* OUII’s Pet. Resp. at 49 (citing *Lubby Holdings LLC v. Chung*, 11 F.4th 1355, 1358 (Fed. Cir. 2021) (“Corporate officers can be personally liable for their *own* acts of infringement, even if those acts were committed in their corporate capacity.”) (emphasis added)).

CEO's "actions began in his personal capacity." *Id.* Thus, given the facts here, *Rubber Resins* indicates that a "piercing the veil" analysis or a finding that any of the corporate respondents is Dr. Wu's "alter ego" would "enable the Commission to hold an individual liable for acts done in the course of his employment or to hold a shareholder liable for acts done by a corporation." *Rubber Resins*, 2014 WL 7497801, at *38.

In the absence of a "piercing the veil" analysis or a finding that Dr. Wu is using the corporate respondent as his "alter ego," the Commission finds no violation of section 337 by Dr. Wu. *See id.* (declining to extend liability to individuals where the complainant did "not even [try] to argue that [the individuals] used one of the [accused] companies as an 'alter ego.'"). Accordingly, the Commission finds no violation of section 337 by Dr. Wu in his personal capacity. The Commission notes, however, that although the remedial orders do not name Dr. Wu in his personal capacity, they prohibit him, in his corporate capacity as an agent of the corporate respondents, from importing, *inter alia*, the covered articles during the pendency of the remedial orders.

C. Order Concerning Sanctions

1. FID's Findings and Parties' Arguments

The FID finds that Respondents engaged in sanctionable conduct when they made false representations in the investigation and violated multiple discovery orders. FID at 49-60. The FID thus grants Complainant's motion for sanctions under Commission Rule 210.33 (19 C.F.R. § 210.33) and imposes non-monetary (adverse inferences) and monetary (\$567,059.85) sanctions against Respondents and/or their former counsel (Rimon PC). *Id.* at 54-59. More specifically, the FID finds that Respondents and Rimon PC "made misrepresentations to the parties and to the tribunal that were detrimental to the efficient progress of discovery in the investigation." *Id.* at 49-51. In particular, the FID finds that "Rimon attorney Michael Heafey stated at a case

management conference held March 3, 2023, that document production was substantially complete,” but that “this statement is demonstrated false given the large amount of documents produced after this date, such as the production on April 11, 2023, totaling over 40,000 pages.” *Id.* at 49.

The FID also finds that “Ascleitis made sworn statements in response to Viking’s interrogatories that were later proved false.” *Id.* at 50. Specifically, “Viking sought information regarding the identity of pharmaceutical companies with which Ascleitis had partnership discussions” but “Ascleitis failed to identify Novartis, Sanofi, or Takeda in its response to this interrogatory, which was verified by respondent Dr. Wu.” *Id.* (citing CX-357C.9-11). Thus, the FID finds that Respondents failed to disclose partnership discussions with certain pharmaceutical companies, which are highly relevant to the issues in the investigation including with respect to actual and threatened injury to the domestic industry. *Id.* at 49-51.

Additionally, the FID finds that Respondents failed to produce relevant documents within the scope of discovery of Order Nos. 14, 24, and 27, which required the production of information included in document and email servers as well as the personal devices of certain custodians. *Id.* at 51-53; Order No. 14 (Mar. 24, 2023) (ordering Respondents to produce emails); Order No. 24 (May 11, 2023) (granting in part Viking’s motion to compel and ordering Respondents to reexamine their document servers for documents responsive to Viking’s requests for production (“RFPs”)); Order No. 27 (June 1, 2023) (providing guidance for forensic examination).

The FID finds that the appropriate remedy for Respondents’ sanctionable conduct is “what is sufficient to deter repetition of such conduct or comparable conduct by others similarly situated.” *Id.* at 55. In particular, the FID finds that certain non-monetary sanctions, including

adverse inferences, are appropriate. *Id.* at 56-57. Specifically, the FID finds with respect to Respondents' clinical trials that, if permitted by the FDA, Respondents will continue to pursue Phase II and Phase III clinical trials, and the accused products if approved by the FDA will compete with Viking's domestic industry product. *Id.* The FID also finds that "Respondents have had, and will continue to have, discussions with potential partners regarding partnerships for the potential future importation and sale of Accused Products in in the United States, including potential partners that have also explored collaboration with Viking." *Id.*

Additionally, the FID imposes monetary sanctions against Respondents and/or their former counsel in the amount of \$567,059.85, including \$444,549.60 in attorney's fees and costs incurred by Complainant in connection with its motion for sanctions, \$109,204 for the violation of Order No. 14 for failure to produce responsive emails and attachments in a timely manner (reasonably ahead of the 100-day evidentiary hearing), and \$13,306.25 for the violation of Order No. 24 for failure to search the email servers for documents responsive to the RFPs. *Id.* at 57-59. The FID does not impose monetary sanctions in connection with Order No. 27 for failure to timely comply with the forensic examination. *Id.* at 58-59. The FID explains that "awarding the costs of the entire forensic examination would be disproportionate to the culpability of Ascletis and the Rimon lawyers," and that "the adverse evidentiary inferences discussed above are sufficient to protect Viking's interests." *Id.*

As to the apportionment of the monetary sanctions, the FID finds that "[t]he monetary sanctions . . . shall be imposed, jointly and severally, on respondent Dr. Jinzi Wu and all Ascletis entities." *Id.* at 59. The FID, however, finds that "[t]he Rimon law firm is not liable for the attorney's fees and costs incurred by Viking for preparing and filing its sanctions motions in the amount of \$444,549.60." *Id.* at 60. The FID reasons that the "difference in liability reflects a

difference between the regard that the Rimon lawyers have manifest[ed] for candor and cooperation with this tribunal as compared to that shown by their former clients[,] the Respondents.” *Id.*

Respondents and their former counsel, Rimon PC, request that the Commission vacate the sanctions order. As to the violation of Order No. 14 for failure to timely produce responsive emails and attachments ahead of the 100-day evidentiary hearing, Respondents argue that the conduct at issue stems from an inadvertent error by Respondents’ vendor, and that Respondents themselves reported the error to the Chief ALJ and to the other parties. Respondents’ Pet. at 31; *accord* Rimon Pet. at 43-45, 48-51. Respondents further argue in connection with Order No. 27 requiring forensic examination, that the scope of that examination was unclear, and therefore they should not be blamed if that examination was incomplete. *Id.* at 32. In any event, Respondents contend that they provided extensive discovery in the aftermath of the forensic examination, thereby curing any prejudice to Viking. *See id.* at 32-33.

Additionally, according to Rimon PC, the Chief ALJ misapprehended Mr. Heafey’s representation that Respondents’ production was substantially complete. That statement, according to Rimon, referred to Respondents’ production of documents, not emails which the parties agreed would be produced later after identification of search terms and custodians. Rimon’s Pet. at 36-38. Thus, Rimon contends, there is no support for awarding fees for violation of Order No. 14. *Id.* at 4-8. Rimon further argues that there is no violation of Order No. 24 because that order directed Respondents to reexamine their document servers, not their emails. *Id.* at 52-53. Rimon explains that the emails were subject to specific search terms unrelated to the discovery sought in Complainant’s RFPs, and thus, the failure to search email servers should not be a basis for imposing sanctions in connection with Order No. 24. *Id.* at 54. As to the

violation of Order No. 27 relating to forensic examination, Rimón argues that the Chief ALJ improperly required imaging of the personal devices of non-parties. *Id.* Thus, Rimón argues that it properly objected to the forensic examination of the personal devices and the parties subsequently reached an agreement, obviating the need for filing a motion for protective order. *Id.* at 55-56.

Complainant contingently requests tougher sanctions against Respondents and Rimón. Complainant argues that adverse inferences must be more than “established facts,” and that Complainant is entitled to the adverse inference that it was injured or threatened with injury. Complainant’s Pet. at 42. In addition, Complainant argues that “[t]he forensic examination was suspended due to [Respondents’ and Rimón’s] misconduct,” but that “the FID erroneously denied Viking’s request for monetary sanctions to reimburse costs and fees totaling \$352,237.65 spent on the forensic examination.” *Id.* at 45-46.

2. Analysis

The Commission finds that the Chief ALJ correctly drew adverse inferences for violation of Order Nos. 14, 24, and 27, establishing certain facts with respect to Respondents’ clinical trials and potential partnerships. The Chief ALJ also correctly imposed monetary sanctions of \$109,204 for violation of Order No.14 in failing to produce responsive emails and attachments ahead of the 100-day evidentiary hearing, \$13,306.25 for violation of Order No. 24 in failing to search email servers for documents responsive to Complainant’s RFPs, and \$444,549.60 relating to attorney’s fees and costs incurred by Complainant in connection with its motion for sanctions.

The Commission, however, finds that the present record does not support sanctioning Dr. Wu in his personal capacity. Dr. Wu verified the interrogatories in his capacity as CEO of the corporate respondents, not in his personal capacity. Respondents’ Pet. at 34. Furthermore, as discussed *supra* at section IV.B, the Commission finds no violation of section 337 by Dr. Wu

PUBLIC VERSION

based on the lack of evidence that any of his actions was taken in his individual rather than his corporate capacity. Thus, he is not jointly and severally liable for the monetary sanctions imposed by the Chief ALJ on the corporate respondents and/or their former counsel.

Accordingly, the Commission has determined to adopt the sanctions order with respect to the corporate respondents and Rimon PC, but to vacate it with respect to Dr. Wu.

The Commission also disagrees with Complainant that the sanctions imposed by the Chief ALJ are inadequate. Complainant fails to adequately support its request for more severe adverse inferences. In particular, Respondents' conduct does not rise to a deliberate destruction or spoliation of evidence to justify relieving Complainant entirely from its burden of establishing an injury to a domestic industry. *Accord* OUII's Pet. Resp. at 30. Additionally, Complainant fails to demonstrate that the adverse inferences are insufficient because they are merely established facts. Rather, the adverse inferences directly resolve certain disputed issues against Respondents, including findings that Respondents intend to conduct Phase III trials and to commercialize the accused products if permitted by the FDA. *See, e.g.,* Respondents' Pet. Resp. at 19; *accord* OUII's Pet. Resp. at 28 n.3.

In sum, the Commission agrees with the Chief ALJ that any prejudice to Viking caused by Respondents' violation of Orders 14, 24, and 27 was mitigated by the adverse inferences the Chief ALJ drew against Respondents and by the extensive discovery Respondents did end up producing (albeit such production was delayed). In addition, given that Respondents delayed discovery and caused Complainant to file the motion for sanctions, we believe the Chief ALJ correctly determined to impose the \$109,204 monetary sanction for violation of Order No. 14, the \$13,306.25 monetary sanction for violation of Order No. 24, and the \$444,549.60 monetary sanction relating to attorney's fees and costs incurred by Complainant in connection with the

motion for sanctions. Accordingly, the Commission has determined to adopt the sanctions order as to the corporate respondents and Rimon PC, but to vacate it as to Dr. Wu.

D. Misappropriation of Trade Secrets

Respondents do not dispute that Viking owns the asserted trade secrets (FID at 66-67), and that Viking disclosed those trade secrets to them while in a confidential relationship (FID at 136-43). Nor do Respondents dispute the FID's finding that the trade secrets exist. FID at 67-135. Respondents, however, contend that they did not use or disclose the asserted trade secrets but independently developed the accused tablet formulation and independently designed the preclinical or clinical studies. Respondents' Pet. at 21-26. Furthermore, as discussed *infra* at section IV.E.2 (injury to a domestic industry), Respondents dispute that the alleged misappropriation caused actual or threatened injury to Viking. *Id.* at 3-15. OUII agrees with Respondents' petition with respect to misappropriation of trade secrets and argues that the FID's conclusion that all the formulation trade secrets were used (and therefore misappropriated) is erroneous. OUII's Pet. at 33-40. Complainant contingently petitioned for review of the FID's finding that not all trade secrets were misappropriated by the Respondents. *See* Complainant's Pet. at 4-25. As explained below, the Commission has determined to affirm the FID's findings with modified analysis.¹⁷

¹⁷ OUII also argues that the FID errs to the extent it finds the preclinical and clinical trade secrets protectable based on their use of the formulation trade secrets. OUII's Pet. at 33-35. The FID also finds, however, that the preclinical and clinical trade secrets are protectable because they include safety, toxicity, pharmacokinetics, and efficacy information that has independent value and that is not generally known or readily ascertainable. FID at 99-123, 126-35. Neither OUII nor Respondents dispute those findings. The Commission thus takes no position on the FID's finding that the preclinical and clinical trade secrets are protectable based solely on their use of the formulation trade secrets. *See Beloit*, 742 F.2d at 1423.

1. FID's Findings and Parties' Arguments

The FID finds that Respondents used or disclosed the asserted trade secrets and rejects Respondents' independent development defense. FID at 143-74. Although the FID appears to conclude that all trade secrets are misappropriated (FID at 218), the FID only specifically finds that Respondents used or disclosed the following trade secrets: TS No. 4 which relates to Viking's [REDACTED] formulation, TS Nos. 18.1 to 18.3 and 37 to 37.4.3 which relate to Viking's preclinical studies, and TS Nos. 12.11, 13.1 to 13.7, and 15.1 which relate to Viking's clinical studies. *Id.* at 144-48, 157-63, 166-73. The FID also finds that Respondents misappropriated TS Nos. 12 (clinical study data), 17 ([REDACTED] study reports), 18 ([REDACTED] study reports), and 38 (clinical study data). *Id.* at 160.

Respondents do not appear to dispute that they used or disclosed the trade secrets specifically analyzed in the FID, but they argue that the FID errs in finding that all asserted trade secrets are misappropriated based on that subset of trade secrets. Respondents' Pet. at 18-21 (citing FID at 218). Respondents argue that Commission precedent requires "substantial" use or disclosure of each trade secret, not merely use or disclosure of "at least one" trade secret. *Id.* at 17-18 (citing *Certain Bone Cements & Bone Cement Accessories*, Inv. No. 337-TA-1175, Comm'n Op., 2021 WL 2948601, *10 (July 9, 2021)). For instance, Respondents note that the FID makes no findings with respect to TS No. 11 which relates to [REDACTED] and there is no evidence that Respondents used that trade secret. *Id.* at 19-20. Respondents also argue that the FID applies an incorrect standard in finding that they did not independently develop certain preclinical trade secrets (TS Nos. 17 and 18). *Id.* at 20-21 (citing FID at 166). Specifically, Respondents contend that the FID incorrectly relied on their arguments as to use, which is subject to a distinct burden and a distinct standard from the independent development defense. *Id.*

PUBLIC VERSION

Additionally, Respondents contend that they independently developed their tablet formulation. *Id.* at 21-26. While Respondents do not dispute that they used the [REDACTED] formulation trade secret to develop the accused ASC41 capsule, they argue that the [REDACTED] formulation is “wholly distinct” from the capsule formulation, and that the development of the [REDACTED] is based on [REDACTED] *Id.* at 21-22. Respondents also argue that through independent research, the optimal formulation active ingredient to excipients was determined to be [REDACTED] which is “far different” from any formulation used by Viking. *Id.* at 23 (citing CX-1279-T.18); *accord* OUII’s Pet. at 35-36. Respondents further contend that the testing and trials with the [REDACTED] formulation were performed independent of any use of Viking’s trade secrets. *Id.* at 23-24. Still further, Respondents deny using the capsule formulation to conduct benchmarking studies for the [REDACTED] formulation. *Id.* at 25-26. OUII also dismisses the use of the capsule formulation as a benchmark for the development of the [REDACTED] formulation. OUII’s Pet. at 39-40. OUII similarly argues that “benchmarking the performance of the [REDACTED] formulation against that of the completely different capsule formulation does not . . . indicate in any way that one formulation was derived from the other.” *Id.*

Complainant contingently argues that “the FID erred by not determining that all asserted trade secrets contained in the [Investigator’s Brochure (‘IB’)] were misappropriated.” Complainant’s Pet. at 4. Complainant contends that “Viking established unlawful disclosure of the IB.” *Id.* at 4-5 (citing FID at 158-59). Complainant further argues that the FID errs in determining that not all the preclinical trade secrets were misappropriated. *Id.* at 8-14. Complainant reasons that circumstantial evidence shows that Respondents concealed their use of Viking’s preclinical trade secrets. *Id.* at 9-10. Additionally, Complainant contends that

“Respondents substantially used all preclinical trade secrets as a road map for their own preclinical testing, which allowed Respondents to skip some tests and run multiple tests in parallel because they had confidence of a positive outcome.” *Id.* at 10-11. Furthermore, according to Complainant, Respondents’ use of Viking’s preclinical trade secrets allowed them to “gain the confidence to launch ASC41.” *Id.* at 11-14. Complainant further argues that the FID errs in finding that other reasons could have accelerated Ascletis’s timeline for conducting its preclinical studies, including advancements by contract research organizations (“CROs”), Metabasis’s financial troubles, and [REDACTED] [REDACTED]. *Id.* at 14-17.

Complainant further petitioned for Commission review of the FID’s findings on misappropriation with respect to TS Nos. 18.9, 18.13, 18.24, 18.26, 18.30, 18.36, and 18.38. Complainant argues that “the FID err[s] by not finding that Respondents also disclosed [those] preclinical trade secrets.” *Id.* at 18. Complainant contend that “Dr. He,¹⁸ who was not granted access to Viking’s virtual data room, was in possession of TS 18.9, 18.13, 18.24, 18.26, 18.30, 18.36, and 18.38 and circulated the trade secret information to other unauthorized Ascletis personnel.” *Id.* at 18-19 (stating that Respondents disclosed certain trade secrets including TS Nos. 18.36 and 18.38) (citing CDX-1045C.30; CX-1001C; CX-1490-T; Hr’g Tr. (Silber¹⁹) at 398:13-399:7); *id.* at 19-20 (stating that Respondents disclosed certain trade secrets including TS Nos. 18.9, 18.13, 18.24, 18.26, and 18.30) (citing CDX-1045C.21, 32; CX-1239C; CX-1240C; Hr’g Tr. (Silber) at 401:1-22).

¹⁸ Dr. Handan He is the chief scientific officer at Ascletis.

¹⁹ Dr. Michael Silber is Complainant’s technical expert in this investigation.

Complainant also requests that the Commission find that Respondents misappropriated TS Nos. 4-11, 34-36, and 44 which are formulation trade secrets. *Id.* at 21-25. Specifically, Complainant argues that Respondents disclosed to their CRO the method of preparation of the [REDACTED] formulation (TS No. 5), the [REDACTED] formulation (TS Nos. 6-9), and [REDACTED] (TS No. 10). *Id.* at 21-22 (citing CX-1289C-T.2; CX-1287C-T.2, 12). Complainant also asserts misappropriation of TS No. 11, which relates to [REDACTED]. *Id.* at 22-23 (citing CX-1360C.5-6). Complainant further argues that Respondents disclosed TS Nos. 4-10 in their regulatory filings in China. *Id.* at 23 (citing JX-1006C (Dep. Tr. 116:16-17, 116:21-22 (Dong²⁰)); CX-1543C-T). Still further, Complainant argues that Respondents disclosed that TS Nos. 6-8, *i.e.*, [REDACTED] [REDACTED] on respondent Gannex Pharma's website. *Id.* at 24.

2. Analysis

The Commission clarifies that the record does not support finding that Respondents misappropriated all the asserted trade secrets. The Commission specifies herein the trade secrets that were in fact misappropriated by the Respondents, including, as explained further below: (1) TS No. 4-9 and 36²¹ which relate to [REDACTED] formulation; (2) TS Nos. 18.1 to 18.3 and 37 to 37.4.3 which relate to Viking's preclinical studies as well as TS Nos. 18.9, 18.13, 18.24, 18.26, 18.30, 18.36, and 18.38 which relate to Viking's [REDACTED] studies; and (3) TS Nos. 12.11, 13.1 to 13.7, and 15.1 which relate to Viking's clinical studies. The FID also correctly finds that Respondents misappropriated TS Nos. 12 (clinical study data), 17

²⁰ Mr. Kunhua Dong is a senior manager of formulation research at Ascleitis and Ascleitis's corporate witness in this investigation.

²¹ Respondents argue that "TS6-9 and 36 are duplicative," Respondents' Pet. at 11-12, and therefore TS No. 36 was misappropriated for the same reasons as TS Nos. 6-9.

██████████ study reports), 18 (██████████ study reports), and 38 (clinical study data).²²
FID at 160.

As to the formulation trade secrets, the FID specifically identifies only TS No. 4 as being misappropriated. FID at 144-48. The Commission agrees with Complainant, however, that Respondents misappropriated other formulation trade secrets, including TS No. 5 ██████████ ██████████ and TS Nos. 6-9 and 36 ██████████. As Complainant notes, Respondents disclosed those trade secrets at least to their CRO. Complainant's Pet. at 21-22 (citing CX-1289C-T.2; CX-1287C-T.2, 12); *compare* CDX-1026C.36-37, 42-48; CDX-1010C.14. OUII provides no argument negating that those trade secrets were misappropriated. *See* OUII's Pet. Resp. at 57. Respondents argue, unpersuasively, that ██████████ ██████████. *See* Respondents' Pet. Resp. at 12.

The Commission disagrees with Complainant that Respondents used or disclosed TS Nos. 10 ██████████, 11 ██████████, 34 ██████████ ██████████, 35 ██████████, and 44 (Initial New Drug Application (IND) information). Complainant's arguments as to those latter trade secrets are unsupported and conclusory. Complainant's Pet. at 24-25. For instance, Complainant argues that "Ascleitis Bioscience disclosed the formulation trade secrets to Gannex Pharma and Gannex Pharma published them in its patent applications." *Id.* at 25. Complainant, however, provides no specific citation to the patent application indicating where specific trade secrets are disclosed. *Id.*; CX-2120. Nor does Complainant explain where ██████████ (TS No. 10) is disclosed in Respondents' Chinese IND. *Id.* at 24-25; CX-1543C-T; Respondents' Pet. Resp. at

²² The FID notes that "TS No. 38 appears to be a duplicate of TS No. 13" (FID at 129) and therefore TS No. 38 was misappropriated for the same reasons as TS No. 13.

13. Additionally, Respondents' decision [REDACTED] (TS No. 11) when Viking [REDACTED] does not necessarily establish use or disclosure of those trade secrets, particularly in view of Respondents' previous experience [REDACTED]. FID at 154; *accord* Respondents' Pet. Resp. at 12-13.

As to the preclinical trade secrets, the FID specifically identifies TS Nos. 18.1 to 18.3 and 37 to 37.4.3 as being misappropriated. FID at 163; *accord* Complainant's Pet. at 18. Additionally, the FID states that certain [REDACTED] toxicity studies were misappropriated. *Id.* The FID, however, does not specifically identify all the trade secrets or subparts thereof associated with those studies. FID at 160-63, 165 ("[T]here is specific documentary evidence of misappropriation for TS Nos. 18.1 to 18.3 and 37 to 37.4.3, in addition to [REDACTED] toxicity information."); *id.* at 165 ("The evidence does not support a finding that the remaining protectable Preclinical Trade Secrets were misappropriated."). For instance, the FID states that the attachment to an email exchange between Dr. He and Dr. Wu "contains nearly exact data from TS No. 18.38," but the FID does not list TS No. 18.38 as one of the misappropriated trade secrets. *Id.* at 160-63 (citing CX-1001C; CX-1490-T; CX-1491C).

Respondents and OUII offer no adequate analysis to negate the FID's findings [REDACTED] [REDACTED] studies were misappropriated. OUII's Pet. Resp. at 55-56; Respondents' Pet. Resp. at 5. Thus, the Commission finds that the related trade secrets (*i.e.*, TS Nos. 18.9, 18.13, 18.24, 18.26, 18.30, 18.36, and 18.38) should also be included in the list of misappropriated preclinical trade secrets. Including those trade secrets is particularly warranted where the FID specifically finds that Ascletis "accessed" Viking information regarding [REDACTED] [REDACTED] toxicity studies, "intermingled Viking's information with its own, and relied on the results in its clinical development efforts for the accused products." FID at 160. Additionally, as

discussed above, the FID finds that the attachment to an email exchange between Dr. He and Dr. Wu “contains nearly exact data from TS No. 18.38, including [REDACTED] [REDACTED].” *Id.* at 160-61 (citing CX-1001C; CX-1490-T; CX-1491C). Thus, the Commission agrees with Complainant that the identified subparts of TS No. 18 were also misappropriated.

As to the clinical trade secrets, the Commission finds that the FID correctly determined that Respondents misappropriated TS Nos. 12.11, 13.1 to 13.7, and 15.1. *Id.* at 166-73. Neither Respondents nor OUII dispute the FID’s findings as to those trade secrets. *See* Respondents’ Pet. at 18-21; OUII’s Pet. at 38.

The Commission declines to disturb the remainder of the FID’s findings on misappropriation. In particular, there is no support for Complainant’s argument that all the trade secrets associated with Viking’s IB were misappropriated. Complainant’s Pet. at 4-6. Rather, Complainant takes out of context the FID’s findings with respect to Viking’s IB by suggesting that the FID finds that the IB was entirely disclosed by Respondents. *Id.* In fact, the FID finds that an email attachment shared with unauthorized personnel included only three paragraphs that appear on page 24 of the IB, not the entirety of the IB. FID at 158-59 (citing CX-1473C; CX-1474C; CDX-1010C (IB)); *accord* Respondents’ Pet. Resp. at 4; OUII’s Pet. Resp. at 51-52. Thus, the record does not support finding that the IB was substantially disclosed to support finding misappropriation of all trade secrets included in the IB. *See Bone Cements*, 2021 WL 2948601, at *10. Complainant also points to an email from Dr. Xiao Dong Li²⁴ referring to the

²³ [REDACTED]

²⁴ Dr. Xiao Dong Li is the head formulation researcher at Ascletis.

PUBLIC VERSION

IB, but the email does not attach the IB or establish that Dr. Xiao Dong Li had access to the IB or a substantial portion thereof. Complainant's Pet. at 5-6 (citing CX-1484C). Rather, the email suggests that Dr. Wu provided information from the IB not that he provided the IB itself. *See* CX-1484C ("[I]n VK2809's IB (from Dr. Wu), VK2809 is reported to show a [REDACTED] [REDACTED]").

As to Complainant's argument that it is entitled to an inference that all the preclinical trade secrets were misappropriated because Respondents concealed the misappropriation and were able to achieve their preclinical research on a much shorter timeline than Complainant, the Commission agrees with the FID that "the evidence does not support a finding that Asclethis misappropriated every Preclinical Trade Secret simply because its preclinical research timeline was shorter than Viking's." FID at 165. Additionally, Complainant was still required to satisfy its burden to show substantial use or disclosure for each trade secret. *See Bone Cements*, 2021 WL 2948601, at *10. Complainant did satisfy that burden with respect to some, but not all, of the preclinical trade secrets.

Nor do we agree with Respondents' argument that they did not use Complainant's [REDACTED] formulation (TS No. 4) in connection with their [REDACTED] formulation but independently developed that formulation. Respondents' Pet. at 21-26. The FID finds (and Respondents do not dispute) that Asclethis's capsule formulation is derived from Viking's [REDACTED] formulation (TS No. 4), including the specific combination of the API and [REDACTED] [REDACTED]. FID at 73-74, 148-53. As to Asclethis's [REDACTED] formulation, the FID recognizes that it is distinct from Asclethis's capsule formulation. *Id.* at 153. Neither OUII nor Respondents, however, adequately address the FID's finding that Respondents used the misappropriated trade secrets to "benchmark[]" their [REDACTED] formulation against their capsule

formulation, and that this “benchmarking” negates Respondents’ independent development defense. FID at 154-56; Respondents’ Pet. at 21-22; OUII’s Pet. at 39-40. As the FID finds, Ascletis’s own expert, Dr. Abato, testified that “Respondents did . . . compare . . . their ASC41 capsule formulation to the ASC41 [REDACTED] formulation,” and that “Ascletis relied on their [ASC41] capsule formulation in drawing conclusions about their [REDACTED] formulation.” FID at 154-55 (citing Hr’g Tr. (Abato) at 913:19-24, 917:10-918:5; Hr’g Tr. (Amidon²⁵) at 284:15-24, 285:12-287:8; CX-1604); *accord* Complainant’s Pet. Resp. at 33-34. The FID also finds that Ascletis’s reliance on the capsule formulation of ASC41 in the development of the [REDACTED] formulation of ASC41 is further demonstrated in email exchanges between Ascletis and its CRO. *Id.* at 155 (citing CX-1413C-T). In particular, the FID finds that “[u]sing ASC41 capsules as a measure, the [CRO] acknowledged that [REDACTED] [REDACTED] *Id.* citing (CX-1434C-T.5-6). Thus, Respondents’ reliance on their capsule formulation allowed them to confirm that the optimal formulation (active ingredient to excipients of [REDACTED]) works and has comparable properties to the capsule formulation including with respect to dissolution and bioavailability. *See* Hr’g Tr. (Amidon) at 285:12-287:8, 288:7-25; CX-1604; CX-1434C.

Lastly, as to Respondents’ arguments that the FID applies an incorrect standard in connection with the preclinical trade secrets, Respondents’ Pet. at 20-21 (citing FID at 166), those arguments fail under both use and independent development defense standards. As to use, Respondents do not address the FID’s findings on pages 160 to 163, stating, for example, that “Ascletis used Viking trade secrets to plan its [REDACTED] toxicity studies,” and that

²⁵ Dr. Gregory Amidon is Complainant’s technical expert in this investigation.

“Ascletis used the information in several Viking studies, including [REDACTED] [REDACTED], to skip steps in its preclinical development process for ASC41.” FID at 161 (citing Hr’g Tr. (Silber) at 376:16-377:25, 380:19-382:5; CX-1384C). The FID also finds that “[t]he evidence shows that Ascletis [REDACTED] [REDACTED]” but that “Ascletis did, however, [REDACTED] [REDACTED] *Id.* at 162 (citing CX-1417C). Respondents fault the FID for addressing their “use” argument in the context of independent development (FID at 166), but Respondents presented no other relevant arguments in their post-hearing briefs (and they identify none in their petition).²⁶ Thus, the FID correctly determines that Respondents used or disclosed the preclinical trade secrets, and the FID correctly rejects Respondents’ independent development defense. *See* FID at 166; *see also id.* at 160-63.

Accordingly, in addition to the trade secrets specifically identified in the FID (including TS No. 4 which relates to Viking’s [REDACTED] formulation, TS Nos. 17, 18.1 to 18.3, and 37 to 37.4.3 which relate to Viking’s preclinical studies, and TS Nos. 12.11, 13.1 to 13.7, 15.1, and 38 which relate to Viking’s clinical studies), the Commission finds that Respondents also used or disclosed, and therefore misappropriated TS Nos. 5-9 and 36 (formulation trade secrets) and TS Nos. 18.9, 18.13, 18.24, 18.26, 18.30, 18.36, and 18.38 (preclinical trade secrets).²⁷ To the extent the FID suggests that all trade secrets were used or disclosed, the record does not support such finding.

²⁶ Respondents do not dispute that they are subject to a heightened standard on independent development defense. *See Sausage Casings*, 1984 WL 273789, at *95; *see also Pioneer Hi-Bred*, 35 F.3d at 1241.

²⁷ As discussed *supra* at section IV.B, the Commission finds that the individual respondent, Dr. Wu, acted in his corporate capacity, and therefore, liability does not attach to Dr. Wu in his personal capacity.

E. Domestic Industry and Injury or Threat of Injury Thereto

As explained below, the Commission affirms with modification the FID's findings that Complainant has satisfied the domestic industry requirement, and that Complainant has demonstrated that Respondents' unfair acts threaten to cause substantial injury to Complainant's domestic industry. The Commission takes no position on the FID's findings that Respondents' unfair acts have caused actual injury to Viking's domestic industry or prevented the establishment of such an industry. *See Beloit*, 742 F.2d at 1423.

1. Domestic Industry

The FID finds that Complainant demonstrated both that a domestic industry exists and that it is in the process of being established. FID at 181-89.

a. Existing Domestic Industry

The FID finds that Complainant has demonstrated an existing domestic industry relating to Viking's "research, development, engineering, and testing to commercialize VK2809." FID at 181-88. In particular, the FID credits expenses relating to Viking's development of the [REDACTED] formulation as well as expenses relating to Viking's payment to contract research organizations and third-party consultants for services in furtherance of development of the VK2809 drug product. *Id.* at 183-86. The FID, however, declined to credit expenses for the manufacture of VK2809, finding that the "[REDACTED] [are] made entirely overseas." *Id.* at 186. No party petitioned for review of the FID's findings that Viking has proven that a domestic industry exists. Nevertheless, Complainant contingently petitioned for Commission review of the FID's failure to credit [REDACTED] towards its existing domestic industry for the domestic manufacturing of VK2809 capsules and tablets, which thereby reduced Complainant's claimed investments from about [REDACTED] to about [REDACTED]. FID at 181-88; Complainant's Pet. at 25-27.

PUBLIC VERSION

More specifically, Complainant argues that the FID failed to credit “payments from Viking to providers [of chemicals, manufacturing, or controls (CMC)], such as [REDACTED] [REDACTED] the contract manufacturer that produced VK2809 [REDACTED], and [REDACTED] [REDACTED] the contract manufacturer that produced one manufacturing run of VK2809 [REDACTED]” totaling [REDACTED]. Complainant’s Pet. at 25-27 (citing FID at 185-86). Complainant faults the FID for finding that “[REDACTED] made entirely overseas” and failing to credit those expenses towards Viking’s domestic industry. FID at 186.

Complainant argues that “[t]he record evidence, including documents and witness testimony, confirm that the VK2809 [REDACTED] manufactured in the United States by [REDACTED].” Complainant’s Pet. at 25. Complainant also argues that the payments to [REDACTED] should be credited because unlike the “off-the-shelf” components at issue in *Lelo*, Viking’s [REDACTED] are “custom products” manufactured in the United States [REDACTED]. *Id.* at 26-27 (citing *Lelo*, 786 F.3d at 884; *Certain Solid State Storage Drives, Stacked Elecs. Components, & Prods. Containing Same*, Inv. No. 337-TA-1097, Comm’n Op., 2018 WL 4300500, *14 (June 29, 2018) (crediting payments to contract manufacturers where “the third-party entities here are, in fact, contractors, who provide specialized services, and do not simply sell ‘off-the-shelf’ products”)).

Respondents do not dispute that the FID errs in failing to credit Viking’s payments to [REDACTED]. There is also no dispute that the FID errs in finding that the [REDACTED] [REDACTED] “made entirely overseas.” FID at 185-86; *see* OUII’s Resp at 57-58 (acknowledging that the [REDACTED] made in the United States [REDACTED]). OUII’s response to Complainant’s Contingent Petition, however, argues that Viking’s payments to those contract manufacturers are “insufficiently documented

and therefore cannot be included in the domestic industry analysis.” OUII’s Pet. Resp. at 58-60 (citing *Lelo Inc. v. ITC*, 786 F.3d 879, 884 (Fed. Cir. 2015); *Certain Collapsible Sockets for Mobile Elec. Devices & Components Thereof*, Inv. No. 337-TA-1056, Comm’n Op., 2018 WL 7680630, *10-11 (July 9, 2018); *Certain Television Sets, Television Receivers, Television Tuners, & Components Thereof*, Comm’n Op., Inv. No. 337-TA-910, 2015 WL 6755093, *34 (Oct. 30, 2015); *Certain Sleep-Disordered Breathing Treatment Sys. & Components Thereof*, Inv. No. 337-TA-890 (Remand), USITC Pub. No. 4856, Initial Determination, 2018 WL 11202378, *70 (Dec. 1, 2018)). OUII reasons that “Viking does not possess a detailed accounting from its subcontractors of the number of hours spent working specifically for Viking or of the amount invested in equipment used to perform the contracted services.” *Id.* at 59.

The Commission finds that the record does not support the FID’s finding that the [REDACTED] “made entirely overseas.” FID at 185-86; *see also* OUII’s Resp at 57-58 (acknowledging that the [REDACTED] made in the United States [REDACTED]). Additionally, the Commission disagrees with OUII’s argument that Viking’s payments to those contract manufacturers are “insufficiently documented and therefore cannot be included in the domestic industry analysis.” OUII’s Pet. Resp. at 58-60. OUII questions what expenses [REDACTED] are actually attributable to Viking’s products such as labor or equipment expenses related to those products, but OUII’s reliance on *Lelo* is inapposite because the payments to [REDACTED] were for manufacturing custom, not off-the-shelf, products. *See Lelo*, 786 F.3d at 884 (“In this case, the U.S. suppliers are neither contractors nor subcontractors. They are retailers and the components are off-the-shelf.”); *Sleep-Disordered Breathing Treatment Sys.*, 2018 WL 11202378, at *64, 70 (no dispute that the domestically-supplied components are “off-the-shelf and generic”); *compare*

Solid State Storage Drives, 2018 WL 4300500, at *14 (crediting payments to third-party contract manufacturers where “the third-party entities here are, in fact, contractors, who provide specialized services, and do not simply sell ‘off-the-shelf’ products”).

Thus, the Commission has determined to credit the [REDACTED] payments to [REDACTED] [REDACTED] for manufacturing Viking’s [REDACTED] in the United States towards Viking’s existing domestic industry. The Commission’s determination to credit the [REDACTED] payments to [REDACTED] would increase Viking’s investments to about [REDACTED] in research, development, engineering, and testing to develop and/or commercialize VK2809. Because we affirm the FID’s finding that Complainant’s investments of about [REDACTED] satisfy the domestic industry requirement under section 337(a)(1)(A) based on the “nature and significance” of those investments, we therefore determine that Viking’s investments in its existing industry, as adjusted for the domestic manufacturing expenditures to [REDACTED] of [REDACTED], for a total of about [REDACTED], would likewise satisfy the domestic industry requirement under section 337(a)(1)(A). *See* FID at 186-88; *see also Botulinum Toxin Prods.*, 2021 WL 141507, at *9; FID at 181-88; 100-Day Tr. (Prowse²⁸) at 303:23-304:13; CDX-7C.49.

b. Industry in the Process of Being Established²⁹

The FID also finds that Complainant has demonstrated a domestic industry in the process of being established based on Viking’s planned “investments in Phase III clinical trials, further investments [in] the FDA approval process, and the future commercialization of VK2809 tablets with a strategic partner.” FID at 188-89. Building upon Viking’s [REDACTED] investments

²⁸ Stephen Prowse is Complainant’s domestic industry expert in this investigation.

²⁹ Commissioner Johanson finds a domestic industry exists, and he takes no position on a domestic industry in the process of being established and does not join this analysis.

discussed above, Complainant has shown that the completion of the FDA approval process and Phase 3 clinical trials is a significant R&D undertaking that is necessary for commercialization for an emerging biopharmaceutical company involving a small molecule drug candidate like VK2809. *See* 100-Day Tr. (Rao) at 229:7-13, 231:18-232:2. In particular, the FID finds that “Viking is taking steps to manufacture VK2809 in the United States for use in Phase III clinical trials and for future commercial sales.” FID at 188 (citing 100-Day Tr. (Morneau³⁰) at 52:10-15). Respondents do not dispute the FID’s findings.

OUII petitioned for review of the FID’s finding that Viking has demonstrated an industry in the process of being established. OUII’s Pet. at 40-46. OUII disputes the FID’s findings with respect to a domestic industry in the process of being established, arguing that the FID failed to apply the correct legal standard under Commission precedent applying section 337(a)(1)(A)(ii) regarding preventing the establishment of an industry, and that under that precedent, Complainant failed to establish “readiness to commence production.” OUII’s Pet. at 40-46 (citing *Certain Ultra-Microtome Freezing Attachments*, Inv. No. 337-TA-10, Comm’n Op., 1976 WL 41463, *4 (Apr. 2, 1976)). OUII also takes issue with the FID’s finding that “engagement with current and potential business partners, progression of FDA clinical trials, and preparation for the commercialization of a drug product are all relevant factors that can indicate whether an industry is likely to soon commence production of the subject articles.” FID at 180-81; OUII’s Pet. at 40-43 (arguing that the FID adopted a new legal test to determine whether there is an industry in the process of being established).

The language of section 337(a)(1)(A) nowhere requires “readiness to commence production” to satisfy the domestic industry requirement. 19 U.S.C. § 1337(a)(1)(A). The

³⁰ Michael Morneau is Viking’s vice president of finance and administration.

PUBLIC VERSION

Commission has long recognized that a domestic industry is not limited to only manufacturing activities, but extends to other non-manufacturing activities. *See, e.g., Certain Cube Puzzles*, Inv. No. 337-TA-112, 1982 WL 974906, *12-*13 (Dec. 30, 1982) (crediting non-manufacturing domestic operations including quality control, repair, and packaging); *Certain Airless Paint Spray Pumps & Components Thereof*, Inv. No. 337-TA-90, 1981 WL 50447, *6 (Nov. 24, 1981) (crediting “frequent servicing” as part of the domestic industry); *Certain Airtight Cast-Iron Stoves*, Inv. No. 337-TA-69, 1980 WL 41970, *5 (Dec. 31, 1980) (relying on repair and installation services to find a domestic industry). Similarly, Congress amended section 337 in 1988 to specifically recite research and development, engineering, and licensing. Pub. L. No. 100–418, § 1342 (1988). Additionally, in the context of section 337(a)(2), the Commission held that “[a]n industry is ‘in the process of being established’ if the complainant can ‘demonstrate that [it] is taking the necessary tangible steps to establish such an industry in the United States’ and that there is a ‘significant likelihood that the industry requirement will be satisfied in the future.’” *Certain Stringed Musical Instruments & Components Thereof*, Inv. No. 337-TA-586, Comm’n Op., 2008 WL 2139143, *8 (May 16, 2008) (citing S. Rep. 100-71, 130 (1987); H. Rep. 100-40, 157 (1987)).³¹ As such, we do not require “readiness to commence production” to satisfy a domestic industry in the process of being established under section 337(a)(1)(A).

The Commission finds that the test outlined in *Stringed Musical Instruments* is applicable for demonstrating an industry in the process of being established under section 337(a)(1)(A). Under that test, the FID’s factual findings demonstrate that Complainant has taken the necessary tangible steps to establish an industry in the United States and there is a significant likelihood

³¹ In the injury section, the FID notes that the “readiness” test is similar to the analysis undertaken to show to a domestic industry “in the process of being established” under section 337(a)(2). FID at 192 n.37 (citing *Stringed Musical Instruments*, 2008 WL 2139143, at *8).

that the domestic industry requirement will be satisfied in the future. *Stringed Musical Instruments*, 2008 WL 2139143, at *8 (citing S. Rep. 100-71 at 130; H. Rep. 100-40 at 157). In particular, Viking’s “engagement with current and potential business partners, progression of FDA clinical trials, and preparation for the commercialization of a drug product” (FID at 181) as well as Viking’s substantial investment in “research, development, engineering, and testing to commercialize VK2809” (FID at 181-82) show that Viking is taking the necessary tangible steps to establish an industry in the United States. Additionally, “Viking is taking steps to manufacture VK2809 in the United States for use in Phase III clinical trials and for future commercial sales” and “Viking has secured a vendor for the VK2809 API and, at the time of the 100-day hearing, expected to have an agreement ‘soon’ with a manufacturer of the drug product itself.” *Id.* at 188-89 (citing 100-Day Tr. (Morneau) at 52:10-20; 100-Day Tr. (Prowse) at 326:22-327:2). Moreover, as further discussed *infra*, the evidence shows there is a significant probability of VK2809’s technical and regulatory success. *Id.* at 209 (crediting expert testimony and independent analysis by financial firm Truist that the probability of VK2809’s success is about 60-65%). Accordingly, there is also a significant likelihood that the industry requirement will be satisfied in the future including with respect to U.S. “investments in Phase III clinical trials, further investments the FDA approval process, and the future commercialization of VK2809 tablets with a strategic partner.” *Id.* at 189.

Thus, the Commission has determined to affirm with modified analysis the FID’s finding that Complainant established a domestic industry in the process of being established.

2. Injury or Threat of Injury to a Domestic Industry

a. FID’s Findings

The FID finds that Respondents’ misappropriation caused actual and threatened injury to Viking’s domestic industry, including that Ascleitis’s unfair acts (1) have substantially injured its

existing domestic industry, (2) threaten to substantially injure its existing domestic industry, and (3) threatens to prevent the establishment of its future domestic industry. FID at 189-217.

The FID relied on the standard set forth in *Oakwood*. *Id.* at 193-95 (citing *Oakwood Labs. LLC v. Thanoo*, 999 F.3d 892, 913 (3d Cir. 2021)). The FID observes that federal courts find that trade secret misappropriation under the DTSA is *per se* injury. *Id.* at 194-95. The FID also states that “substantial” actual or threatened injury is required under section 337(a)(1)(A). *Id.* at 198. Specifically, the FID finds that “the threat or effect of Ascleitis’s past importation of the Accused Products and its intent to sell the Accused Products in the United States will destroy or substantially injure Viking’s current research and development domestic industry and will prevent Viking from establishing a future industry in FDA-approved products containing VK2809.” *Id.* The FID also cites Commission precedent and finds that Viking will suffer: (1) “a pricing disadvantage because the misappropriator will avoid substantial research and development costs that the trade secret owner has already invested in its own product development”; (2) “a lost timing advantage for the trade secret owner when the misappropriator obtains ‘a jumpstart in an industry it would otherwise not have competitively joined’ until a much later time”; and (3) “a loss of market share by the trade secret owner due to rapid market entry by the misappropriator.” *Id.* at 198-99 (citing *Rubber Resins*, 2014 WL 7497801, *32; *Certain Cast Steel Railway Wheels, Processes for Mfg. or Relating to Same & Certain Prods. Containing Same*, Inv. No. 337-TA-655, USITC Pub. No. 4265, 2011 WL 6255116, *68-69 (Oct. 1, 2011) (unreviewed final initial determination); *Certain Elec. Power Tools, Battery Cartridges, & Battery Chargers Contents*, Inv. No. 337-TA-284, 1990 WL 710470, *125 (Feb. 20, 1990) (unreviewed final initial determination)). While the FID mentions Commission

precedent concerning the injury requirement of section 337(a)(1)(A), the analysis centered on *Oakwood* throughout its analysis of the facts in this investigation. *Id.* at 189-92.

More specifically, the FID finds that “Dr. Wu gave testimony that, so long as Ascleitis clinical trials go as expected, Ascleitis ‘would most likely’ seek FDA approval to sell ASC41 in the United States.” *Id.* at 197-98 (citing 100-Day Tr. (Wu) at 403:11-21; Hr’g Tr. (Wu) at 637:1-638:19 (describing Ascleitis’s thinking about Phase III clinical studies in the United States and FDA approval for selling ASC41 in the United States)). Additionally, the FID finds that “Ascleitis also plans to ‘push’ its Phase II clinical trials to ‘make[] it possible for Phase III [trials to] [o]vertake that of VK2809,’” which is “a clear admission that [Ascleitis] intends its Accused Products to disrupt Viking’s domestic industry.” *Id.* at 198 (citing CX-1259C-T.5; CX-596C (email planning timing of clinical trials “in order to catch or beat Viking”))).

The FID further finds that “the record evidence here shows that Ascleitis’s misappropriation of Viking trade secret information and subsequent development of ASC41 and ASC43F interfered with Viking’s ability to contract with a large pharmaceutical company to further develop and commercialize VK2809.” *Id.* at 199. Specifically, the FID explains that “VK2809 and ASC41 contain the same active pharmaceutical ingredient and the same mechanism of action” (*id.* at 201 ((citing JX-7C.3-4)), such that “even though VK2809 is differentiated from other drug such as Madrigal’s resmetirom, VK2809 lacks differentiation from ASC41” (*id.* (citing 100-Day Tr. (Zante³²) at 115:8-15 (“We can differentiate against any other competitor in the space, including Madrigal especially, but we’re unable to differentiate versus Ascleitis”))). The FID finds that “but for Ascleitis’s development of ASC41 based on misappropriation of Viking’s trade secret information, VK2809 would be differentiated from

³² Gregory Scott Zante is Viking’s chief financial officer.

other NASH treatment products existing or in development.” FID at 200. In particular, the FID notes that “industry expert Dr. Peck testified that Phase II clinical trial data for VK2809 indicated it had fewer gastrointestinal (‘GI’) side effects than Madrigal’s resmetirom.” *Id.* (citing 100-Day Tr. (Peck) at 192:6-12). This evidence shows a distinct advantage that VK2809 has over the FDA-approved resmetirom, which has the same mechanism of action as VK2809 but a different API. Thus, the FID concludes, “[b]ringing ASC41 into the market using misappropriated information reduces Viking’s ability to differentiate VK2809 from other NASH treatments, which in turn impairs Viking’s ability to partner with potential collaborators and causes injury to Viking’s present domestic industry and future domestic industry.” *Id.* at 201.

In particular, the FID finds that “[REDACTED] entered into confidential disclosure agreements with both Viking and Ascletis to access confidential data in furtherance of potential partnership discussions.” *Id.* at 202 (citing Hr’g Tr. (Broidrick³³) at 83:16-24, 84:20-85:22; Hr’g Tr. (Gudmundsson³⁴) at 742:4-17; CX-2195C). The FID also finds that “Viking’s failure to partner with [REDACTED] is attributable, at least in part, to the fact that VK2809 and ASC41 have identical APIs and cannot be differentiated for the treatment of NASH.” *Id.* at 203.³⁵

Furthermore, the FID agrees with Complainant that “its ability to partner with a large pharmaceutical company has also been injured because Ascletis’s actions with respect to ASC41 have reduced the net present value of VK2809.” *Id.* at 205-12. Specifically, the FID agrees that “competition between VK2809 and ASC41 in the U.S. market would reduce the net present

³³ Amy Broidrick was Viking’s senior vice president from 2016 to 2020.

³⁴ Dr. Kristjan Gudmundsson is Ascletis’s head of discovery.

³⁵ The FID finds that Viking’s failure to partner with [REDACTED] is not due to Ascletis’s actions. FID at 204-05. Complainant does not petition for review of that finding.

value of VK2809 by [REDACTED]” *Id.* at 206 (citing 100-Day Tr. (Rao³⁶) at 242:9-243:25, 258:7-12). The FID finds that “Dr. Rao used reasonable assumptions when calculating his estimate of the effect ASC41 would have on the net present value of VK2809 were ASC41 to enter the U.S. market.” *Id.* at 211 (citing Hr’g Tr. (Rao) at 561:11-562:5). Thus, the FID concludes that “Viking has been injured by the loss of value of its trade secret information and the loss of opportunities to partner with a large pharmaceutical company in furtherance of continued research and development and commercialization of VK2809.” *Id.* at 212.

The FID further notes Complainant’s argument that “Viking’s domestic industry may suffer if Viking must compete with Ascleptis for Phase III clinical trial resources in the United States.” *Id.* at 212-14. The FID, however, does not resolve the extent of that potential injury. *Id.* Instead, the FID finds that “other record evidence . . . amply supports a finding that Viking has proved the injury requirement of section 337(a)(1)(A) without consideration of clinical trial competition.” *Id.* at 214.

Lastly, the FID rejects Respondents’ and OUII’s argument, predicated upon FDA’s non-approval of Ocaliva, another drug candidate for the treatment of NASH, that “uncertainty of future events make any discussion of injury in this investigation speculative and not supported by evidence.” *Id.* at 214-17. The FID, in fact, finds that the FDA’s decision not to approve Intercept’s Ocaliva provides “little insight into the business or regulatory future of VK2809 or ASC41.” *Id.* at 216. The FID notes that “the FDA will not consider the clinical results of an unrelated drug when evaluating an NDA.” *Id.* (citing Hr’g Tr. (Abrouk³⁷) at 1023:16-1024:6 (agreeing that the target receptor of Ocaliva and VK2809 are different)). The FID recognizes

³⁶ Dr. Mohan Rao is Viking’s expert in this investigation on the pharmaceutical industry.

³⁷ Dr. Nacer Abrouk is Respondents’ expert in drug development, FDA regulation, and clinical development.

that “[s]uccessfully bringing a pharmaceutical product through development to FDA approval and commercial markets has an amount of inherent uncertainty,” but the FID finds that “[t]he industry and the market both recognize the risks of regulatory approval, and both incorporate those risks into evaluations of a company’s net present value or its stock price.” *Id.* at 217 (citing 100-Day Tr. (Zante) at 156:18-158:16). Thus, the FID finds a nexus between Respondents’ unfair acts and Complainant’s injury. *Id.* (“Viking has shown the threat and effect of injury due to unfair acts by Ascletis, even considering the inherent uncertainties present—and accounted for—in the pharmaceutical industry.”).

b. Parties’ Petitions and Supplemental Submissions

Respondents petitioned for review of the FID’s finding of injury, arguing that the FID errs in relying on the Third Circuit’s *Oakwood* decision and effectively finding that a complainant can show injury merely by proving misappropriation. Respondents’ Pet. at 4-6. Respondents also dispute the FID’s finding of injury based on a reduction of the net present value (“NPV”) of VK2809. *Id.* at 6. Respondents contend that the FID’s finding is wrongly premised on the assumption that “VK2809 and ASC41 will achieve regulatory approval because an unrelated drug candidate, Resmetirom, successfully completed clinical trials and obtained FDA approval for NASH.” *Id.* Respondents argue that this finding is “internally inconsistent” because “according to the ID, Resmetirom is so similar to VK2809 and ASC41 that its success all-but guarantees FDA approval, yet so dissimilar that VK2809 would be differentiated in the market.” *Id.* Respondents further argue that the FID “provides no rationale for selecting Resmetirom and dismissing Ocaliva” when “[b]y the ID’s logic, Ocaliva’s failure would guarantee VK2809’s and ASC41’s failure as well.” *Id.* at 8.

Respondents further dispute the FID’s NPV findings based on the FID’s reliance on Dr. Rao and Dr. Peck and their testimony about VK2809’s likelihood of FDA approval. *Id.* at 6-10.

PUBLIC VERSION

Respondents contend that the FID errs by relying on Dr. Peck who “only considered the historical, regulatory probability of success” while “ignor[ing] the copious evidence supporting a much lower chance of approval.” *Id.* at 9. Respondents also fault the FID’s reliance on Mr. Zante’s analysis of VK2809’s plans and value, arguing that such analysis incorrectly “[REDACTED]

[REDACTED]

[REDACTED]” when Complainant itself admits there are several potential substitute products. *Id.* at 10 (citing Complainant’s PI Statement at 3-5).

Furthermore, Respondents argue that Ascletis’s “ASC41 had nothing to do with [REDACTED] decision not to partner with Viking.” *Id.* at 10-12. Respondents contend that “Ascletis never gave [REDACTED], and Viking did not provide any chemistry, manufacturing, and control information about VK2809 to [REDACTED], meaning that [REDACTED] could not have known that ASC41 and VK2809 [REDACTED].” *Id.* at 11. According to Respondents, [REDACTED] was not concerned with [REDACTED]” *Id.* Respondents further argue that “[a]dditional evidence shows that Viking’s failure to partner with [REDACTED]—and with other potential partners—was due to [REDACTED] not ASC41.” *Id.* at 12.

Still further, Respondents argue that the FID’s “final erroneous finding as to injury is that, in a hypothetical world where both ASC41 and VK2809 proceed to Phase 3, Viking could be injured by the overlapping need to recruit trial sites, investigators, and patients.” *Id.* at 12-15 (citing FID at 214). Rather, Respondents continue, “the evidence demonstrates that there is

significant uncertainty about when either drug candidate will enter Phase 3, if at all.³⁸ *Id.* at 12.

Additionally, “if they do move on the Phase 3, [REDACTED]

[REDACTED].” *Id.*

OUII also petitioned for review of the FID’s injury findings and makes similar arguments to Respondents. OUII’s Pet. at 46-74. Specifically, OUII argues that the FID’s “extensive reliance” on Third Circuit precedent (*Oakwood*), “which was analyzing injury under the DTSA as an element of trade secret misappropriation, not injury under subsection 337(a)(1)(A),” means that the “injury analysis and conclusions are fatally flawed and should be reviewed and reversed.” *Id.* at 51. OUII also disputes the FID’s finding of injury based on Viking’s failure to secure a partnership with [REDACTED]. *Id.* at 51-53. According to OUII, “[t]here is no causal nexus between [REDACTED] to not partner with Complainant and Respondents’ unfair acts.” *Id.* at 51. Rather, OUII continues, “[REDACTED] did not partner with Complainant because [REDACTED], not because of the existence of ASC41.” *Id.* at 52.

OUII also argues that the FID errs in finding an injury based on a reduction to VK2809’s net present value (NPV). *Id.* at 54. OUII explains that Dr. Rao’s NPV analysis, on which the FID relies, was based on unsupported assumptions, including: [REDACTED] delay in Viking’s clinical trials, simultaneous entry into the U.S. market by ASC41 or one year after VK2809, capture by ASC41 [REDACTED], a [REDACTED] probability of VK2809’s technical and regulatory success, and FDA approval for both ASC41 and VK2809. *Id.* OUII

³⁸ In Order No. 51, the Chief ALJ rejected Respondents’ argument that Viking “deprioritized” VK2809 as untimely. Order No. 51 at 3. In fact, the record evidence shows that, at least at the time of the 100-day hearing in this investigation, VK2809 was Viking’s “primary drug product receiving most of the research and development budget.” Complainant’s Pet. Resp. at 7 (citing 100-Day Tr. (Morneau) at 41:24-42:2; 100-Day Tr. (Prowse) at 300:19-23, 301:20-22, 304:14-305:4).

further argues that there is no basis for finding an injury based on interference by Ascleitis with Viking's Phase III clinical trials. According to OUII, the likelihood of overlap between Viking's and Ascleitis's clinical trials is "minimal" which "negates much of the basis for this alleged injury." *Id.* at 68-70.

Complainant contingently petitioned for Commission review of the FID's decision not to consider the effect of clinical trial competition from Ascleitis as part of the injury analysis. Complainant's Pet. at 27-28. Complainant argues that "Respondents' Phase III clinical trial for ASC41 substantially threatens the establishment of Viking's future domestic industry." *Id.* at 27. Complainant further contends that "as a result of Respondents' Phase III clinical trial, Viking's Phase III clinical trial will be delayed by [REDACTED] and cost Viking an additional approximately [REDACTED] in Phase III costs for CROs and site expenses." *Id.* at 28.

Additionally, in response to the Commission's Supplemental Notice requesting briefing on "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 [*Rubber Resins*]" (Suppl. Notice at 3), Complainant argues that there is threatened and actual injury under the factors of *Rubber Resins*. See Complainant's Suppl. Br. at 7-12. Complainant also argues that other factors beyond those discussed in *Rubber Resins* are indicative of injury under the facts of this case, including Viking's inability to secure a strategic partnership to commercialize VK2809. *Id.* at 13-18. On the other hand, Respondents and OUII essentially argue that the *Rubber Resins* factors are not satisfied because the domestic industry product and the accused products are not FDA approved and are not commercially available. See Respondents' Suppl. Br. at 6-8; Respondents' Suppl. Reply at 5-6; OUII's Suppl. Br. at 5-11. Respondents further argue that Complainant's NPV analysis is wrong and is not a useful measure of harm. Respondents' Suppl. Br. at 8-12.

c. Analysis

The Commission affirms with modified reasoning the FID’s finding that Respondents’ unfair acts threaten to cause substantial injury to Viking’s domestic industry with respect to its ongoing development and commercialization efforts for VK2809. *See* FID at 189-217. The Commission takes no position on whether Respondents’ unfair acts have caused actual injury to Viking’s domestic industry or prevented the establishment of such an industry. *See Beloit*, 742 F.2d at 1423. However, the Commission finds that the FID erred in relying on the Third Circuit’s *Oakwood* decision to support its finding of injury under section 337(a)(1)(A). FID at 193. As the Commission has previously explained, under the UTSA and the Restatement, a claim of trade secret misappropriation does not require a separate injury showing. Rather, that type of injury is effectively satisfied when the trade secret is used or disclosed. *See Botulinum Toxin Prods.*, 2021 WL 141507, at *8 (citing UTSA § 1(2); Restatement (Third) of Unfair Competition § 40; Restatement of Torts § 757; Milgrim on Trade Secrets § 7.07[1]). On the other hand, the injury requirement under section 337(a)(1)(A) is distinct and it requires a showing of substantial actual or threatened injury to a domestic industry or the prevention of such an industry from being established. *Id.*; *see also* 19 U.S.C. § 1337(a)(1)(A).

The Commission also notes that a commercially sold product is not required under either section 337 or Commission precedent to establish threatened injury, contrary to OUII’s and

Respondents' suggestion.³⁹ The language of the statute does not impose a commercial sale requirement to establish a domestic industry or any threatened injury thereto. 19 U.S.C. § 1337(a)(1)(A). The Commission has never interpreted the statute in such a manner. Nor is it appropriate to do so in the context of Viking's domestic industry, which is focused on research and development, engineering, testing, and advancing efforts toward the completion of the FDA approval process, including Phase III clinical trials, and future commercialization and production of the VK 2809 drug candidate. To the contrary, the Commission expressly declined to impose such a requirement for establishing a domestic industry under section 337(a)(2). *Certain Non-Volatile Memory Devices & Prods. Containing the Same*, Inv. No. 337-TA-1046, Comm'n Op., 2018 WL 6012622, *25 (Oct. 26, 2018) (holding that "[t]he statutory language of section 337(a)(2) on its face does not require commercial production for a domestic industry in the process of being established" and reasoning that "[t]he term 'article' on its own is sufficiently capacious to embrace pre-commercial or non-commercial items"); *see also Certain Strontium-Rubidium Radioisotope Infusion Sys., & Components Thereof*, Inv. No. 337-TA-1110, Comm'n Op., 2019 WL 9596567, *24 (Dec. 11, 2019) (finding the domestic industry requirement satisfied under section 337(a)(3)(B) and (C) even where the domestic industry article lacked FDA approval). The Commission sees no reason to deviate from this precedent in the context of a domestic industry or any threatened injury thereto under section 337(a)(1)(A).

³⁹ Nor does the Commission require proof of lost sales to find actual or threatened injury to a domestic industry. For instance, "where the U.S. presence of an imported product made using misappropriated trade secrets negatively affects the terms upon which the trade secret owner is able to contract with a third party, there is injury to the domestic injury." FID at 198 (citing *Rubber Resins*, 2014 WL 7497801, at *32 (finding injury based on underselling and reduced profitability even as the Commission declined to adopt the ALJ's findings that lost sales resulted from respondents' importations)). Similarly, in *Cast Steel Railway Wheels*, even where "sales of [respondents'] wheels have been minimal," the Commission found injury based on respondents' targeting of complainant's customers. *See* 2011 WL 6255116, at *70.

i. Threatened Injury

The Commission finds that Respondents’ unfair acts threaten to cause substantial injury to Viking’s domestic industry with respect to its ongoing development and commercialization efforts for VK2809. Threatened injury is actionable, and a complainant is not required to wait for actual substantial harm to occur before it may file a complaint. *See* 19 U.S.C. § 1337(a)(1)(A). The record evidence here demonstrates “a threat to substantially injure” a domestic industry under Commission precedent and the indicia for a threatened injury. *Rubber Resins*, 2014 WL 7497801, *32 (considering the following indicia for threatened injury: (1) “substantial foreign manufacturing capacity,” (2) “ability of imported product to undersell the domestic product,” (3) “explicit intention to enter into the U.S. market,” (4) “the inability of the domestic industry to compete with the foreign products because of vastly lower foreign costs of production and lower prices,” and (5) “the significant negative impact this would have on the domestic industry”). As discussed *supra* at section III.D.2, the *Rubber Resins* indicia are exemplary and non-exclusive. The Commission may consider “[o]ther factors [which] may also be indicative of economic injury and threat under the facts of each case.” *Certain Lithium Ion Batteries, Battery Cells, Battery Modules, Battery Packs, Components Thereof, & Processes Therefor*, Inv. No. 337-TA-1159, Comm’n Op., 2021 WL 856373, *21-22 (Mar. 4, 2021). *Rubber Resins Factors*

Respondents do not adequately address the *Rubber Resins* indicia, but argue that “Viking’s alleged injury does not fit into any of [the *Rubber Resins*] categories because the Accused Products—ASC41 and ASC43F—and the DI Product—VK2809—were still in the earliest stages of clinical testing as of the filing of the complaint.” Respondents’ Suppl. Br. at 2, 5. The Commission disagrees as explained below.

PUBLIC VERSION

The record evidence shows that Respondents' misappropriation has put Complainant at a significant disadvantage because Respondents, with the benefit of Viking's trade secrets, have spent less on research and development than they would have without the misappropriation and, thus, will be able to undersell Viking's domestic industry product once they obtain FDA approval (thereby satisfying *Rubber Resins*' second factor (ability of imported product to undersell the domestic product)).⁴⁰ FID at 198 (citing *Rubber Resins*, 2014 WL 7497801, *32); Complainant's Pet. Resp. at 9-10 ("Dr. Prowse concluded that Respondents also have the ability to undersell VK2809 as a result of the significantly lower development costs Respondents incurred for ASC41 as a result of their misappropriation of Viking's trade secrets."); Complainant's Suppl. Br. at 8-9 (citing Complainant's 100-Day Post-Hearing Br. at 101-02); *see also* 100-Day Tr. (Prowse) at 319:8-24 (testifying that Respondents have the ability to undersell VK2809 because they have spent significantly less on clinical trials and they do not have to pay the milestone and royalty payments that Viking must pay under the license agreement with Ligand). For instance, Dr. Prowse testified that Respondents "expect to spend approximately [REDACTED] on their Phase 2 clinical study in China, whereas Viking has already incurred over [REDACTED] in costs through the end of last year on their Phase 2 trials." Prowse) at 319:8-24; CDX-7C.97; Complainant's 100-Day Post-Hearing Br. at 101.

Moreover, although Respondents now claim, without evidentiary support, that they no longer intend to enter the U.S. market, this assertion is contradicted by the record in this investigation. As the FID finds, "Dr. Wu gave testimony that, so long as Ascleitis clinical trials go as expected, Ascleitis 'would most likely' seek FDA approval to sell ASC41 in the United

⁴⁰ As discussed *supra* at section IV.E.1.a, Viking invested about [REDACTED] in exploiting its exclusive rights in the asserted trade secrets.

States.” FID at 197-98 (citing 100-Day Tr. (Wu) at 403:11-21; Hr’g Tr. (Wu) at 637:1-638:19); Complainant’s Suppl. Br. at 9. Furthermore, as part of the sanctions order, the Chief ALJ imposed certain adverse inferences, including findings that Respondents intend to conduct Phase III trials and to commercialize the accused products if permitted by the FDA. *Id.* at 56; Complainant’s Suppl. Br. at 9-10. Neither OUII nor Respondents address the effect of the adverse inferences imposed as sanctions on this factor. Therefore, *Rubber Resins*’ third factor (explicit intention to enter into the U.S. market) is satisfied.

The Commission also finds that the evidence demonstrates that Ascletis potentially has vastly lower foreign costs of production. Specifically, Dr. Prowse testified that the cost to manufacture VK2809 in the United States is [REDACTED] while the cost to manufacture the accused products in China is in the [REDACTED] of that number.” 100-Day Tr. (Prowse) at 318:4-15; *see also* Complainant’s Suppl. Br. at 10-11 (citing Complainant’s 100-Day Post-Hearing Br. at 102 (“Viking’s costs to manufacture a single tablet of VK2809 is [REDACTED] than the cost to manufacture a single tablet of ASC41.”)). Viking has indicated that it intends to manufacture VK2809 in the United States and Viking is negotiating with potential domestic manufacturers of the VK2809 tablet for Phase 3 clinical trials. *See* Complainant’s 100-Day Post-Hearing Br. at 53, 108-09 (citing 100-Day Tr. (Morneau) at 52:10-20; CX-312C). Respondents and OUII argue that Ascletis currently lacks the capacity to manufacture the accused products at a commercial level in China, but Ascletis did produce smaller quantities of the accused products for the purpose of conducting clinical trials. OUII’s Suppl. Br. at 8; Respondents’ Suppl. Br. at 6; *see also* Complainant’s 100-Day Post-Hearing Br. at 100 (“The evidence also showed that during the research and development stage, Ascletis Pharmaceuticals had the manufacturing capacity to produce [REDACTED] in

██████████ or ██████████ in ██████████ while also producing other commercial drugs.”) (citing 100-Day Tr. (Prowse) at 320:15-321:3; JX-1C.32, Wu Dep. Tr. at 101:11-102:22; CX-158C.2). The evidence also shows that “Respondents have scaled up the batch size from ██████████.” Complainant’s 100-Day Post-Hearing Br. at 100 (citing 100-Day Tr. (Wu) at 414:3-7; CX-579C). Additionally, there is no dispute that unlike Viking, Ascleitis has substantial manufacturing facilities in China for producing other drug products and can leverage that capacity to produce the accused products on a commercial scale. OUII’s Suppl. Br. at 8; *see also* 100-Day Tr. (Prowse) at 319:25-320:14; Complainant’s 100-Day Post-Hearing Br. at 100 (“Respondents’ corporate filing shows that its manufacturing facility has ‘state-of-the-art production equipment’ with a ‘total gross floor area of 17,000 square meters’ having the capability to produce ‘530 million tablets per year.’”) (citing 100-Day Tr. (Prowse) at 320:5-14; CX-268.14). In particular, Respondents’ corporate filing states that their product equipment includes “cutting-edge technology capabilities such as hot-melt extrusion” which is the manufacturing process used to produce ASC41. CX-268.14; *see also* Respondents’ Pet. Resp. at 12 (stating that “Respondents had a long history of preparing hot melt extrusion formulations of a variety of drugs prior to its interactions with Complainant” and “Respondents’ decision to pursue a hot melt formulation of ASC41 years later in 2018 was consistent with its established practice”). Thus, the Commission finds that *Rubber Resins*’ fourth factor (the inability of the domestic industry to compete with the foreign products because of vastly lower foreign costs of production and lower prices) is also satisfied.

The Commission further finds that *Rubber Resins*’ fifth factor (the significant negative impact this would have on the domestic industry) supports finding a threat of substantial injury to Complainant’s domestic industry. As the FID finds, Respondents improperly obtained a

PUBLIC VERSION

jumpstart in the development of its NASH treatment, and will therefore be able to enter the market earlier than they would have without the misappropriation and cut into Viking's future market share. FID at 198 (citing *Cast Steel Railway Wheels*, 2011 WL 6255116, *68-69); Complainant's Pet. Resp. at 9-10 ("Dr. Rao concluded that VK2809's projected sales would drop from about [REDACTED]"); 100-Day Tr. (Rao) at 242:9-243:25, 267:14-268:18. Additionally, as discussed in more detail, *infra* (Other Factors), the Commission agrees with the FID that Respondents' misappropriation threatens to prevent Viking from securing a partnership with a large pharmaceutical company due, at least in part, to the lack of differentiation of VK2809 with the accused drug products and to VK2809's reduced NPV. FID at 199-212. Thus, Respondents' unfair acts threaten to have a significant negative impact on Viking's domestic industry. As discussed, *infra* at section IV.E.2.c.ii, Complainant also established a nexus between Respondents' unfair acts and the threatened injury. Such nexus requires establishing a "causal connection" between Respondents' unfair acts and Complainant's injury, not that the unfair acts are the "sole reason" for the injury. *Genband US LLC v. Metaswitch Networks Corp.*, 861 F.3d 1378, 1384 (Fed. Cir. 2017); *Rubber Resins*, 2014 WL 7497801, *32.

Other Factors

Respondents' misappropriation has at least in part contributed to Complainant's inability to secure a strategic partnership with a large pharmaceutical company to further develop and commercialize VK2809. Both Viking and Ascleitis compete for the same potential strategic partners. In particular, the record evidence supports the FID's finding that Ascleitis's misappropriation of Viking's trade secret information and subsequent development of ASC41 and ASC43F, caused VK2809 to lack differentiation from the accused products, which interfered with Viking's ability to contract with [REDACTED] to further develop and commercialize VK2809.

FID at 199 (citing *Rubber Resins*, 2014 WL 7497801, *31-*32). Both Viking and Ascleitis targeted [REDACTED] for partnership, and the evidence shows that [REDACTED] specifically inquired about differentiation between Viking's VK2809 and Ascleitis's ASC41.⁴¹ *Id.* at 202-03 (citing Hr'g Tr. (Broidrick) at 86:14-87:11). As the FID finds, "[REDACTED], [REDACTED] [REDACTED] *Id.* at 203 (citing CX-573C). Ascleitis itself recognized that [REDACTED] was [REDACTED] *Id.* (citing CX-1217C.1); Complainant's Pet. Resp. at 12 (citing Hr'g Tr. (Gudmundsson) at 743:4-10; CX-1217C). In particular, [REDACTED] noticed that [REDACTED] [REDACTED]," and inquired whether ASC41 is "distinct" from VK2809. *Id.* at 203 (citing CX-573C).⁴² Respondents contend that "Ascleitis never gave [REDACTED] information about ASC41's structure, and Viking did not provide any chemistry, manufacturing, and control information about VK2809 to [REDACTED], meaning that [REDACTED] could not have known that ASC41 and VK2809 [REDACTED]." Respondents' Suppl. Br. at 9 (citing Hr'g Tr. (Wu) at 618:23-619:4, 641:10-15). However, regardless of Respondents' unsupported suggestion that [REDACTED] potentially lacked awareness of the [REDACTED] VK2809 and ASC41, that suggestion does not negate the FID's conclusion, based on the record evidence, that whether there was differentiation between the two

⁴¹ At the same time, [REDACTED] "positively differentiated VK2809 from Madrigal's [resmetirom] compound." FID at 202-03 (citing Hr'g Tr. (Broidrick) at 86:14-87:11). In particular, "Phase II clinical trial data for VK2809 indicated it had fewer [GI] side effects than Madrigal's resmetirom." *Id.* at 200 (citing 100-Day Tr. (Peck) at 192:6-12).

⁴² As Viking explained, unlike resmetirom, both VK2809 and ASC41 are "prodrugs that are metabolized to their active forms by CYP3A4 in the liver." Complainant's Post-Hearing Br. at 12, 175; Hr'g Tr. (Chavez) at 108:1-12. These unique features also alerted Viking that Ascleitis may have misappropriated its trade secrets. *Id.* at 175 n.24; Hr'g Tr. (Chavez) at 108:1-3.

drug compounds was important for [REDACTED] to understand as part of its exploration of other potential NASH partnerships (as shown by [REDACTED] communications with potential partners on this record). FID at 202-03; Respondents' Pet. at 10-11. Therefore, the Commission finds that lack of differentiation between VK2809 and the accused products was one of the likely causes of Viking's failure to secure a partnership with [REDACTED].

While OUII argues that [REDACTED] (OUII's Pet. at 52; OUII's Suppl. Br. at 19-20), the evidence indicates that at least at the time of Viking's negotiations with [REDACTED] between June 2018 and March 2022, [REDACTED] was still considering a partner for NASH and there was no indication of a change in pursuing partnerships related to NASH products. Complainant's Pet. Resp. at 11-12. In fact, [REDACTED]
[REDACTED]
[REDACTED]. Respondents' Suppl. Reply at 8; Hr'g Tr. (Chavez⁴³) at 129:4-23. At a minimum, Respondents' unfair acts threaten to cause substantial injury to Complainant's domestic industry, at least in part, because the lack of differentiation between VK2809 and ASC41 undermines Viking's ability to secure a partnership with a large pharmaceutical company ([REDACTED]) to further develop and/or commercialize VK2809. FID at 201; *id.* at 200 ("Viking's expert Dr. Rao credibly testified that, in a pharmaceutical space with multiple products in development (such as the present NASH

⁴³ Dr. Medardo Chavez is Viking's senior director of business development.

treatment field), the inability of a small company to differentiate its product means ‘no chance to be able to get a collaboration deal.’”) (citing 100-Day Tr. (Rao) at 237:4-16).⁴⁴

OUII also dismisses Viking’s argument that it was injured by the loss of exclusivity with respect to VK2809 given that VK2809’s API has been in the public domain since 2007. OUII’s Suppl. Br. at 16-17. That argument misses the mark as Viking’s exclusive rights in the asserted trade secrets do not cover the API itself but the drug product formulation, preparation, and storage, as well as preclinical and clinical information. FID at 22-29. Similarly, Respondents’ argument that Viking’s lack of patent rights was a significant concern for potential partners, is unpersuasive. Respondents’ Suppl. Br. at 10. As the FID finds, even without patent protection, Viking’s trade secrets have independent value and were not generally known or readily ascertainable, and that would have been relevant for potential partnerships, absent Respondents’ misappropriation. FID at 72.

Additionally, as the FID finds, Ascleitis’s unfair acts caused a significant reduction in VK2809’s net present value by [REDACTED], thereby undermining Viking’s ability to secure a partnership with a large pharmaceutical company to further develop and commercialize VK2809.⁴⁵ *Id.* at 205-06. In particular, the FID credits Dr. Rao’s assumptions that: (1) ASC41

⁴⁴ OUII and Respondents also argued that the “lack of 52-week Phase II clinical trial data affected [Viking’s] partnership opportunities.” FID at 201. While the Commission does not rely on the 52-week data (published in 2024) to reach its conclusion, the Commission notes that Viking has now successfully completed the 52-week clinical trial thereby negating OUII’s and Respondents’ argument that the lack of such data caused Viking not to secure a strategic partnership with a large pharmaceutical company. Complainant’s Remedy Br. at 34 & Ex. 17. Additionally, the positive 52-week clinical trial further confirms and corroborates Viking’s expert’s assumptions about the probability of obtaining FDA approval for VK2809.

⁴⁵ As Dr. Rao credibly testified, the two “critical” factors that a large pharmaceutical company considers when evaluating an emerging pharmaceutical company for strategic partnership are “a highly differentiated product” and “a product that has a high net present value or NPV.” 100-Day Tr. (Rao) at 236:6-12.

will enter the United States either at the same time as VK2809 or one year later (*see id.* at 207-08; *see also id.* at 197-98 (discussing Ascletis’s plans to overtake Viking during Phase III trials) (citing CX-1259C-T.5; CX-596C (email planning timing of clinical trials “in order to catch or beat Viking”)); (2) ASC41 could capture ██████████ VK2809’s market share (due to the lack of differentiation between the two compounds) (*id.* at 208 (further crediting Dr. Rao’s testimony that “it doesn’t need to be an assumption of a 50-50 split, [or] a 60-40, 75-25, or 25-75,” and that “[a]ny one of those would lead to a very significant diminution in sales by billions of dollars”) (citing 100-Day Tr. (Rao) at 244:1-11); (3) VK2809’s probability of technical and regulatory success is ██████████ (*id.* at 209-10) (discussing that the FDA already approved resmetirom which has the same mechanism of action as VK2809); (4) if VK2809 is approved by the FDA, ASC41 will be approved as well (FID at 210-11 (crediting Dr. Peck’s testimony that the likelihood of FDA approval for VK2809 and ASC41 is the same)); and (5) VK2809’s cost of capital is ██████████.⁴⁶ FID at 206. Respondents and OUII dispute the FID’s findings as to VK2809’s NPV reduction, arguing that the assumptions underlying Dr. Rao’s ██████████ percent estimate are inaccurate. Respondents’ Pet. at 6-10; OUII’s Pet. at 67. Respondents and OUII are wrong as explained below.

Respondents incorrectly argue that Dr. Rao’s 50-50 split assumption does not account for other market participants. Respondents’ Pet. at 9-10; *see also* OUII’s Pet. at 61; OUII’s Suppl. Br. at 21. To the contrary, Dr. Rao testified that ASC41 could capture ██████████ percent of VK2809’s “market share,” not the *entire* market. FID at 208; Complainant’s Pet. Resp. at 20 (“Dr. Rao used Viking’s estimate that ██████████, VK2809 would have an estimated market share of

⁴⁶ Neither Respondents nor OUII dispute Dr. Rao’s additional assumption that “VK2809’s cost of capital is ██████████ percent.” FID at 206; OUII’s Pet. at 67.

between [REDACTED] of the entire NASH market.”) (citing CX-344C (Tab labelled U.S. NASH at M40-M44); JX-6C at 58:2-59:13); Complainant’s Suppl. Br. at 24-25 (same). Additionally, as the FID finds, even if the accused products capture less than 50 percent (*e.g.*, 25 percent) of VK2809’s market share, that could still lead to “a very significant diminution in sales by billions of dollars” and a “diminution in NPV by likely hundreds of millions of dollars.” *Id.*; 100-Day Tr. (Rao) at 244:1-11.

As to VK2809’s probability of technical and regulatory success, the FID correctly credits Dr. Peck’s and Dr. Rao’s testimony that such probability is [REDACTED] percent. *Id.* at 209-10. As the FID finds, the “estimate is consistent with an independent analysis by financial firm Truist, which credits VK2809 [for NASH] with a 65% probability of success.” *Id.* at 209 (citing CX-262.5). Additionally, Dr. Peck’s testimony was based on the positive Phase IIa data of VK2809 and the fact that Madrigal’s resmetirom, which has the same mechanism of action as VK2809, would proceed through the FDA’s accelerated approval program. *Id.* (citing 100-Day Tr. (Peck) at 189:16-24, 190:13-192:12). As the FID notes, Dr. Peck’s “predictions had been proven true by intervening events,” including VK2809’s positive Phase IIb data and the FDA approval of Madrigal’s resmetirom. *Id.* at 209-10 (citing Hr’g Tr. (Peck) at 509:24-510:4, 511:14-512:9;

CX-2338; CX-2339).⁴⁷ Respondents dispute VK2809’s probability of success, reasoning that Ocaliva failed to obtain FDA approval. Respondents’ Pet. at 8. However, unlike resmetirom, which did obtain FDA approval, Ocaliva has a different mechanism of action from VK2809. FID at 216; Complainant’s Pet. Resp. at 22 (citing Hr’g Tr. (Peck) at 550:12-551:22; Hr’g Tr. (Abrouk) at 1023:16-1024:6). As the FID explained, “it is ‘a well-accepted paradigm’ in the industry that approval of a product with a common mechanism of action leads the way for follow-on drugs to seek FDA approval.” *Id.* at 210-11 (citing Hr’g Tr. (Peck) at 551:3-552:1). Thus, the FID correctly finds that Ocaliva provides “little insight into the business or regulatory future of VK2809 or ASC41.” *Id.* at 216. As such, the Commission concurs with the FID’s finding that the predicate of Respondents’ uncertainty argument is effectively rebutted.

Respondents also improperly rely on an ALJ’s injury findings in a different investigation, not adopted by the Commission, arguing against injury when a drug candidate “has not yet obtained FDA approval, and even in the most optimistic case, approval is more than a year

⁴⁷ The Chief ALJ reopened the record to admit into evidence the news release about resmetirom’s FDA approval, not, as Respondents contend, the 52-week data from Viking’s Phase II clinical trials completed in 2024. Order No. 51 (citing Order No. 47, Attach. A); Respondents’ Pet. at 4. Respondents did not challenge the FID’s reliance on resmetirom’s FDA approval in their petition for Commission review. As the Chief ALJ noted, there is no prejudice to Respondents because they “treated FDA approval of resmetirom as a *fait accompli*” and they “had the opportunity to address—and in fact did address—resmetirom’s approval throughout the investigation.” Order No. 51 at 2-3. Nor did Respondents challenge the FID’s discussion of the 12-week Phase II results obtained in 2023 (they challenged the 2024 data on which the FID does *not* rely). Respondents improperly and belatedly raise these challenges in their response to the Commission’s Supplemental Notice (Respondents’ Suppl. Br. at 4-5), but these arguments are waived at this juncture. *See* 19 C.F.R. § 210.43(b)(2); Complainant’s Suppl. Reply at 2 & Ex. A. In any event, the Commission finds that the FDA approval of resmetirom and the 12-week Phase II data obtained with VK2809 in 2023, are each a “significant and unusual development” in the investigation, and therefore the Commission considers such evidence. *Certain Video Game Sys., Inv. No. 337-TA-743, Comm’n Op.*, 2012 WL 13171643, *3 (Jan. 20, 2012), *aff’d sub nom. Motiva, LLC v. ITC*, 716 F.3d 596 (Fed. Cir. 2013) (noting that the Commission considers “evidence subsequent to the filing of the complaint, for example when a significant and unusual development has occurred after the complaint has been filed”).

away.” Respondents’ Pet. at 5 (quoting *Certain Botulinum Toxin Prods. & Processes for Mfg. or Relating to the Same*, 337-TA-1313 (“*Botulinum Toxin Prods. II*”), Initial Determination, 2024 WL 4122125, *43 (June 10, 2024)). After review of this ID, however, the Commission took no position on those findings, rendering them without effect. *Botulinum Toxin Prods. II*, Comm’n Op., 2024 WL 4922008, *1 (Nov. 1, 2024).⁴⁸ For this reason, Respondents’ contention that threat of substantial injury cannot be established absent FDA approval lacks support in Commission precedent.

In the present investigation, the FID finds “highly credible” Dr. Peck’s testimony that the probability of VK2809’s technical and regulatory success is ■ percent and as discussed above, his estimate was not generic but specific to VK2809. FID at 209-10. As such, rather than a “high-level statistical overview,” the evidence in the present investigation specifically demonstrated that Viking’s domestic industry as to VK2809 is threatened by Respondents’ unfair acts, including Respondents’ explicit intention to enter the U.S. market with the competing accused products developed as a result of trade secret misappropriation. Viking is a smaller drug company and as such, it must rely on a partnership with a large pharmaceutical company to further develop and commercialize VK2809. Without a partner, Viking’s ability to engage in further development or commercialization is substantially impaired. *Id.* at 199-200 (citing 100-Day Tr. (Zante) at 124:1-5); *see also TianRui*, 661 F.3d at 1336 (noting that the Commission relies on a flexible “realities of the marketplace” test in determining the scope of a domestic

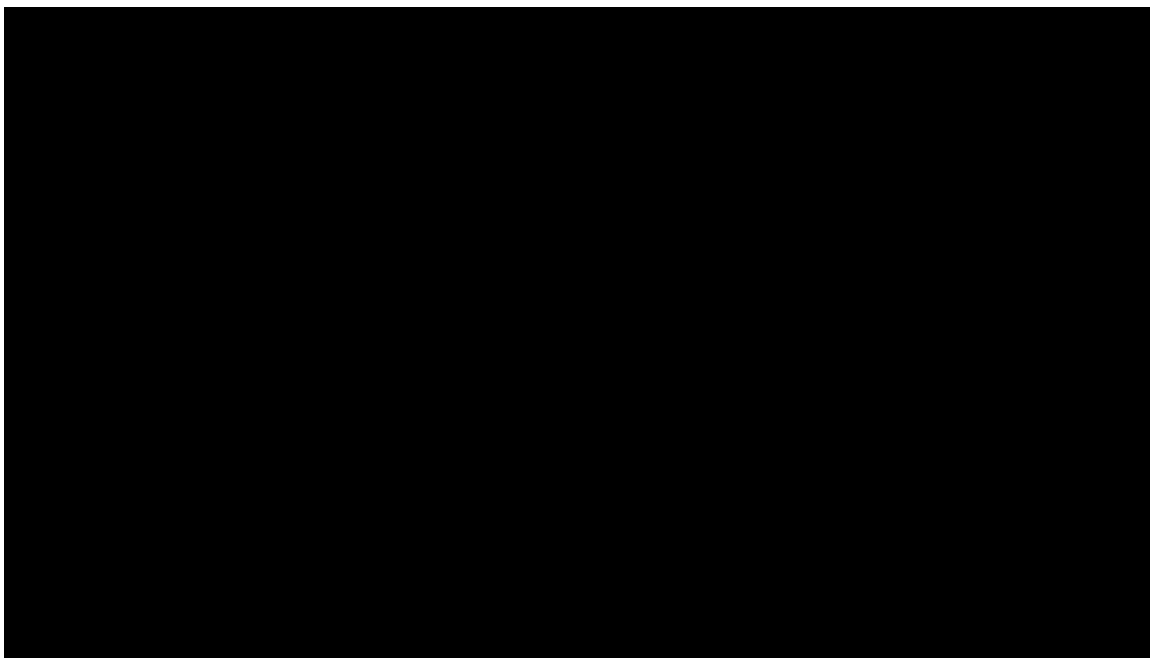
⁴⁸ Respondents incorrectly characterize the Commission’s opinion in *Botulinum Toxin Prods. II* as “not review[ing]” the ID’s finding on injury rather than taking no position on the injury issue. Respondents’ Pet. at 5. Contrary to Respondents’ misunderstanding of the Commission’s Rules of Practice and Procedure, when the Commission declines to review a finding, it effectively affirms the finding. 19 C.F.R. § 210.42(h). However, when the Commission reviews and then determines to take no position on a finding, as it did in Investigation No. 337-TA-1313, this action renders the finding without effect. *Beloit*, 742 F.2d at 1423; 19 C.F.R. § 210.45(c).

industry); *Certain Bone Cements, Components Thereof & Prods. Containing the Same*, Inv. No. 337-TA-1153, Comm’n Op., 2021 WL 287860, *9 (Jan. 25, 2021) (noting that the Commission generally considers “the nature of complainant’s claimed business activities in the United States within ‘the realities of the marketplace,’” and that “[t]his reflects the fact that each industry is unique to its particular facts and circumstances”). For the same reasons, the ALJ’s decision in *Minoxidil Powder* is distinguishable because the complainant in that investigation did not need to rely on a partnership for development or commercialization of its product. OUII Suppl. Br. at 12-13 (citing *Certain Minoxidil Powder, Salts & Compositions for Use in Hair Treatment* (“*Minoxidil Powder*”), Inv. No. 337-TA-267, Initial Determination, 1988 WL 582867, *27 (Feb. 16, 1988)).⁴⁹ Thus, the Commission finds there is threatened injury to Viking’s existing and future domestic industry, even though FDA approval has not yet been obtained.

Furthermore, while Respondents and OUII argue that there is little risk of interference by Ascletis in Viking’s recruitment efforts for Phase III clinical trials, the Commission does not rely upon any alleged clinical trial interference for VK2809 as the basis for finding threatened injury in this investigation. Thus, the Commission finds that the arguments based on clinical trial interference do not change the ultimate finding of threatened injury. Respondents’ Pet. at 12-15; OUII’s Pet. at 67-70. The FID itself does not appear to rely on clinical trial competition between Ascletis and Viking in its injury analysis and declines to “resolve the extent of injury that Viking’s domestic industry may suffer if Viking must compete with Ascletis for Phase III clinical trial resources in the United States.” FID at 214. Moreover, as the FID finds, Dr. Rao provided testimony to support injury “even if the presence of ASC41 delays Phase III clinical

⁴⁹ Although the ALJ in *Minoxidil Powder* did not find “fully manifested injury,” the ALJ found “tendency to injure” a domestic industry. *Minoxidil Powder*, 1988 WL 582867, at *27-*30.

trials for VK2809 by fewer than two years.” FID at 207 (citing 100-Day Tr. (Rao) at 242:9-243:25 (testifying in connection with CDX-6C.14 (reproduced below) that the accused drug products would cause “a significant diminution” in Viking’s sales even in the absence of a delay, and that VK2809 and ASC41 would be “splitting the market”)). Accordingly, there is still a threat of substantial injury even if there is no significant delay in Phase III clinical trials due to clinical trial competition.



CDX-6C.14.

Effect of Other NASH Treatment Drugs

The Commission finds that the FDA approval and commercial availability of resmetirom does not negate the threatened substantial injury to Viking’s existing and future domestic industry. To the contrary, the FDA approval of resmetirom improves VK28019’s own probability of FDA approval because they have the same mechanism of action. FID at 210-11 (“Dr. Peck further testified that it is ‘a well-accepted paradigm’ in the industry that approval of a product with a common mechanism of action leads the way for follow-on drugs to seek FDA

approval.”) (citing Hr’g Tr. (Peck) at 551:3-552:1). Although resmetirom and VK2809 have the same mechanism of action, they are differentiated at least with respect to efficacy and side effects, as opposed to VK2809 and the accused products, which are not differentiated. FID at 200-01 (citing CX-114.1); Complainant’s Remedy Br. at 30-31 (“VK2809 had a ‘higher percentage of fat reduction than resmetirom as well as a lower frequency of side effects.’”) (citing 100-Day Hr’g Tr. (Peck) at 191:24-192:12; CDX-5C.10); Complainant’s Suppl. Br. at 23 (same). Additionally, the market and consumers recognize the value of having more than one FDA approved NASH treatment. As OUII previously acknowledged, “[h]aving more than one approved treatment for a disease provides incremental value to patients in a variety of ways, potentially including differences in efficacy, side effects, allergic reactions, dosing, and price.” OUII’s Post-Hearing Br. at 140 (citing Hr’g Tr. at 1100:12-1101:8, 1128:12-1129:2 (Clarke⁵⁰); RX-2249 (White, C. Michael, “Why Prescription Drugs Can Work Differently for Different People,” *The Conversation* (Oct. 4, 2021))). Thus, the Commission agrees with the FID that “Viking and the market at large both recognize that Viking will not be the first drug treatment marketed for NASH,” and that “both Viking and the market have accounted for that risk — Viking has done so in its decision to continue to pursue a domestic industry developing VK2809 and the market has done so in its assessment of the value of VK2809.” FID at 216; Complainant’s Suppl. Br. at 29.

The Commission has also considered other NASH treatment drugs as part of the injury analysis and finds that these other potential NASH treatments do not negate that Respondents’ unfair acts threaten to cause substantial injury to Viking’s domestic industry. As the FID finds, “[t]he net present value for VK2809 also takes into account other drugs in the NASH treatment

⁵⁰ Mr. Andrew Clarke is Respondents’ expert in economics, domestic industry, and injury.

market.” FID at 205 (citing 100-Day Tr. (Rao) at 241:21-242:3 (testifying that the expected market share reflects that “VK2809 will be one of several NASH drugs that will enter the market”), 268:19-269:14 (testifying that the net present value model considers competitors like Madrigal with NASH drugs that have similar mechanisms as well as competition from drugs that have different mechanisms); *accord* Complainant’s Suppl. Br. at 24-25.

ii. Nexus

The Commission also agrees with the FID that Complainant established the requisite nexus between the threatened injury and the unfair acts. FID at 214-17. Nexus is not a stringent standard. Rather, nexus “lies between the unduly stringent ‘sole reason’ standard . . . and the unduly lax ‘insubstantial connection’ standard.” *Genband*, 861 F.3d at 1384; *Rubber Resins*, 2014 WL 7497801, *32 (“The threatened injury must also be substantive and clearly foreseen, with a causal connection between the action of the respondents and the threatened injury.”).

Here, the FID correctly finds that “Viking will necessarily encounter greater difficulty in bringing its drug to market than if Ascletis had not engaged in misappropriation.” FID at 215; *id.* at 217 (“Viking has shown the threat and effect of injury due to unfair acts by Ascletis, even considering the inherent uncertainties present—and accounted for—in the pharmaceutical industry.”). In particular, Respondents used Complainant’s trade secrets to develop and test the accused ASC41 and ASC43F products, causing lack of differentiation between those products and Viking’s VK2809 and threatening to split the market with VK2809 or to cause a significant diminution in VK2809’s future sales. 100-Day Tr. (Rao) at 242:9-243:25. As Dr. Rao testified, if ASC41 enters the U.S. market, the effect is essentially “two drugs with the same API that are competing with each other, [and] they would end up splitting the market.” *Id.* at 242:21-243:1; *see also TianRui*, 661 F.3d at 1337 (affirming the Commission’s injury determination where, among other considerations, a trade secret misappropriator directly competed with the trade

secret owner). Respondents' unfair acts also reduced VK2809's NPV and undermined Viking's ability to secure a partnership with a large pharmaceutical company to further develop and commercialize VK2809. Accordingly, the Commission finds that the threatened injury is substantive and clearly foreseen and that there is a nexus between Respondents' unfair acts and the threatened injury to Viking's domestic industry.

As discussed above, the market availability of resmetirom and the potential entry of other NASH treatment drugs do not negate injury. Nor do they not negate nexus. Other than the accused products, VK2809 is differentiated from all those other drugs, and both Viking and the market have accounted for them. FID at 216 (citing Hr'g Tr. (Rao) at 561:11-19; CX-262.5; CX-2401.4); *accord* Complainant's Suppl. Br. at 23-25. OUII argues against nexus because resmetirom would enjoy a "first mover advantage," but OUII itself recognizes that subsequent market entrants also capture some (albeit smaller) market shares. OUII's Suppl. Br. at 27 (citing 100-Day Tr. (Prowse) at 350:23-351:1). Additionally, OUII does not address that VK2809 has "significant advantages" over Madrigal's resmetirom. 100-Day Tr. (Prowse) at 351:8-15; 100-Day Hr'g Tr. (Peck) at 191:24-192:12 (testifying that VK2809 has "a higher percentage of fat reduction than Resmetirom as well as a lower frequency of side effects"); CDX-5C.10.

Accordingly, the Commission affirms with modified analysis the FID's finding that Viking has shown that Respondents' unfair acts threaten to cause substantial injury to Viking's domestic industry. The Commission thus finds a violation of section 337 by the corporate respondents.⁵¹

⁵¹ As discussed *supra* at section IV.B, the Commission finds that the individual respondent, Dr. Wu, acted in his corporate capacity, and therefore, liability does not attach to Dr. Wu in his personal capacity.

V. REMEDY, PUBLIC INTEREST, AND BONDING

For the reasons set forth below, the Commission has determined to issue a seven-year LEO prohibiting the unlicensed entry into the United States of certain selective thyroid hormone receptor-beta agonists, processes for manufacturing or relating to same, and products containing same, imported by or on behalf of the corporate respondents. The Commission has also determined to issue CDOs directed to each of the corporate respondents.⁵² The Commission has also determined to set a bond during the period of Presidential review at one hundred percent (100%) of the entered value of the covered articles. The Commission has further determined that the public interest statutory factors do not preclude the issuance of this remedy.

A. Remedy and Bonding

The Commission has “broad discretion in selecting the form, scope, and extent of the remedy.” *Philip Morris Prods. S.A. v. ITC*, 63 F.4th 1328, 1339-1340 (Fed. Cir. 2023) (quoting *Viscofan, S.A. v. USITC*, 787 F.2d 544, 548 (Fed. Cir. 1986)).

1. Limited Exclusion Order

Section 337(d)(1) provides that “[i]f the Commission determines, as a result of an investigation . . . that there is a violation of this section, it shall direct that the articles concerned,

⁵² Commissioner Johanson finds that the record does not support issuance of cease and desist orders against the corporate respondents. There is no evidence of any domestic inventory, and the record shows that the accused products have been imported only twice, and all of the imported products have since been destroyed (with no evidence of further acts of importation). OUII Remedy Br. at 33 (citing SX-1004C at 25; CX-1920C at 7). In addition, there is no evidence to support that Respondents have any significant domestic operations that could undercut the remedy provided by an exclusion order. *See, e.g., Certain Tobacco Heating Articles & Components Thereof*, Inv. No. 337-TA-1199, Comm’n Op. at 49, 2021 WL 4947427, *36 (Oct. 19, 2021), *aff’d*, *Philip Morris Products S.A.*, 63 F.4th at 1332. Here, Respondents represent that they will not be pursuing Phase III clinical trials or importing the accused products into the United States. Respondents’ Remedy Br. at 4 & Exhibit 1 (Wu Decl., ¶¶ 2-4). Further, Respondents did not request an exemption for importation of the accused products for clinical trials, further demonstrating the LEO is sufficient on the present record. *Id.*

imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the [public interest], it finds that such articles should not be excluded from entry.” 19 U.S.C. § 1337(d)(1); *see also Spansion, Inc. v. ITC*, 629 F.3d 1331, 1358 (Fed. Cir. 2010) (“By statute, the Commission is required to issue an exclusion order upon the finding of a Section 337 violation absent a finding that the effects of one of the statutorily-enumerated public interest factors counsel otherwise.”) (citing 19 U.S.C. § 1337(d)(1)).

The RD recommends that the Commission issue an LEO against Respondents’ accused products for a seven-year duration. *See* RD at 223-27. The RD notes that “[f]or a violation of section 337 involving trade secrets . . . the duration of the exclusion order for the trade secrets is the length of time it would have taken the respondent to develop the complainant’s trade secrets.” *Id.* at 219 (citing *Crawler Cranes*, 2015 WL 13817116, at *44; *Rubber Resins*, 2014 WL 7497801, at *43 (“The duration of an [exclusion] order in a trade secret misappropriation case is set as the time it would have taken to independently develop the trade secrets.”)); *id.* at 226 (citing *Viscofan*, 787 F.2d at 550 (“[T]he Commission correctly recognized that ‘the duration of relief in a case of misappropriation of trade secrets should be the period of time it would have taken respondent independently to develop the technology using lawful means.’”)). The RD sets the duration of the exclusion order to seven years to “allow Viking to complete Phase III trials, submit its data for final approval by the FDA, and benefit from exclusive use of its trade secrets in the United States market for at least one year.” *Id.* at 227. The RD rejects Viking’s request for a 12-year exclusive order, finding that such duration includes “marginal time periods that are unjustified by the record.” *Id.* at 224-25.

Furthermore, the RD does not recommend tailoring the LEO to “allow importation of Accused Products for clinical trial purposes.” RD at 234-35. The RD, however, recommends

that “any relief granted Viking should be subject to a periodic reporting requirement to ensure that Viking’s domestic industry in VK2809 continues during the pendency of any remedial order.” *Id.* at 235.

Complainant argues that the LEO should have a duration of at least nine years because “it would have taken Respondents approximately nine years to independently develop the Formulation, Preclinical, and Clinical Trade Secrets.” Complainant’s Remedy Br. at 6. Respondents do not offer an alternative duration for the LEO but argue that Complainant cannot meet the injury requirement, and that Respondents effectively abandoned ASC41 or ASC43F because they “will not progress to Phase III testing for ASC41 or ASC43F, and therefore will never commercialize ASC41 or ASC43F, obviating both any potential injury or need for remedial orders.” Respondents’ Remedy Br. at 1-2. OUII contends that the LEO should expire after six months because “Respondents have been shown to have benefited from just five percent of the asserted trade secrets.” OUII’s Remedy Br. at 28-30.

The Commission has determined to issue a seven-year LEO prohibiting the unlicensed entry in the United States of the covered articles imported by or on behalf of the corporate respondents. As to the duration of the LEO, the Commission does not rely on the period of market exclusivity to set such duration because it would be inconsistent with Commission and Federal Circuit precedent. Rather, the Federal Circuit in *Viscofan* held that “the duration of relief . . . should be the period of time it would have taken respondent independently to develop the technology using lawful means.” *Viscofan*, 787 F.2d at 550. Additionally, the Federal Circuit rejected any argument that the duration should be “the time it would have required [respondent] to discover each particular trade secret independently and without regard to the total process.” *Id.*

PUBLIC VERSION

Following the *Viscofan* analysis, we agree with the RD that a 12-year LEO is unjustified by the record. RD at 224. Viking itself acknowledges that it could take less than twelve years (e.g., nine years) for Respondents to independently develop Viking's trade secrets. *Id.* at 222 (citing Hr'g Tr. (Silber) at 429:15-432:4); *see also* CDX-1045C.49; *accord* Complainant's Remedy Br. at 6. Rather, the record evidence (as limited to those trade secrets found to be misappropriated) supports a seven-year limited exclusion order. Complainant's Remedy Br. at 4-5 (citing Attach. C); Complainant's Remedy Reply at 12 (same).

Specifically, the record evidence shows that it would take: (1) 9 to 12 months to independently develop the formulation trade secrets, including with respect to TS Nos. 4-9; (2) about three years to independently develop the preclinical trade secrets, including with respect to TS Nos. 17-18 (relevant subparts); and (3) about three years to independently develop the clinical trade secrets, including with respect to TS Nos. 12, 13, and 15 (relevant subparts). Complainant's Remedy Br. at 4-5 (citing Attach. C, reproduced below in relevant part); Hr'g. Tr. (Masamune⁵³) at 167:7-23, 168:22-169:15, 174:24-176:16.; Hr'g Tr. (Mancini) at 236:10-238:24, 241:19-24; *see also* Hr'g Tr. (Silber) at 426:24-427:4, 429:18-430:10; Hr'g Tr. (Amidon⁵⁴) at 290:3-19; CDX-1045C.49.

⁵³ Dr. Horoko Masamune is Viking's former chief development officer.

⁵⁴ Dr. Gregory Amidon is Complainant's technical expert in this investigation.

PUBLIC VERSION

Trade Secrets Determined to be Misappropriated in the FID		
Trade Secret Nos.	Trade Secret	Time to Develop and Citation in Record
4-11, 34, 36-37, 44	The Formulation Trade Secrets	9-12 months Hr'g. Tr. at 167:7-23; JX-1012C (267:19-268:2; 269:20-270:5); Hr'g. Tr. 168:22-169:15. CX/CDX-1010C at .0011-.0014; CX/CDX-1033C; CX/CDX-1026C
13.1-13.7 12.11 15.1		36 months Hr'g. Tr. 237:13-238:24; 241:19-24; 244:4-6; 244:16-245:2; Hr'g. Tr. 236:10-237:12. CX/CDX-1011C at .0004-.0010, .0025-.0046; CX/CDX-1019C.0011-.0012
17 ¹ -17.12		32 months Hr'g. Tr. 174:24-176:16. CX/CDX-1016C; CX/CDX-1002C
18.1-18.3		~2 months JX-1012C (Masamune depo) at 308:14-309:7 (TSs 18.1-18.3 are different portions of the same report). CX/CDX-1018C at .0001-.0003, .0005-.0010

The Commission also credits few additional months up to a seven-year LEO for research and analysis to gain confidence on whether to develop the accused products. Complainant's Remedy Br. at 7 (citing Hr'g Tr. (Silber) at 426:24-427:4). The seven-year duration does not simply aggregate the time to develop each trade secret independently but takes into account the consecutive nature of the process of developing the formulation trade secrets, the preclinical trade secrets, and the clinical trade secrets. The duration also takes into account the overlap in developing these various trade secrets. Complainant's Remedy Br. at 7 (citing CDX-1045C.48).

Complainant's request for a longer LEO duration is not supported by the record because such request is not limited to those trade secrets found to be misappropriated by the Respondents. Respondents offer no alternative duration or analysis concerning the LEO. As to OUII's approach to allocate six months per trade secret, the Commission agrees with the RD that it

incorrectly assumes that “all trade secrets are equally important” and therefore, it is “not supported by the record.” RD at 225.

Furthermore, the Commission declines to include an exemption in the LEO for the importation of accused products for use in clinical trials as necessary to obtain FDA approval of those products. To begin, Respondents do not request such an exemption, stating that “[they] have no on-going clinical trials in the United States for ASC41 or ASC43F, will not progress to Phase III testing of these products, and will therefore never import ASC41 or ASC43F into the United States.” Respondents’ Remedy Br. at 4 & Exhibit 1 (Wu Decl., ¶¶ 2-4).

As to the RD’s proposed reporting requirement with respect to Viking’s domestic industry (RD at 233-35), the Commission finds it unnecessary because, if Complainant abandons its domestic industry and Respondents substantiate that “the conditions which led to [the] exclusion from entry or order no longer exist,” Respondents could file a petition for modification or rescission of the LEO under section 337(k) (19 U.S.C. § 1337(k)) and Commission Rule 210.76 (19 C.F.R. § 210.76). *Cf. Enercon GmbH v. USITC*, No. 97-1164, 1997 WL 218517, *1 (Fed. Cir. Apr. 24, 1997) (unpublished) (remanding to the Commission to institute rescission or modification proceedings to consider domestic industry in view of a change in patent ownership).

Lastly, in addition to the standard certification provision,⁵⁵ the Commission has determined to include in the LEO a provision requiring a ruling (via an advisory opinion or a modification proceeding) from the Commission prior to the importation of any covered articles,

⁵⁵ “The standard certification provision does not allow an importer to simply certify that it is not violating the exclusion order.” *Certain Composite Aerogel Insulation Materials & Methods for Mfg. the Same*, Inv. No. 337-TA-1003, Comm’n Op., 2018 WL 8648369, *40 (Feb. 22, 2018). Rather, “CBP only accepts a certification that the goods have been previously determined by CBP or the Commission not to violate the exclusion order.” *Id.*

PUBLIC VERSION

as to whether the articles are based on trade secret misappropriation. This is consistent with the Commission’s opinion in *Botulinum Toxin Products*, which similarly involved trade secret misappropriation and where it was not readily apparent by inspection at the border whether an imported product is manufactured using the misappropriated trade secrets. *See Botulinum Toxin Prods.*, 2021 WL 141507, at *34; *see also* 19 C.F.R. § 210.79 (advisory opinions); 19 C.F.R. § 210.76 (modification proceedings). Here, the covered articles are “drug products and drug substances that are selective thyroid hormone receptor-beta agonists for the treatment of metabolic disorders and liver diseases.” 88 FR at 8456; *see also Hyundai Elecs. Indus. Co. v. USITC*, 899 F.2d 1204, 1210 (Fed. Cir. 1990) (upholding the Commission’s practice of “shift[ing] to would-be importers of potentially infringing articles, as a condition of entry, the burden of establishing noninfringement” and “placing the risk of unfairness associated with a prophylactic order upon potential importers rather than American manufacturers”); *Certain Automated Mech. Transmission Sys. for Medium-Duty & Heavy-Duty Trucks & Components Thereof*, Inv. No. 337-TA-503, Comm’n Op., 2007 WL 4473082, *10 (Aug. 1, 2007) (“[T]he scope of the remedy is dependent upon the scope of the investigation, which is determined by the notice of investigation.”); *Certain Optical Disk Controller Chips & Chipsets & Prods. Containing Same, Including DVD Players And PC Optical Storage Devices*, Inv. No. 337-TA-506, Comm’n Op., 2007 WL 4713920, at *64 (Sept. 28, 2005) (“[W]hile individual models may be evaluated to determine importation and infringement, the Commission’s jurisdiction extends to all models of infringing products that are imported at the time of the Commission’s determination and to all such products that will be imported during the life of the remedial orders.”).

Accordingly, the Commission has determined to issue a seven-year LEO prohibiting the unlicensed entry into the United States of any covered articles imported by or on behalf of the corporate respondents.

2. Cease and Desist Orders

Section 337(f)(1) provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a CDO as a remedy for violation of section 337. *See* 19 U.S.C. § 1337(f)(1). CDOs are generally issued when, with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order. *See, e.g., Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 337-TA-1199, Comm’n Op. at 49 (Sept. 29, 2021), *aff’d*, *Philip Morris Prods.*, 63 F.4th at 1332; *Certain Audio Players and Controllers, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-1191, Comm’n Op. at 26 (Jan. 6, 2022), *aff’d*, *Sonos, Inc. v. Int’l Trade Comm’n*, 2024 WL 1507605 (Fed. Cir. Apr. 8, 2024). Complainants bear the burden on this issue. “A complainant seeking a cease and desist order must demonstrate, based on the record, that this remedy is necessary to address the violation found in the investigation so as to not undercut the relief provided by the exclusion order.” *Tobacco Heating Articles*, Comm’n Op. at 49-50 (citations omitted); *Audio Players*, Comm’n Op. at 26-27 (citations omitted).

The RD recommends that the Commission issue a CDO against each of Respondents. RD at 231. Although the RD recognizes “there currently may be no inventory of the accused products in the United States,” the RD reasons that “the record supports a finding that Ascleitis intends to re-enter the U.S. market.” *Id.* Complainant argues that Respondents have significant operations in the United States because one of Respondents’ subsidiaries, Gannex LLC, is a U.S. entity and is responsible for Respondents’ partnership efforts relating to the accused products.

PUBLIC VERSION

Id. at 229; Complainant’s Remedy Br. at 8-9. Complainant further argues that without CDOs, Respondents can circumvent the LEO by stockpiling the accused products and using them for clinical trials. *Id.* at 229-30; Complainant’s Remedy Br. at 13.

The Commission finds that the present record supports issuing CDOs against the corporate respondents because their representatives are present in the United States, including Dr. Wu, as well as a related entity, Gannex LLC.⁵⁶ *See Certain Power Converter Modules & Computing Sys. Containing the Same*, Comm’n Op., 337-TA-1370, 2025 WL 857695, *72 (Feb. 26, 2025) (“The Commission has previously issued CDOs against foreign respondents where their domestic distributor is not a respondent, so as to effectively bind the domestic distributor.”) (citation omitted). Although there may be no evidence of any current domestic inventory, these representatives are actively engaging with potential partners to commercialize their products, which we view as significant domestic operations in the context of this investigation. RD at 231; *accord* Respondents’ Remedy Reply at 2-3; OUII’s Remedy Br. at 33-34. In particular, as part of the sanctions order, the Chief ALJ imposed certain adverse inferences, including that Respondents intend to conduct Phase III trials and to commercialize the accused products in the United States if permitted by the FDA. FID at 56. As Complainant explains, some of Respondents’ employees reside in the United States and can and do pursue partnership opportunities on behalf of Respondents (Complainant’s Remedy Br. at 8-9), and such efforts by Respondents would further cause threatened injury to Viking’s ability to differentiate its products from those of the adjudicated misappropriator here. While any partnerships between Respondents and other pharmaceutical companies would be constrained by the LEO’s prohibition against the importation of the accused products during the pendency of the LEO,

⁵⁶ *See supra* note 52.

PUBLIC VERSION

Respondents' efforts toward developing partnerships based on imported accused products would wreak additional harm to Complainant's business due to the unfair acts of Respondents.

The Commission also agrees with Complainant's argument that CDOs are necessary to prevent Respondents from stockpiling the accused products during the period of Presidential review to later conduct clinical trials in the United States. Complainant's Remedy Br. at 13. While Respondents represent, without evidentiary support, that they will not be pursuing Phase III clinical trials or importing the accused products into the United States in their remedy brief, the record evidence prior to their submission undermines this recent assertion. Respondents' Remedy Br. at 4 & Exhibit 1 (Wu Decl., ¶¶ 2-4). For that reason, Respondents state that they did not even request an exemption for importation of the accused products for clinical trials. *Id.* Without the protections afforded by CDOs, Complainant remains vulnerable to further unfair acts that may not be addressed by an LEO alone.

Thus, the Commission has determined to issue CDOs against the corporate respondents.

3. Bonding

If the Commission enters an exclusion order and/or a cease and desist order, a respondent may continue to import and sell its products during the 60-day period of Presidential review under a bond in an amount determined by the Commission to be "sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3); *see also* 19 C.F.R. § 210.50(a)(3). When reliable price information is available in the record, the Commission has often set the bond in an amount that would eliminate the price differential between the domestic product and the imported, infringing product. *See Streaming Players*, Comm'n Op. at 41-42 (citations omitted); *Tobacco Heating Articles*, Comm'n Op. at 77 (citations omitted). The Commission also has used a reasonable royalty rate to set the bond amount where a reasonable royalty rate could be ascertained from the evidence in the record. *See id.* Where the record establishes that the

PUBLIC VERSION

calculation of a price differential is impractical or there is insufficient evidence in the record to determine a reasonable royalty, the Commission has imposed a 100 percent bond. *See id.*

The RD recommends that the Commission set a bond of one hundred percent (100%) of the entered value of covered articles imported by or on behalf of the Respondents during the period of Presidential review. RD at 232-33. The RD notes that “Viking and Ascleitis have stipulated that ‘[a] bond rate of 100% would protect Complainant from any injury resulting from ASC41 and ASC43F that are imported under bond during the 60-day Presidential review period.’” *Id.* (citing JX-1001.1 at ¶ 2); *accord* Complainant’s Remedy Br. at 41; OUII’s Remedy Br. at 34.

In view of the stipulation between Viking and Ascleitis, the Commission has determined to set a bond of one hundred percent (100%) of the entered value of covered products imported by or on behalf of the corporate respondents during the period of Presidential review.

B. Public Interest

Section 337 requires the Commission, upon finding a violation of section 337, to issue remedial orders “unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.” 19 U.S.C. § 1337(d)(1). Similarly, the Commission must consider these public interest factors before issuing a CDO. 19 U.S.C. § 1337(f)(1).

Under appropriate facts and circumstances, the Commission may determine that no remedy should issue because of the adverse impacts on the public interest. *See, e.g., Certain Fluidized Supporting Apparatus & Components Thereof*, Inv. Nos. 337-TA-182/188, USITC Pub. 1667, Comm’n Op. at 1-2, 23-25 (Oct. 1984) (finding that the public interest warranted denying complainant’s requested relief); *see Philip Morris Prods.*, 63 F.4th at 1339-1340 (the

PUBLIC VERSION

Commission has “wide latitude for judgment and the courts will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to exist”) (citation omitted). Moreover, when the circumstances of a particular investigation require, the Commission has tailored its relief considering the statutory public interest factors. For example, the Commission has allowed continued importation for ongoing medical research, exempted service parts, grandfathered certain infringing products, and delayed the imposition of remedies to allow affected third-party consumers to transition to non-infringing products. *E.g., Certain Microfluidic Devices*, Inv. No. 337-TA-1068, Comm’n Op. at 1, 22-48, 53-54 (analyzing the public interest, discussing applicable precedent, and ultimately issuing a tailored LEO and a tailored CDO); *Certain Road Milling Machines & Components Thereof*, Inv. No. 337-TA-1067, Comm’n Op. at 32-33 (July 18, 2019) (exempting service parts); *Certain Baseband Processor Chips & Chipsets, Transmitter, & Receiver (Radio) Chips, Power Control Chips, & Prods. Containing Same, Including Cellular Tel. Handsets*, 337-TA-543, USITC Pub. No. 4258, Comm’n Op. at 150-151 (Oct. 2011) (grandfathering certain products); *Certain Personal Data & Mobile Comm’n Devices & Related Software*, 337-TA-710, USITC Pub. No. 4331, Comm’n Op., at 72-73, 80-81 (June 2012) (delaying imposition of remedy).

In the present case, the Commission directed the presiding ALJ to “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 to “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).” 88 FR at 8456. The RD concluded that “none of the public interest factors weigh in favor of curtailing a remedy in this investigation.” RD at 236-38.

As explained below, the Commission has determined that the public interest factors do not preclude the issuance of the remedial orders discussed above.

1. Public Health and Welfare

The RD finds that “the issuance of remedial orders in this investigation would not pose health, safety, or welfare concerns in the United States with respect to the accused ASC41 and ASC43F products.” RD at 236. The RD reasons that “there are no current U.S. clinical trials for ASC41 or ASC43F,” and that “other selective thyroid hormone receptor-beta agonists in advanced stages of development could replace any excluded accused product.” *Id.* at 236-37; Hr’g Tr. (Peck) at 513:1-514:5; *see also* CDX-1040C.8. The RD also recommends against tailoring the remedial orders to allow importation of accused products for clinical trial purposes. *Id.* at 234-35.

The parties do not dispute that NASH treatments are critical to the public health and welfare. Complainant’s Remedy Br. at 16-17; Respondents’ Remedy Br. at 1-3; OUII’s Remedy Br. at 35. NASH, which results from fat buildup in the liver and causes inflammation and liver damage, affects 6 to 15 million patients in the United States. FID at 9-10 (citing 100-Day Tr. (Mancini) at 109:23-110:2); *accord* Complainant’s Remedy Br. at 20; Respondents’ Remedy Br. at 2; OUII’s Remedy Br. at 5. Within that population, about 1.5 million people have been diagnosed with NASH. Complainant’s Remedy Br. at 20.

In addition, the Respondents do not request an exemption for the importation of accused products for use in clinical trials as necessary to obtain FDA approval of those products. Respondents’ Remedy Br. at 4 & Exhibit 1 (Wu Decl., ¶¶ 2-4). As Respondents explain, “[they] have no on-going clinical trials in the United States for ASC41 or ASC43F, will not progress to Phase III testing of these products, and will therefore never import ASC41 or ASC43F into the United States,” and thus “Respondents are not requesting a carve-out for the importation of

PUBLIC VERSION

ASC41 or ASC43F.” *Id.* Although the evidence and adverse inferences in this investigation support a finding that Respondents intend to import the accused products upon obtaining FDA approval, the Commission nonetheless takes to account Respondents’ own representation that they do not request a carve-out and do not intend to import ASC41 or ASC43F. Complainant and OUII also argue that an exemption is not necessary. Specifically, Complainant notes that there are several potential substitutes, including Madrigal’s resmetirom and Viking’s VK2809, as well as other selective thyroid hormone receptor-beta agonists, in more advanced stages of development than the accused products. *See* Complainant’s Remedy Br. at 16-17 (citing Hr’g Tr. (Peck) at 513:1-514:5, Exhibits 1-5 (clinicaltrial.gov printouts for Phase III trials for Survodutide, Efruxifermin, Pegzofermin, Lanifibranor, and Semaglutide)); OUII’s Remedy Br. at 6-7 (same).

Furthermore, there is no dispute that resmetirom is effective for the treatment of NASH, and that resmetirom can presently meet market demand for most NASH patients. OUII’s Remedy Br. at 13-14 (citing Order No. 47, Attach. A (FDA press release on FDA approval of Rezdiffra (resmetirom)); Complainant’s Remedy Br. at 30; Respondents’ Remedy Br. at 7-8; *see also* OUII’s Remedy Reply at 6; Complainant’s Remedy Br. at 33 (“Rezdiffra (resmetirom) is currently meeting market demand.”); Respondents’ Remedy Br. at 10 (“Based on publicly available information, there has been no indication that Madrigal is facing shortages for resmetirom, suggesting that Madrigal has been able to meet demand, and will be able to continue doing so.”). Complainant further argues that its VK2809 drug product may be even more effective than resmetirom for the treatment of NASH. Complainant’s Remedy Br. at 30 (citing 100-Day Hr’g Tr. (Peck) at 191:24-192:12 (testifying that Viking’s drug product has a higher percentage of fat reduction than resmetirom and a lower frequency of side effects); CDX-5C.10).

PUBLIC VERSION

As discussed in our injury analysis above, the evidence shows that VK2809 cannot be differentiated from the accused products because they have the same API and mechanism of action. Thus, even if the accused products are excluded, we find that the market demand for NASH treatments would be satisfied by at least resmetirom and VK2809 (provided it is FDA-approved and commercialized in the absence of unfair competition from Respondents' accused products). The Commission also notes that no members of the public have requested an exemption to the remedial orders based on public health and welfare considerations.

Lastly, neither Viking nor Ascleitis currently have any patients enrolled in clinical trials so the proposed remedial orders will not cause any disruption on such trials. Complainant's Remedy Br. at 34-41; Respondents' Remedy Br. at 11-13; OUII's Remedy Br. at 21-24.

Thus, the Commission finds that the exclusion of the covered articles would not adversely affect the public health and welfare.

2. Competitive Conditions in the United States Economy

The RD finds that "the issuance of remedial orders would not have an adverse impact on the competitive conditions in the U.S. economy." RD at 237. The RD explains that "the prevalence of NASH in the United States is such that a remedial order in this investigation would not affect incentives for the development of other treatments for NASH." *Id.* (citing Hr'g Tr. (Mancini) at 109:23-110:2).

The parties do not dispute the RD's findings as to this public interest factor. Complainant's Remedy Br. at 19 ("The RD correctly determined that the record establishes that the competitive conditions in the U.S. economy will not be adversely impacted by the exclusion of the Accused Products."); Respondents' Remedy Br. at 1 (stating that "Madrigal Pharmaceuticals received FDA approval for the first NASH drug on the market, Rezdiffra (resmetirom)," and that "Eli Lilly and Novo Nordisk both sought approval for their blockbuster

GLP-1 weight loss drugs to treat NASH, making the market even more competitive”); OUII’s Remedy Br. at 36 (agreeing with the RD finds that “the prevalence of NASH in the United States is such that a remedial order in this investigation would not affect incentives for the development of other treatments for NASH”). Thus, the Commission finds that this factor does not preclude the issuance of remedial orders in this investigation.

3. Production of Like or Directly Competitive Articles

The RD finds that the “issuance of remedial orders in this investigation would not have an adverse impact on the production of like or directly competitive articles in the United States.” RD at 237-38. The RD explains that “Respondents manufacture the accused products in China, and thus there would not be any impact on U.S. production of the accused products if a remedial order issued.” *Id.* at 238 (citing 100-Day Tr. (Wu) at 403:22-404:1); *accord* OUII’s Remedy Br. at 36; Complainant’s Remedy Br. at 19. Moreover, the RD continues, “Viking currently manufactures VK2809 in the United States and plans to commercially manufacture it in the United States.” *Id.* (citing Hr’g Tr. (Morneau) at 46:5-14); Complainant’s Remedy Br. at 19.

The parties do not dispute the RD’s findings as to this public interest factor. Complainant’s Remedy Br. at 19-20; OUII’s Remedy Br. at 36. Thus, the Commission finds that this factor does not preclude the issuance of remedial orders in this investigation.

4. United States Consumers

The RD finds that “this public interest factor does not weigh against imposing a remedy in the event the Commission finds a violation of section 337.” RD at 238. The record evidence shows that there is an existing alternative (resmetirom) that is FDA-approved and currently available to U.S. consumers, as well as potential future alternatives other than the accused products. *Id.* (“Madrigal’s resmetirom drug has been FDA-approved to treat NASH, and U.S. consumers will have access to appropriate treatments in the event the accused products are

excluded from entry.”); *id.* (“Viking’s VK2809 will provide the same or substantially the same benefits as the excluded products, and there are other drugs approved or being developed for the treatment of NASH that are in more advanced stages of development than the Accused Products.”); *accord* Complainant’s Remedy Br. at 20; OUII’s Remedy Br. at 36-37. Thus, the Commission finds that the effect of the proposed remedy on U.S. consumers does not warrant denial of remedial relief.

VI. CONCLUSION

For the foregoing reasons,⁵⁷ the Commission has determined that Viking has established a violation of section 337 by the corporate respondents based on the misappropriation of certain trade secrets owned by Viking, the threat of which is to destroy or substantially injure a domestic industry. The Commission has also determined that: (1) the appropriate remedy is a seven-year LEO against certain selective thyroid hormone receptor-beta agonists, processes for manufacturing or relating to same, and products containing same, imported by or on behalf of the corporate respondents, and CDOs against each of the corporate respondents; (2) the public interest does not preclude that remedy; and (3) the bond during the period of Presidential review is set at one hundred percent (100%) of the entered value of covered articles.

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: June 26, 2025

⁵⁷ The Commission has also considered all of the other arguments by the parties and does not find them persuasive.

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

**INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND
RECOMMENDATION ON REMEDY AND BOND**

Chief Administrative Law Judge Clark S. Cheney

(October 3, 2024)

Appearances:

For Complainant Viking Therapeutics, Inc.:

Kecia J. Reynolds, Esq., Jeff A. Pade, Esq., Richard E. Rothman, Esq., Mark Consilvio, Esq., Brandon Howell, Esq., and Josh Lopez, Esq., of Paul Hastings LLP of Washington, DC

Bruce M. Wexler, Esq., Eric W. Dittmann, Esq., Isaac Ashkenazi, Esq., Dana Weir, Esq., Amanda E. Hoffman, Ph.D., Esq., and Zachary D. Hadd, Esq., of Paul Hastings LLP of New York, NY

Mark Smith, Esq., Summer Stevens, Esq., and Cheron Z. Mimms, Esq., of Paul Hastings LLP of Chicago, IL

Richala Jackson, Esq., of Paul Hastings LLP of Houston, TX

For Respondents Ascleitis Bioscience Co., Ltd.; Gannex Pharma Co., Ltd.; Ascleitis Pharmaceuticals Co. Ltd.; Ascleitis Pharma Inc.; and Jinzi Jason Wu:

Paul F. Brinkman, Esq., Gregg F. LoCascio, Esq., and Karthik Ravishankar, Esq., of Kirkland & Ellis LLP of Washington, DC

PUBLIC VERSION

Jeanna Wacker, Esq., Matthew B. Hershkowitz, Esq., and Laura Zhu, Esq., of Kirkland & Ellis LLP of New York, NY

Tasha Francis Gerasimow, Ph.D., Esq., of Kirkland & Ellis LLP of Chicago, IL

Kristen P.L. Reichenbach, Ph.D., Esq., of Kirkland & Ellis LLP of San Francisco, CA

Tianjing Zhang, Esq., Yue Qiu, Esq., and Nan Hu, Esq., of Kirkland & Ellis International LLP of Shanghai, China

Michael F. Heafey, Esq. (withdrawn) and Matthew H. Poppe, Esq. (withdrawn) of Rimon, P.C. of Menlo Park, CA

Jason Xu, Esq. (withdrawn) of Rimon, P.C. of Washington, DC

Amy Baker, Esq. (withdrawn) of Rimon, P.C. of Orlando, FL

For the Office of Unfair Import Investigations:

Margaret D. Macdonald, Esq., Jeffrey T. Hsu, Esq., Anne Goalwin, Esq., and Lisa Murray, Esq.

Table of Contents

I.	Introduction.....	2
A.	Procedural History.....	2
B.	The Private Parties	7
1.	Complainant Viking.....	7
2.	Respondents	7
C.	Overview of NASH.....	9
D.	Overview of the FDA Drug Development Process	10
E.	Products at Issue.....	13
1.	The Alleged Domestic Industry: Viking’s VK2809.....	14
2.	The Accused Products: Ascleitis’s ASC41 Tablets and ASC43F Tablets	16
3.	Relevant Non-Party Products.....	17
F.	Identification of Asserted Trade Secrets.....	17
1.	Formulation Trade Secrets	21
2.	Preclinical Trade Secrets.....	23
3.	Clinical Trade Secrets	26
G.	Findings of Fact Concerning the History of Viking and Ascleitis.....	30
1.	Viking’s Acquisition and Development of VK2809 Assets.....	30
2.	Viking’s 2016 and 2019 Virtual Data Rooms	31
II.	Sanctions for Discovery Violations by Ascleitis.....	33
A.	Timeline of Discovery Events.....	33
B.	Viking’s Omnibus Motion for Sanctions.....	43
C.	Rimon’s Motion to Intervene	44
D.	Legal Standards	46
1.	Sanctions.....	46
2.	Duty of Competence	48
E.	Ascleitis’s Sanctionable Behavior.....	49
1.	Misrepresentations by Ascleitis and Its Counsel at the Rimon Law Firm.....	49
2.	Violation of Order No. 14.....	51
3.	Violation of Order No. 24.....	51
4.	Violation of Order No. 27.....	52
F.	Appropriate Remedy for Ascleitis’s Violations.....	54

1.	Adverse Inferences	56
2.	Monetary Sanctions	57
3.	Apportionment of Liability	59
III.	Statutory Authority	61
IV.	Importation.....	62
V.	Trade Secret Misappropriation by Ascleitis.....	62
A.	Legal Standards	63
B.	Viking Owns the Asserted Trade Secrets	66
C.	Viking Carefully Guards the Secrecy of the Asserted Trade Secrets	67
1.	Factual Findings.....	67
2.	Conclusions Regarding <i>Botox</i> Factors (1), (2), and (3)	71
D.	The Asserted Trade Secrets Are Not Generally Known or Readily Ascertainable and Are Valuable	72
1.	Asserted Formulation Trade Secrets	72
2.	Asserted Preclinical Trade Secrets.....	97
3.	Asserted Clinical Trade Secrets	124
4.	Conclusions Regarding <i>Botox</i> Factors (4), (5), and (6)	135
E.	Ascleitis Accessed Viking's Protectable Trade Secrets While in a Confidential Relationship	136
1.	The Agreements Between Viking and Ascleitis.....	136
2.	The Identity of Documents in the 2016 and 2019 Virtual Data Rooms.....	139
3.	Ascleitis Accessed the Asserted Trade Secrets	140
F.	Disclosure or Use of the Protectable Trade Secrets and Ascleitis's Independent Development Defenses	143
1.	Formulation Trade Secrets	143
2.	Preclinical Trade Secrets.....	156
3.	Clinical Trade Secrets	166
VI.	Domestic Industry.....	174
A.	Legal Standards	174
1.	Requirements for an Industry in the United States	174
2.	Requirements for an Industry in the Process of Being Established.....	179
B.	Viking's Present Domestic Industry.....	181
1.	Investments in the VK2809 Capsule Formulation.....	183
2.	Payments to Consultants, Manufacturers, and Contract Research Organizations	185
3.	Significance of Viking's Domestic Investments	186

C.	Viking's Domestic Industry in the Process of Being Established	188
VII.	Injury.....	189
A.	Injury to Viking Allegedly Attributable to Ascleitis's Unfair Acts	192
1.	Ascleitis's Trade Secret Misappropriation Is Injury under Section 337(a)(1)(A).....	193
2.	Loss of Partnership Opportunities Due to Lack of Drug Differentiation	199
3.	Decrease in VK2809's Net Present Value.....	205
4.	Interference with Viking's Phase III Clinical Trials	212
B.	The Threat and Injury Here Is Not Unduly Speculative	214
VIII.	Conclusions of Law	217
IX.	Recommended Determination on Remedy and Bond.....	218
A.	Limited Exclusion Order	219
1.	Viking's Proposed Duration for a Limited Exclusion Order	220
2.	Ascleitis's Proposed Duration for a Limited Exclusion Order	221
3.	Staff's Proposed Duration for a Limited Exclusion Order	222
4.	Recommendation	223
B.	Cease and Desist Order	227
1.	Viking Argues a Cease and Desist Order Is an Appropriate Remedy.....	228
2.	Ascleitis Argues a Cease and Desist Order Is Not Warranted	230
3.	Staff Argues a Cease and Desist Order Is Not Warranted.....	230
4.	Recommendation	231
C.	Bond During Presidential Review.....	232
D.	Tailoring of Remedial Orders.....	233
X.	Findings of Fact with Respect to the Public Interest	235
A.	Public Health and Welfare.....	236
B.	Competitive Conditions in the U.S. Economy	237
C.	Production of Like or Directly Competitive Articles in the United States.....	237
D.	U.S. Consumers.....	238
E.	Public Interest Conclusion	238
XI.	Initial Determination on Violation.....	238
XII.	Order	239

Table of Abbreviations

100-Day Tr.	100-day evidentiary hearing transcript
API	Active pharmaceutical ingredient
CDA	Confidential disclosure agreement
CDX	Complainant's demonstrative exhibit
CIB	Complainant's initial post-hearing brief
CIBI	Complainant's initial post-hearing brief on injury (100-day proceeding)
CMC	Chemical, manufacturing, and controls
CMC Tr.	Case management conference transcript
CPB	Complainant's pre-hearing brief
CPBI	Complainant's pre-hearing brief on injury (100-day proceeding)
CPX	Complainant's physical exhibit
CRB	Complainant's responsive post-hearing brief
CRBI	Complainant's responsive post-hearing brief on injury (100-day proceeding)
CRO	Contract (or clinical) research organization
CX	Complainant's exhibit
Decl.	Declaration
Depo.	Deposition
DTSA	Defend Trade Secrets Act of 2016
FDA	U.S. Food and Drug Administration
FXR	Farnesoid X receptor
GI	Gastrointestinal
HME	Hot melt extrusion
Hr'g Tr.	Evidentiary hearing transcript
IB	Investigator's brochure
IND	Investigational new drug
JDX	Joint demonstrative exhibit
JX	Joint exhibit
MLA	Master license agreement
NAFLD	Non-alcoholic fatty liver disease
NASH	Non-alcoholic steatohepatitis
NDA	New drug application
NPV	Net present value
PEG	Polyethylene glycol
PK	Pharmacokinetics
PTO	U.S. Patent and Trademark Office
R&D	Research and development
RDX	Respondents' demonstrative exhibit
RFA	Request for admission

PUBLIC VERSION

RFP	Request for production
RIB	Respondents' initial post-hearing brief
RIBI	Respondents' initial post-hearing brief on injury (100-day proceeding)
RPB	Respondents' pre-hearing brief
RPBI	Respondents' pre-hearing brief on injury (100-day proceeding)
RPX	Respondents' physical exhibit
RRB	Respondents' responsive post-hearing brief
RRBI	Respondents' responsive post-hearing brief on injury (100-day proceeding)
RX	Respondents' exhibit
SDX	Staff's demonstrative exhibit
SEC	Securities and Exchange Commission
SIB	Staff's initial post-hearing brief
SIBI	Staff's initial post-hearing brief on injury (100-day proceeding)
SPB	Staff's pre-hearing brief
SPBI	Staff's pre-hearing brief on injury (100-day proceeding)
SPX	Staff's physical exhibit
SRB	Staff's responsive post-hearing brief
SRBI	Staff's responsive post-hearing brief on injury (100-day proceeding)
Stip.	Stipulation
SX	Staff's exhibit
TR- β	Thyroid hormone receptor-beta
TS	Trade secret
UTSA	Uniform trade secrets act
VDR	Virtual data room

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

**INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND
RECOMMENDATION ON REMEDY AND BOND**

Chief Administrative Law Judge Clark S. Cheney

(October 3, 2024)

Pursuant to the Notice of Investigation, 88 Fed. Reg. 8455 (Feb. 9, 2023), and 19 C.F.R. §§ 210.10(b), 210.42(a)(1)(i), this is the final initial determination 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.

For the reasons stated herein, I have determined that a violation of section 337 of the Tariff Act of 1930, as amended, has occurred in the importation into the United States of certain drug products and drug substances that are selective thyroid hormone receptor-beta agonists for the treatment of metabolic disorders and liver diseases, based on 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.

I. INTRODUCTION

A. Procedural History

On December 29, 2022, complainant Viking Therapeutics, Inc. (“Viking”) filed a complaint alleging violations of section 337 of the Tariff Act of 1930, as amended, based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain selective thyroid hormone receptor-beta agonists, processes for manufacturing or relating to same, and products containing same. 88 Fed. Reg. 883 (Jan. 5, 2023); *see* EDIS Doc. IDs 787049 and 787052 (confidential and public filings). Viking supplemented the complaint on January 13, 2023. *See* EDIS Doc. ID 787966.

On February 9, 2023, the Commission instituted Investigation No. 337-TA-1352 to determine:

[W]hether 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.

88 Fed. Reg. 8455 (Feb. 9, 2023) (“Notice of Investigation”).

The plain language description of the accused products in the complaint defines the scope of the investigation. 19 C.F.R. § 210.10(b)(1). The products are described as “drug products and drug substances that are selective thyroid hormone receptor-beta agonists for the treatment of metabolic disorders and liver diseases.” Notice of Investigation.

The Notice of Investigation named the following entities as respondents:

- Ascleitis Pharma Inc. (“Ascleitis Pharma”) of Hangzhou, China
- Ascleitis Pharmaceuticals Co. Ltd. (“Ascleitis Pharmaceuticals”) of Shaoxing, China
- Ascleitis Bioscience Co., Ltd. (“Ascleitis Bioscience”) of Hangzhou, China
- Gannex Pharma Co., Ltd. (“Gannex”) of Shanghai, China

- Jinzi Jason Wu of Seattle, Washington, U.S.A.

Id. These five entities are hereinafter collectively referred to as “Ascletis” or “Respondents.”

The Office of Unfair Import Investigations (“Staff”) is also a party to this investigation.

Id.

The Commission ordered that the presiding administrative law judge “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.” Notice of Investigation (citing 19 C.F.R. § 210.10(b)(3)). The initial determination on issues of injury was therefore due on May 22, 2023. *See* Order No. 9: Revised Procedural Schedule for 100-Day Proceeding (Mar. 6, 2023).

The Commission also ordered that the presiding administrative law judge “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)(1), (f)(1), (g)(1).” Notice of Investigation (citing 19 C.F.R. § 210.50(b)(1)).

I set a 16-month target date of June 10, 2024, for this investigation, thereby making the final initial determination on violation of section 337 due no later than February 9, 2024. Order No. 5 (Feb. 23, 2023). As explained below, subsequent events required extensions of the target date for completion of the investigation.

On April 6, 2023, Viking, Ascleitis, and Staff stipulated to certain facts relevant to this investigation. This stipulation (“100-Day Stip.”) has been entered into the evidentiary record as JX-0007.

I held a prehearing conference on April 13, 2023, and convened the 100-day evidentiary hearing on issues of injury immediately thereafter. The 100-day evidentiary hearing ended on April 17, 2023. *See* 100-Day Tr. at 1-638.¹

Following the conclusion of the 100-day evidentiary hearing, I issued Order No. 22 on May 11, 2023, finding good cause to continue the investigation beyond the 100-day proceeding without issuing an early initial determination on issues of injury.²

On June 30, 2023, Viking filed an omnibus motion for monetary and non-monetary sanctions against Respondents and their counsel based on alleged violation of discovery orders. Motion Docket No. 1352-023. Several rounds of briefing in response to Viking’s motion ensued. The pending omnibus motion for sanctions will be addressed in section II below.³

¹ The transcript of the 100-day evidentiary hearing on issues of injury is available on EDIS. The following table identifies the EDIS Doc. ID for the confidential and public transcripts for each day of the hearing:

Hearing Day	Public Tr.	Conf. Tr.
4/13/2023	794408	794407
4/14/2023	794464	794463
4/17/2023	794467	794466

These documents are hereinafter collectively referred to as “100-Day Tr.”

² On May 31, 2023, Ascleitis moved for certification of Order No. 22 for interlocutory appeal. Motion Docket No. 1352-019. On June 12, 2023, Viking filed an opposition to the pending motion, and Staff filed a responsive brief supporting Ascleitis’s motion in part. Motion No. 1352-019 is hereby denied as moot because any party can obtain Commission review of the issues raised in the motion through a petition for review of this final initial determination.

³ All other motions pending in this investigation that are not addressed in this final initial determination, if any, are hereby denied as moot.

On August 28, 2023, I granted a motion from the law firm of Foster, Murphy, Altman & Nickel, PC (“Foster Murphy”) seeking leave to withdraw as counsel for Ascleitis. Order No. 37. In that same order, I issued an initial determination granting Foster Murphy leave to intervene in this investigation for the “limited purpose of defending Foster Murphy and its attorneys’ interests in response to Complainant Viking Therapeutics, Inc.’s Omnibus Motion for Sanctions (Mot. No. 1352-023).” *Id.* at 4-6. No party petitioned for review of the initial determination. The Commission determined not to review, and thereby adopted, the initial determination. Comm’n Notice (Sept. 22, 2023).

On October 6, 2023, Viking, Ascleitis, and Staff stipulated to certain facts relevant to the issue of bond. This stipulation (“Bond Stip.”) has been entered into the evidentiary record as JX-1001.

On November 9, 2023, I issued an initial determination making findings on summary determination that, among other things, Ascleitis has not imported ASC41 capsules or ASC43F capsules into the United States. Order No. 40. No party petitioned for review of the initial determination. The Commission determined not to review, and therefore adopted, my findings on importation, but reviewed and vacated my findings as to whether or not Ascleitis held “commercially significant” or “significant” inventories of ASC41 or ASC43F in the United States. Comm’n Notice (Dec. 21, 2023).

On November 13, 2023, I issued an initial determination making findings on summary determination that certain documents produced in this investigation were present in secure data rooms established by Viking in 2016 and 2019. Order No. 41. No party petitioned for review of the initial determination. The Commission determined not to review, and therefore adopted, my findings. Comm’n Notice (Dec. 13, 2023).

I held a prehearing conference on November 13, 2023, and convened an evidentiary hearing on all pending issues immediately thereafter. The evidentiary hearing ended on November 16, 2023. *See Hr’g Tr. at 1-1195.*⁴

On February 2, 2024, the law firm of Rimón, P.C. (“Rimón”) filed a motion seeking leave to withdraw as counsel for Ascletis. Motion Docket No. 1352-044. On February 7, 2024, Rimón moved for leave to intervene in this investigation for the “limited purpose of defending Rimón’s and Rimón’s attorneys’ interests in response to Complainant Viking Therapeutics, Inc.’s Omnibus Motion for Sanctions (Mot. No. 1352-023).” Motion Docket No. 1352-045. On March 19, 2024, I issued Order No. 48 granting Rimón’s motion to withdraw. Rimón’s motion to intervene is addressed in section II.C below.

In view of the of the complexity of the issues raised in this investigation and current constraints on judicial resources, I extended the target date for this investigation through a series of initial determinations. Order No. 46 (Feb. 8, 2024), *unreviewed by Comm’n Notice* (Mar. 6, 2024); Order No. 50 (Apr. 5, 2024), *unreviewed by Comm’n Notice* (May 2, 2024); Order No. 52 (Apr. 25, 2024), *unreviewed by Comm’n Notice* (May 10, 2024); Order No. 53 (May 3, 2024), *unreviewed by Comm’n Notice* (May 22, 2024); Order No. 54 (May 17, 2024), *unreviewed by*

⁴ The transcript of the evidentiary hearing on issues other than injury is available on EDIS. The following table identifies the EDIS Doc. ID for the confidential and public transcripts for each day of the hearing:

Hearing Day	Public Tr.	Conf. Tr.
11/13/2023	808528	808526
11/14/2023	808862	808861
11/15/2023	808740	808737
11/16/2023	809358	809357

These documents are hereinafter collectively referred to as “Hr’g Tr.”

Comm’n Notice (June 18, 2024); Order No. 55 (May 31, 2024), *unreviewed by* Comm’n Notice (June 25, 2024), Order No. 56 (June 14, 2024), *unreviewed by* Comm’n Notice (June 27, 2024); Order No. 57 (July 12, 2024), *unreviewed by* Comm’n Notice (July 25, 2024); Order No. 58 (Aug. 2, 2024), *unreviewed by* Comm’n Notice (Aug. 15, 2024); Order No. 59 (Sept. 6, 2024) (pending Commission review). Currently, the target date for this investigation is February 3, 2025, which makes this final initial determination on violation of section 337 due no later than October 3, 2024. Order No. 60 (Sept. 13, 2024) (pending Commission review).

On April 25, 2024, I reopened the evidentiary record to admit a news release issued by the U.S. Food & Drug Administration on March 14, 2024, titled “FDA Approves First Treatment for Patients with Liver Scarring Due to Fatty Liver Disease.” Order No. 51 (Apr. 25, 2024). This news release is available at EDIS Doc. ID 816291 and is hereinafter referred to as “FDA Press Release.” Order No. 47 Attachment A (Mar. 18, 2024).

B. The Private Parties

1. Complainant Viking

Viking, a Delaware corporation, is a U.S. company headquartered at 9220 Pacific Heights Boulevard, Suite 350, San Diego, California 92121. CX-0280.0001. Viking was founded in 2012 by its current CEO, Dr. Brian Lian. *See* CX-0280.0012, .0014. Viking describes itself as “a clinical-stage biopharmaceutical company focused on the development of novel, first-in-class or best-in-class therapies for metabolic and endocrine disorders.” CX-0280.0004.

2. Respondents

Respondents comprise a group of related corporate entities, and Dr. Jinzi Jason Wu is the CEO or President of each of the corporate Respondents. 100-Day Tr. (Wu) at 395:19-21; Hr’g Tr.

(Wu) at 615:19-22; JX-1016C (Wu Depo.) at 40:5-20. Respondents are working collectively to develop drug candidates to treat fatty liver disease, in competition with Viking.

a) *Ascletis Pharma Inc.*

Ascletis Pharma is a Cayman Islands corporation with a principal place of business at Room 1201, No. 3 Building, No. 371 Mingxing Road, Economic and Technological Development Zone, Xiaoshan District, Hangzhou, Zhejiang Province, China. CX-0356C.0008-09. Ascletis Pharma is the parent corporation of respondents Ascletis Bioscience, Ascletis Pharmaceuticals, and Gannex. JX-0007C.0002; CX-0005.0125-26; CX-0356C.0012.

b) *Gannex Pharma Co. Ltd.*

Gannex is a Chinese corporation with a principal place of business at 3rd Floor, No. 665 ZhangJiang Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, China. CX-0356C.0009. Gannex has sponsored clinical trials on Ascletis drug candidates in China and in the United States. JX-0007C.0002, .0005.

c) *Ascletis Bioscience Co.*

Ascletis Bioscience is a Chinese corporation with a principal place of business at Room 1201, No. 3 Building, No. 371 Mingxing Road, Economic and Technological Development Zone, Xiaoshan District, Hangzhou, Zhejiang Province, China. CX-0356.0008. Ascletis Bioscience is the Ascletis entity that entered into confidential disclosure agreements with Viking and engaged in the development of competing drug candidates for treating fatty liver disease. CX-2014; CX-2085; CX-1392C-T.

d) *Ascletis Pharmaceuticals Co. Ltd.*

Ascletis Pharmaceuticals is a Chinese corporation with a principal place of business at No. 1 Yunhai Road, Lihai District, Binhai New Town, Shaoxing City, Zhejiang Province, China.

CX-0356C.0008. Ascletois Pharmaceuticals is the Ascletois entity that manufactured the tablets accused in this investigation and sold them for importation into the United States. CX-1931C.0018; JX-0007C.0002. Ascletois Pharmaceuticals has also sponsored clinical trials on Ascletois drug candidates. *See* SX-0003C (Compl.'s 4th Supp. Resp. to Staff's 1st Set of Interrogs.) at 75.

e) Jinzi Jason Wu

Dr. Wu is the founder, chairman, executive director, and CEO or President of the Ascletois corporate respondents. JX-0007C.0002; JX-0001C (Wu Depo.) at 40:5-20; Hr'g Tr. (Wu) at 615:19-22. Dr. Wu's address is No. 1 Xiaoshan, Xiaoshan District, Hangzhou, Zhejiang Province, China. JX-0001C (Wu Depo.) at 16:9-14. Dr. Wu is primarily responsible for Ascletois's operations, [REDACTED]

[REDACTED] CX-0005.0037; JX-1007C (Gargiulo Depo.) at 103:13-15, 114:14-115:1, 115:9-12; JX-1009C (Gudmundsson Depo.) at 90:7-12; JX-1021C (Yan Depo.) at 77:2-8.

C. Overview of NASH

The technology at issue in this investigation relates to drug products and drug substances that are selective thyroid hormone receptor-beta ("TR- β " or "TR-beta") agonists for the treatment of metabolic disorders and liver diseases, specifically for the therapeutic treatment of non-alcoholic steatohepatitis ("NASH") in humans. *See* Notice of Institution of Investigation; Compl. ¶ 10. NASH is an advanced form of non-alcoholic fatty liver disease ("NAFLD"), which is caused by the buildup of fat in the liver. 100-Day Tr. (Peck) at 198:16-199:1; CX-0142C.0010. Fat buildup in the liver causes inflammation and liver damage. CX-0142C.0010.

The record evidence shows that between 20 and 30 million adults in the United States have NAFLD, and between 6 and 15 million patients have progressed to NASH. 100-Day Tr. (Mancini) at 109:23-110:2. Patient recruitment for NASH studies is challenging because NASH is a silent disease. *Id.* at 87:15-25. A patient may have NASH and not know it, so a definitive diagnosis requires the patient to undergo a liver biopsy. *Id.* at 87:23-88:7. During the pendency of this investigation, a drug called resmetirom, made by non-party Madrigal Pharmaceuticals, was approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of NASH. FDA Press Release. No other drugs have been approved by the FDA for the treatment of NASH. *See* Hr’g Tr. (Mancini) at 250:25-251:2; SX-0005C (Resps.’ 1st Supp. Resp. to Staff’s 1st Set of Interrogs.) at 43.

D. Overview of the FDA Drug Development Process

According to the FDA, there are five steps to the drug development process:

- **Step 1** is “discovery and development,” in which researchers conduct experiments on molecular compounds to gather further information on those compounds. SX-0001 (FDA.gov explanation of drug development process) at 1352-STAFF-000017 to -000018. Thousands of compounds may be potential candidates for development as a medical treatment, but after early testing, only a small number of compounds may merit further study. *Id.*
- **Step 2** consists of “preclinical research.” Before testing a drug in humans, researchers must find out whether it has the potential to cause serious harm, which is also called toxicity. The two types of preclinical research are “in vitro” (literally, testing “in glass” vessels, such as test tubes, but also including other tests outside a living organism) and “in vivo” (literally, testing “in life,” such as animal testing).

Usually, preclinical studies are not very large, but provide information on dosing and toxicity levels. SX-0001 at 1352-STAFF-000019.

- **Step 3** consists of “clinical research,” which means studies that are done in humans. In the United States, drug developers, or “sponsors,” must submit an Investigational New Drug (“IND”) application to the FDA before beginning clinical research. The FDA review team then has 30 days to review the original IND submission. SX-0001 at 1352-STAFF-000023 to -000024.
- Clinical research of a previously untested drug proceeds through several phases, with multiple clinical studies per phase. Although in general the phases are conducted sequentially, they may overlap. *See* SX-0001 at 1352-STAFF-000020 to -000024; 21 C.F.R. § 312.21.
 - **Phase I** studies gather information about how a drug interacts with the human body by testing the drug over several months in 20 to 100 healthy volunteers. The purpose is to determine safety and dosage levels and to test how the drug is absorbed, excreted, metabolized, and distributed. Approximately 70 percent of drugs studied in Phase I clinical studies move on to Phase II. SX-0001 at 1352-STAFF-000021 to -000022.
 - **Phase II** involves administering the drug to up to several hundred patients with the disease or condition for which the drug is being developed. Studies last from several months to two years. SX-0001 at 1352-STAFF-000022. Phase II research may be divided into Phase IIa and Phase IIb studies. A Phase IIa clinical trial is the first clinical trial in humans, intended to study the safety, dosage, and initial efficacy in a limited patient population for a

specific pharmaceutical product. A Phase IIb clinical trial is a relatively longer and larger study designed to research the effectiveness of different doses of a particular product against placebo. *See* 100-Day Tr. (Sharlin) at 452:15-19. According to the FDA, Phase II studies “aren’t large enough to show whether the drug will be beneficial. Instead, Phase 2 studies provide researchers with additional safety data.” SX-0001 at 1352-STAFF-000022. Approximately 33 percent of drugs studied in Phase II clinical studies move on to Phase III. *Id.*

- **Phase III** clinical research involves studies of one to four years involving 300 to 3000 volunteers who have the disease or condition for which the drug is being developed. The purpose is to study efficacy and to monitor adverse reactions. Researchers design Phase III studies to demonstrate whether or not a product offers a treatment benefit to a specific population. Because these studies are larger and longer in duration, the results are more likely to show long-term or rare side effects and drug interactions. SX-0001 at 1352-STAFF-000022 to -000023. Approximately 25-30 percent of drugs studied in Phase III move on to the next step, application for FDA approval.⁵ *Id.*
- **Step 4** of the drug development process consists of “FDA drug review.” Once a drug developer has evidence from Phase III clinical research that a drug is safe and effective for its intended use in the population studied, it can file a New Drug

⁵ There is also a Phase IV in the process, which involves clinical research that occurs after the drug has been approved by the FDA. *See* 100-Day Tr. (Clarke) at 526:12-16. In Phase IV, several thousand volunteers who have the relevant disease or condition are studied for post-market safety monitoring purposes. SX-0001 at 1352-STAFF-000023.

Application (“NDA”) with the FDA seeking permission to market the drug. Once the FDA receives an NDA and determines that the application is complete, the review team has six to ten months to decide whether to approve the drug. SX-0001 at 1352-STAFF-000025 to -000026.

- According to the FDA, during Step 4 remaining issues “often” need to be resolved before a drug can be approved for marketing. “Sometimes FDA requires the developer to address questions based on existing data. In other cases, FDA requires additional studies. At this point, the developer can decide whether or not to continue further development.” SX-0001 at 1352-STAFF-000025 to -000026. In addition, “[s]ometimes, questions arise that require additional consideration. In these cases, FDA may organize a meeting of one of its Advisory Committees to get independent, expert advice and to permit the public to make comments.” *Id.* Between 2011 and 2020, the probability of FDA approval after submitting a new drug application was approximately 90%. CX-0300 (2021 Clinical Development Success Rates 2011-2020 v17) at 6.
- **Step 5** of the drug development process consists of “FDA post-market drug safety monitoring.” Over a product’s lifetime in the marketplace, the FDA reviews reports of problems with the approved drug and can decide to add cautions to the dosage or usage information, as well as to take other measures for more serious issues. SX-0001 at 1352-STAFF-000027 to -000028.

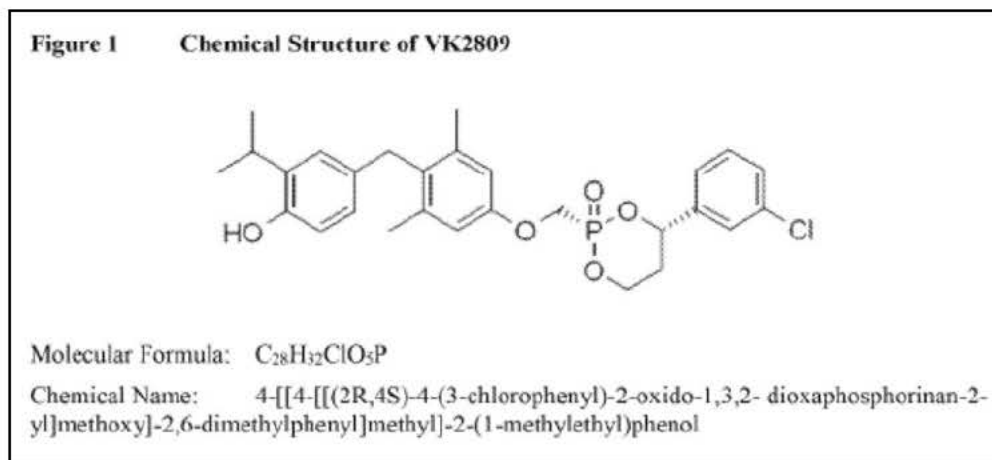
E. Products at Issue

The products at issue in this investigation are thyroid hormone receptor beta agonists that are drug candidates for the treatment of NASH.

1. The Alleged Domestic Industry: Viking's VK2809

On May 21, 2014, Viking became the exclusive licensee of multiple assets developed by Metabasis Therapeutics Inc. ("Metabasis") and Ligand Pharmaceuticals Inc. ("Ligand"),⁶ including the rights to [REDACTED] a drug candidate labeled VK2809. CX-0021C; Compl. ¶ 11; SX-0003C (Compl.'s 4th Supp. Resp. to Staff's 1st Set of Interrogs.) at 14-15. VK2809 was originated by Metabasis, who referred to it as MB07811. *See* Hr'g Tr. (Abato) at 759:18-22.

VK2809 is an orally available, small molecule selective thyroid hormone receptor beta agonist for the treatment of lipid and metabolic disorders, such as NASH. JX-0007C.0004. The active pharmaceutical ingredient in VK2809 is C₂₈H₃₂ClO₅P. CX-0142C.0013. An API is the ingredient in a drug product that has (or is intended to have) a desired medicinal effect. An API is combined with other compounds, known as excipients, to create a specific formulation. The chemical structure of the API in VK2809 is shown below:



CX-0142C.0013 (Viking's Investigator's Brochure); 100-Day Tr. (Schöneich) at 168:9-14.

⁶ Ligand, a U.S. biopharmaceutical company, acquired Metabasis in 2010. *See* JX-1004C (Berkman Depo.) at 30:16-31:9.

Viking is developing VK2809 in capsule [REDACTED]. JX-0003C (Barker Depo.) at 22:3-23:1. VK2809 is prodrug technology, whereby an inactive prodrug is metabolized to its active VK2809A form by an enzyme in the liver. Hr’g Tr. (Chavez) at 108:1-12; Hr’g Tr. (Masamune) at 181:17-22. The active VK2809A form was referred to as MB07344 by Metabasis. *See* Hr’g Tr. (Peck) at 209:20-24 (referring to “active metabolite MB07344 and prodrug MB07811”).

Viking alleges a domestic industry domestic industry exists under 19 U.S.C. § 1337(a)(1) in the research, development, engineering, and testing (including pre-clinical and clinical activities) necessary to launch VK2809 as an FDA-approved drug product in the United States. Compl. ¶ 155-160. Viking also alleges it is working to establish an industry in FDA-approved selective thyroid hormone receptor-beta agonists for the treatment of NASH in the United States. *Id.* at ¶ 161.

Phase I trials for VK2809 began in 2006. *See* Compl. ¶ 163; *see also* SX-0005C (Resps.’ 1st Supp. Resp. to Staff’s 1st Set of Interrogs.) at 38-39. From September 28, 2016, to March 26, 2019, Viking conducted a Phase IIa clinical trial on VK2809 titled “Safety and Tolerability of VK2809 in Patients with Primary Hypercholesterolemia and Non-Alcoholic Fatty Liver Disease.” SX-0003C (Compl.’s 4th Supp. Resp. to Staff’s 1st Set of Interrogs.) at 14. On November 15, 2019, Viking began enrolling patients in a Phase IIb clinical trial for VK2809 titled “A Study to Assess the Efficacy and Safety of VK2809 for 52 Weeks in Subjects with Biopsy Proven NASH (VOYAGE).” *Id.* On January 9, 2023, Viking announced the completion of patient enrollment in its Phase IIb clinical trial and indicated that it expected to report data for the study’s primary endpoint in the first half of 2023. *Id.* at 71-72. Viking expected that the Phase IIb VOYAGE study would conclude in or around the middle of 2024. *Id.* at 14. Viking expects to complete a Phase

III clinical trial for VK2809 in or around [REDACTED] and to obtain FDA approval in or around [REDACTED]. *Id.*; 100-Day Tr. (Mancini) at 84:8-20.

2. The Accused Products: Ascletis's ASC41 Tablets and ASC43F Tablets

The products accused in this investigation are Ascletis's ASC41 and ASC43F drug candidates ("Accused Products"). JX-0007C.0004. ASC41 contains the same API as the domestic product VK2809. *Id.* There have been four completed Phase I clinical trials for ASC41 sponsored by either Gannex Pharma or Ascletis Pharmaceuticals, three in China and one in San Antonio, Texas. *See* SX-0003C (Compl.'s 4th Supp. Resp. to Staff's 1st Set of Interrogs.) at 75. [REDACTED] 100-Day Hr'g Tr. (Wu) at 401:15-21; *see* Order No. 40 at 3, *unreviewed in relevant part by* Comm'n Notice (Dec. 21, 2023). Ascletis has begun a Phase II clinical trial of ASC41 in China, and Ascletis Pharma has announced that the first patient has been dosed in that trial. *See* SX-0003C at 75.

ASC43F is a fixed-dose combination tablet of ASC41 and ASC42, a Farnesoid X Receptor ("FXR") agonist. JX-0007C.0004. ASC43F thus includes the same API as the domestic product VK2809. *Id.* [REDACTED] 100-Day Hr'g Tr. (Wu) at 402:6-15; *see* Order No. 40 at 3, *unreviewed in relevant part by* Comm'n Notice (Dec. 21, 2023).

The Accused Products are currently [REDACTED] by respondent Ascletis Pharmaceuticals for clinical trial purposes in China. SX-0005C (Resps.' 1st Supp. Resp. to Staff's 1st Set of Interrogs.) at 26. According to Ascletis, all Phase II trials of the accused products will take place in China. *Id.* at 28. However, I find that Ascletis plans to commercialize ASC41 in both China and the United States if the Phase II trial results are positive. 100-Day Hr'g Tr. (Wu) at 403:11-21.

3. Relevant Non-Party Products

The only drug treatment for NASH approved by the FDA for sale in the United States is resmetirom, made by non-party Madrigal Pharmaceuticals. FDA Press Release. As of the time of the last evidentiary hearing in this investigation, there were at least 64 potential drug treatments for NASH in various stages of clinical development, including five in Phase III clinical trials (resmetirom was in Phase III at the time of the evidentiary hearing). SX-0005C (Resps.' 1st Supp. Resp. to Staff's 1st Set of Interrogs.) at 43-45. Among those are drug candidates that have similar mechanisms of operation as VK2809 and ASC41. Specifically, there were a total of four selective TR-beta agonist drug candidates for the treatment of NASH in a Phase II or higher developmental stage: the FDA-approved drug resmetirom (developed by non-party Madrigal Pharmaceuticals), VK2809 (developed by Viking), ASC41 (developed by Ascletis), and Tern-501 (developed by non-party Terns Pharmaceuticals). *Id.* at 32-33; Compl.'s Reply to Proposed Resps.' Public Interest Cmts. at 3 (EDIS Doc. ID 788068) (Jan. 17, 2023).

F. Identification of Asserted Trade Secrets

Viking's asserted trade secrets can generally be grouped into three categories: information related to (1) drug formulation, (2) preclinical research and development testing, and (3) clinical research and development trials. For the purposes of this investigation, they have been identified as Viking Trade Secret ("TS") Nos. 1-112, with many including numerous subparts. *See* CDX-1035C (Identification of Trade Secrets by Trade Secret Number) ("Trade Secret Chart"). There are several gaps in numbering because Viking is no longer asserting all of the trade secrets and trade secret subparts it originally identified during discovery.

Thirty-four documents containing the asserted trade secrets have been entered into the record as exhibits CX-1001C to CX-1034C (collectively, "Trade Secret Documents"). Viking has

delineated each asserted trade secret in the Trade Secret Documents by highlighting and annotating a corresponding demonstrative exhibit numbered CDX-1001C to CDX-1034C, respectively. The following table is an excerpt from Viking's final exhibit list and sets forth the production (Bates) number of each of the Trade Secret Documents.

Exhibit Number	Document Description	Start Bates	End Bates
CX-1001C	[REDACTED]	VK-ITC-337-1352_00002572	VK-ITC-337-1352_00003993
CX-1002C	[REDACTED]	VK-ITC-337-1352_00003994	VK-ITC-337-1352_00005032
CX-1003C	[REDACTED]	VK-ITC-337-1352_00005033	VK-ITC-337-1352_00005039
CX-1004C	[REDACTED]	VK-ITC-337-1352_00005040	VK-ITC-337-1352_00005055
CX-1005C	[REDACTED]	VK-ITC-337-1352_00005071	VK-ITC-337-1352_00005110
CX-1006C	[REDACTED]	VK-ITC-337-1352_00005111	VK-ITC-337-1352_00005178
CX-1007C	[REDACTED]	VK-ITC-337-1352_00005179	VK-ITC-337-1352_00005285
CX-1008C	[REDACTED]	VK-ITC-337-1352_00005286	VK-ITC-337-1352_00005343
CX-1009C	[REDACTED]	VK-ITC-337-1352_00005344	VK-ITC-337-1352_00005418

PUBLIC VERSION

Exhibit Number	Document Description	Start Bates	End Bates
CX-1010C	Viking Therapeutics Investigator's Brochure	VK-ITC-337-1352_00005419	VK-ITC-337-1352_00005471
CX-1011C	Viking Clinical Study Protocol: VK2809-201	VK-ITC-337-1352_00005472	VK-ITC-337-1352_00005563
CX-1012C	[REDACTED]	VK-ITC-337-1352_00005564	VK-ITC-337-1352_00005577
CX-1013C	[REDACTED]	VK-ITC-337-1352_00005578	VK-ITC-337-1352_00005831
CX-1014C	[REDACTED]	VK-ITC-337-1352_00005832	VK-ITC-337-1352_00006211
CX-1015C	[REDACTED]	VK-ITC-337-1352_00006212	VK-ITC-337-1352_00006902
CX-1016C	[REDACTED]	VK-ITC-337-1352_00006903	VK-ITC-337-1352_00007516
CX-1017C	[REDACTED]	VK-ITC-337-1352_00007517	VK-ITC-337-1352_00008270
CX-1018C	[REDACTED]	VK-ITC-337-1352_00008348	VK-ITC-337-1352_00008361
CX-1019C	Metabasis Phase I Clinical Study Report Protocol No. MB07811-101	VK-ITC-337-1352_00008385	VK-ITC-337-1352_00008663

Exhibit Number	Document Description	Start Bates	End Bates
CX-1020C	Metabasis Phase I Clinical Study Report Protocol No. MB07811-102	VK-ITC-337-1352_00008664	VK-ITC-337-1352_00009604
CX-1021C	Non-Clinical Safety Study Reports, MB07811	VK-ITC-337-1352_00009748	VK-ITC-337-1352_00009749
CX-1022C	[REDACTED]	VK-ITC-337-1352_00009750	VK-ITC-337-1352_00009750
CX-1023C	[REDACTED]	VK-ITC-337-1352_00009751	VK-ITC-337-1352_00009752
CX-1024C	[REDACTED]	VK-ITC-337-1352_00009753	VK-ITC-337-1352_00009753
CX-1025C	Email from V. Dourado to B. Lian et al re Asclepis-VK2809 due diligence questions	VK-ITC-337-1352_00009754	VK-ITC-337-1352_00009755
CX-1026C	[REDACTED]	VK-ITC-337-1352_00799341	VK-ITC-337-1352_00799397
CX-1027C	[REDACTED]	VK-ITC-337-1352_00871903	VK-ITC-337-1352_00871915
CX-1028C	[REDACTED]	VK-ITC-337-1352_00871916	VK-ITC-337-1352_00871926
CX-1029C	[REDACTED]	VK-ITC-337-1352_00871927	VK-ITC-337-1352_00871947
CX-1030C	[REDACTED]	VK-ITC-337-1352_00872466	VK-ITC-337-1352_00872493

Exhibit Number	Document Description	Start Bates	End Bates
CX-1031C	[REDACTED]	VK-ITC-337-1352_00872573	VK-ITC-337-1352_00872587
CX-1032C	[REDACTED]	VK-ITC-337-1352_00872603	VK-ITC-337-1352_00872655
CX-1033C	Email from V. Dourado to H. Masamune and B. Lian re: Ascleitis meeting to discuss VK2809 in Oslo	VK-ITC-337-1352_01151123	VK-ITC-337-1352_01151124
CX-1034C	Viking VK2809-201 - Initial Primary Analysis - Final Outputs	VK-ITC-337-1352_01597156	VK-ITC-337-1352_01597804

See EDIS Doc. ID 809650.

1. Formulation Trade Secrets

The first category of asserted trade secrets consists of information related to drug formulation. Viking asserts the following Formulation Trade Secrets: TS Nos. 4-11, 34-36, and 44, as well as compilation trade secret TS No. 111. *See* Hr’g Tr. (Amidon) at 272:16-273:2.

The table below is an excerpt from Viking’s demonstrative exhibit CDX-1035C (“Trade Secret Chart”), which lists each asserted trade secret by identifying number and provides Viking’s characterization of the substance of the trade secret. The Trade Secret Chart also identifies the exhibit number for the document containing each asserted trade secret, as well as the corresponding demonstrative exhibit described above.

TS No.	Formulation Trade Secret	Document(s)/Pincite(s)
4		CX/CDX-1010C at .0014; CX/CDX-1026C at .0033-.0034, .0036
5		CX/CDX-1025C at .0002; CX/CDX-1033C at .0002; CX/CDX-1026C at .0036-.0037
6		CX/CDX-1010C at .0014; CX/CDX-1033C at .0002; CX/CDX-1026C at .0042-.0048
7		CX/CDX-1010C at .0014; CX/CDX-1033C at .0002; CX/CDX-1026C at .0042-.0048
8		CX/CDX-1010C at .0014; CX/CDX-1033C at .0002; CX/CDX-1026C at .0042-.0048
9		CX/CDX-1010C at .0014; CX/CDX-1033C at .0002; CX/CDX-1026C at .0042-.0048
10		CX/CDX-1025C at .0002; CX/CDX-1033C at .0002
11		CX/CDX-1025C at .0002; CX/CDX-1033C at .0002
34		CX/CDX-1010C at .0013-.0014

TS No.	Formulation Trade Secret	Document(s)/Pincite(s)
35		CX/CDX-1010C at .0014
36		CX/CDX-1010C at .0014
44 ⁷		CX/CDX-1026C
111	Compilation of formulation trade secrets	The compilation of Viking Trade Secrets #4-11 in CX/CDX-1010C at .0014; CX/CDX-1026C at .0033-.0034, .0036-.0037, .0042-.0048; CX/CDX-1025C at .0002; and CX/CDX-1033C at .0002

2. Preclinical Trade Secrets

The second category of asserted trade secrets consists of information about and obtained through preclinical studies. The Preclinical Trade Secrets, which were generally developed after the Formulation Trade Secrets, relate to the design, implementation, and interpretation of clinical trials conducted in the laboratory and on animals in anticipation of filing an Investigational New Drug application. *See* Hr’g Tr. (Abrouk) at 943:2-6 (“The purpose of preclinical work, in general, is to come up with a safe enough dose to take as a first dose in humans while having some activity.”).

⁷ TS No. 44 originally included 67 individual subparts directed to specific sections of the  of which Viking continues to assert 13 subparts. *See* Order No. 42 at 8 (Nov. 13, 2023) (listing subparts withdrawn by Viking in response to Respondents’ Motion *in limine* No. 3 and striking allegations regarding subparts 44.6 and 44.24). For brevity, the 13 subparts are not listed here, but they are shown in CDX-1035C (Trade Secret Chart).

Viking asserts the following Preclinical Trade Secrets: TS Nos. 16-18, 20-28, 37, 100, 102, and 104 (toxicology-related), as well as TS Nos. 25, 58-60, and 109 (pharmacology-related), and compilation trade secret TS No. 110. CDX-1035C (Trade Secret Chart) at 5-10, 20-21, 22, 27-31. The table below is excerpted from Viking's demonstrative exhibit CDX-1035C (Trade Secret Chart), which lists each asserted trade secret by identifying number and provides Viking's characterization of the substance of the trade secret.

TS No.	Preclinical Trade Secret	Document(s)/Pincite(s)
16		CX/CDX-1021C
17		CX/CDX-1016C; CX/CDX-1002C
18		CX/CDX-1014C; CX/CDX-1015C; CX/CDX-1017C; CX/CDX-1001C; CX/CDX-1018C; CX/CDX-1007C; and CX/CDX-1008C
20		CX/CDX-1009C at .0001-.0012
21		CX/CDX-1013C
22		CX/CDX-1003C
23		CX/CDX-1024C
24		CX/CDX-1022C
25		CX/CDX-1005C; CX/CDX-1006C
26		CX/CDX-1023C
27		CX/CDX-1012C
28		CX/CDX-1004C

TS No.	Preclinical Trade Secret	Document(s)/Pincite(s)
37		CX/CDX-1010C at .0014-.0025
58		CX/CDX-1027C
59		CX/CDX-1028C
60		CX/CDX-1029C
100		CX/CDX-1030C
102		CX/CDX-1031C
104		CX/CDX-1032C
109		CX/CDX-1033C

TS No.	Preclinical Trade Secret	Document(s)/Pincite(s)
110		The compilation of Viking Trade Secrets #16-18, 20-28, 33, 37, 39, 58-60, 100, 102, 104, and 109 in CX/CDX-1021C at .0001; CX/CDX-1016C; CX/CDX-1002C; CX/CDX-1014C; CX/CDX-1015C; CX/CDX-1017C; CX/CDX-1001C; CX/CDX-1018C; CX/CDX-1007C; CX/CDX-1008C; CX/CDX-1018C; CX/CDX-1009C; CX/CDX-1013C; CX/CDX-1003C; CX/CDX-1024C; CX/CDX-1022C; CX/CDX-1005C; CX/CDX-1006C; CX/CDX-1023C; CX/CDX-1012C; CX/CDX-1004C; CX/CDX-1010C at .0009-.0010, .0012-.0013, .0014-.0051; CX/CDX-1026C; CX/CDX-1027C; CX/CDX-1028C; CX/CDX-1029C; CX/CDX-1030C; CX/CDX-1031C; CX/CDX-1032C; and CX/CDX-1033C

3. Clinical Trade Secrets

The remaining asserted trade secrets are related to Viking's clinical research and development of VK2809, including its Phase I and Phase II clinical trials. Viking has identified these as TS Nos. 12-15, 32-33, and 38-39, as well as compilation trade secrets TS Nos. 31, 41-42, and 112. *See* Hr'g Tr. (Mancini) at 235:18-246:3; Hr'g Tr. (Silber) at 441:5-444:11. The table below is excerpted from Viking's demonstrative exhibit CDX-1035C (Trade Secret Chart), which lists each asserted trade secret by identifying number and provides Viking's characterization of the substance of the trade secret.

TS No.	Clinical Trade Secret	Document(s)/Pincite(s)
12		CX/CDX-1019C; CX/CDX-1020C
13	VK2809 clinical study analysis for studies VK2809-101, VK2809-102, VK2809-103, and VK2809-201	CX/CDX-1010C at .0025-.0046
14	VK2809 clinical study reports for VK2809-201	CX/CDX-1034C at .0003-.0004, .0013-.0017, .0030, .0032, .0033, .0254-.0255
15	VK2809 clinical study protocol for VK2809-201	CX/CDX-1011C at .0001-.0038, .0040-.0050, .0052, .0054-.0058
31	The compilation of information in the VK2809 Investigator's Brochure, Edition 5.0, dated January 12, 2018 that, taken together, is used by clinical investigators	CX/CDX-1010C
32	Description of pharmacological class, anticipated indications, and rationale contained in VK2809 Investigator's Brochure, Edition 5.0, dated January 12, 2018	CX/CDX-1010C at .0011-.0012
33	General approach for evaluating VK2809 contained in VK2809 Investigator's Brochure, Edition 5.0, dated January 12, 2018	CX/CDX-1010C at .0012-.0013
38	Description of clinical studies contained in VK2809 Investigator's Brochure, Edition 5.0, dated January 12, 2018	CX/CDX-1010C at .0025-.0046
39	Summary of data and guidance for investigators in VK2809 Investigator's Brochure, Edition 5.0, dated January 12, 2018.	CX/CDX-1010C at .0047-.0051

TS No.	Clinical Trade Secret	Document(s)/Pincite(s)
41	Compilation of VK2809 clinical information	The compilation of Viking Trade Secrets #12-15 in CX/CDX-1019C; CX/CDX-1020C; CX/CDX-1010C at .0025-.0046; CX/CDX-1034C at .0003-.0004, .0013-.0017, .0030, .0032, .0033, .0254-.0255; and CX/CDX-1011C
42	Compilation of all VK2809 testing information	The compilation of Viking Trade Secrets #12-18, 20-28, 33, 37, 39, 44, 58-60, 100, 102, and 104 in CX/CDX-1019C; CX/CDX-1020C; CX/CDX-1010C at .0025-.0046; CX/CDX-1034C at .0003-.0004, .0013-.0017, .0030, .0032, .0033, .0254-.0255; CX/CDX-1011C; CX/CDX-1021C; CX/CDX-1016C; CX/CDX-1002C; CX/CDX-1014C; CX/CDX-1015C; CX/CDX-1017C; CX/CDX-1001C; CX/CDX-1018C; CX/CDX-1007C; CX/CDX-1008C; CX/CDX-1018C; CX/CDX-1009C; CX/CDX-1013C; CX/CDX-1003C; CX/CDX-1024C; CX/CDX-1022C; CX/CDX-1005C; CX/CDX-1006C; CX/CDX-1023C; CX/CDX-1012C; CX/CDX-1004C; CX/CDX-1010C .0009-.0010, .0012-.0013, .0014-.0051; CX/CDX-1026C; CX/CDX-1027C; CX/CDX-1028C; CX/CDX-1029C; CX/CDX-1030C; CX/CDX-1031C; and CX/CDX-1032C

TS No.	Clinical Trade Secret	Document(s)/Pincite(s)
112	Compilation of all Viking Trade Secrets	The compilation of Viking Trade Secrets #4-18, 20-28, 31-39, 44, 58-60, 100, 102, 104, and 109 in CX/CDX-1010C at .0014; CX/CDX-1026C at .0033-.0034, .0036-.0037, .0042-.0048; CX/CDX-1025C at .0002; CX/CDX-1033C at .0002; CX/CDX-1019C; CX/CDX-1020C; CX/CDX-1010C at .0025-.0046; CX/CDX-1034C at .0003-.0004, .0013-.0017, .0030, .0032, .0033, .0254-.0255; CX/CDX-1011C; CX/CDX-1021C at .0001; CX/CDX-1016C; CX/CDX-1002C; CX/CDX-1014C; CX/CDX-1015C; CX/CDX-1017C; CX/CDX-1001C; CX/CDX-1018C; CX/CDX-1007C; CX/CDX-1008C; CX/CDX-1018C; CX/CDX-1009C; CX/CDX-1013C; CX/CDX-1003C; CX/CDX-1024C; CX/CDX-1022C; CX/CDX-1005C; CX/CDX-1006C; CX/CDX-1023C; CX/CDX-1012C; CX/CDX-1004C; CX/CDX-1010C at .0009-.0010; CX/CDX-1010C at .0010-.0011; CX/CDX-1010C; CX/CDX-1010C at .0011-.0012; CX/CDX-1010C at .0012-.0013; CX/CDX-1010C at .0013-.0014; CX/CDX-1010C at .0014; CX/CDX-1010C at .0014; CX/CDX-1010C at .0014-.0025; CX/CDX-1010C at .0025-.0046; CX/CDX-1010C at .0047-.0051; CX/CDX-1026C; CX/CDX-1027C; CX/CDX-1028C; CX/CDX-1029C; CX/CDX-1030C; CX/CDX-1031C; CX/CDX-1032C; and CX/CDX-1033C

G. Findings of Fact Concerning the History of Viking and Ascleitis

The record evidence establishes a timeline of events relevant to the issues raised in this investigation. The sections below summarize these events.

1. Viking's Acquisition and Development of VK2809 Assets

In 2014, Viking entered into a Master License Agreement ("MLA") with Ligand,⁸ whereby Viking gained an exclusive license to [REDACTED] [REDACTED] intellectual property transferred from Metabasis and Ligand. CX-0021C; Hr'g Tr. (Morneau) at 47:3-23. In consideration for this license, Viking paid [REDACTED] [REDACTED] to Ligand, [REDACTED] of which was for the TR-beta program that includes VK2809.

Schedule 2 of the MLA contains a list of "Licensor Know-How" documents that were transferred from Ligand to Viking. CX-0021C.0009, .0071-80; Hr'g Tr. (Morneau) at 47:3-23. Some of the documents listed in Schedule 2 are among those identified by Viking in this investigation as Trade Secret Documents that contain asserted trade secrets. Specifically, asserted formulation TS Nos. 4-10, 34-36, and 44; asserted preclinical TS Nos. 16-18, 20-22, 24-28, 58-60, 100, 102, and 104; and asserted clinical TS Nos. 12 were developed by Metabasis and transferred to Viking as Licensor Know-How under the MLA. CX-0021C.0009, .0071-80; *see, e.g.*, Hr'g Tr. (Masamune) at 167:24-168:3, 195:5-10; Hr'g Tr. (Morneau) at 47:3-23. These documents had been kept confidential by Ligand before they were transferred to Viking. *See* section V.C below.

After Viking acquired the VK2809 assets from Ligand through the MLA, it began research and development to further develop and commercialize VK2809 through preclinical studies,

⁸ The Master License Agreement is between Viking, Ligand, and Metabasis. CX-0021C. For simplicity, at times only Ligand or only Metabasis will be referenced in connection with the transfer of assets to Viking pursuant to the Master License Agreement.

testing, clinical trials, development and optimization of manufacturing processes, quality control, and preparation of regulatory submissions. *See* 100-Day Tr. (Zante) at 114:1-10; Hr’g Tr. (Masamune) at 163:17-24. Viking’s activities resulted in the development of additional asserted trade secrets, including formulation TS No. 11; preclinical TS Nos. 37 and 109; and clinical TS Nos. 13-15, 32, 33, 38, and 39. *See e.g.*, Hr’g Tr. (Mancini) at 237:13-244:6.

2. Viking’s 2016 and 2019 Virtual Data Rooms

In 2016, Viking entered a confidential disclosure agreement (“CDA”) with Ascleitis for the purpose of “engaging in discussions regarding exploration of a business opportunity and/or transaction of mutual interest regarding Viking’s Thyroid Beta Receptor Agonist Program, VK2809.” CX-2085. After ratification of the 2016 CDA, Dr. Kristjan Gudmundsson,⁹ Joseph Musto,¹⁰ and Spike Lo¹¹ accessed a virtual data room (“VDR”) hosted by third-party vendor Donnelley Financial Solutions (“Donnelley”) and viewed documents containing certain asserted trade secrets relating to VK2809. CX-1750C (2016 VDR Access Log); Hr’g Tr. (Broidrick) at 76:17-77:1. Viking subsequently decided not to collaborate with Ascleitis on a business opportunity and terminated Ascleitis’s access to the virtual data room in 2016. CX-1360C.0001-.0002 (email from Varsha Dourado to Spike Lo).

On March 7, 2019, at Ascleitis’s request,¹² Viking entered into a second confidential disclosure agreement with Ascleitis and granted Ascleitis access to its newer, expanded virtual data

⁹ Dr. Gudmundsson is head of discovery at Ascleitis Bioscience. Hr’g Tr. (Gudmundsson) at 701:11-17.

¹⁰ Mr. Musto is a contractor working for Ascleitis. JX-1015C (Musto Depo.) at 67:1-11.

¹¹ Mr. Lo was Ascleitis’s then-director of business development. Hr’g Tr. (Gudmundsson) at 703:23-704:4.

¹² The record shows that Ascleitis began development of an ASC41 formulation in February 2019. JX-1017C (Wu Depo.) at 45:5-6.

room hosted by third-party vendor SecureDocs and containing information related to VK2809. CX-2014; CX-2334C.0007-.0008; Hr’g Tr. (Broidrick) at 76:17-77:1. Compared with the 2016 virtual data room, the 2019 virtual data room contained additional asserted trade secrets relating to VK2809. Order No. 41 at 3-4, *unreviewed by* Comm’n Notice (Dec. 13, 2023). After ratification of the 2019 CDA, Dr. Wu, Dr. Gudmundsson, Mr. Musto, and Lindi Tan¹³ accessed Viking’s virtual data room and viewed documents containing certain asserted trade secrets relating to VK2809. CX-1992C (2019 VDR Audit Log). On March 14, 2019, Dr. Gudmundsson sent an email to Viking’s director of business development, Medrardo Chavez, asking for more information about VK2809. CX-2144C.0002; Hr’g Tr. (Broidrick) at 79:22-80:17. Specifically, Dr. Gudmundsson requested specifics regarding [REDACTED]

[REDACTED]” CX-2144C.0002. Viking did not provide the requested information. Hr’g Tr. (Broidrick) at 80:18-20.

On April 21, 2019, less than 7 weeks after Viking and Ascleitis entered into the 2019 CDA, Ascleitis notified Viking it was terminating the CDA. CX-2325C.0003. Ascleitis’s purported reason for terminating the partnership discussions was because Viking “lack[ed] composition of matter protection for China.” *Id.* On April 23, 2019, Amy Broidrick¹⁴ from Viking sent an email to Dr. Gudmundsson, Dr. Wu, and Ms. Tan requesting that Ascleitis confirm that it had deleted all copies of any data removed from the virtual data room. CX-2325.0002. Ascleitis represented that

¹³ Ms. Tan worked in a business development position for Ascleitis BioScience Co., Ltd., in 2019. JX-1009C (Gudmundsson Depo.) at 104:2-9.

¹⁴ At the time, Ms. Broidrick was senior vice president of Viking and its global head of corporate development. Hr’g Tr. (Broidrick) at 74:22-75:4.

it “deleted all notes regarding Viking project” and “didn’t have download access so [we have] no original documents” on April 30, 2019. *Id.* at .0001.

II. SANCTIONS FOR DISCOVERY VIOLATIONS BY ASCLETIS

Ascletis’s behavior during the discovery period of this investigation was the source of significant, unnecessary burden on the other parties and the tribunal, leading to a motion for sanctions brought by Viking. A summary of Ascletis’s behavior follows.¹⁵

A. Timeline of Discovery Events

Soon after institution of this investigation in February 2023, Ascletis moved for a protective order limiting the scope of discovery during the first 100 days to issues designated by the Commission for early decision. *See* Order No. 7 (Feb. 24, 2023); 19 C.F.R. § 210.10(b)(3). Ascletis’s motion was granted-in-part and denied-in-part. Order No. 7 at 6. I denied Ascletis’s request for a protective order regarding the following categories of documents responsive to Viking’s RFPs:

- Documents responsive to RFP Nos. 22, 44, 80 relating to Ascletis’s potential manufacturing and strategic partnerships—Ascletis’s motion for protective order was denied as to these documents “to the extent they relate to Respondents’ decisions about potential manufacturing partners or strategic partners.”
- Documents responsive to RFP No. 164 relating to Ascletis’s “historical annual costs, and future expected costs, to develop the Accused Products and Related Products, since development started”—Ascletis’s motion for protective order was

¹⁵ A contemporaneous understanding of the dispute can be gleaned from Order No. 14 (Mar. 24, 2023), Order No. 19 (Apr. 12, 2023), Order No. 21 (Apr. 26, 2023), Order No. 25 (May 18, 2023), Order No. 27 (June 1, 2023), Order No. 28 (June 2, 2023), Order No. 29 (June 12, 2023), Order No. 30 (June 15, 2023), Order No. 31 (June 16, 2023), and Order No. 36 (Aug. 23, 2023), as well as transcripts of the case management conferences held during this time frame.

denied as to “documents sufficient to show research and development costs for the period the parties have agreed is relevant to the 100-day proceeding.”

See Order No. 24 at 2.

On February 15, 2023, the parties agreed to produce email relevant to issues to be decided during the 100-day proceeding. Viking Sanctions Mot. Ex. 1. On February 23, 2023, the parties agreed to apply 10 search strings to the email accounts of 5 custodians and exchange the results. *See* Order No. 14 at 1 (Mar. 24, 2023). On March 3, 2023, Ascletis appeared in a case management conference and represented to the tribunal that Ascletis’s document production was “substantially complete”:

Judge Cheney: Ascletis[] has represented that their document production is substantially complete. Am I understanding that right, Mr. Heafey?

Mr. Heafey: Yes, you are correct.

03/03/2023 CMC Tr. at 17:5-19:9.

Despite Ascletis having made that representation at the case management conference on March 3, 2023, attorneys at Rimon had not yet begun searching custodian email. This is demonstrated by an email sent on March 6, 2023, from Rimon attorney Jason Xu to Ascletis employee Chunchun Ye and respondent Jinzi Wu, in which Mr. Xu provided the search terms agreed upon by the parties and stated, “The next hurdle will be for email collection.” Viking Sanctions Mot. Ex. 16.¹⁶

¹⁶ This email, and other evidence that provides insight into Rimon’s actions, were produced in response to Order No. 21, which I issued on April 26, 2023.

From: Jason Xu [<mailto:jason.xu@rimonlaw.com>]

Sent: Monday, March 6, 2023 4:21 AM

To: Chunchun Ye <chunchun.ye@ascletis.com>; Jinzi J Wu <jinzi.wu@ascletis.com>

Cc: Ascletis-Counsel-of-Record <Ascletis-Counsel-of-Record@rimonlaw.com>

Subject: Viking ITC - Email discovery / PRIVILEGED

Dear Chunchun,

Thank you so much for the help so far for the document collection. The next hurdle will be for email collection.

Viking Sanctions Mot. Ex. 16.

On March 16, 2023, at 7:25 p.m., Rimon attorney Mr. Heafey, the same attorney that represented at the March 3 case management conference that Ascletis's document production was "substantially complete," wrote to Viking's counsel and represented that the ten agreed-to search terms had been applied to custodian email and that certain hits had been identified:

Based on Complainant's search terms using logical joiners as "or," Respondents have identified a volume of emails:

1. Jinzi "Jason" Wu > 10,000
2. Yuemei "Helen" Yan > 10,000
3. Kristjan Gudmundsson > 4,000
4. John Gargiulo > 4,000

Respondents will meet and confer to narrow Complainant's search terms and logical joiners so that they yield a more reasonable volume of email hits.

Mike Heafey

Michael F. Heafey | Partner

RIMON PC

Viking Sanctions Mot. Ex. 2.

Viking relied on Mr. Heafey's representations about the volume of Ascletis emails responsive to the ten agreed-to search terms and the attendant burden on Ascletis to produce those emails, and therefore agreed on March 20, 2023, to narrow the search terms to three to help lessen

the burden. Viking Sanctions Mot. at 11 (citing Order No. 14 at 1-2; Viking Sanctions Mot. Ex. 11).

March 22, 2023, was the date set by the parties to produce emails. *See* Order No. 14 at 2. On that date, Viking produced emails for all 10 of Ascleitis’s requested search terms and all 5 of Ascleitis’s requested custodians, amounting to over 45,000 emails and email attachments. Viking Sanctions Mot. Ex. 12; *see* Order No. 14 at 2. By contrast, Ascleitis’s counsel Mr. Heafey sent Viking’s counsel an email stating “Respondents will not be producing email at this time.” Viking Sanctions Mot. Ex. 13.

Kecia
I am following on our recent conversations regarding Respondents’ production of email.

As I have written, the number of email identified according to Complainant’s search terms and identified custodians is unreasonably large. I have asked that the parties both narrow their search terms.

At our recent meet and confer, Complainant marginally narrow its search terms – but the result is still an unreasonable number of hits.

As email is of marginal – if any – relevance to the 100-day proceeding and as it is not possible to process – including searching for privilege and responsiveness – the unreasonable number of emails Complainant’s search terms have yielded, Respondents will not be producing email at this time.

Thank you.

Mike Heafey

Michael F. Heafey | Partner
RIMÓN PC

Viking Sanctions Mot. Ex. 13.

On March 23, 2023, Viking sent me a letter requesting that Ascleitis be ordered to produce the emails that hit upon Viking’s three prioritized search terms. *See* Order No. 14 at 1. I granted Viking’s motion in Order No. 14 on March 24, 2023, and ordered Ascleitis to produce the email by March 30, 2023. *Id.* at 3. I also cautioned all parties, stating “that failure to cooperate in discovery is a serious violation of Commission rules and professional responsibility obligations.” *Id.*

Subsequent discovery revealed certain events leading up to Ascletis's unilateral refusal to produce emails on March 22, 2023:

- Ascletis did not start the process of searching for and collecting emails until hours before Mr. Heafey's March 16 email identifying hit counts, and none of the custodians' hit counts were generated before Mr. Heafey's email was sent. *See* Viking Sanctions Mot. Exs. 4-10.
- The hit counts generated by the custodial search were less than the amounts represented in Mr. Heafey's March 16 email. For example, Ms. Yan did not have ">10,000 hits" as Mr. Heafey represented; her hit count was about 7,000. Viking Sanctions Mot. Ex. 10, at Ascletis-337-1352_00162203. Mr. Gargiulo did not have ">4,000 hits" as Mr. Heafey represented; he had about 2,500 hits. Viking Sanctions Mot. Ex. 7, at Ascletis-337-1352_00162200.
- As of the close of fact discovery on March 22, Ascletis had only provided partial emails from three of the five email custodians to its discovery vendor Consilio. *See* Viking Sanctions Mot. Ex. 3 (Consilio Depo.) at 40:5-9 ("Q: So by March 22nd, 2023 Rimon Law had only provided Consilio with email discovery for John Gargiulo, Yumei Yan, and partially for Kristjan Gudmundsson, is that right? A: I believe that's correct."); Viking Sanctions Mot. Ex. 14, at Consilio-ITC_0002110.
- Consilio did not receive all of the remaining emails from the other custodians until March 24—two days *after* the close of fact discovery. *See* Viking Sanctions Mot. Ex. 3 (Consilio Depo.) at 42:16-21 ("Q: So Consilio didn't receive email discovery from Rimon Law for all of the custodians until March 24th, 2023? A: That's correct . . ."); Viking Sanctions Mot. Ex. 15, at Consilio-ITC_0003297.

- Consilio’s representative confirmed at deposition that the earliest date they could have produced email discovery was March 26, 2023. *See* Viking Sanctions Mot. Ex. 3 (Consilio Depo.) at 50:17-20 (“Q: March 26th is the earliest date that Consilio could have produced email discovery, is that right? A: Correct.”).

On March 30, 2023, the deadline for production set forth in Order No. 14, Ascletis produced some responsive emails. However, Viking’s review of these emails revealed 363 encrypted documents within the production that could not be opened. Viking Sanctions Mot. Ex. 3 (Consilio Depo.) at 70:20-72:7. At the time, Rimón lawyers were aware Ascletis’s discovery vendor Consilio was not able to render these documents for production but nevertheless instructed that the encrypted documents be produced “as is.” *Id.* at 70:20-72:7, 76:20-77:18; Viking Sanctions Mot. Ex. 28 at CONSILIO-ITC_0004629.

Following its incomplete production of emails on March 30, 2023, Ascletis produced a large number of responsive emails on April 11, 2023, two days before the 100-day evidentiary hearing was scheduled to begin. *See* Order No. 19 at 2. As described below, this late production appears to have been caused at least in part by the Rimón lawyers.

On March 26, 2023, Rimón attorney Jason Xu instructed Consilio to run two searches against the emails collected from Ascletis custodians: “1) emails with the three search term hits with privilege hits [and] 2) emails with three search term hits minus privilege hits.” Viking Sanctions Mot. Ex. 22 at CONSILIO-ITC_0004129. Consilio had advised Mr. Xu that this search methodology would exclude certain email attachments from the set of search results—specifically, it would exclude an attachment containing a search term if the top-level email for that attachment did not itself contain a search term. *See* Viking Sanctions Mot. Ex. 21 at CONSILIO-ITC_0004174. Rimón nevertheless instructed Consilio to proceed with searching only the emails

and producing the resulting document set. *See* Viking Sanctions Mot. Ex. 24 at CONSILIO-ITC_0004335. This instruction resulted in the production of only top-level emails on March 30 and did not include the production of attachments responsive to the search strings. Those search strings were later run against the attachments and resulted in Ascleitis's late production of over 40,000 pages of responsive material. *See* Order No. 19 at 2.

The parties brought Ascleitis's late production to my attention in a series of letters. *See id.* In view of the imminent 100-day evidentiary hearing, I offered Ascleitis a choice between two options:

1. Ascleitis voluntarily stipulates that Viking prevails on all matters that were designated by the Commission for decision in the 100-day proceeding, namely that Viking has demonstrated that importation of ASC41 and ASC43F by Ascleitis has substantially injured an industry in the United States within the meaning of 19 U.S.C. § 1337(a)(1)(A). If Ascleitis elects this option, no trial will convene on April 13, the 100-day proceeding will terminate, and the investigation will proceed to a full trial on the merits later this year. Additionally, if Ascleitis elects this option, there will be no further investigation into whether sanctions against respondents, their counsel, and their discovery vendor are appropriate for violation of Order No. 14.

—or—

2. Ascleitis elects to proceed with trial as scheduled on April 13-14, 2023. If Ascleitis elects this option, Viking will be granted leave to move for forensic examination of electronic media relevant to respondents' email production and to move for sanctions as a result of the violation of Order No. 14. If Ascleitis elects this option, respondents, their counsel, and their discovery vendor will assume the risk of liability for attorney fees and costs under Commission Rule 210.33(c) for any additional process necessitated by their conduct, including, but not limited to, attorney fees and costs for forensic examination, additional depositions, additional motions practice, and additional trial time.

Order No. 19 at 3-4. Ascleitis elected Option 2. EDIS Doc. ID 794626 (Apr. 12, 2023).

The 100-day hearing proceeded on April 13, 2023. Additional deficiencies in Ascleitis's document production were revealed through examination of Dr. Wu at the 100-day hearing.

During discovery leading up to the 100-day hearing, Ascletis produced documents (not emails) concerning partnership efforts with two large pharmaceutical companies: Eli Lilly and Boehringer Ingelheim. *See* Viking Sanctions Mot. at 71. And in response to an interrogatory requesting that Ascletis “[l]ist every ‘big pharma’ company with whom any Respondents ever discussed the Accused Products,” Dr. Wu verified an interrogatory response listing only “Eli Lilly and Boehringer Ingelheim.” CX-0357C.0010; 100-Day Tr. (Wu) at 408:21-409:18. When Dr. Wu appeared at the 100-day hearing, he admitted that the interrogatory response he verified under penalty of perjury was inaccurate and that Ascletis had engaged in discussions with at least two additional companies: Sanofi and Novartis. 100-Day Tr. (Wu) at 408:17-20; 409:25-411:3; CX-0603, CX-0595, CX-0597, CX-0598.

The inconsistencies between Dr. Wu’s sworn testimony at the 100-day hearing and his sworn verification of Ascletis’s interrogatory responses, along with Ascletis’s failure to produce documents and email in a timely manner leading up to the 100-day hearing, indicated that a forensic examination of Ascletis’s discovery actions might be warranted under the circumstances.

On April 19, 2023, following the conclusion of the 100-day evidentiary hearing, Viking moved to compel Ascletis to produce documents responsive to Viking RFPs that were allegedly improperly withheld during the 100-day discovery period in violation of Order No. 7. *See* Order No. 24 at 1-2. Viking represented that it reviewed Ascletis’s April 11 document production and found “documents that are directly responsive to the RFPs and should not have been withheld pursuant to Order No. 7.” *See* Order No. 24 at 2. I granted Viking’s motion to compel and ordered Ascletis to re-examine its servers for documents responsive to Viking’s RFPs and to produce any documents found by May 26, 2023. *Id.* at 4-5. I also ordered Ascletis to file a declaration on

May 26 stating it had performed this search and providing details of its document production, if any. *Id.* at 5.

In accordance with Option 2 selected by Ascleitis in response to Order No. 19, on April 26, 2023, I granted Viking leave to take discovery regarding Ascleitis's defective collection and production of emails from its custodians. Specifically, Viking was granted leave to:

[C]onduct an independent forensic examination of Respondents' email server and the five custodians' devices used for email, such as laptops, desktops, and mobile devices. The forensic examination shall be limited to email records of the five custodians and shall not expand to include the entirety of Respondents' email server or the entirety of the five custodians' personal devices. Viking is also granted leave to apply for subpoenas seeking relevant information from Consilio and to serve relevant requests for production and corporate deposition notices on each of the Respondents.

Order No. 21 at 2. But Viking and Ascleitis were not able to agree on a procedure for the forensic examination of Ascleitis's email and I subsequently provided additional guidance on May 18, 2023:

- An independent forensic examiner shall image Respondents' email server.
- The independent forensic examiner shall inspect the laptops provided by Respondents to the email custodians at issue for evidence of corporate email.
- Viking and Respondents shall meet and confer regarding an examination protocol for email on the custodians' personal devices. Respondents shall provide Viking with an updated forensic examination protocol for the custodians' personal devices no later than the close of business on May 19, 2023.
- Viking and Respondents shall provide [the administrative law judge] with an update on the parties' efforts to resolve their disputes over the forensic examination protocol on May 24, 2023.
- If the parties' disputes have been resolved by May 24, then the forensic examination shall begin on June 1, 2023. Otherwise, the forensic examination shall begin on a date after May 24 that [the administrative law judge shall] order.

Order No. 25 at 2.

Following Order No. 25, the parties memorialized a forensic examination protocol. *See* Order No. 27 Ex. B (Viking's letter with protocol attached as Exhibit A). But even after Ascletis agreed to the protocol, the parties were still not able to effect the examination of Ascletis's email systems. I thus issued more instructions on June 1, 2023:

1. Respondents shall permit [forensic vendor] A&M to image Respondents' entire email server as stated in the Revised Forensic Protocol attached as Exhibit D to Viking's letter. The record demonstrates that imaging the entire email server is the most effective way for A&M to obtain electronic information relevant to the email records of the five custodians from the limited time period that is relevant. Respondents have not offered an alternative to imaging the entire email server that would allow for the efficient discovery of the relevant media. The imaging of Respondents' entire email server shall take place as soon as possible at A&M's convenience.
2. Respondents shall permit A&M to image the entirety of the custodians' personal devices. As with the email server, imaging the entirety of the custodians' personal devices is the most effective way for A&M to obtain electronic information relevant to corporate email communications. The imaging of the custodians' personal devices shall take place as soon as possible at A&M's convenience.
3. The parties shall comply with the Revised Forensic Protocol attached as Exhibit D to Viking's letter, which can also be found as Attachment C to this order. As the Revised Forensic Protocol states, to the extent A&M determines that any aspect of the Revised Forensic Protocol is not technically feasible, the parties shall follow the recommendation of A&M to formulate an alternative protocol.

Order No. 27 at 2.

Ascletis continued to resist the forensic examination of its email systems. In particular, Rimón attorneys did not allow the independent forensic investigation firm A&M to image custodian personal devices, claiming that Ascletis would seek a protective order for these devices. Viking Sanctions Mot. Ex. C (Consilvio Decl.) ¶¶ 9-16 (Ascletis counsel refusing to permit imaging of devices for custodians John Gargiulo and Kristjan Gudmundsson); Viking Sanctions

Mot. Ex. D (Howell Decl.) ¶ 5 (Ascletis counsel refusing imaging or inspection of Dr. Wu's mobile device). Ascletis never moved for a protective order.

It became evident that the forensic examination of Ascletis's email systems was not proceeding efficiently. Because the increasing burden of the forensic examination on the parties outweighed the value that information gleaned from the examination would provide, I ordered the suspension of the forensic examination on June 15, 2023. Order No. 30.

Meanwhile, the production of email from Ascletis's custodians required by Order No. 14 was still not complete. At a case management conference held June 14, 2023, Rimon attorney Mr. Heafey represented that aspects of Chinese law precluded the export of responsive documents from China—where certain custodians resided—until after they had been reviewed for privacy and state secrets. 06/14/2023 CMC Tr. at 80:1-19. Although Mr. Heafey admitted that certain emails already produced by Ascletis had not undergone a review to comply with Chinese law, he stated that his client intended to comply with the law going forward. *Id.* After hearing all parties at the case management conference, I ordered Ascletis to complete its email production by June 30, 2023. Order No. 30 at 2.

B. Viking's Omnibus Motion for Sanctions

On June 30, 2023, Viking filed the pending omnibus motion for monetary and non-monetary sanctions against Ascletis and its counsel. Motion Docket No. 1352-023. On July 12, 2023, Staff filed a response and Ascletis filed an opposition to the motion.

On July 21, 2023, Viking filed a motion for leave reply to update its accounting of attorney's fees and costs for filing the sanctions motion and to address statements of Rimon attorneys Shelley Ivan and Jason Xu appended to Ascletis's opposition brief. Motion Docket No. 1352-024. Ascletis opposed Viking's motion for leave to reply on August 2, 2023. Motion No.

1352-024 is granted-in-part. I will consider Viking's updated accounting of expenses set forth in Exhibit 68 to the reply brief; Viking's motion is denied as to all other parts of its reply.

Having reviewed the party briefs, on August 23, 2023, I ordered additional briefing to address whether monetary sanctions would be effective against Ascleitis. Order No. 36. Viking filed its supplemental brief on September 14, 2023. Ascleitis and the Foster Murphy law firm each filed a response on September 21, 2023.

C. Rimon's Motion to Intervene

On February 2, 2024, Rimon sought leave to withdraw as counsel for Ascleitis. Motion Docket No. 1352-044. Viking, Ascleitis, and Foster Murphy filed responses to Rimon's motion to withdraw. On February 7, 2024, Rimon sought leave to intervene in this investigation "for the limited purpose of defending Rimon's and Rimon's attorneys' interests in response to [Viking's Sanctions Motion]." Motion Docket No. 1352-045. On February 16, 2024, Ascleitis filed a response to Rimon's motion to intervene.

I granted Rimon leave to withdraw as Ascleitis's counsel but held Rimon's motion to intervene in abeyance. Order No. 48 (Mar. 19, 2025). I also requested that Rimon submit further briefing on several topics: (1) addressing why its arguments and evidence are timely and support intervention, (2) making all arguments about attorney and law firm liability for sanctions it proposes for consideration, and (3) attaching any evidence supporting its arguments. *Id.* at 8. Rimon filed its supplemental brief on March 22, 2024, and Viking, Ascleitis, and Foster Murphy filed responses to Rimon's supplemental brief. Rimon subsequently moved for leave to file a supplemental reply brief in response to the parties' filings. Motion Docket No. 1352-047. Motion No. 1352-047 for leave to reply is denied.

Commission Rule 210.19 addresses intervention, and provides in part:

Any person desiring to intervene in an investigation or a related proceeding under this part shall make a written motion. . . . The Commission, or the administrative law judge by initial determination, may grant the motion to the extent and upon such terms as may be proper under the circumstances.

19 C.F.R. § 210.19. “[T]here is a strong presumption in favor of intervention.” *Certain Filament Light-Emitting Diodes and Products Containing Same (II)*, Inv. No. 337-TA-1220, Order No. 15 (Nov. 16, 2020).

Having considered Rimón’s motion to intervene, its supplemental brief, and the responses submitted by the other parties, I find that the new arguments and evidence presented by Rimón are untimely. Specifically, when I requested in Order No. 48 that Rimón “address[] why its arguments and evidence are timely and support intervention,” Rimón argues that it did not move to intervene until after “it became apparent that Respondents had no intention of paying Rimón.” Rimón Suppl. Br. at 1-2. But Rimón fails to explain why a payment dispute with its client excuses presentation of evidence months after briefing on Viking’s Sanctions Motion was complete. Indeed, Rimón’s participation in that briefing is demonstrated by Rimón’s inclusion in the signature block and the fact that Rimón personnel submitted declarations in support of Ascleitis’s opposition brief. Ascleitis Sanctions Opp’n Exs. A-C. If Rimón felt that its interests were not adequately represented in the sanctions briefing, it could have emulated Foster Murphy and sought to intervene at that time. But it did not, and Rimón’s untimely submission of evidence and argument will not be considered.

Rimón’s Motion No. 1352-045 for leave to intervene is granted-in-part. It is my initial determination that Rimón may participate in the investigation as an intervenor to address the sanctions decisions, but Rimón must do so based on the existing record of the investigation. *See* 19 C.F.R. § 210.19 (administrative law judge may grant motion to intervene in an initial determination).

D. Legal Standards

1. Sanctions

The Commission “may by rule prescribe sanctions for abuse of discovery and abuse of process to the extent authorized by Rule 11 and Rule 37 of the Federal Rules of Civil Procedure.”

19 U.S.C. § 1337(h).

Under Commission Rule 210.4(c):

By presenting to the presiding administrative law judge or the Commission (whether by signing, filing, submitting, or later advocating) a pleading, written motion, or other paper, an attorney or unrepresented party or proposed party is certifying that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances—

(1) It is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation or related proceeding;

(2) The claims, defenses, and other legal contentions therein are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law;

(3) The allegations and other factual contentions have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and

(4) The denials of factual contentions are warranted on the evidence or, if specifically so identified, are reasonably based on a lack of information or belief.

19 C.F.R. § 210.4(c). If such representations were not “formed after an inquiry reasonable under the circumstances,” the administrative law judge may “impose an appropriate sanction upon the attorneys, law firms, or parties that have violated paragraph (c) or are responsible for the violation.”

19 C.F.R. § 210.4(d). “If any portion of a representation is found to be false, frivolous, misleading, or otherwise in violation of paragraph (c), a sanction may be imposed.” *Id.* The administrative

law judge “will consider whether the representation or disputed portion thereof was objectively reasonable under the circumstances” in determining whether there has been a violation. *Id.*

If the representations warrant a sanction, such sanctions “shall be limited to what is sufficient to deter repetition of such conduct or comparable conduct by others similarly situated.” 19 C.F.R. § 210.4(d)(2). The sanction “may consist of, or include, directives of a nonmonetary nature, an order to pay a penalty, or, if imposed on motion and warranted for effective deterrence, an order directing payment to the movant of some or all of the reasonable attorney's fees and other expenses incurred as a direct result of the violation.” *Id.*

Commission Rule 210.33 authorizes a presiding administrative law judge to impose monetary and non-monetary sanctions for failure to comply with a discovery order. 19 C.F.R. § 210.33(b); *Certain Balanced Armature Devices, Products Containing Same, and Components Thereof*, 337-TA-1186, Comm’n Op. at 4-6 (Mar. 23, 2021) (public version) (“*Balanced Armature Devices*”). Non-monetary sanctions may also be imposed “for the purpose of permitting resolution of relevant issues and disposition of the investigation without unnecessary delay despite the failure to comply, may take such action in regard thereto as is just, including, but not limited to the following:

- (1) Infer that the admission, testimony, documents, or other evidence would have been adverse to the party;
- (2) Rule that for the purposes of the investigation the matter or matters concerning the order or subpoena issued be taken as established adversely to the party;
- (3) Rule that the party may not introduce into evidence or otherwise rely upon testimony by the party, officer, or agent, or documents, or other material in support of his position in the investigation;
- (4) Rule that the party may not be heard to object to introduction and use of secondary evidence to show what the withheld admission, testimony, documents, or other evidence would have shown;

(5) Rule that a motion or other submission by the party concerning the order or subpoena issued be stricken or rule by initial determination that a determination in the investigation be rendered against the party, or both; or

(6) Order any other non-monetary sanction available under Rule 37(b) of the Federal Rules of Civil Procedure.”

19 C.F.R. § 210.33(b).

For monetary sanctions, the administrative law judge or the Commission “may require the party failing to obey the order or the attorney advising that party or both to pay reasonable expenses, including attorney’s fees, caused by the failure, unless the administrative law judge or the Commission finds that the failure was substantially justified or that other circumstances make an award of expenses unjust.” 19 C.F.R. § 210.33(c)(1).

2. Duty of Competence

Attorneys have a duty to “provide competent representation to a client. Competent representation requires the legal knowledge, skill, thoroughness and preparation reasonably necessary for the representation.” *Model Rules of Pro. Conduct* (“ABA Model Rules”) r. 1.1 (Am. Bar Ass’n 2024). This duty extends to discovery, in that counsel must be competent in their knowledge and ability to collect, review, and produce electronically stored information:

Attorneys have a professional and ethical obligation to understand all phases of discovery, including the identification, preservation, collection, processing, review, and production of relevant electronically stored information (ESI). . . . If attorneys are not competent in these areas, they have an ethical duty to become competent, associate themselves with attorneys who are, or to decline the representation. * * * Courts are showing less patience with counsel who plead ignorance regarding ESI or technology in general. Competence in discovery includes having a general understanding of discovery rules, how they apply to the various types of ESI a client may have that could be relevant to the matter, and a more specific understanding of how a client’s information technology systems and ESI are structured. Counsel must investigate how to locate, preserve, and collect relevant ESI from those systems, and should seek to do so in the most efficient and cost-effective manner.

DR Distributors, LLC v. 21 Century Smoking, Inc., 513 F. Supp. 3d 839, 942 (N.D. Ill. 2021) (internal quotation omitted). “Counsel must take affirmative steps to monitor compliance so that all sources of discoverable information are identified and searched.” *Certain Opaque Polymers*, Inv. No. 337-TA-883, Comm’n Op. at 36-37. (quoting *Zubulake v. UBS Warburg LLC*, 229 F.R.D. 422, 432 (S.D.N.Y. 2004)) (public version) (“*Opaque Polymers*”).

E. Ascleitis’s Sanctionable Behavior

Viking raises two categories of potentially sanctionable behavior in its motion for sanctions. First, Viking argues that certain representations by Ascleitis’s counsel to the tribunal were false and should be sanctioned. *See* Viking Sanctions Mot. at 7. Viking also argues that Ascleitis’s violation of certain discovery orders should be sanctioned. *See, e.g., id.* at 7, 60.

1. Misrepresentations by Ascleitis and Its Counsel at the Rimón Law Firm

The record supports a finding that Ascleitis and its counsel made misrepresentations to the parties and to the tribunal that were detrimental to the efficient progress of discovery in the investigation. The circumstances of these representations, and their consequences, lead me to conclude that both Ascleitis and its counsel at the Rimón law firm should be jointly and severally liable for sanctions.

For example, Rimón attorney Michael Heafey stated at a case management conference held March 3, 2023, that document production was substantially complete. 03/03/2023 CMC Tr. at 17:5-19:9. This statement is demonstrated false given the large amount of documents produced after this date, such as the production on April 11, 2023, totaling over 40,000 pages. *See, e.g.,* Order No. 24 at 2.

The record also indicates that on March 16, 2023, Mr. Heafey sent an email to Viking’s counsel that made incorrect statements about steps Ascleitis had taken to gather relevant email and

about search hits within the email collected. Viking Sanctions Mot. Ex. 2. It is not clear that documents Mr. Heafy supposedly counted had even been collected by this time,¹⁷ but in any event, Ascletis now acknowledges that the hit counts reported in the email were not correct. Ascletis Sanctions Opp'n at 4 n.4 ("The initial hit counts generated by Respondents included 17,034 hits for Dr. Jinzi Wu, 7,095 hits for Yumei Yan, 2,428 hits for John Gargiulo, and 12,965 hits for Kristjan Gudmundsson."). Even if Mr. Heafey's email were written with a good faith belief in its accuracy, there was an obligation to correct promptly the misstatements contained therein after Consilio ran the search terms against the custodian emails and came up with an accurate hit count. See 19 C.F.R. § 210.4. Neither Ascletis nor its counsel at Rimon provided Viking with an updated hit count.

In addition, Ascletis made sworn statements in response to Viking's interrogatories that were later proved false. In particular, Viking sought information regarding the identity of pharmaceutical companies with which Ascletis had partnership discussions. CX-357C.009-11 (Viking Interrogatory No. 19). Ascletis failed to identify Novartis, Sanofi, or Takeda in its response to this interrogatory, which was verified by respondent Dr. Wu. *Id.*; 100-Day Tr. (Wu) at 408:21-409:24. Evidence adduced later in the investigation shows that Ascletis did, in fact, have partnership discussions with Novartis and Sanofi, and that Ascletis entered into a confidential disclosure agreement with Takeda. 100-Day Tr. (Wu) at 409:25-411:3; CX-0603, CX-0595, CX-0597, CX-0598; Hr'g Tr. (Gudmundsson) at 743:8-17; Hr'g Tr. (Clarke) at 1121:14-1122:7; CX-1617C.0007. Discussions between Ascletis and potential pharmaceutical partners are highly relevant to the issue of injury in this investigation. Viewing the record of this investigation as a

¹⁷ See fn.16 *supra*.

whole, I find that Mr. Wu's false verification of Ascletis's interrogatory responses indicates an intent to hide relevant facts and prevent a determination on a fulsome evidentiary record.

2. Violation of Order No. 14

Order No. 14 required Ascletis to produce responsive emails for five custodians by March 30, 2023. Order No. 14 at 3. A significant portion of responsive emails were not produced until April 11, 2023, two days before the 100-day evidentiary hearing was set to begin. Order No. 19 at 2. There is no dispute that Ascletis violated Order No. 14. *Id.* I further find that attorneys from the Rimón law firm share responsibility for this violation through their own actions detailed above. And there can be no dispute that this late production not only disrupted preparation for the 100-day evidentiary hearing but also all subsequent proceedings in the investigation. I find that the late production of documents prejudiced Viking and Staff in that they were pressed to review Ascletis's production and make appropriate changes to their hearing strategy given the production's proximity to the start of the 100-day evidentiary hearing.

3. Violation of Order No. 24

Order No. 24 required Ascletis to produce documents related to patient enrollment, business development, budgets, and meeting minutes. During the 100-day evidentiary hearing, Viking elicited testimony from Dr. Wu demonstrating that Ascletis did not comply with this order. When asked at the hearing about Ascletis's discussions with other pharmaceutical companies, Dr. Wu testified, "Our [Business Development] team discusses with other companies regularly. As to whom they discussed, this table gets updated every day or every week. So it has been evolving, and I cannot provide [you with] an accurate answer." 100-Day Tr. at (Wu) 409:19-24. I find, based on Dr. Wu's testimony about the regular nature of the updates to a tracking table "every day or every week," that these documents exist. Their absence from Ascletis's production supports

a finding that Ascletis violated Order No. 24. Dr. Wu also testified that Ascletis “approach[ed] a third-party company and asked about expenses for the clinical trial Phase 3” and that Ascletis has “a framework for expenses” for clinical trials. 100-Day Tr. (Wu) at 414:11-23. Whether Ascletis calls this type of information budgets or “framework for expenses” or some other term, this information unquestionably falls within the scope of discovery required by Order No. 24.

Ascletis argues that no violation of Order No. 24 occurred because the order instructed Ascletis to “re-examine its document servers for documents” responsive to Viking’s RFPs, and that in this context “documents” does not include “emails.” Ascletis Sanctions Opp’n at 23-24; *see* 06/14/2023 CMC Tr. at 59:16-19 (Rimon attorney Jason Xu stating Ascletis did not consider an email search as within the scope of Order No. 24); Viking Sanctions Mot. Ex. 52 (discovery letter arguing “the ‘weekly updates’ that Ms. Yuemei Yan testified about are emails, not documents, and thus not within the scope of Order No. 24”).

Ascletis’s position is untenable. In its discovery requests, Viking explicitly defined “documents” to include “emails.” 06/14/2023 CMC Tr. at 63:25-66:3 (reciting the broad definition of “documents” in discovery requests to include emails and demonstrating Ascletis’s lack of objection to that definition). Based on the record as a whole, I find that Ascletis did not comply with its discovery obligations to produce documents by the date specified in Order No. 24, and its failure to effect a timely production lacks justification. I therefore find that Ascletis violated Order No. 24. I further find that attorneys from the Rimon law firm share responsibility for this violation through their own actions detailed above.

4. Violation of Order No. 27

Order Nos. 21, 25, and 27 stem from Viking’s request for “a full and complete independent examination of Respondents’ email servers and the five custodian[s]’ devices used for email, such

as laptops, desktops, and mobile devices.” Order No. 21 at 2. The parties initially jointly agreed upon the forensic examination protocol. *See* Order No. 27 Ex. B (Viking’s letter with protocol attached as Exhibit A). The parties subsequently disputed various aspects of this protocol, leading me to issue orders clarifying the protocol. *See* Order Nos. 25, 27. Insofar as Ascletis raised reasonable concerns about the scope of the examination protocol outlined in Order Nos. 21 and 25, I find that Ascletis did not violate these orders. However, there is no excuse for Ascletis’s failure to comply with Order No. 27.

Order No. 27 was unambiguous in its statement that “Respondents shall permit A&M to image the entirety of the custodians’ personal devices.” Order No. 27 at 2. Despite this, Ascletis and Rimón attorneys did not permit imaging of personal devices belonging to custodians Dr. Gudmundsson, Mr. Gargiulo, and Dr. Wu. At the time of refusal, Rimón attorneys represented that Ascletis would seek a protective order with respect to these personal devices. Viking Sanctions Mot. Ex. C (Consilvio Decl.) ¶¶ 9-16; Ascletis Sanctions Opp’n at 18-19.

Even assuming that the issue of imaging the custodians’ personal devices was not ripe until Order No. 27 issued, Ascletis never sought a protective order to justify its failure to allow the imaging. Ascletis’s obligation to comply with Order No. 27 was not discharged until I issued Order No. 30 suspending the forensic examination. Thus, Ascletis was in violation from the moment it refused to allow the imaging of its custodian’s personal devices until June 15, 2023, when Order No. 30 issued. I therefore find Ascletis violated Order No. 27. I further find that attorneys from the Rimón law firm share responsibility for this violation through their own actions detailed above.

F. Appropriate Remedy for Ascleitis's Violations

Viking proposes a variety of non-monetary and monetary sanctions as relief for Ascleitis's behavior during discovery. Viking Sanctions Mot. at 34-39, 57-59, 73-76. I find that some of Viking's proposals are disproportionate to Ascleitis's actions and are not warranted by the circumstances of this investigation.

For instance, Viking argues that an appropriate non-monetary sanction would be default judgment against all Respondents, and especially as to Dr. Jinzi Wu. Viking Sanctions Mot. at 32, 57-58, 73-74 (citing *Certain Balanced Armature Devices, Products Containing Same, and Components Thereof*, 337-TA-1186, Comm'n Op. (Mar. 23, 2021); *Certain Lithium Ion Batteries, Battery Cells, Battery Modules, Battery Packs, Components Thereof, and Processes Therefor*, Inv. No. 337-TA-1159, Comm'n Op. (March 4, 2021) ("*Lithium Ion Batteries*"); *Certain Stainless Steel Products, Certain Processes for Manufacturing or Relating to Same, and Certain Products Containing Same*, Inv. No. 337-TA-933, Comm'n Op. (June 9, 2016) ("*Stainless Steel Products*"). But the factual circumstances in the investigations Viking relies on to support its argument are distinguishable from the circumstances here.

Lithium Ion Batteries involved "extraordinary" destruction of evidence "ordered at a high level" by a party that failed "to disclose that massive spoliation to the ALJ notwithstanding the ALJ's order compelling discovery and requiring a report identifying the destroyed documents." *Lithium Ion Batteries*, Comm'n Op. at 2. In *Balanced Armature Devices*, the Commission found the respondent's "pattern of discovery misconduct, including alteration and destruction of evidence, throughout the investigation" meant "no lesser sanction than default as to [respondent] is appropriate." *Balanced Armature Devices*, Comm'n Op. at 4 (Mar. 23, 2021).

Stainless Steel Products involved extensive spoliation of evidence and misrepresentations, including destruction of thirty-six USB storage devices and the data on the laptop of its head of Research and Development and Quality Assurance. *Stainless Steel Products*, Comm’n Op. at 16-18, 20-21. There, the Commission found a sanction of default “necessary to deter similar spoliation of evidence and discovery order violations and to protect the integrity of judicial proceedings.” *Id.* at 21.

In this investigation, although actions by Ascleitis and Rimmon delayed discovery, increased costs, and likely frustrated development of a complete record, they nevertheless do not rise to the level found to justify default in other investigations. The record does not show deliberately destroyed evidence or other evidence of spoliation.

Viking also argues that an appropriate non-monetary sanction would be a finding that Ascleitis “de facto selected Option 1 of Order No. 19.” Viking Sanctions Mot. at 34. Specifically, imposing this sanction would mean finding that “Viking prevails on all matters that were designated by the Commission for decision in the 100-day proceeding, namely that Viking has demonstrated that importation of ASC41 and ASC43F by Ascleitis has substantially injured an industry in the United States within the meaning of 19 U.S.C. § 1337(a)(1)(A).” Order No. 19 at 3. Again, the sanction is too severe given the circumstances of this investigation. Sanctions based on misrepresentations “shall be limited to what is sufficient to deter repetition of such conduct or comparable conduct by others similarly situated,” and non-monetary sanctions for failure to comply with discovery orders are informed by Rule 37 of the Federal Rules of Civil Procedure. *See* 19 C.F.R. §§ 210.4(d)(2), 210.33(b). I find below that lesser sanctions are sufficient to deter repetition of the conduct at issue here. Additionally, I find that the conduct in question resulted at least in part from counsel’s incompetence in managing discovery. Advisory

Committee notes on Rule 37 indicate that such incompetence may warrant lesser sanctions than willful conduct. *See* Fed. R. Civ. P. 37 advisory committee's note to 1970 amendment subdivision (d).

1. Adverse Inferences

As discussed above, Ascleitis violated Order No. 14 by failing to produce emails in a timely manner and also violated Order No. 24 by failing to produce certain documents whose existence were confirmed by the testimony of Ascleitis witnesses. For Ascleitis's failure to comply with these discovery orders, I find that certain adverse inferences are appropriate and just under the circumstances. Indeed, Ascleitis has proposed adverse inferences that "cover the underlying facts Viking could plausibly expect to find in Respondents' emails" and "would adequately address the alleged discovery violations and still permit the Commission to make a determination on the merits." Ascleitis Sanctions Opp'n at 44-45. These specific adverse inferences include:

- If permitted by the FDA, Respondents will continue to pursue Phase II and Phase III clinical trials, and intend to obtain FDA approval and commercialize ASC41 and ASC43F in the United States if approved.
- Respondents will perform Phase III clinical trials in the United States if the FDA clears ASC41 or ASC43F Phase II clinical trials and accepts Respondents' Phase III protocol.
- The Accused Products will compete with VK2809 during Phase III clinical trials, if those products clear Phase II and are permitted by the FDA to conduct Phase III clinical trials.
- The Accused Products will compete with VK2809, if those products are approved by the FDA.

- Respondents have had, and will continue to have, discussions with potential partners regarding partnerships for the potential future importation and sale of Accused Products in the United States, including potential partners that have also explored collaboration with Viking.

Id. at 45.

I find that these adverse inferences are appropriately tailored as a remedy for Ascleitis's failure to provide discovery in accordance with Order Nos. 14 and 24. These six adverse inferences comprise the non-monetary sanctions assessed against Ascleitis.

So that my ruling is clear, I have determined that the facts established by these adverse inferences are adequately supported by other independent evidence in the record. To the extent the Commission does not find one or more of these facts supported by sufficient evidence in the record, the inferences here would independently support these factual findings.

2. Monetary Sanctions

In addition to the non-monetary sanctions in the form of adverse inferences discussed above, I find that certain monetary sanctions are appropriately assessed against Ascleitis for its violation of discovery orders and associated resulting costs incurred by Viking. Specifically, I find that monetary sanctions are appropriate to reimburse Viking for expenses incurred in response to Ascleitis's violations of Order Nos. 14, 24, and 27, and expenses incurred to prepare its Sanctions Motion. These items are discussed further below.

In addition to the three categories of expenses listed above, Viking seeks "attorney's fees and costs incurred by Viking as a result of Respondents' selection of Option 2 in Order No. 19, including all expenses for trial, post-trial briefing, reviewing Respondents' May 26 compelled production, and the motion to compel missing documents." Viking Sanctions Mot. at 76. But

Ascletis's violation of my discovery orders did not cause Viking to incur these enumerated costs. Viking was required to prepare for and prosecute the 100-day hearing, as well as draft post-hearing briefs, even if Ascletis's actions had been entirely proper. Accordingly, these costs are denied.

Ascletis's late production of email and other documents two days before the 100-day evidentiary hearing did, however, cause Viking expense that would not have been incurred but for violation of the email production deadline set in Order No. 14. Monetary sanctions assessed for violation of Order No. 14 should reimburse Viking for the fees and costs created by Ascletis's untimely production. Ascletis agrees that this category of fees and costs is appropriate. Ascletis Sanctions Opp'n at 45 ("Respondents propose the reimbursement of the following [] fees and costs incurred to review the April 11 production prior to the 100-day hearing."). Viking provided an itemized list of its expenses "associated with document review, revising direct and cross-examination outlines in view of new documents, and the costs associated with moving for a forensic examination as a result of the violation of Order No. 14" with its Sanctions Motion—these expenses total \$109,204. Viking Sanctions Mot. at 76; Viking Sanctions Reply Ex. 68 (Table C). I find that monetary sanctions in the amount of \$109,204 are appropriate for violation of Order No. 14.

The monetary sanctions shall also include attorney's fees and costs incurred by Viking as a result of Ascletis's violation of Order No. 24 in the amount of \$13,306.25. Viking Sanctions Reply Ex. 68 (Table D).

With respect to the forensic examination of Ascletis's email systems, Viking requests monetary sanctions to reimburse costs and fees totaling \$352,237.65. Viking Sanctions Reply Ex. 68 (Table B). As discussed above, Order No. 27 was violated by impeding the imaging of personal devices. For this specific violation, I find that awarding the costs of the entire forensic

examination would be disproportionate to the culpability of Ascletis and the Rimon lawyers. Viewing the circumstances as a whole, I find the adverse evidentiary inferences discussed above are sufficient to protect Viking's interests.

Finally, the monetary sanctions shall include attorney's fees and costs incurred by Viking for preparing and filing its sanctions motions. Viking Sanctions Reply Ex. 68 (updated Table E). This sanction is warranted because Ascletis and the Rimon lawyers engaged in an extensive pattern of inappropriate conduct throughout discovery, and documenting that conduct for the sanctions motion was a painstaking and expensive burden on Viking. These costs total \$444,549.60. *Id.*

In total, the monetary sanctions imposed are \$567,059.85.

3. Apportionment of Liability

The monetary sanctions discussed above shall be imposed, jointly and severally, on respondent Dr. Jinzi Wu and all Ascletis entities. As discussed above, Dr. Wu personally verified interrogatory responses that were later proven false. Dr. Wu's other actions throughout the course of his investigation, including his personal refusal to make information on his personal electronic devices available to discovery vendors for imaging, makes his personal liability for sanctions appropriate. Indeed, a review of the discovery record in this investigation leads me to conclude that Dr. Wu has little to no regard for the obligations of discovery in Commission proceedings. Moreover, Dr. Wu is an officer at each of the other respondent entities, thus giving him authority to direct the conduct of Ascletis and its counsel during discovery, and his actions and liability for sanctions are thus appropriately imputed to the Ascletis entities.

In addition, liability for a subset of the monetary sanctions discussed above is appropriately attached to the Rimon law firm, whose attorneys created or exacerbated the discovery violations through incompetence, misrepresentations, and other behaviors well documented in this record.

“Counsel must remain mindful of its own ongoing obligations to protect the integrity of the evidence and the representations provided to the Commission and opposing parties on behalf of its client and itself.” *Opaque Polymers*, Comm’n Op. at 37. “Counsel must take affirmative steps to monitor compliance so that all sources of discoverable information are identified and searched.” *Id.* (quoting *Zubulake v. UBS Warburg LLC*, 229 F.R.D. 422, 432 (S.D.N.Y. 2004)). Here, the Rimón lawyers failed to meet their professional obligation of competence and of ensuring their client’s cooperation in discovery. Instead, the Rimón lawyers took unreasonable positions with respect to discovery disputes and made misrepresentations to the other parties and to the tribunal. The Rimón attorneys also failed to timely correct misrepresentations when they obtained more accurate information. Accordingly, the Rimón law firm shall be jointly and severally liable for the monetary sanctions for violation of Order No. 14 in the amount of \$109,204 and the monetary sanctions for the attorney’s fees and costs incurred by Viking as a result of violation of Order No. 24 in the amount of \$13,306.25. The Rimón law firm is not liable for the attorney’s fees and costs incurred by Viking for preparing and filing its sanctions motions in the amount of \$444,549.60. This difference in liability reflects a difference between the regard that the Rimón lawyers have manifest for candor and cooperation with this tribunal as compared to that shown by their former clients the Respondents.

For clarity, I find that, other than the Rimón law firm, no other attorneys who entered appearances on behalf of the Ascleitis respondents should be liable for monetary sanctions. Indeed, the only reason that this investigation was able to proceed to a decision on the merits was because other competent and professional counsel later represented Ascleitis.

III. STATUTORY AUTHORITY

The Commission has statutory authority¹⁸ to investigate an alleged violation of section 337(a)(1)(A) by named respondents when such respondents have allegedly used unfair methods of competition and unfair acts in the importation of articles into the United States, 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. 19 U.S.C. § 1337(a)(1)(A). Here, Viking’s complaint states that Ascleitis violated section 337 by importing the Accused Products by reason of misappropriation of trade secrets. *See* Notice of Investigation. The Commission thus has statutory authority to conduct this investigation.

As discussed below, the accused ASC41 and ASC43F tablets have been imported into the United States. No party disputes the Commission’s statutory authority to issue a remedy against imported accused products in accordance with 19 U.S.C. § 1337 if there is a violation of that statute. I find that the Commission has statutory authority over the imported accused products in accordance with 19 U.S.C. § 1337. *See Sealed Air Corp. v. Int’l Trade Comm’n*, 645 F.2d 976, 985–86 (C.C.P.A. 1981); 19 U.S.C. § 1337.

Both Viking and Ascleitis have actively participated in this investigation. No party has contested the Commission’s statutory authority over the private parties. *See* CIB at 18-19; RIB at

¹⁸ Prior Commissions decisions have referred to terms such as “subject matter jurisdiction,” “personal jurisdiction,” and/or “in rem jurisdiction.” *Certain Liquid Transfer Devices with an Integral Vial Adapter*, Inv. No. 337-TA-1362, Comm’n Op. at 9 (July 26, 2024). Although the Commission has used such terms in the past as a shorthand for statutory authority, the Commission has “endeavor[ed] to realign its terminology with the language of section 337” and has clarified that “it has ‘statutory authority’ to investigate the alleged violation, rather than ‘subject matter jurisdiction,’ ‘personal jurisdiction,’ and/or ‘in rem jurisdiction’ under Article III” of the U.S. Constitution. *Id.*

23. I find that the Commission has statutory authority over the private parties in accordance with the Commission's governing statutes. *See, e.g.*, 19 U.S.C. §§ 1333, 1337(e)-(f)

IV. IMPORTATION

To prove a violation of section 337 by a particular respondent, a complainant must show that the respondent engaged in “the importation of articles into the United States, 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” pursuant to an unfair act. 19 U.S.C. § 1337(a)(1)(A).

It is undisputed that Ascleitis has imported ASC41 and ASC43F tablets into the United States. *See* Response of Respondents to Complaint and Notice of Investigation (EDIS Doc. ID No. 792345) at ¶ 141 (“Respondent Gannex admits that for the sole purpose of clinical trials, ASC41 and ASC43F, selective thyroid hormone receptor-beta agonists, have been imported into the United States.”); *see also* JX-0007C.0004; CX-0046; CX-0047; CX-0357C; Order No. 40 at 3, *unreviewed in relevant part by* Comm’n Notice (Dec. 21, 2023). In view of the record evidence, I find that the importation requirement of section 337 has been satisfied with respect to the Accused Products.

V. TRADE SECRET MISAPPROPRIATION BY ASCLETIS

This section begins with an overview of the legal standard for adjudicating a violation of section 337 based on the importation and sale of articles developed using misappropriated trade secrets. After laying out the law, I evaluate the evidence showing that Viking owns the information it asserts are trade secrets and how secrecy of the information has been maintained. Next, I analyze the evidence showing that the information meets the standard for legal protection as trade secrets. Then I examine the record for evidence demonstrating that the protectable asserted trade secrets

were disclosed to Ascletis while the parties were in a confidential relationship. The analysis continues by assessing evidence of Ascletis’s use of the disclosed, protectable trade secrets. This section concludes with an evaluation of Ascletis’s independent development defenses.

A. Legal Standards

Section 337 of the Tariff Act of 1930, as amended, makes unlawful “[u]nfair methods of competition and unfair acts in the importation of articles” 19 U.S.C. 1337(a)(1)(A). “The Commission has long interpreted section 337 to apply to trade secret misappropriation.” *TianRui Grp. Co. v. Int’l Trade Comm’n*, 661 F.3d 1322, 1326 (Fed. Cir. 2011). “In cases in which misappropriated trade secrets are used in the manufacture of the imported goods,” the Commission may find a section 337 violation. *Id.* at 1332-35.

Misappropriation of trade secrets “is a method of unfair competition defined by the common law.” *Certain Rubber Resins and Processes for Manufacturing Same*, Inv. No. 337-TA-849, Comm’n Op. at 9 (Feb. 26, 2014) (public version) (“*Rubber Resins*”). The Federal Circuit held that “a single federal standard, rather than the law of a particular state, should determine what constitutes a misappropriation of trade secrets sufficient to establish an ‘unfair method of competition’ under section 337.” *TianRui*, 661 F.3d at 1327. Accordingly, the Commission considers the Restatement (Third) of Unfair Competition, the [Uniform Trade Secrets Act (“UTSA”)], the Restatement of Torts, the Defend Trade Secrets Act of 2016 (18 U.S.C. §§ 1831-39) (“DTSA”),¹⁹ and federal common law when evaluating allegations of trade secret misappropriation. *Certain Botulinum Toxin Products, Processes for Manufacturing or Relating to*

¹⁹ The DTSA provides that “district courts of the United States shall have original jurisdiction of civil actions brought under this section.” 18 U.S.C. § 1836(c).

Same and Certain Products Containing Same, Inv. No. 337-TA-1145, Comm’n Op. at 11 (Jan. 13, 2021) (public version) (“*Botox*”); see *TianRui*, 661 F.3d at 1327-38.

Based on these sources, the Commission has defined four elements a complainant must prove to support a claim of trade secret misappropriation:

- (1) a protectable trade secret exists;
- (2) the complainant is the owner of the trade secret;
- (3) the complainant disclosed the trade secret to respondent while in a confidential relationship or the respondent wrongfully took the trade secret by unfair means; and
- (4) the respondent has used or disclosed the trade secret causing injury to the complainant.

See *Botox*, Comm’n Op. at 13 (citing UTSA § 1(4)).

A complainant has the burden of proving the existence of a protectable trade secret (element one above). See, e.g., *Certain Apparatus for the Continuous Prod. of Copper Rod*, Inv. No. 337-TA-52, Comm’n Op., 1979 WL 445781, at *19 (Nov. 23, 1979) (“*Copper Rod*”). The alleged trade secret must be described with a “reasonable degree of precision and specificity [as] appropriate.” *Certain Crawler Cranes and Components Thereof*, Inv. No. 337-TA-887, Comm’n Op. at 44-45 (May 6, 2015) (public version) (quoting 1 Roger M. Milgrim, *Milgrim on Trade Secrets*, § 1.09[3], at 2-214 (1995)) (“*Crawler Cranes*”). The Commission considers six factors in determining whether a trade secret exists:

- (1) the extent to which the information is known outside of complainant’s business;
- (2) the extent to which it is known by employees and others involved in complainant’s business;
- (3) the extent of measures taken by complainant to guard the secrecy of the information;
- (4) the value of the information to complainant and to his competitors;

(5) the amount of effort or money expended by complainant in developing the information; and

(6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Botox, Comm’n Op. at 10-11. These six so-called *Botox* factors “are not individually dispositive.”

Id. at 11. Rather, they are “instructive guidelines for ascertaining whether a trade secret exists.”

Id. (citing *Learning Curve Toys, Inc. v. PlayWood Toys, Inc.*, 342 F.3d 714, 722 (7th Cir. 2003)).²⁰

The Commission has noted that the UTSA does not define the term “use” (element four of the unfair act of misappropriation of trade secrets), but the Restatement provides that “use” includes “the marketing of goods that embody a trade secret, [where] the trade secret is employed in manufacturing or production, or is relied on to assist or accelerate research or development.” See *Crawler Cranes*, Comm’n Op. at 52-53 (citing Restatement (Third) of Unfair Competition § 40, Comment c).

In its *Bone Cements* opinion, the Commission stated, “While the Commission has not explicitly articulated whether a complainant must show ‘any use’ or ‘substantial use’ of a trade secret to prevail, prior Commission decisions align with the ‘substantial use’ standard.” *Certain Bone Cements and Bone Cement Accessories*, Inv. No. 337-TA-1175, Comm’n Op. at 15 (July 9, 2021) (public version) (“*Bone Cements 1175*”); see also *Crawler Cranes*, Comm’n Op. at 61-62 (finding misappropriation despite incomplete “use” of a trade secret where thirteen of the twenty-two features were included in the accused product).

²⁰ The DTSA’s definition of a trade secret is also instructive here. The DTSA defines a trade secret as “financial, business, scientific, technical, economic, or engineering information” where two conditions are met—“(A) the owner thereof has taken reasonable measures to keep such information secret; and (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information.” 18 U.S.C. § 1839(3).

Although the complainant bears the burden of establishing a *prima facie* case of trade secret misappropriation, “once they make that showing, the burden shifts to Respondents to show independent development,” if it is a defense. *Botox*, Comm’n Op. at 11-12. Under the DTSA, “reverse engineering, independent derivation, or any other lawful means of acquisition” are defenses. 18 U.S.C. § 1839(6)(B); *see also* UTSA § 1(1). There is a “heavy burden of persuasion” in proving independent development. *Certain Processes for the Manufacture of Skinless Sausage Casings and Resulting Product*, Inv. No. 337-TA-148/169, Initial Determination, 1984 WL 273789, at *95 (July 31, 1984) (emphasis added) (“*Sausage Casings*”); *see also Pioneer Hi-Bred Int’l v. Holden Found. Seeds, Inc.*, 35 F.3d 1226, 1241 (8th Cir. 1994) (“[O]nce [plaintiff] produced convincing evidence of misappropriation, [defendant] was obligated to provide persuasive evidence of lawful derivation.”).

B. Viking Owns the Asserted Trade Secrets

The record evidence establishes that Viking is the exclusive licensee of certain information acquired through a 2014 Master License Agreement between Viking as licensee and Ligand Pharmaceuticals Inc. and Metabasis Therapeutics, Inc., as licensors. JX-1004C (Berkman Depo.) at 16:22-17:3; CX-0021C (Viking/Metabasis Master License Agreement (May 21, 2014)). Through that agreement, Viking became an exclusive licensee of “all licensor know-how controlled by licensor as of the effective date” relating to the compound “MB07811.” JX-1004C (Berkman Depo.) at 14:14-17; *see* CX-0021C (Master License Agreement) § 2.3(a). MB07811 is the name previously used by Ligand/Metabasis to refer to VK2809. JX-1010C (Lian Depo.) at 113:9-16. Staff agrees that Viking is either the owner or the exclusive licensee of the intellectual property at issue through the Master License Agreement and Viking’s own research efforts. SIB at 26-27. I find that the information transferred by the Master License Agreement included the

asserted Formulation Trade Secrets and most of the asserted Preclinical Trade Secrets. *Compare* CX-0021C.0071-80, *with* Trade Secret Documents, *and* .Trade Secret Chart.

The evidence also shows that Viking took over the research and development of VK2809 from Ligand/Metabasis after entering into the Master License Agreement. Viking is the owner of all documents relating to VK2809 that were created by or for Viking from 2014 onwards, as well as the owner of the asserted Preclinical and Clinical Trade Secrets set forth in those documents. *Compare* CX-0021C.0071-80, *with* Trade Secret Documents, *and* .Trade Secret Chart.

I find that, as a result of the Master License Agreement and Viking's own subsequent research efforts, Viking is the owner or exclusive licensee of the intellectual property incorporated into the asserted trade secrets.²¹ I therefore find that Viking is the owner of the asserted trade secrets.

C. Viking Carefully Guards the Secrecy of the Asserted Trade Secrets

1. Factual Findings

As established above, Viking licensed intellectual property assets from Ligand/Metabasis, including asserted Formulation Trade Secrets and asserted Preclinical Trade Secrets. Deposition testimony from Ligand's former general counsel establishes that Ligand and Metabasis implemented measures to safeguard the confidential intellectual property that was exclusively licensed to Viking, including the asserted trade secrets. *See* JX-1004C (Berkman Depo.) at 17:13-

²¹ The Master License Agreement [REDACTED] JX-1004C (Berkman Depo.) at 14:14-17; *see* CX-0021C (Master License Agreement) § 2.3(a). Any information about MB07811 that was generally known or readily ascertainable by others would not have been "controlled by" Ligand/Metabasis, and therefore was neither a protectable trade secret nor covered by the license agreement. As discussed further in section V.D below, the asserted trade secrets identified by Viking as having been transferred from Ligand/Metabasis were not publicly known or readily ascertainable by others and are therefore owned by Viking.

18:19, 23:17-24:12, 32:21-34:18, 36:3-37:7. For instance, Ligand employed physical security measures for their facilities, such as requiring a key card for access to the facilities and secure areas within the facilities. *Id.* at 28:15-29:4. Ligand employees had to abide by a code of conduct and ethics policy requiring them to safeguard trade secret information, including by limiting access to trade secret information on a need-to-know basis, implementing controls for remote access to Ligand's systems, and using trade secrets only for legitimate business purposes. *Id.* at 19:3-11, 27:9-12, 27:17-28:14. Ligand also required its employees to undergo annual training regarding their confidentiality obligations. *Id.* at 29:16-22. For remote access to its systems, Ligand required employees to login using a virtual private network with unique password protection. *Id.* at 27:22-28:9. In addition, before accessing Ligand confidential information, employees and third parties had to sign confidentiality agreements. *Id.* at 22:7-11, 20:22-21:22.

After acquiring the intellectual property assets at issue in this investigation, Viking took steps to maintain the confidentiality of those assets and the asserted trade secret information it developed in-house. For example, Viking restricts internal access to the asserted trade secrets by implementing a need-to-know policy limiting access to only those persons needing access for their job responsibilities, and such access requires leadership approval. Hr'g Tr. (Morneau) at 48:2-7; *see also* JX-1014C (Morneau Depo.) at 40:4-16, 40:21-41:11. Viking's physical facilities are secured 24 hours a day and only accessible via keycard. Hr'g Tr. (Morneau) at 55:3-8. If an employee separates from Viking, their access card is either returned or deactivated, thus eliminating the risk of information physically leaving with the employee. *Id.* at 55:9-12.

Viking also implements corporate policies and guidelines designed to safeguard the asserted trade secrets, such as a document retention policy, a code of conduct for employees, an ethics policy, an employee handbook, and a social media policy. *See, e.g., id.* at 53:22-55:2;

CX-1103C; CX-2005C; CX-2006C CX-2007C. For example, Viking's employee handbook states that (1) employees may not use or disclose confidential information except to perform their jobs, (2) employees must return Viking confidential information immediately upon separation, and (3) employees must report any suspicion that the confidentiality of Viking's data has been compromised. CX-2007C.0036-37.

In addition, Viking requires that its employees sign agreements to maintain the confidentiality of Viking's confidential information, including the asserted trade secrets. Hr'g Tr. (Morneau) at 53:22-54:6; CX-1103C. These agreements restrict employees from using any confidential information, including trade secrets, except for the benefit of Viking and to the extent necessary to perform obligations to Viking. CX-1103C.0001-02. Employees are contractually bound not to disclose the confidential information to any person, firm, corporation or other entity, without written authorization from Viking in each instance. *Id.*

Viking's digital repositories are also secured. Viking's internal document repository is DropBox, a commercial product. Hr'g Tr. (Morneau) at 48:2-7. When sharing confidential information with potential external collaborators, Viking uses vendors to host its virtual data rooms. Two of those virtual data rooms are relevant to this investigation: a 2016 virtual data room hosted by vendor Donnelley and a 2019 virtual data room hosted by vendor SecureDocs.²² Hr'g Tr. (Broidrick) at 76:17-77:1. Viking's forensic expert Mr. Bui testified that, in his opinion, DropBox, Donnelley, and SecureDocs had security measures adequate to protect confidential and trade secret documents, such as encryption of files at rest and during transit. Hr'g Tr. (Bui) at 152:12-153:14. Moreover, corporate representatives from Donnelley and SecureDocs provided

²² As summarized in section I.H.2 above and as will be discussed in more detail below, Ascleitis personnel accessed the 2016 Donnelley data room and the 2019 SecureDocs data room.

deposition testimony demonstrating that the virtual data rooms hosted by the vendors met industry standards for security. *See* JX-1002C (Baird Depo.) at 14:20-18:6, 25:4-22; JX-1025C (Zabramski) at 9:1-10, 16:16-17.

The evidence shows that Viking has taken reasonable and necessary secrecy measures when sharing its confidential information, including asserted trade secret information, with contract research organizations (“CRO”) and other potential partners. Before sharing its confidential information, Viking first performs due diligence to evaluate the potential partner. Hr’g Tr. (Broidrick) at 76:4-21. Only if the potential partner satisfies the initial vetting process, and if there is mutual agreement by Viking and the potential partner, would the parties then enter into a confidential disclosure agreement. *Id.* at 76:4-21; Hr’g Tr. (Chavez) at 106:17-107:18. Viking requires an executed confidential disclosure agreement before sharing its confidential information with an outside party. Hr’g Tr. (Chavez) at 113:21-114:7; Hr’g Tr. (Broidrick) at 107:14-18; *see also* JX-1011C (Mancini Depo.) at 48:20-49:4, 75:8-21, 76:15-17, 77:1-11. As Viking’s former chief development officer Dr. Masamune testified, although Viking might share Trade Secret Documents or parts of Trade Secret Documents with an outside contract research organization, Viking would only “ever do that or even talk about doing that” if the contract research organization were under a confidential disclosure agreement. *See* Hr’g Tr. (Masamune) at 169:25-170:5. And upon entering a confidential disclosure agreement with the potential partner, Viking would provide only the minimal amount of confidential information needed to accomplish the purpose of the confidential disclosure agreement. Hr’g Tr. (Broidrick) at 76:4-21; Hr’g Tr. (Chavez) at 106:17-107:18.

2. Conclusions Regarding *Botox* Factors (1), (2), and (3)

As noted in section V.A. above regarding the legal standards for finding trade secret misappropriation, the first *Botox* factor concerns the extent to which information is known to others outside the complainant's business. The record evidence summarized above demonstrates that Viking confidential information is known to others outside Viking's business only when the recipient of that information passes a vetting process and agrees under contract not to disclose the information further. Additionally, even if the recipient of Viking's confidential information were subject to a confidentiality agreement, Viking discloses no more information than is necessary to accomplish its business purpose. I determine that these facts weigh in favor of trade secret protection under *Botox* factor (1).

The second *Botox* factor concerns the extent to which information is known by employees and others involved in the complainant's business. The record evidence summarized above demonstrates that Viking confidential information is segmented within Viking on a need-to-know basis and that Viking employees cannot take information with them when they separate from Viking. I determine that these facts weigh in favor of trade secret protection under *Botox* factor (2).

The third *Botox* factor concerns the extent of measures taken by the complainant to guard the secrecy of the information. The record evidence summarized above demonstrates that Viking takes robust steps to guard confidential information from unauthorized physical transfer, unauthorized digital transfer, unauthorized transfer by Viking personnel, and unauthorized transfer by outside persons. I determine that these facts weigh in favor of trade secret protection under *Botox* factor (3).

D. The Asserted Trade Secrets Are Not Generally Known or Readily Ascertainable and Are Valuable

1. Asserted Formulation Trade Secrets

As summarized in section I.F.1. above, Viking asserts a number of formulation trade secrets, identified individually as TS Nos. 4-11, 34-36, 44, and 111, and identified collectively as “Formulation Trade Secrets.” The Formulation Trade Secrets comprise formulations, excipients, and ingredients used in developing VK2809. *See* CDX-1035C (Trade Secret Chart).

Viking presents argument and evidence that the Formulation Trade Secrets are not known or readily ascertainable and have economic value to competitors. *See, e.g.*, CIB at 59-60. Ascletis argues that none of the Formulation Trade Secrets are protectable because they were either generally known or readily ascertainable and lack independent economic value. *See* RIB at 31-52. Staff takes the position that TS Nos. 4, 34, and 35, along with certain subparts of TS No. 44, are protectable trade secrets, but that the other Formulation Trade Secrets are not protectable. SIB at 29-44.

As discussed below, the evidence shows that the asserted Formulation Trade Secrets are protectable trade secrets.

a) TS Nos. 4, 34, and 35 are protectable.

TS Nos. 4, 34, and 35 relate to the [REDACTED]
 [REDACTED] VK2809, which Viking’s VK2809 Investigator’s Brochure describes [REDACTED]
 [REDACTED]
 [REDACTED] CX-1010C § 4.3 (VK2809 Investigator’s
 Brochure). [REDACTED]
 [REDACTED]
 [REDACTED] Hr’g Tr. (Masamune) at 218:11-219:1. [REDACTED]

[REDACTED]

[REDACTED] *See id.* [REDACTED]

[REDACTED]. *Id.*

at 219:2-16. [REDACTED]

[REDACTED] *Id.* at 219:17-24. [REDACTED]

[REDACTED] *Id.* at 219:25-220:9.

There is no dispute that the chemical structure of the API used in VK2809— $C_{28}H_{32}ClO_5P$ —is not a trade secret. Even Viking’s expert Dr. Silber acknowledges that $C_{28}H_{32}ClO_5P$ was “a known structure.” Hr’g Tr. (Silber) at 480:7-9. Numerous patents and scientific journal articles disclosed the chemical structure of $C_{28}H_{32}ClO_5P$ well before Metabasis entered into the 2014 Master License Agreement with Viking. For example, in September 2007, Metabasis published a journal article in Proceedings of the National Academy of Sciences that disclosed the chemical structure of MB07811 (the former name for VK2809). RX-1356.0002 at col. 1. (Erion *et al.*). The chemical structure of $C_{28}H_{32}ClO_5P$ was also published in the Journal of Medicinal Chemistry in November 2008, in Drug Metabolism and Disposition in August 2008, and in both Hepatology and the British Journal of Pharmacology in February 2009. RX-1359.0007 (compound 72) (Boyer *et al.*); RX-1255.0002 (Fujitaki *et al.*); RX-1358 at fig. 1 (Cable *et al.*); RX-1360.0002 at col. 1 (Ito *et al.*). It also appears in at least one patent obtained by Metabasis. RX-1197 at col. 355 (U.S. Patent No. 7,514,419).

Viking argues that the combination of $C_{28}H_{32}ClO_5P$ with the specific excipients listed in TS Nos. 4, 34, and 35 is a protectable trade secret. CIB at 40-45. Staff agrees, and further argues that without extensive experimentation or hindsight, there is insufficient evidence that a skilled formulator would have known to use [REDACTED]

[REDACTED] in a formulation for the VK2809 compound. SIB at 31, 34. Ascletis counters that the combination of the VK2809 API with [REDACTED] [REDACTED] is not a trade secret because the combination would have been readily ascertainable by a pharmaceutical formulator based on publications by Metabasis and Viking. RIB at 32-35.

As I explain in more detail below, Viking's specific formulation of VK2809, which combines [REDACTED] the API $C_{28}H_{32}ClO_5P$, would not have been readily ascertainable from the publications cited by Ascletis. The evidence also shows that Viking's formulation has economic value and that Viking took reasonable measures to protect the secrecy of its formulation. Accordingly, Viking has established that TS Nos. 4, 34, and 35 are protectable trade secrets.

(1) The combination of the VK2809 API with specific excipients was not readily ascertainable.

Ascletis cites several publications describing the Metabasis drug MB07811, which has the same chemical formula as the API in VK2809: $C_{28}H_{32}ClO_5P$. RIB at 32-33 (citing RX-1356, RX-1255, RX-1359, RX-1358, RX-1360, RX-1197, RX-1747, RX-2011, RX-1199, RX-1198, RX-1226). Ascletis argues that Viking's formulation of VK2809 with Viking's specific excipients would be readily ascertainable from those articles. RIB at 34-35.

The earliest reference cited by Ascletis, Erion *et al.*, discloses the administration of MB07811 in formulations [REDACTED] RX-1356 (Erion *et al.*) at Ascletis-337-1352_00008781; Hr'g Tr. (Abato) at 759:16760:5. Boyer *et al.* discloses formulations [REDACTED] RX-1359 (Boyer *et al.*) at Ascletis-337-1352_00259247, _00259257; Hr'g Tr. (Abato) at 760:17-761:1. Fujitaki *et al.* also discloses formulations [REDACTED] RX 1255 (Fujitaki *et al.*) at

Ascletis-337-1352_00259711, _00259712, _00259713; Hr’g Tr. (Abato) at 760:6-16. Cable *et al.* discloses a formulation [REDACTED] RX 1358 (Cable *et al.*) at Ascletis-337-1352_00259535; Hr’g Tr. (Abato) at 761:2-16. And a February 2009 article by Ito *et al.* discloses the activity of [REDACTED]
[REDACTED]
[REDACTED]. RX-1360 (Ito *et al.*) at Ascletis-337-1352_00259759, -259761; Hr’g Tr. (Abato) at 761:17-762:5.

The journal articles identified above each disclose formulations that combine the API of VK2809— $C_{28}H_{32}ClO_5P$ — [REDACTED]
[REDACTED] Additionally, none disclose [REDACTED]
[REDACTED]

Ascletis also cites various patents and patent publications discussing the MB07811 compound to argue that a skilled formulator would be able to ascertain [REDACTED]
[REDACTED]

[REDACTED] The first patent on which Ascletis relies, U.S. Patent No. 7,514,419 (“the ’419 patent”), is a Metabasis U.S. patent issued in April 2009 and titled “Phosphorus-containing thyromimetics.” RX 1197. The ’419 patent discloses several formulations, including [REDACTED]
[REDACTED]
[REDACTED] *Id.* at 11:20-35, 186:31-34. The ’419 patent also describes [REDACTED] *Id.* at 412:15-17; *see also* Hr’g Tr. (Abato) at 762:11-20.

The second patent publication on which Ascletis relies, PCT Pub. No. WO 2018/094265 A2 (“WO265”), published in May 2018, is a Viking patent publication that discloses [REDACTED]

[REDACTED] RX-1199 at [0058]

[REDACTED], [0067] [REDACTED]

[REDACTED], [0072-0073] [REDACTED]

[REDACTED], [0085] [REDACTED]

[REDACTED]; *see* Hr’g Tr. (Abato) at 765:7-21.

The third patent publication relied on by Ascletis, PCT Pub. No. WO 2018/226604, published in December 2018, is also a Viking patent publication that lists a number of possible formulations for use with compounds [REDACTED]. RX-1198. These formulations, including [REDACTED]

[REDACTED] RX-1198 at [0047] [REDACTED]

[REDACTED], [0057] [REDACTED]

[REDACTED], [0062-0063]

[REDACTED], [0075] [REDACTED]

[REDACTED]; *see* Hr’g Tr. (Abato) at 764:9-765:6.

While the patent documents disclose a wider combination of excipients than the journal articles, Ascletis’s expert Dr. Abato nevertheless admitted that the public literature during the relevant time did not disclose a formulation that contains [REDACTED] [REDACTED] with the API of VK2809. Hr’g Tr. (Abato) at 904:4-10. I find, ultimately, no publication cited by Ascletis expressly discloses Viking’s confidential formulation that incorporates the VK2809 API [REDACTED]

[REDACTED]. See *Uniroyal Goodrich Tire Co. v. Hudson*, 873 F. Supp. 1037, 1046 (E.D. Mich. 1994) (journal articles did not make trade secrets readily ascertainable where the publications referred only to general information about the product but did not disclose confidential formulation and test data), *aff'd*, 97 F.3d 1452 (6th Cir. 1996); *Electro-Craft Corp. v. Controlled Motion, Inc.*, 332 N.W.2d 890, 899 (Minn. 1983) (where “the exact combination of features” was not known, trade secret protection was appropriate “even though none of the processes or features are unique in the industry”).

Ascleitis and its expert Dr. Abato contend that even if the specific formulations in TS Nos. 4, 34, and 35 were not expressly disclosed in the public literature, a skilled formulator reviewing the articles above would be able to readily ascertain Viking’s formulation. Dr. Abato’s chain of reasoning is as follows: $C_{28}H_{32}ClO_5P$ was a publicly known compound, and a researcher would be motivated to make [REDACTED] and is more valuable in the market. Hr’g Tr. (Abato) at 767:6-768:6. But he also testified that “VK2809, [REDACTED] [REDACTED]. *Id.* at 768:7 14. To address that issue, Dr. Abato opined that a researcher would be motivated to start employing “tricks,” such as [REDACTED] [REDACTED] *Id.* at 768:15-18. But he testified that it is not possible to [REDACTED] [REDACTED]. *Id.* at 768:19-25. So, he continued, a researcher would be “directed toward” [REDACTED]. *Id.* at 769:1-10. But he also testified that [REDACTED] [REDACTED] would have an “advantage” of [REDACTED] it would also have “disadvantages” [REDACTED] [REDACTED]. *Id.* at 769:10-20. To deal with “those liabilities,” Dr. Abato testified a researcher would use another “trick”—[REDACTED] *Id.* at

769:20 22. At that point, Dr. Abato opined, a researcher “would be motivated to use” the excipients in literature published by Metabasis and Viking, which he listed as “ [REDACTED]

[REDACTED] *Id.* at 769:23 770:9.

I give no weight to Dr. Abato’s opinion that one would readily ascertain Viking’s formulation and excipients for VK2809 from public sources. In fact, Dr. Abato’s testimony supports the opposite conclusion. Dr. Abato admits several facts that demonstrate the difficulty of arriving at Viking’s formulation. For example, Dr. Abato admitted that the chemical composition of $C_{28}H_{32}ClO_5P$ [REDACTED] is “a problem.” Hr’g Tr. (Abato) at 768:7 14. This admission by Dr. Abato is corroborated by Viking’s expert Dr. Amidon, who testified that coming up with a formulation for the VK2809 product API “is very challenging” because [REDACTED]

[REDACTED] Hr’g Tr. (Amidon) at 290:25-291:13. Given the chemical composition of $C_{28}H_{32}ClO_5P$, the record demonstrates that it would likely be necessary to consider “many excipients”—potentially “hundreds”—to arrive at Viking’s formulation. See *id.*

Additionally, to the extent that Dr. Abato opined that a researcher would be “motivated” to use “the excipients that Metabasis and -- and Viking published,” Hr’g Tr. (Abato) at 769:23 770:9, the [REDACTED] used in Viking’s confidential [REDACTED] [REDACTED] were not published by Metabasis or Viking at all. In fact, Dr. Abato admitted that the references of record “don’t specifically state [REDACTED]” but only disclose the “general [REDACTED]” Hr’g Tr. (Abato) at 784:10-14, 906:9 23. It is undisputed that there are there are many [REDACTED] [REDACTED]. See, e.g., Hr’g Tr. (Masamune) at 218:11-219:1. Dr. Abato’s testimony provides

no explanation as to why a formulator would ascertain from the literature that Viking used [REDACTED]

[REDACTED] found in TS Nos. 4, 34, and 35 to the exclusion of others.

As for the mention [REDACTED], Dr. Abato stated in his direct testimony that a researcher would be “motivated” to use “excipients [REDACTED]” but he admitted on cross-examination that [REDACTED] in WO265, upon which he opined, was [REDACTED]

[REDACTED]. *Compare* Hr’g Tr. (Abato) at 769:23 770:9, *with id.* at 906:3-11.

Dr. Abato also admitted that his citation to [REDACTED] in the ’419 patent relates to [REDACTED]

[REDACTED]. *See* Hr’g Tr. (Abato) at 909:18-910:8. Dr. Abato’s testimony therefore undercuts a conclusion that [REDACTED] excipient for C₂₈H₃₂ClO₅P would be readily ascertainable.

For the references that disclose an excipient ultimately found in TS Nos. 4, 34, and 35, Dr. Abato failed to explain why a formulator would ascertain Viking’s use of one of the disclosed excipients in the literature to the exclusion of numerous other possibilities also included in the same article. As but one example, Dr. Abato cited the formulation [REDACTED] [REDACTED], but he never explained why another excipient in that same formulation [REDACTED] should not be considered when formulating C₂₈H₃₂ClO₅P [REDACTED]. *Compare* Hr’g Tr. (Abato) at 765:12-21, *with* RX-1199 at [0101].

Finally, Dr. Abato admitted that he did not provide an opinion as to “how long it would take a formulator to come up with the alleged trade secret VK2809 with excipients” using only the public information in the references he cited, which demonstrates a lack of foundation to support

his conclusion that Viking's undisclosed formulation would be readily ascertainable. *See* Hr'g Tr. (Abato) at 904:11-905:9.

Dr. Abato's opinion, and Ascleitis's argument, does not meet the legal standard for finding that the VK2809 formulation is "readily ascertainable" from public sources. Matters that are generally or commonly known within the industry are considered readily ascertainable, and conversely, "information that would be difficult or impossible to independently recreate" is not readily ascertainable. 1 Milgrim on Trade Secrets § 1.07A (2024). Even if there is publicly available information about the matter, the matter is not readily ascertainable unless that information would allow a skilled member of the industry to easily reverse engineer and reproduce all elements of the matter. *Id.*; *see SmithKline Beecham Pharms. Co. v. Merck & Co.*, 766A.2d 442, 448 (Del. 2000) (a published patent for producing a varicella vaccine did not make commercial production of the vaccine readily ascertainable because the patent did not explain the commercial procedure). When extensive experimentation is required to discern the content of an alleged trade secret, that secret is not "readily ascertainable" by others. *See, e.g., Reingold v. Swiftships, Inc.*, 126 F.3d 645, 650 (5th Cir. 1997) (affirming trade secret protection where it would have been "expensive and time consuming for anyone to duplicate the mold through independent designing, planning, and construction or by reverse engineering").

I find that Dr. Abato's testimony does not support a conclusion that Viking's specific trade secret formulations would be readily ascertainable from the sources he cited. His testimony shows no reason, other than the hindsight provided by access to Viking's confidential information, for a formulator to select [REDACTED] (which are not specifically mentioned in any reference of record). [REDACTED] with the VK2809 API without also experimenting with the myriad other combinations suggested by the public literature.

Probative testimony from fact witnesses on both sides supports a conclusion that the formulation information in TS Nos. 4, 34, and 35 was not readily ascertainable from the sources cited. For example, Ascleitis corporate representative Kunhua Dong was tasked with creating a capsule formula for Ascleitis's competing drug, ASC41, which has the same $C_{28}H_{32}ClO_5P$ API. Mr. Dong testified that he conducted a search of public literature and patents in February 2019 but he was unable to identify the excipients Viking used in its formulation from that review. *See* JX-1006C (Dong Depo.) at 81:2-14, 95:7-13. Dr. Gudmundsson, the Head of Discovery for Ascleitis, similarly testified that Viking's publications had a "menu of excipients that could be used" but he admitted that "the specific ingredients" used by Viking are not disclosed and the [REDACTED] found in TS No. 4 are "not listed" in those publications. Hr'g Tr. (Gudmundsson) at 747:9-21.

Dr. Horoko Masamune, the former chief development officer of Viking, testified that "there are many, many types, hundreds, perhaps, [REDACTED]. Hr'g Tr. (Masamune) at 218:19-22. When asked if it was common to [REDACTED] she replied that "[i]t is one of many techniques," and "[y]ou would first have to determine that [REDACTED] [REDACTED]" and that there are "many possible solutions [REDACTED] *Id.* at 219:17-24. She also testified that a formulator has "hundreds" of options when attempting [REDACTED] *Id.* at 225:17-21.

The testimony of Mr. Dong, Dr. Gudmundsson, and Dr. Masamune summarized above is consistent with the opinion of Viking's expert Dr. Amidon, who provided credible testimony that it would likely be necessary to consider "many excipients"—potentially "hundreds"—to arrive at Viking's formulation [REDACTED] Hr'g Tr. (Amidon) at 290:25-291:13. Dr. Amidon personally searched the public scientific literature and reviewed the

same documents as Ascleitis's expert Dr. Abato. Like Dr. Abato, Dr. Amidon did not find a disclosure of the specific formulation in TS Nos. 4, 34, and 35. *See id.* at 273:13-274:2. Unlike Dr. Abato, however, Dr. Amidon actually performed an analysis to determine how long it would take a researcher to independently develop Viking's formulation trade secrets from public sources. *Compare* Hr'g Tr. (Amidon) at 290:2-19, *with* Hr'g Tr. (Abato) at 904:11-905:9. Dr. Amidon concluded it would take 9 to 12 months of experimentation to arrive Viking's formulation due to the challenge of identifying appropriate excipients [REDACTED]. Hr'g Tr. (Amidon) at 290:2-19. Dr. Amidon's conclusions are more consistent with the weight of the record evidence than those of Ascleitis's expert Dr. Abato. Accordingly, I find Dr. Amidon's opinion that the Viking formulations were not readily ascertainable from public sources to be more persuasive than Dr. Abato's unsupported conclusion to the contrary.

In sum, I find that the record demonstrates that the formulation trade secrets in TS Nos. 4, 34, and 35 were neither known outside Viking nor readily ascertainable from public sources during the relevant period.

(2) TS Nos. 4, 34, and 35 have independent economic value.

"To have independent economic value, a trade secret must be sufficiently valuable and secret to afford an actual or potential economic advantage over others." *Cisco Sys., Inc. v. Chung*, 462 F. Supp. 3d 1024, 1052 (N.D. Cal. 2020) (quoting *Calendar Research LLC v. StubHub, Inc.*, 2017 WL 10378336, at *3 (C.D. Cal. Aug. 16, 2017)). A complainant may show independent economic value "by circumstantial evidence of the resources invested in producing the information, the precautions taken to protect its secrecy, and the willingness of others to pay for its access." *See id.* Moreover, "the standard to show that trade secrets derive [independent] economic value is not a high standard." *Id.*

The record evidence shows that Viking paid millions of dollars to exclusively acquire confidential information that included the formulation information in TS Nos. 4, 34, and 35. CX-0021C; 100-Day Tr. (Morneau) at 40:7-41:23; 100-Day Tr. (Zante) at 113:13-114:10. This is strong evidence that the Formulation Trade Secrets have independent economic value. Additionally, Viking's former chief development officer Dr. Masamune credibly testified that TS No. 4 was "extremely valuable" to Viking, saving time because Viking "didn't have to develop a new formulation to get into the clinic." Hr'g Tr. (Masamune) at 168:4-11. Dr. Masamune testified that she would not be surprised if developing TS No. 4 took nine months to a year, which demonstrates independent economic value. JX-1012C (Masamune Depo.) at 267:19-268:3, 269:20-270:5.

Viking's expert Dr. Amidon also credibly testified that TS Nos. 4, 34, and 35 each have economic value. Hr'g Tr. (Amidon) at 274:12-275:1. Specifically, Dr. Amidon testified that those trade secrets have value because tests to identify successful formulation properties, such as [REDACTED] properties, are "expensive and time consuming to do." Hr'g Tr. (Amidon) at 274:16-21. In other words, without knowing the information in TS Nos. 4, 34, and 35, a competitor would need to conduct extensive testing to arrive at Viking's specific combination of excipients and to establish that the combination has a therapeutic effect. Staff agrees with this assessment. SIB at 35. The evidence, therefore, shows that TS Nos. 4, 34, and 35 have independent economic value.

b) TS No. 5 is protectable.

Asserted TS No. 5 is the fact that Viking's VK2809 formulation is prepared [REDACTED]

[REDACTED].
See CDX-1035C (Trade Secret Chart). Viking's expert Dr. Silber testified that this information

has independent economic value because a competitor would save time and expense for the extensive testing required to identify an appropriate process for preparing a formulation for VK2809. Hr’g Tr. (Silber) at 275:3-10.

Respondents’ expert Dr. Abato testified that this is not a protectable trade secret because [REDACTED] [REDACTED].” See Hr’g Tr. (Abato) at 792:12-19. As discussed in the previous section, the evidence shows that the composition and properties of the VK2809 API were generally known by the time Viking granted Ascleptis’s employees access to its secure data room in July 2016. Dr. Abato’s testimony suggests that, once having learned [REDACTED] [REDACTED], the formulator could use standard reference texts to learn the [REDACTED] [REDACTED] claimed as TS No. 5, to the extent the formulator was not already familiar with that method. See Hr’g Tr. (Abato) at 792:17-24; *see also* RIB at 39 (arguing TS No. 5 is “a standard process in the field, and thus provided no value”). Staff is of the same view as Ascleptis. SIB at 36-37.

Despite Dr. Abato’s testimony, consideration of the six *Botox* factors weighs in favor of finding that TS No. 5 is a protectable trade secret. In particular, the value of TS No. 5 is not that it was a never-before-seen method [REDACTED], but rather that Viking’s specific [REDACTED] in TS No. 4, and [REDACTED], may be used successfully to formulate VK2809 for use in preclinical and clinical trials. As Dr. Amidon testified, the value lies in knowing that TS No. 5 is an appropriate process. Hr’g Tr. (Amidon) at 275:3-10.

For these reasons, I find that TS No. 5 is a protectable trade secret. See *Interbake Foods, L.L.C. v. Tomasiello*, 461 F. Supp. 2d 943, 966 (N.D. Iowa 2006) (manufacturing process was

sufficiently unique to qualify for trade secret status, particularly as to the order and timing of the mixing process, even though almost all the individual segments of its production system were generally known in the baking industry).

c) TS Nos. 6-9 and 36 are protectable.

TS Nos. 6-9 and 36 are related to the [REDACTED] Viking's VK2809 formulation in TS No. 4, specifically to the fact that it is [REDACTED] CDX-1035C (Trade Secret Chart) at 1, 22. TS No. 9 specifies that the formulation should be [REDACTED]. *Id.* at 1.

Ascletis argues that TS Nos. 6-9 and 36 are not protectable because (1) Viking did not identify any specific formulation that is [REDACTED], (2) "once a formulator has a formulation, he or she can 'readily test it [REDACTED] [REDACTED] and (3) [REDACTED] was made known to patients in clinical trials and therefore is no longer secret. RIB at 38 39. Staff agrees that TS Nos. 6-9 and 36 are not protectable because patients in clinical trials were told [REDACTED]. SIB at 37-39.

Ascletis's first two arguments are readily rejected. First, as to the allegation that Viking has not identified the relevant formulation with sufficient specificity, Ascletis never sought to compel a more detailed explanation of TS Nos. 6-9 and 36, despite the opportunity to do so at multiple case management conferences. Accordingly, Ascletis has waived this argument. But the argument also fails on the merits. Viking clearly and succinctly identified TS Nos. 6-9 and 36 on a handful of pages in three documents: CDX 1010C.0014, CDX-1026C.0042-.0048, and CDX 1033C.0002. Ascletis's claim that they cannot "meaningfully compare the putative trade secret information with information that is generally known in the industry" rings particularly hollow

after Ascleitis has routinely complained that Viking has provided too much detail in its trade secret allegations. *Compare* RIB at 38, with Hr’g Tr. (Ascleitis opening statement) at 21:20-21 (noting “Viking’s 400-plus pages of prehearing brief and 400 plus pages of appendices”); Hr’g Tr. (Masamune) 202:17-19 (“I didn’t even have my team print the trade secrets because I was trying to kill less trees, but there are thousands of pages . . .”).

Ascleitis’s second argument—that [REDACTED] would be ascertainable by testing “once a formulator has a formulation”—is also unavailing. First, it begins with the unfounded assumption that a formulator outside of Viking would know the formulation for VK2809. But, as detailed above, no one outside Viking knew Viking’s formulation [REDACTED] in TS No. 4 together with the C₂₈H₃₂ClO₅P API. Additionally, Ascleitis’s argument lacks merit because it admits that, even if a formulation was known, it would require testing [REDACTED]. In other words, the [REDACTED] [REDACTED] would not be readily apparent.

Ascleitis’s own fact witnesses confirmed that [REDACTED] was not readily apparent from public sources. Mr. Dong testified that he was unable to [REDACTED] [REDACTED] even though he had searched the public literature related to VK2809 for the purpose of creating Respondents’ [REDACTED] for the same API. JX-1006C (Dong Depo.) at 81:8-14, 82:16-83:2. Moreover, Dr. Gudmundsson testified that, based on his review of the Viking public information, he “would not have known” “that the Viking VK2809 [REDACTED]” JX-1009C (Gudmundsson Depo.) at 162:22-163:7.

Ascleitis’s third argument—that Viking instructed patients [REDACTED], an argument joined by Staff—also does not demonstrate that TS Nos. 6-9 and 36 were known or

readily ascertainable. It is true that in November 20219 Viking distributed informed patient consent forms instructing [REDACTED]. JX-1011C (Mancini Depo.) at 87:9-18, 88:8-11; Hr’g Tr. (Mancini) at 262:3-14, 265:224-266:1. In the section of the consent form labeled “Your Responsibilities for This Study,” patients are instructed [REDACTED] RX-1238C.0007 (Informed Consent Form). Patients cannot participate in a VK2809 clinical trial without signing the informed consent form. *See* RX-1238C.0001, .0003. Patients do not sign a confidentiality agreement before being given a copy of the informed consent form, and nothing in the consent form itself requires patients to keep its contents confidential. JX-1011C (Mancini Depo.) at 89:9-13; Hr’g Tr. (Mancini) at 263:7-9. Patients are instead instructed to “take the time to read this document carefully and please feel free to talk about it with your partner, family members, family doctor or others.” RX 1238C.0001.

But the evidence above is not enough to conclude that TS Nos. 6-9 and 36 were generally known. Viking does not merely assert that it was unknown [REDACTED]. Rather, Viking avers through TS Nos. 6-9 and 36 that no one outside of Viking knew [REDACTED] in TS No. 4—[REDACTED]. Ascleitis has pointed to no evidence that anyone outside Viking who was instructed [REDACTED], knew that the formulation [REDACTED], or knew that the instruction [REDACTED]. The cited testimony from Ascleitis’s expert Dr. Abato does not address any of these aspects of TS Nos. 6-9 and 36 in his testimony. *See* Hr’g Tr. (Abato) at 807:3-808:6.

Notably, Ascletis does not contend that it learned [REDACTED] TS No. 4 from Viking's patient consent forms. Rather, the record evidence shows that Ascletis learned that information from accessing Viking's secure data room before the consent form was released in November 2019. CX-1992C (2019 Audit Log); JX-1011C (Mancini Depo.) at 91:8-10 (consent form "was not something that was available during the time that [Ascletis personnel] reviewed data in the [Viking] data room"); Hr'g Tr. (Mancini) at 265:16-266:1 (consent form not available before November 2019). A laboratory notebook kept by Ascletis's contract research organization shows that Ascletis was using the formulation encompassed by TS Nos. 6-9 and 36 several months before the release of the consent form, at least as early as June 15, 2019. *See* Hr'g Tr. (Abato) at 901:24-902:18 (establishing Ascletis's knowledge of a formulation having [REDACTED] [REDACTED] on June 15, 2019). Thus, the evidence does not show that clinical patients knew of the specific formulation in TS Nos. 6-9 and 36 and that [REDACTED], but the evidence does show that Ascletis knew the formulation, knew [REDACTED] and knew [REDACTED] because Ascletis accessed Viking's confidential data in the secure virtual data room.

In contrast to the deficient evidence cited by Ascletis and Staff, Viking's expert Dr. Amidon credibly testified that TS Nos. 6-9 and 36 are valuable because they "provide a competitor with an understanding of the Viking formulation and provide a path forward to identify, for example, a formulation [REDACTED] "provid[ing] a competitive advantage." Hr'g Tr. (Amidon) at 275:12-20.

I find that TS Nos. 6-9 and 36 are protectable trade secrets.

d) TS No. 10 is protectable.

The crux of TS No. 10 is that the API in Viking's confidential [REDACTED] [REDACTED]. See Hr'g Tr. (Masamune) at 171:21-25 (“[W]e’re talking about that the API [REDACTED] [REDACTED], which is an important factor and de-risks the formulation.”). To particularly identify this trade secret, Viking cites and annotates two emails. See CDX-1035C.0001 (Trade Secret Chart). In the first email, Spike Lo at Ascletis asks Viking about [REDACTED].” CDX-1025C at .0002 (annotated version of CX-1025C). In the second email, Viking discloses to Ascletis, “The [REDACTED] [REDACTED] CDX-1033C at .0002 (annotated version of CX-1033C).

Ascletis and Staff contend that TS No. 10 is not a protectable trade secret. Ascletis cites testimony from Dr. Abato stating that a formulator knowing the published composition of the API $C_{28}H_{32}ClO_5P$ would be [REDACTED] because [REDACTED] [REDACTED].” RIB at 42 (citing Hr'g Tr. (Abato) at 769:15-22). Staff cites evidence that [REDACTED] [REDACTED]. SIB at 40 (citing Hr'g Tr. (Masamune) at 217:8-218:10). Staff contends “it doesn’t matter whether [REDACTED] so TS No. 10 has no economic value. *Id.*

The arguments and evidence raised by Ascleitis and Staff do not contradict Viking's showing that, until Viking's confidential email to Ascleitis, [REDACTED]. [REDACTED]. For example, Ascleitis cites testimony from Dr. Abato that a formulator would know "the excipients that Metabasis and -- and Viking published" [REDACTED]. [REDACTED] See Hr'g Tr. (Abato) at 769:25-770:4. This testimony is not credible in multiple respects. First, as has already been demonstrated, no publication cited by Dr. Abato shows [REDACTED]. [REDACTED]. See *Electro-Craft*, 332 N.W.2d at 899 (where "the exact combination of features" was not known, trade secret protection was appropriate "even though none of the processes or features are unique in the industry"). Dr. Abato's opinion begins with the assumption that those excipients were known, but they were not.

A more expansive evaluation of Dr. Abato's testimony also shows the circularity of his reasoning. Dr. Abato first said a formulator would know [REDACTED]
[REDACTED]
[REDACTED] Hr'g Tr. (Abato) at 769:25-770:4. But when Ascleitis's own counsel later asked why a formulator would [REDACTED]
[REDACTED], Dr. Abato said, "[REDACTED]
[REDACTED]
[REDACTED]. *Id.* at 784:18-21. In other words, Dr. Abato's opinion is that [REDACTED]
[REDACTED]. Even if the record showed reasons for such a binary

restriction (and it does not), Dr. Abato never explains why Viking's formulation would be readily ascertainable if [REDACTED] were unknown, as I find was the case.

Next, Dr. Abato makes unjustified leaps of logic. He states that [REDACTED], a formulator would know Viking [REDACTED]. But Dr. Abato never addresses the fact that [REDACTED]. Viking's former employee Dr. Masamune credibly testified that "there are many, many types, hundreds, perhaps, [REDACTED] and that a formulator has "hundreds" of options when attempting to [REDACTED] Hr'g Tr. (Masamune) at 218:19-22, 219:17-24, 225:17-21.

For the reasons above, I find Dr. Abato's opinion that TS No. 10 is readily ascertainable by others lacks foundation and I give it no weight.

I also find no merit in the argument of Staff that TS No. 10 has no value. Ascletis's expert Dr. Abato also admitted [REDACTED] is known to be a difficult problem. Hr'g Tr. (Abato) at 769:17-19 ("So the disadvantages [REDACTED], and that would be bad. And it can [REDACTED]"). Viking's former employee Dr. Masamune gave similar testimony. Hr'g Tr. (Masamune) at 218:9-10 [REDACTED]."). The difficulty of knowing [REDACTED] is corroborated by Mr. Lo's email asking Viking about that very issue. CDX-1025C at .0002 (annotated version of CX-1025C) (inquiring about [REDACTED]). If one would know "extremely quickly" from public sources that [REDACTED], as

Dr. Abato opined, it begs the question as to why Ascleitis needed ask Viking about the issue. *Compare* Hr’g Tr. (Abato) at 810:6-16, *with* CDX-1025C at .0002.

Viking’s expert Dr. Amidon provided credible testimony about the value of knowing [REDACTED]. Dr. Amidon testified that knowing [REDACTED] would be valuable to a competitor because it allows the competitor to know formulation characteristics of a compound with “positive clinical outcomes.” Hr’g Tr. (Amidon) at 275:22-276:3, 353:8-12. He also said that TS No. 10 provides “a perspective on the possibility and the value of [REDACTED].” *Id.* at 275:22-276:6; *see also id.* at 274:17-21 (experiments to [REDACTED] are “expensive and time-consuming”).

Dr. Amidon’s testimony about [REDACTED] is consistent with the admission from Ascleitis’s expert Dr. Abato that [REDACTED] “is the most valuable.” *See* Hr’g Tr. (Abato) at 768:5-6. In fact, Dr. Abato’s entire chain of reasoning as to why a formulator would supposedly be “motivated” to select Viking’s formulation from thousands of potential combinations begins with that value proposition.

Viewing the record evidence as a whole, I find TS No. 10 was not known or readily ascertainable, has value to a competitor, and is a protectable trade secret.

e) TS No. 11 is protectable.

Asserted TS No. 11 states that [REDACTED].” CDX-1035C (Trade Secret Chart) at 1. This is information that Viking provided to Respondents in August 2016 in answer to Respondents’ emailed questions. RX-1207C (email from V. Dourado regarding “Canceled: Ascleitis call to discuss VK2809”) (“[REDACTED]

[REDACTED]). There is no evidence that Viking has ever publicly revealed this information, and Staff agrees that TS No. 11 is a protectable trade secret. SIB at 41.

Ascletis argues that Viking publications “reveal that [REDACTED] [REDACTED]—making it readily apparent [REDACTED]” *See* RIB at 43. But the only thing readily apparent from Ascletis’s argument is the error of its logic. Even if Viking had published statements [REDACTED], that in no way forecloses [REDACTED]. The only contemporaneous evidence Ascletis cites for this supposedly public and exclusive [REDACTED] is a Viking patent application that discloses all manner of potential [REDACTED] [REDACTED]. *See* SIB at 44 (citing RX-1199). Nothing in the patent application remotely suggests that Viking [REDACTED].

Viking’s expert Dr. Amidon testified that “[t]rade secret 10 and 11 touch on [REDACTED]. These trade secrets are valuable in providing a perspective on the possibility and the value of [REDACTED]. And a competitor would have a reason, for example, to consider as one approach [REDACTED] to take advantage of this trade secret.” Hr’g Tr. (Amidon) at 275:22-276:6. Staff concedes that Dr. Amidon’s testimony on [REDACTED] is “sufficient—though barely” to establish the independent economic value derived from the secrecy of TS No. 11. SIB at 41.

I find Dr. Amidon's testimony on this point to be credible and consistent with the weight of the record evidence. Accordingly, I find that TS No. 11 is a protectable trade secret.

f) TS No. 44 and asserted subparts TS Nos. 44.33-44.36, 44.38-39, and 44.46-44.52 are protectable.

TS No. 44 is the confidential Chemistry, Manufacturing, and Controls ("CMC") document for the MB07811 API that Metabasis included as Item 7 of its Initial New Drug ("IND") application. *See* CDX-1026C (annotated version of CX-1026C); CX-2318C (MB07811 CMC document, IND Item 7). TS No. 44 comprises several subparts. Viking currently asserts subparts 44.33-44.36, 44.38-39, and 44.46-44.52 as trade secrets. *See* CDX-1035C (Trade Secret Chart) at 24-25.

TS No. 44 expands on the information in other Formulation Trade Secrets that I have already found to be protectable. For example, while TS No. 4 provides a list of ingredients used in the VK2809 formulation, TS No. 44.33 provides the names for those ingredients that were used to prepare samples for testing. *Compare* CDX-1035C (Trade Secret Chart) at 24, *with* CDX-1035C at 1 (both citing CDX-1026C at .0033). TS No. 44.34 explains the functions of the ingredients. CDX-1026C at .0033. TS No. 44.35 provides amounts of the ingredients [REDACTED] *Id.* at .0034. TS No. 44.36 identifies the drug product manufacturer, packager, and labeler. *Id.* at .0035. TS No. 44.38 identifies suppliers of components used in the drug product. *Id.* at .0035-.0036.

TS No. 44.39 provides [REDACTED] TS No. 5. *Compare* CDX-1035C (Trade Secret Chart) at 24, *with* CDX-1035C at 1. Similarly, TS Nos. 44.46-44.52 [REDACTED] *Compare* CDX-1035C at 24-25, *with* CDX-1035C at 1. Staff argues that TS Nos. 44.46-44.52 concern readily ascertainable information that Viking disseminated to

the public. SIB at 42. I disagree. None of these additional details are known or readily ascertainable outside of Viking. I find TS Nos. 44.39 and 44.46 44.52 are protectable for the reasons discussed above. Additionally, even if TS Nos. 4-9 were known, I find, and Staff agrees, that the additional, detailed information in TS Nos. 44.33-44.36, 44.38-39, and 44.46-44.52 was not known or readily ascertainable by others.

The evidence shows that the asserted subparts of TS. No. 44 identify information of independent economic value that Viking has kept secret. *See* Hr’g Tr. (Amidon) at 276:8-17 (“Trade secret 44 and its subparts would inform the competitors of – provide a very detailed [REDACTED]”). Viking’s former employee Dr. Masamune testified how valuable the CMC document is: “It contains all of the key details on how to manufacture the drug substance and the drug product.” Hr’g Tr. (Masamune) at 169:5-7. She further testified that it would take about 18 months and \$1.5 million to perform the formulation work reflected in Viking’s CMC document. *Id.* at 169:8-15. For the above reasons, I therefore find that TS Nos. 44.33-44.36, 44.38-39, and 44.46 44.52 are protectable trade secrets.

g) TS No. 111 is protectable.

The final Formulation Trade Secret is TS No. 111, which is defined as the “compilation of formulation trade secrets” that I have individually considered above. CDX-1035C (Trade Secret Chart) at 32.

Above I have determined that each of Viking’s other Formulation Trade Secrets—TS Nos. 4-11, 34-36, and 44 (with subparts)—were not known or readily ascertainable outside of Viking. I therefore necessarily also find that the compilation of information represented by TS No. 111 was

not known or readily ascertainable outside of Viking. I additionally find that TS No. 111 has economic value for each of the reasons that its subparts have value.

I alternatively find that, even if some of the constituent information in TS No. 111 is known or readily ascertainable, TS No. 111 as a whole is not known or readily ascertainable and is still protectable. Neither Ascleitis nor Staff have presented any evidence to the contrary. “[A] trade secret may consist of a compilation of data, public sources or a combination of proprietary and public sources.” *United States v. Nosal*, 844 F.3d 1024, 1042 (9th Cir. 2016). “In the case of a compilation trade secret that includes in part publicly known or readily ascertainable information, the collected information derives value from keeping the whole compilation secret.” *Bone Cements 1175*, Comm’n Op. at 16. “A trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, but the unified process design and operation of which in unique combination affords a competitive advantage and is a protectable trade secret[.]” *Computer Care v. Service Sys. Enterprises, Inc.*, 982 F.2d 1063, 1074 (7th Cir. 1992) (internal citation omitted).

Ascleitis and Staff argue that Viking has failed to prove that compilation TS No. 111 is more valuable than the sum of its parts and that TS No. 111 is therefore not protectable. *See* RIB at 89; SIB at 43-44. Their arguments are not persuasive in view of the record evidence. Dr. Silber testified that the asserted compilation trade secrets allow competitors to “very efficiently” assess the value and likelihood of approval of VK2809, which was particularly vital for Ascleitis because its ASC41 drug has the same API as VK2809. Hr’g Tr. (Silber) at 452:20-453:7. Dr. Silber also testified that compilations allow competitors to more quickly make drug development decisions and that knowing Viking’s compilation trade secrets helped Ascleitis gain confidence to launch the ASC41 program. *Id.* And Dr. Amidon testified that the compilation of the Formulation Trade

Secrets is more than the sum of its individual parts because “it provides a very good perspective” as to VK2809’s value and “the likelihood of successfully bringing this to market.” Hr’g Tr. (Amidon) at 276:19-25; *see also* Hr’g Tr. (Masamune) at 168:12-169:15 (“all of the key details” of formulation represent 18 months of work). Beyond the sum of the value of its subparts, I find TS No. 111 has independent economic value as a succinctly organized collection of that information in four documents: CX-1010C, CX-1025C, CX-1026C, and CX-1033C.

I find that TS No. 111 is a protectable trade secret.

2. Asserted Preclinical Trade Secrets

Viking asserts a number of preclinical trade secrets, identified individually as TS Nos. 16-18, 20-28, 37, 58-60, 100, 102, 104, and 109-110, and identified collectively as the “Preclinical Trade Secrets.” Before testing a drug in humans, researchers conduct preclinical studies to find out whether the drug has the potential to cause serious harm, also called toxicity. SX 0001 at 1352-STAFF-000019. Usually, preclinical studies are not very large, but provide information on dosing and toxicity levels. *Id.* Viking’s asserted Preclinical Trade Secrets relate to the design, implementation, and interpretation of studies conducted in the laboratory and with animals in anticipation of obtaining FDA approval to study effects of the drug in humans. *See* Hr’g Tr. (Abrouk) at 943:4-6 (“The purpose of preclinical work, in general, is to come up with a safe enough dose to take as a first dose in humans while having some activity.”).

Complainant’s expert Dr. Silber testified that, in his opinion, the identified Preclinical Trade Secrets “derive independent economic value from not being generally known or readily ascertainable by another person who can obtain economic value from them.” Hr’g Tr. (Silber) at 385:2-15 (“[T]hey inform Respondent[s] about what they would consider themselves in running studies.”).

Ascletis's expert Dr. Abrouk testified that Viking's asserted Preclinical Trade Secrets are generally known or readily ascertainable from at least three sources of information: (1) existing FDA regulatory guidance on the types of preclinical studies required for drug approval and the structure that such studies should have; (2) inferences that can be drawn from the known fact that VK2809 proceeded to trials in humans, something that is not possible unless the required preclinical studies achieved good results; and (3) various public statements made by Metabasis in journal articles or other publications. *See* Hr'g Tr. (Abrouk) at 949:12-950:21, 1056:21-1057:12, 1058:16-21.

Staff takes a middle ground, arguing that asserted preclinical trade secrets of raw data, summaries of results, and conclusions of study reports are likely protectable as trade secret information because they are not readily ascertainable. SIB at 67. But Staff also contends that the "selection of which studies to perform" and "the design and research protocol for a preclinical study" are not protectable because such information would be generally known or readily ascertainable by competitors. *Id.* at 66-67. In Staff's view, only the following subparts of the Asserted Preclinical Trade Secrets qualify as protectable trade secrets: TS Nos. 18.1 to 18.3, 21.3 to 21.6, 25 to 25.156, 27.6 to 27.8, 28.3, 37 to 37.4.3, 100.10 to 100.24, 102.7 to 102.15, 104.10 to 104.17, and 109. *Id.* at 69.

At the outset, I find the record evidence shows that the Formulation Trade Secrets were used to produce the studies in the Preclinical Trade Secrets. In other words, even if some of the study information in the Preclinical Trade Secrets were publicly known, it was not publicly known that the compound investigated in the studies was [REDACTED]

[REDACTED]

[REDACTED]. CX-1010C (VK2809 Investigator's Brochure (Jan. 12, 2018)) § 4.3. As

discussed in section V.D.1 above, the record evidence shows that knowing the specific formulation used in the Preclinical Trade Secrets would have value to a competitor. On at least that basis, I find that the Preclinical Trade Secrets are protectable.

Independent of that finding, I additionally find that the Preclinical Trade Secrets are protectable regardless of whether the specific formulation used in the studies was known or unknown. I address specific arguments and evidence relating to that finding for each of the remaining asserted Preclinical Trade Secrets below.

a) TS Nos. 16, 23, 24, and 26 are protectable.

TS No. 16 is a two-page document listing [REDACTED] reports for VK2809; TS No. 23 is a one-page list of [REDACTED] reports; TS No. 24 is a one-page list of [REDACTED] study reports for MB07811; and TS No. 26 is a two-page list of [REDACTED] reports for MB07811. CDX-1035C.0005, .0011, and .0020 (Trade Secret Chart); CX-1021C; CX-1024C; CX 1022C; CX-1023C. The lists at issue disclose the report titles, the name of the party responsible for the study, species of animal that was studied, and a unique report number. CX-1021C; CX-1024C; CX 1022C; CX-1023C. This set of asserted trade secrets does not disclose any of the results of the studies listed. *See* Hr’g Tr. (Abato) at 822:1-14 (“Q. Do these lists include any data? A. No, they don’t. They are just simply lists. They don’t inform which studies to do. They don’t inform what the results of those studies are, how important those studies were. It is just lists.”).

Viking presents arguments and evidence that TS Nos. 16, 23, 24, and 26 are a valuable and useful overview of the [REDACTED], which can guide decision-making for future studies. CIB at 66 (citing Hr’g Tr. (Masamune) at 191:9-21). Viking also cites testimony from its

expert Dr. Silber that TS Nos. 16, 23, 24, and 26 are neither generally known nor readily ascertainable. CIB at 45 (citing Hr'g Tr. (Silber) at 432:15-19).

Ascletis and Staff both argue that TS No. 16 is not protectable because it contains only lists of preclinical studies conducted on VK2809 and a competitor would already know that such preclinical studies should be conducted. RIB at 72-76; SIB at 69-70. Ascletis alone goes on to argue that TS Nos. 23, 24, and 26 are also not protectable for that same reason. RIB at 72-76. Staff does not present developed argument about TS Nos. 23, 24, and 26 in its post-hearing briefs and therefore has abandoned further arguments as to those trade secrets. Order No. 2 at GR 14.1 (Feb. 7, 2022) (“Any contentions for which a party has the burden of proof that are not set forth in detail in the post-hearing initial brief shall be deemed abandoned or withdrawn.”).

The central argument of both Ascletis and Staff is that the FDA has provided public guidance about the kinds of preclinical testing that should be done before filing an IND application and that therefore a “competent researcher” would know what preclinical tests would need to be conducted to develop VK2809. *See, e.g.*, RIB at 73-74. According to Ascletis and Staff, lists of these kinds of tests have no value and are not protectable as trade secrets.

The argument advanced by Ascletis and Staff is not persuasive. If the documents comprising TS Nos. 16, 23, 24, and 26 merely stated that certain kinds of preclinical studies should be conducted, they might be equivalent to public FDA guidance. But TS Nos. 16, 23, 24, and 26 are confirmation that [REDACTED] of the kinds of studies required for preparing an IND application. The lists organize and categorize the studies conducted as:

[REDACTED]
[REDACTED] CX 1021C; CX 1022C; CX-1023C; CX-1024C. Ascletis’s expert Dr. Abrouk conceded that the information contained in the asserted Preclinical Trade Secrets

do not explicitly appear in any FDA guidance, Hr’g Tr. (Abrouk) at 1034:24-1035:4, and neither Ascletis nor Staff have cited any evidence showing it was publicly known that these dozens of preclinical studies have been performed on VK2809.

The difference in value to a competitor between public knowledge of what should be done to prepare an IND application and knowledge of specific confidential studies that a competitor in fact conducted cannot be disputed. Even Ascletis admits that researchers will change their investigation decisions if it is known that a compound has been “tested before.” *See* RIB at 80. Additionally, the studies listed in TS Nos. 16, 23, 24, and 26 demonstrate a significant expenditure of resources over several years, which is a reflection of the confidence a company has in the potential value of the drug being studied. *See* Hr’g Tr. (Masamune) at 191:22-193:20; Hr’g Tr. (Silber) at 432:5-8. Knowing that information provided competitive value.

The record also shows that details about the studies found in the titles on the lists give a competitor insight into the contours of the particular preclinical program Metabasis developed to study VK2809. As Dr. Silber testified, each preclinical development program must be customized on a case-by-case basis based on the API being studied. *See* Hr’g Tr. (Silber) at 438:21-24 (“A guidance document can’t by itself really address the uniqueness of a particular API.”); *see also id.* at 437:8-21, 490:15-23, 1155:7-15; Hr’g Tr. (Masamune) at 191:18-24; RX-1670.0002 (“The kind, duration, and scope of animal and other studies required in the application will depend on the duration and nature of the proposed clinical investigations.”); RX-1620.0007 (“Since pharmacological effects vary depending on the specific properties of each test substance, the studies should be selected and designed accordingly.”).

The titles of studies in TS Nos. 16, 23, 24, and 26 reflect a specific, customized research program and go beyond generic guidance. For example, the study titles reveal [REDACTED]

[REDACTED]

[REDACTED]

See CX 1021C; CX 1022C; CX-1023C; CX-1024C. All of this would be of value to a competitor.

In view of the evidence showing that TS Nos. 16, 23, 24, and 26 have independent value and were not generally known or readily ascertainable, I find that TS Nos. 16, 23, 24, and 26 are protectable trade secrets.

I additionally find that, even if some of the constituent information in each list in TS Nos. 16, 23, 24, and 26 is known or readily ascertainable, each of the four unique compilations represented in the lists were not known or readily ascertainable. See *Bone Cements 1175*, Comm’n Op. at 16 (“In the case of a compilation trade secret that includes in part publicly known or readily ascertainable information, the collected information derives value from keeping the whole compilation secret.”). The same record evidence noted above shows their value, and I find they are protectable as trade secrets.

b) TS Nos. 17, 18, 28, 37, 100, 102, and 104 are protectable.

TS No. 17 consists of two documents that describe [REDACTED]

[REDACTED] CX-1016C [REDACTED];

CX-1002C [REDACTED]

[REDACTED] Viking’s fact witness Dr. Masamune testified that the former study report is the [REDACTED] and “provides a good roadmap for planning [REDACTED].” Hr’g Tr. (Masamune) at 175:2-10. The latter study report “points to [REDACTED].” *Id.* at 175:21-176:6.

TS No. 18 consists of information found in [REDACTED]
[REDACTED] Viking's witness Dr. Masamune testified that these studies are "[e]xtremely valuable" because they "point[] to [REDACTED] as well as helping you to plan [REDACTED]." Hr'g Tr. (Masamune) at 176:17-177:16. TS Nos. 18.1 through 18.3 relate to a discussion of [REDACTED]
See CX-1018C; CDX-1035C (Trade Secret Chart) at 6-7.

TS No. 28 consists of [REDACTED]
[REDACTED] CX-1004C [REDACTED]
[REDACTED]
Dr. Masamune testified that [REDACTED] that you have to understand in drug development. And so this is informative both in terms of the study itself, [REDACTED]
[REDACTED]."
Hr'g Tr. (Masamune) at 186:1 7.

TS No. 37 is [REDACTED] in Section 5 of the Investigator's Brochure for VK2809. CX-1010C (VK2809 Investigator's Brochure) at 14-25. Dr. Masamune testified that Section 5 is [REDACTED]
[REDACTED] Hr'g Tr. (Masamune) at 172:25-173:3. That information includes [REDACTED]
[REDACTED] For example, TS No. 37.4 refers to a [REDACTED]
[REDACTED]
[REDACTED] Hr'g Tr. (Masamune) at 174:2-10.

TS No. 100 is a [REDACTED]. CX-1030C [REDACTED]
[REDACTED]

[REDACTED] Dr. Masamune testified that “[REDACTED]

[REDACTED] Hr’g Tr. (Masamune) at 187:3-8.

TS No. 102 is a report of a study concerning [REDACTED]

CX 1031C [REDACTED]

[REDACTED] Dr. Masamune testified that “[t]his is an important study because [REDACTED]

[REDACTED].” Hr’g Tr. (Masamune) at 187:21-188:13.

TS No. 104 is a report of a study concerning tissue [REDACTED]

[REDACTED] CX-1032C [REDACTED]

[REDACTED] Dr. Masamune testified that in this study, “this is the first time [REDACTED]

[REDACTED] Hr’g Tr. (Masamune) at 189:2-21.

While TS Nos. Nos. 16, 23, 24, and 26 discussed in the previous section contain only lists of studies conducted, TS Nos. 17, 18, 28, 37, 100, 102, and 104 comprise entire study reports, including details about the structure of the study, the data resulting from the study, and conclusions drawn from the data.

Viking presents evidence and argument that [REDACTED]

[REDACTED] in TS Nos. 17, 18, 28, 37, 100, 102, and 104 are

neither generally known nor readily ascertainable. CIB at 45-46 (citing, *e.g.*, Hr’g Tr. (Silber) at 383:4-9 (“[T]here was no public information for [REDACTED] from Viking.”). Viking’s expert Dr. Silber testified that he carefully studied public materials available for VK2809 and determined that Viking’s preclinical trade secrets include “[REDACTED] [REDACTED] and those are not available in the public domain.” Hr’g Tr. (Silber) at 385:8-15; *see also id.* at 433:6-13. Dr. Silber further testified that these trade secrets have value because they inform competitors “about what they would consider themselves in running studies.” Hr’g Tr. (Silber) at 385:8-15; *see also* CIB at 63-77 (summarizing extensive testimony about the value of TS Nos. 17, 18, 28, 37, 100, 102, and 104).

Ascletis argues that TS Nos. 17, 18, 28, 37, 100, 102, and 104 are not protectable because the information contained therein was generally known or publicly available based on FDA guidance about how to run preclinical programs. *See, e.g.*, RIB at 80. Ascletis also argues that the information encompassed by TS Nos. 17, 18, 28, 37, 100, 102, and 104 has no independent economic value. *Id.* at 80-82. Staff joins much of that argument, but concedes the following subparts are protectable: TS Nos. 18.1-18.3, TS No. 28.3, all asserted subparts of TS No. 37, TS Nos. 100.10 through 100.24, TS Nos. 102.7 through 102.15, and 104.10 through 104.17. SIB at 69.

As discussed below, arguments by Ascletis and Staff that TS Nos. 17, 18, 28, 37, 100, 102, and 104 were publicly known and had no value lack merit.

First, I find no public document in the record discloses any portion of TS Nos. 17, 18, 28, 37, 100, 102, or 104. Neither Ascletis nor Staff cite any evidence to the contrary. Indeed, Ascletis’s expert Dr. Abrouk conceded that the specific study design and results of Viking’s asserted

Preclinical Trade Secrets do not appear in public guidance documents. Hr’g Tr. (Abrouk) at 1034:24-1035:8.

Ascletis and Staff instead argue that “researchers could design comparable tests” to those described in TS Nos. 17, 18, 28, 37, 100, 102, and 104 based on publicly available guidance and information about VK2809, and therefore the information reflected in those documents is not protectable. RIB at 80; SIB at 67 (“competitors could predict that Metabasis would follow” established protocols for preclinical studies). That argument lacks merit for at least the same reasons discussed above in connection with TS Nos. 16, 23, 24, and 26—public FDA guidance describes only generally what tests should be done in preclinical trials, and these trade secret documents reveal to a competitor what tests were actually done. Beyond that, TS Nos. 17, 18, 28, 37, 100, 102, and 104 reveal actual test protocols used, disclose the results of the tests, and guide important [REDACTED] and designs for future studies. *See, e.g.*, Hr’g Tr. (Silber) at 436:2-437:7. None of that information is known outside of Viking, and it is protectable as trade secrets. *See Uniroyal Goodrich Tire Co. v. Hudson*, 873 F. Supp. 1037, 1046 (E.D. Mich. 1994) (general information that did not disclose confidential test data did not make trade secrets readily ascertainable), *aff’d*, 97 F.3d 1452 (6th Cir. 1996).

Ascletis next argues that TS Nos. 17, 18, 28, 37, 100, 102, and 104 provide no competitive advantage because Ascletis must still “conduct their own studies and submit their own data” for FDA approval. RIB at 82. That argument is like saying that stealing the answer key to an exam would not provide an advantage to a student because the student must still fill in the answers on their own exam sheet. Like the answer key to the student, the study questions and answers in TS Nos. 17, 18, 28, 37, 100, 102, and 104 provide a valuable advantage to a competitor. *See, e.g.*, Hr’g Tr. (Masamune) at 185:15-187:17 (discussing the cost in time and money to perform studies

encompassed by these Preclinical Trade Secrets and the advantage the results give in knowing “how to design [REDACTED]”).

Dr. Silber’s testimony also undermines a conclusion that the information in TS Nos. 17, 18, 28, 37, 100, 102, and 104 were generally known and lacked value. Specifically, he testified that guidance documents are non-binding and that “the FDA is expecting the sponsor to use a lot of judgment, and not simply rely upon some kind of a guidance document” when deciding how to design and run [REDACTED] studies. Hr’g Tr. (Silber) at 1152:23-1153:3, 1156:6-15. Knowing the specific contours of the preclinical studies conducted on VK2809 would be valuable to a competitor because it can add “an incredible amount of confidence” to a competitor’s decision to move forward in developing the same API. *Id.* at 385:20-386:7.

Ascletis further argues that even if TS Nos. 17, 18, 28, 37, 100, 102, and 104 once had value, that value would have been lost by publication of results from clinical studies that demonstrated VK2809 can be safely administered to humans. *See* RIB at 81-83. Ascletis’s argument is belied by Dr. Gudmundsson’s testimony. He testified that Ascletis accessed Viking’s 2019 virtual data room for the express purpose of evaluating [REDACTED] of VK2809, even after data for Viking’s Phase II clinical studies had been released, because the information was not in the public domain. Hr’g Tr. (Gudmundsson) at 726:4-727:11. Additionally, as Ascletis admits, a competitor seeking FDA approval of a drug still would have to conduct its own preclinical studies, even after it was known that Viking was safely administering VK2809 to humans. *See* RIB at 82 (competitors “would still have to draft and design themselves” and “conduct their own studies and submit their own data” to the FDA). Knowing the protocols in TS Nos. 17, 18, 28, 37, 100, 102, and 104 would save a competitor time and effort in the “draft and design” of appropriate studies and would provide value by revealing exactly which studies succeeded. Hr’g Tr. (Silber)

385:8-15, 386:3-7, 387:19-23, 389:1-7. Accordingly, I find that public knowledge of the fact that Viking had advanced to clinical studies in humans does not negate the value to a competitor of knowing the information in TS Nos. 17, 18, 28, 37, 100, 102, and 104.

A few arguments unique to Staff merit discussion. Staff concedes that “raw data, summary of results, and conclusions included in a study report” are protectable trade secrets if they are not published. *See* SIB at 67. However, Staff does not follow that standard consistently in its position on particular subparts of TS Nos. 17 and 18. For example, Staff contends “none of asserted subparts TS Nos. 17.1 through 17.12 are protectable,” SIB at 71, but those subparts include data, summaries of results, and conclusions of the very type that Staff says are protectable. For example, with respect to TS No. 17, CX 1016C identifies numerous confidential study results and data. *See* CDX-1016C (annotating CX-1016C to highlight TS No. 17.8 ([REDACTED]), 17.9 ([REDACTED]), 17.10 [REDACTED] [REDACTED]), 17.11 [REDACTED] [REDACTED]), and 17.12 [REDACTED] [REDACTED] Extensive confidential study results, including data, span several pages of CX-1016C. *See* CDX-1016C at .0032-.0038. Staff’s position that this information has no trade secret value lacks consistency and credibility.

Similarly, Staff inconsistently argues that TS No. 18.4 through 18.39 should not be protected. *See* SIB at 71. Those asserted trade secrets are found in six documents, all of which contain unpublished data from preclinical studies of the type that Staff elsewhere argued should be protected. *See, e.g.*, CDX-1001C (annotating CX-1001C.0015-.0018 and .0034-.0040 to highlight experimental results labeled 18.34, 18.36, 18.37, 18.38, and 18.39), CDX-1007C (annotating CX-1007C.0014-.0018 to highlight experimental results labeled as 18.13 and 18.14), CDX-1008C (annotating CX 1008C.0006-.0007 to highlight experimental results labeled 18.7,

18.8, and 18.9), CDX-1014C (annotating CX-1014C.0012-.0014 to highlight experimental results labeled 18.18, 18.19, and 18.20), CDX-1015C (annotating CX 1015C.0015-.0018 to highlight experimental results labeled 18.24, 18.25, and 18.26), CDX-1017C (annotating CX 1017C.0012-.0014 to highlight experimental results labeled 18.30, 18.31, and 18.32). Staff's position that this information has no trade secret value lacks consistency and credibility.

Staff also argues that certain subparts of these asserted Preclinical Trade Secrets are not protectable because "preclinical study selection" and the "general design of a preclinical study" are readily ascertainable. SIB at 70-72, 74, 76-77. But, as Dr. Silber testified, general disclosures do not render preclinical experimental design and methods generally known or readily ascertainable because they must be customized for the API and proposed investigations. Hr'g Tr. (Silber) at 438:21-24 ("A guidance document can't by itself really address the uniqueness of a particular API."); *see* RX-1670.0002 ("The kind, duration, and scope of animal and other studies required in the application will depend on the duration and nature of the proposed clinical investigations."); RX-1620.0007 ("Since pharmacological effects vary depending on the specific properties of each test substance, the studies should be selected and designed accordingly.").

In sum, I find the record evidence shows that TS Nos. 17, 18, 28, 37, 100, 102, and 104 have independent value and were not generally known or readily ascertainable. Accordingly, I find that TS Nos. 17, 18, 28, 37, 100, 102, and 104 are protectable trade secrets.

c) TS Nos. 20-22, 25, 27, 58-60, and 109 are protectable.

TS No. 20 is [REDACTED]

CX-1009C [REDACTED]

[REDACTED]). Viking asserts that only information in the first

twelve pages of the report is a protectable trade secret. *See* CDX-1035C (Trade Secret Chart) at 9 (asserting pages CX-1009C.0001 to -.0012).

TS No. 21 is [REDACTED]
[REDACTED]. CX-1013C ([REDACTED])
[REDACTED]
[REDACTED] *see* Hr'g Tr. (Masamune)
at 177:17-178:17.

TS No. 22 is [REDACTED]
[REDACTED] CX-1003C [REDACTED]
[REDACTED]). Dr. Masamune testified that [REDACTED]
[REDACTED]
[REDACTED] Hr'g Tr. (Masamune) at 181:7-22.

TS No. 25 consists of [REDACTED]
CX-1005C [REDACTED]
CX-1006C ([REDACTED])
According to Dr. Masamune, "[t]hese studies are important studies, also required by the FDA, and
[REDACTED]
[REDACTED] Hr'g Tr. (Masamune) at 190:5-22. The two study reports
consist almost entirely of tables and charts depicting experimental results. CX-1005C; CX-1006C.

TS No. 27 is [REDACTED]
[REDACTED] CX-1012C ([REDACTED])
[REDACTED] Dr. Masamune explained that "[i]t is very

important to understand the [REDACTED].” Hr’g Tr. (Masamune) at 184:17-185: 5.

TS No. 58 is [REDACTED]

[REDACTED]. CX-1027C

([REDACTED]

[REDACTED]). TS No. 59 is [REDACTED]

[REDACTED]

[REDACTED]. CX 1028C ([REDACTED]

[REDACTED]

TS No. 60 is [REDACTED]

[REDACTED]. CX-1029C

([REDACTED]

[REDACTED]

TS No. 109 is an email memorializing information that Viking provided to Respondents in August 2016. *See* RX-1207C (E-mail from Lo to Gudmundsson and Musto (Aug. 26, 2016)). This is the same email exchange that was discussed in connection with formulation TS No. 11 in section V.D.1.e) above. In an email to Spike Lo of Ascleptis, Viking disclosed [REDACTED]

[REDACTED]

[REDACTED]. *Id.*

Viking presents evidence and argument that the preclinical study results for VK2809 and other preclinical study information in TS Nos. 20-22, 25, 27, 58-60, and 109 are neither generally known nor readily ascertainable. CIB at 67-78. Viking contends that these trade secrets provided valuable information on [REDACTED]

information that Ascletis wanted but could not find in the public domain. *See* Hr’g Tr. (Silber) at 446:13-20; Hr’g Tr. (Gudmundsson) at 726:4-727:11.

Ascletis argues TS Nos. 20-22, 25, 27, 58-60, and 109 lack value because they are composed of standard testing procedures and published data. RIB at 86-88. Ascletis also argues that these asserted Preclinical Trade Secrets lack value because a competitor would need to design and conduct some of the studies itself, so knowing Viking’s studies would provide no advantage. *See* RIB at 88. Staff joins much of that argument, but concedes the following subparts are protectable: TS Nos. 21.3 through 21.6, all asserted subparts of TS No. 25, TS Nos. 27.6 through 27.14, and TS No. 109. SIB at 72-78.

I organize the discussion of these issues around the publications that Ascletis cites to defeat trade secret protection.

(1) TS Nos. 20, 21, 22, and 58 (Erion 2007)

In a single sentence, Ascletis argues that TS Nos. 20, 21, 22, and 58 were publicly disclosed in the Erion 2007 (RX-1356) publication. RIB at 87. But Ascletis’s only witness to discuss Erion 2007, Dr. Abato, never identified in his testimony what information he contends was made public in Erion 2007. *See* Hr’g Tr. (Abato) at 839:9-19, 840:6 842:8. Staff argues that only subparts 21.3-21.6 of TS No. 21 are protectable because they [REDACTED] [REDACTED] while the other sections of TS No. 21 [REDACTED] and FDA required testing and are therefore not protectable. SIB at 72-73.

I have examined Erion 2007 and I find it does not reveal the test methods and extensive resulting data represented in TS Nos. 20, 21, 22, and 58. For example, the study in TS No. 20 [REDACTED] [REDACTED] nt,” but [REDACTED] Erion 2007 used “ [REDACTED]

[REDACTED] and Erion 2007 does not [REDACTED]. *Compare* CDX-1009C at .0008, *with* RX 1356 at .0002, .0005. The study in TS No. 21 [REDACTED],
[REDACTED],
but the only mention [REDACTED] in Erion 2007 concerns [REDACTED], and Erion 2007 specifically says the [REDACTED].” *Compare* CDX-1013C at .0031, *with* RX-1356 at .0004. The study in TS No. 22 [REDACTED]
[REDACTED]. *Compare* CDX-1003C at .0003, *with* RX-1356 at .0002. The study in TS No. 58 [REDACTED]
[REDACTED] but Erion 2007 contains no such data. *Compare* CDX-1027C at .0001, *with* RX 1356.

Dr. Silber, a recognized expert in this field, explained this evidence. Dr. Silber credibly testified that, to the extent there was any overlap between the disclosure in Erion 2007 and TS Nos. 20, 21, and 22, Erion 2007 disclosed “only a tiny amount of the information” in the trade secret documents. Hr’g Tr. (Silber) at 1164:3-9.

Moreover, in support of its argument that “key aspects of TS [No. 58] are publicly available” in Erion 2007, Staff relies on the unclear deposition testimony of Dr. Masamune. *See* SIB at 76. But Dr. Masamune later testified at the evidentiary hearing that Erion 2007 is related, but not the same as TS No. 58. Hr’g Tr. (Masamune) at 221:8-223:6.

Based on the record evidence, I find that TS Nos. 20, 21, 22, and 58 were not publicly disclosed in the Erion 2007 publication.

The record also shows that TS Nos. 20, 21, 22, and 58 would have value to a competitor. For example, Dr. Gudmundsson testified that Ascleitis sought out the non-public information in Viking’s Data Room in 2019 to evaluate [REDACTED] VK2809, which was the object

of the studies in at least TS No. 20 and 21. Hr’g Tr. (Gudmundsson) at 726:4-727:11; *see also* CX-1033C.0001 ([REDACTED]); Hr’g Tr. (Masamune) at 178:2-179:16 (cost and time to run similar studies). In addition, the record shows [REDACTED] in TS No. 21 would help a competitor design [REDACTED]. Hr’g Tr. (Masamune) at 187:5-6. Dr. Silber also opined that the documents in TS Nos. 20, 21, 22, and 58 provide valuable [REDACTED] experimental methods and results that would help a competitor gather vital information on [REDACTED]. Hr’g Tr. (Silber) at 446:6-449:5.

Based on the record evidence, I find that possession of TS Nos. 20, 21, 22, and 58 would provide value to a competitor.

(2) TS Nos. 22 and 27 (Fujitaki 2008)

In a single sentence, Ascleitis argues that TS Nos. 22 and 27 were publicly disclosed in the Fujitaki 2008 (RX-1255) publication. RIB at 87. As with Erion 2007, Ascleitis’s expert Dr. Abato failed to demonstrate which portions of Fujitaki 2008 are alleged to disclose the information in TS Nos. 22 and 27. *See* Hr’g Tr. (Abato) at 840:6-842:8. Although Staff fails to address the protectability of TS No. 22 in its post-hearing brief, Staff argues that only subparts 27.6 through 27.13 of TS No. 27, which contain the results and conclusions sections of the report, are protectable. SIB at 73.

I have examined the disclosures of Fujitaki 2008 and find that the publication does not reveal the test methods and extensive resulting data represented in TS Nos. 22 and 27. For example, the study in TS No. 22 was [REDACTED], while [REDACTED] in Fujitaki were conducted [REDACTED]

[REDACTED]

Compare CDX-1003C at .0004, *with* RX-1255 at .0003. I find, therefore, that the two documents necessarily describe different tests and that Fujitaki 2008 does not disclose the information in TS No. 22.

As for TS No. 27, [REDACTED]

[REDACTED] *See, e.g.*, CDX-1012C.0003-.0004. That study and the results therefrom are not disclosed in Fujitaki 2008, which investigated [REDACTED]. *Compare* CDX-1012C at .0004-.0005, *with* RX-1255 at .0008. Ascletis's argument is also belied by testimony from Dr. Silber, who opined that Fujitaki 2008 does not render TS Nos. 22 or 27 generally known or readily ascertainable. Hr'g Tr. (Silber) at 1160:21-1161:10. I find that Fujitaki does not disclose TS No. 27.

As noted above, I have already found value in TS No. 22. I also find value in TS No. 27. Dr. Silber testified that the [REDACTED] in TS No. 27 provide valuable insight into the prospects of the drug candidate. Hr'g Tr. (Silber) at 446:6-447:13. Each test has unique value in contributing to scientific knowledge, and disclosure of one test and its results does not defeat the trade secret status of another. *See Electro-Craft*, 332 N.W.2d at 899 (where "the exact combination of features" was not known, trade secret protection was appropriate).

In sum, I find that TS Nos. 22 and 27 are protectable trade secrets.

(3) TS Nos. 58-60 (U.S. Patent No. 7,514,419, Erion 2007, and Ito 2009)

In a single sentence, Ascletis asserts that TS Nos. 58-60 were disclosed in U.S. Patent No. 7,514,419, Erion 2007, and the Ito 2009 publication (RX-1360). RIB at 87. Staff, who joins this argument, lays out the sources of the information relevant to that argument as follows:

Public Sources for TS Nos. 58-60

TS No.	Exhibit No.	Corresponding TS No.	Public Source
58	CX-1027C	23.1	CX-1315 ('419 patent)
59	CX-1028C	23.4	RX-1356 (Erion et al.)
60	CX-1029C	23.11	RX-1360 (Ito et al.)

SIB at 76.

The argument from Ascletis and Staff relies on the testimony of Viking's former employee Dr. Masamune. Dr. Masamune testified at her deposition that a subset of information described in TS No. 23.1 appears in U.S. Patent No. 7,514,419 ("the '419 patent") as "Example A." JX-1012C (Masamune Depo.) at 140:15-141:3; *see* CX-1315 ('419 patent) cols. 397-400. She further testified that the study in TS No. 23.4 is disclosed in the Erion 2007 publication by Metabasis. JX-1012C (Masamune Depo.) at 170:20-175:2; *see* RX-1356 (Erion 2007). Finally, Dr. Masamune testified that TS No. 23.11 is disclosed in the Ito 2009 publication by Metabasis. JX-1012C (Masamune Depo.) at 226:3-228:19; *see* RX-1360 (Ito 2009).

At the evidentiary hearing, Dr. Masamune clarified her deposition testimony. With respect to the '419 patent and TS No. 58, Dr. Masamune testified, "I recall stating [at my deposition] that they were related and that all I had was the study report title. And so when I looked at this more closely, there – they aren't exactly the same study." Hr'g Tr. (Masamune) at 222:25-223:6. With respect to TS No. 59 and Erion 2007, Dr. Masamune testified that "[w]hat I said [at my deposition] was that I felt that those studies were related, but because I only had the study titles in front of me, I wasn't sure," and that "upon having the opportunity to review the entire study report as opposed to just the title I determined that they are different – that they are describing different studies." Hr'g Tr. (Masamune) at 221:8-222:19. And after recalling that portions of TS Nos. 60 described in Ito 2009 were dropped from the list of asserted trade secrets after her deposition, Dr. Masamune

testified that “all of the highlighted portions [of CDX-1029C] are the trade secret, and they are not disclosed in Ito.” Hr’g Tr. (Masamune) at 227:6-13.

I find Dr. Masamune’s trial clarification of her deposition testimony to be credible because it is corroborated by the documentary evidence of record. With respect to TS No. 58, I have compared CX-1027C to Example A of the ’419 patent, and the evidence shows the two documents describe two different studies. Example A of the ’419 patent describes [REDACTED] while CX-1027C describes a [REDACTED]. *Compare* CX-1315 (’419 patent) at 397:47, *with* CDX-1027C at .0006 (annotating CX-1027C). Further, the resulting data graphs from Example A of the ’419 patent, illustrated in Figs. 1(a), 1(b), and 1(c) of that reference, differ from the data graphs of CX-1027C. *Compare* CX-1315 (’419 patent) at .0009-.0011 (Figs. 1(a)-1(c)), *with* CDX-1027C at .0012-.0013 (annotating CX-1027C). I find that the ’419 patent does not disclose the study in TS No. 58.

Turning to the study in TS No. 59, [REDACTED]
[REDACTED]
[REDACTED] CDX-1028C at .0004. The [REDACTED]
[REDACTED] in Erion 2007 [REDACTED]. RX-1356 at .0017 (“Adult SD rats (Harlan, San Diego) 62-73 days of age were used for all gene expression studies.”). Erion 2007 describes a variety of rat and mice studies, [REDACTED]
[REDACTED]. *Compare* CDX-1028C at .0004, *with* RX-1356 at .0006 (“~4-week-old normal male C57I3Li6 mice”), .0034 (“mice were purchased at 6 weeks of age”). I find that Erion 2007 does not disclose the study in TS No. 59.

With respect to TS No. 60, I have compared CX-1029C to the Ito 2009 reference, and the evidence shows that the Ito 2009 reference does not disclose the trade secret information identified

in CX-1029C. TS No. 60 identifies [REDACTED] “Study 1” and “Study 2,” but focuses the trade secret claim on the methodology and results of Study 1. *See* CDX-1035C (Trade Secret Chart) at .0026-.0027; CDX 1029C (annotating CX-1029C). Study 1 in TS No. 60 used [REDACTED]

[REDACTED] *See* CDX-1029C at .0005. During the study, [REDACTED] *Id.* at .0004. By contrast, the only studies in the Ito 2009 reference [REDACTED] a different compound via a different [REDACTED] [REDACTED] RX-1360 at .0003. Ito 1009 does not [REDACTED] and the results of the different studies in the two documents are not the same. *Compare* CDX-1029C at .0011, *with* RX-1360 at .0006. I find that the Ito 2009 reference does not disclose the information identified in TS No. 60.

As to value, Dr. Silber testified that the Preclinical Trade Secrets exemplified in TS No. 60 are valuable because they provide “[REDACTED] information” and “permit understanding how to do the right kinds” of future studies. Hr’g Tr. (Silber) at 449:6-22.

In sum, I find that that TS Nos. 58-60 are not known or readily ascertainable, and that they have independent economic value. They are protectable as trade secrets.

(4) TS No. 59 (Cable 2009)

With respect to TS No. 59, Ascleitis argues, again in a single sentence, that “Cable 2009 [RX 1358] disclosed information of alleged TS59.” RIB at 87. In support of this argument, Ascleitis relies on the testimony of Dr. Abato, who testified that Cable 2009 shows [REDACTED] [REDACTED]. *Id.* (citing Hr’g Tr. (Abato) at 845:16-846:1). But Ascleitis’s argument relies on the unsupported premise that TS No. 59, and in particular subpart TS No. 59.2 (“[REDACTED]”),

[REDACTED] is limited to conducting a test [REDACTED]. See CDX-1035C.0026 (Trade Secret Chart). The other information in subpart TS No. 59.2, [REDACTED] [REDACTED] were not analyzed by Dr. Abato or Ascleitis. Compare RIB at 87, with CDX-1028C.0004 (annotating CX-1028C to identify particular trade secrets); see also Hr’g Tr. (Silber) at 1162:12-1163:12.

Ascleitis does not address other portions of the study and results set forth in TS No. 59. Comparing CX-1028C (TS No. 59) to RX-1358 (Cable 2009) makes clear that the two documents describe different studies. The study in TS No. 59 [REDACTED] [REDACTED], while Cable 2009 reports on [REDACTED] [REDACTED] as the TS No. 59 study. Compare CDX-1028C at .0004, with RX-1358 at .0002-.0003. I therefore find that the study in TS No. 59 is unique from any study disclosed in Cable 2009, and that Cable 2009 does not disclose anything from the study in TS No. 59.

Accordingly, I find that TS No. 59 and its asserted subparts were not generally known or readily ascertainable in view of Cable 2009.

I also find that Viking has shown the value of TS No. 59. Dr. Masamune called the study in TS No. 59 “a critical study because [REDACTED]” and explained this study reveals [REDACTED].” Hr’g Tr. (Masamune) at 182:11-183:4. Dr. Silber also confirmed the value of this study, testifying that it confirms [REDACTED] and provides an advantage in formulating future studies. Hr’g Tr. (Silber) at 448:17-450:2.

Staff relies upon the testimony of Dr. Abrouk in arguing that TS No. 59 is the same as or related to the study in TS No. 23.4. SIB at 75-76. Staff then concludes that TS No. 23.4, corresponding to TS No. 59, is disclosed in the Erion 2007 publication and that TS No. 59 is therefore not protectable because key aspects of it are publicly available. *Id.* Even were I to accept the position that TS No. 23.4 and TS No. 59 are the same or related studies, as discussed in the section above, I am not persuaded that Erion 2007 discloses the study in TS No. 59.

Accordingly, I find that TS No. 59 and its asserted subparts are protectable as trade secrets.

(5) TS No. 25

Ascletis argues that “alleged TS25, and its 151 sub-secrets relate to standard biochemical assays” that a researcher could conduct based on published literature. RIB at 87. This argument is not persuasive because, for example, the report in TS No. 25.89 states that the methods employed in the study “have been *adapted from the scientific literature* to maximize reliability and reproducibility,” indicating on its face that the report contains study results unique from the published literature. CDX-1006C at .0035 (annotating CX-1006C) (emphasis added).

Moreover, neither Ascletis nor its expert Dr. Abato specified which publications or evidence allegedly render TS No. 25 generally known or readily ascertainable. They also did not demonstrate how the methods in the public literature could be adapted to maximize reliability and reproducibility of the study, as was described in TS No. 25.89. By contrast, Viking’s expert Dr. Silber testified that the information in TS No. 25 provided “really fulsome descriptions of specific experiments, specific design methods, results, conclusions” and that the document in TS No. 25 contained “far more information” than the public literature. *See* Hr’g Tr. (Silber) at 1161:21-1162:11. Moreover, Dr. Masamune gave credible testimony about the value of TS No. 25 and its subparts, particularly that it revealed [REDACTED] and would require

considerable time and money to develop independently. *See* Hr’g Tr. (Masamune) at 190:5-191:8. Staff agrees with Viking’s position. *See* SIB at 73.

For the above reasons, I find that TS No. 25 and its asserted subparts are protectable trade secrets.

(6) TS No. 109

TS No. 109 is an email memorializing information that Viking provided to Ascleitis in August 2016. *See* CDX-1033C (annotating CX-1033C). In the email, Viking disclosed its general plans for [REDACTED]

[REDACTED]. *Id.*

Ascleitis alleges in a single sentence that TS No. 109 “includ[es] information that Complainant had published.” RIB at 87-88. But Ascleitis fails to show any evidence that Viking had published the business plans in this email or that it had publicly disclosed its internal assessment of the preclinical data discussed in this email. Staff agrees with Ascleitis’s position that Viking’s preclinical [REDACTED] studies would be readily ascertainable to a competitor, but concedes that the information about Viking’s clinical plans and plans [REDACTED] [REDACTED] potentially would not. SIB at 78. I therefore find that TS No. 109 was not generally known or readily ascertainable in view of the record evidence.

In addition, Viking’s expert Dr. Silber gave credible testimony that TS No. 109 is valuable to a competitor as an “overview of information” that Viking had on VK2809 and because it provides insight into Viking’s “clinical plans.” *See* Hr’g Tr. (Silber) at 452:3-15.

For these reasons, I find the record evidence establishes TS No. 109 as a protectable trade secret.

(7) Summary of TS Nos. 20-22, 25, 27, 58-60, and 109

Because the record evidence shows that Preclinical Trade Secrets identified as TS Nos. 20-22, 25, 27, 58-60, and 109 have independent value and were not generally known or readily ascertainable, I find that they are protectable trade secrets.

d) TS No. 110 is protectable.

The final Preclinical Trade Secret is TS No. 110, which is defined as the “compilation of all VK2809 pre-clinical information” that I have separately considered above. CDX-1035C (Trade Secret Chart) at 31.

In the above sections, I have determined that each of Viking’s other Preclinical Trade Secrets—TS Nos. 16-18, 20-28, 37, 58-60, 100, 102, 104, and 109 (with subparts)—were not known or readily ascertainable outside of Viking. I therefore necessarily also find that the compilation of information represented by TS No. 110 was not known or readily ascertainable outside of Viking. I additionally find that TS No. 110 has economic value for each of the reasons that its subparts have value.

I alternatively find that, even if some of the constituent information in TS No. 110 is known or readily ascertainable, TS No. 110 as a whole is not known or readily ascertainable and is still protectable. Neither Ascleitis nor Staff have presented any evidence to the contrary. “[A] trade secret may consist of a compilation of data, public sources or a combination of proprietary and public sources.” *United States v. Nosal*, 844 F.3d 1024, 1042 (9th Cir. 2016). “In the case of a compilation trade secret that includes in part publicly known or readily ascertainable information, the collected information derives value from keeping the whole compilation secret.” *Bone Cements 1175*, Comm’n Op. at 16. “A trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, but the unified process design

and operation of which in unique combination affords a competitive advantage and is a protectable trade secret[.]” *Computer Care v. Service Sys. Enterprises, Inc.*, 982 F.2d 1063, 1074 (7th Cir. 1992) (internal citation omitted).

Ascleitis and Staff argue that Viking has failed to prove that compilation TS No. 110 is more valuable than the sum of its parts and that TS No. 110 is therefore not protectable. *See* RIB at 89-90; SIB at 78. Their arguments are not persuasive in view of the record evidence.

TS No. 110 compiles all of Viking’s Preclinical Trade Secret information together in one place. This compilation gives a competitor valuable insight into the universe of Viking’s preclinical work on VK2809 and provides a clear map of how Viking structured and executed its preclinical trials. Dr. Masamune’s testimony supports finding independent value in compilation TS No. 110. She said it took “[r]oughly five years and five months” for Viking’s predecessor to assemble Preclinical Trade Secret data in compiled in TS No. 110. Hr’g Tr. (Masamune) at 193:17-194:5. Additionally, Dr. Silber testified that the asserted compilation trade secrets allow competitors to “very efficiently” assess the value and likelihood of approval of VK2809, which was particularly vital for Ascleitis because its ASC41 drug has the same API as VK2809. Hr’g Tr. (Silber) at 452:17-453:7. Dr. Silber also testified that asserted compilation trade secrets allow competitors to more quickly make drug development decisions and that knowing Viking’s compilation trade secrets helped Ascleitis gain confidence to launch the ASC41 program. *Id.* As Dr. Silber further noted, the fact that Ascleitis kept Viking’s trade secret information after the confidential disclosure agreements with Viking were terminated was an indication that Ascleitis found value in the compilation trade secrets. *Id.* at 453:8-23. Beyond the sum of the value of its subparts, I find TS No. 110 has independent economic value as a succinctly organized collection of preclinical information.

Accordingly, I find that TS No. 110 is a protectable trade secret.

3. Asserted Clinical Trade Secrets

Viking asserts a number of clinical trade secrets, identified individually as TS Nos. 12-15, 31-33, 38-39, 41-42, and 112, and identified collectively as the “Clinical Trade Secrets.” Clinical research is the study of effects when a drug is administered to humans. The goal of clinical research is to gather data sufficient to persuade the FDA to approve the marketing of the drug to the public. As summarized in section I.D above,²³ clinical research of a previously untested drug proceeds through several phases, with multiple clinical studies per phase. Although in general the phases are conducted sequentially, they may overlap. *See* SX-0001 at 1352-STAFF-000020 to 000024; 21 C.F.R. § 312.21. None of Viking’s asserted Clinical Trade Secrets encompass studies beyond Phase II.

²³ The following two bullet points, which contain information introduced in section I.E above, are repeated here for convenience:

- **Phase I** studies gather information about how a drug interacts with the human body by testing the drug over several months in 20 to 100 healthy volunteers. The purpose is to determine safety and dosage levels and to test how the drug is absorbed, excreted, metabolized, and distributed. Approximately 70 percent of drugs studied in Phase I clinical studies move on to Phase II. SX-0001 at 1352-STAFF-000021 to -000022.
- **Phase II** involves administering the drug to up to several hundred patients with the disease or condition for which the drug is being developed. Studies last from several months to two years. SX-0001 at 1352-STAFF-000022. Phase II research may be divided into Phase IIa and Phase IIb studies. A Phase IIa clinical trial is the first clinical trial in humans, intended to study the safety, dosage, and initial efficacy in a limited patient population for a specific pharmaceutical product. A Phase IIb clinical trial is a relatively longer and larger study designed to research the effectiveness of different doses of a particular product against placebo. *See* 100-Day Tr. (Sharlin) at 452:15-19. According to the FDA, Phase II studies “aren’t large enough to show whether the drug will be beneficial. Instead, Phase 2 studies provide researchers with additional safety data.” SX-0001 at 1352-STAFF-000022.

Viking presented argument and evidence that the Clinical Trade Secrets are valuable because they provide study design decisions, details of what was done in studies, and, most importantly, the results and insights from clinical testing in humans. Hr’g Tr. (Silber) at 435:13-435:20. According to Viking’s expert Dr. Silber, knowledge of the Clinical Trade Secrets provides a competitor assurance and confidence in the expected results of its own testing. *Id.* Dr. Silber also testified that the Clinical Trade Secrets report [REDACTED], which are invaluable for a competitor developing the same API and conducting due diligence on clinical information. Hr’g Tr. (Silber) at 442:3-17. Dr. Silber opined that these asserted trade secrets provide a competitor the benefit of foreseeing the likelihood of a positive return on investment before even making an initial investment. *Id.*

Ascleitis argues that the asserted Clinical Trade Secrets lack value and were either generally known or readily ascertainable. RIB at 106-31. Ascleitis cites testimony from its expert Dr. Abrouk that the selection of which clinical studies to perform is largely governed by FDA guidance and that a competitor can easily see studies reported by others at a government website, www.clinicaltrials.gov. *See* Hr’g Tr. (Abrouk) at 949:12-21.

Staff argues in favor of using three guiding principles to determine which of the asserted Clinical Trade Secrets are protectable. First, Staff submits that information regarding the selection of which studies to perform in Phase I trials is generally not protectable because it is governed by the FDA and can easily be predicted by other knowledge competitors. SIB at 95. Second, Staff argues that general design and research protocols for clinical studies are subject to specific scientific guidelines generally known or readily ascertainable by competitors, and thus are unlikely to qualify as trade secrets. *Id.* at 95-96. Third, as with preclinical research, Staff takes the position

that the raw data, summary of results, and conclusions included in a clinical study report are likely to be protectable trade secrets unless they are published elsewhere. *Id.* at 96.

At the outset, I find the record shows that the Formulation Trade Secrets and the Preclinical Trade Secrets were used to produce the studies in the Clinical Trade Secrets. In other words, even if some of the study information in the Clinical Trade Secrets was publicly known, it was not publicly known that the compound investigated in the Clinical Trade Secret studies was [REDACTED]

[REDACTED] CX-1010C (VK2809 Investigator's Brochure (Jan. 12, 2018)) § 4.3. As discussed in section V.D.1 above, the record shows that knowing the specific formulation used in the Clinical Trade Secrets would have value to a competitor. Additionally, the insights of the Preclinical Trade Secrets were not publicly known, and Viking's confidential knowledge of the Preclinical Trade Secrets gave it a competitive advantage in making investment decisions and in designing the studies of the Clinical Trade Secrets. On at least that basis, I find that the Clinical Trade Secrets are protectable.

Independently of that finding, I additionally find that the Clinical Trade Secrets are protectable regardless of whether the specific formulation used in the studies was known or unknown, and regardless of whether the Preclinical Trade Secrets were known or unknown. I address specific arguments and evidence relating to that finding for each of the remaining asserted Clinical Trade Secrets below.

a) TS No. 12 and asserted subparts are protectable.

TS No. 12 relates to the [REDACTED]

[REDACTED]. CX-1019C ([REDACTED])

[REDACTED] CX-1020C [REDACTED]

[REDACTED] *see* CDX-1035C (Trade Secret Chart) at 2.

Ascletis argues that these asserted Preclinical Trade Secrets are generally known or readily ascertainable because (1) “they include standard procedures that would be readily arrived at by following public guidance or publicly available example protocols,” (2) they “are at least partially disclosed or rendered readily ascertainable,” and (3) Viking “published the most important clinical results.” *See* RIB at 115-17; *see also id.* at 123-24. Staff similarly argues that only subparts 12.3 to 12.4, 12.6, 12.10 to 12.14, 12.75, 12.81 to 12.84, 12.112, and 12.150 are protectable because they correspond to the portions of the clinical study reports describing [REDACTED]

[REDACTED] and other non-public information. SIB at 96. Neither Ascletis’s nor Staff’s arguments are persuasive because it is settled law that a trade secret may contain non-public information. *Copper Rod*, Comm’n Op, 1979 WL 445781, at *22 (“It is an established principle that a trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, provided, however, that the unique combination of these elements is not published and affords the complainant a competitive advantage.”) (citations omitted). In addition to information published by Viking, TS No. 12 and its asserted subparts also contain substantial non-public information, [REDACTED]

[REDACTED] Moreover, the publication of top-line clinical results, often used to attract investors or to satisfy regulatory requirements, does not disclose the in-depth details that are included in Viking’s trade secret documents. *Compare* RX-1635, RX-1636, RX-1648, RX-1210, RX-1958, RX-2178, *with* CX-1019C, CX-1020C. For example, CX-1019C is a 279-page [REDACTED]

[REDACTED] while RX-1636 is a 5-page print-out of a June 2008 article from businesswire.com that summarily describes headline results from the study.

Ascletis also argues that TS No. 12 and its asserted subparts lack value because they are “boilerplate” protocols and synopses in the public domain and because the data uses known statistical methods. RIB at 109-116. This argument is not persuasive. As mentioned above, generic FDA guidance documents are not specific to the VK2809 API and do not provide a competitor with a road map for VK2809 research, whereas the Trade Secret Documents—including CX-1019C and CX-1020C that are relevant to TS No. 12 and its asserted subparts—provide specific and detailed guidance for VK2809’s API and NASH-related research. *Compare* CDX-1019C (annotating CX-1019C), *and* CDX-1020C (annotating CDX-1020C), *with* RX-1603.

As Viking’s chief operating officer Ms. Mancini testified, while the FDA guidance can be useful, “every drug has their own, you know, mechanism of action and how they work” and “you have to have data [REDACTED]

[REDACTED] So the guidance is just a – sort of like a small piece to help, you know, with a few things in the protocol, but the protocol really is based on the data that you produce as a company on your drug regarding your formulation, your preclinical studies, your clinical studies, your indication, and what you plan to have from the – to obtain from the results in the clinical study.” JX-1011C (Mancini Depo.) at 315:4-5, 319:6-20. Ms. Mancini also testified that, that [REDACTED]

[REDACTED]. Hr’g Tr. (Mancini) at 255:20-256:6. Moreover, the publicly available NASH guidance itself states it “should be viewed only as recommendations.”

RX-1603.0005; *see also* Hr’g Tr. (Silber) at 1153:6-13 (explaining that FDA guidance cautions that scientists have to use judgment and be careful in making decisions).

In view of the evidence showing that TS No. 12 and its asserted subparts have independent value and were not generally known or readily ascertainable, I find that TS No. 12 and its asserted subparts are protectable trade secrets.

b) TS Nos. 13 and 38 are protectable.

TS No. 13 consists of the “Clinical Studies” section of Viking’s VK2809 Investigator’s Brochure. *See* CDX-1035C (Trade Secret Chart) at 3-4; CX-1010C (VK2809 Investigator’s Brochure (Jan. 12, 2018)) § 6. Its twenty-two subparts are related to particular pages within that section of the brochure. *See* CDX-1035C at 3-4.

TS No. 38 is identified as the “Description of Clinical Studies” provided in section 6 of the VK2809 Investigator’s Brochure. CX-1010C.0025-.0046. TS No. 38 appears to be a duplicate of TS No. 13. *See* CDX-1035C (Trade Secret Chart) at 23. Its subparts also appear to be duplicates of the subparts of TS No. 13. *Compare, e.g., id.* at 3 (TS No. 13.5), *with id.* at 23 (TS No. 38.1) ([REDACTED]).

Viking employee Dr. Mancini testified that TS Nos. 13 and 38 and their subparts contain

[REDACTED]

[REDACTED] Hr’g Tr. (Mancini) at 241:19-24. In other words, the Clinical Studies section of the VK2809 Investigator’s Brochure is a summary of the data, results, and conclusions obtained to date in each completed or ongoing study of VK2809. CX-1010C.0025-.0046 (VK2809 Investigator’s Brochure). As such, it reproduces portions of the Metabasis and Viking clinical study reports in one central location.

Ascletis argues that Viking's Investigator's Brochure "merely contains summaries of the preclinical and clinical studies that are contained in the alleged trade secrets and is therefore not protectable. RIB at 125-26. Ascletis also argues that TS Nos. 13 and 38 are "at least partially disclosed or rendered readily ascertainable" and "could have been obtained from Complainant's publications" because, for example, TS Nos. 13.2 and 38 "merely summarize[] the results of the Phase1b study." RIB at 126, 130. But witnesses testified that the Investigator's Brochure is one of the most important asserted trade secrets because "[i]t contains everything you needed to know about VK2809; [REDACTED]

[REDACTED].” Hr’g Tr. (Mancini) at 240:9-25; *see also* Hr’g Tr. (Silber) at 392:9-18, 445:12-15.

Staff concedes that TS No. 13 and its subparts are protectable, but argues TS No. 38 is not protectable because it is a duplicate of TS No. 13 for which Viking offered no basis for separate protection. SIB at 98.

In view of the evidence showing that TS Nos. 13 and 38 have independent value and were not generally known or readily ascertainable, I find that TS Nos. 13 and 38 are protectable trade secrets.

c) TS Nos. 14 to 14.7 and TS Nos. 15 and 15.1 are protectable.

TS No. 14 is [REDACTED]

[REDACTED] 9. CX-1034C [REDACTED]

[REDACTED]. The document [REDACTED]

[REDACTED] *See id.* Subparts TS Nos. 14.1 to 14.7 correspond to specific pages of the document. CDX-1035C (Trade Secret Chart) at 4-5.

TS No. 15 is [REDACTED] CX-1011C ([REDACTED]). It is an agreement between Viking and its investigators concerning how the study is to be performed. *See id.* at 2-3. Subpart TS No. 15.1 consists of certain pages within the protocol document. CDX-1035C (Trade Secret Chart) at 5. Dr. Mancini testified that “[t]rade secret 15 contains all the information required to run that clinical study, including information on [REDACTED] [REDACTED] [REDACTED]” Hr’g Tr. (Mancini) at 238:3-9. Dr. Silber testified that TS Nos. 15 and 15.1 are not “generally known or readily ascertainable” and that they have independent economic value as a result. Hr’g Tr. (Silber) at 409:13-410:1.

Ascleitis’s expert Dr. Abrouk disputed Dr. Silber’s conclusions, testifying there is “guidance directly from FDA” that “walks you through what you need to have a protocol.” Hr’g Tr. (Abrouk) at 949:23-950:6. These include FDA industry guidance specific to NASH clinical trials. *Id.* at 964:6-965:5; RX-1603 (“Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment Guidance for Industry: Draft Guidance”). Dr. Abrouk further testified that other competitors in the NASH drug treatment space, including at least Novartis, have published information about their clinical study protocols for Phase II studies of NASH treatments. *See* Hr’g Tr. (Abrouk) at 965:6-18; RX-2044 (Global Clinical Development LJN452). Dr.-Abrouk also testified that certain methodology and trial design information concerning the VK2809-201 study has been publicly disclosed in Viking’s poster publications, as well as in SEC filings, press releases and public listings on ClinicalTrials.gov. Hr’g Tr. (Abrouk) at 955:21-957:14. For example, Viking’s 2019 corporate presentation provides eight slides on the study’s design and

results. RX-1210C.0016-.0025 (Presentation – Viking Therapeutics Novel Therapeutics for Metabolic and Endocrine Disorders Corporate Presentation).

Despite Dr. Abrouk's testimony, the evidence shows that none of the sources Dr. Abrouk identifies reveal all of the information provided in the Synopsis [REDACTED]

[REDACTED]. See CX-1011C.0004-.0010 ([REDACTED]).

For example, Viking's 2019 corporate presentation does not disclose [REDACTED]

[REDACTED]. Compare, e.g., CX-1011C.0005 with

RX-1210C.0016-.0025. Viking has identified this Synopsis as TS No. 15.1. CDX-1011C

(annotating CX-1011C). Staff agrees with Viking's position that TS Nos. 14 to 14.7 and TS Nos.

15 and 15.1 are protectable because they contain [REDACTED]

[REDACTED] that is not revealed by any source and is not readily

ascertainable. See SIB at 98-100.

In view of the evidence showing that TS Nos. 14 to 14.7 and TS Nos. 15 and 15.1 have independent value and were not generally known or readily ascertainable, I find that TS Nos. 14 to 14.7 and TS Nos. 15 and 15.1 are protectable trade secrets.

d) TS Nos. 32, 33, and 39 are protectable.

TS No. 32 is [REDACTED]

[REDACTED] provided in section 3.3 of the VK2809 Investigator's Brochure.

CX-1010C (VK2809 Investigator's Brochure (Jan. 12, 2018)) at 11-12. TS No. 33 is [REDACTED]

[REDACTED] provided in section

3.4 of that brochure. *Id.* at 12-13; see CDX-1035C (Trade Secret Chart) at 21. Sections 3.3 and

3.4 of the Investigator's Brochure include summaries of the specific results of preclinical and

clinical studies of VK2809 that preceded the release of the Investigator's Brochure. In addition,

TS No. 39 is the summary of data and guidance for investigators from the VK2809 Investigator's Brochure. CX-1010C (VK2809 Investigator's Brochure (Jan. 12, 2018)) at 47-51. It contains

[REDACTED]

[REDACTED] *Id.*; *see also* Hr'g Tr. (Mancini) at 245:9-16.

Although Staff agrees with Viking's position that TS Nos. 32 and 33 are protectable trade secrets, it takes no position on the protectability of TS No. 39. SIB at 101.

TS Nos. 32, 33, and 39 reproduce protectable portions of prior research by Metabasis and Viking in a central location. Therefore, for the reasons discussed in section V.D.3.b) above in connection with TS No. 13, I find that TS Nos. 32, 33, and 39 are protectable trade secrets.

e) TS Nos. 31, 41-42 and 112 are protectable.

The remainder of Viking's asserted trade secrets are compilations of protectable trade secrets that have already been discussed:

- TS No. 31 is the compilation of information in the VK2809 Investigator's Brochure, as encompassed in TS Nos. 13, 29, 30, 32, 33, 34, 35, 36, 37, 38, 39, 41, 42, 110, 111, and 112. CX-1010C (VK2809 Investigator's Brochure (Jan. 12, 2018)); CDX-1035C (Trade Secret Chart) at 21.
- TS No. 41 is the compilation of VK2809 clinical information found in clinical study reports, clinical study data, Investigator's Brochure excerpts, and clinical study protocol as encompassed in TS Nos. 12, 13, 14, and 15. *See* CDX-1035C (Trade Secret Chart) at 24.
- TS No. 42 is the compilation of VK2809 testing information found in TS Nos. 12-18, 20-29, 33, 37, 39, 44, 58, 59, 60, 100, 102, and 104. *See id.* at 24.
- TS No. 112 is the compilation of all Viking trade secrets. *See id.* at 32. •

As discussed above, the individual trade secret components combined into TS Nos. 31, 41, 42, and 112 are themselves protectable trade secrets. By contrast, Staff argues that, similar to TS No. 110, TS Nos. 31, 41-42 and 112 are not separately protectable as compilations of other trade secrets because Viking has not demonstrated they “constitute a secret ‘integration of the individual elements.’” SIB at 101-02 (quoting *Nosal*, 844 F.3d at 1042 (internal citation omitted); *see also* SIB at 79. But as discussed above with respect to TS No. 111 (Formulation) and TS No. 110 (Preclinical), the evidence shows that compilations of trade secret information are especially valuable because they give a competitor a big picture overview of Viking’s VK2809 program and provide a road map for that competitor to develop their own research program.

The evidence shows that TS No. 31—the VK2809 Investigator’s Brochure (CX/CDX-1010C)—is especially valuable. Former Viking employee Dr. Masamune, who contributed to the Investigator’s Brochure, explained that it condenses thousands of pages of study reports into a single document, making for easy access to the information and providing a clear road map of Viking’s development of VK2809. *See* Hr’g Tr. (Masamune) at 166:5-16. In addition, Viking’s chief operating officer Ms. Mancini testified that the Investigator’s Brochure “contains everything you needed to know about VK2809; [REDACTED]

[REDACTED].” Hr’g Tr. (Mancini) at 240:9-25. And Viking’s expert Dr. Silber testified that the Investigator’s Brochure is valuable because it covers a wide range of topics, each being extremely valuable and would provide a competitor with “readily understandable and a very easy way of looking at the entire picture in one place covering tens of thousands of pages.” Hr’g Tr. (Silber) at 445:21-446:5. The evidence thus shows that TS No. 31

is “one of the most important trade secrets.” Hr’g Tr. (Silber) at 445:12-15; *see also id.* at 392:9-18 (Investigator’s Brochure is “the most important single document from a sponsor”).

Accordingly, I find that TS Nos. 31, 41, 42, and 112—which are comprised of protectable trade secrets—have value and were not generally known or readily ascertainable. Thus, TS Nos. 31, 41, 42, and 112 are protectable trade secrets.

4. Conclusions Regarding *Botox* Factors (4), (5), and (6)

As noted in section V.A above regarding the legal standards for finding trade secret misappropriation, the fourth *Botox* factor concerns the value of the information to complainant and to his competitors. The record evidence discussed above demonstrates that the asserted Formulation Trade Secrets, Preclinical Trade Secrets, and Clinical Trade Secrets all have value to Viking and its competitors. I thus determine that these facts weigh in favor of trade secret protection under *Botox* factor (4).

The fifth *Botox* factor concerns the amount of effort or money expended by complainant in developing the information. The record evidence above demonstrates that Viking expended significant resources to acquire the VK2809 assets from Metabasis and to further develop the VK2809 into preclinical and clinical testing phases. I determine that these facts weigh in favor of trade secret protection under *Botox* factor (5).

The sixth *Botox* factor concerns the ease or difficulty with which the information could be properly acquired or duplicated by others. The record evidence above demonstrates that none of the asserted Formulation Trade Secrets, Preclinical Trade Secrets, or Clinical Trade Secrets were public known or could be readily ascertained by a competitor. I determine that these facts weigh in favor of trade secret protection under *Botox* factor (6).

E. Ascletis Accessed Viking's Protectable Trade Secrets While in a Confidential Relationship

The record evidence demonstrates that Ascletis accessed Viking's protectable trade secrets while in a confidential relationship with Viking. The existence of a confidential relationship is established when there is an agreement between the complainant and the respondent to share information but keep it confidential. *See Copper Rod*, Comm'n Op., 1979 WL 445781, at *23.

1. The Agreements Between Viking and Ascletis

Undisputed evidence shows that, in 2016, Viking established a secure virtual data room hosted by third-party Donnelley to share confidential information with potential collaboration partners. Order No. 41 at 3 (granting motion for summary determination regarding trade secret access); JX-1002C (Baird Depo.) at 9:13-21. Donnelley produced an audit log ("2016 Audit Log") of the Viking documents contained in that data room. JX-1025C (Zabramski Depo.) at 17:6-13; CX-1750C (2016 Audit Log). The log shows the individuals invited to access the data room, when individuals no longer had access, when a document was uploaded, the individuals who accessed certain documents, when a document was accessed (though not the duration of the access), and when a document was downloaded. *See* CX-1750C; Order No. 41 at 3.

Viking closed its Donnelly data room in 2017 and established a new secure virtual data room hosted by SecureDocs. Order No. 41 at 3-4; JX-1002C (Baird Depo.) at 31:1-12; JX-1008C (Gimelberg Depo.) at 10:7-13, 10:20-11:3. SecureDocs produced an audit log ("2019 Audit Log") of the documents contained in the 2019 virtual data room. JX-1008C (Gimelberg Depo.) at 24:1-35:21; CX-1992C (2019 Audit Log). The SecureDocs log includes the date that a document was accessed, the time it was accessed, the file name, the individual who accessed the document, and the individual's corporate affiliation. *See* CX-1992C; Order No. 41 at 4. Unlike the Donnelley 2016 Audit Log, the SecureDocs 2019 Audit Log also indicates which specific pages of a

document have been viewed by a particular individual. JX-1008C (Gimelberg Depo.) at 33:3-7, 35:9-15.

The undisputed evidence demonstrates that Ascleitis BioScience entered into a confidential disclosure agreement with Viking in July 2016. JX-1017C (Wu Depo.) at 64:17-21; CX-2085 (2016 Confidential Disclosure Agreement). Once the agreement was signed, Viking allowed certain individuals from Ascleitis BioScience to access its Donnelley data room, including Kristjan Gudmundsson, Joseph Musto, and Spike Lo.²⁴ CX-1750C (2016 Audit Log). Each of those individuals accessed certain documents in the 2016 data room between August 1 and August 4, 2016. *Id.*

Dr. Gudmundsson later contacted Dr. Brian Lian, the CEO of Viking, to enter into a second confidential disclosure agreement, which was signed in March 2019 between Viking and Ascleitis BioScience. CX-2014 (2019 Mutual Confidential Disclosure Agreement); JX-1009C (Gudmundsson Depo.) at 103:18-104:9; JX-1010C (Lian Depo.) at 166:3-14; JX-1017C (Wu Depo.) at 89:22-90:5. Viking granted the following Ascleitis employees and contractors access to its SecureDocs data room: Jinzi “Jason” Wu, Kristjan Gudmundsson, Joseph Musto, and Lindi Tan.²⁵ CX-1992C (2019 Audit Log). In April 2019, each of these individuals accessed certain pages of certain documents in the SecureDocs data room. *Id.* None of these facts are contested.

²⁴ Kristjan Gudmundsson is the Chief Development Officer of Ascleitis BioScience Co., Ltd., and interacts with individuals at the Gannex entities. JX-1009C (Gudmundsson Depo.) at 14:4-8, 39:8-17, 40:10-17. Joseph Musto is a contractor for Ascleitis BioScience Co., Ltd., and is listed as a Senior Director of Development for Ascleitis BioScience Co., Ltd., and the Gannex entities. JX-1015C (Musto Depo.) at 67:1-73:9. Spike Lo worked in business development for Ascleitis BioScience Co., Ltd., in 2016. JX-1009C (Gudmundsson Depo.) at 104:2-9.

²⁵ Respondent Dr. Jinzi “Jason” Wu is the CEO of Ascleitis BioScience Co., Ltd., and Ascleitis Pharmaceuticals Co., Ltd.; the President of Ascleitis Pharma Inc. and Gannex Pharma Co., Ltd.; and the manager of Gannex LLC. JX-1017C (Wu Depo.) at 40:5-18, 63:11-12. Lindi Tan worked

The evidence shows that Respondents had a duty of confidentiality with regard to any confidential documents accessed pursuant to the confidentiality agreements negotiated with Viking in 2016 and 2019. The 2016 Confidential Disclosure Agreement between Viking and Ascleto Bioscience provided:

With respect to all Confidential Information disclosed hereunder, Recipient agrees that it shall:

- (i) maintain such Confidential Information in strict confidence, using efforts at least as protective as those employed by Recipient for the protection of its own proprietary information of like nature;
- (ii) use such Confidential Information only as required for the Purpose;
- (iii) not disclose or permit the disclosure of such Confidential Information to any persons other than to its directors, officers, or employees (collectively "Personnel") who need to know such Confidential Information for the Purpose and who are bound by written obligations of non-disclosure and non-use of such Confidential Information which are at least as stringent as those set forth herein; and
- (iv) reproduce Confidential Information only to the extent necessary for the Purpose, with all such reproductions being marked and treated as Confidential Information.

CX-2085 (2016 Confidential Disclosure Agreement) at 1 (§ 2.B). The 2019 agreement contained the same provisions. CX-2014 (2019 Mutual Confidential Disclosure Agreement) at 1-2 (§ 2.B). Under either agreement, Ascleto's employees and contractors who accessed a Viking data room had a duty to maintain the secrecy of any confidential materials located there. Thus, any disclosure or use of confidential information obtained from documents reviewed pursuant to either agreement would constitute a breach of that agreement.

in a business development position for Ascleto BioScience Co., Ltd., at least in 2019. JX-1009C (Gudmundsson Depo.) at 104:2-9.

Viking presented evidence that Ascletis's employees took information from the data rooms. Dr. Gudmundsson acknowledged that Ascletis did not have "download access" to documents in the data room. CX-2325C.0001. However, Mr. Musto circumvented the inability to download files, admitting to taking screenshots while viewing documents in Viking's virtual data rooms. JX-1015C (Musto Depo.) at 237:13-18, 238:3-9. Viking's expert Dr. Silber testified that taking screenshots like this in a secure environment without express permission is "[d]efinitely not proper" industry practice. Hr'g Tr. (Silber) at 413:1-414:2. As discussed more fully in section V.F below, the evidence indicates Ascletis kept copies of documents after termination of access to Viking's data room, such as email attachments containing verbatim copies of information present in the virtual data room documents. *See, e.g.*, CX-1474C.

2. The Identity of Documents in the 2016 and 2019 Virtual Data Rooms

Viking adduced evidence to show that documents present in the 2016 and 2019 virtual data rooms accessed by Ascletis pursuant to the 2016 and 2019 confidential disclosure agreements are the same Trade Secret Documents produced by Viking in this investigation. Order No. 41 found on summary determination that all Trade Secret Documents in the 2016 and 2019 virtual data rooms, except for CX-1024C and CX-1034C, are the documents identified in the audit logs for the virtual data rooms. Order No. 41 at 6-8. These findings were affirmed by the Commission. Notice (Dec. 13, 2023). No party petitioned for review of these findings, thereby waiving their right to do so. *See id.*

With respect to CX-1024C, Viking's forensic expert Jerry Bui testified that the produced document had a forensic MD5 hash match with a document currently in Viking's SecureDocs virtual data room. Hr'g Tr. (Bui) at 146:1-7. Mr. Bui then cross-referenced this document title and upload date against the 2019 Audit Log. *Id.* This document had an upload date of 2018, which

predated Ascleitis's access to the 2019 VDR. CX-1816C; Hr'g Tr. (Bui) at 148:22-25. Thus, the record evidence shows that Trade Secret Document CX-1024C produced in this investigation is the same as the document in the 2019 virtual data room accessed by Ascleitis.

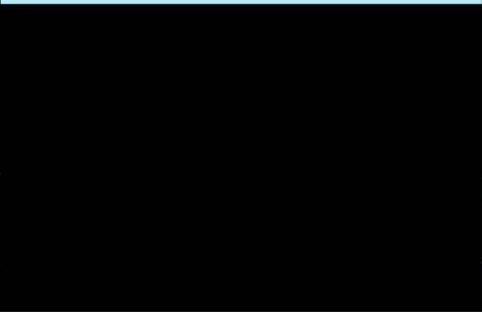
As for CX-1034C, Mr. Bui testified that he used a forensic comparative tool called Diffchecker to compare the internal text of documents in Viking's Dropbox document repository. Hr'g Tr. (Bui) at 150:14-22. He determined that the internal text of CX-1034C was an exact match for a document in Viking's Dropbox with a last-modified date in 2018. *Id.* at 150:18-25. Mr. Bui then compared the internal headings in CX-1034 to file names in the SecureDocs audit log and found six matching file names. *Id.* at 151:12-15. Based on the file name comparison and Dropbox last-modified date, Mr. Bui confirmed that Trade Secret Document CX-1034C produced in this investigation has the same content as the file accessed in the 2019 virtual data room by Ascleitis.

Mr. Bui's testimony at the evidentiary hearing demonstrating that CX-1024C and CX-1034C were present in the 2019 virtual data room was not contradicted. *See* Hr'g Tr. (Bui) at 156:7-158:24. Based on the evidence presented, I find that all Trade Secret Documents were present in either the 2016 or 2019 virtual data rooms.

3. Ascleitis Accessed the Asserted Trade Secrets

Viking adduced evidence to show that Ascleitis accessed the Formulation, Preclinical, and Clinical Trade Secrets asserted in this investigation. As discussed above, Dr. Gudmundsson, Joseph Musto, and Spike Lo accessed Viking's 2016 virtual data room and viewed the documents listed in the 2016 Audit Log, and Dr. Wu, Dr. Gudmundsson, Joseph Musto, and Lindi Tan accessed Viking's 2019 virtual data room and viewed specific pages of documents listed in the 2019 Audit Log.

For each asserted trade secret, Viking identified the exact pages within the Trade Secret Documents that contain the trade secret information, as shown below in an excerpt from CDX-1035C.

Trade Secret No.	Trade Secret	Document(s)/Page(s)
4		CX/CDX-1010C at .0014; CX/CDX-1026C at .0033-.0034, .0036
5		CX/CDX-1025C at .0002; CX/CDX-1033C at .0002; CX/CDX-1026C at .0036-.0037
6		CX/CDX-1010C at .0014; CX/CDX-1033C at .0002; CX/CDX-1026C at .0042-.0048

Using the virtual data room audit logs, Viking's forensic expert Mr. Bui identified the Trade Secret Documents that Respondents accessed, and for Trade Secret Documents in Viking's 2019 virtual data room, he also identified the pages of those documents that Respondents accessed. CX-1750C; CX-1992C; CDX-1041C.0007, .0011; Hr'g Tr. (Bui) at 142:6-17, 143:16-144:17, 146:8-148:8. Mr. Bui illustrated his testimony with two slides reproduced below.

PUBLIC VERSION

CX No.	Document Bates	2016 DFIN Audit Log FileName
CX-1001C	VK-ITC-337-1352_00002572	
CX-1002C	VK-ITC-337-1352_00003994	
CX-1003C	VK-ITC-337-1352_00005033	
CX-1012C	VK-ITC-337-1352_00005564	
CX-1018C	VK-ITC-337-1352_00008348	
CX-1021C	VK-ITC-337-1352_00009748	
CX-1026C	VK-ITC-337-1352_00799341	
CX-1027C	VK-ITC-337-1352_00871903	
CX-1028C	VK-ITC-337-1352_00871916	
CX-1029C	VK-ITC-337-1352_00871927	
CX-1030C	VK-ITC-337-1352_00872466	
CX-1031C	VK-ITC-337-1352_00872573	
CX-1032C	VK-ITC-337-1352_00872603	
CX-1024C	VK-ITC-337-1352_00009753	

Exhibit Number	SecureDocs Title	Pages Accessed
CX-1010C		p. 1-53
CX-1011C		Pgs. 1-38, 40-50, 52, 54-58
CX-1024C		pg. 1
CX-1003C		Pgs. 1-3
CX-1004C		Pgs. 1-7
CX-1005C		Pgs. 1-10, 12-16, 18, 23, 25-40
CX-1006C		1-40, 42-68
CX-1007C		Pgs. 1-5, 8-18
CX-1008C		Pgs. 1-13, 15-41

Exhibit Number	SecureDocs Title	Pages Accessed
CX-1009C		Pgs. 1-12
CX-1012C		Pgs. 1
CX-1013C		Pgs. 1-16, 26, 29, 31, 33-35, 39, 41, 49, 66, 96, 97, 108, 113, 116, 119, 124, 149, 168, 180, 190, 196-197, and 225-238
CX-1014C		Pgs. 1-32
CX-1015C		Pgs. 1-27, 30, 34-39, 41-42, 46-54, 58-59, 61, 99, 101-102, 104, 112, 116, 123, 123, 29, 132, 134-135, 137, 141, 143, 145, 147-150, 152, 154, 156, 165, 174, 177 to 178, 181, 184, 187, 189, 191-193, 195-198, 200, 203-210, 214-219, 221, 224-231, 233, 235-242, 244, 246, 248, 251 to 253, 255, 258-260, 262-263, 265, 271 to 272, 274, 279, 284, 287, 290, 293, 295-296, 306, 330, 348, 353, 370, 390, 407, 428, 441, 451, 462, 464, 480, 493, and 496 to 497

Exhibit Number	SecureDocs Title	Pages Accessed
CX-1019C		Pgs. 1-23
CX-1020		Pgs. 1-15, 19, 23-26, 37, 46, 59, 75, 44, 212, 349, 432, 356, 512, 557, 569, 596, 611, 659, 627, and 659
CX-1034C.0003-4		Pgs. 3-2
CX-1034C.0013-17		Pgs. 3-9
CX-1034C.0010		Pgs. 3
CX-1034C.0032		Pgs. 3
CX-1034C.0033		Pgs. 3
CX-1034C.0254-55		Pgs. 3-2
CX-1022C		Pgs. 3
CX-1023C		Pgs. 1-2

Exhibit Number	SecureDocs Title	Pages Accessed
CX-1016C		Pgs. 1-38, 40, 42, 44, 47-51, 53, 55-57, 59, 61-62, 64-66, 68, 69, 70-72, 74, 76, 78-82, 83-85, 87, 92-94, 97-99, 103-104, 107-113, 117-117, 119, 124 to 122, 124, 126, 128, 130-145, 147, 149-168, 171-172, 174-175, 177-178, 180-186, 188-190, 197-227, 229-231, 234-263, 265-272, 278, 280, 294-299, 401-406, 408-414, 422, 427, 432, 437, 444, 446, 449, 450, 480, 518, 551, 575, 583, 594, and 596-611
CX-1017C		Pgs. 1-48, 64, 77, 94, 100, 119, 124, 137, 141, 155, 168, 176-177, 179, 183-183, 186-188, 190-201, 204, 212-229, 232, 234, 237, 239-241, 245-246, 249-253, 255, 257, 259, 261-262, 264-270, 272, 274-278, 280, 283-287, 290, and 292-304
CX-1001C		Pgs. 1-4, 19, 40-43, 52, 55, 58, 82-84, 127-128, 158, 167, 211, 241, 259, 266, 308, 312, 325-327
CX-1002C		1-7, 9, 76, 89, 125, 137, 140, 142, 145, 151, 177, 184, 175, 183, 192, 198, 205, 211, 222, 231, 242, 244, 255, 264, 274, 282, 289, 297, 301-322, 325, 326, 330, 333, 335-336, 338-339, 340, 347, 351, 354, 357, 364, 367-368, 371, 373, 376, 378-380, 383, 386, 388-389, 397, 399, 401, 403
CX-1018C		1 to 14

CDX-1041C.0007, .0011. Therefore, having considered CDX-1035C and Mr. Bui's demonstratives (which are summaries of the 2016 and 2019 virtual data room audit logs), I

conclude that Viking adduced evidence to show that Respondents accessed each of the asserted trade secrets.

Specifically, the 2019 Audit Log shows the exact pages that were accessed in each of the Trade Secret Documents, and it is possible to correlate the accessed pages with the page numbers listed for each asserted trade secret in Viking's trade secret chart, CDX-1035C. By contrast, the 2016 Audit Log does not have the same level of detail as the 2019 Audit Log and only identifies the filename of the accessed Trade Secret Documents without identifying specific pages accessed. However, based on the record, it is reasonable to assume that Ascletis accessed all pages of every document accessed in the 2016 virtual data room.

F. Disclosure or Use of the Protectable Trade Secrets and Ascletis's Independent Development Defenses

The final element of the unfair act of trade secret misappropriation is that "the respondent has used or disclosed the trade secret, causing injury to the complainant." *E.g., Botox*, Comm'n Op. at 13. To prove misappropriation, Viking has the burden of producing evidence demonstrating it is more likely than not that Ascletis used or disclosed at least one of the protectable trade secrets; it is not enough for Viking to show that Ascletis has not established an affirmative defense of independent development. This section addresses Ascletis's use and/or disclosure of the asserted trade secrets and its independent development defenses. Any injury caused to Viking by Ascletis's actions are addressed below in section VII.

1. Formulation Trade Secrets

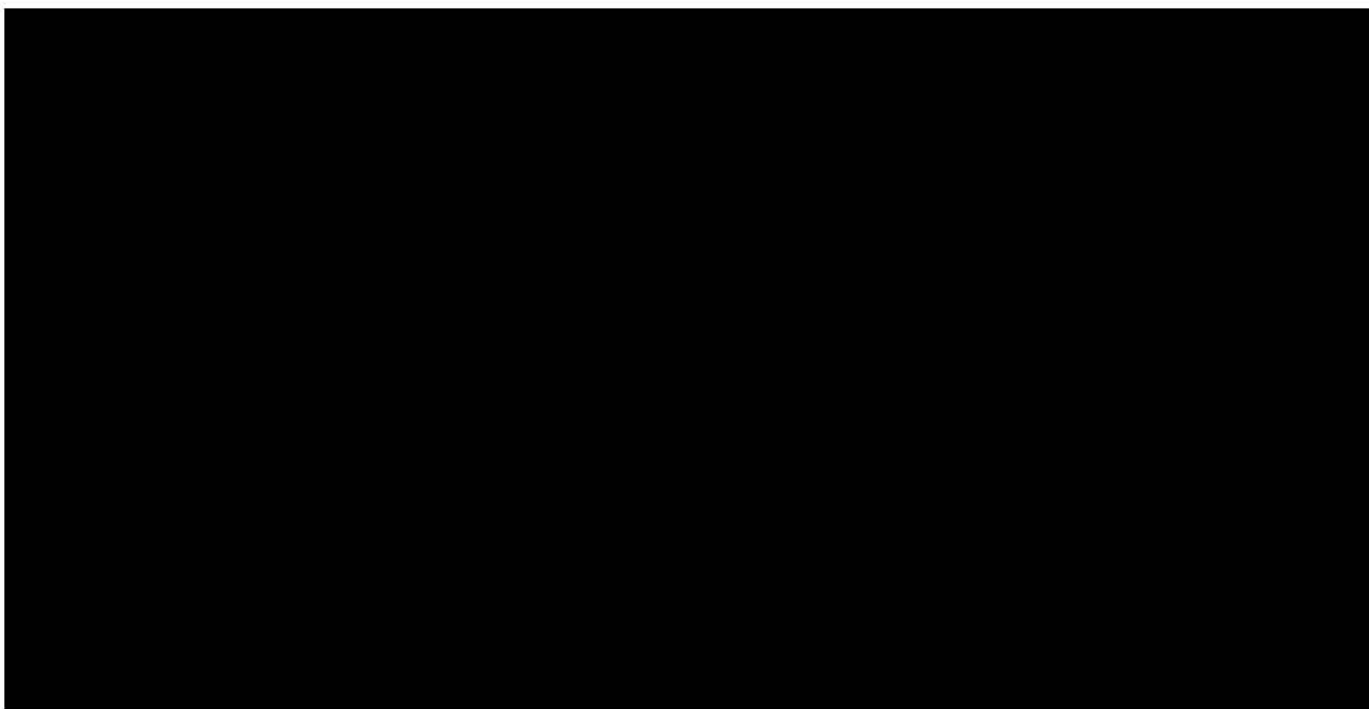
As discussed in more detail below, the record evidence supports a finding that Ascletis misappropriated confidential information regarding Viking's selection of excipients [REDACTED]

[REDACTED].

a) Misappropriation of the Formulation Trade Secrets

Viking argues that Ascletis used the Formulation Trade Secrets to develop ASC41 capsules, and that the knowledge gained was then used to develop Ascletis's tablet formulation for ASC41 and ASC43F. CIB at 121. Staff agrees with this position at least as to TS No. 4. SIB at 60.

At the evidentiary hearing, Viking introduced a set of three emails internal to Ascletis discussing the excipients for the ASC41 capsule. The first email is from Kunhua Dong to Bai Ling Yang dated April 24, 2019, with the subject line "Summary on research of the new project NASH1 ASC41 drug product." CX-1402C (04/24/2019 email from Dong to Yang). A translation of the relevant portion of the email is reproduced below:



CX-1420C-T (translation of 04/24/2019 email from Dong to Yang).

The phrase [REDACTED]

[REDACTED] suggests that Bai Ling Yang provided key excipient information to Mr. Dong. *Id.* at 1. However, the record evidence shows that Bai Ling Yang never accessed Viking's virtual data rooms and thus could not have disclosed TS No. 4 to Mr. Dong unless someone else first disclosed

that information to Dr. Yang. *See* CX-1992C (2019 Audit Log); *see also* CX-1750C (2016 Audit Log).

The second relevant email introduced into evidence was dated May 13, 2019, and sent from Kunhua Dong to Kristjan Gudmundsson, who accessed Viking's virtual data rooms in both 2016 and 2019. CX-1413C (05/13/2019 email from Dong to Gudmundsson); CX-1750C (2016 Audit Log); CX-1992C (2019 Audit Log). The email's subject line reads: [REDACTED]

[REDACTED] CX-1413C at 1. The message begins, [REDACTED]

[REDACTED] *Id.* In response to Mr. Dong's questions, Dr. Gudmundsson replied, [REDACTED]

[REDACTED] *Id.*

During cross-examination of Dr. Gudmundsson at the evidentiary hearing, counsel for Viking attempted to establish that this email exchange is evidence showing that Dr. Gudmundsson disclosed TS No. 4, comprising the excipients used in VK2809 capsules, to Dr. Yang, who then passed the information on to Mr. Dong. *See* Hr'g Tr. (Gudmundsson) at 730:24-734:18. Dr. Gudmundsson denied that either Dr. Yang or Mr. Dong learned of the excipients for the ASC41 capsule formulation from him, testifying, "I don't know what he's referring to." Hr'g Tr. (Gudmundsson) at 732:1-733:20; *see also* JX-1009C (Gudmundsson Depo.) at 241:18-19, 244:18-21 ("Q. You have no recollection of having any discussion with Bailing Yang or Kunhua Dong regarding the excipients to use in the ASC41 project? A. That's correct.").

The third email relevant to the alleged misappropriation of TS No. 4 is a June 2019 email exchange between Bai Ling Yang and Kristjan Gudmundsson with the subject line [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

CX-1427C. Viking argues this third email demonstrates that Ascleitis improperly used Formulation Trade Secrets other than TS No. 4, such as a trade secret describing the method of manufacture. *See* CIB at 122-23.

It is uncontested that Dr. Gudmundsson accessed the 2016 virtual data room and viewed the MB07811 Chemistry, Manufacturing, and Controls document included as Item 7 in Viking's IND application. CX-1750C (2016 Audit Log) at rows 1531-1544 (seven views of IND Item 7 (MB07811 CMC document) by Kristjan Gudmundsson on Aug. 2-3, 2016). But at the evidentiary hearing, Dr. Gudmundsson denied that he provided any information from that document to Dr. Yang, Mr. Dong, or any other Ascleitis employee. *See* Hr'g Tr. (Gudmundsson) at 745:11-18. When Dr. Gudmundsson was expressly asked to provide information regarding excipient proportions and capsule manufacturing processes to Ascleitis personnel, he did not do so, instead referring Dr. Yang to publicly available sources of information. CX-1427C; Hr'g Tr. (Gudmundsson) at 745:11-18 ("And I'm very irritated by them sending me these e-mails asking me about Viking data, when they know I have been in the data room."). Mr. Dong might have provided exculpatory evidence explaining the email evidence at trial, but Ascleitis withdrew him at the last minute. *See* Prehearing Conference Tr. (EDIS Doc. ID 808525) at 10:2-12.

Notwithstanding Dr. Gudmundsson's testimony denying that he disclosed any Formulation Trade Secrets, I find that the weight of the record evidence shows evidence of improper disclosure of at least Viking's TS No. 4 to Dr. Yang and Mr. Dong. The disclosure may or may not have been by Dr. Gudmundsson; it may have been by someone else. The exact means of disclosure is not required for a finding of trade secret misappropriation. The record contains email evidence showing that Dr. Yang and Mr. Dong were in possession of TS No. 4 and were using it to develop the capsule formulation of ASC41. I therefore find that Viking has shown by a

preponderance of the evidence that Ascleitis improperly used at least TS No. 4 in the development of ASC41.

Further, above I noted that the Preclinical Trade Secrets and the Clinical Trade Secrets used the Formulation Trade Secrets to arrive at their results. And later I explain that Ascleitis improperly used some of the Preclinical Trade Secrets and the Clinical Trade Secrets to develop ASC41. Thus, the record also supports a conclusion that Ascleitis improperly used all of the asserted Formulation Trade Secrets because it used the fruit of those secrets—the Preclinical Trade Secrets and the Clinical Trade Secrets. My finding in this paragraph is independent, and the remainder of my initial determination and recommended determination would remain the same whether or not I found use of all Formulation Trade Secrets as described in this paragraph or only use of TS No. 4.

b) Ascleitis's Independent Development Defense

Ascleitis argues there has been no misappropriation of Viking's Formulation Trade Secrets because it independently developed the ASC41 capsules and the tablet formulations of ASC41 and ASC43F. RIB at 57-61.

(1) ASC41 Capsules

Respondent Jinzi Wu testified at his deposition that Ascleitis decided to expand its product line to address fatty liver disease [REDACTED]. JX-1017C (Wu Depo.) at 60:8-15; CX-1641C (01/15/2018 Ltr. from Wu to Colleagues) at 2 [REDACTED]
[REDACTED]
[REDACTED]). However, the record shows that actual development of an ASC41 formulation did not begin until [REDACTED]. JX-1017C (Wu Depo.) at 45:5-6. The key researcher involved in the project was [REDACTED], [REDACTED]
[REDACTED]

[REDACTED] JX-1006C (Dong Depo.) at 48:2-49:4. [REDACTED]

[REDACTED] *Id.* at 52:5-8. [REDACTED]

[REDACTED] *Id.* at 49:16-50:13 [REDACTED]

[REDACTED] *Id.* at 52:9-12, 69:4-13.

[REDACTED] JX-1006C (Dong Depo.) at 54:17-19. Before joining Ascletis, Mr. Dong worked for the Shanghai Medical Industry Research Institute from 2013 to 2016. *Id.* at 55:12-13. While he was there, [REDACTED]

[REDACTED] *Id.* at 55:13-16. [REDACTED]

[REDACTED] *Id.* at 55:12-22. [REDACTED]

[REDACTED] *Id.* at 56:1-3.

[REDACTED] JX-1006C (Dong Depo.) at 59:21-63:8. [REDACTED]

[REDACTED] *Id.* at 63:3-6. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* at 60:12-16, 63:9-10. [REDACTED]

[REDACTED]

[REDACTED] *Id.* at 63:12-13.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

JX-1006C (Dong Depo.) at 63:16-65:6; *see also id.* at 53:8-12 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] RIB at 53-57; *see*

CX-1992C (2019 Audit Log) (Mr. Dong did not access the virtual data room).

Viking's expert Dr. Amidon testified at the evidentiary hearing that Ascleitis's story is not credible:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Hr’g Tr. (Amidon) at 280:11-281:3.

Mr. Dong was scheduled to testify at the evidentiary hearing, but Ascleitis withdrew him at the last minute. *See* Prehearing Conference Tr. (EDIS Doc. ID 808525) at 10:2-12. Thus, it is impossible for me to assess Mr. Dong’s credibility and the reliability of his deposition testimony where he stated he “gathered information” about potential excipients for ASC41 capsules from public sources. It remains unclear whether Mr. Dong’s information gathering was solely based on public sources, or whether he was viewing those public sources in light of trade secret information obtained from Viking and passed on to Mr. Dong by another Ascleitis employee, such as Dr. Yang. Staff takes the position that it was necessary for Mr. Dong to testify at the evidentiary hearing because, without said testimony, Ascleitis lacks sufficient evidence to support an independent development defense. SIB at 53.

In view of the record evidence, I find that Ascleitis has not established independent development of the ASC41 capsules. Establishing an independent development defense is difficult, and a “respondent bears a heavy burden of persuasion[.]” *Sausage Casings*, Comm’n Op., 1984 WL 273789, at *95. The only testimony offered at the hearing on this issue was from Viking’s expert Dr. Amidon, who provided the unrebutted opinion that Ascleitis came up with the excipients for the ASC41 capsule by using Viking’s trade secrets, particularly TS No. 4. Hr’g Tr. (Amidon) at 281:4-9. [REDACTED]

[REDACTED] *Id.* at 281:16-20; CX-1412C (05/13/2019 email from K. Dong to K. Gudmundsson and B. Yang). [REDACTED]

[REDACTED]

[REDACTED]

██████████ Hr'g Tr. at 281:17-20 (Amidon). Respondents did not offer any testimony to rebut Dr. Amidon's argument.²⁷

For the reasons above, I find that Ascleitis has not established that it independently developed the capsule formulation described in Viking's protectable Formulation Trade Secrets.

(2) ASC41 Tablets

In addition to the capsule formulation of ASC41, Ascletis has developed a tablet formulation for ASC41, which it argues was independently developed. RIB at 57-61.

The formulation for ASC41 tablets differs from the formulation for ASC41 capsules. The excipients used in the tablet formulation are:

[REDACTED] SX-1005C

(Resps.' Supp. Resps. to Staff's 2nd Set of Interrogs.) at 54; *see also* RDX-1005C (Abato demonstratives) at 26. The only excipient used for both ASC41 capsules and [REDACTED] is [REDACTED], and the quantity used is very different: [REDACTED]

[REDACTED] Hr'g Tr. (Abato) at 933:15-934:6. Dr. Abato testified that [REDACTED] serves different purposes in the two formulations. [REDACTED]

Id.

²⁷ In section V.F.1.a) above, I discussed the email marked as exhibit CX-1413C, which is Dr. Gudmundsson's response to the email from Mr. Dong to Mr. Gudmundsson marked as exhibit CX-1412C. In that section, I found that CX-1413C is circumstantial evidence of improper disclosure of Viking's TS No. 4 to Dr. Yang and Mr. Dong even though Dr. Gudmundsson denied disclosing TS No. 4 to Ascleitis personnel not authorized to view documents in the Viking virtual data rooms. Here, Mr. Dong's statement in CX-1412C nevertheless suggests that he believes Dr. Gudmundsson provided vital input to the development of ASC41. This weighs against finding that Ascleitis independently developed ASC41.

The evidence also shows that the design for the tablet formulation of ASC41 was based on Ascleitis's previous experience with [REDACTED] manufacturing technology, experience that predated Ascleitis's involvement with Viking. The excipients used in ASC41 [REDACTED] [REDACTED]. Hr'g Tr. (Abato) at 778:23-779:25, 780:1-3. And Ascleitis's expert Dr. Abato testified that Ascleitis worked with a contract research organization experienced with Ascleitis's previous [REDACTED] products to develop the ASC41 [REDACTED] formulation:

Hr'g Tr. (Abato) at 781:6-19.

Viking’s expert Dr. Amidon opined that Ascletis’s ASC41 tablet formulation was derived from Viking’s Formulation Trade Secrets because “[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].” Hr’g Tr. (Amidon)

at 284:15-24. To support his opinion, Dr. Amidon identified a patent publication listing respondent

Jinzi Wu as an inventor, in which a tablet formulation for ASC41 is compared to a capsule formulation containing the same excipients as the ASC41 capsule formulation. *Id.* at 285:12-287:8; CX-1604 (U.S. Patent App. No. 2021/0308155 (Wu)) at [0096], [0161]-[0165]. He also testified that in his opinion, the fact that Ascleitis's Spike Lo emailed a Viking employee in August 2016 to ask [REDACTED]

[REDACTED]
[REDACTED].” Hr’g Tr. (Amidon) at 287:10-15.

Ascleitis’s expert Dr. Abato testified on similar lines that [REDACTED]
[REDACTED]
[REDACTED] Hr’g Tr. (Abato) at 913:19-24, 917:10-918:5. Ascleitis’s reliance on the capsule formulation of ASC41 in the development of the [REDACTED] formulation of ASC41 is further demonstrated in an email between Ascleitis and its contract research organization. CX-1413C-T. Using ASC41 capsules as a measure, the contract research organization acknowledged [REDACTED]
[REDACTED] CX-1434C-T.0005-.0006.

Despite the record evidence discussed above, Staff nevertheless argues that Ascleitis demonstrated the ASC41 [REDACTED] formulation was independently derived through its previous experience with the “nearly identical” excipients used in Ascleitis’s [REDACTED] drugs and the assistance of a contract research organization. SIB at 55-56.

But considering the evidence as a whole, I find Ascleitis’s theory of independent derivation of the ASC41 [REDACTED] formulation is not persuasive. The evidence shows that Ascleitis used Viking’s protectable trade secret information to develop the ASC41 capsule formulation and then

benchmarked against the capsule formulation to develop the [REDACTED] formulation. I therefore find that Ascleitis, working with its contract research organization, used Viking trade secret information to develop the [REDACTED] formulation for ASC41.

(3) ASC43F Tablets

The final accused product is the tablet product ASC43F. Ascleitis's expert Dr. Abato testified that, according to Ascleitis's IND application documents, [REDACTED] [REDACTED] Hr'g Tr. (Abato) at 934:7-935:7.

Staff argues that Ascleitis independently derived the ASC43F [REDACTED] and bases its position on the premise that the ASC43F tablet formulation was independently derived. SIB at 57.

In view of the record evidence, I find that the [REDACTED] of ASC43F was based on the Formulation Trade Secrets for the same reasons as the ASC41 [REDACTED] discussed above.

2. Preclinical Trade Secrets

Viking argues that Ascleitis used all of the asserted Preclinical Trade Secrets in determining whether or not to pursue development of ASC41. CIB at 113. In support of this argument, Viking's expert Dr. Silber testified that "Respondents must have used the valuable Viking trade secret information they improperly acquired when deciding whether to make the substantial investment of undertaking a new drug development program using the same API as VK2809." Hr'g Tr. (Silber) at 480:10-16. When asked whether Ascleitis could have decided to invest in ASC41 before viewing Viking's confidential information, and whether in fact that might have been the reason that it wanted to review that information, Dr. Silber disagreed, citing internal emails from Ascleitis employee Dr. Gudmundsson expressing serious concerns about the project. *Id.* at 480:17-481:20.

Viewing the record evidence as a whole, I find that Dr. Silber’s testimony regarding what Ascletis “must have used” fails to establish that Ascletis actually used the majority of Viking Preclinical Trade Secrets, either to design preclinical studies or to “build confidence” in the ASC41 project. Notwithstanding certain deficiencies in Dr. Silber’s testimony, I find Viking has shown that Ascletis used or disclosed TS Nos. 12, 17, 18.1 to 18.3, 37 to 37.4.3, and 38. This evidence is discussed below.

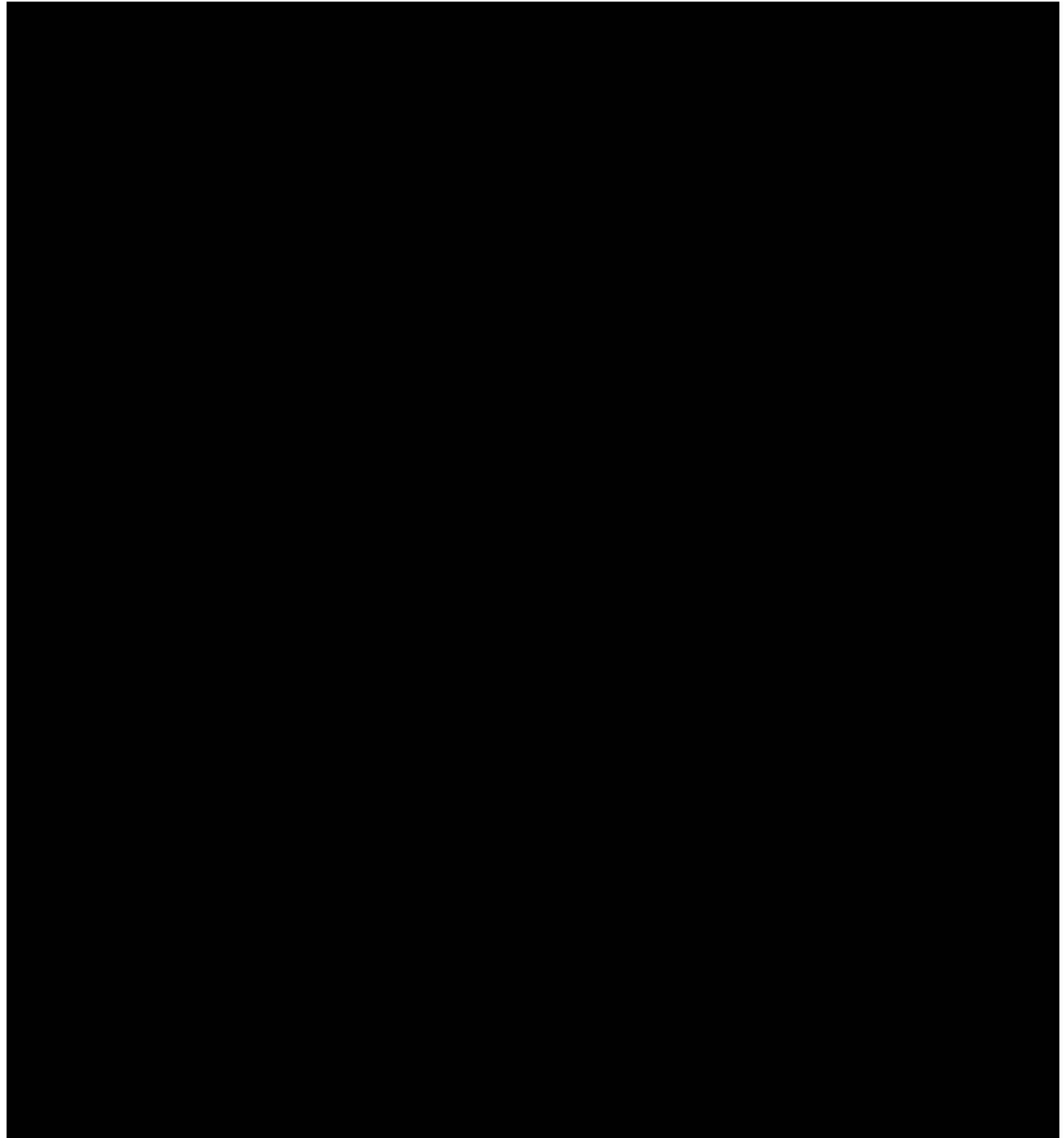
a) Misappropriation of TS Nos. 37 to 37.4.3

The evidence demonstrates that Ascletis’s employees acquired and used at least portions of Viking’s Investigator’s Brochure for VK2809, including the portions identified as TS Nos. 37 to 37.4.3. *See* CX-1010C (VK2809 Investigator’s Brochure). The Investigator’s Brochure is a confidential document that was accessed in Viking’s 2019 virtual data room by Ascletis representatives Lindi Tan, Jinzi Wu, Kristjan Gudmundsson, and Joseph Musto. CX-1992C (2019 Audit Log). The 2019 Audit Log shows that Jinzi Wu and Kristjan Gudmundsson each viewed all 53 pages of Viking’s Investigator’s Brochure in the data room. CX-1992C.

Viking introduced into evidence an email sent November 14, 2019, from Bailing Yang to Handan He and copied to Ya Hong Chen that reads, [REDACTED]

[REDACTED]

CX-1473C; CX-1473C-T. None of these three members of the ASC41 project—Bailing Yang, Handan He, or Ya Hong Chen—had authorized access to Viking’s virtual data rooms. The attachment to the email in question consists of the following three paragraphs:



CX-1474C (attachment to email produced as CX-1473C).

The email attachment is a verbatim copy of three paragraphs that appear on page 24 of Viking's VK2809 Investigator's Brochure and are the part of the document covered by TS Nos. 37 to 37.4.3. CX-1010C (VK2809 IB) at 241. Thus, it appears that unauthorized personnel had

access to the VK2809 Investigator's Brochure in November 2019, several months after Lindi Tan, Jinzi Wu, Kristjan Gudmundsson, and Joseph Musto were required to destroy any notes or other information obtained from Viking's 2019 data room under the confidential disclosure agreement with Viking. *See* CX-2014 (2019 Mutual Confidential Disclosure Agreement) § 7 (requiring return or destruction of all Viking confidential information, whether written or electronic).

There is evidence that Ascletis not only disclosed the Viking Investigator's Brochure to unauthorized personnel, but that it also used the information identified as TS Nos. 37 to 37.4.3 to guide their ASC41 preclinical research. For instance, the record contains a January 5, 2020, email from Xiao Dong Li to Handan He and Jinzi Wu [REDACTED]

[REDACTED] CX-1484C (01/05/2020 email from Li to He and Wu). The email reads:

[REDACTED]

CX-1484C. As the email indicates, at least Dr. Li was under the impression that the VK2809 Investigator's Brochure he was evidently reviewing had come from Jinzi Wu. *Id.* ("VK2809's IB (from Dr. Wu)").

At his deposition, Dr. Wu could not explain how Ascletis was in possession of three paragraphs of Viking's VK2809 Investigator's Brochure. JX-1018C (Wu Depo.) at 261:10-263:8. Nor could he explain why Dr. Li's email referred to "VK2809's IB (from Dr. Wu)[.]" JX-1017C (Wu Depo.) at 125:1-128:19. At the evidentiary hearing, Dr. Wu testified that the passage "in

VK2809's IB (from Dr. Wu)" meant [REDACTED] just information, not physical copies." Hr'g Tr. (Wu) at 655:10-656:4.

But given the length of the passage copied verbatim from the Investigator's Brochure into the attachment to Dr. Yang's November 2019 email, I find Dr. Wu's explanation implausible and lacking credibility. The most reasonable explanation is that someone, possibly Dr. Wu, made a copy of Viking's Investigator's Brochure and circulated it among the ASC41 research team, who used it at least to design [REDACTED]. Staff concurs with this position. SIB at 84-86. I therefore find that Ascletis misappropriated TS Nos. 37 to 37.3.

b) Misappropriation of Viking's [REDACTED] Studies

The evidence also demonstrates that Ascletis accessed TS Nos. 12, 17, 18, and 38 (Viking information regarding [REDACTED] studies), intermingled Viking's information with its own, and relied on the results in its clinical development efforts for the accused products. Specifically, the record contains an email exchange between Handan He and Jinzi Wu dated January 5, 2020. CX-1491C (email from He to Wu regarding ADME data). The email includes an Excel attachment entitled "[REDACTED]," which is reproduced below. CX-1490C (email attachment).

[REDACTED]

CX-1490C-T (translation of Excel attachment) at CX-1490C-T.0003.

The Excel attachment, contains nearly exact data from TS No. 18.38, including the [REDACTED]

[REDACTED]

[REDACTED] See CX-1001C ([REDACTED])

[REDACTED]).

This information is also included in the study report's summary. *Id.* at 16. Moreover, the information identified as being part of TS No. 18 is also summarized in TS No. 37.4 in Viking's Investigator's Brochure, which I also found to be a protectable trade secret. *See* CX-1010C (VK2809 Investigator's Brochure) at CX-1010C.0021 to -.0025. The Excel spreadsheet attached to Dr. He's email therefore contains protected Viking data. As discussed above in section V.D.2.b), the [REDACTED] study were not publicly available, and Ascleitis did not adduce evidence showing otherwise. Thus, the January 5, 2020, email exchange is evidence that Dr. He had access to Viking's protected information and used it in toxicity-related research for ASC41. Staff agrees with this conclusion. SIB at 88-90.

The record also supports a finding that Ascleitis used Viking trade secrets to plan [REDACTED] studies. Specifically, Viking's expert Dr. Silber testified that Ascleitis used the information in several Viking studies, [REDACTED], to skip steps in its preclinical development process for ASC41. Hr'g Tr. (Silber) at 376:16-377:25, 380:19-382:5. The 2019 Audit Log shows that Ascleitis contractor Joseph Musto viewed several [REDACTED] available in Viking's 2019 data room on April 9, 2019. CX-1992C (2019 Audit Log). The next day, [REDACTED] [REDACTED] CX-1384C (04/10/2019 email from Musto to Gudmundsson). [REDACTED]

[REDACTED] *Id.* [REDACTED]

[REDACTED] This email is reproduced below.

[REDACTED]

CX-1384C.

The evidence shows that Ascletis [REDACTED]

[REDACTED] See CX-1417C (email exchange between Musto and Yang). Ascletis did, however, [REDACTED]

[REDACTED]

[REDACTED] *Id.* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In the end, Ascletis used [REDACTED]

[REDACTED] RX-1793C (Preclinical Study Report); Hr'g Tr. (Abato) at 831:22-832:3.

At the evidentiary hearing, Dr. Silber testified:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Hr'g Tr. (Silber) at 386:16-387:7.

The evidence thus shows that Ascleitis used Viking trade secrets to plan their [REDACTED]

[REDACTED]

c) Viking's Argument That All Preclinical Trade Secrets Were Misappropriated

Based on the record evidence discussed above, Viking argues that Ascleitis was able to significantly accelerate *all* of its preclinical testing by using Viking's Preclinical Trade Secrets, including all of TS Nos. 16-18, 20-28, 31, 37, 42, 58-60, 100, 102, 104, 109-110, and 112. CIB at 139. Viking's argument is not persuasive. I find that the evidence showing that Ascleitis used the information in TS Nos. 18.1 to 18.3 and 37 to 37.4.3, plus certain Viking information relating to [REDACTED] does not prove it used any other Preclinical Trade Secret. Nor is the evidence a basis for concluding that Ascleitis's entire preclinical research program was accelerated as a result of its review of Viking's confidential information in the 2019 data room. Staff agrees with my conclusion. SIB at 91.

Misappropriation can be shown through circumstantial evidence that improperly acquired information “assisted or accelerated” a respondent’s research or development of a product that is similar but not identical to the complainant’s product. *See Crawler Cranes*, Comm’n Op. at 65-69. Viking’s expert Dr. Silber testified that, with respect to Ascleitis’s preclinical development work, he was “frankly, astounded at the number, the sheer number of studies that were performed and, most importantly, in a very, very short time frame. Highly unusual.” Hr’g Tr. (Silber) at 373:5-13. He further testified that “when one considers that the – the studies that were performed by Respondents that led to the China filing in February of 2020, that represented less than well under nine months from when they supposedly began their development.” *Id.* at 373:25-374:4. Dr. Silber also testified that “if Respondents had to independently develop Viking’s preclinical trade secret information . . . they would have had to run all the same studies and draft up all the same reports, which would have taken them approximately the same amount of time that it took Metabasis.” *Id.* at 489:2-15 (46 months would have been required).

Dr. Silber’s timeline is not consistent with the balance of the evidence regarding the amount of time needed to conduct preclinical studies for ASC41. Ascleitis has identified a number of factors, other than access to Viking Preclinical Trade Secrets, that explain why Ascleitis’s preclinical research proceeded much faster than the Metabasis research program did. First, as Ascleitis’s expert Dr. Abrouk testified, over the years there have been industry-wide improvements in the preclinical research process:

Q. And you said today’s world is different. How are the CROs different between now – or 2019 and 2005?

A. In the last 15 years, I boil down to six major giant CROs, all the American, one Canadian, Charles River, that dominate the world. They are extremely efficient. It is very, very expensive, but they can help you quite a bit.

Q. And what about efficiencies, has the industry changed in terms of efficiencies?

A. Timelines between the handoffs from one state to the next are much, much more collapsed. And it is much more efficient from a data perspective as well the way you gather data, retrieve it, it is all on the Internet as opposed to old paper type of approaches so, yeah, it is very efficient now for sure.

Hr'g Tr. (Abrouk) at 1001:24-1002:12.

Second, Metabasis had financial troubles throughout the period when it was researching VK2809. *See* Hr'g Tr. (Masamune) at 206:13-21. Ultimately, Metabasis went bankrupt. Hr'g Tr. (Abrouk) at 1066:20-1067:4. Under these circumstances, it is not surprising that Ascletis took an approach to ASC41 drug development that was faster than that of Metabasis or Viking. Ascletis could afford to run preclinical studies in parallel at a rate that would have been beyond Metabasis's financial means. *See id.* at 1067:5-19 (“[R]esources would probably have a big impact.”).

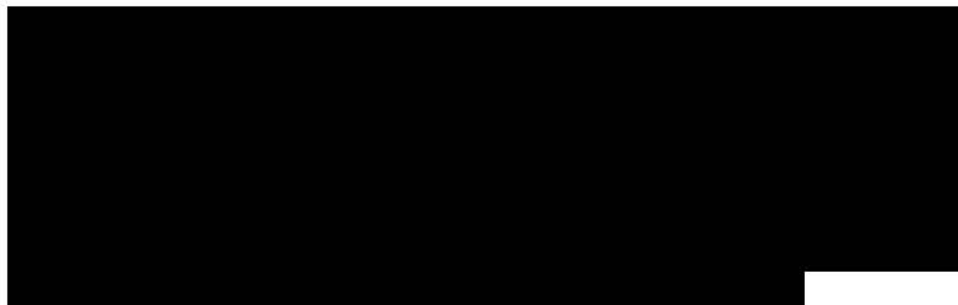
Third, Viking [REDACTED]

[REDACTED]. Hr'g Tr. (Silber) at 491:4-13. Dr. Abrouk testified that as a result, “[y]ou don’t have to do other things, an oncology, say.” Hr'g Tr. (Abrouk) at 1067:20-1068:2 (identifying this as having only a minor effect on timelines).

Given the various reasons why preclinical studies of ASC41 could progress more quickly than the studies of VK2809 did, the evidence does not support a finding that Ascletis misappropriated every Preclinical Trade Secret simply because its preclinical research timeline was shorter than Viking's. As discussed above, there is specific documentary evidence of misappropriation for TS Nos. 18.1 to 18.3 and 37 to 37.4.3, in addition to certain [REDACTED] [REDACTED] information. The evidence does not support a finding that the remaining protectable Preclinical Trade Secrets were misappropriated.

d) Ascletis's Independent Development Defense

Ascletis contends it designed all preclinical studies for ASC41 without referring to any Viking trade secret information. RIB at 93-97. Rather than recreating Viking's trade secrets, it alleges, it conducted its own independent research without attempting to replicate the approach followed by Metabasis and Viking. For example, Ascletis argues:



RIB at 93 (citations to Abato testimony omitted).

Considering the record evidence in total, I find there is insufficient evidence to support an affirmative defense of independent development regarding the design and conduct of Ascletis's preclinical studies. Ascletis's general assertions that it had no need of Viking's Preclinical Trade Secrets do not qualify as evidence. Staff agrees with this conclusion. SIB at 82. Accordingly, I find that Ascletis has not successfully established an independent development affirmative defense regarding Viking's Preclinical Trade Secrets.

3. Clinical Trade Secrets

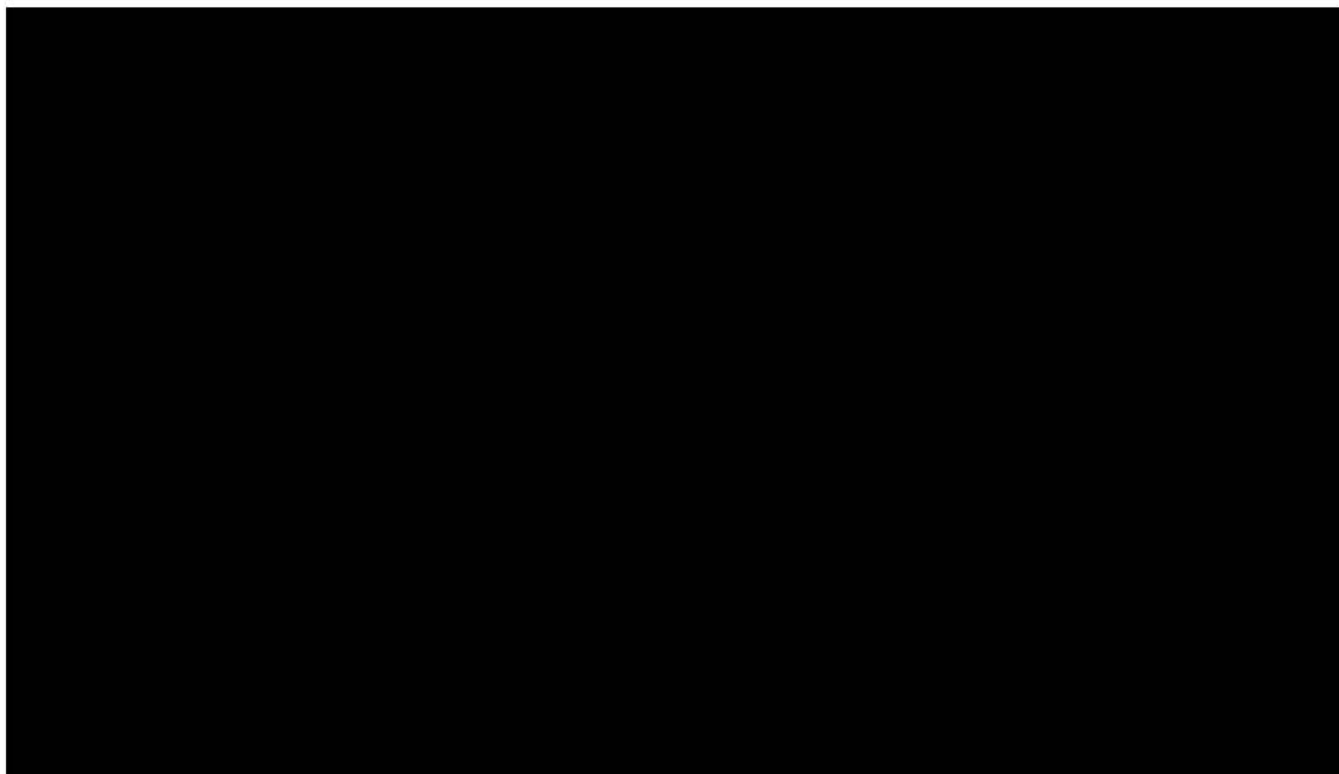
As discussed below, the record evidence supports a finding that Ascletis used or disclosed TS Nos. 12.11, 13.1 to 13.7, and 15.1.

a) Misappropriation of TS No. 12.11

Viking adduced evidence showing that Ascletis employees acquired and made use of information included in a Viking Phase I clinical study report, MB07811-102, and that was reproduced in Viking's VK2809 Investigator's Brochure. See CX-1019C (Metabasis Phase I

Clinical Study Report Protocol No. MB07811-101); CX-1010C (VK2809 Investigator's Brochure). Page CX-1019C.0012 of the MB07811-101 study report discloses TS No. 12.11, which describes [REDACTED]

[REDACTED]. CX-1019C at CX-1019C.0012. The same information appears in the VK2809 Investigator's Brochure at page 27. CX-1010C at CX-1010C.0027. The relevant portion of that page is reproduced below:



CX-1010C.0027.

The evidence demonstrates that on January 5, 2020, Ascleptis employee Handan He²⁸ emailed a spreadsheet to Jinzi Wu containing [REDACTED] CX-1491C (01/05/2020 email exchange between He and Wu regarding [REDACTED]; CX-1490C-T

²⁸ Dr. He was Ascleptis's Chief Scientific Officer. Hr'g Tr. (Silber) at 386:13-15.

(Pharmacokinetic parameters for MB07344 and MB07811 in SD rats: spreadsheet with translation). The Excel attachment was part of the following email exchange:

[REDACTED]

CX-1491C.

The [REDACTED] referenced by Dr. Wu consisted of the following table in Dr. He's Excel spreadsheet:

[REDACTED]

CX-1490C-T.0004.

Dr. He thus appears to have had access to Viking's [REDACTED] data, which his email acknowledged was not in the public domain, [REDACTED]

[REDACTED] CX-1491C.0001;

see Hr'g Tr. (Silber) at 405:6-22. Staff agrees with this interpretation of the evidence. SIB at 108. Ascletis did not provide any other plausible explanation for the January 5, 2020, exchange between Dr. He and Dr. Wu.

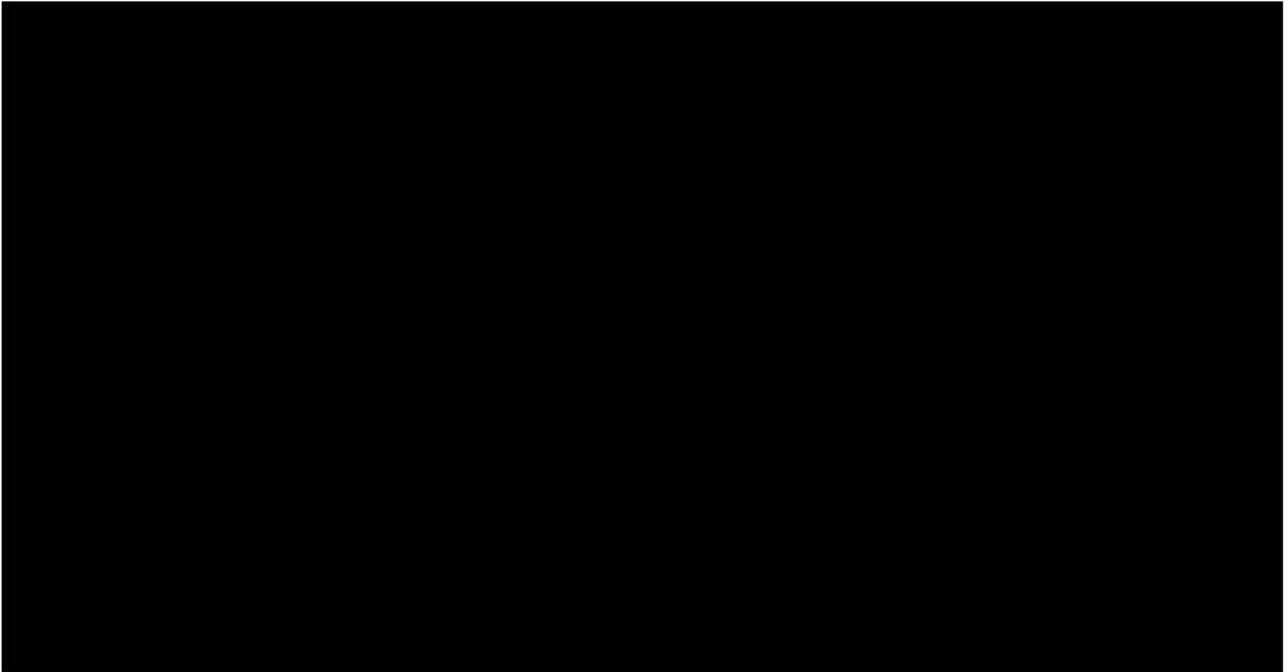
In view of this evidence, I find that Ascletis wrongfully acquired Viking's [REDACTED] and disclosed it at least to Dr. He, who was not authorized to view Viking confidential information, thereby misappropriating TS No. 12.11.

b) Misappropriation of TS Nos. 13.1 to 13.7

As discussed above, the evidence shows that Ascletis employees acquired and used at least portions of Viking's VK2809 Investigator's Brochure. See CX-1010C (VK2809 Investigator's [REDACTED]). The 2019 Audit Log shows that Jinzi Wu and Kristjan Gudmundsson each viewed all 53 pages of the Investigator's Brochure. CX-1992C (2019 Audit Log). Their viewing would have included pages 25-29 of the Investigator's Brochure, which contain [REDACTED] information contained in TS No. 13.1 to 13.7.²⁹ See CDX-1035C (Trade Secret Chart) at 3.

Page 29 of the VK2809 Investigator's Brochure contains the following table of information gathered in a Phase I clinical study, VK2809-102:

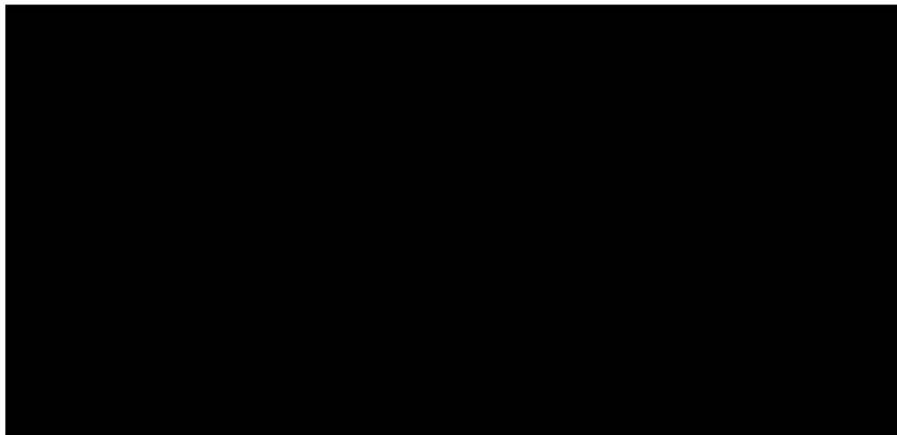
²⁹ These pages are also identified as TS No. 38.1. See section I.F.3 above.



CX-1010C (VK2809 Investigator's Brochure) at 29.

In addition to the [REDACTED] table discussed in section V.F.3.a) above, the spreadsheet that Dr. He emailed to Dr. Wu on January 5, 2020, contained several other tables. CX-1491C; CX-1490C-T. The spreadsheet also includes the following table, labeled "[REDACTED]":

[REDACTED]":



CX-1490C-T.0004.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

CX-1491C.

And as Viking's expert Dr. Silber testified, [REDACTED]

[REDACTED] Hr'g Tr. (Silber) at 396:8-15 (Silber) (" [REDACTED]

[REDACTED]

[REDACTED]).

Having compared the Excel spreadsheet in question with the VK2809 Investigator's Brochure, and having considered the testimony from Dr. He and Dr. Silber, I conclude that Ascleitis wrongfully acquired Viking's [REDACTED] data from [REDACTED] and disclosed it at least to Dr. He, who was not authorized to view Viking confidential information. I therefore find that Ascleitis misappropriated TS Nos. 13.1 to 13.7.³⁰

c) Misappropriation of TS No. 15.1

The record evidence shows that information contained in Viking's [REDACTED] [REDACTED] for VK2809 was retained by Ascleitis after the end of their 2019 Confidential Disclosure Agreement with Viking and was disclosed to Ascleitis personnel who were not authorized to view the information. See CX-1011C (Viking Clinical Study Protocol: VK2809-201).

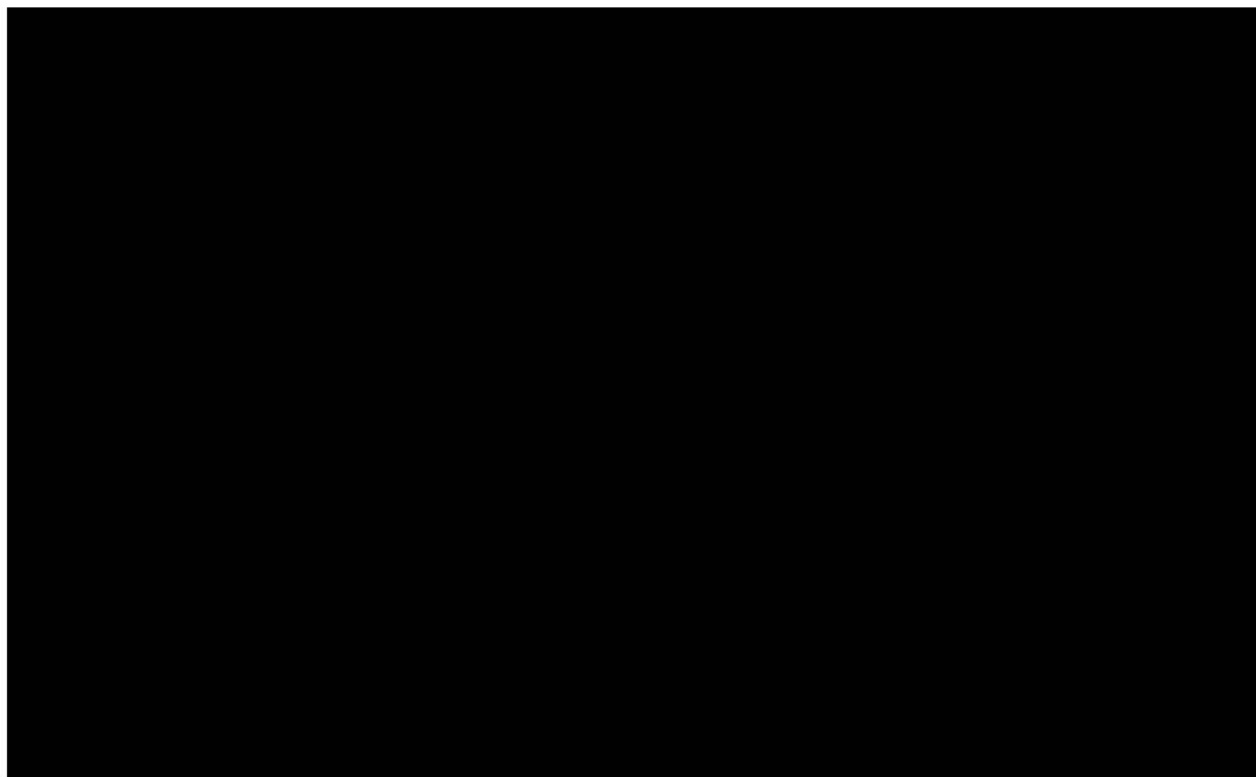
In a May 13, 2021, email to Melissa Palmer and Jinzi Wu, Ascleitis employee Chunchun Ye attached several documents, including one named [REDACTED] CX-1596C

³⁰ Staff agrees with this conclusion. SIB at 110.

(email from Ye to Palmer regarding [REDACTED]);

CX-1597C (attachment). The body of the email reads: [REDACTED]

[REDACTED] CX-1596C. Dr. Silber testified that the attachment is a verbatim reproduction, in English, of the entire Synopsis section of Viking's VK2809-201 Clinical Study Protocol. Hr'gTr. (Silber) at 407:1-409:5. Excerpts of the two documents are reproduced below:



CX-1011.C (VK2809-201 study protocol) at 4; CX-1597C (email attachment) at 1.

TS No. 15.1 encompasses the Synopsis section of the VK2809-201 Clinical Study Protocol. *See* CDX-1035C (Trade Secret Chart) at 7. The evidence, therefore, shows that Chunchun Ye, who was not authorized to access the Viking 2019 virtual data room, possessed a copy of TS No. 15.1 two years after it should have been destroyed. *See* CX-2014 (2019 Mutual

Confidential Disclosure Agreement) § 7 (requiring return or destruction of all Viking confidential information, whether written or electronic, at termination of agreement). At the evidentiary hearing, respondent Dr. Wu acknowledged that the email attachment, which had the file name [REDACTED] was in fact the VK2809 protocol. Hr'g Tr. (Wu) at 658:15-659:5.

Based on this evidence, I find that Ascleitis improperly disclosed TS No. 15.1 to unauthorized individuals for a purpose other than that permitted by the 2019 Confidential Disclosure Agreement, thereby misappropriating TS No. 15.1.³¹

d) Ascleitis's Independent Development Defense

Ascleitis argues that they designed their Phase I and Phase II clinical studies for ASC41 without referring to any Viking trade secret information. RIB at 132-43. Ascleitis also argues that there would have been no benefit to knowing Viking's Clinical Trade Secret information because every competitor must design and conduct its own clinical trials, meaning that knowledge of what Viking had done would not have resulted in any time savings. *See* RIB at 115.

Nevertheless, in view of the evidence adduced at the hearing, the record does not support a finding of independent development of Ascleitis's Phase I and Phase II clinical studies. Ascleitis cannot establish independent development without providing a detailed narrative, supported by documentary evidence, of how their clinical trials were designed and conducted without referring to Viking's trade secret information. Ascleitis did not provide such a narrative at the evidentiary

³¹ Staff agrees with this conclusion. SIB at 110-11

hearing. Accordingly, I find that Respondents have not successfully established an independent development affirmative defense regarding Viking's Clinical Trade Secrets.³²

VI. DOMESTIC INDUSTRY

Viking argues existence of a domestic industry and also the existence of an industry in the process of being established. CIBI at 40-49 (current), 49-55 (future). Viking asserts that its present domestic industry relates to the research and development activities, clinical testing, and business development activities to find a strategic partner to assist in obtaining FDA approval for VK2809. CIBI at 40. Viking describes its future industry as the post-strategic partnership time period for “completion of the FDA approval process, including phase 3 clinical trials, and commercial manufacturing and selling of [REDACTED] with a strategic partner.” CIBI at 49-50; 100-Day Tr. at 117:19-118:10 (Zante); 100-Day Tr. at 307:16-308:1 (Prowse).

A. Legal Standards

1. Requirements for an Industry in the United States

A complainant seeking relief under section 337(a)(1)(A) must establish the existence of a domestic industry. 19 U.S.C. §1337(a)(1)(A). To determine whether a domestic industry exists, “the Commission has traditionally considered the ‘nature and significance’ of the complainant’s domestic activities.” *Certain Bone Cements, Components Thereof and Products Containing the Same*, Inv. No. 337-TA-1153, Comm’n Op. at 16 (Jan. 25, 2021) (public version) (“*Bone Cements 1153*”); *see also Certain Miniature, Battery-Operated, All Terrain, Wheeled Vehicles*, Inv. No. 337-TA-122, USITC Pub. No. 1300, Comm’n Op. at 6 (Oct. 1982) (“The threshold question of the existence of an ‘industry . . . in the United States’ . . . requires an inquiry into the nature and

³² Staff agrees that Ascleptis failed to meet the heavy burden of persuasion to show independent development. SIB at 104-05.

significance of complainants' business activities in the United States which relate to the [imported articles]”), *aff’d*, *Schaper Mfg. Co. v. USITC*, 717 F.2d 1368 (Fed. Cir. 1983); *Certain Cube Puzzles*, Inv. No. 337-TA-112, USITC Pub. No. 1334, Comm’n Op. at 30 (Jan. 1983).

“The Commission does not adhere to any rigid formula in determining the scope of the domestic industry as it is not precisely defined in the statute, but will examine each case in light of the realities of the marketplace.” *Certain Floppy Disk Drives and Components Thereof*, Inv. No. 337-TA-203, Comm’n Action and Order, 0085 WL 1127250, at *27 (Aug. 29, 1985). “This reflects the fact that each industry is unique to its particular facts and circumstances.” *Bone Cements 1153*, Comm’n Op. at 18.

The domestic industry required for relief under section 337 has never been limited to a manufacturing industry. For example, more than 40 years ago, the Commission found a domestic industry servicing foreign-made stoves qualified for protection under section 337. *See Airtight Cast-Iron Stoves*, Inv. No. 337-TA-69, Comm’n Op., 1980 WL 41970, at *5 (Dec. 31, 1980) (“*Stoves*”). In reaching that determination, the Commission examined the legislative history of section 337 of the Tariff Act of 1930 and its predecessor, section 316 of the Tariff Act of 1922. *Id.* The Commission noted that neither piece of legislation was intended “to be limited to the protection of manufacturing activity.” *Id.* The Commission noted that the history of section 316 indicates it was to protect “farming and mining” industries as well as manufacturing industries, and the history of section 337 shows it applies “to all industries alike,” including the “[w]age earner, farmer, stockman, producer, and legitimate business in general . . .” *Id.*³³

³³ A year after the *Stoves* determination, the Commission relied upon it to find that an industry servicing foreign-made spray pumps contributed to the domestic industry. *Certain Airless Paint Spray Pumps & Components Thereof*, Inv. No. 337-TA-90, USITC Pub. No. 1199, Comm’n Op. at 9-11 (Nov. 24, 1981).

The examples in the legislative history make it easy to see why a domestic industry protected by section 337 need not make articles that compete with the imported articles under investigation.³⁴ A domestic farming industry may be injured by the unlawful importation of an invasive species that domestic farms do not produce. A domestic livestock industry may be injured by the unlawful importation of disease-carrying material that does not exist in the domestic market. A domestic mining industry may be injured by the importation of an unlawful synthetic that domestic mines do not produce. Scholarly articles have posited other similar scenarios. *See* Jonathan J. Engler, *Section 337 of the Tariff Act of 1930: A Private Right-of-Action to Enforce Ocean Wildlife Conservation Laws?*, 40 *Env't L. Rep. News & Analysis* 10513, 10513-14 (2010). Congress intended to protect all manner of U.S. industries from unfair trade practices, not just industries that manufactured goods in competition with imported articles.

After amendments were made to section 337 in 1988 to codify the definition of one flavor of domestic industry “with respect to. . . articles protected by” certain statutory intellectual property rights, the Commission still consistently declined to require a manufacturing industry when applying the statute. *See* 19 U.S.C. § 1337(a)(3) (1989); *Bone Cements* 1153, *Comm’n Op.* at 12 (“Congress, however, in choosing to employ the word ‘industry’ rather than ‘manufacturing,’ illustrated that it intended the term ‘industry’ to cover more than just domestic manufacturing.”). Continuing that consistent application to the present, the Commission recently credited investments in labor and facilities for research and development (“R&D”) when evaluating a

³⁴ To be sure, section 337 also protects industries relating to domestic articles that compete with the imported articles under investigation. For example, current section 337(a)(3) describes an “industry in the United States, relating to the articles protected by” a statutory intellectual property right. *See* 19 U.S.C. § 1337(a)(3). And the public interest factors listed in section 337 require consideration of domestic production of competing articles before entry of an exclusion order. *See* 19 U.S.C. § 1337(d)(1). But the competition analysis required by the public interest factors ensures the fashioning of a balanced remedy; it is not a predicate to a finding of a violation.

complaint based on trade secret misappropriation. *See Balanced Armature Devices*, Comm’n Op. at 9 & n.8 (Oct. 29, 2021) (public version). And the Federal Circuit has affirmed that domestic manufacturing is not required for a domestic industry under section 337. *InterDigital Commc’ns, LLC v. Int’l Trade Comm’n*, 707 F.3d 1295, 1301 (Fed. Cir. 2013) (citing legislative history indicating that section 337 can protect a “service industry exploiting [an] intellectual property right within the United States” or “small businesses who do not have the capital to actually make the good in the United States”).

The Commission’s prior determinations also indicate that activities related to seeking FDA approval of a drug candidate may constitute a domestic industry. In *Minoxidil Powder*, for example, the Commission found a domestic industry based on “pre-market” activities of the complainant, including ongoing research and development into a drug product that exploited the asserted patents, investment in plant and equipment to produce the drug, and preparations for marketing and selling the drug after FDA approval. *Certain Minoxidil Powder, Salts and Compositions for Use in Hair Treatment*, Inv. No. 337-TA-267, Initial Determination, 1988 WL 582867 at *26-27 (Feb. 16, 1988). In that investigation, the complainant had already filed a New Drug Application with the FDA and begun manufacturing and stockpiling its drug on a commercial scale, but the complainant did not yet have the legal right to market or sell its patented drug product in the United States.³⁵ *Id.* (noting that “FDA approval appears to be likely, but its timing is speculative”). Other investigations have come to different conclusions, depending on the nature and significance of the complainants’ FDA-related activities. *Compare Bone Cements 1175*, Initial

³⁵ In *Minoxidil Powder*, the respondents were already selling their competing products commercially in the United States, without first obtaining FDA approval for their products. *Minoxidil Powder*, 1988 WL 582867 at *27-28 (holding that as a result, “Upjohn will be injured when Upjohn enters the marketplace. The tendency to injure exists now.”).

Determination at 54 (complainant’s FDA-related activities did not establish a domestic industry where they did not involve “research and development, clinical trials, or maintenance of processes and equipment in the United States in accordance with FDA requirements”) *with, Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators*, Inv. No. 337-TA-1110, USITC Pub. No. 5025, Comm’n Op. at 97 (Feb. 2020) (finding a domestic industry even though the FDA had not yet approved the domestic industry product because complainant had initiated FDA approval activities, employed a number of employees and a third-party consultant to specifically support the regulatory approval activities, and expended significant amounts of money specific to this effort) *and, Certain Salinomycin Biomass and Preparations Containing Same*, Inv. No. 337-TA-370, USITC Pub. No. 2978, Initial Determination at 128 (July 1996) (nonreviewed) (finding a domestic industry based on “FDA regulatory activities” that included an FDA-approved facility for making the chemical, employment of a third-party consultant in the United States to assist with FDA matters related to the chemical, and plans to seek further FDA approval for use of the chemical in animals). But the Federal Circuit has continued to affirm that a domestic industry may exist without FDA approval of a product. *See Philip Morris Products S.A. v. Int’l Trade Comm’n*, 63 F.4th 1328, 1341-42 (Fed. Cir. 2023) (affirming finding of domestic industry in section (a)(1)(B) investigation, where economic prong analysis was based on investments in tobacco products that had not yet been approved for sale by the FDA, on grounds that “[e]ven if the articles could not be sold commercially in the United States, the parties do not dispute that sufficient investment in labor and capital had been expended”).

2. Requirements for an Industry in the Process of Being Established

In many investigations under section 337(a)(1)(A) (and its equivalent before 1988), the Commission's decisions involving industries "in the process of being established" have been domestic manufacturing industries. The Commission used nomenclature describing a "nascent industry" as one where a complainant had just begun manufacturing operations and an "embryo[nic] industry" as one where a complainant was about to commence production. *Certain Meat Deboning Machines*, Inv. No. 337-TA-181, Initial Determination, 1984 WL 273798, at *49-50 (Nov. 16, 1984) (citing *Certain Ultra-Microtome Freezing Attachments*, 337-TA-10, Comm'n Op., 1976 WL 41463, at *4 (April 2, 1976) ("*Freezing Attachments*")). For an embryonic industry, meaning one that is not yet producing or manufacturing a product, the Commission has examined the industry's "readiness to commence production." *See Freezing Attachments*, Comm'n Op., 1976 WL 41463, at *4. When applying the readiness test in the context of a manufacturing industry, the Commission looked for affirmative and overt steps taken by the complainant that would indicate that it intended to produce articles domestically. *See id.* at *4-5. Specifically, the readiness test considered "estimates of production costs, rate of production, or market share relative to the domestic manufacture." *Id.*

Viking argues:

The Commission's readiness factors for a manufacturing industry are not particularly suitable for an emerging pharmaceutical industry. It is therefore necessary to identify industry-specific factors appropriate for determining a pharmaceutical industry in the process of being established. The industry in question here—an emerging pharmaceutical industry—does not necessarily concern manufacturing, but includes research and development, clinical testing, and some manufacturing. In the industry in question here, commercial manufacturing should not be the primary focus because commercial pharmaceutical sales come after some time and significant investment, such as the time needed to engage a strategic partner and after a costly and lengthy regulatory approval process, and not necessarily in that order.

CIBI at 22.

Viking thus proposes a series of factors that should be used in this investigation to analyze whether there is an emerging domestic pharmaceutical industry in the process of being established:

- The substantiality of partnership agreement;
- Agreements with potential partners;
- Corporate statements regarding the desire for partnership;
- The progression of FDA clinical trials; and
- Preparations for next steps in the commercialization process.

Id. at 22-23.

Both Ascleitis and Staff contend that Viking's industry-specific factors should not be considered in this investigation. Ascleitis argues that the factors do not relate to the importation of the accused products or the nature or significance of the domestic industry at issue. RIBI at 117-18. Staff characterizes Viking's proposed factors as an attempt to "rewrite the legal standard for finding a threat of substantial injury," taking the position that "only the Commission itself could make such a major change in the law." SIBI at 33-34. Staff notes that previous Commission decisions have interpreted the prevention clause of section 337 as protecting two types of complainants: those that have "just begun manufacturing operations" and those "about to commence production." *Id.* at 88 (citing *Freezing Attachments*, Comm'n Op.).

The arguments against Viking's context-specific approach are not persuasive. When analyzing one of the earliest decisions under section 316 (the predecessor to section 337), the Court of Customs and Patent Appeals noted that the violation of the rights of a given industry depended "upon the facts in a particular case." *Frischer & Co. v. Bakelite Corp.*, 39 F.2d 247, 260 (C.C.P.A. 1930). Thus, the Commission has long instructed its administrative law judges to look to the

“realities of the marketplace” when determining the existence of a domestic industry. *See, e.g., Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm’n Op. at 27 (Aug. 1, 2007); *see also TianRui*, 661 F.3d at 1336-37. This flexible analysis is a fact-specific process, and Viking’s proposed factors are relevant to the realities of the drug development marketplace at issue in this investigation. Indeed, the record evidence in this investigation amply demonstrates that engagement with current and potential business partners, progression of FDA clinical trials, and preparation for the commercialization of a drug product are all relevant factors that can indicate whether an industry is likely to soon commence production of the subject articles.

B. Viking’s Present Domestic Industry

Viking presented evidence of domestic expenditures with respect to research, development, engineering, and testing to commercialize VK2809. Viking and its 24 employees operate out of one facility in San Diego, California. 100-Day Tr. (Morneau) at 38:12-25. Viking completed seven Phase I clinical studies related to VK2809, and several Phase II studies were underway at the time of the evidentiary hearing. CX-0208C; 100-Day Tr. (Morneau) at 42:8-13. For each study, Viking tracks its investments in three general categories:

1. **Consulting:** research and development consultants for various study and research related tasks;
2. **Chemical, manufacturing, and controls:** manufacture and storage of drug products for clinical trials; and
3. **Studies:** investments to perform the clinical trials themselves, including costs associated with contract research organizations, site expenses, specialty labs, and other related costs.

CX-0208C; 100-Day Tr. (Prowse) at 298:25-300:18.

Viking has other drug candidates in development besides VK2809, and the evidence shows that Viking has domestic investments in facilities, employee labor, and equipment used to support all of Viking's drug candidates, including VK2809. Viking's domestic industry expert Dr. Prowse described these expenses as "Viking's own labor that performs R&D; Viking's facilities, the rent and utility expenses that they spend on their headquarters in San Diego; and the equipment they purchase for the purposes of R&D." 100-Day Tr. (Prowse) at 303:8-22. For purposes of this investigation, Viking allocated these general expenses on an annual basis according to the percentage of Viking's total research and development expenses tracked directly to VK2809. 100-Day Tr. (Prowse) at 302:10-24. I find this method of allocation appropriate to the circumstances of this investigation.

Viking asserts it has investments directly trackable to VK2809 of approximately [REDACTED] for "manufacturing-type activities," [REDACTED] for Phase I clinical trials, and [REDACTED] for the completed Phase IIa study and ongoing Phase IIb study. CIBI at 42-43 (citing CX-0208C). These expenses were all for activities in the United States with two exceptions—[REDACTED] in pre-manufacturing fees to [REDACTED] and [REDACTED] for consultant expenses incurred outside the United States. 100-Day Tr. (Morneau) at 44:22-45:2, 46:21-48:1. When these exceptions are subtracted from Viking's direct VK2809 investments, the domestic investment by Viking trackable directly to VK2809 is approximately [REDACTED]. 100-Day Tr. (Prowse) at 303:23-304:13. The evidence also shows Viking had domestic investments in labor, facility, and equipment totaling approximately [REDACTED] for all its drug candidates, of which [REDACTED] can be allocated to VK2809. 100-Day Tr. at (Prowse) 303:6-22.

The parties do not dispute the amount of investments Viking has made in VK2809, but there is disagreement about which investments should count toward any domestic industry. Ascletis argues that two categories of expenses should be excluded from the domestic industry analysis: (1) investments in the VK2809 [REDACTED] and (2) payments to third-party suppliers that include a profit margin for those suppliers. RIBI at 13-18. Staff takes the position that investments in [REDACTED] are cognizable but agrees with Ascletis that payments to third-party suppliers are not. SIBI at 40. These contested investment categories are addressed below.

1. Investments in the VK2809 Capsule Formulation

Viking developed capsule and [REDACTED] of VK2809 that [REDACTED]. JX-0007C.0003-4; 100-Day Tr. (Prowse) at 306:1-14. Viking [REDACTED], but soon found that [REDACTED]. 100-Day Tr. (Prowse) at 60:16-20; 100-Day Tr. (Rao) at 253:18-24. In the period leading up to the filing of the complaint in this investigation, all but one of Viking's clinical trials involved [REDACTED]. [REDACTED] was examined in one Phase I crossover study to compare [REDACTED] so that Viking could continue its clinical trials with [REDACTED]. 100-Day Tr. (Prowse) at 86:7-17. Viking plans to proceed with Phase III clinical trials and commercialization with only the [REDACTED]. 100-Day Tr. (Prowse) at 60:16-20, 86:4-9, 114:4-8. Ascletis thus argues that Viking has abandoned commercialization of the VK2809 capsule formulation and that Viking's domestic investments in the capsule formulation should not be considered in the domestic industry analysis. RIBI at 18-19.

Ascletis's argument is not persuasive in view of Commission precedent. The Commission has determined that where a complainant continues its operations and improves its products, expenditures linked to predecessor products can be considered for purposes of a domestic industry. *Certain Battery-Powered Ride-On Toy Vehicles and Components Thereof*, Inv. No. 337-TA-314, Order No. 6 at 18-21 (Dec. 5, 1990) (unreviewed in relevant part) (domestic industry found to exist, where manufacturing of protected articles had ceased in favor of an improved model before the complaint was filed, based on substantial past investments in equipment, labor and capital in development and exploitation of the patent combined with continued activities supplying patented replacement units, which are a safety feature of the vehicles); *see also Certain Electronic Digital Media Devices and Components Thereof*, Inv. No. 337-TA-796, Comm'n Op. at 99-102 (Sept. 6, 2013) (finding domestic industry exists where complainant had substantial past investments in engineering and R&D related to discontinued protected articles and continued to exploit the patent through further development of existing products at the time of the complaint).

Here, Viking did not abandon the capsule formulation of VK2809 before filing its complaint, and Viking has continued its research using the VK2809 capsule formulation through at least the ongoing Phase IIb clinical trials. Moreover, [REDACTED] of VK2809 is an improvement made possible through the insights gained from the capsule formulation. Therefore, any investments that would be appropriately credited to the domestic industry of the VK2809 capsule formulation are also properly included in the domestic industry of the VK2809 [REDACTED]. Based on the circumstances documented in this record, I find that Viking's domestic expenses for development of the VK2809 capsule formulation should be counted towards the domestic industry in this investigation.

2. Payments to Consultants, Manufacturers, and Contract Research Organizations

Ascleitis and Staff object to including as part of the domestic industry three categories of payments. RIBI at 14-17; SIBI at 43-47.

The first disputed expenditures are payments from Viking to [REDACTED]

[REDACTED]. 100-Day Tr. (Morneau) at 48:5-49:8; CX-0312C [REDACTED] CX-0521C [REDACTED] Between 2014 and 2022, Viking's payments to CMC providers totaled [REDACTED], or [REDACTED] of total R&D investments tracked to VK2809. See CDX-0007C (Prowse demonstratives) at 42 [REDACTED]

The second dispute concerns a group of payments to contract research organizations, which are third-party entities that operate Viking's clinical studies. Altogether, payments for CROs tracked to VK2809 from 2015 through 2022 totaled [REDACTED], or [REDACTED] of total R&D investments tracked to VK2809. See CDX-0007C (Prowse demonstratives) at 42 [REDACTED]

The third category of disputed expenditures includes payments to third-party consultants who assisted Viking with R&D and regulatory services related to VK2809. JX-0005C (Morneau Depo.) at 138:7-141:2; see CDX-0007C (Prowse demonstratives) at 43. These payments totaled [REDACTED] from 2014 through 2022, or [REDACTED] of total R&D investments tracked to VK2809. See CDX-0007C (Prowse demonstratives) at 43 ("Total Consulting").

Ascleitis and Staff contend these three categories of payments cannot be included in the domestic industry under *Lelo Inc. v. International Trade Commission*, 786 F.3d 879 (Fed. Cir.

2015). In the *Lelo* panel decision, certain payments made by the complainants to U.S. suppliers for “off-the-shelf” components incorporated into the domestic industry products were excluded from the domestic industry. *Lelo*, 786 F.3d at 884. But the *Lelo* opinion also distinguished payments made to material suppliers from payments made to “contractors” and “subcontractors” for the “employment of labor” which had been credited in other investigations. *Id.* (citing *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, USITC Pub. 4005, Comm’n Op. at 24-25 (June 21, 2007)).

The first disputed category—payments to a foreign [REDACTED] [REDACTED]—suffers from the same problem as the payments rejected in *Lelo*. As in *Lelo*, the record here contains no evidence of any domestic investment made “as a result of the purchased components,” which are capsules and tablets made entirely overseas. *See Lelo*, 786 F.3d at 884. Accordingly, I do not include this category of payments in the domestic industry.

But the second and third disputed categories are different. All of the investments in these categories were for specific services performed in the United States by contractors for Viking. These expenditures amount to a domestic employment of labor that should be included in the domestic industry. I therefore find that Viking’s payment of [REDACTED] to contract research organizations and [REDACTED] to third-party consultants for services in furtherance of development of the VK2809 drug product should be counted towards the domestic industry in this investigation.

3. Significance of Viking’s Domestic Investments

The record evidence shows that Viking’s domestic investments in VK2809 are both quantitatively and qualitatively significant. For the quantitative significance analysis, Viking’s expert Dr. Prowse determined that approximately [REDACTED] of Viking’s investments in VK2809 occurred in the United States. 100-Day Tr. (Prowse) at 305:5-19. He also determined that, of

Viking's total domestic research and development expenditures, [REDACTED] were for VK2809. *Id.* Dr. Prowse calculated this percentage by dividing Viking's asserted domestic industry expenditures in VK2809 [REDACTED] by Viking's total domestic research and development expenditures [REDACTED]. *See* CDX-0007C.52. But, as discussed above, I do not credit [REDACTED] paid to CMC providers toward the domestic industry analysis. *See* CDX-0007C.42 (lines for "R&D - Drug Product" and "R&D - Drug Substance"). Thus, the actual percentage of Viking's domestic research and development expenditures attributable to VK2809 is [REDACTED]

Dr. Prowse further determined that Viking's investments in VK2809 represented approximately [REDACTED] of Viking's total company-wide operating expenditures. *Id.* Dr. Prowse calculated this percentage by dividing Viking's asserted domestic industry expenditures in VK2809 [REDACTED] by Viking's total company-wide operating expenditures [REDACTED]. *See* CDX-0007C.52. But, as discussed above, I do not credit [REDACTED] paid to CMC providers toward the domestic industry analysis. *See* CDX-0007C.42 (lines for "R&D - Drug Product" and "R&D - Drug Substance"). Thus, Viking's investments in VK2809 actually represented [REDACTED] of Viking's total company-wide operating expenditures. Based on this analysis, I find that Viking's domestic investments in VK2809 are quantitatively significant.

As for quantitative significance, Viking considers VK2809 its "most prominent drug program and is ascribed a significant amount of Viking's value." *See* 100-Day Tr. (Morneau) at 41:24-42:2. Moreover, industry analysts credit much of Viking's value to its development of VK2809. *Id.* In view of this evidence, I find that Viking's domestic investment in VK2809 are qualitatively significant.

In sum, based on the totality of the record evidence, I find that Viking has demonstrated a domestic industry requirement with respect to its research, development, engineering, and testing to commercialize VK2809.

C. Viking's Domestic Industry in the Process of Being Established

Viking describes its future industry as the post-strategic partnership time period for “completion of the FDA approval process, including phase 3 clinical trials, and commercial manufacturing and selling of VK2809 [REDACTED] with a strategic partner.” CIBI at 49-50; *see also* 100-Day Tr. (Zante) at 117:19-118:10; 100-Day Tr. at (Prowse) 307:16-308:1. Viking adduced evidence to show that it [REDACTED]

[REDACTED] 100-Day Tr. (Zante) at 124:1-5 [REDACTED]

[REDACTED] Viking projects completion of its Phase III trials in [REDACTED], FDA regulatory approval in [REDACTED], and entry into the commercial market in [REDACTED]. 100-Day Tr. (Rao) at 240:14-21.

The evidence shows that Viking is taking steps to manufacture VK2809 in the United States for use in Phase III clinical trials and for future commercial sales. 100-Day Tr. (Morneau) at 52:10-15. [REDACTED]

[REDACTED]. 100-Day Tr. (Morneau) at 52:16-20; *see also* 100-Day Tr. (Prowse) at 326:22-327:2. Dr. Rao testified that commercialization of VK2809 will generate significant revenue after FDA approval. And as discussed below in section VII.A.2, Viking has negotiated with large pharmaceutical companies

seeking a partnership to proceed into Phase III clinical trials and subsequent commercial manufacturing.

In view of the record evidence, I find Viking has shown that it is in the process of establishing a future domestic industry different in kind from its present domestic industry. The industry being established will include investments in Phase III clinical trials, further investments the FDA approval process, and the future commercialization of VK2809 tablets with a strategic partner.

VII. INJURY

To prevail in an investigation alleging a violation of section 337(a)(1)(A), a complainant must not only prove that the respondent committed an unfair act in the importation of articles, but also must prove that the “threat or effect of” the importation is (i) to destroy or substantially injure an industry in the United States; (ii) to prevent the establishment of such an industry; or (iii) to restrain or monopolize trade and commerce in the United States. 19 U.S.C. § 1337(a)(1)(A); *see also TianRui*, 661 F.3d at 1335. Subsections (i) and (ii) are at issue in this investigation.

“In determining whether unfair acts have substantially injured the domestic industry, the Commission considers a broad range of indicia[.]” *Rubber Resins*, Comm’n Op. at 60. For example, injury might be demonstrated by considering the volume of imports and their degree of penetration, a complainant’s lost sales, underselling by respondents, reductions in a complainant’s profits or employment levels, declining production, declining profitability, declining sales, or harm to a complainant’s good will or reputation. *Id.* at 60-61; *see also Certain Cast Steel Railway Wheels*, Inv. No. 337-TA-655, Initial Determination at 80 (Nov. 20, 2009) (public version), *unreviewed*, Comm’n Notice (Dec. 17, 2009). Evidence of injury is case-specific, and other factors beyond those listed above may indicate economic injury. *Lithium Ion Batteries*, Comm’n Op. at

35. “When the complainant alleges actual injury, there must be a causal nexus between the unfair acts of the respondents and the injury.” *Rubber Resins*, Comm’n Op. at 61 (citing *Bally/Midway Mfg. Co. v. Int’l Trade Comm’n*, 714 F.2d 1117, 1125 (Fed. Cir. 1983)).

“The injury requirement can also be met when an assessment of the market in the presence of the accused imported products demonstrates relevant conditions or circumstances from which *probable future injury can be inferred*.” *Certain Footwear Products*, Inv. No. 337-TA-936 (Remand), Comm’n Op. at 83 (Sept. 24, 2020) (public version) (internal quotation omitted and emphasis added). Indeed, in one of the early cases interpreting section 337, the Court of Customs and Patent Appeals affirmed a finding that the injury requirement is satisfied even where “the record does not show that [the complainant] has as yet been substantially damaged” so long as the record “sufficiently supports the holding that [the respondent’s] actions have a tendency to injure substantially” the complainant’s industry. *In re Von Clemm*, 229 F.2d 441, 445 (C.C.P.A. 1955). Later, the Federal Circuit cited *Von Clemm* and the legislative history of section 337 when it affirmed, “[w]here unfair methods and acts have resulted in *conceivable* losses of sales, a tendency to substantially injure such industry has been established.” *See Bally/Midway Mfg. Co. v. U.S. Int’l Trade Comm’n*, 714 F.2d 1117, 1124 (Fed. Cir. 1983) (quoting House Comm. on Ways and Means, Trade Reform Act of 1973, H.R.Rep. No. 571, 93d Cong., 1st Sess. 78 (1973)) (emphasis added).

In determining whether a threat to substantially injure the domestic industry exists, the Commission may consider the following indicia: (1) where there is substantial foreign manufacturing capacity, (2) the ability of imported products to undersell a domestic product, (3) an explicit intention to enter the U.S. market, (4) the inability of the domestic industry to compete with the foreign products because of vastly lower foreign costs of production and lower prices,

and (5) the significant negative impact lower priced goods would have on the domestic industry. *See Rubber Resins*, Comm’n Op. at 64. Depending on the circumstances of the investigation, other factors may be indicative of a threat of future injury. *Lithium Ion Batteries*, Comm’n Op. at 35. “The threatened injury must also be substantive and clearly foreseen, with a causal connection between the action of the respondents and the threatened injury.” *Rubber Resins*, Comm’n Op. at 64 (internal quotation omitted).

With respect to subsection (ii) of section 337(a)(1)(A), “the prevention clause of section 337 protects two categories of parties: (1) parties which have just begun [qualifying activities]³⁶ and for which section 337 violations would have the effect or tendency of frustrating efforts to stabilize such operations; and (2) parties which are about to commence [qualifying activities] and for which section 337 violations would have the effect or tendency of frustrating efforts to found a business.” *Freezing Attachments*, Comm’n Op. at 10 (Apr. 2, 1976). “The criteria which must be fulfilled to show prevention of establishment of an infant industry are, in many respects, the same as those used to establish that there exists a substantial injury or a tendency to substantially injure the domestic industry.” *Certain Composite Diamond Coated Textile Machinery Components*, Inv. No. 337-TA-160, Initial Determination, 1984 WL 273787, at *78 (May 29, 1984), *no position taken after review*, *Certain Composite Diamond Coated Textile Machinery Components*, Inv. No. 337-TA-160, USITC Pub. 1603, Comm’n Action and Order at 3 (July 23,

³⁶ Although many Commission determinations concerning section 337(a)(1)(A) and its predecessor focus on domestic manufacturing, including the one quoted here, the Commission has also determined that domestic manufacturing is not required to qualify a domestic industry for protection under the statute. *See* section VI.A.1 *supra*. Accordingly, to give a more accurate sense of the breadth of industries the Commission has determined may be covered by the statute, I have substituted the phrase “qualifying activities” for the more case-specific term “manufacturing.”

1984). A complainant must also prove a causal nexus between the unfair acts and its inability to establish a domestic industry. *Id.* at *57-58.

For an industry in which the complainant has not yet commenced qualifying activities, the complainant must demonstrate a readiness to commence qualifying activities. *Ultra-Microtome Freezing Attachments*, Comm’n Op. at 10. This requires an examination of the steps taken by the complainant to determine if it is ready to commence these activities.³⁷ *Certain Caulking Guns*, Inv. No. 337-TA-139, USITC Pub. 1507, Initial Determination at 97-107 (Nov. 25, 1983), *unreviewed by* 49 Fed. Reg. 670 (Jan. 5, 1984). “In a case in which domestic [qualifying activity] has not commenced, the most relevant measures of injury include lost customers, volume of imports, underselling, decreased profitability, and respondents’ capacity and intent to enter the United States market.” *Certain Meat Deboning Machines*, Inv. No. 337-TA-181, Initial Determination, 1984 WL 273798, at *54 (Nov. 16, 1984).³⁸

A. Injury to Viking Allegedly Attributable to Ascleitis’s Unfair Acts

Viking alleges that Ascleitis’s unfair acts (1) have substantially injured its existing domestic industry, (2) threaten to substantially injure its existing domestic industry, and (3) threatens to prevent the establishment of its future domestic industry. *See, e.g.*, CIBI at 55-56, 66, 108-11.

These alleged injuries are discussed below.

³⁷ This analysis is similar to that undertaken to show to a domestic industry “in the process of being established” in the context of an industry exploiting statutory intellectual property, where a complainant must show that it is taking necessary tangible steps to establish such an industry and that those steps indicate a significant likelihood the domestic industry requirement will be satisfied in the future. *Certain Stringed Musical Instruments & Components Thereof*, Inv. No. 337-TA-586, Comm’n Op. at 13 (May 16, 2008).

³⁸ *See* n.36 *supra*.

1. Asclethis’s Trade Secret Misappropriation Is Injury under Section 337(a)(1)(A)

When evaluating trade secret claims, federal courts recognize that, “[b]y statutory definition, trade secret misappropriation *is* harm.” *Oakwood Labs. LLC v. Thanoo*, 999 F.3d 892, 913 (3d Cir. 2021) (emphasis original). A decision from the U.S. Court of Appeals for the Third Circuit in *Oakwood Laboratories*, authored by Circuit Judge Kent Jordan, is instructive here. The appeal stemmed from the district court’s serial dismissal of four trade secret misappropriation complaints filed by pharmaceutical company Oakwood Laboratories for failure to state a claim upon which relief can be granted. *See id.* at 899-903. The district court reasoned that documents filed in support of Oakwood’s complaints “do not explain adequately whether Defendants acquired and misappropriated any of the trade secrets with knowledge of their confidentiality, if and how Defendants have used those trade secrets, or the resulting harm that Oakwood has purportedly suffered.” *Id.* at 902-03 (citations to appellate record omitted). The district court then concluded that “any alleged harm is speculative” because “Defendants have not launched any products, and, according to the Third Amended Complaint, Oakwood has not yet suffered any harm from missed partnerships or investment opportunities.” *Id.* at 903.

The Third Circuit panel vacated the district court’s dismissal of Oakwood’s complaint, finding that “Oakwood adequately pled the existence and misappropriation of trade secrets” under the DTSA. *Id.* at 913-14. The court’s reasoning is instructive when evaluating injury under section 337(a)(1)(A) due to trade secret misappropriation:

By statutory definition, trade secret misappropriation *is* harm. *See* 18 U.S.C. §§ 1839(3), (5). That is, trade secret information “derives [its] independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from [that information’s] disclosure or use[.]” 18 U.S.C. § 1839(3)(B); *cf. Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1012, 104 S.Ct. 2862, 81 L.Ed.2d 815 (1984) (“The economic value of that property right lies in

the competitive advantage over others that [the plaintiff] enjoys by virtue of its exclusive access to the data, and disclosure or use by others of the data would destroy that competitive edge.”). “When someone steals a trade secret and discloses it to a competitor he effectively assumes for himself an unrestricted license in the trade secret. And that bears its cost. After all, what value does a trade secret hold when it’s no longer a secret from the trade?” *Storagecraft Tech. Corp.*, 744 F.3d at 1185. The trade secret’s economic value depreciates or is eliminated altogether upon its loss of secrecy when a competitor obtains and uses that information without the owner’s consent. Thus, cognizable harm is pled when a plaintiff adequately alleges the existence of a trade secret and its misappropriation.

Accordingly, even if it is true that the Defendants have not yet launched a competing product, that does not mean that Oakwood is uninjured. It has lost the exclusive use of trade secret information, which is a real and redressable harm. *See* 18 U.S.C. § 1836(b)(3)(B) (permitting damages for actual loss *and* unjust enrichment caused by the misappropriation, *or* damages measured by the imposition of liability for a reasonable royalty for the misappropriator’s unauthorized disclosure or use of the trade secret); *Ruckelshaus*, 467 U.S. at 1011, 104 S.Ct. 2862 (“With respect to a trade secret, the right to exclude others is central to the very definition of the property interest. Once the data that constitute a trade secret are disclosed to others, or others are allowed to use those data, the holder of the trade secret has lost his property interest in the data.”).

And the loss of exclusivity is not the only harm. There are other, if not yet fully realized, injuries. [Defendant] Aurobindo’s rapid market entry into a sector of the pharmaceutical industry with few competitors may well deprive Oakwood of market share. Utilizing Oakwood’s trade secrets provides Aurobindo a jumpstart in an industry it would otherwise not have competitively joined for another decade. Aurobindo will avoid substantial research and development costs that Oakwood has already invested in its own product development. Those are competitive harms recognized in the DTSA, 18 U.S.C. § 1836(b)(3)(B), and they represent a sample of the several approaches by which the amount of harm – not simply the fact of harm (which inheres in the unlawful use itself) – may be measured.

Id. (emphasis original and footnotes omitted).

Thus, according to the Third Circuit, Congress has established in the Defense of Trade Secrets Act (“DTSA”) that a pharmaceutical product developed using misappropriated trade secrets causes *per se* competitive harm to the trade secret owner, even before the product is FDA approved and available in the U.S. market. *Id.* Once secrecy is lost, there is necessarily economic

injury at least from the loss of value of the secret and loss of exclusive use of the secret: “the fact of harm . . . inheres in the unlawful use itself.” *Id.* at 914.

The Third Circuit also makes clear that a trade secret owner is likely to suffer additional “competitive harms” when a rival pharmaceutical product is developed through trade secret misappropriation. These include (1) a pricing disadvantage because the misappropriator will avoid substantial research and development costs that the trade secret owner has already invested in its own product development, (2) a lost timing advantage for the trade secret owner when the misappropriator obtains “a jumpstart in an industry it would otherwise not have competitively joined” until a much later time, and (3) a loss of market share by the trade secret owner due to rapid market entry by the misappropriator. *Id.* at 913-914.

The Commission has found injury under section 337(a)(1)(A) based on circumstances similar to those discussed in *Oakwood Laboratories*. To illustrate, the defendant in *Oakwood Laboratories* was a “new-market-entrant” that was “expected to start filing for FDA approval” of products developed from the plaintiff’s trade secrets. *Id.* at 911. This tracks the Commission’s consideration of a respondent’s intention to enter the U.S. market when evaluating injury in trade secret investigations. For example, in *Certain Cast Steel Railway Wheels*, the Commission affirmed that a respondent’s “intent to target the United States market for railway wheels” indicates injury, particularly where the respondent sought domestic regulatory approval for its imported products. *Certain Cast Steel Railway Wheels*, USITC Inv. No. 337-TA-655, USITC Pub. No. 4265, 2011 WL 6255116 at *69 (Oct. 2011) (unreviewed final initial determination). Similarly, the Commission in *Rubber Resins* affirmed that a respondent’s intention to “move forward with plans to enter the U.S. and European markets” was an indicator of injury. *Rubber Resins*, Final

Initial Determination, 2013 WL 4495127 at *244 (June 17, 2013), *aff'd Rubber Resins*, Comm'n Op. at 64.

The court in *Oakwood Laboratories* also noted a trade secret misappropriator will “avoid substantial research and development costs” as compared to the trade secret owner. *Oakwood Labs.*, 999 F.3d at 914. That fact is akin to “lower foreign costs of production” discussed by the Commission in injury cases. *See Rubber Resins*, Comm'n Op. at 64 (affirming injury by a foreign manufacturer that was able to undersell the domestic industry products due to advantages gained from trade secret misappropriation). Imports made using misappropriated trade secrets can undersell domestic industry products because the importer's research and development costs are lower, and if the domestic industry is required to reduce its prices to compete with the underselling, the domestic industry suffers reduced profitability. *See id.* at 63-64. The Commission has found that is injury. *Id.*

Oakwood Laboratories further reasoned harm is likely when a misappropriator obtains “a jumpstart in an industry it would otherwise not have competitively joined” until a much later time. *Oakwood Labs.*, 999 F.3d at 914. On similar facts, the Commission has affirmed a finding of injury where the complainant argued the misappropriator “had an unfair head start into the United States market.” *See Certain Cast Steel Railway Wheels*, 2011 WL 6255116 at *68-69.

Oakwood Laboratories additionally noted that “rapid market entry” by the misappropriator may well deprive the trade secret owner of “market share,” which is another form of injury. *Oakwood Labs.*, 999 F.3d at 914. The Commission has similarly found injury “due to respondents' entry into the market.” *See Certain Cast Steel Railway Wheels*, 2011 WL 6255116 at *69; *see also Certain Electric Power Tools*, USITC Inv. No. 337-TA-284, 1990 WL 710470 at *125 (Feb. 20,

1990) (unreviewed final initial determination) (intent “to penetrate the U.S. market” is evidence of a threat of injury).

The reasoning in *Oakwood Laboratories* is highly relevant to section 337 investigations involving trade secrets because the Commission looks to the same legislation interpreted in that decision—the DTSA—when evaluating unfair trade practices based on trade secret misappropriation. *See Botox*, Comm’n Op. at 11. And, as demonstrated above, the Commission has applied similar reasoning to *Oakwood Laboratories* in its trade secret determinations.

Applying this framework to the facts here, I have found above that Viking owned protectable trade secrets which had independent economic value from not being generally known or readily ascertainable. *See* sections V.B, C, and D *supra*. I have also found that those trade secrets were misappropriated by Ascleitis in the making of ASC41 and ASC43F tablets. *See* sections V.E and F *supra*. I have also found that Viking has and is establishing a domestic industry that, until Ascleitis’s betrayal, exclusively exploited those trade secrets. *See* sections VI.B and C *supra*. And I have found that Ascleitis has already imported into the United States the ASC41 and ASC43F tablets for use in clinical trials. *See* section IV *supra*.

I now additionally find that Ascleitis has an intent to continue to bring its imported products—developed through trade secret misappropriation—into the United States. [REDACTED]

[REDACTED] which would require importation of the Accused Products again. CX-0367 (clinical trial proposal). [REDACTED]

[REDACTED] Ascleitis’s Dr. Wu gave testimony that, so long as Ascleitis clinical trials go as expected, Ascleitis “would most likely” seek FDA approval to sell ASC41 in the United States. *See* 100-Day Tr. (Wu) at 403:11-21; *see*

also Hr’g Tr. (Wu) at 637:1-638:19 (describing Ascleitis’s thinking about Phase III clinical studies in the United States and FDA approval for selling ASC41 in the United States). Pursuing FDA approval to sell ASC41 in the United States—an approval process that is very expensive—is further evidence that Ascleitis’s imported products are headed for the U.S. market. Ascleitis also plans to “push” its Phase II clinical trials to “make[] it possible for Phase III [trials to] [o]vertake that of VK2809,” a clear admission that it intends its Accused Products to disrupt Viking’s domestic industry. CX-1259C-T.0005; *see also* CX-0596C (email planning timing of clinical trials “in order to catch or beat Viking”).

It follows from these findings that the threat or effect of Ascleitis’s past importation of the Accused Products and its intent to sell the Accused Products in the United States will destroy or substantially injure Viking’s current research and development domestic industry and will prevent Viking from establishing a future industry in FDA-approved products containing VK2809. Viking has lost the exclusive use of its trade secret information and the advantages attendant to that exclusive use, which, under federal law, is “a real and redressable harm.” *Oakwood Labs.*, 999 F.3d at 914. As in *Oakwood Laboratories*, Ascleitis used that information to produce the Accused Products, which, when imported into the United States, gave Ascleitis an unfair advantage over Viking’s domestic industry and over other domestic drug developers who play by the rules. As detailed below, each of the expected injuries in *Oakwood Laboratories* has been shown here: Viking will suffer (1) a pricing disadvantage because the misappropriator will avoid substantial research and development costs that the trade secret owner has already invested in its own product development (*see Rubber Resins*, Comm’n Op. at 64), (2) a lost timing advantage for the trade secret owner when the misappropriator obtains “a jumpstart in an industry it would otherwise not have competitively joined” until a much later time (*see Cast Steel Railway Wheels*, 2011 WL

6255116 at *68-69), and (3) a loss of market share by the trade secret owner due to rapid market entry by the misappropriator (*see Certain Cast Steel Railway Wheels*, 2011 WL 6255116 at *69; *Certain Electric Power Tools*, 1990 WL 710470 at *125).

On the bases above, I find Viking has shown, under section 337(a)(1)(A), that Ascletis's unfair trade acts constitute a threat or effect of injury to Viking's existing domestic industry and to the establishment of Viking's future industry selling FDA-approved products. Additional evidence detailed below provides further bases for such findings.

2. Loss of Partnership Opportunities Due to Lack of Drug Differentiation

The Commission has found that where the U.S. presence of an imported product made using misappropriated trade secrets negatively affects the terms upon which the trade secret owner is able to contract with a third party, there is injury to the domestic injury. *Rubber Resins*, Comm'n Op. at 32. As discussed below, the record evidence here shows that Ascletis's misappropriation of Viking trade secret information and subsequent development of ASC41 and ASC43F interfered with Viking's ability to contract with a large pharmaceutical company to further develop and commercialize VK2809. This resulted in injury to Viking's current domestic industry in research and development of VK2809, as well as injury to Viking's future domestic industry in research and development and commercialization of VK2809.

For a smaller-scale pharmaceutical company such as Viking, the end stage of a drug development process generally involves seeking partnership with a larger pharmaceutical company that has the resources and experience to shepherd the drug through Phase III clinical trials, final approval by the FDA, and commercialization of the approved product. *See* 100-Day Tr. (Zante) at 113:4-10; 100-Day Tr. (Prowse) at 297:6-298:15. A small-scale drug company is unlikely to bring its product through the final stages of the FDA development cycle if it does not

partner with a large pharmaceutical company. 100-Day Tr. (Zante) at 124:1-5. The typical time for establishing these partnerships is during or immediately following Phase II clinical trials. 100-Day Tr. (Rao) at 230:21-212:2; 100-Day Tr. (Zante) at 117:19-118:10.

Consistent with this industry practice, Viking plans to partner with a large pharmaceutical company to further develop VK2809 for commercialization and argues that Ascletis's misappropriation of Viking trade secret information and subsequent development and importation of ASC41 has substantially injured Viking's partnership prospects. CIBI at 58-59. Specifically, Viking asserts that Ascletis's actions have injured Viking's ability to partner with a large company because it is difficult to differentiate VK2809 from ASC41. *Id.*

Generally speaking, large pharmaceutical companies seek to develop drug products that are differentiated from other products in the field, meaning that the differentiated drug products show higher efficacy, have a better side-effect profile, fill an unmet market need, or else are otherwise distinguishable from other products. 100-Day Tr. (Rao) at 237:4-16. Viking's expert Dr. Rao credibly testified that, in a pharmaceutical space with multiple products in development (such as the present NASH treatment field), the inability of a small company to differentiate its product means "no chance to be able to get a collaboration deal." *Id.*

The record evidence establishes that, but for Ascletis's development of ASC41 based on misappropriation of Viking's trade secret information, VK2809 would be differentiated from other NASH treatment products existing or in development. For example, industry expert Dr. Peck testified that [REDACTED]

[REDACTED] 100-Day Tr. (Peck) at 192:6-12. Industry analysts published views that "VK2809 looks promising and differentiated," noting the "lack of GI effect, which for a potentially chronic drug, could be differentiated for prescribers and patients."

CX-0114.0001. The analysts further noted “it is unlikely that the GI effect seen from the competition [resmetirom] is due to the TR-beta target, but rather maybe the compound itself; and the regulatory path could already be paved for Viking as a potentially differentiated fast-follower” to resmetirom. *Id.*

However, VK2809 and ASC41 contain the same active pharmaceutical ingredient and the same mechanism of action. JX-0007C.0003-4. Thus, even though VK2809 is differentiated from other drug such as Madrigal’s resmetirom, VK2809 lacks differentiation from ASC41. *See* 100-Day Tr. (Zante) at 115:8-15 (“We can differentiate against any other competitor in the space, including Madrigal especially, but we’re unable to differentiate versus Ascletis”). Bringing ASC41 into the market using misappropriated information reduces Viking’s ability to differentiate VK2809 from other NASH treatments, which in turn impairs Viking’s ability to partner with potential collaborators and causes injury to Viking’s present domestic industry and future domestic industry.

Ascletis disputes any nexus between Viking’s inability to partner with a large pharmaceutical company and the importation of ASC41 into the United States. *See* RRBI at 23-25. Ascletis argues that Viking’s failure to achieve a partnership is instead caused by the lack of 52-week Phase II clinical trial data for VK2809. *Id.* Ascletis further argues that the pharmaceutical companies Viking approached for partnership discussions [REDACTED] and therefore Viking has not shown that Ascletis’s actions caused this specific injury. *Id.* Staff agrees with Ascletis’s position that Viking’s lack of 52-week Phase II clinical trial data affected its partnership opportunities. SIBI at 118-19. Staff also argues that Viking’s partnership talks with [REDACTED]

[REDACTED]

Id. at 120-21.

I find that both Viking and Ascleitis were in partnership discussions with [REDACTED] [REDACTED] Hr'g Tr. (Broidrick) at 83:16-24, 84:20-85:22; Hr'g Tr. (Gudmundsson) at 742:4-17; CX-2195C; CX-2207C; CX-2209C; CX-1260C. As discussed in more detail below, I find that Viking's failure to partner with [REDACTED] can be attributed in part to the presence of ASC41 in the NASH treatment space, but I also find Viking has not shown that its failure to partner with [REDACTED] was due to Ascleitis's development and importation of ASC41 (or ASC43F).

[REDACTED]

The evidence shows that [REDACTED] entered into confidential disclosure agreements with [REDACTED] Viking and Ascleitis to access confidential data in furtherance of potential partnership discussions. Hr'g Tr. (Broidrick) at 83:16-24, 84:20-85:22; Hr'g Tr. (Gudmundsson) at 742:4-17; CX-2195C. Ascleitis's disclosures to [REDACTED] included Phase I clinical trial data for ASC41, data that was made possible only through the importation of ASC41 and ASC43F into the United States. *See* CX-1610C.0003.

The discussions between [REDACTED] and Viking suggest that [REDACTED] was concerned about differentiation between VK2809 and ASC41. Viking's former vice president of corporate development Amy Broidrick testified about her experience with the discussion and recounted a request from [REDACTED] that she found unusual at the time:

[REDACTED]

Hr’g Tr. (Broidrick) at 86:14-87:11. At the time, Viking was not aware that Ascletis was developing a competing product in ASC41 and thus did not understand the motivation behind [REDACTED] request for comparative data. Hr’g Tr. (Broidrick) at 83:7-12.

[REDACTED] was more explicit in its discussions with Ascletis [REDACTED] a director at [REDACTED] sent an email to Ascletis’s Kristjan Gudmundsson on September 25, 2020, asking,

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] CX-0573C.0002-.0003. [REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

CX-0573C.0001. [REDACTED]
[REDACTED]

[REDACTED] CX-1217C.0001.

Ascletis continued partnership discussions with [REDACTED] at least through January 2022. CX-1910C [REDACTED] subsequently informed Viking in March 2022 that NASH had been “deprioritized across their organization” and did not enter into a partnership with Viking. Hr’g Tr. (Chavez) at 111:19-112:8; RX-0446C at 6.

Viewing the totality of the evidence, I find that Viking’s failure to partner with [REDACTED] is attributable, at least in part, to the fact that VK2809 and ASC41 have identical APIs and cannot be differentiated for the treatment of NASH. Therefore, Ascletis’s development of ASC41 and

ASC43F using trade secret information misappropriated from Viking, and Ascletis's subsequent importation of ASC41 and ASC43F into the United States, has injured Viking's current and future domestic industries.

[REDACTED]
Viking [REDACTED] also signed confidential disclosure agreements with [REDACTED] in furtherance of partnership opportunities. CX-2207C [REDACTED]; CX-2209C [REDACTED]; CX-1260 [REDACTED]. Discussions between Viking and [REDACTED] began in 2016 and ended in 2020 after [REDACTED] stated it was deprioritizing clinical-stage NASH assets for business development. Hr'g. Tr. (Chavez) at 113:1-19; *see* CX-2209C. Viking did not have further discussions with [REDACTED] Hr'g. Tr. (Chavez) at 113:1-19.

According to testimony from Ascletis's Dr. Wu, [REDACTED] did not discuss ASC41 with Ascletis until several years after Viking's last interaction with [REDACTED] about VK2809. Dr. Wu said Ascletis personnel met [REDACTED] representatives at a conference in January 2023 and discussed ASC41, which led to Ascletis and [REDACTED] signing a confidential disclosure agreement in March 2023. Hr'g Tr. (Wu) at 663:16-664:20; CX-1260C. Ascletis represents that its discussions with [REDACTED] were not focused on ASC41, but rather on other drug candidates in development. RRB at 48-49. Ascletis's assertion is supported by the language in the confidential disclosure agreement with [REDACTED] which states [REDACTED]

[REDACTED]

[REDACTED] CX-1260C.0001. [REDACTED]

[REDACTED]

[REDACTED] Hr'g Tr. (Wu) at 640:9-15.

In view of this evidence, I find Viking has not shown that its partnership talks with ██████ were adversely affected by Ascleitis's actions with respect to development and importation of ASC41. ██████ this was years after talks between Viking and ██████ had ceased. The evidence does not suggest that ██████ was aware of ASC41 when it discontinued discussions with Viking in 2020.

3. Decrease in VK2809's Net Present Value

Viking argues that its ability to partner with a large pharmaceutical company has also been injured because Ascleitis's actions with respect to ASC41 have reduced the net present value of VK2809 and "a strategic partner is looking for a high value drug candidate for partnership." CIBI at 58-59, 66. In the context of this investigation, the net present value of VK2809 is the present value of risk-adjusted future cash flows, taking into account costs to develop the drug, operating costs that would continue once the drug is commercially available, revenues, and the risk of an inability to bring the drug to market. 100-Day Tr. (Rao) at 240:8-241:7. The net present value for VK2809 also takes into account other drugs in the NASH treatment market. 100-Day Tr. (Rao) at 241:21-242:3, 268:19-269:14.

At the 100-day evidentiary hearing, Viking's expert Dr. Rao calculated the net present value of VK2809 as ██████ before taking into account any actions by Ascleitis regarding development and importation of ASC41. 100-Day Tr. (Rao) at 240:10-242:3. Dr. Rao's calculation does, however, incorporate the effect of other NASH treatments likely to enter the market before VK2809. *Id.* After the 100-day evidentiary hearing concluded, Viking released favorable clinical trial results and Dr. Rao adjusted his net present value calculations upward to ██████ Hr'g Tr. (Rao) at 561:11-19. Dr. Rao's calculations are consistent with valuations reached by other industry analysts not retained as experts in this investigation. CX-0262.0005

(Truist Securities risk adjusted NPV for VK2809 is \$1.569 billion dated February 8, 2023); CX-2401.0004 (Truist Securities risk adjusted NPV for VK2809 is \$1.855 billion dated July 26, 2023).

Dr. Rao also estimated the effect that ASC41 would on the net present value of VK2809 in ASC41 were on the commercial market at the same time as VK2809. At the 100-day evidentiary hearing, he opined that competition between VK2809 and ASC41 in the U.S. market would reduce the net present value of VK2809 by about [REDACTED] to approximately [REDACTED] depending on when ASC41 entered the market. 100-Day Tr. (Rao) at 242:9-243:25, 258:7-12. Using the same analysis with updated numerical inputs at the evidentiary hearing in December 2023, Dr. Rao opined that the diminished value of VK2809 is [REDACTED], which reflects a [REDACTED] reduction in net present value due to Ascleptis's unlawful actions. Hr'g Tr. (Rao) at 561:11-562:5. For his updated net present value calculation, Dr. Rao began with the adjusted value of [REDACTED] discussed above and then factored in a market split between Viking and Ascleptis plus [REDACTED] of lost Viking sales owing to delayed clinical trials. *Id.*

Specifically, Dr. Rao based his analysis on several inputs:

- Viking's clinical trials will be delayed by [REDACTED] as a result of Ascleptis's unlawful acts;
- ASC41 will enter the United States [REDACTED] VK2809 or [REDACTED];
- ASC41 will capture [REDACTED] percent of VK2809's sales upon launch;
- VK2809's probability of technical and regulatory success is [REDACTED] percent;
- If VK2809 is approved by the FDA, ASC41 will be approved as well; and
- VK2809's cost of capital is [REDACTED] percent.

100-Day Tr. (Rao) at 260:6-261:23. Ascleitis and Staff do not dispute Dr. Rao's reliance on the cost of capital, but they argue that Dr. Rao's other assumptions are not supported by the record. *See* RIBI at 64 (citing Hr'g Tr. (Peck) at 521:10-12); RRBI at 26; SIBI at 81.

As detailed below, I find the totality of the evidence demonstrates that Dr. Rao's calculations are sufficiently reliable to demonstrate a negative effect on the net present value of VK2809 resulting from Ascleitis's unlawful development and importation of ASC41.

a) Delay of VK2809 Clinical Trials

Dr. Rao's assumption that Phase III clinical trials would be delayed by [REDACTED] years due to Ascleitis's actions was based on the testimony of former Viking chief operating officer Mary Ann Mancini. 100-Day Tr. (Rao) at 260:10-17; 100-Day Tr. (Mancini) at 93:7-9. Ascleitis characterizes Dr. Rao's reliance on this testimony as "purely speculative with no evidence," a characterization with which Staff agrees. RRBI at 27; SRB at 11. Ms. Mancini, however, is responsible for Viking's clinical trials and regulatory aspects of clinical trials, and I find that she testified credibly as to those aspects of Viking's operations. *See* 100-Day Tr. (Mancini) at 83:10-15. Moreover, neither Ascleitis nor Staff have presented evidence to contradict Ms. Mancini's statements. And even if the presence of ASC41 delays Phase III clinical trials for VK2809 by fewer than [REDACTED], Dr. Rao's net present value analysis takes this variability into account. 100-Day Tr. (Rao) at 242:9-243:25.

b) Timing of ASC41's Entry into the U.S. Market

As part of his analysis, Dr. Rao assumed that ASC41 would enter the U.S. market at the [REDACTED] later than Viking's VK2809. As discussed above, the record shows a likely [REDACTED] separation between Phase III clinical trials of VK2809 and ASC41. Dr. Rao's assumption is therefore consistent with this finding. And as noted above, Dr. Rao's net present value analysis

covers scenarios where VK2809's launch is both delayed and not delayed by the presence of ASC41. 100-Day Tr. (Rao) at 242:9-243:25. I therefore find that Dr. Rao's opinion regarding a reduced net present value for VK2809 is reliable regardless of whether ASC41 enters the U.S. market at the same time as VK2809 [REDACTED].

c) Market Penetration of ASC41

Even though Dr. Rao assumed that ASC41 would gain [REDACTED] of the market share of VK2809 for his net present value analysis, he later conceded that the market capture of VK2809 and ASC41 would not necessarily be [REDACTED] each. 100-Day Tr. (Rao) at 244:1-11. He clarified his earlier assumption and testified that, in a scenario where VK2809 and ASC41 enter the market, there would be "two drugs with the same API that are competing with each other [and] they would end up splitting the market." 100-Day Tr. (Rao) at 242:21-243:1. He further explained that "it doesn't need to be an assumption of [REDACTED]. Any one of those would lead to a very significant diminution in sales by billions of dollars." 100-Day Tr. at 244:1-11.

Despite Ascleitis and Staff's objections to Dr. Rao's assumption of a [REDACTED] for purposes of his net present value analysis, neither Ascleitis nor Staff provided any expert opinion or other evidence to suggest a more accurate market penetration estimate. *See* 100-Day Tr. at 521:1-9 (Clarke); SRB at 12. In view of the record as a whole, I find Dr. Rao's estimate of a [REDACTED] market penetration for ASC41 a reasonable assumption to make in his net present value analysis. Even if Dr. Rao's estimate of ASC41's market penetration varies from the actual market penetration were ASC41 to enter the U.S. market, I find that the record supports a conclusion that any market penetration by ASC41 would mean lost sales of VK2809 and a resulting diminution of VK2809's net present value and injury to Viking.

d) Technical and Regulatory Success of VK2809

The record also supports Dr. Rao's estimate of a [REDACTED] probability that VK2809 would succeed, both technically and in the regulatory process. In particular, Dr. Rao's estimate is consistent with an independent analysis by financial firm Truist, which credits VK2809 with a 65% probability of success. CX-0262.0005. Dr. Rao's estimate is also consistent with the testimony of Dr. Peck, the former director of the FDA's Center for Drug Evaluation and Research, on the likelihood of FDA approval of VK2809. *See* 100-Day Tr. at 176:6-16.

During the 100-day hearing in April 2023, Dr. Peck opined that VK2809's Phase IIa study showed promising statistical results and "a highly significant reduction in the liver fat, which is a hallmark lesion in NASH." 100-Day Tr. (Peck) at 189:16-24. Dr. Peck also examined the regulatory progression of Madrigal's NASH drug resmetirom, which uses the same mechanism of action as VK2809, and concluded that resmetirom's clinical trial results would permit it to proceed through the FDA's accelerated approval program. 100-Day Tr. (Peck) at 190:13-192:12.

By the time Dr. Peck testified again at the evidentiary hearing in November 2023, his predictions had been proven true by intervening events. For instance, Viking released Phase IIB data for VK2809 showing promising efficacy and low side effects. Hr'g Tr. (Peck) at 511:14-512:9; CX-2339 (Viking press release disclosing Phase IIb top-line results). These results add credibility to Dr. Peck's earlier opinion on the likelihood that VK2809 will proceed to Phase III clinical trials.

In addition, Madrigal's resmetirom drug product was accepted by the FDA for evaluation under a priority review scheme. Hr'g Tr. (Peck) at 509:24-510:4; CX-2338. In April 2023, the FDA granted a Breakthrough Therapy designation to resmetirom for the treatment of adults with NASH. CX-2373.0001. According to Dr. Peck, these developments made FDA approval of

resmetirom nearly certain. *See* Hr’g Tr. (Peck) 509:7-10 (“Q. Has the FDA ever granted, to your knowledge, a breakthrough therapy designation but ultimately decided to not approve that drug? A. I’m not aware of such an instance.”). Ultimately, the FDA approved resmetirom as Dr. Peck predicted. FDA Press Release.

I find Dr. Peck’s opinions highly credible, including his opinions regarding the likely outcomes of the FDA approval process with respect to VK2809, ASC41, and resmetirom. His experience as the former director of the FDA’s Center for Drug Evaluation and Research gave him an extensive knowledge of the drug approval process and the probabilities that a drug would advance from one Phase of the process to the next Phase. He is an expert on a highly regulated and highly analyzed industry, an industry with sufficiently predictable outcomes to attract billions of dollars from investors in regulated markets. Contrary to the characterizations of Ascleitis and Staff, Dr. Peck’s opinions are not mere “speculation.” Dr. Peck’s opinions are grounded in historical facts and experience.

Because Dr. Peck’s opinions have been proven through the course of this investigation to be highly credible, I also find that Dr. Rao’s reliance on Dr. Peck’s opinions as a basis for his net present value analysis is appropriate.

e) FDA Approval of VK2809 and ASC41

Dr. Rao also relied on an opinion rendered by Dr. Peck that the likelihood of FDA approval for VK2809 and ASC41 is the same. Dr. Peck testified that, since both drug products “share the identical active pharmaceutical ingredient[,] once they have developed and gone through their Phase II and Phase III program, they will enjoy the same probability of [FDA] approval.” 100-Day Tr. (Peck) at 194:7-14. Dr. Peck further testified that it is “a well-accepted paradigm” in the

industry that approval of a product with a common mechanism of action leads the way for follow-on drugs to seek FDA approval. Hr’g Tr. (Peck) at 551:3-552:1.

For the reasons explained above with respect to Dr. Peck’s other opinions regarding the FDA approval process for VK2809 and ASC41, I find that it was reasonable for Dr. Rao to rely on Dr. Peck’s opinion here as a basis for his net present value analysis.

f) Net Present Value Conclusion

As discussed above, Dr. Rao used reasonable assumptions when calculating his estimate of the effect ASC41 would have on the net present value of VK2809 were ASC41 to enter the U.S. market. At the evidentiary hearing in December 2023, Dr. Rao opined that the diminished value of VK2809 would be [REDACTED] which reflects a [REDACTED] reduction in net present value due to Ascleitis’s unlawful misappropriation of Viking trade secret information, its use of that trade secret information to develop ASC41, and its importation of ASC41 into the United States. Hr’g Tr. (Rao) at 561:11-562:5.

But even if Dr. Rao’s analysis were not perfectly accurate due to a flawed input, as Ascleitis and Staff argue, I find there is no question that entry of ASC41 into the U.S. market would adversely affect Viking’s development and commercialization of its competing VK2809 drug product. Thus, while a net present value analysis such as the one performed by Dr. Rao may be useful to quantify the dollar amount associated with the injury Viking has and will sustain as a result of Ascleitis’s unlawful actions, such an analysis is not necessary to *prove* the injury to Viking. *See Certain Foodservice Equip. & Components Thereof*, Inv. No. 337-TA-1166, Comm’n Op. at 9 (Dec. 16, 2020) (“*Foodservice Equipment*”) (determining the administrative law judge erred by requiring a complainant to “provide direct evidence that Respondents’ importation and sales substantially harmed Complainants’ domestic activities and investments and to quantify such harm

in order to support a finding of substantial injury”). Dr. Rao’s testimony corroborates that Viking has been injured by the loss of value of its trade secret information and the loss of opportunities to partner with a large pharmaceutical company in furtherance of continued research and development and commercialization of VK2809. Those are substantial injuries, and “quantification with mathematical precision is not required” to prove them. *Id.*

4. Interference with Viking’s Phase III Clinical Trials

Viking argues that its future domestic industry in research and development and commercialization of VK2809 will be injured by Ascleitis’s misappropriation of its trade secret information because ASC41’s importation into the United States will negatively affect Viking’s ability to conduct Phase III clinical trials. *See* CIBI at 85-90. Specifically, Viking argues that if VK2809 and ASC41 are undergoing Phase III clinical trials at the same time, Viking will experience increased difficulties in recruiting trial sites, investigators, and patients for the trials because Ascleitis would be competing for the same resources. CIBI at 93-98. Ascleitis and Staff argue that Viking has not shown that there will be injurious competition for Phase III clinical trial resources in the United States. RRBI at 33-35; RIB at 150-52; RRB at 50-52; SIBI at 68-71.

a) Recruiting Clinical Trial Sites

Both Viking and Ascleitis emphasize the need to recruit high-enrolling NASH clinical trial sites for Phase III clinical trials. 100-Day Tr. (Peck) at 179:25-180:5 (“[I]t takes thousands of patients to be screened, even for a thousand subjects in the trial. And so you need a center that is typically in a metropolitan area, that is high-performing, has had former experience, and can recruit a sufficient number of patients for the trials.”); Tr. at 430:10-13 (Sharlin) (“So the goal is to get the high -- to get the high-enrolling sites and get them quickly so you can make progress in the

execution of your trial.”); 100-Day Tr. (Sharlin) at 440:3-4 (“The first target would be what’s known as the high-enrolling sites.”).

Viking represents that it has budgeted for [REDACTED] Phase III clinical trial sites, [REDACTED]

[REDACTED] CIB at 95 (citing Hr’g Tr. (Mancini) at 87:11-12, 91:11-22, 92:13-16).

b) Recruiting Clinical Trial Investigators

In a related issue, Viking argues competition is likely for a limited number of investigators qualified to conduct Phase III trials for VK2809 and ASC41. The evidence indicates a correlation between clinical trial sites and investigators. 100-Day Tr. (Peck) at 217:1-19 (“[Another problem is] the availability of investigators who would be interested in investigating the same compound in two different clinical trials run by two different drug companies; is that right? A. Yes, in the same site with the same investigator.”); 100-Day Tr. (Sharlin) at 454:20-23 (“[I]f you’re going to recruit a site, you have to recruit the primary -- well, your first stop would be recruiting the primary investigator.”).

c) Recruiting Clinical Trial Patients

Also underlying Viking’s concerns that Ascletis could compete with Viking for Phase III clinical trial resources is the availability of NASH patients to take part in the trials. *See* CIBI at 93-84. The record indicates between 6 and 15 million people in the United States have NASH, but many are not aware they have it because it is a silent disease. 100-Day Tr. (Mancini) at 87:18-22, 109:23-110:2. A NASH diagnosis requires a liver biopsy. 100-Day Tr. (Mancini) at 87:18-25, 107:20-24. According to Viking, these characteristics contribute to the patient recruitment challenges for a Phase III clinical trial. CIBI at 93-94.

d) Conclusion

At the time of the 100-day hearing in 2023, Viking anticipated beginning Phase III clinical trials for VK2809 in [REDACTED] and completing the trials by [REDACTED]. 100-Day Tr. (Mancini) at 84:17-19. Sworn interrogatory responses from Ascletis indicate that their Phase II trials for ASC41 in China would not be complete until “at least the middle of 2024,” leading to the conclusion that Phase III trials for ASC41 would not begin [REDACTED] at the earliest. CX-0356.0028. In view of this timeline, I find Viking has shown that Phase III trials for VK2809 and ASC41 in the United States would overlap by [REDACTED] in which Viking and Ascletis would be attempting to recruit trial sites, investigators, and patients. *See* 100-Day Tr. (Mancini) at 84:24-85:11 (it takes approximately [REDACTED] to recruit Phase III resources). Viking has shown that this competitive injury is due to trade secret misappropriation by Ascletis.

I need not resolve the extent of injury that Viking’s domestic industry may suffer if Viking must compete with Ascletis for Phase III clinical trial resources in the United States. Even if Ascletis and Staff are correct that Viking has not proved that it will be specifically injured by competing for clinical trial resources in Phase III at the same time as Ascletis, that would not change my finding of injury. I find that other record evidence, detailed in the sections before this one, amply supports a finding that Viking has proved the injury requirement of section 337(a)(1)(A) without consideration of clinical trial competition.

B. The Threat and Injury Here Is Not Unduly Speculative

Ascletis and Staff argue that uncertainty of future events make any discussion of injury in this investigation speculative and not supported by evidence. RRBI at 30-35, 55-57; RIB at 145-156; SIBI at 59-94; SIBI at 15-17.

Section 337 requires neither direct evidence nor mathematical precision in a determination that imported goods threaten an industry or threaten to prevent an industry from being established. *See Foodservice Equipment*, Comm’n Op. at 9. The statute expressly includes actions that *threaten* injury, not just those that have the effect of injury. 19 U.S.C. 1337(a)(1)(A) (prohibiting unfair acts in the importation of articles . . . the *threat or effect* of which is to destroy or substantially injure . . .”) (emphasis added). The focus is on the unfair methods or acts in the importations of articles, which is why the Commission requires “a causal nexus between the unfair acts of the respondents and the injury.” *Id.*; *Rubber Resins*, Comm’n Op. at 61.

When evaluating the threat of injury, there is necessarily an amount of uncertainty in forecasting future events. But that has not prevented the Commission from carefully evaluating the threat of injury to an existing industry or to an industry in the process of being established. *See Rubber Resins*, Final Initial Determination, 2013 WL 4495127 at *244 (June 17, 2013) (respondent’s intention to “move forward with plans to enter the U.S. and European markets” was an indicator of injury), *aff’d Rubber Resins*, Comm’n Op. at 64; *Certain Electric Power Tools*, 1990 WL 710470 at *125 (Feb. 20, 1990) (intent “to penetrate the U.S. market” is evidence of a threat of injury).

The fulsome record of this investigation amply supports a finding of injury. It is, of course, a theoretical possibility that Viking will not bring VK2809 to market due to a failure to obtain FDA approval. But, assuming a level playing field, Viking faces the same risk of failing to obtain FDA approval as other market participants at a similar stage of clinical trials. The existence of that risk does not negate the injury that Viking has already experienced due to the misappropriation of its trade secrets, nor does that risk negate the fact that Viking will necessarily encounter greater difficulty in bringing its drug to market than if Ascleptis had not engaged in misappropriation.

To support its arguments that VK2809 has a significant likelihood of failure, Ascleitis points to Intercept's Ocaliva, a NASH treatment candidate that failed to get FDA approval after completion of its Phase III trials. RIB at 148. The FDA raised concerns about Ocaliva's efficacy and safety, but Intercept continued testing the drug. RX-2210 at 2. After failure to receive FDA approval a second time, Intercept chose to discontinue its development of Ocaliva and divested its NASH assets. *Id.* This concluded Intercept's attempts to become the first FDA-approved therapy in "a market estimated to be worth multiple billions of dollars." *Id.*

The isolated case study of Ocaliva provides little insight into the business or regulatory future of VK2809 or ASC41. It is already known that not all drug candidates succeed. *See, e.g.*, CX-0232.0007 (Biotechnology Innovation Organization report). Ascleitis's expert testified that the FDA will not consider the clinical results of an unrelated drug when evaluating an NDA. Hr'g Tr. (Abrouk) at 1023:16-1024:6 (agreeing that the target receptor of Ocaliva and VK2809 are different). Furthermore, Intercept was operating in a different competitive landscape than Viking. Ocaliva at one time had the potential to become the first FDA-approved NASH treatment, and Intercept likely valued the competitive advantages of a first-to-market drug in its decision to cease further clinical testing. Viking and the market at large both recognize that Viking will not be the first drug treatment marketed for NASH. *See* FDA Press Release. Yet both Viking and the market have accounted for that risk—Viking has done so in its decision to continue pursue a domestic industry developing VK2809, and the market has done so in its assessment of the value of VK2809. *See* Hr'g Tr. (Rao) at 561:11-19; CX-0262.0005 (Truist Securities risk adjusted NPV for VK2809 is \$1.569 billion dated February 8, 2023); CX-2401.0004 (Truist Securities risk adjusted NPV for VK2809 is \$1.855 billion dated July 26, 2023).

Successfully bringing a pharmaceutical product through development to FDA approval and commercial markets has an amount of inherent uncertainty. CX-0232.0007 (Biotechnology Innovation Organization report). Not all products in development will succeed, yet numerous pharmaceutical companies raise billions of dollars in capital and bring new products to market through the FDA regulatory process. *See id.* The industry and the market both recognize the risks of regulatory approval, and both incorporate those risks into evaluations of a company's net present value or its stock price. *See, e.g.,* 100-Day Tr. (Zante) at 156:18-158:16.

I find Viking has shown its development VK2809 is progressing as expected and showing promise. The record indicates the market has confidence about the future of VK2809, so long as there is a level playing field. Hr'g Tr. (Rao) at 561:11-19; CX-0262.0005 (Truist Securities risk adjusted NPV for VK2809 is \$1.569 billion dated February 8, 2023); CX-2401.0004 (Truist Securities risk adjusted NPV for VK2809 is \$1.855 billion dated July 26, 2023). As discussed above, Dr. Peck opined that VK2809 has a higher likelihood of progression through the clinical trial process than what may be expected based on published FDA benchmarks. I find Viking has shown the threat and effect of injury due to unfair acts by Ascletis, even considering the inherent uncertainties present—and accounted for—in the pharmaceutical industry.

VIII. CONCLUSIONS OF LAW

- The Commission has statutory authority to conduct this investigation.
- The importation requirement of section 337 has been satisfied with respect to the accused ASC41 and ASC43F tablets.
- Viking owns the asserted Formulation Trade Secrets, Preclinical Trade Secrets, and Clinical Trade Secrets.

- The asserted Formulation Trade Secrets, Preclinical Trade Secrets, and Clinical Trade Secrets are protectable trade secrets.
- Viking disclosed the Formulation Trade Secrets, Preclinical Trade Secrets, and Clinical Trade Secrets to Ascleitis while Viking and Ascleitis were in a confidential relationship.
- Ascleitis has used and disclosed Viking's asserted trade secrets.
- Viking has demonstrated a domestic industry with respect to research, development, engineering, and testing to commercialize VK2809.
- Viking has demonstrated it is in the process of being establishing a domestic industry of further research, development, engineering, and testing to commercialize VK2809, and a domestic industry of FDA-approved sales of VK2809.
- Ascleitis's unfair trade practices—including use and disclosure of Viking's asserted trade secrets and importation of articles developed using those trade secrets—has caused and threatens injury to Viking's existing domestic injury and to Viking's domestic industry in the process of being established.

IX. RECOMMENDED DETERMINATION ON REMEDY AND BOND

The Commission's Rules provide that the administrative law judge shall issue a recommended determination concerning the appropriate remedy in the event that the Commission finds a violation of section 337, and the amount of bond to be posted by respondents during Presidential review of the Commission action under section 337(j). *See* 19 C.F.R. § 210.42(a)(1)(ii).

A. Limited Exclusion Order

Section 337(d)(2) provides that in the event the Commission finds a violation of section 337, the Commission shall issue a limited exclusion order directed to the articles of named respondents to the investigation, unless special circumstances exist that justify the imposition of a general exclusion order. 19 U.S.C. § 1337(d)(2); *see Kyocera Wireless Corp. v. Int’l Trade Comm’n*, 545 F.3d 1340 (Fed. Cir. 2008). The Commission has broad discretion in selecting the form, scope, and extent of the remedy in a section 337 proceeding. *Viscofan, S.A. v. U.S. Int’l Trade Comm’n*, 787 F.2d 544, 548 (Fed. Cir. 1986). Viking does not seek a general exclusion order, and there is no evidence that one would be warranted under 19 U.S.C. § 1337(d)(2). Accordingly, a limited exclusion order will be appropriate in this investigation if a violation of section 337 exists. *See* 19 U.S.C. § 1337(d).

The Federal Circuit has stated that “the duration of relief in a case of misappropriation of trade secrets should be the period of time it would have taken respondent independently to develop the technology using lawful means.” *Viscofan*, 787 F.2d at 550. The Commission has interpreted this to mean that “[f]or a violation of section 337 involving trade secrets [] the duration of the exclusion order for the trade secrets is the length of time it would have taken the respondent to develop the complainant’s trade secrets.” *Crawler Cranes*, Comm’n Op. at 70; *see also Rubber Resins*, Comm’n Op. at 82-83 (“The duration of an [exclusion] order in a trade secret misappropriation case is set as the time it would have taken to independently develop the trade secrets.”). “[W]hen multiple trade secrets are at issue, the remedy may be determined by considering the trade secrets together.” *Crawler Cranes*, Comm’n Op. at 70.

Viking offers an alternative calculation for the appropriate length of a limited exclusion order in a case of misappropriation of trade secrets—the time needed for a respondent to

independently develop the accused products rather than to develop the misappropriated trade secrets. CIB at 188-89; *see also* Hr’g Tr. (Silber) at 425:9-428:7. This approach was not followed by the Commission in either *Crawler Cranes* or *Rubber Resins*.

1. Viking’s Proposed Duration for a Limited Exclusion Order

In the event a violation is found based on misappropriation of Formulation Trade Secrets, Viking argues that a limited exclusion order should be at least 26 months. CIB at 189-92. Viking bases this calculation in part on the testimony of its expert Dr. Silber, who opined that “it would have taken Respondents no less than 12 months of research and analysis to build enough confidence to decide to develop a competing product having the API in ASC41 and VK2809.” CIB at 189 (citing Hr’g Tr. (Silber) at 426:24-427:4). Viking also relies on testimony from its expert Dr. Amidon, who opined that, after this initial 12-month period, Ascleitis would have had to spend approximately 14-16 months to independently develop the Accused Products’ tablet and capsule formulations without the benefit of Viking’s formulation trade secret information.” *Id.* at 189-90 (citing Hr’g Tr. (Amidon) at 290:3-19; 291:15-292:5). As an alternative calculation based on the Commission’s approach in *Rubber Resins*, Dr. Amidon also opined that it would have taken Ascleitis nine to twelve months to independently develop Viking’s Formulation Trade Secrets. *See id.* at 190 (citing Hr’g Tr. (Amidon) at 290:3-19).

In the event a violation is found based on misappropriation of Preclinical Trade Secrets, Viking argues that a limited exclusion order should last at least 28 months. CIB at 192. Viking’s expert Dr. Silber opined that would have taken Ascleitis no less than 48 months to independently complete the pre-clinical development work for ASC41 without benefit of the trade secrets. Hr’g Tr. (Silber) at 427:21-428:1. Dr. Silber based his opinion on the development path and timeline that Metabasis and Viking undertook to develop the Preclinical Trade Secrets and his experience

in the industry. *See id.* at 428:8-17. As an alternative calculation based on the Commission's approach in *Rubber Resins*, Dr. Silber also opined that it would have taken Ascleitis 46 months to independently develop the asserted Preclinical Trade Secrets. Hr'g Tr. (Silber) at 429:18-430:10.

In the event a violation is found based on misappropriation of Clinical Trade Secrets, Viking argues that a limited exclusion order should last at least 72 months. CIB at 192-93. Viking's expert Dr. Silber opined that it would have taken Ascleitis at least six years to independently develop the clinical studies for ASC41 through Phase II clinical trials without benefit of the Clinical Trade Secrets. CIB at 193 (citing Hr'g Tr. (Silber) at 427:9-428:7). Dr. Silber based his opinion on the time it would have taken Ascleitis to initialize Phase I clinical trials, conduct several Phase I studies, and complete a Phase II program. *Id.* (citing Hr'g Tr. (Silber) at 428:18-22). As an alternative approach based on the Commission's approach in *Rubber Resins*, Dr. Silber also opined that it would have taken Ascleitis three years to independently develop the asserted Clinical Trade Secrets. *Id.* (citing Hr'g Tr. (Silber) at 429:18-430:10).

Thus, if violation is found on all three categories of trade secrets—Formulation Trade Secrets, Preclinical Trade Secrets, and Clinical Trade Secrets—Viking proposes that a limited exclusion order last at least 146 months, or just over 12 years.

2. Ascleitis's Proposed Duration for a Limited Exclusion Order

Ascleitis does not contest that a limited exclusion order would be an appropriate remedy in the event the Commission finds a violation of section 337, but Ascleitis disputes Viking's proposals regarding the appropriate length of an exclusion order. *See* RIB at 156-69.

Ascleitis also argues that Viking's requested remedies are flawed because they "fail[] to appropriately analyze the length of a remedy on a trade secret-by-trade secret basis, making it impossible to determine a remedy even under Complainant's proposed remedy." *Id.* at 169-70.

Ascletis argues that, “if the Commission were to find that Respondents had misappropriated a subset of the Asserted Trade Secrets, Complainant’s analysis would be insufficient to determine the duration of the remedy.” *Id.* at 169 (citing Hr’g Tr. (Rao) at 581:5-583:10). Ascletis thus argues that “the Commission has no way to determine the duration of a remedy based on the available record evidence, and accordingly, no remedy should issue.” *Id.* 170.

In addition, Ascletis argues that respondent Dr. Jinzi Wu should not be subject to remedial orders in his personal capacity because he “has had no role in the ‘importation of articles . . . into the United States, or in the sale of such articles’ in his individual capacity and is therefore improperly named as a Respondent in this Investigation.” RIB at 170.

3. Staff’s Proposed Duration for a Limited Exclusion Order

Staff takes the position that, if the Commission finds a violation of section 337, “the appropriate length of a limited exclusion order would be six months.” SIB at 128. Staff acknowledges that Viking’s expert Dr. Silber testified it would have taken Ascletis approximately nine years to independently recreate the Viking Formulation, Preclinical, and Clinical Trade Secrets, but argues that Dr. Silber’s calculations are overstated. *Id.* (citing Hr’g Tr. (Silber) at 429:15-432:4). Specifically, Staff argues:

First, Dr. Silber’s figures include the time needed to independently develop all or most of the asserted trade secrets, not just the twenty-one shown to have been misappropriated. Second, Dr. Silber assumes that to independently develop the accused products, Respondents would have had to design all of the same studies from scratch, without researching or benefiting from any of the publicly available information that Viking has released over the years in its patent applications, press releases, and public presentations. *See* [Hr’g Tr.] at 491:14-18 (Silber) (at least some information about VK2809 was already in the public domain). This scenario is improbable. Finally, Dr. Silber assumes that Respondents would not have progressed any more rapidly than Metabasis in their research. *Id.* at 488:23-489:17 (Silber) (“if Respondents had to independently develop Viking’s clinical trade secret information, Respondents would have had to design their own clinical protocols, and then perform their own clinical

studies, which would have taken them approximately the same amount of time that it took Metabasis and Viking.”). As discussed [above], however, Metabasis had significant financial troubles throughout the period when it was researching VK2809. *See id.* at 490:24-491:3 (Silber). It is reasonable to conclude that even without access to any confidential Viking information, Respondents would have been able to conduct more studies in parallel than Metabasis, with fewer gaps between those studies.

SIB at 129-30.

Staff’s proposal of an exclusion order length of six months is predicated on its position that “of the 455 trade secrets that are currently being asserted, *see* CDX-1035C (Trade Secret Chart), the evidence supports a finding of misappropriation for just twenty-one: TS Nos. 4, 12.11, 13.1 to 13.7, 15.1, 18.1 to 18.3 and 37 to 37.4.3.” SIB at 130. Staff argues: “In other words, Respondents have been shown to have benefited from just five percent of the asserted trade secrets (21/455 = 4.6%). If Dr. Silber is correct that it would have taken Respondents nine years to independently develop the accused products using all 455 trade secrets, then one rough estimate of the amount of time that Respondents actually saved through misappropriation would be 5% * 9 years, or six months total.” *Id.* at 130-31. Staff acknowledges that this approach might seem “simplistic at first glance,” but nevertheless takes the position that “it is consistent with Dr. Silber’s testimony at the hearing that all of the trade secrets are equally important, with no one secret being more significant than any other.” *Id.* at 131-32 (citing Hr’g Tr. (Silber) at 501:19-503:2).

4. Recommendation

As an initial matter, Asclethis’s argument that Dr. Jinzi Wu should not be subject to remedial orders in his personal capacity lacks merit. Despite the fact that Dr. Wu was very cagey at trial in his answers to questions about his role, the evidence shows that Dr. Wu was, in fact, [REDACTED] [REDACTED] *See* Hr’g Tr. (Wu) at 668:6-671:14. Asclethis’s senior vice president Ms. Yan testified that, when Respondents made the decision to conduct

Phase I clinical trials in the United States, [REDACTED], thereby leading to the importation of the Accused Products. *See* Hr’g Tr. (Yan) at 693:1-694:17. Moreover, all of the named respondents are closely affiliated with one another, share senior executives—including respondent Jinzi Wu, who is the CEO or President of each corporate respondent, *see* Resp. to Compl. ¶¶ 34-47—and have overlapping functions with regard to the research and development of the Accused Products. *See* section I.B.2 above. Each respondent played a part in the events resulting in a violation of section 337: Ascleitis Pharma, Inc., is the parent company of the other corporate respondents; Ascleitis Bioscience Co. Ltd. executed the confidentiality agreements with Viking; Ascleitis Pharmaceuticals Co., Ltd., manufactured the accused ASC41 and ASC43F products; Gannex Pharma Co. Ltd. was the consignee for the importation of accused products to the United States; and Dr. Jinzi Wu was personally involved in reviewing Viking’s trade secrets and in later email correspondence about those trade secrets. *See, e.g.*, sections V.E and V.F above. Accordingly, there is no reason why a limited exclusion order, or any other remedial order, should not apply to all of the named respondents.

With respect to the appropriate length of an exclusion order, the record suggests that the total of 12 years of exclusion proposed by Viking’s expert Dr. Silber may have included a few marginal time periods that are unjustified by the record. For example, Metabasis had financial troubles throughout the period when it was researching VK2809. *See* Hr’g Tr. (Masamune) at 206:13-21; Hr’g Tr. (Silber) at 490:24-491:3. It is reasonable to conclude that Metabasis’s financial situation would have had an adverse impact on how long it took to develop the trade secrets later acquired by Ligand and subsequently licensed to Viking. *See* Hr’g Tr. (Silber) at 491:19-24. In addition, former Viking chief development officer Dr. Masamune testified that certain preclinical and clinical studies included in the asserted trade secrets would have taken less

time for a contract research organization to complete. *See* RIB at 162-63 (providing citations to Masamune deposition).

But despite any flaws in Dr. Silber’s estimation of the length of time it would take Ascleitis to develop the trade secrets, Staff’s proposal of a six-month limited exclusion order is based on an overly simplified understanding of Dr. Silber’s opinion that all trade secrets are equally important. Staff interprets Dr. Silber’s testimony to mean that—assuming Dr. Silber’s calculation that it would have taken 9 years to develop all Formulation, Preclinical, and Clinical trade secrets is correct—each individual trade secret is worth 1/455 of 9 years, or just over 1 weeks’ worth of a limited exclusion order. That logic is not supported by the record.

Ascleitis likewise does not provide a useful suggestion on the appropriate length of a limited exclusion order in this investigation. Ascleitis forbears from its own calculations on how long it would have taken to develop the trade secrets and instead pokes holes in Viking’s calculations. *See* RIB at 156-69. Ascleitis then proposes that no limited exclusion order should take effect, which is another conclusion unsupported by the record. *Id.* at 170.

In its fundamental *Viscofan* opinion, the Federal Circuit stated that, under section 337, “the Commission has broad discretion in selecting the form, scope and extent of the remedy, and judicial review of its choice of remedy necessarily is limited.” *Viscofan*, 787 F.2d at 548. The panel continued: “As the Supreme Court stated in the leading case of *Jacob Siegel Co. v. Federal Trade Commission*, 327 U.S. 608, 66 S.Ct. 758, 90 L.Ed. 888 (1946), in words that are equally applicable to this case:

The Commission has wide discretion in its choice of a remedy deemed adequate to cope with the unlawful practices in this area of trade and commerce. Here, as in the case of orders of other administrative agencies under comparable statutes, judicial review is limited. It extends no further than to ascertain whether the Commission made an allowable judgment in its choice of the remedy. ... The Commission is the expert body to determine

what remedy is necessary to eliminate the unfair or deceptive trade practices which have been disclosed. It has wide latitude for judgment and the courts will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to exist.

Id. at 611–13, 66 S.Ct. at 760 (footnote omitted).” *Viscofan*, 787 F.2d at 548; *see also Sealed Air Corp. v. Int’l Trade Comm’n*, 645 F.2d 976, 989 (C.C.P.A. 1981) (“[I]t is not the function of a court to substitute a different remedy of its own design for that chosen by the ITC, or to substitute its view of the public interest for that of the ITC.”).

The *Viscofan* panel affirmed the Commission’s issuance of a 10-year limited exclusion order upon a finding of violation based on the misappropriation of trade secrets. *Viscofan*, 787 F.2d at 550. The Commission determined the length of the exclusion order by assessing “the period of time it would have taken respondent independently to develop the technology using lawful means.” *Id.* In particular, the Commission “concluded that in the circumstances of this case the basis for determining the development time was the time it would have taken Viscofan to create the manufacturing processes involving the misappropriated trade secrets and not, as Viscofan urged, the time it would have required Viscofan to discover each particular trade secret independently and without regard to the total process.” *Id.* The *Viscofan* panel reviewed the Commission’s action and concluded that “we cannot say the Commission abused its discretion or that this aspect of the order is not supported by substantial evidence.” *Id.*

It is my recommendation that the Commission look to the specific injury experienced by Viking resulting from Ascleitis’s misappropriation of trade secrets and craft remedial orders to address that injury. Here, the injury is centered on Ascleitis’s interference with Viking’s ability to partner with a large pharmaceutical company and Viking’s ability to enjoy what should have been exclusive use of its trade secrets. *See* section VII above. This approach accounts for any minor

differences as to exactly which trade secrets were misappropriated and exactly which trade secrets should be included in the timing calculations.

At the 100-day hearing on issues relating to injury, Viking chief operating officer Mary Ann Mancini testified that Viking expects to complete a Phase III clinical trial for VK2809 in or around [REDACTED], and to obtain FDA approval in or around [REDACTED]. 100-Day Tr. (Mancini) at 84:8-20. After Viking obtains FDA approval, Viking should be able to benefit from the exclusive use of its trade secrets that it would have enjoyed but for Ascleptis's misappropriation. *See Oakwood Labs.*, 999 F.3d at 913-914 (loss of "the exclusive use of trade secret information" is "a real and redressable harm"). In view of Viking's projected timeline for VK2809, and allowing for unexpected delays, it seems that a limited exclusion order running through 2031, or approximately 7 years, [REDACTED]

[REDACTED] Although Dr. Silber opined a longer order would be justified, his testimony provides a basis for this recommendation because he indicates that it would take more than 7 years to develop the trade secrets. The testimony of Dr. Rao and Mr. Zante about the importance of market exclusivity, particularly at launch, also supports the recommendation that the remedy provide Viking with at least some exclusive use of its trade secrets in the U.S. market. *See* 100-Day Tr. (Rao) at 245:6-246:12; 100-Day Tr. (Zante) at 154:12-155:24.

B. Cease and Desist Order

Section 337 provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a cease and desist order ("CDO") as a remedy for a violation of section 337. 19 U.S.C. § 1337(f)(1). A cease and desist order may be appropriate where a respondent could engage in acts that would "undercut the remedy provided by an exclusion order." *See*

Certain Laser Imageable Lithographic Printing Plates, Inv. No. 337-TA-636, Initial Determination at 102 (July 24, 2009).

Under Commission precedent, “[c]ease and desist orders are generally issued when, with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order.” *Certain Air Mattress Systems, Components Thereof, and Methods of Using the Same*, Inv. No. 337-TA-971, Comm’n Op. at 49 (May 17, 2017) (citations and footnote omitted). Additionally, at least one Commissioner is of the opinion that the “presence of some infringing domestic inventory, regardless of the commercial significance, provides a basis to issue a cease and desist order.” *Certain L-Tryptophan, L-Tryptophan Products, and Their Methods of Production*, Inv. No. 337-TA-1005, Comm’n Op. at 52 n.49 (Jan. 11, 2018).

1. Viking Argues a Cease and Desist Order Is an Appropriate Remedy

Viking seeks a cease and desist order prohibiting:

(a) the importation, sale for importation, sale after importation of the Accused Products (including sales that are not directly to consumers), offering for sale, offering for clinical trial, marketing (including promotion for partnership or collaborative efforts), use and/or distribution of the Accused Products imported into the United States prior to the entry of the cease and desist order or during the Presidential Review Period, and the aiding or abetting of other entities of the same and (b) the unauthorized acquisition, disclosure, and use of any of the Asserted Trade Secrets, including for example, unauthorized acquisition, disclosure and use through internet activities (though website, e-mail transmission, secure data room access) to, from, and within the United States.

CIB at 196. Viking argues that, “[i]f a cease and desist order is not issued and these U.S. activities are permitted to continue, the substantial injury and threat of substantial injury to Viking’s industry will persist.” *Id.*

Specifically, Viking argues that “further disclosure of the Asserted Trade Secrets, such as disclosure to third party CROs, potential partners, and in patent publications, will substantially injure Viking’s industry.” CIB at 196. Viking further argues that “Respondents are in possession of digital copies of certain of the Asserted Trade Secrets,” and “Respondents’ disclosure and threat of further disclosure of the Asserted Trade Secrets, such as through ‘electronic transmissions,’ warrants a CDO.” *Id.* at 196-97.

Moreover, Viking argues that a cease and desist order “is also appropriate because Respondents have significant operations in the United States that could undercut the remedy provided by an exclusion order.” CIB at 197. Viking argues:

Although each of the Respondent corporate entities is foreign, Respondent Ascletis Pharma owns Gannex LLC, a U.S. subsidiary. *See* JX-0001C.17 (41:4-6). Gannex LLC is responsible for business development, expansion, and consulting work for Respondents concerning its NASH drugs, including ASC41. *Id.* at 54:12-17. In particular, Gannex LLC is responsible for Respondents’ partnership efforts for ASC41 and ASC43F. *Id.* at 54:19-58:21. Dr. Gudmundsson, the Head of Discovery, and the Chief Business Officer, John Gargiulo, who also resides in the United States, are engaged in partnership efforts. *Id.* at 58:13-21; *see also* JX-1007C.0022 (54:1-3).

Respondents also have at least three corporate officers who reside in and do business for Respondents in the United States: Kristjan Gudmundsson, Handan He, and John Gargiulo. *See* CX-1184C (stating Handan He’s address is in New Jersey); JX-1009C.0014 (28:16-18); JX-1007C.0022 (54:1-3). Gannex LLC and Respondents’ officers located in the United States could continue to develop and market to potential partners for out-licensing the Accused Products developed using the Asserted Trade Secrets.

CIB at 197-98.

Viking also argues that “a CDO is warranted as Respondents could import the Accused Products during the Presidential Review Period, and use those imports to conduct clinical trials in the United States.” CIB at 199 (citing Hr’g Tr. (Rao) at 573:14-18). According to Viking, “[b]ecause Respondents manufacture the clinical trial product in-house and already have an

approved IND, Respondents can stockpile the Accused Products in the United States during the Presidential Review Period, and use that stockpile to conduct U.S. testing and U.S. clinical trials to circumvent a LEO, a CDO is warranted.” *Id.* at 200.

2. Ascletis Argues a Cease and Desist Order Is Not Warranted

Ascletis argues a cease and desist order should not be issued in the event the Commission finds a violation of section 337 for the following reasons: Respondents cannot sell the accused products in the United States; there is no domestic inventory of ASC41 or ASC43F in any form, much less commercially significant inventory; there has been no importation of accused ASC41 or ASC43F capsules, and there is no inventory of ASC41 or ASC43F in any formulation in the United States; and Respondents have no current plans to import ASC41 or ASC43F tablets into the United States. RIB at 171 (citing Order No. 40 at 5-6; Hr’g Tr. (Wu) at 636:19-638:8; 662:9-17, 664:7-665:7).

Ascletis argues that Viking’s request for a cease and desist order in the absence of any U.S. inventory of accused products “contravene[es] decades of Commission precedent” and is really a request for “an injunction against hypothetical *domestic* acts untethered from imported Accused Products.” RIB at 171-72 (emphasis original). Ascletis takes the position that the record evidence fails to show the “alleged unfair acts ‘are reasonably related to importation of the unfair imports at issue here,’” and thus “Complainant’s request for an expansive CDO is inconsistent with Commission precedent and arguably outside the purview of Section 337.” *Id.* at 172.

3. Staff Argues a Cease and Desist Order Is Not Warranted

Staff argues that a cease and desist order should not be issued in the event the Commission finds a violation of section 337 because “there is *no* inventory of accused products in the United States.” SIB at 136 (emphasis original). Staff further argues that “Respondents do not have any

significant domestic operations that could undercut the remedy provided by an exclusion order” and thus there is “no basis for issuing a cease and desist order directed to any Respondent in this investigation.” *Id.* at 137-37.

4. Recommendation

Even though there currently may be no inventory of the accused products in the United States, the record supports a finding that Ascleitis intends to re-enter the U.S. market. Moreover, the record indicates that Ascleitis could continue injuring Viking by further using or further disclosing Viking’s trade secrets in the United States. As Viking argues, Ascleitis employees Kristjan Gudmundsson, Handan He, and John Gargiulo reside in the United States, and they would have the opportunity to leverage Viking trade secrets to, for example, continue exploring potential partnerships with pharmaceutical companies to the detriment of Viking’s efforts to partner with those same companies. These types of activities would tend to undercut any relief an exclusion order would provide. Accordingly, it is my recommendation that, in the event the Commission finds a violation of section 337 and public interest factors do not weigh against imposing a remedy, Respondents should be prohibited from activities such as offering for sale, offering for clinical trial, and marketing the Accused Products for at least the period of any exclusion order. Respondents should also be prohibited permanently from further use and disclosure of Viking’s trade secrets, both to outside entities and internally. In other words, to avoid violation of the cease and desist order, if Ascleitis is going to continue to pursue FDA approval of ASC41 and ASC43F in the United States, it must actually independently develop the misappropriated trade secrets through a clean room process, without reference to the misappropriated trade secret materials and without persons with knowledge of the trade secrets.

C. Bond During Presidential Review

Pursuant to section 337(j)(3), the administrative law judge and the Commission must determine the amount of bond be required of a respondent, during the 60-day Presidential review period following the issuance of permanent relief, in the event the Commission determines to issue a remedy. The purpose of the bond is to protect the complainant from any injury. 19 U.S.C. § 1337(j)(3); 19 C.F.R. §§ 210.42(a)(1)(ii), 210.50(a)(3).

When reliable price information is available, the Commission has often set the bond by eliminating the differential in sales prices between the domestic product and the imported, infringing product. *Certain Microsphere Adhesives, Process for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm’n Op. at 24, USITC Pub. No. 2949 (1995). In other cases, the Commission has turned to alternative approaches, especially when the level of a reasonable royalty rate could be ascertained. *See Certain Integrated Circuit Telecommunication Chips and Products Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, Comm’n Op. at 41-43, USITC Pub. No. 2670 (1995). A 100% bond has been required when no effective alternative existed. *Certain Flash Memory Circuits and Products Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm’n Op. at 26–27 (July 1997) (a 100% bond imposed when price comparison was not practical because the parties sold products at different levels of commerce, and the proposed royalty rate appeared to be *de minimis* and without adequate support in the record).

Viking and Ascleitis have stipulated that “[a] bond rate of 100% would protect Complainant from any injury resulting from ASC41 and ASC43F that are imported under bond during the 60-day Presidential review period.” JX-1001.0001 ¶ 2. Staff “submits that a bond rate of 100

percent of entered value would be ‘sufficient to protect the complainant from any injury.’” SIB at 137 (citing 19 C.F.R. § 210.50(a)(3)).

In view of the stipulation between Viking and Ascleitis, it is my recommendation that the Commission set a 100% bond for any importation of ASC41 and ASC43F products during the Presidential review period.

D. Tailoring of Remedial Orders

Ascleitis argues that, if the Commission finds remedial orders are appropriate following a finding of violation of section 337, “such orders should include provisions (1) permitting the importation of Respondents’ accused products for FDA approval; and (2) requiring Complainant to regularly file with the Commission a report on the status of its alleged domestic industry activities.” RIB at 173. Ascleitis argues that such tailoring is warranted because “allowing importation of the Accused Products for FDA clinical trials will help mitigate the adverse impact on the U.S. public health and welfare that can otherwise be expected to result from the requested remedy.” *Id.* Ascleitis further argues that a periodic reporting requirement is warranted because “there are legitimate doubts as to whether the domestic industry will continue into the future,” and “[i]f Complainant abandons its alleged domestic industry activities relating to VK2809—which it may do for various technical or financial reasons, including its prioritization of VK2735—or its activities are not significant, such a reporting requirement would permit Respondents to seek rescission of the remedial orders, as there would be no longer be a domestic industry for the remedial orders to protect.” *Id.* at 175-76.

Viking argues that Ascleitis’s proposal to tailor any remedy to allow clinical trials for the Accused Products in the United States should be rejected because “the Commission has found that ‘importing infringing products for research and development purposes finds no precedent as a

matter of patent law or section 337.” CIB at 193-94 (citing *Certain Microfluidic Sys. and Components Thereof*, Inv. No. 337-TA-1100, Comm’n Op. at 86-88, (Mar. 24, 2020)). Viking also argues that, because “the Accused Products are not currently being administered to any patients and are not currently being tested in the United States,” a tailored limited exclusion order “is not necessary to address ongoing patient treatments or a disruption of any current research and development efforts by Respondents or a third party.” *Id.* at 194. In addition, Viking argues “[t]here is also no precedent that supports permitting importation of products that were developed using misappropriated trade secrets. Indeed, unlike the Hatch-Waxman Act, neither the Commission nor the DTSA provide a safe harbor exemptions for regulatory approval activities for trade secret misappropriation.” *Id.* at 195-96 (comparing 18 U.S.C. § 1836 with 35 U.S.C. §271(e)(1); citing *Certain Microfluidic Sys. and Components Thereof*, Inv. No. 337-TA-1100, Comm’n Op. at 86-88 (Mar. 24, 2020)).

Staff argues that Ascleptis’s proposed reporting requirement is warranted because it is unclear whether a domestic industry would continue given the uncertainty of FDA approval for VK2809. SIB at 132-34. Staff takes the position that “Complainant should be required to demonstrate that not only does Viking Therapeutics, Inc.[,] continue to exist as a corporation, but that it continues to make domestic investments in VK2809 beyond those of a ‘mere importer,’ which are typically insufficient to establish that a domestic industry exists.” *Id.* at 134.

Having considered the arguments of the parties and the record evidence, I do not recommend that any limited exclusion ordered issued by the Commission in this investigation be tailored to allow importation of Accused Products for clinical trial purposes. As discussed in sections VI above and VII above, Viking’s domestic injury partly concerns competition for large pharmaceutical partnerships to continue clinical trials for VK2809 in the United States. Allowing

imports of Ascleptis's competing products into the United States for clinical trials would result in continued competition with Viking for those partnership opportunities. This competition would result in continued injury to Viking and completely vitiate the relief that a limited exclusion order or other trade remedy is meant to provide.

I do recommend, however, that any relief granted Viking should be subject to a periodic reporting requirement to ensure that Viking's domestic industry in VK2809 continues during the pendency of any remedial order.

X. FINDINGS OF FACT WITH RESPECT TO THE PUBLIC INTEREST

Before issuing a remedy for a violation of section 337, the Commission must consider the effect of the remedy on the following statutory public interest factors: (1) the public health and welfare; (2) competitive conditions in the United States economy; (3) the production in the United States of articles like or directly competitive with articles that are the subject of the investigation; and (4) United States consumers. *See* 19 U.S.C. §§ 1337(d)(1), (f)(1). The Commission must weigh these effects against the strong public interest favoring the protection of U.S. intellectual property rights by excluding unlawful imports. *Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (III)*, Inv. No. 337-TA-1076, Comm'n Op. at 64 (June 20, 2019).

Only in rare circumstances will the Commission determine that the public interest considerations outweigh the intellectual property owner's rights. *See Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d at 1359-60 (Fed. Cir. 2010). The Commission has entirely declined to issue a remedy after finding a violation only three times, and it has never done so since 1984. *Id.* at 1360 (listing investigations). In each of those three cases, the exclusion order was denied because inadequate supply within the United States—by both the patentee and domestic licensees—meant that an exclusion order would deprive the public of products necessary for some important health

or welfare need: energy efficient automobiles, fundamental scientific research, or hospital equipment. *Id.*

In this investigation, the Commission delegated to me the task of gathering and evaluating evidence concerning the effect any remedy in this investigation might have on the statutory public interest factors. Notice of Investigation. This evidence included testimony and documents presented at trial.

Viking argues that the remedial orders it requests “would not have an adverse effect on the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or U.S. consumers.” CIB at 200. Ascleitis argues that Viking’s proposed remedies threaten “significant risks of harm to the public health and welfare and to American consumers” but that “[o]ther risks to the public interest—including to competitive conditions and the production of like or directly competitive articles in the United States—remain speculative at best.” RIB at 177. Staff takes the position that, “while exclusion of the Accused Products could conceivably have some adverse effects on the public health and welfare and U.S. consumers in the United States, those effects could be mitigated by tailoring the remedy to permit imports of accused products for clinical trial purposes.” SIB at 137-138.

As discussed below, the record evidence shows that none of the public interest factors weigh in favor of curtailing a remedy in this investigation.

A. Public Health and Welfare

The record evidence demonstrates that the issuance of remedial orders in this investigation would not pose health, safety, or welfare concerns in the United States with respect to the accused ASC41 and ASC43F products. The accused products are not being administered to any patients

in the United States, and Dr. Wu testified that there are no current U.S. clinical trials for ASC41 or ASC43F. Hr’g Tr. (Wu) at 630:23-631:6, 662:9-17. With respect to the general advancement of a treatment for NASH, other selective thyroid hormone receptor-beta agonists in advanced stages of development could replace any excluded accused product. *See e.g.*, Hr’g Tr. (Peck) at 513:1-514:5; CX-1722; CX-2357; CX-2359; CX-2338; CX-2361; CX-2371; CX-2373; CX-2339. Indeed, on March 14, 2024, the FDA issued a press release announcing that Madrigal’s resmetirom drug had been approved for the treatment of NASH. FDA News Release. Thus, having another selective thyroid hormone receptor-beta agonist on the market for treatment of NASH indicates that this statutory public interest factor does not weigh against the issuance of remedial orders in the event the Commission finds a violation of section 337.

B. Competitive Conditions in the U.S. Economy

The record evidence shows that the issuance of remedial orders would not have an adverse impact on the competitive conditions in the U.S. economy. There are multiple drug candidates currently in clinical trials that are seeking FDA approval for the treatment of NASH. Hr’g Tr. (Peck) at 513:1-514:4. And even through Madrigal’s resmetirom drug has been FDA-approved for the treatment of NASH, the prevalence of NASH in the United States is such that a remedial order in this investigation would not affect incentives for the development of other treatments for NASH. *See* Hr’g Tr. (Mancini) at 109:23-110:2.

Accordingly, this public interest factor does not weigh against imposing a remedy in the event the Commission finds a violation of section 337.

C. Production of Like or Directly Competitive Articles in the United States

The record evidence shows that issuance of remedial orders in this investigation would not have an adverse impact on the production of like or directly competitive articles in the United

States. Respondents manufacture the accused products in China, and thus there would not be any impact on U.S. production of the accused products if a remedial order issued. 100-Day Tr. (Wu) at 403:22-404:1. Moreover, Viking currently manufactures VK2809 in the United States and plans to commercially manufacture it in the United States. Hr’g Tr. (Morneau) at 46:5-14. Accordingly, this public interest factor does not weigh against imposing a remedy in the event the Commission finds a violation of section 337.

D. U.S. Consumers

The evidence shows there will be no adverse effect on U.S. consumers if the accused products are excluded from entry into the United States. Viking’s VK2809 will provide the same or substantially the same benefits as the excluded products, and there are other drugs approved or being developed for the treatment of NASH that are in more advanced stages of development than the Accused Products. *See* 100-Day Tr. (Schoneich) at 167:21-168:8; 169:1-5; Hr’g Tr. (Peck) at 513:1-514:5. Specifically, Madrigal’s resmetirom drug has been FDA-approved to treat NASH, and U.S. consumers will have access to appropriate treatments in the event the accused products are excluded from entry. Accordingly, this public interest factor does not weigh against imposing a remedy in the event the Commission finds a violation of section 337.

E. Public Interest Conclusion

In total, the record evidence demonstrates that the statutory public interest factors do not weigh against the issuance of remedial orders, such as a limited exclusion order or cease and desist order, in the event the Commission finds a violation of section 337 in this investigation.

XI. INITIAL DETERMINATION ON VIOLATION

For the reasons set forth above, it is my initial determination that Viking has shown a violation of section 337 in the importation into the United States by Ascleitis of the accused ASC41

and ASC43F tablets by reason of misappropriation of Viking's 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.

This initial determination is hereby certified to the Commission.

The Secretary is ordered to serve the confidential version of this initial determination upon counsel who are signatories to the Protective Order (Order No. 1) issued in this investigation. A public version will be served at a later date upon all parties of record.

Pursuant to 19 C.F.R. § 210.42(h), this initial determination will become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination or certain issues therein.

XII. ORDER

Within seven days of the date of this document, the parties must jointly submit a single proposed public version with any proposed redactions indicated in red. If the parties submit excessive redactions, they may be required to provide declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in 19 C.F.R. § 201.6(a). The proposed redactions should be made electronically, in a single PDF file using the "Redact Tool" within Adobe Acrobat. The proposed redactions should be submitted as "marked" but not yet "applied." The proposed redactions should be submitted via Box, with an email sent to Cheney1352@usitc.gov providing notice of the submission, and not filed on EDIS.

SO ORDERED.



Clark S. Cheney
Chief Administrative Law Judge