PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN DRUG PRODUCTS CONTAINING C-TYPE NATRIURETIC PEPTIDE VARIANTS, AND COMPONENTS THEREOF**	**INV. NO. 337-TA-1447**

ORDER NO. 15: INITIAL DETERMINATION GRANTING COMPLAINANT'S (1) MOTION TO DECLASSIFY AND (2) MOTION TO AMEND THE COMPLAINT AND NOTICE OF INVESTIGATION

(August 14, 2025)

On June 9, 2025, complainant BioMarin Pharmaceutical Inc. ("BioMarin") moved "to declassify a portion of the Ascendis Respondents' confidential response to discovery identifying the name and address of a supplier," Bachem AG ("Bachem"). Mot. No. 1447-004 at 1.

On June 27, 2025, BioMarin moved for "leave to amend the Complaint and the Notice of Investigation in the above referenced investigation to add Bachem AG ('Bachem') as an additional respondent and to add three additional complaint exhibits regarding Bachem in support of the Amended Complaint." Mot. No. 1447-006 at 1. The proposed amended complaint "also summarizes related litigation that did not exist at the time the original complaint was filed" and deletes information that has been discovered to be inaccurate. *Id.* at 7.

This order addresses Ascendis's motion to declassify and motion to amend, which the parties have treated as related.

BIOMARIN EXHIBIT 2011
Ascendis Pharma A/S v. BioMarin Pharmaceutical Inc.
PGR2026-00013

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I. MOTION TO DECLASSIFY

For the following reasons, BioMarin's motion to declassify is granted.

A.

BioMarin indicates that Ascendis disclosed in discovery responses that Bachem [redacted]. Mot. No. 1447-004 at 3. Ascendis designated the pertinent discovery responses as confidential. *Id.*

Based on this information, BioMarin began pursuing a motion to amend the complaint to add Bachem as a respondent. *Id.* According to BioMarin, Ascendis indicated that it would "oppose the motion to amend the Complaint on the grounds that the name of Bachem, as identified in Ascendis' discovery responses, was designated confidential." *Id.* In response to Ascendis's objection, BioMarin filed the present motion to declassify the "name and address" of Bachem. *Id.* at 1. BioMarin "does not seek to declassify the business relationship between the two entities or declassify that Bachem [redacted] for Ascendis." *Id.* at 5.

BioMarin contends that the "existence of Bachem cannot be considered CBI." *Id*. That information, according to BioMarin, does not concern or relate to any of the categories of information set forth in Commission Rule 201.6(a). *Id.* Further, BioMarin contends that the "disclosure of this information would also not cause substantial harm to the competitive position of Ascendis, specifically in light of the fact that BioMarin does not seek to declassify the business relationship between the two entities or declassify that Bachem [redacted] for Ascendis." *Id.* As additional support for its position that there is no substantial harm, BioMarin points to the fact that Ascendis publicly disclosed that Bachem makes another product for Ascendis, although that product is not at issue in this investigation. *Id.* at 6.

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BioMarin also contends that maintaining Bachem's name as confidential information would "frustrate the Commission's ability to grant effective relief" in the event a violation is found. *Id.* at 6-7.

On June 20, 2025, the Office of Unfair Import Investigations ("OUII") filed a response in support of BioMarin's motion to declassify. *See* EDIS Doc. ID 854340. OUII contends that "according to Commission precedent, the names and addresses of potential respondents are not confidential business information pursuant to Commission Rule 201.6(a)." *Id.* at 2-4 (collecting cases). Further OUII contends that it "is not aware of any reason that disclosing the name of a proposed respondent would 'impair[] the Commission's ability to obtain such information as is necessary to perform its statutory functions.'" *Id.* at 4 (quoting 19 C.F.R. § 201.6(a)(1)) (alternation in original). Finally, OUII states that "[w]hile the specific business relationship disclosed in Ascendis' discovery responses may be considered CBI (*e.g.* the fact that Bachem [redacted] the accused products), the Staff submits that it is public that there is some kind of business relationship between Ascendis and Bachem related to the supply of a drug substance." *Id.* at 5.

Also on June 20, 2025, Ascendis filed an opposition to BioMarin's motion to declassify. *See* EDIS Doc. ID 854408. In its opposition, Ascendis does not appear to dispute that the name and address of a company are not confidential business. *See generally id.* Instead, Ascendis contends that "Bachem's role as a [redacted] for TransCon CNP is highly confidential business information." *Id.* at 1. Ascendis contends that "identifying Bachem as a proposed respondent based on its role in the supply chain for the accused products will inherently disclose the metes and bounds of the [redacted], because one can easily infer that Bachem's role in the TransCon CNP [redacted]

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[redacted]." *Id.*; *see also id.* at 6 ("Because Bachem is a [redacted], the very association of its name with this Investigation makes it immediately apparent what Bachem's role is in the Transcon CNP [redacted]."). Ascendis contends provides several examples of the harm that allegedly would result from the disclosure of "Bachem's relationship to the product." *Id.* at 6-8. Finally, Ascendis contends that "maintaining the CBI designation on Bachem would not frustrate the Commission's ability to conduct an investigation." *Id.* at 8-9.

B.

Commission Rule 210.20(a) provides that "[a]ny party may move to declassify documents (or portions thereof) that have been designated confidential by the submitter but that do not satisfy the confidentiality criteria set forth in § 201.6(a) of this chapter." 19 C.F.R. § 210.20(a). Commission Rule 201.6(a)(1), in turn, defines "confidential business information" as:

> [I]nformation which concerns or relates to the trade secrets, processes, operations, style of works, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, or other information of commercial value, the disclosure of which is likely to have the effect of either impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions, or causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the Commission is required by law to disclose such information. The term "confidential business information" includes "proprietary information" within the meaning of section 777(b) of the Tariff Act of 1930 (19 U.S.C. 1677f(b)). Nonnumerical characterizations of numerical confidential business information (e.g., discussion of trends) will be treated as confidential business information only at the request of the submitter for good cause shown.

19 C.F.R. § 201.6(a)(1).

The Commission applies a two-part test that tracks the language of Rule 201.6 to determine if information is properly considered confidential business information. *See Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators*, Inv. No. 337-TA-1110, Comm'n Declassification Op. After

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Remand at 5 (Dec. 10, 2020). First, the Commission determines if the information "concerns or relates" to the types of information defined by the rule. *Id*. at 5-6. Second, the Commission determines whether the disclosure of the information is likely to have the effect of either (1) "impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions," or (2) "causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained." *Id*. at 6 (internal quotations omitted). Both parts of the test must be satisfied for the Commission to find that the information is confidential business information ("CBI"). *Id*.

The burden of proof is on the party seeking to keep the information confidential. *Id*.; *see also Certain Network Devices, Related Software and Components Thereof (I)*, Inv. No. 337-TA-944, Comm'n Declassification Op. at 9 (April 19, 2017) ("Rule 210.5(f) allows the ALJ or the Commission to require the party submitting redactions to provide support for their claim of confidentiality.").

C.

Here, Ascendis has not met its burden of demonstrating that the name of Bachem is confidential business information that should remain under seal.

In prior investigations, the Commission has held that the names and addresses of potential respondents are not confidential business information. *See, e.g.*, *Certain Fiber-Optic Connectors, Adapters, Jump Cables, Patch Cords, Products Containing the Same, and Components Thereof*, Inv. No. 337-TA-1399, Amended Order No. 18 at 4-5 (July 11, 2024) (finding names and addresses of proposed respondents are not confidential business information), *unreviewed*, Comm'n Notice (Aug. 16, 2024); *Certain Handheld Electronic*

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Computing Devices, Related Software, and Components Thereof, Inv. No. 337-TA-769, Order No. 5, 2011 WL 3585255, at *2 (July 7, 2011) (treating the identities of entities as confidential business information would be "inappropriate . . . particularly when such treatment could frustrate the Commission's ability to grant effective relief"); *Certain Self-Cleaning Litter Boxes and Components Thereof*, Inv. No. 337-TA-625, Order No. 8, 2008 WL 2213216, at *1 (May 23, 2008) ("It is clear from Commission precedent that the mere names and addresses of potential respondents are not confidential business information pursuant to Commission Rule 210.6(a)."); *Certain Agricultural Tractors Under 50 Power Take-Off Horsepower*, Inv. No. 337-TA-380, Order No. 11, 1996 WL 965770, at *3 (May 6, 1996) (same); *Certain Integrated Circuit Telecommunication Chips and Products Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, Order No. 46, 1992 WL 811647, at *2 (July 23, 1992) (same); *Certain Novelty Teleidoscopes*, Inv. No. 337-TA-295, Order No. 7, 1989 WL 609835, at *3 (June 13, 1989) (same).

Ascendis does not appear to dispute that the name of a company alone is not confidential business information. *See generally* EDIS Doc. ID 854408. Instead, Ascendis contends that the nature of its "business relationship with Bachem is confidential." *Id.* at 3. Further, Ascendis contends that disclosing the customer relationship between Ascendis and Bachem would harm both Ascendis and Bachem. *Id.* at 6-8. According to Ascendis, "[n]aming Bachem publicly in this case will necessarily destroy the confidentiality of Bachem's relationship with Ascendis." *Id.* at 6.

Ascendis's arguments are not persuasive. BioMarin indicated that it "does not seek to declassify the business relationship between the two entities or declassify that Bachem [redacted] for Ascendis." Mot. No. 1447-004 at 5.

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Ascendis's conclusory assertion that the naming Bachem as a respondent will inherently disclose Bachem's [redacted] is unsupported by logic or by a factual showing.

Independent of the foregoing problem, Ascendis failed to persuasively support its contention that it will be harmed by the disclosure of Bachem's name and address. Ascendis itself has publicly disclosed a list of all "suppliers for the drug substance, drug product or other components of . . . TransCon CNP," the drug at issue in this investigation, and a handful of other TransCon drugs. *See* Compl., Ex. 6 at 32. Bachem appears on that list. *Id*. While Ascendis's public statement does not expressly say that Bachem [redacted], the statement expressly identifies a supplier relationship between Ascendis and Bachem. *See* Compl., Ex. 6 at 32 ("Our PTH as well as our TransCon PTH drug substance is supplied by Bachem[.]"); *see also id.* at 103. Given that Ascendis at one point publicly disclosed all component suppliers for TransCon CNP, Ascendis's claim of harm from "[a]ny disclosure of Bachem" rings hollow. EDIS Doc. ID 854408 at 5. These facts weigh against a finding that Ascendis has met its burden to show that publicly identifying Bachem as a proposed or actual respondent in this investigation will disclose confidential business information and cause competitive harm.

Accordingly, Ascendis's motion to declassify the name and address of Bachem is granted. The business relationship between Ascendis and Bachem shall be maintained as confidential information, at least on the current record, because no party has requested that the relationship be declassified.

II. MOTION TO AMEND

For the following reasons, BioMarin's motion to amend the complaint and notice of investigation is granted.

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A.

i.

BioMarin contends there is good cause to amend because "BioMarin learned through information recently obtained during discovery that Bachem is the [redacted], and that Respondent Ascendis Pharma A/S has an agreement with Bachem for the [redacted]." Mot. No. 1447-006 at 2; *see also* Mot. No. 1447-006 at 5-6 ("Good cause exists to amend the Complaint and Notice of Investigation because BioMarin only learned of Bachem's involvement as the [redacted] after receiving the Ascendis Respondents' Response to the Complaint and Interrogatory Responses. The Interrogatory Responses also indicate that there is an agreement between Bachem and the Ascendis Respondents for the [redacted]. This new information establishes the belief that Bachem has sold for importation and/or imported the accused components of TransCon CNP that infringe the Asserted Patent." (internal citations omitted)). According to BioMarin, "Bachem has engaged in the importation and/or sale for importation and/or importation into the United States of components of the accused products and has information relevant to this Investigation." *Id.* at 2. BioMarin contends that the proposed amendments will promote judicial efficiency, serve the public interest, and will not prejudice any party. *Id.* at 1-2, 6-7.

In response to objections from Ascendis and Bachem, BioMarin supplemented its proposed amended complaint "with additional evidence that Bachem's [redacted] has been sold for importation and that Bachem had knowledge of the Asserted Patent and the role of [redacted] in the infringement of the Asserted Patent." EDIS Doc. ID 858162 at 2-3. BioMarin contends that the proposed amended complaint, as supplemented, "satisfies the

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requirements of Commission Rules 210.14 and 210.12(a)." *Id.* at 3. In particular, BioMarin contends that the second proposed amended complaint properly pleads sale for importation and contributory infringement. *Id.* at 3-4.

ii.

OUII supports the motion to amend. *See* EDIS Doc. ID 855303; EDIS Doc. ID 856726; EDIS Doc. ID 858379. First, OUII contends that there is good cause for the proposed amendments. *See* EDIS Doc. ID 855303 at 5-6. According to OUII, BioMarin could not have reasonably known that Bachem [redacted] prior to receiving Ascendis' discovery responses and response to the complaint. *Id.* at 5-6. OUII further contends that BioMarin acted diligently in moving to amend the Complaint after learning about Bachem. *Id.* at 6. OUII contends that "the foregoing shows good cause for BioMarin to amend the Complaint based on the newly discovered information about Bachem." *Id.* OUII also contends that "there is good cause to amend the Complaint to reflect updated information regarding related litigation" and that "there is good cause to amend the Complaint to delete an incorrect reference to an entity as the [redacted]." *Id.* at 9.

OUII next contends that the motion to amend the complaint was properly served on Bachem in accordance with Commission Rule 210.14(b)(1). *See id.* at 7.

OUII also contends that BioMarin's allegations of importation and unfair acts with respect to Bachem and [redacted] are "likely sufficient" to comply with Commission Rules 210.14(b)(1) and 210.12(a). *Id.* at 8. In particular, OUII notes that "BioMarin contends that Bachem's [redacted] and its agreement with Ascendis for the [redacted] 'establishes the belief that Bachem has sold for importation and/or imported the accused components of TransCon CNP that infringe the Asserted Patent.'" *Id.*

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at 8. OUII further notes that "[redacted] is an accused component of TransCon CNP that falls within the scope of the investigation." *Id.* According to OUII, "[t]his is likely enough to support an allegation of at least sale for importation." *Id.*; *see also* EDIS Doc. ID 856726 at 3-6. Additionally, OUII contends the proposed amended complaint's allegations of contributory infringement "are likely sufficient to comply with Commission Rules." EDIS Doc. ID 856726 at 6; *see also* EDIS Doc. ID 856726 at 6-8.

OUII states that it is "of the view that Bachem may be in possession of unique technical information related to [redacted] and that it would be most efficient for Bachem to produce that information, regardless of whether Ascendis may be able to obtain access to it." EDIS Doc. ID 856726 at 2, 8.

OUII next contends that "Complainant's decision to not name Carbogen, [redacted], as a respondent in its original complaint" has "no bearing on whether Complainant's discovery that Bachem was [redacted] provided good cause for its amendment to the complaint." *Id.* at 8-9.

OUII contends that "any prejudice to Bachem (and Ascendis) can be cured by affording it a reasonable opportunity to meaningfully participate in the investigation." *Id.* at 10.

Finally, OUII contends that "declassification of Bachem's identity and address as confidential business information is a necessary precursor to granting Complainant's motion to amend." EDIS Doc. ID 856726 at 10 n.3.

iii.

Non-party Bachem contends that BioMarin's motion to amend should be denied because the "proposed amendment to the Complaint and NOI does not comply with the Commission Rules,

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lacks good cause, and would prejudice and burden the parties, Bachem, and the public interest if allowed." EDIS Doc. ID 856376 at 1.

In particular, Bachem first contends that the motion should be denied because the proposed amended complaint fails to describe specific instances of alleged unlawful importations or sales as required by Commission Rules 210.12(a)(3) and 210.12(a)(9)(viii). *Id.* at 1; 4-7; EDIS Doc. ID 858466 at 1-4. Bachem also contends that the proposed amended complaint fails to allege contributory infringement. EDIS Doc. ID 858466 at 1-4.

Second, Bachem contends that BioMarin's motion should be denied for lack of good cause. EDIS Doc. ID 856376 at 2, 7-11. According to Bachem, BioMarin purposefully chose not to name Carbogen as a respondent when BioMarin thought that Carbogen [redacted] *Id.* at 7-8. Bachem contends that BioMarin's decision to change its strategy to pursue component suppliers is not a substitute for good cause. *Id.* at 8. Bachem also contends that "BioMarin knew or should have known about Bachem's relationship with Ascendis with respect to the [redacted] used in Ascendis's TransCon product." *Id.* at 2, 9-11.

Third, Bachem contends that "BioMarin's Motion should be denied because Respondent Ascendis has the relevant technical details of [redacted] in its possession, custody, or control, and can provide that information in this case." *Id.* at 3, 11.

Finally, Bachem contends that BioMarin's motion should be denied "because the current Respondents and Bachem will be severely burdened and prejudiced if Bachem is added to this Investigation at this stage, given the lost time (and procedural deadlines that have already come and gone)." *Id.* at 3, 11-13.

In the event BioMarin's motion is granted, Bachem requests "that the CALJ: (1) order the parties to provide new submissions on an appropriate target date (which should be at least 17

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months from the motion to amend), including identifying any conflicts for the *Markman* and evidentiary hearing; and (2) order the parties to provide a new procedural schedule that is appropriate, after the CALJ sets the new target and hearing dates." *Id.* at 3.

iv.

Ascendis also opposes the motion to amend. According to Ascendis, the motion should be denied because the proposed amended complaint fails to properly allege that Bachem infringed the asserted patent or engaged in any activity that could be plausibly characterized as violating section 337. *See* EDIS Doc. ID 855379 at 1, 5-8. Ascendis contends that Exhibit 51C to the second proposed amended complaint "negates BioMarin's allegations of knowledge, no substantial noninfringing uses, and commercial sale for importation." EDIS Doc. ID 858426 at 2-4. Ascendis also contends that BioMarin fails to allege infringing acts when Bachem had knowledge of the patent. *Id.* at 4-5.

Finally, Ascendis asserts that "there is no benefit to BioMarin or the Commission in adding Bachem." EDIS Doc. ID 855379 at 1, 8-10. According to Ascendis:

> The same products will be at issue in the Investigation regardless of whether Bachem is added as a respondent. The remedial orders will have the same scope regardless of whether Bachem is added as a respondent. There is no plausible way Bachem could circumvent an exclusion order regardless of whether or not the Complaint and Notice of Investigation are amended to include Bachem.

Id. at 1-2.

B.

Commission Rule 210.14(b)(1) provides that "[a]fter an investigation has been instituted, the complaint or notice of investigation may be amended only by leave of the Commission for good cause shown and upon such conditions as are necessary to avoid prejudicing the public interest and the rights of the parties to the investigation." 19 C.F.R. § 210.14(b)(1). When "the proposed amendment of the complaint would introduce an additional unfair act or an additional

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respondent, the motion shall be accompanied by a proposed amended complaint that complies with the requirements of § 210.12(a). *Id.*

Commission Rule 210.12(a) provides, *inter alia*, that the complaint shall "[d]escribe specific instances of alleged unlawful importations or sales." 19 C.F.R. § 210.12(a)(3); *see also* 19 C.F.R. § 210.12(a)(9)(viii) (requiring the complaint to a "showing that each person named as violating section 337 of the Tariff Act of 1930 is importing or selling the article covered by, or produced under the involved process covered by, the specific, asserted claims of each involved U.S. patent. The complainant shall make such showing by appropriate allegations, and when practicable, by a chart that applies each asserted independent claim of each involved U.S. patent to a representative involved article of each person named as violating section 337 of the Tariff Act or to the process under which such article was produced[.]").

The complainant bears the burden of establishing good cause for a proposed amendment. *Certain Liquid Crystal Display Modules, Prods. Containing Same, & Methods for Using the Same*, 337-TA-634, Order No. 5 at 2 (Aug. 6, 2008). "Generally, good cause exists for amending a complaint after institution when new information is obtained during discovery that was not previously known to a complainant." *Certain Photodynamic Therapy Systems, Components Thereof, and Pharmaceutical Products Used in Combination with the Same*, Inv. No. 337-TA-1411, Order No. 8 at 3 (Oct. 22, 2024).

C.

I find that BioMarin has demonstrated good cause for the proposed amendments.

"Timely motions to amend the complaint to add additional respondents or assert new claims from the patent at issue are routinely granted." *Certain NOR and NAND Flash Memory Devices and Products Containing Same*, Inv. No. 337-TA-560, Order No. 4 at 3 (Apr. 25, 2006).

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Good cause has been found to exist when a complainant obtains previously unknown information during discovery. *See, e.g.*, *Certain Engines, Components Thereof; and Products Containing the Same*, Inv. No. 337-TA-585, Order No. 6 (Jan. 24, 2007) (good cause found based on documents produced during discovery); *Certain Infotainment Systems, Components Thereof, & Automobiles Containing the Same*, Inv. No. 337-TA-1119, Order No. 14 at 3 (Oct. 3, 2018) ("Generally, good cause exists for amending a complaint after institution when new information is obtained during discovery that was not known to a complainant prior to institution." (citations and internal quotation marks omitted)); *Certain Laminated Floor Panels*, Inv. No. 337-TA-545, Order No. 4 at 2 (Sept. 19, 2005) ("Good cause exists for amending a complaint after institution when new information is obtained during discovery that was not known to complainant prior to institution."). Good cause may also exist when a complainant discovers facts that confirm incomplete previous knowledge with sufficient certainty to support its new allegations. *See, e.g., Certain Electronic Devices, Including Handheld Wireless Communications Devices*, Inv. No. 337-TA-667, Order No. 26 at 4 (Apr. 23, 2009) (motion granted where complainant knew of facts prior to filing complaint, but filed motion to amend only after confirming such facts through discovery); *Certain Fluidized Bed Combustion Systems*, Inv. No. 337-TA-213, Order No. 6 (Apr. 15, 1985) (finding good cause when complainant might have known enough to include an additional infringement allegation in its original complaint but "may not have felt sufficiently confident of proving its allegation of infringement . . . to warrant including this allegation until additional facts were obtained."); *Certain Flash Memory Chips & Prods. Containing Same*, Inv. No. 337-TA-735, Order No. 8 (Sept. 30, 2010) ("Motions to amend the complaint to add respondents have also been granted when the complainant receives information during discovery that confirms information available to the complainant prior to institution.").

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Here, BioMarin only recently learned through discovery of Bachem's involvement in the [redacted] for Ascendis. Shortly after obtaining that information, BioMarin raised the proposed amendment at the preliminary conference. *See* EDIS Doc. ID 854040 (Preliminary Conf. Tr.) at 14:21-26:3. Bachem then filed its motion to amend three days after the preliminary conference.

Under the circumstances of this investigation, I find that BioMarin's discovery of information regarding Bachem provides good cause to amend the complaint and notice of investigation. I also find that considering BioMarin's claims in a single investigation will promote judicial efficiency and conserve the Commission's resources.

For the reasons discussed below, Ascendis's and proposed respondents' objections to the proposed amendment are not persuasive.

D.

First, I do not find persuasive the contentions that BioMarin's motion should be denied because the second proposed amended complaint fails to adequately allege contributory infringement or the importation requirement of section 337.

The proposed second amended complaint alleges, *inter alia*:

- "On information and belief, [redacted]" EDIS Doc. ID 858162, Ex. A (Second Proposed Amended Complaint) ¶ 15.
- "On information and belief, Proposed Respondent [redacted]. On information and belief, Proposed Respondent Bachem and Respondent Ascendis Pharma A/S/ have entered into [redacted]. Ex. 51C at 1, 5. Proposed Respondent Bachem [redacted] for Proposed Respondent Ascendis Pharma A/S for making TransCon CNP drug products that are to be imported, and have been imported, into the United States having a nexus to the unlawful acts." *Id.* ¶¶ 27-28 (internal citations omitted).

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- "On information and belief, Proposed Respondent Bachem had knowledge of the RE'267 Patent and the [redacted] in TransCon CNP's infringement of the RE '267 Patent before the filing of the complaint. Also, Proposed Respondent Bachem has knowledge of the RE'267 Patent and the [redacted] in TransCon CNP's infringement of the RE '267 Patent at least as of the date of service of the Motion to Amend the Complaint. Proposed Respondent Bachem contributes to the direct infringement of the RE'267 Patent by selling for importation into the United States [redacted] claimed in the RE'267 Patent, knowing that they were [redacted] to practice one or more of the claims of the Asserted Patents, and that [redacted] has no substantial noninfringing uses, and knowing they are in fact used to directly infringe one or more of those claims. On information and belief, the TransCon CNP drug product, including TransCon CNP drug substance, [redacted], and other components, such as the synthetic polymer group, have no substantial noninfringing uses." *Id.* ¶¶ 47-49 internal citations omitted).

- "The Ascendis Respondents submitted its NDA to the FDA for TransCon CNP on March 31, 2025. The NDA identifies the commercial manufacturers. On information and belief, infringing TransCon CNP drug product, and components thereof, for commercial sale have been sold for importation and/or imported into the United States." *Id.* ¶ 50.

- "On information and belief, pursuant to a supply agreement, Bachem [redacted] for the Proposed Ascendis Respondents in [redacted] for importation into the United States. On information and belief, [redacted] have been sold to Proposed Ascendis Respondents for importation of TransCon CNP into the United States for the commercial sale of TransCon CNP." *Id.* ¶ 56.

- "On information and belief, Proposed Respondent Ascendis Pharma A/S has entered into agreements for the commercial manufacture and supply of TransCon CNP drug substance, drug product, [redacted] with at least Proposed Respondent Wacker, Proposed Respondent [redacted], and Vetter. On information and belief, the agreements require the manufacture of articles and sale of those articles to Proposed Respondent Ascendis Pharma A/S for importation of the articles into the United States. On information and belief, Proposed Respondent Bachem [redacted] that was sold for importation to Ascendis and shipped to the United States. On information and belief, [redacted]. On information and belief, Proposed Respondent Bachem had knowledge that its [redacted] was for TransCon CNP and that TransCon CNP would be imported into the United States. On information and belief, Proposed Respondent Bachem is also [redacted]

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[redacted] that has been or will be shipped to the United States, including after June 19, 2025. *Id.* ¶ 64-65 (internal citations omitted).

The proposed Second Amended Complaint also attaches an infringement claim chart that details the alleged infringement of the accused TransCon CNP product. EDIS Doc. ID 858162, Ex. E. The infringement chart states that [redacted] is "specially made for Ascendis's TransCon CNP by Proposed Respondent Bachem AG" and is a "necessary non-staple component[ ] of TransCon CNP drug product" that "contribute[s] to infringement of claims 15 and 18 by TransCon CNP." *Id.* at 1. The chart also states that "[o]n information and belief, the Proposed Bachem Respondent had knowledge of the RE '267 Patent and [redacted] role in contributing to TransCon CNP's infringement of the RE'267 Patent by at least June 19, 2025. Also, Proposed Respondent Bachem has knowledge of the RE '267 Patent and [redacted] role in contributing to TransCon CNP's infringement of the RE'267 Patent at least as of the date of service of the Amended Complaint supporting the Supplemental Motion to Amend the Complaint and Notice of Investigation." *Id.*

Taken together, the allegations in the complaint, including those summarized above, adequately allege that Bachem contributorily infringes and that section 337's importation requirement has been met. Although Ascendis and Bachem dispute the accuracy of BioMarin's allegations, I find that the merits of those disputes will be better addressed after BioMarin has been afforded the opportunity of appropriate discovery related to its claim. *See Foman v. Davis*, 371 U.S. 178, 182 (1962) ("If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits."); *Certain Vacuum Insulated Flasks and Components Thereof*, Inv. No. 337-TA-1216, Order No. 12 at 4 (Nov. 6, 2020), *unreviewed*, Comm'n Notice (Nov. 24, 2020) (finding that dispute regarding whether product accused of infringement was "actually sold, offered for sale, or imported" should

be addressed on the merits and granting motion to amend complaint to assert patent against additional products); *Applera Corp. v. Michigan Diagnostics, LLC*, 594 F. Supp. 2d 150, 154 (D. Mass. 2009) (noting that patent owner did not have to prove its claims before making them in order to obtain leave to amend a complaint).

E.

Bachem next contends that BioMarin's motion should be denied "because it knew or should have known about Bachem's relationship with Ascendis with respect to the [redacted]," but that argument also is unpersuasive. EDIS Doc. ID 856376 at 9-11. None of the information cited by Bachem shows that Bachem [redacted] for Ascendis's TransCon CNP product. And, in any event, good cause has been found when a complainant discovers facts that confirm incomplete previous knowledge with sufficient certainty to support its new allegations. *See, e.g., Certain Electronic Devices, Including Handheld Wireless Communications Devices*, Inv. No. 337-TA-667, Order No. 26 at 4 (Apr. 23, 2009) (motion granted where complainant knew of facts prior to filing complaint, but filed motion to amend only after confirming such facts through discovery); *Certain Fluidized Bed Combustion Systems*, Inv. No. 337-TA-213, Order No. 6 (Apr. 15, 1985) (finding good cause when complainant might have known enough to include an additional infringement allegation in its original complaint but "may not have felt sufficiently confident of proving its allegation of infringement . . . to warrant including [the] allegation until additional facts were obtained."); *Certain Flash Memory Chips & Prods. Containing Same*, Inv. No. 337-TA-735, Order No. 8 (Sept. 30, 2010) ("Motions to amend the complaint to add respondents have also been granted when the complainant receives information during discovery that confirms information available to the complainant prior to institution.").

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F.

Finally, I find that the prejudice Bachem contends it will suffer, EDIS Doc. ID 856376 at 11-13, can be ameliorated through procedural schedule adjustments. The parties and Bachem are directed to meet and confer about proposed modifications to the procedural schedule and, if necessary, the target date. Within seven days of this order, the parties and Bachem shall file a joint proposal of modifications to the procedural schedule and target date.

I have considered the other arguments advanced by Ascendis and Bachem and find them without merit.

Accordingly, BioMarin's motion to amend is granted.

III.

This initial determination is hereby certified to the Commission. Pursuant to Commission Rule 210.42(h), this initial determination shall become the determination of the Commission unless a party files a petition for review of the initial determination pursuant to Commission Rule 210.43(a), or the Commission, pursuant to Commission Rule 210.44, orders, on its own motion, a review of the initial determination or certain issues contained herein. *See* 19 C.F.R. § 210.42(d).

Within seven days of the date of this document, the parties and Bachem shall jointly submit a single proposed public version of this document with any proposed redactions indicated in red. They shall also jointly submit proposed public version of Order Nos. 9, 10, 12 and 13. If the parties and non-party 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). To the extent possible, the proposed redactions should be made electronically in a single PDF file with the proposed redactions submitted as

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"marked" but not yet "applied." The proposed redactions should be submitted via email to Cheney1447@usitc.gov and not filed on EDIS.

To the extent there is any confidential information in this order, that information is already in the possession of Bachem. The Secretary is directed to serve this order on Bachem.

SO ORDERED.

Clark S. Cheney
Chief Administrative Law Judge

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PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION** has been served via EDIS upon the Commission Investigative Attorney, **JENNIFER DIENES, Esq.** and the following parties as indicated, on **September 3, 2025**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
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