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August 22, 2025

VIA EDIS

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street S.W.
Washington, DC 20436

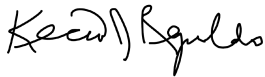
Re: *Certain Drug Products Containing C-Type Natriuretic Peptide Variants, and
Components Thereof*, Inv. No. 337-TA-1447 – Verified Amended Complaint – Public

Dear Secretary Barton:

Enclosed for filing on behalf of Complainant BioMarin Pharmaceutical Inc. (“BioMarin” or “Complainant”) is the public version of the Confidential Verified Amended Complaint and amended complaint exhibit 10C and newly-added exhibits 48C, 49C, 51C, 52C, and 53C filed today.

Thank you for your consideration and attention to this matter. Please feel free to contact me should you have any questions.

Sincerely,



Kecia Reynolds
of PAUL HASTINGS LLP

Counsel for BioMarin Pharmaceutical, Inc.

Enclosures

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**

Investigation No. 337-TA-1447

**AMENDED COMPLAINT OF BIOMARIN PHARMACEUTICAL INC.
UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED**

COMPLAINANT:

BioMarin Pharmaceutical Inc.
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Tel: 415-506-6700

PROPOSED RESPONDENTS:

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PUBLIC VERSION

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. COMPLAINANT BIOMARIN PHARMACEUTICAL INC.	3
III. PROPOSED RESPONDENTS	4
A. Ascendis Pharma A/S	4
B. Ascendis Pharma, Inc.....	6
C. Ascendis Pharma Growth Disorders A/S.....	7
D. Wacker Biotech GmbH.....	7
E. Bachem AG.....	8
IV. THE ASSERTED RE'267 PATENT.....	9
A. Identification of the Patent and Ownership	9
B. Non-Technical Description of the Invention of the RE'267 Patent.....	10
C. Foreign Counterparts	11
D. Licenses to the Asserted Patent.....	11
V. THE ACCUSED PRODUCT AND COMPONENTS THEREOF.....	11
VI. UNLAWFUL AND UNFAIR ACTS OF PATENT INFRINGEMENT	12
VII. SPECIFIC INSTANCES OF IMPORTATION AND SALE FOR IMPORTATION	17
VIII. HARMONIZED TARIFF SCHEDULE CLASSIFICATION FOR THE ACCUSED PRODUCTS	20
IX. DOMESTIC INDUSTRY	20
A. The Technical Prong of the Domestic Industry Requirement	20
B. The Economic Prong of the Domestic Industry Requirement	20
X. RELATED LITIGATION	22
XI. REQUESTED RELIEF.....	23

TABLE OF EXHIBITS

Exhibit No.	Description
1	Certified Copy of Reissue Patent No. 48,267
2	Certified Copy of Assignment Record for Reissue Patent No. 48,267
3	BioMarin Pharmaceutical Inc. Annual Report (10-K)
4	BioMarin – About Us
5	Ascendis Pharma Press Release – March 31, 2025, Ascendis Submits U.S. NDA for TransCon CNP (Navepegritide) for the Treatment of Children with Achondroplasia
6	Ascendis Pharma A/S Annual Report (20-F)
7	Intentionally left blank
8	About Wacker – Production Sites
9	List of Foreign Counterparts
10C	CONFIDENTIAL AMENDED Infringement Claim Chart
11	Intentionally left blank
12	FDA Status and Import Data Entry Search Report for Wacker BioTech GmbH – BUP-5012972-8/11-1
13	FDA Status and Import Data Entry Search Report for Wacker BioTech GmbH – BUP-5012990-0.11-1
14	FDA Status and Import Data Entry Search Report for Wacker BioTech GmbH – BUP-5013587-3/11-1
15	FDA Status and Import Data Entry Search Report for Wacker BioTech GmbH – BUP-5014989-0/11-1
16	FDA Status and Import Data Entry Search Report for Wacker BioTech GmbH – BUP-5015011-2/11-1

PUBLIC VERSION

Exhibit No.	Description
17	FDA Status and Import Data Entry Search Report for Wacker BioTech GmbH – BUP-5015519-4/11-1
18	FDA Status and Import Data Entry Search Report for Wacker BioTech GmbH – BUP-5015520-2/11-1
19	FDA Status and Import Data Entry Search Report for Wacker BioTech GmbH – BUP-5015598-5/11-1
20	FDA Status and Import Data Entry Search Report for Wacker BioTech GmbH – BUP-5015627-5/11-1
21	Ascendis Pharma Press Release September 16, 2024 for TransCon CNP
22	FDA Import Data Entry Search Report for Vetter Pharma Fertigung GmbH Co. KG
23	FDA Status and Import Data Entry Search Report for Vetter Pharma Fertigung GmbH Co. KG – BUP-1744000-2/11-2
24	FDA Status and Import Data Entry Search Report for Ascendis Pharma A/S – BUP-1709300-9/11-1
25	Intentionally left blank
26	DELETED
27	Intentionally left blank
28	Declaration of Daniela Drago, Ph.D.
29	Orange Book Label for Voxzogo®
30	Domestic Industry Claim Chart
31	Voxzogo® Webpage
32	Voxzogo® Label 2024
33	Chan, <i>et al.</i> , Pharmacokinetics and Exposure – Response of Vosoritide in Children with Achondroplasia, Clin. Pharm., 61:263-80 (2022)
34	Center for Drug Evaluation and Research, Application No. 214938Orig1s000, Integrated Review

PUBLIC VERSION

Exhibit No.	Description
35	A Phase 2, Open-Label, Sequential Cohort Dose-Escalation Study of BMN 111 in Children with Achondroplasia, Clinical Study Protocol
36	Breinholt, <i>et al.</i> , TransCon CNP, a Sustained-Release C-Type Natriuretic Peptide Prodrug, a Potentially Safe and Efficacious New Therapeutic Modality for the Treatment of Comorbidities Associated with Fibroblast Growth Factor Receptor 3-Related Skeletal Dysplasias, <i>J. Pharmacol. Ex. Ther.</i> , 370:45-71 (2019)
37	Declaration of Dr. Ulrich Hersel (2022)
38	Savirirayan, <i>et al.</i> , Once-Weekly TransCon CNP (Navepegritide) in Children with Achondroplasia (ACcomplisH): a Phase 2, Multicentre, Randomised, Double-Blind, Placebo-Controlled, Dose-Escalation Trial, <i>Lancet</i> , 65:1-10 (2023)
39	Breinholt, <i>et al.</i> , TransCon CNP, A Sustained-Release Prodrug of C-Type Natriuretic Peptide, Exerts Positive Effect on Bone in Juvenile Cymolpus Monkeys and in a Mouse Model of Achondroplasia (2017)
40	Rasmussen, <i>et al.</i> , Pharmacokinetics and Cardiovascular Assessment of TransCon CNP, a Sustained-Release C-Type Natriuretic Peptide Prodrug, for the Treatment of Achondroplasia (2017)
41	Breinholt, <i>et al.</i> , TransCon CNP, a Sustained-Release Prodrug of C-Type Natriuretic Peptide, Prevents Premature Synchronroses Closure in an Achondroplasia Mouse Model (2017)
42	Breinholt, <i>et al.</i> , Phase 1 Safety, Tolerability, Pharmacokinetics and Pharmacodynamics Results of a Long-Acting C-Type Natriuretic Peptide Prodrug, TransCon CNP (2022)
43C	Confidential Declaration in Support of BioMarin Pharmaceutical Inc.'s Complaint (Public Version submitted)
44	DELETED
45	DELETED
46	Study Details for Clinical Trial NCT04085523, A Dose Escalation Trial Evaluating Safety, Efficacy, and Pharmacokinetics of TransCon CNP Administered Once Weekly in Prepubertal Children With Achondroplasia
47	NCT04085523 Protocol Version 5, 28 December 2022

PUBLIC VERSION

Exhibit No.	Description
48C	Response to the Complaint of BioMarin Pharmaceutical Inc. Under Section 337 of the Tariff Act of 1930, as Amended, and Notice of Investigation
49C	Objections and Responses to Complaint BioMarin Pharmaceutical Inc.'s First Set of Interrogatories (Nos. 1-14)
50	Bachem AG - Commercial Register
51C	
52C	Excerpt of the New Drug Application for Navepegritide (TransCon CNP)
53C	Motion of Non-Part for Partially Opposed Extension of Time to July 9, 2025 and to Respond to the Motion to Amend Complaint and Request for Expedited Treatment

TABLE OF APPENDICES

Appendix	Description
A	Certified Copy of Prosecution History for Reissue Patent No. 48,267
B	Copy of the Prosecution History of U.S. Patent No. 8,598,121
C	Copy of the Prosecution History of U.S. Patent No. 8,198,242
D	Copy of the Prosecution History of U.S. Provisional Application No. 61/254,563
E	Copy of the Prosecution History of U.S. Provisional Application No. 61/180,112

I. INTRODUCTION

1. BioMarin Pharmaceutical Inc. (“BioMarin” or “Complainant”) submits this Amended Complaint under Section 337 of the Tariff Act of 1930, as amended, requesting that the U.S. International Trade Commission institute an investigation to remedy the unlawful and unfair importation into the United States, and sale for importation into the United States, of certain drug products containing C-type natriuretic peptide (“CNP”) variants, and components thereof, by Proposed Respondents Ascendis Pharma Inc., Ascendis Pharma A/S, Ascendis Pharma Growth Disorders A/S (collectively, “Proposed Ascendis Respondents”), Wacker Biotech GmbH (“Proposed Respondent Wacker” or “Wacker”), and Bachem AG (“Proposed Respondent Bachem” or “Bachem”) (altogether, “Proposed Respondents”) that infringe, directly and/or indirectly, one or more claims of U.S. Reissue Patent No. 48,267 (“RE’267 Patent” or the “Asserted Patent”).

2. The Proposed Respondents engage in unlawful acts in violation of Section 337(a)(1)(B) in the importation into the United States and/or sale for importation into the United States of certain drug products containing C-type natriuretic peptide variants, and components thereof, that infringe, literally or under the doctrine of equivalents, the following claims of RE’267 Patent:

Asserted Patent	Asserted Claims (independent claims in bold)
U.S. Reissue Patent No. 48,267	Claims 15 , 16-17, 18 , 19-20, and 31-48

3. Complainant BioMarin is an innovative U.S. biopharmaceutical company focused on research, development, and commercialization of biotechnological therapies specifically for the treatment of rare genetic diseases. BioMarin spent many years and hundreds of millions of dollars to research and develop the drug product known as Voxzogo®. Voxzogo® is the first drug

in the United States and the EU to receive regulatory approval for treating the rare disease achondroplasia—a genetic condition that causes severely short stature (a form of dwarfism) and disproportionate growth. At present, Voxzogo[®] is the only treatment for children with achondroplasia approved by the U.S. Food and Drug Administration (“FDA”).

4. Based on manufacturing and supply agreements for the commercial production and shipment of drug substance, drug products, and components, on information and belief, the Proposed Respondents have imported and/or sold for importation drug products containing C-type natriuretic peptide variants, and components thereof, for commercialization in the United States.

5. The Ascendis Respondents submitted their New Drug Application (“NDA”) for TransCon CNP on March 31, 2025. Ex. 5. Based on the timing of the NDA submission and the quantity of imported drug substance by Proposed Respondent Wacker, on information and belief, the Proposed Ascendis Respondents are prepared to commercially launch a drug product containing C-type natriuretic peptide variants upon FDA approval, which is expected by first quarter 2026.

6. As required by 19 U.S.C. § 1337(a)(2) and (3), an industry exists in the United States relating to drug products containing C-type natriuretic peptide variants, and components thereof, that are covered by the Asserted Patent. BioMarin’s Voxzogo[®] embodies the intellectual property asserted in this Investigation. BioMarin developed the technology disclosed and claimed in the Asserted Patent and is the owner of the Asserted Patent by assignment from the inventors.

7. Complainant files this Complaint seeking, as relief, a permanent limited exclusion order excluding from entry into the United States all infringing drug products containing C-type

natriuretic peptide variants, and necessary non-staple components thereof, of the Proposed Respondents, their subsidiaries, affiliates, related companies, and successors thereof. Pursuant to 19 U.S.C. § 1337(f)(1), Complainant also seeks cease and desist orders against the Proposed Respondents, their subsidiaries, affiliates, related companies, distributors, and agents and successors thereof prohibiting the importation, sale, offer for sale, distribution, transfer, making, advertising, and marketing of all infringing drug products containing C-type natriuretic peptide variants, and necessary non-staple components thereof. Pursuant to 19 U.S.C. § 1337(e)(1), Complainant further requests that the Commission impose a bond during the 60-day Presidential review period that is equal to 100% of the entered value covering any importation of infringing drug products containing C-type natriuretic peptide variants, and components thereof.

8. The requested remedial orders will prevent Respondents' unlawful infringement of Complainant's intellectual property. The requested remedial orders will also protect Complainant's domestic industry in investments in plant and equipment, labor, and research and development for Voxzogo®. The requested remedial orders will also protect Complainant's manufacturing industry, market share, and revenues for Voxzogo®. It is in the public interest to issue the requested remedial orders to protect valid and enforceable intellectual property. It is also in the public interest to encourage the development of drugs for rare diseases by protecting the significant investment expended to develop such drugs.

II. COMPLAINANT BIOMARIN PHARMACEUTICAL INC.

9. BioMarin is a publicly traded U.S. corporation organized and existing under the laws of Delaware. Ex. 3 at 1, 24. BioMarin was founded in 1997 in Novato, California. Ex. 4 at 1. BioMarin is a biopharmaceutical company engaged in the business of research, development,

manufacturing, and commercialization of therapies for the treatment of rare genetic diseases. Ex. 3 at 5.

10. BioMarin's unparalleled expertise in genetics and molecular biology has resulted in the development of eight groundbreaking treatments for patients with rare diseases, including therapies for achondroplasia. Achondroplasia is the most common form of dwarfism. BioMarin has a diverse pipeline of commercial, clinical, and preclinical drug candidates that provide an opportunity to be first-to-market or offer a substantial benefit over existing therapeutic options. Ex. 3 at 5.

11. Although BioMarin has a global presence, it is an American company. BioMarin's headquarters is in San Rafael, California. Ex. 3 at 24. BioMarin also manufactures in the United States at its 553,000-square-foot, Current Good Manufacturing Practices-compliant manufacturing facility in Novato, California. Ex. 43 at ¶10. Voxzogo[®] is manufactured by BioMarin substantially in its Novato, California facility.

III. PROPOSED RESPONDENTS

A. Ascendis Pharma A/S

12. On information and belief, Proposed Respondent Ascendis Pharma A/S is organized under the laws of the Kingdom of Denmark with its headquarters at Tuborg Boulevard 12, 2900 Hellerup, Denmark. On information and belief, Proposed Respondent Ascendis Pharma A/S has offices in Palo Alto and Redwood City, California; and West Windsor Township, New Jersey. Ex. 6 at 129. On information and belief, Proposed Respondent Ascendis Pharma A/S is engaged in the development and commercialization of drug products, including TransCon CNP for the treatment of achondroplasia. Ex. 6 at 108.

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13. On information and belief, Proposed Respondent Ascendis Pharma A/S has contracted with Proposed Respondent Wacker for the manufacture and sale for importation of TransCon CNP drug substance. Ex. 6 at 32 (“CNP drug substance is supplied by Wacker Biotech, Germany.”); Ex. 28 at ¶23 (“Because Ascendis has submitted its NDA for TransCon CNP, it is my expert opinion that Ascendis more likely than not has already entered into agreements for the commercial manufacture and supply of linker intermediates for TransCon CNP drug substance, the drug substance, and the TransCon CNP drug product for importation and distribution of the drug product in the United States.”); Ex. 5 (“COPENHAGEN, Denmark, March 31, 2025 (GLOBE NEWSWIRE) -- Ascendis Pharma A/S (Nasdaq: ASND) today announced that it has submitted its New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) for TransCon CNP (navepegritide) for the treatment of children with achondroplasia.”).

14. On information and belief, Ascendis Pharma A/S has contracted with Vetter Pharma Fertigung (“Vetter”) for the manufacture and sale for importation of TransCon CNP drug product. Ex. 6 at 32 (“Our TransCon CNP drug product in vials is manufactured by Vetter pursuant to our agreement with Vetter.”); Ex. 28 at ¶ 23 (“Because Ascendis has submitted its NDA for TransCon CNP, it is my expert opinion that Ascendis more likely than not has already entered into agreements for the commercial manufacture and supply of linker intermediates for TransCon CNP drug substance, the drug substance, and the TransCon CNP drug product for importation and distribution of the drug product in the United States.”); Ex. 5 (“COPENHAGEN, Denmark, March 31, 2025 (GLOBE NEWSWIRE) -- Ascendis Pharma A/S (Nasdaq: ASND) today announced that it has submitted its New Drug Application (NDA) to the U.S. Food & Drug

Administration (FDA) for TransCon CNP (navepegritide) for the treatment of children with achondroplasia.”).

15. On information and belief, Ascendis Pharma A/S has contracted with [REDACTED] [REDACTED] for TransCon CNP drug product. Ex. 48C at 2 [REDACTED] [REDACTED]; Ex. 49C at 17 (same), 21 [REDACTED] [REDACTED]; Ex. 28 at ¶ 23 (“Because Ascendis has submitted its NDA for TransCon CNP, it is my expert opinion that Ascendis more likely than not has already entered into agreements for the commercial manufacture and supply of linker intermediates for TransCon CNP drug substance, the drug substance, and the TransCon CNP drug product for importation and distribution of the drug product in the United States.”); Ex. 5 (“COPENHAGEN, Denmark, March 31, 2025 (GLOBE NEWSWIRE) -- Ascendis Pharma A/S (Nasdaq: ASND) today announced that it has submitted its New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) for TransCon CNP (navepegritide) for the treatment of children with achondroplasia.”).

16. On information and belief, Ascendis Pharma A/S is responsible for the development and commercial launch of TransCon CNP in the United States. Ex. 6 at 6, 22.

B. Ascendis Pharma, Inc.

17. On information and belief, Proposed Respondent Ascendis Pharma, Inc. is a company organized and existing under the laws of Delaware with a place of business at 1000 Page Mill Road, Palo Alto, CA 94304. Ex. 6 at 73, 128.

18. On information and belief, Proposed Respondent Ascendis Pharma, Inc. is a wholly owned subsidiary of Proposed Respondent Ascendis Pharma A/S. Ex. 6 at 128. On

information and belief, Proposed Respondent Ascendis Pharma, Inc. is Proposed Respondent Ascendis Pharma A/S's agent for service of process in the United States. Ex. 6 at 73.

19. On information and belief, Ascendis Pharma, Inc., as a wholly owned subsidiary, is also involved in the development and commercialization of TransCon CNP having a nexus to the unlawful acts. Ex. 47 (NCT04085523 Protocol showing Ascendis Pharma, Inc. as the Global Medial Monitor); *see also* Ex. 46.

C. Ascendis Pharma Growth Disorders A/S

20. On information and belief, Proposed Respondent Ascendis Pharma Growth Disorders A/S is a company organized under the laws of the Kingdom of Denmark. On information and belief, the principal address for Proposed Respondent Ascendis Pharma Growth Disorders A/S is Tuborg Boulevard 12 2900 Hellerup, Denmark. Ex. 7 at 3.

21. On information and belief, Proposed Respondent Ascendis Pharma Growth Disorders A/S is a wholly owned subsidiary of Proposed Respondent Ascendis Pharma A/S. Ex. 6 at 128, 354.

22. On information and belief, Proposed Respondent Ascendis Pharma Growth Disorders A/S, as a wholly owned subsidiary, is also involved in the development of TransCon CNP for commercialization in the United States having a nexus to the unlawful acts. Ex. 47 at 2 (NCT04085523 Protocol for TransCon CNP showing Ascendis Pharma Growth Disorders A/S as the sponsor).

D. Wacker Biotech GmbH

23. On information and belief, Proposed Respondent Wacker is a company organized under the laws of Germany. Proposed Respondent Wacker has a place of business at Hans-Knöll-Straße 3, 07745 Jena, Germany. Ex. 8 at 9.

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24. On information and belief, Proposed Respondent Wacker is the sole manufacturer and supplier of TransCon CNP drug substance to Proposed Respondent Ascendis Pharma A/S. Ex. 6 at 32 (“CNP drug substance is supplied by Wacker Biotech, Germany.”).

25. On information and belief, pursuant to a supply agreement, Proposed Respondent Wacker sells TransCon CNP drug substance to Proposed Respondent Ascendis Pharma A/S for making developmental and commercial TransCon CNP drug products that are to be imported, and have been imported, into the United States having a nexus to the unlawful acts. Ex. 6 at 32; Ex. 28 at ¶23 (“Because Ascendis has submitted its NDA for TransCon CNP, it is my expert opinion that Ascendis more likely than not has already entered into agreements for the commercial manufacture and supply of linker intermediates for TransCon CNP drug substance, the drug substance, and the TransCon CNP drug product for importation and distribution of the drug product in the United States.”).

E. [REDACTED]

26. On information and belief, Proposed Respondent [REDACTED]

[REDACTED]

[REDACTED]

27. On information and belief, Proposed Respondent [REDACTED]

[REDACTED]

[REDACTED]

28. On information and belief, Proposed Respondent Bachem and Respondent Ascendis Pharma A/S/ have entered into [REDACTED] [REDACTED] that is shipped to the United States. 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. Ex. 48C at 2 [REDACTED]

[REDACTED]; Ex. 49C at 17 (same), 21 [REDACTED]

[REDACTED]; Ex. 6 at 32; Ex. 28 at ¶23 (“Because Ascendis has submitted its NDA for TransCon CNP, it is my expert opinion that Ascendis more likely than not has already entered into agreements for the commercial manufacture and supply of linker intermediates for TransCon CNP drug substance, the drug substance, and the TransCon CNP drug product for importation and distribution of the drug product in the United States.”).

IV. THE ASSERTED RE’267 PATENT

A. Identification of the Patent and Ownership

29. United States Reissue Patent No. 48,267 is titled “Variants of C-Type Natriuretic Peptide,” and was issued on October 20, 2020. Ex. 1 at 1, cover. The RE’267 Patent is a continuation of Reissue Patent Application No. 14/604,262, now U.S. Reissue Patent No. 46,707 (issued on February 13, 2018), which is an application for reissue of U.S. Patent No. 8,598,121 (issued on December 3, 2013), which is a continuation of U.S. Patent Application No. 12/784,117, now U.S. Patent No. 8,198,242 (issued on June 12, 2012), which claims priority to U.S. Provisional Application No. 61/254,563 (filed on October 23, 2009) and U.S. Provisional Application No. 61/180,112 (filed on May 20, 2009). *Id.*

30. The named inventors of the RE’267 Patent are Daniel J. Wendt, Shinong Long, Sianna Castillo, Christopher P. Price, Mika Aoyagi-Scharber, Michel Claude Vellard, and Augustus O. Okhamafe. *Id.*

31. Complainant BioMarin is the sole owner by assignment of the RE'267 Patent.
Ex. 2 at 1.

32. The asserted claims of the RE'267 Patent are valid, enforceable, and currently in full force and effect until the expiration of the RE'267 Patent on May 20, 2030.

33. Pursuant to Commission Rules 210.12(a)(9)(i)-(ii), a certified copy of the RE'267 Patent and a certified copy of the assignment record for the RE'267 Patent are attached hereto as Exhibits 1 and 2, respectively.

34. Pursuant to Commission Rule 210.12(c), a certified copy of the prosecution history of the RE'267 Patent is provided as Appendix A. Also, pursuant to Commission Rule 210.12(c)(2), copies of the prosecution histories of the priority applications of the RE'267 Patent are provided in Appendices B-E.

B. Non-Technical Description of the Invention of the RE'267 Patent

35. The RE'267 Patent is directed to compositions comprising CNP variants, methods of making CNP variants, and methods of using CNP variants to treat bone-related disorders.
Ex. 1 at Abstract, 1:29-35.

36. The inventions disclosed and claimed in the RE'267 Patent concern the treatment of bone-related disorders, such as achondroplasia. Achondroplasia is the most common form of dwarfism, which is characterized by a large head, short limbs, and a normal-sized torso. This genetic disorder is caused by activating mutations of the fibroblast growth factor receptor-3 ("FGFR-3"). Ex. 1 at 3:18-24. CNP modulates the activity of FGFR-3 through inhibition of the FGFR-3 signaling pathway. Ex. 1 at 2:54-3:24. Over-expression of CNP has been shown to counter the effects of FGFR-3 mutations. *Id.* Therefore, CNP and functional analogues of CNP are potential therapeutics for achondroplasia. *Id.*

37. The RE'267 Patent describes recombinant (*i.e.*, non-native) CNP peptides and their modifications (collectively referred to as "CNP variants") that have an extended half-life compared to the naturally occurring mature CNP peptide, "CNP-22." Ex. 1 at 4:38-46.

38. The CNP variants are (1) modified to increase the overall size of molecular weight of CNP-22 peptide by attaching further moieties to it and/or (2) modified at certain amino acid positions within the CNP peptide by way of one or more mutations. Ex. 1 at 4:63-5:21. Examples of CNP variants, including "CNP-38," may be further optimized for drug delivery by coupling them to a hydrophilic polymer, such as polyethylene glycol. Ex. 1 at 9:9-25.

C. Foreign Counterparts

39. The foreign counterparts to the RE'267 patent, and the status of each is set forth in Exhibit 9.

D. Licenses to the Asserted Patent

40. There are no licensees to the RE'267 Patent.

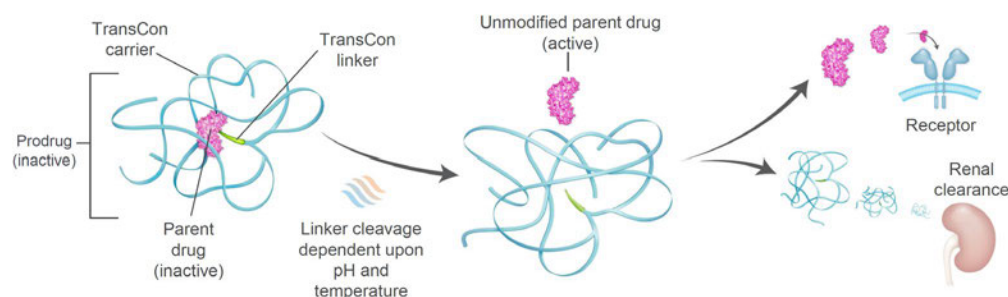
V. THE ACCUSED PRODUCT AND COMPONENTS THEREOF

41. Pursuant to 19 C.F.R. § 210.12(a)(12), the Accused Product is plainly described as a prodrug of CNP, including the drug substance, the linker of the drug substance, and other components, such as the synthetic polymeric group, and vials, prefilled syringes, autoinjectors, or other presentations of TransCon CNP containing the same, for the treatment of achondroplasia.

42. The Accused Product includes, but is not limited to, a drug product containing a C-type natriuretic peptide variant, commercially known as "TransCon CNP," which is also known as "navepegritide." *See* Ex. 6 at 89. TransCon CNP also contains a linker component.

Ex.6 at 78 (“TransCon molecules can have up to three components: a parent drug, an inert carrier that protects it, and a linker that temporarily binds the two.”).

43. In the below illustration of the mechanism of release for TransCon CNP, the release of the active drug via the linker component is shown. Ex. 6 at 78:



VI. UNLAWFUL AND UNFAIR ACTS OF PATENT INFRINGEMENT

44. The TransCon CNP drug product satisfies each and every limitation of claims 15-20 and 31-48 of the RE’267 Patent, literally or under the doctrine of equivalents. Ex. 10.

45. The TransCon CNP drug substance, [REDACTED], and other components, such as the synthetic polymer group, [REDACTED], are necessary non-staple components of TransCon CNP drug product in vials, prefilled syringes, autoinjectors, or other presentations of TransCon CNP containing the same, that contribute to literal infringement or infringement under the doctrine of equivalents of claims 15-20 and 31-48 of the RE’267 Patent. Ex. 10.

46. On information and belief, the Proposed Ascendis Respondents had knowledge of the infringed RE’267 Patent before the filing of the complaint. *See e.g.*, Ex. 6 at 56 (“BioMarin also owns a re-issue patent in the U.S. relating to CNP variants. Although we believe that this patent is not infringed by us and/or is invalid, it is possible that a court or other form of tribunal would come to a different conclusion.”); Appendix A at 857 (“Ascendis Pharma A/S, of Tuborg

PUBLIC VERSION

Boulevard 5, 2900 Hellerup, Denmark, as real party in interest, submits the following protest against the above-captioned application [for RE'267] under 37 CFR 1.291”).

47. 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. *See* Ex. 53C at 2 (confirming Proposed Respondent Bachem “received a copy of Complainant's [original] motion to amend, along with exhibits, by express delivery on June 19, 2025.”). 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.

48. Proposed Respondent Bachem contributes to the direct infringement of the RE'267 Patent by selling for importation into the United States [REDACTED] [REDACTED] claimed in the RE'267 Patent, knowing that they were specially made or specially adapted 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.

49. On information and belief, the TransCon CNP drug product, including TransCon CNP drug substance, [REDACTED] [REDACTED], and other components, such as the synthetic polymer group, have no substantial noninfringing uses.

50. The Ascendis Respondents submitted its NDA to the FDA for TransCon CNP on March 31, 2025. Ex. 5. The NDA identifies the commercial manufacturers. Ex. 28 at ¶15 (“Form 356h requires, among other information, the name, location, and FDA Establishment Identifier (FEI) number of the manufacturer(s) of the commercial product.”). 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.* at ¶¶ 12, 23 (“It is my opinion that Ascendis has most likely entered into an agreement with at least one manufacturer for the commercial supply of TransCon CNP drug product, TransCon CNP drug substance, and components thereof, such as the linker for the distribution and sale of TransCon CNP in the United States.”); Exs. 12-20 (importation records for Wacker); Exs. 22-23 (importation records for Vetter); Ex. 24 at 2 (importation record for Ascendis Pharma A/S); Ex. 48C at 2 [REDACTED]; [REDACTED]; Ex. 49C at 17 (same), 21 [REDACTED]; [REDACTED]; [REDACTED]

51. On information and belief, Proposed Respondent Wacker manufactures TransCon CNP drug substance in Germany. Ex. 6 at 32 (“CNP drug substance is supplied by Wacker Biotech, Germany.”); Exs. 12-20 (importation records for Wacker). On information and belief, pursuant to a supply agreement, Proposed Respondent Wacker manufactures TransCon CNP drug substance for the Proposed Ascendis Respondents for importation and sale of TransCon CNP in the United States. Ex. 28 at ¶ 23 (“Because Ascendis has submitted its NDA for TransCon CNP, it is my expert opinion that Ascendis more likely than not has already entered into agreements for the commercial manufacture and supply of linker intermediates for TransCon CNP drug substance, the drug substance, and the TransCon CNP drug product for importation and distribution of the drug product in the United States.”).

52. On information and belief, the TransCon CNP drug substance that Proposed Respondent Wacker manufactures for the Proposed Ascendis Respondents contains the active, which is the CNP-38 variant. Ex. 6 at 32; Ex. 36 at 459 (“TransCon CNP is a C-type natriuretic

PUBLIC VERSION

peptide (CNP-38) conjugated via a cleavable linker to a polyethylene glycol carrier molecule, designed to provide sustained systemic CNP levels upon weekly subcutaneous administration.”).

53. On information and belief, Proposed Respondent Wacker has imported at least 24 kg of TransCon CNP drug substance into the United States from Germany. Exs. 12-20 (import records for nine batches of TransCon CNP). On information and belief, the quantity imported exceeds any quantity that would be solely for uses reasonably related to the development and submission of information to the FDA. Ex. 21 at 3 (stating patients are given 100 micrograms of TransCon CNP per kilogram of body mass per week).

54. On information and belief, if the FDA approves TransCon CNP for the treatment of achondroplasia by the first quarter of 2026, as expected, the U.S. inventory of TransCon CNP drug substance would support the commercial sale and/or use of TransCon CNP drug product or be available for other commercial purposes unrelated to the development and submission of information to the FDA under 28 U.S.C. § 271(e)(1). Exs. 5; 12-21.

55. On information and belief, pursuant to a supply agreement, Vetter manufactures TransCon CNP drug product for the Proposed Ascendis Respondents. Ex. 6 at 32 (“Our TransCon CNP drug product in vials is manufactured by Vetter pursuant to our agreement with Vetter.”). On information and belief, Vetter manufactures TransCon CNP drug product in Germany. *Id.*, Exs. 22-23 (importation records identifying Germany as the country of origin). On information and belief, Vetter has imported, sold for importation, and will import TransCon CNP drug product into the United States for the Proposed Ascendis Respondents for the commercial sale of TransCon CNP. Ex. 6 at 32; Ex. 22 at 7; Ex. 23.

56. On information and belief, [REDACTED]

[REDACTED]

[REDACTED]. Ex. 48C at 2 [REDACTED]
Ex. 49C at 17 (same), 21 [REDACTED]
[REDACTED] On information and belief, [REDACTED]
[REDACTED]
[REDACTED] Ex. 48C at 2; Ex. 49C at
17, 21.

57. On information and belief, other components for TransCon CNP, such as TransCon systemic carriers (i.e. PEG) are imported from Japan. Ex. 6 at 32 (“For products that utilize soluble TransCon carriers, NOF Corporation (Japan) (‘NOF’), supplies PEGs.”).

58. On information and belief, Proposed Ascendis Respondents rely solely upon third parties for the manufacture of TransCon CNP drug substance, drug product, and components thereof. Ex. 6 at 32 (“We do not currently have any other suppliers for the drug substance, drug product or other components of our TransCon hGH, TransCon PTH and TransCon CNP . . .”).

59. On information and belief, the Proposed Ascendis Respondents have entered into a contract(s) for sale of commercial supply of TransCon CNP drug substance, drug product, and/or components, for importation and distribution in the United States. Ex. 28 at ¶¶ 12, 23 (“Because Ascendis has submitted its NDA for TransCon CNP, it is my expert opinion that Ascendis more likely than not has already entered into agreements for the commercial manufacture and supply of linker intermediates for TransCon CNP drug substance, the drug substance, and the TransCon CNP drug product for importation and distribution of the drug product in the United States.”); Ex. 5 (March 31, 2025, Press Release announcing that Ascendis submitted its NDA for TransCon CNP).

PUBLIC VERSION

VII. SPECIFIC INSTANCES OF IMPORTATION AND SALE FOR IMPORTATION

60. Pursuant to 19 C.F.R. § 210.12(a)(3), on information and belief, Proposed Respondent Wacker manufactures TransCon CNP drug substance in Germany and ships it to the United States, for the Proposed Ascendis Respondents. Ex. 6 at 32; Exs. 12-20.

61. The FDA's importation records show that Proposed Respondent Wacker imported at least nine shipments of TransCon CNP drug substance amounting to approximately 24 kg of drug substance. Exs. 12-20.¹ The importation records shown below are illustrative and not exhaustive:

Shipment ID ^	Arrival Date ↕	Submission Date ↕	Port of Entry Division ↕	Country of Origin ↕	Product Code ↕	Product Code Description ↕	Manufacturer FEI Number ↕	Manufacturer Legal Name ↕
BUP-5012990-0/11/1	04/29/2020	04/28/2020	Division of Northern Border Imports	Germany	66YIY99	EXHIBITS - OTHER DRUG RELATED ITEMS N.E.C.	3005503554	Wacker Biotech GmbH
BUP-5013587-3/11/1	07/23/2020	07/23/2020	Division of Northern Border Imports	Germany	66YIY99	EXHIBITS - OTHER DRUG RELATED ITEMS N.E.C.	3005503554	Wacker Biotech GmbH
BUP-5012972-8/11/1	04/23/2020	04/23/2020	Division of Northern Border Imports	Germany	66YIY99	EXHIBITS - OTHER DRUG RELATED ITEMS N.E.C.	3005503554	Wacker Biotech GmbH
BUP-5014989-0/11/1	12/08/2020	12/08/2020	Division of Northern Border Imports	Germany	66YIY99	EXHIBITS - OTHER DRUG RELATED ITEMS N.E.C.	3005503554	Wacker Biotech GmbH
BUP-5015011-2/11/1	12/09/2020	12/09/2020	Division of Northern Border Imports	Germany	66YIY99	EXHIBITS - OTHER DRUG RELATED ITEMS N.E.C.	3005503554	Wacker Biotech GmbH
BUP-5015519-4/11/1	02/06/2021	02/06/2021	Division of Northern Border Imports	Germany	66YIY99	EXHIBITS - OTHER DRUG RELATED ITEMS N.E.C.	3005503554	Wacker Biotech GmbH
BUP-5015520-2/11/1	02/06/2021	02/06/2021	Division of Northern Border Imports	Germany	66YIY99	EXHIBITS - OTHER DRUG RELATED ITEMS N.E.C.	3005503554	Wacker Biotech GmbH
BUP-5015598-8/11/1	02/14/2021	02/13/2021	Division of Northern Border Imports	Germany	66YIY99	EXHIBITS - OTHER DRUG RELATED ITEMS N.E.C.	3005503554	Wacker Biotech GmbH
BUP-5015627-5/11/1	02/14/2021	02/17/2021	Division of Northern Border Imports	Germany	66YIY99	EXHIBITS - OTHER DRUG RELATED ITEMS N.E.C.	3005503554	Wacker Biotech GmbH

Exs. 12-20.

Select ☐	Entry/CRP-FDA[Suffix]	Product	Product Code	Quantity	Country Name
☐	BUP-5012990-0/11-1	TRANSCON CNP DRUG SUBSTANCE FOR FURTHER MANUFACTURING FOR	66YIY99	Total: 1.0 Carton (1.0 Carton, 4642.5 Grams)	Germany
☐	BUP-5013587-3/11-1	TRANSCON CNP DRUG SUBSTANCE FOR FURTHER MANUFACTURING IND	66YIY99	Total: 1.0 Carton (1.0 Carton, 3040.9 Grams)	Germany

¹ Exhibits 12-20, 22-24, and 26 are records from the U.S. Food & Drug Imports Entry Data Search. The Shipment ID identified on the Imports Entry Data Search is entered into the Import Trade Auxiliary Communications System, which provides product identification information.

PUBLIC VERSION

☐	BUP-5012972-8/11-1	TRANSCON CNP DRUG SUBSTANCE FOR FURTHER MANUFACTURING FOR	66YIY99	Total: 1.0 Carton (1.0 Carton, 4440.1 Grams)	Germany
☐	BUP-5014989-9/11-1	TRANSCON CNP DRUG SUBSTANCE FOR PREPARATION OF DRUG PRODU	66YIY99	Total: 1.0 Carton (1.0 Carton, 1860.6 Grams)	Germany
☐	BUP-5015011-2/11-1	TRANSCON CNP DRUG SUBSTANCE FOR PREPARATION OF DRUG PRODU	66YIY99	Total: 1.0 Carton (1.0 Carton, 1861.6 Grams)	Germany
☐	BUP-5015519-4/11-1	TRANSCON CNP DRUG SUBSTANCE FOR PREPARATION OF DRUG PRODU	66YIY99	Total: 1.0 Box (1.0 Box, 2171.5 Grams)	Germany
☐	BUP-5015520-2/11-1	TRANSCON CNP DRUG SUBSTANCE FOR PREPARATION OF DRUG PRODU	66YIY99	Total: 1.0 Box (1.0 Box, 2114.9 Grams)	Germany
☐	BUP-5015598-8/11-1	TRANSCON CNP DRUG SUBSTANCE FOR PREPARATION OF DRUG PRODU	66YIY99	Total: 1.0 Box (1.0 Box, 2166.6 Grams)	Germany
☐	BUP-5015627-5/11-1	TRANSCON CNP DRUG SUBSTANCE FOR PREPARATION OF DRUG PRODU	66YIY99	Total: 1.0 Carton (1.0 Carton, 2048.4 Grams)	Germany

Exs. 12-20.

62. The FDA's importation records show that Proposed Respondent Ascendis Pharma A/S has imported TransCon CNP, manufactured in Germany, into the United States. Ex. 24.

The importation records shown below are illustrative and not exhaustive:

Shipment ID	Arrival Date	Submission Date	Port of Entry Division	Country of Origin	Product Code	Product Code Description	Manufacturer FEI Number	Manufacturer Legal Name
BUP-1709300-9/11/1	05/21/2022	05/22/2022	Division of Northeast Imports	Germany	66YIY99	EXHIBITS - OTHER DRUG RELATED ITEMS N.E.C.	3013022706	Ascendis Pharma A/S

Select	Entry/CBP FDA(Suffix)	Product	Product Code	Quantity	Country Name
☐	BUP-1709300-9/11-1	TRANSCON CNP	66YIY99	Total: 1.0 Box (1.0 Box, 8.0 Pieces)	Germany

Ex. 24.

63. The FDA's importation records show Vetter has imported TransCon CNP drug product, manufactured in Germany, into the United States for Proposed Respondent Ascendis Pharma A/S. Ex. 23. The importation records shown below are illustrative and not exhaustive:

Shipment ID	Arrival Date	Submission Date	Port of Entry Division	Country of Origin	Product Code	Product Code Description	Manufacturer FEI Number	Manufacturer Legal Name
BUP-1744000-2/11/1	03/16/2024	03/20/2024	Division of Northeast Imports	Germany	66YIY99	EXHIBITS - OTHER DRUG RELATED ITEMS N.E.C.	3009560142	Vetter Pharma Fertigung GmbH & Co. KG (Ravensburg Helmut-Vetter-Strasse)

Select	Entry/CBP FDA(Suffix)	Product	Product Code	Quantity	Country Name
☐	BUP-1744000-2/11-1	TRANSCON CNP 6.9 MG CNP-30 DRUG SUBSTANCE	66YIY99	Total: 1.0 Carton (1.0 Carton, 305.0 Pieces)	Germany

Ex. 23.

64. On information and belief, Proposed Respondent Ascendis Pharma A/S has entered into agreements for the commercial manufacture and supply of TransCon CNP drug

PUBLIC VERSION

substance, drug product, linker with at least Proposed Respondent Wacker, Proposed Respondent [REDACTED], and Vetter. Ex. 28 at ¶ 11; Ex. 48C at 2; Ex. 49C at 17, 21. 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. Ex. 6 at 32; Exs. 12-20; Ex. 48C at 2 [REDACTED]; Ex. 49C at 17 (same), 21 [REDACTED] [REDACTED] Ex. 28 at ¶¶ 12, 23 (“Because Ascendis has submitted its NDA for TransCon CNP, it is my expert opinion that Ascendis more likely than not has already entered into agreements for the commercial manufacture and supply of linker intermediates for TransCon CNP drug substance, the drug substance, and the TransCon CNP drug product for importation and distribution of the drug product in the United States.”).

65. On information and belief, Proposed Respondent [REDACTED] [REDACTED] that was sold for importation to Ascendis and shipped to the United States. Ex. 51C (“[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]”). On information and belief, [REDACTED]
[REDACTED]
[REDACTED] See Ex. 49C at 25 ([REDACTED]
[REDACTED]). On
information and belief, Proposed Respondent [REDACTED]
[REDACTED] and that TransCon CNP would be imported into the United States. On
information and belief, Proposed Respondent Bachem is also [REDACTED]

[REDACTED] that has been or will be shipped to the United States, including after June 19, 2025. Ex. 52C ([REDACTED])

[REDACTED]
[REDACTED]).

66. Complainant expects discovery to identify additional instances of importation and sale for importation of drug products containing C-type natriuretic peptide variants, and components thereof, that infringe the Asserted Patent.

VIII. HARMONIZED TARIFF SCHEDULE CLASSIFICATION FOR THE ACCUSED PRODUCTS

67. The Accused Product, TransCon CNP, is believed to fall within at least the following classification of the Harmonized Tariff Schedule of the United States: 3004.39.0050, 2937.19.0000. This classification is intended for illustration only and is not intended to be restrictive of the Accused Product.

IX. DOMESTIC INDUSTRY

A. The Technical Prong of the Domestic Industry Requirement

68. Complainant developed, manufactures, and sells Voxzogo[®], a C-type natriuretic peptide that practices one or more claims of the Asserted Patent. *See* Ex. 30 (Domestic Industry Product Claim Chart); Ex. 31 (Voxzogo[®] webpage).

69. The RE'267 Patent is listed in the Orange Book for Voxzogo[®]. Ex. 29 at 1. A claim chart illustrating how administration of Voxzogo[®] to a child practices at least one claim of the RE'267 Patent, either literally or under the doctrine of equivalents, is attached as Exhibit 30.

B. The Economic Prong of the Domestic Industry Requirement

70. Pursuant to 19 C.F.R. § 210.12(a)(7), and as required by 19 U.S.C. § 1337(a)(3), a domestic industry exists in the United States with respect to Voxzogo[®], which practices the

PUBLIC VERSION

Asserted Patent. As defined in 19 U.S.C. § 1337(a)(3)(A)-(C), BioMarin has made and continues to make significant investments in plant and equipment and employment of labor and substantial investments in the exploitation of the Asserted Patent through research and development activities relating to Voxzogo[®].

71. BioMarin's domestic industry includes significant U.S. investments in manufacturing, facilities, equipment, and labor for Voxzogo[®]. Ex. 43C at ¶¶ 11-12. Also, BioMarin's domestic industry includes substantial U.S. investments in research and development.

72. BioMarin has extensively invested and continues to invest in activities in the United States relating to Voxzogo[®]. BioMarin spent years and hundreds of millions of dollars researching and developing Voxzogo[®]. Ex. 43C at ¶¶ 23-25. BioMarin's investments and expenditures related to the domestic industry product, Voxzogo[®], are contextually significant and substantial at least because manufacturing of Voxzogo[®] substantially occurs in the United States, utilizing significant U.S. labor and capital. Moreover, BioMarin's substantial domestic research and development for Voxzogo[®] relates directly to the exploitation of the Asserted Patent. BioMarin's domestic expenditures are necessary for development, manufacturing and commercialization of the Voxzogo[®], which is the first drug to receive regulatory approval for treatment of achondroplasia in children in the United States and in the EU. Ex. 43C. Voxzogo[®] is still the only FDA-approved treatment for achondroplasia for children. Ex. 31 at 1; Ex. 43C at ¶¶ 11-12.

73. As set forth in the accompanying Confidential Declaration, BioMarin has made and continues to make significant investments in facilities and equipment in the United States. Ex. 43C at ¶¶ 11-12. BioMarin's U.S. facilities are used for R&D, product development,

manufacturing, manufacturing support, warehousing, compliance, clinical trial oversight and management, marketing, sales, and clinician and patient support for Voxzogo[®]. Ex. 43C at ¶ 8.

74. BioMarin has made and continues to have significant labor-related investments with respect to Voxzogo[®]. Ex. 43C at ¶¶ 20-21. BioMarin's employees engage in work relating to product development, manufacturing, manufacturing support, warehousing, compliance, clinical trial oversight and management, marketing, sales, and clinician and patient support for Voxzogo[®].

75. BioMarin has made and continues to make substantial investments in research and development with respect to the exploitation of the RE'267 Patent and Voxzogo[®]. Ex. 43C at ¶¶ 22-25. BioMarin's research and development exploiting the RE '267 Patent includes, but is not limited to, several clinical trials for Voxzogo[®].

76. The activities and investments described above are explained in detail in Confidential Exhibit 43.

X. RELATED LITIGATION

77. The RE'267 Patent has not been asserted in any other U.S. court action, and has not been the subject of a validity challenge in the U.S. Patent Office.

78. BioMarin filed suit against Ascendis Pharma A/S and Ascendis Pharma Growth Disorders A/S on January 13, 2025, before the Unified Patent Court, Munich Local Division, in Germany, Case No. ACT_1613/2025, UPC_CFI_18/2025. In that action, BioMarin asserts that Ascendis Pharma A/S and Ascendis Pharma Growth Disorders A/S's TransCon CNP product infringes EP 3175863 B1, a foreign counterpart to the RE'267 Patent. The oral hearing is scheduled for March 18, 2026.

PUBLIC VERSION

79. Foreign counterpart EP 3175863 B1 is also currently subject to opposition proceedings before the European Patent Office (“EPO”). The opposition was filed by Proposed Respondent Ascendis Pharma Growth Disorders A/S. The EPO Opposition Division upheld the EP 3175863 B1 in an amended form on September 23, 2024. Proposed Respondent Ascendis Pharma Growth Disorders A/S has appealed the EPO Opposition Division’s finding.

80. Ascendis Pharma Europe A/S and Ascendis Pharma A/S filed two actions against BioMarin in the Danish Maritime Commercial High Court. In the patent-related action, captioned Case No. BS-14603/2025-SHR, Ascendis seeks an order invalidating EP 3175863 B1, which is the same patent at issue in the EPO appeal. This action has been stayed pending resolution of the EPO appeal.

81. Ascendis Pharma A/S, Ascendis Pharma Growth Disorders A/S, and Ascendis Pharma, Inc. filed a declaratory judgment action against BioMarin on April 11, 2025 in the United States District Court for the Northern District of California, captioned *Ascendis Pharma A/S et al. v. BioMarin Pharmaceutical Inc.*, Case No. 4:25-cv-03302-YGR. The declaratory judgment action seeks a judgment of non-infringement of the RE’267 Patent based on the “safe harbor” of 35 U.S.C. § 271(e)(1) and a judgment that BioMarin be restrained and enjoined from stating that Ascendis or the importation of TransCon CNP investigational product infringes the RE ’267 Patent or from pursuing any action or proceeding alleging infringement of the RE ’267 patent against Ascendis or suppliers of the TransCon CNP product. This case is currently pending.

XI. REQUESTED RELIEF

WHEREFORE, by reason of the foregoing, Complainant requests that the U.S. International Trade Commission:

PUBLIC VERSION

(a) institute an immediate investigation, pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to the Proposed Respondents' violations of Section 337 based on the unlawful importation into the United States and/or sale for importation into the United States of certain drug products containing C-type natriuretic peptides, including TransCon CNP and components thereof, that infringe one or more claims of the RE'267 Patent;

(b) schedule and conduct a hearing on the unlawful acts and, following the hearing, determine that there has been a violation of Section 337;

(c) issue a permanent limited exclusion order, pursuant to Section 337(d) of the Tariff Act of 1930, as amended, excluding from entry into the United States drug products containing C-type natriuretic peptides, including TransCon CNP and components thereof, of the Proposed Respondents, their subsidiaries, affiliates, related companies, and successors thereof, that infringe one or more claims of the RE'267 Patent;

(d) issue permanent cease and desist orders, pursuant to Section 337(f) of the Tariff Act of 1930, as amended, prohibiting each Respondent, their subsidiaries, related companies, distributors, and agents from at least using, importing, selling, offering for sale, selling for importation, transferring, distributing, distributing, making, advertising, and marketing, and drug products containing C-type natriuretic peptides, including TransCon CNP and components thereof, that infringe one or more claims of the RE'267 Patent;

(e) impose a bond, pursuant to 19 U.S.C. § 1337(e)(1) and (f)(1), to prevent further injury to Complainant during the 60-day Presidential review period relating to the Proposed Respondents' unlawful and unfair acts of infringement of one or more claims of the RE'267 Patent; and

(f) grant such other and further relief as the Commission deems just and proper based on

PUBLIC VERSION

the facts determined by the investigation and the authority of the Commission.

Dated: August 22, 2025

Respectfully submitted,

/s/ Kecia Reynolds

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Counsel for Complainant

BioMarin Pharmaceutical Inc.

VERIFICATION OF AMENDED COMPLAINT

I, Kecia J. Reynolds, declare, in accordance with 19 C.F.R. §§ 210.4 and 210.14, under penalty of perjury, that the following statements are true and correct:

1. I am a partner at Paul Hastings LLP, counsel to BioMarin Pharmaceutical Inc. (“Complainant”) and am duly authorized to sign this Complaint on behalf of Complainant;
2. I have read the foregoing Amended Complaint and am aware of its contents;
3. To the best of my knowledge, information, and belief, formed after an inquiry reasonable under the circumstances, the allegations and other factual contentions of the foregoing Complaint have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery;
4. To the best of my knowledge, information, and belief, formed after an inquiry reasonable under the circumstances, the foregoing Complaint is not being filed for an improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation or any related proceeding; and
5. To the best of my knowledge, information, and belief, formed after an inquiry reasonable under the circumstances, the claims, defenses, and other legal contentions set forth within the Complaint 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.

Executed on this the 30th of July, 2025.

/S/ Kecia Reynolds

Kecia J. Reynolds, Esq.
Counsel for BioMarin Pharmaceutical Inc.

CERTIFICATE OF SERVICE

I certify that on this day, a true and correct copy of the foregoing document was filed with the Commission and served upon the following parties as indicated:

The Honorable Lisa Barton Secretary U.S. International Trade Commission 500 E Street, S.W. Washington, D.C. 20436	✓ Via EDIS
The Honorable Clark S. Cheney Chief Administrative Law Judge U.S. International Trade Commission 500 E Street, S.W., Room 317 Washington, D.C. 20436	✓ Via EDIS ✓ Via Electronic Mail: Cheney1447@usitc.gov
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Dated: August 22, 2025

/s/ Judith Best

Judith Best, Paralegal Specialist