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INVESTIGATIONS

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Case Investigation

Investigation 337-1447

Certain Drug Products Containing C-Type Natriuretic Peptide Variants, and Components Thereof; Inv. No. 337-TA-1447 (Violation)

VIO

Identifying Information

Full Title:

Certain Drug Products Containing C-Type Natriuretic Peptide Variants, and Components Thereof; Inv. No. 337-TA-1447 (Violation)

Investigation Number:

337-1447

Docket Number:

3819

Investigation Type:

Unfair Imports

Investigation Categories:

337 - Unfair Imports

Topic:

Certain Drug Products Containing C-Type Natriuretic Peptide Variants, and Components Thereof

Investigation Phase:

Violation

Phase Number:

1

Investigation Status:

Pending before the ALJ



Procedural History

	Change Reason	Change Effective Date
Pending before the ALJ	N/A	05/02/2025
Pre-institution	N/A	04/02/2025

F.R. Citation for Notice of Institution:

90 FR 19532

Case Manager:

Nathaniel.Gibson

Identifying Information

Procedural Schedule

Participants

Staff

Unfair Acts

Intellectual Property

HTS Numbers

Document Links

Procedural Schedule

Dates

Initiating Document Received Date:

04/02/2025

Start Date:

05/02/2025

Date of Publication of FR Notice (NOI):

05/08/2025

Markman Hearing Start Date:

02/06/2026



Markman Hearing End Date:

02/06/2026



Markman Hearing Suspended/Canceled:

Suspended/Canceled

Hearing/Conf Start Date:

04/20/2026



Hearing/Conf End Date:

04/24/2026



Hearing/Conf Suspended/Canceled:

Date ALJ Issued Target Date Order:

BIOMARIN EXHIBIT 2002

Ascendis Pharma A/S v. BioMarin Pharmaceutical Inc.

PGR2026-00013

05/27/2025

Initial Determination Type:

Initial Determination Date:

08/21/2026



Final Determination Type:

Final Determination Date:

Target Date:

12/21/2026



Investigation Termination Date:

Participants

Expand All +

	Participant Type	Name	Active Date	Inactive Date
+	Complainant	BioMarin Pharmaceutical Inc. Participant Representative: Paul Hastings	04/02/2025	
+	Respondent	Ascendis Pharma A/S Participant Representative: Sterne Kessler Goldstein & Fox	04/02/2025	
+	Respondent	Ascendis Pharma Growth Disorders A/S Participant Representative: Sterne Kessler Goldstein & Fox	04/02/2025	
+	Respondent	Ascendis Pharma, Inc. Participant Representative: Sterne Kessler Goldstein & Fox	04/02/2025	
+	Respondent	Bachem AG Participant Representative: Mintz, Levin, Cohn, Ferris, Glovsky and Popeo	09/12/2025	
+	Respondent	Wacker Biotech GmbH Participant Representative: Finnegan, Henderson, Farabow, Garrett & Dunner	04/02/2025	

Staff

These are internal ITC staff members associated with this investigation.

OUII Participation

OUII Participation Date:

05/02/2025

OUII Participation Level:

Full

Staff List

Expand All +

	Is Active?	Staff Assigned Type	Staff Name	Staff Active Date	Staff Inactive Date
+		GC Supervisor	Amanda Fisherow	04/02/2025	
+		OUII Supervisory Attorney	Anne Goalwin	05/02/2025	

	<u>Is Active?</u>	<u>Staff Assigned Type</u>	<u>Staff Name</u>	<u>Staff Active Date</u>	<u>Staff Inactive Date</u>
+	✓	ALJ	Clark Cheney	05/08/2025	
+	✓	OUII Investigative Attorney	Jennifer Dienes	05/02/2025	
+	✓	GC Attorney	Jonathan Link	04/02/2025	

Unfair Acts

Expand All +

	<u>Is Instituted?</u>	<u>Unfair Act in Notice</u>	<u>Active Date</u>	<u>Inactive Date</u>	<u>Unfair Act Expiration Date</u>
+	✓	Patent Infringement	04/02/2025		

Intellectual Property

<u>Is Instituted?</u>	<u>Type</u>	<u>Number</u>	<u>Active Date</u>	<u>Inactive Date</u>	<u>IP Expiration Date</u>
✓	Patent	48,267	04/02/2025		05/20/2030

HTS Numbers

Category Basket

Category Basket:

Pharmaceuticals and Medical Devices

HTS Number List

HTS Number & Description

2937.19.00.00 - POLYPEPTIDE, PROTEIN AND GLYCOPROTEIN HORMONES, THEIR DERIVATIVES AND STRUCTURAL ANALOGUES, NESOI

3004.39.00.50 - MEDICAMENTS CONTAINING HORMONES OR OTHER PRODUCTS OF HEADING 2937 BUT NOT CONTAINING ANTIBIOTICS, NESOI

Historic HTS Number List

There are no records of this type.

Document Links

EDIS Documents

<u>Doc Type</u>	<u>Title</u>	<u>Received Date</u>	
Notice	F.R. Notice of Institution of Investigation	05/20/2025	

EDIS Searches

- [Amendments to the NOI for investigation 337-1447](#)

- [Complaints for investigation 337-1447](#)

News Releases and Publications

- [ITC News Articles for investigation 337-1447](#)
- [ITC Publications for investigation 337-1447](#)

Other Documents

There are no records of this type.

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Investigations

v2.3.2

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500 E Street, SW
Washington, DC, 20436
202-205-2000 TDD 202-205-1810