

Exhibit 1

PATENT

**U.S. District Court
District of Delaware (Wilmington)
CIVIL DOCKET FOR CASE #: 1:22-cv-00294-CFC**

Novo Nordisk Inc. et al v. Rio Biopharmaceuticals, Inc. et al

Assigned to: Judge Colm F. Connolly

Related Cases: [1:21-cv-01782-CFC](#)

[1:22-cv-00299-CFC](#)

[1:22-cv-00296-CFC](#)

[1:22-cv-00295-CFC](#)

[1:22-cv-00298-CFC](#)

[1:22-cv-00297-CFC](#)

Date Filed: 03/04/2022

Jury Demand: None

Nature of Suit: 835 Patent – Abbreviated
New Drug Application (ANDA)

Jurisdiction: Federal Question

Cause: 35:271 Patent Infringement

Plaintiff

Novo Nordisk Inc.

represented by **Jack B. Blumenfeld**
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
Email: Jbbefiling@mnat.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Brian P. Egan
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
302-351-9454
Email: began@mnat.com
ATTORNEY TO BE NOTICED

Plaintiff

Novo Nordisk A/S

represented by **Jack B. Blumenfeld**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Brian P. Egan
(See above for address)
ATTORNEY TO BE NOTICED

V.

Defendant

Rio Biopharmaceuticals, Inc.

Defendant

EMS S/A

Date Filed	#	Docket Text
03/04/2022	<u>1</u>	COMPLAINT filed against EMS S/A and Rio Biopharmaceuticals, Inc. – Magistrate Consent Notice to Pltf. (Filing fee \$ 402, receipt number ADEDC-3817543.) – filed

		Civil Cover Sheet)(mal) (Entered: 03/04/2022)
03/04/2022	<u>2</u>	Notice, Consent and Referral forms re: U.S. Magistrate Judge jurisdiction. (mal) (Entered: 03/04/2022)
03/04/2022	<u>3</u>	Supplemental information for patent cases involving an Abbreviated New Drug Application (ANDA) – Date Patentee(s) Received Notice: 01/24/2022. Date of Expiration of Patent: see attached.Thirty Month Stay Deadline: 06/05/2025. (mal) (Entered: 03/04/2022)
03/04/2022	<u>4</u>	Report to the Commissioner of Patents and Trademarks for Patent/Trademark Number(s) 8,129,343 B2 ;9,132,239 B2 ;9,457,154 B2 ;9,687,611 B2 ;10,335,462 B2. (mal) (Entered: 03/04/2022)
03/04/2022	<u>5</u>	Disclosure Statement pursuant to Rule 7.1: identifying Corporate Parent Novo A/S for Novo Nordisk A/S; Corporate Parent Novo Nordisk US Holdings, Inc. for Novo Nordisk Inc. filed by Novo Nordisk A/S, Novo Nordisk Inc.. (mal) (Entered: 03/04/2022)
03/04/2022	<u>6</u>	Summons Issued as to EMS S/A on 3/4/2022; Rio Biopharmaceuticals, Inc. on 3/4/2022. (Attachments: # <u>1</u> Summons Issued EMS S/A)(mal) (Entered: 03/04/2022)
03/07/2022	<u>7</u>	SUMMONS Returned Executed by Novo Nordisk Inc., Novo Nordisk A/S. Rio Biopharmaceuticals, Inc. served on 3/7/2022, answer due 3/28/2022. (Egan, Brian) (Entered: 03/07/2022)
03/09/2022		Case Assigned to Judge Colm F. Connolly. Please include the initials of the Judge (CFC) after the case number on all documents filed. Associated Cases: 1:22-cv-00294-CFC through 1:22-cv-00299-CFC (rjb) (Entered: 03/09/2022)
03/11/2022	<u>8</u>	WAIVER OF SERVICE returned executed by Novo Nordisk Inc., Novo Nordisk A/S: For EMS S/A waiver sent on 3/8/2022, answer due 5/9/2022. (Egan, Brian) (Entered: 03/11/2022)
03/11/2022	<u>9</u>	STIPULATION TO EXTEND TIME for Rio Biopharmaceuticals Inc. and EMS S/A to answer, move or otherwise respond to the Complaint to May 9, 2022 – filed by Novo Nordisk A/S, Novo Nordisk Inc.. (Egan, Brian) (Entered: 03/11/2022)
03/14/2022		SO ORDERED, re <u>9</u> STIPULATION TO EXTEND TIME for Rio Biopharmaceuticals Inc. and EMS S/A to answer, move or otherwise respond to the Complaint to May 9, 2022, filed by Novo Nordisk A/S, Novo Nordisk Inc. Reset Answer Deadlines: Rio Biopharmaceuticals, Inc. answer due 5/9/2022. Ordered by Judge Colm F. Connolly on 3/14/2022. (kmd) (Entered: 03/14/2022)
05/06/2022	<u>10</u>	MOTION for Pro Hac Vice Appearance of Attorney Jeffrey J. Oelke, Ryan P. Johnson, Robert E. Counihan, Laura T. Moran, Erica R. Sutter, Kara Czekai, and Olivia Wheeling – filed by Novo Nordisk A/S, Novo Nordisk Inc.. (Egan, Brian) (Entered: 05/06/2022)
05/06/2022		SO ORDERED, re (15 in 1:22-cv-00298-CFC, 10 in 1:22-cv-00294-CFC, 13 in 1:22-cv-00297-CFC, 10 in 1:22-cv-00296-CFC, 9 in 1:22-cv-00299-CFC) MOTION for Pro Hac Vice Appearance of Attorney Jeffrey J. Oelke, Ryan P. Johnson, Robert E. Counihan, Laura T. Moran, Erica R. Sutter, Kara Czekai, and Olivia Wheeling, filed by Novo Nordisk A/S, Novo Nordisk Inc. Ordered by Judge Colm F. Connolly on 5/6/2022. Associated Cases: 1:22-cv-00294-CFC, 1:22-cv-00296-CFC, 1:22-cv-00297-CFC, 1:22-cv-00298-CFC, 1:22-cv-00299-CFC. (kmd) (Entered: 05/06/2022)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and)	
NOVO NORDISK A/S,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. _____
)	
RIO BIOPHARMACEUTICALS INC. and)	
EMS S/A,)	
)	
Defendants.)	

COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, “Novo Nordisk”), by their undersigned attorneys, for their Complaint against Defendants Rio Biopharmaceuticals, Inc. and EMS S/A (collectively, “Rio”), allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Rio’s submission of an Abbreviated New Drug Application (“ANDA”) to the United States Food and Drug Administration (“FDA”), by which Rio seeks approval to market a generic version of Novo Nordisk’s pharmaceutical product Ozempic® prior to the expiration of United States Patent Nos. 8,129,343 (the “343 patent”), 9,132,239 (the “239 patent”), 9,457,154 (the “154 patent”), 9,687,611 (the “611 patent”), and 10,335,462 (the “462 patent”) which cover *inter alia*, Ozempic® and/or its use.

THE PARTIES

2. Plaintiff Novo Nordisk Inc. (“NNI”) is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

3. Plaintiff Novo Nordisk A/S (“NNAS”) is an entity organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Allé, 2880 Bagsværd, Denmark. NNI is an indirect, wholly-owned subsidiary of NNAS.

4. On information and belief, Defendant Rio Biopharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 55 Ivan Allen Jr. Boulevard NW, Suite 525, Atlanta, Georgia 30313. On information and belief, Rio Biopharmaceuticals, Inc. is in the business of making and selling generic pharmaceutical products, for distribution in the State of Delaware and throughout the United States.

5. On information and belief, Defendant EMS S/A is a corporation organized and existing under the laws of Brazil, having its principal place of business at Rod. Jornalista Francisco Aguirre Proenca S/N KM 08 Bloco I, II E V Hortolandia, Sao Paulo, 13186-901, Brazil. On information and belief, EMS S/A is in the business of making and selling generic pharmaceutical products, for distribution in the State of Delaware and throughout the United States.

6. On information and belief, Defendant Rio Biopharmaceuticals, Inc. is a wholly owned subsidiary of Defendant EMS S/A.

7. On information and belief, Defendants Rio Biopharmaceuticals, Inc. and EMS S/A acted in concert to prepare and submit ANDA No. 216305 (“Rio’s ANDA”) to the FDA.

8. On information and belief, following any FDA approval of Rio’s ANDA, Defendants Rio Biopharmaceuticals, Inc. and EMS S/A will act in concert to distribute and sell a generic version of semaglutide solution, 2 mg/1.5 ml (1.34 mg/ml) and 4 mg/3 ml (1.34 mg/ml) (“Rio’s Product”) throughout the United States, including within Delaware.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.