



Local Division Munich
UPC_CFI_18/2025

Procedural Order
of the Court of First Instance of the Unified Patent Court
Local Division Munich
issued on 2 April 2025

CLAIMANT

1) BioMarin Pharmaceutical Inc.

105 Digital Drive - CA 94949 - Novato - US

represented by: Dr. Christian Paul, Dr. Tobias Mandler, Pascal Grandé, Dr. Olga Bezzubova,
Dr. Ping Li, Dr. Sven Rihm (JONES DAY)

supported by: Jason Raeburn, Alex Morgan (PAUL HASTINGS)

DEFENDANTS

1) Ascendis Pharma A/S

Tuborg Boulevard 12 - 2900 - Hellerup - DK

2) Ascendis Pharma Growth Disorders A/S

Tuborg Boulevard 12 - 2900 - Hellerup - DK

represented by: Agathe Michel-de Cazotte, Anna Leathley, Daniel Wiese (Carpmaels & Ransford)

PATENT AT ISSUE

European patent n° 3 175 863

PANEL/DIVISION

Panel 1 of the Local Division Munich

DECIDING JUDGE/S

This order has been issued by the Presiding Judge Dr. Matthias Zigann acting as judge-rapporteur.

LANGUAGE OF THE PROCEEDINGS

English

SUBJECT-MATTER OF THE PROCEEDINGS

Preliminary objection - App_13067/2025 UPC_CFI_18/2025

SUMMARY OF FACTS

The parties are biopharmaceutical companies. They are competitors on the market for inter alia treatments for the rare disease achondroplasia, a genetic condition that causes severely short stature and disproportionate growth.

BioMarin is the proprietor of European patent 3 175 863 B1 entitled “Variants of C-Type Natriuretic Peptide”. The patent was filed on 20 May 2010, claiming priorities from 20 May 2009 and 23 October 2009. The patent was granted with effect from 1 December 2021 and is currently in force, inter alia, in Germany, France, Italy, Netherlands, Austria, Belgium, Denmark, Estonia, Finland, Luxembourg, Portugal and Sweden.

BioMarin takes action against the Ascendis for direct infringement of claims 1-4 of the patent in suit as upheld in opposition proceedings before the EPO with respect to the Ascendis` product “TransCon CNP” in the territory of Germany, France, Italy, Netherlands, Austria, Belgium, Denmark, Estonia, Finland, Luxembourg, Portugal and Sweden.

The statement of claim was lodged on 23 January 2025. Ascendis were served on 17 February 2025. On 17 March 2025 Ascendis lodged a preliminary objection. On 31 March 2025 BioMarin responded.

REQUESTS BY THE PARTIES

Ascendis requests:

I. Jurisdiction is declined and the infringement action is rejected as being inadmissible;

II. In the alternative: the Claimant is asked to correct the deficiencies in its Statement of claim, particularly providing information required by Rule 13.1(I) RoP and reserve the corrected statement of claim in order to initiate the infringement action.

Ascendis argues that the opt-out had not been effectively withdrawn by BioMarin as the withdrawal lists only the designated states, it does not indicate the states in which the Patent was granted. In particular, the application of the withdrawal of the opt-out lists Latvia and Slovakia as EPC states for which the Patent has been granted, whereas the Patent was not validated in Latvia and is not in force in Slovakia.

Ascendis further argues that BioMarin has not demonstrated competence of the UPC as BioMarin has not alleged any actual or threatened infringing act. BioMarin alleges acts in paras 9 – 29 relating to clinical trials without stating whether it alleges these acts to be infringing (on the contrary as will be shown below, Claimant’s requests make it clear that none of these acts are infringement). Even if it is assumed, in favour of the Claimant, that the acts in paras 9-29 are alleged to be infringing acts, BioMarin does not explain why such acts are infringing. In particular, it has not explained which of the acts relate to “placing on the market”, as TransCon CNP is not even an approved drug. The Claimant has not provided “one or more instances of alleged infringements or threatened infringements specifying the date and place of each”, in non-compliance with Rule 13.1(I) RoP. The deficiency also means that the competence of the Court has not been established.

BioMarin requests:

1. *The preliminary objection of the Defendants, including the auxiliary request, is rejected.*
2. *The proceedings will be continued.*

BioMarin argues that its withdrawal (Exhibit CRPO-1) indisputably identifies the opted-out Patent, and the member states are mentioned only in the context of the “Proprietor” without limiting the withdrawal in any way. Slovakia and Latvia were correctly included as both countries are listed in the decision to grant the Patent under Art. 97(1) EPC.

BioMarin further argues that it has sufficiently shown the infringement (actual and threatened) of the Patent in the statement of claim. The contested embodiment (paras. 69-84) and acts of infringement (paras. 9-29) are clearly explained in the statement of claim and summarized in the legal assessment accordingly (paras. 86-95). Furthermore, it is undisputed that the infringing acts occurred in Germany, i.e., within the jurisdiction of the Munich local division (cf. for example paras. 11-14 and 86 regarding the manufacture in Germany). Nothing more is required to establish the competence of the Court (cf. Munich LD, UPC_CFI_339/2024, March 18, 2025 margin 49; Munich LD, UPC_CFI_235/2024, March 18, 2025 margin 36). Ascendis` objections regarding the acts in dispute solely concern the legal characterization of such acts under substantive law. This is beyond the scope of the Rule 19 examination, and the scope of the alleged exceptions to infringement under the UPCA has not yet been definitively determined by case law and should thus be dealt with in the main proceedings (cf. CoA, UPC_CoA_188/2024, Sept. 3, 2024 – Aylo/Dish, margin 9-29 and 86).

GROUND FOR THE ORDER

The preliminary objection was filed in time but is not successful.

1. Opt-out

The withdrawal (Exhibit CRPO-1) identifies the opted-out patent, and the member states are mentioned only in the context of the “Proprietor” without limiting the withdrawal in any way. Slovakia and Latvia were correctly included as both countries are listed in the decision to grant the Patent under Art. 97(1) EPC.

2. Acts of infringement

BioMarin has sufficiently shown the infringement (actual and threatened) of the Patent in the statement of claim. The contested embodiment (paras. 69-84) and acts of infringement (paras. 9-29) are clearly explained in the statement of claim and summarized in the legal assessment accordingly (paras. 86-95). Furthermore, it is undisputed that the infringing acts occurred in Germany, i.e., within the jurisdiction of the Local Division Munich (cf. for example paras. 11-14 and 86 regarding the manufacture in Germany). Nothing more is required to establish the competence of the Court (cf. LD Munich, UPC_CFI_339/2024, March 18, 2025 margin 49; LD Munich, UPC_CFI_235/2024, March 18, 2025 margin 36). Ascendis` objections regarding the acts in dispute solely concern the legal characterization of such acts under substantive law. This is beyond the scope of the Rule 19 examination.

3. Auxiliary request

As there is no lack of substantiation for the allegation of infringement, a correction of deficiencies and re-service of the action are not warranted.

ORDER

1. Ascendis` preliminary objection, including the auxiliary request, is rejected.
2. The proceedings will be continued.

INSTRUCTIONS TO THE PARTIES

Next step in the proceedings will be the filing of a statement of defense by Ascendis.

INFORMATION ABOUT APPEAL

The present order of the Judge-rapporteur rejecting the preliminary objection may either

- be the subject of an appeal together with the appeal against the final decision of the Court of First Instance in the main proceedings, or
- be appealed with leave of the Court of First Instance within 15 days of service of the Court's decision to that effect (Art. 73(2)(b) UPCA, R. 21.1 2nd sentence and 220.2, 224.1(b) RoP).

DETAILS OF THE ORDER

Order no. ORD_15496/2025 in ACTION NUMBER: ACT_1613/2025
UPC number: UPC_CFI_18/2025
Action type: Infringement Action
Related proceeding no. Application No.: 13067/2025
Application Type: Preliminary objection

Dr. Zigann
Presiding Judge