

**Order
of the Court of First Instance of the Unified Patent Court
delivered on 18/02/2026
regarding R.263 and R.9 RoP**

CLAIMANT

- | | | |
|----|---|---|
| 1) | GlaxoSmithKline Biologicals SA
(Claimant) - Rue de l'Institut 89 - 1330 -
Rixensart – BE,
“Claimant” or “GSK” | Represented by Tjibbe
Douma and others |
|----|---|---|

DEFENDANTS

- | | |
|----|---|
| 1) | Moderna Netherlands B.V.
(Defendant) - Claude Debussylaan 7 - 1082 MC
- Amsterdam - NL |
| 2) | Moderna Biotech Spain, S.L.
(Defendant) - C/Julián Camarillo 31 - 28037 -
Madrid - ES |
| 3) | Moderna Biotech UK Limited
(Defendant) - 54 Portland Place - W1B 1DY -
London - GB |

- 4) **Moderna Biotech Distributor UK Ltd**
(Defendant) - MYO, 123 Victoria Street - SW1E
6DE - London - GB
- 5) **Moderna Switzerland GmbH**
(Defendant) - Peter Merian-Weg 10 - 4052 -
Basel - CH
- 6) **Moderna Poland SP. Z.O.O.**
(Defendant) - Rondo Ignacego Daszynskiego 1
- 00-843 - Warsaw - PL
- 7) **Moderna, Inc.**
(Defendant) - 325 Binney Street - MA 02142 -
Cambridge - US
- 8) **ModernaTX, Inc.**
(Defendant) - 325 Binney Street - MA 02142 -
Cambridge - US
- 9) **Moderna Belgium S.R.L.**
(Defendant) - Avenue Marnix 23 - 1000 -
Brussels - BE
- 10) **Moderna France SASU**
(Defendant) - 19 Rue Cognacq-Jay - 75007 -
Paris - FR
- 11) **Moderna Germany GmbH**
(Defendant) - Brienner Strasse 45 a-d c/o
Design Offices, Campus Königsplatz - 80333 -
Munich - DE

- 12) **Moderna Italy S.R.L.**
(Defendant) - Via Vittorio Veneto 54/B - CAP
00187 - Rome - IT
- 13) **Moderna Portugal Unipessoal LDA**
(Defendant) - Rua João Chagas, 10-B Direito -
1500-493 - Lisbon - PT
- 14) **Moderna Sweden AB**
(Defendant) - c/o Scandinavian Trust AB,
Birder Jarlsgatan 12 - 114 34 - Stockholm - SE
- 15) **Moderna Norway A/S**
(Defendant) - C/o CSC (Norway) AS,
Wergelandsveien 7 - 0167 - Oslo – NO

Defendants 1-15, collectively “defendants” or
“Moderna”, are represented by Gertjan
Kuipers and others

PATENT AT ISSUE

<i>Patent no.</i>	<i>Proprietor/s</i>
EP2590626	GlaxoSmithKline Biologicals SA

DECIDING JUDGE: the judge rapporteur (“JR”)

LANGUAGE OF PROCEEDINGS: English

POINTS AT ISSUE

1. In this procedural order several applications of the parties are addressed, as set out below.

R.263 application to amend the claim

2. Together with its reply/defence to the counterclaim submitted on 6 January 2026, (the “Reply”), GSK submitted an application to amend its claim, to include Moderna’s new product mNEXSPIKE in the definition of ‘Spikevax Infringing Products’, allegedly the latest upgrade of Spikevax. It asserts in support that mNEXSPIKE is a product with the same lipid composition as the other two allegedly infringing products, so the infringement discussion is not materially

affected and defendants are not unreasonably hindered by its inclusion. GSK also points out that this updated product already falls within the requested relief, which is requested for ‘A liposome (...) such as the *Infringing Products (the Spikevax Infringing Products and mRESVIA Infringing Products individually and jointly), and/or further versions or variants thereof*’ The R.263 application is merely made for completeness and clarity.

GSK also points out that the EMA only recently adopted a positive opinion recommending the grant of a marketing authorization for mNEXSPIKE on 11 December 2025. Therefore, there was no indication for GSK that should have prompted the inclusion of mNEXSPIKE in the statement of claim (“SoC”) dated 4 July 2025. The addition of mNEXSPIKE could not have been made with reasonable diligence at an earlier stage (Rule 263(2)a RoP).

3. Moderna opposes the amendment regarding the introduction of a new product, asserting that the amendment could have been made with reasonable diligence at an earlier stage as the FDA had already approved mNEXSPIKE in the US on 30 May 2025, which was reported on publicly, so that GSK knew, or should have known. Defendants also argue that it is unreasonably hindered in its defence because, inter alia, GSK devoted 15 pages of its reply to this new product and Moderna would be deprived of one written round in its response thereto.

Number of ARs R.30.1 RoP

4. With its Reply GSK filed an application to amend the patent pursuant to R. 30.1 RoP, uploading 40 proposed conditional amendments as Auxiliary Requests (“ARs”) 1-40. At the instigation of the JR it explained (submission of 13.1.2026) why the number is reasonable in view of the circumstances of the case, pointing at the complexity of the case, the great number of validity attacks submitted by Moderna referred to by GSK as a ‘scattershot’ approach, and the importance of the patent, evidenced by the fact that the highest possible value in dispute possible has been selected (by both claimant and defendants in the counterclaim, “CC”6). GSK also points out that the forty ARs relate to 18 new features only.
5. Moderna replied, firstly pointing out that the total number of ARs is potentially much higher because combination of ARs with other ARs, other requests and other subject matter is asserted by GSK in its application to amend. According to Moderna the ARs relate to twenty new features. Moderna also challenges inter alia the allegedly unstructured and non-convergent nature of the ARs. It points out that at the EPO opposition proceedings only 11 ARs were pursued. Moderna submits that GSK should be directed to
 - (a) elect a single, genuinely convergent line of amendments tied to the pleaded objections
 - (b) confine themselves to ARs that are properly substantiated with a clear, objection-specific rationale
 - (c) limit the number of ARs to 10 and
 - (d) eschew any further reshuffling or recombination beyond a fixed, notified set.
6. GSK replied to this, the requesting the court to:
 - (i) find that GSK’s 40 ARs is reasonable in number under R. 30.1(c) RoP
 - (ii) dismiss Moderna’s requests to limit GSK’s ARs to 10 ARs or to dismiss ARs en bloc.

R.9 application to dismiss late-filed submissions and arguments

7. On 19 January 2026, Moderna filed a R.9 application, objecting to several of GSK’s allegedly late-filed submissions and arguments in its Reply. In short Moderna requests the court to order GSK to remove:
 - the Cryo-TEM images of the attacked products (**Exhibits BB74A-G**) from the proceedings

- the expert opinion of [REDACTED] including annexes (see **Exhibit BB68A-B**), in the alternative, to remove those sections of the expert opinion of [REDACTED] which are based on the Cryo-TEM images
- any new explanations of why the facts relied on in the SoC would constitute an infringement.
- its extensive new sections on claim construction or at least those parts which are not strictly in response to Moderna's claim construction (p. 37 to 55 of GSK's Reply).

In the alternative Moderna requests the court to disregard the mentioned sections and exhibits.

8. GSK asks the court to dismiss Moderna's application and to allow GSK's submissions in the Reply to stay in the proceedings, awarding costs for the application to GSK, alternatively to defer a decision on the application to the main action. With reference to case law of the UPC it points out that it is permitted to further substantiate arguments already made in its SoC, especially in response to arguments raised by the other party in its defence.
9. On 11 February 2026, Moderna submitted another pleading titled 'Inquiry about decision on application pursuant to R.9 RoP to dismiss late-filed submissions and arguments', requesting the court to issue a decision on the R.9 application and to stay all procedural deadlines until that decision has been rendered. GSK uploaded a request to be allowed to respond to the 'request to stay'.

GROUNDS

R.263 application to amend the claim

10. The R.263 application is admissible and leave to change the claim accordingly shall be granted. As clarified by the CoA, inter alia on 14 February 2025 in UPC_CoA_328/2024 (Abbott/Sibio), there is no need for a limitation of an injunction to specific infringing products. In the present case, GSK, in the SoC, requested general injunctive relief to prohibit infringement of claim 1 and several other claims, whereby the specific products Spikevax and Resvia are mentioned as examples, but where the requested relief is not limited thereto:

"A liposome (...) such as the Infringing Products (the Spikevax Infringing Products and mRESVIA Infringing Products individually and jointly), and/or further versions or variants thereof," [emphasis added]

This means that relief against other products, in particular new versions or variants that fall within the scope of protection of the claims, already fall within the request from the start of the proceedings. There was thus no need to amend the claim to include the new allegedly infringing product mNEXSPIKE.

11. Also, in case defendants reasoning is followed, and the adding of a new product is considered a change of claim or amendment of the case, the court finds the amendment admissible as it meets the requirements of R.263.2 RoP. The court is satisfied that the request could not have been made with reasonable diligence at an earlier stage in the proceedings, as the EMA only gave a positive opinion for the marketing of mNEXSPIKE for the territory relevant for these proceedings in December 2025. The fact that an FDA approval (for the US) had been granted for the product just before the filing of SoC does not imply that GSK should have known that it would become available for the European market shortly. The court is also satisfied that defendants are not reasonably hindered in the conduct of its action by the addition. Defendants did not dispute in its reply to the application that the new product is a newer

version of the products already specifically mentioned in the SoC with the same or a similar relevant composition.

Number of ARs R.30.1 RoP

12. Regarding the number of ARs, the court firstly points out that the number of conditional ARs submitted with the R.30.1 application to amend, is understood to be forty. The admissibility of further possible combinations is subject to approval pursuant to a R.30.2 RoP request.
13. The court is at this point not convinced that the forty proposed conditional ARs (concerning at least eighteen new features), are reasonable in the circumstances of the case. GSK's assertion that this is triggered by the great number of validity attacks, is not shared by the court. The number of attacks seem to be limited in number and reasonable in view of the complexity of the case (the court counted one added matter attack against claim 1, several insufficiency attacks, one directed at second medical use claim 13, two novelty attacks and two main prior art docs relied on for inventive step, whereby one of the prior art documents relied on for inventive step is also combined with CGK and two other prior art documents for further attacks). Furthermore, although GSK did indicate the order in which the court should address the ARs in case the patent as granted is deemed invalid, the forty ARs are not presented in a objection-related way. No tabular overview of the ARs is presented. It is questionable whether, in proceedings before the UPC that aim to render speedy decisions within fourteen months, it is feasible to address so many ARs.
14. However, the possible limitation of the ARs is a topic that will be discussed during the IC. To assist the court and the other parties, GSK is ordered to submit a comprehensive tabular overview of its ARs, clearly indicating which (combination of) features is introduced with each AR and indicating in one column which invalidity attack(s) is(are) addressed. Such overview must be submitted within one week from today. Moderna's requests to dismiss the ARs *en bloc* (Moderna's 21 January 2026 submission at 1.1) or to limit the number to ten, is dismissed.

R.9 application to dismiss late-filed submissions and arguments

15. The contested arguments and further evidence submitted by GSK in its Reply, are permitted as in the circumstances of the present case these are considered a response to position taken by Moderna in the statement of defence/counterclaim concerning non-infringement and claim-construction. The further arguments/submissions objected to, including the Cryo-TEM images in support of infringement, mostly further expand on arguments GSK already made in the SoC. The front-loaded character of the proceedings does not require a claimant to anticipate every defence/argument of defendants in its SoC, if this is even possible. To disallow the arguments/evidence objected to would in the present case interfere with GSK's right to be heard. Moreover, Moderna has sufficient opportunity to respond, both in one more written round and during the oral hearing.
16. The R.9 application to admit allegedly late-filed submissions and arguments, is thus dismissed. Defendants' subsequent request to decide thereon is herewith addressed. The requested stay of all deadlines until a decision on Moderna's R.9 application is taken, is dismissed. In view of the latter decision, there is no need for GSK to respond to the request to stay.

ORDER

The court having heard the parties,

1. grants GSK's R.263 application for leave to amend the claim;

2. dismisses Moderna's R.9 application;
3. orders GSK to submit, within one week from today, a tabular overview of its ARs as set out in 14 above;
4. cost decisions are referred to the main proceedings.

Margot
Elsa Kokke

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by Margot Elsa
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