Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

The Hague - Local Division
UPC_CFI_616/2025
UPC_CFI_1439/2025

Order
of the Court of First Instance of the Unified Patent Court
delivered on 11/09/2026

CLAIMANT/DEFENDANT IN THE COUNTERCLAIM

1) **GlaxoSmithKline Biologicals SA** (Claimant) - Rue de l'Institut 89 - 1330 - Rixensart - BE

Represented by Tjibbe Douma, Carlos van Staveren, Nicole Jadeja and Emilia Zalewska of Bird & Bird LLP

DEFENDANTS/COUNTERCLAIMANTS

1) **Moderna Netherlands B.V.**
Claude Debussylaan 7 - 1082 MC - Amsterdam - NL

2) **Moderna Biotech Spain, S.L.**
C/Julián Camarillo 31 - 28037 - Madrid - ES

3) **Moderna Biotech UK Limited**
54 Portland Place - W1B 1DY - London - GB

4) **Moderna Biotech Distributor UK Ltd**
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.**
Rondo Ignacego Daszynskiego 1 - 00-843 - Warsaw - PL

7) **Moderna, Inc.**
325 Binney Street - MA 02142 - Cambridge - US

8) **ModernaTX, Inc.**
325 Binney Street - MA 02142 - Cambridge - US

9) **Moderna Belgium S.R.L.**
Avenue Marnix 23 - 1000 - Brussels - BE

10) **Moderna France SASU**
19 Rue Cognacq-Jay - 75007 - Paris - FR

11) **Moderna Germany GmbH**
Brienner Strasse 45 a-d c/o Design Offices, Campus Köningsplatz - 80333 - Munich - DE

12) **Moderna Italy S.R.L.**
Via Vittorio Veneto 54/B - CAP 00187 - Rome - IT

13) **Moderna Portugal Unipessoal LDA**
Rua Joâo Chagas, 10-B Direito - 1500-493 - Lisbon - PT

14) **Moderna Sweden AB**
c/o Scandinavian Trust AB, Birder Jarlsgatan 12 - 114 34 - Stockholm - SE

15) **Moderna Norway A/S**
c/o CSC (Norway) AS, Wergelandsveien 7 - 0167 - Oslo – NO

Defendants 1-15 are **represented by** Gertjan Kuipers, Andreas von Falck, Lukas Sievers, Floris Patijn and others of Hogan Lovells Cadwalader

PATENT AT ISSUE

EP2590626 B1	GlaxoSmithKline Biologicals SA

The panel/deciding judge

The composition of the panel is as follows:

Edger Brinkman	presiding judge
Stefan Schilling	legally qualified judge
Martin Schmidt	technically qualified judge
Margot Kokke	judge-rapporteur

This order is issued by panel.

Language of the proceedings: English

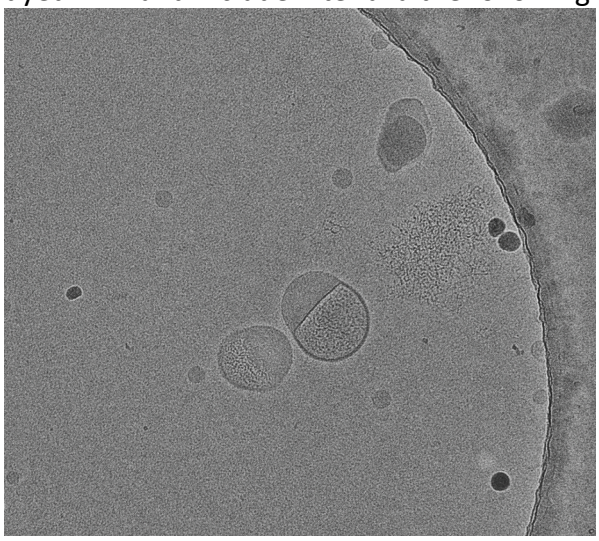
Subject matter of the proceedings: Infringement action, counterclaim for revocation and application to amend the patent.

SUMMARY OF FACTS AND GROUNDS

1. The claimant, **GSK**, initiated infringement proceedings against the defendants, collectively: **Moderna**. Moderna filed a counterclaim for revocation as part of their defence. During the interim conference (**IC**), held on 12 June 2026, the judge-rapporteur (**JR**) dismissed exhibits BB140A-E and the parts of the second expert declaration by Forrest relating thereto, including exhibit BB137B.11. Exhibits BB140A-E and BB137B.11 are collectively referred to as the **New ATEM reports**. These exhibits were considered late-filed, as they pertain to the issue of

infringement yet were only submitted with GSK's final written submission regarding the counterclaim. The rejection was confirmed in the R.105.5 RoP order of 12 June 2026 (in the operative part at I.). The New ATEM reports were generated by the research company ATEM and contain Cryo-TEM data with stained/dyed RNA of the accused products.

2. ATEM reports with cryo-TEM images of the attacked products submitted by GSK as exhibit BB74(A-G) and supplemented by Moderna with the ATEM document titled '*Method notes, LNP Classification, Precision & Accuracy*' (exhibit HL75), are part of the file (collectively: the **First ATEM Reports**). These reports describe and depict images of the attacked products without dyed RNA and include inter alia the following image of attacked product Spikevax:



3. The oral hearing (OH) in the infringement proceedings and the counterclaim for revocation took place on 1 September 2026. During the OH, the defendants not only maintained their position that the cryo-TEM images shown in Figure 3 of the publication referred to as "Brader", are not indicative for the accused products, but furthermore (inter alia) disputed that an aqueous core is present in the accused products and that RNA is present in that aqueous core.

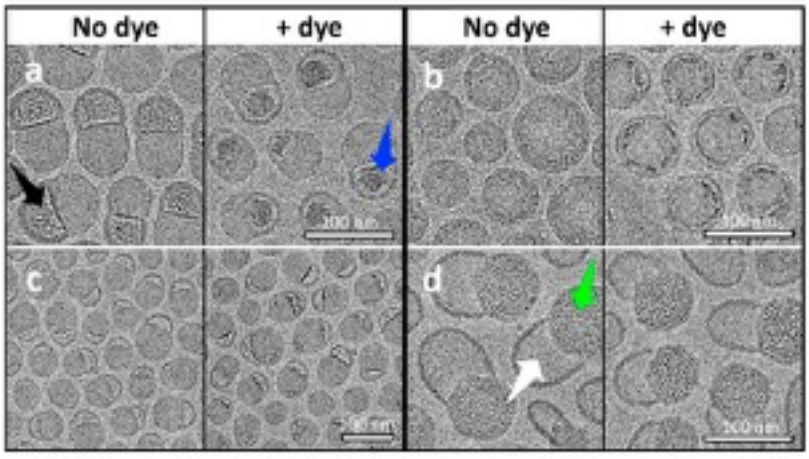


FIGURE 3 Locating encapsulated mRNA in LNPs by cryo-EM. The effect of thionine on mRNA-LNPs of different morphologies reveals that lipid-dissociated mRNA may reside in bleb compartments (*a*) or may be more lipid-associated in spherical (*b*) or less prominently blebbed particles (*c*). The black arrow in (*a*) indicates the distinctive mottled mass density of mRNA inside the bleb cavity, which itself is distinguished by a thick, dark periphery. The blue arrow indicates the significant contrast enhancement that occurs when thionine dye is present, thereby identifying mRNA within the bleb. (*d*) Charge-driven migration of mRNA from the bleb into the body of the LNP. When the mRNA-LNP sample of (*a*) (no dye) was dialyzed into pH 5 buffer, the images of (*d*) resulted. The mottled density is now associated with the body of the LNP (*green arrow*), leaving the bleb cavity devoid of mRNA (*white arrow*). Addition of thionine to this sample produced no notable contrast change (*right*), indicating that thionine did not displace lipid.

4. After the OH, on 3 September 2026, the presiding judge sent the following communication to the parties via CMS:

The panel is contemplating to revoke the order of the JR regarding the admissibility of the stained/dyed Cryo-TEM images of the attack product in view of the arguments made and positions taken by the respective parties during the OH (R.335 RoP). Pursuant to R.337 RoP parties are herewith given the opportunity to comment ultimately on Monday 7 September 2026 (maximum 600 words).

5. Both parties responded on 7 September 2026. GSK requests the reports to be admitted. Moderna consider the proposed admissions of the New ATEM reports procedurally impermissible and improper. Alternatively, Moderna submits that it could agree to the admission of the New ATEM reports into the proceedings subject to the following two conditions:

   (1) GSK should fully and clearly explain how and where the claimed structural features of a liposome, as well as the position of SM-102, are shown in the Cryo-TEM images.
   (2) Moderna should be given the opportunity to respond thereto. This material was not a subject of the oral hearing. Thus, giving Moderna the opportunity to at least respond in writing is necessary to safeguard its right to be heard (Art. 76(2) UPCA; Art. 6 EHRC, Art. 47, 41(2) CFR).

GROUNDS

6. The panel makes use of its case management powers and revokes the R.105.5 order of the JR dated 12 June 2026 according to R. 335 RoP insofar as it concerns the rejection of the New ATEM reports into the proceedings.

7. While the rejecting order was appropriate at the time of its issuance because the evidence provided was not made within the briefs relating to the infringement action, the discussion at the oral hearing requires a new assessment of this order. During the oral hearing it became more apparent that the exact location of the mRNA within the particles, the presence of water and the nature of the aqueous core was at the centre of the infringement discussion. Hence, the new ATEM Reports containing Cryo-TEM data with stained/dyed RNA of the accused products have matured to be of significance to the assessment of infringement. Fairness requires their admittance to the case. And fairness also requires that the opposing party is given a chance to comment on them (see below).

8. In addition, admitting this – already provided – evidence is suitable to promote fact-finding and to serve the interest of justice. Furthermore, the evidence in question is limited and very specific. It consists of the New ATEM reports containing Cryo-TEM images of the attacked products with stained/dyed RNA. As this evidence was previously submitted to the proceedings but rejected as late-filed (see 1 above) the parties are already familiar with it. The evidence is readily available and straightforward to re-admit. It relates to the defendants' own products whose exact specifications and design should be known to them in any case.

9. Admitting this evidence is therefore appropriate and proportionate, as well as necessary for a proper assessment of the proceedings. It will assist the Court, including in the event of an appeal, where such new evidence may not be permitted.

10. Moderna's procedural objection is dismissed. The panel finds a procedural basis for admitting further evidence in its case management powers according to R. 334 RoP in combination with R.335 RoP. R.331.3 RoP, when read with R.335 RoP, creates the possibility to revoke or vary an

earlier case management order. In this case, this would mean overturning the JR's decision not to admit the evidence in question, as confirmed in the R.105.5 order of 12 June 2026 at I. This can be done at any stage of the proceedings, also in the oral phase.

11. To safeguard the right to be heard, GSK is given the opportunity to submit a concise written explanation alongside the uploading of the New ATEM reports only, as set out below. Re-submission of the original, unrevised, second declaration of Forrest is not permitted. Moderna can respond to this submission in writing, as set out below. Given the limited scope of the additional evidence and the fact that it was previously submitted but rejected, such response is considered sufficient to meet the requirements of Art. 76(2) UPCA.

12. The target date for the issuing of the decision (R.118.6 RoP), as communicated at the OH, remains unaffected.

13. In view of the above, the panel does not consider the revocation of the JR decision to fall within the scope of R.114 RoP. However, should R.114 RoP be nonetheless considered to apply, the panel finds that the specific circumstances of this case constitute an exceptional case (the evidence is already available, it will not lead to any (noticeable) delay and hence no need for adjournment of the case).

ORDER

For all these reasons and after having heard the parties, the Court

I. Revokes the R.105.5 order of the JR dated 12 June 2026 insofar as it concerns the rejection of the New ATEM reports into the proceedings;

II. Orders GSK to resubmit the dismissed exhibits BB140A-E and exhibit BB137B.11 into the proceedings, together with a concise explanation of no more than 600 words, by **16 September 2026**;

III. Allows Moderna to respond to the aforementioned submission within one week of the exhibits being uploaded to the CMS, with a submission of no more than 900 words.

Brinkman	Brinkman Edger Frank Digitally signed by Brinkman Edger Frank Date: 2026.09.11 12:49:35 +02'00'
Schilling	STEFAN SCHILLING Digital signiert von STEFAN SCHILLING DN: cn=STEFAN SCHILLING, c=DE, email=stefan.schilling@unifiedpatentcourt.org Datum: 2026.09.11 13:45:19 +02'00'
Schmidt	Martin SCHMIDT Signature numérique de Martin SCHMIDT Date : 2026.09.11 14:49:45 +02'00'
Kokke	Digitally signed Kokke Margot Elsa 2026-09-11 15:43:55 +0200 Unified Patent Court Einheitliches Patentgericht Juridiction unifiée du brevet
On behalf of the deputy registrar	Digitally signed Swinkels Nikki 2026-09-11 16:06:18 +0200 Unified Patent Court Einheitliches Patentgericht Juridiction unifiée du brevet