UPC CFI, Local Division Munich, 3 April 2025, Promosome v BioNTech

reengineering mrna primary structure for enhanced protein production

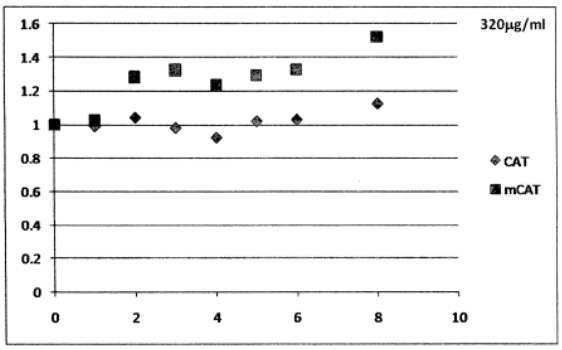

Figure 1A

PATENT LAW – PROCEDURAL LAW

Request to produce evidence rejected (Article 59 UPCA, R. 190 RoP)

- **The Defendants have not indicated what fact(s) they intend to prove by relying on the requested evidence. For this reason, the requests in the Application to produce evidence must be rejected as inadmissible or, at least, not well-founded.**

Source: Unified Patent Court

UPC CFI, Local Division Munich,
2 April 2025
(Kupecz)
UPC_CFI_846/2024
Order
of the Court of First Instance of the Unified Patent Court issued on 3 April 2025
CLAIMANT IN THE MAIN PROCEEDINGS
Promosome LLC, 48 Gurley Road, 06902 Stamford, Connecticut, US,
represented by: Georg A. Rauh of Vossius & Partner Patentanwälte Rechtsanwälte mbB, Siebertstr. 3, 81675 München, DE.
DEFENDANTS IN THE MAIN PROCEEDINGS (APPLICANTS):
1. BioNTech SE, An der Goldgrube 12, 55131 Mainz, Germany,
2. BioNTech Manufacturing GmbH, An der Goldgrube 12, 55131 Mainz, Germany,
3. BioNTech Manufacturing Marburg GmbH, Emil-von-Bering-Straße 76, 35041 Marburg, Germany,
4. BioNTech Innovative Manufacturing Services GmbH, Vollmersbachstraße 66, 55743 IdarOberstein, Germany,
5. BioNTech Europe GmbH, An der Goldgrube 12, c/o BioNTech SE, 55131 Mainz, Germany,
represented by: Christine Kanz of HOYNG ROKH MONEGIER, Steinstrasse 20 - 40212 – Düsseldorf, DE. (for Defendants 1-5).
6. Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs-Sint-Amands, Belgium,
7. Pfizer SAS, 23-25 Avenue du Docteur Lannelongue, 75014 Paris, France,
8. Pfizer AB, Solnavägen 3h, 11363 Stockholm, Sweden,
9. Pfizer, Inc., 66 Hudson Boulevard East, 10001-2192, New York, USA.
represented by: Tobias J. Hessel of Clifford Chance Partnerschaft mbB Königsallee 59 - 40215 – Düsseldorf, DE (for Defendants 6-9)
Defendants 1-9 are collectively referred to as *"the Defendants"*.
PATENT AT ISSUE:
European patent EP 2 401 365.
PANEL/DIVISION:
Panel 2 of the Local Division Munich.
DECIDING JUDGE:
This order has been issued by András Kupecz as judge-rapporteur.
LANGUAGE OF THE PROCEEDINGS:
English.
SUBJECT OF THE PROCEEDINGS:
Patent infringement action – R. 190 RoP Request to produce evidence.
SUMMARY OF FACTS AND REQUESTS
In their applications dated 7 March 2025 (number 11376/2025, on behalf of Defendants 1-5, and number 11372/2025 on behalf of Defendants 6-9, with identical substance, herein jointly referred to as *'the Application'*), the Defendants bring forward that the submission of the detailed materials and methods of all experiments and raw data underlying the report submitted in the infringement proceeding under docket numbers ACT_68533/2024_UPC_CFI_846/2024 as Exhibit VB 6 and named *"Expert Report in the context of patent infringement proceedings Promosome LLC against BioNTech SE et al. Unified Patent Court, Local Division Munich*" by [redacted] is required to assess the accuracy, reliability and relevance of the test results as put forward in the [redacted] and thereby to be able to defend against the infringement assertions that the Claimant bases upon such test results. Defendants further submit that the [redacted] is based on an analysis of experiments conducted not by [redacted] but by [redacted] allegedly supervised by [redacted] and summarized in a report submitted in these proceedings as Exhibit VB 6a. The experiments therein were carried out to measure the effect of (mutating out/in) certain codons within specific polynucleotide sequences on the expression of the SARS-CoV-2 Spike protein (*"S-protein*") and on the stability of the mRNA constructs tested.
According to the Defendants, in order to be able to properly understand the data presented in the [redacted] and the conclusions drawn in the [redacted] so that the Defendants can properly engage with and respond to them in the Defendants' defences, it is necessary for them to obtain access to the detailed materials and methods of all

experiments and raw data underlying the experiments and forming the basis for [redacted] conclusions.
The Rules of Procedure, which provide for *"front-loaded"* proceedings, require the Defendants to be able to build their counterarguments as early as possible on the basis of all the data and findings used by the Claimant. Even if the Claimant were to submit the detailed materials and methods of all experiments and raw data at a later stage in the proceedings, the Defendants would be significantly restricted in their ability to defend themselves.
On this basis, the Defendants request:
I. to order the Claimant to submit detailed materials and methods of all experiments and the raw data underlying the qPCR experiments of the report submitted as Exhibit VB 6 and named "*Expert Report in the context of patent infringement proceedings Promosome LLC against BioNTech SE et al. Unified Patent Court, Local Division Munich*" by [redacted] within five working days after service of the order;
II. to order severe periodic penalty payments (Art. 82(4) UPCA) for each day of non-compliance and other sanctions according to R. 190.4(b) RoP against the Claimant in the event the evidence according to request I. is not produced, the specific form of which is left to the discretion of the court.
The Claimant opposes the request. According to the Claimant, the request by the Defendants is inadmissible and, in any case, disproportionate, since it does not aim to grant Defendants access to the means to meet their burden of proof, asforeseen in the respective provisions of the UPCA and the UPC's Rules of Procedure. The Claimant argues that Defendants would first need to dispute infringement and substantiate this claim for non-infringement by submitting own tests and experiments. Defendants are well-known and worldwide active pharmaceutical companies which have the capacities and are undisputedly able to analyze their own products (which they anyhow had to do for marketing authorization reasons). At this stage in which the Defendants have not even disputed infringement, the requested evidence is obviously not aimed at further substantiating Defendants' (non-existing) claim for non-infringement. The request is further inadmissible according to the Claimant because Defendants failed to properly specify the evidence to be provided.
On this basis, the Claimant requests to dismiss Defendants' request to provide evidence.

ORDER

The Defendants´ requests to produce evidence are rejected as inadmissible or, in any event, unfounded.

1. General principles.

According to **Art. 59(1) of the Agreement on a Unified Patent Court (*´UPCA´*)** and **Rule 190.1 Rules of Procedure (*´RoP´*)** of the Unified Patent Court (*´UPC´*), the Court may, where a party has presented reasonably available and plausible evidence in support of its claims and has, in substantiating those claims, specified evidence which lies in the control of the other party or a third party, on a reasoned request by the party specifying such evidence, order that other party or third party to produce such evidence. For the protection of confidential information, the Court may order that the evidence be disclosed to certain named persons only and be subject to appropriate terms of non-disclosure.
In accordance with the case law of the Court of Appeal (*´CoA´*) of the UPC, see order of **24 September 2024 in cases UPC CoA 298,299 and 300/2024 (Guangdong OPPO and Orope/Panasonic),** as also adopted by the **Local Division Mannheim in its order dated 20 October 2024, order number 47065/2024 in UPC CFI 471/2023 (Dish/Aylo**), the following principles apply to a request under **Rule 190 RoP.**
First of all, it should be noted that the possibility to order the production of evidence pursuant to **Rule 190 RoP** is also open for a request by a defendant, such as in the present case, to produce (counter)evidence in support of a defence (**see CoA in Guangdong OPPO and Orope/Panasonic, para. 32 et seq.).** It should furthermore be recalled that **Rule 190 RoP** implements and must be interpreted in accordance with Article 6(1) of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (see CoA, referred to above, para. 39).
As a rule, an order to produce evidence presupposes that there is a fact that is relevant to the substantiation of claims (or defences) and that the fact requires proof by the party who is making the application (also cf. the CoA referred to above, para. 36, explaining that the purpose of these provisions is to ensure that the party who has the burden of proof will have access to the tools for carrying this burden). To this end, the applicant must set out in the application which fact it wishes to prove by which means of evidence and for what reason. No evidence is required for a fact that is not (specifically) contested (see **Rule 171.2 RoP**). If a fact is not relevant to the claims (or defences) being pursued, ordering the production of evidence for such a fact is generally at least disproportionate.
An applicant for an order pursuant to **Rule 190 RoP** must have presented reasonably available and plausible evidence in support of its claims (or defences) before an application under **Rule 190 RoP** can be granted. Whether the applicant has met this requirement and, as a result, whether an order to evidence against the opponent or a third party can be considered is at the discretion of the Court. When exercising this discretion, the circumstances of the individual case must be taken into account, taking into account the mutual interests and the principle of efficient conduct of proceedings (see CoA, referred to above, para. 47, 54).
In addition, with regard to the case management powers of the judge-rapporteur, the presiding judge or the panel, there is a margin of discretion when adjudicating on a request for an order to produce evidence which also includes determining the order in which points in dispute are to be decided. In exceptional cases, an oral hearing may be adjourned in accordance with **Rule 114 RoP** in order to invite further submissions of evidence (see

CoA, referred to above, para. 54-55). The burden of presentation and proof for the existence of the prerequisites for an order to produce evidence, lies with the applicant.

2. The case at hand.

Applying the above principles to the present case, the Defendants´ requests are inadmissible or, at least, not well-founded.

The Defendants have not indicated what fact(s) they intend to prove by relying on the requested evidence. For this reason, the requests in the Application to produce evidence must be rejected as inadmissible or, at least, not well-founded.

The Defendants have stated in the Application that the experiments in Exhibit VB 6 were carried out to measure the effect of (mutating out/in) certain codons within specific polynucleotide sequences on the expression of the SARS-CoV-2 Spike protein ("*S-protein*") and on the stability of the mRNA constructs tested (para. 3 of the Application). The assays performed, according to the Defendants, are alleged to show that the absence of putative secondary start codons (within Claimant's interpretation of the patent in suit) in the Test construct 5 would lead to more S protein in cellstransfected with that construct. Defendants have questioned what weight can be attached to the data referred to in VB 6. The Defendants give as an example that certainmeasurements and (statistical) analyses are notshown or documented in VB 6. Furthermore, according to the Defendants, it is not clear from VB 6 whether N1-methylpseudouridine was used in the constructs in the experiments or not. This is important and crucial information to understand the relevance and the conclusions of these experiments, still according to the Defendants.

The Defendants have, however, so far in these proceedings, not (in any event not specifically, in a substantiated way) contested any of the facts relied on by the Claimant by reference to VB 6 nor have they raised any concrete facts or defences for which the requested evidence is likely to be required. From the assertion that "*the Defendants are not able to verify or refute the Claimant's allegations made in the Complaint based on the data relied upon in the* [redacted] *[Exhibit VB6, JR]",* it does not follow that the facts in support of which VB 6 is relied on by the Claimant are or will be disputed by the Defendants and why. At the present stage of the proceedings, i.e. after the Statement of claim has been served and before the Statement of defence is lodged, it falls first to the Defendants to indicate the facts they are relying on, including any challenge to the facts relied on by the Claimant, the evidence relied on, where available, and an indication of any further evidence which will be offered in support, as well as the reasons and arguments (of law) why the action shall fail including any challenge to the claimant´s proposed claim interpretation (see **Rule 24(e)-(g) RoP**). It is not in line with the procedural principles following from the RoP, to order the Claimant to produce the requested detailed materials and methods of all experiments and the raw data underlying the qPCR experiments of the report submitted as Exhibit VB 6, even before any concrete contestation of any relevant fact(s) has taken place and before the Defendant has made clear on which facts it will rely. This renders the Application inadmissible or, at least, makes the requested order to produce evidence disproportionate.

Secondly, it also follows from the above that, at this point in the proceedings, the Defendants have not (yet) presented any (reasonably available and plausible) evidence in support of (the facts relied on for) their defences for which the requested evidence can reasonably be expected to be relevant. Furthermore, since the facts in question ultimately relate to an alleged patent infringement by their own products, the Defendants should be able to set out why in their view the action should fail including any challenge to the facts relied upon by the Claimant. That this is impossible for the Defendants without the requested evidence has not been argued and is also not apparent to the Court. In the absence of the required reasonably available evidence, the Application must be rejected as inadmissible or, at least, not well-founded.

Thirdly, especially in the light of the foregoing, it is at least doubtful, but it does not have to be decided conclusively, whether the requested evidence ("*detailed materials and methods of all experiments and the raw data underlying the qPCR experiments")* has been sufficiently specified for the purposes of the requirements of **Rule 190.1 RoP** (which refers to "*specified evidence*"). The Defendants should have explained which concrete means of evidence – in the control of another party – they would like to obtain and for what reason (**also see Local Division The Hague, order of 14 October 2024, UPC CFI 327/2024, Winnow/Orbisk**). The Defendantsstate that they seek to "*assess the experiments and defend themselves against the conclusions drawn from them*". In the absence of any specific fact that is contested and/or relied upon by the Defendant for which the requested evidence may be relevant, this statement does, however, not make sufficiently concrete which evidence exactly is requested and for what reason.

Finally, there is no general rule connected with or following from the front-loaded nature of UPC proceedings which requires that all the data and findings used by the Claimant, including detailed materials and methods of all experiments and raw data, are submitted by the Claimant into the proceedings, let alone at this stage of the proceedings. Generally, a party is free to determine the subject-matter of, and the supporting evidence for, their case (**Art. 43 UPCA, second sentence**).

For the sake of completeness, and notwithstanding the foregoing, the Court notes that, in case this is deemed necessary, it may, at any stage in the further course of these proceedings, on request of a party, or of its own motion, order a party making a statement of fact to produce evidence that lies in the control of that party (**Rule 190**, **172.2 RoP**) and/or may order a party to answer any question or provide any clarification or evidence (**Rule 9.1 RoP**).

In conclusion, the request to produce evidence is rejected as inadmissible or, in any event, unfounded. As the request to order penalty payments (II) is dependent on the request to produce evidence (I), this request must be rejected as well.

ORDER

For these reasons, having heard the parties, the Court orders as follows:

- Defendants´ requests made in the Application dated 7 March 2025 are rejected.

INFORMATION ABOUT PANEL REVIEW

Any party may request that this Order be referred to the panel for a review pursuant to **R. 333 RoP**. Pending review, the Order shall be effective (**R. 102.2 RoP**).

DETAILS OF THE ORDER

Order no. ORD_11610/2025 in ACTION NUMBER: ACT_68533/2024 and
Order no. ORD_11611/2025 in ACTION NUMBER: ACT_68533/2024
UPC number: UPC_CFI_846/2024
Action type: Infringement Action
Related proceeding no. Application No.: 11376/2025 and
Related proceeding no. Application No.: 11372/2025
Application Type: Application for an Order to produce evidence (RoP190)
