



**Local Division Munich
UPC_CFI_15/2023**

**Procedural Order
of the Court of First Instance of the Unified Patent Court
Local Division Munich
issued on 15 November 2024**

CLAIMANT (RESPONDENT)

Edwards Lifesciences Corporation, 1 Edwards Way - 92614 - Irvine - US

represented by: Boris Kreye, Elsa Tzschope (Bird & Bird)

assisted by: Bernhard Thum, Dr. Jonas Weickert (Thum & Partner); Siddharth Kusumakar, Tessa Waldron and Bryce Matthewson (Powell Gilbert)

DEFENDANT (APPLICANT)

1) Meril Gmbh

Bornheimer Straße 135-137 - 53119 - Bonn - DE

2) Meril Life Sciences Pvt Ltd.

M1-M2, Meril Park, Survey No 135/2/B & 174/2 Muktanand Marg, Chala, Vapi - 396 191
Gujara- Vapi – IN

represented by: Dr. Andreas von Falck, Dr. Roman Würtenberger, Dr. Lukas Wollenschlaeger, Beatrice Wilden, Dr. Alexander Klicznik, Dr. Felipe Zilly (Hogan Lovells)

assisted by: Peter-Michael Weisse, Ole Dirks, Dr. Eva Maria Thörner (Wildanger)

PATENT AT ISSUE

European patent n° 3646825

PANEL/DIVISION

Panel 1 of the Local Division Munich

DECIDING JUDGE/S

This decision has been delivered by the presiding judge Dr. Matthias Zigann acting as judge-rapporteur, the legally qualified judges Margot Kokke and Tobias Pichlmaier and the technically qualified judge Dr. Stefan Wilhelm.

LANGUAGE OF THE PROCEEDINGS

English

SUBJECT-MATTER OF THE PROCEEDINGS

Infringement Action - Generic procedural Application

SUMMARY OF FACTS

The Claimant sued the Defendants for infringement of EP 3 646 825. The Defendants filed, inter alia, counterclaims for revocation. The Local Division Munich referred the counterclaims to the Central Division for decision. The patent was partially upheld.

The written procedure was closed on 15 July 2002. The interim conference was held on 5 September 2024. The interim proceedings were closed on 6 September 2024. The oral hearing was held on 24 September 2024. A date for the announcement of the decision has been set for 15 November 2024.

With brief dated 16 October 2024 defendants requested that the court asks questions to the European Commission.

The Judge-rapporteur has referred the request to the panel for decision (R 102.1 RoP).

REQUESTS

Defendants request:

On behalf and in the name of Defendants, we ask the Division to

I. ask the European Commission to transmit information about the status of the investigations into the potential violation by Claimant of EU antitrust law that prohibits the abuse of a dominant market position, the reasons for the initiation of these investigations and the timing for the next steps

II. ask the European Commission to provide a copy of any decisions that have been adopted so far, in particular, of any decisions that relate to or concern Claimant's patent filing strategy, Claimant's Global Unilateral Pro-Innovation (Anti-Copycatting) Policy and/or Claimant's patent litigation strategy against Defendants, distributors distributing products of the Defendant company and/or companies of the Defendant group; and request that

III. leave be granted for the parties to submit further written pleadings and the oral hearing be reopened, if necessary, after the European Commission has provided the information requested

Claimant requests:

Claimant requests that Defendants' Request is dismissed.

ARGUMENTS OF THE PARTIES

Defendants argue:

1. *In 2023, the European Commission carried out unannounced inspections at the premises of Claimant companies (see, for example, the European Commission's press release of 19 September 2023, submitted as Exhibit HL 48, and the article by F. Y. Chee, submitted as Exhibit HL 49). Defendants referred to these investigations inter alia in their Statement of Defence (at pp. 129 et seqq. / pp. 121 et seqq. of Exhibit HL-E 2a/b). The unannounced inspections were based on a concern about a potential violation of Art. 102 TFEU (see Exhibit HL 48). According to a publicly available article referring to a person who wished to remain anonymous, the concerns centred on Claimant's patent practices and another area in focus was Claimant's Global Unilateral Pro-Innovation (Anti-Copycatting) Policy of 15 November 2019 (submitted as Exhibit HL 50). To the best of Defendants' knowledge, the investigations are still ongoing.*

2. *Defendants take the view that further information about the status of these investigations, details about the specific grounds that gave rise to the investigations and access to decisions that have been issued in the context of these proceedings so far are highly relevant for the decision of the Court. This is true in particular with regard to Defendants' defence based on the disproportionality of an injunction and corrective measures and their request to render a decision – if in Claimant's favour – under the condition (aufschiebende Bedingung) that the patent is not held to be wholly or partially invalid by the final decision in the revocation proceedings (i.e. that the patent is held to be valid in the form as asserted by Claimant) which were discussed at the oral hearing.*

a) *Defendants brought to the attention of the Division that and why an injunction would have a significant impact on their interests. They inter alia explained that it would severely impact Defendants' business activities, that it would interfere with clinical studies and that it would be detrimental to the interests of the public (see, in addition to what was submitted with Defendants' Statement of Defence and their Rejoinder, the arguments submitted with Defendants' stay request, App_48488/2024). With reference to the litigation concerning – now revoked – EP 3 583 920 B1, Defendants underlined the severeness of the consequences an (unjustified) injunction would have. Also on this basis, Defendants take the view that neither an injunction nor corrective measures should be ordered and that Defendants' interests should be safeguarded by, for example, rendering any decision in Claimant's favour under the condition that the patent is held valid on the basis of R. 118.2(a) RoP.*

b) *For the assessment of whether there are any interests of Claimant worthy of protection that would outweigh Defendants' legitimate interests in the Division not ordering an injunction and corrective measures or in safeguarding their interests by other measures, it is highly relevant for the Division to obtain additional information on the status of, the reasons for and the next steps in the investigations by the European Commission as well as to be given access to any decisions issued so far (in particular, to those as specified in request under item II.). There will certainly be no interests of Claimant worthy of protection if Claimant's conduct is found to be abusive by the European Commission.*

3. With their requests under items no. I and II., Defendants therefore kindly ask the Division to approach the European Commission and to ask the Commission to provide further information about the investigations into the potential violation of European Union antitrust law by Claimant. The request is to be addressed by email to the Directorate-General for Competition (comp-greffe-antitrust@ec.europa.eu), with a copy to the dedicated COMP AMICUS (comp-amicus@ec.europa.eu).

Since the European Commission is subject to a general duty to assist European courts when applying EU antitrust law, based on the duty of sincere cooperation established in the Zwartveld case (see ECJ, judgement of 13 July 1990, case 2/88, ECLI:EU:C:1990:440 – Zwartveld and Others, paras. 17 and 18), the European Commission is legally required to provide information upon the Division's request. Such a request is thereby necessary because the European Commission cannot provide such information to the Court absent a request filed by the Court.

4. With their request under item no. III., Defendants further ask that the Division grants leave for the parties to submit further written pleadings and, if necessary, reopens the oral hearing after the European Commission has provided the information requested by the Division. This request is based on the interest of safeguarding Defendants' right to be heard and their right to a fair trial and submitted with a view on the duty of the Court to organize the proceedings in a flexible and balanced manner (see Art. 52(1) UPCA; recital no. 2, 4 of the Preamble of the Rules of Procedure) and on that fairness and equity shall be ensured by having regard to the legitimate interests of all parties (recital no. 5 of the Preamble of the Rules of Procedure).

Claimant argues:

Defendants' Request is to be dismissed because it is late-filed and, over and above, not justified. The Procedural Order of this Court of 18 October 2024 records that the written procedure was closed on 15 July 2024, the interim conference was held on 5 September 2024, the interim proceedings were closed on 6 September 2024, and the oral hearing was held on 24 September 2024. The Court did not grant leave for any post-hearing submissions.

Defendants' Request is, thus, filed outside of any procedural realm that would allow filing of a further written submission, let alone a request. In addition, the Court set a date for announcing its decision, namely on 15 November 2024, which could be in jeopardy if Defendants' Request is allowed.

Defendants' Request has no merit and is merely a further attempt to delay a decision of this Court in relation to the infringement of Claimant's patent. This is particularly apparent given that (i) Defendants specifically had the opportunity to make submissions in relation to the European Commission procedure at the oral hearing on 24 September 2024, when the Court enquired about its status and (ii) there has been no change in the status of the European Commission procedure since the oral hearing, and no change in circumstances that would precipitate or justify Defendants' Request. In the circumstances, Defendants' Request is clearly a delaying tactic, and allowing it would severely interfere with Claimant's right to a fair trial.

I. Information Request Late Filed

Defendants' Request was not filed within the regular procedural timetable in this case and is, therefore, contrary to the front-loaded character of UPC proceedings. Moreover, Defendants have not submitted any reason why Defendants' Request could not have been filed earlier, in particular not before the interim conference on 5 September 2024

or at least during the hearing on 24 September 2024. For this reason alone, Defendants' Request must be dismissed.

Furthermore, the UPCA and RoP do not provide for any further submissions concerning the subject-matter of the dispute at this very late stage of the proceedings. The order refers to 2002 but this is a clear typographical error.

The period after the closure of the oral hearing is dedicated exclusively to the judicial decision-making process, so that the Court may give a decision on the merits within the time set out in R. 118.6 RoP. It is to be inferred from the RoP that further submissions by the parties are excluded after the conclusion of the oral hearing except for a withdrawal of the action (Kircher in Bopp/Kircher, *Handbuch Europäischer Patentprozess*, 2nd Ed. 2023, § 12 mn. 179).

In proceedings before the UPC, the parties shall set out their full case as early as possible. This follows from point 7 of the Preamble of the RoP, which requires that proceedings are conducted in a way which will normally allow the final oral hearing at first instance to take place within one year. For this purpose, the parties shall cooperate with the Court and set out their full case as early as possible in the proceedings.

The front-loaded nature of UPC proceedings has been confirmed by multiple divisions of the UPC2, including the Munich Central Division in its order of 25 July 2024 (ORD_43029/2024, CFI_252/2023, *Nanostring v. President and Fellows of Harvard College*) in which is stated as follows:

"In proceedings at the UPC, parties shall set out their full case as early as possible. This is also referred to as the "front-loaded character" of UPC proceedings. The front-loaded character of UPC proceedings is aimed at ensuring that proceedings can normally be conducted in a way which allows the oral hearing to be conducted in within one year (point 7 of the Preamble of the RoP, also see CoA order of 28 May 2024 in case 22/2024, at 23). The front-loaded character also serves the principles of fairness and equity by preventing a party (and the Court) from being confronted with and having to react to new evidence and arguments unreasonably late in the proceedings."

While R. 12.5, R.36 RoP allow for the exchange of further written pleadings before the written procedure is closed, this is only allowed upon a reasoned request by a party. In addition to this not being applicable in the post-hearing phase of the proceedings, Defendants have not in any case made a reasoned request. In particular, no attempt has been made to explain why Defendants' Request was not made at an earlier stage of the proceedings, notwithstanding that Defendants referred to the European Commission's review already when filing their Statement of Defence and the Court invited further submissions as to the status of the European Commission's procedure at the oral hearing on 24 September 2024.

In the circumstances, Defendants' Request is clearly late-filed and should not be admitted into the proceedings.

II. No Further Information Required

European Commission Procedure

In any event, Defendants' Request serves no legitimate purpose and appears to be a thinly veiled tactic to disrupt, yet again, the Claimant's infringement claim.

Defendants ask the Court to seek information about the status of the procedure (Request I). However, as the Court will recall, the Court asked for an update in relation to the European Commission procedure already at the oral hearing on 24 September 2024. At this time, Claimant confirmed that there were no updates since the Reply, and that the preliminary procedure before the European Commission remains in the preliminary, fact-gathering stage. This remains the case. It therefore also remains the case that the European Commission has not opened any formal investigation (or even taken any steps towards opening a formal investigation). In this context, we note that while the procedure was discussed during the oral hearing, Defendants chose not to make any submissions on this topic during the oral hearing although they clearly could have done this.

It is striking that Defendants ask the Court to inquire about the reasons for the initiation of the procedure (also Request I), as – contrary to what is suggested in paragraph 1 of Defendants’ Request – it was Defendants themselves who filed the complaint with the European Commission back in 2020.

Defendants also unnecessarily seek information about the timing of the procedure (also Request I). As Defendants certainly know, if in the future the European Commission should decide to initiate a formal investigation that will become public. They know that until the European Commission reaches any such decision to open a formal proceeding there is nothing the Commission will be able to say about its preliminary review.

11. Also, Request II in Defendants’ Request that the European Commission shall “provide a copy of any decisions that have been adopted so far” is unfounded and should be dismissed. Since the procedure is still ongoing and the European Commission has not opened a formal investigation, there is no decision of the European Commission in this regard.

As the status of the procedure with the European Commission remains unchanged since the oral hearing on 24 September 2024, there is no reason why the decision scheduled for 15 November 2024 shall be delayed. Specifically, the present proceedings are ready for a decision (“entscheidungsreif”) given that the oral hearing took place and no further exchange of submissions was allowed by the Court or requested by the parties.

In addition, as stated above, the judge-rapporteur held an interim conference on 5 September 2024, which served to prepare the oral hearing (R. 109 (g) RoP). In advance of this interim conference, the parties were asked to provide a summary of orders being sought, but Defendants did not raise this issue.

During the intensive oral hearing that lasted a full day, the MLD asked the parties several questions and, inter alia, inquired further about the status of any ongoing procedure before the European Commission. Claimant explained that no formal investigation was ongoing, and that the procedure was in a fact-gathering stage. As mentioned, Defendants chose not to raise this topic or make any request, albeit they had the possibility. The MLD then closed the oral hearing after it ensured that the action was ready for a decision.

Defendants have not explained how the information sought now is relevant to the present proceedings or why it would be required to render the final decision. In particular, Defendants’ submission does not contain any new arguments that would suggest that the proceedings are not ready for a decision. Rather, Defendants refer to general statements on why an injunction would impact their business activities (p. 4). This, however, cannot be a reason for Defendants’ Request. Any potential impact an

injunction allegedly might have on Defendants should have been presented by Defendants before the closure of the hearing in the main proceedings on 24 September 2024— and in fact was presented in writing and during the hearing by them.

Defendants already had knowledge of and explicitly referred to the procedure before the European Commission in their Statement of Defence submitted on 2 November 2024 (p. 129 et seqq.). Claimant replied to Defendants' allegations in their Reply submitted on 9 January 2024 and pointed out to the fact that this procedure is merely an informal evidence-gathering procedure with no relevance to the present proceedings (mn. 50) – which is still the case.

That Defendants' Request was filed this late in the proceedings confirms that their only intention is to delay the present proceedings and the granting of an injunction by any means. Defendants have tried several times to delay and torpedo the present proceedings, inter alia, by requesting deadline extensions, filing a separate revocation action by another legal entity of the Meril group before the Paris Central Division and by submitting a stay request after the Patent-in-Suit was upheld by the Paris Central Division. However, this procedural behaviour is not in line with the aims of the UPC and the principles of proportionality, flexibility, fairness and equity as stated in point 2 of the Preamble of the RoP.

III. Claimant's Right to an Effective Legal Remedy

Admitting Defendants' Request after the oral hearing would interfere with Claimant's fundamental right to an effective legal remedy and a fair and public hearing within reasonable time as guaranteed by Art. 6 of the European Convention for the Protection of Human Rights and Fundamental Freedoms and, to the extent that European Law is concerned, Art. 47 of the Charter (see also the order of the CoA of 28 May 2024, UPC_CoA_22/2024, Carrier v. BITZER, mn. 22).

Claimant brought the infringement action against Defendants before the Court on the first day of the UPCA's entry into force (1 June 2023) and has a legitimate interest in a timely decision in its case (see also point 6 of the Preamble of the RoP).

IV. On an Auxiliary Basis: Requirements of R. 263.2 RoP are not Fulfilled

Claimant submits on an auxiliary basis that by raising new requests in Defendants' Request, Defendants amend their case within the meaning of R. 263.1 RoP. However, Defendants did not explain why such amendment was not included in their original pleading and they did not satisfy the requirements of R. 263.2 RoP.

As stated above (mn. 5), the amendment could have been made with reasonable diligence at an earlier stage pursuant to R. 263.2 (a) RoP, as Defendants were aware of the procedure initiated by the European Commission. Furthermore, the amendment obviously hinders Claimant in the conduct of its action as it would very likely delay the rendering of a final decision before this Court on 15 November 2024.

GROUND FOR THE ORDER

Defendants' Request is rejected because it is late filed.

I. Under R 9.2 RoP the Court may disregard any step, fact, evidence or argument which a party has not taken or submitted in accordance with a time limit set by the Court or these Rules. Under R 36 RoP the judge-rapporteur, without prejudice to the powers of the judge-rapporteur pursuant to Rule 110.1, on a reasoned request by a party lodged before the date on which the judge-rapporteur intends to close the written procedure [Rule 35(a)], may allow the exchange of further written pleadings, within a period to be specified. Where the exchange of further written pleadings is allowed, the written procedure shall be deemed closed upon expiry of the specified period.

II. The written procedure was closed on 15 July 2024, the interim conference was held on 5 September 2024, the interim proceedings were closed on 6 September 2024 and the oral hearing was held on 24 September 2024. The Court did not allow any post-hearing submissions. The Defendants' request is thus filed outside any procedural realm that would permit the filing of a further written submission, let alone a request.

III. In addition, the Court has set a date for the announcement of its decision, namely 15 November 2024, which could be jeopardised if the defendants' request is granted.

IV. The Court had already asked for an update on the European Commission's proceedings at the hearing on 24 September 2024, and the Claimant confirmed that there had been no update since the reply and that the preliminary proceedings before the European Commission remained at the preliminary stage of fact-finding. It therefore remains the case that the European Commission has not opened a formal investigation (or even taken any steps towards opening a formal investigation). This was undisputed at the time of the Oral Hearing. The Defendants do not claim that this has changed since then. Therefore, the Panel considers that there is no need to ask the European Commission as requested.

ORDER

Defendants' request is rejected.

INFORMATION ABOUT APPEAL IN CASE OF AN ORDER FALLING UNDER ART. 73(2)(B) UPCA:

The present order may either - be the subject of an appeal by any party which has been unsuccessful, in whole or in part, in its submissions together with the appeal against the final decision of the Court of First Instance in the main proceedings, or - be appealed by any party which has been unsuccessful, in whole or in part, in its submissions at the Court of Appeal with the leave of the Court of First Instance within 15 days of service of the Court of First Instance's decision to that effect (Art. 73(2)(b) UPCA, R. 220.2, 224.1(b) RoP)

DETAILS OF THE ORDER

Order no. ORD_56918/2024 in ACTION NUMBER: ACT_459987/2023

UPC number: UPC_CFI_15/2023

Action type: Infringement Action

Related proceeding no. Application No.: 56354/2024

Application Type: Generic procedural Application

Done and delivered in Munich on 15 November 2024

Dr. Zigann Presiding Judge and Judge-rapporteur	
Kokke Legally Qualified Judge	
Pichlmaier Legally Qualified Judge	
Dr. Wilhelm Technically Qualified Judge	
for the Deputy Registrar	