



Central Division (Section Munich)

UPC_CFI_80/2023

Order

**of the Court of First Instance of the Unified Patent Court
delivered on 17/11/2023**

APPLICANT

- 1) **ASTELLAS INSTITUTE FOR REGENERATIVE MEDICINE** Represented by David Carling
(Claimant in the main proceedings) - 9 Technology Drive - MA 01581 - Westborough - US

RESPONDENTS

- 1) **Healios K.K** Represented by James Nicholls
(Defendant in the main proceedings) - 7-1, Yuraku-cho 1-chome Chiyoda-ku - 100-0006 - Tokyo - JP
- 2) **Osaka University** Represented by James Nicholls
(Defendant in the main proceedings) 1-1 Yamadaoka Suita-shi - 565-0871 - Osaka - JP

PATENT AT ISSUE

Patent no.

Proprietor/s

EP3056564

Healios K.K, Osaka University

PANEL/DIVISION

Panel 1 of the Central Division (Section Munich).

DECIDING JUDGE

This Order is an order of the Judge-rapporteur András Kupecz.

LANGUAGE OF PROCEEDINGS:

English.

SUBJECT-MATTER OF THE PROCEEDINGS

Revocation action. Rule 262A RoP.

STATEMENT OF THE FORMS OF ORDER SOUGHT BY THE PARTIES

The applicant, claimant in the main proceedings (herein referred to as ‘Claimant’), is requesting:

1. Access to the Confidential Annex to be restricted solely to such persons referenced in, and to the extent necessary to comply with, RoP Rule 262A(6), and for no wider access by the Defendants (or any third party accessing, or requesting to access, the case file on the CMS) to be permitted by the Court.
2. Along with the UPC Representative for the Defendants, the Defendants propose a single person at each Defendant entity who shall be permitted to access the Confidential Annex, and give instructions to the Defendants’ UPC Representative, in response to this Application, pursuant to RoP Rule 262A(4).

The respondents, defendants in the main proceedings (herein referred to as ‘Defendants’), is requesting:

1. Unrestricted access to the Confidential Annex.
2. (In an auxiliary way as understood by the Court) access to be restricted to a number of specific persons listed.

SUMMARY OF THE FACTS AND POINTS AT ISSUE

The present application for the protection of confidential information (‘the Application’) was made by the Claimant in the main proceedings pursuant to Rule 262A of the Rules of Procedure of the Unified Patent Court (‘RoP’), but could for technical reasons not be submitted using the dedicated workflow in the Case Management System (‘CMS’). The Claimant for this reason made the Application using the Rule 9 RoP workflow. In view of the nature of the present Application, the Court decided to proceed in the present workflow pending resolution of the technical issues with the CMS.

The Application relates to an exhibit referred to as the “Confidential Annex” submitted by the Claimant and relied upon in the context of a request to stay proceedings pending the outcome of opposition proceedings at the European Patent Office made by Defendants. The Confidential Annex is described in the Claimant’s response to the Defendants’ request for a stay as “the

development timeline of the Product, as presented in an internal leadership meeting on 14 June 2023 (the “Launch Date”), and is being filed to corroborate the statement that “product launch will be achieved significantly ahead of the expiry of the Patent in 2034” (paragraph 10 of the Claimant’s response).

Defendants oppose the Application arguing that they should have unrestricted access as the timing of the “Launch Date” both relative to patent expiry and relative to the expected date of the EPO’s decision in the opposition proceedings is important for determining whether a stay is appropriate, and hence for fully understanding the Claimant’s position.

Pursuant to Rule 262A.4 RoP, before an order restricting access to specific persons as requested by the Applicant can be issued, the representative of the other parties must be invited to submit written comments. As held by the Hamburg Local Division in its (preliminary) Order dated 4 October 2023 (577763 in case ACT_463258/2023, published on the UPC website under “Decisions and Orders”), in the interest of the effective protection of (alleged) trade secrets, at that stage of the proceedings, until a final order upon the Application is rendered, access to the Confidential Annex may be further restricted to the (UPC) representatives of the parties only. Accordingly, the Court in the present case, by way of Preliminary Order dated 2 November 2023, restricted access to the Confidential Annex to the UPC representatives of the Defendants until a final order upon the Application was rendered and ordered the Defendants to identify and name specific persons, including their employers and job titles, that should obtain access to the Confidential Annex.

The Defendants provided written comments to the Application on 9 November 2023. The Claimant provide further comments on 14 November 2023.

Further facts and arguments as brought forward by the parties will, where relevant, be discussed in the below.

GROUNDS FOR THE ORDER

In line with the Hamburg Local Division in its final order following the above preliminary order (same order number, dated 3 November 2023, also published on the UPC website), the Central Division Munich section recognises that according to Article 9 (1) and (2) (sub a) of Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure that, in legal proceedings, access to any document containing trade secrets or alleged trade secrets submitted by the parties may be restricted, in whole or in part, to a limited number of persons. In the Agreement on a Unified Patent Court (‘UPCA’), the protection of trade secrets, personal data or other confidential information is provided for in Article 58 UPCA which has been implemented in Rule 262A RoP.

In the present case, the Application made by the Claimant meets the (formal) requirements of Rule 262A RoP. It contains the grounds upon which the Applicant believes the access to the Confidential Annex should be restricted (Rule 262A.2 RoP). The Claimant indicated that it did not wish to submit a redacted version of the Confidential Annex. In the view of the Court this is permissible as Rule 262A.3 RoP does not oblige a party to submit a redacted version (cf. “if applicable” in Rule 262A.3 RoP). The Court has invited written comments from the other parties pursuant to Rule 262A.4 RoP and the other parties provided comments as outlined above.

It is not in dispute between the parties that the contents of the Confidential Annex constitute highly confidential, commercially sensitive information within the meaning of Article 58 UPCA. The parties have different views on whether access to this information should be limited and, if so, who should have access. The Claimant requests that access to the Confidential Annex is restricted to a single person at each Defendant entity and the Defendants' UPC representative. The Defendants consider that they should be allowed unrestricted access to the Confidential Annex to fully understand the Claimant's legal position in relation to a requested stay of proceedings pending the conclusion of EPO opposition proceedings.

In the Court's view, it is not necessary for the Defendants to have *unrestricted* access to the Confidential Annex in order to meet the objective of understanding Claimant's legal position. Claimant is asking for a confidentiality order in relation to a specific document, whereas its legal position is set out in detail in its pleadings which have not been marked as confidential by the Claimant. The interests of the Claimant in keeping confidential the commercially sensitive information embodied in the Confidential Annex in any event outweigh the interests of the Defendants in having unrestricted access. Access shall therefore be restricted to specific natural persons.

As to how many (and which) persons should have access, in accordance with Rule 262A.6 RoP, the number of persons shall be no greater than necessary in order to ensure compliance with the right of the parties to the legal proceedings to an effective remedy and to a fair trial, and shall include, at least, one natural person from each party and the respective lawyers or other representatives of those parties to the legal proceedings.

Against this background, the Court will restrict access to, apart from the UPC representatives of the Defendants, three named natural persons. The Court takes into account that, even though the Defendants did not suggest any specific persons for Defendant 2, also this party has a right to have at least one natural person access the information pursuant to Rule 262A.6 RoP. A "natural person from a party" in the sense of said provision is, as held by the Hamburg Local Division (final order referenced above, p. 7, 4th par.), not limited to employees of that party.

The natural persons who should have access – under a strict confidentiality obligation as set out below – will be restricted to the two employees of HEALIOS K.K.'s legal division named below and one of the Defendants' external Japanese patent attorneys named below (who is understood to be an external advisor for Defendant 2, see Defendants' reply to Preliminary Order dated 9 November 2023, p. 2, bottom). Given the nature of the Confidential Annex and the limited context it is relied upon in these legal proceedings, restricting access to these persons is deemed adequate (but also necessary) to comply with the Defendants' procedural rights as mentioned above. Particularly, the Court does not see a necessity for HEALIOS K.K. employees outside the legal function, in a general management or business development function, to have access to the Confidential Annex.

The Claimant has furthermore requested the Court to keep confidential the information in the Confidential Annex from any third party accessing, or requesting to access, the case file on the CMS. The Court understands this to be a request pursuant to Rule 262.2 RoP (which deals with public access as opposed to Rule 262A RoP which deals with the protection of confidential information vis-à-vis the parties to legal proceedings). The Court grants this request for the reasons set out above. In accordance with Rule 262.2 RoP, the Claimant should, however, have provided a redacted version of the Confidential Annex for this purpose (cf. "shall also provide copies ... when making the request" in Rule 262.2 RoP, last sentence). The Court will therefore

order the Claimant to upload a redacted version of the Confidential Annex within seven calendar days of the date of this order.

Leave to appeal is granted as this is one of the first orders of the UPC deciding on a request pursuant to Rule 262A and the Court shall endeavour to ensure consistent application and interpretation of these Rules (Preamble RoP, 8).

ORDER

For these grounds, having heard the parties on all aspects of relevance for the following order, the Court orders:

1. The Confidential Annex is to be treated as strictly confidential and may not be used or disclosed outside of or for any other purpose than the present legal proceedings, even after the conclusion thereof. Access to the Confidential Annex is restricted to the UPC representatives of the Defendants in these legal proceedings and the following natural persons:

- ..., HEALIOS K.K.
- ..., HEALIOS K.K.
- ..., TAKASHIMA International Patent Office.

2. Any further access to the Confidential Annex is prohibited.

3. The Court's Preliminary Order dated 2 November 2023 ceases to have effect to the extent it goes beyond the present order.

4. The Confidential Annex is to be kept confidential in accordance with Rule 262.2 RoP.

5. The Claimant is ordered to provide a redacted version of the Confidential Annex for the purposes of Rule 262.2 RoP within seven calendar days of the date of this order.

6. Leave to appeal this order is granted.

Issued on 17 November 2023

KUPECZ
Judge-rapporteur

ORDER DETAILS

Order no. 584830 in ACTION NUMBER: ACT_465342/2023

UPC number: UPC_CFI_80/2023

Action type: Revocation Action

Related proceeding no. Application No.: 584332/2023

Application Type: Generic procedural Application

INFORMATION ABOUT APPEAL

Leave to appeal is granted. The present Order may be appealed within 15 days of service of this Order which shall be regarded as the Court's decision to that effect (Art. 73(2)(b)(ii) UPCA, Rule 220.2, 224.1(b) RoP).