

IN THE CENTRAL DIVISION (MUNICH SECTION) OF THE UNIFIED PATENT COURT

CASE NUMBER ACT_464985/2023 (UPC_CFI_75/2023)

EUROPEAN PATENT NUMBER EP 3 056 563

APPLICANT:

MATHYS & SQUIRE LLP

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(Applicant)

RELEVANT PROCEEDING PARTIES:

1) ASTELLAS INSTITUTE FOR REGENERATIVE MEDICINE

9 Technology Drive, MA 01581, Westborough, USA

(Claimant)

2) HEALIOS K.K

Hamamatsu-cho 2-chome Minato-ku, 105-6115, Tokyo, Japan

(Defendant)

3) RIKEN

2-1, Hirosawa Wako-shi, 351-0198, Saitama, Japan

(Defendant)

4) OSAKA UNIVERSITY

1-1 Yamadaoka Suita-shi, 565-0871, Osaka, Japan

(Defendant)

REQUEST FOR REMOVAL OF CONFIDENTIALITY UNDER RULE 262.3



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A. THE APPLICATION

1. By an order dated 22 August 2024¹ the Court granted Mathys & Squire LLP (the “Applicant”) access to the written pleadings and evidence from the action no. ACT_464985/2023 (UPC_CFI_75/2023) (the “Main Proceedings”) subject to redactions requested by the Claimant. Those pleadings and evidence were duly provided to the Applicant by the Registry on 12 September.
2. This is an application under Rule 262.3 of the Rules of Procedure (“RoP”) requesting that the following documents should be made available to the Applicant in unredacted form or alternatively with redactions limited to those strictly necessary to protect information which might be established by the parties to the Main Proceedings to be confidential:
 - the Claimant’s Reply dated 29 November 2023; and
 - the Defendant’s Rejoinder dated 29 December 2023.
3. As is discussed in greater detail in the rest of this submission, this application is made on the grounds that:
 - a) the reasons for redaction provided by the Claimant were insufficient to justify continued non-disclosure of the information which has been redacted; and
 - b) the information which has been redacted appears *prima facie* to be available to the public elsewhere. Hence the redacted information is not confidential, and no purpose is served by maintaining the redaction of that information in the pleadings provided to the Applicant.
4. The purpose for which the Applicant is requesting access to documents in unredacted (or less extensively redacted) form corresponds to the reasons which were put forward when the Applicant requested access under Rule 262.1(b) RoP to all written pleadings and evidence filed in relation to the Main Proceedings. Rather than repeating those reasons at length here, the Applicant refers the Court to the Reasoned Request under Rule 262.1(b) RoP as submitted on 21 November 2023 and to the comments on the Court of Appeal’s *Ocado* decision² which were lodged with the Court on 1 May 2024 when requesting access to the written pleadings and evidence.
5. In short, the Applicant submits that access to the allegedly confidential information is sought because there is a general public interest in having access in full to any pleadings and evidence submitted in proceedings before the Court, and such access should be granted unless there are good reasons not to do so. Disclosure

¹ [Order of 22 August 2024, ORD 591107/2023 in case no. App 588681/2023 \(UPC CFI 75/2023\), Mathys & Squire LLP v Astellas Institute for Regenerative Medicine](#)

² [Ocado Innovation Limited v Christopher Stothers, Decision of 10 April 2024, ORD 19369/2024 in action no. APL 584498/2023 \(UPC CoA 404/2023\)](#)

of pleadings and evidence enables the public to be better informed as to merits of cases which are brought before the court and to form their own opinions on the merits of such cases even if (as in the present case) they are settled before a final determination is made by the Court. Providing members of the public with access to such pleadings and evidence enables the public to be better placed to comment on the activities of the Court and to hold the Court to account.³ Such general interests were recognised by the Court of Appeal in *Ocado* as justifying public access to pleadings and evidence, including in cases which are concluded by a settlement between the parties.⁴

6. Further, the Applicant has specific professional reasons for requesting access to the allegedly confidential information which has been redacted, which is said to relate to the Claimant's position in relation to the valuation of the claim.
7. The concept of a "value of an action" in proceedings before the UPC, and in particular the concept that parties to a dispute may put forward competing valuations with a final value to be determined by the Court, is something which has no parallel in the domestic legal systems of many UPC Contracting States or third countries. Although a similar concept exists in German domestic patent litigation it is not a given that the UPC will necessarily determine the value of litigation analogously to the German courts.
8. Accordingly, the Applicant (being an intellectual property law firm) has both a general interest and a specific professional interest in understanding how the concept of a "value of an action" might operate in proceedings before the UPC. To this end, it is submitted that access to the full pleadings and evidence, including the allegedly confidential portions, will better enable it to understand the nature and strength of the arguments put forward by the parties in respect of their competing valuations and therefore enable a better understanding of the conclusion which was reached by the present Court in its order of 18 March 2024 in which it was held that a valuation of EUR 4 000 000 (being the revised value set forth by the Claimant)⁵ should apply.⁶

B. THE REDACTED INFORMATION REQUESTED IS NOT CONFIDENTIAL

9. The following information was redacted in the documents made available to the Applicant pursuant to the requests for redaction which were made by the Claimant:
 - *Claimant's Reply*: paragraph 4(b); paragraphs 15-17; and at paragraph 20,

³ See paragraphs 5 and 6 of the Reasoned Request under Rule 262.1(b) RoP as submitted in the previous access request.

⁴ *Ocado* at [47] and [51]

⁵ See *e.g.* paragraph 7 of the unredacted Statement of Defence.

⁶ [Order of 18 March 2024, ORD_598255/2023 in action no. ACT_464985/2023 \(UPC_CFI_75/2023\), *Astellas Institute for Regenerative Medicine v Healius K.K., Riken & Osaka University*](#), page 3, "Value of the dispute"

both clause (b) of the first sentence and subparagraph (b); and

- *Defendant's Rejoinder*: paragraph 5.3(ii) and paragraph 5.8.

10. Paragraph 4(b) in the Claimant's Reply purportedly summarises submissions made by the Defendants at paragraphs 6-24 in their Defence. That Defence has already been provided to the Applicants in full. To the extent that Paragraph 4(b) is a summary of the information contained within the Defence, that information is no longer confidential as it has already been provided to the Applicant and its continued redaction is not justified.
11. Similarly, Paragraph 20, first sentence, clause (b), purportedly summarises previous submissions made by the Defendants. The Defendants' submissions were made available to the Applicants in unredacted form and hence information contained within a summary of those submissions in Paragraph 20 is not confidential.
12. Paragraph 5.3(ii) in the Defendants' Rejoinder is said to relate to the Defendants "*maintain[ing] all of their submissions regarding the value of proceedings*" and thus appears *prima facie* to be a summary of part of a position stated by the Defendants in their unredacted Defence. Hence for similar reasons to the other redacted paragraphs, the information contained in this paragraph is not confidential as it has already been made available to the Applicants in a different form.
13. Hence the redactions should therefore be removed from at least paragraph 4(b) and paragraph 20, first sentence, clause (b) of the Claimant's Reply; and from paragraph 5.3(ii) of the Defendants' Rejoinder. These sections merely summarise information which is already visible elsewhere. There is no justification for keeping the content of these sections confidential.
14. Further, from context, it appears that redacted paragraph 5.8 of the Defendants' Rejoinder must relate to some aspect of the parallel proceedings before this Court concerning EP 3056564, *i.e.* Action Number ACT_465342/2023 (UPC_CFI_80/2023). This is because unredacted paragraph 5.9 discusses differences in the defendants between the two cases and argues that "*it would not be equitable*" for the Claimant to incorporate submissions from the EP '564 case merely by reference.
15. To the extent that the information redacted from paragraph 5.8 merely reiterates information which is already publicly available *e.g.* due to public orders or other public information in the proceedings relating to EP '564, such information is also not confidential.
16. Further, to the extent that the Claimant's requested redactions relate to the anticipated launch date of the product ASP7317, that information is also not

confidential.

17. The Defendants identified that the Claimant “*has, as one of the products in its pipeline, an RPE product for treating geographic atrophy secondary to age-related macular degeneration*”.⁷ It can be seen at first glance from the publicly-available documents cited by the Defendant that this “pipeline” retinal pigment epithelial cell (RPE) product, which is alleged to be relevant to the valuation of the action, has the codename ASP7317.⁸
18. Based on the publicly-available information regarding clinical trials for ASP7317, and publicly-available timescales of clinical trials for alternative RPE products not falling under the patent, the Defendants estimated that the Claimant would not be able to put its RPE product ASP7317 on the market prior to expiry of the patent in 2034, with the Defendants asserting a “reasonable estimate” of 2036 for completion of Phase II and Phase III trials.⁹
19. Information relating to the identity of the Claimant’s RPE product and its anticipated launch date is also publicly available from orders which have been delivered in the parallel UPC litigation concerning EP ‘564. EP ‘564 shares a claim to priority with the patent which is the subject of the Main Proceedings (EP 3056563) and shares the same filing date. The ‘563 and ‘564 patents relate to similar subject matter, with the claims of the ‘564 patent being directed to methods of purifying RPE cells and of producing RPE cells.
20. In the dispute concerning the ‘564 patent, the publicly-available order of 17 November 2023 indicates that the Claimant argued that “product launch will be achieved significantly ahead of the expiry of the Patent in 2034”.¹⁰ A further publicly-available order dated 20 November 2023¹¹ indicates that the product alleged to be relevant to that dispute is ASP7317¹² and that the Claimant “*anticipates that European market approval for the Product will be obtained, and product launch will be achieved, significantly ahead of the expiry of the Patent in 2034*”.¹³

⁷ Defence, paragraph 16, referring to documents D10, D11 and D12. The Defendant made this identification based on publicly-available information which can be found on the Claimant’s website and on the United States government’s public clinicaltrials.gov website.

⁸ ASP7317 is the only product identified in D10 or D12 and it is the only product in D11 (the Claimant’s list of pipeline products) which is stated to relate to RPE cells, i.e. to the subject-matter of the patent. None of the Claimant’s other pipeline products as identified in D11 relate to the same subject-matter as the patent.

⁹ Defence, paragraphs 19-21

¹⁰ [Order of 17 November 2023 \(Order no. 58480\) in Action Number ACT 465342/2023 \(UPC CFI 80/2023\), *Astellas Institute for Regenerative Medicine v HealiOS K.K. & Osaka University*](#): see page 3, first paragraph.

¹¹ [Order of 20 November 2023 \(Order no. 579547\) in Action Number ACT 465342/2023 \(UPC CFI 80/2023\), *Astellas Institute for Regenerative Medicine v HealiOS K.K. & Osaka University*](#)

¹² Order of 20 November 2023, page 3, first paragraph

¹³ Order of 20 November 2023, page 5, penultimate paragraph

21. It is therefore already a matter of public record that the Claimant anticipates that ASP7317 will be launched “significantly ahead of” the expiry of the ‘564 patent in 2034. As the ‘563 and ‘564 patents share the same filing date it is therefore also a matter of public record that the Claimant anticipates that ASP7317 will be launched “significantly ahead of” the expiry of the ‘563 patent in 2034.
22. To the extent that any of the redacted information in the Claimant’s Reply and Defendants’ Rejoinder corresponds to information which is already publicly available *via* the published orders in proceedings concerning the ‘564 patent, its continued redaction cannot be justified.

C. THE REASONS PROVIDED BY THE CLAIMANT ARE INSUFFICIENT TO JUSTIFY CONTINUED REDACTION

23. Rule 262.2 RoP, first sentence, requires that a party requesting certain information of written pleadings or evidence be kept confidential must “*provide specific reasons for confidentiality.*”
24. The sole reason asserted by the Claimant for confidentiality of the information identified above is that this information is allegedly said to be “commercially sensitive” and that:

“Understandably, disclosure of this information to third parties would risk causing commercial damage to our client, particularly when taking into account that the Applicant may well act for competitors of our client or other interested parties. Preserving the confidentiality of this information is even more pertinent following the confidential settlement agreed between the parties.”¹⁴

25. No weight can be given to the Claimant’s assertion that the settlement of the Main Proceedings should make it “*even more pertinent*” to keep the redacted information confidential. The Court of Appeal recognised in *Ocado* that the fact that a settlement “may have been made on confidential terms” does not override the principle of access to pleadings and evidence.¹⁵
26. The Claimant has not substantiated the existence of any actual, specific or concrete prejudice which would occur if the redacted information were to be released. Rather, the Claimant has merely alluded to a hypothetical (not an actual or concrete) “risk” of some kind of undefined and indeterminate “commercial damage” of an unknown nature and magnitude. What sort of risk might occur under

¹⁴ Claimant’s letter of 14 August 2024 as filed in the proceedings under Rule 262.1(b) RoP.

¹⁵ *Ocado* at [51]-[52]

what sort of circumstances, what type of damage might arise, and how significant any such damage might be, are entirely unspecified.

27. Indeed, the Claimant has not provided any explanation of *why* the redacted information is commercially sensitive (which would be an essential prerequisite for assessing the consequences of its disclosure) but has merely asserted that it is so.
28. The Claimant has not provided anything to support its vague suggestion that the Applicant “may well” act for any competitors in the field of technology covered by the patent, or for any other “interested parties” in that field. Nor has it established that the mere fact of acting for any such hypothetical, unidentified competitors or interested parties would in fact give rise to any (unspecified) “risk” of (unspecified and unquantified) “commercial damage” arising from disclosure of the redacted information to the Applicant.¹⁶ The Claimant’s speculative (“*may well*”) reasoning in this respect cannot therefore be given any weight when balancing the interests of the parties. In any case, even if it were to be established that the Applicant did act for any “competitors” or “interested parties”, this would not by itself be sufficient to deny access to the information sought.
29. In short, the Claimant’s justifications for the redaction, which rely on the spectre of an unquantified “risk” of some kind of unspecified, unquantified and wholly hypothetical “commercial damage”, do not meet the level required under the Rules of Procedure to justify the redacted information continuing to be withheld from the Applicant following this Application.

D. PRESUMPTION IN FAVOUR OF PROVISION OF UNREDACTED INFORMATION

30. Rule 262.5 RoP provides that following an application for removal of redactions under Rule 262.3, the Court shall invite written comments from the parties prior to making an order on the request.
31. Rule 262.6 RoP then specifies that the Court “*shall allow*” an application under Rule 262.3 for the disclosure of confidential information “*unless legitimate reasons given by the party concerned for the confidentiality of the information outweigh the interest of the applicant to access such information*”.
32. Rule 262.6 RoP therefore establishes a presumption in favour of the disclosure of information notwithstanding the fact that it is provisionally made confidential upon

¹⁶ It is further noted that if any risk of damage were to be attached to the disclosure of such information, this would presumably only be realised if the information were to fall into the hands of the unidentified “competitors or other interested parties”. Such a hypothetical risk could therefore be mitigated simply by disclosing the information to the Applicant subject to conditions restricting its wider dissemination.

receipt of a request under Rule 262.3 RoP.¹⁷

33. The wording of Rule 262.6 RoP which requires that any “*legitimate reasons*” justifying non-disclosure of information need to “*outweigh the interest of the Applicant*” clearly indicates that the correct test to be applied under Rule 262.3 RoP is a “balance of interests” test. This was expressly recognised by the Court of Appeal in its *Ocado* decision, where the Court held that when applying Rule 262.3 RoP it is for the court “*to balance the interest of the member of the public by accessing the information (only) against the legitimate interest of the party by keeping it confidential.*”¹⁸
34. Access to information which is requested under Rule 262.3 RoP should therefore only be refused if parties can establish “*specific*”¹⁹, “*legitimate*”²⁰ reasons which outweigh the default presumption in favour of disclosure after a balancing test has been performed. This is in keeping with the general principle laid down in the UPC Agreement that the register is public and the proceedings (including the written procedure) are open to the public, unless the balance of interests involved is such that they are to be kept confidential.²¹
35. The onus is therefore on the party requesting non-disclosure to duly substantiate the existence of specific, legitimate reasons for non-disclosure; to explain in which specific way the legitimate personal or economic interests of a party may be affected by disclosure of the information; and to establish what the actual consequences thereof would be.
36. In *Aylo v DISH* the Court of Appeal upheld an order of the Local Division Mannheim to the effect that an “abstract risk” that an in-house counsel, if admitted to a confidentiality club, “might” breach the confidentiality obligation due to conflicts of interest is not sufficient to refuse admission, unless there are concrete circumstances justifying such a suspicion”.²²
37. Similarly, when applying Rules 262.2, 262.3 and 262.6 RoP, the Applicant contends that an abstract risk posed by disclosure of allegedly confidential information is insufficient to deny access to that information; there must be concrete circumstances justifying its non-disclosure and which should be established by the

¹⁷ The *provisional* (and therefore reversible) nature of such confidentiality was confirmed by the Munich Local Division in its [order of 3 October 2023, ORD 575878/2023 in action no. ACT 459771/2023 \(UPC CFI 9/2023\), Huawei v Netgear](#). See headnote 2 and paragraph 1 of the reasons for the decision.

¹⁸ [Ocado Innovation Limited v Christopher Stothers, Decision of 10 April 2024, ORD 19369/2024 in action no. APL 584498/2023 \(UPC CoA 404/2023\)](#) at [46]

¹⁹ Rule 262.2 RoP, first sentence

²⁰ Rule 262.6 RoP

²¹ *Ocado* at [42]

²² [Order of 21 August 2024, ORD 45793/2024 in action no. APL 45142/2024 \(CoA 469/2024\), Aylo Premium Ltd & Others v DISH Technologies LLC & Another](#) at [17]-[19] (reasoning translated from the original German)

party requesting such non-disclosure. This has not been achieved in the present case.

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For and on behalf of Mathys & Squire LLP