



Hamburg – Local Division

UPC_CFI_88/2024
Preliminary Order
of the Court of First Instance of the Unified Patent Court
Issued: 09/09/2024

PARTIES:

Roche Diabetes Care GmbH, represented by Herrn Götzl, Sandhofer Straße 116, 68305 Mannheim, Germany,

Plaintiff and Counterdefendant 1)

represented by:

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F. Hoffmann-La Roche AG, Grenzacherstraße 124, 4058 Basel, Switzerland,

Counterdefendant 2)

represented by:

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and

1. **Tandem Diabetes Care, Inc.**, represented by its legal representative, 12400 High Bluff Drive, CA 92130, San Diego, United States of America,

Defendant 1)

2. **Tandem Diabetes Care Europe B.V.**, .represented by its legal representative, Schiphol Boulevard 359, WTC Schiphol Airport, D-Tower 11th floor, 1118 BJ, Schiphol, Netherland,

Defendant 2)

3. **VitalAire GmbH**, represented by its legal representative, von Bornbarch 2, 22848 Norderstedt, Deutschland

Defendant 3) and Counterclaimant

Defendant 1) und 2) represented by: Taylor Wessing N.V., Charlotte Garnitsch (111867/2023), Dr. Wim Maas (112021/2023), Iris van der Heijdt, Pauline Springorum, Kennedyplein 201, 5611 ZT Eindhoven, NL,
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Defendant 3) represented by: Hoyng Rokh Monegier, Dr. Christine Kanz, Steinstraße 20, 40212 Düsseldorf,

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Patent at issue

Patent no. Proprietor

EP2196231

Roche Diabetes Care GmbH, F.Hoffmann-La Roche AG

Deciding Judges:

This order is issued by
Presiding Judge and Judge Rapporteur Sabine Klepsch
Legally qualified judge Dr. Stefan Schilling
Legally qualified Judge Dr. Tatyana Zhilova
Technically qualified Judge Giorgio Checcacci

Language of Proceedings:

English

Subject-Matter of the Proceedings:

Patent infringement

Request to stay proceedings

Statement of the forms of order sought by the parties:

The requesting parties, defendants 1) and 2), with the consent of the defendant 3), are requesting:

- I. to stay the infringement action with Ref. 10800/2024 (the 'Infringement Action') pursuant to Rules 295(f) and (m), 75 and 37(4) of the Rules of Procedure and Articles 33(5) and 33(3)(b) UPCA
- II. in the meantime, based on Rule 295(m) in conjunction with Rule 9 of the Rules of Procedure to stay the infringement proceedings until the court has ruled on Request I.

The respondent, claimant, is requesting:

1. Dismissal of the defendants' application for stay of the present proceedings,
2. to decide, pursuant to Rule 37.2 of the Rules of Procedure, to hear the proceedings under Art. 33(3) UPCA together before the Local Division Hamburg.

Summary of Facts:

The Claimant alleges infringement of European Patent 2 196 231 by the defendants' t:slim X2 insulin pump with the interchangeable t:slim X2 reservoir (attacked embodiment). Defendant 1) is a US manufacturer of medical devices based in San Diego, California. The company develops medical technologies for the treatment of diabetes and in particular for insulin infusion therapy. Its products include insulin pumps, such as the t:slim X2 insulin pump. Defendant 2) is the importer and operates the Dutch distribution centre of Defendant 1) for Europe. Defendant 3) is a German healthcare company with its headquarters in Norderstedt. It offers holistic solutions and concepts for home therapy. In particular, it distributes insulin therapy products of Defendant 1). The infringement action was filed February 2024.

Defendant 1) and Defendant 2) filed an action for annulment against the patent in suit before the Central Division in Paris on 30 November 2023. The revocation action is registered under case number UPC_CFI_454/2023 (register number ACT_589997/2023). In the same pleading dated 30 November 2023, the Defendants 1) and 2) also filed an action for a declaration of non-infringement of the patent in suit before the Central Division in Paris. This action is pending under case number UPC_CFI_454/2023 (registration number ACT_589997/2023).

Defendant 3) filed a counterclaim for revocation of the patent in suit on 17 June 2024.

The defendants filed an application to stay the infringement proceedings pursuant R. 295 sub f and m, 75, 37 sub 4 RoP, Art. 33(5) and 33(3) UPCA. The interim hearing on the revocation action at the CD Paris will take place on 11 September 2024. The date for the oral hearing is set for 6 November 2024.

In a preliminary order the Judge-rapporteur was of the opinion, that the request for a stay of the infringement proceedings until the decision on the action for revocation concerning the legal validity of the patent in dispute should not to be granted. It was reasoned that the panel is already exercising its discretion under R. 37.2 RoP at this point in time to hear both the infringement action and the legal status under Art. 33(5) and (3)(a) UPCA together. Paragraph 5

expressly provides that where an action for a declaration of invalidity is pending before the central division, the local division may, at its discretion, proceed in accordance with paragraph 3 in the case of an infringement action between the same parties and the same patent (see Luginbühl/Hüttermann-Luginbühl, Unitary Patent System, 2024, Art. 33 para. 33). Paragraph 3 lit. a) stipulates that the local division may hear both the infringement action and the (counter)action for revocation. The court exercises its discretion to the effect that such a joint hearing is deemed appropriate. A joint hearing of infringement and nullity actions appears to make sense for reasons of efficiency alone. It is also advantageous in terms of content, as it allows a decision to be made on both the legal status and the infringement issue on the basis of a uniform interpretation by the same panel of judges in the same composition. In the present case, no aspects are apparent that could speak against such a joint hearing.

The defendants 1) and 2) are of the opinion, that, firstly, there is a high probability that the patent in suit is invalid. They refer to the statement of claim in the nullity action, which shows that the patent contains an inadmissible intermediate generalisation and lacks both novelty and inventive step. In this context, it is noted that the USPTO has rejected corresponding claims in the corresponding US application from the patent family of the patent published as U.S. 8,827,976 - see Exhibit App_4. The high likelihood that the patent is invalid in its current form is evidenced by the fact that the claimant has filed 26 auxiliary requests, and should be dispositive in favour of staying the infringement action. Second, even if some new claims survive the invalidity challenge, it is unclear whether claimant intends to assert some of the new claims. It would not be a litigative economical use of the court's and the parties' resources to litigate a set of claims if claimant ultimately decides to assert infringement based on some of the new auxiliary claims. The scope of protection of the patent will undoubtedly change in the course of the proceedings if it is not invalidated in its entirety. The 26 auxiliary requests are currently not part of the ongoing infringement proceedings. Continuing the infringement action under these circumstances would disrupt the carefully crafted UPC procedural system: Continuing litigation on the basis of a patent whose scope of protection is so unclear violates due process principles.

The Claimant is in summary of the opinion that the infringement proceedings should be continued for reasons of efficiency. As a monopoly right with a time limit, the patent requires a speedy decision. Any delay in a decision already de facto devalues the patent proprietor's monopoly right. It is therefore justified to suspend patent infringement proceedings due to parallel revocation proceedings only if there is a high probability of revocation. This is in line with the case law of the German courts, which only suspend the infringement proceedings pursuant to Section 148 ZPO if there is a high probability of revocation until a decision on the legal validity has been made. Considerations such as those of the defendant to first clarify the legal status in order to only then continue the infringement proceedings are inefficient. A patent infringement case is ready for a decision even if the patent has not been infringed. The validity proceedings are then no longer relevant. The Rules of Procedure of the Unified Patent Court have taken up these requirements. Thus, R 118.2 lit. b RoP authorises the court to issue a stay if, after examining the facts of the case, it determines that there is a high probability of revocation. This systematic position in the decision after the oral hearing speaks in favour of first examining the facts of the infringement before the question of suspension can even become relevant. For reasons of efficiency, to clarify the question of infringement in parallel and to take account of the

defendant's idea of avoiding contradictory decisions, the court seized should, in the opinion of the claimant, proceed in accordance with Art. 33 (3) lit. a UPCA and decide on the legal status and infringement together. It is therefore simply wrong that the court runs the risk of 'making an incorrect, unfounded decision or one that does not take all the circumstances into account'. In the present proceedings, it is necessary to examine arguments from both directions, so that both parties have to commit themselves to a uniform argument on infringement and legal validity, thereby enabling the court to make a more informed decision. This would address one of the defendant's concerns, namely that contradictory arguments are presented in both proceedings.

Grounds for the order:

Under Rule 295(f) RoP, the court may stay the proceedings under Rule 75 RoP. Rule 75 RoP governs the case under Article 33(5) UPCA in which:

- (a) an action for revocation is filed with the central division and
- (b) infringement proceedings are subsequently instituted before a local or regional division between the same parties and in respect of the same patent.

If invalidity proceedings between the same parties and relating to the same patent are already pending before the central division, it is at the discretion of the local or regional division before which the infringement proceedings are instituted to proceed in accordance with Article 33(3) UPCA pursuant to Article 33(5) UPCA. Pursuant to Article 33(3)(b) UPCA, the local or regional division may then decide whether to stay or continue the infringement proceedings. In making this decision, the division which is responsible for the infringement action under Rule 75(4) RoP should take into account how far the nullity action had progressed in the central division before the stay.

According to Rule 75(6) RoP, Rule 37(4) RoP applies *mutatis mutandis* in the case of Article 33(5) UPCA. Rule 37(4) RoP states that in the case of a decision under Article 33(3)(b) UPCA, the local or regional division may stay the infringement proceedings pending the final decision in the invalidity action. Moreover, Rule 37(4) RoP states that the infringement proceedings shall be stayed if there is a high probability that the relevant claims of the patent will be invalidated for any reason by the final decision in the invalidity proceedings. Furthermore, under Rule 295(m) of the Rules of Procedure, the court may stay the proceedings if the proper administration of justice so requires.

In the exercise of its discretion, the Panel decides to proceed with the infringement proceeding, but reserves the right to consider the possibility of suspending the infringement proceeding pursuant to Art. 33 (3)c UPCA or to suspend the proceedings for any other reason put forward by the Defendants.

In its order of 28 May 2024 (UPC_CoA_22/2024, App_21545/2024; Carrier v. BITZER Electronics), the Court of Appeal stated that a stay must be ruled out in principle. Art. 33(10) UPCA and Rule 295(2) RoP, which were relevant in the case to be decided, must be applied and interpreted in accordance with the fundamental right to an effective legal remedy and a fair and public hearing within a reasonable time as guaranteed by Article 6 of the European Convention for the

Protection of Human Rights and Fundamental Freedoms and, to the extent that European Union Law is concerned, Article 47 of the Charter. These provisions must also be applied and interpreted in accordance with Articles 41(3), 42 and 52(1) UPCA on the basis of the principles of proportionality, flexibility, fairness and equity (point 2 of the Preamble of the RoP). In accordance with these principles, proceedings must be conducted in a way which will normally allow the final oral hearing at first instance to take place within one year whilst recognizing that complex actions may require more time and procedural steps, and simple actions less time and fewer procedural steps (point 7 of the Preamble of the RoP). Case management must be organized in accordance with this objective (point 7 of the Preamble of the RoP). It follows that, as a general principle, the Court will not stay proceedings. Otherwise, the Court cannot ensure that the final oral hearing will normally take place within one year. The principle of avoiding irreconcilable decisions does not require that the UPC always stays revocation proceedings pending opposition proceedings. Firstly, decisions in which the UPC and EPO issue different rulings on the revocation of a European patent are not irreconcilable. Where one body upholds the patent and the other revokes it, the latter decision will prevail. Secondly, the interests of harmonising decisions on the validity of a European patent can be promoted by ensuring that the body that decides last can take the decision of the body that decides first into account in its decision. That means that the interests of harmonisation in general do not require a stay by the UPC where it can be expected that the UPC will issue its decision first.

Based on these principles, a stay of the proceedings cannot be considered in the present case. Claimant's interest to continue the proceedings outweighs Defendant's interest to stay the proceedings. Due to the circumstance that the UPCA and the RoP provide the parties with a system designed to ensure fast and effective legal protection, there is currently no reason to suspend the infringement proceedings, even though the interim hearing on the revocation action will take place on 11 September 2024 and the oral hearing on 6 November 2024. The outcome of the proceeding is uncertain in terms of time - it is not possible to predict when the Central Division Paris will issue a written decision - and the substantive outcome. Regardless of this, the decision would not bind the Local Division.

In addition to this, the parties to the action for revocation are not identical to those of the infringement action and the counterclaim of revocation, so that a uniform decision affecting all parties cannot be issued in this respect either.

The Defendant's interest to (potentially) save litigation costs does not weigh up to the legitimate interest of Claimant in pursuing the infringement action. The relevant costs have already been incurred through the exchange of pleadings in the infringement proceedings. The Statement of defence was filed and the reply to defence as well. In view of any amendments to the claims of the patent in suit and a complete revocation of the patent in suit, the local division has the opportunity to react appropriately.

Therefore, there is no need for this panel to consider now whether the defendants have demonstrated a strong likelihood that the relevant claims of the patent will be held invalid on any ground by the final decision in the revocation proceedings.

Insofar as the Judge-rapporteur was in the provisional order of 14 June 2024 of the opinion that the Local Division Hamburg could hear the revocation action brought by defendants 1) and 2), which would be appropriate, this will not be adhered to for the time being. The assumption that Art. 33(5) UPCA merely refers to the legal consequence of Art. 33(3) UPCA, with the consequence that in the case in which a revocation action is pending before the central division, the local division can proceed at its discretion in accordance with paragraph 3 in the case of an infringement action between the same parties and the same patent, is in any case not held by the majority. In this respect, a decision as requested by the claimant is ruled out. The situation may be different with regard to the revocation action brought by defendant 3).

Order:

1. The request to stay proceedings is dismissed.
2. The request to hear the proceedings under Art. 33(3) UPCA together before the Local Division Hamburg, is dismissed.

Order Details:

Order no. ORD_28786/2024 in ACTION NUMBER: ACT_10800/2024

Action type: UPC_CFI_88/2024

Related proceeding no. Application No.: 28467/2024

Application Type: Request for procedural order

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, rules 220.2 and 224.1(b) RoP).

Sabine Klepsch
Presiding Judge and Judge Rapporteur

Dr. Stefan Schilling
Legally qualified Judge

Dr. Tatyana Zhilova
Legally qualified Judge

Giorgio Checcacci
Technically qualified Judge