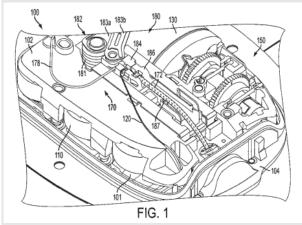
UPC CFI, Central Division Milan, 11 April 2025, Eoflow v Insulet

fluid delivery device with transcutaneous access tool, insertion mechanism and blood glucose monitoring for use therewith



PATENT AND PROCEDURAL LAW

No further exchange of written pleadings after CoA decision of 30 April 2025 in PI proceedings (R. 36 RoP)

• The parties have fully argued their respective positions at both the preliminary and the substantive stages of the proceedings and their positions have been well examined, sometimes even repeatedly.

Instructions for interim conference (<u>Article 76 UPCA</u>, <u>R. 103 RoP</u>)

US'159 (Flaherty) inadmissible as late filed: could have been produced earlier

• in a revocation action, prior art (potentially detrimental to the patent or not) cannot be filed at a later stage.

The filing of prior art at late stage, or at the stage of the replies prevents the opponent from filing full observations (reply and rejoinder) on a crucial point of the legal assessment. This is contrary to the adversarial principle laid down in **Art. 76 UPCA**

Eoflow to provide security for costs of € 500.000 (R. 158 RoP)

• the company's overall situation appears to be not positive, either from the point of view of its assets and liabilities or from the point of view of its sales and expansion prospects, and it is at least doubtful from the point of view of its liquidity.

Source: Unified Patent Court

UPC Court of First Instance, Central Division Milan, 11 April 2025 (Postiglione, Klein, Schwengelbeck) UPC CFI 597/2024

Procedural Order

of the Court of First Instance of the Unified Patent Court Central Division (Milan section)

delivered on 11/04/2025

APPLICANT

EOFLOW Co., Ltd. (Applicant) - 302Ho, HUMAX VILLAGE, 216, Hwangsaeul-ro, Bundang-gu - 13595 - Seongnam-si, Gyeonggi-do - KR Represented by Christopher Pierce - Hoyng Rokh Monegier - Amsterdam NL

RESPONDENT

INSULET Corporation (Main proceeding party - Defendant) - 100 Nagog Park - MA 01720 - Acton - USA - represented by Frank Peterreins - Peterreins Schley Patent- und Rechtsanwälte PartG mbH Munich,

PATENT AT ISSUE

Patent no. <u>EP4201327</u> – owned by Insulet Corporation **DECIDING JUDGE**:

This order has been issued by the judge rapporteur, Andrea Postiglione

LANGUAGE OF PROCEEDINGS: English SUBJECT-MATTER OF THE PROCEEDINGS: Revocation

GROUNDS FOR THE ORDER ON THE WRITTEN PROCEEDINGS

- 1. On 9 April 2025 EOFLOW filed a request before this Court under Rule 36 of the Rules of Procedure seeking leave to exchange further written submissions with INSULET Ltd and also to inform the Court of the decision of the Court of Appeal of the Unified Patent Court (UPC CoA 768/2024) on the appeal on the action for PI.
- 2. The Court is aware of the matter.
- 3. On 3 July 2024, INSULET Co. (INSULET in the action) filed before this Milan CD an ex parte application for a preliminary injunction requesting the Court to order EOFLOW co. Ltd (EOFLOW in the following) from manufacturing, offering, placing on the market, using or possessing a fluid delivery device called 'Omnipod5', a disposable, wearable, tubeless insulin management system that allows automatic insulin delivery (a so-called insulin pump).
- 4. EOFLOW is a medical device developer and manufacturer based in South Korea and produces the 'EOPatch' insulin pump, which is marketed in Europe under the trade name 'GlucoMen Day Pump'.
- 5. During the trial, EOFLOW filed a patent revocation action in October 2024. INSULET resisted by filing a patent infringement suit and auxiliary claim amendments.
- 6. With respect to the revocation action, the parties filed:
- a revocation application (14.10.2024)
- a revocation defence (10.12.2024)
- a reply to the revocation defence (10.02.2025)
- a rejoinder to the revocation application (06.03.2025).
- 7. As regards the counterclaim for infringement, the parties have filed:
- a counterclaim for infringement (10/12/2024)
- a defence to the counterclaim for infringement (10/02/2025)

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- a reply to the defence to the counterclaim for infringement (06/03/25)
- a rejoinder to the reply to the defence to the counterclaim for infringement (07/04/25).
- 8. Regarding the request for amendment of the patent, INSULET filed on 10.12.24 a conditional request for amendment of EP 4201327 C0 and EOFLOW filed on 10.02.2025 a defence to the request for amendment of the patent and also a rejoinder to the reply to the request for amendment of the patent (07.03.25). INSULET filed a rejoinder to the revocation on 06.03.25 which also contains arguments on claim amendments.
- 9. The written procedure is closed.
- 10. The Court does not deem it necessary to grant the parties time for further written submissions pursuant to Rule 36 of the Rules of Procedure. The parties have fully argued their respective positions at both the preliminary and the substantive stages of the proceedings and their positions have been well examined, sometimes even repeatedly.
- 11. The Tribunal therefore considers it appropriate to close the written phase and to schedule an Interim Conference. The request pursuant to **Rule 36 RoP** is consequently dismissed.
- 12. At the interim conference, the parties may also discuss the outcome of the proceedings before the Court of Appeal, if this was the purpose of the further submissions.
- 13. The Interim Conference will be held by videoconference on

- 20 May 2025 at 10:00 -

A link will be provided in due course.

- 14. The interim conference will be audio recorded (Rule 106 of the Rules of Procedure). A copy of the audio recording will be provided to the Parties after the IC.
- 15. The Interim Conference will be conducted in English or in any other language agreed by the representatives of the Parties in due time before the IC.
- 16. The main subject matter of the interim conference will be the claim construction with particular reference to the meaning of "pass through" referred to in claim feature 4.5.1, it will in fact be appropriate to clarify, the scope of the claim as it can be derived from reading the proceeding documents.
- 17. In arguing this point, the parties may use the patent description and the drawings attached to the patent, but not other drawings or explanatory illustrations.
- 18. The duration of the IC will be approximately 2 hours. The parties may choose to plead for one hour each, without reply, or to plead for 45 minutes each and reserve 15 minutes for reply.
- 19. The first party to speak will be the patent proprietor. 20. The judges reserve the right to interrupt the parties and ask questions.
- 21. After the IC, a brief discussion on how to carry out the OH might take place. The possibility of a settlement between the parties may also be discussed.
- 22. The ORAL hearing will be held (unless otherwise specified in the future) on
- 15 July 2025 -

at the premises of Milan Central Division Via San Barnaba 50 Milan (at 09.30 a.m.). The final date will be set though a formal statement in accordance with the deadline referred to in **Rule 108 RoP** with all necessary details. The date is provided for information purposes only, in order to give the parties the opportunity to highlight in due time potential unavailability.

ON THE REQUEST TO ADMIT US 6656159 (FLAHERTY)

- 23. US '159 (filed by INSULET in April 2002 and published in December 2003) was mentioned for the first time by EOFLOW in the reply to the defence to the revocation filed on 10.03.25.
- 24. According to <u>Art. 54 UPCA</u>, the burden of proof is on the party who puts forward the facts, a rule which is specified by <u>Rules 171</u> and <u>172 RoP</u>, according to which the party who puts forward a fact which is disputed or likely to be disputed by the other party must indicate the means of proving it.
- 25. This means that whenever a party proposes to bring an action before the UPC, it must take care to collect in advance the documents supporting the claim. The procedure before the UPC is in fact a front-loaded procedure, where the written procedure allows the parties to confront with replies and rejoinders based on a wealth of knowledge and documents that are supposed to be stable and consolidated from the very moment the claim is filed. In general, the parties are obliged to present their complete case as early as possible (RoP Preamble, para, 7, last sentence).
- 26. Art. 76 UPCA provides for the admissibility of new evidence in the appeal only if such evidence "could not reasonably have been expected during the proceedings before the court of first instance". The same may apply to the stages of the first instance proceedings; also LD Mannheim (UPC CFI 218/2023 Order of the Court of First Instance of the Unified Patent Court, Mannheim Local Chamber, issued on 30 April 2024 App 14035/2024) observed to this regard: "in the present context it is not a matter of proving disputed facts, It is a matter of making submissions - often for the first time - on facts which are the only legally controversial subject of discussion, but which of course cannot actually be in dispute due to lack of knowledge of the intended submission. In proceedings before the Unified Patent Court, too, a distinction must be made between the submission of facts, the disputed submission of facts, the need for evidence and different legal arguments, as Rules 171 and 172.1 of the Rules of Procedure show (see only Tilmann/Plassmann/Ahrens, R. 171 VerfO para. 2).
- 27. This means that when a party files an action before this court, it must take care to show and possess the evidence in support of the claim in advance.
- 28. Therefore, in a revocation action, prior art (potentially detrimental to the patent or not) cannot be filed at a later stage.
- 29. The filing of prior art at late stage, or at the stage of the replies prevents the opponent from filing full observations (reply and rejoinder) on a crucial point of the legal assessment. This is contrary to the adversarial

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principle laid down in Art. 76 UPCA: "Decisions on the merits may be based only on reasons, facts and evidence submitted by the parties or introduced into the proceedings by order of the court and on which the parties have had an opportunity to comment".

- 30. Submission of a document at a later stage appears to be justified only if the party submitting it proves that the document was not previously available or could not have been submitted earlier.
- 31. The submission of new documents is indeed subject to a general principle of diligence and good faith, also because it affects the duration of the proceedings.
- 32. In this case, it is undisputed that EOFLOW could have produced this document earlier; the PI was filed in July '24. EOFLOW had plenty of time to search for prior destructive art and, moreover, when it requested payment of the costs of the PI phase, it showed that it had already done thorough research on the prior art documents (ROE and YODFAT) and it seems farfetched that the claimant did not first research all of the plaintiff's previously filed patents relating to fluid delivery mechanisms.
- 33. Moreover, the case-law references relied on by EOFLOW in support of its request are off base: the LD Paris (<u>UPC CFI 311/2023, CD Paris, decision of 21 January 2025, NJOY v. VMR Products.</u>) affirmed a principle of flexibility in the admission of new documents, emphasising that under <u>Rule 44 RoP</u> a party could file at a later stage a document that was (though) indicated in the statement of revocation.
- 34. In the present case, however, US '159 was not even mentioned in the statement of revocation.
- 35. Secondly, LD Paris only referred to documents submitted by the party by way of rebuttal, i.e. by way of counterargument. In fact, in the same decision, the LD Paris wrote ". By order issued pursuant to Rule 105 'RoP' on 12 June 2024 the judge-rapporteur stated that grounds of revocation not asserted in the statement for revocation, as well as any new facts and/or evidence submitted after the first writ, that do not directly respond to arguments raised by the opposing party, shall be excluded from consideration. The panel agrees with the rapporteur's statement and considers appropriate to give a more accurate reasoning on the issue". LD Paris continues: '. It can therefore be stated that, in revocation actions, the claimant is required to specify the grounds of invalidity allegedly affecting the contested patent, as well as the prior art documents relied upon to support any allegation of lack of novelty or inventive step. This defines the subject-matter of the dispute and enables the defendant to understand the allegations made against him and to prepare an adequate defence, as well as enabling the court to determine the scope of its jurisdiction in relation to the claim. As a consequence, the plaintiff cannot introduce new grounds for invalidity of the attacked patent or introduce new documents in subsequent written acts which are considered to destroy novelty or affect the inventive step. This would lead to an extension or, in any event, a modification of the subject-matter of the dispute, which would constitute an amendment of the case and

fall within the scope of <u>Rule 263 of the Rules of Procedure</u>, which can only be allowed by the Court upon specific request and after proof that the requirements of that Rule have been met. Similarly, the applicant must specify in the application for revocation the facts which it considers necessary to prove in order to succeed in its application, together with the evidence in support thereof".

36. Nor can EOFLOW rely on <u>Rule 263 RoP</u>, since this rule clearly refers to the change/amendments of legal claims and cannot be used to introduce new evidence on the same legal claim (revocation).

US '159 Flaherty is therefore inadmissible.

ON THE SECURITY REQUEST

- 37. In its 'statement of defence against revocation and counterclaim for infringement', INSULET requested the Court to order an appropriate security for the costs of the proceedings, both under <u>Art. 69 UPC</u> in respect of the revocation action and <u>Rule 158.1 RoP</u> in respect of the infringement action.
- 38. INSULET submits that EOFLOW's financial position raises serious doubts as to its ability to pay the costs of the proceedings if EOFLOW were to lose the case. INSULET highlights the financial risk facing EOFLOW after the US District Court of Massachusetts awarded INSULET [...] in compensatory damages and an additional [...] in punitive damages for malicious misappropriation of trade secrets.

39. [...]

- 40. On 10.02.2025, EOFLOW replied (page 167 et seq.) that INSULET, as the plaintiff in the infringement action, was not entitled to file a motion pursuant to Rule 158.1, which could only be filed by the defendants, since Art. 69 (4) UPCA clearly limits this request to the "defendant" and the RoP cannot extend this scope defined by the UPCA, but must be interpreted in accordance with the UPCA (Art. 41). Moreover, if this remedy were to be applied in favour of the applicant, it would be contrary to Art. 47 of the Charter of Fundamental Rights of the Union, Art. 6 ECHR and Art. 42 TRIPS, because if the plaintiff were burdened with additional costs, this would put an unbearable financial pressure on the defendant, and such pressure would actually limit the defendant's ability to defend itself, e.g. by having to pay funds as security instead of using them for a private party expert, etc. The defendant would be in a position to pay both his costs and the counterpart's costs of proceedings, enduring significant disadvantage compared to the claimant.
- 41. EOFLOW's concluded that the alleged imbalance between production, margins and revenues occurred only immediately after the Massachusetts District Court issued a preliminary decision, which was overturned on appeal. Finally, EOFLOW contends that cost recovery would not be burdensome in South Korea and that there was no indication that a UPC decision would not be enforced in that country.
- 42. Subordinately, EOFLOW requested that the costs order not be set at its maximum level.
- 43. INSULET replied (defence filed on 06.03.25) that the Düsseldorf District Court (UPC CFI 463/24,

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<u>UPC CFI 140/24</u>) had already issued orders for security of costs in favour of the claimant and that Rule 158 of the Rules of Procedure had to be interpreted as a general provision concerning the possibility to require security of costs in all cases where the financial situation of the counterpart is strained and leaves doubts about the solvency of the company in the future. INSULET also notes that EOFLOW has not provided any document to rebut its allegations, and that it is for EOFLOW to prove that foreign judgments are recognised and enforced by the Korean legal system. INSULET insisted on the demand of 400,000 Euros as security for the counterclaim for infringement and 600,000 Euros as further security for the claim for revocation, making it 1mln euro in total.

INSULET's claim is well founded.

44. The Court considers that both parties have been given the opportunity to be heard on the request for security in accordance with Rule 158(2) RoP.

45. Rule 158 of the Rules of Procedure states that "at any time during the proceedings, the court may, upon reasoned application by a party, order the other party to provide adequate security within a specified period for the legal and other costs incurred and/or to be incurred by the applicant party and which the other party may be liable to pay".

46. The provision does not distinguish between claimants and defendants. Rule 158 RoP does not conflict with art. 69 UPCA. In fact, the provision in the UPCA that a security must be provided for the defendant does not preclude the possibility that a similar procedural security may not be provided also for the plaintiff in the RoP. Indeed, as in the present case, the roles of plaintiff and defendant overlap in cross-actions for revocation and infringement.

47. The legal background for the application of the security is therefore not the likelihood of the outcome of the judgment, but the fairness of the proceedings or the equality of arms, based on the assumption that a company in financial distress might be more inclined to take unfounded and reckless legal action (for itself or on behalf of others) having little to lose. The seriousness of a legal action is also measured by the willingness of the concerned party to bear the consequences of a judicial defeat.

48. Security fosters therefore the overall reliability of the procedure and the fairness of the proceedings, since no party acting in legitimate defence of its interests and in good faith may fear a security which automatically is released at the moment a decision in its favour is taken. 49. Thus, in accordance with the case law of the UPC (see CoA, Order of 17 September 2024 in case UPC CoA 217/2024, Audi./.NST), the Court, in exercising its discretion under Art. 69(4) UPCA and Rule 158 RoP, must determine, in the light of the facts and arguments presented by the parties, whether the financial situation of the claimant gives rise to a legitimate and real concern that a possible order for costs may not be recoverable and/or the likelihood that a possible order for costs by the UPC may not be enforceable or may be unduly burdensome. The burden of substantiating and proving why an order for security for costs is appropriate in a particular case lies with the defendant making such a request, but that - once the reasons and facts in the request have been credibly presented - it is for the claimant to challenge those reasons and facts in a substantiated manner, especially since that party will normally have knowledge and evidence of its financial situation. It is for the claimant to argue that and why a security order would unduly interfere with its right to an effective remedy (see also CoA, Order of 29 November 2024 in case UPC CoA 548/2024, Arke/ SodaStream).

50. [...] 51. [...]

52. In summary, the company's overall situation appears to be not positive, either from the point of view of its assets and liabilities or from the point of view of its sales and expansion prospects, and it is at least doubtful from the point of view of its liquidity.

53. EOFLOW replied that its financial situation was sound, without, however, rebutting with documents at hand the data provided by INSULET and, in any event, without providing any evidence of greater financial stability than that shown by the abovementioned figures. 54. It must be specified that the Court considers that the litigation pending between the parties before the Massachusetts court is of little relevance to the issue of the security. It is true that, on the one hand, the confirmation of the order to pay [...] would certainly seriously prejudice EOFLOW, but not INSULET, which in that very case is not a third party but the plaintiff (and the creditor). Therefore, even if EOFLOW were unable to pay before the UPC the sums due to INSULET as a result of a payment to INSULET of more than [...], in the end, this would result in a no big harm to INSULET. 55. The claim that the UPC judgments would be unenforceable in Korea is also unconvincing. Neither party has been able to substantiate this beyond very general considerations.

56. The relevant criteria to be taken into account when deciding on a request for a security under R. 158 RdP have been established – as said before - by the Court of Appeal of Luxembourg, recalling that the court must determine, in the exercise of its discretion, whether the financial situation of the other party gives rise to a legitimate and substantial concern that a possible order for costs cannot be recovered and/or the likelihood that a possible order for costs by the court cannot be enforced, (UPC_CoA_548/2024, 29 November 2024).

57. What is relevant here, therefore, is whether INSULET might not be able to get the costs of the litigation even in the event of a success here and a defeat in the US, and therefore even if the US judgment is not upheld.

58. The Court considers that this risk is real in light of the above indicators: [...].

59. Finally, as to the amount of the security, it must be said that EOFLOW set the value of the revocation dispute at EUR 2.5 million, whereas INSULET set the value of the infringement action at 5 million euros. For the revocation action, the maximum amount of

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recoverable costs is set at 400,000 euros, whereas for the infringement action, the recoverable costs cannot exceed 600,000 euros. Considering that the Interim conference will be held in short time and that and that the Court of Appeal could define in the meantime the infringement procedure, the panel considers it appropriate to set the security sum at 50% of the maximum amount of recoverable costs, and therefore at 500,000 euros.

60. Considering the size of the sum, the panel believes that a period of 3 weeks for paying the security is adequate. In case of difficulty, the interested party may always request an extension.

Note: If the party fails to provide adequate security within the time stated, the Court may give a decision by default pursuant to Rule 355.

FOR THESE REASONS **ORDER**

- the application pursuant to Rule 36 RoP is dismissed;
- the written procedure is closed,
- An interim conference is set on May 20Th 10.00 am in VC. Details above.
- US'159 is inadmissible in these proceedings.
- Pursuant to Rule 158.1 RoP, EOFLOW is ordered to provide adequate security for the costs of the proceedings within a period of three weeks (from the date below) by depositing it in the UPC's account for security deposits, the exact amount of which is fixed at EUR 500,000 (five hundred thousand euros).

Note: If a party fails to provide adequate security within the time stated, the Court may give a decision by default pursuant to Rule 355.

INFORMATION ABOUT APPEAL

Security orders are subject to an appeal in accordance with Article 73 of the Agreement and Rule 220.2.

ORDER DETAILS

Order no. ORD 17190/2025 in ACTION NUMBER: ACT 56003/2024

UPC number: UPC CFI 597/2024 Action type: Revocation Action

Related proceeding no. Application No.: 16766/2025 Application Type: Generic procedural Application

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