

UPC Mock Trial

The two-part insulin pump

Oral hearing in provisional injunction (PI) proceedings before the UPC Court of First Instance, Local Division Düsseldorf

— UPC Mock Trial – Overview

Introduction: Mock Trial Set-up

Mock Trial

- Case introduction by Presiding Judge
- Claimant's pleadings
- Defendant's pleadings
- Claimant's response
- Defendant's response
- Further discussion
- Conclusion of oral hearing

— Introduction: Mock Trial Set-up

Simulation of oral hearing in provisional injunction (PI) proceedings before the UPC Court of First Instance, Local Division Düsseldorf on September 13, 2024

— Claimant and Patent in Suit

- Claimant *Claimifuse, Inc.* is a U.S. company and proprietor of Patent in Suit EP'764 claiming an „infusion device and system“.
- Independent claim 1 of the Patent in Suit protects an insulin pump with an integrated processor which receives instructions from a remote control through a wireless receiver and controls the insulin supply to the patient through access into the skin.
- In contrast to the prior art, an insulin pump according to the Patent in Suit does not require any control elements for the quantity and timing of insulin delivery. It can therefore be manufactured in a cost-efficient way and even as a disposable article.
- *Claimifuse* markets infusion devices in the UPC territory which are manufactured in accordance with EP'764.
- The Patent in Suit has not been opposed. It has been validated in Germany, France and Italy (within the UPCA territory) as well as in Spain and the UK.
- The Patent in Suit has not been opted out from the jurisdiction of the UPC.

— Defendant and background of PI request

- Defendant has shown and demonstrated a new insulin pump “*Dualifuse Eco*” during commercial trade fair in Barcelona in March 2024.
- Claimant has obtained sample of “*Dualifuse Eco*” and sent warning letter in Spain after trade fair, claiming infringement of Spanish part of the patent in suit and asking for undertaking to cease and desist from marketing “*Dualifuse Eco*” in all countries where EP’764 is in force.
- Defendant has responded that Patent in Suit is not valid and not infringed.
- Follow-up correspondence until June 2024 with no agreement between the Parties.
- On July 1, 2024 Defendant publicly announces the Europe-wide launch of a new eco-friendly insulin pump in “later 2024” with a picture of “*Dualifuse Eco*”.

— PI procedure

- Claimant has filed a request for issuing a provisional injunction before the LD Duesseldorf on August 3, 2024, requesting the Court to order Defendant to cease and desist from making, offering, placing on the market or using a product according to claim 2 of the Patent in Suit.
- Defendant has filed a response to the PI request and both parties have filed further briefs to exchange their arguments in accordance with the terms set by the court.
- The Court has set the date of the oral hearing for September 13, 2024.

Special issue in dispute: Relevance of post-published prior art

- The Patent in Suit mentions in its description post-published prior art (in the mock trial referred to as “EP’802”)
- The relevance of post-published prior art for validity is governed by Art. 54 EPC:
 - State of the art relevant for the assessment of novelty comprises also the content of European patent applications filed prior to but published on or after the filing date of the relevant patent application.
 - Such prior art is not considered for the assessment of inventive step.
- It is in dispute between the parties whether and how this is relevant **for the interpretation** of the Patent in Suit

Article 54⁴², ⁴³ Novelty

- (1) An invention shall be considered to be new if it does not form part of the state of the art.
- (2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.
- (3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in [paragraph 2](#) and which were published on or after that date, shall be considered as comprised in the state of the art.

— Oral hearing - Roles of the participants

- **UPC Court of First Instance**, Local Division Düsseldorf
 - Dr. Klaus Grabinski, Presiding Judge (Legally Qualified Judge (LQJ))
 - Dr. Marc Dernauer (LQJ)
 - Dr. Katrin Winkelmann (LQJ)
 - Dr. Daniel Grohs, Technically Qualified Judge (TQJ)
- **Claimant** Claimifuse, represented by Dr. Dirk Schüßler-Langeheine, UPC Representative
- **Defendant** Dualifuse, represented by Dr. Christian Lederer, UPC Representative

— Mock Trial

— Case introduction by Presiding Judge

- General explanation:
- In the oral hearing the presiding judge and the judges *may* provide a preliminary introduction to the action, Rule 112.4 UPC Rules of Procedure.
- If a preliminary introduction is given, it is usually provided on the basis of
 - the statements of the parties submitted in the written procedure (*front loading procedure*) and
 - an internal pre-deliberation of the case by the judges.
- The introduction
 - is „preliminary“ and
 - aims at focusing the pleadings in the oral hearing on the issues relevant for deciding the case.

Case introduction by Presiding Judge

- In the case at hand, the presiding judge gives a preliminary introduction by inviting party representatives to focus the discussion on the following issues:
 - Meaning of the term “housing”
 - as part of the teaching of claim 1 of the patent in suit and
 - also considering the description, in particular mentioning of post-published prior art EP’802 in paragraph 8.
 - Squeeze situation: If “housing” is interpreted narrowly, is claim 1 infringed? If it is interpreted broadly, is claim 1 novel over EP’802?
 - Disclosure of EP’802: Given the presumption of validity regarding claim 2, is it more likely than not that the patent is not novel over EP’802 even though it does not explicitly disclose the volume of the reservoir of the insulin pump as provided for in claim 2?
 - Party representatives may also discuss whether a launch of the allegedly infringing product “Dualifuse Eco” is imminent and whether there was an unreasonable delay in seeking the PI.

— Claimant's pleadings

The Patent in Suit – Claim 1

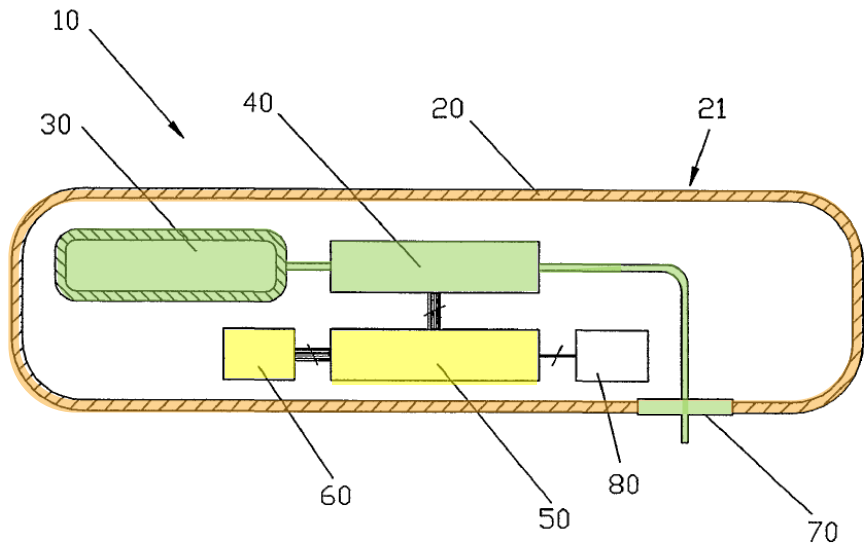


Fig. 1

Independent claim 1 of EP '764 reads:

“A device (10) for delivering fluid to a patient, comprising:

an **exit port assembly (70)** adapted to connect to a transcutaneous patient access tool;

a **dispenser (40) for causing fluid from a reservoir (30) to flow** to the exit port assembly;

a **local processor (50)** connected to the dispenser and programmed to cause a flow of fluid to the exit port assembly based on flow instructions;

a **wireless receiver (60)** connected to the local processor for receiving flow instructions from a separate, remote control device and delivering the flow instructions to the local processor;

and a **housing (20) containing the exit port assembly, the dispenser, the local processor, and the wireless receiver;**

wherein the housing is free of user input components for providing flow instructions to the local processor.”

The Patent in Suit – Claim 2

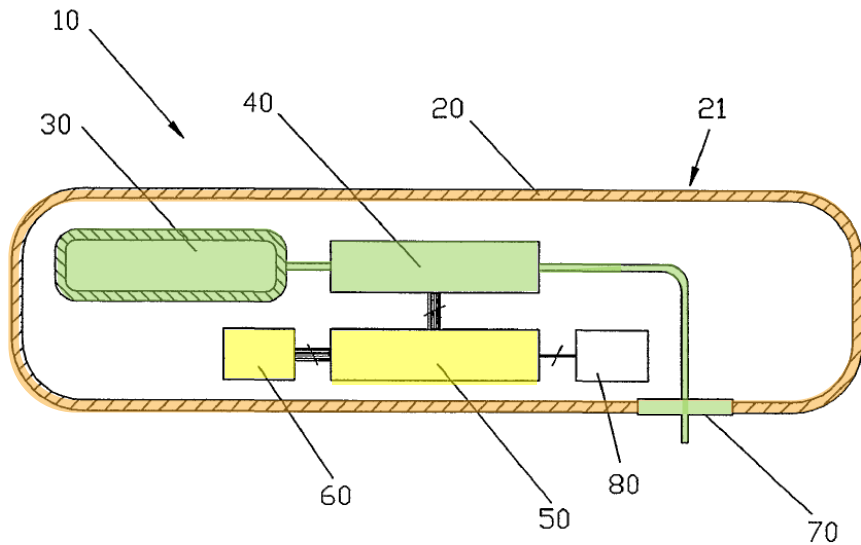


Fig. 1

Claim 2 of EP '764 protects a device according to claim 1, wherein:

“the **reservoir (30)** is contained in the **housing (20)** and has a volume within the range of **2 to 3 ml.**”

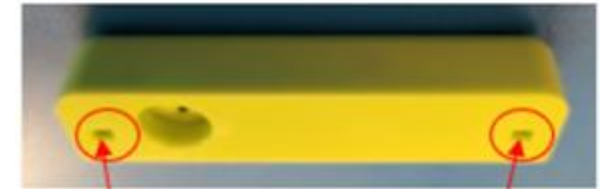
The contested embodiment (I)

- Defendant's insulin pump „Dualifuse Eco“ is composed of two parts that can be separated from each other without being destroyed.
- It is undisputed by the Defendant that both parts taken together, if considered as „a housing“ contain the other elements of claims 1 and 2 of EP'764.
- The reusable pump base, which contains a processor and a wireless receiver (green or yellow part in the picture).
- The disposable patch container, which holds a reservoir for 2ml of insulin, a pump and a needle (white part in the picture).



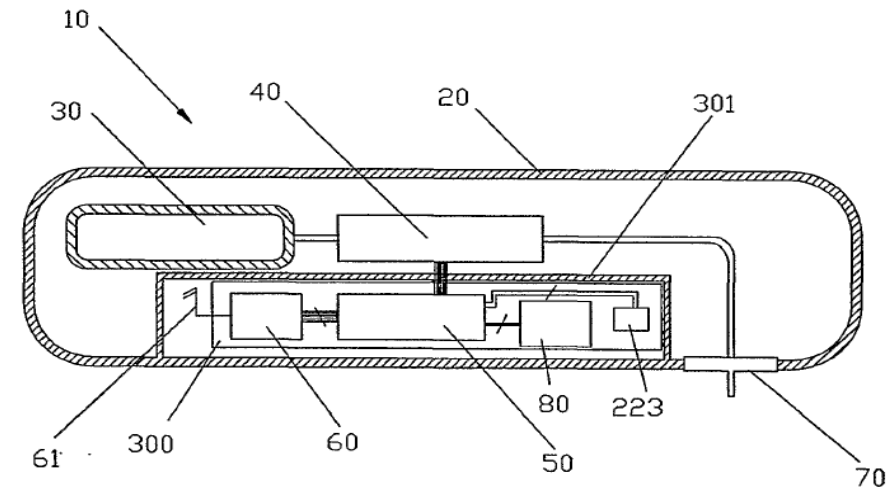
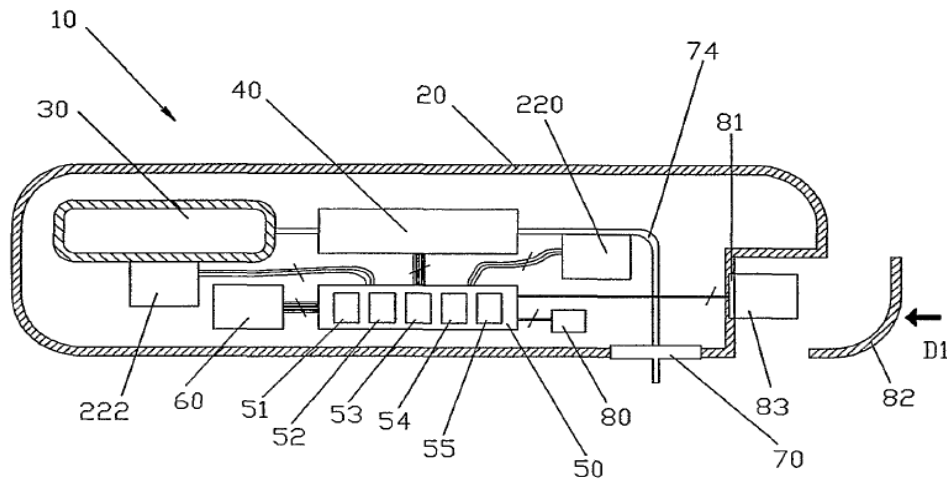
— The contested embodiment (II)

- Defendant has disputed that the claim encompassess the contested embodiment in that the insulin pump is composed of **two parts that can be separated from each other without being destroyed.**
- However, the contested embodiment as a whole, i.e. its two parts taken together, consititute „a housing“ according to claim 1.



Claimant's arguments: Infringement

- The housing does not need to be a single, outer encasement, as there is **no indication of such limitation in the claims.**
- On the contrary, the **housing can consist of multiple parts** as long as they form an integral housing when used as intended.
- As shown in the drawings and description, the housing can have a battery door (82) or separate segments (like module housing 301).



— Claimant's arguments in view of post-published prior art EP'802

- The interpretation of the claim feature „housing“ cannot be affected by the existence of post-published prior art EP'802.
- According to Art. 54(3) EPC, post-published prior art is relevant only for the assessment of novelty – it is not relevant of claim interpretation.
- It does not have to be decided in the present PI proceedings whether claim 1 of the Patent in Suit is anticipated by EP'802.
- Invalidity objections irrelevant due to lack of pending validity challenge
- The PI request is based on claim 2, and there can be no doubt that claim 2 is novel over EP'802.
- At least the reservoir size claimed in claim 2 is neither explicitly nor implicitly disclosed in EP'802

— Claimant's arguments: Justification of PI request and its urgency

- Announcement of „Europe-wide“ product launch constitutes infringing offer, at least imminent threat of infringement in the UPC territory.
- Picture in announcement of product launch is identical to „Dualifuse Eco“ shown during Barcelona Trade Fair.
- As product launch was announced for „later 2024“ there is no sufficient time to wait for the outcome of main infringement proceedings.
- Indeed, already the announcement of a product launch has impacted the market.
- As Defendant has refused to give any undertaking to wait until decision of the Court, product launch resulting in irreparable harm for Claimant can happen at any point in time from now on.
- Consequently, there is particular urgency, requiring the grant of the requested PI without further delay, i.e. at the end of the oral hearing.

— Defendant's pleadings

— Defendant's arguments: PI not justified and not urgent

- There is no threat of infringement in the UPC territory based on showing of product in Spain.
- Based on Spanish case law, mere presentation at a trade fair is no infringing act in Spain (which is proven by the fact Claimant has not instituted any legal action in Spain).
- In any event there is no threat of imminent infringement in Germany or the UPC territory that would justify pre-emptive PI of the UPC.
- In any event there is no urgency as more than three months have passed between Barcelona trade fair and filing of request for PI
- Announcement of product launch does not specify product name – Claimant's PI request thus lacks sufficient substantiation.
- In any event the PI request has been filed more than one month after announcement of July 1 and thus lacks urgency.

— Defendant's arguments: No infringement

- The Patent in Suit understands a housing to be an **indestructible outer encasement** that contains the exit port assembly, the dispenser, the processor and the wireless receiver.
- A skilled person understands housing to be a **protective spatial entity** that encases something.
- Additionally, a skilled person recognizes under a technical and functional aspect that the Patent in Suit is configured as a **disposable article without reusable parts**.
- The contested insulin pump is composed of **two separate parts, each containing functional elements**. As there is **no enclosing housing**, it does not infringe the Patent in Suit.

Defendant's arguments: Narrow interpretation required as description of Patent in Suit mentions post-published prior art (EP'802)

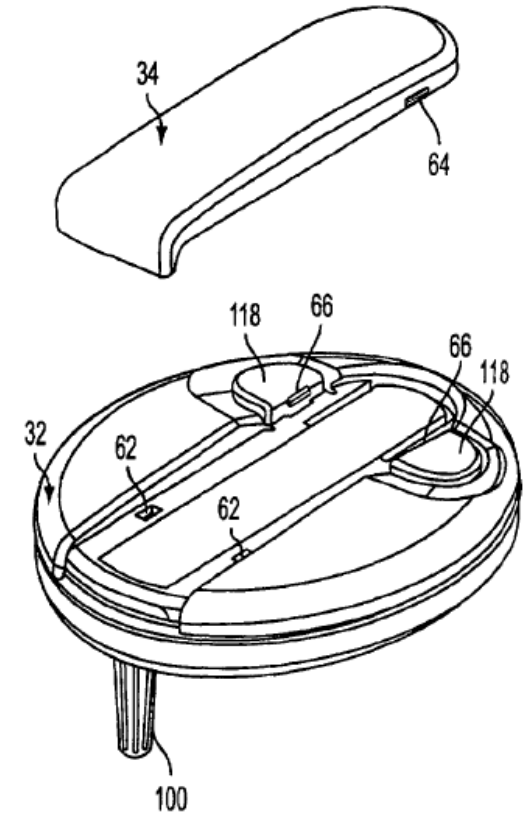
[0008] WO 00/29047 published 25 May 2000 discloses a device and a method for supplying medicaments by a mobile, portable, non-implantable means with wireless operation or programming. WO 00/10628 published 2 March 2000 discloses an infusion system with remote programming, bolus estimator and vibration alarm capabilities and containing a fluid that is expelled through an outlet in a reservoir and housing, and then into a body of a user through tubing and a set. US4559037 published 17 December 1985 discloses a device for pre-programmable infusion of liquids. EP1177802 published 6 February 2002 and falling under Article 54(3) European Patent Convention discloses a self-contained drug infusion device with a disposable portion and a reusable portion remotely connected to the disposable portion.

Features of post-published EP'802 referenced in the Patent in Suit

- It is undisputed that an embodiment disclosed in EP'802 consists of two parts (like the Defendant's product), and discloses all other features of an insulin pump according to Claim 1 of the Patent in Suit.
- In EP'802 the upper part (34) contains the processor, receiver and pump, while the lower part (32) contains the insulin container and the injection needle.

EP'802:

FIG. 2



— Defendant's arguments: No infringement

- As the Patent in Suit mentions EP'802, the claims should be interpreted in a way that they do not encompass prior art embodiments according to EP'802.
- In particular insulin pumps consisting of two parts should thus be excluded from the scope of the claims.
- Consequently, the term „a housing“ in claim 1 should be interpreted as a single or integrated housing consisting of one piece.

— Defendant's arguments: Claimant is in a squeeze situation

- In any event, Claimants cannot claim that claim 1 is valid and infringed:
 - If the Court were to follow Claimant's broad interpretation of "housing" it would be invalid as it would not be novel over EP'802
- The additional feature of claim 2 (i.e. the volume of the reservoir) is trivial and does not justify a different result for claim 2.
- Separate nullity action not required due to PI proceedings.

— Claimant's response

— Claimant's counter-arguments on justification of PI and urgency

- There is no strict requirement to file a PI request within one month.
- It is sufficient that Claimant has pursued enforcing the Patent in Suit by following up after trade fair by way of a warning letter, negotiations, etc.
- Claimant has considered re-opening of negotiations, undertaken market research and pursued preparation of PI request diligently after Defendant's announcement of Europe-wide product launch.

— Claimant's counter-arguments on infringement

- The Patent in Suit does not refer to and thus does not require a (fully) disposable article, the disposability is merely a consequence of the lack of user input components in the housing.
- The reference to EP'802 in the description of the Patent in Suit is not relevant for claim interpretation.
- According to Art. 54(3) EPC, post-published prior art is relevant only for the assessment of novelty.
- There is no justification or need for an effect on claim interpretation by an acknowledgement of the post-published prior art in the description.

— Claimant's counter-arguments on the alleged squeeze

- Defendant cannot argue against infringement of the Patent in Suit on the basis that the patented invention is obvious from EP'802 as EP'802 is not relevant for the assessment of inventive step
- Regarding novelty of claim 2:
 - Also in PI proceedings it is not appropriate to consider invalidity arguments if validity of the asserted patent is not challenged.
 - In any event, EP'802 does not specify the volume of the reservoir (different from claim 2 of the Patent in Suit) – the volume of the reservoir is not disclosed or otherwise anticipated.
 - Person skilled in the art would have rather inferred a higher volume of app. 11ml.

— Defendant's response

— Defendant's counter-arguments on the squeeze and validity

- Claimant has to demonstrate sufficiently secured validity, revocation action is under preparation.
- Person skilled in the art would have inferred volume according to claim 2 from EP'802 even without express mentioning, i.e. EP'802 implicitly discloses all features of claims 1 and 2.
- Claim 2 also lacks novelty:
 - A skilled Person knows that a **typical reservoir** has a volume of 2 to 3 ml. This volume is normally sufficient for a daily insulin dose for 1 to 3 days.
 - A change of the insulin pump is necessary after 3 days due to the **risk of infection** and to the **need for a change of position** (otherwise a reduction in insulin absorption is possible).
 - It is **not advisable** for needles to remain in the body for **longer than 3 days**. They should be replaced at that point.
- Consequently, if the Court were to follow Claimant's claim interpretation, not only claim 1, but also claim 2 would be invalid.

— Further discussion

— Conclusion of oral hearing