



ACT_582093/2023
CC_14323/2024
CC_14326/2024
CC_14317/2024
CC_14320/2024
CC_14325/2024
CC_14226/2024

UPC_CFI_380/2023
Order
of the Court of First Instance of the Unified Patent Court
delivered on 10 December 2024

CLAIMANT

- 1) **EDWARDS LIFESCIENCES CORPORATION** - One Edwards Way - 92614 - Irvine, California – US

Represented by Jens Olsson, Siddharth Kusumakar and Tessa Waldron

DEFENDANTS

- 1) **MERIL LIFE SCIENCES PVT LIMITED** - Bilakhia House, Survey No. 135/139, Muktanand Marg, Chala - Gujarat 396191 - Vapi – IN
- 2) **MERIL GMBH** - Bornheimer Strasse 135 – 137 - D – 53119 - Bonn – DE
- 3) **SMIS INTERNATIONAL OÜ** - Harju maakond, Tallinn, Kesklinna linnaosa, Kaarli pst 9-1a - 10119 - Tallinn – EE
- 4) **SORMEDICA, UAB** - V. Kuzmos str. 28 - LT-08431 - Vilnius – LT
- 5) **INTERLUX, UAB** - Aviečių g. 16 - LT-08418 - Vilnius – LT
- 6) **VAB-LOGISTIK, UAB** - Laisvės pr. 60 - LT-05120 - Vilnius – LT

Represented by Andreas von Falck, Alexander Klicznik, Kerstin Jonen, Roman Wurtenberger, Lars-Fabian Blume, Friederike Rohn and Beatrice Wilden

PATENT AT ISSUE

EP3769722

DECIDING JUDGE

This order has been issued by the judge-rapporteur/presiding judge Stefan Johansson

COMPOSITION OF FULL PANEL

Presiding judge & judge-rapporteur	Stefan Johansson
Legally qualified judge	Kai Härmand
Legally qualified judge	Mélanie Bessaud
Technically qualified judge	Stefan Wilhelm

LANGUAGE OF THE PROCEEDINGS

English

SUBJECT-MATTER OF THE PROCEEDINGS

Infringement action & Counterclaim for revocation

BACKGROUND

The Court held an interim conference on 5 November 2024 by video. During the interim conference, the discussions focussed on

- the value of the case,
- the fact that the EPO has scheduled its hearing for 17 January 2025,
- the fact that Romania has ratified the Agreement on a Unified Patent Court (UPCA),
- the request to exclude/disregard certain attacks on inventive step that were not included in the counterclaim for revocation,
- other requests to exclude/disregard grounds, auxiliary requests, evidence and/or argumentation,
- the previous request on how to deal with the Public Interest Defence,
- the alternative request for a preliminary referral to the CJEU,
- the request for a Court expert,
- the “offer” to hear party experts, and
- practical questions relating to the oral hearing, including the question whether the Parties should be ordered to submit preliminary estimates of the legal costs that they will seek to recover.

This Order sets out the decisions taken during – or following – the interim conference.

GROUNDINGS FOR THE ORDER

The value of the case

The Parties have suggested that the value of the infringement action shall be set to 3.000.000 EUR, that the value of the six counterclaims for revocation shall be set to 3.000.000 EUR, and that the value of the whole proceeding (for the purpose of applying the scale of ceilings for recoverable costs) therefore shall be set to 6.000.000 EUR.

The Court agrees to set the value to these amounts.

The parallel proceedings at the EPO

The Court has scheduled the oral hearing for 16 January 2025. Thereafter, the Parties have informed the Court that the EPO has accelerated an opposition by a third party, targeting the same Patent, and that the EPO Opposition Division has scheduled its hearing for 17 January 2025.

The Defendants have suggested that the Court reschedule its oral hearing and set a new date, after the decision by the EPO Opposition Division. The Claimant has suggested that the Court proceed as planned with the oral hearing on 16 January 2025.

Proceedings before the UPC shall be conducted in a way which will normally allow the final oral hearing at first instance to take place within one year. This infringement action was initiated in October 2023, which means that this clear ambition will not be met in this case, not even if the Court proceeds as planned with its hearing in January 2025. It is also clear that rescheduling the oral hearing could, *inter alia* because of other commitments, mean that the decision was significantly delayed further. At the same time, there are good reasons for trying to avoid that conflicting decisions are issued by the UPC and the EPO.

The Parties have provided the Court with a copy of the EPO Opposition Division's preliminary opinion, and the grounds for opposition are very similar to the grounds for revocation in the Counterclaims that will be decided by this Court in accordance with Article 33.3(a) UPCA. Since the EPO Opposition Division normally deliver its decision orally at the conclusion of the oral hearing, it can be expected that the outcome of the opposition proceedings will be available before this Court issues its decision on the merits (even if the Court proceeds as planned with the oral hearing on 16 January 2025). Furthermore, it can reasonably be assumed that the future decision by the EPO Opposition Division will be subject to an appeal.

Against this background, taking into account the interests of the parties and the relevant circumstances of the case, the Court decides not to reschedule the oral hearing. This means that the oral hearing will take place as planned on 16 January 2025. However, at the hearing, the Court will request the Parties to inform the Court (after the hearing) of the outcome of the opposition proceedings. Thereafter, the Court may decide if further procedural steps are needed.

Romania's ratification of the UPCA

During the interim conference, the Claimant confirmed (again) that this case is only based on the Patent with unitary effect (not any European Patents validated in other States), and that the remedies sought are limited to the States where the Patent has this unitary effect (i.e. does not cover e.g. Romania).

The Claimant's request to exclude/disregard certain attacks on inventive step

In the Counterclaim for revocation, the Defendants alleged that the Patent lacks inventive step based on two separate lines of attacks. The first line of attacks was based on US patent application US 2008/0065011 A1 (**HL-CC6**) as a reasonable starting point ("closest prior art"), in combination with the common general knowledge and/or any of the documents HL-CC9 to HL-CC13 or the prior public use of the CoreValve system. The second line of attacks was based on European patent EP 0787019 B1 (**HL-CC7**) as a reasonable starting point ("closest prior art"), in combination with the common general knowledge and/or any of the documents HL-CC9 to HL-CC13 or the prior public use of the CoreValve delivery system.

In the Reply to the Response to the Counterclaim, and to the Application to Amend the Patent, the Defendants alleged that the starting point for the first line of attacks were US 2008/0065011 A1 (**HL-CC 6**) / **RetroFlex**, i.e. not only the patent application as such but also the product "Retroflex". The Defendants also added attacks based on **HL-CC 9 to HL-CC 13** as reasonable starting points ("closest prior art"), in the light of "the common general knowledge as evidenced by HL-CC 6 / Retroflex and HL-CC 7".

The Claimant has requested that these additional attacks on inventive step should be excluded from the proceedings. In this context, the Claimant has *inter alia* referred to the front-loaded character of the UPC proceedings and the position taken by Paris CD in ACT_555899/2023 (order issued on 5 April and decision issued on 29 July 2024), where the Court concludes that "[g]rounds for revocation that could have been included in the initial statement to revocation are inadmissible if they do not relate to the content of the defence raised by the opposing party or to the application to amend the patent and, therefore, do not constitute a legitimate response to them". According to the Claimant, the additional grounds for revocation submitted in this case could have been included in the initial Counterclaim for revocation, and do not relate to the content of the defence raised by the opposing party or to the application to amend the patent.

The Defendants have *inter alia* argued that these additional starting points for attacks on inventive step are a direct response to the Claimant's position – in its Response – on the scope of the common general knowledge. The Defendants also argue that the UPC Court of Appeal recently has clarified that it is permissible to use several reasonable starting points for attacks on inventive step (not only one "closest prior art") and that this should allow them to add alternative starting points for the attacks on inventive step.

The Court agrees with Paris CD's conclusion that "[g]rounds for revocation that could have been included in the initial statement to revocation are inadmissible and shall be disregarded (Rule 9.2 RoP) if they do not relate to the content of the defence raised by the opposing party or to the application to amend the patent and, therefore, do not constitute a legitimate response to them".

Retroflex as a starting point

The Court notes that the US patent application (HL-CC6) and the product RetroFlex in this context are to be treated as two separate pieces of prior art, even if the product RetroFlex corresponds to something described in the patent application. This means that the starting point for an attack on inventive step ("closest prior art") cannot be a combination of the document and the product.

The product RetroFlex was not used as a starting point for an attack on inventive step (“closest prior art”) in the Counterclaim, even though it could have been so, and to add it as an alternative starting point cannot be seen as a legitimate response to the Claimant’s position on the scope of common general knowledge. Nor can it be justified based on said clarification by the Court of Appeal, *inter alia* since the existence of several attacks in the Counterclaim confirm that the Defendants were aware that several attacks could be made. Therefore, the Court agrees with the Claimant that the product RetroFlex shall be excluded and disregarded as a starting point for an attack on inventive step.

However, as further discussed below (concerning documents HL-CC 20 to HL-CC 28.2), this does not prevent the Defendants from using arguments and evidence relating to RetroFlex to prove the alleged scope of the common general knowledge.

Documents HL-CC 9 to HL-CC 13 as starting points

Documents HL-CC 9 to HL-CC 13 were not used as a starting point for an attack on inventive step (“closest prior art”) in the Counterclaim, even though they could have been so, and to add them as alternative starting points cannot be seen as a legitimate response to the Claimant’s position on the scope of common general knowledge. Nor can they be justified based on said clarification by the Court of Appeal. Therefore, the Court agrees with the Claimant that they shall be excluded and disregarded as alternative starting points for attacks on inventive step.

The Claimant’s request to exclude/disregard some attacks based on added matter

The Counterclaim for revocation is partly based on added matter, i.e. Article 138.1 c) EPC. Some of these attacks were originally described by using the expression “there is no suggestion” (cf. the established term disclosure). In relation to claim 2, the Defendants argued e.g. that *“there is no suggestion in paragraph [0166] of HL-CC 3, nor any other paragraph in the earliest parent application as filed, that the flex indicating device 150 can include “indicia” without also including the other features of the flex indicating device 150 disclosed in paragraphs [0162] to [0165]. Therefore, claim 2 adds subject-matter”*.

During the written procedure, the Claimant argued that these are not admissible attacks based on intermediate generalisation, since the standard to be applied for such attacks is not whether something is “suggested” in the original application, and that any subsequent attempts to amend/clarify such attacks should be disregarded since they would violate the principle of front-loaded proceedings at the UPC.

During the interim conference, the Claimant confirmed that the requests for inadmissibility of these (“there is no suggestion”) attacks are no longer maintained and that the Court is not expected to decide on their admissibility.

The Claimant’s request to exclude/disregard documents HL-CC 20 to HL-CC 28.2, and arguments based on these documents

The Claimant has requested that documents HL-CC 20 to HL-CC 28.2, and arguments based on these documents, shall be excluded from the proceedings. The Claimant has *inter alia* argued as follows. Documents HL-CC 20 to HL-CC 25, HL-CC 28.1 and HL-CC 28.2 are directed towards supporting a new allegation from Meril that the internal mechanism of the RetroFlex Delivery System and RetroFlex II Delivery System were common general knowledge. No argument to this

effect was presented in the Counterclaim for revocation. Meril now seeks to extensively rely on this alleged common general knowledge as part of its inventive step attack. This should not be permitted. Documents HL-CC 26 and HL-CC 27 are irrelevant or unsuitable to prove what Meril alleges.

On this question, the Court would like to point out that the fact that the UPC procedure is a front-loaded system does not mean that the claimant must envisage every possible line of defence and include all arguments, facts and evidence in, and submit it with, the Statement of claim and that nothing could be added thereafter. As recently confirmed by the Court of Appeal, claims and arguments may be further substantiated at a later stage of the main proceedings (see Order issued on 18 September 2024, CoA_265/2024).

In the Counterclaim, the Defendants attacks on inventive step included several specific statements concerning e.g. the common general knowledge. They alleged e.g. that apparatuses for flexing a distal end of a catheter comprising a rotatable member with an internally threaded surface portion which is configured to receive a slide member connected to the at least one pull wire which causes the distal end of a catheter to flex, were part of the common general knowledge, and that the skilled person would combine HL-CC 6 with HL-CC 9.

When the Claimant disputed a number of these specific statements, the Defendants submitted documents HL-CC 20 to HL-CC 28.2. The documents relate to such specific statements in the Counterclaim and are, according to the Defendants, intended to prove that the statements in the Counterclaim are correct. Against this background, the Court concludes that they are admissible. The question whether the documents prove what they are intended to prove will be assessed in connection with the decision on the merits and does not affect the question of admissibility.

The request to declare auxiliary requests inadmissible

The Claimant has filed eleven auxiliary requests 1 to 11 and a further ten Auxiliary Requests 1' to 10' which are identical to Auxiliary Requests 1 to 10, respectively, except that all dependent claims are deleted.

The Defendants have requested that these auxiliary requests shall be declared inadmissible and argued, *inter alia*, 1) that the number of auxiliary requests is not reasonable in view of the circumstances of the case, 2) that the claimant has failed to comply with an established principle under EPO case law that auxiliary requests must be convergent, and 3) that the Claimant has failed to indicate the condition under which the respective auxiliary request should be considered.

According to Rule 30.1 (c) RoP, an Application by the proprietor of the patent to amend the patent which shall contain an “indication whether the proposals are conditional or unconditional; the proposed amendments, if conditional, must be reasonable in number in the circumstances of the case.”. It is not required that auxiliary requests are convergent, but convergence may be relevant when assessing whether the number of auxiliary requests is reasonable.

In this case, the Defendants have raised several different attacks on the validity of the Patent. Some of them are directed to claim 1, while others are directed to different dependent claims. In view of the number and nature of these attacks, the Court finds that the number of auxiliary requests is reasonable. The Claimant has also clarified the condition under which the respective auxiliary request should be considered. Therefore, the requests are admissible.

Equivalence

In its Statement of Claim, the Claimant made the general statement that “[t]o the extent that the Defendants and each of them allege that any of the features of claims 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12 and 13 of EP 722 are not present in the Navigator, the Navigator nevertheless falls within the scope of the claims as a matter of equivalents. Further particulars will be provided if and when the Defendants and each of them allege as such”.

In its Reply to the Statements of Defence, the Claimant specified that “[i]n the event that the Court reaches the conclusion that the “elongated shaft” in claim 1 of EP 722 is required to be the shaft of a “guide catheter”, and that for this reason the Navigator does not fall within the literal meaning of the claim by virtue of it not having such a “guide catheter”, Edwards submits that the Navigator would nevertheless infringe claim 1 as an equivalent”. The Claimant also specified its opinion on how the doctrine of equivalence should be applied by the UPC.

In the Rejoinder, the Defendants have requested that the Claimant's argument regarding an alleged equivalent patent infringement shall be rejected since it is late filed and/or since it not successful in terms of content. Regarding late filing, the Defendants have argued, *inter alia*, that the parties have a general obligation to present their arguments in full as early as possible in the proceedings, and that the Claimant could and therefore should have included the detailed outline of the arguments in the Statement of Claim.

As recently confirmed by the Court of Appeal in case UPC_CoA_456/2024, an equivalence argument does not involve an amendment of a case within the meaning of Rule 263 RoP (Order on 21 November 2024, APL_44633/2024). The Court of Appeal also confirmed that Rule 13 RoP “does not preclude a claimant from raising any new argument after the submission of the Statement of Claim. Whether a new argument is admissible depends on the circumstances of the case, including the reasons why the claimant had not already raised the argument in the Statement of Claim and the procedural opportunities for the defendant to respond to the new argument. In making this assessment, the Court of First Instance has a certain discretion”.

In this case, the Claimant made a general reference to equivalence in its Statement of Claim, but did not elaborate on this in relation to every feature in the claims that potentially could be subject to dispute. Instead, the Claimant waited for the statement of defence and thereafter limited the discussion on equivalence to the event that the Court would reach the conclusion that the “elongated shaft” in claim 1 of EP 722 is required to be the shaft of a “guide catheter”.

The Defendants have not convinced the Court that the Claimant should have foreseen that this is where equivalence would become relevant and, for reasons of procedural economy, the Claimant cannot be expected to include in its Statement of Claim a detailed outline of the arguments on equivalence in relation to every feature where this doctrine may become relevant. Furthermore, the Defendants have already had the opportunity to respond to the argument, and will also be able to do so at the oral hearing.

For these reasons, the Court concludes that the Claimant’s arguments based on equivalence are admissible.

The request to exclude/disregard a ground for non-infringement of claim 2

In their Statements of defence, the Defendants argued, *inter alia*, that the attacked embodiment does not infringe claim 1, because the feature “elongated shaft” in claim 1 requires that this shaft is part of a guide catheter / the guide catheter itself, while the attacked embodiment consists solely of a balloon catheter which in turn consists of an inner and an outer shaft. The Defendants further argued that since independent claim 1 is not realized by the attacked embodiment, dependent claim 2 is not realized either. Dependent claim 2 reads as follows: “The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.

In the Rejoinder and the Reply to an Application to amend the Patent, the Defendants added that the skilled person would understand Claim 2 (as granted) to require that the indicia allow a quantitative determination of the amount of flex (for example by means of a scale), preferably by triangular marking system or numbers. According to the Defendants, the attacked embodiment does not have indicia allowing a quantitative amount of flex (especially, it does not have scale, for example a triangular marking system or numbers).

The Claimant has requested that the Defendants new non-infringement position with respect to claim 2 shall not be admitted into proceedings and argue, *inter alia*, that this would not be in line with the obligation under Rule 25(g) RoP to set out its position on the interpretation and infringement of all claims in its Statement of Defence, and that it at least would require an application for leave from the Court to amend its Defence.

The Defendants have replied, *inter alia*, that Rule 24(g) RoP does not preclude Defendants from submitting additional non-infringement arguments at a later stage. There will also be no delay of the proceedings or any disadvantage to Claimant. In any case, the non-infringement argument is not to be considered as being late filed in the present proceedings to Amend the Patent as Defendants for the first time had the chance to raise this argument in their Defence dated 22 July 2024.

The Court of Appeal has in Case UPC_CoA_456/2024 (Order on 21 November 2024, APL_44633/2024) clarified that “[a]n amendment of a case occurs when the nature or scope of the dispute changes. For example, in an infringement case, this occurs if the plaintiff invokes a different patent or objects to a different product”.

Accordingly, the new argument provided by the Defendants cannot be seen as an amendment that requires an application for leave from the Court to amend the Defence. Instead, the question is whether Rule 13 RoP, interpreted in light of the final sentence of Recital 7 of the Preamble to the Rules of Procedure (the requirement to set out the case as early as possible in the proceedings), prevents the Defendants from relying on this new argument. This question shall, according to the order from the Court of Appeal mentioned above, be assessed based on “the circumstances of the case, including the reasons why the claimant had not already raised the argument in the Statement of Claim and the procedural opportunities for the defendant to respond to the new argument. In making this assessment, the Court of First Instance has a certain discretion”.

The Defendants have – in general terms – explained that their new position on claim construction is caused by the application to amend the patent. The Claimant has already responded to the new argument (in the reply to the defence to the application to amend the patent) and will have an

additional opportunity to do so at the oral hearing. For these reasons, the Court concludes that this rather limited modification of the Defendants position in relation to Claim 2 can and should be held admissible.

How to deal with the Public Interest Defence

During the interim conference, the Claimant confirmed its withdrawal of its previous request to deal with the Public Interest Defence at a separate hearing, if needed. Therefore, the Court concludes that all aspects of the case will be dealt with at the oral hearing on 16 January 2025.

The alternative request for a referral to the CJEU

During the interim conference, the Defendants confirmed that they don't expect the Court to take a decision on a referral to the CJEU unless the Court comes to the conclusion that there is a need for such a referral. At this stage, the Court does not see the need for a preliminary ruling.

The request for a Court expert

The Defendants have requested the allocation of a Court expert, but not convinced the Court that there is a need for such an expert. Therefore, it shall be rejected.

The “offer” to hear party experts

In the Replies to the Response to the Counterclaims and to the Application to amend the Patent, the Defendants submitted a written expert opinion by ■■■■■■■■ (HL-CC 28) and requested – “in case of dispute and as a matter of precaution” – that the expert witness of Defendants be summoned to the oral hearing and be heard at the oral hearing and the parties be allowed to question him. The expert was offered for several different statements made by the Defendants in their Replies as well as for the understanding and knowledge of the skilled person evidence.

During the interim conference, the Defendants clarified that this request should not be understood as an application to hear the expert (Rule 176 RoP), it was an “offer” to hear him. At the same time, the Defendants clarified that it could be seen as a conditional request, since they were of the opinion that the Court had to hear the expert if it intended to decide against the Defendants in any respect covered by the written expert opinion and/or the offer to hear him.

The Claimant has argued that there is no need to hear the party experts but have added that if the Court intends to hear the Defendant's expert the Court should also hear the Claimant's expert.

According to Article 53 UPCA, the questioning of witnesses and experts shall be limited to what is necessary. Furthermore, Rule 113.2 RoP specify that any oral testimony shall be limited to issues identified by the judge-rapporteur or the presiding judge as having to be decided on the basis of oral evidence. The provisions in Rules 176 and 177.1, which applies *mutatis mutandis* to experts of the parties (see Rule 191 RoP), must be read against that background.

According to Rule 176 RoP, a party seeking to offer oral witness evidence shall make an Application for the hearing of a witness in person which shall set out:

- (a) the reasons why the witness should be heard in person;
- (b) the facts which the party expects the witness to confirm; and
- (c) the language in which the witness shall give evidence.

According to Rule 177.1 RoP, the Court may order that a witness be heard in person:

- (a) of its own motion;
- (b) where a written witness statement is challenged by the other party; or
- (c) on an Application for the hearing of a witness in person [Rule 176].

In this case, the Defendants have submitted an expert opinion by ■■■■■■■■■■ where he *inter alia* explains – with reference to certain patent documents – his opinion on whether and/or why certain things were common general knowledge at the priority date.

The Defendants have chosen not to submit an application pursuant Rule 176 RoP, specifying concrete facts where there – in the Defendants opinion – is a need to hear ■■■■■■■■■■ in person. Instead, the expert has been offered for several different statements made by the Defendants in their Replies as well as for the understanding and knowledge of the skilled person evidence.

Against this background, and since the Court finds it hard to see the additional value of also hearing ■■■■■■■■■■ in person, there is – according to the Court – not sufficient reasons for hearing him in person. However, unlike what the Defendants seems to suggest, this does not mean that the Court – in its Decision – is prevented from disagreeing with the relevant statements made by the Defendants and/or in the expert opinion. The written statement made by ■■■■■■■■■■ will be treated just like any other evidence.

Practical questions relating to the oral hearing

Practical questions relating to the oral hearing were discussed, including:

- At the oral hearing, validity will be discussed before infringement. The Court intends to provide more detailed instructions.
- All parties expressed the opinion that no one would benefit of an order requesting the parties to submit preliminary estimates of the legal costs that they will seek to recover. The Court accepted this position.
- Any slides used by the parties during the presentations at the oral hearing shall be sent to Court and the opposing party's representatives by e-mail when respective presentation begins.

ORDER

1. The value of the infringement action is set to 3.000.000 EUR, the value of the six counterclaims for revocation is set to 3.000.000 EUR, and the value of the whole proceeding (for the purpose of applying the scale of ceilings for recoverable costs) is set to 6.000.000 EUR.

2. The oral hearing will take place as planned on 16 January 2025. However, at the hearing, the Court will request the Parties to inform the Court (after the hearing) of the outcome of the opposition proceedings. Thereafter, the Court may decide if further procedural steps are needed.

3. The late filed attacks on inventive step, based on the product RetroFlex or documents HL-CC 9 to HL-CC 13 as a starting point, are excluded and will be disregarded as attacks on inventive step.

4. The auxiliary requests are admissible.

5. The Claimant's arguments based on equivalence are admissible.

6. The Defendants new position in relation to Claim 2 is admissible.
7. At this stage, there is no need to make a request for a preliminary ruling by the ECJ.
8. The request for a Court expert is rejected.
9. There are not sufficient reasons for hearing party experts in person.

Stockholm, 10 December 2024

Stefan Erik Digitally signed by
Johansson Stefan Erik Johansson
Date: 2024.12.10
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Stefan Johansson
Presiding judge and judge-rapporteur

INFORMATION ABOUT APPEAL/REVIEW

According to Rule 333.1 RoP, a case management order made by the judge-rapporteur or the presiding judge can be reviewed by the panel, on a reasoned Application by a party.