

UPC Court of Appeal, 21 November 2024, OrthoApnea



PATENT LAW – PROCEDURAL LAW

Not every new argument constitutes an “amendment of a case” (**R. 263 RoP**)

- **An amendment of the case in the sense of art. 263 only occurs when the nature and scope of the dispute changes such as through the introduction of a new patent or objection to a new product.**
- **A new basis for infringement (such as equivalence) merely concerns the extent of protection conferred under the art. 69 EPC and the corresponding protocol.**

Where **R. 263 RoP** does not apply, no leave is required to amend the pleadings.

If a new argument is not an amendment of the case, the CFI has discretion regarding a violation of the obligation under **R. 13 RoP** to set out the case as early as possible

- **R. 13 RoP sets limitations on what arguments may be raised after the Statement of claim because parties are required to set out their cases as early as possible.**
- **The CFI has discretion to hold that new argumentation does not violate R. 13 RoP.** The fact that the new argumentation is in line with arguments of the Statement of claim, and that the defence is not unreasonably prejudiced contributes to such a decision falling within said discretion.

Source: **Unified Patent Court**

UPC Court of Appeal, 21 November 2024

(Grabinski, Blok, Germano)

UPC_CoA_456/2024

APL_44633/2024

Order

of the Court of Appeal of the Unified Patent Court issued on 21 November 2024

HEADNOTE

1. Not every new argument constitutes an “amendment of a case” requiring a party to apply for leave under **R. 263 RoP**. An 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.

2. If a new argument is not an amendment of the case for which judicial leave is required under **R. 263 RoP**, there still are restrictions on raising new arguments. **R. 13 RoP** requires that the Statement of claim contains the reasons why the facts relied on constitute an infringement of the patent claims, including arguments of law. This provision must be interpreted in light of the final sentence of **Recital 7 of the Preamble to the Rules of Procedure**, which requires parties to set out their case as early as possible in the proceedings.

3. However, **R. 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. The Court of Appeal's review is thus limited.

4. If a new argument does not amend the case within the meaning of **R. 263 RoP**, the claimant need not apply to the Court for leave. If the opposing party is of the opinion that a new argument is inadmissible, it can object to it. The Court may raise the issue of admissibility of a new argument ex officio. The Court will decide after hearing the parties. The Court may defer that decision until the interim procedure or the final decision. If the new argument is inadmissible and the opposing party has submitted a defence on the substance of the new argument, the Court may take this into account when awarding costs.

KEYWORDS

Appeal; leave for change of a claim or amendment of a case; new arguments

APPELLANTS (DEFENDANTS IN THE MAIN PROCEEDINGS BEFORE THE COURT OF FIRST INSTANCE)

1. OrthoApnea S.L. Flauta Mágica 22, 29006 Malaga, Spain,

2. Vivisol B BV Zoning Ouest 14, 7860 Lessines, Belgium,

hereinafter: OrthoApnea,

represented by attorney-at-law Marleen van den Horst (La Gro Geelkerken Advocaten),

RESPONDENT (CLAIMANT IN THE MAIN PROCEEDINGS BEFORE THE COURT OF FIRST INSTANCE)

[...]

hereinafter: the respondent,

represented by attorney-at-law Christophe Ronse (ALTIUS Advocaten),

PATENT AT ISSUE

European Patent **2331036**

LANGUAGE OF THE PROCEEDINGS:

Dutch

PANEL AND DECIDING JUDGES

Panel 1c Klaus Grabinski, President of the Court of Appeal Peter Blok, Legally qualified judge and judge-rapporteur Emanuela Germano, Legally qualified Judge
IMPUGNED ORDERS OF THE COURT OF FIRST INSTANCE

□ [Order of the Court of First Instance of the Unified Patent Court, Brussels Local Division, dated 8 July 2024](#) Reference numbers:

ACT_581538/2023

UPC_CFI_376/2023

App_37702/2024

ORD_37783/2024 3

□ [Order of the Court of First Instance of the Unified Patent Court, Brussels Local Division, dated 19 July 2024](#) Reference numbers:

ACT_581538/2023

UPC_CFI_376/2023

App_41533/2024

ORD_42503/2024

FACTS AND REQUESTS OF THE PARTIES

5. The respondent is the proprietor of European patent 2 331 036 B1 for a ‘device for treating night time breathing problems’ (hereinafter: the patent at issue). The patent at issue concerns a device to be placed in the mouth for treating night time breathing problems, also known as a snore or sleep brace. Claim 1 of the patent at issue reads as follows, divided into features as structured by the respondent:

1.0 Device for treating breathing problems, comprising

1.1 a lower part (2) mountable on the lower jaw and an upper part (3) mountable on the upper jaw, which lower and upper parts are adapted to be situated at least in the vicinity of the back teeth; and

1.2.0 left and right coupling means (4) for coupling the lower part to the upper part close to the back teeth; wherein each of the left and right coupling means comprises an upper coupling element (6) connected to the upper part and a lower coupling element connected to the lower part (5); which left and right coupling means are adapted to move the lower jaw forward in relation to the upper jaw;

1.2.1 wherein the upper coupling element is provided with a stop (13) for co-action with a contact surface (12) of the lower coupling element; and

1.2.2 wherein each upper coupling element (5, 6) is provided with a portion with a concave or convex surface (15) directed toward the front teeth, and that each lower coupling element is provided with a complementarily shaped surface (16), this such that the upper coupling element can engage in the lower coupling element and that rearward movement of the lower jaw is avoided;

1.2.3 characterized in that the upper and lower coupling elements (5, 6) are connected to respectively the upper and lower part such that these upper and lower coupling elements are situated in the oral vestibule in the position of the device placed in the mouth,

1.2.4 and in that said stop (13) and said contact surface (12) are located in the oral vestibule, on the

vestibular side of the tooth arch, in the position of the device placed in the mouth, such that when lower jaw and upper jaw are moved toward each other a further closing of the mouth is prevented when the contact surface comes up against the stop.

6. The respondent has noted that OrthoApnea offers a product under the name NOA which according to the respondent falls within the scope of protection of the patent at issue.

7. Since March 2021, the parties have been in correspondence regarding the alleged infringement. In a letter dated 14 June 2021, OrthoApnea contested the infringement, arguing that the coupling elements of the NOA do not prevent the further closing of the mouth.

8. Upon application by the Respondent, the Court of First Instance, Brussels Local Division, granted an order for the preservation of evidence and a description on 21 September 2023. In the context of the enforcement of this order, the expert appointed by the Court submitted her report on 28 September 2023 (hereinafter: the Pitch report). The Pitch report describes, inter alia, the results of two experiments conducted by the expert with respect to claim feature 1.2.4 of the patent at issue: in one experiment, the upper and lower pieces are pressed against each other; in the other, the pieces are held in a laterally tilted position. The expert notes that, on the basis of the information available, she cannot determine whether the laterally tilted position actually occurs when the NOA is used by patients and, consequently, whether the lower surface of the upper coupling elements actually functions as a stop. She presents the following results from the experiments:

In the closed position, i.e. with the upper and lower parts pressed together, the above-defined ‘lower surfaces’ of the upper coupling elements or followers do not form a stop for the abovedefined ‘upper surfaces’ of the lower coupling elements or combs. (Experiment; Photos 25 to 31.)

In the laterally tilted position, one of the above-defined ‘lower surfaces’ of the upper coupling elements or followers forms a stop for the corresponding ‘upper surface’ of the lower coupling elements or combs. (Experiment; Photos 32 to 35.)

9. The respondent brought an action for infringement of the patent at issue against OrthoApnea before the Brussels Local Division of the Court of First Instance of the Unified Patent Court. The Statement of claim includes, among other things, the following remarks about claim feature 1.2.4:

In its letter of 14 June 2021, OrthoApnea further stated that the coupling elements would play no role in closing the mouth.

OrthoApnea seems to be arguing that, in addition to the stop and the contact surface, the upper and lower parts at the molars can also come into contact with each other during the complete and equal closure of the upper jaw and the lower jaw [...].

Even if this were so, this has no impact on the assessment under feature 1.2.4.

After all, firstly, claim feature 1.2.4 does not rule out the possibility of other surfaces also coming into contact. Instead, claim feature 1.2.4 only requires that 'when lower jaw and upper jaw are moved toward each other a further closing of the mouth is prevented when the contact surface comes up against the stop'.

Secondly, the patient will also not always close the mouth perfectly evenly as in the representation by OrthoApnea, and while sleeping will often even be in a laterally tilted position. As described above, the expert observed even ex vivo that at that time there is a contact surface between (the lower surface of) the follower of the upper part and (the upper surface of) the ridge of the lower part [...].

10. OrthoApnea filed a Statement of defence. In it, OrthoApnea contested, inter alia, that the NOA complies with claim feature 1.2.4. In that regard, it argued that the tilted position of the second experiment of the Pitch report does not occur in practice when using the NOA.

11. The Respondent filed a Statement of Reply. In it, he further discussed the presence of claim feature 1.2.4. In addition, if the Court were to find that the NOA did not literally infringe feature 1.2.4, he argued that there is at least infringement by equivalence.

12. OrthoApnea objected to certain parts of the Statement of Reply. It primarily requested that the judge-rapporteur reject: i) the extension of the basis of the request by invoking equivalence, ii) the newly alleged facts, and iii) the new (amended) claims. In the alternative, OrthoApnea requested that the deadline for their Statement of rejoinder be extended to 18 August 2024.

13. In his order of 8 July 2024, the judge-rapporteur rejected the primary request (hereinafter: the primary order). He extended the deadline for filing OrthoApnea's Statement of rejoinder to 1 August 2024.

14. OrthoApnea sought a review of the primary order by the panel of the Brussels Local Division of the Court of First Instance. In that context, it did not maintain parts (ii) and (iii) of its primary application.

15. After hearing the respondent, the panel of the Brussels Local Division by order of 19 July 2024 decided, so far as relevant on appeal, to reject the application for review and to uphold the order of the judge-rapporteur (hereinafter: the review order). The panel granted leave to appeal against the review order. The grounds of the review order can be summarised as follows:

- The panel's review was narrow in scope in the sense that it was limited to verifying whether the judge-rapporteur relied on the correct facts, whether he assessed them correctly and whether he took his decision within the bounds of reasonableness;
- The judge-rapporteur correctly held that [R. 263 of the Rules of Procedure](#) of the Unified Patent Court (hereinafter RoP) did not apply because the equivalence argumentation does not affect the subject matter of the proceedings;

- In line with the procedural evolution of a legal dispute and after receiving the initial defence, the respondent additionally and subordinately invoked infringement on the basis of equivalence. It cannot be accepted that the respondent was required to address all possible defences in its Statement of claim without OrthoApnea having set them out in detail. Moreover, it has not been established that the respondent was aware that OrthoApnea would dispute the presence of feature 1.2.4 and, if so, with what arguments;

- OrthoApnea has not argued (substantiated) that its defence was affected by the equivalence argument;

- The fact that the doctrine of equivalence has not yet been developed within the Unified Patent Court case-law and that it has also given rise to extensive discussions in national proceedings is insufficient to regard the argument in this case as a new ground or otherwise inadmissible;

- The extended time limit for submitting the Statement of rejoinder granted by the judge-rapporteur to the appellants is sufficient. OrthoApnea failed to provide a sufficiently concrete and substantiated explanation as to why it needs a longer period.

16. OrthoApnea filed an appeal against the primary order and the review order and applied for suspensive effect under [R. 223 RoP](#).

17. By order of 26 July 2024, the standing judge of the Court of Appeal dismissed OrthoApnea's request for suspensive effect.

18. In its Statement of appeal, OrthoApnea requests that the Court of Appeal set aside the primary order and review order and:

- I. determine that raising equivalence as a new basis for the infringement action in the Statement of reply was submitted too late, having regard to the specific circumstances of the case, and must not be allowed;

- II. order the respondent to pay the costs of these proceedings or suspend the decision on the costs of these proceedings until judgment in the main action is rendered.

The grounds of appeal can be summarised as follows:

- Equivalence is a fundamentally new legal basis for which leave must be sought under [R. 263.1 RoP](#);

- [Recital 7](#) and [R. 13 RoP](#) require that the claimant set out in the Statement of claim the reasons why the facts alleged constitute patent infringement, including legal arguments;

- This is all the more true in this case because, prior to the proceedings, OrthoApnea had already informed the respondent that there was no (literal) infringement and the expert had established that there was no (literal) infringement in the context of the evidence seizure;

- A defendant should be able to take the decision to settle the case or request expert evidence based on the Statement of claim;

- The front-loaded system of the Rules of Procedure ensures the legal certainty and predictability of the proceedings.

19. The respondent requests that the Court of Appeal dismiss OrthoApnea's request and order OrthoApnea to pay the costs of the proceedings or suspend the decision on costs until the final judgment is rendered in the main action. The response may be summarised as follows:

- Equivalence is a subsidiary argument raised by the respondent in the Statement of reply in response to the non-infringement argument raised by OrthoApnea for the first time in their Statement of defence. There is no change in the basis of the infringement claim;

- [R. 13 RoP](#) leaves room for raising new facts;

- OrthoApnea have not been harmed in their defence. It presents mere theoretical considerations;

- In the event that the Court of Appeal should find that [R. 263 RoP](#) applies, the respondent refers to the request for amendment which it included in its defence at first instance against OrthoApnea's application.

GROUND FOR THE ORDER

Admissibility of the appeal

20. The appeal against the primary order is inadmissible. The appropriate remedy against the *jugerapporteur's* case management order is not an appeal, but an application for review pursuant to [R. 333.1 RoP \(Court of Appeal 21 March 2024, UPC CoA 486/2023 APL 595643/2023\)](#).

21. The appeal against the review order is admissible.

[R. 263 RoP not applicable](#)

22. Pursuant to [R. 263.1 RoP](#) a party may at any stage of the proceedings apply to the Court for leave to change its claim or to amend its case, including by adding a counterclaim. OrthoApnea argues that the introduction of the equivalence argument constitutes an amendment of the case.

23. Not every new argument constitutes an "amendment of a case" requiring a party to apply for leave under [R. 263 RoP](#). An 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.

24. The Court of First Instance correctly held that the equivalence argument did not involve an amendment of a case within the meaning of [R. 263 RoP](#). The equivalence argument does not change the nature or scope of the dispute. It is in line with the infringement argument put forward by the respondent in the statement of claim. The equivalence argument is based on the same patent and is directed against the same product. Like the argument of a literal infringement, the equivalence argument, in the case at hand, concerns the extent of protection conferred by the patent at issue under [Art. 69\(1\) European Patent Convention](#) and the [Protocol on the Interpretation of the Art. 69\(1\) EPC](#).

25. Since [R. 263 RoP](#) does not apply to the equivalence argument in this case, OrthoApnea's complaint that the

respondent failed to file an application for amendment of the case or failed to do so in time is unfounded.

[R. 13 RoP not violated](#)

26. If a new argument is not an amendment of the case for which judicial leave is required under [R. 263 RoP](#), there still are restrictions on raising new arguments. [R. 13 RoP](#) requires that the Statement of claim contains the reasons why the facts relied on constitute an infringement of the patent claims, including arguments of law. OrthoApnea correctly argue that this provision must be interpreted in light of the final sentence of [Recital 7 of the Preamble to the Rules of Procedure](#), which requires parties to set out their case as early as possible in the proceedings.

27. However, [R. 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. The Court of Appeal's review is thus limited.

28. If a new argument does not amend the case within the meaning of [R. 263 RoP](#), the claimant need not apply to the Court for leave. If the opposing party is of the opinion that a new argument is inadmissible, it can object to it. The Court may raise the issue of admissibility of a new argument ex officio. The Court will decide after hearing the parties. The Court may defer that decision until the interim procedure or the final decision. If the new argument is inadmissible and the opposing party has submitted a defence on the substance of the new argument, the Court may take this into account when awarding costs.

29. In holding that the respondent did not violate [R. 13 RoP](#) by failing to include the equivalence argument in the Statement of claim, the Court of First Instance did not exceed the limits of its discretion. The equivalence

argument is a response to the Statement of defence, in which OrthoApnea argued that feature 1.2.4 of the patent at issue is not present in their products. In addition, as the Court of Appeal has indicated above, the equivalence argument is in line with the argumentation on literal infringement presented by the respondent in the Statement of claim. The equivalence argument is based on the same patent, is directed against the same products and relates to a claim feature that the respondent has specifically addressed in the Statement of claim, including by means of a description of the functioning of the elements of the NOA that the defendant claims correspond to that claim feature.

30. OrthoApnea's defence is not unreasonably prejudiced, as it has the opportunity to respond to the equivalence argument both in writing (in their Statement of rejoinder), and orally (at the oral hearing in the main proceedings). Moreover, the Court of First Instance extended the time limit for the Statement of rejoinder to give OrthoApnea additional time for their response to the equivalence argument.

31. OrthoApnea's argument that the respondent could have anticipated that it would dispute in the Statement of defence that the NOA has claim feature 1.2.4, also in view of the correspondence between the parties and the Pitch report, does not alter the assessment. In the Statement of claim, the respondent discussed OrthoApnea's counterarguments as known from the correspondence and the Pitch Report. The respondent believed it had thereby sufficiently rebutted these counterarguments and substantiated the alleged literal infringement. However, the correspondence and the Pitch Report do not include all the arguments raised by OrthoApnea in respect of claim feature 1.2.4. It is undisputed that OrthoApnea argued for the first time in the Statement of defence that the tilted positions on which the respondent also based its infringement argument in the Statement of claim could not occur when using the NOA. The Court of First Instance's finding that the respondent did not know that OrthoApnea would contest the realisation of feature 1.2.4 with this argument is not incomprehensible.

Conclusion

32. The appeal against the primary order is inadmissible. While the appeal against the review order is admissible, it must be rejected. The Court of Appeal will not issue an order for costs in this instance, since this order is not a final order or decision concluding an action.

ORDER

- The appeal against the primary order is declared inadmissible;
- The appeal against the review order is rejected.

This order was issued on 21 November 2024

NAMES AND SIGNATURES

Presiding Judge Grabinski
Legally qualified judge and judge-rapporteur Blok
Legally qualified judge Germano
