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**Datasheet for the decision
of 29 September 2025**

Case Number: T 0321/24 - 3.3.07

Application Number: 18821995.0

Publication Number: 3720497

IPC: A61K47/02, A61K9/00, A61K9/08,
A61K9/14, A61K9/20, A61K31/465,
A61P25/34

Language of the proceedings: EN

Title of invention:
HIGH NICOTINE CONCENTRATION

Applicant:
Fertin Pharma A/S

Headword:
High nicotine concentration / FERTIN

Relevant legal provisions:
EPC Art. 108
EPC R. 99(2), 101(1)

Keyword:
Admissibility of appeal - appeal sufficiently substantiated
(no)

Decisions cited:

T 1407/17, T 0899/13



Beschwerdekammern

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Case Number: T 0321/24 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 29 September 2025

Appellant: Fertin Pharma A/S
(Applicant) Dandyvej 19
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Representative: Patentgruppen A/S
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 22 September
2023 refusing European patent application No.
18821995.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman A. Uselli
Members: E. Duval
L. Basterreix

Summary of Facts and Submissions

I. The appeal was filed by the applicant (appellant) against the decision of the examining division to refuse the European patent application No 18821995.0 (hereinafter "the application"). The decision was based on a main request and auxiliary requests 1-9 filed on 10 August 2023.

II. Claims 1 and 18 of the main request read as follows:

"1. An orally disintegrating nicotine tablet for use in the alleviation of nicotine craving, the orally disintegrating tablet comprising a content of nicotine and a content of a pH regulating agent, wherein the orally disintegrating tablet provides a peak saliva concentration of nicotine of more than 0.3 mg/mL and a peak saliva pH of more than 7.5 during the first 120 seconds upon oral administration, wherein the tablet comprises at least one polyol and wherein the polyol comprises more than 40% by weight of the tablet."

"18. An orally disintegrating nicotine tablet, the orally disintegrating tablet comprising a content of nicotine and a content of a pH regulating agent, wherein the orally disintegrating tablet is adapted to provide a peak saliva concentration of nicotine of more than 0.3 mg/mL and a peak saliva pH of more than 7.5 during the first 120 seconds upon oral administration, wherein the tablet comprises at least one polyol and wherein the polyol comprises more than 40% by weight of the tablet."

In each of the auxiliary requests, the claims also comprised the features relating to "a peak saliva concentration of nicotine of more than 0.3 mg/mL" and "a peak saliva pH of more than 7.5 [or 8.0] during the first 120 seconds upon oral administration".

III. The examining division decided that the subject-matter of the main request was neither clear nor sufficiently disclosed with respect to the feature "the orally disintegrating tablet provides a peak saliva concentration of nicotine of more than 0.3 mg/mL" and "a peak saliva pH of more than 7.5 during the first 120 seconds upon oral administration". Furthermore, the subject-matter of the main request lacked novelty and inventive step. The same objections applied to each of the auxiliary requests 1-9.

IV. With their statement setting out the grounds of appeal, the appellant filed a main request and auxiliary requests 1-9.

The main request is identical to the main request underlying the decision. Auxiliary requests 1-9 also comprise the features relating to "a peak saliva concentration of nicotine of more than 0.3 mg/mL" and "a peak saliva pH of more than 7.5 [or 8.0] during the first 120 seconds upon oral administration".

V. In a communication under Article 15(1) RPBA, the Board expressed the preliminary opinion that the appeal was not admissible.

VI. Oral proceedings were held before the Board by videoconference.

- VII. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the main request, or, in the alternative, on the basis of one of auxiliary requests 1-9, all filed with the statement setting out the grounds of appeal.
- VIII. The appellant's arguments regarding admissibility of the appeal may be summarised as follows:

The statement setting out the grounds of appeal contained counterarguments against all arguments presented in the appealed decision, and explicitly stated that the claims fulfilled the requirement of clarity. The decision found the claims to violate Articles 83 and 84 EPC for the same reasons. The grounds of appeal thus provided the Board with all the elements necessary to decide whether or not to set aside the contested decision.

Page 11 of the decision merely presented observations without relating these to any objection, such that the appellant could not be required to respond to them. In addition, the reference to table 13C had no relation with claim 1 and could result from a confusion with the co-pending application number 18821996.8, i.e. case T 8/24.

Hence, the appeal was admissible.

Reasons for the Decision

1. Admissibility of the appeal

- 1.1 The proceedings before the examining division may be summarised as follows.
 - 1.1.1 In response to objections under Articles 83 and 84 EPC, the appellant submitted, with their letter dated 7 July 2022, under the heading "Sufficiency of disclosure" (see page 2), arguments based on pages 65 and 71 of the description (see the section "*In vivo* measurements" on pages 3-4).
 - 1.1.2 With the summons to oral proceedings issued on 23 March 2023, the examining division provided detailed objections under Articles 83 and 84 EPC (see §3). Section §3.6 in particular explains that the features relating to peak saliva concentration of nicotine and peak saliva pH are unclear because neither the test subjects nor the experimental methods are specified in the application or known generally, and because there are inherent variations among different subjects and different testing conditions. This section §3.6 also contains a reasoning regarding pages 65 and 71 of the description.
 - 1.1.3 After the appellant withdrew their request for oral proceedings, the examining division issued the appealed decision refusing the application in writing. This decision comprises the same passages regarding Articles 83 and 84 EPC as in the summons (see §2 and especially §2.6 in the impugned decision).
- 1.2 The decision under appeal is thus based among other grounds on a lack of clarity (Article 84 EPC) in relation with the features pertaining to peak saliva concentration of nicotine and peak saliva pH (see §2, especially §2.6). While sections §2.1-§2.5 relate to Article 83 EPC and cite part of the Guidelines for

Examination in the EPO regarding insufficiency of disclosure (namely part F-III), section §2.6 clearly relates first and foremost to Article 84 EPC and relies on criteria for clarity set out in part F-IV of the Guidelines. Contrary to the appellant's view, it is also clear that the reasoning on page 11 is part of section §2.6 on clarity and addresses the appellant's arguments based on pages 65 and 71 in the context of said criteria for clarity. The fact that the impugned decision additionally concludes that the criteria of Article 83 EPC are not met does not change this conclusion (see the fifth paragraph on page 11).

- 1.3 The grounds of appeal do not address the ground of refusal under Article 84 EPC. Neither clarity nor Article 84 EPC are explicitly mentioned in the grounds of appeal.

At most, the grounds of appeal contain a passage entitled "*in vivo* measurements" (see page 5), as part of the reasoning on sufficiency of disclosure (see the heading on page 3). However, this passage is essentially identical to the passage with the same heading in the letter submitted to the examination division on 7 July 2022 (see pages 3-4), and quotes the same passages from the description without adding anything. The examining division addressed these arguments in their reasoning on page 11 of the decision. The grounds of appeal do not address the examining division's reasoning as such.

The appellant argues that the sentence "the skilled person can readily determine if a tablet falls under the scope of claim 1 or not" in the passage entitled "*in vivo* measurements" is a clear statement that the claims fulfil the requirement of clarity. However, this

passage remains within a part of the grounds of appeal explicitly dealing with sufficiency of disclosure (see the heading on page 3 and the second paragraph on page 5 of the grounds). Furthermore, it does not address the reasoning on page 11 of the decision. In any case, the mere affirmation that "the skilled person can readily determine if a tablet falls under the scope of claim 1 or not" does not constitute a reasoned statement explaining why the appeal decision should be set aside in respect of lack of clarity.

- 1.4 Where there are several independent reasons for the decision to refuse the application and at least one of those reasons is not addressed in the statement of grounds at all or only in insufficient detail, the requirements of Article 108 and Rule 99(2) EPC are not met (see T 899/13 and T 1407/17).

Furthermore, where the appellant, in its grounds of appeal, repeats the arguments it put forward during the examination phase without taking into account the contested decision, it fails to understand the function of the Boards of Appeal, which are not responsible for re-examining the examination procedure but for reviewing the decision taken by the examination division on the basis of the grounds of appeal raised, which must therefore relate to the grounds on which the contested decision is based (see the Case Law of the Boards of Appeal, 11th edition, 2025, V.A.2.6.3.d)).

- 1.5 In the case at hand, one of the grounds for refusing the patent application, namely lack of clarity, is not addressed by the appellant in their statement setting out the grounds of appeal. Instead of addressing the objection of lack of clarity specifically raised in the impugned decision, the appellant merely reproduced a

passage they had submitted during the examination phase on 7 July 2022. This does not enable the Board to assess whether or not the decision is incorrect.

The appellant expressed the view that the grounds of appeal address the common reasoning underlying both the objections under Article 83 EPC and under Article 84 EPC. The Board is not convinced by this argument, because the grounds explicitly relate their reasoning to Article 83 EPC, and do not take into account the reasoning relating specifically to Article 84 EPC in section §2.6 of the decision under appeal.

The Board emphasizes that it is not for the appellant to decide which part of the impugned decision deserve to be addressed in their grounds of appeal or not. The statement of grounds of appeal has to deal with all the main reasons for the contested decision in order to be considered sufficient.

Lastly, the criticisms levelled by the appellant against the reasoning of the examining division, in particular on page 11 of the decision, were only submitted with their letter of 4 July 2025 or during the oral proceedings before the Board. The appellant in particular regards page 11 of the decision as mere observations, or submits substantive arguments regarding clarity, or suggests that the reference to table 13C is made out of a confusion with a co-pending case. However, the admissibility of the appeal under Article 108 EPC and Rule 99(2) EPC must be assessed based on the content of the statement of grounds of appeal, which in the present case does not contain any of these arguments.

1.6 Accordingly, the appeal is not admissible and must be rejected under Rule 101(1) EPC.

Order

For these reasons it is decided that:

The appeal is rejected as inadmissible.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated