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**Datasheet for the decision
of 6 September 2024**

Case Number: T 1403/22 - 3.3.07

Application Number: 18821993.5

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A61K9/20, A61K31/465, A61P25/34

Language of the proceedings: EN

Title of invention:
SOLID ORAL NICOTINE FORMULATION

Applicant:
Fertin Pharma A/S

Headword:
Solid Oral Nicotine Formulation / FERTIN

Relevant legal provisions:
RPBA 2020 Art. 13(2)
EPC Art. 84, 83, 123(2)

Keyword:
Amendment after notification of Art. 15(1) RPBA communication
- exceptional circumstances (yes)
Claims - clarity after amendment (yes)
Sufficiency of disclosure - (yes)
Remittal - special reasons for remittal (yes)



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Case Number: T 1403/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 6 September 2024

Appellant: Fertin Pharma A/S
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 24 March 2022
refusing European patent application No.
18821993.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman A. Usuelli
Members: E. Duval
Y. Podbielski

Summary of Facts and Submissions

- I. The appeal was filed by the applicant (appellant) against the decision of the examining division to refuse the patent application in suit.

- II. The decision was based on a main request and auxiliary requests 1-4 filed on 10 February 2022.

Claim 1 of the main request read as follows:

"An orally disintegrating nicotine tablet for fast onset nicotine craving relief comprising a pressed powder formulation, the formulation comprising nicotine and a pH regulating agent, wherein the orally disintegrating nicotine tablet is designed to release the content of nicotine within a period of 60 seconds in contact with oral saliva and the orally disintegrating nicotine tablet is designed to release the content of pH regulating agent within a period of 60 seconds in contact with oral saliva, wherein the orally disintegrating nicotine tablet comprises at least one polyol, wherein the polyol comprises more than 40% by weight of the orally disintegrating nicotine tablet, wherein the at least one polyol is selected from the list consisting of sorbitol, erythritol, xylitol, maltitol, mannitol, lactitol, and isomalt, wherein the orally disintegrating nicotine tablet comprises nicotine in an amount of at least 0.5 mg, wherein the nicotine is provided as free base nicotine or nicotine salt, and wherein the pH regulating agent is an alkaline buffering agent."

In dependent claims 2 and 4 of the main request, alternative time periods for the release of the nicotine content and for the content of pH regulating agent were defined, namely "between 10 and 40 seconds" and "40 seconds".

III. The examining division decided that all requests fulfilled the requirements of Article 123(2) EPC, but that none of the requests met the requirements of Article 83 EPC with respect to the features "the orally disintegrating nicotine tablet is designed to release the content of nicotine within a period of 60 seconds in contact with oral saliva" and "the orally disintegrating nicotine tablet is designed to release the content of pH regulating agent within a period of 60 seconds in contact with oral saliva".

IV. With their grounds of appeal, the appellant upheld the same main request and auxiliary requests 1-4, and filed, among others, Appendix 2:

Appendix 2: NCI Thesaurus C42999;

V. The Board set out its preliminary opinion in a communication under Article 15(1) RPBA. In this communication, the Board expressed the view that the criteria of clarity were not met.

VI. Oral proceedings were held before the Board. During the oral proceedings, the appellant filed a new auxiliary request 5, which they subsequently renumbered as the main request.

This new main request differed from the previous main request by the addition in claim 1 of the feature

"wherein the nicotine is without carrier", and by the deletion of previous dependent claims 2 and 4.

- 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, filed as auxiliary request 5 during the oral proceedings before the Board, or, in the alternative, on the basis of one of auxiliary requests 1-4 filed with the grounds of appeal.
- VIII. The appellant's argument may be summarised as follows:
- (a) The amended main request filed during the oral proceedings was to be admitted into the proceedings, considering the new objection of lack of clarity raised for the first time in the Board's communication. The amendment carried out *prima facie* overcame the objection.
 - (b) Claim 1 of the main request was limited to nicotine forms such that the release time parameters were both identical to the tablet disintegration time. Oral disintegrating tablets and the measurement of their *in vivo* disintegration time were well-known. It would be unreasonable to require claim 1 to disclaim additional steps during this measurement, such as chewing, considering their generally known property of disintegrating upon simple contact with saliva. Consequently the main request met the requirements of Article 84 EPC.
 - (c) As to sufficiency of disclosure, the appealed decision divided the claimed subject-matter into three possible scenarios/embodiments corresponding to the release of nicotine occurring slower, simultaneously or faster than the release of the

buffering agent. These scenarios were not expressed in the claims, and were not relevant for the question of sufficiency of disclosure. The application provided several examples of how to obtain tablets in accordance with claim 1, as well as guidance on the relevant parameters for the skilled person to adjust in order to achieve the desired disintegration time. The criteria of Article 83 EPC were thus met.

Reasons for the Decision

The following decision is based on the appellant's main request, filed as auxiliary request 5 during the oral proceedings before the Board.

1. Admittance

The main request, submitted during the oral proceedings before the Board on 6 September 2024, represents an amendment to the appellant's appeal case filed after notification of the communication under Article 15(1) RPBA dated 25 April 2024. Under Article 13(2) RPBA, this request shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons.

The Board agrees with the appellant that such exceptional circumstances are apparent in the case at hand, considering that the Board's communication raised for the first time an objection of lack of clarity which was not contained as such in the appealed decision. Furthermore, in its submissions in reply to the Board's communication the appellant attempted to meet the Board's objection by reference to the feature

"the nicotine is provided as free base nicotine or nicotine salt"; the Board's interpretation of that feature as allowing for nicotine bound to a carrier, which motivated the Board to maintain the objection of lack of clarity against the previous main request, was explained to the appellant at the oral proceedings only.

Lastly, for the reasons set out below, the Board considers that the amendments are suitable to resolve the issues raised by the Board.

Accordingly, the Board admitted the new main request into the proceedings.

2. Article 123(2) EPC

The examining division found the (previous) main request underlying the appealed decision to comply with the requirements of Article 123(2) EPC (see §1.1 of the decision). The Board agrees with this assessment. In the present, amended main request, the feature "the nicotine is without carrier" has been introduced in claim 1, and finds basis on page 48, line 24 of the application as filed. Furthermore, dependent claims 2 and 4 were deleted. Neither of these amendments adds any subject-matter.

Accordingly, the criteria of Article 123(2) EPC are met.

3. Clarity

3.1 Claim 1 mandates that:

- "the orally disintegrating nicotine tablet is designed to release the content of nicotine within a period of 60 seconds in contact with oral saliva", and
- "the orally disintegrating nicotine tablet is designed to release the content of pH regulating agent within a period of 60 seconds in contact with oral saliva".

3.2 In the communication under Article 15(1) RPBA, the Board raised an objection of lack of clarity against the above features of claim 1, because the points in time corresponding to the releases of these contents were unclear and could not be equated with the time point at which disintegration of the tablet is completed, and because neither the claims nor the description defined how to measure these release time parameters (see the communication, §1.4.1 and §1.4.2).

The Board considers that the amendments carried out in the present main request, and the appellant's arguments, overcome this objection, for the following reasons.

3.2.1 Claim 1 mandates not only that the nicotine is provided as free base nicotine or nicotine salt, but also that the nicotine is without carrier. This last feature does not exclude the presence of carrier excipients from the composition in general, but specifically the presence of nicotine with a carrier. This is understood as excluding nicotine forms which require the nicotine to be released from a carrier before being made bioavailable (see page 26, lines 29-31), such as nicotine bound to ion exchange resins, to zeolites, or

the likes (see page 26, lines 7-10). As a result of this negative limitation, the claim only covers the use of nicotine forms with a fast release (see page 48, lines 22-25), namely (carrier-free) nicotine free base, which is released upon disintegration of the solid formulation matrix (see page 27, lines 2-3), and (carrier-free) nicotine salts, which readily dissolve upon disintegration of the matrix of the solid formulation (page 26, last line, to page 27, first line). Consequently, the time used to release the content of nicotine can be taken as the disintegration time of the matrix, not only in the context of the nicotine bitartrate used in the examples (see especially examples 4 and 6 on pages 56 and 59), but more generally in the context of claim 1.

As to the pH regulating agent, the Board accepts the appellant's argument that no question of bioavailability or absorption arises in this case, such that the release time for the pH regulating agent equates with the tablet disintegration time.

The Board concludes that, as a result of the amendments, both parameters, namely the time to release the content of nicotine and the time to release the content of pH regulating agent, are in the context of claim 1 one and the same thing, namely the time for disintegration of the tablet to be completed. This conclusion is not contradicted by the claims, considering that the upper limit is set to the same value (60 seconds) for both release times in claim 1, and that any dependent claims defining the release times differently for the two components have been deleted.

3.2.2 It is not contested that claim 1 specifies times measured *in vivo*, and not *in vitro* times. The fact that *in vivo* measurements and *in vitro* measurements do not correlate in a straightforward way is thus not prejudicial to the clarity of the claims. The application shows measurements of *in vivo* disintegration times in example 3 and in tables 6 and 7 (see page 55), given as the value for the actual disintegration of the sublingual tablet under the tongue. In this respect, orally disintegrating tablets in general are a well-known dosage form (see the definitions in Appendix 2), and the Board has no reason to consider that the skilled person would not be in a position to measure their fast disintegration properties without undue burden. In particular, the examining division's objection regarding the influence of unclaimed factors on *in vivo* release time does not establish that a disintegration time could not be measured reliably. Appendix 2, which reflects the common general knowledge, shows that orally disintegrating tablets are generally known to disperse rapidly when placed upon the tongue or in saliva. This document does not mention aspects of the subject's behaviour such as chewing, and the skilled person would be aware, even without indication to that effect in the claim, that the patient may not chew the tablet as this would lead to incorrect measurements of disintegration time.

3.3 Accordingly, the Board concludes that the main request meets the requirements of clarity.

4. Sufficiency of disclosure

The examining division found that the requirements of sufficiency of disclosure were not met with respect to

the above release time features (see 3.1 above; appealed decision, §1.2).

4.1 A first reason put forward by the examining division was that the application did not teach how to achieve an embodiment or scenario of claim 1 in which the release of nicotine and the release of the pH regulating agent occur in specific orders. The Board agrees with the appellant that such an order in the releases is not required by the claim. In addition, considering the Board's interpretation of these features as both relating to the same point in time, namely the completion of the tablet disintegration, this reason cannot be upheld.

4.2 The examining division's second reason was that the release rates as claimed are unreliable, that the skilled person neither has guidance to reproduce the invention over the whole scope as claimed, nor the knowledge whether they are working inside or outside the scope of the claims.

The question as to whether the skilled person knows whether they are working inside or outside the scope of the claims properly arises under Article 84 EPC. For the reasons set out above (see 3.), the Board considers that, as a result of the amendments, this deficiency is solved in the main request.

Furthermore, the application contains examples of orally disintegrating nicotine tablets as claimed, meeting the condition of a time to completion of tablet disintegration within 60 seconds in contact with saliva (see e.g. formulation FDT(12) in table 3J of example 3; example 4, tables 6-7 on page 55, e.g. formulation FDT(a)). The application also provides guidance on the

parameters allowing to prepare tablets meeting the claimed conditions (see page 46, line 12, to page 48, line 29).

4.3 The Board concludes that the criteria of sufficiency of disclosure are met.

5. Remittal for further prosecution

The examining division refused the application on the ground of insufficiency of disclosure. For the reasons set out above, the Board comes to the conclusion that the amended main request overcomes this deficiency and also satisfies the requirements of Articles 123(2) and 84 EPC. The appealed decision does not address the remaining criteria for patentability, and in particular inventive step.

Under Article 11 RPBA, the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so.

The Board considers that the lack of an appealable decision on the issue of inventive step constitutes such special reasons. Accordingly, the case is to be remitted to the examining division.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the Examining Division for further prosecution.

The Registrar:

The Chairman:



S. Sánchez Chiquero

A. Uselli

Decision electronically authenticated