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Datasheet for the decision of 20 February 2025

Case Number: T 1330/23 - 3.3.07

Application Number: 18821992.7

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Language of the proceedings: EN

Title of invention:
NICOTINE TABLET

Patent Proprietor:
Fertin Pharma A/S

Opponent:
McNeil AB

Headword:
Nicotin tablet/FERTIN

Relevant legal provisions:
EPC Art. 123(2), 111(1)
RPBA 2020 Art. 11

Keyword:
Amendments - added subject-matter (no)
Remittal - (yes)

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 1330/23 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 20 February 2025

Appellant: (Patent Proprietor)	Fertin Pharma A/S Dandyvej 19 7100 Vejle (DK)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Opponent)	McNeil AB Norrbroplatsen 2 251 09 Helsingborg (SE)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 5 June 2023 revoking European patent No. 3720418 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Molina de Alba
	S. Ruhwinkel

Summary of Facts and Submissions

I. The decision under appeal is the opposition division's decision revoking the European patent. The decision is based on the claims of a main request and ten auxiliary requests.

In the decision, the opposition division concluded that claim 1 of each of the main request and auxiliary requests 1 and 3 to 10 added subject-matter, and that claim 1 of auxiliary request 2 extended the scope of protection of the patent as granted.

II. The following documents are mentioned in the present decision:

D25 K. O'Donnel et al., Sweeteners and Sugar Alternatives in Food Technology, 1st edn., Wiley-Blackwell, 2012, 1-484

D26 Dictionary of Food Science and Technology, 1st edn., Blackwell Publishing, 2005, 292 and 354

D27 Internet entry https://polyols-eu.org/legislation/pharmaceutics/ as published in 2018 (retrieved by The Wayback Machine)

III. The patent proprietor (appellant) filed an appeal against the decision. With the statement of grounds of appeal, the appellant filed 11 sets of claims as its main request and auxiliary requests 1 to 10. It also filed documents D25 and D26 as prior-art documents representative of the common general knowledge on polyols.

Claim 1 of the main request is identical to claim 1 as granted and to claim 1 of the main request on which the decision under appeal is based. It reads as follows:

"*1. An orally disintegrating nicotine tablet for nicotine craving relief comprising a pressed powder formulation, the tablet being designed to disintegrate within a period of less than 60 seconds upon oral administration, the powder formulation comprising an amount of nicotine, a pH regulating agent, at least one polyol, and a disintegrant, wherein the polyol comprises more than 40% by weight of the tablet, wherein the at least one polyol is selected from the list consisting of sorbitol, erythritol, xylitol, maltitol, mannitol, lactitol, and isomalt, wherein the tablet comprises the disintegrant in an amount of 1-10% by weight of the tablet, wherein the disintegrant comprises cross-linked polyvinylpyrrolidone, and wherein the pH regulating agent is an alkaline buffering agent.*"

IV. In its reply to the statement of grounds of appeal, the respondent (opponent) requested that the appeal be dismissed. In addition, it filed D27 as a prior-art document representative of the common general knowledge on polyols.

V. The board scheduled oral proceedings, in line with the parties' requests, and gave its preliminary opinion on the case.

VI. The appellant filed decision T 1403/22, a decision on a related case published shortly after the board's communication under Article 15(1) RPBA was issued.

VII. Oral proceedings were held before the board. At the end of the oral proceedings, the board announced its decision.

VIII. The appellant's arguments, where relevant to the present decision, can be summarised as follows.

The subject-matter of claim 1 of the main request was directly and unambiguously disclosed in the application as filed. The main basis was found in the combination of claims 1, 19, 25, 26 and 29 as filed. The features not disclosed in these claims, namely the preferred polyols in accordance with claim 19 and the limitation of the pH regulating agent to an alkaline buffering agent, were disclosed as preferred embodiments in the description.

The preferred polyols were disclosed in the passage on page 32, lines 16 to 19. It was clear from its context that the teaching of this passage was generally applicable to the invention and that it was not limited to the examples. The passage contained the only definition of polyols in the whole application. Furthermore, the polyols were disclosed as bulk sweeteners, meaning that they were a major ingredient of the tablet. Therefore, it was clear that the polyols on page 32, lines 16 to 19 were the preferred polyols in claim 19.

With regard to the limitation that the pH regulating agent was an alkaline buffering agent, it was disclosed on page 22, lines 8 to 18, and page 34, lines 6 to 9, 29 and 30. The general teaching of the application as filed, including the examples, made it clear that alkaline buffering agents were preferred over acidic buffering agents. This was also derivable from the

common general knowledge that nicotine had to be at an alkaline pH to be absorbed by the mucosa.

The features in claim 1 were not only disclosed individually, but also in combination. Claim 1 specified a broad embodiment which was narrowed down by the dependent claims. Claims 19, 25, 26 and 29 each disclosed a preferred embodiment in relation to a feature in claim 1. No alternative choices or more preferred embodiments were presented. Therefore, they could be combined with claim 1. The same was true for the features taken from the description. It was established case law that some features of a claim could be limited by the most preferred embodiments without adding subject-matter. It was not necessary to limit all the features to their most preferred embodiments.

IX. The respondent's arguments, where relevant to the present decision, can be summarised as follows.

Claim 1 of the main request was not supported by the application as filed. The application contained a reservoir of features in the description and claims from which the appellant had arbitrarily selected some. There was no link between all those features. Even if the selected embodiments were preferred, there were other preferred embodiments that had not been combined with claim 1 as filed, e.g. those relating to flavouring agents, bulk sweeteners or fillers.

With regard to the selected preferred embodiments, there was no link between the embodiment that the disintegrant was cross-linked polyvinylpyrrolidone and the embodiment that the amount of disintegrant was 1 to 10 wt.%. Similarly, there was no link between the

amount of polyols in claim 19 being more than 40 wt.% and the list of sugar alcohols disclosed on page 32, lines 16 to 19. In the context of the invention, polyols were used to set the tablet disintegration time (application, page 3, lines 13 to 16); however, the sugar alcohols on page 32, lines 16 to 19 were used as bulk sweeteners. There was no basis in the application as filed for equating polyols and bulk sweeteners. Furthermore, the passage on page 32, lines 13 to 16, referred to the examples and was not generally applicable to the invention. Therefore, the sugar alcohols on page 32, lines 16 to 18 could not be used to limit the polyols in claim 19. Lastly, the application as filed disclosed alkaline and acidic buffering agents at the same level of preference. Although the pH regulating agent in the examples was alkaline, it was very specific and the limitation of claim 1 to alkaline buffering agents constituted an unallowable intermediate generalisation.

X. The parties' final requests, where relevant to the present decision, were as follows.

- The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution.

  In the event that the board decided not to remit the case to the opposition division, the appellant requested that the patent be maintained in amended form on the basis of the claims of the main request or one of auxiliary requests 1 to 10, all filed with the statement of grounds of appeal.

In addition, the appellant requested that documents D25 and D26 be admitted into the appeal proceedings.

- The respondent requested that the appeal be dismissed and that the decision under appeal be upheld.

  In the event that the decision under appeal was not upheld because the patent was considered to meet the requirements of Article 123(2) and (3) EPC, the respondent requested that the case be remitted to the opposition division for further prosecution.

  The respondent also requested that documents D25, D26 not be admitted into the appeal proceedings and, if documents D25 and D26 were admitted, that document D27 be admitted too.

Reasons for the Decision

1. Main request - amendments (Article 123(2) EPC)

1.1 The main basis in the application as filed cited by the appellant for claim 1 of the main request is the combination of claims 1, 19, 25, 26 and 29. These claims read as follows:

"*1. An orally disintegrating nicotine tablet for nicotine craving relief comprising a pressed powder formulation, the tablet being designed to disintegrate within a period of less than 60 seconds upon oral*

administration, the powder formulation comprising an amount of nicotine and a pH regulating agent."

"*19. The tablet according to any of the claims 1-18, wherein the pressed powder comprises at least one polyol and wherein the polyol comprises more than 40% by weight of the tablet*."

"*25. The tablet according to any of the claims 1-24, wherein said tablet further comprises a disintegrant*."

"*26. The tablet according to any of the claims 1-25, wherein the disintegrant comprises cross-linked polyvinylpyrrolidone*."

"*29. The tablet according to any of the claims 1-28, wherein the tablet comprises disintegrant in an amount of 1-10% by weight of the tablet.*"

Therefore, the combination of claims 1, 19, 25, 26 and 29 as filed discloses all the features in claim 1 of the main request, except for two that were taken from the description, namely:

(i) the at least one polyol is selected from sorbitol, erythritol, xylitol, maltitol, mannitol, lactitol and isomalt, and
(ii) the pH regulating agent is an alkaline buffering agent.

The appellant cited the passage on page 32, lines 16 to 19 as the main basis for feature (i). The passage reads:

"*Sugarless sweeteners generally include, but are not limited to sugar alcohols (also sometimes referred to*

as polyols) such as sorbitol, erythritol, xylitol, maltitol, mannitol, lactitol, and isomalt."

With regard to the basis for feature (ii), the appellant referred to common general knowledge and the general teaching of the application as filed. Although the application disclosed both acidic buffering agents and alkaline buffering agents as pH regulating agents (page 22, lines 10, 11 and 16 to 18; page 34, lines 7 to 9), the skilled person would understand that alkaline buffering agents were preferred. On the one hand, this is because it was common general knowledge that nicotine had to be at an alkaline pH to be absorbed by the oral mucosa. This had been acknowledged in the decision under appeal and the respondent had not contested it. On the other hand, this is because the buffering agent in all the examples was alkaline.

1.2 It was undisputed that the elements in the application as filed mentioned by the appellant provide support for each of the features in claim 1 individually. The matter under dispute was whether the application disclosed all those features in combination. For the reasons given in the following paragraphs, the board holds that the answer to this question must be in the affirmative.

1.2.1 Claims 1, 19, 25, 26 and 29 are linked by their dependencies.

Claim 19 as filed specifies that the tablet in claim 1 contains at least one polyol, which is present in an amount of at least 40% by weight of the tablet. This feature can also be found at several points in the description, namely on page 9, lines 7 and 8, page 17, lines 13, 14, 22 and 23, and page 18, lines 2, 3, 12

and 13. The feature was also generally illustrated in the examples of the application, which disclose 30 nicotine tablets, of which only two (FDT(56) and FDT(8)) contain less than 40 wt.% polyol. Therefore, the presence of at least one polyol at 40 wt.% of the tablet was a preferred feature of the tablets of the invention. In addition, neither the claims nor the description provide an alternative to polyols or to a polyol amount of at least 40 wt.% of the tablet. Therefore, the embodiment of claim 19 was most preferred and generally applicable.

Claim 25 requires that the tablet in claim 1 contains a disintegrant. This is necessarily a preferred embodiment for a tablet that should disintegrate in less than 60 seconds upon oral administration, as required by claim 1. Subsequently, claims 26 and 29, both linked by their dependencies and referring back to claim 25, disclose the preferred disintegrant and the preferred amount of disintegrant, respectively. These are cross-linked polyvinylpyrrolidone and 1 to 10 wt.% of the tablet. The claims do not provide any alternative to these embodiments. More preferred disintegrants or amounts of disintegrant are not disclosed in the claims, either.

The respondent considered that the description disclosed other disintegrants at the same level of preference of cross-linked polyvinylpyrrolidone and that there was no link between cross-linked polyvinylpyrrolidone and an amount of disintegrant of 1 to 10 wt.%; however, this consideration is incorrect. Merely the fact that cross-linked polyvinylpyrrolidone is the only disintegrant mentioned in the claims is indicative of its higher preference. Furthermore, although page 32, lines 20 and 21 of the description

refer to other preferred disintegrants, namely croscarmellose sodium and sodium starch glycolate, the passage on page 11, lines 8 to 16 makes it clear that cross-linked polyvinylpyrrolidone is the most preferred disintegrant. It describes the particular advantages of cross-linked polyvinylpyrrolidone and states that these advantages "*may be very preferred especially for fast disintegrating tablets*". No passage in the application as filed discloses the advantages of the other disintegrants.

1.2.2 With regard to feature (i), the question was whether the polyols listed on page 32, lines 16 to 18 were preferred polyols in accordance with claim 19 as filed. Claim 19 does not specify the function of the polyols in the tablet of the invention, but it is clear from their amount (more than 40 wt.%) that they constitute a major ingredient. The passage on page 32, lines 16 to 18, belongs to the disclosure of the bulk sweeteners that can be used in the tablet of the invention. Starting on page 32, line 5, the application describes two groups of bulk sweeteners, namely sugar sweeteners and sugarless sweeteners. The passage on page 32, lines 16 to 18 describes the sugarless sweeteners. They in particular include sugar alcohols, also referred to as polyols, such as sorbitol, erythritol, xylitol, maltitol, mannitol, lactitol and isomalt. This is the only disclosure in the whole description referring to specific embodiments of polyols. Furthermore, the polyols are disclosed as bulk sweeteners, meaning that they are present in large amounts and constitute a major ingredient of the tablet. Therefore, the skilled person would derive that sorbitol, erythritol, xylitol, maltitol, mannitol, lactitol and isomalt are examples of polyols in accordance with claim 19. Consequently, feature (i) was directly and unambiguously disclosed in

combination with the features in claims 1, 19, 25, 26 and 29 as filed.

The respondent argued that the polyols in claim 19 could not be the sugarless bulk sweeteners on page 32, lines 16 to 18 because they had a different function in the context of the application as filed. The application stated on page 3, lines 13 to 15 that polyols were useful for setting the disintegration rate. In contrast, the polyols on page 32, lines 16 to 18 were bulk sweeteners and their function was merely to support flavour. The respondent also argued that the disclosure on page 32, lines 16 to 18 referred to the examples and that it could not be generalised.

These arguments are not convincing. Claim 19 does not mention any function of the polyols. It is common that formulation excipients play more than one role in a formulation. There is no contradiction in that a polyol helps to regulate the disintegration rate of the tablet and, at the same time, supports its flavour. With regard to whether the disclosure on page 32, lines 16 to 18 is general or limited to the examples, the board agrees with the appellant that, starting on page 31, line 9, the application discloses generally applicable embodiments even if it refers to the previously described examples to illustrate those embodiments.

1.2.3 With regard to feature (ii), the respondent is right that page 22, lines 10, 11 and 16 to 18 teaches that acidic and alkaline buffering agents are pH regulating agents and that no preference is disclosed. Also on page 34, lines 6 to 9, the application discloses examples of buffering agents which include acidic buffering agents (e.g. acetate and citrate) and alkaline buffering agents (e.g. carbonate and ammonium)

with no preference for any of them; however, the board does not agree that these two options for pH regulating agents have identical preference in the context of the application as filed.

On the one hand, the respondent did not dispute the common general knowledge, recognised in the decision under appeal (page 18, lines 8 to 13), that the pH is decisive for an alkaloid such as nicotine to be absorbed by the oral mucosa, and that this needs to be alkaline. On the other hand, in the tablets described in tables 1 and 3A to 3F and in the embodiment on page 34, lines 29 and 30, the pH regulating agent is sodium carbonate or a buffer sodium carbonate-sodium bicarbonate. These embodiments clearly point towards a preference for an alkaline buffering agent.

1.2.4 In an additional argument, the respondent submitted that the tablet in claim 1 of the main request had been arbitrarily limited by selecting some preferred embodiments while leaving out other preferred embodiments, e.g. those relating to flavouring agents, bulk sweeteners or fillers. According to the respondent, such a limitation was arbitrary and added subject-matter.

The board disagrees. As explained in the paragraphs above, claim 1 of the main request was limited by incorporating the most preferred embodiment of each of the features that were limited (disintegrants, polyols, amounts, pH regulating agents). The application as filed did not disclose embodiments of the same feature having equal or higher preference than those incorporated into claim 1. Therefore, in accordance with established case law, the limitations were allowable. The fact that only some features were

limited to their most preferred embodiments did not add subject-matter. The appellant was not obliged to also limit the remaining features to their most preferred embodiments.

1.3 Therefore, the subject-matter of claim 1 of the main request meets the requirements of Article 123(2) EPC.

2. The objections under Article 123(2) EPC raised by the respondent against the main request were directed only to claim 1. Articles 123(3) EPC and 84 EPC are not applicable to claim 1, which is identical to claim 1 as granted.

3. Remittal (Article 111(1) EPC and Article 11 RPBA)

Both parties requested that, if the board came to the conclusion that one of the claim requests on file met the requirements of Article 123(2) and (3) EPC, the case be remitted to the opposition division for further prosecution. Considering the parties' requests and the fact that the decision under appeal dealt only with the ground for opposition of added subject-matter, special reasons within the meaning of Article 11 RPBA present themselves to remit the case to the opposition division in accordance with Article 111(1) EPC.

4. Admittance of documents D25 to D27 (Article 12(4) RPBA)

At oral proceedings, the board decided to admit documents D25 to D27 under Article 12(4) RPBA. Ultimately, the board did not need to consider D25 to D27 to decide on the present case but, as the case is being remitted to the opposition division for further prosecution and D25 to D27 could become relevant in the

subsequent proceedings, in the following the board briefly sets out the reasons for their admittance.

D25 and D26 were filed by the appellant with the statement of grounds of appeal to show that the person skilled in the field of food chemistry would understand that "sugar alcohol" and "polyol" are synonymous. The board admitted these documents as an adequate response to the decision under appeal (page 22, penultimate paragraph and page 23, last paragraph). Considering that D27 was filed by the respondent in reply to the filing of D25 and D26, that it also discloses common general knowledge on polyols, and that the appellant had no objection to the admittance of D27 if D25 and D26 were admitted, the board decided to also admit D27.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairman:

S. Sánchez Chiquero A. Usuelli

Decision electronically authenticated