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**Datasheet for the decision  
of 18 September 2020**

**Case Number:** T 0534/18 - 3.3.07

**Application Number:** 09002569.3

**Publication Number:** 2186507

**IPC:** A61K9/00, A61K31/465

**Language of the proceedings:** EN

**Title of invention:**

A liquid pharmaceutical formulation comprising nicotine for the administration to the oral cavity

**Patent Proprietor:**

McNeil AB

**Opponent:**

Fertin Pharma A/S

**Headword:**

Liquid nicotine formulation / McNeil AB

**Relevant legal provisions:**

EPC Art. 100(c)

RPBA 2020 Art. 11, 12(2)

**Keyword:**

Grounds for opposition - added subject-matter (no)  
Remittal to the department of first instance

**Decisions cited:**

T 0411/17



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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Case Number: T 0534/18 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 18 September 2020**

**Appellant:** McNeil AB  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 22 December  
2017 revoking European patent No. 2186507  
pursuant to Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman** A. Uselli  
**Members:** M. Steendijk  
C. Schmidt

## Summary of Facts and Submissions

I. European patent 2 186 507 (hereinafter "the patent"), which derives from a divisional application with respect to the earlier application EP02793665.7 (hereinafter "the parent application"), was granted on the basis of 16 claims. The parent application was originally published as international application WO03/055486.

The independent claim 1 as granted related to:

"A pharmaceutical formulation for use in the treatment of addiction to tobacco or nicotine comprising nicotine and characterized in that

- (i) the nicotine is present as a free nicotine base;
- (ii) the pharmaceutical formulation is a buffered alkaline liquid formulation for administration to the oral cavity of a subject by spraying, dropping or pipetting; and in that
- (iii) the nicotine is co-administered with a buffering agent."

II. The patent was opposed on the grounds that its subject-matter lacked inventive step, that the claimed invention was not sufficiently disclosed and that the patent comprised subject-matter extending beyond the content of the parent application as filed.

The opposition division decided to revoke the patent. The decision was based on the main request relating to the patent as granted, auxiliary requests 1 and 3-4 as

filed on 10 August 2017 and auxiliary request 2 filed during the oral proceedings held on 13 October 2017. The opposition division found that the subject-matter in accordance with claim 1 of the main request and auxiliary requests 1, 3 and 4 included subject-matter extending beyond the content of the parent application as filed and that the subject-matter of claim 1 of the auxiliary requests 2 and 3 resulted in a broadening of the scope of protection.

According to the opposition division the original applications described the defined therapeutic indication as preferred and provided a clear basis for the expression "buffered alkaline liquid formulation". However, the opposition division was of the opinion that claim 1 as granted resulted from an unallowable combined selection of the nicotine form present in the formulation ("*nicotine free base form*") and the alkalizing means ("*buffered alkaline*").

Moreover, the opposition division held the feature defining that the nicotine is co-administered with a buffering agent meant that the buffered formulation containing the nicotine was to be administered together with a separate buffering agent. The application as filed and the parent application only related to formulations comprising nicotine which might be alkalized by including a buffering agent and provided no basis for the defined co-administration with a separate buffering agent.

In the reasons for the decision the opposition division did not express its opinion as to the further raised grounds of opposition.

III. The patent proprietor filed an appeal against this decision. In the statement setting out the grounds of appeal on 27 April 2018 the appellant-patent proprietor relied on the patent as granted (main request) and submitted new auxiliary requests 1-6 as well as the following document:

D9 Online Medical dictionary - "Co-administration"

IV. With the reply of 12 September 2018 the respondent-opponent requested that the appeal be dismissed and auxiliarily that oral proceedings be held.

V. With the summons of 12 July 2019 the Board invited the parties to attend oral proceedings on 4 September 2020.

In a communication pursuant to Article 15(1) RPBA issued on 14 July 2020 the Board expressed the preliminary opinion that the patent as granted did not include subject-matter extending beyond the content of the parent application or the divisional application as filed and informed the parties that it intended to remit the case to the opposition division if this opinion were confirmed.

VI. The respondent-opponent replied on 12 August 2020 that it withdrew its request for oral proceedings if the Board were to decide on issues regarding Articles 123(2), 123(3) and 76 EPC without addressing the issues of sufficiency and inventive step.

With its communication of 18 August 2020 the Board informed the parties that the oral proceedings appointed for 4 September 2020 were cancelled.

VII. The arguments of the appellant-patent proprietor, in as far as relevant to the present decision, can be summarised as follows:

The liquid formulation for use in therapy of claim 1 as granted found its basis in claims 29 and 30 of the application as filed and claims 51 and 52 of the parent application. The defined therapeutic use regarding addiction to tobacco or nicotine was originally described as preferred. Moreover, the original disclosure clearly disclosed that the nicotine can be present as free nicotine, which is the form predominantly absorbed through the mucosa, and specifically taught that it is preferable to use a buffering agent in combination with nicotine base.

The original disclosure further explained that administration of nicotine with a buffering agent allowed for rapid nicotine uptake whereas absorption would be slower in case nicotine is not co-administered with a buffer according to the invention. Such co-administration did not require administration with a further separate buffer, but meant that the nicotine is administered at the same time as the buffering agent, which would also follow from the definition of the term "co-administration" in document D9.

VIII. The arguments of the respondent-opponent, in as far as relevant to the present decision, can be summarised as follows:

The term "alkaline" in the expression "buffered alkaline liquid formulation" in claim 1 as granted did not find an appropriate basis in the original disclosure. References in the original disclosure to the capacity of the formulation to raise the pH of the

saliva in the mouth to above 7 were not equivalent. Moreover, the disclosure that the composition may be alkalized meant that its pH may be increased, but not that the pH was raised to above 7.

The original disclosure described that the nicotine could be in any form, including the free base form, salt form and derivative forms, and that the alkalization could be performed by buffering, pH regulation or both. Moreover, the original disclosure presented addiction to tobacco or nicotine as part of a list of possible diseases to be treated using the described formulations. Accordingly, claim 1 as granted resulted from a multiple new selection concerning the nicotine form, the alkalization means and the disease to be treated.

The feature of claim 1 as granted that the nicotine was to be co-administered with a buffering agent implied administration of the buffered nicotine composition with a separate buffering agent, for which the original disclosure provided no basis.

Dependent claims 5 and 6 as granted comprised further added subject-matter in view of the defined dependencies, which extended beyond the dependencies of the corresponding claims of the parent application.

Dependent claims 14-16 as granted comprised further added subject-matter concerning the definition of the amount of nicotine which is delivered.

IX. The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or maintained on the basis of one of auxiliary requests 1-6 as filed



with its statement setting out the grounds of appeal. The appellant-patent proprietor further requested that the case be remitted to the opposition division if the Board finds that any of the main or auxiliary requests meets the requirements of Article 123(2) EPC.

- X. The respondent-opponent requested that the appeal be dismissed.

## **Reasons for the Decision**

### *Main request*

1. Added subject-matter
- 1.1 Claim 1 as granted
- 1.1.1 The formulation defined in Claim 1 as granted is characterized by the following features:
  - the formulation is a liquid pharmaceutical formulation comprising nicotine,
  - the formulation is for use in the treatment of addiction to tobacco or nicotine,
  - the nicotine is present as a free nicotine base,
  - the pharmaceutical formulation is a buffered alkaline liquid formulation for administration to the oral cavity of a subject by spraying, dropping or pipetting,
  - the nicotine is co-administered with a buffering agent.
- 1.1.2 The parent application as originally filed discloses in its claims 1-2 a liquid pharmaceutical formulation

comprising nicotine, which is alkalized by buffering and/or pH regulation and which is for administration to the oral cavity of a subject by spraying, dropping or pipetting. Furthermore, the earlier application as filed presents on page 12 the incorporation of nicotine as the free base form or as water-soluble salt or as inclusion complex as most preferred embodiment.

- 1.1.3 With respect to the options for alkalizing the formulation the parent application as filed indicates on page 28, lines 7-11 that nicotine base has too weak a buffering capacity and that the buffering capacity of the formulation is significantly and sufficiently increased when a buffering agent is added. On pages 9-10 the parent application as filed further states that nicotine in free base form is the form of nicotine predominantly absorbed through the mucosa and that hence according to the invention the liquid formulation is alkalized.
- 1.1.4 In its claims 51-52 the parent application as filed further discloses that the liquid pharmaceutical formulation is for use in therapy, inter alia for treatment of addiction to tobacco or nicotine. On page 5, lines 16-21, the parent application as filed specifically indicates that administration of nicotine to provide fast satisfaction to a person craving for nicotine or to provide a sense of smoking satisfaction without smoking is the principle object of the claimed invention.
- 1.1.5 Similar disclosure of subject-matter can be found in found in the divisional application as filed (claims 1-2, paragraphs 64, 147 and 46-48, claims 29-30 and paragraph 27).

1.1.6 In view of the above identified passages in the parent application as filed and the divisional application as filed the Board considers that the therapeutic utility in the treatment of addiction to tobacco or nicotine, the nicotine being present as a free nicotine base and the alkalization by a buffering agent rather than by mere pH regulations correspond to the originally disclosed preferred embodiments concerning the therapeutic use, the form of the nicotine and the means for alkalization.

The limitation of the subject-matter in claim 1 as granted in accordance with the preferred embodiments does not imply any multiple new selection of subject-matter, because such selection can be directly and unambiguously derived from the very disclosure of the embodiments as preferred, and can therefore not give rise to subject-matter extending beyond the original disclosure.

1.1.7 The Board further observes that the skilled person understands that a pharmaceutical formulation comprising nicotine in which the nicotine is present as free nicotine base and which is alkalized with a buffer, is as a matter of fact an alkaline formulation.

1.1.8 In the decision under appeal the feature that the nicotine is co-administered with a buffering agent has been understood to imply that the buffered formulation containing nicotine is to be administered together with a separate buffering agent, which is not contained in the buffered nicotine containing formulation.

The Board observes that on page 10, lines 7-10 the parent application as filed states that the absorption kinetics of nicotine that is not co-administered with a

buffer according to the invention will generally be slower and the bioavailability will generally be lower than when administered together with a buffer (see also paragraph 48 of the divisional application as filed). The same passage also occurs in the patent as granted (see paragraph 48).

The Board concludes therefrom that in accordance with the original disclosures as well as the patent as granted the expression "co-administered with a buffer" is to be understood as merely requiring that with the defined formulation the nicotine and a buffering agent are administered together. Such understanding is indeed in line with the definition of "co-administration" in document D9 as the administration two or more therapeutic agents at the same time.

The use of this expression in claim 1 of the main request does therefore not give rise to subject-matter extending beyond the content of the original disclosure.

1.1.9 Accordingly, the Board is of the opinion that the subject-matter as defined in claim 1 as granted can be directly and unambiguously derived from the disclosure in the parent application as well as from the divisional application as originally filed.

1.2 Dependent claims

Dependent claims 5 and 6 as granted more specifically define ingredients of the liquid phase in line with the explanations on page 14, line 28 to page 15, line 15 of the parent application.

Dependent claims 14-16 more specifically define the amount of nicotine delivered at each incidence of administration in line with the embodiments described on page 14, lines 7-11 of the parent application as filed.

- 1.3 The Board therefore concludes that that the ground of added subject-matter (Article 100(c) EPC) does not prejudice to the maintenance of the patent as granted.

*Remittal and cancellation of the oral proceedings*

2. The Board observes that the appellant-patent proprietor explicitly requested remittal of the case to the opposition division for the remaining grounds of opposition and that in its reply to the communication pursuant to Article 15(1) RPBA the respondent-opponent did not present any argument against such remittal and conditionally withdrew its request for oral proceedings.

Taking further account of the fact that the reasons for the decision under appeal were not based on any of the further raised grounds of opposition (lack of sufficient disclosure and lack of inventive step) the Board is of the opinion that, having regard to Articles 11 and 12(2) of the RPBA 2020 and in line with T0411/17 (point 5), the case is to be remitted to the opposition division for examination of the remaining raised grounds of opposition.

3. In view of the conditional withdrawal of the request for oral proceedings by the respondent-opponent in its reply to the to the communication pursuant to Article 15(1) RPBA the present decision can be issued following the cancellation of the oral proceedings.

## 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 examination of the remaining grounds of opposition.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated