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**Datasheet for the decision
of 2 March 2010**

Case Number: T 1126/06 - 3.3.02

Application Number: 94923977.6

Publication Number: 0707478

IPC: A61K 9/00

Language of the proceedings: EN

Title of invention:

Improved nicotine lozenge and therapeutic method for smoking cessation

Applicant:

McNeil AB

Opponent:

-

Headword:

Improved nicotine lozenges/MC NEIL AB

Relevant legal provisions:

EPC Art. 56

Relevant legal provisions (EPC 1973):

-

Keyword:

"Reformulation of the problem to be solved in the light of comparative tests filed in appeal proceedings"

Decisions cited:

-

Catchword:

-



Case Number: T 1126/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 2 March 2010

Appellant: McNeil AB
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 26 January 2006
refusing European patent application
No. 94923977.6 pursuant to Article 97(1) EPC
1973.

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
J.-P. Seitz

Summary of Facts and Submissions

I. European patent application No 94 923 977.6, based on international application WO 95/03050, was filed with 43 claims. Claim 1 read as follows:

"1. A nicotine lozenge comprising nicotine, an absorbent excipient, and a nonnutritive sweetener."

II. The following documents have been cited during the examination and appeal proceedings:

(4) US 5 135 753

(5) Grant E. DuBois and Janice F. Lee, Chemical Senses, vol. 7 No 3/4, 1983, 237-247

III. The appeal lies from the decision of the examining division refusing the patent application under Article 97(1) EPC 1973 pursuant to the requirements of Article 56 EPC, for lack of inventive step of the main request and the second auxiliary request, and for non-compliance with Article 123(2) EPC of the first auxiliary request.

IV. The examining division considered that the main request met the requirements of Articles 123(2) and 84 EPC.

The examining division was of the opinion that the subject-matter claimed was novel over the cited prior art. In particular, the subject-matter claimed in the main request was novel over examples 36 and 37 in document (4) in view of the presence of the sweeteners saccharine, cyclamate and aspartame.

As regards the inventive step issue, the examining division considered document (4) as the closest prior art. The examining division defined the problem to be solved as the provision of lozenges which do not cause weight gain and are non-cariogenic. The proposed solution was lozenges containing non-nutritive sweeteners. The examining division was of the opinion that the proposed solution was obvious since the said non-nutritive sweeteners were known to the skilled person for the intended benefits. The examining division considered that this view was supported by document (5) which had been submitted by the applicant during the oral proceedings. Therefore, in the examining division's view, the main request lacked an inventive step (Article 56 EPC).

As regards the first auxiliary request the examining division considered that claim 1 related to an unallowable selection from the application as filed. Therefore, the first auxiliary request did not meet the requirements of Article 123(2) EPC.

The examining division further considered that the second auxiliary request met the requirements of Articles 84 and 123(2) EPC. In its opinion the claimed subject-matter was novel over the cited prior art in view of the presence of the sweetener aspartame.

However, the examining division considered that the second auxiliary request lacked an inventive step (Article 56 EPC). In particular, it did not accept the existence of an improved effect for reformulating the problem to be solved since technical evidence was lacking.

- V. The appellant lodged an appeal against the said decision and filed with its grounds of appeal a main request and two auxiliary requests (first and second). Moreover, the appellant filed experimental data with its letter dated 30 January 2007 in order to support its argument that the lozenges claimed in the present application were superior to the lozenges known from the closest prior art document (4).
- VI. On 24 March 2009 the board sent a communication expressing its preliminary opinion in relation to the sets of claims in the three requests filed with the grounds of appeal. In particular, the board raised some objections re Articles 84 and 123(2) EPC for these three sets of claims and made some observations in relation to the comparative tests filed by the appellant.
- VII. The appellant filed a letter dated 3 August 2009 in response to the board's communication and filed therewith a new main request and three auxiliary requests to replace the requests on file.

Claim 1 of the main request reads as follows:

"1. A nicotine lozenge comprising nicotine or a mono- or bis- pharmaceutically acceptable acid addition salt or metal salt of nicotine, an absorbent excipient and a combination of first and second sweeteners in which the first sweetener is aspartame and in which the second sweetener is selected from ammonium glycyrrhizinate, neohesperidine dihydrochalcone and stevioside."

- VIII. The board sent a communication conveying its preliminary opinion in relation to the inventive step issue as an annex to the summons to oral proceedings.
- IX. Oral proceedings took place on 2 March 2010.
- X. At the beginning of the oral proceedings the board informed the appellant that it did not have any objections re Articles 123(2) and 84 EPC to the set of claims of the main request.
- XI. The appellant's arguments can be summarised as follows:

The experimental tests filed with the letter of 30 January 2007 represented a fair comparison between the invention claimed in the present application and the closest prior art document (4). The lozenges prepared for the comparative experiments were produced according to example 36 in document (4). The reasons for halving the size of the lozenge had to do with the workability of the samples when following the steps disclosed in document (4). As stated on page 2, fourth paragraph, of the experimental test report: "In step 5, considerable difficulty was encountered in compressing the formulation using a single punch press to form tablets. In fact, the lozenges had more or less to be taken out manually from the tableting machine. This was probably due to the nature and proportions of the lubricants used in the formulation, i.e. talc (3.383%) and stearic acid (0.129%)".

The appellant was of the view that the fact that half-sized lozenges were used in the comparative examples did not affect the results of the tests. The appellant

stated that it could be accepted that a very small-sized lozenge or a very big-sized lozenge would have been unacceptable for performing a fair comparison, but a half-sized lozenge was an acceptable choice since the relative amounts of the components remained the same as those in example 36 in document (4). Moreover, the appellant pointed to the amounts used in example 37 in document (4) in order to show that there was a certain size variation in the formulations exemplified in document (4).

The appellant further submitted that the amounts in the lozenges of the comparative examples were sufficient to saturate the taste receptors. In fact, the tests supported the improved effects achieved by the claimed invention. The appellant believed that the test results were the same as if the lozenges had been "full size". Additionally, the two lozenges compared were of the same size and the amounts of the components were sufficient for the tested properties, which had to do with the taste. In particular, 17 panellists compared the taste, the sweetness, the nicotine masking effect and the off-taste of the two lozenges. The test results showed that the lozenge according to the claimed invention tasted better, was sweeter, had a better masking of nicotine and showed less off-taste than the lozenge according to the prior art document (4).

The appellant defined the problem to be solved as the provision of improved nicotine lozenges that showed better nicotine masking and less off-taste. This problem was not artificial and related to a more specific version of the problem as previously defined: "to provide more palatable nicotine lozenges". In fact,

what the applicant was seeking to do in the present invention was to mask the burning and acrid taste of nicotine, as mentioned in the application as filed. What the applicant had recognised was that by using the specific combinations of sweeteners as defined in claim 1 these effects were achieved. Thus, the effects of the invention were achieved by using aspartame combined with the other sweeteners mentioned in the claim. To combine aspartame (strong and fast-acting sweetener with a relative short time of extinction) and a long-lasting sweetener provided improved lozenges with a continuing sweetness profile. The tests demonstrated that the stated problem had been solved for the combination aspartame and ammonium glycyrrhinate. Moreover, the extinction times of neohesperidine dihydrochalcone and stevioside (in this context the appellant pointed to table II on page 243 of document (5)) made it credible that the achieved effects were also present for lozenges containing aspartame combined with one of the other sweeteners listed in the claim.

The appellant submitted that the proposed solution was not obvious in the light of the prior art. The skilled person starting from document (4) would have found no pointer to the claimed solution. Document (4) was to be regarded as a near miss on novelty but was not necessarily as important for the inventive step issue. In fact, document (4) did not relate to the use of sweeteners for taste masking of nicotine. The aim of document (4) was to provide a lozenge useful for smoking cessation therapy. The only mention of taste masking in document (4) referred to candy taste using mint or another flavour (column 16, lines 41 to 43).

The aim of the examples in document (4) was to provide optimal absorption of nicotine by the buccal cavity (column 16, first paragraph); there was no concern expressed in document (4) in relation to effective taste masking of nicotine.

As regards example 36, the appellant further submitted that it had been chosen for the comparison as being the closest example of the prior art document (4). The reasons given by the appellant were as follows: on the one hand the application in suit employed low caloric and non-cariogenic sweeteners in nicotine lozenges and on the other hand mannitol, which was a valid option for the absorbent excipient according to the present application, was also employed in example 36 in document (4). The other examples in document (4) either contained no mannitol or employed a nutritive, cariogenic sweetener such as sucrose. Thus, the comparative examples filed with the letter of 30 January 2007 represented the closest approximation possible and showed that the improvement achieved in the taste profile over the prior art formulation was due to the addition of aspartame to the nicotine formulation already containing a long-lasting sweetener.

When asked by the board about the definition of the term "lozenge" on page 8, line 16 of the application as filed, as being (any) "other device for buccal delivery of nicotine", the appellant stated that it was prepared to delete this when the description was adapted.

XII. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request filed on 3 August 2009, or,

subsidiarily on the basis of one of his auxiliary requests 1 to 3 filed on the same day.

Reasons for the Decision

1. *Admissibility*

1.1 The appeal is admissible.

1.2 The sets of claims filed with the letter of 3 August 2009 were filed in a fair attempt to overcome the objections raised by the board in the communication sent on 24 March 2009. Therefore they are admissible.

2. *Main request*

2.1 Claim 1 of the main request is based on claim 1 of the application as originally filed and on the generic description in the application as originally filed, in particular on pages 8, 10, 11 and 13. The combination of two sweeteners has been defined according to the generic disclosure on page 13 of the application as originally filed, in which the first sweetener is restricted to aspartame. Since the list for the second sweetener includes all the options listed on page 13, the definition of the sweeteners has been restricted only in one direction and is thus allowable under Article 123(2) EPC. Dependent claims 2 and 3 have their basis in the generic disclosure on pages 7 and 13 of the application as originally filed.

Accordingly, the set of claims of the main request meets the requirements of Article 123(2) EPC.

Moreover, the board sees no reason to object to the other terms in the claim under Article 84 EPC.

2.2 None of the documents of the prior art available to the board discloses nicotine lozenges containing aspartame. Therefore, the novelty of the subject-matter claimed is not at stake.

2.3 Document (4), which specifically discloses nicotine lozenges (suitable for buccal delivery of nicotine) comprising an absorbent excipient (such as mannitol) and a low caloric, non-cariogenic sweetener (ammonium glycyrrhizinate) (example 36 in document (4)), represents the closest prior art. This was not disputed by the appellant.

In the light of the closest prior art the problem to be solved lies in the provision of improved nicotine lozenges with better nicotine masking and less off-taste.

The solution as defined in claim 1 of the main request relates to the addition of aspartame to the nicotine formulation.

The appellant has submitted experimental tests during appeal proceedings (see the letter dated 30 January 2007). In particular, the appellant has chosen the closest approximation possible to the lozenges exemplified in example 36 in document (4) (the only difference is the presence of aspartame). The results of the organoleptic comparative tests with 17 panellists show that the lozenges according to claim 1

of the main request have better taste, sweetness and nicotine masking than the prior art lozenges and that they have less off-taste.

Additionally, although the lozenges tested are half-sized, when considering the lozenge size in example 36 in document (4) it can be accepted that the comparative experimental tests represent a fair comparison with the closest prior art since in both cases the lozenge is half-sized and the relative amounts for all components as given in example 36 are respected. Furthermore, the reasons behind this choice which have been stated by the appellant are plausible. Additionally, the amount of 1 mg nicotine is within the usual ranges for nicotine tablets or lozenges suitable for smoking cessation therapy.

Moreover, the experimental comparative tests make it credible that the achieved effects are linked to the addition of aspartame to a long-lasting sweetener, i.e. ammonium glycyrrhizinate. These results are plausible for the combination of aspartame with one of the other two long-lasting sweeteners in the claim (see document (5), table II for their sweetness extinction times).

Thus, the board is satisfied that the problem has been credibly solved in the light of the comparative experimental results submitted during appeal proceedings with the letter of 30 January 2007.

Therefore, it has to be assessed whether the proposed solution is obvious in the light of the prior art.

The skilled person looking for a solution to the above problem does not find any hint in document (4). In fact, the only explicit teaching in relation to nicotine masking is: "the lozenge may contain a candy taste, such as mint or another flavour to mask the effect of nicotine" (column 16, lines 41 to 43).

Moreover, none of the other prior art documents available to the board addresses the benefits linked to a possible use of fast-acting sweeteners such as aspartame (alone or in combination with a long-lasting sweetener) in nicotine lozenges or tablets (suitable for buccal delivery).

Accordingly, the proposed solution is not obvious in the light of the prior art.

Consequently, the subject-matter of claim 1 of the main request involves an inventive step within the meaning of Article 56 EPC.

Since claims 2 and 3 are dependent on claim 1, the main request meets the requirements of Article 56 EPC.

- 2.4 Since it is necessary to adapt the description, due care should be taken in relation to the meaning of the expression "lozenge" which appears on page 8, line 16 (see also the appellant's comment made during the oral proceedings before the board which has been mentioned in point XI of "Facts and submissions").

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of claims 1 to 3 of the main request filed on 3 August 2009, and a description still to be adapted thereto.

The Registrar

The Chairman

A. Counillon

U. Oswald