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Datasheet for the decision of 15 January 2025

Case Number: T 1091/22 - 3.3.07

Application Number: 07007326.7

Publication Number: 1803444

IPC: A61K9/16, A61K31/465

Language of the proceedings: EN

Title of invention:
A method for the preparation of a nicotine-containing particulate material with a crystalline cellulose (in particular MCC)

Patent Proprietor:
NicoNovum AB

Opponents:
Philip Morris Products S.A.
Swedish Match North Europe AB

Headword:
Preparation of a nicotine-containing material / NICONOVUM

Relevant legal provisions:
RPBA 2020 Art. 12(4)
EPC Art. 114(2), 111(1) sentence 2, 56

Keyword:
Admittance of items of evidence - admissibly raised and maintained in the first instance proceedings (yes)
Admittance of arguments - Amendment to the case (no)
Inventive step - reasonable expectation of success - auxiliary request 13 (new main request) (no)

Decisions cited:
T 1912/10, T 0311/22

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Case Number: T 1091/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 15 January 2025

Respondent: (Patent Proprietor)	NicoNovum AB Järnvägsgatan 13 252 24 Helsingborg (SE)
Representative:	D Young & Co LLP 3 Noble Street London EC2V 7BQ (GB)
Appellant: (Opponent 1)	Philip Morris Products S.A. Quai Jeanrenaud 3 2000 Neuchâtel (CH)
Representative:	HGF HGF Limited 1 City Walk Leeds LS11 9DX (GB)
Party as of right: (Opponent 2)	Swedish Match North Europe AB Sveavägen 44 118 85 Stockholm (SE)
Representative:	Valea AB Box 1098 405 23 Göteborg (SE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 2 March 2022 concerning maintenance of the European Patent No. 1803444 in amended form.**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Lécaillon
	L. Basterreix

Summary of Facts and Submissions

I. European patent 1 803 444 (hereinafter "the patent") was granted on the basis of 14 claims. The independent claim of the patent as granted read as follows:

"1. A method for preparation of a nicotine-containing particulate material for release of nicotine, the method comprising

i) dissolving nicotine or a pharmaceutically acceptable salt, complex or solvate thereof in a hydrophilic solvent, and

ii) entrapping the nicotine contained in the hydrophilic solvent in a microcrystalline cellulose to obtain a particulate material,

wherein nicotine or the pharmaceutically acceptable salt, complex or solvate thereof is retained inside the voids of the microcrystalline cellulose, and wherein the concentration of the nicotine or the pharmaceutically acceptable salt, complex or solvent thereof in the particulate material obtained is at the most about 8% w/w, and the concentration being calculated as the nicotine base."

II. Two oppositions were filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the (parent) application as originally filed.

III. The opposition division took the interlocutory decision that, on the basis of auxiliary request 1, the patent met the requirements of the EPC.

This decision was based on the patent as granted (main request) and auxiliary request 1 filed during oral proceedings on 1 February 2022. Auxiliary request 1 contained 10 claims. Claim 1 of auxiliary request 1 corresponded to granted claim 1 wherein the feature "wherein the hydrophilic solvent is water, alcohol or mixtures thereof" was added at the end of step i) and the feature "by removing the hydrophilic solvent" was added at the end of step ii). Granted dependent claims 4, 6 and 7 were deleted and the numbering of the claims adapted. Moreover, the volume of 37°C phosphate buffer at pH 7.4 ("one liter") was introduced in the dependent claims 4 and 5 corresponding to granted claims 8 and 9.

IV. The following documents cited in the decision of the opposition division, posted on 2 March 2022, are relevant for the present decision:

D1: US 5,362,496
D2: WO 00/35295 A1
D5: GB 2 193 092 A
D6: US 4,907,605
D7: US 5,939,100
D8: Ek *et al.*, International Journal of Pharmaceutics, 122, (1995), 49-56
D10: WO 95/03050 A2
D14: Technical Stability Investigation Protocol on TS-1511-01 nicotine adducts, 2015
D15: Franz *et al.*, Journal of Pharmaceutical Sciences, Vol. 71, No.11, November 1982
D16: Steele *et al.*, Drug Development and Industrial Pharmacy, Vol. 29, No. 4, pp. 475-487, 2003

D19: Experimental report from Niconovum

V. The opposition division decided in particular as follows:

(a) No decision regarding the admittance of D15 and D16 was required. D19 was taken into account.

(b) The subject-matter of claims 1, 4 and 6 to 9 of the main request did not meet the requirements of Articles 123(2) and 76(1) EPC.

(c) Auxiliary request 1 overcame the objections raised under Articles 123(2) and 76(1) EPC for the previous request.

(d) Sufficiency of disclosure and novelty of auxiliary request 1 were not contested.

(e) Auxiliary request 1 met the requirement of Article 56 EPC starting from D1 as closest prior art.

VI. The patent proprietor and opponent 1 lodged an appeal against the above decision of the opposition division.

VII. With its statement setting out the grounds of appeal the patent proprietor defended its case on the basis of the patent as granted as the main request, and on the basis of auxiliary requests 1 to 30 filed therewith.

VIII. Oral proceedings were held before the Board on 15 January 2025 using videoconference technology.

IX. At the beginning of the oral proceedings, the patent proprietor withdrew its main request and auxiliary requests 1 to 12 and defended its case based on

auxiliary request 13 as new main request. This request was identical to auxiliary request 1 forming the basis of the impugned decision. During the oral proceedings, the patent proprietor (respondent) subsequently withdrew its appeal.

X. The appellant (opponent 1) and the party as of right (opponent 2) requested that the decision under appeal be set aside and the patent be revoked.

XI. The respondent (patent proprietor) requested that the patent be maintained on the basis of auxiliary request 13 (new main request), which corresponded to the auxiliary request upheld by the opposition division, or on the basis of one of auxiliary request 14 to 30 submitted with the statement setting out the grounds of appeal.

The respondent further requested that D15 and D16 not be admitted. By referring to its submissions made in the parallel case T 311/22, the respondent also requested that the following arguments of the appellants not be admitted:

- the inventive step objection of the party as of right,
- the following arguments of the appellant concerning inventive step:
  - the argument based on the passage on column 17 of D1, and
  - the argument regarding the use of MCC in rapid release compositions in D2 based on example HH.

XII. The arguments of the appellant and party as of right, submitted in the present case in writing and during oral proceedings including by reference to the parallel

case T 311/22, as far as relevant for the present decision, can be summarised as follows:

(a) D15 and D16 were to be admitted into the appeal proceedings because they were *prima facie* relevant and had been filed and maintained during the first instance proceedings.

(b) The arguments provided by the appellant and the party as of right in their inventive step objections had either already been raised or represented further developments of already raised objections and were therefore to be admitted.

(c) Starting from example 32 of D1, which represented the closest prior art, the distinguishing features were the steps of introduction of nicotine in solution and of subsequent solvent removal. Both the appellant and the party as of right disputed that D14 and D19 supported any improved technical effect compared to the closest prior art. Hence, appellant 1 formulated the objective technical problem to be solved as the provision of an alternative method for loading nicotine onto the MCC carrier. The party as of right considered that the objective technical problem resided in the provision of an alternative composition for the delivery of nicotine. Even if the alleged technical effects would be recognised, the appellant and the party as of right considered that the present solution was obvious in light of D1 combined with D2, D8, D15 or D16, which suggested to introduce nicotine in the form of a solution to improve drug loading within MCC and hence nicotine stability. Appellant 2 additionally mentioned D5, D6 or D7 as combination documents, since they would disclose

the introduction of nicotine in solubilised form onto inert carriers. As a result, the subject-matter of claim 1 of auxiliary request 13 (new main request) did not involve an inventive step.

XIII. The arguments of the respondent submitted in the present case in writing and during oral proceedings including by reference to the parallel case T 311/22, as far as relevant for the present decision, can be summarised as follows:

(a) D15 and D16 should not be admitted into the appeal proceedings. These documents were filed late during the first instance proceedings and were not *prima facie* relevant. Moreover the appellant and the party as of right did not refer to these documents during oral proceedings in first instance, so that they had been abandoned.

(b) The inventive step objection against the main request raised by the party as of right and the following inventive step arguments of the appellant, should not be admitted into the appeal proceedings because they represented amendments to the appellants' case and their admittance had not been substantiated:

(i) the argument based on the passage on column 17 of D1, and

(ii) the argument regarding the use of MCC in rapid release compositions in D2 based on example HH.

(c) Starting from example 32 of D1, which represented the closest prior art, the distinguishing features

were the steps of introduction of nicotine in solution and of subsequent solvent removal. As substantiated *inter alia* in the patent, D14 and D19, the process resulted in a product having increased nicotine storage stability while maintaining rapid release of nicotine. Hence, the objective technical problem resided in the provision of a nicotine-containing material that has improved stability whilst still at least maintaining a rapid release of the nicotine from the material. None of the cited prior art documents suggested to prepare a particulate material containing nicotine retained inside MCC voids wherein nicotine had been introduced whilst being in form of a solution and wherein the solvent had been subsequently removed to solve this problem. As a result, the subject-matter of claim 1 of auxiliary request 13 (new main request) involved an inventive step.

Reasons for the Decision

Auxiliary request 13 (new main request)

1. Claim 1 of auxiliary request 13 reads as follows:

"1. A method for preparation of a nicotine-containing particulate material for release of nicotine, the method comprising

i) dissolving nicotine or a pharmaceutically acceptable salt, complex or solvate thereof in a hydrophilic solvent, wherein the hydrophilic solvent is water, alcohol or mixtures thereof and

ii) entrapping the nicotine contained in the hydrophilic solvent in a microcrystalline cellulose

to obtain a particulate material by removing the hydrophilic solvent,

wherein nicotine or the pharmaceutically acceptable salt, complex or solvate thereof is retained inside the voids of the microcrystalline cellulose, and wherein the concentration of the nicotine or the pharmaceutically acceptable salt, complex or solvent thereof in the particulate material obtained is at the most about 8% w/w, and the concentration being calculated as the nicotine base.

2. Amendments, sufficiency of disclosure and novelty

2.1 The party as of right did not raise any objections concerning the amendments made in auxiliary request 13. During oral proceedings, the appellant had no longer any objection against auxiliary request 13 under Articles 123(2) and 76(1) EPC. No objection of lack of compliance with Article 123(3) EPC was raised. The Board is satisfied that the requirements of Articles 76(1), 123(2) and 123(3) EPC are met as stated in the impugned decision.

2.2 Neither the appellant nor the party as of right raised any objection of lack of compliance with Articles 83 and 54 EPC for auxiliary request 13. The Board is satisfied that the requirements of Articles 83 and 54 EPC are met as stated in the impugned decision.

3. Inventive step

3.1 It was undisputed that the subject-matter of claim 1 of auxiliary request 13 defines a process for the preparation of a product, which is claimed in claim 1 of auxiliary request 2 of the parallel case T 311/22.

3.2 The parties provided essentially the same arguments regarding the issue of inventive step of the product (in T 311/22) and of its process of preparation (in the present case). Since the Board previously came to the conclusion in case T 311/22 that the product of auxiliary request 2 was inventive, the process for its preparation necessarily involves an inventive step for the same reasons.

3.3 The reasons for finding that the product of the present process is inventive as stated in T 311/22 are reproduced below (see 3.4 to 3.9.11). The correspondence of the documents numbering between the cases is the following (the numbering of the documents cited in the decision and not mentioned in the following table is the same in the two cases):

T 311/22	T 1091/22
D8	D7
D9	D8
D11	D10
D15	D14
D16	D15
D17	D16
D21	D19

The correspondence of the status of the parties between the cases is the following:

First instance	T 1091/22	T 311/22
Patent proprietor	respondent	respondent
Opponent 1	appellant	appellant 1
Opponent 2	party as of right - opponent 2	appellant 2

3.4 Admittance of items of evidence D16 and D17

3.4.1 D16 and D17 were filed by appellant 2 (then opponent 2) during the fist instance proceedings.

3.4.2 The impugned decision explicitly stated that the admissibility of D16 and D17 was "not further examined" (see point 32 last paragraph of the decision), i.e. no decision on their admittance was taken and the impugned decision was not based thereupon. It follows that these documents do not form part of the appeal proceedings according to Article 12(2) RPBA unless appellant 2 demonstrates that they have been admissibly raised and maintained during the first instance proceedings (Article 12(4) RPBA).

3.4.3 It therefore has first to be assessed whether D16 and D17 were admissibly filed during the first instance proceedings according to Article 114(2) EPC (Article 111(1), 2nd sentence, 1st part).

The Board observes that D16 and D17 were filed during the first instance proceedings after the 9-months period according to Article 99(1) EPC but within the first time period according to Rule 116(1) EPC. These documents both aim at studying the mechanisms involved in the adsorption of drugs from aqueous solutions onto MCC. While, as argued by the respondent, they relate to different drugs than nicotine and potentially different

release profiles than in the present patent, the Board considers that the properties of MCC involved in the studied adsorption mechanisms are potentially prima facie relevant for the present case despite the use of a different drug and a different release profile (i.e. desorption mechanism). As a result, the Board considers that D16 and D17 were admissibly raised in the first instance proceedings.

3.4.4 The respondent further disputed that D16 and D17 had been maintained during the first instance proceedings. According to the respondent, these documents had not been referred to by the appellants (then opponents) during the oral proceedings of the first instance proceedings (see minutes of the oral proceedings, item 3. and impugned decision page 25 item 32.). In the respondent's view D16 and D17 had not been actively maintained and hence implicitly abandoned.

As argued by appellant 1 during oral proceedings, there is no evidence that the arguments of the appellants (then opponents) based on D16 and D17 were abandoned during the first instance proceedings. Said arguments were indeed part of the summary of the parties' arguments in the impugned decision (see page 11, starting from the third full paragraph). As a result, the Board considers that D16 and D17 were maintained during the first instance proceedings.

3.4.5 Hence, documents D16 and D17 are part of the appeal proceedings (Article 12(4) RPBA).

3.5 Admittance of objections and arguments

3.5.1 During the oral proceedings, the respondent requested that the objection of lack of inventive step of

appellant 1, in particular the following arguments not be admitted into the appeal proceedings according to Article 13(2) RPBA because they had not been raised earlier and hence represented unsubstantiated amendments to appellant 1's case:

(a) the argument based on the passage on column 17 of D1, and

(b) the argument regarding the use of MCC in rapid release compositions in D2 based on example HH.

The arguments of appellant 1 regarding inventive step of claim 1 of auxiliary request 9 were limited to those raised against claim 1 of the main request. As argued by appellant 1, the content of the passage on column 17 of D1 had already been brought forward by appellant 2 in its notice of opposition by reference to the same content in D11, WO 95/03050 (see final paragraph of appellant 2's submission dated 31 July 2019 with reference to page 10 of "D3" which is WO 95/03050). As also argued by appellant 1, the argument based on D2, in particular example HH, constitutes a further development of an argument already discussed by the parties and identified in the preliminary opinion of the Board as a point of discussion for the oral proceedings (see item 7.5.2 of the preliminary opinion) regarding the issue of whether D2 would provide a teaching away from a rapid release or not.

The Board therefore considers that these arguments do not represent amendments to the case of appellant 1 (Article 12(4) RPBA) and are therefore admitted into the appeal proceedings.

3.5.2 Furthermore, during the written proceedings, the respondent requested that the inventive step objection against the main request raised by appellant 2 not be admitted into the appeal proceedings.

As indicated in the preliminary opinion (see item 7.1), these arguments are taken into account in so far as they apply to auxiliary request 2, since they had already been submitted and maintained during the first instance proceedings and do thus not constitute amendments to appellant 2's case according to Article 12(4) RPBA.

3.6 Closest prior art and distinguishing feature

3.6.1 In the appeal proceedings, all the parties considered example 32 of D1 as the closest prior art. This example describes the process of preparation of a nicotine sublingual tablet. Avicel PH 101 (an MCC) and Aerosil 200 (a colloidal silica) are first blended. Nicotine free base is then "adsorbed" onto the obtained Avicel / Aerosil blend, which "acts as a carrier", by means of a mixing process in a mortar without any aqueous solvent that results in a homogeneous dispersion (see column 33 last paragraph). This dispersion is then further processed with further excipients to the final tablet.

3.6.2 It was furthermore undisputed that the product of claim 1 of auxiliary request 2 differs from the one of example 32 of D1 in the distribution of nicotine in the MCC containing carrier. The retention of nicotine inside the voids of the MCC containing carrier obtainable as a result of the process defined in present claim 1 including the use of aqueous solvents is indeed not unambiguously disclosed in D1.

3.7 Associated technical effect

3.7.1 The respondent argued that the claimed product would have increased nicotine storage stability while maintaining rapid release of nicotine as substantiated by the results provided in the patent and in inter alia D15 and D21.

3.7.2 Regarding storage stability, this property was already described for material according to the invention in the original application (see Table 1). Furthermore, as argued by the respondent, D15 substantiates an improved storage stability for products obtained by introducing nicotine dissolved in a hydrophilic solvent compared to in the absence of any solvent (compare samples 90900-1511-10 and 90900-1511-09 in Tables 6 and 7). The fact that, as argued by appellant 2, the comparative sample in D15 is not a true repetition of the example of D1 is not deleterious. The effect has indeed been substantiated for the identified distinguishing feature, which is the sole difference between samples 90900-1511-09 and 90900-1511-10. A similar trend is observed in D21 (compare samples A-1 and B-1 or A-2 and B-2).

3.7.3 According to the appellants, rapid release of nicotine could not be taken into account for the formulation of the technical problem due to the absence of a comparison to a product according to example 32 of D1.

The Board observes that, as indicated by the respondent, the effect relied upon does not consist in an improvement over the closest prior art product. The results provided in the granted patent (see paragraphs [0074] to [0076] and Table 3) do indeed not provide any comparison with a product according to example 32 of

D1. However they substantiate that products according to the claims have a rapid in vitro nicotine dissolution profile (i.e. over 90% w/w within 10 minutes). However, D1 also provides a fast nicotine release (see Figure 2 of D1). Therefore with regard to nicotine release, an effect of the same order as in the closest prior art, i.e. an alternative, has been substantiated.

3.8 Objective technical problem

In view of the above considerations, the objective technical problem resides in the provision of an alternative nicotine containing particulate material having improved storage stability.

3.9 Obviousness

3.9.1 The Board observes that neither D1 nor the prior art documents used by the appellants as combination documents (i.e. D2, D5, D6, D8, D9, D16 and D17) provide any explicit hint towards improvement of storage stability of a nicotine containing MCC particulate material, in particular while maintaining fast nicotine release.

D1

3.9.2 During oral proceedings, appellant 1 argued that D1 itself provided a hint to improved storage stability since it provided the teaching that MCC as absorbent could reduce the volatility of nicotine (see columns 17-18) and volatility was a key factor to storage stability as stated in the patent (see paragraphs [0072] to [0073] and [0021]).

3.9.3 This argument is however not convincing because:

(a) D1 describes several absorbents being capable of reducing the volatility of nicotine including MCC among many other examples, and

(b) this teaching does not point to the retention of nicotine inside the MCC voids nor to the introduction of nicotine in a dissolved form.

D5, D6, D8

3.9.4 Documents D5, D6 and D8 cited by appellant 2 do not even relate specifically to MCC as carrier (D5, page 1 lines 50 to 55, concerns synthetic silica; D6, column 2 lines 14-23, mentions cellulose derivatives such as cellulose acetate; D8, column 4 lines 1-2, relates to starch) and cannot thus provide any pointer to the claimed solution.

D2

3.9.5 The appellants also argued that the claimed subject-matter would be obvious in view of D1 in combination with D2. D2 describes chewing gum products containing active ingredients including nicotine (see list of examples of active ingredients on e.g. page 7 last paragraph). According to the general preparation procedure, the active ingredient is added to the carrier material in the form of a solution in water or other solvents such as ethanol (see paragraph bridging pages 15 and 16).

According to appellant 1, D2 would teach that encapsulation of the active ingredient improves stability of the active agent (see page 2 lines 11 to

12). Furthermore, the absorption according to D2 would lead to encapsulation i.e. entrapment:
- according to page 15 lines 16 to 18 the active ingredient absorbed onto a porous component becomes entrapped in the matrix thereof, and
- according to the last paragraph of page 16 absorption provides encapsulation.

Moreover, appellant 1 argued that, contrary to the opinion of the respondent, D2 and its purpose of reducing bitterness did not teach away from a fast release. According to appellant 1, D2 related to both fast and delayed releases (see page 3 lines 26 to 27) and MCC was not mentioned in the list of slow release carriers on page 15 while cellulose materials were listed amongst fast release materials (see page 13 lines 20 to 31 and page 14 starting from line 24) and used in examples reducing bitterness (see examples M and N page 40). MCC itself was used in example HH (see page 43).

3.9.6 These arguments do however not convincingly lead to the conclusion that the skilled person would have modified the preparation of the nicotine product of D1 by using the general method of D2 with the reasonable expectation of success in improving nicotine storage stability and maintaining rapid release.

The Board first considers that, even if there is no outright teaching away from rapid release in D2, it remains that the skilled person would only combine documents which appear compatible. In the present case, as brought forward by the respondent, D2 is primarily concerned with caffeine containing chewing gum and the reduction of bitterness, including by delaying the release of the agent until it enters the digestive

track (see page 2 lines 17 to 21). In contrast D1 concerns rapid release of nicotine by transmucosal administration. The Board is therefore not convinced that the skilled person would have combined the teachings of D1 and D2.

Furthermore, even if the skilled person would have taken D2 into consideration, the passage on page 2 of D2 mentioning improved stability relates to "various methods of encapsulation" and does not specifically concern nicotine, let alone absorption onto MCC and retention of nicotine inside MCC voids. Moreover, the further passages mentioned by appellant 1 (see pages 13 and 14 and examples M and N) relate to various (cellulose) materials but not specifically to MCC, let alone absorption.

The sole passage of D2 involving MCC is example HH. This example concerns reduction of the bitterness of caffeine by absorption onto MCC. It does not contain nicotine. Furthermore no information regarding the storage stability and release of the agent in example HH is provided. Appellant 1 concluded that the release should be rapid due to the list of agents on page 13, line 30. However this list relates exclusively to cellulose derivatives and not to MCC. Moreover this passage on page 13 concern encapsulation in general and not specifically absorption. In contrast, as argued by the respondent during oral proceedings, it is specified on page 15 of D2, when describing absorption (including the general preparation method) that all materials used to absorb the active agent "result in a delayed release of caffeine or other active agent" (see lines 16 to 22).

It follows that, contrary to the opinion of appellant 1, there is no disclosure in D2 that absorption of an active agent onto MCC following the general method described on pages 15-16 (active agent added in form of a solution and subsequent solvent removal) would indeed improve storage stability and at the same time maintain rapid release.

D9

3.9.7 A further argument of the appellants was based on D9. According to the appellants, it would be known from D9 that drugs can be applied as aqueous or alcoholic solutions to porous cellulose beads (see Abstract). They explained that D9 explicitly states that the pore size and porosity of cellulose beads increase due to swelling upon contact with water so that drug loading can be increased (see Figure 3 and paragraph "4. Conclusion" of D9). In the appellants' view, the skilled person would therefore understand that absorption can be increased by adding nicotine in the form of an aqueous solution to MCC. Since D1 would already teach that increased absorption results in increased stability, appellant 1 concludes that it would have appeared obvious to the skilled person to modify the preparation method of D1 by adding nicotine in the form of an aqueous solution in order to improve storage stability.

3.9.8 This argument is not convincing.

D9 is a scientific study of the pores size of porous cellulose beads upon swelling in different solvents. As argued by the respondent, these beads are specific products obtained from MCC via specific processes (see page 50, right column) so that the observed results

cannot be with certainty extrapolated to MCC in general. Furthermore, as underlined by the respondent, the introduction of D9 refers to sustained drug release (see page 49, first paragraph below "Introduction").

The Board therefore considers that the skilled person would not have combined this teaching with the one of D1, and would in any case not have had any reasonable expectation of success of achieving the present effects when modifying the method of preparation of the product of D1 accordingly, in particular the maintenance of a rapid release.

D16 and D17

3.9.9 The appellants also referred to D16 and D17. In their view, these documents described the importance of an aqueous environment for adsorption of model drugs onto MCC through ion exchange (see D16, pages 1196 to 1197 "Effect of pH on Adsorption" and page 1198 penultimate paragraph, last sentence and last paragraph; D17, page 476 right column, second full paragraph, page 485 penultimate paragraph). According to the appellants, the skilled person would therefore have been motivated to modify D1 by applying nicotine in aqueous solution.

3.9.10 The Board disagrees.

As argued by the respondent, although D16 and D17 refer to amine drugs as "model drugs", differences are nevertheless observed between the drugs used (see e.g. D16, Table IV and D17, page 482 right column, first full paragraph and page 483, left column, last paragraph). It is therefore questionable whether the skilled person would necessarily have expected the same results for nicotine.

Furthermore, D16 and D17 specify that the release occurs in the gastrointestinal tract (i.e. the release is delayed), see D16, page 1198, right column, last paragraph and D17, page 482, right column, second full paragraph.

The Board therefore considers that the skilled person would not have combined these teachings with the one of D1, and would in any case not have had any reasonable expectation of success of achieving the present effects when modifying the method of preparation of the product of D1 accordingly, in particular the maintenance of a rapid release.

T 1912/10

3.9.11 *Finally, the appellants referred to the decision T 1912/10 relating to the patent originating from the parent application. The Board observes that, as indicated by the respondent, the facts underlying the present case and the one of T 1912/10 are not entirely identical. In particular additional experimental data have been provided in the present case (see in particular D15 and D21). It follows that the conclusion reached in this earlier decision on the parent application does not necessarily apply to the present case.*

3.9.12 *As a result, the subject-matter of the claims of auxiliary request 2 meets the requirement of inventive step (Article 56 EPC).*

3.10 As a result, the subject-matter of the claims of auxiliary request 13 (new main request) meets the requirement of inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated