

Internal distribution code:

- (A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

**Datasheet for the decision
of 19 March 2015**

Case Number: T 2129/11 - 3.3.07

Application Number: 04703370.9

Publication Number: 1594478

IPC: A61K9/24

Language of the proceedings: EN

Title of invention:

CHEWING GUM IN THE FORM OF MULTI-LAYER TABLETS

Patent Proprietor:

JAGOTEC AG

Opponent:

Fertin Pharma A/S

Relevant legal provisions:

EPC Art. 56

Keyword:

Main request and first auxiliary request, prohibition of
reformatio in peius - (yes)
Second to fourth auxiliary requests, inventive step - (no)

Decisions cited:

G 0009/92



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 2129/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 19 March 2015

Respondent:
(Patent Proprietor)

JAGOTEC AG
Eptingerstrasse 51
4132 MuttENZ (CH)

Representative:

Mintz Levin Cohn Ferris Glovsky and Popeo LLP
Alder Castle
10 Noble Street
London EC2V 7JX (GB)

Appellant:
(Opponent)

Fertin Pharma A/S
Industrivej 8
DK - 7120 Vejle (DK)

Representative:

Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München (DE)

Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
11 July 2011 concerning maintenance of the
European Patent No. 1594478 in amended form.**

Composition of the Board:

Chairman J. Riolo
Members: R. Hauss
W. Ungler

Summary of Facts and Submissions

- I. European patent No. 1 594 478 was granted on the basis of ten claims.

Independent claim 1 reads as follows:

"1. Tablets containing one or more active pharmaceutical, dietetic or nutritional ingredients comprising at least one inner layer of gum base and outer layers comprising antiadhesion excipients and compression adjuvants selected from Isomalt, Maltol, Maltodextrin, Maltitol, Mannitol, Xylitol, Lactitol, Lactose, Skim Milk, Eritritol, Oligofructose, Retrograded Starch, polysorbates, polyethyleneoxide, dextrans, Cyclodextrins, Oligosaccharose, fructose, hydrogenated starch hydrosilates, said tablets having a sandwich like structure, the external layers containing said antiadhesion excipients being not in contact one with the other and respectively coating only the upper and the bottom part of the gum core, leaving the peripheral side thereof uncoated."

Claims 2 to 8 are dependent on claim 1. Independent claim 9 is directed to a process for the preparation of the tablets of claims 1 to 8. Independent claim 10 is directed to tablets obtainable by the process of claim 9.

- II. A notice of opposition was filed in which the patent was opposed under Article 100(a) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step and extended beyond the content of the application as filed.
- III. The documents cited during the opposition and appeal proceedings included the following:

D2: EP 0 151 344 A2

D6: US 4 139 589

D10: Bauer, Frömming, Führer: Lehrbuch der Pharmazeutischen Technologie, 7th edn. Stuttgart 2002, pages 166 to 191, 318 to 334

D11: Sucker, Fuchs, Speiser: Pharmazeutische Technologie, Stuttgart 1978, pages 320 to 337, 371 to 382

D12: Test report filed by the patent proprietor with the statement setting out the grounds of appeal

IV. The appeal by the opponent (see point XIV below) lies from the interlocutory decision of the opposition division, pronounced on 17 May 2011 and posted on 11 July 2011, finding that the patent as amended in the form of the second auxiliary request met the requirements of the EPC.

V. The decision under appeal is based on the patent proprietor's main request directed to the rejection of the opposition, and on two auxiliary requests.

Claim 1 of the second auxiliary request is identical to claim 1 of the patent as granted but contains in addition the following feature: "*wherein the tablets are obtainable by direct compression of mixtures or granulates of the different components of each layer*".

Since the feature added in claim 1 was taken from granted claim 4, that claim was deleted, the subsequent claims were renumbered and their cross-references were adapted accordingly. Apart from those amendments, claims 2 to 9 of the second auxiliary request are identical to claims 2, 3 and 5 to 10 as granted.

VI. In the decision under appeal, the opposition division held *inter alia* with regard to the main request that document D6, which required the fewest structural modifications to arrive at the claimed tablets,

represented the closest prior art. The tablets defined in claim 1 of the opposed patent comprised mandatory excipients not disclosed in document D6. Starting from the technical teaching of document D6, the objective technical problem could be defined as the provision of alternative tablets. Since the excipients recited in claim 1 of the opposed patent were commonly used in pharmaceutical tablets, as corroborated by textbook citations D10 and D11, the claimed tablets were obvious alternatives to the tablet compositions described in document D6.

In contravention of Rule 80 EPC, the first auxiliary request contained an amendment not occasioned by a ground for opposition.

The amendment of claim 1 in the second auxiliary request was an attempt to overcome the objection concerning lack of inventive step (Rule 80 EPC). The requirements of Articles 123(2) and (3) and 54 EPC were met. The opposition division considered that the process used to prepare the tablets of claim 1 according to the second auxiliary request required that the pressure of the punch of the tableting machine be applied to the whole system. Document D2 represented the closest prior art since it was directed to the same technical problem as mentioned in the opposed patent, viz. to provide a method of manufacturing chewing gum using direct compression which avoided problems caused by the processed mixture adhering to the punch. Starting from the mono-layer product described in document D2 and having regard to the cited prior art, the claimed multi-layer product was not an obvious alternative. Nor was the claimed subject-matter obvious starting from the teaching of document D6, since that document did not disclose direct compression and did

not mention the relevant technical problem of avoiding stickiness during processing.

- VII. Both the patent proprietor and the opponent lodged an appeal against that decision.
- VIII. In its statement setting out the grounds of appeal dated 17 November 2011 the appellant (opponent) contended that the second auxiliary request lacked inventive step.
- IX. The patent proprietor, in its statement setting out the grounds of appeal dated 21 November 2011, requested as its main request that the decision under appeal be set aside and that the patent be maintained with the claims as granted. In addition, five sets of claims designated as main request and first to fourth auxiliary requests were annexed to that letter.

The independent claims of the new set of claims entitled "Main Request" are identical to those of the patent as granted, apart from typographical corrections and an error in claim 1, in which "*oligosaccharose*" has been replaced with "*oligosaccharoseoligosaccharose*".

Apart from typographical corrections, the independent claims of the first auxiliary request are identical to those of the patent as granted, with the sole difference that claim 1 is directed to "*Compressed tablets*" instead of "*Tablets*".

Apart from typographical corrections, the independent claims of the second auxiliary request are identical to those of the former second auxiliary request on which the decision under appeal is based.

Apart from typographical corrections, the independent claims of the third auxiliary request are identical to those of the patent as granted, with the sole

difference that claim 1 further specifies: *"wherein the active component content is between 0.5% and 90% of the weight of the layer in which said active component is carried"*.

Apart from typographical corrections, the independent claims of the fourth auxiliary request are identical to those of the patent as granted, with the sole difference that claim 1 further specifies: *"wherein the outer layers are free of gum base"*.

- X. With letters dated 2 April 2012 and 3 September 2013, the parties submitted further arguments.
- XI. As far as relevant to the present decision, the patent proprietor's arguments as filed in writing can be summarised as follows:
- It was acknowledged that document D6 represented the closest prior art with regard to claim 1 as granted. Due to their structure and composition, it was an intrinsic feature of the claimed tablets that they could be effectively processed by means which avoided hot molten extrusion, without encountering the problem of tablet adhesion occurring with known ambient-temperature tableting methods. Test report D12 was submitted in order to show that the claimed composition of the outer layer allowed 100 tablets to be obtained without any adherence problems. Taking that technical effect into account, the objective technical problem should therefore be defined as the provision of chewing gum tablets and a process for their manufacture which overcame adherence problems associated with existing tableting processes. According to claim 1 that problem was solved by including antiadhesion excipients and compression adjuvants, selected from the specified list, in the outer layers of the tablets. The skilled

person seeking to solve the technical problem would find no incentive in document D6 in combination with common general knowledge or any other cited prior art to replace any of the tablet excipients of D6 with those specified in claim 1 of the patent in suit. That would also be the case were the technical problem deemed to be merely the provision of alternative tablets: even though it was acknowledged that the excipients recited in claim 1 were commonly used in pharmaceutical tablet formulation, there was nothing in D6 to suggest that adding further excipients would be beneficial or that the specifically recited excipients should be chosen.

- The term "direct compression" employed in claim 1 of the second auxiliary request meant that all the component layers of the tablet were compressed in one step to form the tablets. The reader would infer this from certain passages of the patent specification (paragraphs [0008] and [0015], examples) and also from the fact that no other way of producing the chewing gum tablets was described in the patent in suit. The feature concerning direct compression was both a limiting feature and a distinguishing feature relative to document D6.

- Adherence problems associated with existing tableting processes should also be taken into account in the formulation of the technical problem with regard to claim 1 of the second auxiliary request. Since document D2, which disclosed non-layered chewing gum tablets, mentioned the same processing difficulties, that document represented the closest prior art. The claimed tablets were inventive over the disclosure of document D2, alone or in combination with D6, since the relevant teaching of those documents would not lead the skilled person to layered tablets comprising the specific

excipients listed in claim 1. If on the other hand document D6 were to be chosen as the starting point, then the patent proprietor agreed with the opposition division's assessment that the tablets of claim 1 of the second auxiliary request were not obvious because document D6 did not avoid adherence problems associated with the tableting process.

The patent proprietor did not provide a separate inventive-step analysis taking account of the technical features added to claims 1 of the first, third or fourth auxiliary requests.

XII. As far as relevant to the present decision, the appellant (opponent)'s arguments can be summarised as follows:

- The appellant agreed with the opposition division's inventive-step assessment of claim 1 as granted (main request).
- The same assessment starting from document D6 as the closest prior art was also applicable to claim 1 of the second auxiliary request, since the added feature "*...wherein the tablets are obtainable by direct compression of mixtures or granulates of the different components of each layer*" did not give rise to an identifiable difference of the tablets of claim 1 over the tablet embodiments disclosed in document D6. Thus the additional feature could not affect the inventive-step analysis.
- The alleged advantageous technical effect, viz. that the outer tablet layers did not stick to the tableting machinery, concerned the avoidance of handling problems during tablet processing. That issue could not however be relevant to the assessment of inventive step of a claim which was directed to the product (i.e. the

tablets) as such, and which did not reflect the alleged technical effect in its mandatory technical features. Since no other argument in favour of inventive step had been presented by the patent proprietor with regard to the product claims of any of its requests, the subject-matter of none of the auxiliary requests involved an inventive step.

XIII. In a communication issued in preparation for oral proceedings and advising the parties of the board's preliminary opinion, the board mentioned the following points:

a) With regard to claim 1 as granted, document D6 was a suitable starting point for the assessment of inventive step. Since the selection of outer layer components from a list of specified "anti-adhesion excipients and compression adjuvants" had not been shown to provide any particular property in the finished tablets, the technical problem could be defined as the provision of alternative layered chewing gum tablets. The excipients mentioned in claim 1, e.g. mannitol, were known tableting excipients (points 3.1 to 3.5 of the board's communication).

b) The modified claims of the separate request of 21 November 2011, likewise designated as "Main Request", did not seem to give rise to a different assessment (point 4.1 of the board's communication).

c) The term "compressed" which had been introduced into claim 1 of the first auxiliary request was not regarded as limiting, since the claimed dosage form was in any event restricted to tablets, which were by definition comprimates (points 5.1 and 5.2 of the board's communication).

d) Where a claim directed to a product was concerned, a technical feature concerning the process of its preparation could be taken into account in the assessment of inventive step only to the extent that it resulted inevitably in a limiting feature or property of the claimed product. The product-by-process feature in claim 1 of the second auxiliary request, *"wherein the tablets are obtainable by direct compression of mixtures or granulates of the different components of each layer"*, seemed to imply in terms of structural product features that not only the tablet core was compacted, but also the outer layers (points 6.2.1, 6.2.2 and 6.2.5 of the board's communication). That feature did not however appear to provide a further distinction relative to the tablets described in document D6. Since claim 1 of auxiliary request 2 was directed to a product (the tablets), processing problems which might occur during the preparation of said tablets could not be relevant to the formulation of the technical problem in respect of the tablets themselves (point 6.5 of the board's communication).

e) The additional features which had been introduced into claims 1 of the third and fourth auxiliary requests did not appear to be distinguishing features relative to the embodiments described in document D6 and thus could not affect the conclusions reached with regard to inventive step (points 7.2 and 8.4 of the board's communication).

XIV. With letter dated 13 February 2015 the patent proprietor withdrew its appeal and stated that it would not be attending the scheduled oral proceedings.

As a consequence, the appellant (opponent) remained as the sole appellant, the patent proprietor being party

to the proceedings as of right under Article 107 EPC as the respondent.

The respondent neither amended its claim requests nor submitted any further arguments.

XV. Oral proceedings were held on 19 March 2015 in the absence of the respondent.

In addition to its previous requests, the appellant pointed out that, with the exception of the second auxiliary request, all the respondent's claim requests appeared to run counter to the prohibition of *reformatio in peius* and should not be taken into account in the appeal proceedings.

XVI. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

XVII. The respondent requested in writing that the decision under appeal be set aside and that the patent be maintained on the basis of the claims as granted, or on the basis of the claims of the main request or auxiliary requests 1 to 4 filed on 21 November 2011.

Reasons for the Decision

1. Prohibition of *reformatio in peius*

1.1 As a consequence of the withdrawal of the patent proprietor's appeal, the opponent is left as the sole appellant against an interlocutory decision concerning the maintenance of the patent in amended form.

1.2 The Enlarged Board of Appeal in decision G9/92 held that in such a constellation the patent proprietor is primarily restricted during the appeal proceedings to

defending the patent in the version on which the opposition division based its interlocutory decision.

This is because by not filing an appeal or, as in the present case, by withdrawing its appeal, the respondent has indicated that it will not contest the maintenance of the patent in the version accepted by the opposition division in its decision.

- 1.3 The prohibition of *reformatio in peius* has the effect that an amendment proposed during appeal proceedings which would put the opponent and sole appellant in a worse situation than if it had not appealed must be rejected. Therefore, in appeal proceedings where the opponent is the sole appellant, amendments that broaden the scope of a claim compared with the claim found allowable by the opposition division are, as a rule, to be rejected.
- 1.4 In the present case, the version which was accepted by the opposition division is that of the second auxiliary request. The claims of the second auxiliary request filed in the appeal proceedings correspond to those of the former second auxiliary request on which the decision under appeal is based (see point IX above).
- 1.5 Claims of the patent as granted (main request)
 - 1.5.1 Compared to claim 1 of the second auxiliary request, claim 1 as granted does not contain the feature "*..., wherein the tablets are obtainable by direct compression of mixtures or granulates of the different components of each layer*".
 - 1.5.2 That feature has previously been regarded as limiting, although its exact meaning has been a matter of dispute.

The board is likewise of the opinion that it is a limiting feature, since the compression of mixtures or granulates of the different components of each layer to obtain a tablet as defined in claim 1 must result in a structure in which not only the tablet core but also the outer layers of the tablet are compacted. Therefore a layered tablet which is "obtainable" by such a process must have compacted outer layers. In contrast, there is no reason to assume that sandwich-like tablets according to claim 1 as granted could only be prepared in ways which must inevitably result in all outer layers being compacted. As a consequence, the scope of claim 1 as granted is broader than the scope of claim 1 of the second auxiliary request accepted by the opposition division.

- 1.5.3 The respondent has not given any reasons which could, in a departure from the principle of prohibition of *reformatio in peius*, necessitate the deletion of the limiting feature in reaction to a new situation arising on appeal. Nor are any such reasons apparent to the board.
- 1.5.4 On this basis, claim 1 as granted contravenes the principle of prohibition of *reformatio in peius*. The main request must therefore be refused.
- 1.6 Claims entitled "Main Request" of 21 November 2011
 - 1.6.1 The minor modifications introduced into the claims of the separate request of 21 November 2011, likewise designated as "Main Request" (see point IX above), are irrelevant to the issue and thus cannot give rise to a conclusion different from that reached in respect of the claims as granted.

1.6.2 Said separate claim request is accordingly refused for the same reason as the main request directed to the claims as granted (see points 1.5.1 to 1.5.4 above).

1.7 First auxiliary request

1.7.1 Apart from some typographical corrections, claim 1 of the first auxiliary request differs from claim 1 as granted solely in that the term "tablets" has been replaced by "compressed tablets" (see point IX above).

1.7.2 According to common understanding in the pharmaceutical field, tablets are always comprimates, since they are by definition prepared by compression (see for instance document D10: page 318, column 2). Thus claim 1 of the first auxiliary request effectively has the same scope as granted claim 1, since in the context of the dosage form of tablets the term "compressed" is redundant and not limiting.

1.7.3 The first auxiliary request is accordingly refused for the same reason as the main request directed to the claims as granted (see points 1.5.1 to 1.5.4 above).

2. Second auxiliary request - inventive step

Patent in suit

2.1 The patent in suit concerns chewing gum in the form of multi-layer tablets containing one or more active pharmaceutical, dietetic or nutritional ingredients.

2.2 Since many such active ingredients are sensitive to heat, the patent seeks to avoid the conventional manufacturing process for gum products which requires the gum base to be heated and drawn into strips, while addressing difficulties typically encountered with alternative processes which involve compression of the

gum base. In particular, adhesion of the gum material to the punches of a tablet press is to be avoided by the presence of anti-adhesion excipients among the components of the outer tablet layers.

- 2.3 Claim 1 as defined in the second auxiliary request is however directed not to a process of manufacture but to multi-layer gum tablets as such, containing certain specified excipients in the outer layers.

Starting point for the assessment of inventive step

- 2.4 The appellant has argued that the subject-matter of claim 1 of the second auxiliary request lacks inventive step starting from the teaching of document D6.

- 2.5 Document D6 discloses the preparation of multi-zone tablets which may be multi-layer tablets comprising layers of a plastic chewing gum mass and a non-plastic tablet mass and having a sandwich-like structure (see D6: figures 1 to 4). Either type of layer may comprise pharmaceutically active ingredients. D6 describes a process of compressing a first layer of tablet mass material (in powder or granulate form; D6: column 2, lines 3 to 5), adding a pre-formed layer of chewing gum mass and adding on top another layer of tablet mass material, and compressing the whole (D6: figure 7; column 4, line 45 to column 5, line 6). In a variation of that process (D6: figure 10; column 6, lines 30 to column 7, line 7), the chewing gum layer is obtained by compression of granules of gum mass. Such granules are obtained by cooling the gum mass until it is breakable and can be ground to form granules; then the granules are re-heated to 18°C, pelletised and optionally coated with a lubricant before further processing. The excipients used in the examples of D6 are not the same as the anti-adhesion excipients and compression

adjuvants of the patent in suit. In example formulation 2 of D6 (column 8), which describes a three-layered tablet prepared with a pressure of 1000 kg/cm² exerted during tablet manufacture, sorbitol and glucose ("grape sugar") are used as tableting excipients in the outer tablet layers, and all layers contain active ingredients intended to have an antitussive effect at 1% or 2% by weight (the actives being ipecacuanha, fennel oil and eucalyptus oil). The tablet core contains chicle gum while the outer layers do not contain a gum base.

- 2.6 Since document D6 discloses the same type of multi-layer gum tablet product as the patent in suit, manufactured by a process involving compression, the board considers that D6 is a suitable starting point for the assessment of inventive step.
- 2.7 The respondent acknowledged in its submissions that document D6 could be regarded as the closest prior art as far as claim 1 as granted was concerned (see point XI above). With regard to claim 1 of the second auxiliary request, the respondent took the view that document D2 was a more suitable starting point, but did not provide any reason disqualifying D6 as a possible starting point.
- 2.8 Since the appellant argued lack of inventive step on the basis of document D6 and since that document is not manifestly unsuitable as a starting point, inventive step is assessed starting from document D6, irrespective of whether document D2 might also be suitable.

Distinguishing features

- 2.9 The multi-layer chewing gum tablets disclosed in document D6 differ from the tablets defined in claim 1

of the second auxiliary request by having different excipients in the outer layers. For instance, the embodiment described in example 2 of D6 contains glucose and sorbitol as tableting excipients in the outer layers, but does not contain one or more of the mandatory antiadhesion excipients and compression adjuvants listed in claim 1.

2.10 The feature "*..., wherein the tablets are obtainable by direct compression of mixtures or granulates of the different components of each layer*", which relates to the manufacturing process of the tablets, does not, in the board's opinion, give rise to a further distinction of the claimed tablets relative to the tablets disclosed in document D6, for the following reasons:

2.10.1 In the context of a claim directed to a product (i.e. in the present instance the tablets) such a process definition is not by itself a technical feature of the claim; rather, the process definition can be taken into account in claim analysis only to the extent that it inevitably results in a structural feature or property of the claimed product.

2.10.2 The process definition chosen in claim 1 indicates that the components of each layer (which may be granulated) are subjected to compression at some point during the preparation of the tablets. This implies in terms of structural product features that not only the tablet core is compacted, but also the outer layers. Hence, a tablet which is "obtainable" by such a process must have compacted outer layers (see point 1.5.2 above).

2.10.3 Nothing more can be inferred from the process definition with regard to the structure or properties of the tablets.

In particular, it cannot be inferred from the wording "direct compression of mixtures or granulates of the

different components of each layer" that only one compression step would be used in the manufacture of the tablets, or that the punches of the tablet press would come into contact only with the material of the outer tablet layers containing antiadhesion excipients (since it is not excluded that direct compression might be applied to separate layers).

Even if that were the case, nothing suggests that such process requirements would inevitably translate into structural differences or different properties of the tablets so prepared (or so obtainable) compared to e.g. tablets prepared with several compression steps including direct compression of the middle gum-containing layer.

- 2.10.4 The tablets prepared according to the methods described in document D6 have compacted outer layers, since those methods involve a final step of compression of all layers, in which the layers are bonded together by the pressure applied (see point 2.5 above and D6: figures 1, 7, 10; column 4, line 45 to column 5, line 6; column 6, lines 30 to 55). Hence that feature of the claimed tablets is not a distinguishing feature relative to the tablets of D6.

Technical problem and solution

- 2.11 The feature which requires that the external layers contain certain specified "anti-adhesion excipients and compression adjuvants" has not been shown to provide any particular property or effect in the finished tablets.
- 2.12 Hence the technical problem starting from the teaching of document D6 can be defined as the provision of further layered chewing gum tablets containing an active ingredient.

- 2.13 The board is satisfied that the technical problem is solved by multi-layer chewing gum tablets as defined in claim 1, containing in the external layers at least one excipient or adjuvant from the list recited in claim 1.
- 2.14 In the framework of the problem-and-solution approach employed by the boards for assessing inventive step, an alleged advantage in the form of a technical effect can be taken into account in the definition of the objective technical problem only if said effect is reflected in the technical features of the claim and is based on a distinguishing feature over the disclosure of the prior art.

Contrary to the respondent's view, the alleged technical effect of avoiding tablet adhesion to machine parts during manufacture cannot be taken into account in the definition of the technical problem, since such an effect is not reflected in the technical features of claim 1 of the second auxiliary request. This is because the claim is not directed to a process of manufacture and does not contain any manufacturing steps as mandatory technical features. According to the respondent, the alleged technical effect of avoiding undesirable adhesion is achieved by following a manufacturing process in which only the outer tablet layers come into contact with the punches of the tableting machine. Such a requirement is not present in the technical features of claim 1, which do not define a process in terms of process steps.

Instead, the claim is directed to a product which is defined by its structure and mandatory components. As explained above (see points 2.10.1 to 2.10.4 above), the added feature relating to the process of preparation ("obtainable by ...") can be taken into account in the assessment of the present product claim

only insofar as it imparts a structural restriction to the final product. In the present case, that structural restriction (viz. compacted outer layers) is not a distinguishing feature relative to the tablets described in document D6 and thus can have no part in the formulation of the technical problem.

The experimental data filed with test report D12, intended to illustrate the avoidance of undesirable tablet adhesion, do not provide any additional information relevant to the technical problem of providing further tablets.

Obviousness of the solution

- 2.15 The respondent has conceded (see point XI above) that the excipients mentioned in claim 1, e.g. mannitol or lactose, are conventional known tableting excipients and fillers (see also document D10: page 167, column 2 to page 169, column 1; document D11: page 320).
- 2.16 In order to solve the technical problem of providing further layered chewing gum tablets, the skilled person would envisage employing in such tablets any further known tableting excipients, instead of or in addition to those disclosed in document D6, without the exercise of inventive skill. The selection of the specific components listed in claim 1 is arbitrary since it has not been linked to any specific technical effect or advantage.
- 2.17 As a consequence, the subject-matter of claim 1 of the second auxiliary request does not involve an inventive step within the meaning of Article 56 EPC.
- 2.18 In view of this outcome, a separate inventive-step analysis starting from the disclosure of document D2 is not required.

3. Third auxiliary request - inventive step
 - 3.1 Apart from some typographical corrections, claim 1 of the third auxiliary request differs from claim 1 of the second auxiliary request by specifying that the active component content is between 0.5 and 90% by weight of the layer in which the active component is carried, and by deletion of the feature "*wherein the tablets are obtainable by direct compression of mixtures or granulates of the different components of each layer*".
 - 3.2 Neither of those features, when present, distinguishes the claimed subject-matter from the tablets described in document D6, such as in the embodiment of example 2 of D6 (see point 2.5 above and D6: example 2 in combination with figure 1 and column 3, lines 53 to 63).
 - 3.3 Hence their introduction or deletion cannot change the situation with regard to the assessment of inventive step starting from document D6.
 - 3.4 As a consequence, the subject-matter of claim 1 of the third auxiliary request does not involve an inventive step within the meaning of Article 56 EPC, for the same reasons as explained in the context of the second auxiliary request (see points 2.9 to 2.17 above).
4. Fourth auxiliary request - inventive step
 - 4.1 Apart from some typographical corrections, claim 1 of the fourth auxiliary request differs from claim 1 of the second auxiliary request by specifying that the outer layers are free of gum base, and by deletion of the feature "*wherein the tablets are obtainable by direct compression of mixtures or granulates of the different components of each layer*".

- 4.2 The new limitation is not a distinguishing feature over the embodiments described in document D6, which do not contain gum base in the outer layers.
- 4.3 Accordingly, neither of the above-mentioned features "the outer layers are free of gum base" and "wherein the tablets are obtainable by direct compression ...", when present, distinguishes the claimed tablets from the tablets described in document D6, such as in the embodiment of example 2 of D6.
- 4.4 Hence the proposed amendments do not change the situation with regard to the assessment of inventive step starting from document D6.
- 4.5 As a consequence, the subject-matter of claim 1 of the fourth auxiliary request does not involve an inventive step within the meaning of Article 56 EPC, for the same reasons as explained in the context of the second auxiliary request (see points 2.9 to 2.17 above).
5. In view of the conclusions reached with regard to inventive step of the third and fourth auxiliary requests, the question whether those requests, due to the deletion of the feature "*wherein the tablets are obtainable by direct compression of mixtures or granulates of the different components of each layer*", also contravene the prohibition of *reformatio in peius* has no bearing on the outcome of the proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated