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**Datasheet for the decision  
of 18 December 2018**

**Case Number:** T 0477/15 - 3.3.09

**Application Number:** 00989548.3

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A23G4/12, A23G4/20, A61K9/00

**Language of the proceedings:** EN

**Title of invention:**  
RELEASE OF LIPOPHILIC ACTIVE AGENTS FROM CHEWING GUM

**Patent Proprietor:**  
WM. WRIGLEY JR. COMPANY

**Opponent:**  
Gumlink A/S

**Headword:**

**Relevant legal provisions:**  
EPC Art. 54, 56, 84, 123(2)

**Keyword:**

Main request: novelty (no)

Auxiliary request 1: added subject-matter (yes)

New auxiliary request 2: clarity (yes), added subject-matter (no), inventive step (yes)

**Decisions cited:**

G 0003/14

**Catchword:**



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Case Number: T 0477/15 - 3.3.09

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.09**  
**of 18 December 2018**

**Appellant:** Gumlink A/S  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 22 December  
2014 rejecting the opposition filed against  
European patent No. 1241949 pursuant to Article  
101(2) EPC.**

**Composition of the Board:**

**Chairman** W. Sieber  
**Members:** N. Perakis  
E. Kossonakou

## Summary of Facts and Submissions

I. This decision concerns the appeal filed by the opponent against the opposition division's decision rejecting the opposition filed against European patent No. 1 241 949.

Claims 1, 7, 8 and 10 as granted read as follows:

"1. A hydrophilic gum base comprising:

from 20% to 90% hydrophilic polymers selected from the group consisting of polyvinyl acetate, short and medium chain polyesters, short and medium chain polyamides, and short and medium side chain poly(vinyl esters), high molecular weight polyvinyl acetate, low molecular weight polyvinyl acetate, polyvinyl butyrates, polyvinyl propionates and combinations thereof;

from 5% to 35% hydrophilic softeners/emulsifiers;  
and

from 4% to 50% filler;

the chewing gum base being free of hydrophobic polymers, elastomer solvents, waxes and hydrophobic softeners."

"7. A chewing gum product comprising a gum base according to any one of claims 1 to 6."

"8. A coated chewing gum product comprising:

a chewing gum core comprising a hydrophilic gum base according to any of claims 1 to 6; and

a coating on the core, the coating including a lipophilic active agent."

"10. A method of producing coated chewing gum products containing at least one lipophilic active agent in the coating comprising the steps of:

providing chewing gum product cores wherein the chewing gum is made from a hydrophilic gum base according to any of claims 1 to 6;

providing a coating solution; and

coating the chewing gum product cores with the coating solution to provide coated chewing gum products, the coating including a lipophilic active agent at a level of from 12 micrograms to 250 milligrams per gram of coated chewing gum product."

II. In its notice of opposition, the opponent requested that the patent be revoked in its entirety on the grounds of Article 100(a) (lack of novelty and lack of inventive step), 100(b) and 100(c) EPC.

III. The documents cited in the notice of opposition included:

D1: WO 96/20609 A1;

D5: WO 91/01132 A1;

D7: WO 99/44436 A1; and

D9: WO 98/23165 A1.

IV. The opposition division rejected the opposition because it considered that

- the invention underlying the granted claims was sufficiently disclosed and that the opponent had not provided any evidence to the contrary;
- the granted claims did not contain subject-matter extending beyond the content of the application as filed;
- the subject-matter of the granted claims was novel over D1, because the chewing gum base used was free of hydrophobic polymers, elastomer solvent, waxes and hydrophobic solvents; and
- the subject-matter of the granted claims involved an inventive step, whereby
  - D1 was considered to represent the closest prior art,
  - the technical problem in view of D1 consisted in the improvement of the release rate of the lipophilic active agent from the chewing gum, and
  - the skilled person would not have found any motivation in the art to remove hydrophobic polymers, elastomer solvent, waxes and hydrophobic solvents from the gum base of D1 in order to improve the release rate of the lipophilic active agent.

V. This decision was appealed by the opponent (in the following: the appellant) who requested that the opposition division's decision be set aside and that the patent be revoked in its entirety.

VI. The patent proprietor (in the following: the respondent) requested that the appeal be dismissed (main request) or, alternatively, that the patent be maintained on the basis of any of the first to fourth

auxiliary requests filed during the opposition proceedings by letter dated 1 September 2014, or of the fifth auxiliary request filed during the appeal proceedings by letter dated 10 September 2015.

VII. On 17 August 2018 the board issued a communication in preparation of the oral proceedings.

VIII. By letter of 15 November 2018 the respondent replaced its requests by a new main request and new first to fourth auxiliary requests, which were based on the first to fifth auxiliary requests previously on file.

Claim 1 of the new main request and new first and second auxiliary requests reads as follows:

Main request

"1. A hydrophilic gum base comprising:

20% to 90% hydrophilic polymers selected from the group consisting of polyvinyl acetate, short and medium chain polyesters, short and medium chain polyamides, and short and medium side chain poly(vinyl esters) and combinations thereof, or

20% to 90% hydrophilic polymers selected from the group consisting of high molecular weight polyvinyl acetate, low molecular weight polyvinyl acetate, polyvinyl butyrates, polyvinyl propionates and combinations thereof; and

5% to 35% hydrophilic softeners/emulsifiers; and

4% to 50% filler;

the chewing gum base being free of hydrophobic polymers, elastomer solvents, waxes and hydrophobic softeners."

First auxiliary request

"1. A chewing gum product comprising:

a hydrophilic gum base and a lipophilic active agent, said hydrophilic gum base comprising:

"20% to 90% hydrophilic polymers selected from the group consisting of polyvinyl acetate, short and medium chain polyesters, short and medium chain polyamides, and short and medium side chain poly(vinyl esters) and combinations thereof, or

20% to 90% hydrophilic polymers selected from the group consisting of high molecular weight polyvinyl acetate, low molecular weight polyvinyl acetate, polyvinyl butyrates, polyvinyl propionates and combinations thereof; and

5% to 35% hydrophilic softeners/emulsifiers; and

4% to 50% filler;

the chewing gum base being free of hydrophobic polymers, elastomer solvents, waxes and hydrophobic softeners."

Second auxiliary request

"1. A coated chewing gum product comprising:



a chewing gum core comprising a hydrophilic gum base and a coating on the core, the coating including a lipophilic active agent, said hydrophilic gum base comprising:

"20% to 90% hydrophilic polymers selected from the group consisting of polyvinyl acetate, short and medium chain polyesters, short and medium chain polyamides, and short and medium side chain poly(vinyl esters) and combinations thereof, or

20% to 90% hydrophilic polymers selected from the group consisting of high molecular weight polyvinyl acetate, low molecular weight polyvinyl acetate, polyvinyl butyrates, polyvinyl propionates and combinations thereof; and

5% to 35% hydrophilic softeners/emulsifiers; and

4% to 50% filler;

the chewing gum base being free of hydrophobic polymers, elastomer solvents, waxes and hydrophobic softeners."

- IX. By letter of 21 November 2018, the appellant submitted additional arguments concerning the disclosure of D1.
- X. Oral proceedings were held before the board on 18 December 2018 as scheduled. During the oral proceedings the appellant raised for the first time an objection under Rule 80 EPC against an amendment in dependent claim 5 of all the requests ("terpene resins" as opposed to "terpene resins" in claim 5 as granted). Eventually, the respondent filed a **new second auxiliary request** which differed from the previous second

auxiliary request only in that the apparently inadvertent clerical error in claim 5 was corrected to "terpene resins". The appellant raised no objection as to the admissibility of this request.

XI. The relevant arguments put forward by the appellant in its written submissions and during the oral proceedings may be summarised as follows:

- The main request was not patentable, because the subject-matter of claim 1 lacked novelty over the disclosure of D1. Claim 3 of this document not only disclosed the claimed gum base composition but also that said composition was free of hydrophobic polymers, elastomer solvents, waxes and hydrophobic softeners.
- The first auxiliary request was not patentable because claim 1 contained subject-matter extending beyond the content of the application as filed. The subject-matter of this claim resulted from an intermediate generalisation of the disclosure of the application as filed.
- The second auxiliary request was not patentable because claim 1 lacked clarity in view of the unclear expressions "high" and "low" molecular weight polyvinyl acetate and contained subject-matter extending beyond the content of the application as filed. It also did not involve an inventive step in view of the obvious combination of D1, considered as the closest prior art, with D7 or D9.

XII. The relevant arguments put forward by the respondent in its written submissions and during the oral proceedings may be summarised as follows:

- The subject-matter of claim 1 of the main request was novel over D1, claim 3 of which concerned a gum base composition "comprising" the disclosed ingredients and thus not limited to them. Furthermore, the composition in claim 3 was not free of hydrophobic polymers, elastomer solvents, waxes and hydrophobic softeners.
- The subject-matter of claim 1 of the first auxiliary request found support in the examples of the application as filed and thus did not extend beyond its content.
- Claim 1 of the second auxiliary request was clear because the expressions "high" and "low" molecular weight polyvinyl acetate were already present in the granted claims. Claim 1 did not contain subject-matter extending beyond the content of the application as filed because it derived from the direct and unambiguous combination of claims as filed. Lastly, its subject-matter involved an inventive step since the skilled person, starting from D5, considered as closest prior art, and seeking to improve the release of the lipophilic active agent from the coated chewing gum product, would not have found any hint in the state of the art that he should modify the chewing gum core of the coated chewing gum product of D5.

## Reasons for the Decision

### *Main request*

#### 1. Novelty

1.1 The appellant contested the novelty of the subject-matter of claim 1 of the main request exclusively on the basis of D1.

D1 (claim 3) discloses a gum composition comprising:

- (a) 39-75 wt% of a low molecular weight polyvinyl acetate;
- (b) 5-41 wt% of a medium molecular weight polyvinyl acetate;
- (c) up to 10 wt% of a high molecular weight polyvinyl acetate;
- (d) 3-15 wt% of a non-fat, non-wax and non elastomer solvent resin plasticizer; and
- (e) 5-30 wt% of a filler.

wherein said percentages by weight are based on the total weight of the gum base composition.

This results in a total amount of the polyvinyl acetates of 44 wt% to 92 wt% of the gum base. The upper limit is determined taking into account the presence of at least 3 wt% plasticizer and at least 5 wt% filler.

1.2 With regard to the plasticizer, it is expressly said in claim 3 of D1 that it is a non-fat, non-wax and non-elastomer solvent. Furthermore, the only plasticizers disclosed in D1 are hydrophilic compounds (page 6, lines 31-34). Thus hydrophobic polymers are excluded.

1.3 The respondent argued that claim 3 of D1 was not novelty-destroying because it concerned a gum base composition "comprising" and not "consisting of" the disclosed ingredients.

The board does not agree. The term "comprising" in claim 3 of D1 allows for the presence of further components in the claimed composition, but this does not mean that said composition cannot comprise only components (a) to (e). There is no reason to assume that other compounds have to be present. The fact that the examples of D3 contain a butyl rubber, polyisobutylene or styrene-butadiene (page 14, lines 3-4 and page 15, table) does not alter this finding. Claim 3 does not mention any components other than those listed. Thus claim 3 encompasses the possibility of only comprising these components, i.e. consisting of these components.

With regard to the resinous gum materials including synthetic rubber elastomers disclosed in page 6, lines 18-22 and claim 4, they are optional and not compulsory components of the chewing gum composition of claim 3 of D1.

Thus this argument of the respondent must fail.

1.4 The respondent also argued that the composition of claim 3 of D1 did not fulfil the requirement of claim 1:

"the chewing gum base being free of hydrophobic polymers, elastomer solvents, waxes and hydrophobic softeners",

because the polyvinyl acetates used as components (a) to (c) of D1 were not necessarily hydrophilic. It relied on page 1, lines 33-36, of D1 which refers to "hydrophobic synthetic polymers (e.g., polyvinyl acetates, ethylene/vinyl acetate, vinyl laurate/vinyl acetate copolymer, and the like)".

The board does not agree. The skilled person knows that, irrespective of their molecular weight, polyvinyl acetates are polar compounds and thus hydrophilic. Moreover, even the patent in suit acknowledges that polyvinyl acetates, irrespective of their molecular weight, are hydrophilic polymers, also referred to as polar compounds (paragraph [0034]). Thus the disclosure of D1 to which the respondent made reference must be erroneous. Thus this argument of the respondent must also fail.

- 1.5 In summary, the subject-matter of claim 1 of the main request lacks novelty over D1. Therefore, this request is not patentable.

***First auxiliary request***

2. Added subject-matter
- 2.1 Claim 1 of the first auxiliary request concerns a chewing gum product comprising a specific hydrophilic gum base and a lipophilic active agent.
- 2.2 The board concurs with the appellant that none of the product claims as filed discloses the combination of the specific hydrophilic gum base with a lipophilic active agent.

The board concurs with the appellant that claim 23 as filed relates to the preparation of a coated chewing gum product comprising a lipophilic active agent in both the coating and the chewing gum core. It is evident that the subject-matter of claim 1 of the first auxiliary request, which does not incorporate all the features of the chewing gum product of claim 23 as filed, results from an unallowable intermediate generalisation of that claim.

2.3 The respondent relied on examples 1 to 4 of the application as filed, which concern non-coated gum base formulations based on a hydrophilic gum base to which vitamin E acetate (a lipophilic agent) was added. In these examples the gum base is made of the same ingredients in different weight ratios (page 19, table). These specific embodiments do not provide support for the chewing gum product of claim 1 of the first auxiliary request and an unallowable intermediate generalisation is required to arrive at the claimed chewing gum product. Furthermore, these examples were designed to evaluate the release of vitamin E acetate from the gum bolus and not to define a final chewing gum product as that of claim 1 of the first auxiliary request.

2.4 To conclude, the subject-matter of claim 1 of the first auxiliary request extends beyond the content of the application as filed, with the consequence that this request is not patentable.

***Second auxiliary request***

3. Independent product claim 1

### 3.1 Clarity

3.1.1 The appellant contested the clarity of claim 1 of the second auxiliary request in view of the definition of the alternative group of hydrophilic polymers comprised in the hydrophilic gum base, which alternative group includes the components "high" and "low" molecular polyvinyl acetate or their combination.

In claim 1 as granted the hydrophilic polymers are, however, defined as one group which includes not only "high" and "low" molecular polyvinyl acetate, but also polyvinyl acetate in general, without specification of its molecular weight.

According to the appellant, the lack of clarity of the components "high" molecular weight polyvinyl acetate and "low" molecular weight polyvinyl acetate in granted claim 1 was irrelevant in view of the component polyvinyl acetate present in the same group of hydrophilic polymers. This was not so in claim 1 of the second auxiliary request, in which the components are split into two alternative groups of hydrophilic polymers with the component polyvinyl acetate (without specification of its molecular weight) being in a different group from the "high" molecular weight polyvinyl acetate and "low" molecular weight polyvinyl acetate.

3.1.2 The board does not agree. Already in claim 1 as granted the hydrophilic polymers could be selected from "high" molecular weight polyvinyl acetate and "low" molecular polyvinyl acetate. Thus, the lack of clarity had already been present in claim 1 as granted, against which no clarity objection could be raised as clarity is not a ground for opposition. On the basis of G 3/14



the clarity of claim 1 of auxiliary request 2 can therefore not be questioned.

3.2 Added subject-matter

3.2.1 The coated chewing gum product of claim 1 of the second auxiliary request is based on the coated chewing gum product of claim 10 as filed and the hydrophilic gum base defined according to claims 1, 2 and 3 as filed.

3.2.2 The appellant contested the combination of claim 10 as filed with claims 1, 2 and 3 as filed, firstly because claim 10 does not make reference to any preceding claim and secondly because claim 3 depends exclusively on claim 1.

3.2.3 The board does not agree. Claims 1, 2 and 3 as filed provide the broadest definition of the hydrophilic gum base, which the skilled person would directly and unambiguously use in the manufacture of the coated chewing gum product of claim 10 as filed. Furthermore, the single dependency of claim 3 on claim 1 does not represent a barrier to its direct and unambiguous combination with claim 2. This combination is corroborated by the description as filed (page 8, lines 8-12).

3.2.4 The additional features of dependent claims 2-5 of the second auxiliary request correspond to those of dependent claims 4-7 as filed. Although dependent claims 4-7 as filed relate to specific embodiments of the hydrophilic gum base of claim 1 as filed, the skilled person would directly and unambiguously derive from the application as filed that they can also be used to define specific embodiments of the hydrophilic gum base used in the coated chewing gum product of

claim 10 and thus lead to the subject-matter of claims 2 to 5 of the second auxiliary request.

3.2.5 In view of the above, the claims concerning the coated chewing gum product of the second auxiliary request do not contain subject-matter extending beyond the content of the application as filed.

3.3 Inventive step

3.3.1 Closest prior art

According to the patent in suit, the claimed invention relates to a coated chewing gum product with a chewing gum core comprising a hydrophilic gum base and a coating on the core including a lipophilic active agent, the latter being quickly released without the risk of becoming partially bound in the chewing gum base and gum matrix and not being completely released (paragraph [0008]).

D5, which relates to the release rate of active agents, including lipophilic agents from a coated chewing gum composition, is considered by the board, in line with the appellant, as the closest prior art (abstract; page 1, lines 7-14; page 6, lines 4-14; page 16, line 16 to page 19, line 29; page 22, line 34 to page 23, line 3; claims 13-15).

D5 acknowledges that by placing the active agents in the dragée layer of a chewing gum (equivalent to the coating layer of the claimed invention), a faster and larger release could be obtained than the one obtained by a conventional incorporation of the active agent into the core of the chewing gum. According to D5, experience, however, showed that the use of this

principle meant that although a larger portion of the active agent was released, a large portion of said active agent was quickly resorbed by the gum base in the beginning of the chewing period, whereby on the whole only a relative small advantage in the form of a larger release during the first minute of the chewing is obtained (page 8, lines 26-36).

To solve this problem, D5 incorporated the active agent into the gum base and used a solubilizer for accelerated controlled release of the active agent (page 1, lines 10-14; page 8, line 36 to page 9, line 5). The gum base of D5 contained at least 25 wt% of a resin selected among terpene resins, glycerol ester of polymerised rosin, pentaerythritol ester of wood or gum rosin, pentaerythritol ester of partially hydrogenated wood or gum rosin, and high molecular weight polyvinyl acetate resins (claim 1).

The respondent considered D1 as the closest prior art. However, D1 is a remote prior art compared with D5. D1 discloses a gum base composition which does not have any coating and seeks to solve a different technical problem, namely the easy removal of the chewing gum composition from a variety of surfaces (abstract; page 4, lines 26-38).

### 3.3.2 The technical problem and its solution

The claimed coated chewing gum composition differs from that of D5 in that (i) it comprises a specific hydrophilic gum base core, and (ii) the lipophilic active agent is included in the coating.

The technical problem solved in view of D5 is the provision of a coated chewing gum product with quick

release of the lipophilic active agent from the coating without the risk of resorption.

The technical evidence contained in the patent in suit shows that the specific gum base according to the claimed invention, which is free of hydrophobic polymers, elastomer solvents, waxes and hydrophobic softeners (examples 1 to 4), provides a remarkably faster release of a lipophilic active agent compared with the release of the same active agent from typical prior art gum bases which include hydrophobic polymers (comparative examples A, B and C). Indeed, the release of Vitamin E acetate (the lipophilic active ingredient used) from the gum base of the comparative examples after 30 minutes of chewing is 0.21%, 2.88% and 0.52% respectively, whereas the release of the same lipophilic agent from the gum base of the examples according to the invention is 34.2%, 59.0%, 57.0% and 43.1%, respectively. These results demonstrate that, contrary to the expectations of the skilled person as disclosed in D5 (page 8, lines 26-36), the gum base used in the coated chewing gum product of claim 1 does not prevent the release of active agents by resorbing them.

This is plausible also in view of the further technical evidence in the patent in suit (paragraph [0078]), where a coated chewing gum product according to claim 1, i.e. a product combining the specific hydrophilic gum base and a coating with the lipophilic active agent Vitamin E acetate, released the lipophilic active agent faster than the conventional coated gum formulations. Indeed, 80.8% of Vitamin E acetate was released after chewing a coated chewing gum product according to claim 1 for 30 minutes.

### 3.3.3 Obviousness

The skilled person starting from the disclosure of D5 and seeking to solve the set technical problem would not find in D5 or any other prior-art document the necessary motivation to select the specific hydrophilic gum base in order to accelerate the release of a lipophilic active ingredient incorporated in the coating of a chewing gum product.

As already mentioned above, D5 points in another direction, namely the incorporation of the active agent into the gum base and the addition of a solubilizer in order to prevent the active agent from being quickly resorbed by the gum base in the beginning of the chewing period.

D1 discloses the hydrophilic gum base used in the product of claim 1. But even if the skilled person combined D1 with D5 and used the hydrophilic gum base disclosed in D1, he would not arrive at the coated product of claim 1, which states that the lipophilic active agent must be comprised in the coating.

D7 discloses coated chewing gum products with a lipophilic active agent in the coating of a conventional chewing gum base (page 1, lines 6-10; page 2, lines 24-27; page 4, lines 1-5; page 12, line 21). D7 corresponds to the conventional coated gum formulations cited in the patent in suit (paragraph [0078]), which have a slower release than the claimed coated chewing gum products. Even if the skilled person combined D7 with D5, he would not arrive at the claimed product since the gum base would still be that of a conventional chewing gum composition.

D9 discloses the modification of the release rate of caffeine (a lipophilic active agent) from the coating of a conventional chewing gum by physical modification such as encapsulation, agglomeration, fixation or absorption and entrapment into an extruded compound (page 1, lines 6-12; page 3, lines 10-11; page 5, lines 9-11; page 6, lines 17-24 and 33-34; page 8, lines 15-17; page 11, lines 14-25; page 12, lines 14-28). The combination of D9 with D5 would not lead to the claimed coated product, which comprises a specific hydrophilic gum base.

3.4 In view of the above, the subject-matter of claim 1 involves an inventive step.

4. Independent method claim 7

Claim 7 reads as follows:

"7. A method of producing coated chewing gum products according to any of claims 1 to 6 comprising the steps of:

providing chewing gum product cores;  
providing a coating solution; and  
coating the chewing gum product cores with the coating solution to provide coated chewing gum products, the coating including a lipophilic active agent at a level of from 12 micrograms to 250 milligrams per gram of coated chewing gum product."

For the reasons given above with regard to the subject-matter of claim 1, the subject-matter of claim 7, which concerns the method of producing the product of claim 1, is also patentable.

5. Dependent claims 2 to 6 and 8 to 21

Dependent claims 2 to 6 correspond to specific embodiments of independent claim 1 and dependent claims 8 to 21 correspond to specific embodiments of independent claim 7. They are therefore patentable for the same reasons.

6. Auxiliary requests 3 and 4

Since the board has come to the conclusion that auxiliary request 2 is patentable, any discussion with respect to the hierarchically lower auxiliary requests 3 and 4 becomes redundant.

## 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 with the order to maintain the patent on the basis of claims 1 to 21 of the new second auxiliary request filed during the oral proceedings before the board on 18 December 2018 and a description to be adapted thereto.

The Registrar:

The Chairman:



M. Cañueto Carbajo

W. Sieber

Decision electronically authenticated