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**Datasheet for the decision
of 25 March 2014**

Case Number: T 0325/13 - 3.2.07

Application Number: 07760898.2

Publication Number: 2007640

IPC: B65D35/14

Language of the proceedings: EN

Title of invention:

CONTAINER FOR PRODUCTS CONTAINING AROMATIC COMPOUNDS

Patent Proprietor:

Colgate-Palmolive Company

Opponent:

Procter & Gamble, Inc.

Headword:

Relevant legal provisions:

EPC Art. 83, 123(2)

Keyword:

Amendments - added subject-matter (second to fourth auxiliary request - yes)
Sufficiency of disclosure -
undue burden (sixth to eighth auxiliary request - yes)
(other requests: withdrawn)

Decisions cited:

T 0339/05, T 0063/06

Catchword:



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Case Number: T 0325/13 - 3.2.07

D E C I S I O N
of Technical Board of Appeal 3.2.07
of 25 March 2014

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 14 December
2012 revoking European patent No. 2007640
pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: H. Meinders
Members: H. Hahn
O. Loizou

Summary of Facts and Submissions

- I. The appellant (patent proprietor) lodged an appeal against the decision of the Opposition Division to revoke European patent No. 2 007 640.
- II. In the present decision the following documents of the opposition proceedings are cited:

D1 = EP-A-0 467 548

S1 = Colgate Total (printout dated 26.10.2012 from the Internet: <http://www.colgate.com/app/ColgateTotal/US/EN/Products/Home.cwsp>)

S2 = Colgate Total Whitening (printout dated 25.10.2012 from the Internet: http://www.codecheck.info/kosmetische_mittel/zahnpflege/zahnpaste/ean_871478959...)

While the following documents submitted in the appeal procedure were also taken into account:

E1 = "Kolynos" (print out dated 19.04.2013 from Wikipedia: <http://en.wikipedia.org/wiki/Kolynos>)

E2 = "The clinical efficacy of Colgate Total Plus Whitening Toothpaste containing a special grade of silica and Colgate Total Fresh Stripe Toothpaste in the control of plaque and gingivitis: a six month clinical study", Allen et. al., J. Clin. Dent, 2002, 13(2), pages 59-64 (only abstract print out dated 19.04.2013 from the Internet page: <http://www.ncbi.nlm.nih.gov/pubmed/11695207>)

E3 = Sorriso Xtreme White 4D (print out dated 28.08.2013 from the Internet page: <http://www.colgate.com/br/app/PDP/Sorriso/BR/produtos/XtremeWhite4D.cvsp>)

III. Insofar as relevant to the present decision, the opposition had been filed against the patent under Article 100(b) EPC, that the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by the person skilled in the art.

In respect of this ground of opposition, the Opposition Division considered that the invention does not fulfil this condition since the skilled person does not get sufficient information to determine the adsorption rate as mentioned in claim 1 of the patent as granted (main request), contrary to Article 83 EPC. The Opposition Division considered that this conclusion likewise applied to claim 1 of all auxiliary requests 1-4 filed with letter of 28 September 2011. Consequently, the patent was revoked.

IV. With a communication annexed to the summons to oral proceedings the Board presented its preliminary opinion with respect to all five requests underlying the impugned decision as re-filed with the statement setting out the grounds of appeal, i.e. the claims 1-14 of the patent as granted (main request) and the claims of the first to fourth auxiliary requests.

The Board remarked amongst others that the claims 1 of the first to fourth auxiliary requests appeared to contravene Article 123(3) EPC.

Furthermore, it appeared that the patent as granted did not enable the person skilled in the art to carry out the claimed invention without undue burden, over the whole scope of claim 1 as granted. Consequently, the main request appeared not to be allowable under Article 83 EPC.

V. With letter dated 24 February 2014 the appellant filed, as a response to the Board's communication, first to eighth auxiliary requests in combination with arguments concerning the basis for the amendments made therein as well as further arguments with respect to sufficiency of disclosure.

VI. The respondent did not make any further submission.

VII. Oral proceedings before the Board were held on 25 March 2014. To start, the appellant withdrew its main request and the first and fifth auxiliary requests while keeping the numbering of the remaining requests unamended. The second to fourth auxiliary requests were then discussed for compliance with the requirements of Article 123(2) EPC. Thereafter the sixth to eighth auxiliary requests were discussed for compliance with the requirements of Article 83 EPC.

a) The appellant requested that the decision under appeal be set aside and that the case be remitted to the department of first instance for further prosecution on the basis of one of the second to fourth and the sixth to eighth auxiliary request, all filed with letter dated 24 February 2014.

b) The respondent requested that the appeal be dismissed.

At the end of the oral proceedings the Board announced its decision.

VIII. Claim 1 of the second auxiliary request reads as follows (amendments as compared to claim 1 of the

patent as granted are in bold with deletions in brackets; emphasis added by the Board):

"1. A container (10) **containing a for** substances that contains at least one antibacterial compound, **wherein said antibacterial compound contains an aromatic group**, the container comprising a lower body portion and an upper shoulder portion (14) the shoulder portion comprised of **a polyethylene or polypropylene an-alkene polymer-containing** shoulder wall, a barrier unit (22, 30, 32, 34) within the shoulder portion, the barrier unit comprised of a polymeric material having an adsorption for the antibacterial of less than 10 mg/dm² at 40°C for 90 days, **wherein the polymeric material is selected from the group consisting of acrylonitrile/methacrylate copolymers, polyethylene naphthalate polymers, and polytrimethylene naphthalate polymers"**.

IX. Claim 1 of the third auxiliary request reads as follows (amendments as compared to claim 1 of the patent as granted are in bold with deletions in strike through; emphasis added by the Board):

"1. A **tube** container (10) **containing a for** substances that contains at least one antibacterial compound, **wherein said antibacterial compound contains an aromatic group** is triclosan, the container comprising a lower body portion and an **injection moulded** upper shoulder portion (14) the shoulder portion comprised of **a polyethylene or polypropylene an-alkene polymer containing** shoulder wall, a barrier unit (22, 30, 32, 34) within the shoulder portion, the barrier unit comprised of a polymeric material having an adsorption for the antibacterial of less than 10 mg/dm² at 40°C for 90 days, **wherein the polymeric material is selected from the group consisting of acrylonitrile/methacrylate**

copolymers, polyethylene naphthalate polymers, and polytrimethylene naphthalate polymers."

- X. Claim 1 of the fourth auxiliary request reads as follows (amendments as compared to claim 1 of the patent as granted are in bold with deletions in strike through; emphasis added by the Board):

"1. A **tube** container (10) **containing a for substances dentifrice** that contains **at least one antibacterial compound, about 0.3% triclosan**, the container comprising a lower body portion and an **injection moulded** upper shoulder portion (14) the shoulder portion comprised of **a polyethylene or polypropylene an alkene polymer containing** shoulder wall, a barrier unit (22, 30, 32, 34) within the shoulder portion, the barrier unit comprised of a polymeric material having an adsorption for the antibacterial of less than 10 mg/dm² at 40°C for 90 days, **wherein the polymeric material is selected from the group consisting of biaxially oriented polyethylene naphthalate polymers, and biaxially oriented polytrimethylene naphthalate polymers."**

- XI. Claims 1 of the sixth to eighth auxiliary requests differ from those of the second to fourth auxiliary requests in that the feature "the shoulder portion comprised of a polyethylene or polypropylene shoulder wall" has been replaced by the feature "the shoulder portion comprised of **a shoulder wall which is of polyethylene or polypropylene**".

- XII. The appellant argued, insofar as relevant for the present decision, essentially as follows:

The definition of claim 1 of the patent as granted "an alkene polymer containing" has been amended in the claims 1 of the second to fourth auxiliary requests to "a polyethylene or polypropylene" where the term is still used in an adjectival sense. Since the object of the verb "comprised of" is "shoulder wall" it is implicit that the shoulder wall is of polyethylene or polypropylene (see the original application WO-A-2007/124350, paragraphs [0007] and [0032]). A supposed lack of clarity or extension of subject-matter through this amendment cannot be seen. The amendment made in the claims 1 of these auxiliary requests can only be interpreted in that manner. Consequently, there exists a direct and unambiguous support for it which therefore complies with Article 123(2) EPC.

The terms "adsorption" and "**absorption**" are somehow interchangeably used in the description of the patent in suit, although strictly they have different dictionary definitions while the generic term "sorption", which covers both definitions, is referred to in the context of the graphs shown in its figures. The test for the measurement of the threshold value for the correct term "adsorption" specified in claim 1 - which is given in the unit " mg/dm^2 " - as described in paragraph [0047] of the patent in suit enables the person skilled in the art to carry out the extraction method of triclosan according to the test and he can see what amount in " mg/dm^2 " was extracted and shown in the graphs as "sorption" of a material. Therefore, since the test is clear the person skilled in the art can carry out the test and achieve a reliable result.

Although it is admitted that this extraction test cannot distinguish between "adsorption" or "**absorption**" the patent proprietor could even have named this

threshold value a "parameter x" rather than what it actually is and what it measures.

Claim 1 of the eighth auxiliary request, likewise as those of the sixth and seventh auxiliary requests, overcomes the problem of an alleged necessary research program, since it now claims a system of a container with:

- the specific antibacterial compound triclosan which is present in a concentration of about 0.3%;
- the substance is a dentifrice;
- the shoulder portion is comprised of a shoulder wall which is of polyethylene or polypropylene;
- the polymeric material of the barrier unit is selected from the group consisting of biaxially oriented polyethylene naphthalate polymers and biaxially oriented polytrimethylene naphthalate polymers.

Paragraph [0004] of the patent in suit, which mentions the problems of the shoulder/nozzle portion related to the relative thickness of this container portion compared to the remaining portion, concerns the prior art and additionally does not talk about the barrier unit.

It is also clear from the unit "mg/dm²" that "adsorption" is meant, i.e. no thickness is necessary to be known. Furthermore, since an equilibrium is reached after 40 days (see paragraph [0048]) it is not plausible that the thickness is in any way material to the result of the described test and this means that a reliable threshold can be obtained for any thickness. Even if the thickness of the polymeric barrier unit would be material to the result, the person skilled in

the art could always determine whether said threshold value of $< 10 \text{ mg/dm}^2$ is met or not.

The respondent has not submitted any test results which show an influence of the thickness on said value.

According to the Case Law (see 7th edition 2013, sections II.C.4.2 and II.C.4.3) an invention is sufficiently disclosed if at least one way of carrying out the invention is described in the patent in suit which enables the person skilled in the art to carry out the invention. The patent in suit discloses one way of carrying out the invention, i.e. the examples of the dentifrice containing 0.3% triclosan. Thereby the skilled person would get a measurable result and would know whether he is within the scope of the claims. The fact that the complete composition of the dentifrice is not specified is not an insufficiency.

The composition of the dentifrice mentioned in paragraph [0032] of the patent in suit is not relevant since it concerns only a comparative example. The person skilled in the art would try to understand what is meant by the trade mark quoted in the context of the examples and in view of E2 would see that Colgate Total Plus Whitening is actually meant. Therefore, even if the specific examples could not be repeated as such, the skilled person could carry out the test method.

The concentration of triclosan has no effect on the threshold value.

The Opposition Division in its decision asserted that the equilibrium would be much affected by the concentration or further components, however without any evidence.

There is no undue burden if the skilled person can test the dentifrices.

D1 does not disclose that an additional component affects the sorption of triclosan in a plastic material. The quoted passages (page 3, lines 27 to 31; page 4, line 55 to page 5, line 2 and page 5, lines 10 to 14) only concern a theory or hypothesis of inhibition so that it is not a fact nor can it be plausibly argued that a terpene such as limonene would affect the triclosan test described in the patent in suit.

XIII. The respondent argued, insofar as relevant for the present decision, essentially as follows:

It is understood what the appellant is trying to say with respect to the amendment "comprised of polyethylene and polypropylene" made in the claims 1 of the second to fourth auxiliary requests but if half a page is necessary to explain this amendment then it is evident that there exists a clarity problem. Taking account of this unclarity it is evident that this amendment is not directly and unambiguously derivable from paragraph [0007] of the application as originally filed and still can be understood as a separate clause so that the objection with respect to Article 123(2) EPC already mentioned in the Board's communication still exists.

As regards the "adsorption/**absorption**" issue it is clear that sorption from the bulk material takes place but the skilled person does not know how he should consider the thickness of the polymer in the barrier

unit which influences the **absorption** of triclosan (see patent in suit, paragraph [0004]).

The appellant's argument that paragraph [0004] of the patent in suit relates only to the prior art would mean that the claimed invention completely prevents an **absorption** which, however, does not appear to be the case as proven by its examples.

Thus it is clear that the measured threshold value is not an adsorption value but a mixture of adsorption/**absorption**, i.e. sorption, which equilibrium allegedly is reached after 40 days (see patent in suit, paragraph [0048]). However, the graphs of the figures still show an increase of the sorption after 40 days (see figures 5 to 15).

The skilled person must be enabled to precisely determine said threshold value. However, he is not in a position to do so since the thickness of the polymer to be analysed is not specified. It is clear that the sorption of triclosan in a thicker polymeric material results in a higher value whereas a thinner material results in a lower value. Consequently, the skilled person does not know whether he is within the scope of claim 1 or not.

The appellant argues only on the basis of the test described in paragraph [0047] that the invention of the patent in suit is sufficiently disclosed but not on the basis of the working examples since the underlying disclosed dentifrices were and are not available.

The skilled person is taught that he should use a dentifrice with 0.3% triclosan but it is evident from a comparison of the graphs of figures 5 and 16 - the

examples of both are based on the same high density polyethylene shoulder/nozzle barrier unit part but on two different dentifrices each of them containing 0.3% triclosan - that the further components of the dentifrice influence the threshold values of "about 45 mg/dm²" and "more than 20 mg/dm²" obtained by the test (see paragraphs [0032] and [0043]). Thus it is clear that the remaining 99.7% of the dentifrice can influence the test result so that the number of tests to be made by the skilled person to establish the scope of the invention is increased considerably. This places an undue burden on the skilled person. The fact that figure 5 relates to a comparative example only is irrelevant in this context.

The above conclusion would be different if the thickness of the polymer and the remaining 99.7% of the dentifrice would have been specified in the test method of paragraph [0047] of the patent in suit.

In this context it has also to be considered that only the appellant knows which composition the dentifrices used in the examples of the patent in suit actually had. As a consequence thereof only the appellant is in a position to prove any infringement of claim 1. The dentifrices of the patent proprietor commonly contain limonene as a flavour component (see e.g. document S2) which, however, decreases the threshold value so that a polymer which without such an additional component would be outside the scope of claim 1 is then within the scope of claim 1. The respondent therefore does not know even which experiments it should carry out to clarify this issue.

In the present case the situation that a single way of carrying out the invention would be sufficient to

comply with Article 83 EPC is not given since the patent in suit does not specify the complete composition of the dentifrices used in the examples which also cannot be purchased due to their erroneous trade mark names. The skilled person would not use a dentifrice product having a similar name since he would expect that a different trade mark means a different composition. Thus only the appellant can repeat the examples of the patent in suit since the dentifrices specified therein could not be purchased and since the thickness of the polymers tested therein is not specified.

Furthermore, the embodiments of figures 10 and 13, which were made with the same acrylonitrile/methacrylate polymer but the latter with an additional aluminium foil, show that the sorption is additionally influenced by this aluminium foil (see paragraphs [0037] and [0040]).

Concerning the burden of proof in accordance with decision T 63/06 (not published in OJ EPO) it is plausibly argued on the basis of D1 that the common general knowledge does not enable the skilled person to put the functional feature of the threshold value on the basis of the missing 99.7% of the dentifrice composition into practice so that the burden of proof is shifted to the appellant/patent proprietor. The skilled person is also not in a position to complete the missing information. Consequently, he can only carry out experiments which in the end amount to a research program (see T 339/05; not published in OJ EPO).

The threshold value can be reached via a stabilisation (inhibition) of the triclosan in the dentifrice but not

through the direct contact thereof with the barrier unit polymeric material. Therefore the invention of claim 1 covers ranges which have not been shown to function at all.

Therefore claim 1 of all auxiliary requests does not comply with Article 83 EPC.

Reasons for the Decision

1. Admissibility of amendments (Articles 84 and 123(2) EPC)

Second to fourth auxiliary requests

1.1 Claim 1 of the patent as granted contained the feature "... the shoulder portion comprised of an alkene polymer containing shoulder wall" which in the claims 1 of the second to fourth auxiliary requests has been replaced by the feature "... the shoulder portion **comprised of a polyethylene or polypropylene shoulder wall**" (see points VIII to X above).

1.1.1 The application as originally filed (corresponding to the published WO-A-2007/124350) discloses only that "Tube containers are comprised of a tube body and a tube shoulder/nozzle. The tube body **is** usually **of** a laminate structure and the tube shoulder/nozzle **of** an alkene polymer containing plastic. **These** usually **are** polyethylenes and polypropylenes." and "The barrier polymer comprising the barrier unit 34 is co-injection molded with the shoulder/nozzle 14/16 polymer which **is** an alkene polymer such as a polyethylene or polypropylene." (see paragraphs [0007] and [0032]; emphasis added by the Board).

1.1.2 The use of the term "**comprised of**" in combination with the two alkene polymer materials "**polyethylene and polypropylene**" (i.e. PE and PP) is considered to introduce ambiguity into the subject-matter of the claims 1 of the second to fourth auxiliary requests since the adjective use of this term "polyethylene and polypropylene" is, without knowledge of the history of this amendment, namely the deletion of the term "containing" from the feature "the alkene polymer containing shoulder wall" of claim 1 of the patent as granted and the replacement of the "alkene polymer" by "PE and PP" and contrary to the appellant's arguments, **not** clearly apparent. From the Board's point of view the amended wording "... the shoulder portion comprised of a polyethylene or polypropylene shoulder wall" of the claims 1 of the second to fourth auxiliary requests due to the open definition of the term "comprised of", can also be interpreted such that the shoulder portion additionally can comprise polymeric materials other than polyethylenes and polypropylenes. There exists, however, **no** basis for such an embodiment which therefore results in adding information to the application as originally filed.

1.1.3 Consequently, the amendment of claims 1 of the second to fourth auxiliary requests contravenes Article 123(2) EPC. The second to fourth auxiliary requests are therefore not allowable.

Sixth to eighth auxiliary requests

1.2 Since the Board considers that the subject-matter of the claims 1 of the sixth to eighth auxiliary requests does not comply with the requirements of Article 83 EPC (see point 2 below) there is no need to consider in

this decision whether these claims (see point XI above) comply with the requirements of Articles 84 and 123(2) EPC.

2. *Sufficiency of disclosure (Article 83 EPC)*

Eighth auxiliary request

2.1 The discussion of sufficiency of disclosure is more efficient if the Board first turns to the most limited product claim 1 of the eighth auxiliary request (see points X and XI above), since this embodiment of "a **tube** container containing a dentifrice that contains **about 0.3%** triclosan, the container comprising ... an **injection moulded** upper shoulder portion ... and the polymeric material is selected from the group consisting of **biaxially oriented** polyethylene naphthalate polymers, and **biaxially oriented** polytrimethylene naphthalate polymers" is encompassed by the subject-matter of the claims 1 of the sixth and seventh auxiliary requests. Claim 1 of the former is not restricted to any tube container having an injection moulded shoulder portion and does not specify any triclosan concentration in a dentifrice and any biaxially oriented polymer while claim 1 of the latter does not define any concentration of triclosan in a dentifrice and any biaxially oriented polymer (see points VIII to XI above). If the container of claim 1 of the eighth auxiliary request is not sufficiently disclosed, this is all the more so for the less limited versions.

2.2 The Opposition Division in its impugned decision concluded that the invention is not disclosed in a manner sufficiently clear and complete to be carried out by the person skilled in the art since he does not

get enough information to determine the adsorption rate defined in claim 1 of all pending requests, including the second to fourth auxiliary requests which form the basis of the present sixth to eighth auxiliary requests (see points IV and VIII to XI above).

This conclusion of the Opposition Division was based on the reasoning that the skilled person cannot carry out the test to determine the adsorption threshold value defined in claim 1 of all requests as described in paragraph [0047] of the patent in suit since the two dentifrices with the trademarks "*Colgate Total Plus Whitening*" and "*Sorriso (Brazil)*" used in the working examples only disclose a content of 0.3% of the antibacterial triclosan while the remainder of 99.7% of the composition of these dentifrices, i.e. all other components thereof, are unspecified. In order to be able to execute this test the skilled person has to know the complete composition of the dentifrice since he knows from D1 that the adsorption rate of triclosan at certain polymers is reduced by terpenes such as limonene which are comprised in some dentifrices. Therefore the adsorption rate defined in claim 1 depends not only on the material of the barrier provided in the shoulder/nozzle but also on the other components of the dentifrice (see points 2.1.2 and 3 of the reasons).

2.3 Since the appellant failed to show that the impugned decision is wrong the Board reaches the same conclusion with respect to Article 83 EPC, however for the following reasons.

2.4 First of all, claim 1 of the eighth auxiliary request (identically as claim 1 of the patent as granted according to the impugned decision) defines that the

polymeric material of the barrier unit within the shoulder portion has "an adsorption for the antibacterial of less than 10 mg/dm^2 at 40°C for 90 days", i.e. less than 10 mg/dm^2 of triclosan may be adsorbed by the biaxially oriented polyethylene naphthalate polymers or biaxially oriented polytrimethylene naphthalate polymers (see points X and XI above).

- 2.4.1 The Opposition Division in its decision implicitly considered that the test according to paragraph [0047] of the patent in suit determines the adsorbed triclosan, i.e. only the triclosan sorbed on the outer surface of the barrier unit polymer, since this would be apparent from the unit " mg/dm^2 " used in the definition of the threshold value of "an adsorption for the antibacterial of less than 10 mg/dm^2 at 40°C for 90 days" according to claim 1 of the patent as granted.
- 2.4.2 The Board establishes, however, that this test of paragraph [0047] of the patent in suit using an extraction method with dichloromethane - as admitted by the appellant at the oral proceedings - **cannot** distinguish between "adsorption" and "**absorption**". This test actually determines the total amount of triclosan being adsorbed on the surface and being **absorbed** in the bulk of the barrier polymer shoulder/nozzle part tested.

This is due to the fact that according to this test, after wiping off occluded dentifrice and rinsing the surface with water to remove all occluded dentifrice and drying the samples, defined surface areas are cut from the polymer sample - which has a certain thickness that, however, is **not** specified anywhere in the patent in suit - and are then extracted by immersion with

dichloromethane for 24 hours at 40°C, which step is repeated for each sample to ascertain that the extraction was **complete**. The resulting dichloromethane extractant is then analysed for its triclosan content by gas chromatography to provide the "final level of triclosan **absorbed** by the particular polymer" (see patent in suit, paragraph [0047]). Hence it is clear to the person skilled in the art that this **extraction** method - since said paragraph [0047] does not describe any masking of the other sample surfaces - analyses **all triclosan** that can be extracted from the barrier unit polymer sample, irrespective of whether it is adsorbed or **absorbed**, i.e. it includes also the triclosan migrated/penetrated into the barrier unit polymer within the 90 days period specified in claim 1.

The appellant's argument that the threshold value determined by the test hypothetically could have been named "parameter x" rather than what it actually is and what it measures is considered irrelevant since neither claim 1 of the eighth auxiliary request nor the test contains such a restriction to a "parameter x".

2.4.3 The fact that this test cannot distinguish between adsorption and **absorption** directly leads the person skilled in the art to the conclusion that the **thickness** of the barrier polymer sample also **determines the amount of triclosan** to be extracted and analysed by said test since a thicker barrier polymer sample, within said 90 days period, will **absorb** a larger amount of triclosan from a dentifrice than a thinner sample of the identical barrier polymer.

2.4.4 In this context it has also to be considered that the patent in suit uses the two distinct terms "adsorption" (see paragraphs [0004], [0005], [0032] and

[0049]; claim 1 as granted) and "**absorption**" (see paragraphs [0001], [0002], [0004], [0006] to [0008], [0013] to [0027], [0032] to [0049]; claims 2 and 3 as granted) somehow interchangeably in its description, although - as admitted by the appellant - strictly they have different dictionary definitions, while the generic term "sorption" or the term "desorption" are referred to in the context of the graphs shown in the figures (see paragraph [0048] and figures 5-28).

- 2.4.5 The appellant stated that the definition "adsorption" included in claim 1 is correct due to the used unit " mg/dm^2 " (i.e. weight per surface area) of the threshold value.

The Board, however, does **not** share this view of the appellant taking account of the following facts:

- i) the aforementioned extraction analysing method according to the test determines the total amount of adsorbed and **absorbed** triclosan;
- ii) the other definition "**absorption**" is used in the majority of the description and the English language uses the term "**absorptivity**" - which is used in paragraphs [[0004], [0008] and [0029] to [0031] of the patent in suit - for the **absorption** capacity but the different term "adsorptive capacity" for the capacity of adsorption which latter expression is not used at all in the patent in suit;
- iii) the statement in the context of the prior art concerning the influence of the thickness of the barrier polymer "The thicker the polymer the greater the **absorption**. The thickness leads to an unacceptable level of antibacterial compound adsorption. This

problem is thought to be solved for flavors by the use of an insert which is material that has a very low **absorptivity** for the flavor components" (see patent in suit, paragraph [0004], column 1, lines 51 to 54); and

iv) the same unit "mg/dm²" can be used for the **absorption** provided that the thickness is separately indicated.

From the Board's point of view it is thus more credible that "**absorption**" was intended for claim 1.

The generic term "sorption" (likewise as the term "desorption") used in the patent in suit does **not** allow to clarify the definition of claim 1 since it covers both definitions.

2.4.6 This ambiguity concerning the interpretation of claim 1 - either "**adsorption**" or "**absorption**" - results in any case in an additional parameter that the person skilled in the art has to consider when trying to carry out the test specified in paragraph [0047] of the patent in suit. Consequently, the person skilled in the art has to carry out this test at least for a range of thicknesses of polymers generally used for such barrier units in tube containers.

It is additionally clear that said test, as implicitly admitted by the appellant, for the case of the first interpretation does **not** produce the value of "**adsorption**" of triclosan on the barrier unit polymer as required by claim 1. For the second interpretation "**absorption**" the required thickness is nowhere specified in the patent in suit.

2.4.7 The appellant's further argument that it would not be plausible that the thickness is material to the result of the extraction test since as specified in paragraph [0048] an equilibrium would be reached (in general) after 40 days at 40°C, cannot hold. Firstly, the graphs of figures 5-15 (when ignoring outliers) show a more or less steady increase of the amount of triclosan (**ab**)sorbed by the polymers up to a period of 90 days. Hence an equilibrium after 40 days is not derivable from these figures 5-15. This long period of 90 days - which is also specified in claim 1 of the eighth auxiliary request, is **not** indicative for an adsorption - which only takes place on the other surface and therefore needs only a relatively short time - but rather for an **absorption** which takes place in the bulk of the polymer and therefore, more similar to a diffusion, needs much more time than adsorption.

However, the adsorption/**absorption** values of triclosan obtained after 40 days are not decisive since claim 1 of the eighth auxiliary request requires the corresponding value after 90 days.

2.4.8 The appellant's argument that the respondent has not submitted any evidence which would show an influence of the thickness on the test result cannot be accepted as there exists no need for such evidence since it is as such plausible that an extraction process with the solvent dichloromethane as applied in the test of paragraph [0047] of the patent in suit does not remove only the adhered triclosan but also removes all the **absorbed** triclosan, as admitted by the appellant.

2.5 The appellant further argued that the patent in suit would disclose one way of carrying out the invention and that the invention, in accordance with established

case law, therefore would be sufficiently disclosed. It further argued in this context that provided that the test of paragraph [0047] is clear the person skilled in the art can carry it out and always achieves a reliable result, particularly since claim 1 of the eighth auxiliary request completely answers the "necessary research program" problem. These arguments cannot hold for the following reasons.

2.5.1 Although this test for the measurement of the threshold value given in the unit "mg/dm²" specified in claim 1 as described in point 2.4.2 above enables the person skilled in the art to carry out an extraction method of triclosan and to determine which amount in "mg/dm²" is extracted from the polymer sample, he still does **not** know whether this amount refers to "adsorption" or "**ab**sorption" (see point 2.4.5 above). All the graphs of the patent in suit are not helpful in this respect since they only mention "sorption" of triclosan.

2.5.2 Furthermore, the working examples of the patent in suit are **not** helpful to the person skilled in the art in this respect, either. In order to be able to repeat the tests for measuring this "adsorption"/"**ab**sorption" threshold for triclosan described in the patent in suit it is necessary that the skilled person either would know the exact composition of the used dentifrices or at least he would be able to purchase the same.

However, the composition of the dentifrices with the trademarks "*Sorriso (Brazil)*", "*Colgate Total Whitening Plus*" and "*Colgate Total White gel*" used in these examples (see paragraphs [0032], [0033] to [0046] and [0048], respectively) - except for their content of 0.3% of the antibacterial triclosan - is unknown. The Opposition Division thus correctly established that the

remaining 99.7% of the composition of these dentifrices is **not** known, i.e. all other components are unspecified. However, they do have an influence on the result of this test (see point 2.2 above).

2.5.3 With respect to the trade marks "*Sorriso*", "*Colgate Total Whitening Plus*" and "*Colgate Total White*" as specified in the patent in suit the Board considers that they are different from the trademarks "*Colgate Total*", "*Colgate Total Whitening*", "*Kolynos*", "*Colgate Total Plus Whitening*" and "*Sorriso Xtreme White 4D*" disclosed in the documents S1, S2, and E1 to E3, respectively. The Board therefore considers that it has **not** been proven that the dentifrices commercialised under the trade marks used in the patent in suit are or were purchasable at the time of its priority date. The appellant has **not** contested this consideration that was already addressed in point 4.4.3 of the Board's communication annexed to the summons to oral proceedings.

2.5.4 The appellant's argument that the person skilled in the art, in order to repeat the tests of the patent in suit, would also use a brand product **not** having the identical but only a similar trade name is **not** credible since he would expect that a different composition is linked to a different trade name, thus giving a different result in the said test.

2.5.5 In the context of the unknown dentifrice composition the skilled person would also consider the knowledge derived from D1, which by the way originates from the patent proprietor, namely that terpene flavour ingredients (e.g. limonene, menthol, diterpenes, polyterpenes) of dentifrices have a stabilizing effect on triclosan and thereby influence the sorption of

triclosan by inhibiting its absorption by the polymer. The triclosan activity losses caused by its contact with the polymeric material of the container are reduced (see D1, page 3, lines 24 to 31; page 4, line 55 to page 5, line 14; page 7, lines 8 to 12 and lines 18 to 24).

The arguments of the appellant that D1 discloses only a hypothesis or a theory so that it would not be a fact or that it cannot be plausibly argued that a terpene such as limonene would affect the triclosan test cannot hold since it is evident from the disclosure of D1 that the addition of stabilizing compounds such as terpenes, in particular limonene, reduces the activity losses of triclosan in dentifrices that are contained in polymeric containers (see e.g. page 4, line 55 to page 5, line 2).

The type of mechanism underlying this effect is not considered to be relevant in this context since it does not matter whether a solubilization of triclosan in the dentifrice through limonene molecules takes place so that less triclosan will be available for any sorption/absorption on/into the polymeric material of the container, or limonene compared to triclosan is preferably sorbed/absorbed on/into the polymeric material of the container. The result is in both cases the same, i.e. the extraction test result is shifted to a lower value.

- 2.5.6 The effect of different dentifrice compositions is also evident from a comparison of the graphs of figures 5 and 16 of the patent in suit, the former using "*Sorriso (Brazil)*" dentifrice while the latter uses "*Colgate Total Whitening Plus gel*" dentifrice, both containing 0.3% triclosan. The fact that figure 5 only relates to

a comparative example, as stated by the appellant, is however irrelevant in this context. The two examples of figures 5 and 16 are based on the same polymeric barrier unit material for the shoulder/nozzle part, i.e. high density polyethylene (which is not further characterised). Since all other conditions of these two examples are the same it has therefore to be concluded that the difference of the threshold values within the time period of up to 40 days obtained by the extraction test (resulting in final triclosan values of "about 45 mg/dm²" after 90 days for figure 5 and "more than 20 mg/dm²" after 40 days for figure 16, respectively; see paragraphs [0032] and [0043]) is affected by the further components of the dentifrice.

2.5.7 It needs further to be considered that the dentifrices of the patent proprietor commonly contain limonene as a flavour component (see e.g. S2) which, however, decreases the threshold value so that a polymer which without such an additional component would be outside the scope of claim 1 will then be within the scope of claim 1 of the eighth auxiliary request.

2.5.8 Taking account of the above considerations in the points 2.4.2 to 2.5.6 it is evident that the remaining 99.7% of the dentifrice influence the result of the test of paragraph [0047] of the patent in suit but that the skilled person is **not** taught by the patent in suit which composition the dentifrice for the test should have.

Consequently, in the present case the situation is that a single way of carrying out the invention is sufficient to comply with Article 83 EPC is **not** given since the patent in suit does **not** specify the complete composition of the dentifrices used in the examples,

which dentifrices additionally cannot be purchased due to their non-establishable trade mark names.

The Board additionally remarks in this context that according to the established case law the disclosure of one way of performing the invention is **only** sufficient if it allows the invention to be performed in the whole range claimed, i.e. the skilled person is able to obtain substantially all embodiments falling within the ambit of the claims (see Case Law of the Boards of Appeal, 7th edition 2013, section II.C.4.4).

- 2.5.9 The appellant's arguments that the burden of proof concerning the influence of terpenes such as limonene onto the adsorption/absorption of triclosan in the light of D1 would lie with the respondent who has not submitted any corresponding evidence, cannot hold.

This is due to the fact that the patent in suit has been revoked by the impugned decision and as a consequence it is the appellant who has to show why the decision is wrong. Further, the respondent - in accordance with the established case law (see e.g. T 63/06, *supra*, points 3 to 3.3.4 of the reasons) - on the basis of D1 has plausibly argued with respect to the missing 99.7% of the dentifrice composition. Finally, the common general knowledge does **not** enable the person skilled in the art to put the functional feature of the threshold value into practice. All this shifts this burden of proof onto the appellant/patent proprietor. The appellant has not, however, submitted any evidence to prove what it alleges and thus to discharge this burden.

- 2.5.10 As correctly argued by the respondent the skilled person is not in a position to complete the missing

information by his common general knowledge and therefore has to carry out a large number of experiments based on the test of paragraph [0047] of the patent in suit which amount to a research program (see T 339/05; *supra*, point 3.6 of the reasons).

As a first parameter of this research program he has to test (or at least simulate the compositions) of a representative number of the known dentifrices by including about 0.3% triclosan as antibacterial.

As a second parameter each of these dentifrices has to be modified by adding effective amounts of at least one of the stabilising flavoring components mentioned in D1 (see point 2.5.5 above).

As a third parameter he has to select a specific polymer from the two generic classes of biaxially oriented polyethylene naphthalates and biaxially oriented trimethylene naphthalates for the shoulder portion of the tube container as specified in claim 1 of the eighth auxiliary request, which polymer can be amorphous, semi-crystalline or crystalline which, however, have not been further characterised in the patent in suit by e.g. the glass transition temperature, the melting point or the molecular weight, etc. Each of these polymers has to be tested with each of the dentifrices with or without said stabilising terpene.

Finally, as a fourth parameter he has to consider the adsorbent/~~absorbent~~ issue, i.e. the possible thickness range of the polymer (see point 2.4.5 above), which has also to be tested with each of the aforementioned parameters.

In this context it is further noted that the - according to the test of paragraph [0047] of the patent in suit admissible - use of an aluminium foil in the described test results in a reduction of the measured triclosan value (compare the examples according to the figures 10 and 13 which apart from the use of an aluminium foil are apparently identical) which resulted in triclosan values after 90 days of 0.8 mg/dm^2 and 0.4 mg/dm^2 , respectively; the lower value of figure 13 was obtained with the aluminium foil; see paragraphs [0037] and [0040]).

Thereby the skilled person ends up with an unduly high number of tests to be performed to determine whether said threshold value of $< 10 \text{ mg/dm}^2$ is met or not. Such a research program is, however, considered to represent an undue burden on the skilled person.

2.5.11 The appellant's further argument that the influence of the thickness of the barrier material mentioned in paragraph [0004] of the patent in suit would relate only to the prior art cannot hold either since this would imply that the claimed invention completely prevents any **absorption** of triclosan. This, however, is **not** apparent from the disclosure of the patent in suit which neither contains any such explicit statement nor is such an allegation proven by its examples.

2.6 Therefore the container of claim 1 of the eighth auxiliary request, in the light of the description and the figures of the patent in suit, does not comply with Article 83 EPC. The eighth auxiliary request is therefore not allowable.

Sixth and seventh auxiliary requests

2.7 Since product claim 1 of the eighth auxiliary request is narrower in scope than the product claims 1 of the sixth and seventh auxiliary requests, which in their more generic definitions include the tube container of claim 1 of the eighth auxiliary request containing a dentifrice including about 0.3% triclosan and having an injection moulded upper shoulder portion with a barrier unit within the shoulder portion being selected from from the group of biaxially oriented polyethylene naphthalates and biaxially oriented trimethylene naphthalates (see points VIII to XI and 2.1 above), the above conclusion with respect to claim 1 of the eighth auxiliary request applies *a fortiori* to the claims 1 of the sixth and seventh auxiliary requests. The sixth and seventh auxiliary requests are therefore not allowable either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



G. Nachtigall

H. Meinders

Decision electronically authenticated