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**Datasheet for the decision of 12 December 2014**

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| **Case Number:** | T 0784/13 - 3.2.07 |
| **Application Number:** | 06848703.2 |
| **Publication Number:** | 1979244 |
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| **Language of the proceedings:** | EN |

**Title of invention:**
METALLIZED PACKAGING BLISTER CONTAINER

**Applicant:**
Naik, Praful Ramchandra
Nair, Ajit Sashidharan
Bhandari, Mohan Harakchand
Bharadia, Rahul
Tilak, Ammanabrolu Balgangadhar
Itkar, Sachin Chandrashekhar

**Headword:**

**Relevant legal provisions:**
EPC Art. 84

**Keyword:**
Claims - clarity (all requests - no)

**Decisions cited:**

**Catchword:**

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**Case Number: T 0784/13 - 3.2.07**

# D E C I S I O N
## of Technical Board of Appeal 3.2.07
## of 12 December 2014

**Appellant:** (Applicant 1)
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**Representative:**
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**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted on 14 November 2012 refusing European patent application No. 06848703.2 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

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

## Summary of Facts and Submissions

I. The applicants lodged an appeal against the decision of the Examining Division to refuse the European patent application No. 06 848 703.2.

With their statement of grounds of appeal the appellants requested that the decision be set aside and a patent be granted on the basis of claims 1-18 of the main request, alternatively on the basis of claims 1-18 of the first auxiliary request (the former being identical with the main request and the latter being identical with the second auxiliary request underlying the impugned decision), claims 1-17 of the second or third auxiliary requests, all as (re)filed with the statement of grounds of appeal. As an auxiliary request oral proceedings were requested.

II. The following documents are relevant for the present decision:

of the examination proceedings:

D1 = "Standard Test Method for Haze and Luminous Transmittance of Transparent Plastics", ASTM Designation D 1003-00, ASTM International, US, July 2000
D2 = US-A-2005/170161;

introduced by the appellants:

D9 = "Understanding Illuminants", M. DiCosola, X-Rite® Incorporated, US, 1995, pages 1-10
D10 = "Standard Practice for Goniometric Optical Scatter Measurements", ASTM Designation E2387-05, ASTM International, US, July 2011

D13 = "Opacity (optics)", printout from Wikipedia (http://en.wikipedia.org/wiki/Opacity (optics), 4.3.2013), pages 1-3
D14 = "Opazität", printout from Wikipedia (http://de.wikipedia.org/wiki/Opazit%C3%A4t, 4.3.2013), pages 1-3;

introduced by the Board:

D15 = Thermal In-Pouch Microwave Sterilization, Final Report dated 9.01.2012, including F. Kero et al., "Quantification of Hexanal in Yogurt and Extra Virgin Olive Oil as an Indicator of Photo Oxidation", pages 1-4.

III. The Examining Division held that claim 1 of the then main request, including the amendment made at the oral proceedings to the former main request and all the auxiliary requests that the feature "opacity **to visible light**" was amended to read "opacity **to light from a visible light source**", does not comply with Article 84 EPC. Claims 1 of the then auxiliary requests 1 and 3 were considered not to comply with Article 123(2) EPC while claim 1 of auxiliary request 2 was considered not to comply with Article 84 EPC, all requests filed electronically on 11 October 2012 (all requests include the aforementioned amendment made at the oral proceedings on 17 October 2012 ).

IV. With a communication annexed to its summons for oral proceedings the Board presented its preliminary and non-binding opinion with respect to the claims of the main request and the first to third auxiliary requests as (re)filed with the statement of the grounds of appeal.

The Board stated amongst others that it appeared that the Examining Division's conclusions with respect to lack of clarity of claim 1 of all requests due to a lack of disclosure concerning the method for measuring the opacity values hold true for all the present requests, i.e. the main request and the first to third auxiliary requests. In this context D15 was introduced and referred to for describing different procedures for determining opacity values.

The Board additionally raised some purely formal clarity objections with respect to claims of all four requests on file.

V. With letter dated 12 November 2014 the appellants filed sets of claims for new fourth to seventh auxiliary requests, taking account of the Boards purely formal clarity objections raised against the main and the first to third auxiliary requests; the latter were maintained unamended.

VI. Oral proceedings were held on 12 December 2014. The subject-matter of the independent claims of all requests was discussed in view of Article 84 EPC, in particular the method of measurement of opacity as described in the application regarding various parameters and terms as scattering, transmission and reflection, and the wavelength of visible light, particularly in view of the documents D1 and D10 and in the light of the common general knowledge of the person skilled in the art.

The appellants requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims of the main request, or alternatively on the basis of one of the 1st to 3rd auxiliary requests as

filed with their statement of grounds of appeal dated 15 March 2013, or alternatively on the basis of one of the 4th to 7th auxiliary requests as filed with letter dated 12 November 2014.

At the end of the oral proceedings the Chairman announced the decision.

VII. Claim 1 of the main request as filed with the statement of the grounds of appeal reads as follows (amendments as compared to claim 1 as originally filed are in bold; emphasis added by the Board):

"1. A container for packaging pharmaceutical products, said container consisting of a lid element and a base element, sealingly securable to each other, the base comprising a composite multilayer film having a substrate of thickness 100 to 1000 microns of pharmaceutical grade polyvinyl chloride, at least one metallized layer of effective thickness of 0.005 to 2 microns provided at least on one side of the said substrate and optionally at least one 0.001 to 250 microns thick pharmaceutical grade predominantly organic layer provided at least on one side of the substrate to form a composite multi layer film having an opacity **to light from a visible light source** ranging from 90% to 100%, said base having at least one formation for holding a pharmaceutical product, said formation having a controllable opacity **to light from a visible light source** of 99.9% to 10% and a controllable MVTR between 0.01 to 15 g/$m^2$/day **measured at 38°C and 90% relative humidity**."

VIII. Claim 1 of the first auxiliary request differs from that of the main request in that the feature "**such as to provide accurate visual inspection through a non**

**filled detection system,**" has been inserted between the terms "... of 99.9% to 10%" and "and a controllable MVTR ...".

IX. Claim 1 of the second auxiliary request differs from that of the main request in that it has been amended to read "at least one metallized layer **of aluminium** of effective thickness of 0.005 to **0.5~~2~~** microns" (emphasis in bold with deletion in strikethrough added by the Board).

X. Claim 1 of the third auxiliary request reads as follows (amendments as compared to claim 1 of the main request are in bold with deletions in strikethrough; emphasis added by the Rapporteur):

"1. A **method for producing a** container for packaging pharmaceutical products, said container consisting of a lid element and a base element, sealingly securable to each other, **comprising the steps of:**
**a) proving a** ~~the~~ base comprising a composite multi-layer film having a substrate of thickness 100 to 1000 microns of pharmaceutical grade polyvinyl chloride, at least one metallized layer **of aluminium** of effective thickness of 0.005 to **0.5** ~~2~~ microns provided at least on one side of the said substrate and optionally at least one 0.001 to 250 microns thick pharmaceutical grade predominantly organic layer provided at least on one side of the substrate to form a composite multi layer film having an opacity **to light from a visible light source** ranging from 90% to 100%,
**b) deforming said base comprising a composite multi-layer film thereby forming** ~~said base having~~ at least one formation for holding a pharmaceutical product, said formation having a controllable opacity to light from a visible light source of 99.9% to 10% and a

controllable MVTR between 0.01 to 15 g/$m^2$/day measured at 38°C and 90% relative humidity."

XI. Claims 1 of the fourth to seventh auxiliary requests differ from those of the main request and the first to third auxiliary requests on which they are based, respectively, in that in all of them the two terms "effective thickness" and "predominantly organic layer" have been amended to read "**~~effective~~** thickness" and "**~~predominantly~~** organic layer".

XII. The appellants argued, insofar as relevant to the present decision, essentially as follows:

The composite multilayer film of the present application includes a PVC layer of a certain thickness and a metallized layer, also of a certain thickness, which multilayer film has a specific opacity. Page 20 of the application (corresponding to the published WO-A-2007/072505 which in the following is quoted) discloses the method for measuring this opacity. It is clear to the skilled person that opacity not only describes absorption but also scattering of radiation (see page 18, fourth paragraph; see also D13 and D14).

High opacity values can be obtained for strongly scattering media even if the absorbance for one specific wavelength is low. A material that strongly scatters over a broad wavelength range will have high opacity values even if the absorbance at one wavelength is higher than at another wavelength (see point 1.2 of the reasons). The metallized layer defined in claim 1 of the main request is in general strongly scattering so that high opacity values can be obtained independent of the wavelength at which it is measured.

According to the method disclosed in the application a Spectrophotometer indicating the relative opacity of plastic film is used for measuring relative light transmission using a visible light source and a photoelectric detector but also to determine the colour variation. For measuring the opacity the film sample is first kept on a black ground and the light reflected from the sample is determined. The procedure is repeated on a white background and the reflected light is measured and finally the reflection from the white background is measured to calculate the opacity of the film based on these readings (see page 20, fourth and fifth paragraphs).

This calculation of the opacity is based on the information contained in the present application and in D10 and on the knowledge of the person skilled in the art.

D10 describes a standard method for measuring opacity in cases where samples reveal high scattering (see figure 1 and paragraph 1.4). D10 also teaches the skilled person how the values L, a and b enter into the calculation of the opacity.

It is admitted that D10 does not mention any black and/or white background for the measurement of the opacity. However, the person skilled in the art derives this information from page 20 of the present application.

The Examining Division based its objections with respect to the measurement of the "opacity" on the norm D1, which cannot hold since it is out of date. The standard test method of D1 for haze and luminous transmittance of transparent plastics (and of planar sections) is not a suitable basis for determining

opacity of metallized plastics which are not necessarily planar. Materials having a haze value of greater than 30% are not tested according to D1 but in accordance with ASTM practice E167 (see chapter 1.1), which has been replaced by D10 in 2005.

The Examining Division obviously confused the terms "illuminant" and "light source" (compare D9, page 2, first paragraph). D1 merely refers to illuminants A and C whereas a large variety of different illuminants is available (see D9, appendix). Illuminant C is a historical representation of average or north sky daylight which, however, is still in active use while D9 rather refers to D65 being the most commonly used daylight illuminant. D9 notes that D65 illuminant should be used if there are no prior conditions or requirements.

The present application, which forms its own dictionary with respect to definitions, mentions a region of 410 to 680 nm as visible light (see page 16) whereas the Examining Division in point 1.2 of the reasons applied a different definition, namely of 380 to 780 nm. Applying the definition of D10 and the information given in the application as originally filed, in particular the definitions on page 20, there is no doubt that the term opacity means relative light transmission on a scale of 0 to 100 opacity units measured using a visible light source. Therefore it is not apparent why claim 1 of the main request should violate Article 84 or 83 EPC.

The same argumentation is valid for the subject-matter of the claims 1 of the first to seventh auxiliary requests.

## Reasons for the Decision

*1. Admissibility of amendments (Article 123(2) EPC)*

Since the Board considers that the subject-matter of the claims 1 of the main request, and the first to seventh auxiliary requests in any case does not comply with Article 84 EPC (see point 2 below) there is no need in this decision to deal with the question whether the amendments made therein comply with Article 123(2) EPC.

*2. Clarity (Article 84 EPC)*

*Main request*

2.1 The Board comes to the conclusion that the subject-matter of claim 1 of the main request, which contains the features "a composite multi layer film having **an opacity to light from a visible light source ranging from 90% to 100%**" and "said formation having **a** controllable **opacity to light from a visible light source of 99.9% to 10%**", taking account of the method for measuring the opacity disclosed in the present application (corresponding to the published International application WO-A-2007/072505, which in the following is quoted) does not comply with Article 84 EPC, for the following reasons.

2.2 Each of the aforementioned two features of claim 1 of the main request defines a range for a parameter, namely either "the opacity to light of a visible light source ranging from 90% to 100%" of the composite multilayer film or after a forming operation of the

same an "opacity to light from a visible light source of 99.9% to 10%".

Therefore, in order that the product of claim 1 of the main request complies with the requirement of clarity, i.e. that the parameters can be determined with consistent results and that the subject-matter of the claim can be established, the skilled person must be in a position to determine the parameter of opacity clearly and reliably by an objective procedure which is usual in the art (see Case Law of the Boards of Appeal, 7th edition 2013, sections II.A.3.1 and II.A.3.5).

2.2.1 First of all, the application itself is silent with respect to any standard or standard method to be used for the measurement of the opacity and it is likewise silent as to the wavelength or the wavelength range to be used for this measurement.

2.2.2 Concerning the opacity measurement the application gives only the following information on page 20, fourth paragraph to to page 21, first paragraph:

"*Opacity of the container was checked using a Spectrophotometer [make X rite] which indicates relative opacity of plastic film, with a single pass of the light through the material, the system measures relative light transmission on a scale of 0 to 100 Opacity Units, representing perfectly transparent to purely opaque materials, respectively using a visible light source and a photoelectric detector. This instrument was also used to determine the colour variation by measuring l, a, b values which denotes the lighter and darker shades, bluer and yellower shades, and greener and reder shades.*

*For measuring the opacity the flat film sample was first kept in a black ground and the light reflected from the sample was determined. Further the sample was kept on a white back ground and the reflected light was determined. Further reading [sic] were taken on the reflection from the white back ground without the sample. Opacity of the film was then calculated on the analysis of these readings.*

*The same set of readings and analysis was performed on the formed portion [blisters] on the film. The figures in the examples represent an average of the readings taken at about 8 different areas on the sample. The instrument was also used to measure L, a and b values and therefore calculations were obtained for the transmitted blocked and reflected wave lengths of light from the sample.*"

2.2.3 From the above rather succinct description of the spectrophotometer, of which the model type is not specified, it is clear that it neither excludes that this visible light source covers a range of from approximately 380 nm to 750 nm - as considered by the manufacturer X-rite of the spectrophotometer used for the measurements (see D9, page 1, third paragraph) - which would be broader than the range of 410 to 680 nm given in the present application on page 16, fifth paragraph, nor does it exclude the presence of a monochromator, i.e. that only one specific wavelength within said visible light spectrum is to be measured, nor does it exclude the presence of filters which may cut off a certain range or certain ranges of one the aforementioned visible light ranges.

In this context the Board further remarks that D9 mentions in total **seven different standard illuminants**

including ranges of **visible light** which can apparently be used in X-Rite spectrophotometers (see D9, Appendix) among which the person skilled in the art in any case would have to choose. Each of these seven illuminants results in a different result of the measured opacity value. Furthermore, even the selection of a specific illuminant, such as the illuminant D65 suggested by the appellants, does **not** exclude that the spectrophotometer includes a monochromator or a filter to restrict the measurement of opacity to only a specific wavelength or wavelength region which, however, influences the result of the opacity measurement. It is also remarked that the selection of illuminant D65 is not straightforward in view of the fact that illuminants C or A are used for the opacity measurement according to D1 (see page 2, point 7.1.2) or that illuminant C is used for the opacity measurement according to ASTM D589 (see D15, page 3, fourth paragraph).

2.2.4 From the description of the measuring procedure in above point 2.2.2 it is likewise clear that this procedure does **not** measure the transmittance of light coming from a visible light source through the film sample with a photoelectric detector behind the sample, i.e. a transmission configuration as applied by e.g. the ASTM norms according to D1 (see page 5, figure 2) or D10 (see pages 10-12, points X1.1 to X1.5 and figure X1.1) but is only a method which measures **the reflectance** of light as a function of the material placed on different backgrounds (which measurement includes scattered light and light transmitted through the film and reflected from the underlying background and thus transmitted back through the film).

2.2.5 The opacity measuring procedure described in the present application thus resembles the procedures used

for determining the opacity of paper which are based on different norms and wavelengths within the visible light using specific illuminants, such as e.g. ASTM D589 or TAPPI T425, which measure opacity at a single wavelength in the blue region using illuminants A or C. However, there exist other norms as well.

The article in the post-published D15 uses said ASTM D589 (TAPPI 425) test procedure with said black/white background (but without measuring the reflectance of only the white background in the absence of any sample for the calculation of the opacity) for measuring the opacity of light barrier polymeric laminations and specifies that the light source is compliant with CIE standard illuminant C (see page 3, second paragraph).

2.2.6 Taking account of the fact that opacity includes scattering, reflection and absorption (see e.g. D13, first paragraph) the Board accepts that the skilled reader of the application, also in view of the procedure described therein, would not apply the Norm D1 when assessing strongly scattering metallized polymeric films, as argued by the appellants. This is due to the fact that the standard test method for haze and luminous transmittance of transparent plastics according to D1 is **not** suitable for materials having a haze value of greater than 30% so that these materials are not tested according to D1 but in accordance with ASTM practice E167 (see D1, chapter 1.1) which norm has been replaced by ASTM E2387-05 (=D10).

2.2.7 However, the appellants' arguments based on D10 cannot hold in view of the procedure described in the application. First of all, D10 is silent with respect to the use of a white and a black backing to measure the BSDF (the bidirectional scattering distribution

function) of the sample in question and the term "opacity" is not mentioned at all therein.

Secondly, as already mentioned in point 2.2.4 above the standard practice for optical scatter measurements according to D10 measures - in analogy to the standard of D1 - the (single) **transmittance** though the polymeric sample but not its reflectance, let alone uses a white and a black background. Therefore the skilled reader would not apply the general method suggested in D10 but would have to look for another method, with more similarities with the one described in the present application.

2.2.8 Furthermore, D10 (likewise as D1, see point 1.2 of the reasons, second paragraph) makes clear that for carrying out measurements in accordance with ASTM E2387-05 the **specific illuminant or the wavelength used has to be specified** (see page 3, points 3.2.9.1; pages 5-6, points 5.1 to 5.1.1 and 5.1.1.9; page 9, point 6.3.4.3; page 10, point 9.1, 9.3, 9.3.8; page 12, points X2.2 and X3.2). D10 also states that the described "practice does not provide a method to extrapolate data from one wavelength, scattering geometry, sample location, or polarization to any other wavelengths, scattering geometries, sample locations, and polarizations that are of interest to his or her application" (see page 1, paragraph 1.9).

In this context the Board also remarks that already D13 mentions that opacity depends on the frequency of the light being considered (see first paragraph, line 9). Indeed, D13 reflects the common general knowledge of the person skilled in the art.

Consequently, the appellants' argument that high opacity values can be measured independent of the wavelength measured cannot hold either. This conclusion is also apparent in view of the fact (as already argued by the Examining Division, see point 1.2 of the decision's reasons, third paragraph) that the subject-matter of claim 1 of the main request includes coloured coatings (the following working examples of the present application comprise such a coloured lacquer coating: 5, 20, 40 (red lacquer), 10 (green lacquer), 15 (violet lacquer), 25 (blue lacquer), 30 and 35 (golden lacquer)), which makes the opacity strongly wavelength dependent. This fact, however, similarly implies - likewise as the norms D1 or D10 or the norm described in D15 - that the wavelength range of the visible light source (or the type of illuminant) has to be specified in order that the opacity values can be exactly reproduced.

2.2.9 During the discussion at the oral proceedings on how the person skilled in the art, based on the three readings of reflectance (i.e. multilayer sample on a white background, then on a black background, and finally the white background without a sample) would then calculate the opacity value, and how the measured values L, a and b for the colour of the film samples would enter into the opacity calculation, the appellants - in view of the fact that the application is silent in this respect - argued in general that these calculations should be made in accordance with D10 but could not quote any specific passage dealing with this aspect. But even if the person skilled in the art were taught by D10 how he should consider said L, a and b values in the method of measuring the transmission BSDF he does not derive any teaching

whatsoever what he should do with said three reflectance readings.

2.2.10 Taking account of the above it is clear that the person skilled in the art would **not** apply the procedure of D10 in order to measure the opacity values of the products claimed in claim 1 of the main request.

2.2.11 The further argument of the appellants that the person skilled in the art, taking account of the fact that D10 does not mention any black and/or white background for the measurement of the opacity, would derive this information from page 20 of the present application cannot hold either.

This argument firstly causes the person skilled in the art to move in a circle: starting from the disclosed measuring method of the present application, he would have to turn to D10 in order to obtain the necessary missing informations, and after consultation of D10, he would have to turn back to the disclosure of the present application to fill in the gaps remaining in the disclosure of D10. This does not make any sense.

Secondly, as mentioned in point 2.2.4 above, the approach of measuring the transmittance BSDF according to D10 is totally different from that of measuring the reflectance disclosed on page 20 of the present application. Already for this reason alone the person skilled in the art would **not** turn to the Norm D10.

2.2.12 Consequently, the Board considers that the Examining Division's conclusion, i.e. lack of clarity of product claim 1 of the main request due to a lack of disclosure concerning the method for measuring the opacity values, holds true for claim 1 the main request.

Claim 1 of the main request therefore does not comply with Article 84 EPC. The main request is therefore not allowable.

*First to seventh auxiliary requests*

2.3 Since the subject-matter of the claims 1 of the first to seventh auxiliary requests contain the two identical features relating to measured opacity value ranges of the product claimed in claim 1 of the main request, the above conclusion with respect to claim 1 of the main request applies *mutatis mutandis* to claim 1 of the first to seventh auxiliary requests.

The Board therefore concludes that their subject-matter does not comply with the requirements of Article 84 EPC either. The first to seventh auxiliary requests are therefore also not allowable.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar: The Chairman:

G. Nachtigall H. Meinders

Decision electronically authenticated