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Datasheet for the decision of 26 September 2024

Case Number: T 1858/22 - 3.3.09

Application Number: 14700755.3

Publication Number: 2945799

IPC: B32B27/08, B32B27/30, B32B27/32, B65D65/40

Language of the proceedings: EN

Title of invention:
MULTILAYER FILM COMPRISING A CONTACT LAYER, CORE LAYER AND OUTER LAYER FOR THE WALL OF A SINGLE-USE POUCH

Patent Proprietor:
SARTORIUS STEDIM FMT SAS

Opponent:
Renolit SE

Headword:
Multilayer film/SARTORIUS

Relevant legal provisions:
EPC Art. 123(2), 84, 56, 83
RPBA 2020 Art. 13(2)
EPC R. 80

Keyword:

Amendment after notification of Art. 15(1) RPBA communication - taken into account (yes)
Sufficiency of disclosure - main request (yes)
Inventive step - main request (yes)

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Case Number: T 1858/22 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 26 September 2024

Appellant: (Opponent)	Renolit SE Horchheimer Strasse 50 67547 Worms (DE)
Representative:	Zellentin & Partner mbB Patentanwälte Rubensstraße 30 67061 Ludwigshafen (DE)
Respondent: (Patent Proprietor)	SARTORIUS STEDIM FMT SAS Z.I. des Paluds, Avenue de Jouques 13400 Aubagne (FR)
Representative:	Plasseraud IP 104 Rue de Richelieu CS92104 75080 Paris Cedex 02 (FR)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 30 May 2022 rejecting the opposition filed against European patent No. 2945799 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	R. Romandini
Members:	F. Rinaldi
	A. Veronese

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the opponent (appellant) against the opposition division's decision to reject the opposition against the European patent.

II. In the notice of opposition, the opponent had requested that the patent be revoked under Article 100(a) (lack of novelty and lack of inventive step) and (b) EPC.

III. The documents cited during opposition proceedings included:

D1: EP 0 561 428 A1

D2: WO 95/26268 A1

D6: US 2012/0052225 A1

D16: M. Hammond *et al.*, "Identification of a leachable compound detrimental to cell growth in single-use bioprocess containers", Pharmaceutical Science and Technology 67, 2013, 123-34

D19: A.A. Schukla *et al.*, "Single-use disposable technologies for biopharmaceutical manufacturing", Trends in Biotechnology 31(3), March 2013, 147-54

D37: ASTM F 392 - 93 (Standard test method for flex durability of flexible barrier materials, reapproved 2004)

IV. In its reply to the statement setting out the grounds of appeal, the respondent (patent proprietor) re-filed auxiliary requests 1 to 22, which it had filed by letter of 21 January 2022.

V. By letter dated 19 June 2024, the respondent filed 23 auxiliary requests (numbered auxiliary request 0 and auxiliary requests 1bis to 22bis). These requests are based on the claims of the patent as granted and on auxiliary requests 1 to 22, with an additional feature incorporated in each respective claim 1 to define the method used to measure the flex-crack resistance.

VI. At the end of the oral proceedings before the board, the respondent modified the order of the requests and made auxiliary request 3bis, filed by letter dated 19 June 2024, the main request. All requests on file, including the claims of the patent as granted, were maintained as lower-ranking requests.

VII. Claims 1, 12 and 14 of the main request are the only claims relevant to this decision. They read as follows.

"1. *A multilayer film for manufacturing a pouch, said multilayer film comprising:*
- *a contact layer,*
- *a core layer,*
- *an outer layer,*

wherein:
- *the contact layer and the core layer are made integral with a first tie layer,*
- *the outer layer and the core layer are made integral with a second tie layer,*
- *the contact layer comprises (A) a copolymer of ethylene and α-olefin having a density in the range of 0.870 g/cm^3 to 0.910 g/cm^3, alone or in mixture with (B) a polyolefin having a density in the range of 0.910 g/cm^3 to 0.940 g/cm^3,*
- *the core layer comprises (C') a flex-crack resistant ethylene vinyl alcohol copolymer having a*

content of ethylene in the range of 25 to 48 mol % or a mixture of (C) an ethylene vinyl alcohol copolymer having a content of ethylene in the range of 25 to 48 mol % and (D) an ionomer acid ethylene copolymer, wherein the ethylene vinyl alcohol copolymer is flex-crack resistant if the number of pinholes measured after 100 cycles according to the method of ASTM F392 (2004) is less than or equal to 30, the test being performed on a film sample which is a 30 µm mono layer, at 23°C, with a Gelbo flex tester and a 440° twisting motion,

- *the outer layer comprises (E) a polyolefin having a density in the range of 0.910 g/cm³ to 0.940 g/cm³, alone or in mixture with (F) a copolymer of ethylene and α-olefin having a density in the range of 0.870 g/cm³ to 0.910 g/cm³,*
- *the first tie layer and second tie layer comprise independently of each other (G) a copolymer of polyolefin grafted with a carboxylic acid or an anhydride of carboxylic acid, alone or in mixture with (H) a copolymer of polyolefin,*

and wherein:

- *the thickness of the contact layer is from 150 µm and 300 µm, preferably from 200 and 250 µm, more preferably from 225 µm and 245 µm,*
- *the thickness of the core layer is from 5 µm and 50 µm, preferably from 15 and 40 µm, more preferably from 20 µm and 30 µm, and*
- *the thickness of the outer layer is from 50 µm and 150 µm, in particular from 55 µm to 150 µm, preferably from 80 and 120 µm, more preferably from 90 µm and 110 µm.*"

"*12. The multilayer film according to any one of claims 1 to 11, wherein the outer layer comprises a mixture of (E) and (F) with a mass ratio (E)/(F) more*

than or equal to 5/95, preferably in the range of 5/95 to 100/0, more preferably in the range of 1 to 5, even more preferably in the range of 1 to 2.5."

"*14. The multilayer film according to any one of claims 1 to 13, wherein the contact layer contains no additives or limited amounts, preferably less than 0.10 wt %, more preferably less than 0.07 wt %, of additives able to release a degradation compound further to gamma irradiation that can slow down or delay cellular growth, such as Tris(2,4-ditert-butylphenyl) phosphite*."

VIII. The appellant's arguments relevant to this decision may be summarised as follows.

- All requests filed by letter dated 19 June 2024, which include the current main request, were late filed and *prima facie* not allowable. Therefore, they should not be admitted into the proceedings. The requests did not comply with the requirement of Rule 80 EPC and included matter that was neither sufficiently disclosed nor clear.
- The amendment in the main request also involved a new combination of features and did not comply with the requirement of Article 123(2) EPC.
- The subject-matter of claim 1 of the main request lacked inventive step starting from example 1 of D1 as the closest prior art.

IX. The respondent's arguments relevant to this decision may be summarised as follows.

- All requests filed by letter dated 19 June 2024, which include the current main request, were filed to resolve an objection of lack of novelty raised

for the first time in the board's communication. The amendment was admissible and *prima facie* allowable. All objections raised by the appellant had been addressed in the board's communication and found to be not convincing.

- The amendment in the main request complied with the requirement of Article 123(2) EPC. The features added to claim 1 defined the thicknesses of the layers as described in the application as filed.
- The subject-matter of claim 1 of the main request involved an inventive step even when starting from D1, which was not the closest prior art.

X. Final requests

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

The respondent requested that the patent be maintained on the basis of the main request originally filed as auxiliary request 3bis with the letter of 19 June 2024, or on the basis of any of auxiliary requests 1 to 22, filed by letter of 21 January 2022 and re-filed with the reply to the statement setting out the grounds of appeal, or on the basis of auxiliary requests 0, 1bis, 2bis or 4bis to 22bis, all filed by letter dated 19 June 2024, or on the basis of new auxiliary request 3bis, which are the claims of the patent as granted.

Reasons for the Decision

1. *Patent*

The patent concerns a multilayer film for the wall of a single-use pouch which may be used for preparing, storing or conveying a cell media or a cell culture. The patent also concerns a process for manufacturing such a multilayer film (paragraph [0001]).

2. *Admittance of the main request*

2.1 The main request was filed as auxiliary request 3bis after notification of the board's communication under Article 15(1) RPBA.

2.2 Compared to claim 1 as granted, claim 1 of the main request (wording, see above, section VII.) includes two separate amendments.

2.2.1 The first amendment relates to the features added to define the thicknesses of the contact layer, the core layer and the outer layer. This amendment is present in auxiliary request 3 filed with the reply to the statement setting out the grounds of appeal. The appellant did not contest the admittance of this first amendment.

2.2.2 The second amendment relates to the feature added to define the method used for measuring flex-crack resistance. The method is disclosed in paragraph [0059] of the patent specification and on page 8, lines 22 to 26 of the application as filed. This amendment is

present in all auxiliary requests filed by letter dated 19 June 2024.

2.3 The appellant argued that all claim requests which included the measuring method from paragraph [0059], i.e. the second amendment, were late filed and *prima facie* not allowable. The arguments were as follows.

2.3.1 As early as in the notice of opposition, the objection had been raised that the term "flex-crack resistant" in claim 1 of the patent as granted was not well defined. Also, it was not possible to distinguish between the ethylene vinyl alcohol copolymer (C') and the seemingly not flex-crack resistant ethylene vinyl alcohol copolymer (C) mentioned in claim 1.

2.3.2 Moreover, the amendment merely remedied a lack of clarity and contravened Rule 80 EPC.

2.3.3 Finally, the amendment was *prima facie* not allowable because the method incorporated in claim 1 of the main request was not sufficiently disclosed. The standard method ASTM F 392, described in D37, did not envisage any test involving twisting the sample at an angle of 440° and 100 cycles, as opposed to claim 1 of the main request. In addition, claim 1 of the main request did not provide any information on the horizontal movement of the sample which was envisaged by the standard method. Since this information was missing, claim 1 of the main request did not fulfil the requirements of Articles 83 and 84 EPC.

2.4 As the claim requests filed by letter dated 19 June 2024, including the main request, constitute an amendment to the respondent's case after the notification of the board's communication, it has to be

examined whether the main request may be admitted under Article 13(2) RPBA.

2.5 For the board, it is plain to see that the filing of the main request constitutes a prompt reaction to the board's preliminary opinion, which noted that claim 1 of the patent as granted did not specify a threshold value for defining flex-crack resistance. This term's interpretation was relevant for assessing novelty of the claimed subject-matter over D1. The board is unaware of this objection being raised earlier in the opposition-appeal proceedings.

2.6 Indeed, before the board issued its preliminary opinion, the respondent's view was that flex-crack resistance had to be read with the restriction set out in paragraph [0059] of the patent. Similarly, the appellant had acknowledged that for a prior art to fall under the definition of claim 1 of the patent as granted, it had to disclose an ethylene vinyl alcohol copolymer that was flex-crack resistant when measured as defined in paragraph [0059] of the opposed patent (statement setting out the grounds of appeal, page 4). Thus, until the board issued its preliminary opinion, both parties had considered the feature of flex-crack resistance to be restricted by the threshold value determined according to the measuring method in paragraph [0059] of the patent. For completeness, the appellant's argument that the term flex-crack resistance was not well defined was restricted to the objection that there was an undue burden in carrying out the test to identify suitable polymers and that the test was allegedly not sufficiently disclosed.

2.7 The appellant's argument that the claim requests filed by letter dated 19 June 2024, including the main

request, did not comply with the requirement of Rule 80 EPC is not convincing either. The amendment defines more narrowly the feature of flex-crack resistance. It unequivocally addresses an objection of lack of novelty.

2.8 The appellant argued that the claim requests filed by letter dated 19 June 2024, including the main request, were *prima facie* not allowable because they allegedly did not resolve a possible ground for opposition and involved insufficient and unclear matter.

2.9 The objections of lack of clarity and sufficiency of disclosure identified by the appellant concern precisely the same issues that it had raised in statement setting out the grounds of appeal. In its communication under Article 15(1) RPBA, the board then dealt with these objections and concluded that none of them was convincing. In view of this, the board has already examined the alleged issues and had no apparent reason to regard the main request as *prima facie* not allowable.

2.10 In sum, the board is satisfied that there were exceptional circumstances for filing the main request. For this reason, Article 13(2) RPBA does not prejudice the admittance of the main request. The main request is admitted into the appeal proceedings.

3. *Article 123(2) EPC*

3.1 The appellant argued that the addition of the features defining the thicknesses of the contact layer, the core layer and the outer layer to claim 1 of the main request created a new combination of features not disclosed in the application as filed. This was not

allowable under Article 123 EPC. In the application as filed, the individual thicknesses were disclosed independently from each other.

3.2 However, the amendment in claim 1 of the main request consists in nothing other than adding to claim 1 as granted the values of the broadest ranges which define the thicknesses of the three layers in the application as filed (contact layer, page 8, lines 8 and 9; core layer, page 9, lines 41 and 42; outer layer, page 11, lines 29 to 30). In other words, the application as filed directly and unambiguously discloses a film comprising layers having the thicknesses defined by the broadest ranges described for the contact layer, the core layer and the outer layer. This amendment is therefore allowable.

3.3 For completeness, the method for measuring crack-flex resistance defined in amended claim 1 is based on the application as filed (page 8, lines 22 to 26).

3.4 Therefore, the subject-matter of claim 1 complies with the requirements of Article 123(2) EPC.

4. *Sufficiency of disclosure*

4.1 At the oral proceedings before the board, the appellant did not raise objections under Article 83 EPC when asked to present the objections it had against the main request. Nevertheless, objections under this article were discussed at the oral proceedings before the board for a previously higher-ranking request. The objections were also directed to and equally concern features in claims 1, 12 and 14 of the current main request. For the sake of completeness, the considerations made when

dealing with that previously higher-ranking request are set out here for the main request.

4.2 As to claim 1 of the main request, the appellant's arguments were as follows.

4.2.1 Identifying flex-crack resistant ethylene vinyl alcohol copolymers suitable to carry out the invention, from among those which had the required ethylene content, called for a research programme. The opposed patent did not give any information on what made an ethylene vinyl alcohol copolymer flex-crack resistant. This placed an undue burden on the skilled person, who had to identify suitable (commercial) polymers.

4.2.2 The test conditions for carrying out the standard method ASTM F392 (2004) (described in D37) did not correspond to those of the method described in paragraph [0059] of the patent and in claim 1 of the main request. The standard method did not envisage tests involving 100 twisting cycles. Furthermore, all standard tests involving a 440° twisting angle envisaged an additional horizontal movement of the sample. The test in paragraph [0059] of the patent did not mention this horizontal movement. Furthermore, the condition without horizontal movement in D37 involved only 400° twisting, not 440° twisting.

4.3 The appellant's arguments failed to convince the board.

4.4 It is true that the patent does not identify a specific polymer which is flex-crack resistant and has the compositional features of the core layer set out in claim 1. Nor is there an explanation as to what might cause the property sought. Whether a polymer complies with the flex-crack resistance called for in claim 1

has to be determined by carrying out the experiment set out in the claim. Nevertheless, ethylene vinyl alcohol copolymer containing films which are flex-crack resistant are generally known in the art. This is confirmed by e.g. D2 and D6. The fact that a standard method for establishing whether a material is flex-crack resistant exists, namely ASTM F 392, cited as D37, underscores that this property is not an unusual parameter and that the method for measuring this parameter is known in the art. Therefore, establishing whether a polymer having the compositional features of the core layer of claim 1 is flex-crack resistant cannot be seen to involve an undue burden. In this context it is observed that the requirement set in claim 1 is not particularly rigorous or hard to achieve.

4.5 As to the argument that the measuring method in D37 did not exactly correspond to the one described in paragraph [0059] of the patent, the skilled person would readily understand how to modify the method in D37 and carry out tests using the parameter settings specified in the patent. They would not have any difficulty in carrying out tests involving 100 twisting cycles. Clearly, the number of cycles can be freely chosen, depending on the number of pinholes that are tolerated. The skilled person would also understand that although no horizontal movement is mentioned in the patent, this is unavoidable when performing the 440° twisting motion specified in paragraph [0059] and claim 1 of the main request. In other words, the skilled person would understand that when they carry out the test defined in paragraph [0059] and claim 1 of the main request, they will also need to perform the horizontal movement of the method in D37.

4.6 To conclude, the invention as set out in claim 1 of the main request is sufficiently disclosed.

4.7 As to claim 12 of the main request, the appellant's argument was that the mixture of (E) and (F) could be construed to have a mass ratio (E)/(F) of 100/0 (wording of the claim, see above, section VII.). In this case, the "mixture" would comprise only (E) and no (F). Therefore, it would not be a mixture. For this reason, the invention in claim 12 was not sufficiently disclosed.

4.8 This is not convincing for the following reasons.

4.8.1 It can be agreed that there is no mixture of a single substance. But even if the literal wording of claim 12 raised any doubt as to whether no (F) is present or whether a true mixture of (E) and (F) is required, the doubt is nothing more than an issue of a potentially unclear scope of the claim. Manifestly, both options can be carried out. The only question is simply which option (true mixture and/or no (F) present) is covered by claim 12.

4.8.2 According to Case Law of the Boards of Appeal of the EPO, 10th edn. 2022, Chapter II.C.6.6.4, "*today there is a clearly predominant opinion among the boards that the definition of the 'forbidden area' of a claim should not be considered as a matter related to Art. 83 and 100(b) EPC*". This board agrees with this opinion.

4.8.3 Therefore, no issue of lack of sufficiency of disclosure arises from the features of claim 12.

4.9 As to claim 14 of the main request, the appellant's argument was that the amounts of additive allowed

according to this claim were still detrimental in cell growing processes. This was allegedly demonstrated by D16.

4.10 This is not convincing for the following reasons.

4.10.1 Claim 14 defines that the contact layer contains no additives able to release a degradation compound further to gamma irradiation that can slow down or delay cellular growth. Clearly, no issue arises if no additive is present.

4.10.2 Moreover, claim 14 discloses a preferred maximum amount of additives in the contact layer. The skilled person would have no difficulties in preparing that contact layer. In fact, the type of additives which can be present in the contact layer are disclosed in the patent (paragraph [0047] and following). Furthermore, degradation compounds able to slow down or delay cellular growth can be detected by applying the test disclosed in paragraph [0050] of the patent. In other words, the skilled person is provided with sufficient instructions on how to avoid undesired additives.

4.10.3 In this context, D16 is not relevant. D16 discusses compounds detrimental to cell growth that can be leached out of single-use containers. Thus, it concerns a separate issue to the subject-matter of claim 14, which is solely directed to providing the specified contact layer. Claim 14 does not require that the technical effect of not delaying cellular growth is obtained. Such a technical effect is not mentioned in claim 14. Therefore, whether such an effect is achieved is not relevant when assessing sufficiency of disclosure.

4.11 In conclusion, the invention of the main request complies with the requirement set out in Article 83 EPC.

5. *Article 84 EPC*

5.1 The appellant argued that the amendment in claim 1 of the main request lacked clarity. The amendment defined the preferable thicknesses of the various layers, and this rendered the claim unclear. Furthermore, based on the objection raised in the context of sufficiency of disclosure, the measuring method added to claim 1 did not specify that a horizontal movement was required during the measuring step. Therefore, the skilled person would have had doubts as to what had to be done to correctly carry out the measurement.

5.2 None of these arguments is convincing.

5.2.1 The appellant simply stated that, taking into account the EPO case law, the use of the term "preferably" rendered claim 1 unclear. However, it did not cite the relevant decision, let alone explain to what extent it was applicable to the amendment under scrutiny. The board considers that in the context of the claimed invention, the addition of the term "preferably" to claim 1 does not render the scope of the claim unclear.

5.2.2 The appellant alleged that a reference to a horizontal movement was missing in the definition of the method for measuring flex-crack resistance set out in claim 1. In its opinion, this rendered the claimed subject-matter unclear. This argument is not convincing either for the reasons given when dealing with sufficiency of disclosure in point 4.5.

5.3 To conclude, the amendments comply with the requirement of Article 84 EPC.

6. *Article 56 EPC*

6.1 For the main request, the only objection that the board has to consider is the appellant's argument that the subject-matter of claim 1 lacked an inventive step starting from example 1 of D1.

6.2 Example 1 of D1 relates to a multilayer film suitable for packaging applications and having the properties of a shrink film. The final film has a thickness of about 25 µm. It was not contested that the features distinguishing the subject-matter of claim 1 from the closest prior art are:

- the ethylene vinyl alcohol copolymer being flex-crack resistant, i.e. the number of pinholes measured after 100 cycles at a 440° twisting motion according to the method of ASTM F392 (2004) being less than or equal to 30

- the thicknesses of the contact layer, the core layer and the outer layer

6.3 The appellant was of the view that the distinguishing features addressed two separate aspects, namely that of increasing the stability of the multilayer film and that of producing larger pouches. The skilled person would have known that the stability of a multilayer film was increased by flex-crack resistant polymers. Furthermore, they would have adapted the thickness of the film to the desired intended use of the multilayer film. This was confirmed e.g. by D6 and D19.

6.4 However, the teaching of D1 focuses on shrink films. The film of example 1 is an order of magnitude thinner than the minimal thickness of the multilayer film of claim 1. D1 dissuades the skilled reader from providing too thick films and suggests that the shrink film should not have a thickness of more than 50 µm (page 5, lines 27 to 36). Therefore, the thinnest film envisaged by claim 1 is more than four times thicker than the maximum thickness specified by D1.

6.5 While different starting points can be used for developing an inventive-step attack, the starting point not only determines the subject-matter that serves as a starting point but also defines the framework for further development (Case Law of the Boards of Appeal of the EPO, 10th edn., 2022, Chapter I.D.3.6).

6.6 In view of this and irrespective of any other consideration, the board considers that the skilled person starting from D1 as the closest prior art would not have arrived at the subject-matter of claim 1 in an obvious way. The skilled person would not have increased the thicknesses of the layers of the film to the thickness ranges called for in claim 1.

6.7 Therefore, the subject-matter of claim 1 complies with the requirement of Article 56 EPC. The same conclusion applies also to the remaining claims of the main request, in particular claims 16, 17 and 18.

7. *Conclusion*

7.1 Claims 1 to 18 of auxiliary request 3bis filed by letter of 19 June 2024 are allowable, this being the main request referred to in this decision. In the order of this decision below, the main request is referred to

as auxiliary request 3bis filed by letter of 19 June 2024.

7.2 The respondent argued that no adaptation of the description was required.

7.3 Nevertheless, the board considered it appropriate to remit the case to the opposition division for a possible adaptation of the description, to the extent the division considers it necessary.

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 No. 1 to 18 of auxiliary request 3bis filed by letter of 19 June 2024 and a description and the drawings to be adapted thereto, if necessary.

The Registrar: The Chairman:

K. Götz-Wein R. Romandini

Decision electronically authenticated