

Amended claims (marked relative to claims as filed)

1. Biodegradable disposable respiratory face mask comprising at least one filter layer comprising cellulose fibres,
wherein the at least one filter layer comprises cellulose nanofibres,
wherein the cellulose nanofibres are native cellulose nanofibres,
wherein the pore size of the filter layer is less than about 100 nm.
2. The biodegradable disposable respiratory face mask according to claim 1 wherein the cellulose fibres are derived from cotton or hemp.
- ~~3. The biodegradable disposable respiratory face mask according to any one of claims 1 or 2 wherein the at least one filter layer is made of cellulose nanofibres.~~
- ~~43. The biodegradable disposable respiratory face mask according to any one of claims 1 or 23 wherein the cellulose nanofibres are derived from papermaking waste residues,
wherein the waste residues comprising gelatin and at least 1% (in weight) of cellulose fibres.~~
- ~~54. The biodegradable disposable respiratory face mask according to any one of claims 1 to ~~43~~ which is a surgical face mask or a dust face mask.~~
- ~~65. The biodegradable disposable respiratory face mask according to claim ~~54~~ which is an FFP2-type face mask.~~
- ~~76. The biodegradable disposable respiratory face mask according to claim ~~65~~ wherein the FFP2 face mask comprises a multilayer structure with at least three layers comprising at least one outer layer (A) with a thickness of about 40 µm acting as a water barrier; at least one inner (middle) layer (B) with a thickness of about 8 µm acting as a filter layer; and at least another outer layer (A') with a thickness of about 40 µm for contact with the skin.~~
- ~~87. The biodegradable disposable respiratory face mask according to claim ~~76~~ wherein the FFP2 face mask comprises five layers comprising the outer layers (A and A') and further comprising two inner (middle) layers (B and B'), acting as filter layers, separated by a hydrophilic separation layer (C).~~
- ~~98. The biodegradable disposable respiratory face mask according to any one of claims ~~76~~ or ~~87~~ wherein at least one layer is manufactured by conventional techniques for making nonwoven fabrics such as melt-blowing or spunbonding.~~
- ~~109. The biodegradable disposable respiratory face mask according to any one of claims ~~76~~ to ~~98~~ wherein the outer layers (A and A') are made of nonwoven cotton or hemp fabric.~~
- ~~110. Process for manufacturing a biodegradable filter layer for a multilayer FFP2-type face mask, the process comprising:
providing papermaking waste residues, wherein the waste residues comprising about 1% (in weight) of cellulose fibres and about 0.1% (in weight) of gelatin
milling using grinding balls, and
casting into a thin nonwoven layer by melt-blowing or spunbonding.~~

Letter to the EPO

In response to search opinion under R. 62(1) EPC the Applicant submits the enclosed set of amended claims and the following accompanying arguments.

Payment of the examination fee (R. 70 EPC, Art. 2(1) Nr. 6 RFees) to complete the request for examination (Art. 94(1), R.

70(1) EPC) and designation fee (Art. 79(2), R. 39(1), Art. 2(1) Nr. 3 Rfees) has been affected separately.

Amendments (Art. 123(2) EPC)

All amendments have direct and unambiguous basis in the application as filed and thus comply with the "gold standard" for assessing the compliance with Article 123(2) EPC (GL H-3.1).

Amended claim 1 as filed has been amended to include the feature that the at least one filter layer comprises cellulose nanofibres. This feature has literal basis in [22] of the application as filed. The only other feature disclosed in connection with the cellulose nanofibres is that the face mask comprises at least one filter layer ([21] of the application as filed). This feature is included in amended claim 1. Consequently, no extraction or generalisation of features is required.

Additionally, claim 1 has been amended to include the feature that the cellulose nanofibres are native cellulose nanofibres. This feature has literal basis in [23] of the application as filed. The only feature disclosed in connection with the fibres being native cellulose fibres is that the fibres are nanofibres. This feature is also included in amended claim 1, therefore, no extraction or generalisation of features is required, either.

The pore size of the filter layer has direct and unambiguous basis in [35] of the application as filed.

Amended claim 3 has been removed, without prejudice.

Amended claim 4 has been amended to specify that the waste residues comprise gelatin and at least 1% (in weight) of cellulose fibres. This amendment has direct and unambiguous basis in [44] and [45] of the application as filed. These two components are the only two components mentioned as certainly contained in the papermaking waste. For the cellulose fibres the original disclosure specifies that the waste contains at least 1% (in weight), this has been included in the claim. However, for gelatin, there is no requirement in the original disclosure on this level of generality that, as reflected in [45] of the application as filed, that requires any specific amount, merely that gelatin is a component of the papermaking waste, as is included in amended claim 4.

Amended claim 10 has been amended to specify that the waste residues comprises about 1% (in weight) of cellulose fibres and about 0.1% (in weight) of gelatin. This amendment has basis in [49] of the application as filed. [49] of the application as filed also specifies that grinding balls with diameters between 0.1 and 1 mm are used to induce separation of cellulose into single nanofibres. However, this feature is not highlighted as essential in the application as filed and can be omitted: Extracting the paperwaste composition as in amended claim 10 from [45] in isolation is allowable as the feature is there is no structural or functional relationship between the features and, thus, does not result in an unallowable intermediate generalisation (GL H-V. 3.2.1). The feature is not inextricably linked to the size of the grinding balls. There is no disclosure that could justify the conclusion that the specific composition only works in combination with the specific size of the grinding balls. Additionally, the overall disclosure justifies the generalising isolation of the feature of the composition of the paperwaste and its introduction into the claim. As outlined above, the disclosure provides evidence that the paperwaste can comprise any amount of gelatin. Additionally, [48] explains that the desired result, i.e., the absence of chemical modification, can be obtained by any mechanical milling process. Consequently, limitation to grinding by balls as included in the claim is entirely sufficient and the generalisation to any size grinding balls is justified.

The remaining claims and dependencies have been renumbered where appropriate.

The subject matter of the amended claims is directly and unambiguously derivable from the claims as filed, and the claims comply with Article 123(2) EPC.

Clarity (Art. 84 EPC)

The Examiner has raised an objection concerning an alleged lack of clarity of the term "*papermaking waste residues*" in claims 4 and 11 as filed (page 2 of the communication, points 4 and 5).

In response, the papermaking waste residue has been further defined in clear structural features in amended claim 3 and 10, see above. The essential structural features of the papermaking waste, i.e., that it comprises cellulose and gelatin as specified, have been included. As will be further elaborated hereinbelow, all essential features to achieve the technical effect are included (T 32/85).

The term "*about*" included in amended claim 10 is generally allowable (GL F-IV 4.7.1) and cannot give rise to a further objection.

Therefore, the objection is resolved by the amendments.

The subject matter of the amended claims is clear, and the amended claims meet the requirement of Article. 84 EPC.

Sufficiency of disclosure (Art. 83 EPC)

The claimed subject matter is also sufficiently disclosed. Concerning both claims 1 and 10 there is a detailed description in the application as filed of at least one way to carry out the invention (GL F-III 1). Therefore, no serious doubts substantiated by verifiable facts (T 409/91 and T 694/92) to question sufficiency of disclosure are on file.

The subject matter of the amended claims is sufficiently and disclosed, and the amended claims comply with Art. 83 EPC.

Novelty (Art. 54 EPC)

The subject matter of the amended claim is also novel. Amended claim 1 requires that the cellulose fibres are native nanofibres. Amended claim 10 specifies a process for manufacturing a biodegradable filter layer for a multilayer FFP2-type face mask.

Claim 1

D1 discloses masks made of cellulose fibres ([3]), specifically from cotton and hemp ([5] onwards and [10] onwards). It appears that these fibres are not chemically or mechanically modified, and, thus, native, i.e., in the cellulose-I crystal structure. However, D1 only discloses that the masks are from cotton cloth or hemp felt. However, D1 in either case only discloses compacted cellulose fibres (see also communication, page 1, 3.1, see also D1 [12]). Consequently, the Examiner also considered the subject matter of claim 3 as filed novel over D1 (page 2 line 25 of the communication). D1 certainly does not disclose a mask wherein the pore size of the filter layer is less than 1 µm. for the cotton embodiment no pore size is specified and for the hemp embodiment [11] specifies that only particles of 3 µm or above can be filtered.

D2 discloses cellulose based nanofibres ([5] of D2 and communication page 2 first paragraph). However, D2 does not disclose native cellulose nanofibres. Firstly, D2 specifies that the fibres are synthetic, i.e., chemically modified (see [1] of D3). For this reason alone, the fibres cannot be considered native. More particularly, the application as filed explains that chemical treatment with chemical solvents such as TFE (used in D2, see [2]), necessarily results in a change in the crystal structure of the cellulose: the native cellulose-I crystal structure changes to the cellulose-II crystal structure. Therefore, D2 does not directly and unambiguously disclose native cellulose nanofibres

No objection concerning novelty over D3 have been raised.

Claim 10

None of the prior art documents D1-D3 specify any processing of papermaking waste residues of the claimed composition by mechanical treatment, specifically by milling using grinding balls.

D1 does not disclose any processing of the starting material at all.

D2 and D3 both describe chemical treatment of cellulose ([2] of D2 and [1] of D3). Therefore, the subject matter of claim 10 is novel over D1-D3.

All further claims depend on claim 1 and are thus novel for the same reason.

Consequently, the claimed subject matter of the amended claims is novel over the prior art, and the claims comply with Article 56 EPC.

Inventive step (Art. 56 EPC)

The claimed subject matter is also not obvious and thus inventive over the prior art.

Claim 1

Closest prior art

The first consideration when choosing the closest prior art is that it relates to the same purpose as that of the claimed invention. It should provide the most promising springboard for the skilled person (GL G-VII 5.1). The object of claim 1 relates to disposable respiratory face masks made from biodegradable fibres of natural origin, in particular, those made from native cellulose nanofibres.

D1 relates to ecological face masks which are biodegradable (title and [1], [15]). However, as outlined above, D1 does not relate to any nanofibres or the pore size as specified. D3 relates to cellulose acetate, i.e., not to masks at all and can be disregarded in the consideration of closest prior art.

D2 relates to nanofilters based on cellulose acetate nanofibres. It appears that the Examiner considers these to also be biodegradable (page 2 of the communication, first paragraph) and that, conversely, the term "*biodegradable*" does not limit

the claimed subject matter. D2 also discloses cellulose nanofibres (see above). Additionally, the Examiner appears to consider, within their interpretation of the claimed subject matter and the object of the invention, D2 a suitable starting point at least for claim 8 as filed.

Consequently D2 is considered the closest prior art as (GL G-VII, 5.1).

Distinguishing feature

D2 discloses a biodegradable (interpretation of the Examiner in view of D3, [3]) disposable respiratory face mask comprising at least one filter layer comprising cellulose fibres (cellulose acetate fibres, [4] of D2, generic/specific, GL G-VI, 5), wherein the at least one filter layer comprises cellulose nanofibres ([4] of D2).

Therefore, as outlined under novelty, D2 does not disclose that the cellulose nanofibres are native cellulose nanofibres. Native cellulose is that of cellulose-I crystal structure, as opposed to cellulose-II crystal structure ([42] of the application as filed). The chemical treatment of D2 inevitably leads to this transformation ([42] of the application as filed).

Technical effect

The technical effect associated with this difference is that native cellulose nanofibres (cellulose-I crystals) have better mechanical properties ([42] of the application as filed). Enhancing the mechanical properties of the nanofilter layer, in particular air permeability decreases breathing resistance, improving user comfort ([37] of the application as filed).

The Applicant herewith files D4 (Behrens and Krokovski) and the following experimental data to show that the masks made with native cellulose nanofibres indeed show the technical effect. As outlined, this technical effect can be derived as being encompassed by the technical teaching and is embodied by the same originally disclosed invention, thus, the post-filed date is admissible (G 2/21, GL, G-VII, 11):

The results have been obtained using tests that have been performed according to the method of Behrens and Krokovski described in D4, which we enclose for your information and for the sake of completeness.

In particular, the results show that a mask using native cellulose nanofibres shows greatly improved lung function parameters, in particular improved ventilation (VE), the most important parameter for breathing resistance. A high VE value indicates a dramatic decrease in breathing resistance, correlating with excellent air permeability. The mask of D2 (Mickey-Mask) has a VE value of 95, while a mask according to the invention has a VE value of 123.5, comparable to free breathing without a mask (see table in [4] of D4). The breathability is also greatly improved relative to known surgical and FFP2 masks (see [4] in D4 with VE values of 114+/-23 and 99+/-19, respectively)

The SEM image in Figure 2 also shows that the pore size is <100 nm, therefore the woven native cellulose nanofibres retain the ability to filter even the smallest particles, including coronavirus (see [50] of the application as filed).

Objective technical problem

Therefore, the objective technical problem is the provision of improved user comfort for masks made from cellulose fibres.

Non-obviousness

The claimed solution was not obvious from the prior art.

D2 itself discloses a process for obtaining cellulose nanofibres. However, that process necessarily leads to the production of cellulose-II crystals, see above, with the undesired breathability. D2 does not mention any other way of producing the fibres, this is even reinforced by D3 (which represents common general knowledge, as it is an entry into an encyclopedia) which only teaches chemical modification, see [1]. D2 also does not explicitly mention reduced breathability as an issue, thus providing no incentive for the skilled person to even consider modifying its teaching or turning to any of the remaining documents on file.

Even if the skilled person did turn to D1, which we refute, the document teaches a different solution, thus pointing a way from the claimed invention. D1 teaches to use compacted fibres, i.e., not nanofibres, which have not been extracted from the cellulose ([40] onwards of the application as filed), to improve breathability (see [5] of D1 onwards for cotton and [10] of D1 onwards for hemp). However, this solution comes with the drawback that resulting masks are much less efficient at capturing small aerosols than existing masks ([5] and [11] of D1). D1 appears to be limited to 3 µm or above ([11] of D1) while the native nanofibres of the invention allow a pore size of 100nm and less (see Figure 1) capable of filtering even small viruses, such as the coronavirus.

Consequently, D2 would not have prompted the skilled person towards solving the objective technical problem with a reasonable expectation of success.

Even if the skilled person did turn to D3, which we refute, D3 solely concerns the synthetic cellulose acetate fibres also in D2. Consequently, D3 is also of no help to the skilled person in solving the objective problem with a reasonable expectation of success.

Furthermore, D4 does not disclose any masks made from cellulose fibres at all.

Finally, the skilled person would also not have arrived at the claimed solution in a combination from all documents, as non teach the solution as claimed.

Therefore, the claimed subject matter of amended claim 1 is inventive over the cited prior art, and the claim complies with Art. 56 EPC.

Claims 2-9 depend on claim 1 and are thus inventive for the same reason.

Claim 10

Closest prior art

Claim 10 concerns a process for manufacturing a biodegradable filter layer for a multilayer FFP2-type face mask using the specified process steps.

D1 produces masks that are not suitable for the FFP-2 standard, as the pore size is too large (see above). D3 does not concern production of any masks.

Therefore, D2 is the closest prior art. As outlined above, D2 uses a chemical process for production of the masks.

Distinguishing feature

D2 only discloses the chemical process in [2]-[4] of D2. Therefore, the subject matter of claim 10 is distinct at least through the mechanical modification using milling using grinding balls.

Technical effect

The technical effect of this feature is that native cellulose nanofibres can be obtained from the papermaking waste residues by a simple mechanical milling technique that loosens and separates cellulose into single nanofibres without any need for chemical treatment, and without introducing hazardous chemicals, such as organic solvents in D2, while retaining the cellulose-I crystal structure of native cellulose (as opposed to the cellulose-II crystal structure).

The effect associated with the masks comprising such native cellulose nanofibres is outlined in detail above.

Objective technical problem

The objective technical problem could be the provision of an improved method for manufacturing a biodegradable filter layer for a multilayer FFP2-type face mask

Non-obviousness

The claimed solution would not have been obvious from D2 alone. D2 alone only explains the chemical process and provides no hint or incentive to even modify the process, not to mention to arrive at the mechanical method claimed. D2, as outlined above, also provides no incentive to even turn to any of the remaining disclosures.

In particular, the skilled person would not have considered D1 as the masks of D1 are unsuitable for the FFP-2 type of mask due to their larger pore size. Even if they did turn to D1, D1 does not disclose a method as claimed and, consequently, cannot fill the gap between the claimed method and D2.

The skilled person would also not have turned to D3 as it does not relate to a method for producing masks as claimed. Additionally, D3 also does not disclose the specific method steps.

Even in combination of all documents, the distinguishing features are not disclosed.

Thus, the subject matter of claim 10 is inventive over the cited prior art, and the claim complies with Article 56 EPC.

Conclusion

The claimed subject matter of all claims is inventive over the cited prior art, and the claims comply with Article 56 EPC.

Unity (Art. 82 EPC)

There are no issues concerning the unity of invention between the subject matter of amended claim 1 and 10. Both define a shared, inventive contribution, i.e., special technical feature (GL F-V, 3), over the prior art in that they concern a mask and a process for making a mask of native cellulose nanofibres. This results in improved mechanical properties, see above.

The subject matter of the amended claims is unified, and the amended claims comply with Art. 82 EPC.

Requests and conclusion

The Applicant considers that the above arguments and the amendments filed herewith address all the objections in the search opinion. Accordingly, grant of a patent based on the enclosed set of claims is respectfully requested. As an auxiliary measure, oral proceedings are requested.

//Mr. Arturo Barea//

European Patent Attorney

Enclosed: Amended claims (marked and clean), D4