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EUROPEAN QUALIFYING EXAMINATION 2024

Paper B

This paper comprises:

Description of the application

Technical field of the invention

[001] The present invention relates to environmentally friendly, biodegradable, disposable respiratory face masks.

Background

[002] In December 2019, a novel beta-coronavirus called Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), which causes the disease COVID-19, was identified.

[003] During 2020, COVID-19 spread across the world in a global pandemic threatening public health.

[004] Early evidence that COVID-19 is mainly transmitted from person to person via muco-salivary microscopic droplets (aerosols) produced when talking, coughing or sneezing, which act as a carrier for the virus, led to the extensive use of face masks to curb transmission of the infection in indoor public spaces where social distancing cannot be observed.

[005] When a person breathes, talks, coughs or sneezes, 900 to 300 000 respiratory droplets are thrown from the mouth in the air at a travelling speed of up to 100 km/h.

[006] Face masks act as physical barriers protecting the wearer from inhalation exposure to aerosols present in the air by capturing those respiratory droplets that can otherwise enter the mouth and nose.

[007] By the same token, face masks also function in the opposite direction by reducing the emission of aerosols, thus preventing the infection of others.

[008] As the use of face masks became essential and compulsory against the spread of the pandemic, their production worldwide increased enormously.

[009] Conventional textile fabrics made of plant fibres, like cotton or linen cloth, can be used to manufacture face masks offering limited protection.

[010] By contrast, commercially available face masks approved by regulatory authorities for use in the COVID-19 pandemic are (i) surgical face masks or (ii) dust face masks having a multilayer structure comprising multiple layers of nonwoven synthetic polymer fibres derived from petrochemicals, such as polypropylene (PP) or polyethylene (PE), which are non-biodegradable.

[011] Face masks are, by definition, disposable single-use articles that need to be frequently replaced.

[012] By the end of 2021, the worldwide estimate of daily production of single-use face masks was 1.6 million tonnes per day. Approximately 3.4 billion disposable single-use face masks were discarded daily due to COVID-19.

[013] While this trend may have diminished slightly, disposal of synthetic polymer face masks since the outbreak of COVID-19 has generated an unprecedented increase of single-use plastic waste in the environment globally, exacerbating the existing severe ecological situation attributable to plastic pollution.

[014] Synthetic polymer fibres, such as polypropylene (PP) or polyethylene (PE), from face masks disposed in the environment can take up to 450 years to degrade.

[015] In particular, face masks ending up in the ocean add to the eight-million tonne mass of plastic waste entering the sea every year, slowly breaking down into microplastics which then enter the marine food chains with disastrous lasting environmental consequences for wildlife and human health.

[016] There is therefore an urgent need for biodegradable and eco-friendly face masks offering a level of protection against COVID-19 that is comparable to the currently available synthetic polymer face masks and which can be easily manufactured to replace production of the latter.

Summary of the invention

[017] The present application describes disposable respiratory face masks made from biodegradable fibres of natural origin.

[018] The biodegradable disposable face masks are designed to offer high levels of protection against COVID-19 and to reduce plastic waste.

[019] According to the invention, the face mask is manufactured from cellulose fibres.

[020] Preferably, the cellulose fibres are derived from cotton or hemp.

[021] According to the invention, the face mask comprises at least one filter layer.

[022] The filter layer comprises cellulose nanofibres.

[023] Advantageously, the cellulose nanofibres are native cellulose nanofibres.

[024] The native cellulose nanofibres can be derived from papermaking waste residues.

Brief description of the drawings

[025] Figure 1: Scanning electron microscopy (SEM) image of cellulose nanofibres from hemp forming a network with an average pore size of less than 100 nm.

[026] Figure 2: Cross-section of a five-layer FFP2 face mask with two inner (middle) cellulose nanofilter layers (B and B’), separated by a hydrophilic layer (C), showing electrostatic charges enhancing filtration of very fine aerosols.

Description of the invention

[027] Most recommended disposable face masks used in the COVID-19 pandemic are non-reusable dust face masks called Filtering Face Pieces (FFP).

[028] Dust face masks offer higher protection than surgical face masks by preventing the passage of liquid as well as dry aerosols.

[029] Dust face masks are certified according to European standard EN 149, and classified into three categories of increasing particle filtration efficiency (PFE):

	FFP1	FFP2	FFP3
PFE (at 95 L/min air flow)	Aerosol filtration minimum 80%	Aerosol filtration minimum 94%	Aerosol filtration minimum 99%
Particle filtration	Solid particles and droplets (>5 µm)	Solid particles and droplets (>2 µm)	Very fine solid particles and droplets (<2 µm)

[030] According to the invention, FFP2 face masks comprising at least one filter layer are designed to have a PFE of at least 94% of all particles present in the surrounding air having a size of 2 μm or more.

[031] Porosity of the filter layer is the most important property of FFP2 face masks for mechanically blocking respiratory aerosols.

[032] Furthermore, we believe that the filtration capacity can additionally be improved by intermolecular interactions between the aerosols and the surface of the filter layer. For example, the filter layer can bear electrostatic charges that enhance aerosol retention and filtration efficiency.

[033] The approximate size of a coronavirus is about 0.1-0.16 μm (100-160 nm). It is a tiny particle that cannot be filtered by most commercially available FFP face masks. However, the respiratory aerosols in which the coronavirus is carried have bigger particle sizes of about 5 μm.

[034] Accordingly, the invention provides FFP2 masks able to efficiently block respiratory aerosols having a particle size of about 5 μm.

[035] Preferably, the filter layer in FFP2 face masks according to the invention has a small pore size in the nanometre scale (nanofilter layer) in order to also protect the wearer from aerosols that can evaporate in the air into nanoparticles smaller than 1 μm; even better, a pore size in the range of less than about 100 nm, which is the size of the coronavirus.

Biodegradable nanofilter layer

[036] The first challenge for the development of biodegradable FFP2 face masks with high filtration capacity is to provide a nanofilter layer having a pore size in the range of about 100 nm from biodegradable fibres of natural origin.

[037] An additional challenge is to enhance the mechanical properties of the nanofilter layer, in particular air permeability, because the small pore size can result in an undesirable increase of breathing resistance, impairing user comfort.

[038] In the present invention, we demonstrate that a biodegradable nanofilter layer with excellent filtration capacity and low breathing resistance, allowing for excellent user comfort, can be manufactured from cellulose nanofibres.

[039] Cellulose is the most common biopolymer on Earth. Since it is formed via photosynthesis in plants, it is a sustainable and renewable source of natural and biodegradable fibres.

[040] The production of nanofibres from cellulose is not a trivial task.

[041] Cellulose consists of cellulose nanofibres of about 25 nm in diameter. Owing to strong bonding between the nanofibres, it is difficult to separate cellulose into single nanofibres.

[042] Importantly, the nanofibres have to be individually loosened without destroying their crystal morphology. For example, cellulose nanofibres prepared by chemical treatment of cellulose using organic solvents, such as acetone, dimethylformamide (DMF), or trifluoroethanol (TFE), change from the native cellulose-I crystal structure to the cellulose-II crystal structure, which provides poorer mechanical properties in a nanofilter layer.

[043] Moreover, the use of chemical treatments and the use of organic solvents for processing cellulose is not regarded as “green”, but as a source of safety and environmental issues.

[044] Recently, we developed a method of papermaking from plant fibres comprising cotton, hemp, or other plants (published international patent application PCT/EQE/2022A).

[045] As a by-product of that method of papermaking, waste residues comprising at least 1% (in weight) of cellulose fibres are generated.

[046] The waste residues also comprise gelatin. This is because in our method of papermaking, gelatin is admixed to the plant fibres during processing. Thus, gelatin remains as a component of the papermaking waste residues.

[047] Gelatin is a biopolymer derived from collagen in animal skin, cartilage, bones and connective tissues. Gelatin is non-toxic and biodegradable.

[048] We have surprisingly discovered that native cellulose nanofibres can be obtained from our 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, while retaining the cellulose-I crystal structure of native cellulose.

[049] A preferred embodiment of the invention provides that papermaking waste residues comprising about 1% (in weight) of cellulose fibres and about 0.1% (in weight) of gelatin are milled using grinding balls with diameters between 0.1 and 1 mm to induce separation of cellulose into single nanofibres.

[050] Referring now to Figure 1, native cellulose nanofibres derived from papermaking waste residues are cast into a thin nonwoven layer having a thickness of about 8 μm by melt-blowing or spunbonding, thereby providing a biodegradable nanofilter layer according to the invention. From the SEM image, it is apparent that the cellulose nanofibres form a network with an average pore size of less than 100 nm, capable of filtering the coronavirus.

[051] Referring now to Figure 2, the invention further provides that native cellulose nanofibres derived from papermaking waste residues become coated with gelatin during the mechanical milling with grinding balls. Since gelatin bears electrostatic charges, a strong interfacial interaction between the nanofilter layer bearing electrostatic charges and the charged surface of aerosols and coronavirus can therefore be expected.

[052] As a result, the biodegradable nanofilter layer according to the invention exhibits high filtration capacity attributable to the small pore size and to the occurrence of electrostatic interactions retaining the coronavirus.

[053] A biodegradable nanofilter layer as described in the foregoing disclosure is used as the inner (middle) layer (B) in the multilayer FFP2 face mask according to the present invention.

[054] For example, the biodegradable nanofilter layer can be cast or deposited, as explained before, on a biodegradable nonwoven cotton or hemp fabric forming the outer layers (A and A’) of the multilayer FFP2 face mask.

[055] The biodegradable nanofilter layer is regarded as fully compostable, since it disintegrates completely within 30 days. The multilayer FFP2 face mask disintegrates completely within 90 days.

[056] The high filtration capacity of biodegradable FFP2 masks according to the invention scores better than most commercially available FFP2 masks made from synthetic polymers, while affording a feeling of extremely light breathing resistance and excellent air permeability and breathing comfort, similar to or even better than surgical face masks.

Claims

1. Biodegradable disposable respiratory face mask comprising at least one filter layer comprising cellulose fibres.

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.

4. The biodegradable disposable respiratory face mask according to claim 3 wherein the cellulose nanofibres are derived from papermaking waste residues.

5. The biodegradable disposable respiratory face mask according to any one of claims 1 to 4 which is a surgical face mask or a dust face mask.

6. The biodegradable disposable respiratory face mask according to claim 5 which is an FFP2-type face mask.

7. The biodegradable disposable respiratory face mask according to claim 6 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.

8. The biodegradable disposable respiratory face mask according to claim 7 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).

9. The biodegradable disposable respiratory face mask according to any one of claims 7 or 8 wherein at least one layer is manufactured by conventional techniques for making nonwoven fabrics such as melt-blowing or spunbonding.

10. The biodegradable disposable respiratory face mask according to any one of claims 7 to 9 wherein the outer layers (A and A') are made of nonwoven cotton or hemp fabric.

11. Process for manufacturing a biodegradable filter layer for a multilayer FFP2-type face mask, the process comprising: providing papermaking waste residues, milling using grinding balls, and casting into a thin nonwoven layer by melt-blowing or spunbonding.

<u>Drawings of the application</u>

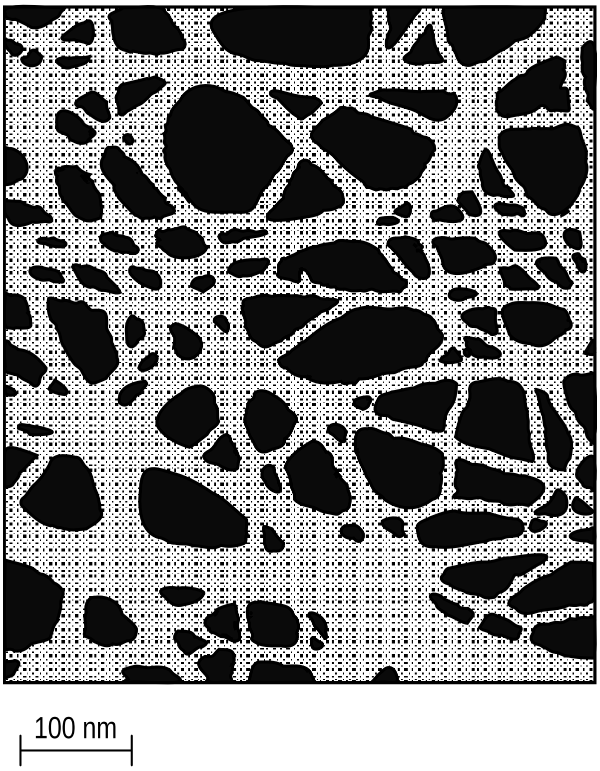

FIG. 1

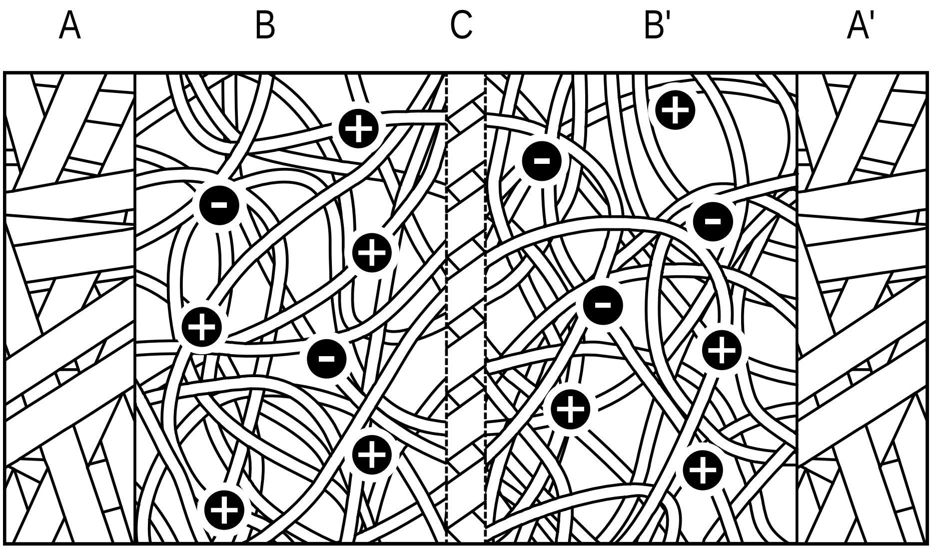

FIG. 2

<u>Document D1: Ecological face masks for protecting against COVID-19</u>

French company in Provence launches a new, fully biodegradable face mask based on natural hemp fibres.

[001] Cellulose fibres from cultivated plants like cotton, flax, hemp, etc., have good mechanical strength, hydrophilicity, and biocompatibility, can resist pathogens effectively, and can neutralise viruses.

[002] This makes them suitable for use in antifungal, antibacterial and antiviral filters.

[003] Face masks made of cellulose fibres from cotton, flax or hemp could thus be a potential substitute for face masks made from synthetic polymers.

[004] Face masks made from synthetic polymers can cause respiratory harm to a healthy wearer due to low breathability.

[005] It has been reported that cotton double-layer cloth can be about 75% as efficient as a surgical face mask for capturing small aerosols, while having much better breathability.

[006] The antiviral efficiency can be further enhanced by impregnation of the cotton cloth with an antiviral chemical substance bearing electrostatic charges, for example polyethyleneimine (PEI), by a process of adsorption by soaking.

[007] The enhanced ability to trap the virus is attributed to the electrostatic interaction between the positively charged PEI and the negatively charged virus surface.

[008] The impregnated cotton fabric is thus antiviral, and can be used to manufacture antiviral face masks.

[009] Building on this idea, cotton double-layer cloth face masks have been developed which are made of super-soft 100% organic cotton in a tightly knitted fabric.

[010] Hemp is another source of cellulose fibres having a large surface area for trapping microparticles and microbes.

[011] A 100% organic hemp face mask can protect the nose and mouth from inhaling aerosols with a 98% filtration efficacy guarantee for particles of 3 μm or above, while providing excellent air permeability and breathability.

[012] These biodegradable hemp face masks are composed of a single layer (thickness 2 mm) of 100% organic filtering felt made of compacted cellulose fibres from hemp without chemical treatment.

[013] In order to increase cohesion of the compacted cellulose fibres from hemp, a glue of natural origin such as gelatin or collagen is used as the only non-toxic, biodegradable additive.

[014] These face masks are ecological, biodegradable and washable, and they can be either disposed of or reused after disinfection in boiling water for 30 seconds.

[015] When disposed of, the face masks are completely compostable within three months.

[016] In addition to cultivated plants, agricultural waste rich in cellulose fibres can also be used as the starting material.

D1: Photo

<u>Document D2: EP 6 001 001</u>

Title: Reusable antiviral nanofilters based on cellulose acetate nanofibres

[001] Trilayer nanofilter systems are provided comprising a middle layer of a synthetic polymer, which is cellulose acetate, with a smooth ultrafine nanofibre structure.

[002] A solution of cellulose acetate at 2% by weight in trifluoroethanol (TFE) (caution: toxic solvent!) was prepared. Once dissolved, a nonwoven nanofibre layer (nanofilter) was manufactured by electrospinning.

[003] Electrospinning is a complex technique in which high voltage is applied to a polymer solution to form a fine filamentous structure. For this, an emitter voltage of 18kV and a collector voltage of -8kV were used, with a flow rate of 20 mL/h, through a linear multi-emitter injector.

[004] The cellulose acetate nanofibre layer was deposited on a rotating collector at a speed of 200 rpm at a distance of 20 cm. The rotating collector was covered with a biodegradable, 40 μm-thick, nonwoven, cotton spunbond fabric forming the first outer layer of the trilayer nanofilter system. The deposited cellulose acetate nanofibre layer (middle layer) had a thickness of about 8 μm. Then, another 40 μm thick nonwoven cotton spunbond fabric layer forming the second outer layer of the trilayer nanofilter system was placed over the cellulose acetate nanofibre layer to produce the final trilayer structure. Four-layer or five-layer nanofilter systems can also be produced using this process.

[005] The cellulose acetate nanofibre layer generated by electrospinning was studied by scanning electron microscopy (SEM). The cellulose acetate nanofibres form a network with an average pore size of between 80 nm and 100 nm, which can be used as a nanofilter.

[006] FFP2 respiratory face masks are manufactured using the nanofilter system described above.

[007] The FFP2 respiratory face masks are advantageous in that they can be washed and reused several times, thus reducing waste and plastic pollution.

Document D3: The Encyclopedia of Polymers – Cellulose acetate

[001] Cellulose acetate is one of the first synthetic fibres to have been derived from cellulose. It was first prepared by French chemist Paul Schützenberger in 1865 by chemical treatment of cellulose with acetic anhydride using organic solvents such as methylene chloride.

[002] Cellulose acetate fibres are used as a film base in photography and in the manufacture of cigarette filters.

Disposal and biodegradation:

[003] While it was initially believed that cellulose acetate was virtually non-biodegradable, it has been shown that the cellulose backbone can be broken down by enzymes present in the soil. In biologically highly active soils, cellulose acetate fibres can biodegrade after nine months.

[004] However, it is also well known that cigarette filters made of cellulose acetate fibres can take years to completely biodegrade in the open. This currently presents a significant environmental challenge worldwide.

Communication

1. The documents D1-D3 are prior art within the meaning of Article 54(2) EPC.

2. Search opinion under Rule 62(1) EPC:

The application and the invention to which it relates do not seem to meet the requirements of the EPC, for the following reasons:

3. The subject-matter of independent claim 1 is not novel within the meaning of Article 54(1) and (2) EPC.

3.1 D1 discloses biodegradable disposable antiviral face masks for protecting against COVID-19 comprising at least one layer comprising cellulose fibres, such as a cotton fabric, or a felt made of compacted cellulose fibres from hemp, acting as a filter layer.

Thus, claim 1 lacks novelty in view of D1.

3.2 Claim 1 defines “at least one filter layer comprising cellulose fibres”. The term “cellulose fibres” is a generic term encompassing any fibres derived from cellulose, including any processed cellulose fibres, or any synthetic cellulose fibres obtained by chemical treatment of cellulose.

D2 discloses a trilayer nanofilter system and FFP2 face masks comprising one filter layer of cellulose acetate nanofibres. The specific disclosure of cellulose acetate nanofibres in D2 falls within the terms of the generic concept “cellulose fibres” required in claim 1, and therefore takes away the novelty of a generic claim embracing that specific disclosure (Guidelines G-VI 5).

Furthermore, the feature “biodegradable” in claim 1 does not limit the subject-matter vis-à-vis D2. The term “biodegradable” is a broad functional term referring to a natural process of breakdown of an organic material by micro-organisms. Cellulose acetate nanofibres as disclosed in D2 are subject to biodegradation, the progression and extent thereof being merely a matter of environmental conditions and time (see D3).

Thus, claim 1 lacks novelty in view of D2.

4. Independent claim 11 contravenes Article 84 EPC.

Claim 11 requires “papermaking waste residues” as the starting material in the claimed process.

However, the “papermaking waste residues” are not further defined in the claim. The composition of the “papermaking waste residues” required in the process of claim 11 remains totally undetermined. Thus, claim 11 violates Article 84 EPC in that it does not clearly define the subject-matter for which protection is sought in terms of the essential features of the invention.

5. With regard to the dependent claims, the following is noted:

Claim 2: D1 further discloses cellulose fibres derived from cotton and hemp. Claim 2 lacks novelty (Article 54(1) and (2) EPC).

Claim 3: D2 further discloses one filter layer made of cellulose acetate nanofibres. Claim 3 lacks novelty (Article 54(1) and (2) EPC).

Claim 4: “Papermaking waste residues” is vague and undetermined. Claim 4 lacks clarity (Article 84 EPC).

Claims 5 and 6: D2 further discloses dust face masks of the FFP2 type. Claims 5 and 6 lack novelty (Article 54(1) and (2) EPC).

Claims 7, 9 and 10: D2 further discloses a trilayer FFP2 face mask comprising one outer layer with a thickness of 40 μm; one inner (middle) layer with a thickness of about 8 μm acting as a filter layer; and another outer layer with a thickness of 40 μm. D2 further discloses that the outer layers are made of nonwoven cotton fabric by spunbonding. Since D2 anticipates the material/composition of the outer layers as defined in present claims 9 and 10, it necessarily follows that D2 implicitly anticipates the functions thereof (water barrier and suitability for contact with the skin), as defined in claim 7, too. Claims 7, 9 and 10 lack novelty (Article 54(1) and (2) EPC).

Claim 8: In the application, no particular technical effect or advantage appears to be associated with a five-layer structure of the FFP2 face mask comprising two inner (middle) filter layers. A five-layer structure seems to be conventional in the art (see D2). As a consequence, this subject-matter does not seem to involve an inventive step (Article 56 EPC).

6. The applicant is invited to file new claims which take account of the above comments.

Care should be taken not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC). In order to facilitate the examination of conformity with the requirements of Article 123(2) EPC, the applicant is requested to clearly identify the amendments made, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate their basis in the application as filed (Article 123(2) EPC and Rule 137(4) EPC).

7. The new claims should fulfil all the requirements of the EPC with respect to clarity, novelty, inventive step, sufficiency of disclosure, and, if relevant, unity of the invention (Articles 84, 54, 56, 83 and 82 EPC).

For substantiation of compliance with Article 56 EPC in the letter of reply, the problem-solution approach should be followed. The difference between the claimed subject-matter and the closest prior art, the technical problem underlying the invention in view of the closest prior art, and the solution to this problem should be indicated.

<u>Client’s letter</u>

M&B Mascaretes de Paper
Alcoi

Mr Arturo Barea, Patentes
Calle de Alcalá 40
Madrid

Dear Mr Barea,

We have read the search opinion attached to the search report issued by the EPO. We are surprised that objections to patentability have been raised. It looks like the examiner did not make a sufficient effort to understand the invention.

Our invention is different from D1. The ecological face masks described in D1 are heavy and uncomfortable, they do not have the three-layer structure of our invention, and they do not provide high-efficiency filtration.

Our invention is also different from the invention described in D2, which uses synthetic polymer nanofibres in the nanofilter layer. The cellulose acetate described in D2 is obtained by chemical treatment of cellulose using hazardous chemicals comprising chlorine. Importantly, cellulose acetate cannot be regarded as biodegradable. We have carefully considered the examiner’s opinion, but we wish to stress that biodegradability can be measured and compared according to international standards. For example, a standard used by the EU is that more than 90% of the original material must be converted into CO_2, water and minerals by biological processes within six-to-eight months. Cellulose acetate does not pass this test. One does not have to be an expert to see this: cigarette butts (cigarette filters) made of cellulose acetate fibres accumulate in the environment and take years to degrade. This fact is also confirmed in D3 cited by the examiner.

We would also like to inform you that we have recently launched on the market FFP2 face masks according to the invention wherein the biodegradable nanofilter layer is made of cellulose nanofibres from hemp. We therefore need to have our invention solidly protected by the patent to stop competitors from selling similar products, such as FFP2 face masks comprising nanofilter layers made using other plant fibres.

Furthermore, we have carried out additional laboratory experiments to show the advantages of our invention as compared to the FFP2 masks described in D2 (which are available on the market under the commercial name Mickey-Mask®). We copy-pasted the experimental results below (mean values), which you may wish to file with your reply to the EPO.

Lung function parameters	Our invention	Mickey-Mask® (D2)
FVC (litre)	5.7	5.1
FEV1 (litre)	4.1	3.5
PEF (litre/second)	9.0	7.2
VE (litre/min)	**123.5**	**95**

The tests 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.

Again, one does not need to be an expert to see that the Mickey-Mask® (in our opinion a rather ridiculous name) does not compare to our invention. In the above table, ventilation (VE) is the most important parameter. A high VE value indicates a dramatic decrease in breathing resistance, correlating with excellent air permeability. We attribute the enhanced breathing comfort of our FFP2 face masks to the excellent mechanical properties of the biodegradable nanofilter layer according to our invention.

Finally, in order to emphasise the differences of our invention over D1 and D2, we propose to file the enclosed draft set of amended claims together with your reply. Since claims 4 and 11 were objected to as lacking clarity, we propose to cancel them in order to expedite the procedure, unless you see a better way.

Best regards,
Dr Krokovski

Enclosures: Draft set of amended claims
D4

Document D4: Provided with client's letter

Effects on lung function of wearing surgical and FFP2 face masks

Hofrat Dr. Behrens & Dr. Krokovski
Balmy Breezes International Sanatorium, Davos-Platz
Journal of Inhaleability Vol. 1, page 12 (2021)

Background

[001] Following the outbreak of the SARS-CoV-2 pandemic, use of face masks is widely recommended or even mandatory. Millions of persons are required to wear a face mask when they come into contact with other individuals for long periods of time. We have studied the effects of wearing disposable surgical and FFP2 face masks on lung function.

Materials and methods

[002] For the study, 12 healthy male volunteers (aged 32 to 44 years) were enrolled. Each subject performed three tests, one "no mask" (control), one with a surgical face mask, and one with an FFP2 mask. Lung function parameters were monitored according to known methods [1].

[003] We used typical and widely used disposable surgical face masks and FFP2 protective face masks comprising multiple layers of nonwoven synthetic polypropylene (PP) fibres available on the market (Kung-Fu Protection Technology Co. Ltd., China).

Results and discussion

[004] Table 1. Lung function parameters of health volunteers wearing a surgical mask or an FFP2 mask compared to no mask (control). Mean ± standard deviation. FVC (forced vital capacity), FEV1 (forced expiratory volume in 1 s), PEF (peak expiratory flow), VE (ventilation). Statistically significant differences compared to no mask (control) indicated by an *.

	No mask	Surgical mask	FFP2 mask
FVC (litre)	6.1 ± 1.0	5.6 ± 1.0 *	5.3 ± 0.8 *
FEV1 (litre)	4.3 ± 0.7	4.0 ± 0.7 *	3.7 ± 0.6 *
PEF (litre/second)	9.7 ± 1.6	8.7 ± 1.4 *	7.5 ± 1.1 *
VE (litre/min)	131 ± 28	114 ± 23	99 ± 19 *
Breathing frequency (breaths per min)	15 ± 2	13 ± 3	12 ± 3 *

[005] The use of face masks showed a marked effect on lung function.

[006] All lung function parameters were significantly lower with the use of a face mask as compared to wearing no face mask. The impairment was greater with the use of an FFP2 mask.

[007] The calculated ventilation rate (VE), which indicates the volume of air inhaled or exhaled from a person's lungs per minute, was significantly reduced with both types of face mask, especially when wearing an FFP2 mask, which resulted in a reduction of ventilation by 23% as compared to no mask.

[008] The reduction in ventilation (VE) was associated with a lower breathing frequency with a corresponding reduction in inhaled air volume.

[009] All participants reported consistent and marked discomfort wearing face masks, especially FFP2 face masks which were perceived as very uncomfortable, creating a feeling of strong breathing resistance.

[010] We conclude that wearing a disposable face mask has a marked negative impact on lung function and breathing comfort, both at rest and during exercise, which significantly impairs strenuous physical and occupational activities.

References

[1] Fikenzer S. et al. Clin Res Cardiol 109, 1522-1530 (2020)

Draft set of amended claims (marked up)

1. Biodegradable disposable respiratory face mask comprising at least one filter layer ~~comprising~~ made of cellulose nanofibres from hemp.

~~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.~~

~~4. The biodegradable disposable respiratory face mask according to claim 3 wherein the cellulose nanofibres are derived from papermaking waste residues.~~

~~5~~. 2. The biodegradable disposable respiratory face mask according to ~~any one of~~ claim~~s~~ 1 ~~to 4~~ which is a surgical face mask or a dust face mask.

~~6~~. 3. The biodegradable disposable respiratory face mask according to claim ~~5~~ 2 which is an FFP2-type face mask.

~~7~~. 4. The biodegradable disposable respiratory face mask according to claim ~~6~~ 3 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 filter layer; and at least another outer layer (A’) with a thickness of about 40 μm for contact with the skin.

~~8~~. 5. The biodegradable disposable respiratory face mask according to claim ~~7~~ 4 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).

~~9~~. 6. The biodegradable disposable respiratory face mask according to any one of claims ~~7 or 8~~ 4 or 5 wherein at least one layer is manufactured by conventional techniques for making nonwoven fabrics such as melt-blowing or spunbonding.

~~10~~. 7. The biodegradable disposable respiratory face mask according to any one of claims ~~7 to 9~~ 4 to 6 wherein the outer layers (A and A’) are made of nonwoven cotton or hemp fabric.

~~11. Process for manufacturing a biodegradable filter layer for a multilayer FFP2 type face mask, the process comprising: providing papermaking waste residues, milling using grinding balls, and casting into a thin nonwoven layer by melt-blowing or spunbonding.~~