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Datasheet for the decision of 3 June 2015

Case Number: T 0954/11 - 3.2.02

Application Number: 04724556.8

Publication Number: 1608268

IPC: A61B10/00, B01L3/00, C12M1/30, A61M35/00

Language of the proceedings: EN

Title of invention:
SWAB FOR COLLECTING BIOLOGICAL SPECIMENS

Patent Proprietor:
Copan Italia S.p.A.

Opponent:
JFA Flock-Applikationen GmbH

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 100(a)
RPBA Art. 12(4), 12(2)

Keyword:
Novelty - (yes)
Inventive step - (yes)
Late-filed evidence

Decisions cited:

Catchword:

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Case Number: T 0954/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 3 June 2015

Appellant: (Opponent)	JFA Flock-Applikationen GmbH Kunstwiesenweg 17 76456 Kuppenheim (DE)
Representative:	Reiser & Partner Patentanwälte Weinheimer Straße 102 69469 Weinheim (DE)
Respondent: (Patent Proprietor)	Copan Italia S.p.A. Via Perotti, 10 25125 Brescia (IT)
Representative:	Peterreins, Frank Peterreins Schley Patent- und Rechtsanwälte Söltlstraße 2a 81545 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 1 March 2011 concerning maintenance of the European Patent No. 1608268 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	C. Körber
	P. L. P. Weber

Summary of Facts and Submissions

I. On 1 March 2011 the Opposition Division posted its interlocutory decision concerning maintenance of European patent 1 608 268 in amended form according to the main request.

II. An appeal was lodged against this decision by the opponent, by notice received on 28 April 2011. The appeal fee was paid on 3 May 2011. The statement setting out the grounds of appeal was received on 1 July 2011.

III. By communication of 24 February 2015, the Board forwarded its provisional opinion to the parties and summoned them to oral proceedings.

IV. Oral proceedings were held on 3 June 2015.

The final requests of the parties were as follows:

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

The respondent (patent proprietor) requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of one of the auxiliary requests 1 to 11, all filed with letter dated 27 April 2015.

Furthermore, the respondent requested that documents D1 to D4, D17 to D19, D20a, D21a, D22a and D23a not be admitted into the proceedings.

V. The following documents are dealt with in the present decision:

D1: EP-A-0 643 131
D2: US-A-4749655
D3: US-A-5 009 846
D4: DE-U-298 09 833
D5: US-A-5 623 941
D6: US-A-4 767 398
D7: US-A-5 944 519
D8: US-A-3 163 160
D16: US-A-4 922 936
D17: Printout of a page entitled "Swab" from Wikipedia (last modified on 20 March 2010)
D18: Pages 8-2 and 14-19 of the proceedings of the 17th Int. Flock Symposium held on 31 March and 1 April 2003 in Dresden, Germany
D19: DE-A-36 19 033
D20a: F. Bader and F. Dorn (Eds.): "Physik Mittelstufe", Schroedel Schulbuchverlag, Hannover (1980), page 111
D21a: K. Gabler: "Untersuchungen zum elektrostatischen Beflocken", doctoral dissertation submitted at RWTH Aachen (1980), page 1 and table of contents
D22a: J. Bersev and U. Liebscher: "Elektostatisches Beflocken", Verlag Chemie, Leipzig (1983), page 15
D23a: "Bild 5: Flockdiagramm" presented by J. Hoffmann at a seminar entitled "Flocktechnologie" held from 17 to 19 April 1991.

VI. Claim 1 of the main request reads (with feature denotation used in the statement of grounds of appeal indicated at the left margin):

1.1 "A swab (20) for collecting biological specimens
1.2 comprising a rod (14) terminating in a tip (16)
1.3 covered with fibre (17)

1.4 with hydrophilic properties to allow absorption of said specimens
wherein
1.5 said fibre (17) covers said tip (16) in the form of a layer having uniform thickness
1.6 deposited by flocking in an ordered arrangement of the fibre normal to the surface of the tip (16) of the rod (14),
1.7 wherein said layer of fibre (17) has a thickness between 0.6 and 3 mm and
1.8 the fibre has a count between 1.7 and 3.3 Dtex."

Claims 2 to 5 are dependent claims.

Claim 6 of the main request reads:

"A device for collecting and transporting biological specimens comprising a test-tube (10) containing a culture medium (11), and a swab (20) as claimed in one or more of the preceding claims."

Claim 7 of the main request reads:

"A method for preparing a swab as claimed in one or more of the preceding claims, comprising the steps of applying an adhesive to the tip (16) of said rod (14) of said swab (20) to be covered by fibre (17), and subjecting said swab to flocking with the pre-selected fibre in an electrostatic field."

VII. The appellant's arguments are summarised as follows:

Document D17 should be admitted since it clarified the meaning of the term "swab". Document D18 was part of a symposium brochure which was handed out to the participants at the beginning of the symposium.

Document D7 anticipated all features of claim 1 of the main request. In particular, it disclosed features 1.4 and 1.5. Column 3, lines 1 to 5 gave fibre-count values falling within the range claimed in feature 1.8. The fibre count was the only parameter mentioned in the patent in suit with regard to the hydrophilic properties claimed in feature 1.4. The small fibre counts disclosed in D7 permitted a high number of fibres per surface area and thus disclosed feature 1.4 implicitly. The fibre layer shown in Figure 14 had a uniform thickness. Moreover, flocking fibres were always supplied on the market in standardised batches of uniform fibre length and count ("Sackware"). With the fibres being of a uniform length, the fibre layer was necessarily of uniform thickness. Moreover, in line 4 of column 3 reference was made to a "preferred" fibre length of 0.5mm, which implied that all the fibres had the same length.

The features of claim 1 were also anticipated by D16. As argued with respect to D7, the fibre counts disclosed in D16 were also small enough to permit a high number of fibres per surface area, thus disclosing feature 1.4 implicitly. A layer of uniform thickness was depicted in Figures 1 to 3 of D16. Moreover, uniform flocking was explicitly mentioned in lines 63 and 64 of column 2.

Claim 10 of D16 disclosed electrostatic flocking such that the subject-matter of claim 7 of the main request was also anticipated by this document.

The only feature of claim 1 not disclosed in D5 was the fibre-count range defined in feature 1.8. The larger fibre count disclosed in D5 implied a rigid, brush-like character of the swab. Since it was known that sampling

with stiff and rigid bristles caused pain, the skilled person would be motivated to look for softer swabs, as indicated in lines 21 to 27 of column 1 and lines 44 to 47 of column 3 of D5. The issue of pain or discomfort for the patient was also addressed in paragraph [0031] of the patent is suit. Since the skilled person knew that softness was related to the fibre count for a given length, he would obviously reduce the fibre count. Flocking fibres were only available in batches with certain fibre counts, as evidenced by D18. In all the examples described in D19 a fibre count of 3.3 Dtex was used. Accordingly, it was obvious to use a fibre count as claimed in feature 1.8 in order to obtain a softer swab which was less painful.

Moreover, D3, which was in the same technical field as D5, disclosed hydrophilic fibres with good absorption properties (column 3, lines 10 to 11 and 65 to 66). In line 19 of column 3 a fibre count of 1.7 Dtex was mentioned as particularly advantageous in that respect. The skilled person would thus take into consideration D3 and arrive in an obvious manner at the subject-matter of claim 1.

Furthermore, D6, D7 and D16 all disclosed swabs with soft fibres having counts falling within the range claimed in feature 1.8. It was obvious that the swabs for use in the oral cavity disclosed in D7 and D16 had to be soft in order to avoid injury. In order to be able to achieve the desired purpose of removing food particles or plaque, the fibres disclosed in D7 and D16 also had to be suitable for picking up and retaining biological material. Accordingly, when starting from D5 the subject-matter of claim 1 was also not inventive in view of these documents.

Documents D1, D2 and D8 all disclosed devices for collecting and transporting biological specimens comprising a test-tube containing a culture medium with a swab introduced into it. Consequently the subject-matter of claim 6 of the main request was obvious from these documents in view of D3, D7 and D16.

Since document D16 disclosed the application of flock fibres in an electrostatic field, the subject-matter of claim 7 of the main request was obvious in view of D5, where electrostatic flocking was also explicitly described in Figures 12 to 16.

VIII. The respondent's arguments are essentially those on which the following reasons of this decision are based. Documents D1 to D3 were not used or discussed during the opposition proceedings and should thus not be admitted. D19 was entirely irrelevant. D20a, D21a, D22a and D23a were filed late with appellant's letter of 6 November 2014 and should also not be admitted.

Reasons for the Decision

1. The appeal is admissible.

2. Admissibility of documents

Document D4 was merely cited as such in the opposition brief. No reference was made to it in the statement setting out the grounds of appeal. In neither the opposition nor the appeal proceedings were any arguments based on this document brought forward. Under Article 12(4) RPBA, a document that is merely mentioned and not substantiated in any way cannot be considered in the appeal proceedings since the conditions of Article 12(2) RPBA are not fulfilled. Moreover, D4

relates to a weighing apparatus with linkages for ensuring parallel motion. The Board does not see how this document could be of any relevance for the present case.

Documents D17 and D18 were filed with the statement of grounds of appeal. The publication date of D17, cited with respect to the meaning of the term "swab" in claim 1, is well after the priority date of the patent in suit. D18 was cited in order to show that flocking materials were only available with certain concrete fibre counts. The document comprises two pages relating to a symposium entitled "FLOCK 2003" held on 31 March and 1 April 2003, the latter date being the priority date of the patent in suit. No evidence was submitted by the appellant to prove its assertion that the information comprised in the two pages was presented to the audience before the priority date or that the whole symposium brochure was handed out to the participants at the beginning of the symposium. Accordingly, it cannot be established beyond reasonable doubt that the two pages were made available to the public before the priority date. Accordingly, D17 and D18 do not form part of the prior art in the sense of Articles 54(1) and (2) and 56 EPC. Under these circumstances, their teachings cannot be used for the assessment of patentability.

Consequently, documents D4, D17 and D18 are not admitted into the proceedings.

The fact that D1 to D3 (filed with the notice of opposition) were not discussed during the opposition proceedings does not mean that these documents are not to be admitted into the appeal proceedings. D19 was filed with the statement setting out the grounds of

appeal. D20a, D21a, D22a and D23a were filed by the appellant in order to document technical background knowledge. Accordingly, the Board sees no valid reason not to admit these documents.

3. Novelty – main request

Before considering novelty the Board would point out that the term "hydrophilic" in feature 1.4 of claim 1 is not to be understood in the usual sense of a material property of the fibres themselves. As explained in paragraphs [0021] to [0023] of the patent in suit, it is rather the capillarity in the interstices between the fibres forming the layer by virtue of which the absorption of the specimens is achieved. Such "hydrophilic properties" by capillarity can even be achieved with fibre materials which are themselves hydrophobic, as in some of the examples mentioned in paragraph [0023]. Even though the surface density, i.e. the number of fibres per surface area, is nowhere specified in the patent in suit, this kind of hydrophilicity requires a relatively dense spacing of the fibres, which is also reflected by the fact that feature 1.3 specifies that the tip is "covered with fibre".

3.1 Document D7

Document D7 relates to an oral cleaner (Figure 14) comprising a rod (131) terminating in a tip (132) covered with an inner resilient layer (206) and an outer resilient layer (207), both made of foam (paragraph bridging columns 6 and 7), with flock fibres being applied to the outer layer (column 6, line 58).

As admitted by the appellant, it is not explicitly disclosed that the flock fibre layer has hydrophilic properties to allow absorption as defined in feature 1.4 of claim 1. However, according to the appellant, D7 discloses in column 3, lines 1 to 5 fibre-count values within the range claimed in feature 1.8, such small fibre counts permitting a high number of fibres per surface area and thus disclosing feature 1.4 implicitly. The Board does not follow this line of reasoning. From the paragraph bridging columns 6 and 7 it becomes clear that it is mainly the outer foam layer (207) that absorbs the water (**through** the "layer" of flock fibres). Moreover, it is stated in lines 23 to 26 of column 3 that the aim of D7 is to have few fibres remaining on the foam after the flocking process. This corresponds to what is shown in Figure 14 and indicates a relatively low rather than a high fibre density (as required for hydrophilicity). Accordingly, feature 1.4 is not directly and unambiguously derivable from D7.

There is also no explicit disclosure in D7 that the fibre layer has a uniform thickness, as required in feature 1.5. Figure 14 is only a schematic drawing which does not make it possible to clearly and unambiguously derive that the fibre "layer" is of uniform thickness. Claim 1 of D7 discloses that the flock fibres are from about 0.2 to about 1.5 mm long. This, however, does not imply that all fibres have a uniform length. The appellant's argument that a uniform length is implied by the fact that flocking fibres were always supplied on the market in standardised batches of uniform fibre length and count ("Sackware") is entirely speculative, since no evidence was presented that this was actually the case at the publication date of D7. In the second paragraph of column 3 of D7 a preferred fibre length of 0.5 mm is mentioned, which

might imply a uniform length (and layer thickness, if all the fibres are oriented normal to the surface of the underlying foam layer, and if the relatively small number of fibres per surface area can be regarded as forming a "layer"). However, this specific value is only disclosed in combination with a specific fibre count of 1.7 Dtex which does not fall inside the range claimed in feature 1.8. Hence even if this passage clearly and unambiguously disclosed a uniform thickness, feature 1.4 would not be disclosed in combination with feature 1.8.

Accordingly, the subject-matter of claim 1 is distinguished over D7 by (at least) features 1.4 and 1.5.

3.2 Document D16

D16 relates to a dental cleaner (Figure 1). Its tip (3) is directly covered with a flock coating (2). Again it is not explicitly disclosed that the flock fibre layer has hydrophilic properties to allow absorption as defined in feature 1.4 of claim 1. The appellant essentially repeated its argument presented in relation to D7, i.e. that D16 discloses small fibre-count values, permitting a high number of fibres per surface area, and thus anticipates feature 1.4 implicitly. However, D16 does not say anything about fibre surface density, and does not address hydrophilicity or absorption at all. Under these circumstances, feature 1.4 is not directly and unambiguously derivable from D16.

With regard to feature 1.5, D16 refers to a "flock coating" in lines 45 to 46 of column 2, which may be equated to a "layer" as stated in feature 1.5. In

relation to the requirement of uniform thickness of this layer, the appellant referred to Figures 1 to 3 of D16. In this respect, it is again noted that these drawings are schematic and thus not suitable for deriving the feature of uniform thickness. Moreover, the teaching of D16 is even to the contrary, because it explicitly discloses (column 2, lines 8 to 10 and 53 to 55) that the fibres are of different lengths, resulting in a layer of non-uniform thickness. The term "uniformly flocked" in lines 62 to 64 of column 2 does not imply a uniform thickness since it is specified as "over a length of about 5 cm", i.e. over a certain length of the wire-shaped support in Figure 5. It follows that D16 also fails to disclose feature 1.5 of claim 1.

Accordingly, the subject-matter of claim 1 is distinguished over D16 by (at least) features 1.4 and 1.5.

Claim 7 relates to a method for preparing a swab "as claimed in one or more of the preceding claims". Accordingly, a method disclosed in the prior art must result in a swab as claimed in claim 1 in order to anticipate the subject-matter of claim 7. Since D16 fails to disclose a swab as defined in claim 1 as indicated above, it cannot anticipate the method of claim 7 either.

3.3 It follows that the ground of opposition under Article 100(a) EPC of lack of novelty (Article 54 EPC) does not prejudice the maintenance of the patent in amended form on the basis of claims 1 to 7 of the main request.

4. Inventive step – main request

4.1 Document D5 relates to a device for collecting biological material and retaining it for transfer from a collection site to a deposit site where it may be subjected to further analysis, as described in column 1, lines 9 to 32, dealing with the background of the invention of D5, where such devices are referred to as brushes or swabs. Accordingly, the overall goal and usage is basically similar to that described in paragraph [0005] of the patent in suit. For this reason and since it shares most features of claim 1, D5 forms the closest prior art, even though the device claimed in D5 is always referred to as a "brush", rather than a swab as claimed. D7 and D16, which relate to oral and dental cleaners, are more remote since they do not relate to collection devices.

4.2 D5 fails to disclose feature 1.8 of claim 1. This was not disputed by the parties. The smallest fibre diameter disclosed in D5 is about 0.06 mm (column 6, lines 1 and 56), corresponding to 35.8 Dtex for nylon as stated by the respondent and not disputed by the appellant, which is far removed from the claimed range of between 1.7 and 3.3 Dtex (corresponding to about 0.014 and 0.019 mm for nylon, the preferred material of D5 as indicated in column 6, lines 9 to 11).

4.3 By virtue of feature 1.8 (in combination with features 1.4 and 1.7) it is possible to achieve what the respondent refers to as "quantitative" analysis, i.e. collecting a large amount of specimen by absorption into the capillary interstices between the fibres and retaining it therein, e.g. for transport (which may involve mechanical vibration etc.), and then releasing

essentially the same quantity by "swabbing" for subsequent analysis, as credibly explained in paragraphs [5], [21], and [30] of the patent in suit.

4.4 The objective technical problem underlying feature 1.8 is to provide a swab which is more effective for specimen collection and handling. This problem is clearly derivable from the description of the patent in suit as indicated above. It is more ambitious than simply further increasing the softness in order to reduce pain for the patient, as stated by the appellant. As explained below, there is no reason to further reduce the softness of the brush of D5 since the disclosed values represent a compromise between softness and scraping ability. The hint in column 6, lines 4 to 8 of D5 to make the surface of the fibres hydrophilic in order to improve the collection and retention of material between the fibres suggests an approach different from that taken according to the invention, as explained above in the first paragraph of point 3.

4.5 The Board shares the respondent's view that D5 even teaches away from substantially reducing the fibre count or diameter of the disclosed flocked brush towards the claimed range, as will be explained in the following.

D5 aims at providing a soft brush (column 1, line 60) (in relation to previously known brushes) having "very thin bristles" (see column l, line 58) causing "less pain when sampling" (column 3, lines 43 to 47), but defining at the same time a "rough brushlike surface" (column 2, line 29) and most important, being also "effective as far as scraping" (column 4, lines 43 to 45). The teaching is that a compromise has to be

found between the thinness and the rigidity of the bristles, to guarantee softness but at the same time a sufficient scraping effect, as stated in column 4, lines 43 to 55 ("The brush of the invention is kind to tissues and at the same time is effective as far as scraping of secrete, surface fragments or cells is concerned") and also derivable from column 1, lines 15 to 27. Accordingly, scraping ability is very important and an essential feature of the device disclosed in D5. Scraping ability clearly requires a sufficient rigidity of the bristles, which is directly correlated to the fibre diameter, i.e. the fibre count (for a given length and material).

There is no teaching or hint in D5 to reduce the fibre diameter to values below the above-stated value of 0.06 mm (corresponding to about 36 Dtex for nylon, as indicated above). In column 3, lines 65 to 66 a much larger value of 0.12 mm is mentioned (corresponding to about 130 Dtex) in combination with a fibre length of 2 mm. In column 6, lines 1 to 5, a value of 0.063 mm is indicated in addition to 0.060 mm, both in combination with a range of lengths from about 0.5 mm to 1.5 mm. In the diagram of D23a, these values are clearly located well within the rigid region ("hart, bürstenartig"). This is consistent with the fact that D5 always refers to its invention in terms of a "brush". Reducing the fibre count by a factor of more than ten to the claimed range of between 1.7 and 3.3 Dtex in combination with the above-mentioned length range disclosed in D5 would result in a shift entirely outside the rigid region of D23a, mostly into the soft region ("weich, loser Flock, watteartig"). Under these conditions, the desired rigidity and scraping ability would be lost. For this reason, D5 teaches away from feature 1.8.

4.6 It follows that the skilled person starting from D5 as closest prior art would not consider the teaching of D3 (which discloses in line 19 of column 3 a Dtex value of 1.7, yet without mentioning any particular advantages associated therewith). It is further noted that the absorption properties mentioned in this document are due to the hydrophilicity of the fibre material (e.g. column 3, lines 8 to 11). D7 (column 3, lines 1 to 9) and D16 (column 1, lines 64 to column 2, line 1) also do not address any particular advantages associated with the disclosed fibre counts. Moreover, these documents relate to oral and dental cleaners, thus raising the additional question of whether their teaching would even be taken into account by the skilled person starting from D5 which deals with a collection device. Similarly, D6 discloses a swab, for applying cosmetics, flocked with fibres of about 1 to 1.5 denier (corresponding to about 1.1 to 1.7 Dtex, the upper value thus also coinciding with the lower limit value of the range claimed in feature 1.8), which range was found suitable for spraying the fibres onto an adhesive (column 2, line 65 to column 3, line 2), thus also not addressing the above-mentioned objective technical problem. D19 only demonstrates the commercial availability of flocked fibres of a count of 3.3 Dtex, i.e. the upper limit value of the claimed range, yet in an entirely different field of application, as indicated in the abstract, and without addressing any advantages achievable thereby. Accordingly, the subject-matter of claim 1 is not rendered obvious in view of these documents.

4.7 With regard to claim 6, the appellant cited documents D1, D2 and D8 as examples disclosing devices for collecting and transporting biological specimens comprising a test-tube containing a culture medium with

a swab introduced into it, and argued that the subject-matter of claim 6 was rendered obvious in view of D3, D7 and D16. However, this argument must already fail since, as none of these documents discloses or suggests a swab according to claim 1 (which also forms part of claim 6), their combination cannot lead in an obvious manner to the subject-matter of claim 6.

With regard to claim 7, the appellant cited document D16 as disclosing the application of flock fibres in an electrostatic field and argued that the subject-matter of claim 7 was obvious in view of D5 where electrostatic flocking is also explicitly described in Figures 12 to 16. However, a method disclosed in the prior art must also render obvious a swab as claimed in claim 1 in order to anticipate the subject-matter of claim 7. Since the combination of D5 and D16 does not lead to a swab according to claim 1, as indicated above, it cannot render obvious the method of claim 7 either.

4.8 It follows that the ground of opposition under Article 100(a) EPC of lack of inventive step (Article 56 EPC) does not prejudice the maintenance of the patent in amended form on the basis of claims 1 to 7 of the main request.

5. Since the patent can be maintained on the basis of the main request it is not necessary for the Board to deal with the auxiliary requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated