Candidate's answer

Facts and Arguments

Effective Dates:

All claims 1-7 have filing date of 29.5.2008 as effective date, as no priority is claimed

List of evidence

All Annexes (A) A2-A6 are published before filing date A1, all are thus prior art under Art. 54(2)

Objections under Art. 100(a)

I.A. Claim 1 not novel over Annex A3

A3 discloses in [4] a cosmetic patch (30), which is a <u>patch</u>, composed of at least three layers, thus <u>multi-layered</u>, comprising a depot layer (31) constituted from a polymeric matrix layer storing an anti-wrinkle compound, such compound is an <u>active ingredient</u> according to [4], [13] of A1, suitable to be <u>delivered to the skin</u> ("to be" is construed as "suitable to be", GL C-III, 4.13; C-IV, 9.7) according to [3] of A3, the compound being stored in the depot layer from a polymeric matrix makes the depot layer a storage layer according [5] of A1,

- an adhesive layer (32), and
- a fabric carrier (33), which is a <u>textile</u> according to the definition given in [5] of A1, the carrier also being a <u>layer</u> according to [4] of A3 ("three <u>layers</u>")

I.B. Claim 1 not novel over A5

A5 discloses in [4] a deodorant patch, which is a <u>patch</u>, having a matrix layer (53) an adhesive layer (52) a release layer (51), a fibre layer (54), and a polymeric layer (55), thus multi-layered

- the polymeric matrix layer (52) enclosing, i.e. comprising, a perfume composition which is liberated, i.e. released, during use, and which is thus an active ingredient according to [5] of A1 because it has a pleasant smell, and is suitable to be delivered to the skin also according to [2] of A5 (Roll-ons, etc. are applied to the skin), the ingredient being enclosed in the polymeric matrix prior to liberation makes the matrix layer (52) a storage layer in the sense of [5] of A1,
- an adhesive layer (52), and
- a nonwoven fibre layer (54), which is a textile layer according to [5], lines 5-7, of A1.

II. Claim 2: not inventive over A2 with A6

- A2 is closest prior art, as it is only Annex which discloses a patch suitable for wound healing, i.e. directed to same purpose as claim 2 ("for" is construed as meaning that the patch must be "suitable for", GL C-III, 4.13; C-IV, 9.7)
- 2. A2 discloses a wound dressing (title) suitable for wound healing ("promotes wound healing" [2], and [7] of A2), the dressing having a size suitable to provide a margin around the wound ([2]), it is thus construed to have the form of a patch, it is formed from several layers ([1]), thus multi-layered, having a polymeric layer containing a wound healing compound absorbed therein ([7]), the compound being in use delivered to the skin ([8]). The compound is thus an active ingredient in the sense of [5] of A1, and the polymeric layer is a storage layer ([5] of A1: "Any layer which can be loaded or soaked ...") The patch further comprises an adhesive layer (23).

Moreover, the patch delivers, i.e. releases, 7-8 mg/cm² per hour of active ingredient ([8]), which falls in the range of 5-10 mg/cm² per hour.

Difference features: According to claim 2, the patch comprises a textile layer.
 The patch according to A2 comprises instead a backing layer (22) from a thin elastic sheet ([5] of A2).

4. Technical effect:

According [3] and [5] of A1, textile layer acting as a support makes patch both highly flexible and highly mechanically stable. Same effects are to an extent also present in backing layer according [5] of A2 ("elastic" "does not easily tear").

- 5. Problem thus: Finding a support layer with improved properties
- 6. Skilled person would read A6, as it also relates to a patch that is applied to the skin, and in particular to the support structure of such a patch, which fits the problem.
- 7. A6 teaches in [7] to use <u>textile layer</u> (63) as carrier, i.e. as support
- 8. This has effect to provide mechanical stability to prevent tearing ([7] of A6), also provides flexibility ([9] of A6). In addition, it provides protection from mechanical impact, which is an improvement over the backing layer of A2, motivating the skilled person to use the textile layer instead
- 9. A6 also refers to patches for therapeutic applications in [3], thus the skilled person would see no problem in using this textile layer in a patch according A2, giving a patch according to claim 2.

III. Claim 3: Not inventive over A4 with A6

- 1. A4 closest prior art as it only Annex which is directed to the purpose of alleviating pain ([1] of A4).
- 2. A4 discloses an analgesic dressing ([3]), which is placed onto skin and held there by user, it is thus implied to have the form and function of a patch, comprising several layers (claim 1) thus multi-layered, the layers comprising:
 - a storage layer (41) comprising a wax-encapsulated analgesic agent (42), an analgesic agent is a pain alleviating agent that blocks the perception of pain ([1]), it is thus suitable for alleviating pain, moreover the storage layer with the wax capsules stores the agent and releases it in use according [3] of A4, it is thus a storage layer in the sense of [5] of A1 ("Any layer which can be loaded ..."), and the analgesic agent is an active agent in the sense of [5] of A1,
 - a textile layer (43) (claim 1 of A4), and
 - a hydrogel layer (44) (claim of A4)
- 3. <u>Difference features:</u> Claim 3 specifies the patch to also have an <u>adhesive</u> <u>layer</u>. In A4, the patch is simply held by user.
- 4. <u>Technical effect:</u> The effect of the adhesive layer is the same as the user holding it, namely to adhere the patch to the skin ([9] of A1 and [3] of A4)
- 5. Problem thus: Provide an alternative way of adhering the patch
- 6. Skilled person would read A6, as it also relates to patches that adhere to the skin
- 7. A6 teaches to use adhesive layer as alternative to user holding it ([3] of A6).
- 8. Moreover, the adhesive layer is disclosed to be most convenient for the user, giving motivation to use this instead
- Skilled person would see no problem of adding adhesive layer of A6 to patch
 of A4, as A6 also refers to patches for therapeutic purposes in [3], and
 patches having a hydrogel layer in [10], thus resulting in a patch according
 claim 3

IV. Claim 4: Not inventive over A3 with A4

1. A3 is closest prior art as it is only Annex directed to patch for treating wrinkles, which is purpose of claim 4

- 2. A3 discloses the features of claim 1, see I.A., and further the active ingredient being a anti-wrinkle compound suitable to reduce the presence or appearance of facial wrinkles [2], thus it is suitable for treating wrinkles in the sense of [4], [13], [14] of A1
- 3. Difference features: In claim 4, patch comprises hydrogel layer.

4. Technical effect of difference:

According [14] of A1: hydrogel layer enhances transport of active ingredient to skin by formation of a hydrophilic bridge, which enhances wrinkles reduction.

- 5. <u>Problem thus:</u> To enhance transport of active ingredient to skin to enhance wrinkle reduction. The desirability of this is also mentioned in [3], [5] of A3.
- 6. Skilled person would read A4, as it also relates to patches that deliver an active ingredient to the skin ([1] of A4)
- 7. A4 teaches in [5], [6] to use a hydrogel layer ...
- 8. ... to improve the transport of active ingredients due to the formation of a hydrophilic bridge ([5]), which is the desired effect.
- 9. Skilled person would see no problem in adding such a hydrogel to the patch of A3, as A4 states it to be usable for all types of active ingredients ([5] of A4), thus leading to a patch according to claim 4.

V. Claim 5: Not novel over A3.

A3 discloses in addition to the features of claim 1, see I.A., also that the fabric, i.e. textile layer comprises a perfume composition ([6] of A3), thus a perfume, in order to mask any unpleasant odour of the depot layer or to provide a pleasant smell. It is thus suitable as a deodorant in the sense of [10] of A1. The formulation "for use" in claim 5 is here construed as "suitable for" in the sense of GL C-III, 4.13; it cannot be interpreted as indication of therapeutic use in the sense of Art. 54(4), as the use is non-therapeutic [T9/81], the formulation implies thus no additional limitations in the sense of G2/08b.

VI. Claim 6: Not inventive over A4

1. A4 closest prior art, as it also relates to hydrogel layer, which is directed to same purpose as in A1, namely to enhance transport of active ingredient by formation of hydrophilic bridge [5] of A4

- 2. A4 discloses hydrogel suitable for use in patch according claim 4, see IV.9., the hydrogel comprising ([7]): water, starch to form a stable gel structure, alcohol, and silver particles in an amount of 40-60 g per 200 g hydrogel, thus 20-30 g per 100 g, thus 20-30 % by weight, which falls within range of 10-30 of claim 6.
- 3. <u>Difference features:</u> In claim 6, gelatine is used instead of starch.
- 4. <u>Technical effect:</u> Effect is the same, provide a gel structure / gelling agent. No additional effect is disclosed in A1.
- 5. Problem thus: Provide an alternative gelling agent.
- 6, 7, 8. A4 discloses additionally that gelatine is an alternative gelling agent in [5].
- 9. Skilled person would thus see gelatine as an obvious alternative, thus giving a hydrogel according claim 6.

VII. Claim 7: not inventive over A6 with A5

- A6 closest prior art, as it explicitly refers to a carrier, i.e. support structure for a patch, moreover it is directed to same purpose as claim 7, as stated in [11] of A1, namely to provide more versatility by first preparing the support structure ([11] of A6), which can then be combined with various other layers ([10] of A6)
- 2. A6 discloses in [11] a manufacturing process for a carrier structure, i.e. a support structure because suitable to support a patch (title), wherein the following layers are laid on top of each other ([4] and figure of A6): release layer (61), adhesive layer (62), textile layer (63), melt adhesive layer (64), perforated layer (65). The layers are placed i.e. laid) on top of each other according to their numbering ([11] of A6)
- b) the layers are pressed together ([11] of A6)
- Difference features: According claim 7, the process includes the step that the structure is then cured.
- 4. <u>Technical effect:</u> improves the structural integrity thereby reducing likelihood of separation of layers ([11] of A1).
- 5. Technical problem: Reduce likelihood of layer separation
- 6. Skilled person would read A5, as it relates to a patch with several layers, and a carrier structure (carrier sheet)

- 7. A5 teaches to thermally treat the patch at elevated temperature after adhering the layers together ([6] of A5), i.e. <u>cured</u> in the sense of [11] of A1.
- 8. This has effect to enhance adhesive strength of adhesive layers and avoids separation problem, which is the desired effect.
- 9. Skilled person would see no problem in adding this step to the process of A6, as A5 states in [6] that this step can be used with the desired effect irrespective of the structure of the layers present, thus giving a process according claim 7.

EXAMINATION COMMITTEE II

Candidate No.

Paper C 2012 - Marking Sheet

Category	Maximum	Marks awarded	
	possible	Marker	Marker
Use of information	42	29	30
Argumentation	58	41	43
Total	100	70	73

Examination Committee II agrees on 72 marks and recommends the following grade to the Examination Board:

X PASS (50-100)	COMPENSABLE FAIL (45-49)	FAIL (0-44)
28 June 2012		

Chairman of Examination Committee II