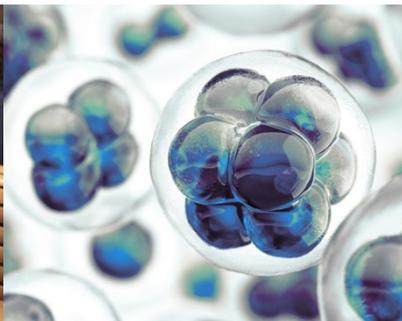




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Examination Matters reloaded

Borderline cases in cosmetics



Presenter



Ilknur Durand-Oral

- Master in Organic Chemistry, Food Engineering
- Examiner at the EPO since 2008 in HBC, Cosmetics
- Active in discussions about patentability of medical indications in cosmetics within the EPO and with external stakeholders
- EPO Talent Academy instructor



Presenter

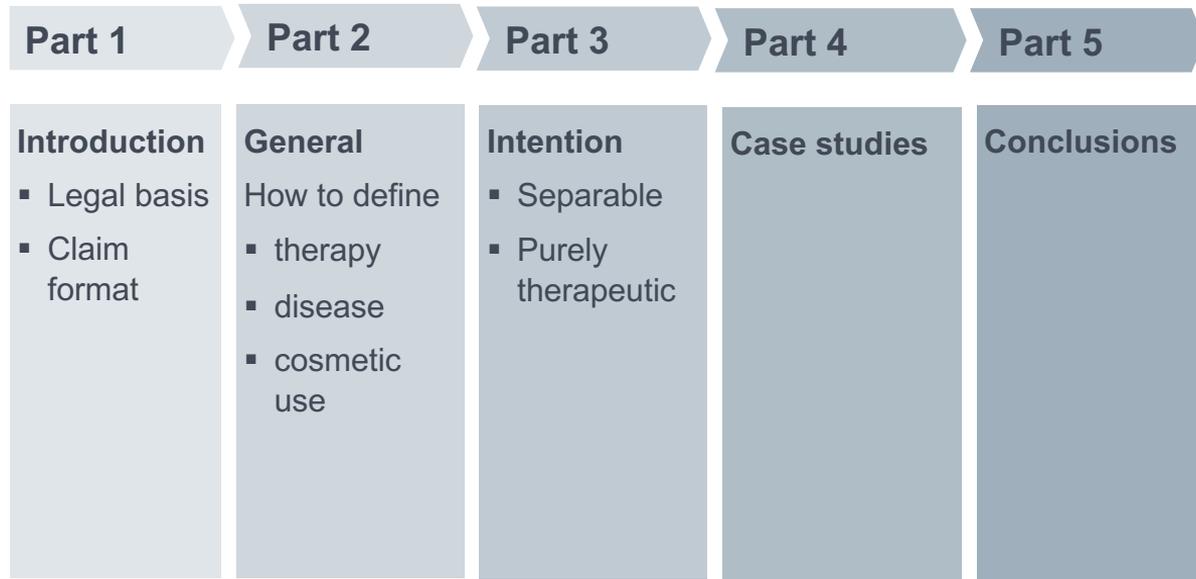


Inma Estañol

- PhD in Pharmacy/Microbiology,
Master in Nutraceuticals, CEIPI
- Examination and Opposition (multi-party
complex cases, Chairperson)
- More than 25 years representing the EPO
in symposia and events related to the
patentability of medical indications
worldwide
- CKT lecturer & WIPO expert



Objectives: Medical use aspects in patent applications in the field of cosmetics



Overview

- Introduction
- Cosmetic vs. therapeutic claims
- Legal basis
- Allowable claim formats for therapeutic treatment
- How to define therapy/disease
- Intention: Is there a therapy/disease?
- Claims and scope
- Intention
- Conclusion
- Borderline cases
- Case studies
- Conclusions

1. Introduction

- Cosmetic vs. therapeutic claims
- Legal basis
- Allowable claim formats

1. Cosmetic vs. therapeutic claims

Claims directed to *cosmetic uses*

Claims directed to *therapeutic uses* – in the "cosmetic" field often overlap or are difficult to separate

Why it is so important to be able to separate?

- Difference in legal interpretation
- Claims must be drafted in a different way

1. Legal basis

Article 53(c) EPC

Exclusion of patentability of methods of treatment

To ensure that the physician is not hindered in the practice of medicine

Article 54(4) and (5) EPC

Allows claims to a substance or composition for use in medicine (first time or in a further medical use): **purpose-limited product claim**

Guidelines for Examination

Therapy implies the curing of a disease or malfunction of the body and covers prophylactic treatment, e.g. immunisation against a certain disease (see [T 19/86](#)) or the removal of plaque (see [T 290/86](#)) (GL G-II 4.2.1.2).

1. Allowable claim formats for therapeutic treatment

- Purpose-related product claim (or Swiss-type format)*:
 - the therapeutic indication is a functional feature – implications under Art. 83 EPC – Plausibility
- Compound X **for use as** a medicament
- Compound X **for use in** the treatment of acne
- *Use of compound X for the preparation of a composition for use in the treatment of acne (only for applications/patents with filing/priority date before 29 January 2011)

2. How to define therapy/disease (1/4)

- Understanding the meaning of these terms in general
- Understanding the meaning of these terms in the light of the EPC
- Strategy to follow

2. How to define therapy/disease (2/4)

What do *these words* commonly mean?

- Therapy literally means "curing", "healing" and is
 - the attempted remediation of a **health problem**
 - a treatment to **cure** or **improve an illness, a disease** or **any pathological condition**.
- A disease is an **abnormal** condition that affects the body of an organism:
 - refers to a condition that causes **pain, dysfunction, distress**, social problems, or **death** to the person afflicted.
 - sometimes includes **injuries, disabilities, disorders, syndromes, infections, isolated symptoms**, deviant behaviours, and **atypical variations of structure and function**.

2. How to define therapy/disease (3/4)

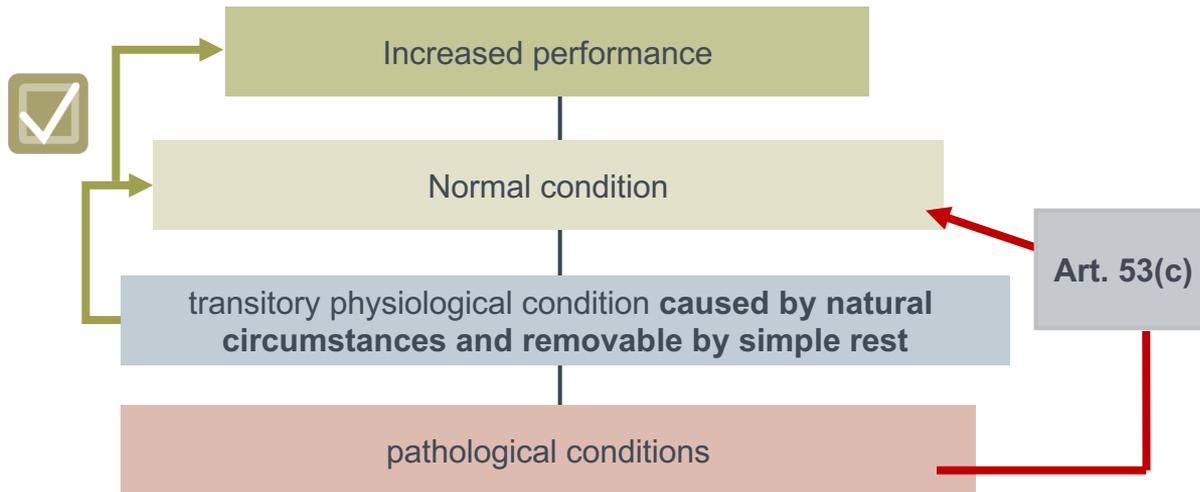
What do the EPC and the Guidelines say?

- Therapy:
 - treatment of a disease in general or
 - a curative treatment in the narrow sense as well as the alleviation of the symptoms of **pain** and **suffering or any disorder or malfunction of the human or animal body**Both prophylactic and curative methods of treating disease are covered by the word therapy.

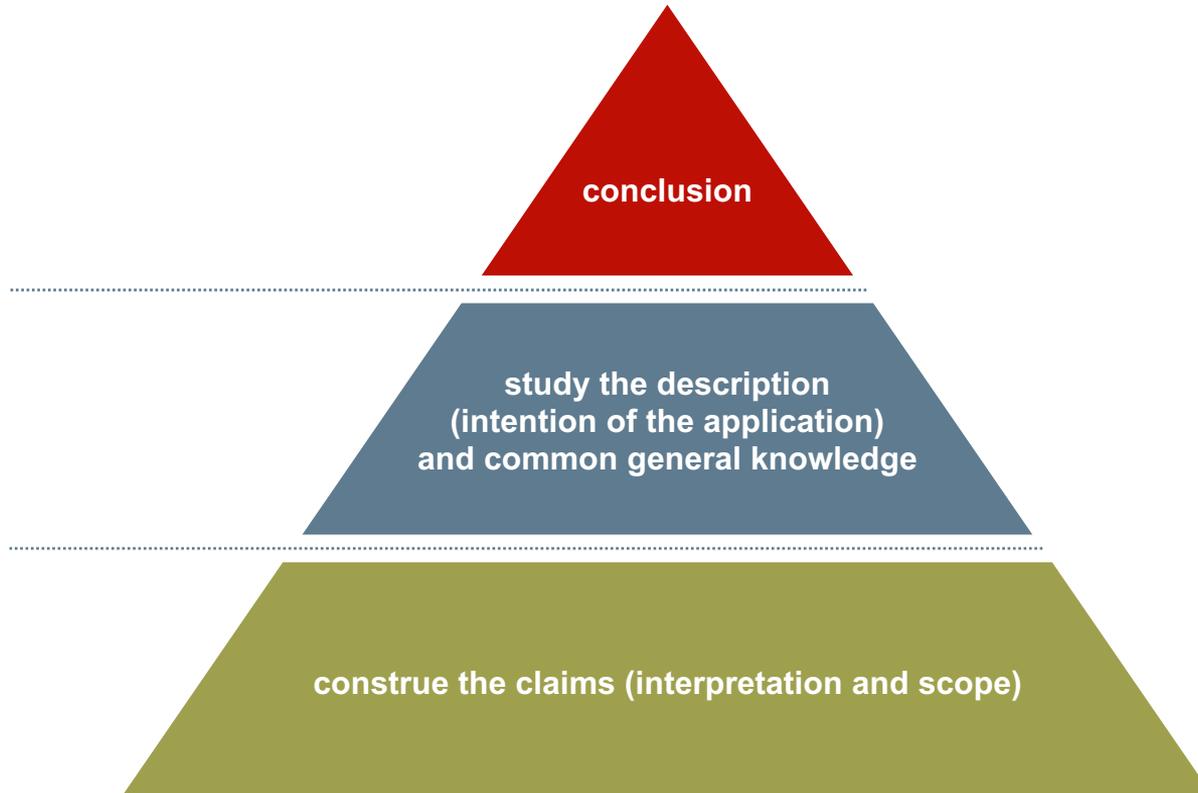
- Irrespective of the origin of **pain, discomfort** or **incapacity***, its relief, by the administration of an appropriate agent, is to be construed as therapy within the meaning of Art. 53(c):
 - *caused by natural circumstances (e.g. menstruation, pregnancy or **age**, etc.) or by
 - *a reaction to situations in the human environment (e.g. **atmospheric conditions** provoking tiredness, headaches, etc.)

2. How to define therapy/disease (4/4)

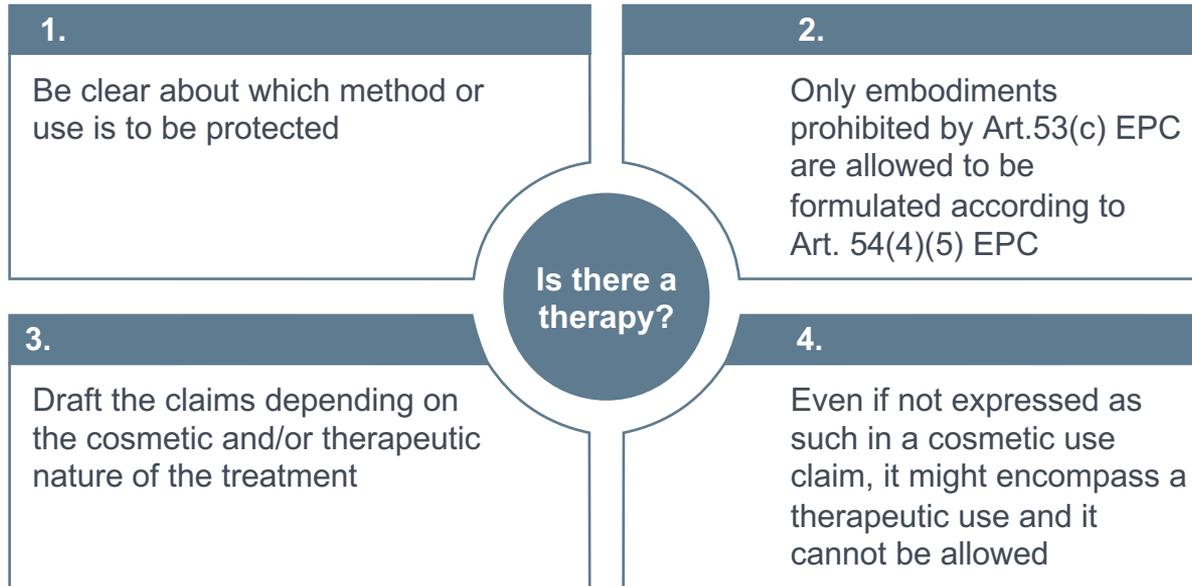
However, *not all improvements of physiological capacities or physical inability is to be regarded as therapy*



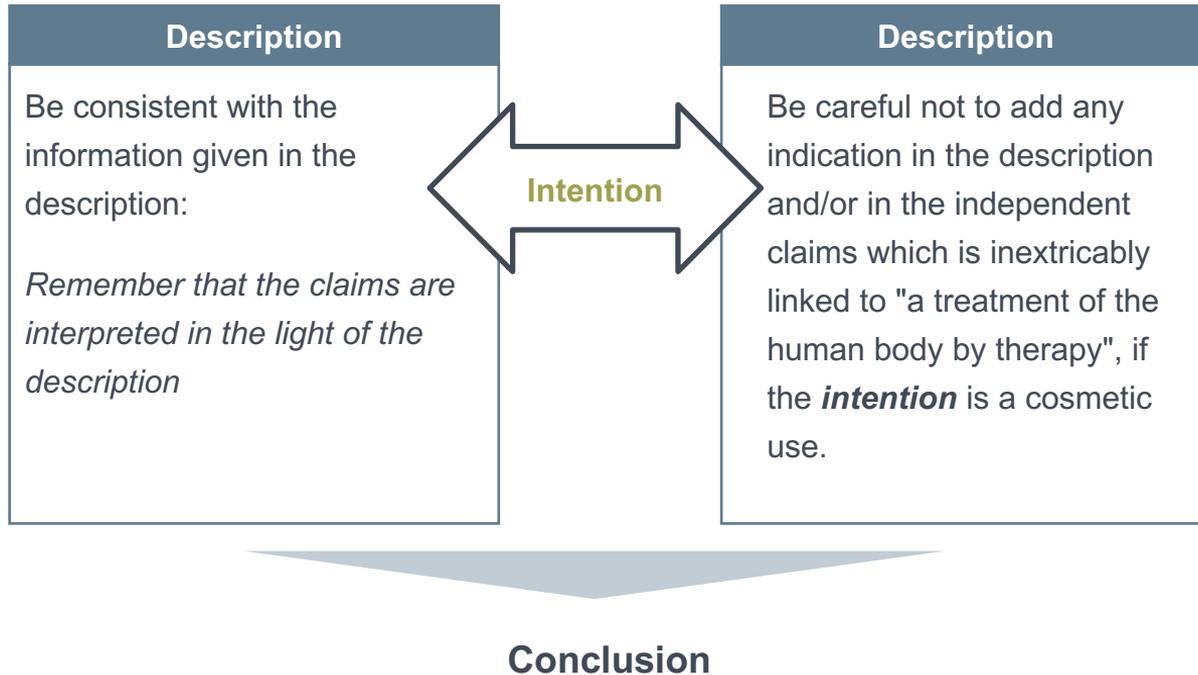
3. Intention: Is there a therapy/disease?



3. Claims and scope



3. Intention



3. Conclusion (1/2)

| a. | b. | c. | d. |
|--|---|---|-------------------------------------|
| <p>Depending on the intention stated in the description, a cosmetic use claim is allowable when it is NOT inextricably therapeutic</p> | <p>If the cosmetic effect is caused by a therapeutic effect, the cosmetic use is not allowed</p> <p>NOT SEPARABLE</p> | <p>If the cosmetic effect is a functional feature clearly distinguishable from a therapeutic method, the cosmetic use is allowed</p> <p>SEPARABLE</p> | <p>Be clear about the intention</p> |

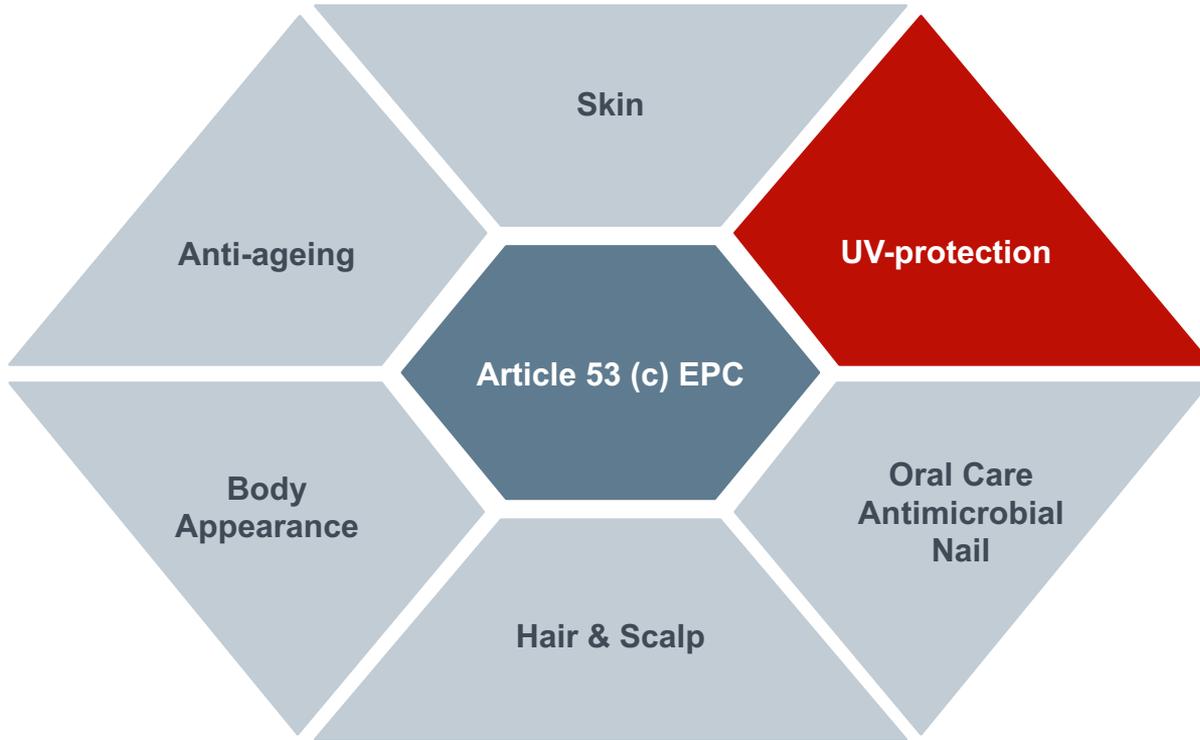
Continued ...

3. Conclusion (2/2)

| e. | f. | g. | h. |
|--|--|--|--|
| <p>Link the experimental data and the effect shown to the intended use</p> | <p>Draft the claims accordingly</p> <p>The formulation of the claims is key to the definition of the scope of protection</p> | <p>Only separable uses are allowed to be claimed as independent claims:</p> <ul style="list-style-type: none">▪ the purpose-limited product claim▪ the non-therapeutic cosmetic use (or method) claim | <p>A pure cosmetic use is not allowed to be drafted as a medical use claim</p> |

Intention matters – Claim drafting is essential

3. Borderline cases



Case studies 1-10

- Analyse the subject-matter (SM) covered by the claims and find out whether the subject-matter claimed A) is 100% therapeutic; B) it encompasses separable therapeutic and non-therapeutic aspects that can be drafted in two independent claims : one covering the non-therapeutic matter and one drafted under Art. 54(5) EPC; and C) it is 100% non-therapeutic
- For each case study, please mark:
 - ✓ , if you consider that the SM is either 100% therapeutic or it can be separated - options A and B; or
 - ✗ , if it is 100% non-therapeutic – option C

4. Case studies: (1/10) Dandruff

Claim

*"A method of **cosmetic anti-dandruff treatment**, comprising the application of a composition comprising A and B"*

Do you consider that the SM is either 100% therapeutic or it can be separated? 

Do you think that it is 100% non-therapeutic? 

4. Case studies: (2/10) Dandruff

Claim

*"An **anti-dandruff composition** comprising **C for use** in treating or preventing *Malassezia* induced dandruff formation and/or *Malassezia* induced itching of the skin"*

Do you consider that the SM is either 100% therapeutic or it can be separated? 

Do you think that it is 100% non-therapeutic? 

Case studies: (1-2/10) Examining division's conclusion

Case 1

- Malasseria (Pityrosporum) yeasts make up to 46% of microflora of normal subjects:
 - 74% for subjects with dandruff
 - 83% for subjects with seborrheic dermatitis
- Dandruff is non-inflammatory, whereas seborrheic dermatitis is a chronic, recurring cutaneous disease, causing erythema
- The purpose of the invention is to combat dandruff.
- Claim allowed with the addition of “non-therapeutic”

Case 2

- C is known and the composition per se is known
- The applicant referred to journal articles and explained that the excessive colonisation of Malassezia on the scalp is associated with an inflammatory response, and that its treatment or prophylaxis is a therapeutic use, which is hence suitable to establish novelty
- The invention was directed to the therapeutic use and the format under Art. 54(5) EPC was correct and allowed

4. Case studies: (3/10) Body odour

Claim

"A method of **reducing body odour**, comprising applying a rinse-off personal care composition comprising an **antimicrobial agent** to an underarm hair follicle to deposit the particulate **antimicrobial agent** into the hair follicle"

Do you consider that the SM is either 100% therapeutic or it can be separated? 

Do you think that it is 100% non-therapeutic? 

Case studies: (3/10) Body odour

Examining division's position

- Microbial suppression using an antimicrobial agent, in particular zinc pyrithione, may also concomitantly suppress pathogenic microorganisms (e. g. *Staphylococcus aureus*), which may be present in microbial flora
- The therapeutic aspect is **inextricably linked** to the method and claim 1 should be drafted in the appropriate therapeutic claim format
- The claim was finally allowed with the addition of “non-therapeutic”

Applicant's arguments

- A normal, healthy underarm is inhabited by microbial flora, which flora will typically result in body odour
- The invention concerns the cosmetic control of the natural odour of a healthy underarm
- The microbial suppression in the invention is not directed to the treatment of a disease state of a human or to restoring health, which is the concern of Art.53(c) EPC

4. Case studies: (4/10) Body appearance

Claim

"A method of **improving bodily appearance** of a non-opiate addicted mammal which comprises orally administering to said mammal naltrexone or a pharmaceutically effective salt thereof in a dosage effective **to reduce appetite**, and repeating said dosage until a cosmetically beneficial loss of body weight has occurred"

Do you consider that the SM is either 100% therapeutic or it can be separated? 

Do you think that it is 100% non-therapeutic? 

Case studies: (4/10) Body appearance

Examination phase

- Interview (1980) between the examiner and the applicant
- Arguments by the applicant
 - naltrexone is an effective anorectic and can have a therapeutic effect in obese subjects and a non-therapeutic effect in subjects not having the pathological condition
 - the invention relates to a physiological treatment to obtain a non-therapeutic result

T144/83 Appetite suppressant

- Bodily appearance is not a disease whereas obesity is a pathological condition
- The BoA decided that the fact that a chemical product has both a cosmetic and therapeutic effect when used to treat the human or animal body does not render the cosmetic treatment unpatentable (as in the present case where it may be used to cause loss of weight or to cure obesity)
- Different group of subjects (“patients”)

4. Case studies: (5/10) Hair loss - Alopecia

Claim 12

"Cosmetic method for improving hair growth, wherein the method comprises administering mixed salts of carnitine and tartaric acid ”

Do you consider that the SM is either 100% therapeutic or it can be separated? 

Claim 13

"Use of mixed salts of carnitine and tartaric acid for preparing a pharmaceutical agent for promoting hair growth and /or preventing hair loss”

Do you think that it is 100% non-therapeutic? 

Swiss type formulation of the medical use

Case studies: (5/10) Hair loss and Alopecia

Appellant /Respondent arguments

- With the addition of 'cosmetic' to characterize the method of new claim 1, the therapeutic aspect is excluded
- The cosmetic method still encompasses a therapeutic treatment encompasses two aspects

T1711/08

- Cosmetic reduction of hair growth (reduction of 'normal' hair loss) is distinguishable and separable from therapeutic treatment of hair loss (alopecia). The group of users is not the same
- Alopecia androgenetica (including male baldness) is therapeutic (T536/94)
- A method for reducing 'normal average daily hair loss' is non-therapeutic (T453/95)
- Non-therapeutic' versus 'Cosmetic'

4. Case studies: (6/10) Halitosis

Claim

"The use of a haloperoxidase in the manufacture of an antimicrobial agent for selectively killing pathogenic bacteria while selectively preserving normal flora, wherein the antibacterial agent is a liquid and comprises ..."

Swiss format for a medical use claim

Do you consider that the SM is either 100% therapeutic or it can be separated? 

Do you think that it is 100% non-therapeutic? 

Case studies: (6/10) Halitosis

Examining division's position

- Halitosis (bad breath) has both aspects:
 - non-therapeutic: the subject has eaten garlic
 - therapeutic: the subject has gingival infection
- The disclosure encompasses two aspects
 - The selective antimicrobial activity against pathogenic bacteria
 - The in-vitro use of the compound as surface disinfectant (contact lens cleaning formulation)
- The non-therapeutic use of the compound to combat bad breath could be allowed, if it would have been originally disclosed

T292/04

- Treatment of halitosis can be therapeutic and non-therapeutic
- Novelty can be acknowledged if a known compound is used in medicine for the first time and for a new and inventive medical indication
- The technical effect of selectively killing the pathogen bacteria was not a distinguishing feature vis-à-vis the prior art disclosing the antimicrobial activity of the same compound

4. Case studies: (7/10) Oral care

Claim

"A **dentifrice** composition which effects **enhanced antiplaque and breath freshening** which comprises an orally acceptable vehicle containing a combination of an abrasive having a cationic antibacterial agent and at least one proteolytic enzyme for use in the treatment of halitosis"

Do you consider that the SM is either 100% therapeutic or it can be separated? 

Do you think that it is 100% non-therapeutic? 

Case studies: (7/10) Oral care

Oral care

- What about tooth whitening?
 - If the description includes only tooth whitening and no simultaneous tooth cleaning is involved --> non-therapeutic
 - If the whitening agent is comprised in a dentifrice, mouth cleansing solution, etc --> therapeutic
- What about collateral uses?
 - Use of a colouring agent to indicate brushing time --> depends on the wording of the claim

T0675/11

- Treatment of halitosis include both therapeutic and non-therapeutic

T290/86

- Any method or use for cleaning teeth is therapeutic

T2071/15

- Use for restoring pH in the mouth involving inhibition of bacteria and prevention of caries, tooth erosion, etc is a therapeutic use

4. Case studies: (8/10) Light sensitive make-up

Claim 1: "A method of making up human keratinous material with light-sensitive makeup, the method comprising:

- applying to the keratinous material a 1st composition comprising a photochromic agent developable by radiation of a wavelength λ ;
- then covering the first photochromic composition by a photo-protective layer as a 2nd composition comprising an optical agent that forms a screen to the said radiation;
- exposing the 1st and 2nd composition to the said radiation to develop the photochromic agent and to form an active photo-protective layer from the optical agent present in an inactive or in a precursor state to become active"

Do you consider that the SM is either 100% therapeutic or it can be separated?



Do you think that it is 100% non-therapeutic?



Case studies: (8/10) Light sensitive make-up

Description

- A method of making up human keratinous material with light-sensitive makeup, for instance making up the skin, lips or the integuments, in particular the nails, or the hair
- Purpose: to avoid reduction of colour sharpness over time and increase stability and duration of the effect
- The make-up comprises an optical agent forming a photo-protective layer that screens the said radiation and has a solar UV radiation screening power F that is greater than 2, better greater than 5 or greater than 10

Examining division's conclusion

- UV-protection is considered 100% therapeutic (prophylactic)
- A light-sensitive make-up that comprises a photo-protective layer with UV radiation screening power falls under the exclusion of patentability of Art. 53(c) EPC, if it is for protecting skin and lips
- If the application is restricted to nails and hair, then it is of cosmetic nature and the non-therapeutic cosmetic method can be allowed
- Co-existence of both types of claims can be allowed because there was basis in the original disclosure

4. Case studies: (9/10) Skin and UV protection

Claims

1. "Active eutectic mixture of butyl methoxydibenzoylmethane and isopropyl myristate wherein the weight ratio of butyl methoxydibenzoylmethane to isopropyl myristate is from 3:7 to 1:15 and wherein the eutectic mixture has a melting point below 15 degrees Celsius, and wherein the mixture further comprises 12-hydroxystearic acid in an amount from 0.1 to 6 wt% by total weight of the mixture"
5. "Personal care composition comprising the active eutectic mixture of claim 1 and a cosmetically acceptable carrier"
7. "A non-therapeutic method of applying to human skin the personal care composition according to any one of claims 5 to 12"

Note: the eutectic mixture is a UV filter

Do you consider that the SM is either 100% therapeutic or it can be separated? 

Do you think that it is 100% non-therapeutic? 

Case studies: (9/10) Skin and UV protection

Appellant /Respondent arguments

Respondent:

A composition comprising a UV sunscreen agent to be applied to human skin must always be regarded as therapeutic for its prophylactic effect

Appellant:

- Exposure to UV radiation is essential for such a prophylactic effect to occur
- Personal care compositions had different purposes and could be applied to different parts of the body - The therapeutic and non-therapeutic application could be clearly separated depending on the purpose and body part

T2275/18

Non-therapeutic methods of a composition comprising a UV filter are allowable with the disclaimer 'non-therapeutic', if these are intended for non-UV exposure (shower gels) or for application to the hair (shampoos, hair conditioners)

4. Case studies: (10/10) Skin treatment

Claims as filed

1. "A skin treatment composition comprising (a) polymer A and (b) at least two essential oils selected from B, C, D and E"
6. "A method of providing an antimicrobial effect to skin comprising the steps of applying a composition comprising (a) and (b) to the skin, and waiting for at least 15 seconds"
7. "Use of a composition according to claim 1 for providing an antimicrobial effect to the skin"

Do you consider that the SM is either 100% therapeutic or it can be separated? 

Do you think that it is 100% non-therapeutic? 

Case studies: (10/10) Description

- The essential oils are known for anti-microbial activity.
- Skin has a normal population of a variety of microorganisms, exceeding millions of cfus /cm²
- Many of the microorganisms are harmless, like *S. epidermidis*, known for producing body mal odour. Pathogenic bacteria might be also present, e.g. *E. coli* and *S. aureus*
- Compositions may be hand hygiene products, deodorants, face or body wash, shampoos or hair conditioners

Case studies: (10/10) Skin treatment

Objections of the examining division

- Skin disinfection always remove pathogenic bacteria and provide a prophylactic effect to various diseases
- The prophylactic /therapeutic effect is inevitable due to the antimicrobial activity of the essential oils. No separation is possible
- The method and use claims contravene Art. 53 c) EPC
- Product claim is not novel

Applicant's arguments

- Non-therapeutic uses are clearly separable from therapeutic uses e.g. hand wash versus wound disinfection
- Removing non-pathogenic bacteria responsible for unpleasant body odour is not therapeutic
- A method of using a handwash or hand sanitiser is non-therapeutic and purely cosmetic
- The disclaimer “non-therapeutic” per definition could not cover a therapeutic treatment

Case studies: (10/10) Skin treatment

Revised claims

1. A non-therapeutic method of providing an anti-microbial effect to skin comprising the steps of applying a composition comprising (a) and (b) and waiting for at least 15 seconds.

5. Non-therapeutic use of a composition comprising (a) and (b) for providing an antimicrobial effect to the skin.

6. Composition for use in therapeutically providing an antimicrobial effect to the skin, wherein the composition comprises (a) and (b).

T1916/19: Skin treatment composition

Claim 1: A non-therapeutic method of providing an anti-microbial effect to skin comprising the steps of applying a composition comprising (a) a polymer ...and (b) at least two essential oils.... And waiting for at least 15 seconds.

Claim 5: Non-therapeutic use of a composition comprising (a) ... and (b) ... for providing an antimicrobial effect to the skin.

Claim 6: Composition for use in therapeutically providing an antimicrobial effect to the skin, wherein the composition comprises (a) ... and (b)....

T1916/19: Skin treatment composition

Appeal grounds

- There is a clear non-therapeutic realisation that does not inextricably encompass a therapeutic effect
- Removal of non-pathogenic bacteria for cosmetic purposes is not a prophylactic realisation, for instance reducing body odour by killing or removing *Staphylococcus epidermidis*
- The disclaimer “non-therapeutic” ensures that protection is only conferred to the separable non-therapeutic realisations

Reasons for the decision

- At least some realisations of the claimed method (and use) are non-therapeutic
- Therapeutic and non-therapeutic effects are not inextricably linked in this case
- The disclaimer is allowable and exclude the therapeutic aspects
- The therapeutic methods are claimed in independent claim 6, correctly drafted under Art. 54(5) EPC
- None of the claims is directed to subject-matter excluded from patentability under Art. 53 c) EPC

Decision set aside and remitted for further prosecution.

Conclusions (1/4)



The intention of the application should be clear.



If the intention is to protect both uses and they are separable, then the two types of claims can be allowed:

purpose-limited product claims according to Art. 54(4)(5) EPC, non-therapeutic use claims.



If the intended use is NOT separable, only one type of claims is allowable.

Conclusions (2/4)



Only embodiments prohibited by Art. 53(c) EPC are allowed to be formulated according to Art. 54(4)(5) EPC (medical indication)



Non-therapeutic uses should be claimed as normal use claims:
Herbal extract of aloe vera in a cosmetic composition **for use** in moisturising the skin → NO
Cosmetic use of an herbal extract of aloe vera for moisturising the skin → YES



Art. 123(2) EPC trap → Claim granted as a medical use claim for a non-therapeutic invention might be considered by the BoA as extending the content of the application as originally filed (T0586/16)

Conclusions (3/4)



Natural Ageing is not a sickness.



In oral care, except for whitening strips, cosmetic use claims are practically not allowed.



Photo-ageing, hyper/hypo pigmentation is separable.



UV protection is considered 100% therapeutic.

Conclusions (4/4)



Relevant Case Law

G decisions: G0001/16; G0001/07; G0001/03

T decisions: T1916/19 (skin washing and cleansing - two types of claims possible); T675/11 (halitosis); T0767/12; T1635/09; T0385/09; T0290/86 (separation of cosmetic and therapeutic effect); T0144/83; T0036/83 (acne); T892/94 landmark decision; T1172/03 (cosmetic effect must be a technical feature); T0488/05 and T0527/08 (cosmetic and inventive step); T2275/18, 1993/08 and T333/96 (UV protection); T290/86 and T2071/15 (oral care); T0675/11 (halitosis); T1649/06 (skin ageing and UV filter); T1711/08, T453/95 and T0536/94 (hair and scalp)



Pending cases skin protection: T0273/19; T3001/18; T0903/19; T0230/19; T0233/19; T1420/18; T0229/19

Further questions



Now

via chat to "All Panelists"

Later

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