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Datasheet for the decision of 9 December 2013

Case Number: T 0920/10 - 3.3.04

Application Number: 99968490.5

Publication Number: 1140180

IPC: A61K41/00

Language of the proceedings: EN

Title of invention:
Targeting of sebaceous follicles as a treatment of sebaceous gland disorders

Applicant:
The General Hospital Corporation d/b/a
Massachusetts General Hospital

Headword:
Sebaceous gland disorders/ GENERAL HOSPITAL CORPORATION

Relevant legal provisions:
EPC Art. 54, 56, 83, 84, 123(2)

Keyword:
"Claim 1 of the main request - after amendment: requirements of the EPC met (yes)"

Decisions cited:
T 0609/02, T 1254/07, T 0716/08, T 0188/09

Catchword:
see points 6 to 8 and 14

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Case Number: T 0920/10 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 9 December 2013

Appellant: (Applicant)	The General Hospital Corporation d/b/a Massachusetts General Hospital 55 Fruit Street Boston, MA 02114 (US)
Representative:	Braun, Nils Ortlieb, Alexander Maiwald Patentanwalts GmbH Postfach 330523 80065 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 20 October 2009 refusing European patent application No. 99968490.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: C. Rennie-Smith
Members: G. Alt
R. Morawetz

Summary of Facts and Submissions

I. The appeal is against the decision of the examining division refusing the European patent application No. 99 968 490.5 for the reason that its claimed subject-matter lacked an inventive step. The application has the title *"Targeting of sebaceous follicles as a treatment of sebaceous gland disorders"*.

II. The following documents are cited in the present decision:

D1 WO 96/39188

D2 Dermatol. Monatsschrift, vol. 178 (1992), pages 297-300, König, K. and Meyer, H.

D3 Akt. Dermatol., vol. 19 (1993), pages 195-198, König, K. and Meyer, H.

D4 Proc. SPIE - Int. Soc. Opt. Eng. (1998), pages 106-110, König, K. et al.

D5 US 5,752,949

D6 J. Invest. Dermatol., vol. 108 (1997), pages 87-91, Rhodes, L.E. et al.

D7 WO 96/09853

D8 Lasers in Surgery and Medicine, vol. 31 (2002), pages 115-120, Lloyd, J.R. and Mirkov, M.

D9 J. Invest. Dermatol., vol. 115 (2000), pages 1-10, Hongcharu, W. et al.

D10 Eye and Skin Disease (1996), eds. Mannis, M.J., Macsai, M.S. and Huntley, A.C., pages 335-341 (Chapter 41)

D11 Eur. J. Pharma. Biopharma., vol. 66 (2007), pages 159-164, Lademann, J. et al.

D12 Clays and Clay Minerals, vol. 36 (1988), pages 214-224, Cenens, J. and Schoonheydt, R.A.

D13 Experimental data filed with letter of 5 August 2013

D14 J. Am. Acad. Dermatol., vol. 6 (1982), pages 746-750, Gomez, E.C.

D15 Brit. J. Dermatol., vol. 117 (1987), page 317-323, Dalziel, K. et al.

D16 Acne and Rosacea, 2nd completely revised and enlarged edition (1993) eds. Plewig, G. and Kligman, A.M., pages 646-647

D17 J. Am. Acad.Dermatol., vol. 27 (1992), pages S23-S28, Saurat, J.-H.

D18 Science, vol. 220 (1983), pages 524-527, Anderson, R.R. and Parrish, J.A.

D19 Declaration of E.V. Ross, Jr. dated 19 November 2013

III. Claim 1 of the only request before the examining division read as follows:

"1. Use of an energy activatable material in the preparation of a pharmaceutical preparation for the treatment of a sebaceous gland disorder such as acne vulgaris, acne rosacea or sebaceous gland hyperplasia, wherein

a) said energy activatable material comprising a chromophore-containing group, suitable for delivery to the infundibulum or to a pilosebaceous unit, and activated by a species of energy which penetrates outer layers or epidermis, and

b) said energy activatable material being compounded such that upon topical application to a section of skin, an amount of said material infiltrates into spaces and selectively concentrates about said infundibulum or pilosebaceous unit without adversely affecting surrounding tissue,

so that exposure of the section of skin to energy causes said material to become photochemically or photothermally activated, to effectively treat a sebaceous gland disorder such as acne vulgaris, acne rosacea or sebaceous gland hyperplasia."

IV. In the written reasons for the decision the examining division held that the claimed subject-matter was novel over the disclosure in any of the documents D2 to D4, but that it lacked an inventive step. Two different lines of argumentation in accordance with the problem-solution-approach were followed, one departing from documents D2 to D4 as the closest prior art and the other from document D1.

First, each of documents D2 to D4 suggested the treatment of acne by photodynamically (i.e. photochemically) induced inactivation of *Propionibacterium acnes* (*P. acnes*) by using the photosensitizer methylene blue and red light. The problem to be solved could be regarded as finding a treatment for acne by targeting the pilosebaceous unit. However, the examining division stated that *"it has not been convincingly shown in the application that a photodynamic treatment according to the claims does actually bring the claimed effect, i.e. that a reshaping of the sebaceous gland can be obtained. The only experiment describes the topical application of a methylene blue solution on the skin and measure of the fluorescence. A dense blue staining of the epidermis, of some sebaceous glands and entire hair follicles was observed. Apart from the fact that this result does not provide evidence for reshaping of the pilosebaceous unit, it seems obvious that the pore-shaped pilosebaceous gland accumulates more dye and have* [sic] *more staining than the remaining part of the skin. Since it has not been plausibly shown that the technical problem has been solved, inventive step has to be denied."* (see point 1.1 of the decision under appeal). The examining division further held that even if it could be acknowledged that the results presented in the application supported the claimed effect on the pilosebaceous unit, a similar effect was described in Example 8 of document D1 with a 5-aminolevulinic acid (ALA) solution.

Second, document D1 disclosed the use of ALA in combination with photodynamic therapy for the treatment of acne. The subject-matter of claim 1 differed from this disclosure in that the energy-activatable material

comprised a chromophore-containing group. The problem to be solved was finding an alternative to ALA. Each of documents D2 to D4 disclosed that methylene blue, when used as a photosensitizer, was able to inactivate *P. acnes* and that it should be possible to treat acne with photodynamic therapy and topical application of photosensitizers, for example methylene blue. By combining the teachings of document D1 with that of documents D2 to D4 the skilled person would have arrived at the claimed subject-matter in an obvious way.

The examining division finally stated that none of the dependent claims 2 to 14 appeared to contain any additional features which, in combination with the features of any claim to which they referred, would meet the requirements of the EPC with respect to inventive step. Consequently, the examining division decided that the subject-matter of all claims lacked an inventive step.

V. With its statement of the grounds of appeal the applicant (hereinafter "appellant") filed an amended main request and three auxiliary requests. In response to the board's communication of 22 February 2013 the appellant filed with a letter of 5 August 2013 a new main request comprising one independent claim and 14 claims dependent thereon, an auxiliary request 1 and auxiliary requests 2 to 5 corresponding to the 4 requests filed with the statement of the grounds of appeal.

VI. Oral proceedings were held on 5 September 2013. The appellant was heard on the question of whether or not it was plausible from the application as filed that the therapeutic effect which underlay the claimed treatment

was achieved, such evidence being necessary according to established case law such as decisions T 609/02 or T 380/05 for the requirements of Article 83 EPC to be considered as fulfilled in relation to a claim to a second medical use.

The board decided to adjourn the oral proceedings in order to give the appellant the possibility to file evidence about the skilled person's understanding of the disclosure in the application.

In a communication dated 17 September 2013 the board informed the appellant that the oral proceedings were to be resumed on 9 December 2013.

VII. The appellant filed written submissions on 22 November 2013 which included *inter alia* documents D14 to D19.

VIII. Oral proceedings were resumed on 9 December 2013. After objections by the board pursuant to Articles 123(2), 84 and 56 EPC the appellant filed a new main request. Its claims were identical to those of the previous main request with the exception of claim 1 which now read:

"1. An energy activatable material for use in the treatment of a sebaceous gland disorder, wherein

a) said energy activatable material is a chromophore, is suitable for delivery to the opening to the infundibulum or to a pilosebaceous unit, and is activated by a species of energy which penetrates outer layers of epidermis, and wherein

b) said energy activatable material is compounded such that upon topical application to a section of skin a

sufficient amount of said material infiltrates into spaces about the infundibulum and selectively concentrates about said infundibulum, or infiltrates the pilosebaceous unit, and wherein

c) said treatment is topically applying said energy activatable material to a section of skin afflicted with a sebaceous gland disorder and exposing the section of skin to pulsed energy characterized by an energy density no greater than 100 J/cm^2 causing said material to become photothermally activated to effectively treat a sebaceous gland disorder while there is minimal to no destruction of normal adjacent epidermal and dermal structures."

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed at the oral proceedings or on the basis of one of auxiliary requests 1 to 5 filed on 5 August 2013.

At the end of the oral proceedings the chairman announced the board's decision.

IX. The appellant's arguments, as far as they are relevant for the present decision, may be summarized as follows:

Claim 1 of the amended main request fulfilled the requirements of Articles 123(2), 84, 54 EPC.

The application elaborated in detail all the parameters necessary to carry out the claimed treatment which consisted of the topical administration of a chromophore and its infiltration into the pilosebaceous unit or the infundibulum, and its subsequent photothermal activation by pulsed energy, resulting in

localized heating and selective tissue damage. Anyhow, the technique applied according to the application for the treatment of sebaceous gland disorders was known per se at the priority date of the application and commonly denoted as "selective photothermolysis", see document D18 and the application, page 1, line 32. In view of the firm and reliable connection between the means applied and their consequential effect, the achievement of the therapeutic effect was plausibly described in the application itself and strongly supported by the disclosure in the post-published documents D8 and D13. The circumstances underlying the case dealt with in decision T 609/02, where the board denied sufficiency of disclosure, were completely different from the present ones. Decision T 380/05 was not relevant either because in this decision the board acknowledged sufficiency of disclosure. Thus, the requirements of Article 83 EPC were fulfilled.

The invention aimed at providing a curative treatment for sebaceous gland disorders, i.e. a treatment which affected the deregulated sebum production and not one which treated only secondary effects, for example, in the case of acne the inhibition of the growth of *P. acnes*. Therefore, the treatment of sebaceous gland disorders with orally administered retinoids, for example isotretinoin, could be considered as the closest prior art because this treatment, as disclosed in the application on page 6, lines 20 and 21, was considered to *"achieve a significant cure rate for acne"*.

The problem underlying the application was the provision of an alternative curative treatment for sebaceous gland disorders. The solution as provided by the claims was not obvious in the light of the

documents referred to in the decision under appeal, i.e. documents D1 to D4. They all suggested as a treatment the photochemical inactivation of *P. acnes* either by using the photosensitizer methylene blue (D2 to D4) or ALA as a precursor to protoporphyrin IX which again acted in a photochemical reaction. The requirements of Article 56 EPC were thus fulfilled.

Reasons for the Decision

1. The issues dealt with in the decision under appeal were novelty - which was acknowledged in the light of the disclosures in documents D2 to D4 - and inventive step - which was found lacking in relation to documents D1 to D4. After the board found the appeal allowable (see points 11 to 17 below), it considered whether to remit the case to the department of first instance, at least for the examination of sufficiency of disclosure in accordance with Article 111(1) EPC, second sentence, second half-sentence. However, the board decided in accordance with the first half sentence of that provision to examine these issues itself, mainly because one of the issues to be dealt with in the context of Article 83 EPC - evidence of the suitability of the claimed means to achieve the claimed treatment - has been already considered in the decision under appeal, though in the context of the evaluation of inventive step.

Allowability of amendments (Article 123(2) EPC)/ Clarity, support (Article 84 EPC) - Claim 1

2. Basis for the amended claim 1 is present in the application as filed in claims 1, 2, 22 and 23 and on page 5, line 19 to 20 and 31 to 32, page 7, lines 31 to

32, page 11, lines 11 and 15, page 12, lines 1 to 3 and page 14, lines 9 to 10.

The board has no objections pursuant to Article 84 EPC.

Claim 1 fulfils the requirements of Articles 123(2) and 84 EPC.

Sufficiency of disclosure (Article 83 EPC) - Claim 1

3. The claimed treatment for a sebaceous gland disorder is achieved by the topical administration of a chromophore and its infiltration into the pilosebaceous unit, spaces about the infundibulum or the infundibulum itself, and its subsequent photothermal activation by pulsed energy resulting in localized heating and selective tissue damage.

The "pilosebaceous unit" or the "sebaceous follicle" as it is also called is an invagination of the epidermis which consists essentially of the hair follicle and the sebaceous gland. The upper portion of the follicle, i.e. the "pore" into which sebum is secreted and which is directly in communication with the skin surface, is called the infundibulum (see page 1, lines 14 and 15 of the application). The tissue damage will in particular lead to an opening of the follicle and/or a modification of the sebaceous gland resulting in reduced sebum production.

4. The application provides on pages 11 to 25 a detailed disclosure of all the technical means necessary to carry out the claimed treatment, for example of the usable chromophores, the required concentration thereof, the energy source, etc. At the priority date of the application the technique, i.e. the selective

absorption of an energy pulse to generate and confine heat at pigmented or stained targets, was per se known and had been used for dermatologic treatments other than sebaceous gland disorders, for example for skin resurfacing, portwine stain treatment, tattoo and pigmented lesion removal and hair removal. It is denoted as "selective photothermolysis" (see document D18 and page 1 of the application, line 32).

5. The application contains evidence that the chromophore specifically enters the target tissue defined in claim 1, i.e. the "pilosebaceous unit", "spaces about the infundibulum" or the "infundibulum" (see the worked examples on page 25, line 19 to page 26, line 21 and Figures 9 and 10). The selective staining of the pilosebaceous unit is in particular visible in Figure 9. The examining division observed in the decision under appeal: *"[I]t seems obvious that the pore-shaped pilosebaceous gland accumulates more dye and therefore have* [sic] *more staining than the remaining part of the skin."*

6. The application does not provide explicit evidence of the exposure of the stained skin to pulsed energy and the effects of such an exposure on the pilosebaceous unit or the infundibulum. However, document D18 discloses on page 524, third column, last paragraph that an *"absolute requirement"* for a successful treatment by selective photothermolysis is that the pulsed energy is selectively absorbed, i.e. that *"the targets have greater optical absorption at some wavelength than their surrounding tissues"* and that *"[t]his requirement can be met by choosing endogenously pigmented targets [...], or by using staining or dye-labelling techniques".* The board considers therefore that the demonstration in the application of the

specific targeting of the chromophore to the pilosebaceous unit or the infundibulum also provides evidence for the suitability of the means according to claim 1 for the treatment of the disease in that claim, a treatment which is based on the selective heating and subsequent damage of tissue of the pilosebaceous unit and/or cells of the infundibulum.

7. The circumstances of the present case are distinguishable from those underlying the case dealt with in decision T 609/02 of 27 October 2004.

In that case the second-medical use claim 6 related to the use of a steroid hormone or analogue thereof which **failed to promote** transcriptional activation of glucocorticoid receptor- or retinoic acid receptor-responsive genes, for the preparation of a pharmaceutical for the treatment of **AP-1 stimulated** tumour formation, arthritis, asthma, allergies and rashes, said hormone being identified by the method according to the previous claims.

However, as is derivable from point 5 of that decision, the patent specification did not identify a single steroid hormone binding to the glucocorticoid receptor or retinoic acid receptor in such a way that the complex so formed (a) will disrupt the AP-1 stimulated transcription and (b) at the same time will not stimulate steroid hormone regulated transcription. Moreover, no data of any kind were presented indicating that such an hormone (if it were identified) could have an impact on any of the listed specific diseases.

Thus, in the case underlying decision T 609/02 (*supra*) neither the means for the treatment were known or were sufficiently disclosed in the application nor was their

suitability for the indicated treatment known or plausibly disclosed, whereas in the present case both the means are known and disclosed and their suitability for the treatment is plausible (see points 4 to 6 above).

8. In the decision under appeal the examining division held that the application did not convincingly show that the claimed means did *"actually bring the claimed effect"* since *"[t]he only experiment describes the topical application of a methylene blue solution on the skin and measure of fluorescence"*. Hence, basically the examining division considered that the data which are present in the application were insufficient to support the plausibility of the medical effect on which the treatment relies.

However, there is no fixed standard as to the quality or quantity of the evidence which can be considered as appropriate to support a claimed medical effect. Moreover, "absolute proof" of the achievement of a medical effect is not required for the effect to be "plausible" (see for example decision T 716/08 of 19 August 2010, point 16 of the reasons). This has the consequence that it has to be decided in the circumstances of each case whether or not the available evidence is appropriate to show the suitability of the claimed means for the claimed medical treatment. Consequently, unless this is self-evident - which it is not in the present case - the mere observation that the present data are insufficient is not, in the absence of any explanation as to why this is so, a persuasive reasoning.

9. The requirements of Article 83 EPC are fulfilled in relation to the invention as defined in claim 1.

Novelty (Article 54 EPC) - Claim 1

10. As observed above, at the priority date of the application the methodology referred to in claim 1, "selective photothermolysis", had been used for skin resurfacing, portwine stain treatment, tattoo and pigmented lesion removal and hair removal. Yet, there is no disclosure in the prior art available to the board of the use of this technique for the treatment of sebaceous gland disorders. The subject-matter of claim 1 fulfils the requirements of Article 54 EPC.

Inventive step (Article 56 EPC) - Claim 1

11. To assess inventive step the Boards of Appeal of the European Patent Office normally apply the problem-solution approach, a practice to which the board adheres in the present case (Case Law of the Boards of Appeal 6th edition 2010, I.D.2).

The problem-solution approach involves as a first step identifying the closest prior art which normally is subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention. A secondary criterion is the commonality of technical features (Case Law of the Boards of Appeal 6th edition 2010, I.D.3.1).

12. The purpose of the present invention is *inter alia* derivable from page 6, lines 8 to 24 of the application:

"Sebaceous glands are components of the pilosebaceous unit. They are located throughout the body, especially on the face and upper trunk, and produce sebum, a lipid rich secretion that coats the hair and the epidermal

surface. Sebaceous glands are involved in the pathogenesis of several diseases, the most frequent one being acne vulgaris. Acne is a multifactorial disease characterized by the occlusion of follicles by plugs made out of abnormally shed keratinocytes of the infundibulum (upper portion of the hair follicle) in the setting of excess sebum production by hyperactive sebaceous glands. Various treatment modalities for acne exist that aim in modifying the rate of sebum secretion by the sebaceous glands (e.g., retinoids), inhibiting the bacterial overgrowth in the follicular duct (antibiotics), or decreasing the inflammation of acne lesions (anti-inflammatory agents). Most of these agents are not curative of acne and simply control the disease by affecting one of the aforementioned pathogenic factors. Oral retinoids are a notable exception: they are potent drugs that can achieve a significant cure rate for acne, but their side effect profile often limits their use. Advantages of the present invention include that treatment can permanently alter the pilosebaceous unit, rendering it no longer susceptible to pore pluggage without the side effects associated with oral retinoids."

In view of the foregoing citation the board concludes that the claimed invention is concerned with a curative treatment for sebaceous gland disorders and that the closest prior art with respect to this invention is the treatment with oral retinoids (as mentioned in the application, see the passage cited above), such as for example isotretinoin (see page 1 of the application, line 9; there wrongly spelled as "*isotetinoin*").

12.1 The treatment disclosed in the documents considered by the first instance as the closest prior art - documents D2 to D4 - is not considered as "subject-matter

conceived for the same purpose or aiming at the same objective as the claimed invention" because it is based on the inactivation of bacteria, which is according to the application (see the paragraph cited above) not considered as a curative treatment, but as merely affecting one of the pathogenic factors.

13. In view of the closest prior art and the claimed invention the problem to be solved is formulated as the provision of an alternative curative treatment for sebaceous gland disorders.

The solution is a treatment relying on the means according to claim 1. On the basis of the evidence in the application it is acknowledged that the claimed means are suitable for the claimed treatment (see points 5 and 6 above). Thus, the board does not concur with the finding in the decision under appeal (see section IV above) that *"it has not been plausibly shown that the technical problem had been solved"*.

14. In this context the board also notes that it disagrees with the consequence drawn by the examining division from this finding, namely that *"inventive step has to be denied"* (see section IV above).

Article 56 EPC stipulates that *"an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to the skilled person"*. Therefore, in the board's understanding, the decision on whether or not the requirements of Article 56 EPC are fulfilled requires a mandatory examination as to whether or not the claimed subject-matter is obvious. Therefore, it has been established by case law that, if an initially formulated problem is found not to have been solved,

the problem is reformulated to one which is considered as having been solved and the obviousness of the claimed subject-matter is then assessed on that new basis (see for example decisions T 188/09 of 21 July 2011, point 18 of the reasons and T 1254/07 of 8 May 2012, points 10 to 12 of the reasons and the further decisions cited in these two decisions).

Obviousness

15. For the assessment of the obviousness or non-obviousness of the subject-matter of claim 1 the question to be answered in the present case is whether or not the skilled person would have been motivated, for example by hints in the prior art, to modify the closest prior art-treatment of sebaceous gland disorders, i.e. the oral administration of retinoids, such as to arrive at the claimed treatment, i.e. the treatment by selective photothermolysis.

16. Documents D1 to D4 disclose the photo-chemotherapeutic inactivation of *P. acnes* either by using the photosensitizer methylene blue (documents D2 to D4) or ALA as a precursor to protoporphyrin IX (document D1) in combination with light of photoactivating wavelengths. Since this treatment targets *P. acnes* and not the pilosebaceous unit itself, it would not be considered to have a permanent, i.e. curative effect on a sebaceous gland disorder (see the paragraph cited in point 12 above). Therefore, the skilled person would not have been motivated by these documents to find a solution to the underlying problem, i.e. the provision of a curative treatment for sebaceous gland disorders.

As already mentioned above document D18 discloses the technique applied according to the present invention

for the treatment of sebaceous gland disorder, i.e selective photothermolysis. Document D18 specifically studied the treatment of cutaneous microvasculature and cutaneous melanosomes (see page 526, second column first full paragraph and third column, third paragraph), which are both not "sebaceous gland disorders". In the last paragraph of document D18 on page 527 it is mentioned that *"the general technique may find many biomedical applications"* and that *"[i]f tunable lasers and cell-specific dye delivery systems can be used, choice among many targets is possible."* The board considers that this hint to other medical applications is too general to suggest to the skilled person the application of selective photothermolysis for the treatment of sebaceous gland disorders.

Documents D14 to D17 disclose the treatment of acne vulgaris and acne rosacea with systemic retinoids and side effects of such a treatment. They thus deal with the same treatment as the closest prior art and would therefore not give any impulse to the skilled person to modify this treatment.

Document D6 and documents D5 and D7, respectively, deal with photodynamic therapy for the treatment of skin cancer and the permanent prevention of growth of unwanted hair, respectively, i.e. diseases or disorders which have a different pathophysiology compared to sebaceous gland disorders.

Document D10 is a a chapter from a medical book dealing with acne rosacea.

Document D12 deals with the absorption properties of methylene blue on clays.

Documents D8, D9, D11, D13 and D19 are scientific publications, experiments and a declaration, respectively, all published after the priority date of the application. They are therefore not relevant for the evaluation of what the skilled person would or would not have considered at the priority date, which is the relevant date for the assessment of obviousness.

17. In the light of the observations above the board comes to the conclusion that the skilled person would not have been motivated to modify the closest prior art-treatment of sebaceous gland disorders, i.e. oral administration of retinoids such as to arrive at the claimed treatment, i.e. the treatment by selective photothermolysis. Consequently, the subject-matter of claim 1 is not obvious.

18. Claim 1 fulfils the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of claim 1 of the main request filed during the oral proceedings on 9 December 2013 and any dependent claims subsequently allowed by the department of first instance and a description and drawings to be adapted thereto.

The Registrar: The Chairman:

P. Cremona C. Rennie-Smith

Decision electronically authenticated