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D E C I S I O N
of 10 May 2005

Case Number: T 0074/03 - 3.3.2

Application Number: 88303918.2

Publication Number: 0289342

IPC: A61K 31/465

Language of the proceedings: EN

Title of invention:
Method for the treatment of withdrawal symptoms associated with smoking cessation and preparations for use in said method.

Patentee:
Aveva Drug Delivery Systems, Inc.

Opponent:
LTS Lohmann Therapie-Systeme AG

Headword:
Nicotine preparations for transdermal delivery/AVEVA DRUG DELIVERY SYSTEMS

Relevant legal provisions:
EPC Art. 54, 123(2), 111(1)

Keyword:
"Admissibility of late filed requests (yes): direct response to objections raised for the first time"
"Main request and auxiliary requests 1 to 3: novelty (no)"
"The functional feature in claim 11 cannot serve to delimit the product vis-à-vis known products"
"Auxiliary request 4: not allowable under Article 84 since the set of claims taken as a whole lacks clarity"
"Auxiliary request 5: formal requirements met; subject-matter claimed novel vis-à-vis the prior art cited by the appellant (opponent)"
"Remittal (yes): inventive step not within the framework of the appeal proceedings"

Decisions cited:
T 0068/85, T 0243/91, T 0893/90, T 0332/87

Catchword:
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Case Number: T 0074/03 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 10 May 2005

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 29 November 2002 concerning maintenance of European patent No. 0289342 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: M. Ortega-Plaza
J. H. P. Willems

Summary of Facts and Submissions

I. European patent application No. EP-0 289 342, based on application No. 88 303 918.2, was granted on the basis of 22 claims.

Independent claim 1 as granted read as follows:

"1. A preparation for the once-daily, percutaneous administration of nicotine, which comprises nicotine uniformly distributed in a solid, semi-solid or mucilaginous medium which can be placed in intimate contact with the skin, said solid, semi-solid or mucilaginous medium being formed by adding a given amount of nicotine to a solution of a solidifying or gel-forming agent or mixture thereof in a suitable solvent or mixture of solvents and mixing or heating the mixture thereby obtained so as to form said solid, semi-solid or mucilaginous medium, said medium further being effective to permit controlled release of nicotine to the skin and containing an amount of nicotine sufficient to achieve a plasma nicotine concentration in excess of 2 ng/ml within 1 hour after administration and to maintain such plasma nicotine concentration between 5 to 30 ng/ml over a period of from 1 to 24 hours."

Independent claim 11 as granted read as follows:

"11. A device for the once-daily administration of nicotine, comprising nicotine uniformly distributed in a solid, semi-solid or mucilaginous medium which can be placed in intimate contact with the skin, and said medium being effective to permit controlled release of

nicotine to the skin and containing an amount of nicotine sufficient to achieve a plasma nicotine concentration in excess of 2 ng/ml within 1 hour after administration and to maintain such plasma nicotine concentration between 5 to 30 ng/ml over a period of from 1 to 24 hours."

Independent claim 21 as granted read as follows:

"21. Use of nicotine for the manufacture of a medicament for use in the once-daily, percutaneous administration of nicotine in a method for the treatment of withdrawal symptoms associated with smoking cessation and in which the nicotine is administered in an amount sufficient to maintain plasma levels of nicotine substantially equivalent to trough plasma levels resulting from intermittent smoking."

Independent claim 22 as granted read as follows:

"22. Use of nicotine for the manufacture of a medicament for use in the once-daily, percutaneous administration of nicotine in a method for combating the psychological dependence that occurs through frequent smoking and in which the nicotine is administered in an amount sufficient to maintain plasma levels of nicotine substantially equivalent to trough plasma levels resulting from intermittent smoking."

II. The following documents were cited *inter alia* during the proceedings:

(1) EP-A-0 261 402

(2) Deutsche Mediziniche Wochenschrift, Heft 14, Jahrgang 112, 03.04.1987, pp. 559-564

(8) US patent 4 597 961

(9) Goodman-Gilman A., et al; Pharmacological Basic of Therapeutics, 556, 1985

(10) U. Klotz, Einführung in die Pharmakokinetik, Govi-Verlag, pp. 127-165, 1988

(11) H. Derendorf, E. R. Garrett, Pharmakokinetik, Wissenschaftliche Verlagsgessellschaft mbH Stuttgart, pp. 15-71, 1987

(12) Sworn statement of Mr C. L. Adams filed with appellant's (patentee's) letter of 21 November 2003

(13) Written statement of Mr C. L. Adams filed with appellant's (patentee's) letter of 8 April 2005

III. Opposition was filed and revocation of the patent in its entirety was requested pursuant to Article 100(a) EPC on the ground of lack of novelty. Later on during the opposition proceedings the ground pursuant to Article 100(b) EPC was introduced.

IV. The appeal lies from the interlocutory decision of the opposition division maintaining the patent in amended form, on the basis of the second auxiliary request (Articles 102(3) and 106(3) EPC).

The opposition division considered that the main request (set of claims as granted) met the requirements of Article 83 EPC because the patent in suit contained sufficient information to enable the skilled person to carry out the invention as claimed. In particular, the opposition division considered the plasma levels according to claim 1 to be workable and that no "jump" in plasma concentrations was necessary to fulfil the plasma concentrations according to claim 1.

According to the opposition division's findings the subject-matter claimed in claims 1, 10 and 11 met the requirements of novelty (Article 54(1) and (3) EPC) since the opponent had not shown beyond any reasonable doubt that the plasma concentration levels provided by the preparations of the patent in suit were anticipated by document (1). In particular, the opponent had not provided experimental data demonstrating that the preparations according to example 1 of document (1) would inevitably provide the plasma nicotine levels as specified in claims 1 and 11. Moreover, the opposition division further found that it had not been demonstrated by the opponent without any reasonable doubt that Nicotinell^{R} TTS was identical to the preparations described in example 1 of document (1).

The opposition division considered that the subject-matter of claims 21 and 22, which was not restricted to the use of the preparations according to claims 1 and 11, lacked novelty in the light of document (2). In the opposition division's view document (2) was an enabling disclosure since the skilled person would have known how to make a suitable transdermal delivery system for controlled delivery of nicotine, given the general

state of the art at the time of the priority date of the patent in suit.

With respect to the first auxiliary request (filed during the oral proceedings before the opposition division), the opposition division considered that the requirements of Article 123 EPC had been met.

However, the opposition division held that the amendment introduced in claims 21 and 22 was insufficient for establishing the novelty of the subject-matter claimed since the relevant plasma levels were generally known. The opposition division cited document (8)(which was cited in the patent in suit) and stated that in the said document there was an obvious error with respect to the units and that it was evident for the skilled person that the correct units were ng/ml. In support of this analysis the opposition division further cited a general text book (cited in the examination dossier), namely document (9).

The opposition division considered the set of claims of the second auxiliary request (filed during the oral proceedings before the opposition division) to be allowable since claims 21 and 22 were deleted.

V. The appellant (patentee) lodged an appeal against said decision and filed grounds of appeal.

VI. The appellant (opponent) also lodged an appeal against said decision and filed grounds of appeal.

VII. The appellant (opponent) filed with its grounds of appeal some additional in vitro tests results and calculations.

VIII. The appellant (opponent) filed with its letter of 18 August 2003 some copies from general books about pharmacokinetics (10) (11).

IX. The appellant (patentee) filed with its letter of 21 November 2003 a sworn statement of Mr C. L. Adams (12).

X. A board communication expressing some preliminary comments was sent as an annex to the invitation for oral proceedings. In this communication the board expressed its preliminary opinion that the ground pursuant to Article 56 EPC was not within the framework of the appeal proceedings and asked the appellant (patentee) whether it gave its consent to the ground being introduced.

XI. The appellant (opponent) filed with its letter of 5 April 2005 evidence that the publication date stated in document (2) was 3 April 1987 and that the date of receipt in The British Library, where it was made available to the public, was 15 April 1987.

XII. The appellant (patentee) filed with its letter of 8 April 2005 a written statement of Mr C. L. Adams (13), accompanied by some additional documents. The appellant (patentee) also filed an amended set of claims as the third auxiliary request. The appellant (patentee) did not give its consent to the introduction of inventive

step as a new ground in the opposition appeal proceedings.

XIII. Oral proceedings were held before the board on 10 May 2005.

XIV. During the oral proceedings before the board the appellant (patentee) filed two sets of claims as the fourth and fifth auxiliary requests.

Claim 1 of auxiliary request 4 differs from claim 1 as granted in that the term "mucilaginous" was deleted and the following passage was incorporated after "semi-solid medium," and before "said medium further being effective":

"with a surface area in the range 2 to 15 cm^2, more especially 5 to 10 cm^2 and a thickness in the range 0.5 to 3 mm, more especially 1 to 2 mm."

Dependent claim 3 of auxiliary request 4 read as follows:

"3. A preparation according to Claim 1 or 2, characterised in that it is in the form of a cream, gel, jelly, mucilage, ointment or paste."

Claim 10 of auxiliary request 4 differs from claim 11 as granted in that the term "mucilaginous" was deleted and the passage mentioned above for claim 1 was incorporated after "semi-solid medium," and before "said medium further being effective".

Claims 19 and 20 of auxiliary request 4 differ from granted claims 21 and 22, respectively, in that the following passage was introduced at the end of each of the claims:

"wherein said nicotine is uniformly distributed in a solid or semi-solid medium with a surface area in the range 2 to 15 cm^2, more especially 5 to 10 cm^2 and a thickness in the range 0.5 to 3 mm, more especially 1 to 2 mm which can be placed in intimate contact with the skin."

Claims 1, 9, 18 and 19 of auxiliary request 5 are identical to claims 1, 10, 19 and 20 of auxiliary request 4, respectively. Claim 3 of auxiliary request 4 was deleted and the other claims renumbered. The term "mucilaginous" was deleted from claims 7 and 8 of auxiliary request 5.

XV. The appellant's (patentee's) arguments with respect to the admissibility of the written statement (13), the additional documents annexed thereto and the third auxiliary request were as follows:

The statement (13) and the additional documents were filed as direct responses to some of the issues raised in the board's communication in respect to Article 83 EPC. Auxiliary request 3 was filed to respond to some of the drafting issues raised during the written proceedings. All these submissions were filed about one month before the date of the oral proceedings. Moreover, a copy of the new submissions was sent directly to the appellant (opponent). Therefore, the appellant

(opponent) had had sufficient time to consider the submissions.

The appellant's (patentee's) arguments with respect to the admissibility of the auxiliary requests 4 and 5 filed during the oral proceedings were as follows:

Both requests were a direct and clear response to issues raised for the first time during the oral proceedings. The amendments were not complex in their nature and could be immediately dealt with without further delay.

With respect to the novelty of the subject-matter of claim 11 of the main request the appellant's (patentee's) arguments may be summarised as follows:

Claim 11 related to a once-daily product which was a device having a specific plasma profile defined in the claim. A plasma nicotine concentration between 5 to 30 ng/ml was maintained over the whole period of 1 to 24 hours. It also referred to exhibit 1 annexed to the written statement (13).

Document (1) was the appellant's (opponent's) own application and, since it was state of the art within the meaning of Article 54(3) EPC, it could only be relevant for the assessment of the novelty of the subject-matter claimed.

The appellant (opponent) had not shown that each of the claim features was unambiguously and directly derivable from the contents of document (1). It was not shown that example 1 of document (1) fell within claim 11

beyond any doubt. The system for transdermal administration claimed was quite different from the two-compartment system disclosed in document (1).

The appellant (patentee) also contested the validity of the in vitro tests and the calculations made by the appellant (opponent) and mentioned the reasons given in its letter of 27 October 2003 and the sworn statement (12). In particular, the in vitro tests were not suitable in the field of transdermal drug delivery for proving in vivo parameters. The tests related to permeation on not quite clearly "modified" Franz cells. The skin was taken from a cadaver but there were no details given in the protocol about the choice of the cadaver and the handling of the skin. These elements were critical for the results obtained. Moreover, there were a very low number of essays and hence a high variability in the average values. Additionally, the formula taken from document (11) for performing the calculations was very general and did not specifically concern the cutaneous absorption of drugs, and it did not take into account the skin metabolism. Moreover, the data taken from document (10) for the chewing gum Nicorette^{R} was not directly applicable to a device for transdermal application due to the difference concerning the first pass effect. Finally, document (10) itself referred the lack of security and completeness for translating the data from one system to another.

The appellant (patentee) further stated that document (1) did not disclose a device for once-daily administration. In document (1) the nicotine was put in a resin for painting the fleece which was then the matrix. The fleece was not in intimate contact with the

skin and the nicotine was not distributed uniformly. It was not disclosed in document (1) that the nicotine was uniformly distributed in a solid, semi-solid or mucilaginous medium in direct contact with the skin. Intimate contact meant direct contact with the skin.

Asked by the board why it was not possible to maintain the plasma levels defined in claim 11 by the device of document (1) and which characteristic linked to the constitution of the device according to claim 11 allowed the plasma levels to be maintained, the appellant (patentee) replied that the patent in suit was very clear as to how one constructed the devices according to claim 11. It also cited column 6 of the patent in suit and the written statement (13). Moreover, it was unknown whether the devices of document (1) attained and maintained the plasma levels defined in claim 11, since the appellant (opponent) had not provided the evidence. To compare two devices by measuring the plasma levels attained and maintained within a certain period was not putting an undue burden onto the skilled person.

Further to the functional feature present in claim 11 the appellant (patentee) stated that clarity was not a question for the patent as granted. Additionally, the criteria for allowing the presence of functional features, as laid down in several decisions of the boards of appeal (T 68/85, OJ 1987, 228, T 243/91 of 24 July 1991 and T 893/90 of 22 July 1993) had been met.

The tests required were routine trials in the medical field (such tests were required, for instance, in the process for approval of a medicament). Although several

individuals would respond to pharmaceutical preparations differently, the skilled person would take as a usual measure statistically relevant results.

With respect to the comments by the appellant (opponent) about the in vivo data of the product Nicotinell^{R}, the appellant (patentee) referred to the opposition's division decision and to the several physical characteristics that differ between Nicotinell^{R} as disclosed in the further documents referred to by the appellant (opponent) and the device of example 1 of document (1). The appellant (patentee) made use of the table it submitted during the oral proceedings before the opposition division and was annexed thereto.

In the appellant's (patentee's) view, even if one could expect diffusion in the devices of document (1), the diffusion was time dependent and it was not disclosed in the said document when the diffusion was completed. Moreover, the system may not be perfectly sealed and then there would be some nicotine loss resulting in a higher concentration in the centre of the patch and lower on the edges.

Moreover, figure 5 of document (1) showed two matrixes, one in which the nicotine was initially put and a second to which it diffused. Therefore, there was no uniform distribution between both matrixes.

With respect to auxiliary request 4, the appellant (patentee) mentioned page 8, lines 23 to 25, of the application as originally filed as the basis for the deletion of the term "mucilaginous" from the claims. The options appearing in claim 3 related to a semi-

solid medium. In the appellant's (patentee) view, the term "semi-solid" reflected some flow ability but not free flow ability. The term "mucilaginous" was a subset of semi-solid.

The appellant (patentee) also stated that the compounds listed in claims 4 and 5 were the solidifying or gel-forming agents.

With respect to auxiliary request 5, the appellant (patentee) stressed that claim 3 appearing in auxiliary request 4 had been deleted and hence there should be no problem left concerning the coherence of the claims. Furthermore the arguments put forward for auxiliary request 4 in respect of Article 123 EPC also applied to auxiliary request 5.

The plasma level achieved as defined in the claims was directly linked to the feature specified in the independent claims of auxiliary request 5 concerning the particular surface area and thickness for the solid or semi-solid medium in which the nicotine is uniformly distributed. The appellant (opponent) had tried to pick up different pieces of information from document (1) and combined them in a way which went beyond its contents. The nicotine was not uniformly distributed in the reservoir layers 12 + 14 of figure 5 and the surface area of example 1 was 33.8 cm^2.

With respect to the use claims, the appellant (patentee) stated *inter alia* that document (2) was a non enabling disclosure with respect to the patches containing nicotine since it did not give any information about

their constitution other than that there was an adhesive layer.

Asked by the board whether it would give its consent to the introduction of Article 56 EPC as a new ground for opposition in the appeal proceedings, the appellant (patentee) responded that it did not give its consent. In the appellant's (patentee's) opinion, inventive step had been extensively discussed in the examination proceedings, the appellant (opponent) was a leading company in the field of transdermal therapeutic systems and had not put forward inventive step as an opposition ground in the opposition proceedings. It was the opposition division which made a comment as *obiter dictum* in its decision only with respect to claims 21 and 22 of the first auxiliary request.

The appellant (patentee) disagreed with a remittal of the case to the first instance in view of the long time that had elapsed since the filing of the application in 1988 and it reminded the board that the priority date of the patent in suit was 1987. However, it reluctantly preferred remittal to discuss the inventive step for the first time at such a late stage in the opposition appeal proceedings.

XVI. The appellant (opponent) contested the admissibility of the written statement (13), the additional documents annexed thereto and the third auxiliary request but did not put forward any arguments.

The appellant (opponent) did not contest the admissibility of the appellant's (patentee's) late filed auxiliary requests 4 and 5.

With respect to the novelty of the subject-matter of claim 11 of the main request, the appellant's (opponent's) arguments may be summarised as follows:

Document (1), which was state of the art within the meaning of Article 54(3) EPC, anticipated the subject-matter of claim 11. The only feature of claim 11 which was not expressly disclosed in document (1) was the functional feature concerning the in vivo plasma levels attained by the device. However, this feature could not be correlated to any parameter linked to the constitution of the device in view of the absence in claim 11 of a reference to any of the following technical features: the diffusion coefficient of the matrix, solubility values related to the saturation of the matrix, the actual concentration of nicotine in the matrix, the amount of nicotine in relation to the surface or the surface area of the particular system. Moreover, it was not acceptable to set higher standards concerning sufficiency of the disclosure for the state of the art documents than for the patent in suit.

The appellant (opponent) denied that to measure in vivo plasma levels related to routine experimentation, since the German authorities required a permit to be issued by an ethics commission and such a permit was difficult to obtain on the grounds of a patent dispute. Moreover, in vivo plasma levels were dependent on the individual patient. The appellant (opponent) further mentioned its unsuccessful attempt in the first instance proceedings to use the subsequently published studies relating to Nicotinell^{R} TTS as further proof of a lack of novelty of the claimed devices. However, the appellant (opponent)

did not put forward any argument to refute the decision taken by the opposition division in this respect.

The appellant (opponent) cited decision T 332/87 of 23 November 1990 and argued that the alleged new functional feature should be linked to a difference in the product's substance or constitution vis-à-vis the known products.

In the device of example 1 and figure 5 there was direct contact with the skin. The nicotine was put in the resin solution into the fleece. Then a uniformly distribution took place in the matrix. The fleece was an inert support and the nicotine distributed itself by diffusion, following the laws of physics, in a uniform way. The matrix was in direct contact with the skin.

During storage the reservoir matrix depicted in figure 15 would be saturated and the nicotine would be uniformly distributed.

The arguments brought by the appellant (patentee) concerning a possible loss of nicotine and a non-uniform distribution were not acceptable, since then such a formulation would not be suitable for its medical use.

With respect to the auxiliary request 4 the appellant (opponent) raised some objections with respect to Article 123(2) EPC. In the appellant's (opponent's) view the deletion of the term "mucilaginous" from the claims contravened the requirements of Article 123(2) EPC, since the solid or semi-solid medium was not disclosed as preferred in the application as filed.

Moreover, it stated that alginates still appearing in claim 4 or carrageenan still appearing in claim 5 were a mucilaginous medium. In the appellant's (opponent's) opinion these arguments also applied to auxiliary request 5.

With respect to claims 18 and 19 of auxiliary request 5, the appellant (opponent) contested their novelty vis-à-vis the contents of document (2) since the features relating to the pharmaceutical preparation were not suitable for establishing the novelty of the second medical use indication.

The appellant (opponent) also contested the novelty of the subject-matter of claims 1 and 9 of auxiliary request 5 since document (1) disclosed a solid matrix containing nicotine and the surface area and thickness specified in the amended claims were standard values. It referred to the values disclosed in column 8 of document (1) and mentioned that the reservoir was reflected by compartments 14 and 12 of figure 5. Moreover, the surface area of the matrix according to example 1 was 12.5 cm^2 and its thickness 0.3 mm (in example 2 the thickness was 0.4 mm). The appellant (opponent) also cited column 5, lines 9-11, of document (1).

The appellant (opponent) did not object to auxiliary request 5 on the grounds set out in Article 83 EPC.

XVII. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of the first or second auxiliary requests (filed during

the oral proceedings before the opposition division) or of the third auxiliary request, filed with letter of 8 April 2005, or, more alternatively, on the basis of the 4th or 5th auxiliary requests, filed during today's oral proceedings.

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

Reasons for the Decision

1. The appeal is admissible.

2. *Admissibility of the late filed evidence and late filed auxiliary requests*

2.1 The evidence filed by the appellant (patentee) with its letter of 8 April 2005, i.e. about one month before the oral proceedings is a direct and clear response to the issues raised in the board's communication sent as an annex to the invitation to the oral proceedings. The appellant (opponent) contested its admissibility but did not put forward any reasons in support of its request.

The auxiliary request 3 was also filed with the appellant's (patentee's) letter of 8 April 2005. The use claims contained some clear and simple amendments.

The board considers that the appellant (opponent) had sufficient time to consider these late filed submissions. Moreover, in the absence of any counterargument from the appellant's (opponent's) side,

the board sees no objective reason for not admitting the late filed evidence and the auxiliary request 3 into the proceedings.

2.2 The auxiliary requests 4 and 5 were both late filed since they were filed by the appellant (patentee) during the oral proceedings before the board. The appellant (opponent) did not contest their admissibility.

The amendments introduced in both requests were a direct and clear response to the issues put forward for the first time during the oral proceedings before the board. Moreover, the amendments were simple and easy to handle. Therefore, the board considers that auxiliary requests 4 and 5 are admissible.

3. *Prior art*

3.1 In view of the evidence submitted by the appellant (opponent) with its letter of 5 April 2005 it has been shown that document (2) was available to the public before the first priority date of the patent in suit (1 May 1987) and hence it forms part of the state of the art within the meaning of Article 54(2) EPC. This has not been disputed by the appellant (patentee).

3.2 Document (1) clearly forms part of the state of the art within the meaning of Article 54(3) EPC.

4. *Main request and auxiliary requests 1 to 3*

4.1 Claim 11 of the main request (set of claims as granted) is present in auxiliary requests 1 to 3 as claim 11.

Therefore, the conclusions reached for claim 11 of the main request apply directly to claim 11 of auxiliary requests 1 to 3.

4.2 Although Article 84 EPC is not an opposition ground, in the present case it is necessary to give an interpretation to the wording of claim 11. The device claimed is characterised by the presence of nicotine uniformly distributed in a solid, semi-solid or mucilaginous medium which has to fulfil the following functional feature:

"containing an amount of nicotine sufficient to achieve a plasma nicotine concentration in excess of 2 ng/ml within 1 hour after administration and to maintain such plasma nicotine concentration between 5 to 30 ng/ml over a period of from 1 to 24 hours".

Therefore, before it can be assessed whether the requirements of novelty have been met vis-à-vis the cited prior art, it has to be determined whether the above mentioned functional feature can serve to delimit the subject-matter claimed in claim 11.

As shown by the constant jurisprudence of the boards of appeal (Case Law of the Boards of Appeal, 4th edition, 2001, II.B.1), it is allowed in principle to define a product by functional features provided that some requirements are met such as that those features cannot be defined otherwise without unduly restricting the scope of the claim and that the tests required do not put an undue burden on the skilled person when reading the claim. However, even assuming that these criteria have been met in the present case, in order that the

functional feature can serve to impart novelty to the product claimed it is required that it can be linked to or correlated with at least one difference in the product's substance or constitution vis-à-vis the known products.

The appellant (patentee) referred to the disclosure of the invention in the description of the patent in suit in order to show that there was sufficient information for the skilled person to perform the invention and about how to measure the plasma levels.

The board is convinced that the plasma nicotine concentration can be measured by the skilled person, but in view of the lack of correlation with any parameter directly linked to the constitution of the product, the skilled person can vary, when measuring the plasma levels, several parameters without restriction. For example, nothing hinders the skilled person from taking two pads from example 1 of document (1) if one pad turns out to be insufficient for achieving the targeted plasma levels.

The question why it is not possible to maintain the plasma levels defined in claim 11 by the devices of document (1) (example 1 or figure 5) remained unanswered by the appellant (patentee).

Therefore, the board has come to the conclusion that the functional feature appearing at the end of claim 11 and mentioned above cannot serve to delimit the product claimed in view of the absence of a correlation with a parameter linked to the constitution of the product.

4.3 Document (1) discloses a transdermal therapeutic system characterised in that it contains a drug depot and a reservoir matrix. The drug depot initially contains a higher concentration of the drug than the reservoir matrix which may, at the time of the preparation of the system, be drug-free. However, during storage the saturation of the reservoir matrix with the drug takes place (cf. last paragraph of column 2 first paragraph of column 3).

The board is convinced that the saturation of the reservoir matrix with the drug takes place in the system disclosed in document (1) through diffusion and ends up, following the laws of physics, in a uniformly distributed drug in the reservoir matrix. This process takes place during the storage since, due to the fact that the device is sealed, the system is a closed system.

The preferred drug in document (1) is nicotine (first choice appearing in column 3, line 45 and exemplified in all the examples).

The reservoir matrix where the nicotine is uniformly distributed is a solid or semi-solid medium to be chosen among the adhesive or non adhesive options given in column 4, lines 38-58, and column 5, lines 1-4. Figure 5 is one preferred embodiment of the transdermal system of document (1). The system shows a back layer, an adhesive layer and a drug depot (14) which can be supported by an inert carrier such as a fleece. Additionally, over the surface of the drug depot extends a reservoir matrix (12) which is covered by a

protective film which can be taken away (cf. first paragraph in column 8 and figure 5).

Therefore, the reservoir matrix depicted in figure 5 of document (1) can be placed in intimate contact with the skin.

The reservoir matrix of document (1) is a solid or semi-solid medium which permits controlled release of the drug to the skin; this allows the avoidance of a membrane as a component of the system (cf. column 3, second paragraph).

There is no objective reason to doubt that the system of document (1) is suitable for the once-daily administration of nicotine. On the contrary, the measurements undertaken in the examples related to the liberation of nicotine, although relating to in vitro essays, indicate a clear suitability for the once-daily administration (columns 9 to 10).

In the light of the above analysis, claim 11 of the main request lacks novelty vis-à-vis the devices disclosed in document (1), in particular in view of that depicted in figure 5.

4.4 The appellant (patentee) has stressed that, contrary to the device according to claim 11, the device of figure 5 of document (1) is a two-compartment system. However, claim 11 does not exclude such a possibility since it uses the term "comprising" before the definition of the medium.

Moreover, it may be true that there is no uniform distribution between the depot layer (14) and the reservoir matrix (12) of figure 5 but, as already mentioned above, the fact that the system is sealed during storage allows diffusion of the nicotine through the reservoir matrix. This process ends up in nicotine uniformly distributed in the reservoir matrix which can be placed in intimate contact with the skin. The reservoir matrix is "the medium" defined in claim 11.

As regards the fact that the diffusion is time dependent, this cannot be taken in support of a difference between the systems, since no reference to the time in which the nicotine is uniformly distributed is given in the claim.

Having regard to the fact that the functional feature appearing at the end of claim 11 has not been considered, in the absence of a correlation with a parameter linked to the constitution of the device, to be suitable for delimiting the product claim it is not necessary to further comment on the validity of the in vitro tests results submitted by the appellant (opponent) and contested by the appellant (patentee).

4.5 Consequently, the main request and the auxiliary requests 1 to 3 fail for lack of novelty of the subject-matter of claim 11.

5. *Auxiliary request 4*

5.1 The restriction undertaken in amended claim 1 of auxiliary request 4 has a clear basis in the

application as filed (page 8, last paragraph, and page 9, first paragraph).

However, the deletion of "mucilaginous" as an option for the medium in claim 1 would require, in order to meet the requirements of Article 84 EPC, the deletion of claim 3 since there is now a lack of coherence between the two claims as shown by the contents of the description as originally filed. Claim 3 relates to a preparation according to claim 1, characterised in that it is in the form of a cream, gel, jelly, mucilage, ointment or paste. These forms have been disclosed in the application as filed as examples of the term "mucilaginous medium" (page 12, lines 28-30).

Accordingly, the amended set of claims of auxiliary request 4 does not meet the requirements of Article 84 EPC since the claims taken as a whole lack clarity.

5.2 The appellant's (patentee's) submission that the term "mucilaginous medium" is a subset of the "semi-solid medium" cannot be seen to be supported by the application as originally filed.

6. *Auxiliary request 5*

6.1 The deletion from the claims of the term "mucilaginous" as an option for the medium in which the nicotine is uniformly distributed has been contested by the appellant (opponent) as contravening the requirements of Article 123(2) EPC.

The board does not share this opinion for the following reasons: the deletion is a mono-dimensional restriction

which is in principle allowable and there is a clear basis in the application as originally filed for a solid or semi-solid medium having the surface area and thickness now defined in all the independent claims (page 8, last paragraph, and page 9, first paragraph).

None of the other amendments introduced in the claims have been contested by the appellant (opponent) under Article 123(2) EPC and the board sees no reason to differ.

Additionally, the amended claims are restricted in comparison with the claims as granted.

Accordingly, auxiliary request 5 meets the requirements of Article 123(2) and (3) EPC.

6.2 Claim 3 of auxiliary request 4 has been deleted in auxiliary request 5. Therefore there is no longer a problem relating to Article 84 EPC left.

However, the appellant (opponent) submitted that some of the compounds listed in claims 3 and 4 were mucilaginous and hence there was still a problem relating to Article 84 EPC in auxiliary request 5.

The board disagrees with this view because the agents listed in claims 3 and 4 are solidifying or gel-forming agents but do not alone constitute the medium per se.

No further objections relating to Article 84 EPC were raised by the appellant (opponent) for the amendments introduced and the board sees no reason to differ.

Accordingly, auxiliary request 5 meets the requirements of Article 84 EPC.

6.3 Both independent product claims, claims 1 and 9, now require the solid or semi-solid medium in which the nicotine is uniformly distributed to have "a surface area in the range 2 to 15 cm^2, more especially 5 to 10 cm^2, and a thickness in the range 0.5 to 3 mm, more especially 1 to 2 mm."

The appellant (patentee) has stated that this feature is clearly linked to the constitution of the products claimed and that it is critical for the establishment of the plasma levels defined in the claims.

The appellant (opponent) has not submitted any argument disputing the validity of this appellant's (patentee's) argument.

On the contrary, the surface area is one of the possible features mentioned by the appellant (opponent) necessary for correlating the constitution of the product with the plasma levels when discussing the functional feature of claim 11 as granted.

Apart from this, the appellant (opponent) has acknowledged that the thickness 100-5000 µm (0.1 to 5 mm) (disclosed in document (1) as the thickness of the reservoir) is disclosed in general terms and it encompasses, in the specific case of figure 5, both the depot (14) and the matrix reservoir (12) (column 8, lines 32-39, figure 5). Moreover, the appellant (opponent) has also acknowledged that the thickness for the reservoir disclosed in examples 1 and 2 of

document (1) (0.3 and 0.4 mm respectively) lies below the values stated in the claims.

Consequently, the novelty of the product claims 1 and 9 can be acknowledged over the contents of document (1) since it is not clearly and unambiguously derivable therefrom.

6.4 As regards the use claims 18 and 19, both have incorporated the feature:

"wherein said nicotine is uniformly distributed in a solid or semi-solid medium with a surface area in the range 2 to 15 cm^2, more especially 5 to 10 cm^2 and a thickness in the range 0.5 to 3 mm, more especially 1 to 2 mm which can be placed in intimate contact with the skin."

This requirement is clearly attributable to the preparation or device comprised in the medicament. Therefore, this feature directly linked to the nature of the medicament is not anticipated by document (1) as it becomes evident from the analysis in point 6.3 above. Moreover, the appellant (opponent) has not objected to the novelty of the use claims vis-à-vis document (1).

As regards the contents of document (2), the only specific feature relating to the nature of the medicament disclosed therein is that the patch possesses an adhesive film or layer in which the nicotine is distributed (page 562, right column). However, none of the other features appearing now in the use claims are disclosed in document (2).

Accordingly, the subject-matter of claims 18 and 19 can be considered to be novel over the contents of document (2).

With respect to the appellant's (opponent's) argument that the nature of the medicament cannot confer novelty on the subject-matter of a Swiss-type use claim, the board refers the reader to the case law of the boards of appeal (Case law of the Boards of Appeal, 4th edition 2001, I.C-5.2) and would point out that there are three blocks in a Swiss-type claim: substance, medicament and therapy, each of which may be linked to a novelty bringing feature. In the present case there are several features linked to the constitution of the medicament which bring novelty to claims 18 and 19 over the contents of document (2), such as the uniform distribution of nicotine in the medium or the surface area and the thickness of the medium.

6.5 Consequently, in view of the above analysis, the board has concluded that the subject-matter of auxiliary request 5 is novel vis-à-vis documents (1) and (2) (Article 54(1), (2) and (3) EPC).

7. The appellant (opponent) did not object to auxiliary request 5 within the meaning of Article 83 EPC and the board is satisfied that the requirements relating to sufficiency of disclosure have been met.

8. *Remittal to the department of first instance*

The grounds of opposition filed by the opponent did not contain inventive step as a ground. The opponent did

not raise such an objection during the opposition procedure.

It was the opposition division which made a comment about inventive step at the oral proceedings after announcing that the subject-matter of claims 21 and 22 lacked novelty. This comment about a lack of inventive step for the subject-matter of amended claims 21 and 22 of the first auxiliary request (cf. point 8 of the minutes of the oral proceedings) was made as an obiter dictum. The parties were not asked to present their arguments in respect of inventive step during the oral proceedings, since immediately after the announcement mentioned above an interruption of the oral proceedings took place. After the break the patentee filed its second auxiliary request.

The opposition division also expressed its opinion in its interlocutory decision as an obiter dictum, without detailed substantiation of a lack of inventive step in the subject-matter of amended claims 21 and 22 of the first auxiliary request (cf. page 9 of the decision).

The inventive step issue cannot therefore be regarded as discussed in the proceedings before the opposition division and is not within the framework of these appeal proceedings.

Nevertheless, the board understands from this obiter dictum that the opposition division did want to exercise its discretionary power to examine inventive step of its own motion and has only omitted to do so in its full extent because it found it unnecessary in the absence of novelty. Now that novelty has been

established by the board, the opposition division should have the opportunity to discuss this aspect with the parties in full.

The board is conscious of the long time that has elapsed since the priority date of the patent in suit. However, a patent cannot be maintained in an amended form filed for the first time during the appeal proceedings, without investigation of whether all the EPC requirements have been met. The appellant (patentee) has not given its approval to introducing this new ground into the appeal proceedings.

Since, in the present case, the board has no power to examine whether the requirements of Article 56 EPC have been met, the board will make use of its discretionary power and remit the case to the department of first instance for further prosecution (Article 111(1) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution on the basis of the 5th auxiliary request.

The Registrar: The Chairman:

U. Bultmann U. Oswald