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Datasheet for the decision of 24 September 2018

Case Number: T 1457/16 - 3.2.06

Application Number: 05713798.6

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Language of the proceedings: EN

Title of invention:
TRANSDERMAL SYSTEMS CONTAINING MULTILAYER ADHESIVE MATRICES TO MODIFY DRUG DELIVERY

Patent Proprietor:
MYLAN TECHNOLOGIES, INC.

Opponents:
Vossius & Partner
Patentanwälte Rechtsanwälte mbB
JWP PATENT & TRADEMARK ATTORNEYS

Relevant legal provisions:
EPC Art. 54

Keyword:
Novelty - (no)

Decisions cited:
T 0500/89

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Case Number: T 1457/16 - 3.2.06

D E C I S I O N
of Technical Board of Appeal 3.2.06
of 24 September 2018

Appellant: (Patent Proprietor)	MYLAN TECHNOLOGIES, INC. 110 Lake Street St. Albans, VT 05478 (US)
Representative:	Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburger Straße 4 80335 München (DE)
Respondent: (Opponent 1)	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstraße 3 81675 München (DE)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstraße 3 81675 München (DE)
Respondent: (Opponent 2)	JWP PATENT & TRADEMARK ATTORNEYS Dorota Rzazewska Sienna Center, ul. Zelazna 28/30, 00-833 Warszawa (PL)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 22 April 2016 concerning maintenance of the European Patent No. 1737406 in amended form.**

Composition of the Board:

Chairman	M. Harrison
Members:	G. de Crignis
	E. Kossonakou

Summary of Facts and Submissions

I. By way of its interlocutory decision, the opposition division found that European Patent No. 1 737 406 as amended according to subsidiary request 2 met the requirements of the European Patent Convention (EPC).

II. The patent proprietor (appellant) filed an appeal against this decision and requested that the decision be set aside and the patent be maintained as granted. It also submitted a set of auxiliary requests 1 to 8 and requested oral proceedings as well as remittal of the case to the opposition division for the assessment of the further requirements of the EPC on the basis of the main request.

III. Opponent OII (respondent II) requested that the appeal be dismissed and, as an auxiliary request, that oral proceedings be held.

IV. In a communication annexed to the summons to oral proceedings, the Board indicated its preliminary view that with regard to claim 1 of the main request and of auxiliary request 1 the requirement of Article 54 EPC was not met in view inter alia of D1. Concerning auxiliary request 2 it was noted: "Claim 1 of auxiliary request 2 is identical to claim 1 of auxiliary request 2 found allowable by the opposition division (dependent claim 3 of this latter request having been deleted). No appeal was filed by the opponent, nor has the opponent objected to the second auxiliary request. The Board thus considers that there is no need to discuss this request or the subsequent requests further."

V. In reply to the summons opponent OI (respondent I) announced that it would not attend the oral proceedings

and requested dismissal of the appeal. No comments were submitted in response to the opinion which was set out in the communication of the Board.

The appellant announced that it would not attend the oral proceedings and withdrew its request for oral proceedings but maintained its previously filed requests. No comments were submitted in response to the opinion which was set out in the communication of the Board.

VI. Finally, respondent II announced that it would not attend the oral proceedings, that it agreed with the preliminary view of the Board and requested that the case be remitted to the first instance for the assessment of inventive step if the subject-matter of claim 1 of the main request or any other of the proprietor's sets of claims would be considered as being novel.

Oral proceedings were nevertheless held before the Board on 24 September 2018 as scheduled.

VII. Claim 1 of the main request reads as follows:

" A transdermal drug-containing dosage unit which comprises:
(a) a backing layer impervious to a drug to be delivered transdermally;
(b) a first polymeric adhesive matrix comprising an acrylic adhesive, in contact with the backing layer, having dispersed therein the drug and having a first initial rate of delivery of the drug;
(c) a second polymeric adhesive matrix comprising a silicone adhesive or a polyisobutylene adhesive, in contact with said first polymeric adhesive matrix,

having dispersed therein the drug and having a second initial rate of delivery of the drug, wherein said second initial rate of delivery is different from said first initial rate of delivery, and wherein the first polymeric adhesive matrix delivers said drug more slowly than said second polymeric adhesive matrix; and (d) a release liner in contact with the second polymeric adhesive matrix;
wherein the drug is selected from the group consisting of: a cardiovascular drug, an androgenic steroid, an estrogen, a progestational agent, a sedative, a hypnotic, an analgesic, an anesthetic, an anti-anxiety agent, a nutritional agent, an anti-inflammatory agent, an antihistamine, a miotic, a dermatological agent, an anti-spasmodic, an anti-depressant, an anti-cancer drug, an anti-diabetic drug, an anti-estrogen agent, an anti-hormone drug, an anti-infective, an anti-allergenic agent, an anti-pyretic agent, an anti-migraine agent, a tranquilizer, and an anti-psychotic agent."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that, in feature (b), the first polymeric adhesive matrix is defined as "forming an anchor layer" and, in feature (c), the second polymeric adhesive matrix is defined as "forming a skin contact layer", and in that it is further specified that the anchor layer and the skin contact layer form a bi-layer matrix.

Claim 1 of auxiliary request 2 corresponds to claim 1 of subsidiary request 2 which the opposition division found to meet the requirements of the EPC.

VIII. The arguments of the appellant relevant for the decision may be summarised as follows:

The subject-matter of claim 1 as granted was novel over the disclosure in D1.

There was no disclosure in D1 about the features of claim 1 requiring the initial rate of delivery of the second layer to be different from the initial rate of delivery of the first layer, nor the first polymeric layer to deliver the drug more slowly than the second polymeric layer. Only the combination of these features led inevitably to the effect described in paragraph 13 of the patent in suit. Moreover, these features represented essential technical, i.e. distinguishing features, of the invention as claimed and should be considered in the assessment of novelty (cf. T 500/89).

D1 merely disclosed on page 10, l. 23-28 that the first adhesive layer (corresponding to the second polymeric adhesive matrix of claim 1) might be made of a non-functional pressure-sensitive adhesive with a low affinity for the active substance and the second layer (corresponding to the first polymeric adhesive matrix of claim 1) might be made of a functionally pressure-sensitive adhesive or a mixture of a functional and non-functional pressure-sensitive adhesive with a higher affinity and higher power of retention. The technical effect achieved by the combination of the first layer with the second layer in D1 was that the second layer could replenish the first layer (i.e. the skin contact layer) with drug, as it was lost from the first layer to the patient, thus achieving a highly constant efflux rate.

Also in Example 5 of D1, no disclosure was present of the initial delivery rates of the first and second

adhesive layers. Thus D1 could not anticipate the subject-matter of claim 1 as granted.

Auxiliary request 1 was based on the claims as granted, wherein claim 1 had been amended by specifying that the first polymeric adhesive matrix formed an anchor layer and the second polymeric adhesive matrix formed a skin contact layer, both layers forming a bi-layer matrix, which was supported by the disclosure on page 4, paragraph 13 of the application as filed.

IX. The arguments of respondent I may be summarised, as far as relevant for the decision, as follows:

The subject-matter of claim 1 lacked novelty in view of, in particular, Example 5 of D1.

D1 referred to a device wherein both adhesive layers were superimposed, and thus formed a bi-layer matrix. The first adhesive layer corresponded to the second polymeric adhesive matrix of claim 1 of the patent in suit and was disclosed as being in contact with the skin (D1, page 7, l. 28/29). The second layer corresponded to the first polymeric adhesive matrix of claim 1 of the patent in suit and was disclosed as being in contact with the backing layer and thus, could be considered as an anchor layer (D1, page 16, l. 8-20 and Figure 2).

D1, page 10, lines 23 - 28, further disclosed that the first adhesive layer was made of a non-functional pressure-sensitive adhesive with a low affinity for the active substance and that the second layer was made of a functional pressure-sensitive adhesive or a mixture of a functional and non-functional pressure sensitive

adhesives with a higher affinity and higher power of retention of the active substance.

Claim 1 did not define to what extent the initial drug delivery rates were different. It was also not specified which time period after administration of the transdermal unit should be considered as "initial". The terms "faster" and "more slowly" used in paragraph 13 of the patent in suit were not further defined.

Paragraph 17 of the patent in suit indicated that the two materials should be chosen so as to have significantly different drug delivery rates and that the first adhesive matrix should preferably comprise an acrylic adhesive (having relatively slow delivery characteristics) and the second adhesive matrix should comprise a silicone or polyisobutylene adhesive (having more rapid delivery characteristics). All these characteristics were also present in the delivery system of Example 5 of D1.

T 500/89 was not relevant to the current case.

The subject-matter of claim 1 of auxiliary request 1 also lacked novelty in view of D1, which disclosed the first layer being in contact with the skin and the second layer being in contact with the backing layer.

Reasons for the Decision

1. Main request - claim 1 - novelty - D1

1.1 D1 discloses a transdermal delivery system with two superimposed adhesive layers (title). Example 5 discloses the preparation of a device with two superimposed layers for the administration of fentanyl (pages 21/22) wherein:

- the first adhesive layer (corresponding to the second polymeric adhesive matrix of claim 1 of the patent in suit) includes a pressure-sensitive adhesive (Duro Tak 87-2353, acrylic pressure-sensitive adhesive) and is defined as the reservoir layer, and
- the second layer (corresponding to the first polymeric adhesive matrix of claim 1 of the patent in suit) includes a pressure-sensitive adhesive (including polyisobutylene) and is defined as the skin contact layer.

D1 discloses that the first adhesive layer made of a non-functional pressure-sensitive adhesive has a low affinity for the active substance (between about 1.15 to 10 times lower than that of the second layer) and that the second layer is made of a functional pressure-sensitive adhesive or a mixture of a functional and non-functional pressure-sensitive adhesive having a higher affinity and higher power of retention of the active substance (see page 10, l. 23-28 and page 11, l. 25-27)).

1.2 No explicit disclosure is present in D1 concerning the initial delivery rates of the first and second adhesive layers.

1.3 The appellant argued that there was no disclosure in D1 about the features of claim 1 requiring that the initial rate of delivery of the first and second layer would differ in combination with the feature that the first polymeric layer should deliver the drug more slowly than the second polymeric layer - and that it was this combination of features which lead inevitably to the effect of initial burst, or spike, of drug delivered through the skin of the wearer, followed by a slower more steady release of the drug.

1.4 However, in paragraph 17 of the patent in suit, the delivery characteristics are disclosed as inherent characteristics and consequences of the acrylic/ silicone or acrylic/polyisobutylene matrices of the dosage unit. Accordingly, the claimed functional features concerning the delivery rates (independent of the skin or the other layer) are not suitable to distinguish the claimed dosage unit structurally from Example 5 of D1 which discloses the identical structural features, as such functional features are inherently present.

1.5 The appellant argued that the technical effect achieved by the combination of the first layer with the second layer in D1 would be that the second layer could replenish the first layer (i.e. the skin contact layer) with the drug, as it was lost from the first layer to the patient, thus achieving a highly constant efflux rate.

1.6 However, for the same reason as set out above, namely the structural identity, the function of the second layer replenishing the first layer with the drug as disclosed in D1 implicitly applies also to the claimed dosage unit of the patent in suit, otherwise any dispersion of the drug in the first polymeric adhesive matrix would be superfluous. Thus, also this function is a consequence of the chemical composition of the matrices selected in the delivery system.

1.7 The appellant further referred to the functional features as having to be considered in the assessment of novelty, citing T 500/89 in this regard. However, T 500/89 concerns a method for the production of a photographic material, where according to the prior art relevant in that particular case, viscosity and thickness of the layers, as well as velocity of coating and the kind of support material had to be chosen such that the step of "intermixing" of two adjacent layers could occur, whereas in the method claimed in the case underlying that appeal "intermixing" was to be avoided. No such distinguishing process step is present in claim 1 under consideration in the present case. The conclusion drawn in T 500/89 thus lacks any relevance to the present case.

1.8 No response was received from the appellant or from the respondents with regard to the view of the Board on these issues as already set out in its communication.

1.9 Accordingly, the Board sees no reason to alter its provisional opinion and confirms same herewith, namely that the dosage unit defined in claim 1 is not novel (Article 54 EPC) with regard to Example 5 of D1, such that the main request is not allowable.

2. Auxiliary request 1 - claim 1

2.1 Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that, in feature (b), the first polymeric adhesive matrix is defined as "forming an anchor layer" and, in feature (c), the second polymeric adhesive matrix is defined as "forming a skin contact layer", and in that it is further specified that the anchor layer and the skin contact layer form a bi-layer matrix.

2.2 These amendments find a basis in the application as filed (page 4, paragraph 13, page 6, paragraph 17). Hence, the requirement of Article 123(2) EPC is met. This was also not contested.

2.3 However, the additional features are also present in Example 5 of D1 and thus the amendments to claim 1 in auxiliary request 1 do not alter the above finding on novelty. No arguments in this respect were submitted by the appellant either in response to the Board's provisional opinion. Thus, the Board concludes that the subject-matter of claim 1 of auxiliary request 1 does not meet the requirement of Article 54 EPC for the same reasons that apply to claim 1 of the main request. It follows that auxiliary request 1 is also not allowable.

3. Auxiliary request 2

3.1 Auxiliary request 2 (filed 18 August 2016) contains claims 1 to 8 which correspond to claims 1, 2 and 4 to 9 (with removal of multiple dependencies) of subsidiary request 2 (filed 10 March 2016) which was found to meet the requirements of the EPC by the opposition division. The substantive conclusion reached by the opposition division thus was not altered by this request.

3.2 The Board already indicated in its communication prior to oral proceedings that since no appeal had been filed by the opponent and the opponent had not objected to the second auxiliary request, the Board saw no reason to consider the second auxiliary request further. Neither the appellant nor the respondents replied to the communication in substance and, in particular, no objections or arguments were raised by the respondents with regard to claims 1 to 8 of this request. *Ex officio* also the Board sees no issue that should be addressed. Thus the Board finds that the claims of the second auxiliary request are to be maintained with the description as already adapted in the opposition proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent in amended form as follows:
   - claims 1 to 8 of auxiliary request 2 filed with the grounds of appeal dated 18 August 2016,
   - description pages 1 to 11 dated 11 April 2016, annexed to the decision under appeal, and
   - Figures 1 and 2 of the patent specification.

The Registrar: The Chairman:

M. H. A. Patin M. Harrison

Decision electronically authenticated