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**Datasheet for the decision
of 30 January 2018**

Case Number: T 1236/12 - 3.3.01
Application Number: 07003694.2
Publication Number: 1837023
IPC: A61K31/485, A61K9/70,
A61K31/445, B09B3/00, A61F13/00
Language of the proceedings: EN

Title of invention:

Disposal systems of transdermal delivery devices to prevent
misuse of the active agents contained therein

Applicant:

EURO-CELTIQUE S.A.

Headword:

Disposal systems for transdermal delivery devices/EURO-
CELTIQUE

Relevant legal provisions:

EPC Art. 56

Keyword:

Inventive step - (no) - all requests



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Case Number: T 1236/12 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 30 January 2018

Appellant: EURO-CELTIQUE S.A.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted on 28 December
2011 refusing European patent application No.
07003694.2 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairwoman R. Hauss
Members: M. Pregetter
P. de Heij

Summary of Facts and Submissions

I. The present appeal lies from the decision of the examining division refusing European patent application No. 07 003 694.2, published as EP-A-1 837 023.

II. Reference is made herein to the following documents cited during the examination/appeal proceedings:

(6) US 5,804,215

(10) Morgan J. E. , Plastic and Reconstructive Surgery, vol. 67, no. 5, pages 685 to 691 (1981)

(11) Experimental report received on 17 October 2011 and re-submitted with grounds of appeal, pages 1 to 8

III. The decision under appeal was based on a main request and three auxiliary requests.

Claim 1 of the main request reads as follows:

"1. A kit comprising:
a transdermal delivery device comprising buprenorphine or any pharmaceutically acceptable form or derivative of buprenorphin or fentanyl or any pharmaceutically acceptable form or derivative of fentanyl; and
a disposal system for the transdermal delivery device comprising at least a first substrate of the disposal system having an adhesive coating on one face thereof, wherein the adhesive is an acrylate-based adhesive."

Claim 1 of auxiliary request I reads as follows:

"1. A kit comprising:

a transdermal delivery device comprising buprenorphine or any pharmaceutically acceptable form or derivative of buprenorphin or fentanyl or any pharmaceutically acceptable form or derivative of fentanyl; wherein the transdermal delivery device further comprises an impermeable backing layer, which is a polymer selected [sic!] from polyurethane, polyesters, polyether amide, copolyester, polyisobutylene, high and low density polyethylene, polypropylene and polyvinylchloride, and a disposal system for the transdermal delivery device comprising at least a first substrate of the disposal system having an adhesive coating on one face thereof, wherein the adhesive is an acrylate-based adhesive."

Claim 1 of auxiliary request II reads as follows:

"1. A kit comprising:

a transdermal delivery device comprising buprenorphine or any pharmaceutically acceptable form or derivative of buprenorphin or fentanyl or any pharmaceutically acceptable form or derivative of fentanyl; wherein the transdermal delivery device further comprises an impermeable backing layer, which is a polyester; and a disposal system for the transdermal delivery device comprising at least a first substrate of the disposal system having an adhesive coating on one face thereof, wherein the adhesive is an acrylate-based adhesive."

Claim 1 of auxiliary request III reads as follows:

"1. A kit comprising:

a transdermal delivery device comprising buprenorphine or any pharmaceutically acceptable form or derivative of buprenorphin or fentanyl or any pharmaceutically acceptable form or derivative of fentanyl wherein the transdermal delivery device further comprises an

impermeable backing layer, which is a poly(ethylene phthalate); and
a disposal system for the transdermal delivery device comprising at least a first substrate of the disposal system having an adhesive coating on one face thereof, wherein the adhesive is an acrylate-based adhesive."

- IV. In the decision under appeal the examining division found that the subject-matter of none of those requests involved an inventive step when starting from document (6) as the closest prior art. The argumentation was based, *inter alia*, on the type of adhesive used. Auxiliary requests II and III furthermore contravened Article 123(2) EPC.
- V. With its statement setting out the grounds of appeal, the appellant (applicant) submitted a main request and five auxiliary requests. The main request and auxiliary requests I and II are identical to the corresponding requests examined in the decision under appeal. Auxiliary request IV is identical to former auxiliary request III examined in the decision under appeal.
- VI. The board issued a communication pursuant to Article 15(1) RPBA, indicating some issues to be discussed in view of Articles 123(2), 84 and 56 EPC. In its preliminary opinion, the board stated that the active agents of the transdermal delivery device could not establish an inventive step. It also addressed the spatial relationship of the substrate(s) of the disposal device and the position of the transdermal delivery device. The board observed that the experimental data on file did not appear to cover the entire scope claimed.

VII. With letter dated 20 December 2017, the appellant filed amended versions of auxiliary requests III and V.

Claim 1 of amended auxiliary request III reads as follows:

"1. A kit comprising:
a transdermal delivery device comprising buprenorphine or any pharmaceutically acceptable form or derivative of buprenorphine or fentanyl or any pharmaceutically acceptable form or derivative of fentanyl wherein the transdermal delivery device further comprises an impermeable backing layer, which is a polyester; and
a disposal system for the transdermal delivery device comprising at least a first substrate of the disposal system having an adhesive coating on one face thereof, wherein the adhesive is an acrylate-based adhesive, wherein the transdermal delivery device comprises an adhesive being identical to the adhesive on the disposal system."

Claim 1 of auxiliary request V reads as follows:

"1. A kit comprising:
a transdermal delivery device comprising buprenorphine or any pharmaceutically acceptable form or derivative of buprenorphine or fentanyl or any pharmaceutically acceptable form or derivative of fentanyl wherein the transdermal delivery device further comprises an impermeable backing layer, which is a poly(ethylene phthalate); and
a disposal system for the transdermal delivery device comprising at least a first substrate of the disposal system having an adhesive coating on one face thereof, wherein the adhesive is an acrylate-based adhesive, wherein the transdermal delivery device comprises an adhesive being identical to the adhesive on the

disposal system."

- VIII. With letter dated 25 January 2018 the appellant informed the board that it would not be attending the oral proceedings and requested that the case be decided according to the state of the file.
- IX. Oral proceedings took place on 30 January 2018 in the absence of the appellant.
- X. The appellant submitted arguments concerning inventive step in its statement of grounds of appeal. Insofar as these arguments are relevant to the present decision, they may be summarised as follows:

The subject-matter of the present application was distinguished from document (6) inter alia in that the disposal system for the transdermal delivery device comprised an acrylate-based adhesive. In contrast, document (6) used a rubber-based adhesive. The experimental data on file showed unexpected advantages of acrylate-based adhesives over rubber-based adhesives (document (11)). According to document (11), the mechanical accessibility of transdermal delivery devices included in a disposal system comprising an acrylate-based adhesive was surprisingly reduced compared with disposal systems using rubber-based adhesives. Since these results were generalisable with respect to typical polymeric backings of other transdermal systems, the main request involved an inventive step. The auxiliary requests further defined details of the structural materials employed in the claimed kit.

- XI. The appellant has requested in writing implicitly that the decision under appeal be set aside and explicitly

that a patent be granted on the basis of the claims of the main request, filed with the statement setting out the grounds of appeal, or alternatively, on the basis of the claims of one of auxiliary requests I to V, where auxiliary requests I, II and IV were filed with the statement of grounds and auxiliary requests III and V with letter dated 20 December 2017.

Reasons for the Decision

1. The appeal is admissible.
2. The oral proceedings before the board took place in the absence of the appellant, who had been duly summoned but who had chosen not to attend, as announced with the letter of 25 January 2018. According to Rule 115(2) EPC and Article 15(3) RPBA, the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case. Hence, the board was in a position to announce a decision at the conclusion of the oral proceedings, as foreseen by Article 15(6) RPBA.
3. In view of the conclusion reached with regard to inventive step for all requests, it is not necessary to examine whether the requests on file comply with Articles 84 and 123(2) EPC.

4. *Inventive step*

4.1 *Main request*

4.1.1 The application relates to a disposal system for preventing, inhibiting and/or diminishing the intentional and/or inadvertent misuse or abuse of a transdermal delivery device containing an active pharmaceutical agent, such as an opioid. A kit is provided comprising a transdermal delivery device containing as an active agent a pharmaceutically acceptable form of either buprenorphine or fentanyl and a disposal system comprising at least one substrate having an adhesive coating on one face thereof. Claim 1 of the main request defines the adhesive to be acrylate-based.

4.1.2 The closest prior art is represented by document (6). Document (6) defines a transdermal patch disposal member comprising a generally planar sheet made of a tear-resistant flexible material having an adhesive applied to at least an outer periphery of one surface of said sheet. The transdermal patch is to be placed upon said sheet such that when said sheet is folded the adhesive coated one surface bonds to itself for encapsulating the transdermal patch. The adhesive is a rubber-based adhesive or some other adhesive known to those skilled in the art (claim 1, Figure 2 in combination with column 3, lines 1 to 7). The transdermal patch disposal system is aimed at safely disposing of transdermal patches containing residual medication (column 1, lines 4 to 31).

4.1.3 The difference between the subject-matter of claim 1 of the main request and the disclosure of document (6) lies in the specific pharmaceutically active agents

chosen (namely buprenorphine or fentanyl in their various forms) and in the acrylate-based adhesive of the disposal system.

Buprenorphine and fentanyl are two well-known pharmaceutically active agents. In the transdermal delivery device, they will exhibit their known pharmaceutical activity. The appellant has not provided any arguments concerning these active agents.

The acrylate-based adhesive is said to lead to an improved blocking effect. The appellant has filed experimental data (document (11)) in order to show an improved blocking of the mechanical accessibility of the transdermal delivery device.

- 4.1.4 Having regard to the two differences, the active agents and the adhesive, that are not interdependently contributing to the same technical effect, two partial problems can be identified:

The first problem is the provision of kits for the safe disposal of used transdermal delivery devices containing further potentially harmful active pharmaceutical ingredients.

The second problem may be formulated as the provision of kits, wherein the disposal system shows an improved blocking of the mechanical accessibility of the transdermal delivery device.

- 4.1.5 The solution to the first partial problem is the selection of various forms of buprenorphine and fentanyl as the active ingredients. As already indicated in the communication pursuant to Article 15(1) RPBA, the board considers that it is obvious for

the person skilled in the art to provide transdermal delivery devices comprising various forms of buprenorphine or fentanyl. It was known to the skilled person that these active agents were often delivered by a transdermal delivery device and potentially harmful after use of said transdermal delivery device. The selection of these two active ingredients can thus not lead to the acknowledgement of an inventive step. This has not been contested by the appellant.

- 4.1.6 The second partial problem will be considered next. The focus is on the question whether the used transdermal delivery device can be safely contained within the disposal system. The solution proposed in claim 1 of the main request is the use of a disposal system comprising an acrylate-based adhesive.

The appellant has provided an experimental report purportedly showing that acrylate-type adhesives have a higher adhesive strength towards typical polymeric backings and/or adhesives used in transdermal delivery devices, as shown by loop tack and peel adhesion measurements (document (11), Figure 3). The experimental set-up is depicted in Figure 1. It can be clearly seen from Figure 1 of document (11) that there is direct contact between the transdermal delivery device and the adhesive carrying side of two laminates each consisting of a backing film coated with a single adhesive layer and meant to represent the substrate coated with adhesive of the disposal device. The improved blocking of the mechanical accessibility to the transdermal delivery device purportedly shown in document (11) thus relies on the direct contact between the transdermal delivery device and the adhesive coated onto one face of the substrate of the disposal device.

The relevance of the data reported in document (11) for the main request needs to be discussed. The board notes that the structure of the disposal device in claim 1 of the main request is not defined, except for the requirement that said device comprises at least one surface having an adhesive coating on one face thereof.

Claim 1 of the main request does not define a mandatory contact between the transdermal delivery device and the surface coated with the adhesive. Such a mandatory contact is also not generally necessary for the functioning of disposal devices. Various forms of disposal devices, all having at least one adhesive-coated substrate and thus falling within the scope of claim 1 of the main request, can be envisaged which will lead to safe disposal of the transdermal delivery device without necessitating physical contact between the adhesive and the transdermal delivery device. For example, the transdermal delivery device may be enclosed by some type of casing/body which is then sealed using an adhesive covered flap.

Since there is no mandatory contact between the transdermal delivery device and the adhesive, the experimental data of document (11) would at most be relevant for some embodiments falling within the scope of the claim, viz. embodiments of the disposal device having direct contact with the transdermal delivery device. Therefore, the data of document (11) does not show a technical effect over the whole scope of claim 1. There are no further examples or other experimental evidence on file that show an improvement due to the use of certain types of adhesives. In summary, it has not been rendered credible that the above-mentioned second partial problem is solved over

the whole scope of the claim (see point 4.1.4).

Consequently, the technical problem needs to be reformulated:

The second partial problem is thus the provision of kits for the safe disposal of used transdermal delivery devices, comprising an alternative disposal device.

Various adhesives, including acrylate-based adhesives, are known in the field of pharmacy. In the communication pursuant to Article 15(1) RPBA, the board pointed to the fact that the use of acrylates as adhesives in various forms and for a broad range of purposes was common general knowledge. Acrylate-based adhesives are also more specifically known for use in pharmaceutical applications. Document (10) describes their use in surgical tapes (page 687, left-hand column, last paragraph to right-hand column, second paragraph and Table I). Although document (10) does not deal with disposal systems for transdermal delivery devices, it clearly shows that the well-known group of acrylate-based adhesives is common in pharmaceutical applications. A person skilled in the art, looking for an alternative disposal device, would use any adhesive known for use in the field under consideration. The skilled person would thus arrive at a disposal device with acrylate-based adhesives as one of the alternatives, and thus at the subject-matter defined in claim 1 of the main request, without employing inventive skill.

As a consequence, the subject-matter of claim 1 of the main request does not involve an inventive step (Article 56 EPC).

4.2 *Auxiliary requests I to V*

Additional features with regard to claim 1 of the main request have been introduced into claim 1 of the auxiliary requests:

Claim 1 of auxiliary request I additionally defines materials for the backing layer of the transdermal delivery device. A list of usual polymeric materials for impermeable backing layers is given.

Claim 1 of auxiliary request II limits the material of the backing layer of the transdermal delivery device still further, i.e. to polyester, a common material for such a layer.

Claim 1 of auxiliary request III further adds the definition that the transdermal delivery device comprises an adhesive which is identical to the adhesive of the disposal system. Acrylate-based adhesives are usual for transdermal delivery devices.

Claim 1 of auxiliary request IV does not contain any limitations for the adhesive of the transdermal delivery device, but specifies the impermeable backing layer of the transdermal delivery device to be a poly(ethylene phthalate). Poly(ethylene phthalate) is commonly used as material for impermeable backing layers of transdermal delivery devices.

Claim 1 of auxiliary request V combines the technical features of claim 1 of auxiliary request III and claim 1 of auxiliary request IV.

The technical features added to claim 1 of the auxiliary requests all further define the transdermal

delivery device. These features have presumably been introduced to align the scope of the claims with the experiments of document (11). The board notes, however, that none of the technical features of the auxiliary requests define the spatial relationship or a mandatory contact between the at least one surface of the disposal device and the transdermal delivery device. Since there is no mandatory contact between the transdermal delivery device and the disposal system, the materials making up the transdermal delivery device do not influence the interaction between said transdermal delivery device and said disposal system. Therefore, the appellant's argument that the structural materials employed in the kit will lead to a different assessment cannot be followed. The same line of argument as for the main request equally applies to the auxiliary requests. The appellant has not argued that the additional technical features render the transdermal delivery device as such inventive.

As a consequence, the subject-matter of claims 1 of auxiliary requests I to V does not involve an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairwoman:



M. Schalow

R. Hauss

Decision electronically authenticated