

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen
(D) No distribution

**Datasheet for the decision
of 17 May 2011**

Case Number: T 0922/10 - 3.3.02

Application Number: 02715112.5

Publication Number: 1381352

IPC: A61K 9/70

Language of the proceedings: EN

Title of invention:

Transdermal patch for administering fentanyl

Patentee:

ALZA Corporation

Opponents:

Ratiopharm GmbH
HEXAL PHARMA AG
Actavis Group hf
PLIVA HRVATSKA d.o.o.
LTS LOHMANN Therapie-Systeme AG
Acino AG
Sandoz Pharmaceuticals GmbH

Headword:

Transdermal patch/ALZA

Relevant legal provisions:

EPC Art. 123(2)

Relevant legal provisions (EPC 1973):

-

Keyword:

"All requests: added subject-matter (yes)"
"Features not individualised in original application"

Decisions cited:

-

Catchword:

-



Case Number: T 0922/10 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 17 May 2011

Appellant:
(Patent Proprietor)

ALZA Corporation
700 Eubanks Drive
Vacaville
CA 95688 (US)

Representative:

Williams, Paul Edwin
Ablett & Stebbing
Caparo House
101-103 Baker Street
London W1U 6FQ (GB)

Respondents:
(Opponent 01)

Ratiopharm GmbH
D-89070 Ulm (DE)

Representative:

Best, Michael
Lederer & Keller
Patentanwälte
Unsöldstrasse 2
D-80538 München (DE)

(Opponent 02)

HEXAL PHARMA AG
Industriestrasse 25
D-83607 Holzkirchen (DE)

Representative:

Merkle, Gebhard
Patentanwälte
TER MEER - MÜLLER - STEINMEISTER & PARTNER
Mauerkircherstrasse 45
D-81679 München (DE)

(Opponent 03)

Actavis Group hf
Dalshraun 1
IS-220 Hafnarfjodur (IS)

Representative:

Alt, Michael
Bird & Bird
Pacellistrasse 14
D-80333 München (DE)

(Opponent 04) PLIVA HRVATSKA d.o.o.
Ulica grada Vukovara 49
HR-10000 Zagreb (HR)

Representative: Best, Michael
Lederer & Keller
Patentanwälte
Unsöldstrasse 2
D-80538 München (DE)

(Opponent 05) LTS LOHMANN Therapie-Systeme AG
Lohmannstrasse 2
D-56626 Andernach (DE)

Representative: -

(Opponent 06) Acino AG
Carl-Feichtner-Ring 1
D-83714 Miesbach (DE)

Representative: Forstmeyer, Dietmar
BOETERS & LIECK
Oberanger 32
D-80331 München (DE)

(Opponent 07) Sandoz Pharmaceuticals GmbH
Carl-Zeiss-Ring 3
D-85737 Ismaning (DE)

Representative: Merkle, Gebhard
TER MEER STEINMEISTER & PARTNER GbR
Patentanwälte
Mauerkircherstrasse 45
D-81679 München (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 4 March 2010
revoking European patent No. 1381352 pursuant
to Article 103(2)(b) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
J.-P. Seitz

Summary of Facts and Submissions

- I. European application No. 02 715 112.5 was granted as European patent No. 1 381 352 with 21 claims, based on the international application PCT/US2002/007701, published as WO 2002/074286.

Independent claim 1 as granted read as follows:

"A monolithic transdermal patch for administering fentanyl, alfentanil, carfentanil, lofentanil, remifentanil, sufentanil or trefentanil through the skin comprising:

(a) a backing layer;

(b) a reservoir disposed on the backing layer, at least the skin contacting surface of said reservoir being adhesive; said reservoir comprising a single phase polymeric composition free of undissolved components containing an amount of a drug selected from the group consisting of fentanyl, alfentanil, carfentanil, lofentanil, remifentanil, sufentanil and trefentanil sufficient to induce and maintain analgesia in a human for at least three days;

characterised in that the reservoir is formed from a polyacrylate adhesive and has a thickness of 0.0125 mm (0.5 mil) to 0.1 mm (4 mil)."

- II. Oppositions were filed against the granted patent under Article 100(a) EPC (novelty and inventive step), Article 100(b) EPC (added subject-matter) and Article 100(c) EPC (sufficiency of disclosure).
- III. By its decision pronounced at oral proceedings on 17 December 2009 and posted on 4 March 2010, the

opposition division revoked the patent under Article 101(3)(b) EPC.

The opposition division held that the single remaining request, called the "main request", did not meet the requirements of Article 54(2) and (3) EPC.

IV. The appellant lodged an appeal against that decision and filed grounds of appeal together with a request that the patent be maintained according to its main request as granted or to one of its first to third auxiliary requests. The second auxiliary request corresponded to the main request before the opposition division.

V. In a communication dated 1 March 2011, the Board stated that in the proceedings before it the current requests appeared to require examination under Article 123(2) EPC, and specific problems in this respect were indicated.

Inter alia page 7, line 33 to page 8, line 5 (paragraph [00030]) together with page 8, lines 16 to 22 (paragraph [00032]) of the description as originally filed was assumed to form the most comprehensive basis for assessing the original disclosure of claim 1 of the second auxiliary request. Even on this basis, however, it appeared not possible to directly and unambiguously derive the subject-matter of the requests from the original disclosure.

VI. With fax dated 31 March 2011 but received in the Office on 6 May 2011, the appellant filed three new requests replacing all previous requests.

Claim 1 of the main request reads as follows
(amendments compared to claim 1 as granted in bold):

"A monolithic **subsaturated non-rate controlled** transdermal patch for administering fentanyl, ~~alfentanil, carfentanil, lofentanil, remifentanil, sufentanil or trefentanil~~ through the skin comprising:

(a) a backing layer;

(b) a reservoir disposed on the backing layer, at least the skin contacting surface of said reservoir being adhesive; said reservoir comprising a single phase polymeric **pressure sensitive adhesive** composition free of undissolved components containing an amount of ~~a drug selected from the group consisting of fentanyl, alfentanil, carfentanil, lofentanil, remifentanil, sufentanil and trefentanil~~ for delivery at an **administration rate** sufficient to induce and maintain analgesia in a human for at least three days; ~~characterised in that wherein~~ the reservoir is formed from a polyacrylate adhesive and has a thickness of 0.0125 mm (0.5 mil) to 0.1 mm (4 mil);

characterised in that

the patch is bioequivalent to Duragesic® transdermal fentanyl system;

with the exception of a 10 cm² composite of three laminated layers consisting of a peelable backing layer made of fluorocarbon-coated polyester film (3M, Scotchpak 1022) on top of a 50 µm thick adhesive layer of National Starch DUROTAK 87-4098 acrylate / vinylacetate copolymer containing 12 wt% of fentanyl

base on top of a support layer made of aluminium-coated polyester film (3M, Scotchpak 1009)."

Claim 1 of the first auxiliary request is worded like claim 1 of the main request, with the characterising feature being replaced by

"... the polyacrylate adhesive consists of about 68 wt% 2-ethylhexylacrylate, about 5 wt% 2-hydroxyethylacrylate, about 27 wt% vinyl acetate, and optionally up to 1 wt% glycidylmethacrylate, to a total of 100 wt%".

In claim 1 of the second auxiliary request, the words "with the exception of ... film (3M, Scotchpak 1009)" in the main request are replaced by the characterising feature of the first auxiliary request as cited above.

VII. On 17 May 2011, oral proceedings took place before the Board.

VIII. The appellant's submissions may be summarised as follows:

The amendments in the current requests as filed in writing were occasioned by the comments of the Board and the decision of the opposition division. Some of these amendments had been included "as requested by the Board" (with reference to paragraph [00030] and paragraph [00032]) and together with further amendments removed all problems that might prejudice the maintenance of the European patent with respect to the relevant articles of the EPC; Article 56 EPC, however, had so far been discussed only partly, in writing, and

not during the oral proceedings before the opposition division.

At the beginning of the oral proceedings, the features appearing in claims 1 of the requests were presented as originally disclosed when starting with paragraphs [00044] and [00045] of the description as originally filed in connection with the paragraphs following.

On this basis, it was totally clear for the skilled person that not only each of the features in the claims was disclosed in the application as filed, but that these features could and should be combined. The skilled person was motivated to put these features together because they were disclosed as preferred and because they appeared together in the examples. It was not relevant whether these features were disclosed together in a single sentence because the purpose of Article 123(2) EPC was only to protect the public from surprises with respect to the subject-matter of emerging patents. In the current case, the public would never be surprised by the contents of the requested claims.

It was established case law that only the introduction of additional information violated Article 123(2) EPC, and the restriction to fentanyl as active substance was directly derivable from the overall aim in the original application of finding a substitute for the Duragesic® transdermal fentanyl system. Therefore, the feature of bioequivalence was clearly also originally disclosed, particularly preferred as subject-matter of original

claim 2, and polyacrylate as the adhesive in the reservoir also was marked as preferred.

It was the clear teaching of the application as originally filed that the relevant features could be read together; it was nowhere expressed that they should not be read together - and, consequently, they were to be read together in the current claims. Any other reasoning would be overly literal and semantic. In addition, the argumentation to be found in the jurisprudence with respect to multiple choice of several lists of some length was restricted to the field of chemical substances and parameters, and was therefore not to be applied to the current case.

Moreover, in this case, it was clear to the skilled person that a patch for transdermal application had to contain different parts, and the only thing he had to do was to sequentially look up what material to use for instance for the drug, the backing layer and the reservoir, and how to use the components. Applying this procedure, the skilled person would be guided from one paragraph in the application to the other and would necessarily find exactly the features contained in claim 1 to be realised for arriving at the requested subject-matter.

IX. The respondents' arguments may be summarised as follows:

The problems discussed in the proceedings before the opposition division and the objections set out in the communication of the Board with respect to Article 123(2) EPC still remained.

In particular, regarding whatever part of the application as originally filed, the teaching of the current claims 1 represented a combination of individually disclosed features which were not allowed to be connected as realised in the present claims.

Also, a generalisation from examples was normally not allowed and, even if this was not intended by the appellant, the examples at least contained features that were not represented in the claims as requested.

In case of reference to paragraph [00045], starting with the wording "Referring now to Figures 1 and 2, a preferred embodiment of the transdermal monolithic patch 1 according to this invention comprises ...", it was to be set out that, first, a preferred embodiment was described per se and, second, particular characteristics were assigned to this embodiment that were also not represented in the claims as requested.

- X. The appellant withdrew its objection under Rule 106 EPC raised with the letter dated 31 March 2011 and received at the EPO on 7 April 2011.
- XI. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims filed as main request, or auxiliarily on the basis of its first or second auxiliary requests, all requests filed with letter dated 31 March 2011 and received at the EPO on 6 May 2011.
- XII. The respondents (opponents) requested that the appeal be dismissed.

Reasons for the decision

1. The appeal is admissible.

2. The amended claims filed as main request and first and second auxiliary request with fax dated 31 March 2011 and received at the EPO on 6 May 2011 are a *bona fide* attempt to respond to the arguments set out in the communication of the Board and are therefore admitted into the proceedings.

3. *Claim 1 of the main request; Article 123(2) EPC*
 - 3.1 This claim 1 relates *inter alia* to
 - a monolithic subsaturated non-rate controlled transdermal patch
 - for administering fentanyl ... comprising:
 - (a) ...
 - (b) a reservoir ..., at least the skin contacting surface of said reservoir being adhesive;
 - said reservoir comprising a single phase polymeric pressure sensitive adhesive composition ...
 - containing an amount of fentanyl for delivery at an administration rate sufficient to induce and maintain analgesia in a human for at least three days;
 - wherein the reservoir is formed from a polyacrylate adhesive ...;

- in particular,

- the selection of the drug is restricted to **fentanyl**,
and
 - the reservoir is formed from a **polyacrylate** adhesive.
- 3.2 The disclosure of this subject-matter in the application as originally filed is to be assessed:

3.2.1 Basically, the application as originally filed is directed to the application of "**fentanyl and analogs thereof**". This wording is to be found at all relevant places of the application, be it in the first sentence of the description, in the definition of what had been discovered (paragraph [00012]), or in one of the first sentences after headings like "Summary of the invention" (paragraph [00030]) or "Modes of carrying out the invention" (paragraph [00044]), and additionally in the introduction to the examples (paragraph [00076]) and in the definition of the term "drug" (paragraph [00016]). Further, "an analog of fentanyl" is defined as referring to analgesics such as "alfentanil, carfentanil, lofentanil, remifentanil, sufentanil, trefentanil, and the like" (paragraph [00015]).

Whenever a "drug" is characterised as preferred, fentanyl and sufentanyl appear together (see for instance paragraphs [00030], [00052] (lines 13 and 14 on page 13 of the description as filed), [00067] (lines 1 and 8 on page 20), [00073] (line 12 on page 22) or paragraph [00076], the examples and the original claims (claims 1 to 16 referring to analogs, 17 to 54 to fentanyl and 55 to 91 to sufentanyl). Even when trying to find a bioequivalent substitute to Duragesic® transdermal fentanyl system by in vitro experiments,

fentanyl and sufentanyl are used (see for instance figures 3 to 6).

Thus, with respect to the drug fentanyl as claimed, it is selected from a list of alternatives (fentanyl and analogs thereof), and even in the preferred embodiment of the teaching of the application as originally filed a drug chosen from fentanyl and sufentanyl is to be administered.

3.2.2 In the original description in paragraph [00049], first line, it is disclosed that the "reservoir 3 **or** the adhesive coating 6" is formed from a pressure sensitive adhesive. The adhesive coating 6 relates to figure 2, where the reservoir 3 itself is formed from a material that does **not** have adequate adhesive properties (see paragraph [00046], emphasis by the Board).

According to claim 1 of the main request, on the one hand the reservoir is formed from a polyacrylate adhesive, although, according to another part of the same claim, only "at least the skin contacting surface of said reservoir" should be adhesive (the latter being represented in figure 2). This is only possible if the skin contacting surface and the reservoir are identical.

Thus, with respect to the original disclosure, the subject-matter of claim 1 of the main request is *de facto* restricted to the teaching of figure 1, and the teaching of figure 2, referring to an adhesive surface of the reservoir, is omitted.

The "preferred embodiments" as described in paragraph [00048] necessarily correspond in terms of

their characteristics to this selection based on figure 1, and the material they are formed from is defined by the following sentence in this paragraph: "In preferred embodiments, the reservoir 3 is formed from a pharmaceutically acceptable pressure sensitive adhesive, preferably a polyacrylate or a styrenic block copolymer-based adhesive, as described in greater detail below". In paragraph [00049] it is set out that "The adhesive reservoir 3 ... is formed from standard pressure sensitive adhesives known in the art. Examples of pressure sensitive adhesives include, but are not limited to, polyacrylates, polysiloxanes, polyisobutylene (PIB), polyisoprene, polybutadiene, styrenic block polymers, and the like".

From this information, polyacrylate is chosen as the reservoir-forming material to arrive at the teaching of claim 1 of the main request.

- 3.2.3 However, nowhere in the application as originally filed can any information be found that only the teaching of figure 1 and not of figure 2 should be the invention, let alone that polyacrylate was the material of choice for the reservoir and that such a teaching should be applied in combination with fentanyl as the drug to be administered and not sufentanyl.

Thus, the teaching of claim 1 of the main request contains information that is not supplied by the application as originally filed, and therefore is not directly and unambiguously derivable from the application as originally filed. That is in breach of Article 123(2) EPC.

4. These arguments apply *mutatis mutandis* to the teaching of claims 1 of the first and second auxiliary requests because the relevant features are contained in these claims in the same way as in claim 1 of the main request.
5. Under these circumstances, the additional arguments of the appellant cannot hold.

As can be seen from points 3 and 4 above, applying the principle of direct and unambiguous derivability gives rise to a clear and unequivocal conclusion in the present case.

- 5.1 There is no room for any question as to what the skilled person would have been motivated to do and whether any teaching that the relevant features could **not** be read together was present in the application or not.
- 5.2 The question as to whether a skilled person would have been taken by surprise if claims 1 of the current requests had formed the basis for maintaining the patent in suit also finds its answer on the basis of direct and unambiguous derivability (see above).

If a teaching in an application - in this case referring to a monolithic patch for administering fentanyl - is presented in different places of the same application by using multiple wordings that are similar but not the same in their terms and in their technical meaning, any skilled person must be taken by surprise if one of these wordings arbitrarily becomes the subject-matter of the patent or, as in the current case,

a freely chosen agglomeration of emerging parts of them, while other parts are left aside.

- 5.3 For the sake of completeness, having already answered, under points 3 and 4 of this decision, the question of the direct and unambiguous derivability of the requested teaching, the Board additionally deals with the argument of the appellant that the skilled person would be guided from one paragraph in the application to the other and would necessarily find the features contained in claim 1 to be realised for arriving at the requested subject-matter.

However, starting for instance at paragraph [00044], he would not only find the features as they are represented in claims 1 of the requests, but he would also find further features, for instance relating to the concentration and quantity of the drug in the reservoir. He would find that "the drug and all other components are present at concentrations no greater than, and preferably less than, their saturation concentrations in the reservoir 3" (paragraph [00045]) and that "the material forming the reservoir 3 has a solubility for the drug of about 1 wt% to about 25 wt% of the total polymer composition" (paragraph [00053]) and - in preferred embodiments - that "the drug reservoir comprises about 0.05 to about 1.75 mg/cm² of the drug" (paragraph [00052] lines 6 and 7).

Since such features are not contained in claims 1 of the current requests and there is no information as to why they are not, here too the Board comes to the conclusion that the requested teaching is not directly

and unambiguously derivable from the application as originally filed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

N. Maslin

U. Oswald