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Datasheet for the decision of 14 September 2017

Case Number: T 0666/16 - 3.3.07

Application Number: 09176390.4

Publication Number: 2158905

IPC: A61K9/70, A61K31/4468

Language of the proceedings: EN

Title of invention:
Composition for the Transdermal Delivery of Fentanyl

Patent Proprietor:
3M Innovative Properties Company

Opponents:
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Generics [UK] Limited
Actavis Group PTC ehf
Patentanwälte
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Acino Supply AG
Teva Pharmaceutical Industries Ltd/ratiopharm GmbH
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Headword:
Composition for the Transdermal Delivery of Fentanyl/3M Innovative Properties Company

Relevant legal provisions:
EPC Art. 56
RPBA Art. 13

Keyword:
Late filed documents - Admission into the proceedings (yes)
Inventive step - All requests (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

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Case Number: T 0666/16 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 14 September 2017

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 20 January 2016 concerning maintenance of the European Patent No. 2158905 in amended form.**

Composition of the Board:

Chairman A. Usuelli
Members: D. Boulois
P. Schmitz

Summary of Facts and Submissions

I. European patent No. 2 158 905 was granted on the basis of a set of 15 claims.

Independent claim 1 as granted read as follows:

"1. A transdermal drug delivery composition comprising
(a) a copolymer comprising
(i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and
(ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer and containing a functional group selected from the group consisting of sulfonamide, urea, carbamate, carboxamide, hydroxy, amino, and cyano; and
(b) 8% to 30% by weight fentanyl based on the total weight of the composition."

II. Eight oppositions were filed against the granted patent under Article 100(a), (b) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed or of the parent application.

III. The appeal lies from the decision of the opposition division to maintain the patent as amended. The decision was based on 2 sets of claims, namely the claims as granted as main request and the claims filed on 9 October 2015 as auxiliary request 1.

IV. The documents cited during the opposition proceedings included the following:

P2: WO96/08229
P4: Roy et al., J. Pharm. Sci., 85(5), 1996
P5: Declaration Yu
P7: WO01/26705
P8: WO00/41538
P9: EP 887075 A2
P10: US5656286
P11: Determination of solubility of fentanyl in polyacrylates
P16: WO99/02141
P18: US4954343
P20: WO03/018075
P23: MSDS Gelva 737
P34: WO93/00058
P43: Technical Report 1 (Adam Cantor)

V. According to the decision under appeal, the description of the main request did not meet the requirements of Article 76(1) EPC and the subject-matter of claim 1 of the main request was considered to lack novelty over P18.

P18 was not novelty destroying anymore for the subject-matter of claim 1 of auxiliary request 1, in view of the deletion of the amino group, from the list of functional groups recited in (a)(ii) of claim 1.

As regards inventive step of auxiliary request 1, the opposition division considered P5 as the closest prior art. The difference over P5 was the fentanyl concentration in the composition, which was not mentioned in P5, whereas it was said to be 8-30% in claim 1 of auxiliary request 1. In the absence of an effect linked with said difference, the objective technical problem was formulated as being the provision of an alternative drug delivery system for fentanyl

suitable for delivery over extended periods of time. Concerning the obviousness of the solution, the opposition division was of the opinion that starting from P5 and looking for an alternative transdermal system for the release of fentanyl over extended periods of time, the skilled person would not had been incited to include 8-30% fentanyl in the composition with a reasonable expectation of success. There was no pointer in P5 to select the claimed concentrations. The subject matter of the claims of the first auxiliary request was inventive.

VI. Opponents 02, 03, 04, 06, 08 and the patent proprietor (hereinafter appellants-opponents 02, 03, 04, 06, 08 and appellant-proprietor) filed an appeal against said decision.

VII. With the statement setting out the grounds of appeal dated 30 May 2016, the appellant-proprietor requested that the patent be maintained as granted and submitted auxiliary requests 1-4 which were already filed before the opposition division. It also submitted the following items of evidence:
P50: Opinion: Applicability of drugs listed in P18 (US4954343) for transdermal delivery
P51: “Challenge of Patch Drugs: Getting Under the Skin”, A. Zuger, The New York Times, August 17, 1999.

The subject-matter of independent claim 1 of auxiliary requests 1-4 read as following, difference(s) compared with claim 1 of the main request as granted shown in bold:

(a) Auxiliary request 1

"1. A transdermal drug delivery composition comprising

(a) a copolymer comprising
(i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and
(ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer and containing a functional group selected from the group consisting of sulfonamide, urea, ~~**carbamate**~~, ~~**carboxamide**~~, hydroxy, ~~**amino**~~, and cyano;
(b) 8% to 30% by weight fentanyl based on the total weight of the composition."

(b) Auxiliary request 2

"1. A transdermal drug delivery composition comprising
(a) a copolymer comprising
(i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and
"ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer **and containing a hydroxy functional group**; and "
(b) 8% to 30% by weight fentanyl based on the total weight of the composition."

(c) Auxiliary request 3

"1. A transdermal drug delivery composition comprising
(a) a copolymer comprising
(i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and

(ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer **and containing a hydroxy functional group**; and
(b) 8% to **24**% by weight fentanyl based on the total weight of the composition."

(d) Auxiliary request 4

"1. A transdermal drug delivery composition comprising
(a) a copolymer comprising
(i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and
(ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer **and containing a hydroxy functional group, wherein the one or more ethylenically unsaturated B monomers are present in an amount of 5 to 55 percent by weight based on the total weight of all monomers in the copolymer**; and
(b) 8% to 30% by weight fentanyl based on the total weight of the composition."

VIII. With a letter dated 7 July 2016, opponent 03 withdrew its appeal.

IX. With a letter dated 11 August 2016, opponent 08 withdrew its appeal.

X. With a letter dated 25 August 2016, opponent 01 filed new evidences P52-P55:
P52: "Weichmacher" in Römpps Chemie Lexikon, O.-A. Neumüller, 1988, p. 4604-4607
P53: M.C. Musolf, "Pressure-Sensitive Adhesives: Sciences and Engineering", Transdermal Controlled Systemic Medications, 1987, p. 93-112

P54: D. Satas, "Acrylic Adhesives", Handbook of Pressure Sensitive Adhesive Technology, 1989, p. 396-456
P55: A.C. Watkinson, "Transdermal and Topical Drug Delivery Today", 2012, p. 357-366

XI. With a letter dated 18 October 2016, opponent-appellant 06 filed new evidences P56 and P57.
P56: R. Vanbever et al, "Transdermal Delivery of Fentanyl: Rapid Onset of Analgesia using Skin Electroporation"; J. of Cont. Release, 50, 1998, p. 225-235
P57: US 5 820 875

XII. With a letter dated 21 April 2017, opponent 02 withdrew its appeal, and informed that it will not be attending the oral proceedings.

XIII. A communication from the Board dated 21 July 2017 was sent to the parties. It considered in particular that none of the requests met the requirements of inventive step. The Board emphasized that fentanyl appeared to have a limited solubility in some copolymers which fell under the claimed invention, such as those disclosed in P4 or P5.

XIV. With a letter dated 14 August 2017, the appellant-proprietor filed two new documents:
P56bis: Citizen's petition regarding ANDA 76-258 submitted by Brookoff, MD, PhDk
P57bis: Declaration by Dr Majella E. Lane dated August 13, 2017.

XV. Oral proceedings took place on 14 September 2017.

XVI. The arguments of the appellant-proprietor may be summarised as follows:

The difference between the claimed subject-matter and the disclosure of P4 and P5 was the fentanyl concentration in the transdermal device. Examples 47 and 48 of the patent showed that the claimed device was able to provide a safe and extended release of fentanyl up to a week. The problem to be solved was the provision of a transdermal delivery device which can safely deliver fentanyl over an extended period of time.

There was no motivation from the teaching of P4 and P5 to increase the fentanyl concentration, especially with the claimed acrylate adhesive. P4 mentioned a concentration of fentanyl of 6% by weight but in a different adhesive matrix, namely PIB. P4 anyway did not recommend to use an acrylate adhesive, and thus taught away form the claimed solution. There was no teaching at all in P5 as regarded the concentration of fentanyl; a maximal solubility of around 4% in the acrylate adhesive of P5 was given as only information. None of the other cited documents, namely P10, P15, P23 or P40, disclosed a concentration of fentanyl falling in the scope of the claims, in particular not in an acrylate adhesive system.

P56bis mentioned that the amount of fentanyl in a patch had to be as low as possible in the transdermal devices, in view of avoiding potential abuse and to increase the safety of use of the transdermal device.

P11 also showed that the solubility of fentanyl in Gelva 737 was as high as 14% by weight and not 4% as

shown in P4, and that it was thus possible to make smaller devices.

Moreover, a simple increase of the fentanyl concentration in the claimed acrylate adhesive had an unpredictable effect on the properties of the transdermal device, since it could for instance impair the adhesiveness, and it could not guaranty a safe and extended release of fentanyl.

XVII. The arguments of the appellant-opponents and of the other parties as of right to the proceedings may be summarised as follows:

According to appellant-opponent 04, the difference in concentration in fentanyl between the claimed subject-matter and the disclosure of P4 or P5 did not provide any effect. The claimed weight range of 8-30% was indeed not an amount but a concentration; any effect on safety or on the release of fentanyl from the transdermal device was however dependent on its dosage in the transdermal device, and on the characteristics of said device, e.g. its size or thickness. All these features were absent from the claimed subject-matter. The problem could only be seen as the provision of an alternative transdermal device of fentanyl. The solution was obvious, since nothing would have prevented a skilled person to increase the fentanyl concentration. An increase of concentration of fentanyl in the transdermal device would have also an inevitable and predictable increase of fentanyl flux.

The appellant-opponent 06 emphasized the importance of the size and thickness of the transdermal device in the release profile of fentanyl; all these parameters were not defined in the claims. Moreover, the experiments of

examples 47 and 48 of the contested patent disclosed a specific adhesive copolymer which was not related to the polymers used in P4 or P5, and these examples did not give any indications as to the size and thickness of the devices. The experimental results could therefore not be used for showing an effect, and no improvement over the prior art P4 or P5 was shown. As regards the solubility, the claimed subject-matter did not have any limitation on solubility.
There was therefore no effect linked with the weight concentration, and the problem had to be defined as the provision of an alternative transdermal device. P6 suggested to use high percentages of fentanyl in transdermal devices as well as P10 which disclosed a range of 0.3-30%, P15 which disclosed a range of 0.05-20%, and P40 which disclosed a range of 1-20%.

Opponent 01 pointed out that it was not clear what was meant by safety in the appellant-proprietor definition of the problem to be solved, and that a prolonged release was not claimed in claim 1, but only in the dependent claims.

XVIII. Requests

The appellant-opponent 04 and the appellant-opponent 06 requested that the decision under appeal be set aside and that the patent be revoked.

The appellant-proprietor requested that the decision under appeal be set aside and that the patent be maintained according to the set of claims as granted, or alternatively that the patent be maintained on the basis of the sets of claims filed as auxiliary requests 1-4 with letter of 30 May 2016. Additionally, it requested that the documents filed by opponents 01 and

06 in the appeal proceedings not be admitted, because they were late filed.

Reasons for the Decision

1. Admission of documents P52-P55, P56-P57, P56bis and P57bis into the proceedings

All documents P52-P55, P56, and P57 were filed late, either by the appellant-opponents or by the appellant-proprietor. During oral proceedings, the Board admitted all documents into the proceedings.
Since said documents are not used in the decision of the Board, it does not appear necessary to provide the arguments and reasons why the Board decided to admit them.

Although late-filed by the appellant-proprietor, the admission of documents P56bis and P57bis into the proceedings was not contested by the appellant-opponents. Both documents do not provide new information and only serve to illustrate arguments brought forward by the appellant-proprietor in the discussion on inventive step and relate to common general knowledge. The Board, in the exercise of its discretion, decides to admit these documents into the appeal proceedings (Article 13(1) and 13(3) RPBA).

2. Main request - Inventive step

2.1 The invention relates to a transdermal drug delivery composition containing fentanyl, in particular to methods of providing sustained analgesia to subjects in need thereof.

2.2 Documents P4 and P5 were *inter alia* considered as potential closest prior art by the opponents, while the appellant-proprietor considered preferably P4. Document P5 was the choice of the opposition division in its decision.

2.2.1 Document P4 discloses a transdermal device made from the pressure sensitive adhesive acrylate copolymer Gelva 737 (a copolymer of 67% by weight of ethyl hexyl acrylate, 28% by weight of vinyl acetate, less than 0.5% by weight of glycidyl methacrylate and 5% by weight of hydroxy ethylacrylate, as shown in P9, as well as in P23) and fentanyl at a concentration of 2-4% by weight (see for instance "Materials" and Figure 2). The solubility of fentanyl in Gelva 737, which is a copolymer falling under the definition of the claimed copolymer, is 21.9 mg/ml (see P4, Table 1). The device of P4 provides a sustained delivery of fentanyl, without any apparent burst effect (see P4, Table 3 and Figure 4). This document does not disclose a fentanyl concentration of at least 8% by weight.

2.2.2 Document P5 discloses transdermal devices comprising fentanyl in a pressure sensitive adhesive, such as the acrylate copolymer Durotak 2287, a polymer comprising vinyl acetate, 2-ethylhexyl acrylate, glycidyl methacrylate and 2-hydroxyethyl acrylate, thus having a hydroxyl as functional group. Figures 1 and 2 of P5 show the sustained delivery over several days and cumulative released amounts of fentanyl which are similar or close to most of the examples of the contested patent (see attachment P5B of P5, Figures 1 and 2). Figure 2 shows for instance cumulative released amounts of fentanyl of around 60 at 24 hours and 120 g/cm2 at 50 hours. P5 and its annexes do not specify

explicitly the fentanyl concentration in the disclosed devices.

2.2.3 The subject-matter of claim 1 of the main request differs from the compositions disclosed in both documents only by the concentration in fentanyl. As P4 was the preferred choice of the appellant-proprietor, its relevance will be assessed first.

2.3 The problem to be solved according to the appellant-proprietor is the provision of a transdermal delivery device which can safely deliver fentanyl over an extended period of time.

2.4 As a solution to this problem, claim 1 of the main request proposes a transdermal drug delivery composition comprising in particular 8% to 30% by weight fentanyl based on the total weight of the composition.

2.5 It has to be investigated whether there is sufficient evidence supporting the alleged effect.

2.5.1 The patent in suit provides numerous examples of the preparation of transdermal devices and their corresponding release profile. In particular, examples 47 and 48 were mentioned by the appellant-proprietor. These examples show transdermal devices providing without any doubts a sustained and safe release.

2.5.2 However none of the examples of the contested patent provides a comparison of the release of fentanyl when present in a concentration lower than 8% in the transdermal devices; it is thus not possible to deduce from said examples that a increased concentration of 8-30% of fentanyl would provide a safer or a more

sustained release of fentanyl, in comparison to a lower concentration of fentanyl in the device. In other words, the examples of the patent provide no evidence of an improvement over P4. In this regard, the Board emphasizes again that the broad definition of the copolymer given in P4 covers the copolymer used in P4 (Gelva 737) in which fentanyl appears to have limited solubility.

2.5.3 It appears furthermore that the cumulative amounts of penetrated fentanyl as shown in P4 are at the same level as most of the data presented in the examples of the contested patent (see for instance Table 6 of the contested patent and figure 4 of P4).

2.5.4 None of the examples of the contested patent offer thus sufficient evidence to support the assumptions of the existence of an improvement over the teaching of documents P4. Consequently, in the absence of any experimental evidence, the presence of an improvement as regards the safety and the release of fentanyl over the transdermal devices of P4 has not been credibly demonstrated and the technical problem must be reformulated as the provision of an **alternative** transdermal device containing fentanyl as active ingredient.

2.5.5 In view of the information found in the examples of the contested patent, the problem has been plausibly and convincingly solved.

2.6 It remains to be determined whether the solution was obvious to the person skilled in the art.

2.6.1 P4 discloses the solubility of fentanyl in the adhesive Gelva 737, which is 21.9 mg/ml, thus around 2% by

weight (see P4 Table 1). The skin flux obtained with an adhesive matrix with 2% by weight of fentanyl is 0.9 µg/cm2/hr which gives a cumulative release comparable to some devices of the contested patent (see Table 4 of P4 and see for instance Table 6 of the contested patent).

2.6.2 P4 discloses however also transdermal devices comprising Gelva 737 as adhesive and 4% by weight of fentanyl, thus beyond the solubility limit of fentanyl in this adhesive (see P4, Table 2); P4 mentions furthermore that said increase in fentanyl loading from 2% to 4% in the acrylate adhesive matrices had very little effect or no effect on the release rate constant and the apparent diffusion coefficient of fentanyl (see P4, page 493, last par.).

Hence, the solubility of fentanyl in the adhesive therefore cannot be seen as a limiting factor for increasing the concentration of fentanyl in the adhesive matrix over the solubility limit; the skilled person has been furthermore taught by P4 that said concentration did not have any effect on the release of fentanyl. The skilled person confronted with the problem of providing an alternative device would thus have considered an increase of the fentanyl concentration, such as over 8% by weight.

2.6.3 Moreover, if, as argued by the appellant-opponents, it had been obvious for the skilled person at the effective date of the contested patent, that the solubility limit of fentanyl in Gelva 737 of 4% by weight disclosed in P4 was not credible, and was in fact much higher, namely around 14% by weight as shown in P11, an increase of the fentanyl concentration would have been even more obvious. However, in view of the

disclosure of P4 as such, this argument does not have any impact on the obviousness of the solution over P4.

2.6.4 The argument of the appellant-proprietor as regards the unpredictability of the properties of the acrylate adhesive matrices of P4 loaded with 8-30% by weight of fentanyl can also not be followed. It is indeed common practice to incorporate an active agent into an adhesive matrix over its solubility limit, as shown by the disclosure of P4 for different silicone, PIB and acrylate adhesives. The skilled person might expect logically an increase of the flux linked with an increased concentration or in the worst situation simply a release plateau. The existence of a technical prejudice of loading fentanyl at a concentration higher than the 4% disclosed in P4 lacks credibility in view of the disclosure of P4 and has anyway not been substantiated or proven by the appellant-proprietor.

2.6.5 As to the question of safety and potential abuse of a transdermal device comprising fentanyl raised by the appellant-proprietor, as supported by document P56bis, this question depends on the total amount of fentanyl comprised in said transdermal device. The amount of fentanyl is the same in a device comprising 4% by weight of fentanyl as in a half-sized device loaded with 8% by weight of fentanyl. This point is therefore irrelevant.

2.6.6 The choice of a concentration over 8% by weight can thus only be seen as an obvious alternative over the disclosure of P4. It follows that the subject-matter of claim 1 of the main request does not involve an inventive step.

The main request does not meet the requirements of Article 56 EPC.

3. Auxiliary request 1 - Inventive step

The subject-matter of claim 1 of auxiliary request 1 has been restricted as regards the nature of the B monomer, namely to "one or more ethylenically unsaturated B monomers copolymerizable with the A monomer and containing a functional group selected from the group consisting of sulfonamide, urea, hydroxy, and cyano".

The copolymer Gelva 737 disclosed in the closest prior art P4 comprises inter alia 5% by weight of a monomer having a hydroxy functional group, namely hydroxy ethylacrylate (see P9, Table 2, as well as P23). Hence, the amendments made to claim 1 of this request do not have any incidence on the reasoning and conclusions on inventive step outlined for the main request, which apply *mutatis mutandis* to claim 1 of auxiliary request 1. No inventive step can therefore be seen as a result of the specification of the B monomer.

Consequently, auxiliary request 1 does not meet the requirements of Article 56 EPC.

4. Auxiliary requests 2

The subject-matter of claim 1 of auxiliary request 1 has been restricted as regards the nature of the B monomer, namely to "one or more ethylenically unsaturated B monomers copolymerizable with the A monomer and containing a hydroxy functional group".

The restriction of the monomer B to a monomer having an hydroxy functional group or the restriction in the concentration of fentanyl has no incidence on the assessment on inventive step as discussed for the main request or auxiliary request 1 above, since P4 discloses also a copolymer with an hydroxy functional group.

Consequently, auxiliary request 2 does not meet the requirements of Article 56 EPC.

5. Auxiliary request 3

In comparison to auxiliary request 2, the subject-matter of claim 1 of auxiliary request 3 has been further restricted in the fentanyl concentration, namely, "8% to 24% by weight of fentanyl on the total weight of the composition".

This amendment made to claim 1 of this request does not have any incidence on the reasoning and conclusions on inventive step outlined for the main request or for auxiliary request 2 and 3, which apply *mutatis mutandis* to claim 1 of auxiliary request 3.

Consequently, auxiliary request 3 does not meet the requirements of Article 56 EPC.

6. Auxiliary request 4

The subject-matter of claim 1 has been further restricted by the introduction of the amounts of the B monomer, namely "ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer and containing a hydroxy functional group, wherein the one or more ethylenically unsaturated B

monomers are present in an amount of 5 to 55 percent by weight based on the total weight of all monomers in the copolymer".

The restriction to a B momer with a hydroxy functional group and to the amount of B monomer does have any incidence on the assessment on inventive step over P4, since the copolymer Gelva 737 disclosed therein comprises 5% by weight of hydroxy ethylacrylate (see P9 or P23).

Consequently, auxiliary request 4 does not meet the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1.The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

S. Fabiani A. Usuelli

Decision electronically authenticated