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D E C I S I O N
of 18 July 2001

Case Number: T 0436/00 - 3.3.2

Application Number: 94923905.7

Publication Number: 0705097

IPC: A61K 9/70

Language of the proceedings: EN

Title of invention:

Incorporating poly-N-vinyl amide in a transdermal system

Patentee:

Alza Corporation

Opponent:

Ortho Pharmaceutical Corp.

Headword:

-

Relevant legal provisions:

EPC Art. 123, 84, 113

Keyword:

"Admissibility: yes - situation comparable to the case where the opposition is withdrawn after revocation of the patent"

"Main request: no - undisclosed combination of features"

"First auxiliary request - yes - remittal"

"Right to be heard: yes - party absent at the oral proceedings sharing the same interests as the patentee"

Decisions cited:

G 0009/93, T 0629/90, T 0002/81

Catchword:

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Boards of Appeal

Chambres de recours

Case Number: T 0436/00 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 18 July 2001

Appellant:
(Proprietor of the patent) Alza Corporation
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Respondent:
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Representative:
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Decision under appeal: Decision of the Opposition Division of the European Patent Office posted 3 March 2000 revoking European patent No. 0 705 097 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: P. A. M. Lançon
Members: J. Riolo
S. U. Hoffmann

Summary of Facts and Submissions

I. European Patent No. 0 705 097 based on application No. 94 923 905.7 was granted on the basis of 11 claims.

Independent claims 1 and 6 as granted read as follows:

"1. A device for the transdermal administration, at a therapeutically effective rate, of a drug, which device comprises:

- (a) a reservoir comprising a transdermally administrable drug, a skin permeation-enhancing amount of a monoglyceride or a mixture of monoglycerides of a fatty acid with a total monoesters content of at least 51% or a lactic ester of an alcohol, separately or in combination, and a poly-N-vinyl amide;
- (b) a backing on the skin-distal surface of the device; and
- (c) means for maintaining the reservoir in drug- and permeation enhancer-transmitting relation with the skin.

6. A device for the transdermal administration of a drug at a therapeutically effective rate which device comprises:

- (a) a first reservoir comprising an amount of drug sufficient to administer at a therapeutic effective rate, a skin permeation-enhancing amount of a monoglyceride or a mixture of monoglycerides of a fatty acid with a total monoesters content of at least 51% or a lactic ester of an alcohol, separately or in combination, and a poly-N-vinyl amide;
- (b) a second reservoir comprising an excess of the permeation enhancer and a poly-N-vinyl amide and said

drug;

- (c) a rate-controlling membrane between the first reservoir and the second reservoir;
- (d) a backing on the skin-distal surface of the device; and
- (e) means for maintaining the first and second reservoirs in drug- and permeation enhancer-transmitting relation with the skin."

II. Opposition was filed against the granted patent. The patent was opposed under Article 100(b) EPC for insufficiency of disclosure and under Article 100(a) EPC for lack of novelty and inventive step.

III. The decision of the Opposition Division pronounced on 1 February 2000 revoked the patent under Article 102(1) EPC.

The Opposition Division was of the opinion that independent claims 1 and 6 of the sole set of claims under consideration, which was filed on 22 January 2000, did not fulfil the requirements of Article 84 EPC.

It considered that the feature "wherein the combination of permeation enhancer and poly-N-vinyl amide enhances the flux of drug from the device as compared with a corresponding device without the poly-N-vinyl amide" introduced respectively in step (c) and (e) of claims 1 and 6 was not clear, as it was questionable whether a flux of drug that was decreased in an initial period and then enhanced in a second period, as illustrated in the description of the patent in suit, would be nevertheless also encompassed by these claims.

IV. The appellant (patentee) lodged an appeal against the said

decision.

V. In a letter dated 11 July 2001, the respondent (opponent) informed the Board that it would not be present at the oral proceedings as a result of the opponent's purchase of the patentee's business.

VI. Oral proceedings were held before the Board on 18 July 2001.

A main request and auxiliary requests one to five were filed during the oral proceedings.

Independent Claims 1 and 6 of the set of claims of the main request read as follows:

"1. A device for the transdermal administration, at a therapeutically effective rate, of a drug **selected from tacrine, testosterone, estrogens and progestins**, which device comprises:

- (a) a reservoir comprising: **30 to 70 weight % polymer; 1 to 40 weight % of the drug**, a skin permeation-enhancing amount, **within the range 10 to 40 weight %**, of a monoglyceride or a mixture of monoglycerides of a fatty acid with a total monoesters content of at least 51% or a lactic ester of an alcohol, separately or in combination, and **10 to 25 weight % of a poly-N-vinyl amide**;
- (b) a backing on the skin-distal surface of the device;
and
- (c) means for maintaining the reservoir in drug- and permeation enhancer-transmitting relation with the skin,

wherein the combination of permeation enhancer and poly-N-vinyl amide causes the flux of drug, during a

substantial portion (at least 60%) of the period of 16 hours to seven days after the flux begins, to be enhanced as compared to a corresponding device without the said combination.

6. A device for the transdermal administration, at a therapeutically effective rate, of a drug **selected from tacrine, testosterone, estrogens and progestins**, which device comprises:

- (a) a first reservoir comprising: **30 to 70 weight % polymer; 1 to 40 weight % of the drug**, a skin permeation-enhancing amount, **within the range 10 to 40 weight %**, of a monoglyceride or a mixture of monoglycerides of a fatty acid with a total monoesters content of at least 51% or a lactic ester of an alcohol, separately or in combination, and **10 to 25 weight % of a poly-N-vinyl amide**;
- (b) a second reservoir comprising an excess of the permeation enhancer and a poly-N-vinyl amide and said drug;
- (c) a rate-controlling membrane between the first reservoir and the second reservoir;
- (d) a backing on the skin-distal surface of the device; and
- (e) means for maintaining the first and second reservoirs in drug- and permeation enhancer-transmitting relation with the skin, **wherein the combination of permeation enhancer and poly-N-vinyl amide causes the flux of drug, during a substantial portion (at least 60%) of the period of 16 hours to seven days after the flux begins, to be enhanced as compared to a corresponding device without the said combination."**

The set of claims of the first auxiliary request corresponds

to the set of claims of the main request wherein the range of glycerides or lactic ester has been amended to read **1 to 50 weight%** and the range of poly-N-vinyl amide **5 to 40 weight%** instead of respectively 10 to 40 weight% and 10 to 25 weight% in both independent claims 1 and 6.

VII. The appellant first argued that, having regard to the decision of the Enlarged Board of Appeal G 9/93, it was questionable whether the opposition proceedings were admissible in view of the fact that the opponent and the patentee were now part of the same enterprise and had common owners.

It then submitted that the main request filed during the oral proceedings complied with both Articles 123 and 84 EPC.

It also requested the correction of a mistake in Figure 7 of the contested patent.

VIII. The appellant requested that the decision of the Opposition Division be set aside and that the patent be maintained on the basis of the main and alternatively of the first, second, third or fourth auxiliary request, all submitted during the oral proceedings.

After its letter of 11 July 2001, the respondent neither confirmed nor withdrew its written request to dismiss the appeal.

Reasons for the Decision

1. Admissibility of the opposition and of the appeal

Contrary to the situation under consideration in the case G 9/93 (OJ EPO 1984, 481) wherein the opponents were *ab initio* the two joint proprietors of the patent in suit, in the present case, the opposition proceedings were, in

fact, initiated by two parties representing opposing interests.

Accordingly, it is the view of the Board that the decision G 9/93 does not apply under the present circumstances as it is not a case of self-opposition *ab initio*.

First of all, the Board notes that, according to the limited information provided by the parties, ie merely that the Johnson & Johnson group, of which Ortho, the opponent, is a member, has merged with the patentee's company Alza corporation, it cannot be concluded that both former companies are now the same legal person. Moreover, in response to a question of the Board in that respect, the appellant (patentee) replied that it was itself not able to provide an answer.

It is, however, not contested, as apparent from the letters from the parties of 11 July 2001 and 16 July 2001 separately informing the Board of the merger of the two companies, that, from the date of the merger, ie 22 June 2001, the respondent (opponent) and the appellant (patentee) have obviously the same instructions and that they share the same interest and information.

This situation, which is clearly not the one envisaged in G 9/93 as explained above, could be compared with the case where an admissible opposition is subsequently withdrawn, since, also in the present case, there are no more parties having opposing interests after the admissible opposition has produced its effects.

As regards the effect of the withdrawal of the opposition on the opposition proceedings, Rule 60(2) EPC provides that the opposition proceedings may be continued by the EPO of its own motion.

The significance of the withdrawal of the opposition during

the appeal proceedings has been considered in several cases by the Boards of Appeal. According to the case law, it has no direct significance in terms of procedural law if the Opposition Division revoked the European patent. As a matter of fact, in such a case, the Board of Appeal has to examine the substance of the Opposition Division's decision (see for instance, T 629/90, OJ EPO 1992, 654, point 2.2).

Under these circumstances, the Board concludes that the opposition and the appeal are both admissible.

2. *Main request*

2.1 Article 123(2) and (3) EPC

Compared with claim 1 as granted, claim 1 of the main request is now restricted to **four specific types of drugs** which were chosen among the numerous drugs disclosed in the application as originally filed (page 14, line 3 to page 15, line 12). Moreover, the amounts of the four ingredients present in the reservoir of the claimed device are now specified in the claim as follows:

- (a) **30 to 70 weight%** polymer
- (b) **1 to 40 weight%** of the specific drugs
- (c) **10 to 40 weight%** of monoglycerides or a lactic ester
- (d) **10 to 25 weight%** of a poly-N-vinyl amide (see paragraphs I and VI supra).

The Board observes that two different ranges were in fact explicitly disclosed in the application as originally filed for (c) and (d), namely 1 to 50 weight% or preferably 10 to 40 weight% and 5 to 40 weight% or preferably 10 to 25 weight% respectively (page 11, paragraph 2).

According to the reasoning in point 3 of the grounds in T 02/81, the simple sub-combination of the part ranges would not merit novelty as "selection", so that this mere restriction would not represent new subject-matter (T 02/81, JO EPO 1982, 394, 398). But it is not the situation in the present case where a specific combination has been made by choosing, on the one hand, specific drugs from one list and, on the other hand, specific ranges of ingredients from two other lists.

On the one hand, the appellant argued that the fact that the chosen ranges for (c) and (d) were disclosed as preferred without any relation to the amounts of the other ingredients would imply that all combinations were envisaged. On the other hand, however, it acknowledged during the oral proceedings that the choice of the specific ranges was in fact dictated by the restriction to the specific group of drugs in order to strengthen the patent with respect to the prior art. Such a relationship could obviously not be found in the application as filed.

Nor did the appellant provide further arguments to show that the disclosure of the application as filed pointed towards the specific combination of the main request.

Accordingly, the Board concludes that a potential selection has been made by combining specific drugs with specific ranges of ingredients, which contravenes Article 123(2) EPC.

3. *First auxiliary request*

3.1 Articles 123 and 84 EPC

The problem with the undisclosed combination of features discussed above has been overcome by the wording of the first auxiliary request which now recites the broad ranges for each ingredient.

All the other amendments introduced into independent claims 1 and 6 are adequately disclosed in the originally filed documents and comply in this respect with Article 123(2) EPC.

Compared with independent claims 1 and 6 (see paragraph I supra) as granted, the corresponding independent claims 1 and 6 as amended are limited in view of the additional technical features.

The amendments to present claims 1 and 6 are therefore also acceptable under the terms of Article 123(3) EPC.

The Board moreover sees no objection with respect to Article 84 EPC as far as this request is concerned.

Under these circumstances there is no need for the Board to consider the other requests.

4. *Remittal to the department of first instance*

- 4.1 Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered at two instances, it is well recognised that any party may be given the opportunity of two readings of the important elements of the case. The essential function of an appeal is to consider whether the decision which has been issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is considered by the boards in cases where a first instance department issues a decision against a party solely upon one particular issue which is decisive for the case, and leaves other essential issues outstanding.

If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111(1) EPC).

4.2 The observations made above apply fully to the present case. The Opposition Division decided that claim 1 was not patentable on the grounds of lack of clarity, but disregarded the essential issues of sufficiency of disclosure (Article 83), novelty (Articles 52(1), 54 EPC) and inventive step (Articles 52(1), 56 EPC). These issues, however, formed, *inter alia*, the basis for the requests that the patent be revoked in its entirety and must therefore be considered as essential substantive issues in the present case.

4.3 Thus, in view of the above considerations, the board has reached the conclusion that, in the circumstances of the present case, it is necessary to remit the case to the Opposition Division for further prosecution on the basis of the set of claims of the first auxiliary request filed by the appellant during the oral proceedings.

It is also left to the discretion of the first-instance department to decide on the request for correction of a mistake in Figure 7 of the contested patent, since this issue depends on the fate of the patent in suit.

5. *Article 113 EPC*

As explained above (see point 1, paragraph 5), it is apparent from the letters from the parties of 11 July 2001 and 16 July 2001 separately informing the Board of the merger of the two companies, that they now obviously have the same interest with respect to the fate of the patent under consideration. Under these circumstances, the Board concludes that the examination of the claims filed during oral proceedings in the absence of the respondent cannot, in any case conflict with its right to be heard.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:

A. Townend

P. Lançon