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D E C I S I O N
of 20 October 2005

Case Number: T 0034/03 - 3.4.01

Application Number: 95936233.6

Publication Number: 0783346

IPC: A61N 1/30

Language of the proceedings: EN

Title of invention:
Improved iontophoretic drug delivery device

Patentee:
Vyteris, Inc.

Opponent:
ALZA CORPORATION

Headword:
-

Relevant legal provisions:
EPC Art. 100(a), 100(b), 100(c), 56, 83, 123(2)
EPC R. 57a

Keyword:
"Amendments occasioned by a ground of opposition (yes, main request)"
"Added subject-matter (no, main request)"
"Adjournement of the oral proceedings (refused)"
"Inventive step (yes, main request)"
"Sufficiency of disclosure (yes, main request)"

Decisions cited:
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Catchword:
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Case Number: T 0034/03 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 20 October 2005

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 6 November 2002 concerning maintenance of European patent No. 0783346 in amended form.

Composition of the Board:

Chairman: B. Schachenmann
Members: H. Wolfrum
G. Assi

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the interlocutory decision of the opposition division, dispatched on 6 November 2002 maintaining European patent No. 0 783 346 in amended form.

The notice of appeal was received on 7 January 2003 and the prescribed fee was paid on the same day. On 14 March 2003 a statement of grounds of appeal was filed.

II. In response to a communication of the Board of Appeal dated 31 August 2005, the respondent (patent proprietor) filed by letter of 21 September 2005 amended patent documents including new claim versions according to a main and four auxiliary requests.

III. Oral proceedings were held at the request of the parties on 20 October 2005.

In the oral proceedings the respondent further amended claim 1 of its main request.

IV. The appellant requested that the decision under appeal be set aside and the patent be revoked in its entirety on the grounds of Articles 100(a) EPC (substantiated on the ground of lack of inventive step (Articles 52(1) and 56 EPC) and 100(b) EPC.

Furthermore, the appellant requested not to admit some of the amendments made to claim 1 of the main request filed by letter of 21 September 2005 for the reason that they were not occasioned by the grounds of

opposition and thus did not comply with Rule 57a EPC. Insofar as further amendments were requested in the oral proceedings, these were belated and, moreover, infringed the requirement of Article 123(2) EPC. In case said further amendments were admitted by the Board and interpreted as limiting the scope of the claim, adjournment of the oral proceedings and continuation of the procedure in writing was requested.

V. As regards the objection of lack of inventive step, the appellant made reference to the following documents :

D1: US-A-4 865 582,
D3: US-A-5 160 316,
D10: US-A-4 835 060,
D12: US-A-4 257 661, and
D13: US-A-3 982 320.

VI. The respondent requested, according to a main request, that the patent be maintained in amended form on the basis of the following documents:

claims:	1 to 11 filed in the oral proceedings;
description:	columns 1 to 10, filed by letter of 21 September 2005;
drawings:	figures 1 to 8, filed by letter of 21 September 2005.

Alternatively, the respondent requested maintenance of the patent in amended form on the basis of one of the sets of claims filed as first to fourth auxiliary requests by letter of 21 September 2005.

VII. Independent claim 1 of the respondent's main request reads as follows:

"*1. An iontophoretic drug delivery system for delivering medication to an applied area of a patient, which includes: an iontophoretic drug delivery patch (12) for placement against the skin of a patient, the iontophoretic drug delivery patch (12) including a medicament, and at least first and second electrodes (28,30); a controller (14) mateable with the patch (12), the controller (14) being adapted to control current provided to the electrodes (28,30) of the patch, the controller (14) having at least two controller contacts (37) characterised in that the patch (12) includes a plurality of spaced-apart electrical contacts (36), wherein at least a first electrical contact and a second electrical contact of the plurality of spaced-apart electrical contacts (36) are respectively electrically coupled to the first and second electrodes (28,30), and in that the controller (14) includes an elastomeric connector (46) disposed between and electrically in contact with the at least two contacts (37) of the controller and the first and second electrical contacts (36) of the patch (12) when the controller (14) is mated with the patch (12) and thereby establishing an electric current path from the controller, between the first and second electrodes through the skin of the patient, and back to the controller.*"

Claims 2 to 11 are dependent claims.

Claims 1 of the auxiliary requests are further amended by the introduction of features from the dependent claims.

VIII. The appellant essentially relied on the following submissions:

As regards the admissibility of amended claim 1 of the main request, the clause "*and thereby establishing an electric current path …* " added at the end of the claim constituted a clarification of the claim definition as regards the role and nature of the patch electrodes. Merely clarifying amendments were however not occasioned by a ground of opposition, and thus not admissible according to Rule 57a EPC. Moreover, the clause was isolated from the detailed description of a specific embodiment. By omitting in present claim 1 features from the disclosed context, the amendment constituted an unallowable intermediate generalisation. Finally, the further amendment to said clause not filed until the oral proceedings, replacing the expression "*between the pair of electrodes*" of the main request of 21 September 2005 by the expression "*between the first and second electrodes*", if considered as limiting the scope of the claim to patch electrodes of different polarity, took the appellant, which had prepared its argumentation on inventive step on the previous equivocal claim definition, by surprise. For these reasons, the main request should not be admitted into the proceedings or the oral proceedings be adjourned and the appeal procedure continued in writing.

As regards the issue of inventive step, it had to be taken into consideration that the claim wording was

extremely broad as regards the type of the system and the definition of its constituents, in particular the controller, the patch electrodes and the elastomeric connector as well as nature of the mating of the controller to the patch. Claim 1 on file was for instance by no means limited to an iontophoretic system being portable or having a reusable controller. Moreover, even after amendment, the claim definition was not unambiguously limited to the first and second electrodes being electrodes of different polarity, *ie* donor and counter-electrodes, respectively.

Given the broad claim definition, the closest piece of the prior art, *ie* document D3, disclosed an iontophoretic drug delivery system from which the subject-matter of claim 1 of the main request differed only in that the known electrical connection between the contacts of the controller and those of the drug delivery patch by means of a ribbon connector was replaced by a connection via an elastomeric connector. Associated with this difference was the objective problem of improving the electrical connection in terms of reliability and resistance to corrosion such as indicated in items [0014], [0015] and [0016] of the patent specification. The notional skilled person thus included an expert in the field of electrical connectors who would have been aware of elastomeric connectors promising the looked for advantages as evidenced by documents D10, D12 or D13. Therefore, a combination of the teachings of document D3 and any one of documents D10, D12 and D13 would have directly led the skilled person to the claimed iontophoretic drug delivery system.

Moreover, even if the claim wording was interpreted as referring to the variant of a patch structure combining donor electrodes and counter electrodes on the drug delivery patch, such variant would, apart from the fact that it did not address any of the problems referred to in the patent specification, constitute a widely used alternative as regards the structure of the pad, which was known for instance from document D1.

Alternatively, starting from the teaching of document D1, the sole difference between the claimed subject-matter and said teaching was also the provision of an elastomeric connector for establishing the electrical connection between the contacts of the patch and the controller instead of a connection by means of electrically conductive adhesive. In view of the tight connection provided by the adhesive and the flexible nature of the system known from D1 the objective problem should be seen in a desire for a functionally equivalent alternative to the flexible interconnection which would in particular maintain the mechanical flexibility of the system. Again the claimed solution would have been rendered obvious by any one of the teachings of documents D10, D12 and D13.

Moreover, since claim 1 under consideration was excessively broad, its wording covered embodiments, such as the provision of a homogeneously conducting elastomeric connector, which would short-circuit contacts of different polarity and thus would not work. The necessary structural limitation was only the subject of dependent claim 3 of the patent as granted. Analogous to widespread case law in chemistry, requiring that a technical advantage must be achievable

over the whole area claimed, the claimed subject-matter should be considered to lack inventive step. Furthermore, for any embodiment falling outside the scope of claim 3, but within the scope of claim 1, the patent did not provide an enabling disclosure and thus contravened Article 100(b) EPC (Article 83 EPC).

IX. The respondent's submissions may be summarised as follows:

As regards the admissibility of the proposed amendments to the main request, these responded to a debate concerning the interpretation of the claim wording in the context of a discussion of inventive step, in particular with respect to the teaching of document D3, and thus were occasioned by a ground of opposition. This applied in particular to the clause added at the end of claim 1, which was intended to remove an ambiguity as to whether the first and second electrodes of the iontophoretic drug delivery patch would form the donor and counter electrodes of the iontophoretic system, respectively, as became evident from the patent specification, or could as well be understood as referring to electrodes of the same polarity, as was shown in document D3. The clause, which was disclosed in the paragraph bridging pages 8 and 9 of the published application description in fact limited the scope of the claim. Moreover, since such limitation was consistent with the respondent's claim interpretation consistently relied on throughout the opposition and appeal proceedings no surprising situation was created by the addition of this clause. The further amendment made to the clause in the oral proceedings merely

rendered the terminology consistent with the remainder of the claim wording.

With respect to the issue of inventive step, it was to be kept in mind that iontophoresis was a highly sophisticated art. A skilled person being confronted with the problem of improving the reliability of an iontophoretic drug delivery system addressed by the present invention, *ie* a system which was small, portable and had a reusable controller, would not necessarily know where to look for a solution and which expert was to be consulted.

Document D3 disclosed a system which was totally different from the invention in that a stationary controller was connected to a iontophoretic drug delivery patch by means of a wire or ribbon connection. Moreover, the electrodes on the patch were all of the same polarity, thus necessitating a separate patch for the counter electrode. In order to use an elastomeric connector instead of the wire or ribbon connection, the system of D3 would have had to be completely redesigned, for which the skilled person would not have had any motivation nor guidance.

Document D1, on the other hand, referred to a portable flexible iontophoretic drug delivery system, in which the controller was electrically connected to the drug delivery patch by means of a conductive adhesive. Although electrical connections by means of elastomeric connectors were certainly known as such and theoretically could have been used for connecting the contacts of the controller to the corresponding contacts of the patch, there was no incitation for the

skilled person in the relevant technical field to attempt to improve the known structure in this manner. Thus, although the skilled person could have devised the claimed subject-matter he would have had no reason to do so.

As regards the question of enabling disclosure, the patent description provided ample technical information to put a skilled reader in a position to successfully implement an elastomeric connector for interconnection of contacts of different polarity in an iontophoretic drug delivery system. The reader of the patent could be expected to make a technically sensible interpretation of the claim, which took account of the disclosure of the patent as a whole.

Reasons for the Decision

1. The appeal complies with the requirements of Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.

2. *Admissibility of the amendments*

2.1 Requirements of Rule 57a EPC and lateness of requests

Amended claim 1 according to the main request is based on claim 1 of the patent as granted. The amendments concern the correction of clerical and grammatical errors (replacement of "*respectfully*" by "*respectively*"; deletion of the word "*with*" in the expression "*and with the first and second electrical contacts of the patch*"), minor editorial corrections

(insertion of "*and*" following the phrase "*including a medicament*"; insertion of the words "*at least*" in the phrase "*and electrically in contact with the at least two contacts*") and the addition of the clause "*and thereby establishing an electric current path from the controller, between the first and second electrodes through the skin of the patient, and back to the controller.*"

In the Board's view, the added clause, in particular after its further amendment in the oral proceedings (by which a former expression "*the pair of electrodes*" was replaced by "*the first and second electrodes*" in order to render the clause consistent with the terminology introduced in the preamble of the claim) leaves no reasonable doubt that electrical current has to flow through the skin of the patient from the first electrodes to the second electrodes of the patch having different polarities and thus forming donor and counter electrodes, respectively, of the iontophoretic system. Having thus a limiting effect on the subject-matter of claim 1, the added clause is considered as being occasioned by one of the grounds of opposition under Article 100(a) EPC, and therefore to comply with the requirement of Rule 57(a) EPC. Moreover, the Board, having found the substantive amendment to the claim formally admissible, does not object to the minor editorial amendments further made to claim 1 of the main request.

Furthermore, given the fact that the aforementioned amendments restrict the claim definition to subject-matter which was consistently defended by the respondent throughout the opposition and appeal

proceedings, the Board considers the appellant's complaint unfounded that it was taken by surprise by the course of events in the oral proceedings since its prepared attack on the patent was sidestepped if the amendments were admitted. Rather, as the oral proceedings showed, the appellant could easily adapt its argumentation to the amendments referred to above. Thus, the Board is convinced that the appellant's right to be heard was met.

Consequently, the Board saw no reason to grant the appellant's request for adjournment of the oral proceedings.

2.2 Basis of disclosure

As regards the definition of the current path for the iontophoretic delivery of drugs, the pertinent original disclosure is given by the paragraph bridging pages 8 and 9 of the specification of the published application WO 96/10442 in the context of the description of the specific embodiment of Figures 1 and 2:

"*Skin contacting surface 24 of the patch may further include at least a pair of spaced apart electrodes 28 and 30. Each of electrodes 28 and 30 are positioned to be in contact with the skin when the patch 12 is attached thereto. The electrodes 28 and 30 are positioned such that an electric current path is established between the electrodes 28 and 30 through the skin of the patient. Electrode 28 is also electrically coupled to reservoir 26 in a manner well-known in the iontophoretic drug delivery industry. A direct current source may be coupled to the electrodes*

28 and 30 such that electrode 28, which is in contact with reservoir 26, assumes the same charge as the ionized drug contained therein. Under the influence of electrical current passing from electrode 28 to electrode 30 through the skin, the drug contained in reservoir 26 is transcutaneously transmitted to the patient."

This description of the current path between the electrodes is in fact preceded by a description of various structural details of the patch, none of which has been included in amended claim 1. However, a skilled reader of the application specification immediately realises that the described role of the electrodes in establishing the current path through the skin, as cited above, is functionally independent from any of the structural features of the iontophoretic drug delivery patch further described in the context of the embodiment of Figures 1 and 2. Therefore, introducing into claim 1 the disclosed information relating to the current path without simultaneously indicating details of the structure of the patch described for the embodiment of Figures 1 and 2, does not add technical information to the patent which would not have been apparent from the application documents as originally filed and thus cannot constitute an unallowable generalisation of the originally disclosed teaching.

Amended claim 1 thus complies with the requirement of Article 123(2) EPC.

2.3 In summary, the Board has found the amendments made to claim 1 according to the main request admissible.

3. *Inventive step*

3.1 The appellant considered document D3 to constitute the closest prior art.

3.1.1 The document shows several embodiments of an iontophoretic drug delivery system which generally comprises a disposable iontophoretic drug delivery patch ("15","18" in Figure 2; "21" in Figure 3; "34" in Figure 4) for placement against the skin of a patient, the patch including a medicament, a multichannel ("14") or single ("33") electrode and associated contacts, and a separate, stationary controller ("10" in Figure 1) comprising a source of electrical energy and being adapted to control current provided to the electrodes of the patch. According to the specific embodiment of Figure 2, the patch includes a multichannel electrode ("14") with a plurality of spaced apart, individually operable channels, each being respectively electrically coupled to one of a plurality of spaced-apart lead wires ("16") with electrical contacts ("19"). The electrical contacts of the patch are electrically connected to corresponding contacts (not shown) of the controller by means of a ribbon connector (column 4, lines 29 to 37).

3.1.2 The subject-matter of claim 1 of the main request differs from the system according to document D3 in that the electrical connection between the controller and the electrodes of the patch, instead of being made by means of a ribbon connector, is constituted by an elastomeric connector, which is disposed between and electrically in contact with the contacts of the

controller and the electrical contacts of the patch when the controller is mated with the patch.

In this respect, a further distinguishing feature is to be seen in the requirement that, according to claim 1 under consideration, the controller has to be mateable with the patch. In the Board's understanding of the claim definition, this requirement refers to a direct and intimate connection between the controller and the patch and thus excludes an indirect connection as known from D3 via a ribbon connector which is separate from the controller, even if the ribbon connector itself is considered to be mateable with the contacts of the patch.

A still further difference lies in the requirement according to claim 1 under consideration that the electrical current path runs between the first and second electrodes through the skin of the patient, from which, in the Board's opinion, it becomes evident that the first and second electrodes on the patch are necessarily of different polarity and thus constitute the donor and counter electrodes for iontophoretic drug delivery arranged on the same patch. In distinction thereto, in the system known from document D3 the patch represents a multichannel electrode and a separate grounding electrode is provided (D3, column 4, lines 25 to 28).

The claimed subject-matter thus constitutes an alternative structure of an iontophoretic drug delivery system which is more compact and has an electrical connection between the patch and the controller that is not subject to electrolysis and/or corrosion.

3.1.3 As is undisputed by both parties, each of said distinguishing features was as such known in the art before the priority date claimed by the present patent. Elastomeric connectors, for example, were known as alternatives to more conventional wire connections or connections by mating spring contacts from each of documents D10, D12 and D13. Moreover, an iontophoretic drug delivery patch carrying donor and counter electrodes and being mated to a controller is known for instance from document D1 (see for instance Figures 1 to 3).

However, implementing all these features in a system as known from document D3, whose type of structure is substantially different from that according to claim 1 of the main request, would have required to significantly redesign the known system. Although, theoretically, the skilled person could have assembled the claimed subject-matter from known technical elements, it is not apparent, in the absence of any specific hint at or clear motive for such a redesign, what would have incited the skilled person in particular to replace the known ribbon connection between the contacts of the patch and the controller by a connection via an elastomeric connector. In such a situation, any hindsight knowing the claimed solution should be avoided.

For this reason, the claimed subject-matter is not rendered obvious for the skilled person setting out from an iontophoretic drug delivery system as known from document D3.

3.2 An alternative starting point for an inventive step consideration is given by document D1. In fact, the structure of the iontophoretic drug delivery system known from document D1 is more similar to that of the claimed system than the structure known from document D3.

3.2.1 Document D1 discloses various constructions of iontophoretic drug delivery systems which are flexible and each include an iontophoretic drug delivery patch carrying iontophoretic donor and counter electrodes as well as associated contacts and a controller being mechanically as well as electrically mated to the patch and adapted to control current provided to the electrodes of the patch (see in particular Figures 1, 2, 2A, 3, 8 to 12 and 14 to 22 with the corresponding description). Common to all embodiments is that the controller is mechanically mated to the patch in a releasable manner by means of adhesive layers and that a releasable electrical connection between the contacts of the patch and the controller is established by means of an electrically conductive adhesive.

3.2.2 It is indeed common ground between the parties that document D1 discloses an iontophoretic drug delivery system from which the subject-matter of claim 1 of the main request differs only in that the electrical connection between the contacts of the patch and the controller is provided by an elastomeric connector.

Since the physical properties of electrical connections by an elastomeric connector and an electrically conductive adhesive in terms of reliability, resistance to electrolysis and corrosion, detachability and

cleanness are comparable, the objective problem associated with the aforementioned difference is, in the Board's view, to be seen in the desire for employing an alternative type of electrical interconnection having equivalent effects.

3.2.3 Undisputed by the parties, elastomeric connectors were known as such before the priority date, as is respectively evidenced by documents D10, D12 and D13. Moreover, in view of the fact that iontophoretic drug delivery systems inevitably require electrical interconnections between electrodes and controller contacts, an expert in the specific field of iontophoretic devices is expected to possess some knowledge of existing types of electrical interconnections useful for iontophoretic systems.

Nevertheless, in the flexible structure of the iontophoretic system known from D1 the electrically conducting adhesive does not only serve for electrically connecting the controller contacts to those of the patch but also helps to preserve the integrity of the mechanical connection between the controller and the patch when the system is bent during application to an uneven skin surface. As is well known, elastomeric connectors, on the other hand, require a certain amount of squeezing pressure so as to establish a proper electrical connection with oppositely arranged contact surfaces. Employing in the specific structure of the iontophoretic system known from document D1 an elastomeric connector instead of conductive adhesive would either have required the provision of additional mechanical means to produce the necessary squeezing pressure for establishing the

electrical contact or have entailed the risk of weakening the mechanical connection of the controller to the patch due to a separating force exerted by the elastomeric connector when being bent during application.

For these reasons and in the absence of any incentive to change the known system, the skilled person, even if he would have been aware of electrical elastomeric connectors such as shown by any one of documents D10, D12 or D13, would not have considered an elastomeric connector to constitute in the specific structure of the iontophoretic system known from document D1 a viable alternative to the electrically conducting adhesive. Therefore, the claimed subject-matter was not rendered obvious for the skilled person either when starting from the iontophoretic system known from document D1.

3.3 In summary, the subject-matter of claim 1 of the main request is novel and inventive and thus meets the requirements of Articles 54 and 56 EPC.

Dependent claims 2 to 11 relate to embodiments of the invention defined in claim 1.

4. With respect to the matter of lack of an enabling disclosure raised by the appellant, the Board considers the patent specification and in particular the description of Figures 1 to 8 to provide ample information for the skilled person to put the invention successfully into practice.

More specifically, in view of the fact that various types of elastomeric connectors having a unidirectional electrically conducting structure were known as such, the Board does not share the appellant's objection that any embodiment falling within the scope of claim 1, but outside the scope of claim 3, would constitute a structure in which the first and second electrodes were inevitably short-circuited so that claim 1 encompassed subject-matter which contravened Article 100(b) EPC (Article 83 EPC). Claim 3 adds the feature that the elastomeric connector has isolated electrically conductive sections extending from a first to a second surface of the connector and thus in fact defines a structure which provides the unidirectional electrical connection required for interconnecting in parallel contacts of different polarity. However, the structure defined by claim 3 is not the only conceivable (and in fact known) unidirectionally conductive structure of an elastomeric connector so that the Board sees no reason to limit the scope of claim 1 to the subject-matter of claim 3.

5. Due to the amendments made to the description and drawings bring the patent specification is in accordance with the subject-matter of the amended claims.

6. In summary, the Board has come to the conclusion that, taking into consideration the amendments made to the patent documents according to the respondent's main request, the patent and the invention to which it relates meet the requirements of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent in amended form on the basis of the following documents:

   - claims 1 to 11, filed in the oral proceedings as main request;
   - description, columns 1 to 10 filed by letter of 21 September 2005;
   - drawings, figures 1 to 8, filed by letter of 21 September 2005.

The Registrar: The Chairman:

R. Schumacher B. Schachenmann