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**Datasheet for the decision  
of 24 February 2016**

**Case Number:** T 2365/11 - 3.2.02

**Application Number:** 01977734.1

**Publication Number:** 1341453

**IPC:** A61B17/20, A61M37/00,  
A61M35/00, A61N1/30

**Language of the proceedings:** EN

**Title of invention:**

APPARATUS AND METHOD FOR PIERCING SKIN WITH MICROPROTRUSIONS

**Patent Proprietor:**

Alza Corporation

**Opponent:**

Engelhard, Dorothea

**Headword:**

**Relevant legal provisions:**

EPC Art. 19, 113, 100(b)  
EPC R. 11(1), 41(2)(c), 76(2)(c)

**Keyword:**

Admissibility of opposition - (yes)

Right to be heard - substantial procedural violation (no)

Sufficiency of disclosure - (yes)

**Decisions cited:**

G 0003/97, T 1652/08

**Catchword:**



**Beschwerdekammern**  
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Case Number: T 2365/11 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 24 February 2016**

**Appellant:** Alza Corporation  
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**Representative:** Maschio, Antonio  
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**Respondent:** Engelhard, Dorothee  
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**Representative:** Hoffmann Eitle  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 20 October 2011  
revoking European patent No. 1341453 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** P. L. P. Weber  
D. Ceccarelli

## **Summary of Facts and Submissions**

- I. The appeal of the patent proprietor is directed against the decision of the Opposition Division, posted on 20 October 2011, to revoke the patent. The Opposition Division considered that the ground for opposition pursuant to Article 100(c) EPC did not prejudice the maintenance of the patent but that the ground for opposition pursuant to Article 100(b) EPC did.
- II. The opposition proceedings had been initiated by the filing of a notice of opposition on 4 December 2009 by the European patent attorney of a natural person, Dr Dorothea Engelhard (hereinafter Dr D.E.).

Summons to oral proceedings were sent out on 26 May 2011, together with an annex in which the Opposition Division stated its provisional opinion that the objection under Article 100(b) EPC did not prejudice the maintenance of the patent.

With letter of 24 August 2011, the same attorney informed the Opposition Division that the representative of the opponent Hisamitsu would be using English at the oral proceedings scheduled for 5 October 2011.

In the oral proceedings on 5 October 2011 the patent in suit was revoked by the Opposition Division in a different composition from the one which had sent out the summons (change of chairperson).

- III. The notice of appeal was filed on 15 November 2011 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 16 February 2012.

IV. The Board summoned the parties to oral proceedings with letter dated 25 November 2015, also expressing its provisional opinion.

V. Oral proceedings before the Board were held on 24 February 2016.

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of auxiliary requests 1 to 6, all filed with letter dated 16 February 2012.

Subsidiarily the appellant (patent proprietor) requested that:

1. the opposition be declared inadmissible,
2. if the opposition was considered admissible, the case be remitted for the Opposition Division to hear the case again, and that the appeal fee be reimbursed because of a substantial procedural violation,
3. if the Board did not remit the case because of a substantial procedural violation, it do so for examination of novelty and inventive step.

The respondent (opponent) requested that the appeal be dismissed.

During the oral proceedings the respondent (opponent) said it too was in favour of remittal to the first-instance department for further prosecution if the Board came to the conclusion that the objection under Article 100(b) EPC did not prejudice the maintenance of the patent.

VI. Documents cited in the appeal proceedings, and relating to the objection pursuant to Article 100(b) EPC or to the admissibility of the opposition:

D1: WO-A-00/09184

D8 (appellant (patent proprietor)): WO-A-2011/105496

D8' (respondent (opponent)): WO-A-2006/105272

D9: Declaration of Dr Peter E. Daddona dated 3 February 2012

D10: "Transdermal delivery of desmopressin using a coated microneedle array patch system", Michel Cormier et al., Journal of Controlled Release 97 (2004), 503-511.

D11: "Parathyroid Hormone (1-34)-Coated Microneedle Patch System: Clinical Pharmacokinetics and Pharmacodynamics for Treatment of Osteoporosis", Dr Peter E. Daddona et al., Pharm. Res. (2011) 28:159-165.

VII. Claim 1 of the patent as granted reads as follows:

"A device (80) for impacting a microprotrusion member (44), said microprotrusion member (44) having thereon one or more microprotrusions (90), said microprotrusion member (44) being adapted to form one or more microslits through the stratum corneum through which an agent can be delivered or sampled, said device (80) comprising:

an applicator (60) having a contacting surface (68) and characterised by

said applicator (60) being adapted to cause said contacting surface (68) to impact said microprotrusion member (44) in such a manner that said microprotrusion member (44) strikes the stratum corneum with a power of

at least 0.05 joules per cm<sup>2</sup> of microprotrusion member (44) in 10 milliseconds or less.”

VIII. The arguments of the appellant (patent proprietor) relevant for the decision can be summarised as follows:

Admissibility of the opposition

The notice of opposition had been filed by a natural person but during the opposition proceedings, in one of the submissions of the opponent, the name of a firm was mentioned as opponent. Since the “true” opponent was therefore not known, and in any case the original opponent had no legal capacity, this constituted a circumvention of law by abuse of due process according to G3/97, rendering the opposition inadmissible.

Substantial procedural violation

At the beginning of the oral proceedings before the Opposition Division, the chairman had announced that he had taken over the case the day before. Therefore he had potentially had only a few hours to familiarise himself with it. This amounted to a violation of the right to be heard under Article 113 EPC. This violation was obvious from the fact that at the oral proceedings the opinion of the division had been different from that expressed in the summons.

Objection pursuant to Article 100(b) EPC

The claim was directed to a device that had to be able to deliver a specified minimum amount of kinetic energy within a specified maximum amount of time as indicated in paragraph [0012] of the patent. For the person skilled in the art, these were parameters of the device

that were easy to calculate. Paragraph [0026] mentioned equations usable for such calculations. The time parameter was the time of the impact or the time needed to decelerate to zero after first touching the skin. This parameter could for instance be measured with a high speed camera. The respondent (opponent) had not demonstrated any influence of the nature of the skin and in any case it was known to use hairless guinea pigs for testing because their skin was similar to human skin. Thus, the person skilled in the art could build a device according to the invention without any undue burden.

- IX. The arguments of the respondent (opponent) relevant for the decision can be summarised as follows:

Admissibility of the opposition

The opponent had been identified right from the start of the opposition proceedings, so the opposition was admissible.

Substantial procedural violation

The respondent (opponent) agreed with the appellant (patent proprietor) about what the chairman had said, but could not remember any details of the oral proceedings suggesting that he lacked knowledge of the case.

Objection pursuant to Article 100(b) EPC

Many parameters cited in paragraph [0025] had an influence on the device, and no embodiment was described in detail in the patent. This placed an undue burden on the person skilled in the art to determine all the relevant features of the device. In addition, no testing



method was disclosed that allowed the person skilled in the art to know if the parameters of the device were present or not. In particular, the time parameter depended on the nature of the skin and other external factors, and was particularly difficult to test. The description of the patent merely cited the parameters to be achieved, without giving any indication as to how this could be done.

Hence, the person skilled in the art wishing to carry out the invention faced an undue burden, which justified the revocation of the patent.

### **Reasons for the Decision**

1. The appeal is admissible.

2. The invention

The invention relates to a device for the delivery of medicine to the stratum corneum via micro-protrusions penetrating the skin. The known devices applied manually result in large variations of puncture depth. According to the invention, a member (applicator) is launched to impact the skin with a certain level of energy delivered within a certain time, so that potentially all the piercing micro-protrusions penetrate the skin in the same way.

3. Admissibility of the opposition

The notice of opposition was filed by a natural person (Dr D.E.). According to the appellant (patent proprietor), the difficulty with the admissibility of the opposition arose from the submission of 24 August

2011 (filed by the opponent's attorney to indicate the language which would be used during the oral proceedings before the Opposition Division) referring to Hisamitsu as the opponent. It took the view that the law had been circumvented by abuse of due process, because the opponent mentioned was different from that which had filed the notice of opposition. This created ambiguity, in that the identity of the opponent was not clear. This was different from the situation in which the "true" opponent was not known at all, as in the case leading to G3/97 (OJ EPO 1998, 245). D8 showed that Hisamitsu was active in the same field of technology. Moreover, as the declared opponent was acting on behalf of Hisamitsu it did not have full legal capacity, because it could not for instance withdraw the opposition without asking the true opponent, Hisamitsu. Therefore the opposition was not admissible.

In the Board's opinion, while there is a general obligation for the Board to determine ex officio who is a party in the proceedings should there be any doubt, in the present case, there is no doubt. The opponent Dr D.E. was clearly identified in the notice of opposition. Whether or not the correctly identified opponent is acting on behalf of a third person does not affect the admissibility of the opposition. In decision G3/97 the Enlarged Board of Appeal explained that according to the EPC a third person could act on behalf of a "true opponent": "*An opposition is not inadmissible purely because the person named as opponent according to Rule 55(a) EPC (1973) is acting on behalf of a third party.*", (Order, 1(a)). According to that decision, such an opposition is inadmissible only if the law has been circumvented by abuse of process, for example if the third person is acting on behalf of the patent proprietor or as a representative (Order, 1(b) and

1(c)). Both these situations can be excluded in the present case: since the patent proprietor is complaining, it seems rather unlikely that the opponent is acting in its name; the opponent is represented by a European patent attorney, and therefore is not itself acting as representative.

No further circumvention of law by abuse of process was established by the appellant in the present case.

The fact that the opponent may get instructions from a "true opponent", or in other words may not be acting on its own in all situations, is in any case only relevant to the internal relationship between the opponent and the "true opponent"; it has no bearing on the opposition proceedings (G3/97, last sentence of point 2.1 and point 3.2.2). Moreover, the Board notes that apart from the similar field of technology no further explanations were given as to why "Hisamitsu" is the "true opponent" in the present case. Anyhow, the fact that a name different from that of the opponent identified in the notice of opposition was additionally mentioned in a letter from the opponent's attorney has no bearing on the correctly identified opponent in the notice of opposition (Rules 76(2)(a) and 41(2)(c) EPC).

For the above reasons, the opposition filed by Dr D.E. is admissible.

#### 4. Substantial procedural violation

According to the appellant (patent proprietor), and not contested by the respondent (opponent), at the beginning of the oral proceedings the chairman of the Opposition Division informed the parties that its composition (chairperson) had changed the day before. The appellant (patent proprietor) regarded this replacement just one

day (possibly only hours) before the oral proceedings as a substantial procedural violation: at such short notice the new chairman could not familiarise himself with the case, so there had been a breach of its right to be heard pursuant to Article 113 EPC. Clear evidence of the difficulty encountered by the chairman was the Opposition Division's complete change of mind between the summons and the oral proceedings.

In the Board's opinion, the second argument is not valid, because the Opposition Division clearly indicated in its annex to the summons (page 3 of the annex posted on 26 May 2011) that its opinion on the objection pursuant to Article 100(b) EPC was provisional and non-binding. Moreover, it is in the nature of oral proceedings that the parties' written arguments are heard orally, and possibly expanded on, before all three members of the division. Obviously this can lead to the division changing its mind compared with the opinion it may have expressed before the oral proceedings. Hence, such a change of mind cannot in itself constitute a procedural violation infringing Article 113 EPC.

Concerning the change of composition, the Board would like to point out that, under Rule 11(1) EPC, *"Technically qualified examiners acting as members of Search, Examination or Opposition Divisions shall be assigned to Directorates."* And according to the Guidelines Part D IV.2, *"The director responsible will then designate the three technical members of the competent Opposition Division."* Hence, the director has the administrative and hierarchical power to designate the three technically competent members of the Opposition Division in charge of a particular case (Article 19 EPC). By extension, he also has the power to

designate alternate members if one of the original members has to be replaced.

It seems self-evident that any new member must be equally competent in the technical field of the case and must be able to familiarise himself with the file. This is a prerequisite for respecting the right to be heard, which presupposes that the content of the file is reasonably known to all the members of the Opposition Division, so that they can each understand the positions expressed by the parties during oral proceedings, and take their own position on every aspect to be decided. In this context the Board would stress that it is not the time available for studying the file which is important, but the objective knowledge of it. That a change in the composition of the opposition division does not in itself lead to a breach of a party's right to be heard has been made clear for instance in T 1652/08 (point 2 of the reasons) cited by the appellant (patent proprietor) itself. The present Board shares the opinion expressed in that decision. In that case, the composition of the opposition division also changed before the oral proceedings, albeit earlier than only one day before, and the Board ruled, in point 2.2, that *„Die neue Vorsitzende hatte somit Gelegenheit, die gesamten, vor ihrer Einsetzung vorgetragenen Tatsachen und Argumente der Parteien in gleicher Weise zur Kenntnis zu nehmen und zu würdigen wie die ursprüngliche Vorsitzende.“* (“The new chairwoman thus had the opportunity to note and consider all facts and arguments submitted by the parties before her assignment to the case, in the same way as the original chairwoman”). In the present case, even though the chairman said he had been designated one day before the oral proceedings, neither the appellant (patent proprietor) nor the respondent (opponent) has presented evidence to show

that the chairman did not have the requisite knowledge of the file. In the absence of any such evidence, it cannot be assumed that one day was not enough. Whether or not the necessary knowledge can be acquired in one day depends on the technical and legal complexity of the file. This question has to be assessed by the director, together with the member concerned. In the present case, in the absence of objective evidence to the contrary, it has to be assumed that the time available was sufficient.

For these reasons, no infringement of Article 113 EPC and no substantial procedural violation have been established, and there is therefore no need to consider the question of reimbursement of the appeal fee.

5. Objection under Article 100(b) EPC

The feature at stake is the last of claim 1 of the patent as granted:

*"said applicator (60) being adapted to cause said contacting surface (68) to impact said microprotrusion member (44) in such a manner that said microprotrusion member (44) strikes the stratum corneum with a power of at least 0.05 joules per cm<sup>2</sup> of microprotrusion member (44) in 10 milliseconds or less."*

The respondent (opponent) essentially considered that whether the parameter conditions were fulfilled or not was influenced by the type of skin, and no method or test was defined in the patent to indicate when a device fell within the scope of the claim. More particularly it argued that paragraphs [0022] and [0025] of the patent listed numerous parameters which affected the functioning of the device, but no device fulfilling the

claimed parameters was actually described in detail in the patent. The last sentence of paragraph [0025] indicating that the external conditions had been taken into account in determining the impact power was a mere assertion. Moreover, high-technology measuring devices were required for checking whether or not the parameters in the claim were present in a particular device.

It must first be assessed, in the light of the patent as a whole, what the invention is about. Paragraph [0001] of the patent already explains that *"the invention relates to an applicator device providing an impact to reproducibly penetrate the stratum corneum with a microprotrusion array for delivery or sampling of an agent."* (emphasis added).

Paragraph [0006] explains the difficulties with the prior art: *"...Manual application of a skin patch including microprotrusions often results in significant variation in puncture depth across the microprotrusion array. In addition, manual application results in large variations in puncture depth between applications due to the manner in which the user applies the array..."*

The concept of the invention is presented in paragraph [0007] and repeated in the first sentence of paragraph [0008] (emphasis added):

*"It would be desirable to provide an applicator for consistent and repeatable application of a microprotrusion array to the skin with the applicator applying an impact capable of achieving effective penetration of the stratum corneum with the microprotrusion array."* And:

*"The present invention relates to a device for applying a microprotrusion member including a plurality of microprotrusions to the stratum corneum with impact."*

That the device should be able to apply an impact to the array of micro-protrusions allowing penetration is confirmed several times in the detailed description:

Paragraph [0011]: *"...The applicator device 10 is configured to achieve a predefined and consistent impact of a microprotrusion member including an array of microprotrusions on the stratum corneum to provide acceptable penetration of the stratum corneum with the microprotrusions..."*

Paragraph [0012]: *"... The range of power per unit area is represented as a minimum energy per unit area delivered to the skin site in a maximum amount of time."*

In paragraph [0025] the time parameter for the specific example is said to be *"the time (t) in which the potential energy (PE) of the impact spring 20 is imparted as kinetic energy (KE) to the skin"*.

Paragraph [0028]: *"The impact spring 20 is preferably selected to deliver a minimum amount of energy of 0.05 Joules per cm<sup>2</sup>, which is delivered in less than 10 milliseconds."*

From the above, it follows that the whole teaching of the patent is that the micro-protrusion array should be impacted onto the skin instead of being manually pressed against the skin, and that this will lead to a better therapeutic effect. The claimed device is thus meant to be able to create such an impact, which is expressed in words by the definition of the impact length and intensity to be applied to the array and skin. The claim namely defines that a minimum of 0.05 joules per cm<sup>2</sup> should be applied to the micro-protrusion member (and hence to the skin) during a limited period of 10



milliseconds maximum. In other words, the device should be able to apply an impact lasting no longer than 10 milliseconds, during which time at least 0.05 joules per  $\text{cm}^2$  of energy are transferred.

It should be noted here that although the wording of the claim, taken alone, could possibly cover a device still transferring significant energy after the initial impact duration (here: 10 milliseconds), the claim cannot be read in that way because to do so would go against the teaching of the patent as a whole.

In the Board's opinion, two questions are thus relevant for the objection under Article 100(b) EPC:

- (i) Is it possible without undue burden to build a device capable of developing and subsequently applying kinetic energy of 0.05 joules per  $\text{cm}^2$ ?
- (ii) Is it possible without undue burden to build a device able to transfer this energy to the micro-protrusion array or the skin in less than 10 milliseconds and to check it?

In the Board's opinion, both questions have to be answered positively.

(i) The generation of an impact to be applied to the array implies movement of an element such as the applicator having a contacting surface oriented towards the array, before the impact of the contacting surface against the array or skin can take place. The kinetic energy accumulated by this applicator during the movement and, hence, theoretically transferable during the impact is determined by well-known laws of mechanics and physics. Examples of applicable laws are given for instance in paragraph [0026] of the patent. It follows that for a given device the person skilled in the art

can without undue burden calculate the accumulated or transferable energy or, in other words construct a device with an applicator being able to transfer at least 0.05 joules per cm<sup>2</sup>. Basic designs of possible devices are presented in the figures and the corresponding description parts. For instance, one embodiment of a device able to achieve the above-mentioned impact is shown in Figures 1 to 3 and 5, and presented with its essential features in the corresponding parts of the description. In particular, adapted helicoidal springs are mentioned in paragraphs [0027] and [0028]. It is noted here that the respondent (opponent) has not demonstrated or even alleged that it was not possible to build a functioning device starting from these figures and spring features. Moreover, mechanically it is self-evident that the necessary actuating force does not need to come from a helicoidal spring, but could come from various other energy sources as indicated in paragraph [0031] of the patent in suit. The Board does not see any undue burden for the person skilled in the art to determine such a suitable energy source. Of course, in any such constructed device some internal energy loss due inter alia to friction or array-retaining connections will be unavoidable, but such losses can easily be evaluated and compensated for. Such adaptations are part of the daily work of the person skilled in the art of developing such small devices.

(ii) The second question is whether it is possible to check or test without undue burden whether the accumulated energy is transferable to the skin within the maximum of 10 milliseconds required by the claim, and, hence, built the corresponding device. While accepting that the patent specification gives no indication of any specific test to establish this

parameter, the Board is of the opinion that the person skilled in the art does not need such an explicit test to check the presence of this feature.

This device is in the first place meant to be used on human skin. This is also specifically indicated in the patent, for instance in paragraph [0002] (*"Interest in the percutaneous or transdermal delivery of peptides and proteins to the human body continues to grow as the number of medically useful peptides and proteins becoming increasingly available in large quantities and pure form"* (emphasis added)) or paragraph [0027] (*"The following are examples of applicator systems having impact springs which provide acceptable power per unit area for delivery of a microprotrusion member, as tested on human skin"* (emphasis added)). Also the experiments made according to Example 1 (starting paragraph [0040]) and Example 2 (starting paragraph [0042]) are said to have been performed on hairless guinea pigs (HGPs), which are known to have a skin anatomy close to that of human skin. Should there be any doubt about that, it is indirectly confirmed by the tests presented in D10 (although published after the priority date), which are also said to have been performed on HGPs.

It follows that the person skilled in the art is used to employing HGPs rather than human skin for testing purposes. In other words, for the person skilled in the art the patent presents at least one usual way to test the devices, namely on such HGPs, as was done in the experiments of Examples 1 and 2 presented in the patent, and just as is usually done.

For this reason the Board considers that the person skilled in the art has no difficulty finding out a reference skin to test said parameter of the devices.

As regards the 10 milliseconds, what has to be measurable is the time between the moment when the penetration or contact of the micro-protrusions with the skin starts and the moment when there is essentially no further movement of the applicator, or in other words the impact duration. The person skilled in the art knows of several possibilities for doing this, such as high speed cameras, pressure or force measurements over time, etc. All these measurement possibilities are well known in the art and do not need to be mentioned in the patent in suit.

From the above it follows that with the designs addressed in the patent, the use of the (usually used) HGPs' skin as reference, and standard measuring and testing devices, the person skilled in the art will be able to build a device for carrying out the invention without undue burden.

For the reasons given above, the ground for opposition pursuant to Article 100(b) EPC does not prejudice the maintenance of the patent as granted.

6. Remittal

Both appellant (patent proprietor) and respondent (opponent) were in favour of remittal for further prosecution. The Board sees no reason not to remit the case for further prosecution, in particular for examination of novelty and inventive step which were not considered in the impugned decision, so that both parties can have the benefit of two instances on these matters.

## 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:



D. Hampe

E. Dufrasne

Decision electronically authenticated