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Datasheet for the decision of 31 January 2007

Case Number: T 0691/04 - 3.3.02

Application Number: 94301695.6

Publication Number: 0614659

IPC: A61K 9/00

Language of the proceedings: EN

Title of invention:
Pharmaceutical compositions in semisolid form and a device for administration thereof

Applicant:
TARO PHARMACEUTICAL INDUSTRIES LIMITED

Opponent:
-

Headword:
Assembly comprising a device and a pharmaceutical composition in semisolid form/TARO PHARMACEUTICAL

Relevant legal provisions:
EPC Art. 123(2), 109, 111(1)
EPC R. 67

Keyword:
"The requirements of Article 123(2) EPC are not met for any of the requests"
"Reimbursement of one of the two appeal fees (yes)"

Decisions cited:
G 0004/92

Catchword:
-

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Case Number: T 0691/04 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 31 January 2007

Appellant: TARO PHARMACEUTICAL INDUSTRIES LIMITED
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Representative: Chajmowicz, Marion
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 29 March 2004 refusing European application No. 94301695.6 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
P. Mühlens

Summary of Facts and Submissions

I. European patent application No EP-A-0 614 659 based on European application No. 94 301 695.6 was filed with 18 claims.

Claim 1 read as follows:

"1. A pharmaceutical composition comprising a semisolid in the form of a gel or suspension containing an effective amount of an orally active pharmaceutical agent useful for systemic treatment in combination with a pharmaceutical agent useful for systemic treatment in combination with a pharmaceutically acceptable vehicle consisting essentially of liquid base selected from a member of the group consisting of water, propylene glycol, glycerin and a combination thereof; thickening agent selected from a member of the group consisting of starch, sodium carboxymethyl cellulose, hydroxypropyl methyl cellulose, microcrystalline cellulose, tragacanth, acacia, pectin, gelatin, polyethylene glycol and carbomer in an amount effective to provide Brookfield a viscosity [*sic*] of about 2500 to 70,000 cps and a consistency which allows the composition to be squeezed easily through an orifice of about 0.1 mm to 5 mm in diameter; sweetener, preservative and optionally, flavouring matter, colouring matter, buffer, sodium chloride and solubilising agent for the orally active pharmaceutical agent."

Independent claim 6 read as follows:

"6. A device for containing and measuring a unit dose of a pharmaceutical composition in semisolid form comprising a squeezable container for holding the pharmaceutical composition having an outlet defining a flow channel for delivering said composition from the container, and closure means adapted to be connected to the outlet, the closure means comprising a spoon-shaped element having a shaft with channel means connected thereto so that the bowl of the spoon-shaped element projects from the closure means and the channel means are in fluid communication with the flow channel of the squeezable container and sealing means in said closure means positioned to seal the container when the closure means is fully closed and to provide space for the contents of the container to flow through the channel means into the spoon-shaped element in response to pressure on the container when the closure means is partially opened, whereby contents of the squeezable container can be squeezed into the bowl of the spoon-shaped element and administered therefrom."

Independent claim 7 read as follows:

"7. A device for containing and measuring a unit dose of a pharmaceutical composition in semisolid form comprising a squeezable container for holding the pharmaceutical composition having an open neck with threads for attaching a cap thereto and a cap with threads suitable to engage the threads of the neck of the squeezable container, a spoon having a shaft with channel means fixed in the cap so that the bowl-shaped end of the spoon projects outside the cap and the shaft

projects into the cap and the channel means are in alignment with the open neck of the squeezable container and sealing means in said cap positioned to seal the container when the cap is fully closed and to provide space for the contents of the container to flow through the channel means into the spoon in response to pressure on the container when the cap is partially opened, whereby contents of the squeezable container can be squeezed into the bowl-shaped end of the spoon and administered therefrom."

Independent claim 16 read as follows:

"16. A child proof device for containing a pharmaceutical composition useful for administration to children comprising a container with an open neck for holding said pharmaceutical composition, a cap fitted permanently on the neck of said container, a rotatable spring biased step cylinder positioned in said cap having channel means which allows for passage of said pharmaceutical composition through the cap when said rotatable spring biased step cylinder is pressed downward against the spring and seals the container when not pressed, a button on the exterior and near the top of said rotatable spring biased step cylinder and a cavity in the exterior of the cap adjacent to said rotatable spring biased step cylinder which matches the size and shape of said button, said button being positioned on said rotatable spring biased step cylinder so as to prevent the downward movement of said spring biased cylinder unless said button is aligned with said cavity."

Independent claim 17 read as follows:

"17. An assembly comprising a pharmaceutical composition in semisolid form which comprises an effective amount of an orally active pharmaceutical agent useful for systemic treatment in combination with a pharmaceutically acceptable vehicle comprising a thickening agent in an amount effective to provide a Brookfield viscosity of about 2500 to 70,000 cps at 25°C at a spindle speed of 10 rpm contained in the device defined in any of Claims 6 to 16."

II. The following documents have been cited inter alia during the examination proceedings:

(1) EP-A-0 479 005
(2) EP-A-0 379 147

III. The present appeal lies from the **second** decision of the examining division refusing the application under Article 97(1) EPC, pursuant to the requirements of Article 56 EPC, which was sent to the applicant on 29 March 2004.

IV. Briefly, the examining division considered document (2) to represent the closest prior art. The examining division defined the problem to be solved as "to provide an assembly allowing easily [sic] administration of orally active pharmaceutical agents for systemic treatment, avoiding spillage, particularly when used by children or adults with motoric problems." (page 5 of the examining division's decision).

The examining division considered that the proposed solution was obvious in the light of the prior art documents (2) and (1). Moreover, in the examining division's view, to increase viscosity for avoiding spillage was a trivial measure, merely reflecting the skilled person's common general knowledge.

V. The appellant (applicant) lodged an appeal (second appeal) against the (second) decision of the examining division, paid a (second) appeal fee and filed grounds of appeal. The appellant filed with the (second) grounds of appeal a main request, and a first and a second auxiliary request (they had been previously filed as second, third and fourth auxiliary requests. The appellant abandoned its previous main request and first auxiliary request).

Claim 1 of the main request read as follows:

"1. An assembly comprising:
a semisolid pharmaceutical composition in the form of a gel or a suspension, which comprises an effective amount of an orally active pharmaceutical agent useful for systemic treatment in combination with a pharmaceutically acceptable vehicle consisting essentially of liquid base selected from a member of the group consisting of water, propylene glycol, glycerin and a combination therefore [*sic*]; thickening agent selected from a member of the group consisting of starch, sodium carboxymethyl cellulose, hydroxypropyl methyl cellulose, microcrystalline cellulose, tragacanth, acacia, pectin, polyethylene glycol and carbomer in an amount effective to provide a Brookfield viscosity of 250 to 7,000 Pa.s (2,500 to 70,000 cps) at

25°C at a spindle of 10 rpm, and a consistency which allows the composition to be squeezed easily through an orifice of about 0.1 mm to 5 mm in diameter, sweetener as necessary to make the semisolid palatable; and optionally, flavoring, coloring matter, filler, preservative, buffer, sodium chloride and carriers usual in pharmaceutical compositions,
contained in a device for containing and measuring a unit dose of said pharmaceutical composition, said device comprising a sealed squeezable container, said container having an outlet, the container comprising an outer flexible squeezable wall which can be squeezed laterally with respect to an axis of said outlet whereby a predetermined unit dose of the pharmaceutical composition can be easily squeezed from the container, measured, and administered orally."

Claim 1 of the first auxiliary request merely differs from claim 1 of the main request in that the viscosity values have been specified as a "Brookfield viscosity of 750 to 4,000 Pa.s (7,500 to 40,000 cps)".

Claim 1 of the second auxiliary request differs from claim 1 of the main request in that the thickening agent has been defined as follows: "carbomer as thickening agent and in an amount effective to provide a Brookfield viscosity of 750 to 4,000 Pa.s (7,500 to 40,000 cps) at 25°C at a spindle speed of 10 rpm, and a consistency which allows the composition to be squeezed easily through an orifice of about 0.1 mm to 5 mm in diameter".

VI. The board expressed in its communication of 11 July 2006 that there had been a wrong interpretation of Article 109(1)EPC by the department of the first instance, which constituted a substantive procedural violation. The board also mentioned that it was inclined to decide the reimbursement of at least one appeal fee.

In the said communication the board raised objections re Article 123(2) EPC in respect of all sets of claims.

VII. As a response to the board's communication mentioned above, the appellant filed a letter dated 6 September 2006. It also filed two further auxiliary requests. The appellant also requested oral proceedings pursuant to Article 116 EPC.

Claim 1 of the third auxiliary request differs from claim 1 of the main request in that the device was defined as follows:

"in a device for containing said semisolid pharmaceutical composition, said device comprising a squeezable container with means for measuring and administering therefrom a single dose of said semisolid pharmaceutical composition and resealing the container thereafter."

Claim 1 of the fourth auxiliary request differs from claim 1 of the main request in that the device was defined as follows:

"in a device for containing said semisolid pharmaceutical composition, said device comprising a

squeezable tube with means for measuring and administering therefrom a single dose of said semisolid pharmaceutical composition, said tube being sealed by a cap".

VIII. The board sent a communication as an annex to the summons to oral proceedings in which it raised objections re Articles 123(2) and 84 EPC to all requests.

IX. The appellant announced in a letter dated 19 December 2006 that it would not attend oral proceedings. It did not comment on the objections raised by the board in the communication sent as an annex to the invitation to oral proceedings.

X. Oral proceedings took place on 31 January 2007 in the absence of the appellant.

XI. The appellant's arguments filed in writing with its letter of 6 September 2006 may be summarised as follows:

Claim 1 of the main request related to an assembly comprising a semisolid pharmaceutical composition contained in a device for containing a unit dose of said pharmaceutical composition. Claim 1 of the main request recited that the container comprises an outer flexible squeezable wall and an outlet, and that said flexible squeezable wall can be squeezed laterally with respect to an axis of said outlet.

In the appellant's view these features appearing in claim 1 were directly and unambiguously derivable from page 14 of the application as originally filed. In

particular, a tube 1 was disclosed with reference to figures 1-4, from which a semisolid composition can be squeezed.

Furthermore, the appellant submitted that a device of the invention was shown on figure 1 which represented a container sealed with a cap 3. Said cap 3 could be replaced by a cap 5 arranged with a spoon-shaped element 7 as depicted in figure 2. Figure 4 showed a cross sectional view of said container in which said cap 5 was provided. Such a device was used to measure and administer therefrom a unit dose (or single dose) of the semisolid pharmaceutical composition of the invention, as disclosed on page 14 as originally filed.

In the appellant's opinion, figure 1 clearly showed that the tube 1 comprised an outer side wall and it was common knowledge for any person that, in order to squeeze the content out of the tube, the side wall must be squeezed to collapse. Moreover, it was common general knowledge that the outer side of a tube must be squeezed laterally with respect to an axis to the opening of the tube in order to squeeze the content out of the tube. Additionally, it was shown in figure 4 that the tube 1 of the application as filed had an outlet within its neck 2.

The appellant further submitted that the reasoning for the main request also applied mutatis mutandis to the auxiliary requests 1 to 4.

Additionally, the appellant also submitted that the additional restrictions further undertaken in the

auxiliary requests were also derivable from the description as originally filed.

The appellant's letter of 19 December 2006 did not contain any comment in respect of Articles 123(2) and 84 EPC.

As regards the appellant's request for reimbursement of at least one appeal fee, the arguments on file may be summarised as follows:

The second decision of refusal (date of decision 29 March 2004) of the application in suit was caused by a practice of the examining division which was in total contradiction to Article 109 EPC.

The application was already refused (date of first decision: 20 March 2003) and a notice of appeal was filed on 20 May 2003. The statement of grounds were then filed on 18 July 2003. More than three months later, the examining division sent a summons to attend oral proceedings, still considering that the invention lacked inventive step over the same documents.

The appellant also stressed that it had unsuccessfully requested that the case be remitted to the board of appeal in accordance with Article 109(2) EPC. In the appellant's view there was no basis for such invitation to oral proceedings before the examining division. The appellant also stressed that it had been asked by the examining division to withdraw its request for oral proceedings, although that request was in the notice of appeal for the attention of the board of appeal and not for the attention of the examining division.

Moreover, the appellant submitted that upon its withdrawal of the request for oral proceedings, another decision of refusal (dated 29 March 2004) was issued.

The appellant also submitted that its (first) statement of grounds of appeal was filed on 18 July 2003, i.e. more than three months before the examining division acted on the file. The fact that additional technical data concerning formulations according to documents (1) and (2) were filed with the first grounds of appeal for comparison purposes with the technical data filed on 28 January 2003 (the latter being filed before the first decision of refusal) was insubstantial for the examining division's course of action since the examining division was still unconvinced by the applicant's arguments and still considered the claims to lack an inventive step over the same documents.

Furthermore, the appellant stressed that the requests presented in its first appeal had already been examined by the examining division. In the decision of refusal of 20 March 2003 the examining division had already decided to refuse all requests for lack of inventive step based on the same objections and over the same documents.

XII. The appellant had requested in writing that a patent be granted on the basis of the main request or first or second auxiliary request filed with the grounds of appeal of 30.04.04, or on the basis of one of the third or fourth auxiliary requests filed with letter dated 06.09.06, and the reimbursement of at least one of the appeal fees.

Reasons for the Decision

1. *Admissibility*

2. The present appeal is admissible.

3. The oral proceedings before the board took place in the absence of the appellant who was duly summoned but decided not to attend, as announced in its letter of 19 December 2006. The present decision is based on facts and evidence put forward during the written proceedings. Therefore the conditions set forth in decision G 4/92 (OJ EPO 1994, 149) are met.

4. *Article 123(2) EPC*

4.1 Claim 1 of the sets of claims of the main request, and of the first and second auxiliary requests relate to an **assembly** comprising a certain semisolid pharmaceutical composition contained in a device which is a device for **containing and measuring a unit dose** of the semisolid pharmaceutical composition.
Moreover, said device is further defined in said claims as comprising **a sealed squeezable container.** This container is defined as having **an outlet** and as comprising **an outer flexible squeezable wall.**
Additionally, the outer flexible wall of the container can be squeezed laterally with respect to an axis of said outlet whereby a predetermined unit dose of the pharmaceutical composition can be easily squeezed from the container, measured, and administered orally.

4.2 Claim 1 of the third auxiliary request relates to an assembly comprising a specified semisolid pharmaceutical composition contained in a device for containing said semisolid pharmaceutical composition which comprises a squeezable container with means for measuring and administering therefrom a single dose of said semisolid pharmaceutical composition and resealing the container thereafter.

Claim 1 of the fourth auxiliary request relates to an assembly comprising a specified semisolid pharmaceutical composition contained in a device for containing said semisolid composition, said device comprising a squeezable tube with means for measuring and administering therefrom a single dose of said semisolid pharmaceutical composition, said tube being sealed by a cap.

4.3 The application as originally filed contained five independent claims, all reproduced in point I of "Facts and submissions". Three independent claims related to a device (claims 6, 7 and 16) and one independent claim, claim 17, related to an assembly comprising a pharmaceutical composition in semisolid form contained in the device defined in any one of the claims 6 to 16 as originally filed. Moreover, claim 18, dependent on claim 17, referred back for the definitions of the composition to claims 1 to 5.

However, the device defined in claims 6 to 16 as originally filed contains several specific technical features which are lacking in the device defined in claim 1 of the main and the first two auxiliary requests. Suffice to say that the devices of originally

filed claims 6 and 7 are necessarily seal-a-spoon devices in order to be suitable for measuring a unit dose.

In particular, originally filed claim 6 defines the container as comprising at least a squeezable container **and closure means comprising a spoon-shaped element and sealing means**. Originally filed claim 7 requires the device to be a system comprising a container with an open neck, a cap, a spoon having a shaft with channel means fixed in the cap and sealing means in said cap.

Additionally, originally filed claim 16 relates to a child-proof device comprising, inter alia, a container with an open neck, a cap **fitted permanently** on the neck of the said container, a rotatable spring-biased step cylinder positioned in said cap having channel means and a button on the exterior and near the top of said rotatable spring-biased step cylinder.

4.4 Therefore, none of the claims of the application as originally filed can serve as a basis for the assembly claimed in amended claim 1 of any of the requests on file, which comprises a device defined in more generic terms than the devices defined in the originally filed claims.

4.5 Furthermore, an inspection of the description as originally filed shows that, basically, two embodiments are disclosed concerning the device, one suitable for a single unit dose and the other for containing a multiple unit dose and measuring therefrom a single unit dose. The first of these embodiments is a "**flexible packet** which can be opened by tearing or

cutting" and hence relates to a **container for a single dose** (page 5, second paragraph from the bottom). It is self-evident that this embodiment cannot serve as a basis for the amended claims.

As regards the second embodiment, it is "a device for containing the semisolid pharmaceutical composition ... which comprises a squeezable container **with means for measuring and administering therefrom a single dose** of the semisolid composition of the invention **and resealing the container** thereafter". (paragraph bridging pages 5 and 6)

This passage of the originally filed description cannot serve either as a basis for the amended claims of the main request, or first and second auxiliary requests, since the squeezable container mentioned in said claims does not necessarily have the means for measuring, administering and resealing.

4.6 Furthermore, even if one considers as a separate disclosure the squeezable container appearing in the description (including the examples) to be a device as originally disclosed, it has to fulfil certain specific requirements apart from having an outlet and an outer flexible wall. These requirements do not appear reflected by any of the features of the device in claim 1 of any of the requests on file.

4.7 As regards the third and fourth auxiliary requests it has to be stressed that what is claimed is not a device containing a generically defined composition, but an assembly containing specifically defined semisolid pharmaceutical compositions, in particular in respect

of the thickening agent present and the viscosity and consistency of the composition.

Such specifically defined semisolid compositions are disclosed in the description as originally filed only in connection with either "a single dose packet" or "a seal-a-spoon device" (second paragraph of page 10 of the application as originally filed).

4.8 Therefore, there is no feature in claim 1 of all requests reflecting that the device which forms part of the assembly for containing a multiple dose and measuring a unit dose has to be "a seal-a-spoon device" and hence claim 1 of all requests contravenes Article 123(2) EPC.

4.9 Correspondingly, the subject-matter of claim 1 of all sets of claims does not meet the requirements of Article 123(2) EPC.

4.10 As regards the appellant's arguments, they do not hold for the following reasons:

The devices "for containing multiple doses and measuring a single dose of the semisolid composition" disclosed on pages 6 and 7 of the description as originally filed (this also applies to the drawings as originally filed) comprise **a particular squeezable container together with specific means** for measuring, administering and resealing, none of them appearing in the amended claims.

In particular, figures 1 to 4, cited by the appellant as a basis for the amendments, illustrate all together **a specific device** for containing a multiple dose and measuring and administering a unit dose. However, figure 1 alone only illustrates "a closed tube containing a semisolid composition" (page 7, paragraph following the heading "Brief Description of the Drawings") which, isolated from the spoon appearing in figure 2, does not fulfil the requirement necessary for measuring a unit dose of the pharmaceutical composition. Hence, the container of figure 1 alone is not the device for containing and measuring the unit dose disclosed in the originally filed application.

5. *Reimbursement of appeal fees*

5.1 First fee for appeal.

The applicant had filed a notice of appeal (20 May 2003) and had paid the fee for appeal a first time. Moreover, it also had filed in due time (18 July 2003) grounds of appeal (Article 108 EPC) in response to a (first) decision of the examining division refusing to grant a patent for lack of inventive step within the meaning of Articles 97(1) and 56 EPC.

Rule 67 EPC foresees the reimbursement of appeal fees in the event of interlocutory revision or where the board of appeal deems an appeal to be allowable, if such reimbursement is equitable by reason of a substantial procedural violation.

The examining division continued the examination proceedings after the applicant had filed its first notice of appeal and first grounds of appeal and did not remit the case to the boards of appeal.

However, an interlocutory revision is only possible in accordance with Article 109 (EPC) when the department whose decision is contested considers the appeal admissible and well founded. The latter was not the case as it becomes evident from the examining division's communication sent on 22 October 2003 as an annex to the summons for oral proceedings, as well as from a careful reading of the reasons of the second decision of refusal (sent on 29 March 2004, i.e. almost one year after the first notice of appeal was filed). Indeed, the examining division maintained the same objections of lack of inventive step over the same documents and on the basis of sets of claims which already served as a basis for the first decision of refusal.

The department of first instance should grant an interlocutory revision if it considers the deficiencies underlying the refusal to be overcome when it allows the appeal. If this is not the case or if in doubt, the case has to be remitted to the boards of appeal within three months after receipt of the statement of grounds (Article 109 EPC).

Consequently, the examining division took a wrong decision concerning a procedural step since it did not rectify its decision of refusal as to the substance and did nevertheless not remit the case to the boards of appeal.

Additionally , the procedural violation led to the loss of the appeal fee because the appellant got neither a rectification of the decision as to the substance (i.e. could not overcome the problems that led to the refusal for lack of inventive step) nor a decision of the second instance.

Hence, the first fee for appeal has to be reimbursed.

5.2 Second fee for appeal.

After a second decision of refusal was issued on 29 March 2004 by the examining division, the appellant filed a second appeal and paid in due time appeal fees (second fee for appeal). It also filed grounds of appeal within the meaning of Article 108 EPC.

Having regard to the facts that the examining division did not grant an interlocutory revision for this second appeal and remitted the case to the boards of appeal in due time, and that the board dismissed the appeal, the second fee for appeal has not to be reimbursed.

5.3 As regards the appellant's submissions in respect of the several procedural violations made by the examining division during the examination proceedings as possible justification for the reimbursement of both appeal fees, the following has to be said:

A simple file inspection shows that the applicant was never informed of the examining division's intention of granting an interlocutory revision after the filing of the applicant's first appeal (since EPO Form 2710,

"Rectification (Article 109(1) EPC)", was not dispatched) and that, as a consequence, the applicant was taken by surprise by an unexpected invitation to attend oral proceedings before the examining division, followed by an advice to withdraw its request for oral proceedings in the event that it wished the case to be referred to the board. The request for oral proceedings was filed by the applicant, however, with the (first) grounds of appeal in relation to a future appeal's hearings before the board of appeal.

Leaving aside the discussion of whether this course of events in the present case constitutes in itself a substantial procedural violation justifying the reimbursement of the first appeal fee, it is an indisputable fact that the examination proceedings were continued by the examining division with the consequence that the (first) appeal was never referred to the board of appeal. Hence, the reimbursement of the first appeal fee is sufficiently justified as assessed in point 5.1 above without requiring additional reasons.

However, it would not be equitable to reimburse both appeal fees in view of the fact that the procedural violations made by the department of first instance in connection with the wrong decision concerning a procedural step (i.e. the decision of continuing the examination proceedings without considering the first appeal well founded) do not affect the second appeal.

Order

For these reasons it is decided that:

1. The appeal is dismissed

2. One of the two appeal fees paid by the appellant is to be reimbursed.

The Registrar | The Chairman

A. Townend | U. Oswald