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Datasheet for the decision of 1 April 2008

Case Number: T 1286/05 - 3.3.02

Application Number: 95911394.5

Publication Number: 0750495

IPC: A61K 9/48

Language of the proceedings: EN

Title of invention:
Use of a lipophilic surfactant in a pharmaceutical composition

Patentee:
R.P. Scherer Technologies, Inc.

Opponent:
LTP Lipid Technologies Provider AB

Headword:
Use of a Lipophilic surfactant/R.P. SCHERER TECHNOLOGIES, INC.

Relevant legal provisions:
EPC Art. 54, 123(2), 123(3)

Relevant legal provisions (EPC 1973):
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Keyword:
"Main, second and fourth auxiliary requests: novelty (no)"
"First and third auxiliary requests: allowability of amendments (no) - no basis for the disclaimer in the original application"

Decisions cited:
G 0005/83, G 0002/88, G 0001/03, G 0002/03

Catchword:
If a claim drawn up as a "Swiss-type" claim relates defacto to a further non-therapeutic use, the feature defining the non-therapeutic use is of a merely illustrative character and, as a consequence, not suitable for establishing novelty.

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Case Number: T 1286/05 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 1 April 2008

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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 27 July 2005 revoking European patent No. 0750495 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
P. Mühlens

Summary of Facts and Submissions

I. European patent No. 0 750 495 based on application No. 95 911 394.5 was granted on the basis of a set of 13 claims.

The independent claim reads as follows:

"1. The use of a lipophilic surfactant component for the manufacture of a pharmaceutical composition comprising a hydrophobic drug dispersed or dissolved in a digestible oil which contains a hydrophilic surfactant component and where some or all of which oil is optionally comprised by the lipophilic surfactant component, for substantially reducing the inhibitory effect of the hydrophilic surfactant component on the in vivo lipolysis of the digestible oil."

II. A notice of opposition was filed on 2 September 2003 by Lipocore Holding AB. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(b) EPC for insufficiently clear and complete disclosure of the invention.

III. The following documents were *inter alia* cited during the opposition and appeal proceedings:

(1) GB-A-2 228 198
(3) EP-B-0 215 313

IV. In the decision pronounced on 9 June 2005, the opposition division revoked the patent in suit. Its principal findings were as follows:

In connection with the novelty of the main request, the opposition division argued that, although document (1) did not disclose the lipophilic surfactant's reduction of the inhibitory effect of the hydrophilic surfactant on the in vivo lipolysis of the digestible oil, the skilled person became aware of this effect when working with the compositions, which were identical to the compositions disclosed in the patent in suit and which showed the same desired effect in terms of an improved bioavailability. As a consequence, the subject-matter of the main request lacked novelty.

As for auxiliary request 1 - 4, the opposition division held that the disclaimer "said drug not being cyclosporin" had no basis in the application as originally filed. Moreover, it was not allowable according to decisions G 01/03 (OJ EPO 2004, 413) and G 02/03 (OJ EPO 2004, 448), so that the requirements of Article 123(2) EPC were not met.

V. The patentee lodged an appeal against that decision.

VI. With the statement of the grounds of appeal dated 5 December 2005, the appellant (patentee) filed new auxiliary requests 1 - 3. Claim 1 of auxiliary request 1 reads as follows:

"1. The use of a lipophilic surfactant component for the manufacture of a pharmaceutical composition comprising a hydrophobic drug, said drug not being cyclosporin, dispersed or dissolved in a digestible oil which contains a hydrophilic surfactant component and where some or all of which oil is optionally comprised by the lipophilic surfactant component, for substantially reducing the inhibitory effect of the hydrophilic

surfactant component on the in vivo lipolysis of the digestible oil."

Claim 1 of auxiliary request 2 reads as follows:

"1. The use of a lipophilic surfactant component for the manufacture of a pharmaceutical composition comprising a hydrophobic drug, dispersed or dissolved in a digestible oil which contains a hydrophilic surfactant component and where some or all of which oil is optionally comprised by the lipophilic surfactant component, for increasing the bioavailability of the hydrophobic drug by substantially reducing the inhibitory effect of the hydrophilic surfactant component on the in vivo lipolysis of the digestible oil."

Claim 1 of auxiliary request 3 reads as follows:

"1. The use of a lipophilic surfactant component for the manufacture of a pharmaceutical composition comprising a hydrophobic drug, said drug not being cyclosporin, dispersed or dissolved in a digestible oil which contains a hydrophilic surfactant component and where some or all of which oil is optionally comprised by the lipophilic surfactant component, for increasing the bioavailability of the hydrophobic drug by substantially reducing the inhibitory effect of the hydrophilic surfactant component on the in vivo lipolysis of the digestible oil."

VII. With his letter dated 29 February 2008, the appellant filed experimental data as well as a new auxiliary request 4, of which claim 1 reads as follows:

"1. The use of a lipophilic surfactant component in the manufacture of a pharmaceutical composition comprising a hydrophobic drug dispersed or dissolved in a digestible oil which contains a hydrophilic surfactant component and where some or all of which oil is optionally comprised by the lipophilic surfactant component, for substantially reducing the inhibitory effect of the hydrophilic surfactant component on the in vivo lipolysis of the digestible oil, characterised in that the hydrophobic drug is selected from anti-arrhythmic agents, anti-coagulants, anti-depressants, anti-diabetics, anti-epileptics, anti-fungal agents, anti-gout agents, anti-hypertensive agents, anti-malarials, anti-migraine agents, anti-muscarinic agents, anti-neoplastic agents, anti-thyroid agents, anxiolytic, sedatives, hypnotics and neuroleptics, ß-blockers, cardiac inotropic agents, corticosteroids, diuretics, anti-parkinsonian agents, gastro-intestinal agents, histamine H-receptor antagonists, lipid regulating agents, nitrates and other anti-anginal agents, nutritional agents, opioid analgesics, sex hormones, stimulants, aloxiprin, auranofin, azapropazone, benorylate, diflunisal, etodolac, fenbufen, fenoprofen calcim, flurbiprofen, ibuprofen, indomethacin, ketoprofen, meclofenamic acid, mefanamic acid, nabumetone, naproxen, oxyphenbutazone, phenylbutazone, piroxicam, sulindac, benznidazole, clioquinol, decoquinate, diiodohydroxyquinoline, diloxanide furoate, dinitolmide, furzolidone, metronidazole, nimorazole, nitrofurazone, ornidazole, tinidazole.

VIII. The appellant's arguments can be summarised as follows:

In connection with novelty, it was held that the claims contained features relating to a new technical effect which had hitherto been unknown and could therefore establish novelty in accordance with decision G 02/88 (OJ EPO 1990, 93): while in the prior art a lipophilic surfactant had been added to compositions comprising a hydrophobic drug, a digestible oil and a hydrophilic surfactant for increasing the solubility, the reason for its addition in the present invention was a different one: it was added in order to reduce the inhibitory effect of the hydrophilic surfactant on the lipolysis of the digestible oil. This feature was not merely a mechanism of action that explained the enhanced bioavailability, but related to a new technical effect and therefore rendered the claimed subject-matter novel. As regards the disclaimer in claim 1 of auxiliary requests 1 and 3, there was a basis in the paragraph bridging pages 29 and 30 of the original application.

IX. The respondent's arguments can be summarised as follows:

The claimed subject-matter was directed to a non-therapeutic use, wherein the feature "for substantially reducing the inhibitory effect of the hydrophilic surfactant component on the in vivo lipolysis of the digestible oil" merely provided an explanation for the enhanced bioavailability. As the enhanced bioavailability of compositions comprising a lipophilic surfactant, a hydrophobic drug, a digestible oil and a hydrophilic surfactant was already known e.g. from document (1), the claims lacked novelty. Regarding the allowability of the disclaimer in claim 1 of auxiliary

requests 1 and 3, there was no clear basis in the original application for disclaiming cyclosporin.

X. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), or on the basis of one of the auxiliary requests 1 to 3 filed with letter dated 5 December 2005, or on the basis of auxiliary request 4 filed with letter dated 29 February 2008.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request - novelty:*

2.1. Independent claim 1 is drawn up in the form of a "second (further) medical use claim" as defined in decision G 05/83 (OJ EPO 1985, 64). However, in spite of the chosen format, this claim does not in fact reflect a second (further) medical use, as the feature "for substantially reducing the inhibitory effect of the hydrophilic surfactant component on the in vivo lipolysis of the digestible oil" clearly defines a non-therapeutic use. Although the reduction of the inhibitory effect of the hydrophilic surfactant on the in vivo lipolysis of the digestible oil has a significant influence on the bioavailability of the hydrophobic drug, which in its turn is an important factor for the administration of the drug, it does not *per se* involve the treatment or alleviation of an

illness or of any pathological condition and is therefore non-therapeutic. As a consequence, it has to be established how a claim drawn up in the second medical use format but relating to a non-therapeutic activity has to be read for the assessment of novelty.

2.2. Example 2a of document (1) discloses the preparation of a pharmaceutical composition comprising a lipophilic surfactant (Imwitor 742), a hydrophobic drug (cyclosporin), a digestible oil (Miglyol 812) and a hydrophilic surfactant (Cremophore RH 40). These compositions are characterised by enhanced resorption/bioavailability levels and/or a reduced variability in resorption/bioavailability levels (see page 10, first complete paragraph). Document (1) does not mention the effect of the lipophilic surfactant in terms of a reduction of the inhibitory effect of the hydrophilic surfactant component on the in vivo lipolysis of the digestible oil. As a consequence, with all other features already being disclosed in document (1), the non-therapeutic use ("for substantially reducing the inhibitory effect of the hydrophilic surfactant component on the in vivo lipolysis of the digestible oil") is the only potentially distinguishing feature of present claim 1.

2.3. In decision G 05/83, the novelty derived from a new therapeutic use of a medicament in a "Swiss-type" claim, which relates to the use of a compound for the preparation of a medicament, was acknowledged by making reference to Article 54(5) EPC 1973, according to which known substances or compositions used for the first time in a method as defined in Article 52(4) EPC 1973 are novel. However, it was made clear that this special

approach to the derivation of novelty can only be applied to claims to the use of substances or compositions intended for use in a method referred to in Article 52(4) EPC 1973 (see G 05/83, point 21).

2.4. As a consequence, this special approach to the derivation of novelty cannot be applied to present claim 1, which has to be interpreted as a claim defining a conventional process of preparation. In this context, it is emphasised that the claim format "the use of a lipophilic surfactant component for the manufacture of a pharmaceutical composition (for a non-therapeutic use)…" is equivalent to a claim directed to a "process of preparing a pharmaceutical composition comprising a lipophilic surfactant component…". In the present claim 1, the indication of an additional non-therapeutic effect ("for substantially reducing the inhibitory effect of the hydrophilic surfactant component on the in vivo lipolysis of the digestible oil") of one of the components in the finished composition has a merely illustrative character and thus no influence whatsoever on the process of preparing the composition. Therefore, it is not suitable for establishing novelty over example 2a of document (1).

It is additionally noted that the present claim 1 - as is frequently the case with "Swiss-type" claims - does not specifically mention any process steps. Therefore, any non-naturally occurring product comprising all the features of the composition resulting from the process of preparation as claimed, such as e.g. the composition according to example 2a of document (1), is detrimental for the novelty of the subject-matter claimed therein. As a consequence, the subject-matter of claim 1 of the

main request does not meet the requirements of Article 54 EPC.

2.5. The board is aware of the fact that according to decision G 02/88 novelty over document (1) could in principle be established by reformulating claim 1 into a conventional non-medical use claim, as in such a claim the feature "for substantially reducing the inhibitory effect of the hydrophilic surfactant component on the in vivo lipolysis of the digestible oil" would refer to a technical effect which is not disclosed in document (1). However, the board sees no possibility for such a reformulation without offending against the provisions of Article 123(3) EPC, as the change from the only independent claim of the patent as granted relating to a **process of preparation** ("Use of a lipophilic surfactant component for the manufacture of a pharmaceutical composition…) to a claim referring to a **use for achieving a particular effect** ("Use of a lipophilic surfactant component for reducing the inhibitory effect of the hydrophilic surfactant…) would extend the protection conferred.

3. *First auxiliary request - basis for the disclaimer "said drug not being cyclosporin":*

3.1. Basis in the original application:

The paragraph bridging pages 29 and 30 of the original application cites example 2a of document (1) and concludes with the statement: "Nonetheless, no claim is made herein to a pharmaceutical composition which comprises cyclosporin".

On the other hand, the passage on pages 21-25 contains a list of hydrophobic drugs which may be formulated in accordance with the present invention. This list cites cyclosporin among the anti-neoplastic agents and immunosuppressants (see page 21, lines 20-22 and page 23, line 17).

In the opinion of the board, there is only one way of logically reconciling these two seemingly contradictory passages: the original application intends to disclaim compositions comprising cyclosporin as such (see page 30, lines 8-9), but does not intend to disclaim any use related to cyclosporin or to compositions comprising cyclosporin (see page 21, lines 20-22 and page 23, line 17). As the disclaimer in present claim 1 is not directed to the exclusion of a composition as such, it is not based on the application as originally filed.

The only alternative way of interpreting these two passages would be to simply state that they are contradictory, in which case the original application would not provide a clear and unambiguous disclosure for the disclaimer either.

3.2. Basis in document (1):

As was already mentioned in paragraph 2.2 above, document (1) discloses pharmaceutical compositions which are identical to those of the patent in suit. Moreover, the compositions according to document (1) are characterised by an enhanced bioavailability level which is also an important aspect of the teaching of the patent is suit (see page 1, lines 1-4 of the original application). Hence, the claimed subject-matter does not

concern a technical field and purpose remote from that of the document (1). Consequently, the skilled person would consider document (1) when seeking to solve the problem underlying the invention. Thus, document (1) is no accidental anticipation in the meaning of G 01/03 and G 02/03.

3.3. As a consequence, the disclaimer does not comply with Article 123(2) EPC.

4. *Second auxiliary request:*

4.1. Amendments - Article 123(2) EPC:

Claim 1 is now directed to the use of a lipophilic surfactant component for the manufacture of a pharmaceutical composition … for **increasing the bioavailability** of the hydrophobic drug [emphasis added by the board]. The whole teaching of the present invention is concerned with the improvement of the bioavailability of the hydrophobic drug and consequently, the original application contains numerous passages in which wherein this feature is disclosed (see e.g. page 1, lines 1-4). Therefore, the requirements of Article 123(2) EPC are met.

4.2. Clarity (Article 84 EPC):

The respondent held that the term "bioavailability" in claim 1 is not clear. However, the disclosure of a patent has to be read with the eyes of the person skilled in the art, who is perfectly aware of what the term "bioavailability" means. As a consequence, the requirements of Article 84 EPC are met.

4.3. Novelty (Article 54 EPC):

The reasoning developed in connection with claim 1 of the main request (see paragraphs 2.1 - 2.4 above) applies *mutatis mutandis* to claim 1 of the second auxiliary request: again, the indication of an additional effect ("for increasing the bioavailability of the hydrophobic drug by substantially reducing the inhibitory effect of the hydrophilic surfactant component on the in vivo lipolysis of the digestible oil") relates to a non-therapeutic use. As was already pointed out in paragraph 2.1. above, an increase in the bioavailability is an important factor for the therapeutic use of a drug, but does not constitute a method for treatment of the human or animal body by therapy *per se.* Therefore, the subject-matter of claim 1 of the second auxiliary request also relates to a non-therapeutic use. As a consequence, example 2a of document (1) is detrimental for the novelty of claim 1.

5. *Third auxiliary request - basis for the disclaimer "said drug not being cyclosporin":*

The disclaimer in claim 1 of the third auxiliary request is identical to the disclaimer in claim 1 of the first auxiliary request. As a consequence, the reasoning of paragraph 3 above applies *mutatis mutandis* to claim 1 of the third auxiliary request. The requirements of Article 123(2) EPC are therefore not met.

6. *Fourth auxiliary request:*

6.1. Admissibility:

The fourth auxiliary request was filed at a very late stage of the appeal procedure, i.e. one month before the oral proceedings. However, by introducing the list of hydrophobic drugs and classes of hydrophobic drugs and deleting the disclaimer, the appellant made a serious effort to overcome the objections raised in connection with the disclaimer. The board therefore found the fourth auxiliary request admissible.

6.2. Amendments (Article 123(2) EPC):

The hydrophobic drugs and classes of hydrophobic drugs introduced into claim 1 are taken from the list of drugs on pages 21-25 of the original application. This list discloses both the general classes as well as the specific hydrophobic drugs of claim 1. The requirements of Article 123(2) EPC are therefore met.

6.3. Novelty (Article 54 EPC):

Claim 1 of the fourth auxiliary request differs from claim 1 as granted in that the hydrophobic drug is further defined by a list of compounds or pharmacological classes of compounds. For the reasons outlined in paragraph 2.1 above, this claim still relates to a non-therapeutic use.

Example 6 of document (3) discloses the preparation of a pharmaceutical composition comprising a lipophilic surfactant (oleic acid), a hydrophobic anti-neoplastic

drug (bisantrene), a digestible oil (sesame oil) and a hydrophilic surfactant (egg lecithin). This composition is identical to compositions obtained from the process of preparation as claimed in claim 1 of the fourth auxiliary request. As a consequence, for the same reasons as given in paragraphs 2.1 - 2.4 above, the subject-matter of present claim 1 is not novel over example 6 of document (3). It is emphasised that the fact that example 6 of document (3) does not specifically mention compositions for oral use is of no importance, as the subject-matter of present claim 1, contrary to the allegation of the appellant, is not limited to the preparation of oral compositions either. The requirements of Article 54 EPC are therefore not met.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald