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D E C I S I O N
of 21 February 2002

Case Number: T 0568/97 - 3.3.2

Application Number: 89909891.7

Publication Number: 0432199

IPC: A61K 9/06

Language of the proceedings: EN

Title of invention:
Composition for the treament of erectile dysfunction

Patentee:
AMSU. Ltd

Opponent:
PHARMEDIC COMPANY

Headword:
Erectile dysfunction/AMSU

Relevant legal provisions:
EPC Art. 84, 111

Keyword:
"Main request, first and second auxiliary request - functional feature not supported by the description for all alternative compositions within the meaning of Article 84 EPC"

Decisions cited:
T 0068/85

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0568/97 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 21 February 2002

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 21 March 1997 concerning maintenance of European patent No. 0 432 199 in amended form.**

Composition of the Board:

Chairman: J. Riolo
Members: U. Oswald
S. U. Hoffmann

Summary of Facts and Submissions

I. European patent No. 0 432 199 based on the international application No. PCT/SE89/00462 was granted on the basis of 31 claims.

Claim 1 reads as follows:

"A composition for the treatment of erectile dysfunction via urethra, comprising a lipophilic active substance selected from á-receptor blockers, vasoactive polypeptide, prostaglandins and nitroglycerine dispersed in a hydrophilic vehicle and optionally an antibacterial agent."

II. Opposition was filed against the granted patent by the former Appellant (Opponent) who withdrew the appeal on 23 June 1997 and subsequently the opposition on 26 July 2001.

The grounds of opposition were lack of novelty and lack of inventive step under Article 100(a) EPC.

III. In its interlocutory decision dated 13 November 1996, the Opposition Division maintained the patent in suit in amended form under Article 102(3) EPC.

According to the decision, the main request, relating to a pharmaceutical composition comprising prostaglandins as an active agent, lacked novelty over the prior art. In essence it was argued that the reference in claim 1 to transurethral administration of the active agent could not establish novelty within the meaning of a first medical use under Article 54(5) EPC.

In the Opposition Division's view, however, the subject matter of the auxiliary request relating to a so-called second medical use of the active agent was novel and inventive.

IV. The former Appellant (Opponent) and the Appellant (Patentee) filed an appeal against this decision. On 18 February 2002 the Appellant (Patentee) filed a new main request and seven auxiliary requests.

Claim 1 of the main request reads as follows:

"A pharmaceutical composition for transurethral administration of an active agent to treat erectile dysfunction comprising one or more lipophilic vasodilating active agents selected from the group consisting of á-receptor blockers, vasoactive intestinal polypeptide, prostaglandins and nitroglycerine, and optionally an antibacterial agent, said pharmaceutical composition characterised in that said active agent is dispersed in a hydrophilic vehicle for urethral administration and that the amount of active agent is at a concentration sufficiently high to provide a physiologically effective dose of the active agent when administered via the urethra; with the provisos that the composition does not include: papaverine; or prostaglandin E_2."

Oral proceedings took place on 21 February 2002.

V. With regard to the requirements of Article 84 EPC concerning the amended claims of each of the requests the Appellant (Patentee) inter alia argued that the description of the patent in suit contained detailed technical information to support a functional feature

in the claims defining the amount of each of the alternative active agents alone or in combination by the wording "at a concentration sufficiently high to provide a physiologically effective dose" ... "when administered to the urethra".

The Appellant (Patentee) accepted that the description of the patent in suit as originally filed and as granted did not contain numerical examples for the amounts of vasoactive intestinal polypeptide and prostaglandins, but argued that these active agents produced the physiological effect by using the same mechanism as e.g. nitroglycerine, for which detailed figures were given inter alia in Table I of the patent in suit.

Moreover, the examples given in the patent in suit for phenoxybenzamine, phentholamine and papaverine showed that the dose of active agent was at least ten times that used for intracorporeal injection and that formulations that are 10 to 100 times more concentrated than those used for injection are necessary for successful treatment of erectile dysfunction by transurethral delivery.

In any case, the description of the patent in suit disclosed the need to use a much higher amount for transurethral administration than intracorporeal injection in order to achieve the required physiological effect.

VI. The Appellant (Patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or one of the auxiliary requests 1 to 7 filed on 18 February

2002, or as a final request, the maintenance of the patent in the form allowed by the Opposition Division.

Reasons for the Decision

1. The appeal is admissible.

2. The main request as well as auxiliary requests 1 to 7 comprise, in comparison with the set of claims as granted, amended subject-matter relating to a pharmaceutical composition *"characterised in that ... the amount of active agent is at a concentration sufficiently high to provide a physiologically effective dose of the active agent when administered via the urethra".*

   Accordingly, it is first necessary to examine whether these claims regarding the amendments in combination with all the claimed features fulfil the requirements of Article 84 EPC in that the claims shall define the subject-matter for which protection is sought and shall be clear and concise and supported by the description.

3. As in the present case, where the characterising part of the claim is a functional feature directed to a result to be achieved, in accordance with well-established case law of the Boards of Appeal, the requirements of Article 84 EPC are only met if, from an objective viewpoint, such features cannot otherwise be defined more precisely without restricting the scope of the invention and if these features provide instructions which are sufficiently clear for the

expert to reduce them to practice without undue burden, if necessary with reasonable experiments (see decision T 68/85, OJ 1987, pages 228 to 236, in particular point 8.4.2 and 8.4.3). In other words, the functional feature must not only be such that the skilled person can understand it, but he must also be able to implement it in accordance with the requirements of Article 84 EPC (the claims ....shall be clear and concise ***and supported by the description***).

4. Having regard to the requirements of Article 84 EPC above, particularly those for functional features directed to the result to be achieved, it is to be noted that the main request as well as auxiliary requests 1 to 2 comprise claims defining the physiological effect to be achieved by a sufficiently high concentration of vasoactive intestinal polypeptide and/or prostaglandins as active agents in the pharmaceutical composition for transurethral administration.

In contrast to the active agents selected from the group consisting of á-receptor blockers and nitroglycerine, for which the description of the patent in suit as originally filed and as granted contained detailed information about individual values and ranges of the amounts in milligrams to be administered via intracorporeal injection and via the urethra (see in particular original disclosure, page 4, second paragraph, and page 8, **Table 1**), the patent in suit neither discloses individual values nor ranges of the amounts of vasoactive intestinal polypeptide and/or prostaglandins to be administered via intracorporeal injection or via the urethra.

From an **objective point of view based on the disclosure of the description of the patent in suit**, there is no reason to exclude vasoactive intestinal polypeptide and/or prostaglandins as active agents from detailed information about individual values and/or ranges of the amounts in milligrams to be administered via the urethra. In other words the description of the patent in suit lacks support within the meaning of Article 84 EPC as to the amount of vasoactive intestinal polypeptide and/or prostaglandins required to achieve a concentration sufficiently high to provide a physiologically effective dose when administered via the urethra.

5. In the absence of any **concrete information** in the patent in suit about the activity or effectiveness of vasoactive intestinal polypeptide and/or prostaglandins in pharmaceutical compositions alone and/or in comparison with the activity or effectiveness of á-receptor blockers and/or nitroglycerine, the Board cannot accept the Appellant's argument that the amounts specifically shown for á-receptor blockers and nitroglycerin according to the patent in suit allow the conclusion that as a general rule formulations that are 10 to 100 times more concentrated than those used for injection are necessary for successful treatment of erectile dysfunction by transurethral delivery. In any case, the group of active agents, consisting of á-receptor blockers, vasoactive intestinal polypeptide, prostaglandins and nitroglycerine as claimed, represents a totally heterogenic group of compounds with different chemical structures and different physico-chemical behaviour for each class [type] of active agent.

Even if it is accepted that as a specific rule formulations containing vasoactive intestinal polypeptide and/or prostaglandins which are 10 to 100 times more concentrated than those used for injection allow successful treatment of erectile dysfunction by transurethral delivery, there is a **lack of disclosure** in the patent in suit **in relation to which amount or reference values** of vasoactive intestinal polypeptide and/or prostaglandins the claimed pharmaceutical composition must be 10 to 100 times more concentrated.

6. Moreover, having regard to the plurality of research articles filed during the proceedings by the parties about the treatment of erectile dysfunction, e.g. by different active agents and different methods of administration, such as peroral, topical and intracorporeal injection, and having regard to contradictory expert opinions on file as to the amount of prostaglandins necessary for different groups of patients (population, age, etc.), in the Board's judgment, it is impossible to find out without undue burden the physiologically effective amounts as claimed merely on the basis of the common general knowledge that the amount of vasoactive intestinal polypeptide and/or prostaglandins used for transurethral administration must be much higher than for intracorporeal injection.

Accordingly, the main request and auxiliary requests 1 to 2 are deemed not to comply with Article 84 EPC and must therefore be rejected.

7. The subject-matter of claim 1 of the third auxiliary request not defining the physiological effect to be achieved by a sufficiently high concentration of

vasoactive intestinal polypeptide and/or prostaglandins as active agents in the pharmaceutical composition for transurethral administration fulfils the requirements of Article 84 EPC.

However, the decision of the Opposition Division, other than in a more or less general statement, does not relate to the question of novelty and inventive step of the other active agents - á-receptor blockers and/or nitroglycerine - by virtue of prior art relating to **pharmaceutical compositions *per se*** containing these active agents.

The examination for novelty of a pharmaceutical composition under Article 54(5) EPC and subsequently the examination for inventive step under Article 56 EPC has to be carried out by taking into account the whole prior art relating to pharmaceutical compositions independently of the specific medical use(s) exemplified in the patent in suit.

Accordingly, the Board has decided to make use of its powers under Article 111 EPC to remit the case to the first instance in order to carry out a full examination of the pharmaceutical compositions of the patent in suit containing active agents other than vasoactive intestinal polypeptide and/or prostaglandins.

8. Since, after withdrawal of the appeal and opposition by the Appellant (Opponent), the Appellant (Patentee) remains the only party to the proceedings, the present decision does not affect the maintenance of the patent in suit on the basis of the documents indicated on page 2 of the interlocutory decision (EPO Form 2339.4 11.93) dated 21 March 1997 (*reformatio in peius*).

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 for further prosecution.

The Registrar: The Chairman:

A. Townend J. Riolo