

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

D E C I S I O N
of 9 February 2006

Case Number: T 0151/01 - 3.3.02

Application Number: 95919867.2

Publication Number: 0764018

IPC: A61K 9/10

Language of the proceedings: EN

Title of invention:

Non-steroidal anti-inflammatory ophthalmic suspensions

Patentee:

INSITE VISION INCORPORATED

Opponent:

-

Headword:

Ophthalmic suspensions/INSITE VISION INCORPORATED

Relevant legal provisions:

EPC Art. 84

Keyword:

"Main request, auxiliary requests 1 to 6 - clarity - no:
functional feature not clear in the absence of standard test"
"Auxiliary requests IIIa and IVa - admissibility - no: not a
direct reply to a new argument"

Decisions cited:

-

Catchword:

-



Case Number: T 0151/01 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 9 February 2006

Appellant:

INSITE VISION INCORPORATED
965 Atlantic Avenue
Alameda
CA 94501 (US)

Representative:

von Menges, Albrecht
Uexküll & Stolberg
Patentanwälte
Beselerstrasse 4
D-22607 Hamburg (DE)

Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 7 September 2000
refusing European application No. 95919867.2
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Willems

Summary of Facts and Submissions

- I. European patent application No. 95 919 867.2 concerning non-steroidal anti-inflammatory ophthalmic suspensions was refused by a decision of the Examining Division dated 26 July 2000 under Article 97(1) EPC with regard to Articles 84, 83 and 56 EPC.
- II. The decision was based on claims 1 to 19 of the main request and on claims 1 to 13 of the auxiliary request filed with the letters of 9 June 1998 and 21 June 2000 respectively.

Independent claim 1 of the main request reads as follows:

"1. A composition adapted for topical ophthalmic application comprising an aqueous mixture of a non-steroidal anti-inflammatory agent, the composition being formulated with a pH and concentration of agent which maintains at least a therapeutic amount of the non-steroidal anti-inflammatory agent of the formulation in suspension and a therapeutic amount of the non-steroidal anti-inflammatory agent of the formulation in solution."

Independent claim 1 of the auxiliary request reads as follows:

"1. A composition adapted for topical ophthalmic application comprising an aqueous mixture of diclofenac, the composition being formulated with a pH of from 4 to 8 and concentration of diclofenac of from 0.1% to 1% by weight of the composition which maintains

from 70% to 99% of the diclofenac in suspension and a therapeutic amount thereof in solution."

III. The arguments in the decision may be summarised as follows:

The Examining Division considered that the expression "a therapeutic amount" used in claim 1 of the main and auxiliary request was not clear because the application did not disclose any test in relation to this feature and because the applicant did not establish that there existed a well-known and accepted test in the field.

It also concluded that the disclosure in the application was insufficient to enable the skilled person to carry out the invention over the whole scope of the claims.

As to inventive step, the Examining Division expressed the view that, in the absence of any data demonstrating a surprising and/or beneficial effect over the prior art compositions, the claimed subject-matter was just an obvious alternative to the prior art since the skilled person could change the pH and the concentration of the active drug without inventive activity.

IV. The appellant (applicant) lodged an appeal against the said decision. He filed a main request and auxiliary requests 1 and 2 together with grounds of appeal.

The main request is identical to the main request before the Examining Division.

Claim 1 of auxiliary request 1 reads:

"1. A composition adapted for topical ophthalmic application comprising an aqueous mixture of a non-steroidal anti-inflammatory agent, the composition being formulated with a pH of from 4 to 8 and concentration of agent of from 0.1 to 1% by weight of the composition which maintains from 70% to 99% of the agent in suspension and a therapeutic amount of the non-steroidal anti-inflammatory agent of the formulation in solution."

Claim 1 of auxiliary request 2 corresponds to claim 1 of the auxiliary request before the Examining Division.

V. In a communication dated 27 December 2005, the Board expressed its view that the feature "a therapeutic amount" present in claim 1 of all the requests on file was not clear and that, as a consequence, no distinguishing feature could be established vis-à-vis the prior art as regards the main request and auxiliary request 1.

VI. In reply to this communication, the appellant filed auxiliary requests 3 to 6 with its letter dated 13 January 2006.

The feature "a therapeutic amount" was still present in claim 1 of all these further requests.

VII. Oral proceedings were held before the Board on 9 February 2006.

During the oral proceedings two more requests were filed (IIIa, IVa).

VIII. The appellant's submissions both in the written procedure and at the oral proceedings as to the clarity objection can essentially be summarised as follows:

The term "therapeutic amount" was clear to the skilled person as it referred to an amount sufficient to initiate treatment, contrary to an "amount effective to treat" a condition, which implied an amount necessary for complete treatment of that condition.

Thus, if the amount of agent in solution did not enable a therapeutic effect from occurring in the target, then a therapeutic amount was not present in the solution.

As to the auxiliary requests, the appellant moreover put forward that the specification of the total concentration of the agent in the claims (ie 0,1 to 1% by weight based on the total weight of the composition) in combination with the mention of the amount in suspension (10 to 99%) defined the amount in solution, so that the "therapeutic amount" was thus clearly defined.

IX. The appellant requested that the decision under appeal be set aside and that the patent be granted on the basis of the set of claims of the main request or auxiliary requests 1 and 2 all filed with its letter dated 2 September 2002 or, alternatively, of auxiliary requests 3 to 6 filed with its letter dated 13 January 2006 or auxiliary requests IIIa or IVa filed during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. *Main request*
- 2.1 Article 84

The question to be answered with respect to clarity under Article 84 EPC is whether it is possible to determine if an embodiment falls within the scope of the claims or not.

In the present case, the product claim of independent claim 1 is intended to be restricted vis-à-vis the prior art embodiments by a functional feature, namely that the amount of the ingredient present in the composition must be a "therapeutic amount".

The Board has no doubt, that the skilled person is perfectly able in most cases to decide whether a certain amount of a given non-steroidal anti-inflammatory agent has a therapeutic effect or not.

However, the Board is also convinced that, in order to establish the lower limit of the therapeutic amount for a given non-steroidal anti-inflammatory agent, in other words, in order to clearly establish the scope of protection of the claims, a standard test is required, since the result would strongly depend on the experimental method used.

Under these circumstances, as there is no such test in the description describing how a therapeutic amount should be quantified and as the appellant did not provide any evidence that there exists in the field of ophthalmology such a standard test known to the skilled person, the Board concludes that claim 1 of the main request does not fulfill the requirement of Article 84 EPC.

2.2 The Board agrees with the submissions of the appellant, that the term *per se* has a clear meaning and that it does not imply a full treatment of the condition. This does not, however, remedy the deficiency discussed under point 2.1 above.

3. *Auxiliary requests 1 to 6*

As these requests all contain the functional feature "a therapeutic amount", the above conclusions apply to these requests as well.

It is indeed true, as submitted by the appellant, that the indication in the claims of the total concentration of the agent (ie 0,1 to 1% by weight based on the total weight of the composition) in combination with the mention of the amount in suspension (10 to 99%) will define the amount remaining in solution.

However, according to the wording of the claims this amount in solution is further restricted by the functional feature "therapeutic", so that again a standard test is required in order to assess whether this further requirement of the claim is also fulfilled

for the amount in solution for any non-steroidal anti-inflammatory agent.

4. *Admissibility of auxiliary requests IIIa and IVa*

The Board observes that these two requests, presented by the appellant as a reply to the clarity objection raised against the requests on file, were filed after the debate was closed.

In that respect, the Board notes that the clarity objection was one of the grounds which led to the refusal of the application and that this objection was repeated in the Board's communication.

As no new arguments with respect to the clarity objection were put forward by the Board compared with the ones put forward by the Examining Division, either in its communication or during the oral proceedings, the Board considers that these requests cannot be introduced into the proceedings at this stage of the procedure as they were filed too late.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

A. Townend

U. Oswald