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D E C I S I O N
of 7 July 1999

Case Number: T 0315/98 - 3.3.2

Application Number: 88906506.6

Publication Number: 0324007

IPC: A61K 31/19

Language of the proceedings: EN

Title of invention:

A pharmaceutical composition containing S(+)ibuprofen substantially free of its R(-)antipode

Patentee:

Sterling Winthrop Inc.

Opponent:

- (01) Spirig AG
(02) The Boots Company PLC Patent Dept. R4
(03) Zambon Group S.p.A.
(04) Gebro Broschek Gesellschaft m.b.H.
(05) Knoll AG
(07) PAZ Arzneimittelentwicklungsgesellschaft GmbH

Headword:

S(+)ibuprofen/STERLING

Relevant legal provisions:

EPC Art. 123, 54(3)
EPC R. 57(1), 58(2), 57a

Keyword:

"No extension of the claims as granted beyond the content of the application as filed - normal understanding of the release function of a carrier or diluent of a pharmaceutical composition"

"Novelty - no - prior art describes the same subject-matter in

other words"

Decisions cited:

-

Catchword:

-



Case Number: T 0315/98 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 7 July 1999

Appellant: Sterling Winthrop Inc.
(Proprietor of the patent) 90 Park Avenue
New York
NY 10016 (US)

Representative: Vossius, Volker, Dr.
Dr. Volker Vossius
Patentanwaltskanzlei
Rechtsanwaltskanzlei
Holbeinstrasse 5
81679 München (DE)

Respondents: Spirig AG
(Opponent 01) Postfach
4622 Egerkingen (CH)

Representative: Zimmermann, Hans, Dr.
c/o A. Braun Braun Héritier Eschmann AG
Patentanwälte VSP
Holbeinstrasse 36-38
Postfach 160
4003 Basel (CH)

(Opponent 02) The Boots Company PLC
Pennyfoot St
Nottingham NG2 3AA (GB)

Representative: Thacker, Michael Anthony
The Boots Company plc
Group Patents Department
D31
1 Thane Road West
Nottingham NG2 3AA (GB)

(Opponent 03) Zambon Group S.p.A
Via Lillo del Duca, 10
20091 Bresso (Milano) (IT)

Representative: -

- 2 -

(Opponent 04) Gebro Broschek Gesellschaft m.b.H.
Bahnhofsbichl 13
6391 Fieberbrunn (AT)

Representative: Wildhack, Helmut, Dipl.-Ing. Dr.
Patentanwälte Dipl.-Ing. Leo Brauneiss
Dipl.-Ing. Dr. Helmut Wildhack
Dipl.-Ing. Dr. Gerhard Jellinek
Landstrasser Hauptstrasse 50
1030 Wien (AT)

(Opponent 05) Knoll AG
Knoll Strasse
67008 Ludwigshafen (DE)

Representative: Miller, T. K. Dr.
Knoll Pharmaceuticals
Patents Department
R4 Pennyfoot Street
Nottingham NG2 3AA (GB)

(Opponent 07) PAZ Arzneimittelentwicklungsgesellschaft mbH
In der Schildwacht 13
65933 Frankfurt (DE)

Representative: Grussdorf, Jürgen, Dr.
Patentanwälte Zellentin & Partner
Rubensstrasse 30
67061 Ludwigshafen (DE)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 11 February 1998
revoking European patent No. 0 324 007 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: P. A. M. Lançon
Members: U. Oswald
R. E. Teschemacher

C. Germinario
C. Rennie-Smith

Summary of Facts and Submissions

I. European patent No. 0 324 007 was granted for the contracting states AT, BE, CH, DE, FR, GB, IT, LI, LU, NL and SE, on the basis of nine claims contained in the European patent application No. 88 906 506.6 originating from international application No. PCT/US88/02253 (international publication No. WO 89/00421 - hereafter called "the originally filed application"), filed 8 July 1988, claiming a priority date of 10 July 1987 from US application No. 71914.

Claim 1 as granted reads as follows:

"1. Use of a mixture of the enantiomers of ibuprofen formulated in combination with a nontoxic pharmaceutically acceptable carrier or diluent that permits release of said mixture so as to obtain hastened onset of analgesia, said mixture of the enantiomers of ibuprofen comprising at least 90% by weight of S(+)-ibuprofen and no greater than 10% by weight of R(-)-ibuprofen, for the manufacture of a solid-state medicament that elicits an onset-hastened and enhanced analgesic response in a human suffering from pain and in need of such treatment."

II. Seven oppositions were filed against the granted patent by the Respondents and Opponent 06 who withdrew his opposition during first instance proceedings. Each Opponent objected to the patent on two or more of the grounds of lack of novelty, lack of inventive step under Article 100(a) EPC, insufficiency of disclosure

under Article 100(b) EPC and extension beyond the application as originally filed under Article 100(c) EPC. Of the numerous documents cited during the opposition proceedings only the following remains relevant to the present decision:

- (1) EP-A-0 267 321, filed on 14 November 1986 for the contracting states AT, BE, CH, DE, ES, FR, GB, GR, IT, LI, LU, NL and SE and published on 18 May 1988.

III. By a decision posted on 11 February 1998, the Opposition Division revoked the patent under Article 102(1) EPC.

The Opposition Division found that the wording of claim 1 as granted "**carrier....that permits...so as to obtain...**" introduced a specific function of the carrier, which could not be derived from the application document as originally filed.

More particularly, it was pointed out that the originally filed application clearly indicated that the claimed hastened onset and enhanced analgesic effect resulted only from the use of the S(+)*ibuprofen* enantiomer and that accordingly the feature "...acceptable carrier or diluent that permits release of said mixture so as to obtain hastened onset of analgesia..." was not allowable under Article 123(2) EPC.

The deletion of said feature would result in the broadening of the scope of claim 1 as granted contrary to Article 123(3) EPC.

In the Opposition Division's view the two auxiliary requests presented in the course of the proceedings in the same way comprised unallowable amendments as to the release function of the said carrier or diluent in order to obtain hastened onset of analgesia and accordingly also contravened Article 123(2) EPC.

The Opposition Division did not share the Opponents objections to another feature of claim 1 as granted explaining in detail that the use of a **mixture** of enantiomers found support in the originally filed documents.

- IV. The Appellant (Patentee) lodged an appeal against the said decision and filed new claims in the form of three auxiliary requests. Oral proceedings took place on 7 July 1999 during which the Appellant requested that in claim 1 as granted (main request) and in claim 1 of each of the auxiliary requests between the words **with** and **non-toxic "a"** should be replaced by "**an inert**".

At the end of the oral proceedings the Appellant sought to introduce a fourth auxiliary request. Since no basis could be shown for the newly added disclaimer in claim 1 of this request, this request was regarded as clearly unallowable under Article 123(2) EPC and therefore not admitted into the proceedings.

Claim 1 of the first auxiliary request reads as follows:

- "1. Use of a mixture of the enantiomers of ibuprofen formulated in combination with **an inert** nontoxic pharmaceutically acceptable carrier or diluent,

said mixture of the enantiomers of ibuprofen comprising at least 90% by weight of S(+)ibuprofen and no greater than 10% by weight of R(-)ibuprofen, for the manufacture of a solid-state medicament **that permits release of said mixture so as to obtain hastened onset of analgesia and** that elicits an onset-hastened and enhanced analgesic response in a human suffering from pain and in need of such treatment."
(emphasis added in order to show amendments in comparison with claim 1 as granted)

Claim 1 of the second auxiliary request contains the following amendments:

- "1. Use of a mixture of the enantiomers of ibuprofen formulated in combination with **an inert** nontoxic pharmaceutically acceptable carrier or diluent, **with the proviso that sustained release formulations are excluded,....**"
(emphasis added in order to show amendments in comparison with claim 1 as granted)

Claim 1 of the third auxiliary request contains the following amendments:

- "1. Use of a mixture of the enantiomers of ibuprofen formulated in combination with **an inert** nontoxic pharmaceutically acceptable carrier or diluent that permits release of said mixture so as to **allow** hastened onset of analgesia,...."
(emphasis added in order to show amendments in comparison with claim 1 as granted)

V. The arguments of the Appellant, both in the written procedure and at the oral proceedings may be summarised as follows:

The core of the claimed invention was simply the use of S(+)-ibuprofen containing at most 10% by weight of the R(-)-form to achieve a hastened onset and an enhanced analgesic response. The description of the patent in suit contained a reference to sustained release formulations but the claimed subject-matter clearly excluded sustained release formulations. Moreover, several passages in the description as originally filed expressly referred to preferred immediate release formulations. Having regard to the disclosure of the description, inter alia pages 16/17 and particularly claim 37 as originally filed, there was no doubt that the medicament should be formulated or the pharmaceutical composition should be adapted so as to obtain the desired degree of hastened onset and enhanced analgesia. It was particularly pointed out that the carrier or diluent allowed this effect to occur but that there was no pharmaceutical activity by the carrier or diluent itself.

Since the hastened onset of analgesia was only caused by the S(+)-ibuprofen, the recitation of "permits" excluded protection when the carrier or diluent did not permit such release of the ibuprofen mixture. The Appellant emphasised that there was no legitimate basis for interpretation of the claims in a manner which was contrary to the disclosure of the description of the patent in suit.

Accordingly, in the Appellant's view the claimed

subject matter did not contravene Article 123(2) EPC and there was no ground to object under Article 123(3) EPC.

The Appellant furthermore took the view that document (1) did not disclose hastened onset of analgesia and thus the claimed subject matter was novel under Article 54(3) EPC.

It was stressed that neither the serum plasma level of the active agent nor the distribution of a medicament in a mammalian organism was correlated to analgesic response in mammalian organisms. Accordingly, it was not possible to conclude that increased plasma levels after administration of S(+)-ibuprofen instead of R(-)-ibuprofen as described on page 9 in document (1) was to be regarded as a disclosure of hastened onset of analgesia. Moreover, there was no suggestion that quick distribution to, and occurrence of the active agent of an analgesic medicament at, the site of action immediately cause analgesia.

The Appellant agreed that regarding the use for analgesia treatment in general and the components in the pharmaceutical composition there was no difference between the patent in suit and document (1) but by the specific use of the said pharmaceutical composition the patent in suit provided a new technical teaching for the improved handling of pain. Before the priority date of the patent in suit S(+)-ibuprofen was not known as a so-called pain killer and patients had never been treated with S(+)-ibuprofen for hastened onset. The numerical results (figures) of Table 1 on page 8 and the graphs of Figure 1 on page 9 of document (1)

showing receptiveness to electric stimuli of the nerves of monkeys did not allow any conclusion as to the time when the analgesic effect can be first detected. The numerical results and graphs of document (1) showed nothing more than an onset of insensitivity over increased electricity after about thirty minutes.

VI. The Respondents contested these arguments and inter alia took the view that having regard to the common general knowledge in the field of pharmaceuticals, it was technically meaningless to assume that the carrier of a medicament could be inert as to the release function of the active component. Therefore, the additional characterisation of the carrier or diluent by the [later] introduction of the wording "**an inert**" into the use claim could either be regarded as pure cosmetic change to the wording of the claim or would introduce new matter if the intention was to change the function of the carrier or diluent in the composition as to a specific drug release profile.

Moreover, in the Respondents' view the sequence of the wording of claim 1 as granted "**carrier....that permits...so as to obtain...**" should be read as one technical function and therefore must be understood to mean that only in combination with a specific release function of the carrier was it possible to achieve the hastened onset of analgesia. There was, however, no support for such a very special function of the carrier in the originally filed application. The Respondents put particular weight on the fact that the Appellant only introduced the particular function of the carrier or diluent into the claim in order to establish novelty of the subject-matter of the patent in suit over the

prior art disclosure. In the Respondents' view the disclosure of preferred immediate release formulations in the description as originally filed and the exclusion of sustained release formulations could not support the claimed specific functional release requirement of the carrier or diluent. The relevant passages in the description as originally filed did not say that immediate release of the active ingredient was necessary to obtain an onset-hastened analgesic effect and there was no disclosure about the release rate or profile required for non-sustained release compositions to achieve an onset-hastened effect. Moreover, parts of the said relevant passages were deleted in the text of the granted specification. It was accordingly the Respondents view that none of the requests fulfilled the requirements of Article 123(2) EPC and after deletion of the disputed passages were open to objections under Article 123(3) EPC.

As regards the question of novelty under Article 54(3) EPC it was pointed out that the ibuprofen medicament described in the originally filed application could not be distinguished from the medicament disclosed in document (1). The worked examples in document (1) clearly showed that this prior art did not exclusively relate to sustained release formulations but also related to immediate or rapid release formulations by using conventional carrier material. Moreover, document (1) clearly indicated that the S(+)form is responsible for a quick distribution of ibuprofen in high concentrations to the site of action. The quick appearance of ibuprofen in high concentrations at the site of action was clearly an indication of a hastened onset of analgesia. This was confirmed by the

experimental results shown in Table 1 and Figure 1 of document (1). Accordingly, the Respondents concluded that the patent in suit related to subject matter already described in the prior art but claimed in a different wording.

VII. The Appellant requested that the decision under appeal be set aside and that the case be remitted to the Opposition Division for the examination of novelty and inventive step on the basis of one of the following sets of claims:

Claims 1 to 9 as granted - main request,

Claims 1 to 9 as filed with letter dated 1 July 1999 - first auxiliary request,

Claims 1 to 9 as filed with letter dated 7 June 1999 - second auxiliary request,

Claims 1 to 9 as filed with letter dated 2 July 1999 - third auxiliary request,

with the further amendment in Claim 1 of all four sets of claims that in Claim 1 between the words **with** and **nontoxic "a"** is replaced by "**an inert**".

The Respondents requested that the appeal be dismissed.

VIII. After the decision of the Board was made and, on 8 July 1999, announced at the conclusion of the oral proceedings, the Appellant sought to submit further requests by a letter of 22 July 1999. Having given its decision, by which it is bound, the Board could not

consider these further requests.

Reasons for the Decision

1. The appeal is admissible.
2. Taking into account the disclosure of the patent in suit as originally filed (see particularly page 15, lines 10 to 29 and page 17, lines 7 to 19), showing that the solid-state medicament manufactured for the claimed use of S(+)-ibuprofen may contain any suitable nontoxic pharmaceutically acceptable inert carrier material well known to those skilled in the art of pharmaceutical formulations, the Board shares the Respondents' view that the addition of "**an inert**" in claim 1 of each of the four requests represents pure cosmetic amendment to the claimed subject matter. Having regard to former Rules 57(1) and 58(2) EPC (new Rule 57(a) EPC entered into force 1 June 1995), it has rightly been emphasised eg in decisions T 295/87, OJ EPO 1990, 470; and T 829/93 of 24 May 1996, (see 6.2 of the reasons), that opposition proceedings do not provide an opportunity to the Patentee merely to improve the drafting of the claims. Accordingly, there is sufficient reason not to allow the cosmetic addition of the words "**an inert**".

However, this amendment is only peripheral to the substantive issues to which the parties' arguments have been principally addressed and accordingly, the Board considers it would be inappropriate to allow this formal issue to determine the appeal.

3. The Board notes that the Opposition Division did not decide on the grounds of opposition under Article 100(b) EPC and that in the course of the appeal proceedings the Respondents did not continue to argue for insufficiency of disclosure of the invention. Nevertheless, the Board has carefully studied the written submissions during the proceedings before the Opposition Division and as a consequence sees no reason to return to the question of sufficiency of disclosure.
4. The Board also sees no reason to take up the question of clarity of the amendments to the claims in each of the four requests under Article 84 EPC.
5. Articles 54(1) and (2) EPC as well as Article 56 EPC are in this case not at issue.

However, it is observed that the disputed passage "**carrier....that permits...so as to obtain...**" was introduced in claim 1 before the grant of the patent in order to overcome a novelty objection under Article 54(3) EPC vis-à-vis document (1), that the Respondents subsequently raised an objection under Article 123(2) EPC that the added passage involved a new particular meaning and that in reply the Appellant argued that the said passage did not have that meaning but a more restricted one. The interpretation of this passage much disputed between the parties is decisive not only for the question of added subject-matter under Article 123 (2) EPC but also, and equally for the objection to novelty under Article 54(3) EPC maintained in appeal proceedings in particular by Respondent (Opponent) 04. In this situation it is appropriate that both these grounds be considered together. This not

only avoids an unnecessary delay caused by a remittal, it also ensures that the judgement is based on the same interpretation for both questions. In those circumstances the Board exercised its power under Article 111(1) EPC and did not remit the case to the first instance for the purpose of deciding the issue under Article 54(3) EPC.

6. Apart from the functional interpretation of the wording "**carrier....that permits...so as to obtain...**", the Board sees no reason to deviate from the Opposition Division's decision that the use of "**a mixture**" of the enantiomers according to claim 1 as granted does not contravene Article 123(2) EPC and also concludes that each of the other features of claim 1 as granted finds support in the originally filed application. The same applies to claim 1 of the main request and each of the three auxiliary requests in the appeal proceedings since the auxiliary requests merely represent attempts to reformulate the wording of claim 1 in order to clarify the intended understanding of the function of the carrier.

- 7.1 In addition to the disclosure in the originally filed application referred to at the start of paragraph 2 relating to the carrier materials suitable for the claimed use, the description as originally filed on page 11, lines 5 to 13, contains the clear teaching that one aspect of the invention underlying the patent in suit is a "**pharmaceutical composition of matter for use in eliciting an onset hastened and enhanced analgesic response in mammals.....comprising an effective analgesic unit dosage amount of**

S(+)*ibuprofen*..."

and that "**Typically, S(+)*ibuprofen* is associated with a nontoxic pharmaceutically acceptable inert carrier or diluent therefor**" (emphasis added).

7.2 Moreover claim 37 as originally filed relates to "**A pharmaceutical composition of matter adapted to elicit an onset-hastened and enhanced analgesic response in a mammalian organism...comprising...an effective amount of the S(+)*ibuprofen* enantiomer...and a nontoxic pharmaceutically acceptable carrier or diluent therefor**" (emphasis added).

7.3 In the light of this disclosure, the Board concludes that the wording of claim 1 both as granted and according to the main request and the auxiliary requests can only be understood as meaning that in the mixture of the enantiomers of *ibuprofen* formulated in combination with a carrier or diluent, the carrier or diluent has at least the normal function of permitting release of that mixture in order to allow the effect of hastened onset of analgesia to be obtained. It was undisputed by the parties that the action of release of the active ingredients of a medicament cannot be functionally separated from the presence of the carrier in the pharmaceutical composition.

Accordingly, there is in any event a minimal, but only minimal, contribution of a carrier or diluent to the pharmaceutical effect of a medicament, in the present case the absence of inhibition of the desired hastened onset of analgesia; in other words, it at least allows

that effect to occur.

7.5 For these reasons the Board cannot see any basis for stretching the plain meaning of claim 1 to the technically speculative interpretation of the claim such that achievement of the desired hastened onset of analgesia is not linked to the normal release function of a pharmaceutically inert carrier but is exclusively linked to a specific pharmaceutical interaction of the carrier or diluent with S(+)*ibuprofen*. Such an interpretation would contradict the clear disclosure of the originally filed document.

7.6 In these circumstances, the Board can only conclude that claim 1 of the main request does not contravene Article 123(2) EPC and that the same reasoning as to the function of the carrier or diluent would apply to claim 1 of each of the auxiliary requests, which accordingly can be regarded as describing the same subject-matter. Consequently, an objection under Article 123(3) EPC does not arise.

8.1 Document (1) (see claim 1, Example 1 and page 3, lines 4 to 11 and 48 to 51) discloses **the use of S(+)*ibuprofen* formulated in combination with a nontoxic pharmaceutically acceptable carrier or diluent that permits release of S(+)*ibuprofen*, for the manufacture of a solid-state medicament that elicits an analgesic response in a human suffering from pain and in need of such treatment.**

8.2 Document (1) clearly teaches on page 3, lines 18 to 22 that in order to achieve sufficient pharmacological

effect in humans it is of decisive importance that pure S(+)enantiomer is used, since only then is a sufficiently high concentration in the blood achieved quickly enough, this being necessary for quick distribution to the site of action. Subsequently, it is indicated that after administration of the S(+)form a substantially higher concentration at the site of action is achieved than when the racemate or R(-)form is applied.

- 8.3 Document (1) does not expressly mention the use of a mixture of the enantiomers to obtain hastened onset but refers to pure S(+)ibuprofen in order to obtain analgesic response. However, it is to be noted that claim 1 of the main request and the auxiliary requests relates to the "use of a mixture of the enantiomers of ibuprofen.....comprising at least 90 % by weight of S(+)ibuprofen and no greater than 10 % by weight of R(-)ibuprofen...", without defining an upper limit of the S(+)enantiomer and a lower limit of the R(-)enantiomer. According to several passages in the description as originally filed, inter alia on page 10, lines 23 to 28, it is indicated that one aspect of the invention is "administering....an effective onset-hastening analgesic amount of S(+)ibuprofen substantially free of R(-)ibuprofen" and it is further indicated in the description as originally filed (see page 12, second paragraph) and the specification of the patent in suit (see page 6, lines 8 to 12) that most preferably 99% or more of the ibuprofen content is in the form of the S(+)enantiomer. This means that the mixture as claimed may contain the R(-)enantiomer in very low amounts down to the detection limit. That meaning is not affected by the fact that the

characterisation "S(+)ibuprofen substantially free of R(-)ibuprofen" has been removed from the description before granting the patent in suit since, with the lack of a lower limit of R(-)ibuprofen, claim 1 of the main request still comprises an embodiment with the attribute "substantially free of R(-)ibuprofen".

8.4 Moreover, the description as originally filed on pages 20/22 and the specification of the patent in suit on page 8, lines 17 to 37 contain a reference to prior art showing a common method of preparing S(+)ibuprofen by resolution of racemic ibuprofen and purification from an ether extract and the possibility of achieving 95% optical purity and in a special method the possibility of obtaining a mixture with 99% S-isomer and 1% R-isomer (w/w). Further, the said prior art was also published before the priority date of document (1).

8.5 Since document (1) also indicates that S(+)ibuprofen is obtained by a conventional optical resolution including purification with an ether extract, it is clear that the reference to a pure S(+)enantiomer in document (1) means the same grade of purification as required by the meaning "mixture of the enantiomers of ibuprofen" in the patent in suit. In the light of these facts there is no room for the assumption that document (1) and the patent in suit refer to different pharmaceutical activities.

8.6 The Appellant argued that the patent in suit, in addition to the teaching of document (1), provided in the form of a second medical indication within the meaning of decision G 5/83, OJ EPO 1985, 64, the

achievement of hastened onset of analgesia as a novel teaching not made available to the public before the filing date of the patent in suit.

8.7 The Board can agree that the achievement of an analgesic response in a human by using a specific pharmaceutical composition may represent a medical indication, but has strong doubts whether the mere reference in a claim to hastened onset of analgesia, if the analgesic effect of that composition is known from the prior art, can be regarded as a second or further medical indication within the meaning of G 5/83.

8.8 The fact of the matter is that in the field of pharmacodynamics there is a lack of a convention or quantitative definition about the meaning of hastened onset of analgesia and that the description of the patent in suit contains merely an explanation of onset time in relative terms (see page 14, first paragraph of the originally filed application, and specification of the patent in suit page 6, lines 32 ff - "...onset time for analgesia can be reached, on the average, about one-third sooner when S(+)-ibuprofen is used rather than when racemic ibuprofen is administered, **depending on the dose level and the severity of the pain...**" (emphasis added) -). Accordingly, the fact that the prior art does not expressly mention hastened onset does not automatically establish novelty of the claimed use.

8.9 It remains therefore to decide whether, on the basis of what is commonly understood in the field of pharmaceuticals, the formulation "hastened onset" in combination with the other features of claim 1 allows

one to distinguish at least quantitatively the analgesic response to be achieved by S(+)-ibuprofen as described in the patent in suit from that disclosed by document (1).

8.10 The Board agrees with the Appellant's submission that a quicker distribution in higher concentration of a pharmaceutically active agent to the site of action in comparison with another active agent does not necessarily mean that the quicker agent shows a better pharmacological activity. However, as regards the activity of the S(+)-form, document (1) refers on page 3, lines 32/33 to a so-called reverse synergism in that S(+)-ibuprofen shows at half the dose a greater activity than the corresponding racemate.

8.11 Since the patent in suit and document (1) refer to the same racemate of ibuprofen as a basis for comparing the pharmacological activity of the S(+)-enantiomer and since both refer to pharmacological activity in the form of analgesic response, it can only be concluded that the reference in document (1) to S(+)-ibuprofen in higher concentrations reaching the site of action more quickly with a higher activity means nothing else than hastened onset of analgesia. Accordingly, document (1) discloses the same pharmacological effect of S(+)-ibuprofen as the patent in suit but simply expressed by other wording.

8.12 This conclusion is supported by the evaluation of the analgesic activity of ibuprofen as described in document (1) on pages 5 to 9 by tests with electrically stimulated afferent nerves of the feet of female Rhesus monkeys. As regards the validity of tests carried out

with monkeys, document (1) indicates on page 3, lines 9 to 11 more generally that "These findings originate from analgesia tests on monkeys which, on the basis of their phylogenetic position are most similar to humans in their metabolic characteristics. These results could also be shown in humans." According to the numerical values of the test results on page 8 and the corresponding graphs in Figure 1 on page 9, S(+)-ibuprofen shows in comparison with the ibuprofen racemate that, after the first 30 minute interval of the test period a nearly 50% higher change (+9.5 in comparison with +6.4) of the voltage was required to achieve a stimulus response in the female Rhesus monkeys. By extrapolation from the corresponding graphs in Figure 1, it is clear that these test results not only show an enhanced analgesic response at a fixed time, which was not disputed by the Appellant, but also show in relative terms that during the first test interval a fixed value of median percentage change in the threshold value is achieved earlier in the case of S(+)-ibuprofen (the steep slope of the curve representing the test values), which means that a quantitative difference in the onset of analgesia to be achievable by S(+)-ibuprofen is also derivable from Figure 1, which accordingly also allows the conclusion to be drawn that the solid-state medicament described in document (1), when containing S(+)-ibuprofen instead of the racemate, elicits an onset-hastened analgesic response in a human suffering from pain and in need of such treatment.

- 8.13 The Board agrees with the Appellant's submission that neither Table 1 nor Figure 1 allow a conclusion as to the absolute time of hastened onset to be drawn.

However, since claim 1 of the main request does not require an absolute time interval for the hastened onset of analgesia to be achieved by the medicament, the Appellant's criticism of that aspect of the test results in document (1) and the statement that according to the patent in suit hastened onset of analgesia is already achieved after a period of 15 minutes, cannot have any influence on the question of novelty of the subject matter of the patent in suit in comparison with the disclosure in document (1).

Therefore, in the light of the disclosures in document (1), the Board can only conclude that the subject matter of claim 1 of the main request lacks novelty within the meaning of Article 54(3) EPC.

8.14 The same applies to the subject matter of claim 1 of each of the three auxiliary requests since the auxiliary requests merely represent attempts to reformulate the wording of claim 1 in order to clarify the intended understanding of the function of the carrier.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

P. Martorana

P. A. M. Lançon