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Datasheet for the decision of 20 September 2011

Case Number: T 1525/10 - 3.3.02

Application Number: 97944240.7

Publication Number: 948320

IPC: A61K 9/20, A61K 31/19

Language of the proceedings: EN

Title of invention:
Pharmaceutical compositions for sustained release of the HMG-CoA reductase inhibitor fluvastatin

Patentee:
Novartis AG
Novartis Pharma GmbH

Opponents:
Ratiopharm GmbH
Actavis UK Ltd
Actavis GmbH
Mylan S.A.S.

Headword:
Sustained release of fluvastatin/NOVARTIS AG

Relevant legal provisions:
EPC Art. 84, 123(2)
RPBA Art. 12(4)

Relevant legal provisions (EPC 1973):
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Keyword:
"Main request and auxiliary request I - clarity (no): parameter and method for measuring it not clearly defined"
"Auxiliary request I - Article 123(2) EPC (no): unallowable generalisation"
"Auxiliary request II - admission (no): request withdrawn in first instance proceedings"

Decisions cited:
G 0009/92, G 0004/93, G 0002/97, R 0011/08, R 0011/11, T 0240/04, T 0390/07, T 1469/07, T 1705/07, T 0023/10

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1525/10 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 20 September 2011

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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 3 May 2010 revoking European patent No. 948320 pursuant to Article 101(3)(b) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
L. Bühler

Summary of Facts and Submissions

I. European patent No. 0 948 320 based on application No. 97 944 240.7 was granted on the basis of a set of 11 claims.

II. An opposition was filed against the patent. The patent was opposed under Article 100(a) EPC for lack of inventive step and under Article 100(b) EPC for insufficiency of disclosure.

III. The documents cited during the opposition and appeal proceedings included the following:

(13) US-A-5 356 896
(36) C. Bogentoft and J. Sjögren, "Towards Better Safety of Drugs and Pharmaceutical Products", D.D. Breimer (ed.), Elsevier/North Holland Biomedical Press (1980), 229-246
(41) H. Cheng et al., Pharmaceutical Research (1993), vol. 10, no. 11, 1683-1687
(53) Expert Statement of Prof. John Collett of 25 November 2009
(57) USP 23/NF 18 (1995), 1790-1796 and 3208-3212.

IV. In its interlocutory decision pronounced on 27 March 2007 and dispatched on 8 June 2007, the opposition division held that the patent could be maintained in an amended form on the basis of a text submitted during the oral proceedings which met the requirements of Articles 123, 83, 54 and 56 EPC.

V. The opponent (hereafter respondent O1) lodged an appeal against said decision.

VI. On 17 January 2008 an intervention pursuant to Article 105 EPC was filed by intervener O1 (hereafter respondent O2), who opposed the contested patent under Article 100(a) EPC for lack of novelty and inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC for added subject-matter.

VII. On 23 January 2009 a further intervention pursuant to Article 105 EPC was filed by intervener O2 (hereafter respondent O3), who opposed the contested patent under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(b) EPC for insufficiency of disclosure.

VIII. With decision T 1469/07 dated 3 February 2009 the board set aside the decision of the opposition division dated 8 June 2007 and remitted the case to the department of first instance for further prosecution.

IX. On 27 February 2009 a further intervention pursuant to Article 105 EPC was filed by intervener O3 (hereafter respondent O4), who opposed the contested patent under Article 100(a) EPC for lack of novelty and inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC for added subject-matter.

X. In its decision pronounced at the oral proceedings on 17 March 2010 and posted on 3 May 2010, the opposition division revoked the patent pursuant to Article 101(3)(b) EPC. It came to the conclusion that all the requests on file were allowable under Rule 80

EPC and under Article 123(2) EPC. However, none of the requests met the requirements of Article 84 EPC, because the feature "wherein the sustained release formulation releases the active ingredient over more than 3 hours" was not clear. Firstly, it was not clear whether the release rate referred to *in vitro* or to *in vivo* release. Secondly, the description did not provide any standard test for measuring it and finally, the release data provided in the patent specification were not sufficient for characterising the sustained release.

XI. The patent proprietors (appellants) lodged an appeal against said decision.

XII. With the statement of the grounds of appeal dated 30 July 2010, the appellants filed a main request and auxiliary requests I to V. The independent claims of the main request and of auxiliary requests I and II read as follows:

(i) Main request

"1. A sustained release pharmaceutical composition comprising a water soluble salt of fluvastatin as active ingredient and being selected from the group consisting of matrix formulations, diffusion-controlled membrane coated formulations and combinations thereof, wherein the sustained release formulation releases the active ingredient over more than 3 hours.

10. The use of a water soluble salt of fluvastatin for the manufacture of a sustained release pharmaceutical composition for the treatment of hypercholesterolemia, said sustained release pharmaceutical composition being

selected from the group consisting of matrix formulations, diffusion-controlled membrane coated formulations and combinations thereof, wherein the sustained release formulation releases the active ingredient over more than 3 hours."

(ii) Auxiliary request I:

"1. A sustained release pharmaceutical composition comprising a water soluble salt of fluvastatin as active ingredient and being selected from the group consisting of matrix formulations, diffusion-controlled membrane coated formulations and combinations thereof, wherein the sustained release formulation releases the active ingredient over more than 3 hours as determined in pH 6.8, +37°C, by use of an USP II apparatus at a paddle stirring rate of 75 rpm.

10. The use of a water soluble salt of fluvastatin for the manufacture of a sustained release pharmaceutical composition for the treatment of hypercholesterolemia, said sustained release pharmaceutical composition being selected from the group consisting of matrix formulations, diffusion-controlled membrane coated formulations and combinations thereof, wherein the sustained release formulation releases the active ingredient over more than 3 hours as determined in pH 6.8, +37°C, by use of an USP II apparatus at a paddle stirring rate of 75 rpm."

(iii) Auxiliary request II:

"1. A sustained release pharmaceutical composition comprising a water soluble salt of fluvastatin as

active ingredient and being selected from the group consisting of matrix formulations, diffusion-controlled membrane coated formulations and combinations thereof.

10. The use of a water soluble salt of fluvastatin for the manufacture of a sustained release pharmaceutical composition for the treatment of hypercholesterolemia."

XIII. Oral proceedings were held before the board on 20 September 2011. In the course of these proceedings, the appellants withdrew auxiliary requests III to V.

XIV. The appellants' arguments can be summarised as follows:

Regarding clarity of claim 1 of the main request, the appellants argued that the release rate of more than 3 hours clearly related to *in vitro* release. Thus, the only test figuring in the original application (page 11, lines 9-13) was an *in vitro* test and the results obtained therewith were summarised in figures 1 to 3. No *in vivo* tests were mentioned in the original application. Moreover, reliable results were obtainable only via *in vitro* tests, as the *in vivo* determination was a secondary measurement, in which the serum concentration of the active agent over time was measured, which was not identical to the release rate from the galenic form. Reference was made to documents (53), (36) and (41) in this context.

In connection with the question whether the method for determining the release rate was sufficiently described in the original application, the appellants argued that the passage on page 11, lines 9-13, contained all the necessary information as it defined the apparatus to be

used, which was well known and standardised, and listed all the parameters necessary for obtaining reproducible results, namely a pH of 6.8, a temperature of +37°C and a paddle stirring rate of 75 rpm. The indication of the amount of solvent to be used was not necessary in view of the standardised size of the USP II apparatus, neither was it essential to define the buffer to be used for getting a pH of 6.8.

Regarding the question whether the feature "more than 3 hours" was insufficient for reliably defining a sustained release profile, the appellants held that said feature defined three points in time: one before 3 hours, another one at 3 hours and a third one after 3 hours. Moreover, said feature was supported by figure 3, where several samples were measured over time and where a clear distinction was made between sustained release and immediate release.

As regards the requirements of Article 123(2) EPC, the appellants referred to page 1, lines 22-25, of the original application, which disclosed a release period of more than 3 hours and which was argued to be directly correlated to the passage on page 11, lines 9-14, which described how it could be determined. Reference was also made to figures 1 to 3, which showed that several measurements were made over a period of 12 hours. There was no new combination of features.

Regarding the admissibility of auxiliary request II, it was argued that its filing was a reaction to objections raised under Rule 80 EPC in connection with the higher ranking requests. Moreover, its renewed filing, which was no case of *reformatio in peius*, became necessary,

as the appeal proceedings could not be expected to be restricted to an evaluation of the requirements of Article 84 EPC, which had been the only ground for revocation in the decision under appeal. This request had already been filed during the opposition proceedings, but later withdrawn, as it had been procedurally pointless to present it to the opposition division in view of its first decision of 20 August 2007. Decisions T 1067/08 and T 23/10 did not apply to the present case.

XV. The respondents' arguments can be summarised as follows:

The subject-matter of the main request was not clear as claim 1 did not contain any information as to whether the release profile was measured *in vitro* or *in vivo*. The fact that the *in vivo* measurement was called a secondary measurement did not mean that it could not be done. Regarding the method for measuring the release profile, it was argued that essential data such as the volume of the solvent or the buffer to be used for adjusting the pH to 6.8 were missing. Moreover, the release profile was inadequately described as only one point in time had been defined.

Regarding claim 1 of auxiliary request I, it was argued that, among other things, the method for measuring the release profile was limited to tablets in the original application and could therefore not be extended to other galenic forms. Moreover, the specific combination of features figuring in present claim 1 was not disclosed in the original application either.

Auxiliary request II was not admissible in the light of decisions T 1067/08 and T 23/10, which fully applied to the present case. The respondents submitted that the appellants, following an adverse finding of the opposition division on the main request in respect of the wording "more than three hours" characterising the sustained release, had withdrawn their auxiliary requests I to III filed on 25 November 2009 in which this wording was omitted. The respondents contended that these requests were withdrawn with the intention of avoiding a decision thereon. Although the appellants, when withdrawing auxiliary requests I to III during oral proceedings before the opposition division, reserved the right to file these requests on appeal, they should be precluded to reintroduce such claims under Article 12(4) RPBA. The appellants should not have withdrawn the requests and thereby prevented a discussion on the merits if they had intended to pursue them. Moreover, the appellants' submission was argued not to be allowable in view of *reformatio in peius*.

XVI. The appellants requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or, alternatively, of auxiliary requests I or II filed with the statement of grounds of appeal.

The respondents requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Admission of auxiliary request II*

2.1 Pursuant to Article 12(4) RPBA an appeal board can hold inadmissible facts, evidence or requests that could have been presented in the opposition proceedings. The boards of appeal thus retain discretion, as a review instance, to refuse new material including requests (claim sets) not submitted during opposition proceedings (T 240/04 of 13 December 2007, point 16.2 of the Reasons, T 1705/07 of 10 June 2010, point 8.4 of the Reasons). The request at issue is one which was before the opposition division, but which was withdrawn so that no decision was taken thereon. In the board's view, Article 12(4) RPBA equally confers discretionary powers to hold inadmissible requests that were filed and subsequently withdrawn in the first instance proceedings, since such a course of events shows that these requests could have been presented in the first instance proceedings. The discretionary power under Article 12(4) RPBA has to be exercised appropriately, which requires the appeal board to consider and weigh up the relevant factors having regard to the particular circumstances of each case.

2.2 It is clear from the minutes of the oral proceedings before the opposition division of 17 March 2010 that the appellants, following the discussion on the main request, withdrew auxiliary requests I to III filed on 25 November 2009, in which the wording "wherein the sustained release formulation releases the active

ingredient over more than 3 hours" was omitted. The opposition division had beforehand informed the parties that it considered the main request to meet the requirements of Rule 80 EPC (minutes, page 2) and Article 123 EPC (minutes, page 4), whereas the words "wherein the sustained release formulation releases the active ingredient over more than 3 hours" did not satisfy the requirement of Article 84 EPC (minutes, page 9). In view of this finding, the withdrawal of those claim requests, in which the objected wording was omitted, appears - as the respondents argue - to be made with the intention of preventing a decision on novelty and inventive step. However, the appellants adverted to the opposition division's decision of 20 August 2007 which was later set aside by decision T 1469/07 of 3 February 2009. According to this decision, the release time was critical for establishing novelty vis-à-vis document (13) (see points 4.2 to 4.4 of the reasons). Bearing in mind the opposition division's opinion on novelty, the appellants regarded it pointless to discuss auxiliary requests I to III filed on 25 November 2009, since it was predictable that the opposition division would refuse these requests for lack of novelty. For procedural economy, the appellants did not maintain their request that would set back the discussions to the state of the proceedings before the opposition division's decision of 20 August 2007.

2.3 While the auxiliary requests I to III filed on 25 November 2009 may not have been withdrawn with the intention of delaying the opposition and appeal proceedings by seeking remittal upon introduction of these requests into appeal proceedings, the inevitable

result of the withdrawal of the requests was that a decision thereon was avoided. As soon as those requests had been withdrawn, they were no longer the subject of a reasoned decision. However, the purpose of appeal proceedings is to review what has been decided at first instance and not to review what has not been decided (T 390/07 of 20 November 2008, point 2 of the Reasons, also considering circumstances under which a request withdrawn at first instance may be admitted on appeal). As has been repeatedly stated in the case law, it is neither the purpose of an appeal proceedings to give the patent proprietor the opportunity to recast its claims as it sees fit and to have all its requests admitted into the appeal proceedings. Thus, if the appellants had wanted to preserve their right to have any of auxiliary requests I to III filed on 25 November 2009 considered by a board of appeal, they should have maintained them, all the more so in the light of the opposition division's opinion on the main request. Procedural economy, which in the present circumstances consists in the time it would have taken at oral proceedings to consider auxiliary requests I to III and to reach a decision thereon, and in the time for the opposition division to provide written reasons, is not a sufficient justification for the appellants' way to proceed. Moreover, it is incumbent on both the EPO and users of the European patent system who are parties to proceedings before it to act in good faith (G 2/97, OJ 1999, 123, point 4.2 of the Reasons). A proprietor who files auxiliary requests by which it delimits the framework of the opposition proceedings and then deliberately withdraws them in order to avoid any adverse decision being reached infringes this general principle by seeking to introduce these requests into

appeal proceedings. In conclusion, the board, having regard to the facts and arguments presented to it, decided to make use of its discretionary powers according to Article 12(4) RPBA not to admit auxiliary request II, in which the words "wherein the sustained release formulation releases the active ingredient over more than 3 hours" had been omitted, into the appeal proceedings.

2.4 Although the following considerations are not relevant for the board's decision not to admit auxiliary request II into the proceedings, the board wishes to take a stance with regard to additional arguments submitted in this context.

The respondent O1 argued that the admission of auxiliary request II would be contrary to the interdiction of *reformatio in peius*, i.e. the prohibition of a possible worse outcome of appeal proceedings for the (sole) appellant as compared to the decision under appeal. The legal situation in this regard has been elucidated in the decisions of the Enlarged Board of Appeal G 9/92 and G 4/93 (OJ 1994, 875). The implications are limited to cases in which an interlocutory decision on the maintenance of a patent in amended form is appealed only by one of the parties. Since the present appeal lies from the opposition division's decision to revoke the patent, the interdiction of *reformatio in peius* cannot have a bearing on the appeal and all the more on the question of admission of auxiliary request II.

The respondents O2 to O4 relied on the decisions T 1067/08 of 10 December 2010 and T 23/10 of 18 January 2011 refusing late filed claim requests pursuant to Article 12(4) RPBA. The appellants contested the pertinence of these decisions in view of the different factual circumstances. The board notes in this respect that the exercise of the discretionary power under Article 12(4) RPBA requires the appeal board to have regard to the particular circumstances of each case. The facts of the individual case will thus clearly affect any decision on the admission of late filed requests. Therefore, the decision invoked by the respondents cannot foreclose the weighing of the relevant factors having regard to the particular circumstances of each case. Nevertheless, as the Enlarged Board of Appeal pointed out in its decision R 11/08 of 6 April 2009 (point 11 of the Reasons), the usefulness of case-law is not confined to similar or identical facts; rather it lies in the legal principles or guidance which, whether the facts are similar or not, can be extracted from earlier cases. In this respect the present decision conforms with the legal principle stated in the cited decisions that there is no right of the patent proprietor, be it pursuant to Article 133(1) or Article 113(2) EPC, to have claim requests admitted at any stage of opposition and opposition appeal proceedings. Thus, the admission of new claim requests remains a matter of discretion which may or may not be exercised in a party's favour on the basis of the facts of the individual case. This legal principle has also been confirmed by the Enlarged Board of Appeal (R 10/09 of 22 June 2010, point 2.2 of the Reasons; R 11/11 of 14 November 2011, point 9 and 10 of the Reasons).

3. *Main request - Article 84 EPC*

The pharmaceutical composition according to claim 1 is defined by the release rate according to which the active ingredient should be released over more than three hours. The respondent raised three different clarity objection against this feature:

(a) the feature "release over more than three hours" identified only a single point in time and did therefore not clearly define the release profile;
(b) there was no indication as to whether the release profile related to *in vitro* or *in vivo* release; and
(c) the method for determining the release profile was not clearly defined.

3.1 Ad (a)

The board is of the opinion that the feature "wherein the sustained release formulation releases the active ingredient over more than 3 hours" comprises any release profile, in which any quantity of active ingredient is continuously released over the claimed period of more than 3 hours. The release period may start immediately after administration or after a lag phase of undefined duration. The only important point is that there is an uninterrupted release over the claimed period of time. This means of course that a vast amount of release profiles is included in present claim 1. That alone, however, does not render the subject-matter of the claim unclear. The board is of the opinion that the indication of the amount of active

ingredient released at no less than three different points in time is not a mandatory condition for meeting the requirements of Article 84 EPC.

3.2 Ad (b)

3.2.1 According to the established jurisprudence of the boards of appeal, the requirement of clarity for a composition defined by parameters is fulfilled only if those parameters can be clearly and reliably determined by objective procedures which are usual in the art. This requires as a first step a clear and unambiguous definition of the parameter to be measured by said procedures. In the present case, the parameter in question concerns the release profile, for which the information whether it is measured *in vitro* or *in vivo* has a significant influence on the results and is therefore of paramount importance. As a consequence, it should be included in the claims. As this is not the case and as the claims do not comprise any further indications which might allow to deduce which type is meant, such as a method for determining the release profile or at least a reference to such a method, the subject-matter of claim 1 of the main request lacks clarity.

3.2.2 Additional arguments of the appellants

The appellants argued that it was well known in the art that the release profile could be determined only *in vitro*. The *in vivo* determination involved the measurement of the concentration of active agent in the plasma which was a so called "secondary measurement" constituting the sum of release rate from the galenic

formulation plus distribution plus rate of absorption. Reference was made to documents (36), (41) and (53) in this context. As a consequence, it was clear that claim 1 of the main request referred to a release profile measured *in vitro*.

This argument cannot succeed for the following reasons: the board does not contest that the *in vivo* determination of the release rate is a secondary measurement as alleged by the appellants. Furthermore, the board notes that the prior art distinguishes between *in vitro* dissolution rate and steady state plasma concentration (see figures 4-5 of document (36)) or between *in vitro* release profile and plasma concentration-time profile (see figures 1-4 of document (41)). On the other hand, the prior art also shows that it is not unusual to express the release rate in terms of *in vivo* release. Thus, document (36) states on page 239 (see lines 8-9) that the "release rate determined in vitro should preferably correlate directly with the release in vivo." If such correlations are envisaged, it must be possible to express the release rate in terms of an *in vivo* release, otherwise this sentence would be without meaning. A similar statement going into the same direction is made in point 13 of document (53), which reads: "In the case of sustained release formulations, the *in vitro* dissolution profile is often regarded as being indicative of how the active ingredient will be released from the formulation *in vivo*." As a consequence, the feature "wherein the sustained release formulation releases the active ingredient over more than 3 hours" according to claim 1 of the main request

does not unambiguously refer to *in vitro* release as alleged by the appellant.

The appellant also made reference to page 237, lines 9-11 of document (36), which reads as follows: "Although this principle seems to be useful in controlling the rate of release in vitro for a number of drugs[22], the release appears to be erratic in vivo[23]." This passage does not allow the conclusion that *in vivo* release profiles are in general more erratic than their *in vitro* counterparts. If read in the context of the whole paragraph, this passage rather suggests that the release of **non-porous matrices** appears to be erratic *in vivo*, because of its being significantly affected by gastrointestinal motility. In other words, the erratic release is caused by a specific property of a specific galenic form, which cannot be generalised to the sustained release pharmaceutical compositions according to claim 1 of the main request.

3.3 Ad (c)

According to page 11, lines 9-13 of the original application, drug release from various types of tablets was determined at pH 6.8 and +37°C by use of an USP II apparatus at a paddle stirring rate of 75 rpm, which means that a standardised apparatus was used for a non-standardised method. This non-standardised method was characterised by the pH, the temperature and the stirring rate, other important parameters such as solvent volume and solvent constitution are, however, not mentioned in this passage. The appellant held that this was not necessary as the solvent volume was defined by the volume of the apparatus which has a

nominal capacity of 1000 ml. As regards the definition of the solvent, all the essential parameters, i.e. temperature and pH were mentioned. Bearing in mind that a patent should be read with a mind willing to understand, it was clear that the pH would be adjusted with the most common buffers such as phosphate buffers.

The board notes that the definition of a composition by a parameter such as the release profile means that third parties trying to verify whether they infringe the contested patent with their own products are obliged to carry out tests. Such definitions should therefore be the exception rather than the rule. If, as in the present case, the method for determining the parameter in question is specifically adapted and therefore not usual in the art, the applicant must be expected to describe it elaborately and with due care, thus avoiding guesswork and uncertainties. To be specific: the board is not convinced that the skilled person would automatically fill the USP apparatus II up to its rim. In the absence of any indication as to the amount of solvent to be used, it is equally plausible that he would select a quantity which is common and easy to calculate and measure such as e.g. 500 ml. By defining specific conditions the appellants made clear that the standardised USP paddle method was not to be applied. Therefore, the skilled person would not automatically apply the conditions used in the US paddle method for every step not mentioned in the original application. Thus, the original application does not contain any information as to when the paddle should be put into rotation. The USP paddle method chooses the moment when the composition reaches the bottom (see paragraph "Apparatus 2" on page 1792 of

document (57)), but it would be equally plausible to start the rotation at the moment when it is added to the solvent. These two approaches might lead to considerable differences with regard to the release profile, in particular if sinking is slow. The board concludes therefore that the method for determining the release profile is not described in a sufficiently clear manner in the original application.

3.4 In view of the reasoning according to points 3.2 and 3.3 above, the subject-matter of claim 1 of the main request does not meet the requirements of Article 84 EPC.

4. *Auxiliary request I - Article 123(2) EPC*

As compared to claim 1 of the main request, claim 1 of auxiliary request I additionally includes the method for measuring the release profile. This method is disclosed on page 11, lines 9-13 of the original application, but only in connection with tablets. However, present claim 1 includes any matrix formulation or diffusion-controlled membrane coated formulation wherein the water soluble salt of fluvastatin is released over more than 3 hours, which includes galenic forms such as capsules, pellets and the like. The board concludes that a method which is adapted for measuring the release profile of a tablet, cannot be extended to galenic forms such as pellets, which, as far as their physical properties are concerned, are very different from tablets. As a consequence, the subject-matter of claim 1 of auxiliary request I does not meet the requirements of Article 123(2) EPC.

5. It is additionally noted that the objections raised in point 3.3 above in connection with claim 1 of the main request apply *mutatis mutandis* to claim 1 of auxiliary request I. The requirements of Article 84 EPC are therefore not met either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald