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**Datasheet for the decision
of 4 October 2007**

Case Number: T 0319/04 - 3.3.02

Application Number: 97934768.9

Publication Number: 0860170

IPC: A61K 49/00

Language of the proceedings: EN

Title of invention:

Tablets based on isotope-labeled urea

Patentee:

KYOWA HAKKO KOGYO CO., LTD.

Opponent:

Otsuka Pharmaceutical Co. Ltd.

Headword:

Isotope-labeled urea/KYOWA HAKKO KOGYO CO., LTD.

Relevant legal provisions:

EPC Art. 84

Keyword:

"Clarity of claim (no): no unequivocal meaning of the features
"practical disintegration time" and "sufficient hardness"

Decisions cited:

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Catchword:

-



Case Number: T 0319/04 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 4 October 2007

Appellant: Otsuka Pharmaceutical Co. Ltd.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
22 December 2003 concerning maintenance of
European patent No. 0860170 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
J. Van Moer

Summary of Facts and Submissions

I. European patent No. 0 860 170 based on application No. 97 934 768.9 was granted on the basis of a set of seven claims.

Independent claim 1 reads as follows:

"1. A tablet containing isotope-labeled urea and an inorganic compound."

II. A notice of opposition was filed on 22 December 2000 by Otsuka Pharmaceutical Co., Ltd. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step.

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

(1) US-A-4 830 010

(2) Lachmann L. et al., "The Theory and Practice of Industrial Pharmacy", 2nd ed., Lea & Febiger, Philadelphia, 1976, pp. 325 to 331

IV. In the decision pronounced on 11 June 2002, the opposition division found that, account being taken of the amendments made by the patentee during the opposition proceedings, the patent and the invention to which it related in the form of the second auxiliary request met the requirements of the EPC. Its principal findings were as follows:

(1) In connection with the main request in the form of the claims as granted, the opposition division came to the conclusion that the subject-matter of claims 1 and 2 was anticipated by document (1) wherein the disclosure of document (2) was incorporated by reference.

(2) The first auxiliary request as filed at the oral proceedings of 11 June 2002 was not admitted under Rule 57(a) EPC, because it introduced an additional independent claim and a new claim category.

(3) The second auxiliary request also filed at the oral proceedings of 11 June 2002 was found to meet the requirements of Articles 54, 56, 83, 84, 123(2) and (3) EPC. In connection with the requirements of Article 84 EPC, the opposition division held that the functional features seemed justified in the light of the ample examples.

V. Both the patentee and the opponent lodged an appeal against that decision.

VI. With his statement of the grounds of appeal dated 23 April 2004, the appellant-patentee filed a new main request. The independent claims read as follows:

"1. A tablet containing isotop-labeled urea and an inorganic compound, containing silica.

7. Use of an inorganic compound for conferring practical disintegration time and sufficient hardness to a tablet containing isotope-labeled urea, which is formulated to detect urease-producing bacteria."

VII. At the oral proceedings of 4 October 2007, the appellant-patentee filed a new main request as well as four auxiliary requests. The independent claims read as follows:

(a) Main request:

"1. A tablet containing isotope-labeled urea and an inorganic compound, containing silica.

7. Use of an inorganic compound for conferring practical disintegration time and sufficient hardness to a tablet containing isotope-labeled urea mixed with said inorganic compound, wherein the tablet is for diagnosing the infection with urease generating bacteria."

(b) Auxiliary request 1:

The sole independent claim of auxiliary request 1 is identical to claim 7 of the main request.

(c) Auxiliary request 2:

"1. Use of an inorganic compound containing silica for conferring practical disintegration time and sufficient hardness to a tablet containing isotope-labeled urea mixed with said inorganic compound, wherein the tablet is for diagnosing the infection with urease generating bacteria."

(d) Auxiliary request 3:

"1. A tablet containing isotope-labeled urea and an inorganic compound, containing silica, wherein the content of the inorganic compound is 0.5 to 100 parts by weight based on 100 parts of the isotope-labeled urea.

7. Use of an inorganic compound for conferring practical disintegration time and sufficient hardness to a tablet containing isotope-labeled urea mixed with said inorganic compound, wherein the tablet is for diagnosing the infection with urease generating bacteria."

(e) Auxiliary request 4:

"1. Use of an inorganic compound containing silica selected from a group consisting of silicic acid anhydride, silicic acid and silicate for conferring practical disintegration time and sufficient hardness to a tablet containing isotope-labeled urea mixed with said inorganic compound, wherein the tablet is for diagnosing the infection with urease generating bacteria."

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

(1) In connection with the admissibility of the new requests, the appellant-patentee held that the amendment in claim 1 of the main request concerned a correction under Rule 88 EPC. As for claim 7 of the main request, it was held that the amendments were an attempt to overcome the doubts in connection with Article 123(3) EPC which the board had expressed in the annex to the summons to attend oral proceedings of 12 July 2007.

(2) As regards the clarity of claim 7 of the main request, it was emphasised that the use of the inorganic compound as claimed therein had to be seen in

the context of tablets which were used for diagnosing infections caused by urease generating bacteria. As a consequence, the feature "practical disintegration time" could be correctly interpreted, as the person skilled in the art knew that for this type of diagnosis, the tablet had to disintegrate in the stomach and the description contained clear indications about the disintegration time of the tablet in the stomach.

In connection with the feature "sufficient hardness", the appellant-patentee argued that the description of the patent under appeal cited conventional test methods for determining the hardness as well as the disintegration time so that the person skilled in the art could also correctly interpret this feature.

IX. The appellant-opponent's arguments can be summarised as follows:

(1) In connection with the admissibility of the sets of claims filed at the oral proceedings of 4 October 2007, it was held that they were late-filed and should therefore not be admitted. There was no reason for the late filing, as the previous main request had already been filed in 2004 and no new evidence, facts or arguments had been submitted for more than two years.

(2) As far as the requirements of Article 84 EPC are concerned, it was argued that the features "practical disintegration time" and "sufficient hardness" (claim 7 of the main request) were not commonly used in the art. As these relative terms did not allow a clear

definition of the scope of protection, the claims lacked clarity.

- X. 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 in the alternative on the basis of the first to fourth auxiliary requests, all filed during the oral proceedings.

The appellant-opponent requested that the decision under appeal be set aside and that the European patent be revoked.

Reasons for the Decision

1. The appeal is admissible.
2. *Admissibility of the requests filed at the oral proceedings of 4 October 2007:*
 - 2.1 Apart from the correction of a typing error under Rule 88 EPC, claim 1 of the new main request corresponds word for word to that of the main request filed with the statement of the grounds of appeal dated 23 April 2004; the amendments to claim 7 must be interpreted as a reaction to a possible objection under Article 123(3) EPC as indicated by the board in the annex to the summons to oral proceedings of 12 July 2007.
 - 2.2 The claims of auxiliary request 1 correspond to claims 7 to 13 of the main request. As a consequence,

the reasoning of paragraph 2.1 above in connection with claim 7 applies *mutatis mutandis* to this set of claims.

2.3 The further amendments made in auxiliary requests 2, 3 and 4 concern restrictions to preferred embodiments which were made as a precautionary measure against possible objections in connection with novelty and/or inventive step.

2.4 All the amendments were of a clear and simple nature and hence easy to handle so that the appellant-opponent was not taken by surprise. As a consequence, the main request as well as auxiliary requests 1 to 4 are admitted into the proceedings.

3. *Article 84 EPC:*

3.1 Main request:

Article 84 EPC stipulates that the claims shall define the matter for which protection is sought. They shall be clear, concise and supported by the description. These requirements are fundamental for the principle of legal certainty in that they ensure that a clear distinction can be made as to which subject-matter is included in a claim and which is not.

In the present case, the subject-matter of claim 7 concerns the use of an inorganic compound for conferring "practical disintegration time" and "sufficient hardness" to a tablet and it has to be examined whether these two features, which are to be regarded as the prominent characterising features defining the use to which the claim is directed, are or

are not clear. It is noted that these two features were introduced into the claims in the course of the opposition procedure. As a consequence, the board is competent under Article 102(3) EPC to examine whether or not these amendments are in accordance with the requirements of the EPC.

3.1.1 Practical disintegration time:

The term "practical disintegration time" is not commonly used in the galenic field and hence open to interpretation. Moreover, it is noted that the description does not give any guidance with respect to this feature, either: paragraph [0005] of the patent under appeal is the only passage relating to the practical disintegration time. However, all that this paragraph says is that tablets of practical disintegration time and sufficient hardness can be produced by mixing urea with one or several additives of inorganic compounds. Further information about the practical disintegration time is not provided there.

The passage on page 3, lines 13-17, of the patent under appeal reveals that the disintegration time of the tablet of the present invention in the stomach is from 5 seconds to 10 minutes. However, there is no indication that this time period is equivalent to the term "practical disintegration time". The appellant-patentee submitted that the tablets of the patent under appeal were used for the diagnosis of infections with urease generating bacteria. As these bacteria are located in the stomach, the person skilled in the art would identify the disintegration time in the stomach as practical disintegration time.

The board cannot, however, agree with this reasoning. Although this definition of the appellant-patentee is one possible way of interpreting the term "practical disintegration time", other equally plausible interpretations are also feasible: thus, "practical disintegration time" may e.g. stand for a disintegration time which is "practical" with regard to the specific diagnostic method in which the tablets are used. In that case, the "practical disintegration time" depends on and varies with the specific conditions of the diagnostic method applied. As these specific conditions are unknown, the "practical disintegration time" cannot be regarded as defined. In the absence of a clear definition for the feature "practical disintegration time", the principle of legal certainty as mentioned in paragraph 3.1. above is not fulfilled. As a consequence, the feature "practical disintegration time" is not clear. For this reason alone, the subject-matter of claim 1 does not meet the requirements of Article 84 EPC. However, there are further considerations:

3.1.2 Sufficient hardness:

Again, the patent specification does not give any definition for this relative term. It is noted that paragraph [0022] as well as the examples (see e.g. tables 4, 6 and 7) of the patent under appeal disclose hardness values that must be assumed to be "sufficient". However, these specific values do not allow the skilled person to draw the line between sufficient and insufficient hardness, so that the principle of legal certainty as mentioned above in

paragraph 3.1 is again not fulfilled. As a consequence, the feature "sufficient hardness" likewise does not meet the requirements of Article 84 EPC.

3.1.3 Additional arguments of the appellant-patentee:

The subject-matter of claim 7 is clear, as the patent under appeal contains test methods for measuring the hardness and disintegration time.

However, the fact that hardness and disintegration time can be determined by specific test methods does not enable the person skilled in the art to generally define these terms. It is not possible to draw the line between sufficient and insufficient hardness or between practical and impractical disintegration time.

Therefore, the citation of these tests in the patent under appeal does not per se render the subject-matter of claim 7 clear.

3.2 Auxiliary request 1:

Claim 1 of auxiliary request 1 is identical with claim 7 of the main request. As a consequence, the subject-matter of this claim does not meet the requirements of Article 84 EPC, either.

3.3 Auxiliary request 2:

Claim 1 of auxiliary request 2 is identical with claim 7 of the main request except that the inorganic compound is now limited to silica. However, this limitation to silica does not allow the person skilled in the art to generally define the terms "practical

disintegration time" and "sufficient hardness". Again, it is not possible to draw the line between sufficient and insufficient hardness or between practical and impractical disintegration time. Therefore, claim 1 of auxiliary request 2 also lacks clarity in the light of the reasoning given above for claim 7 of the main request.

3.4 Auxiliary request 3:

Claim 7 of auxiliary request 3 is identical with claim 7 of the main request. As a consequence, the subject-matter of this claim does not meet the requirements of Article 84 EPC, either.

3.5 Auxiliary request 4:

Claim 1 of auxiliary request 4 is identical with claim 7 of the main request except that the inorganic compound is now limited to silicic acid anhydride, silicic acid and silicate. However, the limitation to these specific inorganic compounds cannot overcome the lack of clarity of the features "practical disintegration time" and "sufficient hardness" (cf. paragraph 3.3. above). Therefore, claim 1 of auxiliary request 4 also lacks clarity in the light of the reasoning given for claim 7 of the main request which applies *mutatis mutandis* to this claim.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar:

The Chairman:

A. Townend

U. Oswald