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D E C I S I O N
of 27 September 2005

Case Number: T 0662/02 - 3.3.02

Application Number: 92115410.0

Publication Number: 0531964

IPC: A61K 9/20

Language of the proceedings: EN

Title of invention:

Divisible Tablet

Patentee:

Takeda Chemical Industries, Ltd.

Opponents:

BASF AG

Desitin Arzneimittel GmbH

Headword:

Divisible Tablet/TAKEDA CHEMICAL

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (no): the claimed tablet is an obvious alternative of the prior art tablet"

Decisions cited:

T 0799/91, T 0056/87

Catchword:

-



Case Number: T 0662/02 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 27 September 2005

Appellant I: BASF AG, Patente, Marken und Lizenzen
(Opponent I) D-67056 Ludwigshafen (DE)

Representative: Richter, Werdermann, Gebaulet & Hofmann
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Respondent: Takeda Chemical Industries, Ltd.
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(Opponent II) Desitin Arzneimittel GmbH
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Representative: Uexküll & Stolberg
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 24 April 2002
rejecting the opposition filed against European
patent No. 0531964 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega-Plaza
J-P. Seitz

Summary of Facts and Submissions

- I. European patent EP-0 531 964, based on application No. 92 115 410.0, was granted on the basis of three claims.

Independent claim 1 as granted read as follows:

"1. A tablet of round or oval configuration comprising first and second surfaces opposite to each other and a side surface lying perpendicular to any one of the first and second surfaces; a peripheral edge delimited between each of the first and second surfaces and the side surface, said peripheral edge being chamfered to provide a respective inclined edge face over the entire perimeter of the tablet; a first generally V-sectioned score defined on the first surface so as to leave two tablet divisions of uniform size on respective sides of the first V-sectioned score; a second generally V-sectioned score defined on the second surface in alignment with and parallel to the first V-sectioned score and wherein said V-sectioned side scores are also continued at the opposite end to opposite ends of the second V-sectioned score; characterized by a pair or [*sic*] generally V-sectioned side scores defined on the side surface of the tablet at respective locations opposite to each other and continued at one end to opposite ends of the first V-sectioned score, wherein each of said side scores has a groove depth within the range of 7 to 20% of the length of the first score."

Independent claim 2 as granted read as follows:

"2. A tablet of round configuration comprising

first and second surfaces opposite to each other and a side surface lying perpendicular to any one of the first and second surfaces;

a peripheral edge delimited between each of the first and second surfaces and the side surface, said peripheral edge being chamfered to provide a respective inclined edge face over the entire perimeter of the tablet;

first and second generally V-sectioned scores defined in the first surface so as to extend perpendicular to each other while leaving two tablet divisions of uniform size on respective quadrants defined by the transversely extending first and second scores;

third and fourth generally V-sectioned scores defined on the second surface so as to extend perpendicular to each other and in alignment with and parallel to the first and second scores, respectively, and wherein said V-side scores are also continued at the opposite end to opposite ends of the first and second scores;

characterized by two pairs of generally V-sectioned side scores defined in the side surface of the tablet at respective locations opposite to each other and continued at one end to opposite ends of the first and second scores, wherein each of said side scores has a groove depth within the range of 7 to 20% of the length of any one of the first scores."

II. The following documents *inter alia* were cited during the proceedings:

- (1) Physicians' Desk Reference, 19th ed., Medical Economics Inc., 1964; Product Information XX, 438-Schering-897 "Naqua" Tablets
- (2) Physicians' Desk Reference, 42nd ed., Medical Economics Inc., 1988, p. 428, Schering "Naqua"^R Tablets
- (3) US-A-4 258 027
- (4) Excerpt from "Die Pharmazeutika Bestimmungsliste", 6th ed., IMP Kommunikationsgesellschaft mbH, Neu-Isenburg, Germany, 1989, Tavor^R and Ergocalm^R tablets
- (8) US-A-4 824 677
- (11) Drawing for "Tavor-Tabs 2,0 mg" from the Notter company (Notter GmbH Werkzeugbau) dated 20 May 1987, filed as an annex together with the drawings of the stamps for producing the tablets ("Anlage N2") to the appellant's letter of 3 September 2002.

III. Opposition was filed and revocation of the patent in its entirety was requested pursuant to Article 100(a) EPC on the grounds of lack of novelty and lack of inventive step.

IV. The appeal lies from the decision of the opposition division rejecting the opposition under Article 102(2) EPC.

The opposition division considered that the subject-matter of claims 1 to 3 as granted was novel over the Naqua^R tablet shown in documents (1) and (2), since the pictures depicted therein showed only the top (or bottom) surface of said tablet. The assumption that both surfaces were to be identical could not be made. In this context the opposition division did not accept the statement of 2 November 1999 by MediMedia Medizinische Medien Informations GmbH, Neu-Isenburg, Germany. This analysis also applied to the pictures shown in document (4). Accordingly, the opposition division considered that the only information which was unambiguously derivable from documents (1), (2) and (4) was the overall configuration of the top and side surfaces of the Naqua^R and Tavor^R tablets respectively at the date of publication of said documents.

Moreover, it was not possible in the opposition division's opinion to determine without ambiguity from the bad quality of the pictures whether or not there was a gap separating each of the ends of the top surface scores from the end of the closest side surface scores in the Naqua^R tablets or whether the side scores of the Tavor^R tablets were indeed V-shaped.

Furthermore, the opposition division was of the opinion that since the date of manufacture of the sample of Tavor^R tablets submitted by opponent II was unknown, it could not be considered to be an accurate reproduction of the Tavor^R tablet which was publicly available at the priority date of the contested patent.

Additionally, the opposition division stated that opponent I had not provided any evidence to prove unambiguously that the Naqua^R tablet depicted in documents (1) and (2) was indeed available on the market at the priority date of the contested patent.

Moreover, the opposition division considered that the subject-matter claimed in the patent as granted met the requirements of inventive step since the structural features of the tablet appearing in claim 1 were not rendered obvious by the cited prior art, in particular by the Tavor^R tablet of document (4) which was identified by the opponents as closest prior art.

- V. The appellant (opponent I) lodged an appeal against said decision and filed grounds of appeal and new evidence as an annex to its letter of 3 September 2002 ("Anlage N2": letter from the company Wyeth of 21 August 2002 with the attached annexes corresponding to the drawings of the stamps and the drawing of the form of the tablet Tavor-tabs 2,0mg by company Notter for company Wyeth, numbered as document (11)).
- VI. The respondent contested the appeal with arguments.
- VII. A communication from the board was sent as an annex to the invitation for oral proceedings.
- VIII. Oral proceedings were held before the board on 27 September 2005.
- IX. During the oral proceedings, the respondent requested that the appeal be dismissed, i.e. that the patent be maintained as granted. He further requested that the

patent be maintained on the basis of the set of claims filed with the letter of 7 August 2000 as auxiliary request.

Claim 1 of the first auxiliary request differs from claim 1 as granted only in the following passage introduced at the end of the claim:

"so that the length of the joint between the tablet pieces obtainable by dividing the tablet is greater than double the length of each side groove as measured along the direction of thickness of the tablet."

- X. The appellant had no comments on the novelty of the subject-matter claimed.

With respect to the public availability of the drawing shown in document (11) the appellant stated that company Notter had made it for company Wyeth in order to produce the Tavor tablets. There was no confidentiality agreement between the two companies as shown by the letter from company Wyeth filed as an annex to the reply of 9 September 2005.

The appellant's arguments in respect of the inventive step of the claimed subject-matter may be summarised as follows.

The problem to be solved as stated in the patent in suit was to provide a tablet which could be divided into two identical pieces without breaking into small pieces (paragraph [0009] of the patent in suit). This problem had already been solved by document (8) and the Tavor^R tablets. Therefore the problem to be solved was

to provide an alternative tablet to those known. The solution as defined in the claims related to the presence of a pair of V-sectioned side scores defined on the side surface of the tablet at respective locations opposite to each other and continued at one end to opposite ends of the first V-sectioned score, wherein each of said side scores had a groove depth within the range of 7 to 20% of the length of the first score.

The appellant developed two alternative routes for the inventive step analysis: either starting from document (8) and then combining it with the teaching of document (3) or starting from the Tavor^R tablets and further using the teaching of document (3).

The appellant's further arguments were as follows. It was irrelevant that the Tavor^R tablet had three scores on the top surface and three scores on the bottom surface since the condition relating to the division into two tablet pieces of uniform size was met when breaking the tablet using the score in the middle.

Document (3), Figure T, showed a round tablet with peripheral chamfered edge and having scores on the top and side surfaces. It was evident from Figure T in document (3) that the proportion between the groove depth of the side scores and the length of the score of the top surface corresponded more or less to the values given in claim 1 of the main request. Moreover, since there was no effect shown for the specific range of 7-20%, this feature did not contribute to the presence of an inventive step.

Furthermore, the difficulties encountered when breaking a tablet were dependent not only on the form but also on the composition of the tablet.

In the appellant's opinion a V-sectioned score was a wedge-shaped score, pointing to a sharp edge, but it included those scores ending in a curved or linear flat end. The all-round V-sectioned score was known from the prior art (8) and it was obvious for the skilled person that it would facilitate the division of the tablet. The chamfered peripheral edges and the V-sectioned score were features known from the tablets disclosed in document (3).

With respect to the first auxiliary request the appellant stated that the arguments put forward for the main request applied *mutatis mutandis*. Moreover, the condition introduced in claim 1 reflected the proportions of depth of the side groove to the length of the top surface score shown in the tablets depicted in Figure T of document (3).

- XI. The respondent contested that it had been proven that the samples of Tavor^R tablets provided by the appellant corresponded to the Tavor^R tablets depicted in document (4) or (11). Moreover, there was no proof that such tablets had been commercialised before the priority date of the patent in suit.

Additionally, the respondent stated that document (11) did not form part of the state of the art since this document could not be considered to be publicly available due to the fact that company Notter was a contractor of Wyeth for providing the means to produce

the Tavor^R tablets. In this context the respondent referred to unpublished decision T 799/91 of 3 February 1994. In the respondent's view the drawing of the tablet form shown in document (11), which contained both names Notter and Wyeth, was an in-house drawing between the companies Wyeth and Notter and hence was not publicly available. Furthermore, the respondent argued that the appellant had the burden of proof to demonstrate that the drawing had been made publicly available.

The respondent denied that Notter and Wyeth constituted the public.

The respondent stated that in case the board considered the Tavor^R tablet to be publicly available prior art it requested remittal to the department of first instance.

The respondent also referred to decision T 56/87 OJ EPO, 1990, 188 and argued that the values calculated from the pictures and figures of the prior art could not be used to invalidate the contested patent.

The respondent argued that document (8) concerned the provision of a tablet which had very small breaking surfaces in order to address the problem that upon division the new surface led to significant change in the release rate as compared to the whole tablet. Moreover, it was clear from Figures 2, 7 and 11 of document (8) that the score was not V-sectioned. the tablets according to document (8) would not provide for accurate breaking into two identical parts. Additionally, even if starting from the tablets according to document (8), there was no incentive for

the skilled person to introduce the several structural modifications - V-sectioned score, chamfered edges, proportion of depth of side score to length of top surface score - which were needed in order to arrive at the claimed invention.

In this context the respondent referred to the additional data filed as Annexes I, II and III to the letter of 7 August 2000. The comparison made in Annex I served to demonstrate the improvement achieved by flat tablets with chamfered peripheral edge (tablet F) when compared to oblong tablets (such as the Tavor^R tablet) with a curved surface (tablet R). This conclusion was also valid for tablets having side scores.

In the respondent's opinion the comparison made in Annex I was a valid comparison for demonstrating the presence of an effect achieved by the claimed tablets, since an oblong tablet lay closer to a flat tablet with chamfered edges than a flat tablet without chamfered edges. When a tablet was divided, sharp edges were formed, giving rise to brittle small parts, especially in case of non-chamfered flat tablets. This problem was reduced when breaking, flat tablets with chamfered peripheral edges.

In the respondent's view the problem to be solved lay in the provision of a divisible tablet with superior effect when breaking and the solution related to the combination of the peripheral chamfered edge together with the all-round score. The solution was not rendered obvious by the cited prior art.

The respondent disputed the appellant's definition of a V-sectioned score since in its opinion the wedge-shaped score had to finish in a sharp end.

Furthermore the meaning of V-sectioned score was to be understood in the context of the patent in suit and was shown by the figures in the patent.

With respect to the first auxiliary request the respondent again cited decision T 56/87, which stipulated that specific values could not be derived from a schematic drawing.

XII. The appellant (opponent I) requested that the decision under appeal be set aside and that the European patent No. 0 531 964 be revoked.

The respondent (patentee) requested that the appeal be dismissed, or that the patent be maintained on the basis of the set of claims filed as first auxiliary request on 7 August 2000.

Reasons for the Decision

1. The appeal is admissible.

2. *Prior art*

2.1 The allegation of prior use in relation to the Tavor^R tablet sold by Wyeth Pharma GmbH was filed with the opposition grounds by opponent II. The appellant filed the material concerning the manufacture of the Tavor^R tablet ("Anlage N2": letter from company Wyeth of

21 August 2002 with the attached annexes corresponding to the drawings of the stamps and the drawing of the form of the tablet Tavor-tabs 2,0mg by company Notter for company Wyeth, numbered as document (11)) within the time limit set in Article 108 EPC.

The allegation of prior use made by the appellant is not based on the opponents' own activities, neither opponent II nor opponent I. Therefore the third parties, companies Wyeth and Notter, are part of the public.

The drawing of the Tavor-Tabs 2,0mg, document (11), is dated, as is usual in Germany, and the date is 20 May 1987, i.e. before the priority date of the patent in suit.

Additionally, as shown by the evidence filed by the appellant as an annex to its letter of 9 September 2005, there was no confidentiality agreement between the companies Wyeth and Notter about the Tavor^R tablet.

Therefore, the teaching concerning the manufacture of tablets with the form of the Tavor-tabs shown in drawing (11) was made available to the public before the priority date of the patent in suit within the meaning of Article 54(2) EPC.

- 2.2 There has been dispute between the parties as to whether or not the teaching concerning the manufacture of tablets in the form depicted in the drawing of document (11) was part of the state of the art within the meaning of Article 54(2) EPC.

According to the respondent's submissions made in view of decision T 799/91, the fact that the manufacture of the Tavor^R tablet was sub-contracted by company Wyeth to company Notter resulted in the drawing of document (11) being an in-house document and hence not publicly available. However, the board disagrees with the respondent's approach since, in the present case, the third parties, companies Wyeth and Notter, are part of the public and none of them had a sub-contract with any of the opponents in respect of the manufacture of the Tavor^R tablet. Therefore, the conclusions reached in the cited decision do not apply to the present case.

Moreover, there is a further indication that the drawing (document (11)) was part of the public domain, namely that document (11) displays on its borderline the following warning: "Für diese Zeichnung gelten die Bestimmungen über den Schutz für Urheberrecht", i.e. the regulations on trade mark protection apply to the present drawing (*translation by the board*). There is no need for such a warning in relation to an in-house document.

- 2.3 In view of the conclusion reached in point 2.2 above, it is not necessary to decide whether or not the actual Tavor^R tablets submitted as samples by the opponents corresponded identically to the tablet depicted in document (4), which was commercialised before the priority date of the patent in suit.

3. *Main request*

3.1 Novelty

None of the prior art documents cited during the opposition and appeal proceedings discloses a tablet having all the features appearing in the independent claims of the patent as granted. The appellant no longer maintained its former novelty objection.

Therefore the subject-matter claimed in the main request meets the requirements of novelty (Article 54(1), (2) EPC).

3.2 Inventive step

Document (11), which relates to a clear teaching for manufacturing a tablet with specific form and measurements, represents the closest prior art.

The board agrees with the respondent's opinion that an oblong tablet lies closer to a flat tablet with chamfered edges than a flat tablet without chamfered edges.

The tablet according to document (11) is an oblong tablet with three V-sectioned scores defined on the top surface. One of the V-sectioned scores of the top surface is placed in the middle of the tablet. The tablet also has three V-sectioned scores defined on the bottom surface in an alignment and parallel to those on the top surface. The side surface has six V-sectioned scores. They are defined on the side surface of the tablet, each three of them at respective locations

opposite to each of the other three on the side surface and continued at one end to opposite ends of the three V-sectioned scores of the top surface.

The drawing of document (11) is a detailed technical drawing with the scale 10:1. This detailed technical drawing shows the exact measurements for the length, depth and angles of the scores. Each of the side scores has a groove depth of 0.637 mm ($(5.000 \text{ mm} - 3.726 \text{ mm})/2$), and the length of the score on the top surface is 3.726 mm. Therefore, the groove depth of the side score is 17.1% of the length of the score on the top surface.

The location of the score on the top and bottom surfaces of the tablet is suitable for leaving two tablet divisions of uniform size on respective sides of the score.

- 3.3 In the light of this prior art the problem to be solved is to provide an alternative tablet which can be divided into two identical pieces.

The solution relates to a tablet with flat top and bottom surfaces and with chamfered peripheral edge.

The board is satisfied that the problem has been plausibly solved in the light of the description, in particular the figures and the corresponding examples.

- 3.4 It now has to be assessed whether the proposed solution is obvious in the light of the prior art.

Starting from the teaching of document (11), the skilled person looking for an alternative thereto would be aware of the existence of document (3), which relates to a United States patent concerning divisible tablets. Document (3) discloses multi-fractionable flat tablets with chamfered peripheral edges. The tablets according to document (3) bear several V-sectioned scores, although not in all-round form.

In particular, document (3) discloses that the tablets may be divided accurately and separated conveniently into multi-sectional sub-dosage units for patient consumption (column 1, lines 10 to 18).

Therefore, the skilled person has an incentive to try a flat tablet structure with chamfered peripheral edges as an obvious alternative to the oblong tablet structure according to document (11).

Consequently the subject-matter of claim 1 lacks an inventive step (Article 56 EPC).

- 3.5 In the respondent's view the problem to be solved lies in the provision of a divisible tablet with a superior effect when breaking into two identical pieces.

In this context it referred to the additional data it had submitted as Annex I in order to demonstrate an improvement achieved by the flat tablet with chamfered edges when compared to an oblong tablet with a curved surface.

However, this data cannot serve to demonstrate the existence of an effect over the closest prior art

tablets since neither the tablet of type R nor the tablet of type F has scores on the side surface. Therefore, the results of this comparison cannot be extrapolated to the case of tablets possessing V-sectioned scores on the side surface such as is the case with the tablet of document (11) and the tablet according to claim 1.

Furthermore, none of the tests performed according to Annexes II and III to the letter of 7 August 2000 relates to a comparison with an oblong tablet according to document (11).

Therefore, the respondent's allegation that there is a superior effect when breaking the tablet according to claim 1 linked to the combination of the peripheral chamfered edge together with the all-round score has not been proven vis-à-vis the closest prior art.

In view of the above, the problem to be solved had to be defined in a less ambitious way.

- 3.6 As regards the respondent's submission that values calculated from pictures and figures of the prior art cannot be used to invalidate a patent, the board cannot accept such a generalisation from the conclusions reached in decision T 56/87. The reason lies in the fact that the drawings according to document (11) are not a schematic figure but precise and detailed technical drawings showing specific measurements. Hence, the technical teaching of document (11) concerning the geometrical form of the tablet is clear and precise.

- 3.7 There has been dispute between the parties concerning the definition of V-sectioned score, in particular in respect of its edges. In this respect however, the board is convinced that the sectioned scores shown by the drawings of the tablet according to document (11) fall within the definition appearing in claim 1, namely "**generally** V-sectioned score".

A certain curvature in the scores can be seen when looking at the drawing of the top surface from the top view, but this is due to the curved top surface of the oblong form of the tablet. Nevertheless, the scores on the top surface are clearly depicted as V-sectioned in the drawing showing the perspective from the side of the tablet.

- 3.8 In view of the conclusions reached above there is no need to deal with the appellant's submissions concerning document (8).

4. *First auxiliary request*

- 4.1 The amendment introduced in claim 1 of the first auxiliary request finds a basis in the application as originally filed and relates to a restriction of the subject-matter claimed. Hence, the requirements of Article 123 EPC have been met. This has not been disputed by the appellant.

- 4.2 It has not been contested either that the subject-matter claimed in the first auxiliary request meets the requirements of novelty.

4.3 The analysis in points 3.2 to 3.8 above with regard to the inventive step of the subject-matter of claim 1 of the main request applies *mutatis mutandis* to the subject-matter of claim 1 of the first auxiliary request.

Claim 1 of the first auxiliary request differs from claim 1 of the main request only in that it includes the condition that the length of the joint between the tablet pieces obtainable by dividing the tablet is greater than double the length of each side groove as measured along the direction of thickness of the tablet.

That condition merely reinforces the fact that the proportions of the tablet according to claim 1 are roughly the same as those of the tablet according to document (11). Furthermore, it has not been shown by the respondent that any effect is linked to a specific value for the ratio of the length of the joint to the length of the side groove.

4.4 Therefore, the first auxiliary request fails for lack of inventive step of the subject-matter of claim 1.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside,
2. The patent is revoked.

The Registrar:

The Chairman:

A. Townend

U. Oswald