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**Datasheet for the decision
of 24 April 2012**

Case Number: T 0075/11 - 3.3.01

Application Number: 02764081.2

Publication Number: 1390360

IPC: C07D 401/12, A61K 31/4439,
A61P 1/04

Language of the proceedings: EN

Title of invention:
Crystalline form of Omeprazole

Patentee:
LEK Pharmaceuticals d.d.

Opponent:
Quimica Sintetica. S.A.

Headword:
-

Relevant legal provisions:
EPC Art. 111(1)
RPBA Art. 12(4)

Keyword:
"Late-filed documents not admitted by the opposition division"
"Discretionary power exercised according to the right
principles"
"Evidence provided with the statement setting out the grounds
of appeal - not admitted - should and could have been
submitted before the first instance"
"Remittal - (no) - Failure to present evidence in due time"

Decisions cited:
-

Catchword:
-



Case Number: T 0075/11 - 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 24 April 2012

Appellant: Quimica Sintetica. S.A.
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 28 October 2010
rejecting the opposition filed against European
patent No. 1390360 pursuant to Article 101(2)
EPC.

Composition of the Board:

Chairman: P. Ranguis
Members: J.-B. Ousset
L. Bühler

Summary of Facts and Submissions

- I. An appeal was lodged against the decision of the opposition division to reject the opposition filed on 9 August 2007 against European patent No. 1 390 360, filed on 24 April 2002 under priority of 25 April 2001.

- II. The patent was granted on 22 November 2006 with fourteen claims. Claims 1 to 3 related to Omeprazole form C. Claims 4 to 11 related to a process for the preparation of Omeprazole form C. Claims 12 to 14 related to the use of Omeprazole form C (in the form of first and second therapeutic use).

Claim 1 reads as follows:

"1. Omeprazole form C, characterized in providing an X-ray powder diffraction pattern exhibiting substantially the following d-values:

d-values (Å)	Relative intensity
9.5 - 9.6	very strong
7.9 - 8.0	strong
7.4 - 7.5	weak
7.2	very strong
5.9 - 6.0	medium
5.6	medium
5.1 - 5.2	very strong
4.88 - 4.90	weak
4.81 - 4.84	weak
4.65 - 4.67	medium
4.57 - 4.60	medium
4.48 - 4.51	strong
4.34 - 4.36	medium
4.16 - 4.19	weak
3.94 - 3.97	weak
3.72 - 3.73	strong
3.58 - 3.59	medium
3.46 - 3.47	strong
3.29 - 3.30	medium
3.23 - 3.25	strong
3.19 - 3.20	medium
3.11 - 3.12	weak
3.03 - 3.04	weak

" .

III. The opponent sought revocation of the patent in suit insofar as it related to Claims 1 to 3 and 12 to 14 under Article 100(a) EPC (lack of novelty or inventive step).

IV. The opposition was based on an alleged prior use constituted by the sale to the firm CEPA Schwarz Pharma of batch OMM8020. The documents cited in support thereof included the following:

- (1) WO-A-96/01623
- (5) Copy of a new print of Figure 35 (Document (3)) and list of the peaks corresponding to powder X-ray diffractogram of omeprazole batch OMM8020.
- (6) Copy of analytical certificate of omeprazole batch OMM8020 of 29 October 1998

With letter dated 5 September 2008, the opponent submitted documents (16) to (21) to show that batch OMM8020 had been sold to the firm BETACHEM prior to the filing date of the patent in suit.

Summons were issued on 3 March 2010, setting the date for oral proceedings for 22 September 2010 and setting the final date for submissions (Rule 116 EPC) as 22 July 2010. In the summons to oral proceedings, the opposition division gave a preliminary opinion according to which the prior use consisting of the sale to BETACHEM had been sufficiently substantiated, but there was no evidence that the sold product OMM8020 could be reproduced as required by G 1/92.

With letter dated 15 July 2010, the opponent submitted further documents:

- (22) The Merck Index monograph for omeprazole
- (23) CN1160050-A
- (23b) Chinese patent office machine translation of CN1160050-A into English
- (24) Bhatt P.M: "Tautomeric polymorphism in omeprazole", Chem. Commun. 2007, 2057-2059

to show that batch OMM8020 could be reproduced.

During oral proceedings before the opposition division the opponent filed the following documents:

- (25) WO-A-01/13919 published 1 March 2001
- (25a) US6780880 (bibliographic page), published 24 August 2004, US patent corresponding to document (25)

in order to support the alleged prior use (see minutes, page 1, bottom) and to show that document (25) disclosed form C and its preparation.

- V. In its decision, the opposition division did not admit documents (22), (23), (23b), (24), (25) and (25a) in accordance with Article 114(2) EPC.

Although it acknowledged that batch OMM8020 was constituted of omeprazole as shown by document (6) and was identical to the claimed crystalline form of omeprazole as shown by document (5), it did not however constitute a prior use. It was doubtful that the sale to CEPA was made without confidentiality. The sale to

BETACHEM, in contrast, was regarded as public. However, in the absence of any process to reproduce the said crystalline compound, the second criteria of G 1/92 was not fulfilled. Hence, novelty was acknowledged. Inventive step was also acknowledged, since the sole argument against its presence was based on a combination of document (1) with the said prior use (which was denied).

VI. With the statement of grounds of appeal, the appellant filed two documents:

(26) Electronic supplementary information relating to document (24) available at <http://pubs.rsc.org/en/Content/ArticleLanding/2007/CC/B700506G>.

(27) Report relating to experimental work carried out by Dr. Andres Molina.

The appellant argued that document (27) confirmed that by repeating "Standard 4" of document (25) one directly and unambiguously obtained form C of Omeprazole as claimed in claim 1 of the patent.

Furthermore, document (24) disclosed that Omeprazole (IV) contained 12% of compound 1 (5-methoxy derivative) and 88% of compound 2 (6-methoxy derivative). It corresponded *prima facie* to "Standard 4" of document (25). Document (26) confirmed what the authors of document (24) had asserted, namely that the simulated PXRD pattern for Omeprazole (IV) corresponded to form C. The sole gap between document (24) and the patent was that the solvent used in document (24) was different from that of the patent. However, document

(27) showed that the same product was obtained with methylene chloride as solvent.

VII. As regards the admission into the proceedings of documents (24), (25), (25a) and/or (26) and (27), the appellant argued substantially as follows:

- Document (24) disclosed a crystalline compound (IV) which corresponded to form C of the patent in suit (see page 2058, third line of the last paragraph) in which the tautomeric ratio between the two tautomeric forms of omeprazole, namely the 5-methoxy and the 6-methoxy, was identical to the tautomeric ratio disclosed in standard 4 of document (25) (see first paragraph on page 2058 of (24) and standard 4, page 10, lines 18 to 20). Since "Standard 4" of document (25) disclosed the preparation of a crystalline mixture containing from 11 to 13 % of 5-methoxy, like compound IV of document (24), the appellant concluded that, contrary to the opposition division's decision, identity between form IV of document (24) and form C of the patent in suit had been established.
- Document (24) mentioned a crystalline form C in which the ratio between the tautomeric forms of omeprazole was identical to the ratio mentioned in document (25).
- Document (25) should be admitted into the appeal proceedings. This document was highly relevant as shown by document (27). The experimental results summarized in document (27) showed that

"Standard 4" of document (25) corresponded to the same compound as claimed in claim 1 of the patent in suit.

- When document (25) had been found, one day before the oral proceedings before the opposition division, the respondent had been informed by telephone.
- Document (27) repeating the "Standard 4" example of document (25) had been provided in time, in response to the "proof" issue raised in the decision of the opposition division (see page 8). It was the normal behaviour of a losing party to provide additional evidence.
- "Standard 4" example of document (25) disclosed the claimed form C of Omeprazole, as confirmed by the experimental results of document (27).
- Document (25) was also cited in conjunction with the alleged prior use. The person skilled in the art would have considered "Standard 4" of document (25) to routinely reproduce OMM8020.
- It was a surprise that documents (24) to (27) were not admitted into the opposition proceedings.
- The case should be remitted to the department of first instance in order to have the admissibility of documents (24) to (27) reassessed in view of the experimental results submitted with the statement of the grounds of appeal.

VIII. The respondent (patentee) argued mainly as follows:

- The opposition division had properly exercised its discretionary power by not admitting documents (22), (23), (24), (25) and (25a) into the proceedings.
- It could not be derived *prima facie* that "Standard 4" in document (25) or (25a) led to a compound as defined in claim 1 of the main request, because document (27) was not a fair repetition of "Standard 4" of document (25).
- The appellant had submitted no grounds justifying the late filing of these documents.
- Documents (24) and (26) had been published after the priority and filing dates of the patent in suit and were thus not prior art.
- The allegation that Omeprazole (IV) of document (24) corresponded to "Standard 4" of document (25) was not supported.
- Remittal of the case to the first instance was not justified.

IX. The appellant (opponent) requested that the decision under appeal be set aside and that claims 1-3 and claims 12-14 of European patent No. 1390360 be revoked. Furthermore, it requested that the case be remitted to the department of first instance for reassessment of the admission of documents (24) to (27).

X. The respondent (patent proprietor) requested that the appeal be dismissed and that documents (22), (23), (23b), (24), (25), (25a), (26) and (27) not be admitted into the proceedings. Alternatively, if documents (22) to (25a) and/or (26) and (27) were admitted into the proceedings, it requested the case be remitted to the department of first instance. Alternatively, it requested that the patent be maintained as granted (main request) or in amended form according to auxiliary requests 1 to 3 filed with letter of 26 March 2012. Furthermore, it requested apportionment of the costs if the case was remitted to the department of first instance.

XI. At the end of the oral proceedings the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.

Admission into the proceedings of documents (22), (23), (23b), (24), (25) and (25a).

2. The department of first instance did not admit into the proceedings late-filed documents (22), (23), (23b), (24), (25) and (25a), using its discretionary power under Article 114(2) EPC.

2.1 Although the board of appeal may overrule the way in which a first-instance department has exercised its discretion, it is not the function of a board of appeal to review all the facts and circumstances of the case

as if it were in the place of the first instance (emphasis added by the board) in order to decide whether or not it would have exercised such discretion in the same way. Rather, the board must confine its review to whether the first instance has exercised its discretion incorrectly or unreasonably (see G 7/93, OJ EPO 1994, 775, point 2.6). Since documents (22), (23) and (23b) were no longer relied on by the appellant in the appeal proceedings, the board confined its review of the decision under appeal to the refusal to admit documents (24), (25) and (25b).

2.2 The opposition division gave four reasons for reaching its conclusion (see page 8 of its decision):

2.2.1 The identity between form IV of document (24) and the claimed Omeprazole form C was not sufficiently established by document (24).

It is noted that since document (24) does not disclose the X-ray powder diffraction pattern of form IV, the opposition division could rely only upon the assertion in document (24) that "Simulation of the PXRD patterns of crystal I-V showed that ... form IV corresponds to form C". The opposition division stated in that respect that this assertion was impossible to verify (see page 7, point 3.4, line 12 of the decision). Since the opposition division was not able to check by itself the veracity of this assertion, it reasonably concluded that the identity was not **sufficiently** established.

2.2.2 The identity between form IV of document (24) and "Standard 4" of document (25) was doubtful because the processes for their preparation differed. The opponent

seemed to take the view that the identity of tautomeric ratio implied identity of polymorphic form, a fact which had not been established.

In the absence of evidence regarding this alleged correlation between tautomeric ratio and crystalline form, the board finds that there was a doubt in that respect and that the opposition division could reasonably conclude that it was sufficient for not concurring with the opponent's opinion.

- 2.2.3 Document (25) did not disclose any XRPD data. Therefore, it was not established that the crystalline form of document (25) fell within the scope of claim 1.

This fact was not contested by the appellant.

- 2.2.4 Further evidence or investigation would be necessary to establish whether document (25) could be said to disclose form C and a process for its preparation.

In view of the submission by the appellant of document (27), it does not appear that this finding was unreasonable.

- 2.2.5 Document (25a) was post-published and corresponded to document (25) (see point II above). It appears reasonable to apply to this document the same conclusion as for document (25).

- 2.3 In conclusion, the board finds that the opposition division has not exceeded the proper limits of its discretion. Therefore, no objection can be raised

against the way the opposition division exercised its discretionary power.

Newly submitted documents - Rule 12(4) RPBA

3. Documents (26) and (27) were submitted with the statement setting out the grounds of appeal, in support of the evidence submitted to but not admitted by the first instance, i.e. documents (24) and (25). Since documents (26) and (27) complement documents (24) and (25), the admission of these documents must be considered together.

3.1 The admission into the appeal proceeding of documents (24), (25), (26) and (27) is governed by Article 12(4) RPBA (see Supplement to OJ 2011, 1, 38) which states:

"Without prejudice to the power of the Board to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first instance proceedings, everything presented by the parties under (1) shall be taken into account by the Board if and to the extent it relates to the case under appeal and meets the requirements in (2)".

3.2 The statement of grounds of opposition relied only upon prior use in view of batch OMM8020 (see point IV above). The decision under appeal only addressed this issue (see point V above). Documents (24) and (25)/(25a) were not admitted into the opposition proceedings, within proper exercise of discretionary power (see point 2 above). In the statement of grounds of appeal, the appellant has objected that claim 1 lacks novelty on the basis of "Standard 4" of document (25), page 10,

i.e. preparation of 5/6-methoxy (11%-13% 5-methoxy), relying upon evidence (27) and documents (24) and (26). This objection does not relate to the case under appeal but represents a complete shift compared with the situation prevailing before the department of first instance. The function of the appeal proceedings is not to give the losing party an opportunity to make up for its omissions in the proceedings before the department of first instance and to conduct the case anew. Article 12(4) RPBA thus requires all parties to complete their relevant submissions during the proceedings before the department of first instance. The appellant was thus under the procedural obligation to file documents (24), (25), (26) and (27) within the time limit for opposition, unless there were compelling reasons for being given an opportunity to complement the case at a later stage. Since the appellant has not presented any good reasons in this regard, the board is not able to exercise its discretion in the appellant's favour.

- 3.3 The respondent (patentee) moreover rightly pointed out that the temperature of dissolution of Omeprazole in document (25), "Standard 4", was not mentioned, whereas it was given as between 23°C and 27°C in document (27), and the crystallisation occurred at 7°C in document (27) instead of "approximately 5°C" in document (25). In the absence of information concerning the role of the temperature for obtaining a defined polymorph, the relevance of the new documents is doubtful.

As argued by the respondent, the reference to documents (24) and (26) suffers from a fundamental deficiency, because form IV Omeprazole is obtained by

crystallisation from acetone or from a 70:30 methanol:carbon tetrachloride mixture (see page 7 of the statement setting out the grounds of appeal). None of these solvents is included in the process disclosed in document (25) for preparing "Standard 4". For this reason, those documents cannot be related to document (25) in support of a lack-of-novelty attack and are to be disregarded.

Therefore, the objection of lack of novelty based on document (25) and related facts and evidence (24), (26) and (27) is not admitted into the appeal proceedings because it represents a complete shift of the case before the first instance, the respondent did not agree to the admission of this objection, and these documents are not relevant in the sense that they constitute a clear case of lack of novelty.

3.4 Furthermore, the appellant contended that document (25) had been submitted in the appeal proceedings to reinforce the objection based on the prior use, and to show that the person skilled in the art would routinely use the process of "Standard 4" of document (25) to reproduce the batch OMM8020.

3.5 The board concedes that a losing party before the department of first instance is entitled to provide further evidence and/or documents at the appeal stage in order to overcome the reasons of the decision of the first instance. However, such a possibility is subject to Article 12(4) RPBA, i.e. " the power of the board to hold inadmissible facts, evidence ... which could have been presented ... in the first instance proceedings ...". Document (25) was submitted during oral proceedings

before the first instance, whereas document (25a) was already mentioned in document (24), the latter being submitted by the appellant two months before the oral proceedings before the department of first instance. To have realised at the hotel the day before oral proceedings that this document was allegedly relevant cannot be considered as a valid reason for its late filing. This document could have been presented earlier and appeal proceedings are not meant to remedy this fundamental flaw. Under Article 12(4) RBPA, document (25) is not admitted into the appeal proceedings for this reason too.

Remittal of the case for reassessment of admission of documents (24) to (27)

3.6 After having informed the parties of its conclusion regarding the admissibility of the above cited documents, the chairman asked the appellant to present its case, reminding him that he was bound by his submissions as set out in the statement of grounds for appeal. After an adjournment, the appellant requested that the case be remitted to the first instance in order to have it reconsidered on the basis of document (27) filed with the statement setting out the grounds for appeal. To justify this request, the appellant argued that he was surprised that these documents had not been admitted into the proceedings. The respondent disagreed.

3.7 The board does not see any reason to delay the proceedings by remitting the case to the department of first instance. The late filing of documents (26) and (27) results from the appellant's failure to present

them in due time. Moreover, document (25) was not admitted by the opposition division, and the admissibility of this document was also disputed by the respondent in its reply to the statement setting out the grounds of appeal. Hence, the appellant cannot be surprised that the admissibility of late-filed documents was discussed during oral proceedings before the board.

3.8 Thus, the request to remit the case to the department of first instance (Article 111(1) EPC) is rejected.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

M. Schalow

P. Ranguis