BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Publication in the Official Journal [redacted] / No

File Number: T 990/91 - 3.3.1

Application No.: 89 308 480.6

Publication No.: 0 357 315

Title of invention: Hemiphosphate hemihydrate of 2-(1-pentyl-3-guanidino-4-imidazolyl)thiazole

Classification: C07D 417/04

D E C I S I O N
of 25 May 1992

Applicant: Pfizer Inc.

Headword: Amendment/PFIZER

EPC Article 113(1), Rules 67 and 88

Keyword: "Amendment of chemical name (allowed)"
"Substantial procedural violation (no) - reimbursement of appeal fee refused"

Headnote

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : T 990/91 - 3.3.1

D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 25 May 1992

Appellant : Pfizer Inc.
235 East 42nd Street
New York, N.Y. 10017 (US)

Representative : Moore, James William, Dr.
Pfizer Limited
Ramsgate Road
Sandwich, Kent. CT13 9NJ (GB)

Decision under appeal : Decision of Examining Division 008 of the European Patent Office dated 9 July 1991 refusing European patent application No. 89 308 480.6 pursuant to Article 97(1) EPC.

Composition of the Board :

Chairman : K.J.A. Jahn
Members : R.W. Andrews
J.A. Stephens-Ofner

Summary of Facts and Submissions

I. European patent application No. 89 308 480.6 (publication No. 0 357 315) was filed on 22 August 1989. The only claim for all Contracting States except ES and GR reads as follows:

"2-(1-Pentyl-3-guanidino-4-imidazolyl)thiazole hemiphosphate hemihydrate".

The claim for the Contracting States ES and GR is directed to a process for the preparation of the said hemiphosphate hemihydrate.

II. By a decision dated 9 July 1991, the Examining Division rejected the application on the ground that, since the correction of an error under Rule 88 EPC could not be allowed, the requirements of Article 84 and 83 EPC were not met.

Although the Examining Division concluded that an error had in fact been made in the naming of the claimed compound, it did not find that it was obvious that the correction should be the insertion of ")-4-(2-methyl" between "guanidino and -4-imidazoyl" in the present name.

III. An appeal was lodged against this decision on 23 July 1991 and the prescribed fee duly paid.

In his statement of grounds of appeal filed on 11 November 1991 the Appellant contended that from the prior art cited on page 1, lines 9 to 22 of the application, i.e. WO 88/03141 (International application No. PCT/US86/02308, document (1)) and US-A-4 560 690 (document (2)), it would be immediately evident to the skilled person that the correction must be the insertion of ")-4-(2-methyl"

between "guanidino" and "-4-imidazolyl". Thus, the primary focus of document (1) is undoubtedly 2-(1-pentyl-3-guanidino)-4-(2-methyl-4-imidazolyl)thiazole and its dihydrochloride trihydrate. Furthermore, this document discloses only two compounds with the molecular formula $C_{13}H_{20}N_6S.2HCl.3H_2O$. Similarly, document (2) only discloses two compounds with a free base portion having the molecular formula $C_{13}H_{20}N_6S$. Although neither of these compounds is in the form of an anhydrous dihydrochloride salt as stated on page 1, lines 12 to 14 of the present application, the skilled person would immediately be led to these two compounds. Since the only free base with the above-mentioned molecular formula commonly appearing in documents (1) and (2) is 2-(1-pentyl-3-guanidino)-4-(2-methyl-4-imidazolyl)thiazole, the requested correction would be immediately evident to the skilled person.

The Appellant has supported this by the submission of a Statutory Declaration of Dr. S.G. Davies.

IV. The Appellant requests that the decision under appeal be set aside and that the compound name 2-(1-pentyl-3-guanidino-4-imidazolyl)thiazole be corrected to 2-(1-pentyl-3-guanidino)-4-(2-methyl-4-imidazolyl)thiazole wherever it occurs in the application. The Appellant also requests the reimbursement of the appeal fee.

Reasons for the Decision

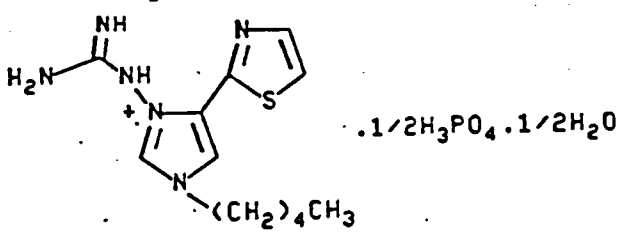
1. The appeal is admissible.

2. The application as originally filed related to the hemiphosphate hemihydrate salt of 2-(1-pentyl-3-guanidino-

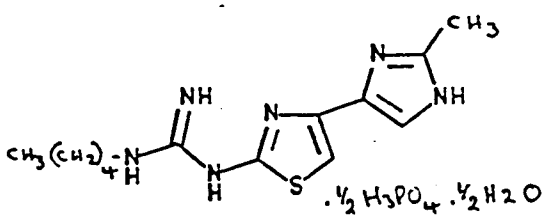
4-imidazolyl)thiazole (cf. for example, title, page 2, lines 1 to 2 and Example and the heading to Table 2 on page 3 and the claims).

2.1 It was not disputed in the decision under appeal that it was obvious that an error had occurred in the naming of the salt which is the subject-matter of the application. The Board agrees that the structure corresponding to the present name requires the existence of a quaternary nitrogen atom in the imidozole ring. Since no possible counter ion is mentioned in the application, an error must have occurred. Furthermore, from the table on page 2 of the application, it is clear that the salt which is the subject of the application has a molecular formula $C_{13}H_{20}N_6S\ ^1/_2H_3PO_4.^1/_2H_2O$, whereas the structure corresponding to the present name has a molecular formula $C_{12}H_{19}N_6S\ ^1/_2H_3PO_4.^1/_2H_2O$.

In accordance with the present and corrected nomenclature, the compounds have the following structures:



.1/2H3PO4.1/2H2O



Therefore, it would be immediately evident to the skilled person that an error had occurred in the naming of the salt.

2.2 In order for a correction to be allowable under Rule 88 EPC, a correction to the description, claims or drawings must not only be obvious but it must be immediately evident that nothing else would have been intended than what is offered as the correction.

Having decided that an error has obviously occurred in the drafting of the application, the skilled reader to whom it is addressed would attempt to formulate a notional correction which would enable him to make sense of what he reads. In making this attempt the skilled person would be guided by the content of the application. In the present case the skilled person would pay particular attention to the discussion of the prior art on page 2, lines 3 to 8, the statement of invention on page 2, lines 9 to 11 and the Table on the same page. In this passage, which refers exclusively to documents (1) and (2), it is stated that these documents are concerned with the likewise erroneously named compounds in the form of certain salts which possess certain disadvantages. In contrast to these prior art salts, the hemiphosphate hemihydrate is said to offer many advantages. This indicates that the present application is concerned with the problem of improving this prior art. This problem is solved by providing a novel salt of this basic compound. Thus, since these prior art documents were made available to the public before the claimed priority date of the present application, they may be taken into consideration regarding the correction of the obvious error which has occurred.

Thus, document (1) refers to processes for the preparation of 2-(1-pentyl-3-guanidino)-4-(2-methyl-4-imidazolyl)thiazole and analogues (cf. last paragraph on page 4). Moreover, a further investigation of document (1) reveals that only two compounds having the molecular formula $C_{13}H_{20}N_6S.2HCl.3H_2O$ (molecular weight 419.4) referred to in the Table on page 2 of the present application are specifically disclosed. These are 2-(1-pentyl-3-guanidino) -4-(2-methyl-4-imidazolyl)thiazole dihydrochloride trihydrate (Example 1) and 2-[1-(2-methylbutyl)-3-guanidino]-4-(2-methyl-4-imidazolyl)thiazole dihydrochloride trihydrate (Example 2). However, although the latter compound carries

an alkyl radical with 5 carbon atoms at the 1-position of the guanidino group, it cannot be taken into consideration as a possible correction, since chemical nomenclature makes a clear distinction between the (unbranched) pentyl radical and the (branched) 2-methylbutyl radical.

2.3 Document (2), which relates to 2-(N-substituted guanidino)-4-heteroarylthiazole compounds, specifically discloses two compounds with a free base portion having a molecular formula $C_{13}H_{20}N_6S$, viz. the products of Examples 6(c) and 7. Although neither of these compounds is in the form of an anhydrous dihydrochloride as stated on page 2, lines 3 to 6 of the present application, the skilled person would concentrate his attention on the molecular formula of the free base rather than the particular salt disclosed. Particularly, since in the discussion of document (2) in document (1) it is stated that in the earlier document the products are generally isolated as the dihydrobromide salts and converted to the dihydrochloride salts via their free base forms (cf. document (1), page 1, line 9, to page 2, line 33). The compound of Example 7 having an hexyl radical at the 1-position of the guanidino radical is excluded right from the start as a possible correction since it is clear from the introduction to the description of the present application that an improvement over the salts of the 1-pentyl compound is sought. Therefore, the application must relate to compounds having a pentyl radical of the 1-position of the guanidino group.

Therefore, in the Board's judgment, it would be immediately evident to the skilled person that the correction required must be the insertion of ")-4-(2-methyl" between "guanidino" or "-4-imidazolyl" in every occurrence of the compound name.

In the Board's opinion, the finding is clearly supported by the Statutory Declaration of Dr. S.G. Davies in which he concluded that no compound other than 2-(1-pentyl-3-guanidino)-4-(2-methyl-4-imidazolyl)thiazole could be logically deduced from a reading of the application and documents (1) and (2).

3. The Appellant supports his request for refund of the appeal fee on the basis that a substantial procedural violation had occurred insofar as an argument, which had not been raised previously, was introduced into the decision under appeal. This argument was based on the premise that the reference to the salt of 2-(1-pentyl-3-guandino)-4-(2-methyl-4-imidazolyl)thiazol in document (2) as the hydrate dihydrobromide rather than the anhydrous dihydrochloride referred to in the application introduced confusion with the result that the description on page 2, lines 3 to 8 could not be relied upon to support the contention that only a compound common to documents (1) and (2) could be intended as the subject-matter of the present application.

According to Article 113(1) decisions of the European Patent Office may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments.

However, in the Board's judgment, the above-mentioned argument of the Examining Division was supererogatory and incidental, insofar as it did not alter the Examining Division's decision which was based on arguments fully convassed in its communication of 15 March 1991. Since there was no need for the Examining Division to put forward this new argument in order to refuse the application, the lack of opportunity to reply to it cannot

be considered to be a procedural violation, let alone a substantial one sufficient to warrant the reimbursement of the appeal fee.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Examining Division for further prosecution on the basis that the compound name 2-(1-pentyl-3-guanidino-4-imidazolyl)thiazole is amended to read 2-(1-pentyl-3-guanidino)-4-(2-methyl-4-imidazolyl)thiazole wherever it occurs.

3. Reimbursement of the appeal fee is refused.

The Registrar: The Chairman:

E. Görgmaier K.J.A. Jahn