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**Datasheet for the decision
of 15 December 2011**

Case Number: T 1285/11 - 3.3.01
Application Number: 08806952.1
Publication Number: 2185516
IPC: C07D 213/71, A61K 31/435
Language of the proceedings: EN

Title of invention:

Polymorphs of 3-(((4-tert-butyl-benzyl)-(pyridine-3-sulfonyl)-amino)-methyl)-phenoxy)-acetic acid sodium salt or a hydrate thereof and methods for making the same

Applicant:

Pfizer Products Inc.

Headword:

Polymorphs/PFIZER

Relevant legal provisions:

EPC Art. 113(1), 111(1), 82
EPC R. 164(2), 137(5), 103(1)(a), 71(2), 44(1)

Relevant legal provisions (EPC 1973):

EPC R. 86(4)

Keyword:

"Admissibility of amendments under Rules 137(5) and 164(2) EPC (yes)"
"Substantial procedural violation (yes) - lack of essential reasoning prior to refusal"
"Reimbursement of the appeal fee (yes)"
"Remittal (yes)"

Decisions cited:

G 0002/92, J 0003/09, T 0708/00, T 0951/92, T 0631/97

Catchword:

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Case Number: T 1285/11 - 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 15 December 2011

Appellant: Pfizer Products Inc.
(Applicant) Eastern Point Road
Groton, CT 06340 (US)

Representative: Rudge, Andrew John
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 17 March 2011
refusing European patent application
No. 08806952.1 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: P. Ranguis
Members: L. Seymour
C.-P. Brandt

Summary of Facts and Submissions

- I. This appeal lies from the decision of the examining division refusing the European patent application No. 08 806 952.1, based on international application WO 2009/027811, under Article 97(2) EPC.
- II. The application as originally filed contained 28 claims. The product claims 1 to 22 and 26 to 28 were directed to various solid-state forms of (3-(((4-*tert*-butylbenzyl)-(pyridine-3-sulfonyl)-amino)-methyl)-phenoxy)-acetic acid sodium salt or a hydrate thereof.
- III. The European Patent Office (EPO), acting as an International Searching Authority (ISA), considered the application to be non-unitary and the claims to cover nine inventions, as follows (see International Search Report (ISR) and Form PCT/ISA/210 annexed thereto; note: the full chemical name of the sodium salt appearing in the previous paragraph has been omitted by the board for reasons of conciseness):
1. claims: 1 (in part); 20,21 (fully)
Crystalline forms of ... sodium salt or a hydrate thereof excluding forms of inventions 2-7; and a substantially pure crystalline form of ... sodium salt, and an isolated crystalline form of ... sodium salt.
 2. claims: 1 (in part); 2-4, 17-19, 22-25 (fully)
A crystalline form A of ... sodium salt and a method for preparing form A
 3. claims: 1 (in part); 5-7 (fully)

A crystalline form B of ... sodium salt

4. claims: 1 (in part); 8-10 (fully)

A crystalline form C of ... sodium salt

5. claims: 1 (in part); 11,12 (fully)

A crystalline form E of ... sodium salt

6. claims: 1 (in part); 13-14 (fully)

A crystalline form F of ... sodium salt

7. claims: 1 (in part); 15-16 (fully)

A crystalline form G of ... sodium salt

8. claims: 26-27 (fully)

A non-crystalline form H of ... sodium salt

9. claims: claim 28 (fully)

An amorphous form I of ... sodium salt

The following document was cited:

- (1) WO 99/19300

The reasons given for the finding of non-unity (see "International Preliminary Report on Patentability (Chapter I of the Patent Cooperation Treaty)", Item IV of written opinion) were indicated as being essentially that document (1) already disclosed (3-(((4-*tert*-butylbenzyl)-(pyridine-3-sulfonyl)-amino)-methyl)-phenoxy)-acetic acid sodium salt as a white solid (page 200, lines 10 to 19) for use in treating conditions that are related to the modulation of prostaglandin (abstract).

Because it already belonged to the prior art, said salt could not be viewed as constituting a "special technical feature" in the sense of Rule 13.2 PCT. The problem of providing further forms of said salt had been solved by providing different polymorphs thereof according to the nine inventions listed. These inventions were therefore not so linked as to form a single general inventive concept, contrary to the requirements of Rule 13.1 PCT.

Since no additional search fees were paid, the international search report was "restricted to the invention first mentioned in the claims" (see ISR, Box No. III).

- IV. With the request for entry into the European phase dated 11 March 2010, amended claims 1 to 10 were filed as basis for the proceedings before the EPO. These claims related to crystalline form A (cf. "invention 2" listed above under point III).
- V. In a first communication dated 21 September 2010, the examining division referred to the written opinion of the ISA, and noted that no additional fees had been paid in the international phase, following an objection of lack of unity by the ISA. It was therefore requested that the applicant "restrict the claims to invention 1 as required by R. 164(2) EPC".
- VI. In its reply of 21 October 2010, the applicant disputed that Rule 164(2) EPC could be seen as a bar to further prosecution based on the subject-matter now claimed, since a search with respect to the subject-matter as defined under "invention 1" would inevitably also have

- covered crystalline form A of the present salt. No further search was therefore required.
- VII. In its second communication of 11 November 2010, the examining division stated that its previous objection under Rule 164(2) EPC was maintained.
- VIII. In its letter of 26 November 2010, the applicant noted that the examining division's second communication did not contain a reasoned statement in the sense of Rule 71(2) EPC. In addition, the applicant disputed the ISA's analysis of lack unity (cf. point III above), arguing that "crystallinity" was to be regarded as a common "special technical feature" in the sense of Rule 44(1) EPC.
- IX. In the annex to the summons to attend oral proceedings issued on 17 December 2010, the examining division reiterated its request for restriction of the claims to "invention 1". Failure to file a set of claims fulfilling Rule 164(2) EPC would lead to refusal of the application.
- X. In its letter of 4 February 2011, the applicant provided further detailed arguments in support of its case, and emphasised that it was the examining division's duty to review the correctness of any decision of the search division. Furthermore, the applicant complained that it had not been provided with any reasoned response to the arguments submitted in its previous letters (cf. above points VI and VIII). It therefore remained unaware of the essential legal and factual reasoning which would, according to the summons, lead to the refusal of the application.

XI. The examining division refused the application at the end of oral proceedings held on 7 March 2011, based on the main and sole request filed on 11 March 2010 with the request for entry into the European phase (see point IV above).

According to the written decision dated 8 March 2011, the examining division considered that the subject-matter of this request contravened Rules 164(2) and 137(5) EPC.

The examining division considered that the fact that no further search fees or protest fees had been paid in the international phase amounted to a tacit agreement on the part of the applicant with the findings of non-unity of the ISA. The practice of issuing a communication dealing exclusively with the subject-matter of the searched invention was in conformity with Rule 164(2) EPC and the Guidelines for Examination, chapter III, point 7.11.1(ii).

The examining division submitted that, since it had invoked and applied Rule 164(2) EPC in its communications, it was implicit that it had reviewed the non-unity objection brought forward in the international phase (cf. point III above) and found this to be justified. Thus, the "special technical feature", namely, the salt itself, was known from document (1). Therefore, a single general inventive concept unifying all the inventions as defined in the written opinion was indeed absent. The examining division further noted that, although the written opinion had found "invention 1" to be novel with regard

to document (1), it had not considered it to be inventive with regard to said document.

The examining division also expressed the opinion that the subject-matter now claimed, that is, "invention 2", was not covered by the ISR, or at least that it must be assumed that this was the case. Agreeing to allow this invention to be pursued would require an extra search and examination effort, and would contravene Rule 137(5) EPC, since "invention 2" did not combine with the remaining originally claimed groups of inventions to form a single general inventive concept. In this context, the examining division also referred to the Guidelines for Examination, chapter III, point 7.11.1(iv).

With reference to the decision of the Enlarged Board of Appeal G 2/92 and the Guidelines for Examination, chapter III, point 7.11.4, the examining division submitted that the only way for the applicant to seek protection for the present subject-matter would be to file a divisional application.

XII. The applicant (appellant) lodged an appeal against this decision. The arguments submitted in writing in the statement of grounds of appeal, insofar as they are relevant to the present decision, may be summarised as follows:

The appellant argued that the examining division had an obligation to review the correctness of any decision of the search division with respect to lack of unity regardless of whether additional search fees had been paid or not. In the present case, both "inventions 1

and 2" as identified by the ISA related to crystalline forms of the claimed salt. This "crystallinity" made a contribution over the prior art and constituted a common "special technical feature" in the sense of Article 82 and Rule 44(1) EPC. The ISA had therefore been incorrect in assessing that said inventions were non-unitary. Moreover, the international search for "invention 1" (crystalline forms other than the A, B, C, E, F and G) would necessarily also have covered all polymorphs of the claimed salt, including that of "invention 2" (Form A), since a document relating to the latter subject-matter would be highly relevant as closest prior art for the assessment of inventive step of "invention 1". The claims of the present main request, relating to the subject-matter listed as "invention 2", therefore complied with the provisions of Rule 164(2) EPC.

Finally, the appellant argued that his right to be heard under Article 113(1) EPC had been infringed: The examining division's conduct of the written procedure had been contrary to Rule 71(2) EPC, since the communications sent pursuant to Articles 94(3) EPC did not contain a reasoned statement explaining why the application did not meet the requirements of the EPC. The appellant therefore found himself in the position of attending oral proceedings before the examining division without being informed of the essential legal and factual reasoning which could lead to the ultimate refusal of the application, and was therefore unable to prepare for those oral proceedings in a meaningful way. This constituted a substantial procedural violation justifying reimbursement of the appeal fee.

XIII. The appellant (applicant) requested in writing that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution on the basis of the main and sole request filed with the request for entry into the European phase dated 11 March 2010. Oral proceedings were requested for the case that this request could not be granted on the basis of the written submissions.

The appellant further requested reimbursement of the appeal fee according to Rule 103(1)(a) EPC on the basis that such reimbursement was equitable by reason of a substantial procedural violation.

Reasons for the Decision

1. The appeal is admissible.
2. *Refusal based on Rule 137(5) EPC*

The examining division *inter alia* relied on Rule 137(5) EPC in refusing the present main request, citing the text of this rule according to which "amended claims may not relate to unsearched subject-matter which does not combine with the originally claimed invention or group of inventions to form a single general inventive concept".

The board notes that this wording is the same as that of Rule 86(4) EPC 1973. This rule was introduced to give the EPO the means to react appropriately when the applicant dropped existing claims and replaced them with originally non-unitary subject-matter extracted

from the description (see the Notice published in OJ EPO 1995, 409, in particular pages 420 and 421, point 2; see also Guidelines for Examination, C-VI, 5.2(ii), in particular the second paragraph of this section). This is also reflected in the passage of the Guidelines for Examination cited by the examining division in this context, namely, chapter III, point 7.11.1(iv), which states that, "if the claims to be examined relate to an invention which differs from **any of the originally claimed inventions** and which does not combine with these inventions to form a single inventive concept, an objection under Rule 137(5) should be raised in the first communication" (emphasis added).

Indeed, according to well-established case law, "Rule 86(4) EPC does not apply when the applicant has not paid the search fee in respect of a non-unitary invention relating to the originally filed claims" (see T 708/00, OJ EPO 2004, 160, point 7, see also points 5, 6 and 8).

In the present case, the subject-matter of the amended claims according to the main request was already present in the claims as originally filed (see claims 2 to 4, 17 to 19, 22 to 25). Therefore, the main request does not contravene Rule 137(5) EPC and may not be refused on this basis.

3. *Refusal based on Rule 164(2) EPC*

3.1 Rule 164(2) EPC, which entered into force with the EPC 2000 on 13 December 2007, applies to the present application, since the international application on which it is based (see above point I) was filed on

25 August 2008. This rule requires that, "where the examining division finds that the application documents on which the European grant procedure is to be based do not meet the requirements of unity of invention, or protection is sought for **an invention not covered by the international search report** ..., it shall invite the applicant to limit the application to **one invention covered by the international search report...**"

(emphasis added).

The board notes that it can already be deduced from the juxtaposition of the expressions "an invention not covered by the international search report" and "one invention covered by the international search report" that, in order for Rule 164(2) EPC to be applicable, the respective non-searched and searched inventions being referred to cannot belong to a single invention and must indeed be non-unitary with respect to one another. As aptly analysed in the decision of the Legal Board of Appeal J 3/09, it is also implied by the wording of Rule 164(2) EPC, giving the EPO the power to invite the applicant to limit the application to one invention covered by the international search report, that where there is in fact only "one" invention there is no sanction (see Reasons, point 3.5.7).

According to the practice of the EPO, as set out in the Guidelines for Examination (C-III, 7.10, first paragraph) and explained in detail in decision J 3/09 (see Reasons, points 3.5.4 to 3.5.7, in particular point 3.5.6), the responsibility for establishing whether or not the application meets the requirements of unity of invention ultimately rests with the examining division, and the opinion of the EPO acting

as the ISA on lack of unity is not final or binding on the examining division. The fact that the applicant did not pay further search fees or protest fees in the international phase cannot therefore be seen as a tacit agreement with the findings of non-unity of the ISA, as submitted by the examining division in the decision under appeal.

The situation referred to by the examining division, whereby subject-matter in respect of which a search fee has not been paid can only be pursued in a divisional application, presupposes that the searched and non-searched inventions are in fact found to be non-unitary when the examining division upon review agrees with the opinion of the search division (see decision J 3/09, Reasons, points 5.1 to 5.7 and references therein to decisions G 2/92 and T 631/97; see also Guidelines for Examination, C-III, 7.10, third and fourth paragraphs, and 7.11.1(ii),(iii)).

To the extent that an objection of non-unity raised by the ISA turns out to be unjustified, the applicant is entitled as of right to have the whole subject-matter of his unitary invention searched. If need be, an additional search would have to be performed (see Guidelines for Examination, C-III, 7.10, third paragraph, last sentence, and 7.11.1(v); decision J 3/09, Reasons, points 3.5.6 and 5.2), regardless of whether or not this might involve an additional effort.

With respect to the examining division's reference to the Guidelines for Examination, chapter III, point 7.11.4 (cf. decision under appeal, point 3.2.7), it is noted, for the sake of completeness, that this

relates to the situation where the EPO has established an international preliminary examination report (IPER). An IPER has not been issued in the present case, since the applicant did not file a demand requesting examination of the international application by the international preliminary examining authority (Chapter II of the PCT). In addition, it is noted that point 7.11.4 must be read in the context of preceding point 7.11.3, which explicitly refers to the case where "the applicant successfully refutes the objection ... or the interpretation of the rules regarding unity of invention was erroneous".

- 3.2 Consequently, in order to establish whether Rule 164(2) EPC is applicable in the present case, it must be decided whether the examining division was correct in its assessment that the subject-matter now claimed in the main request ("invention 2") and the searched subject-matter ("invention 1") are non-unitary.

The objection of lack of unity of the ISA, on which the examination division relied, was raised *a posteriori*, based on document (1) (see above point III). In Step D of Example 14d (page 200), a process is disclosed for the synthesis of the present sodium salt, which is obtained as a "white solid". Thus, this material already forms part of the prior art, but its solid-state structure is not specified, that is, whether it is crystalline, non-crystalline or amorphous (cf. application in suit, originally filed claims 1 to 25; 26, 27; and 28, respectively). It must therefore be concluded, *prima facie*, that any one of these features, including "crystallinity", defines a contribution over the prior art, and therefore qualifies as a potential

"special technical feature" in the sense of Rule 44(1) EPC.

The examining division argued in this context that, although the ISA had found "invention 1" to be novel with respect to document (1), it had not considered it to be inventive with regard to said document (cf. above point XI). However, it is noted that this opinion of the ISA on novelty and inventive step was not included as part of the analysis relating to unity, and for good reason. Indeed, in the present case, a definitive conclusion as to whether the common concept of "crystallinity" is novel and inventive cannot be reached without a full substantive examination procedure, with active participation of the appellant. This is clearly required in order to establish what solid-state form is actually obtained in Example 14d of document (1) (cf. also point 4 below), and whether any claimed subject-matter possesses surprising properties with respect to the prior art material, as contended by the appellant (see application in suit, page 9, lines 29 to 31 and statement of grounds of appeal, point 3.4).

Consequently, the board concludes that, *prima facie*, the feature of "crystallinity" can be regarded as constituting a "special technical feature" in the sense of Rule 44(1) EPC, establishing unity between present "invention 1" and "invention 2" in accordance with Article 82 EPC. Accordingly, as explained above under point 3.1, Rule 164(2) EPC cannot be seen as a bar to further prosecution based on the subject-matter now claimed in the main request.

4. *Remittal to the first instance*

It follows from the preceding considerations that the reasons for the refusal of the present application by the examining division were not justified. Under these circumstances, the board exercises its power under Article 111(1) EPC and remits the case to the examining division for further prosecution.

Examination can thus be resumed on the basis of the main request.

The examining division will have to consider whether an additional search is required in the present case (cf. above point 3.1).

With respect to the issue of clarity, it will in particular have to be examined whether the main request meets the requirements of Article 84 EPC, taken in combination with Rule 43(2) EPC, in respect of the number of independent claims in the same category.

In addressing the issue of novelty, the examining division should assess whether convincing evidence or arguments have been provided to establish that the claimed crystal form is in fact novel over the product produced by the process according to Example 14d of document (1).

5. *Reimbursement of the appeal fee*

According to Article 113(1) EPC, the decisions of the EPO may only be based on grounds on which the parties concerned have had an opportunity to present their

comments. In this context, the word "grounds" should be interpreted as referring to the essential reasoning, both legal and factual, which leads to the refusal of the application (see T 951/92, OJ EPO 1996, 53, point 3(v)).

In the present case, the examining division referred in a first communication to the written opinion of the ISA stating that the claims as originally filed were non-unitary, and, with reference to Rule 164(2) EPC, requested that the applicant restrict the claims to the invention for which a search fee had been paid (see above point V). This is in accordance with standard procedure as outlined in the Guidelines for Examination, chapter III, point 7.10.

However, in response to the counter-arguments submitted by the applicant, the examining division merely referred once again to Rule 164(2) EPC (see above points VI and VII). This pattern was repeated in the subsequent reply of the applicant and summons to attend oral proceedings, despite the fact that the applicant had submitted additional arguments and requested a reasoned response from the examining division (see above points VIII and IX). Finally, in its letter of 4 February 2011, the applicant provided a yet more detailed analysis of the case and once again complained of the lack of reasoned response on the part of the examining division (see above point X). This letter remained unanswered prior to oral proceedings held before the examining division on 7 March 2011.

Thus, neither of the communications of the examining division referred to in the previous paragraph was in

line with the requirements of Rule 71(2) EPC, since they contained no reasoned statement as to why the arguments of the applicant had not been accepted and the objection under Rule 164(2) EPC maintained. This conduct of the examining division thus deprived the applicant of the possibility of preparing meaningfully for the scheduled oral proceedings since it was not clearly informed of the essential reasons on which the findings of non-compliance were based.

Regarding the decisive question of whether "inventions 1 and 2" were to be considered unitary (cf. above point 3), the examining division submitted that, since it had invoked and applied Rule 164(2) EPC in its communications, it was implicit that it had reviewed the non-unity objection brought forward in the international phase and found this to be justified (see decision under appeal, point 3.2.5). However, in order to satisfy Article 113(1) EPC, the outcome of this review should have been communicated in such a way as to permit the applicant to understand and respond to the essential reasons for the conclusion reached.

Indeed, from the statement of grounds of appeal (see point 3.4; cf. decision under appeal, point 3.2.4.3), it is apparent that the reasoning of the examining division for rejecting the applicant's argument that "crystallinity" was to be seen as a "special technical feature" was only communicated to the applicant with the decision under appeal.

Moreover, it is apparent, from the communications of the examining division and from the minutes of the oral proceedings before the examining division, that the

objection under Rule 137(5) EPC, on which the refusal was also based, was communicated to the applicant for the first time in the form of a statement at the conclusion of oral proceedings.

In view of the above, it must be concluded that the refusal of the application was based on legal and factual reasons which were presented for the first time in the decision under appeal and on which the appellant was therefore given no opportunity to present its comments. The board considers that this failure to comply with the requirements of Article 113(1) EPC constitutes a substantial procedural violation and that it is therefore equitable to order the appeal fee to be reimbursed in accordance with Rule 103(1)(a) EPC.

6. *Oral proceedings*

In view of the decision of the board, oral proceedings were not necessary in the present case, in accordance with the appellant's conditional request (see above point XIII).

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 of claims 1 to 10 of the main (sole) request filed on 11 March 2010 with the request for entry into the European phase.
3. The request for reimbursement of the appeal fee is allowed.

The Registrar:

The Chairman:

M. Schalow

P. Ranguis