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D E C I S I O N
of 25 May 2005

Case Number: T 0194/03 - 3.3.1

Application Number: 98936529.1

Publication Number: 1000046

IPC: C07D 281/16

Language of the proceedings: EN

Title of invention:
A crystalline dibenzothiazepine derivative and its use as an antipsychotic agent

Applicant:
AstraZeneca AB

Opponent:
-

Headword:
Quetiapine/ASTRAZENECA

Relevant legal provisions:
EPC Art. 56, 111(1), 123(2)

Keyword:
"Claims substantially amended on appeal - fresh case - remittal"

Decisions cited:
G 0010/93, T 0063/86, T 0139/87, T 0047/90

Catchword:
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Case Number: T 0194/03 - 3.3.1

D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 25 May 2005

Appellant: AstraZeneca AB
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Representative: Denerley, Paul Millington
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 9 September 2002 refusing European application No. 98936529.1 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: A. J. Nuss
Members: R. Freimuth
S. C. Perryman

Summary of Facts and Submissions

I. The appeal lodged on 8 November 2002 lies from the decision of the Examining Division posted on 9 September 2002 refusing European patent application No. 98 936 529.1 (European publication No. 1 000 043), which was filed as international application published as WO-A-99/06381.

II. The decision under appeal was based on claims 1 to 22 according to the then pending request submitted on 11 November 2001. That request comprised two independent product claims, four independent process claims and two independent use claims. Independent claim 1 was directed to the crystalline form of an individual dibenzothiazepine.

The Examining Division found that the subject-matter claimed lacked inventive step (Article 56 EPC) in view of documents

(1) EP-A-240 228 and
(2) EP-A-282 236.

The Examining Division held in particular that the individual compound according to claim 1 was known from documents (1) and (2), though not in a crystalline form. The problem underlying the present application was seen in providing a crystalline form of that compound. However, it was common general knowledge that a crystalline form could be expected to provide advantages in different aspects, e.g. in the formulation and processing technology. Thus, it was obvious to try to obtain the crystalline form of the

known compound in order to capitalise these advantages. It was also mere routine work to find out whether the crystalline form could be obtained by applying common crystallisation techniques since the process claimed specified only operation measures common in the art.

III. In a communication from the Board pursuant to Article 11(2) of the Rules of Procedure of the Boards of Appeal, the Appellant's attention was drawn to chemical handbooks addressing common general knowledge for crystals and crystallisation technique:

(3) Laboratory Technique in Organic Chemistry, K. W. Wiberg, 1960, pages 104 and 105, and
(4) Houben-Weyl, Methoden der Organischen Chemie, Volume I/1 Allgemeine Laboratoriumspraxis, 1958, page 355.

IV. At the oral proceedings before the Board held on 25 May 2005 the Appellant (Applicant) no longer maintained the former request. He submitted a fresh request of nine claims superseding any previous request. The sole independent claim of that request read as follows:

"1. A process for preparing 11(-(4-[2-(2-hydroxyethoxy) ethyl]-1-piperazinyl)-dibenzo[b,f][1,4]thiazepine, or a pharmaceutically-acceptable salt thereof, which comprises crystallising 11(-(4-[2-(2-hydroxyethoxy) ethyl]-1-piperazinyl)-dibenzo[b,f][1,4]thiazepine from a solution of 11(-(4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl)-dibenzo[b,f][1,4]thiazepine in a solvent which is an ester of formula $R^1CO_2R^2$ wherein R^1 and R^2 are (1-4C)alkyl groups; an ether of formula R^3OR^4 wherein R^3 and R^4 are (1-4C)alkyl groups; or a ketone of

formula R^5COR^6 wherein R^5 and R^6 are (1-4C)alkyl groups; and in which the solution is substantially free from water; and whereafter, when a pharmaceutically acceptable salt is required, reacting 11(-(4-[2-(2-hydroxyethoxy) ethyl]-1-piperazinyl)-dibenzo[b,f][1,4]thiazepine with an acid which affords a pharmaceutically acceptable anion."

Claims 2 to 9 of that fresh request were dependent on that claim 1.

V. The Appellant argued in respect of inventive step that the objections raised in the decision under appeal were met since product claims directed to the crystalline individual compound were no longer present and since none of the independent process claims, apart from one, was maintained. Furthermore, the remaining sole independent process claim was substantially restricted by specifying particular solvents to be used which were essential in the performance of the invention.

VI. The Appellant requested that the decision under appeal be set aside and that the application be granted on the basis of the "main request" submitted at the oral proceedings on 25 May 2005.

VII. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. *Scope of examination on appeal*

While Article 111(1) EPC gives the Boards of Appeal the power to raise new grounds in *ex-parte* proceedings where the application has been refused on other grounds, proceedings before the Boards of Appeal in *ex-parte* cases are primarily concerned with examining the contested decision (see decision G 10/93, OJ EPO 1995, 172, points 4 and 5 of the reasons), other objections normally being left to the Examining Division to consider after a referral back, so that the Appellant has the opportunity for these to be considered without loss of an instance.

In the present case the Board, thus, restricts itself to examining whether the amended claims meet the requirements of Article 123(2) EPC and whether the objection as to lack of inventive step pursuant to Article 56 EPC as formulated in the decision under appeal and forming the sole ground for refusal of the application, can still be considered as applying to the amended claims.

3. *Amendments (Article 123(2) EPC)*

The subject-matter of claim 1 is based on original claim 5 in combination with page 3, lines 6 to 8 of the application as filed. The particular solvents in amended claim 1 find support in original claims 6 and 7. Claims 2 to 7 and 9 are backed up by original claims 8,

9, 11 to 14 and 16. Claim 8 is supported by original claim 15 in combination with page 4, lines 28 to 30 of the application as filed.

For these reasons, the Board concludes that that the present claims as amended comply with the requirements of Article 123(2) EPC.

4. *Ground for refusal*

The decision under appeal exclusively dealt with lack of inventive step of the independent product claim 1 of the then pending request directed to the crystalline form of an individual dibenzothiazepine *per se* and merely addressed the then pending independent process claims in general. The amendments made to the claimed subject-matter in the fresh request, in particular by dropping any product claim while presenting a sole fresh independent process claim which was substantially restricted in scope by specifying particular solvents to be used, have the effect that the reasons given in the contested decision for refusing the present application no longer apply since the present process claim 1 has never been challenged under Article 56 EPC.

Thus, the Board considers that the amendments made by the Appellant avoids the inventive step objection as formulated in the decision under appeal and are substantial in the sense that in the present case the examination has to be done on a new basis, with the consequence that the appeal is well founded.

This finding is in line with established jurisprudence of the Boards of Appeal that an appeal is to be

considered well founded if the Appellant no longer seeks grant of the patent with a text as refused by the Examining Division and if substantial amendments are proposed which clearly meet the objections on which the decision relies (see decisions T 63/86, OJ EPO 1988, 224; T 139/87, OJ EPO 1990, 68 and T 47/90, OJ EPO 1991, 486).

5. *Remittal*

Having so decided, the Board has not, however, taken a decision on the whole matter, since as set out above substantial amendments to the subject-matter claimed have been made by submitting, as only independent claim, fresh process claim 1 which was only presented at the oral proceedings before the Board. The decision under appeal did not consider fresh process claim 1 in the form of the present request as such request was never submitted to the first instance. It is only before the Board that the Appellant has dropped any product claim and pointed to fresh facts and arguments in support of the amended process claim 1 in order to overcome the objections raised, thereby emphasizing that the particular solvents now indicated in the claim are indeed the essential feature to be considered in the assessment of inventive step. Thus, fresh process claim 1 generates a fresh case not yet addressed in examination proceedings and requiring reexamination.

Under these circumstances, the examination not having been concluded, the Board considers it appropriate to exercise its power conferred on it by Article 111(1), second sentence, second alternative, EPC to remit the case to the Examining Division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The matter is remitted to the first instance for further prosecution on the basis of claims 1 to 9 according to the main request submitted at the oral proceedings on 25 May 2005.

The Registrar: The Chairman:

U. Bultmann A. Nuss