

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

**Datasheet for the decision
of 21 April 2009**

Case Number: T 0708/06 - 3.3.02

Application Number: 01976082.6

Publication Number: 1313468

IPC: A61K 31/403

Language of the proceedings: EN

Title of invention:

Pharmaceutical combination of Angiotensin II antagonists and
ACE inhibitors

Applicant:

Boehringer Ingelheim Pharma GmbH & Co. KG

Opponent:

-

Headword:

Pharmaceutical combination/BOEHRINGER INGELHEIM PHARMA GMBH &
CO. KG

Relevant legal provisions:

EPC Art. 56

Relevant legal provisions (EPC 1973):

-

Keyword:

"Main and auxiliary request - inventive step - no: arbitrary
combination"

Decisions cited:

-

Catchword:

-



Case Number: T 0708/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 21 April 2009

Appellant: Boehringer Ingelheim Pharma GmbH & Co. KG
Binger Strasse 173
D-55216 Ingelheim am Rhein (DE)

Representative: -

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 27 December 2005
refusing European application No. 01976082.6
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Van Moer

Summary of Facts and Submissions

- I. European patent application No. 01 976 082.6 was refused by a decision of the Examining Division dated 27 December 2005 on the grounds of lack of novelty and inventive step and because its content extended beyond the content of the application as originally filed.
- II. The decision was based on claims 1 to 8 of the main request received on 23 November 2004.

The independent use claim 1 of this request reads as follows:

1. Use of the ANG II antagonist telmisartan for the manufacture of a pharmaceutical composition for the treatment of fibrosis wherein the composition comprises telmisartan and an ACE inhibitor.

The independent product claim 6 of this request read as follows:

6. A pharmaceutical composition comprising the ANG II antagonist telmisartan and the ACE inhibitor ramipril.

- III. The arguments in the decision may be summarised as follows:

The Examining Division held that the feature "a patient with elevated blood pressure or congestive heart failure" in dependent claims 5 and 8 was not disclosed in the application as originally filed, which infringed the requirements of Article 123(2) EPC.

It further considered that document (1) (WO-A-97/02032) anticipated the subject-matter of the application because it disclosed a pharmaceutical composition comprising the ACE inhibitor ramipril and the ANG II receptor telmisartan and that they could be used for the treatment of fibrosis.

It was moreover of the opinion that the claimed subject-matter was in any case not inventive because, amongst other, there was no evidence, i.e. no examples or experimental data, in the application supporting the claimed use.

In that respect, the Examining Division pointed out that the applicant had had many opportunities to file such data.

IV. The appellant (applicant) lodged an appeal against the said decision.

With its grounds of appeal, it filed an auxiliary request corresponding to the main request, wherein dependent claims 5 and 8 were deleted.

Claim 1 of this request reads:

1. Use of the ANG II antagonist telmisartan for the manufacture of a pharmaceutical composition for the treatment of fibrosis wherein the composition comprises telmisartan and an ACE inhibitor selected from benazepril, captopril, ceronapril, enalapril, fosinopril, imidapril, lisinopril, moexipril, guinapril, ramipril, trandolapril and perindopril.

- V. In a communication dated 20 March 2009, the appellant informed the Board that it would not attend the oral proceedings.
- VI. In a communication faxed on 03 April 2009, the Board informed the appellant that it agreed with the Examining Division's conclusions and that the appeal should be dismissed.
- VII. Oral proceedings were held before the Board on 21 April 2009.
- VIII. The appellant's written submissions can be summarised as follows:

As to the objection under Article 123(2) EPC, the appellant argued that the contested feature was in fact disclosed in the description of the application as originally filed in the part relating to the "background of the invention" and that this disclosure was also valid in the context of the subsequently disclosed invention.

Concerning novelty, the appellant submitted that the specific combination of ramipril and telmisartan was nowhere disclosed in document (1).

Finally, it contended that the claimed subject-matter was inventive because document (1) was strictly restricted to the treatment of renal diseases, so that the claimed use for the treatment of fibrosis was not rendered obvious by this disclosure.

IX. The appellant requested in writing that the decision under appeal be set aside or that the patent be granted on the basis of claims 1 to 6 of the request filed with its letter dated 24 April 2006.

Reasons for the Decision

1. The appeal is admissible.
2. Main request

Preliminary remarks

The set of claims of the main request consists, on the one hand, of an independent use claim (claim 1) and its four dependent use claims (claims 2 to 5), and, on the other hand, of an independent product claim (claim 6) and its dependent product claims (claims 7 and 8).

Under these circumstances it appears suitable to start with the product claims and in particular with independent product claim 6.

2.1 Novelty

Document (1)discloses pharmaceutical compositions comprising an ACE inhibitor and an ANG II receptor antagonist for treating renal diseases such as nephropathies (page 3, lines 19 to 22).

It moreover discloses ramipril as an ACE inhibitor within a list of 8 compounds (page 4, lines 24 to 33; claims 7, 8, 19 and 20) and telmisartan as an ANG II

receptor antagonist within a list of 10 compounds (page 5, line 6 and 17; claims 9, 10, 21 and 22).

Nowhere in this document is a combination of ramipril and telmisartan mentioned.

Under these circumstances, the specific composition according to claim 6 containing ramipril and telmisartan must be regarded as novel since it is the result of an undisclosed choice within two lists.

Accordingly, the subject-matter of claim 6 is novel vis-à-vis the disclosure in document (1)(Article 54 EPC).

2.2 Inventive step

- 2.2.1 The Board considers that document (1), which also discloses the use of an ACE inhibitor and an ANG II receptor antagonist for treating diseases, represents the closest state of the art (page 3, lines 19 to 22).

According to the description of the contested application as originally filed, the claimed composition is useful for treating indications including "reduction of the incidence of stroke, acute myocardial infarction or cardiovascular death, especially in persons having elevated risk of cardiovascular events or stroke, renoprotection, e.g. in renal failure or diabetic nephropathy, left ventricular hypertrophy, vascular thickening, e.g. prevention of thickening of blood vessel walls after vascular operations, prevention of arterial re-stenosis after angioplasty, prevention or treatment of

atherosclerosis, prevention of diabetic angiopathy, ischaemic peripheral circulatory disorders, myocardial ischaemia (angina), prevention of the progression of cardiac insufficiency after myocardial infarction, obstructive airways diseases, chronic obstructive pulmonary disease, e.g. bronchitis or chronic bronchitis, emphysema, likewise from asthma, cystic fibrosis, interstitial lung disease, lung cancer, pulmonary vascular disease, and increased resistance to airflow during forced expiration, adults respiratory distress syndrome (ARDS), reducing the proliferative capacity of the epithelium in lung and breast cancer, the treatment of sepsis syndrome, lung injury forms, such as pneumonia aspiration of gastric content, chest trauma, shock, burns, fat embolia, cardiopulmonary bypass, O₂ toxicity, haemorrhagic pancreatitis, interstitial and bronchoalveolar inflammation, proliferation of epithelial and interstitial cells, collagen accumulation or fibrosis" (page 7, line 3 to page 8, line 4).

However, according to the objection raised by the Examining Division in its decision and during the whole examination procedure (paragraph 14 of the decision), "there is no evidence, i.e. no examples or experimental data, in the present application supporting the use of any medicament(s) (including telmisartan/ ACE inhibitor) to treat any disease(s) (including fibrosis)".

The grounds of appeal are also silent in that respect.

Accordingly, in the absence of any data in the application as filed and of any submission showing that

the claimed effect in relation to the treatment of fibrosis was plausibly achieved, starting from document (1), the technical problem to be solved can only be defined as the provision of further pharmaceutical compositions containing an ACE inhibitor and an ANG II receptor antagonist.

The proposed solution is the subject-matter of independent claim 1, namely a pharmaceutical composition comprising the ANG II antagonist telmisartan and the ACE inhibitor ramipril.

The Board is satisfied that this problem is plausibly solved.

The question to be answered is thus whether the proposed solution, i.e. a pharmaceutical composition comprising the ANG II antagonist telmisartan and the ACE inhibitor ramipril, is obvious to the skilled person faced with the problem defined above in the light of the available prior art documents.

In that respect, document (1) teaches pharmaceutical compositions comprising ACE inhibitors and ANG II receptors. Moreover, ramipril is mentioned among the list of possible ACE inhibitors and telimsartan is mentioned among the list of possible ANG II receptors (page 4, lines 24 to 33; claims 7, 8, 19 and 20, and page 5, line 6 and 17; claims 9, 10, 21 and 22).

Accordingly, the skilled person could arrive at the claimed compositions without inventive activity by merely following the teaching of document (1).

It follows, that, contrary to the requirement of Article 56 EPC, the subject-matter of claim 6 lacks an inventive step.

2.2.2 In its grounds of appeal, the appellant did not consider the point raised in the Examining Division decision that the application as filed did not provide any element rendering the claimed effect plausible, which in the present case leads to the rejection of the application.

In its communication dated 03 April 2009, the Board again drew the appellant's attention to this objection and to its possible consequences in terms of the rejection of the application.

Again, the appellant did not react to this objection.

Under these circumstances, as the application does not contain any evidence that a novel effect is achieved by the claimed combination and in the absence of any submissions in that respect, the Board concludes that the subject-matter of claim 6 lacks an inventive step as required by Article 56 EPC for the reasons given above.

Under these circumstances, there is no need to consider the remaining claims.

For the sake of completeness, the Board wishes however to indicate that, as explained in its communication dated 03 April 2009, the use claims would also have to be rejected in the absence of plausible evidence of any new effect.

3. Auxiliary request

As product claim 6 is still present in the auxiliary request, the above also applies to this set of claims, which must therefore also be rejected for lack of inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

N. Maslin

U. Oswald