

Internal distribution code:

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

**Datasheet for the decision
of 24 February 2020**

Case Number: T 0641/18 - 3.3.01

Application Number: 14191084.4

Publication Number: 2845594

IPC: A61K31/5377, A61K31/515,
A61P25/08, A61P25/22

Language of the proceedings: EN

Title of invention:
Use of dihydroimidazolones for the treatment of dogs

Applicant:
Boehringer Ingelheim Vetmedica GmbH

Headword:
Dihydroimidazolones for treating dogs / BOEHRINGER

Relevant legal provisions:
EPC Art. 56

Keyword:
Main request - Inventive step - (yes)



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0641/18 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 24 February 2020

Appellant: Boehringer Ingelheim Vetmedica GmbH
(Applicant) Binger Strasse 173
55216 Ingelheim am Rhein (DE)

Representative: Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München (DE)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 6 October 2017
refusing European patent application No.
14191084.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman A. Lindner
Members: S. Albrecht
R. Romandini

Summary of Facts and Submissions

- I. The appeal of the applicant ("the appellant") lies against the decision of the examining division to refuse European patent application No. 14191084.4. This application is a divisional application of earlier European patent application No. 08167818.7 ("earlier application"), which itself is a divisional application of European patent application No. 03757945.5 ("earliest application").
- II. The decision of the examining division was based on a main request and eight auxiliary requests, identified in the decision as auxiliary requests I to VIII, respectively. The main request and auxiliary requests I to III were filed electronically on 7 September 2015, whereas auxiliary requests IV to VIII were filed during oral proceedings before the examining division on 22 September 2017.
- III. The documents cited in the examination proceedings include the following:
- D3: A. Rostock et al., *Drugs of the Future*, 1998, 23(3): 253-255
- D5: C. Belzung et al., *Behavioural Brain Research*, 2001, 125: 141-149
- D15: Experimental report by Boehringer Ingelheim with the title "Case series study concerning the use of imepitoin for the treatment of anxiety related problems in dogs" (three pages in total)
- IV. In its decision, the examining division concluded, *inter alia*, that the claimed subject-matter of all

requests lacked an inventive step starting from D3 as the closest prior art.

- V. With its statement setting out the grounds of appeal, the appellant filed six sets of amended claims as its main and first to fifth auxiliary requests, respectively.

Claim 1 of the main request reads as follows:

"Use of 1-(4-Chlorophenyl)-4-(4-morpholinyl)-2,5-dihydro-1 H-imidazol-2-one or a physiologically acceptable salt thereof as an active ingredient for the manufacture of a medicament for the treatment of behavioral abnormalities, which is anxiety, in dogs."

With its statement setting out the grounds of appeal, the appellant also submitted the following documents:

D16: Excerpt from AMIS Data base concerning Selgian®
D17: Excerpt from the FDA documentation of Clomicalm®
D18: Expert declaration by O. Engel

- VI. In a communication pursuant to Article 15(1) RPBA 2007, the board expressed its preliminary opinion on all requests on file.
- VII. Oral proceedings were held before the board on 24 February 2020 in the presence of the appellant. At the end of the oral proceedings, the chairman announced the board's decision.

VIII. The appellant's arguments, as far as they are relevant to the present decision, can be summarised as follows:

Document D3 constituted a less suitable starting point for the assessment of inventive step than documents D16 and D17. However, even if D3 were to be taken as the closest prior art, it nonetheless did not render the claimed subject-matter obvious, neither by itself nor in combination with any other prior-art document on file. D3 solely disclosed animal models of 'normal' or 'state' anxiety, i.e. a developmentally normative or stress-induced transient anxiety experienced by healthy animals in response to a threatening stimulus. By contrast, the claimed invention aimed to treat pathological anxiety-related behavioural abnormalities in dogs. As it was known for instance from document D5 that normal anxiety and pathological anxiety were unrelated and not released by the same treatment, the skilled person would not have had any expectation that 1-(4-Chlorophenyl)-4-(4-morpholinyl)-2,5-dihydro-1H-imidazol-2-one or a physiologically acceptable salt thereof ("imepitoin") could successfully treat the claimed disorders in dogs. Accordingly, an inventive step had to be acknowledged.

IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request submitted with the statement setting out the grounds of appeal or, as an auxiliary measure, on the basis of one of the sets of claims of auxiliary requests 1 to 5 filed with the same statement.

Reasons for the Decision

Admittance of documents D16 to D18 and the appellant's main and auxiliary requests 1 to 5, all filed with its statement setting out the grounds of appeal

1. The board does not see any reason in exercising its discretion to hold these documents and requests inadmissible pursuant to Article 12(4) RPBA 2007. Accordingly, D16 to D18 and the main and auxiliary requests 1 to 5 form part of the appeal proceedings pursuant to Article 12(1) RPBA 2007.

Main request

2. Amendments (Article 76(1) EPC and Article 123(2) EPC)

The board is satisfied that the claims of the main request find a basis in both the earlier and the earliest application as filed as well as in the present application as filed. Accordingly, the main request complies with both Article 76(1) EPC and Article 123(2) EPC.

3. Novelty - Article 54 EPC

In its decision, the examining division considered the subject-matter of the main and auxiliary requests filed before it to be novel over the cited prior art. In the board's judgement, this also holds for the present claims. Accordingly, the main request fulfils the requirements of Article 54 EPC.

4. Inventive step - Article 56 EPC

The closest prior art

- 4.1 According to the established case law of the Boards of Appeal, the closest prior art for assessing inventive step is generally a prior art conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural and functional modifications.
- 4.2 In the present case, the board agrees with the appellant that the purpose of the claimed invention is to reduce disproportionately elevated levels of state anxiety in dogs afflicted with pathological anxiety.
- 4.3 In the decision under appeal, the examining division identified document D3 as the closest prior art.
- 4.3.1 This document discloses the anxiolytic effects of AWD 131-138 (i.e. imepitoin) in healthy rats subjected to three different tests, i.e. the Vogel conflict test, the elevated plus maze test and the light-dark box test (see page 253, right column, the first two paragraphs). These tests are known models of state anxiety (see D5, page 143, table 1). Hence, the technical effect by means of which imepitoin exerts its anxiolytic activity in D3 is a reduction of the animals' elevated state anxiety levels. Since this effect corresponds, in qualitative terms, to the technical effect underlying the claimed invention (see point 4.2 above), D3 represents, in the board's view, a suitable starting point for the assessment of inventive step.

4.3.2 As for documents D16 and D17, identified by the appellant as the closest prior art in its statement setting out the grounds of appeal, the board notes the following.

These documents pertain to the treatment of the claimed patient group, that is dogs suffering from pathological anxiety by means of two approved and commercially available drugs (i.e. Selgian® in D16 and Clomicalm® in D17). Nevertheless, these two active agents are neither structurally related to imepitoin, nor do they involve the same or a similar mechanism of action. For these reasons, the board considers these documents to be less suitable starting points for the discussion of inventive step than D3. Accordingly, D3 represents the closest prior art.

4.4 The subject-matter of claim 1 differs from D3 in terms of the medical use, i.e. the treatment of anxiety-related behavioural abnormalities in dogs.

Objective technical problem and solution

4.5 In agreement with the appellant, the board considers that the objective technical problem to be solved by the claimed invention starting from D3 is the provision of means to reduce disproportionately elevated state anxiety levels in dogs afflicted with pathological anxiety.

4.6 In light of the disclosure of paragraph 0009 of the present application as published and the experimental data reported in document D15, the board is satisfied that this problem is credibly solved by means of imepitoin as claimed.

Obviousness

- 4.7 It remains to be established whether the claimed subject-matter is rendered obvious by the relevant prior art. In this regard, the board observes the following.
- 4.7.1 The animal models disclosed in D3 are well known in the art, as attested by document D5 (see page 143, right column, first paragraph and table 1). This document is a review article on the measuring of normal and pathological anxiety-like behaviour. It teaches that the animal tests of D3 are animal models of 'normal' or 'state' anxiety that do not involve any pathological anxiety-related behaviours (see page 143, left column, last paragraph). It further reports that normal anxiety and 'pathological anxiety' are two different types of anxiety that are not released by the same treatment (see page 143, left column, chapter 4).
- 4.7.2 Against this background, the board considers that the skilled person would not have envisaged that imepitoin could effectively treat dogs afflicted with anxiety-related behavioural abnormalities characterised by disproportionately increased state anxiety levels. Accordingly, the claimed subject-matter involves an inventive step pursuant to Article 56 EPC.

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 with the order to grant a patent on the basis of the claims of the main request filed with the statement setting out the grounds of appeal dated 14 February 2018 and a description to be adapted thereto.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated