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**Datasheet for the decision  
of 8 April 2020**

**Case Number:** T 2214/18 - 3.3.07

**Application Number:** 14166070.4

**Publication Number:** 2762145

**IPC:** A61K33/36, A61P35/00, A61P29/00

**Language of the proceedings:** EN

**Title of invention:**  
Sodium meta arsenite for use in the treatment of pain and/or  
inflammation associated with cancer

**Applicant:**  
Kominox, Inc.

**Headword:**  
Treatment of inflammation / KOMINOX

**Relevant legal provisions:**  
EPC Art. 83

**Keyword:**  
Sufficiency of disclosure - (no)



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Case Number: T 2214/18 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 8 April 2020**

**Appellant:** Kominox, Inc.  
(Applicant) 1 Cayman Financial Centre  
36A Dr Roy's Drive  
George Town, Grand Cayman KY1-1104 (KY)

**Representative:** EIP  
Fairfax House  
15 Fulwood Place  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted on 27 March 2018  
refusing European patent application No.  
14166070.4 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman** A. Uselli  
**Members:** E. Duval  
C. Schmidt

## Summary of Facts and Submissions

- I. The appeal was filed by the appellant (applicant) against the decision of the examining division to refuse the European patent application No 14166070.4 (hereinafter "the application").

The decision was based on the main request and auxiliary requests 1 and 2 filed by letter dated 17 October 2016, and on auxiliary request 3 filed during the oral proceedings before the examining division. In each request, claim 1 pertained to sodium meta arsenite for use in a treatment of inflammation, which treatment was further defined by a dosage regimen.

- II. The examining division decided that:

- (a) Neither the main request nor auxiliary request 1 complied with the requirements of Article 76(1) EPC.
- (b) Auxiliary request 2 did not meet the requirements of Article 56 EPC.

In an *obiter dictum*, the opposition division considered that the claimed use of sodium meta arsenite for treating inflammation was not demonstrated by the data relating to prostate selective antigen (PSA) levels in the application. As a consequence, auxiliary request 2 did not meet the requirements of Article 83 EPC.

- (c) Auxiliary request 3 was found to infringe Articles 123(2) and 76(1) EPC.

III. With the statement of grounds of appeal, the appellant filed a main request and auxiliary requests 1 and 2, and provided arguments regarding added subject-matter, inventive step and sufficiency of disclosure.

Claim 1 of both the main request and auxiliary request 1 is identical to claim 1 of the main request filed before the examining division and reads as follows:

"Sodium meta arsenite for use in the treatment of inflammation in a mammal having cancer, wherein said treatment comprises the administration of from 0.01 to 50mg of sodium meta-arsenite per kilogram of body weight per day."

Claim 1 of auxiliary request 2 is identical to claim 1 of auxiliary request 2 filed before the examining division and reads as follows:

"Sodium meta arsenite for use in the treatment of inflammation, wherein said treatment comprises the administration of from 0.01 to 50mg of sodium meta-arsenite per kilogram of body weight per day."

IV. The Board summoned the appellant to oral proceedings.

In a communication pursuant to Article 15(1) RPBA issued on 19 November 2019, the Board gave its preliminary opinion regarding the issues of added subject-matter (Articles 76(1) and 123(2) EPC) as well as inventive step. In relation with the issue of sufficiency of disclosure, the Board pointed out that the application contained no data explicitly related to the claimed therapeutic application against inflammation.

By letter dated 5 March 2020, the appellant announced that it would not attend the scheduled oral proceedings. The appellant made no further submissions regarding the issues identified in the Board's communication.

The oral proceedings were cancelled.

- V. The appellant's arguments regarding sufficiency of disclosure can be summarised as follows:

The application demonstrated that the treatment with sodium meta-arsenite could not only reduce tumour size, but also reduce PSA levels even in the absence of a reduction in tumour size. This could be seen in Example 2 of the specification, in which a patient suffering from advanced prostate cancer was treated with three different dosage amounts of sodium meta arsenite. As set out in the final paragraph of page 52, at dose levels 1 and 3, both PSA level and tumour activity were decreased. However, at dose level 5 there was a significant decrease in PSA, but no significant change in tumour activity. A similar result was obtained for the prostate cancer patient of Example 4. These results therefore clearly demonstrated that the effect on PSA levels was achieved even in the absence of an effect on tumour size.

This data showing a reduction in PSA levels demonstrated a effect on inflammation, and was not indicative of a condition other than inflammation. This is because this data was obtained during clinical trials on human patients, where the presence of any other condition (such as benign prostatic hypertrophy) would have been controlled for and noted.

Hence, the examining division's *obiter dictum* comments on Article 83 EPC were without basis.

- VI. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, on the basis of one of auxiliary requests 1 and 2, all filed with the statement of grounds of appeal.

### **Reasons for the Decision**

1. Sufficiency of disclosure, all requests
- 1.1 Claim 1 of the main request relates to sodium meta arsenite for use in the treatment of inflammation in a mammal having cancer, which treatment is further defined by a dosage regimen. The therapeutic application against inflammation is thus a functional feature of claim 1. For this medical use claim to fulfil the requirements of Article 83 EPC, the application must disclose the suitability of sodium meta arsenite for the claimed therapeutic application.
- 1.2 However, the application contains no data explicitly related to inflammation.

The application contains data showing an effect of sodium meta arsenite on prostate selective antigen (PSA) levels in patients. It is not indicated that the patients which were subjected to the tests suffered from any inflammatory condition. PSA is a marker commonly related not only to prostate cancer but also to prostatic inflammation and benign prostatic

hypertrophy. In the context of the present application, PSA is explicitly used as a tumour marker (see page 48). The appellant argues that, since the data in the application were obtained during clinical trials on human patients, the presence of any other condition would have been controlled for and noted. However, in the Board's view, since the tests were explicitly conducted in order to test the anti-cancer activity, and no observation is made as to the improvement of other conditions, such an argument rather contradicts a relevance to inflammation.

- 1.3 The appellant further pointed out that the treatment with sodium meta-arsenite led to an effect on PSA levels even in the absence of an effect on tumour size. The Board fails to see how the absence of activity on tumour could be seen as a demonstration of an activity on inflammation. The passages cited by the applicant (examples 2 and 4) relate to only 2 particular cancer patients, none of which are said to suffer from inflammatory conditions, and report PSA level variations of debatable significance. The Board finds that this data cannot lead to any meaningful conclusion as to an activity of sodium meta-arsenite on inflammation.
- 1.4 Since the application does not disclose the suitability of sodium meta arsenite for the claimed therapeutic application against inflammation, the main request does not fulfil the requirements of Article 83 EPC.
- 1.5 Claim 1 of the auxiliary requests 1 is identical to claim 1 of the main request. Auxiliary request 1 thus fails for the same reason.

1.6 Claim 1 of auxiliary request 2 does not contain the feature that the treatment occurs in a mammal having cancer, but still relates to sodium meta arsenite for use in the treatment of inflammation. Therefore the conclusion as to insufficiency of disclosure also applies to this request.

## Order

### **For these reasons it is decided that:**

The appeal is dismissed

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated