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**Datasheet for the decision of 2 April 2020**

**Case Number:** T 1959/15 - 3.3.01

**Application Number:** 06772386.6

**Publication Number:** 1904050

**IPC:** A61K31/185, A61K31/336, C12N15/113, A61K45/06

**Language of the proceedings:** EN

**Title of invention:**
USE OF CIS-EPOXYEICOSATRIENOIC ACIDS AND INHIBITORS OF SOLUBLE EPOXIDE HYDROLASE TO REDUCE CARDIOMYOPATHY

**Patent Proprietor:**
The Regents of the University of California

**Opponent:**
Bayer Intellectual Property GmbH /
Bayer Pharma Aktiengesellschaft

**Headword:**
Inhibitors of epoxide hydrolase for cardiomyopathy/THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

**Relevant legal provisions:**
EPC R. 84(1)
EPC Art. 100(b), 113(1)

**Keyword:**
Lapse of patent in all designated states - continuation of appeal proceedings (yes)
Grounds for opposition - insufficiency of disclosure (yes)
Right to be heard - opportunity to comment (yes)

**Decisions cited:**
T 0409/91, T 0435/91, T 1063/06, T 0852/09, T 0155/08

**Catchword:**

Europäisches Patentamt
European Patent Office
Office européen des brevets

**Beschwerdekammern**

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**Case Number: T 1959/15 - 3.3.01**

# D E C I S I O N
# of Technical Board of Appeal 3.3.01
# of 2 April 2020

| | |
|---|---|
| **Appellants:** (Opponents) | Bayer Intellectual Property GmbH<br>Alfred-Nobel-Strasse 10<br>40789 Monheim (DE)<br><br>Bayer Pharma Aktiengesellschaft<br>Müllerstrasse 178<br>13353 Berlin (DE) |
| **Representative:** | Hoffmann Eitle<br>Patent- und Rechtsanwälte PartmbB<br>Arabellastraße 30<br>81925 München (DE) |
| **Respondent:** (Patent Proprietor) | The Regents of the University of California<br>1111 Franklin Street, 12th Floor<br>Oakland, CA 94607 (US) |
| **Representative:** | J A Kemp<br>14 South Square<br>Gray's Inn<br>London WC1R 5JJ (GB) |
| **Decision under appeal:** | **Decision of the Opposition Division of the European Patent Office posted on 3 August 2015 rejecting the opposition filed against European patent No. 1904050 pursuant to Article 101(2) EPC** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | A. Lindner |
| **Members:** | T. Sommerfeld |
| | M. Blasi |

## Summary of Facts and Submissions

I. European patent 1 904 050 is based on application 06772386.6, which was filed as an international application published as WO 2006/133257. The patent is entitled "Use of cis-epoxyeicosatrienoic acids and inhibitors of soluble epoxide hydrolase to reduce cardiomyopathy" and was granted with 25 claims.

Claim 1 as granted reads as follows:

"1. An agent or agents selected from the group consisting of an inhibitor of soluble epoxide hydrolase ("sEH"), and a combination of a cis-epoxyeicosantrienoic acid ("EET") and an inhibitor of sEH, for use in inhibiting cardiomyopathy in a subject in need thereof, by administering to said subject an effective amount of said agent or agents and thereby inhibiting cardiomyopathy in said subject."

II. The granted patent was opposed, the joint opponents requesting revocation of the patent in its entirety on the grounds of lack of inventive step (Article 56 EPC and Article 100(a) EPC), insufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

III. The joint opponents (appellants) appealed against the decision of the opposition division to reject the opposition under Article 101(2) EPC.

IV. In the statement of grounds of appeal, the appellants requested that the decision of the opposition division be set aside and that the patent be revoked in its entirety on the grounds that the patent did not

disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

V. The patent proprietor (respondent) did not reply to the grounds of appeal.

VI. By letter dated 10 August 2016, filed in reply to the board's communication dated 28 July 2016, the appellants requested that the appeal proceedings be continued despite the patent having lapsed in all designated contracting states. They maintained their requests submitted with the statement of grounds of appeal.

VII. The appellants' submissions, in so far as they are relevant to the present decision, may be summarised as follows:

Claim 1 was drafted in the form of a "reach-through claim" in which the therapeutic agent was defined merely by functional features. There were many possible levels of soluble epoxide hydrolase inhibition, and the possible compounds thus falling under the definition of sEH inhibitors had no structural feature or mechanism of action in common. Thus, the knowledge derived from one class of "inhibitor" could not be used to find a different class of inhibitor. Moreover, the patent provided data for only two compounds, AUDA-BE and 950, two urea derivatives which were substantially similar in structure, and it was not possible to derive any general concept from them. The same conclusions had been reached in decisions T 852/09 ("enhancer") and T 155/08 ("inhibitor of an IMP dehydrogenase").

VIII. The appellants requested in writing that the decision under appeal be set aside and that the patent be revoked in its entirety.

There are no requests on file from the respondent.

## Reasons for the Decision

1. The appeal is admissible.

2. The European patent in suit has lapsed for all the designated contracting states. Under Rule 84(1) EPC, which is applied *mutatis mutandis* in opposition appeal proceedings pursuant to Rule 100(1) EPC, the opposition appeal proceedings may be continued at the request of the appellant-opponent filed within two months of a communication from the board informing it of the lapse.

In the reply to the communication of the board informing them of the lapse, the appellant-opponents requested, within the set time limit of two months, continuation of the appeal proceedings and confirmed their requests that the decision under appeal be set aside and that the patent in suit be revoked. Having regard to the legitimate interest of the appellant-opponents in attempting to reverse the decision of the opposition division rejecting the opposition and to the circumstance that the board's decision on the patent has an *ex tunc* effect under Article 68 EPC, the board, exercising its discretion under Rule 84(1) EPC, decided to continue the appeal proceedings.

3. Extent of the appeal

3.1 According to Rule 99(2) EPC, in the statement of grounds of appeal the appellants must indicate the

reasons for setting aside the decision impugned, or the extent to which it is to be amended, and the facts and evidence on which the appeal is based.

3.2 In the appealed decision, the opposition division came to the conclusion that none of the grounds for opposition raised by the opponents (Article 100(a), (b) and (c) EPC) prejudiced the maintenance of the patent as granted. Therefore, it rejected the opposition. In the statement of grounds of appeal, the appellants requested that the decision be set aside and the patent revoked in its entirety "because the claimed subject matter does not meet the requirements of Article 83 EPC / Article 100b EPC". However, it provided arguments against the findings of the opposition division pursuant to Article 100(b) EPC only in relation to claim 1. Hence, the board concludes that the appeal contests the decision of the opposition division only to the extent that it found that the invention as defined by granted claim 1 was sufficiently disclosed (Article 100(b) EPC). This is thus the extent of the appeal.

4. Article 100(b) EPC

4.1 Article 100(b) EPC stipulates that opposition may be filed on the ground that the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. It is the established jurisprudence of the boards of appeal that the requirement of sufficiency of disclosure is met only if the invention as defined in the independent claims can be performed by a skilled person within the entire scope claimed without undue burden, using common general knowledge and having regard to further information given in the

application (see e.g. T 409/91, OJ EPO 1994, 653, Reasons 3.5; T 435/91, OJ EPO 1995, 188, Reasons 2.2.1).

4.2 Granted claim 1 is a second medical use claim in the format of a purpose-restricted product claim pursuant to Article 54(5) EPC. According to Article 54(5) EPC, patentability is not excluded for substances or compositions comprised in the state of the art for a specific use in a method referred to in Article 53(c) EPC, provided that such use is not comprised in the state of the art. When a technical effect (which, in the case of a second medical use claim, is the therapeutic effect) is a feature of a claim, whether this effect is achieved by substantially all embodiments covered by the claim is a question of sufficiency of disclosure. Hence, because the subject-matter of second medical use claims is commonly limited to a known therapeutic agent for use in a new therapeutic application, it is usually only necessary that the patent renders it plausible that the known therapeutic agent (i.e. the product) is suitable for the claimed therapeutic application (i.e. the purpose: the technical effect).

4.3 In the present case, the therapeutic agent to be used is defined as consisting of or comprising "an inhibitor of soluble epoxide hydrolase" ("sEH"), while the therapeutic application is for "inhibiting cardiomyopathy" (for the exact wording of the claim, see section I above). Hence, the therapeutic agent includes known compounds, such as "compound 950" and "AUDA-BE", which are used in the examples of the patent, but also unknown compounds which are solely defined by the functional property of being able to inhibit sEH. Because not all possible therapeutic

agents falling within the scope of the claim are known, it is necessary to examine whether they are sufficiently disclosed in the patent.

4.4 The board agrees with the appellants that the designation "inhibitor of soluble epoxide hydrolase" indeed encompasses a myriad of possible compounds which need not have more in common than the ability to inhibit (at different possible levels) the soluble epoxide hydrolase enzyme. They can be structurally very distinct – examples being synthetic compounds, antibodies, nucleic acids and nucleic acid binding factors – and the only definition given in the patent is a functional one: that they should be able to inhibit soluble epoxide hydrolase. Although means for identifying such compounds may be readily available as they require just testing this functional feature, the skilled person would still have to resort to trial-and-error experimentation on arbitrarily selected chemical compounds to establish whether they possess the capability according to the claim. This represents an invitation to perform a research programme and thus is an undue burden (see also decisions T 1063/06, OJ EPO 2009, 516, Headnote 2; T 852/09, Reasons 10 to 12; T 155/08, Reasons 5 and 6).

4.5 Hence, for this reason alone, the board considers that granted claim 1 relates to subject-matter which is not sufficiently disclosed in the patent and, thus, Article 100(b) EPC prejudices maintenance of the patent.

4.6 In addition, the board agrees with the appellants' argument that, because the patent only shows an effect on cardiomyopathy for two exemplary compounds having the desired capability, these two compounds being

structurally very similar, it is not plausible that all possible (structurally distinct) compounds having this capability will have the same effect. It cannot be concluded from the experimental examples of the patent that the observed effect is linked to this common functional property of the two compounds. Since they are structurally similar, it is likely that they have other common properties, even unrelated to sEH, which could instead be responsible for the effect. Therefore, the board concludes that it is not plausible that all possible compounds falling within the functional definition of the claim are suitable for the claimed medical application. Hence, also for this reason, granted claim 1 encompasses subject-matter which is not sufficiently disclosed in the patent.

4.7 In the appealed decision, the opposition division came to the conclusion that the requirements of sufficiency of disclosure were fulfilled. Essentially, the opposition division considered that the claims were not to be considered "reach-through" claims as set out in decision T 1063/06 because they did not relate to a new screening method, a new mechanism of action or compounds identified for the first time via the use of a new screening method. The patent identified a large number of such inhibitors and also provided numerous references to documents disclosing appropriate compounds. Moreover, it disclosed that compounds could be tested for inhibition of sEH activity using standard assays. Finally, the appellants had not provided any example of a compound falling within the scope of the claim which was not effective.

4.8 The board is not convinced by these arguments. As correctly pointed out by the opposition division, the patent provides a list of a number of known compounds

fulfilling the functional requirements (e.g. paragraphs [0057] to [0066]). All these compounds which are structurally similar to and encompass "compound 950" and "AUDA-BE" (see point 4.3 above) may be considered sufficiently disclosed. However, claim 1 does not cover only such compounds but, as mentioned above, also any other possible compounds to be identified which present the designated functional property but no common structural characteristics that could serve as a selection rule.

4.9 As for the argument of the opposition division that the appellants had not provided any example of a compound falling within the scope of the claim which was not effective, the board notes the following. For second medical use claims, the burden is on the patent proprietor to demonstrate or at least render it plausible that the claimed technical effect (the therapeutic effect) is achieved. However, as set out above, the board considers that the experimental data of the patent, which show a therapeutic effect for two structurally related inhibitors of sEH in an animal model of cardiomyopathy, do not make it possible to conclude that there is a mechanism or effect that would apply to all possible, structurally distinct, inhibitors of sEH.

4.10 The invention defined in claim 1 as granted is thus not sufficiently disclosed. Consequently, the ground for opposition under Article 100(b) EPC prejudices the maintenance of the patent.

5. Right to be heard (Article 113(1) EPC)

5.1 During the whole appeal proceedings, the respondent has not made any submissions. Since there were no requests

from the respondent on file, let alone a request for oral proceedings, the board could take the present decision without the need to hold oral proceedings. The board made sure that the respondent was aware of the appeal by sending a communication, dated 27 March 2019, by registered letter with advice of delivery, in which it informed the parties that, in spite of the patent having lapsed in all designated contracting states, the appeal proceedings were being continued in view of the appellants' request.

5.2 The present decision is thus based on grounds and evidence put forward during the appeal proceedings and on which the parties have had an opportunity to comment. The provisions of Article 113(1) EPC, which govern the right to be heard, have been fulfilled since it was the respondent's own choice to remain silent during the whole appeal proceedings.

**Order**

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

1. The appealed decision is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated