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**Datasheet for the decision  
of 18 March 2014**

**Case Number:** T 0336/09 - 3.3.02

**Application Number:** 01900186.6

**Publication Number:** 1250138

**IPC:** A61K31/565, A61P35/00,  
A61K47/14, A61K47/44

**Language of the proceedings:** EN

**Title of invention:**  
FULVESTRANT FORMULATION

**Patent Proprietor:**  
AstraZeneca AB

**Opponent:**  
Gedeon Richter Ltd.

**Headword:**  
Fulvestrant formulation/ ASTRAZENECA

**Relevant legal provisions:**  
EPC Art. 114(2), 111(1)

**Keyword:**  
Late submitted material - document admitted (yes)  
Appeal decision - remittal to the department of first instance  
(yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern  
Boards of Appeal  
Chambres de recours**

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Case Number: T 0336/09 - 3.3.02

**D E C I S I O N  
of Technical Board of Appeal 3.3.02  
of 18 March 2014**

**Appellant:** Gedeon Richter Ltd.  
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**Respondent:** AstraZeneca AB  
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**Decision under appeal:** **Decision of the Opposition Division of the European Patent Office posted on 27 November 2008 rejecting the opposition filed against European patent No. 1250138 pursuant to Article 101(2) EPC.**

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** H. Kellner  
D. Rogers

## Summary of Facts and Submissions

- I. European patent No. 1 250 138 with application No. 01 900 186.6 based on international application PCT/GB2001/000049 and published as WO 2001/051056, was granted with 33 claims.

Independent claim 1 as granted reads as follows:

"A pharmaceutical formulation comprising fulvestrant in a ricinoleate vehicle, a pharmaceutically acceptable non-aqueous ester solvent, and a pharmaceutically acceptable alcohol wherein the formulation is adapted for intramuscular administration and attaining a therapeutically significant blood plasma fulvestrant concentration for at least 2 weeks."

- II. Opposition was filed against the granted patent. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step.

- III. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

D13 S. McLeskey et al., "Tamoxifen-resistant Fibroblast Growth Factor-transfected MCF-7 Cells Are Cross-Resistant in Vivo to the Antiestrogen ICI 182,780 and Two Aromatase Inhibitors", *Clinical Cancer Research* 4, 1998, 697-711

D14 *The Merck Index*, ninth Edition, 1976, pages 1294, 148, 31

D15 A. Howell et al., "Pharmacokinetics, pharmacological and anti-tumour effects of the

specific anti-oestrogen ICI 182780 in women with advanced breast cancer", British Journal of Cancer 74, 1996, 300-308

- D16 Third party observation filed 9 December 2011 and signed on 8 December 2011
- D17 Third party observation filed 11 April 2012 and signed on 11 April 2012
- D18 A. Howell et al., "Response to a specific antioestrogen (ICI 182780) in tamoxifen-resistant breast cancer", Lancet 345, 1995, 29-30
- D19 M. Dukes et al., "Antiuterotrophic effects of a pure antioestrogen, ICI 182,780: magnetic resonance imaging of the uterus in ovariectomized monkeys", Journal of Endocrinology 135, 1992, 239-247
- D20 M. Dukes et al., "Antiuterotrophic effects of the pure antioestrogen ICI 182,780 in adult female monkeys (Macaca nemestrina): quantitative magnetic resonance imaging", Journal of Endocrinology 138, 1993, 203-209
- D21 R. O'Regan et al., "Effects of the Antiestrogens Tamoxifen, Toremifene, and ICI 182,780 on Endometrial Cancer Growth", Journal of the National Cancer Institute 90, 1998, 1552-1558
- D22 Third party observation filed 24 January 2013 with letter dated 22 January 2013

- D23 A. Howell et al., "ICI 182,780 (Faslodex™)  
Development of a Novel, "Pure" Antiestrogen",  
American Cancer Society 89, 2000, 817-825
- D24 Revised version of Abstract 28, formerly published  
in Breast Cancer Research and Treatment 57, No. 1:  
J. Robertson et al., "THE ANTI-TUMOR EFFECTS OF  
SINGLE DOSE, LONG ACTING FASLODEX™ (ICI182780)  
COMPARED WITH TAMOXIFEN IN POST-MENOPAUSAL PRIMARY  
BREAST CANCER PATIENTS TREATED BEFORE SURGERY",  
Breast Cancer Research and Treatment 59, 2000, 99
- D25 Third party observation filed 31 January 2014
- D26 Handbook of Pharmaceutical Excipients, Second  
Edition, The Pharmaceutical Press London 1994,  
"Benzyl Benzoate" 38-39

IV. The appeal lies from the decision of the opposition  
division to reject the opposition, posted on  
27 November 2008.

The opposition division found that the subject-matter  
of the patent in suit was new and inventive.

It held that none of the grounds of opposition  
prejudiced the maintenance of the European patent and  
therefore rejected the opposition.

V. The opponent filed an appeal against that decision.

According to its statement of grounds of appeal it  
requested *inter alia* that

I.1 "... the decision under appeal will be set aside  
without substantive decision on its merits, and the

case will be remitted back to the Opposition Division ..." and that

I.2 "In view of this substantial procedural violation of the principle of Art. 113 EPC (right to be heard) ... the appeal fee shall be re-imbursed to the opponent pursuant to Rule 103(1)a EPC".

VI. The board's communication dated 15 January 2013, dispatched together with the summons for oral proceedings to be held on 12 April 2013, stated that the only issue that the board intended to discuss was the appellant's request to remit the case to the opposition division because of a substantial procedural violation and to reimburse the appeal fee.

VII. On 12 April 2013, the first oral proceedings took place before the board.

The appellant filed a document informing the board that it withdrew its "previous request to remit the case back to the first instance (opposition division) and all requests for reimbursement of the appeal fee".

Since all parties declared that there was nothing more to submit, the oral proceedings were closed.

VIII. Under cover of a letter dated 25 April 2013, the minutes of the first oral proceedings were dispatched.

IX. During the written proceedings, after the filing of the grounds of appeal, four third party observations were filed (9 December 2011; 11 April 2012; 24 January 2013 and 31 January 2014) including five documents. The appellant numbered the first three third party observations D16, D17, and D22, and adopted them as its

own. It also adopted the documents D13, D15, D23 and D24 cited therein. In addition, it filed four further documents itself. The last third party observation (numbered D25 by the board) and the document D26 cited therein were not adopted by the appellant.

- X. The respondent, on 27 August 2009, with its reply to the grounds of appeal requested that the appeal be dismissed and that the patent be maintained as granted. In addition, it submitted 9 auxiliary requests.

With its reply of 27 February 2012 to the third party observation of 8 December 2011, the respondent filed a reworded main request and 14 new auxiliary requests.

With letter of 11 February 2014, the respondent "consolidated and summarized" its requests. Firstly, it requested that the appeal be dismissed and that the patent be maintained as granted. In addition, it submitted 14 new auxiliary requests and explained that auxiliary requests 1 to 5 were based on auxiliary requests 3, 5, 6, 8 and 9 as submitted on 27 August 2009. It further stated that auxiliary requests 6 to 14 comprised amendments in view of appellant's submission dated 26 October 2012 and related to the main request and auxiliary requests 1 to 14 filed on 27 February 2012.

- XI. On 18 March 2014, the second oral proceedings took place before the board. The representative of the appellant was not present.

During these proceedings the board announced that it had come to the conclusion that documents D13 and D15 to D24 were admitted into the proceedings.



XII. The appellant's written submissions, as far as relevant for the present decision, may be summarised as follows:

Documents D13 and D15 to D24 were *prima facie* highly relevant and should for this reason alone be admitted into the proceedings. In particular, document D13, which inadvertently had not been located by earlier searches, anticipated at least the subject-matter of claim 1 of the main request. In document D13 the same composition was used as was disclosed in the only example of the contested patent which in fact represented the subject-matter of the claim - the appellant referred specifically to page 698 second column under the heading "Materials and Methods.-Drugs" of document D13 (see document D16, point 2.1). Since the composition used in document D13 was identical to the compositions claimed according to the patent in suit, it also exhibited the functional features of the claim. The other cited documents and arguments gained particular relevance in this context. Moreover, documents D15, D18 to D21, D23 and D24 had been submitted as a reaction to the amendments of the claims. Especially, documents D18 to D21 had been submitted to show that fulvestrant was normally administered in humans by intramuscular administration.

XIII. The respondent's submissions, as far as relevant for the present decision, may be summarised as follows:

Numerous documents, numbered D13 and D15 to D24, had been filed during the appeal proceedings after the submission of the grounds of appeal and must therefore be considered late filed. The purpose of an appeal was to review the correctness of the opposition division's decision, thus such late filed documents should not be

admitted into the proceedings, particularly as they changed the appellant's case.

Moreover, most of these documents were filed as anonymous third party observations and no reason was given for the late filing. In view of the jurisprudence of the boards, wherein anonymous third party observations were considered "deemed not to have been filed", these observations and the documents cited therein should not be admitted into the proceedings.

Concerning the relevance of these documents, it was not appropriate in the context of the question of the admissibility of these documents to comment upon their substantive content.

XIV. The appellant requested (in writing) that:

1. document D11 be admitted into the proceedings; and
2. the ground of opposition under Article 100(b) EPC be admitted into the proceedings; and
3. all third party observations filed anonymously during the appeal proceedings, i.e. documents D16, D17 and D22 be admitted into the proceedings; and
4. documents D13, D15, D18 to D21, D23 and D24, all filed during appeal proceedings, be admitted into the proceedings; and
5. the decision under appeal be set aside and the patent be revoked "unless the Board prefers to set aside the Opposition Division's decision and to remit the case to the Opposition Division as was initially requested under section I.1 and I.2 of our substantiation of the appeal of April 7, 2009" (see appellant's letter dated 31 January 2014).

XV. The respondent (patentee) requested that

1. all third party observations filed anonymously during the appeal proceedings, i.e. documents D16, D17, and D22, be disregarded; and
2. new documents D13, D15, D18 to D21, D23 and D24 be not admitted into the proceedings;  
or alternatively
3. the case be remitted to the opposition division, if the third party observations and the new documents were admitted into the proceedings;  
or as a further alternative
4. the appeal be dismissed and the patent be maintained in the form as granted or, alternatively, on the basis of one of the auxiliary requests 1 to 14 as submitted under cover of a letter dated 11 February 2014.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Appellant's request for remittal of the case to the department of first instance because of a substantial procedural violation and request for reimbursement of the appeal fee*

The appellant withdrew these requests during the first oral proceedings on 12 April 2013. The board sees no reason to assess the merits of these requests of its own motion.

3. *Admissibility of documents D13 and D15 to D24*
  - 3.1 Documents D13 and D15 to D24 have either been filed by the appellant himself or adopted by him from anonymous

third parties submissions all of which were made after the date of the filing of the statement of grounds of appeal. Therefore, all these documents are to be considered as late filed documents of the appellant. The jurisprudence of the boards of appeal dealing with the problem of anonymously filed third party observations is of no relevance.

- 3.2 Document D13, in view of the arguments submitted with document D16, in particular point 2.1, is found highly relevant with regard to the question of novelty of the subject-matter of claim 1 of the main request. This is because of the disclosure in document D13 at the right column of page 698. Due to this finding, the factual framework of the case has substantially changed. One of the results of this is that the disclosure of the further documents D15 and D17 to D24 becomes of relevance.

Therefore, the board admits all these documents (D13 and D15 to D24) into the proceedings.

4. *Remittal*

The opposition division decided on the maintenance of the patent as granted, without knowledge of document D13.

The consequence of the admission of documents D13 and D15 to D24 into the proceedings is the creation of a fresh case, entirely different from that originally before the opposition division.

Therefore, the board exercises its discretion under Article 111 EPC and remits the case to the opposition division for further prosecution.

5. *Requests of the appellant (in writing)*

There is a certain contradiction in the appellant's requests that could not be resolved at the oral proceedings of 18 March 2014 due to the non-attendance of the appellant. This contradiction is that at the first oral proceedings before the board on 12 April 2013, the appellant withdrew its requests for remittal to the department of first instance and for reimbursement of the appeal fee. In its letter of 31 January 2014, however, following the introduction "... unless the board prefers to ..." it nevertheless referred to these requests originally filed with the statement of grounds of appeal - see point 5 of paragraph XIV above.

Because of the wording "... unless the board prefers to ...", the board considers that the appellant's position is that it has no objections to the remittal of the case to the department of first instance.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. Documents D13 and D15 to D24 are admitted into the proceedings.
3. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:



N. Maslin

U. Oswald

Decision electronically authenticated