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Datasheet for the decision of 14 February 2013

Case Number: T 0108/09 - 3.3.02

Application Number: 01917289.9

Publication Number: 1272195

IPC: A61K 31/565, A61P 35/00

Language of the proceedings: EN

Title of invention:
Use of fulvestrant in the treatment of resistant breast cancer

Patent Proprietor:
AstraZeneca AB

Opponent:
Teva Pharmaceutical Industries Ltd.

Headword:
Fulvestrant for treating resistant breast cancer/ASTRA ZENECA AB

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)

Keyword:
"Added matter (no)"
"Sufficiency of disclosure, novelty and inventive step (yes)"

Decisions cited:
G 0005/83, G 0001/03, G 0002/08, T 0019/86, T 0893/90, T 0233/96, T 1319/04, T 1329/04, T 0425/09

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0108/09 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 14 February 2013

Appellant I: AstraZeneca AB
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 14 November 2008 concerning maintenance of European patent No. 1272195 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
R. Cramer

Summary of Facts and Submissions

I. European patent No. 1 272 195, based on application No. 01 917 289.9, was granted on the basis of 6 claims.

The sole independent claim 1 and dependent claim 2 read as follows:

"1. Use of fulvestrant in the preparation of a medicament for the treatment of a patient with breast cancer who previously has been treated with an aromatase inhibitor and tamoxifen and has failed with such previous treatment.

2. A use as claimed in claim 1 provided that the patient has not been prior treated for breast cancer with more than 2 different hormonal agents."

II. An opposition was filed against the patent. The patent was opposed under Article 100(a) EPC 1973 for lack of novelty and inventive step, for exclusion from patentability pursuant to Articles 52(2)(d) and 52(4) EPC 1973 and for lack of industrial application (Article 52(1) in conjunction with Article 57 EPC 1973), under Article 100(b) EPC 1973 for insufficiency of disclosure and under Article 100(c) EPC 1973 for amendments that contained subject-matter extending beyond the content of the application as filed.

III. The documents cited during the opposition and appeal proceedings included the following:

(2) M. Gale et al., Oncology Research (1997), vol. 9, 397-402

(3) A. Howell et al., The Breast (1996), vol. 5, 192-195

(6) Qing Lu et al., Breast Cancer Research and Treatment (1998), vol. 50, 63-71

(8) R.J. Santen et al., Endocrine-Related Cancer (1999), vol. 6, 75-92

(10) L. Perey et al., Annals of Oncology (2007), vol. 18, 64-69

IV. The appeal lies from a decision of the opposition division pronounced on 28 October 2008 and posted on 14 November 2008, finding that auxiliary request I met the requirements of the EPC.

V. Regarding the main request, the opposition division came to the conclusion that the ground for opposition according to Article 100(c) EPC 1973 prejudiced the maintenance of the patent, as the feature "that the patient has not been prior treated for breast cancer with more than two hormonal agents" in claim 2 extended beyond the content of the application as filed.

The subject-matter of auxiliary request I was found to meet the requirements of Articles 83, 54 and 56 EPC 1973. Moreover, the opposition division concluded that the claims were not excluded from patentability under Articles 52(2)(d) and 53(c) EPC and Article 57 EPC 1973.

The opposition division concluded that the feature "a patient with breast cancer who previously has been treated with an aromatase inhibitor and tamoxifen and has failed with such previous treatment" of claim 1 was not related to presentation of information but

constituted a technical feature so that auxiliary request I was not excluded from patentability by Article 52(2)(d) EPC. Moreover, the claims were drafted in the second medical use format according to decision G 05/83 (OJ EPO 1985, 64), wherein the feature "a patient with breast cancer who previously has been treated with an aromatase inhibitor and tamoxifen and has failed with such previous treatment" defined a patient group having a different pathological status. As a consequence, the subject-matter of auxiliary request I was not excluded from patentability by Article 53(c) EPC and met the requirements of Article 57 EPC 1973. Regarding the ground for opposition pursuant to Article 100(b) EPC 1973, the opposition division argued that it was sufficient to disclose the means intended to carry out the invention - in the present case the active agent (fulvestrant), the disease to be treated (breast cancer) and the specific patient subgroup (having failed treatment with aromatase inhibitor and tamoxifen) - in terms of technical terms which could be verified by the skilled person. The fact that there were several ways of testing the concept of "having failed a previous treatment" did not lead to insufficiency. It only made the claims broader. Taking into consideration that the feature "a patient with breast cancer who previously has been treated with an aromatase inhibitor and tamoxifen and has failed with such previous treatment" had a technical meaning, the subject-matter of auxiliary request was novel, as said feature was not disclosed in any of the cited prior-art documents. Regarding inventive step, the opposition division defined the provision of an effective third-line treatment as the problem to be solved over

document (6), which had been identified as closest prior art. The skilled person, faced with this problem, could certainly have considered the use of fulvestrant but had no incentive to do so, as there was no particular expectation of success and no hint leading him towards the solution proposed by the invention defined in auxiliary request I.

VI. The parties lodged an appeal against that decision.

VII. Oral proceedings were held on 14 February 2013.

VIII. The appellant-opponent's arguments can be summarised as follows:

Claim 2 as granted contained the undisclosed disclaimer "provided that the patient has not been prior treated for breast cancer with more than 2 different hormonal agents", which was not allowable under Article 123(2) EPC in the light of decision G 01/03 (OJ EPO 2004, 413). Furthermore, the switch from "comprising" to "consisting of" was not allowable. Reference was made to decision T 0425/09.

Regarding insufficiency, claim 1 concerned a second medical application in which the treatment constituted a functional technical feature of the claim. The patent in suit did not, however, contain any information how the failed pretreatment with the aromatase inhibitor and tamoxifen should be determined. Nor did it contain any examples showing that the claimed treatment was indeed successful. The detailed protocol for a clinical trial which might or might not be carried out in the future was not sufficient, as it did not contain any

results at all. Moreover, according to the passage on page 9, lines 28 to 31, of the patent in suit, the exclusion criteria of that protocol did not even mandatorily exclude tamoxifen. On the other hand, the third inclusion criterion on page 9, lines 5 to 7, had nothing to do with the method claimed in the claims as granted. Document (10) was post-published and therefore not suitable as a basis for sufficient disclosure.

Regarding novelty, reference was made to decision T 1319/04 (referral decision for decision G 02/08 (OJ EPO 2010, 456). If the answer to the first question was "no", there was lack of novelty over documents (2) and (3), which disclosed all the features of the claimed subject-matter except for the third-line treatment. However, even if the answer was "yes", the claimed subject-matter lacked novelty in the light of decisions T 0019/86 (OJ EPO 1989, 24), T 0893/90 and T 0233/96, which defined two separate requirements for a new patient group to establish novelty in a Swiss-type claim: firstly, the new group of patients had to be distinguished from the patients of the prior art by its physiological or pathological status and, secondly, the choice of said patient group could not be arbitrary, i.e. there had to be a functional relationship between the particular physiological or pathological status of these patients and the therapeutic or pharmacological effect achieved. The selected patient group that had failed with tamoxifen and the aromatase inhibitor did not have this functional relationship.

As far as inventive step was concerned, document (2), which identified fulvestrant or, alternatively, an

aromatase inhibitor as second-line agent after tamoxifen failure in patients suffering from breast cancer, constituted the closest prior art. The problem to be solved vis-à-vis document (2) could be defined as provision of a treatment for some patients who were resistant to tamoxifen and did not respond to an aromatase inhibitor. The subject-matter of the claims lacked an inventive step, as there was no evidence showing that this problem was solved. The patent itself did not contain any examples showing the desired effect. Regarding document (10), reference was made to decision T 1329/04, according to which post-published evidence could not serve as the sole basis to establish that the application did indeed solve the problem it purported to solve. Furthermore, there was lack of inventive step even if document (10) was taken into account, as the beneficial effects disclosed therein could not be clearly attributed to a patient group corresponding to the patient group defined in claim 1 as granted.

IX. The appellant-patentee's arguments can be summarised as follows:

The wording of claim 2 as granted was specifically disclosed on page 14, section 2.2(c) of the application as filed. Furthermore, claim 2 was dependent on claim 1, which meant that the two different hormonal agents mentioned therein were an aromatase inhibitor and tamoxifen according to claim 1. As a consequence, claim 2 only specified that the pretreatment according to claim 1 consisted of rather than comprised an aromatase inhibitor and tamoxifen.

Regarding insufficiency, it was not necessary for the patent in suit to contain a description of how the failed pretreatment with the aromatase inhibitor and tamoxifen should be determined, as said failure would be diagnosed by the doctor in charge of the treatment. With regard to the alleged absence of information concerning the success of the claimed method, paragraph [0019] of the contested patent contained clear instructions including mode of administration, amount of active agent to be delivered and dosage intervals. If the skilled person followed these instructions, he would obtain the desired results in a certain number of patients. As a consequence, the invention defined in the claims as granted was sufficiently disclosed.

The claimed subject-matter was novel, as neither document (2) nor document (3) disclosed the use of fulvestrant as third-line agent after failure of tamoxifen and aromatase inhibitors.

Regarding inventive step, the demonstration of the suitability of fulvestrant as third-line agent was not based solely on post-published evidence, as the patent in suit also contained detailed information concerning the mode of administration, treatment schedules and pharmaceutical formulations.

X. The appellant-patentee requested that the decision under appeal be set aside and that the patent be maintained as granted, or alternatively that the opponent's appeal be dismissed.

The appellant-opponent requested that the decision under appeal be set aside and that the European patent No. 1 272 195 be revoked.

Reasons for the Decision

1. The appeal is admissible.

2. Main request - claims as granted

2.1 Amendments

2.1.1 Claim 1

Claim 1 is based on claims 7 and 10 of the application as filed. Claim 7 of the application as filed comprises all the features of claim 1 as granted except for tamoxifen, which is replaced by the functional term SERM. Claim 10 of the application as filed is a dependent claim referring back to any of claims 7 to 9 and specifies that the SERM according to claim 7 is tamoxifen. As a consequence, claim 7 and 10 of the application as filed provide a basis for claim 1 as granted.

2.1.2 Claim 2

Claim 2 as granted refers back to claim 1 and therefore, being a dependent claim, comprises all the features thereof. As a consequence, the two different hormonal agents mentioned therein are not any hormonal agents but concern the aromatase inhibitor and the tamoxifen according to claim 1. Claim 2 therefore only

clarifies that the pretreatment of claim 1 consists of an aromatase inhibitor and tamoxifen, thereby excluding administration of any additional active agents. This is, however, what the skilled person would already have deduced from claim 1. Claims have to be read in a technically meaningful way. The skilled person would conclude from the passage "a patient with breast cancer who previously has been treated with an aromatase inhibitor and tamoxifen and has failed with such previous treatment" that said patient had been treated with an aromatase inhibitor and tamoxifen and nothing else. As a consequence, claim 2 does not change the content of claim 1. It is therefore superfluous, which in principle could be objected to under Article 84 EPC 1973, which, however, does not constitute a ground for opposition under Article 100 EPC 1973 and is therefore not applicable to the claims as granted.

Furthermore, it follows from the above reasoning that decisions G 01/03 and T 0425/09, cited by the appellant-opponent in this context, are not relevant for the present case.

As a consequence, the ground for opposition pursuant to Article 100(c) 1973 EPC does not prejudice the maintenance of the patent as granted.

2.2 Insufficiency

2.2.1 Determination of the failure of the pretreatment with an aromatase inhibitor and tamoxifen

The present claims concern the treatment of breast cancer which is under strict surveillance of a

physician who will decide which medicaments are given at which periods of the disease. The physician will also diagnose the failure of a treatment and then change the medication or apply other therapeutic means. Such diagnosis normally involves a thorough examination of the patient and therefore constitutes a decision of the physician based on the specific circumstances of the individual patient. As a consequence, it is not necessary for sufficiency that the patent discloses a general method for determining failure of the pretreatment with an aromatase inhibitor and tamoxifen.

2.2.2 Missing examples

The board concurs with the appellant-opponent that the sole example of the patent in suit, concerning a protocol for a clinical trial which may or may not be carried out in the future, does not put into practice the invention defined in the claims as granted and can therefore not serve as a basis for sufficient disclosure. However, the evaluation of sufficiency of disclosure takes account of the entire information to be found in the patent, including claims, description, examples and figures. Paragraph [0019] of the patent in suit contains detailed information regarding the administration of fulvestrant. The skilled person learns that especially preferred is 200-300mg fulvestrant given intramuscularly in a castor-oil-based formulation, preferably at intervals of at least one month. Most preferred is about 250mg fulvestrant given at approximately monthly intervals. The same paragraph indicates that doses should be administered so as to achieve blood serum levels of fulvestrant of from 5 to 20 mg/ml. The subsequent paragraph [0020] relates to

the composition of the pharmaceutical formulation and comprises specific indications as to the individual constituents and their preferred concentrations. As a consequence, the application as filed contains detailed information as to how the claimed invention should be put into practice. Under these circumstances, the skilled person does not need specific examples in order to carry out the invention.

2.2.3 The ground for opposition under Article 100(b) EPC 1973 therefore does not prejudice the maintenance of the patent.

2.3 Novelty

2.3.1 Document (2) discloses the use of fulvestrant (ICI 182,780) for the second-line treatment of breast cancer after tamoxifen failure (see summary). It therefore has to be determined whether or not the change from second-line treatment to third-line treatment, expressed in claim 1 as granted by the feature "who previously has been treated with an aromatase inhibitor and tamoxifen and has failed with such previous treatment", can establish novelty. In this context, it is noted that, as was correctly pointed out in the decision under appeal, this feature does not relate to the presentation of information (Article 52(2)(d) EPC) by merely describing the medical history of the patient but constitutes a technical feature. This can be deduced from document (2), according to which tamoxifen cannot cure breast cancer, as drug resistance will develop (see summary on page 397), which means that physiological changes in the tumour occur in the course of tamoxifen

administration. As a consequence, this feature has to be taken into consideration for the evaluation of novelty and inventive step.

According to decision G 02/08, Article 54(5) EPC does not exclude a medicament already known to be used in the treatment of an illness from being patented for use in a different treatment by therapy of the same illness. This finding applies *mutatis mutandis* to the Swiss-type claims of the patent in suit (see G 02/08, order). In point 5.10.7, G 02/08 also refers to "well-established case law" which includes decisions T 0019/86, T 0893/90 and T 0233/96, all of which pertain to a novel group of subjects treated and were relied on by the appellant-opponent. Although decision T 0233/96, by taking into consideration the jurisprudence created by T 0019/86 and T 0893/90, attempts to define general criteria which must be met for a particular group of subjects to establish novelty and/or inventive step in a Swiss-type claim (see T 0233/96, point 8.7), this board concludes that these three decisions relate to three different situations which have to be distinguished from one another.

(a) In decision T 0019/86, a new group of subjects (sero-positive piglets) was vaccinated against the same disease (Aujeszky's disease) against which vaccination had already been disclosed for sero-negative piglets. This means that in this case the group of subjects to be treated does indeed constitute the distinguishing feature over the prior art.

(b) Decision T 0893/90 concerns the use of a composition for controlling bleeding in non-hemophilic mammals as compared to the use of the same composition for controlling bleeding in hemophilic subjects. Here, unlike T 0019/86 where the disease according to the claims is identical to the disease defined in the prior art, the group of subjects (non-hemophilic mammals) serve to further define the disease or pathological symptoms to be treated (bleeding) and the disease or pathological symptom thus defined (non-hemophilic bleeding) is different from the disease of the prior art (hemophilic bleeding). As a consequence, T 0893/90 concerns the classical case in which the disease to be treated constitutes the distinguishing feature of a Swiss-type claim over the prior art.

(c) Decision T 0233/96 is of no importance to the present case. It concerns a diagnostic method for detecting the presence, or assessing the severity, of vascular disease of coronary arteries, for which novelty was denied as no functional relationship existed between the incapability of a patient to exercise adequately (group of subjects) and the pharmacological effect achieved by administration of the active agent in the diagnosis of various types of coronary disease (see point 8.8).

In the light of these decisions, and in particular in the light of decision T 0893/90, the board considers it appropriate to evaluate whether the breast cancer of claim 1 as granted is identical to the breast cancer

according to document (2). In the first paragraph of point 2.3.1, it has already been concluded that tamoxifen resistance leads to physiological changes in the tumour, which means that the tumour can be distinguished from the same tumour before tamoxifen resistance set in. It would stand to reason that the same development would be observed with the aromatase inhibitor. Resistance would set in after a certain period of time, leading to physiological changes in the tumour. However, the appellant-opponent contested this, pointing out that in some cases there was *de novo* resistance to aromatase inhibitors. Reference was made to document (10), which concerns a phase II clinical study of the clinical benefit of fulvestrant in post-menopausal women with advanced breast cancer. This study included in group B (see page 65, bottom of the left-hand column) patients who did not respond to aromatase inhibitor treatment and were therefore *de novo* resistant (see also the sentence bridging the left-hand and right-hand columns on page 64).

De novo resistance means that the tumour does not change during treatment with an aromatase inhibitor. In view of the existence of *de novo* resistance to aromatase inhibitors, it might be argued that the group of patients treated in document (2) inevitably included patients with *de novo* resistance to aromatase inhibitors. For these patients, fulvestrant would inadvertently be used as a third-line agent, so that there was lack of novelty with respect to this particular patient group. However, the board cannot agree with that argumentation. The fact that document (10) mentions patients with *de novo* resistance to aromatase inhibitors does not mean that this kind of

resistance is ubiquitous. As a consequence, document (2), which does not mention *de novo* resistance to aromatase inhibitors, does not implicitly disclose third-line treatment involving fulvestrant, so that the tumours of document (2), being only resistant to tamoxifen, can be distinguished from the tumours of claim 1 as granted, which are additionally resistant to an aromatase inhibitor. This distinction means that two different diseases or two subsets of a disease (tumour) are concerned, which in analogy to the findings in point 2.3.1 (b) above establishes novelty. The subject-matter of claim 1 as granted is therefore novel over document (2).

2.3.2 The reasoning of paragraph 2.3.1 above also applies to the novelty of claim 1 as granted vis-à-vis document (3), which also discloses the use of fulvestrant (ICI 182,780) for the second-line treatment of breast cancer after tamoxifen failure (see summary).

2.4 Inventive step

2.4.1 The present invention concerns the use of fulvestrant in the treatment of breast cancer in patients who have previously been treated with tamoxifen and an aromatase inhibitor (see paragraph [0001] of the patent in suit).

2.4.2 Document (2), mentioned in paragraph 2.3.1 above, discloses the use of fulvestrant for the second-line treatment of breast cancer after tamoxifen failure, and constitutes the closest prior art.

2.4.3 In view of this prior art, the problem to be solved can be defined as the provision of a method which allows

treatment of patients with breast cancer who have previously been treated with an aromatase inhibitor and with tamoxifen and have failed with such previous treatments.

2.4.4 The proposed solution to this problem concerns administration of fulvestrant for the third-line treatment.

2.4.5 Regarding the question whether the problem has been plausibly solved by the claimed subject-matter in its entirety, the appellant-patentee made reference to paragraphs [0019] and [0020] of the contested patent and to document (10).

As regards whether it is permissible to submit post-published evidence (document (10)) for demonstrating that alleged effects are indeed obtained, the board notes that the present case is different from the situation described in decision T 1329/04, which had been cited by the appellant-opponent in this context. In decision T 1329/04, there had been *prima facie* serious doubts that the polypeptide denominated GDF-9 belonged to the TGF-ß superfamily and thus solved the problem of the invention. The board then concluded that post-published evidence may in the proper circumstances also be taken into consideration, but may not serve as the sole basis to establish that the application does indeed solve the problem it purports to solve (see catchword). In the present case, however, it was already known that fulvestrant was effective as a second-line agent in the treatment of breast cancer (see points 2.3.1 and 2.3.2 above). Regarding the use of fulvestrant as a third-line agent, which constitutes

the contribution of the present invention to the state of the art, the patent in suit contains, as was mentioned above (see point 2.2.2 above) detailed information as to how fulvestrant has to be formulated and administered in order to obtain the desired effect. Document (10) is therefore far from being the only source of information regarding the question whether fulvestrant is useful as a third-line agent, so that the data contained therein may be used in the evaluation of whether or not the problem underlying the present invention has been plausibly solved.

Regarding the question whether the content of document (10) provides sufficient evidence for demonstrating that the problem has been plausibly solved, which was also contested by the appellant-opponent, the board notes the following: 54 of the 67 patients of group A (patients who had progressed during treatment with an aromatase inhibitor) had also received tamoxifen (see results on page 66). 30% of all 90 patients (70 of group A and 20 of group B), most of whom had also been exposed to tamoxifen, experienced a clinical benefit with fulvestrant (see last paragraph of the right-hand column on page 68). The data do not allow to determine the exact percentage of those patients with a clinical benefit who had progressed on treatment with an aromatase inhibitor and who had also received tamoxifen, but it can be concluded that they form a substantial part of the 30% mentioned above, which is sufficient to demonstrate the desired effect. Furthermore, the board wishes to emphasise that the exclusion criteria listed in the second paragraph of the section "patients" (see left-hand column on page 65) do not allow the conclusion that a clinical

benefit would be completely excluded for such patients, so that the problem was not plausibly solved in its entirety. Such criteria are primarily defined to exclude the desired effect being attributable to factors not related to the activity of fulvestrant.

Therefore, in view of the disclosure of paragraphs [0019] and [0020] of the contested patent and in view of the data of document (10), the board is satisfied that the above problem has been plausibly solved by the subject-matter of claim 1 as granted.

2.4.6 The following factors have to be taken into consideration for evaluating whether the use of fulvestrant as a third-line agent instead of a second-line agent is obvious:

(a) With each new resistance, the tumour becomes more "malignant" and more difficult to treat. As a consequence, it is by no means evident that an active agent which is effective in second-line treatment is suitable in third-line treatment.

(b) If the tumour is, as in the present case, resistant to an aromatase inhibitor and a partial estrogen agonist such as tamoxifen, the skilled person would tend to choose a third-line agent whose mechanism of action is different from that of a partial estrogen agonist and an aromatase inhibitor. Whether this would induce the skilled person to take into consideration a compound such as fulvestrant is, however, debatable in view of the fact that, despite the disclosure in paragraph [0010] of the patent in suit, according to which

fulvestrant has a novel mechanism of action, fulvestrant is not fundamentally different from tamoxifen as far as its mechanism of action is concerned. At the oral proceedings, both parties agreed that fulvestrant is a pure antiestrogen which, like tamoxifen, binds to the estrogen receptor, but which, unlike the partial estrogen agonist tamoxifen which stimulates the estrogen receptor less intensely than estrogen and thus reduces estrogen activity, completely inactivates the estrogen receptor. Binding at the same site, the difference between those two classes of agents appears to lie in the degree of estrogen inhibition rather than in a fundamentally different mechanism of action. In contrast thereto, the mechanism of an aromatase inhibitor which inhibits an enzyme involved in the biosynthesis of estrogen is fundamentally different from tamoxifen and fulvestrant. Therefore, a compound like fulvestrant would not constitute the first choice for the skilled person under these circumstances.

(c) The skilled person, trying to solve the problem defined in point 2.4.3 above, would consult documents mentioning third-line treatment such as document (8), where he would learn that a progestin rather than fulvestrant is a promising candidate for third-line treatment after failure of tamoxifen and an aromatase inhibitor (see section "Future perspectives" in the left-hand column of page 89).

For all these reasons, the skilled person has no incentive to select fulvestrant for solving the problem

defined in point 2.4.3 above. As a consequence, the requirements of Article 56 EPC 1973 are met.

2.4.7 In view of this finding, a discussion of the further documents cited by the parties is not necessary.

2.5 The further ground for opposition cited in the notice of opposition under Article 100(a) EPC 1973, namely the exclusion from patentability pursuant to Article 53(c) EPC (Article 52(4) EPC 1973), was not maintained in the appeal proceedings and is no longer relevant in view of decision G 02/08.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

The Registrar: The Chairman:

N. Maslin U. Oswald