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Title of invention:
TABLETS COMPRISING ELTROMBOPAG OLAMINE

Applicant:
Novartis Pharma AG

Headword:
TABLETS COMPRISING ELTROMBOPAG OLAMINE/Novartis Pharma AG

Relevant legal provisions:
EPC Art. 76(1)

Keyword:
Divisional application - added subject-matter (yes)

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Boards of Appeal

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Case Number: T 1365/24 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 5 June 2025

Appellant: (Applicant)	Novartis Pharma AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 11 September 2024 refusing European patent application No. 23166857.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	D. Boulois
	Y. Podbielski

Summary of Facts and Submissions

I. The appeal lies from the decision on the state of the file of the examining division to refuse the European patent application n°23166857.5.

II. The present patent application is a divisional application of the patent application n°15199469.6 with the publication number EP 3 090 730 and the patent application n°07840632.9 published under the number EP 2 152 237.

III. The decision was based on claims 1 and 2 as filed.

Claims 1 and 2 as filed read:

"1. A pharmaceutical tablet comprising 3'-[(2Z)-[1-(3,4-dimethylphenyl)-1,5-dihydro-3-methyl-5-oxo-4H-pyrazol-4-ylidene]hydrazino]-2'-hydroxy-[1,1'-biphenyl]-3-carboxylic acid bis-(monoethanolamine) that is formulated with a defined drug particle size distribution in which X90 is from 41 to 68 micrometres.

2. The pharmaceutical tablet of claim 1, wherein the tablet is formulated with a defined drug particle size distribution in which X90 is 41, 52 or 68 micrometres."

The compound specified in claim 1 is known as eltrombopag olamine.

IV. The grounds for the decision on the state of the file were contained in the communication of the examining division dated 3 July 2024. According to this communication of the examining division, the claims contravened Article 76(1) EPC, since no basis could be

found in the parent application for the defined drug particle size distribution in which X90 is from 41 to 68 micrometres or where X90 is 41, 52 or 68 micrometres.

The data in Figure 2 related to tablets described in Example 9, in which it was stated that the tablets were made according to Example 5. The data thus stemmed from specific formulations and the subject-matter of claims 1-2 constituted an unallowable generalization of the disclosure of Figure 2.

It had not been shown that the specific particle size was not so closely associated with the other features of the example as to determine the effect of that embodiment of the invention as a whole in a unique manner and to a significant degree. The fact that specific ranges, such as 10-90 micrometer, were disclosed in the application was not a basis for a direct and unambiguous disclosure for values disclosed in another context in the application.

V. The patent applicant (hereinafter the appellant), filed an appeal against said decision on the state of the file and requested to grant a patent on the basis of the claims considered by the examining division in its decision, namely the claims filed on 5 April 2023.

VI. A communication from the Board, dated 10 February 2025, was sent to the appellant. In it, the Board expressed its preliminary opinion that the claimed subject-matter did not meet the requirements of Article 76(1) EPC.

VII. With a letter dated 28 April 2025, the appellant withdrew its request for oral proceedings.

VIII. The arguments of the appellant may be summarised as follows:

Figure 2 of the application as filed provided basis for the X90 values recited in the claims. It was clear from the application as filed as a whole that it was justified to recite the X90 values in the claims without also requiring that the tablet had the formulation of example 5. In particular, the application explained in a general sense that the drug particle size had an important impact on the properties of eltrombopag olamine tablets by providing tablets that had improved properties which helped to ensure safe and effective treatment, without reference to the formulation of example 5 or indeed any other specific formulation. This provided a clear indication to the skilled person that the drug particle size had an impact on the properties of eltrombopag olamine tablets, beyond the context of tablets having a specific formulation.

Moreover, the data in Figure 2 showed that the X90 value of the eltrombopag olamine had a significant effect on the dissolution profile of eltrombopag olamine tablets when all other factors were kept constant. This tied in with the teaching referenced on page 4 of the application that the particle size of the drug influenced the properties of the tablet. Consequently, it was a permissible intermediate generalisation, since the feature X90 was not related or inextricably linked to the other features of the relevant embodiment and the overall disclosure justified the generalising isolation of the feature. No new technical information was added by referring to the X90 value of eltrombopag olamine particles independently from the composition of the tablet.

Generalising from the disclosure of examples 5 and 9 and Figure 2 to any eltrombopag olamine pharmaceutical tablet in which the drug has the X90 values recited in the claims therefore did not add new subject-matter.

IX. Requests

The appellant requested that the decision under appeal be set aside and the case be remitted to the examining division with an order to grant a patent on the basis of the claims filed on 5th April 2023.

Reasons for the Decision

1. Main request - Article 76(1) EPC

1.1 The Board notes that the parent and grandparent applications, i.e. the application n°15 199 469.6 and the application n°07 840 632.9 have the same content. The references in this decision to "parent application" thus refer to either of these applications.

1.2 The fundamental test for determining whether subject-matter meets the requirements of Article 123(2) EPC or Article 76(1) EPC, is the "gold standard" (see G 1/05 of 28 June 2007, point 5.1 of the reasons, and G 2/10, point 4.3 of the reasons). This standard requires that the subject-matter of an amended claim of a patent application or of a granted patent remains within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the earlier applications as filed. The skilled person may not be presented with new

technical information (see G 2/10, point 4.5.1 of the reasons).

1.3 In the present case, the question is whether there is a basis in the parent application for the claimed features "**particle size distribution in which X90 is from 41 to 68 micrometres**" and "**a defined drug particle size distribution in which X90 is 41, 52 or 68 micrometres**" in claims 1 and 2 respectively.

1.3.1 The description of the parent application does not provide a basis for the X90 range values or the specific X90 values of claims 1 and 2, even if it refers repeatedly to the size of 90% of the particles.

The particle size is indeed mentioned in the following passages of the description of the parent application, without any reference to the specific values included in the claims:

- on page 4 (lines 14 to 18) it is disclosed that "*another aspect of this invention relates to granules and solid oral pharmaceutical dosage forms comprising eltrombopag olamine that are formulated with a defined drug particle size range* ***where about 90% of drug particle size is in the range of 10 to 90 microns***";

- on page 12, it is disclosed several times that "***about 90%*** *of the eltrombopag olamine particles have* ***a particle size greater than 10 micron but less than 90 micron***" or "*about 90% of the eltrombopag olamine particles have* ***a particle size greater than 10 micron but less than 90 micron, suitably greater than 20 micron but less than 50 micron***";

- on pages 20-21, it is disclosed that "*about 90% of the eltrombopag olamine particles have* ***a particle size greater than 10 micron but less than 90 micron***", "*about 90% of the eltrombopag olamine particles have* ***a particle size greater than 10 micron but less than 90 micron, suitably greater than 20 micron but less than 50 micron***" and "*about 50% of the eltrombopag olamine particles have* ***a particle size greater than 5 micron but less than 50 micron, suitably greater than 5 micron but less than 20 micron***".

Moreover, the range values identified on pages 12 and 20 mentioned above are linked with further technical features absent from claims 1 and 2 of the present application. Page 12 disclose indeed the above mentioned X90 ranges with a specific process of preparation of the tablet and specific excipients, while the disclosure of the X90 ranges on page 20-21 relates specifically to capsules, a technical feature also absent from claims 1 and 2.

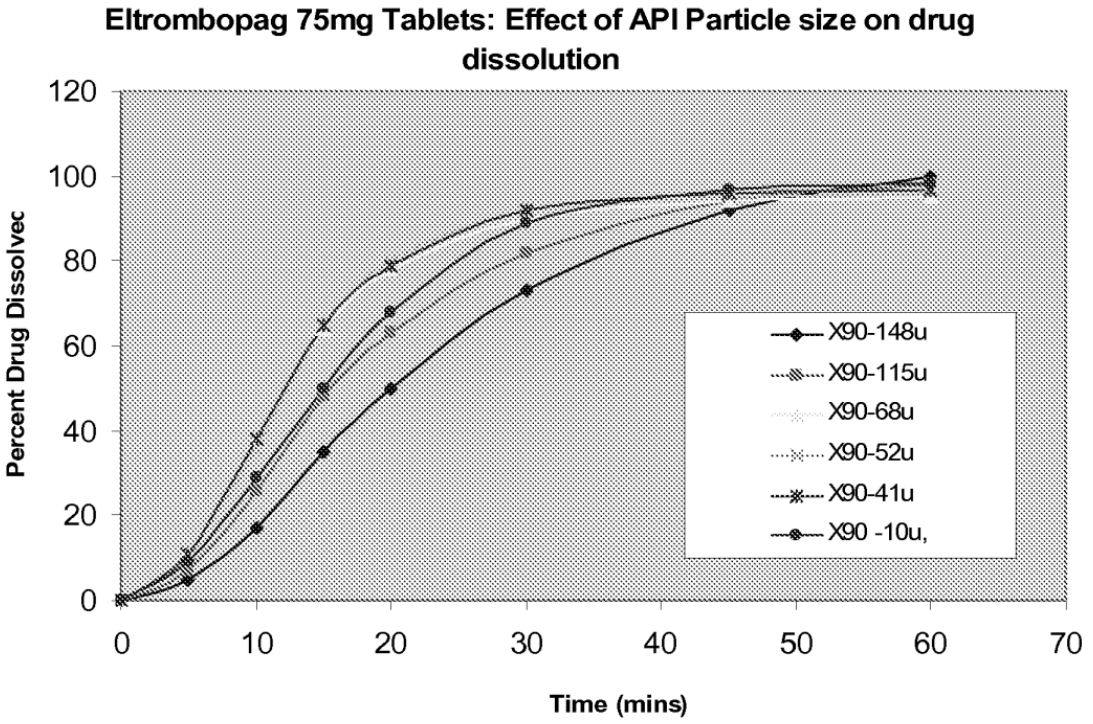
1.3.2 The same conclusion applies for the claims of the parent application. Indeed, claims 3-5 and 30 of the parent application disclose respectively a X90 of "a particle size **greater than 10 micron but less than 90 micron**" or "a particle size greater than **20 micron but less than 50 micron**", but do not disclose the claimed X90 range limits or specific values. This subject-matter is furthermore dependent on claims 1 or 2 which comprise further features also absent from the present claims 1 and 2.

1.3.3 The X90 particle sizes disclosed in the description and the claims of the parent application are therefore inconsistent with the claimed X90 ranges or values.

Moreover, they are linked with specific features absent from claims 1 and 2.

Consequently, the claimed X90 ranges or specific values are not derivable directly and unambiguously from the description and claims of the parent application.

1.4 Hence, the only possible basis for the claimed X90 values could be Figure 2 of the parent application as shown below with curves according to six different X90 values, where it is possible to identify the values 41, 52 and 68 µm (see the table inserted in Figure 2).



Example 9 of the parent application refers to the data of Figure 2 as follows:
"Figure 2 depicts the effect of API particle size distribution on eltrombopag olamine dissolution. Eltrombopag olamine 75mg tablets were generally prepared in the manner described in Example 5, using

different particle sizes. The particle size refers to the particle size of the drug granules used in the formulation."

The Board notes first that the original description does not clearly identify an "Example 5". Page 23 refers to examples 1 to 7. Example 5 could possibly correspond to the composition in the fifth column of Table 1 of Examples 1 to 7. However, this composition has a tablet strength of 50 mg whereas example 9 refers to "Eltrombopag olamine 75 mg tablets". It is therefore unclear which tablets have been used to generate the data of Figure 2. This uncertainty about the origin of the tablets used for the experiments of Figure 2 undermines in the Board's view the possibility of using this figure as a basis for the X90 values introduced in claim 1.

1.4.1 Moreover, it appears from Figure 2, that the upper and lower **limits of the range of claim 1 (i.e. 41 and 68 micrometers) or the specific X90 values of claim 2 (i.e. 41 ,52 and 68 micrometers) correspond to the isolated X90 values providing the fastest dissolution profiles**. Consequently, the X90 range limits of claim 1 or the values of claim 2 have been isolated from a specific context and selected among several possibilities from the data of Figure 2.

In the Board's view, the list in Figure 2 of five individual particle sizes provides discrete values rather than defining one or more ranges. Alone for this reason the range of 41 to 68 micrometers of claim 1 cannot be derived directly and unambiguously from Figure 2.

Moreover, as correctly argued by the examining division, example 5 relates to a specific tablet comprising a mixture of active granulates with specific excipients, extragranular components and film-coating components. The extraction of one parameter (i.e. the particle size) from this example and its introduction in the context of the present claims constitutes a generalization of the original disclosure. The claimed subject-matter relates now to tablets obtainable by any process and comprising any kind of excipient, and is limited only by the particle size of eltrombopag olamine. The Board is unable to identify in the original application any passage disclosing tablets characterised only by the particle size distributions defined in claims 1 and 2.

1.4.2 According to the appellant, the X90 value of the eltrombopag olamine had a significant effect on the dissolution profile. However, this argument does not modify the conclusion that the subject-matter of claim 1 cannot be derived directly and unambiguously from the parent application. In any case, the Board notes that there is no disclosure in the parent application of a preference for the dissolution profiles of the compositions in which the active ingredient has a particles size distribution wherein X90 is from 41 to 68 micrometers.

Importantly, there is furthermore no basis in the parent application that the particle size is the sole feature involved in the dissolution properties. It is not credible that it is the X90 alone which is responsible for the dissolution profile. On the contrary, it appears clear that the dosage form, its structure and the nature of excipients are also important (see for instance page 2, line 30 to page 3,

line 8; page 3, lines 12-18). Figure 1 is also illustrative of this point, since it shows a dissolution profile depending on the type of diluents. The data provided in Figure 2 are therefore the result of several features inextricably linked together, among which there is also the X90 parameter.

Accordingly, the selection of particular X90 values from Figure 2 or the creation of ranges therefrom constitutes an unallowable generalization.

1.4.3 For all these reasons, the subject-matter of claims 1 and 2 can neither be derived from example 5 nor from Figure 2.

1.5 Consequently, the Board concurs with the conclusions of the examining division that the claimed subject-matter does not meet the requirements of Article 76(1) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Sánchez Chiquero A. Usuelli

Decision electronically authenticated