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Datasheet for the decision of 15 April 2024

Case Number: T 1659/21 - 3.3.07

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Language of the proceedings: EN

Title of invention:
CAPSULE PHARMACEUTICAL DOSAGE FORM COMPRISING A SUSPENSION FORMULATION OF AN INDOLINONE DERIVATIVE

Patent Proprietor:
Boehringer Ingelheim International GmbH

Opponents:
Zentiva Group, a.s.
Teva Pharmaceutical Industries Ltd.
Generics (U.K.) Limited
Galenicum Health S.L.U.

Headword:
Suspension formulation /BOEHRINGER

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments - allowable (yes)

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Case Number: T 1659/21 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 15 April 2024

Appellant: (Patent Proprietor)	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein (DE)
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Respondent: (Opponent 4)	Galenicum Health S.L.U. CL Sant Gabriel n°50 08950 Esplugues de Llobregat (ES)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 27 July 2021 revoking European patent No. 2299987 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	D. Boulois
	A. Jimenez

Summary of Facts and Submissions

I. European Patent 2 299 987 had been opposed under Article 100 (a), (b), (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed and extended beyond the content of the application as filed.

II. The appeal lies from the decision of the opposition division to revoke the patent. The decision was based on the claims as granted as main request and on auxiliary requests 1-2 filed with letter of 31 July 2020.

Claim 1 as granted read:

"1. Formulation of the active substance 3 -Z- [1 -(4-(N-((4-methyl-piperazin- 1 -yl)- methylcarbonyl)-N-methyl-amino)-anilino)- 1 -phenyl-methylene] -6-methoxycarbonyl-2- indolinone-monoethanesulphonate which comprises a viscous lipid suspension of the active substance in 1 to 90 wt.% of medium chain triglycerides, 1 to 30 wt.% of hard fat and 0.1 to 10 wt.% of lecithin.".

III. According to the decision under appeal, claim 1 as granted did not meet the requirements of Article 123(2) EPC.

Claim 1 derived from the disclosure of the description of the application as filed on pages 11 and 12. However, the percentages of MCT, hard fat and lecithin as disclosed on pages 11 and 12 related to "the lipid suspension formulation" and this reference to the lipid suspension was not present in claim 1 of the patent in

view of the wording "suspension of the active substance in...". As claim 1 as such was clear and made technical sense, there was no need to consult the description to interpret the claim.

Auxiliary requests 1 and 2 did not meet the requirements of Article 123(3) EPC in view of the amended wording "of the lipid suspension formulation" in claim 1.

IV. The patent proprietor (hereinafter the appellant) filed an appeal against said decision. With the statement setting out the grounds of appeal dated 2 December 2021, the appellant submitted auxiliary requests 1 and 2.

V. Opponent 01 (hereinafter respondent 01), opponent 02 (hereinafter respondent 02) and opponent 03 (hereinafter respondent 03) replied to the statement of grounds of appeal. Opponent 04 has not filed any substantive submission in the appeal proceedings.

VI. A communication from the Board, dated 12 December 2023, was sent to the parties.

VII. Oral proceedings took place on 15 April 2024, in the presence of the appellant and respondent 02 and 03.

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

The opposition division's interpretation that the ranges in claim 1 related solely to the carrier system rather than the entire suspension was one interpretation, but clearly not the only one, and was based on incorrect assumptions that lack an objective

basis in the plain wording of the claim as such and provided a technically highly questionable result since it did not make sense.

The three claimed ranges did indeed not add up to 100 wt% in total, in particular where MCT is in the range below 60 wt%. Hence, the plain wording of claim 1 did not unequivocally support the opposition division's conclusion. To the contrary, the three percentage ranges provided a strong “further indication” to the skilled reader that further components needed to be taken into consideration, i.e the active agent. At a minimum, it indicated that the correct interpretation deserved clarification based on the information provided in the description and the examples. Thus, the interpretation arrived at by the opposition division that the three ranges provided necessarily referred to the carrier system lacked any objective basis.

IX. The arguments of the respondents may be summarised as follows:

According to respondent 01, the literal wording of claim 1 indicated that the claimed percentages related to the medium wherein the active substance was suspended, i.e. the combination of MCT, hard fat and lecithin, but not to the formulation as a whole and the literal wording of claim 1 was by no means vague and left no room for interpretation. It was established case law that the description could not be used to interpret such a feature in a different way (let alone in contrast to the literal wording), even if there was a discrepancy between the claims and the description. Moreover, the claimed ranges were the results of multiple selections and infringed also Article 123(2) EPC for this reason.

According to respondent 02, the question to be answered regarding Article 123(2) EPC was whether the indicated percentages referred to the suspending medium or to the lipid suspension formulation as a whole, thus including the active substance. In the original application these amounts relate to the lipid suspension formulation as a whole, i.e., including the active substance. This restriction was however not present in granted claim 1. Therefore, the subject matter of granted claim 1 was not directly and unambiguously derivable from the original application. The language of the claim was clear and the description should not be considered for the interpretation of this feature.

According to respondent 03, there was no basis for the claimed ranges. Due to the absence of any other basis for the percentages of claim 1, the skilled person would interpret claim 1 in that the percentages were based on the three ingredients listed in claim 1 forming the carrier system, which had no basis in the original application. This was a logical interpretation that made technical sense, contrary to the proprietor's allegations. The description might offer other possible interpretations which were different from the claim wording. However, due to the clear structure of claim 1, there was no need to consult the description at all. Moreover, claim 1 as granted resulted from a selection of different lists. The ranges introduced into claim 1 were disclosed in separate passages and the combination of these ranges was not directly and unambiguously disclosed in the application as filed. Furthermore, it was evident from these passages in the application as filed that the ranges introduced into claim 1 in relation to hard fat and lecithin were preferred features of the present invention, whereas a non-

preferred range for medium chain triglycerides had been introduced.

X. Requests

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted, or alternatively according to the set of claims filed as auxiliary requests 1-2 with the statement of grounds of appeal.

The respondents requested that the appeal be dismissed.

Reasons for the Decision

1. Main request - Amendments

1.1 Claim 1 relates to a formulation of the active substance nintedanib esilate which comprises a viscous lipid suspension of said active substance in 1 to 90 wt.% of medium chain triglycerides, 1 to 30 wt.% of hard fat and 0.1 to 10 wt.% of lecithin. The feature "a viscous lipid suspension of the active substance in 1 to 90 wt.% of medium chain triglycerides, 1 to 30 wt.% of hard fat and 0.1 to 10 wt.% of lecithin" has been found to not meet the requirements of Article 123(2) EPC by the opposition division and this conclusion is shared by the respondents in the appeal proceedings.

1.2 As correctly indicated by the opposition division in its decision, claim 1 finds a general basis in the original description in particular on page 6, lines 5-8 which reads:
"a further object of the present invention is the above formulation comprising a viscous suspension of 3- Z-[1 -(4-(N-((4-methyl-piperazin- 1 -yl)- methylcarbonyl)-N-

methyl- amino)-anilino)- 1 -phenyl-methylene] -6-methoxycarbonyl-2-indo linone-monoethanesulphonate in medium chain triglycerides (MCT), hard fat and lecithin".

The same reference to a viscous suspension of the active substance in MCT, hard fat and lecithin can be found on page 8, lines 31-34 and original claim 8.

1.3 The claimed amounts of MCT, hard fat and lecithin are found on page 11, lines 12-16 and 26-28 and page 12, lines 13-15 of the original description which read respectively as follows (claimed ranges shown in bold):
- the MCT is comprised "within the range of **1 to 90 weight%** of the lipid suspension formulation, preferably between 10 and 70%";
- the hard fat is comprised "within the range of **1 to 30 weight**% of the suspension formulation, most preferably within 10 and 30 weight%";
- the amount of lecithin is comprised "within the range of **0.1 to 10 weight%** of the lipid suspension formulation, most preferably within 0.25 and 2.5%".

Said passages refer to amounts related to "the lipid suspension formulation" which explicitly includes the active substance, while the opposition division concluded that the wording of claim 1 refers to the presence of the active substance in a carrier comprising different range amounts of MCT, hard fat and lecithin, thereby excluding the active agent and leading to claimed ranges which are different from the ranges disclosed in the original description.

The key question to be answered is whether the percentages of claim 1 refer to the suspending medium, thus excluding the active substance, or to the lipid

suspension formulation as a whole, thus including the active substance.

1.4 It is undisputed that claim 1 does not explicitly indicate whether the percentages defining the relative amounts of MCT, hard fat and lecithin relate to the whole formulation or to the suspending medium. The absence of this important information leaves in principle room to different interpretations.

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The interpretation adopted by the opposition division, namely that the percentages of claim 1 relate to the carrier system rather than the whole formulation, is however incompatible with the very value of the percentages. Indeed, as is also immediately apparent, the three claimed ranges of claim 1 cannot add up to 100 wt% in total, when MCT is in an amount below 60 wt%, i.e. for most of the claimed range of "1 to 90 wt%". The claimed ranges of 1 to 90 wt.%, 1 to 30 wt.% and 0.1 to 10 wt.% literally allow for both a sum of all three excipients of 100 wt.% and of clearly below 100 wt.%, thereby leaving room for the presence of the active substance in an amount adding up to 100%. The fact that the three percentage ranges cannot add up to 100% for the most part of the range defining the amount of MCT provides a strong indication to the skilled reader that further components need to be taken into consideration in addition to the components of the carrier system and that said percentage ranges refer to the whole "viscous lipid suspension of the active substance".

Hence, the only logical interpretation of the ranges of claim 1 is that said ranges refer to the "viscous lipid suspension of the active substance" and not to a medium limited to MCT, hard fat and lecithin. This

interpretation is in line with the passages of pages 11 and 12 mentioned in point 1.3 above which refer to the "suspension formulation" and with the examples.

1.5 Moreover, the Board does not see in the feature "a viscous lipid suspension of the active substance in 1 to 90 wt.% of medium chain triglycerides, 1 to 30 wt.% of hard fat and 0.1 to 10 wt.% of lecithin" a combination of multiple selections which does not find any basis in the original application, as argued by the respondents.

The respondents consider indeed that such combination of ranges was not directly and unambiguously derivable from the application as filed, in particular since the ranges introduced in claim 1 are the result of a three-fold selection from different lists. Respondent 03 also argues that the ranges of hard fat and lecithin are preferred ranges, whereas a non-preferred range for medium chain triglycerides has been introduced.

In the present case, all the claimed ranges are explicitly disclosed in the original application as the broadest preferred ranges. The combination of several individual ranges emerging from several separate lists and pertaining to several distinct features may be considered to be derivable from the application as filed in particular when there is a clear pointer to such a combination, which appears to be the case in the application as originally filed. For instance, the Board notes that claim 8 as originally filed relates specifically to a combination of the active substance "in medium chain triglycerides, hard fat and lecithin"; said claim is therefore a clear pointer for the association of the three components of the viscous lipid suspension. Other part of the description

mentioned above also refer explicitly to such combination (cf. point 1.3 above). Furthermore, as discussed above the relative amounts of MCT, hard fat and lecithin in claim 1 correspond to the broadest preferred ranges disclosed in the original description.

1.6 The Board could neither follow the arguments of respondent 02 in its written submissions regarding a possible extension of the subject-matter in view of the closed combination claimed. According to respondent 02, the fact that the claimed suspension constitutes a closed list, thus excluding the presence of further excipients, constitutes a further violation of Article 123(2) EPC (see letter of 14 April 2022, point 4.12).

In the Board's view, the application as filed envisages clearly an embodiment consisting in a suspension with exclusively the active substance, MCT, hard fat and lecithin; this is shown for instance in the description of page 8, line 31 to page 9, line 5, in original claim 8 and in most examples of the original application (cf. examples 1, 4-8).

This objection is therefore not founded.

1.7 Consequently, claim 1 meets the requirements of Article 123(2) EPC.

2. Remittal to the opposition division

As mentioned above, the subject-matter of present claim 1 of the main request meets the requirements of Article 123(2) EPC. However, the main request has not yet been examined with regard to the remaining grounds of opposition, namely Article 100 (a) and (b) EPC.

Article 11 RPBA provides that the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so. The Board holds that such special reasons are apparent in the present case.

The provision of Article 11 RPBA 2020 has indeed to be read in conjunction with Article 12(2) RPBA 2020, which provides that it is the primary object of the appeal proceedings to review the decision under appeal in a judicial manner. This principle would not be respected if the Board were to conduct a complete examination of the opposition.

As discussed above, in the present case the opposition division decided only on the question of the extension of subject-matter and did not consider the further issues. Under these circumstances, the Board considers it appropriate to exercise its discretion under Article 111(1) EPC and to remit the case to the department of first instance for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated