

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 26 March 2021**

Case Number: T 1731/18 - 3.3.07

Application Number: 06842712.9

Publication Number: 1906937

IPC: A61K9/20, A61K31/55, A61K47/32,
A61K47/36, A61K47/38

Language of the proceedings: EN

Title of invention:
NOVEL DISPERSIBLE TABLET COMPOSITION

Patent Proprietor:
RUBICON RESEARCH PVT LTD.

Opponent:
Tillotts Pharma AG

Headword:
Novel dispersible tablet composition / RUBICON

Relevant legal provisions:
EPC Art. 100(c)
RPBA Art. 12(4)

Keyword:
Amendments, main request - added subject-matter (yes)
Late-filed auxiliary request - admitted (no)

Decisions cited:

T 1511/07, T 1621/16, T 0027/16, T 0936/09



Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1731/18 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 26 March 2021

Appellant: RUBICON RESEARCH PVT LTD.
(Patent Proprietor) 221, Annexe Building
Goregaon-Mulund Link Road
Opposite Indira Container Yard,, Off L.B.S. Marg,
Bhandup (w), Mumbai 400 078 (IN)

Representative: Harrison IP Limited
3 Ebor House
Millfield Lane
Nether Poppleton, York YO26 6QY (GB)

Respondent: Tillotts Pharma AG
(Opponent) P.O. Box Baslerstrasse 15
4310 Rheinfelden (CH)

Representative: Beck Greener LLP
Fulwood House
12 Fulwood Place
London WC1V 6HR (GB)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 8 May 2018
revoking European patent No. 1906937 pursuant to
Article 101(2) EPC.**

Composition of the Board:

Chairman A. Uselli
Members: E. Duval
Y. Podbielski

Summary of Facts and Submissions

I. European Patent 1 906 937 (hereinafter "the patent") was granted on the basis of 8 claims. Claim 1 of the patent read as follows:

"A novel dispersible tablet which is capable of disintegrating within 3 minutes in water at 15-25°C comprising

- (i) at least one water-insoluble pharmacologically active ingredient;
- (ii) 5 % to 50% by weight of composition of hydroxyethyl cellulose which reduces the sedimentation rate of the pharmacologically active ingredient; and
- (iii) 0.5% to 20% by weight of composition of at least one disintegrant."

II. An opposition was filed against the patent on the grounds that its subject-matter lacked inventive step, it was not sufficiently disclosed and it extended beyond the content of the application as filed.

III. During the proceedings before the opposition division, the patent proprietor neither replied in substance to the opposition nor requested oral proceedings. The opposition division took the decision to revoke the patent. The decision was issued in writing on 8 May 2018 and was based on the patent as granted.

IV. The opposition division decided in particular that the ground under Article 100(c) EPC prejudiced the maintenance of the patent, because there was no disclosure, in the application as filed, for the claimed combination of 5% to 50% by weight of

composition of hydroxyethyl cellulose (hereinafter "HEC") with 0.5% to 20% by weight of composition of at least one disintegrant.

- V. The patent proprietor (appellant) lodged an appeal against the decision of the opposition division. With its statement setting out the grounds of appeal filed on 14 September 2018, the appellant defended its case on the basis of the patent as granted as its main request, and filed an auxiliary request.

Claim 1 of the auxiliary request differed from claim 1 of the main request in that the amount of disintegrant was in the range of "1% to 20% by weight of composition".

- VI. The Board set out its preliminary opinion in a communication under Article 15(1) RPBA 2020.

- VII. Oral proceedings were held before the Board.

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

- (a) Main request, Article 100(c) EPC

As compared with claim 1 as filed, claim 1 of the main request

- limited the excipient "which reduces the sedimentation rate of the pharmacologically active ingredient" to HEC, and
- limited the amount of disintegrant to 0.5-20% by weight.

Basis for the limitation to HEC was found in claims 8 and 9, and page 8 (lines 21 to 24) of the application as filed. According to these passages,

preferred excipients were hydrophilic polymers, and the list of preferred hydrophilic polymers included HEC.

The claimed range of 0.5-20% disintegrant found basis on page 9 (lines 12-15) of the application as filed, and resulted from the allowable combination of the more preferred range "about 0.5% to about 30.0%" with the most preferred range "about 1-20%".

The combination of the disintegrant with a hydrophilic polymer was disclosed in claim 16 as filed and in all of the examples (except control example 1A). The sole selection of HEC from one list did not add subject-matter. Additionally, claim 17 as filed and examples 1 and 5 further directed the skilled person towards the choice of HEC and the claimed combination of features.

The issue of added matter was to be assessed following decisions T 1621/16 and T 27/16, rather than T 1511/07. Thus, the range of 0.5-50% disintegrant was subsumed in the range of 0.25-50%, which formed part of a list of converging ranges on page 9. Although HEC had been selected from the non-converging list of hydrophilic polymers, the criteria of T 1621/16 were still applicable in view of paragraph 1.8.2 of that decision.

Consequently, the main request did not add subject-matter.

(b) Auxiliary request, admittance into the proceedings

The deferred reaction to the opposition, and the filing of the auxiliary request only at the stage

of appeal, were justified by the fact that, during the proceedings before the opposition division, the patent proprietor and the opponent were engaged in discussions regarding a possible withdrawal of the opposition. Considering these circumstances, the auxiliary request should be admitted into the appeal proceedings.

IX. The respondent's arguments can be summarised as follows:

(a) Main request, Article 100(c) EPC

HEC was listed among a number of possible excipients in the application as filed. Neither claim 17 nor the examples of the application as filed contained a pointer to the selection of HEC. The claimed amount of disintegrant resulted from the combination of the lower limit of the more preferred range (0.5%) with the upper limit of the most preferred range (20%). The resulting range was not expressed as preferred over the other ranges. Hence, to arrive at the claimed subject-matter, at least two selections were necessary in respect of the excipient HEC and the amount of disintegrant. As a result, the amendments presented the skilled person with information which was not directly and unambiguously derivable from the application as filed. In this respect, the present situation had to be distinguished from the multiple selections from convergent lists of T 1621/16. Claim 16 and page 9 (lines 3-15) of the application as filed provided basis for the combination of a hydrophilic polymer and a disintegrant, but not for the specific combination of HEC with 0.5-20% by weight

of a disintegrant. Thus the main request contained added subject-matter.

(b) Auxiliary request, Admittance into the proceedings

The filing of the auxiliary request at appeal stage only was contrary to a fair and reliable conduct. The relevant question was whether the appellant could have filed this auxiliary request earlier. This was the case here, since the objection of added matter had been raised in the notice of opposition. While it was true that some negotiations took place between the parties, this negotiations failed at an early stage. In any case, these negotiations did not justify the appellant's absence of defence during the first-instance proceedings. Accordingly, the auxiliary request should not be admitted into the proceedings.

X. The appellant requests that the decision under appeal be set aside and the patent be maintained as granted or that the patent be maintained on the basis of the auxiliary request filed with the statement setting out the grounds of appeal dated 14 September 2018.

XI. The respondent requests that the appeal be dismissed.

Reasons for the Decision

1. Main request (patent as granted), Article 100(c) EPC

1.1 Claim 1 of the main request differs from claim 1 of the application as filed in particular by the following additional features:

(a) the excipient (ii) which reduces the sedimentation rate of the pharmacologically active ingredient is selected to be HEC, and

(b) the amount of disintegrant (iii) is defined to be 0.5 % to 20 % by weight of the composition.

1.2 The range 0.5-20wt% for the disintegrant derives from the passage on page 9, lines 12-15, disclosing a general range of 0.25-50%, a more preferred range of 0.5-30% and a most preferred range of 1-20%. This combination of the more preferred lower limit with the most preferred upper limit does not *per se* introduce added subject-matter. However it must be seen as a first selection out of the various ranges which may be created from the general, more preferred and most preferred ranges. No preference for this newly created range can be discerned in the application as filed.

1.3 A further selection is made in respect of HEC, which appears among a list of 9 hydrophilic polymers on page 8, lines 21-24 of the description as filed. Claim 9 as filed contains the same disclosure. Although it describes this whole list of hydrophilic polymers as preferred, this passage does not express any preference for HEC over the other polymers.

No particular pointer to HEC as excipient (ii) can be derived from the rest of the application as filed. HEC is only one of the four hydrophilic polymers used in the examples, and is not present in the compositions of examples 1A, 1B, 3, 4, 6 and 7. In the compositions of examples 1C, 1D and 5, HEC is not shown to perform any better or worse than the other polymers. Claim 17 of the application as filed relates to a particular composition comprising not only HEC but also a specific

active ingredient and specific excipients. Thus claim 17 does not express a general preference for HEC any more than the examples do.

1.4 Thus, although each amendment (a) and (b) individually finds basis in the application as filed, their combination does not. The application as filed contains no pointer to the combination of the selected range with the selected polymer, such that a new technical teaching is generated by the amendments.

1.5 In this respect, the Board shares the view expressed in T 1511/07 (point 2.1 of the reasons; see Case Law of the Boards of Appeal of the European Patent Office, 9th Edition, II.E.1.6.2). The selection of explicitly disclosed borderline values defining several (sub)ranges, in order to form a new (narrower) subrange, is not contestable under Article 123(2) EPC when the ranges belong to the same list (here, the list of disintegrant amounts). However, the combination of an individual range formed from this list with another selection from a second list relating to a different feature (here, the excipients) is not considered to be disclosed in the application as filed, unless there is a clear pointer to such a combination.

1.6 This conclusion is not modified by the appellant's reference to decisions T 1621/16 and T 27/16.

1.6.1 In T 1621/16, the Board distinguished between multiple selections from lists of converging alternatives (i.e. lists of options ranked from the least to the most preferred, wherein each of the more preferred alternatives is fully encompassed by all the less preferred and broader options in the list), and selections from lists of non-converging elements (i.e.

mutually exclusive or partially overlapping alternatives). The situation underlying T 1621/16 involved in particular multiple selections from converging lists.

In the present case, HEC is selected from the non-converging list of hydrophilic polymers of page 8, line 21-24 of the application as filed. As to the amount of disintegrant, the range 0.5-20wt% is not selected from the converging list of general, preferred and most preferred ranges given on page 9, lines 12-15, but from the non-converging list of ranges obtainable by combining their upper and lower limits. Consequently, the criteria proposed in T 1621/16 for multiple selections from converging lists are in any case not relevant to the present situation.

1.6.2 The appellant further referred to T 27/16 and to point 1.8.2 of T 1621/16 (2nd paragraph). In the first decision, the board took the sole example of the original application as a pointer to the combination of features defined in claim 1 (see Reasons, point 13.10). In the second decision, all the examples of the application as filed included an anionic surfactant, therefore pointing to this specific type of surfactant as a preferred one. In contrast, in the case at hand, the examples neither point to the use of HEC as preferred polymer nor to its combination with the selected amount of disintegrant, for the reasons given above (see 1.3).

1.7 Accordingly, the ground under Article 100(c) EPC prejudices the maintenance of the patent according to the main request.

2. Auxiliary request, admittance into the proceedings
 - 2.1 Together with the statement setting out the grounds of appeal, the appellant submitted an auxiliary request. This auxiliary request aims at overcoming the objection of added subject-matter regarding the combination of features a) and b) (see 1.1 above). The question arises as to whether the Board should exercise its discretion not to admit this new request into the proceedings.
 - 2.2 Since the appellant's statement of grounds of appeal was submitted before 1 January 2020, Article 12(4) to (6) RPBA 2020 does not apply (Article 25(2) RPBA 2020, see OJ EPO 2019, A63). Instead, the question whether or not the auxiliary request should be admitted must be decided on the basis of Article 12(4) RPBA 2007, which gives the Board discretion not to admit, on appeal, requests that could have been presented in the opposition proceedings.
 - 2.3 During the proceedings before the opposition division, the EPO notified the opposition to the patent proprietor, pursuant to Rule 79(1) EPC, on 25 August 2017, and set a 4-month time limit to file observations. The patent proprietor requested an extension of this time limit by 2 months. This request was refused by the EPO. The patent proprietor neither filed any observations or amendments nor requested oral proceedings, within or after the expiry of this time limit.

The opposition division issued the decision to revoke the patent in writing on 8 May 2018. The decision was based, *inter alia*, on the ground of Article 100(c) EPC in relation with the combination of features a) and b).

This objection was among the objections raised in the notice of opposition communicated to the appellant.

2.4 Considering the appellant's absence of a reaction to the opposition filed against its patent, the arguments set out in the grounds of appeal and the newly filed auxiliary request constitute the appellant's first attempt to defend its patent and to overcome the added subject-matter objection. The decision under appeal was issued more than 8 months after the communication pursuant to Rule 79(1) EPC, yet the appellant omitted to file any observation or amended request in that time.

2.5 As set out in decision T 936/09 (see the Headnote), the patent proprietor is not free to present or complete his case at any time that he wishes during the opposition or opposition appeal proceedings. In view of the judicial nature and purpose of inter partes appeal proceedings and in the interests of an efficient and fair procedure, it is necessary that all parties to opposition proceedings complete their submissions during the first-instance proceedings in so far as this is possible. If a patent proprietor presents or completes his case only in the notice of appeal or the statement setting out the grounds of appeal, then he will need to face the prospect of being held to account for such conduct by the board when, for example, exercising its discretion under Article 12(4) RPBA 2007.

2.6 This applies in the present case, since the objection under Article 100(c) EPC was known to the appellant before it received the impugned decision. The fact that negotiations took place between the parties after the opposition was filed does not justify the appellant's

absence of reaction in the proceedings before the opposition division. Despite these negotiations, the appellant could, and should, have preserved its position in the opposition proceedings by addressing the opponent's objections.

2.7 Accordingly, the Board does not admit the auxiliary request into the proceedings, pursuant to Article 12(4) RPBA 2007.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Usuelli

Decision electronically authenticated