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**Datasheet for the decision
of 9 February 2023**

Case Number: T 0428/21 - 3.3.07

Application Number: 09725784.4

Publication Number: 2280687

IPC: A61K9/00, A61K31/352,
A61P25/04, A61P29/00

Language of the proceedings: EN

Title of invention:

CHEWING GUM COMPOSITIONS COMPRISING CANNABINOIDS

Patent Proprietor:

Stichting Sanammad

Opponent:

MedCan Pharma A/S

Headword:

Chewing gum compositions comprising cannabinoids / SANAMMAD

Relevant legal provisions:

EPC Art. 83

RPBA 2020 Art. 13(2), 13(1)

Keyword:

Sufficiency of disclosure - (no)

Amendment after summons - cogent reasons (no)

Decisions cited:

T 0347/15



Beschwerdekammern

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Case Number: T 0428/21 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 9 February 2023

Appellant: Stichting Sanammad
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Respondent: MedCan Pharma A/S
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 18 February
2021 revoking European patent No. 2280687
pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appeal was filed by the patent proprietor (appellant) against the decision of the opposition division to revoke European patent 2 280 687 (the patent).
- II. The opposition division decided that the main request (the patent as granted) contained added subject-matter, and furthermore that none of the requests met the requirements of sufficiency of disclosure. The appealed decision cited the following documents:

D5: Experimental data submitted by the appellant on 7 June 2017 in the examination phase

D6: Svenson (2004), Carrier-Based Drug Delivery, ACS Symposium Series, Chapter 1

- III. With the statement setting out the grounds of appeal, the appellant submitted a main request and auxiliary request 1. Claim 1 was identical in both requests and corresponded to claim 1 of auxiliary request 3 on which the appealed decision is based. It read as follows:

"A chewing gum composition comprising a cannabinoid, wherein the chewing gum composition comprises 25 to 85% by weight of a gum base, based on the total weight of the chewing gum composition, and a carrier comprising internal voids, wherein the voids at least partially comprise said cannabinoid, wherein said carrier is a microcrystalline cellulose, wherein at least 1% by weight to not more than 30% by weight, based on the total weight of the cannabinoid, in the chewing gum composition is released within 5 minutes after

ingestion, and wherein the onset of the release starts within 3 minutes after."

- IV. The opponent (respondent) replied to the appeal on 5 November 2021.
- V. On 14 April 2022, the Board summoned the parties to oral proceedings scheduled for 9 February 2023. The Board set out its preliminary opinion in a communication under Article 15(1) RPBA issued on 30 September 2022.
- VI. By letter dated 2 February 2023, the appellant submitted auxiliary request 2 and the following documents D7-D9.

D7: GB 2377633 A

D8: Handbook of Pharmaceutical Excipients; Fifth Edition, 2006, pages i-viii, 132-135 and 385-398

D9: Ishikawa T. et al., Chem. Pharm. Bull. 49(2), pages 134-139 (2001)

Claim 1 of auxiliary request 2 differed from claim 1 of the main request in that the "carrier comprising internal voids, wherein the voids at least partially comprise said cannabinoid, wherein said carrier is a microcrystalline cellulose" was amended to "a solid material composed of a cellulose, wherein the cannabinoid is provided in and on voids within the solid material composed of a cellulose, wherein the cellulose is a microcrystalline cellulose having said internal voids".

- VII. Oral proceedings were held before the Board on 9 February 2023.

- VIII. The appellant requests that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or auxiliary request 1, both filed with the grounds of appeal, or auxiliary request 2 filed on 2 February 2023. In the event that the Board reverses the appealed decision on added matter and insufficiency, the appellant requests that the case be remitted to the opposition division.
- IX. The respondent requests that the appeal be dismissed. In the event that the Board reverses the appealed decision on added matter and insufficiency, the respondent requests that the case be remitted to the opposition division.
- X. The appellant's arguments can be summarised as follows:
- (a) Auxiliary request 2 was timely filed in response to, and *prima facie* overcame, the respondent's newly raised objections under Articles 84 and 123(3) EPC. Documents D7-D9 had been timely filed in response to the preliminary opinion of the Board, and represented common general knowledge. Hence both auxiliary request 2 and D7-D9 were to be admitted into the proceedings.
 - (b) Regarding the main request and auxiliary request 1, the patent provided sufficient guidance on how to achieve the claimed drug release profile because it led the skilled person to vary the type and amount of microcrystalline cellulose in the gum composition. The use of a carrier such as the known disintegrant microcrystalline cellulose for tailoring the release profile was well-known. D5 contained no evidence regarding a chewing gum comprising microcrystalline cellulose as the

carrier. The burden of proof of insufficiency remained with the opponents. Hence the criteria of sufficiency of disclosure were met.

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

- (a) Neither auxiliary request 2 nor D7-D9 were to be admitted into the proceedings, because their late filing was not occasioned by any exceptional circumstances in the sense of Article 13(2) RPBA 2020.
- (b) The subject-matter of the main request and auxiliary request 1 was not sufficiently disclosed. The patent did not teach how to simultaneously achieve the recited release rate and use microcrystalline cellulose as required by the claim. The difficulties with reproducing the claimed invention were confirmed by D5.

Reasons for the Decision

- 1. Main request and auxiliary request 1, sufficiency of disclosure
 - 1.1 The chewing gum compositions of claim 1 of the main request (and of the identical claim 1 of auxiliary request 1) are functionally defined by parameters pertaining to release properties, namely "at least 1% by weight to not more than 30 % by weight, based on the total weight of the cannabinoid, in the chewing gum composition is released within 5 minutes after ingestion, and wherein the onset of the release starts within 3 minutes after".

The Board concurs with the opposition division that the claimed invention is not sufficiently disclosed because the patent does not enable the skilled person to prepare chewing-gum compositions that achieve the recited release properties.

1.2 In accordance with established case law (see the Case Law of the Boards of Appeal, 10th edition, 2022, II.C. 5.2), an invention is in principle sufficiently disclosed if at least one way is clearly indicated enabling the person skilled in the art to carry out the invention. This is not the case here, because the sole exemplified chewing gum composition in the patent does not contain microcrystalline cellulose, and the patent does not contain any evidence that even this (comparative) composition would achieve the claimed release feature. The patent as a whole does not offer any guidance at all on how to achieve the claimed release profile using microcrystalline cellulose.

1.3 Furthermore, the post-published evidence D5 (see pages 3 and 4 and figures 1 and 2) shows that:

- in a chewing gum comprising cannabidiol (CBD) and no cellulose, the onset of the release does not start within 3 minutes after ingestion, and
- a chewing gum comprising CBD and a solid cellulose carrier releases more than 30% (namely about 43%) of CBD within 5 minutes after ingestion.

Thus neither the cellulose-free nor the cellulose-containing chewing gum satisfy the functional requirements of claim 1.

The appellant points out that nothing has been disclosed in D5 regarding a chewing gum comprising microcrystalline cellulose as the carrier. However,

this argument, even if it were accepted, cannot help the appellant's case. Firstly, it remains that no evidence or example of a chewing-gum comprising microcrystalline cellulose and fulfilling the claimed release profile requirement is adduced. And secondly, D5 at least shows that a related carrier (cellulose) fails to satisfy this requirement. No guidance in the patent or explanation is given as to why the claimed release profile could be expected when using microcrystalline cellulose instead. The patent fails to provide instruction on how to achieve the recited release profile with a chewing gum composition having the features defined in claim 1.

1.4 In the present circumstances, the Board does not agree with the appellant that the burden of proof remains on the respondent. The patent contains no detailed information about how to put the invention into practice. Consequently, only a weak presumption exists that the patent meets the requirements of sufficiency of disclosure (see in this respect the Case Law of the Boards of Appeal, 10th edition, 2022, II.C.9.1. and 3. and T 347/15, point 2.2 of the reasons). The appealed decision rightly found that this presumption had been rebutted because the respondent had submitted comprehensible and plausible arguments giving rise to serious doubts about whether the skilled person could prepare a microcrystalline cellulose-based chewing gum with the claimed release profile.

1.5 The appellant further relies on the common general knowledge reflected in D6 (page 4, 2nd paragraph), according to which a carrier would be known to be used for tailoring the release profile of an encapsulated drug. However, D6 only generally mentions the influence of the choice of "an appropriate encapsulation

material" on the release profile, but it does not cure the above deficiency in the patent. Likewise, the appellant's assertion that the skilled person could, without undue burden, adjust the release rate by choosing the type of microcrystalline cellulose from those listed in paragraph [0030] of the patent, or its amount in the gum composition, is unsubstantiated and not supported by the patent or by evidence of common general knowledge. The patent lists several types of microcrystalline cellulose as equally suitable, without disclosing that the choice of one type over the others, or the selection of its amount, could play any role in the release of the cannabinoid. This is not shown to be part of common general knowledge either. The appellant's reference to a common general knowledge regarding the disintegrant properties of microcrystalline cellulose e.g. in tablets is not relevant to their release properties in chewing gums, especially considering the contradictory statement in paragraph [0025] of the patent regarding the non-disintegrating properties of the chewing gum compositions. Lastly, the appellant did not indicate which types and which amounts of microcrystalline cellulose actually lead to both 1-30 wt% cannabinoid release within 5 minutes after ingestion and an onset within 3 minutes.

Accordingly, the criteria of sufficiency of disclosure are not met.

2. Admittance of auxiliary request 2 and documents D7-D9
- 2.1 The appellant submitted auxiliary request 2 and documents D7-D9 by letter dated 2 February 2023, i.e. after notification of the summons to oral proceedings dated 14 April 2022. Auxiliary request 2 and the new

evidence D7-D9 represent an amendment to the appellant's appeal case, and shall, in principle, not be taken into account unless there are exceptional circumstances justified with cogent reasons by the appellant, in accordance with Article 13(2) RPBA 2020.

2.2 According to the appellant, auxiliary request 2 was timely filed in response to, and *prima facie* overcomes, the respondent's new objections under Articles 84 and 123(3) EPC raised for the first time in their reply to the appeal. Documents D7-D9 were timely filed in response to the preliminary opinion of the Board that it did not agree that the burden of proof regarding sufficiency of disclosure remained on the respondent, and that the appellant's argument based on D6 was not convincing. Furthermore, D7-D9 would represent common general knowledge and would *prima facie* support arguments presented in the statement setting out the grounds of appeal.

2.3 The Board does not consider that the appellant's arguments are indicative of any exceptional circumstances in the sense of Article 13(2) RPBA 2020.

2.3.1 Firstly, the Board cannot share the appellant's position that auxiliary request 2 was timely filed in response to new objections raised by the respondent in their reply dated 5 November 2021, or that D7-D9 were a timely reaction to the Board's communication under Article 15(1) RPBA issued on 30 September 2022. There is nothing timely in filing D7-D9 and auxiliary request 2 on 2 February 2023, namely 4 months or more than 1 year after the alleged triggering events, and only one week before the oral proceedings before the Board. The appellant provided no compelling reasons justifying their filing at such a late stage of the proceedings.

2.3.2 Secondly, the fact that the Board's preliminary opinion issued under Article 15(1) RPBA was unfavourable to the appellant does not constitute any exceptional circumstances. The primary purpose of a Board's preliminary opinion is to establish the framework of the appointed oral proceedings, i.e. to prepare the oral proceedings, rather than constituting an invitation to a party to make further submissions or to file further requests (see the Case Law of the Boards of Appeal, 10th edition, 2022, V.A.4.5.6.a)). In the present case, the Board did not raise any novel objection, but merely expressed the preliminary view that the case put forward by the appellant, including their reference to a common general knowledge reflected in D6, did not overcome the opposition division's finding of insufficiency of disclosure.

2.3.3 Lastly, the Board does not consider that the admission of these late submissions can be justified by their alleged *prima facie* relevance either, and that they thus do not meet the criteria of Article 13(1) RPBA 2020, which apply, in the present case of submissions filed after notification of a summons to oral proceedings, in addition to those of Article 13(2) RPBA 2020. The amendments in auxiliary request 2 are immaterial to the issue of insufficiency of disclosure on which the appealed decision is based, and do not *prima facie* overcome this objection (see 1. above). As to D7-D9, they do not contain any evidence of common general knowledge regarding the use of microcrystalline cellulose to adjust release properties in chewing gums.

2.4 Hence neither auxiliary request 2 nor any of D7-D9 are admitted into the proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated