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Datasheet for the decision of 13 December 2022

Case Number: T 2082/19 - 3.3.07

Application Number: 05722417.2

Publication Number: 1773302

IPC: A61K9/40, A61K9/44

Language of the proceedings: EN

Title of invention:
RAPIDLY DISINTEGRATING GELATINOUS COATED TABLETS

Patent Proprietor:
Johnson & Johnson Consumer Inc.

Opponent:
Pfizer Inc.

Headword:
RAPIDLY DISINTEGRATING GELATINOUS COATED TABLETS/Johnson & Johnson Consumer Inc.

Relevant legal provisions:
RPBA Art. 12(4)
EPC Art. 54, 56
RPBA 2020 Art. 13(2)

Keyword:

Admission of new documents (No)
Alleged prior use (No)
Main request - Sufficiency of disclosure (Yes)
Main request - Inventive step (No)
Admission of auxiliary request 1 during oral proceedings (Yes)
Auxiliary request 1 - Sufficiency of disclosure (Yes)
Auxiliary request 1 - Inventive step (Yes)

Decisions cited:

T 0748/91, T 2080/18, T 0055/01

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Case Number: T 2082/19 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 13 December 2022

Appellant: (Opponent)	Pfizer Inc. 235 East 42nd Street New York, New York 10017 (US)
Representative:	Wall, Leythem Oxon IP B.V. Evert Van De Beekstraat 354 1118 CZ Schiphol (NL)
Respondent: (Patent Proprietor)	Johnson & Johnson Consumer Inc. 199 Grandview Road Skillman, NJ 08558 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 15 May 2019 concerning maintenance of the European Patent No. 1773302 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. European Patent 1 773 302 had been opposed under Article 100 (a) and (b) EPC on the grounds that its subject-matter lacked novelty and inventive step, and was not sufficiently disclosed.

II. The opposition division took a first interlocutory decision posted on 2 December 2011 finding that the patent as amended in the form of the main request filed on 2 November 2011 met the requirements of the EPC.

III. This first decision of the opposition division was set aside by the Board in decision T 282/12 of 9 November 2017. The Board's decision was based on the set of claims of the same main request filed on 2 November 2011 and remitted the case to the opposition division on this basis for further prosecution, with the conclusion that part of claim 1 of the main request was not entitled to the priority date.

IV. The present appeal lies from the decision of the opposition division that the patent as amended in the form of the main request filed on 2 November 2011 meets the requirements of the EPC.

Claims 1, 7 and 9 of the main request read:

"1. A dosage form comprising:
a) a core having an exterior surface and first and second ends;
b) a subcoating over portions of the exterior surface of the core;

c) a first gelatinous coating over at least part of the subcoating; and
d) a second gelatinous coating over at least part of the subcoating;
(i) wherein the core is a compressed tablet;
(ii) wherein the compressed tablet has an elongated shape;
(iii) wherein the first and second gelatinous coatings are provided on said first and second ends of the core;
(iv) wherein said first and second gelatinous coatings form a gap through which the subcoating is exposed, the gap being from 3% to 33% of the length of the elongated tablet as measured along its longest axis; and
(v) wherein at least one opening is provided through at least the subcoating to expose the exterior surface of the core" (renumbering i)-v) added).

"7. A dosage form according to claim 1, wherein the core contains at least one active ingredient and at least about 40%, preferably about 60%, of said at least one active ingredient dissolves within 3 minutes in 900 mLs of water when tested using USP dissolution apparatus II with a paddle speed of 50 rpm."

"9. A dosage form comprising:
a) a core having an exterior surface and first and second ends;
b) a subcoating over portions of the exterior surface of the core;
c) a first gelatinous coating over at least part of the subcoating; and
d) a second gelatinous coating over at least part of the subcoating;
(i) wherein the core is a compressed tablet;
(ii) wherein the compressed tablet has an elongated shape;

(iii) wherein the first and second gelatinous coatings are provided on said first and second ends of the core
(iv) wherein said first and second gelatinous coatings form a gap through which the subcoating is exposed, the gap being from 3% to 33% of the length of the elongated tablet as measured along its longest axis; and
(v) wherein the subcoating weight gain is less than or equal to about 3%" (renumbering i)-v) added).

V. The documents cited during the opposition proceedings included the following:

D5: WO 97/37629
D8: US 2004/0062806
D11: Report A. Notte
D12, D14-D19: Screenshots comprised in D11
D20: Report from ACNielsen Inc. NITRO database
D21: Measurement of the delivery of acetaminophen rapid release gelcaps
D25. Annex 1: Experimental Evidence
D26 - Experimental Evidence ("Effect of Varying Sub Coating Weight Gain")
D27 - Experimental Evidence ("Effect of Varying Coating Gap")
D28 - Laboratory book extract of D21 test conditions
D29 - Photograph of D21 products tested

VI. According to the decision under appeal, there was no lack of reproducibility issue.

It was considered that the product disclosed by D29 was made available to the public before the relevant date. However features (b), (c), (i)-(iv) of claim 1 were not anticipated by the disclosure of D29, and the claims of the main request complied with the requirements of Article 54 EPC.

With regard to inventive step, D24 was the closest prior art. Claim 1 differed from D24 in that it comprised the features (b), (iv) and (v). The technical effect was an improved dissolution without compromising the swallowability of the dosage from, and the problem was defined as the provision of an improved capsule-like dosage form in terms of the dissolution time while at the same time providing suitable swallowability. The solution of claim 1 was not obvious. The opposition division came to the same conclusion for claim 9.

VII. The opponent (hereinafter the appellant) filed an appeal against said decision. With the statement setting out the grounds of appeal dated 25 September 2019, the appellant submitted the following items of evidence:

A30: Summary of testing on Tylenol product (related to D20, D21, D28, D29) received in Colmar, France on 7 February 2005
A31: Email confirmation Tylenol product delivery (related to D20, D21, D28, D29)
A32: Email confirming Tylenol product testing (related to D20, D21, D28, D29)
A33: Picture of Tylenol product received (related to D20, D21, D28, D29)
A34: Tylenol product advert January 2005 (related to D20 and D29)
A35: Declaration of Delphine Nombret, testing of Tylenol product (related to D20, D21, D28, D29 and D30)
A36: Declaration of William Chekan, purchaser of Tylenol product (related to D20, D21, D28, D29 and D30)

VIII. With its reply to the appeal dated 12 February 2020, the patent proprietor (hereinafter the respondent), filed auxiliary request 1-42.

IX. A communication from the Board, dated 23 September 2022, was sent to the parties.

X. Oral proceedings took place on 13 December 2022. During oral proceedings, the main request was found to lack inventive step over D24, as well as auxiliary requests 1-3. Auxiliary requests 4-8 were found to not meet the requirements of Article 123(2) EPC. The respondent filed a new auxiliary request 1, based on auxiliary request 4 where claims 9-12 and 17 had been deleted and withdrew all auxiliary requests on file.

In comparison to claim 1 of the main request, claim 1 of the new auxiliary request 1 was amended with regard to the gap feature, namely "wherein said first and second gelatinous coatings form a gap through which the subcoating is exposed, the gap being from 3% to **21%** of the length of the elongated tablet as measured along its longest axis;".

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

Admission of documents A30-A36 into the appeal proceedings.

The documents were filed at an early stage of the appeal proceedings, were a reaction to the decision of the opposition division regarding the prior use and did not present new objections or arguments. They provided in particular the missing link identified in the decision.

Request to hear Ms Nombret

Ms Nombret could provide oral testimony corroborating declaration A35 and the experimental summary report A30.

Main request - Sufficiency of disclosure

Claim 7 of the main request included a technical effect, i.e. that "at least about 40%, preferably about 60%, of at least one active ingredient dissolves within 3 minutes in 900 mLs water when tested using USP dissolution apparatus with a paddle speed of 50 rpm". Examples 6A, 2C and 3B of the patent failed to provide this effect. Said examples were non-working embodiments and the claimed subject-matter lacks reproducibility.

Main request - Lack of novelty in view of the alleged prior use

D20 was a sale report proving that the claimed Tylenol product was massively sold in January 2005. The "Universal Prod code" on this document brought directly to the picture of D29 which mentioned the same product number, and to D28. There was no need to prove the actual sale of a product which was massively sold in January 2005.

Main request - Inventive step

The closest prior art was D24, and the distinguishing features were the gap width of 3-33% and the openings (points iv) and v) of the independent claims). There was no technical effect associated with the differences, in view of D25, D26 and D27. The results

of example 8 with regard to the sensory detection of the gap width were not credible and the nature and number of the openings was undefined in the claims. The solution was obvious, in particular in view of D8 or D4.

Admission of the new auxiliary request 1

There were no exceptional circumstances, since the objection under Article 123(2) EPC against claim 9 of auxiliary request 4, on which this request was based, was already raised in the opposition proceedings. A preliminary opinion of the Board could not provide an invitation to file a new request, and the same applied to the absence of preliminary opinion on Article 123(2) EPC. This request shall not be taken into account pursuant to Article 13(2) RPBDA 2020.

New auxiliary request 1 - Sufficiency of disclosure

Claim 7 of this request was not sufficiently disclosed for the same reasons as claim 7 of the main request.

New auxiliary request 1 - Inventive step

D24 did not recite the claimed gap width. The embodiments of examples 8 or 9 were not embodiments with an opening, and no effect was shown. the problem was still an alternative, and the solution was obvious.

XII. The arguments of the respondent may be summarised as follows:

Admission of documents A30-A36 into the appeal proceedings.

These documents should have been filed earlier, since the summons to oral proceedings before the opposition division already raised some deficiencies in relation to the evidences concerning the prior use; the decision of the opposition could not constitute a surprise. The contents of some documents was known already as early as 2005. Moreover, the relevance of the documents was *prima facie* contested.

Request to hear Ms Nombret

This request had to be rejected, since Ms Nombret could not add anything with regard to the documents on file.

Main request - Sufficiency of disclosure

The patent provided sufficient information to achieve the requirements of claim 7, in particular in view of example 7 and paragraphs [0042] and [0068].

Main request - Lack of novelty in view of the alleged prior use

D20 was a Table with undefined provenance, which could not provide sufficient evidence and substantiate the alleged prior use. D21 and D28 could also not be seen as an evidence, and D29 was a simple picture of a box, without any evidence where it came from. All these documents could not show all the claimed features anyway.

Main request - Inventive step

Starting from D24, the skilled person would need to include a subcoating, since this was not disclosed in Figure 1B. The presence of a subcoating had an effect as shown in paragraph [0040] and examples 2A/2C of the

patent. Paragraphs [0068] and examples 8 and 9 showed also the effect linked with the gap width. The problem was seen as the provision of a dosage form having improved dissolution properties while maintaining the consumer preferences. The skilled person would not have had any incentive to add a subcoating and adapt the gap width.

Admission of the new auxiliary request 1

No objection under Article 123(2) EPC was raised against claim 9 of the main request, which presented the same contested features as claim 9 of auxiliary request 4, on which new auxiliary request 1 was based. The objection under Article 123(2) EPC was discussed for the first time during the oral proceedings. The new auxiliary request 1 contained no new subject-matter since it was the same as auxiliary request 4 without claims 9-12 and 17. This led to the existence of exceptional circumstances, which allowed the admittance of this new request.

Auxiliary request 1 - Inventive step

According to example 9, a gap of the claimed width, namely 3-21% did not affect the swalloability.

XIII. Requests

The appellant (opponent) requested that the decision under appeal be set aside and the patent be revoked.

The appellant also requested that the new auxiliary request 1 be not admitted into the proceedings and that Ms Delphine Nombret be able to provide oral testimony corroborating declaration A35, the experimental support

A30 and documents D20, D21, D28, D29, A31 and A35. They also requested inspection of the sample of Tylenol product.

The respondent (patent proprietor) requested that the appeal be dismissed, alternatively that the decision under appeal be set aside and the patent be maintained according to the sets of claims filed as new auxiliary request 1 during the oral proceedings.

The respondent also requested that documents A30-A36 not be admitted into the proceedings and in case that these documents were admitted that the case be remitted to the opposition division and that the request to hear Ms Nombret be rejected.

Reasons for the Decision

1. Admission of documents A30-A36 into the appeal proceedings

1.1 Documents A30-A36 were filed for the first time with the appellant's statement of grounds of appeal on 25 September 2019. The respondent objected to the admittance of these documents into the appeal proceedings. In view of their date of filing, i.e. before the entry into force of the revised Rules of procedure of the Boards of Appeal (RPBA 2020, OJ EPO 2019, A63), the admittance of these documents is to be decided under Article 12(4) RPBA 2007 (Article 25 RPBA 2020). Pursuant to Article 12(4) RPBA 2007, the Board has discretion to hold inadmissible facts, evidence or requests which could have been presented in the first instance proceedings.

A30 is an experimental report established by Capsugel Lonza - R&D department in September 2019 on "Tylenol Extra Strength - Rapid release gels" allegedly received in Colmar, France, on 7 February 2005. It comprises pictures of bottles and tablets of Tylenol product, coating and subcoating identification, gap size calculation, coating and subcoating weight gain calculation, pictures of Tylenol product before and after coating and subcoating removal and results of dissolution tests conducted in February 2005 and February 2006.

A31 is an e-mail dated 7 February 2005 from Dominique Cade to Ewart Cole, confirming the reception of "Tylenol RR samples".

A32 is an e-mail dated 8 February 2005 from William Checkan to Dominique Cade relating to the sending of additional acetaminophen samples.

A33 is a dissolution test of Tylenol RR Gelcaps dated 3 March 2005.

A34 is an advert for Tylenol Rapid Release Gels allegedly published in "USA Today" on 21 January 2005.

A35 is an Declaration of Delphine Nombret relating to the reception on 7 February 2015 of tylenol gelcaps and the testing of this product shown in document D29, D30 and D33.

A36 is a declaration of William Chekan relating to the purchase of a Tylenol "extra strengh rapid release Gels" gelcap in a retail store in new jersey, USA prior to 16 February 2005.

1.2 The appellant argued that these documents relate to evidence already on file, particularly to D20, D21, D28 and D29, that they were filed at the very beginning of the appeal proceedings and are very straightforward. According to the appellant, they were filed directly in response to points made in the decision of the opposition division, which confirmed that there had been a prior disclosure of the Tylenol product but surprisingly considered that D29 was not enough to confirm the presence of all the claim features. They are prima facie highly relevant for the discussion of lack of novelty in light of public prior use and for inventive-step. They relate to a product massively sold by the respondent by the beginning of February 2015 and of which they were already aware for over 15 years, so that there are no reasons why the respondent could not review these straightforward documents.

1.3 The respondent considers that these documents should have been filed during the opposition proceedings since they relate to a prior use objection which was raised by the appellant with their notice of opposition on 10 March 2010 and to a product which was in possession of the appellant since 2005. They alleged that the appellant made a tactical decision to delay submitting the documents until the appeal stage, forcing the Board of Appeal to investigate their relevance for the first time and depriving the respondent the opportunity of having two instances on them. They further contest their prima-facie relevance in particular in terms of whether the newly filed experiments are actually reflective of knowledge that could be gained by the skilled person using their general technical knowledge to discover the internal structure of the product at the filing date.

1.4 The Board takes the view that documents A30-A36 could and should have been filed in the opposition proceedings.

The Board notes first that the prior use objection was raised in the notice of opposition on 10 March 2010 and that the main request is on file since 2 November 2011. It is established case-law that where lack of novelty is alleged over a public prior use, the burden of proof lies with the party claiming that the claimed features were disclosed in the alleged public prior use before the relevant date. This requires a provision of a complete chain of evidence that the product "Tylenol Extra Strength - Rapid release gels" disclosed all the claim features and was made available to the public before the filing date of the contested patent.

Yet, for the first-time in appeal the appellant files a document (A30) relating to the composition of the Tylenol gelcaps, in particular to the presence of a sub-coating and to the width of the gap. These features were at the heart of the substantive discussion in the opposition proceedings. During the opposition proceedings, the appellant relied on D29 only in support to its allegation that all claimed features were present in the Tylenol gelcaps (see decision point 3.3). The decision of the opposition division that the figure of D29 did not allow the skilled person to determine the presence of a sub-coating nor the presence of a gap width having 3% to 33% of the elongated tablet did not come as a surprise since it was based on the arguments of the respondent (see for instance their letter of 20 March 2018) and already presented in the annex to the summons to attend opposition oral proceedings dated 6 June 2018 (see point 1.10). Furthermore, the appellant claims that

they are in possession of the Tylenol Tablets since 2005. This means that they had ample time to test the product in the course of the opposition proceedings to support their allegation that it disclosed all the claimed features. The same holds true for the dissolution tests of A33 that were performed in 2005.

Documents A31, A32 and A34-A36 are intended to demonstrate the public availability of the Tylenol product before the priority date. The content of documents A31, A32 and A34 was available already in 2005, while A35 and A36 are declarations relating to the purchase and the receipt of the Tylenol product in 2005. As they relate to the prior use objection raised in the notice of opposition, the Board could not find any reason why these documents could not have been filed earlier. The appellant had several opportunity during the opposition proceedings to provide evidence regarding the public availability of this product. In particular, after receipt of the annex to the summons to attend the opposition oral proceedings of 6 June 2018, which expressed doubts as to the public availability of the claimed prior use before the relevant date (see point 1.9), the appellant filed documents D26-D29. If the appellant wanted to complete their case on this, they could and should have filed documents A31, A32, A34-A36 at the same time. The circumstances of the case do not justify that these documents were submitted only in appeal.

The alleged prima facie relevance of documents A30-A36 cannot justify their late-filing. In this regard the Board notes that the criterion under Article 12(4) RPBA 2007 is whether the documents in question could and should have been filed in the first-instance proceedings.

Accordingly, the Board exercises its discretion not to admit A30-A36 into the appeal proceedings (Article 12(4) RPBA 2007).

2. Request to hear Ms Nombret during oral proceedings

In view of the decision to not admit documents A30 and A35 into the appeal proceedings, the request to hear Ms Delphine Nombret on these documents must also be rejected.

3. Main request - Sufficiency of disclosure

The appellant objected to claim 7 of the main request.

Dependent claim 7 of the main request includes a technical effect, i.e. that "at least about 40%, preferably about 60%, of at least one active ingredient dissolves within 3 minutes in 900 mLs water when tested using USP dissolution apparatus with a paddle speed of 50 rpm".

The Board concurs with the appellant that the gelcaps of examples 6A, 2C and 3B contain all the features of claim 1 of the main request, yet they do not show the dissolution profile of dependent claim 7. Hence example 6A shows 0% dissolution within 3 minutes, while examples 2C and 3B show 4% and 17% respectively after the first 3 minutes.

The Board notes however that claim 7 is a dependent claim relating to more restricted specific embodiments of the invention. Independent claim 1 of the main request relates to a broader subject-matter, and the presence of alleged "non-working embodiments", such as

examples 6A, 2C or 3B as mentioned by the appellant, does not lead to an insufficient disclosure, as long as the description as a whole provides also all technical information to realize more specific embodiments, which is the case in the contested patent.

The opposition division mentions in particular example 7 and paragraphs [0042] and [0068] of the opposed patent as providing the relevant information to achieve the claimed technical effect.

In example 7, several dosage forms present the claimed dissolution profile of dependent claim 7, such as at least examples 6B and 5B. The invention claimed in dependent claim 7 is therefore specifically illustrated in these specific examples. Moreover, paragraphs [0042] and [0068] provide sufficient teaching regarding the openings and the gap width to adapt the claimed dosage form to the dissolution profile of dependent claim 7.

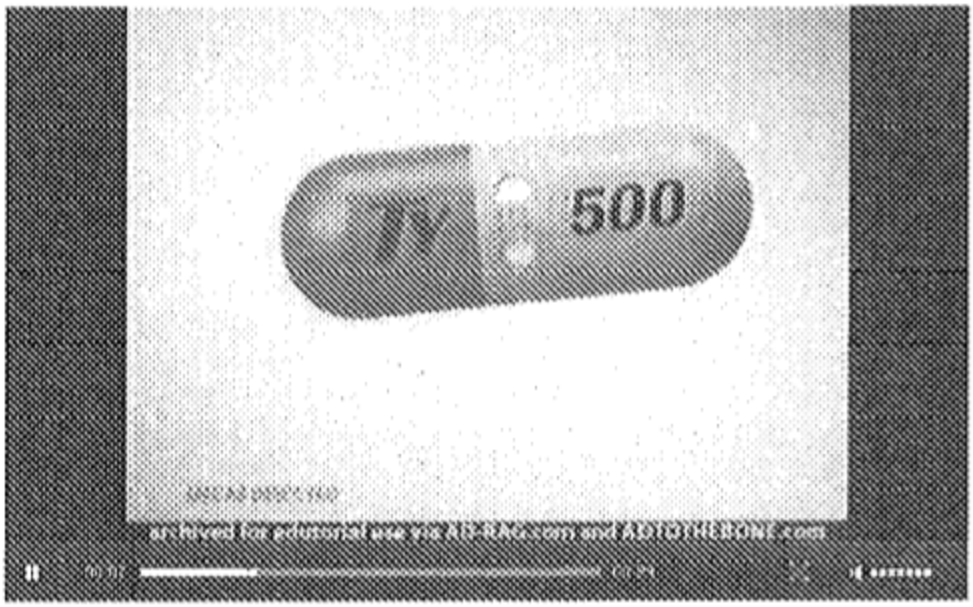
Consequently, the subject-matter of the main request is sufficiency disclosed.

4. Main request - Lack of novelty in view of the alleged prior use

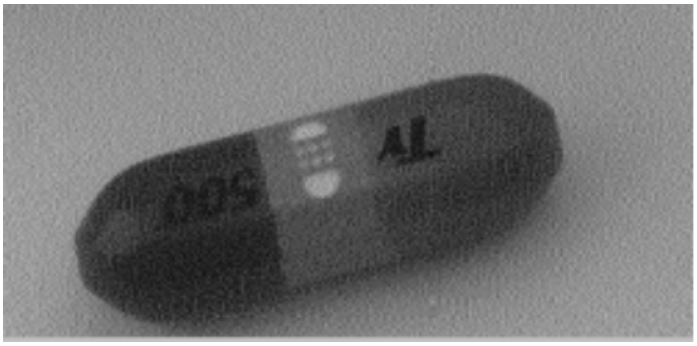
4.1 The appellant based its allegation on public prior use on documents D29, D20, D21 and D28 and on a video commercial shown to the public on 6th February 2005 during the Super Bowl pre-program advertisements.

4.2 The video commercial was shown to the public on 6th February 2005 during the Super Bowl pre-program advertisements (Cf. D11 and screenshots of D12, D14-D19). D11 comprises screen grabs of a commercial that has been broadcast on 6 February 2005 relating to

"Extra Strength Tylenol Rapid Release Gels". Page 10 shows a dosage form in form of a caplet that has different colours and holes in the middle.



4.3 D29 is a photograph of the box and bottle of Tylenol Rapid Release Gels product allegedly received on 7 February 2005 in Colmar, France, which lists a product code number 3-0045-0488-24, a limit date of 10/06, and a batch number JSA246; it also shows a Tylenol gelcap aside the box as following:



According to the appellant, the product of D29 known as "Extra Strength Tylenol Rapid Release Gels" was

publicly sold prior to the effective date of the patent and was purchased by the appellant before 7 February 2005 with a proof of public sales given by D20. The purchased product has been analyzed as shown by D21 and D28.

Both parties agreed that the sample of Tylenol product brought by the appellant at the oral proceedings for inspection corresponded to the one showed in D29. The parties also agreed that for this reason an inspection of the sample was not necessary.

D20 is a table comprising several columns, showing aside from a product code 030045048824 two different numbered results namely 158.975 for the week ending 29 January 2005 and 1.149.126 for the week ending 26 February 2005. This is shown on the second page, last line as follows:

BE HIGH DESCRIPTION	BE LOW DESCRIPTION	FORM	Universal Prod Code	WEEKS ENDING 01/29/05	WEEKS ENDING 02/26/05
JOHNSON JOHNSON	MCNEIL CONSUMER HEALTHCARE	GELCAP	030045048810	8305	157847
JOHNSON JOHNSON	MCNEIL CONSUMER HEALTHCARE	GELCAP	030045048850	38309	473888
JOHNSON JOHNSON	MCNEIL CONSUMER HEALTHCARE	GELCAP	030045048824	158975	1149126

According to the appellant, the table is a sales report from the AC Nielsen database indicating a summary of sales of Tylenol product for the period ending 29 January 2005. For the product code 030045048824 there were specifically 158.975 units sold by the week ending 29 January 2005. Said product code 3-0045-0488-24 mentioned in D20 is also visible on the picture of document D29, which shows also the batch number JSA246 on the medicament box of Tylenol Rapid Release Gels.

D21 shows a Table and a figure disclosing the in vitro release profile of Tylenol rapid release gels of batch JSA246 received on 7 February 2005.

D28 is an extract from a laboratory book dated 24 February 2005. According to this document, the product tested in a dissolution test is Tylenol Rapid Release Gels with batch number JSA246, received on 7 February 2005. The results of said tests are shown in D21.

4.4 Under established case law, when determining whether an invention has been made available to the public by prior use, the following has to be clarified: (i) when the prior use occurred, (ii) what was made available to the public through that use and (iii) the circumstances of the use, i.e. where, how and by whom the subject-matter was made public through that use (see Case Law of the Boards of Appeal, I.C.3.2.4, 10th edition).

In the present case, the crucial document appears to be D20, which is supposed to make the link between the product "Extra Strength Tylenol Rapid Release Gels" seen in D29 or in the video commercial and proving that the same product was effectively sold before the effective date of the contested patent, namely 16 February 2005. However, document D20 merely discloses a table of undefined provenance, without any evidence or certificate of authenticity. As observed by the respondent, the appellant has offered no substantiation of exactly what the data of D20 demonstrate or any further explanation to corroborate the alleged sales. In the Board's view, D20 cannot provide any evidence in relation to the questions that need to be answered to substantiate an allegation of prior use, here to the occurrence of a public use in the form of the sale of the product, since its authenticity cannot be certified and it does not mentions *inter alia* where, how or to or by whom the product was indeed sold.

Moreover, the medicament box of the batch number JSA246 has been reported in documents D21 and D28 for its reception on 7 February 2005 and for the dissolution experiments performed on 24 February 2005, i.e. after the filing date of the contested patent. The Board concurs with the respondent that neither D21 nor D28 provides details or evidence in relation to the circumstances surrounding the tested samples. It is therefore not clear how the medicament box with the code number 3-0045-0488-24 and the batch number JSA246 has been acquired and there is in particular no evidence that it has been purchased.

Referring to T 55/01, the appellant argued that in case of mass-produced and distributed consumer products there were no need to prove that the product was sold to specific customer. However, this decision is not relevant to the present case since there is no convincing evidence that the product Tylenol Rapid Release Gels was massively distributed before the filing date of the patent.

Consequently, the circumstances relating to the alleged prior use are not shown by document D20 and by any other cited documents, in particular D21 or D28. Thus, the evidence submitted fails to support the appellant's allegation of public prior use.

It follows that the main request complies with the requirements of novelty.

5. Main request - Inventive step

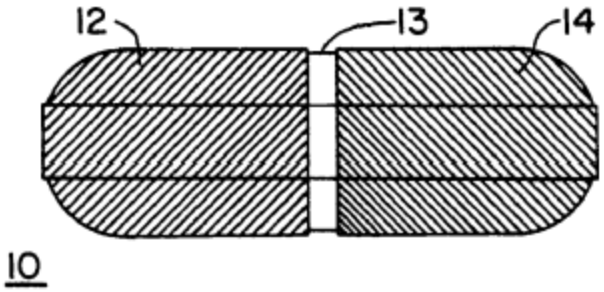
5.1 The present invention relates to a dosage form comprising a tablet core having two ends. The tablet

core is provided with gelatinous coatings over both ends and has a faster disintegration and/or dissolution than other gelatinous coated products (see par. [0007] of specification).

5.2 Closest prior art

5.2.1 D24 discloses a caplet in Fig.IB made from a compressed core in elongated shape, that is coated with gelatin (12, 14), without any subcoating and wherein a seam area 13 is devoid of gelatin coating (see also column 5, lines 45-55).

FIG. IB



The sentence bridging columns 5 and 6 of D24 discloses that in certain embodiments the caplets may comprise a subcoating applied to the entire surface of the uncoated compressed product. This passage, which is not limited to the caplets of Fig. IB but relates also e.g. to caplets that do not contain a seam area, also indicates the kind of material used for such subcoating (see D24, col. 5, line 66-col. 6, line 16). The following passage of D24 mentions that the preferred embodiment is an oblong shaped caplet coated at each end with a different color coating, in particular with gelatin.

D24 does not give any information as to the presence of openings through the subcoating. Furthermore, D24 is silent as to the gap width. It is also not possible to determine the width of the gap on the basis of the figure, due to the absence of a scale in the schematic view of Figure IB of D24. Indeed, according to established jurisprudence, dimensions obtained merely by measuring a diagrammatic representation in a document do not form part of the disclosure, and schematic drawings cannot be used to derive a ratio between two dimensions, since the drawings at issue are not marked as true to scale (see Case Law Book I.C. 4.6). The situation is different from the case T 748/91, where it was simply a question of determining if one dimension was smaller than another. In contrast in the present case the determination of the gap width as percentage of the length of the uncoated core ratios would require accurate measurement of the drawings.

Consequently, this document does not disclose a dosage form combining the features (b), (iv) and (v).

5.2.2 The appellant also considered D5 as potential closest prior art in its written submissions.

D5 relates to the process for encapsulating of caplets in a capsule and to the solid dosage form obtainable by such a process. The process consists in providing empty capsule parts, filling at least one of said capsules part with one or more caplet, putting the capsules parts together and treating the final capsule by cold shrinking (see page 3, lines 28-34). The Board considers the disclosure of D5 to be very remote from the claimed invention, and this document cannot be considered to be relevant for the assessment of inventive step.

5.2.3 The closest prior art is therefore D24.

5.3 Problem to be solved

The opposition division defined the problem as the provision of an improved capsule-like dosage form in terms of the dissolution time while at the same time providing suitable swallowability. The respondent had a similar definition of the problem, namely to provide a dosage form with improved dissolution while maintaining consumer preferences.

In the appellant's view, the problem is the provision of an alternative dosage form.

5.4 As a solution to any of these alleged problems, claim 1 of the main request proposes a dosage form wherein the first and second claimed gelatinous coatings form a gap through which the subcoating is exposed, the gap being from 3% to 33% of the length of the elongated tablet as measured along its longest axis (feature (iv)) and wherein at least one opening is provided through at least the subcoating to expose the exterior surface of the core (feature (v) of claim 1.

5.5 Examples 6A, 6B, 5B and 5C, as well as examples 7-9 and paragraphs [0057] or [0068] and documents D25 and D27 were discussed in the opposition and appeal proceedings with regard to the alleged technical effects.

5.5.1 The content of paragraph [0057] is the statement that for a dosage form of about 1.905 cm, a gap width of about 0.061 to 0.406 cm (about 2-21%), the slipperiness of the dosage form is not effected, and a majority of panelists cannot detect a height transition, i.e a step

transition from the subcoating band to the geldipped ends. This passage refers however to a gap width of 2-21% which is not the subject of claim 1 of the main request, which claims a gap width of 3-33% of the length of the elongated tablet.

The same conclusion applies for the content of paragraph [0068], which mentions that, if the gap becomes too small, inter alia the level of improved dissolution diminishes, while, if the gap becomes too large, some of the consumer preferences, such as swallowability of the gelcap may be compromised.

These statements in paragraphs [0057] and [0068] are supported by the experiments of examples 8 and 9 of the patent.

Example 8 of the contested patent provides a sensory evaluation of the gap width, wherein different gap width categories were evaluated by panelists, in order to evaluate a texture difference of the gelcap, i.e a "step-up" or a perceptible texture transition from the subcoating band to the geldipped ends of the gelcaps. Example 8 shows that a texture difference between the exposed subcoating band and gelatin dipped ends started to be detected when the gap width was about 18-22% of the uncoated core, and a significant proportion of the panelists detected a definite texture transition between said geldipped ends and exposed subcoating band for this width gap of about 18-22% (see Table of par. [0098] and [0100])).

These results are confirmed by the experiments of example 9 of the patent. A texture difference between the subcoated bandwidth and geldipped ends was not readily detectable among the samples which had a gap

width comprised between 3 and 21% of the uncoated core (see Table of par. [0105]). For all samples evaluated, 44-51% of the panelists could not detect a texture difference between the exposed subcoating gap in the middle of the gelcap and the geldipped ends.

An effect as to the maintenance of the consumer preference, i.e. the absence of a texture difference on the gelcaps, is therefore proven in examples 8 and 9, but this effect is exclusively linked with a gap width of less than about 21%, which is not claimed in claim 1 of the main request. Consequently, the effect of providing suitable swallowability or maintenance of the consumer preferences while keeping a speed of dissolution demonstrated in examples 8 and 9 cannot be extrapolated to the claimed subject-matter.

5.5.2 The patent discloses in example 7 dissolution tests of different type of dosage forms such as in particular examples 6B and 5C.

Said Examples 6B and 5C of the opposed patent provide evidence that the presence of openings improves the speed of the dissolution rate in comparison to dosage form without openings, as represented by Ex 6A and Ex. 5B. Said dosage form of examples 6B and 5C have been prepared through ablation of plurality of openings into the exposed subcoating portion in a given pattern as shown for instance in Figure 3 (see openings 32).

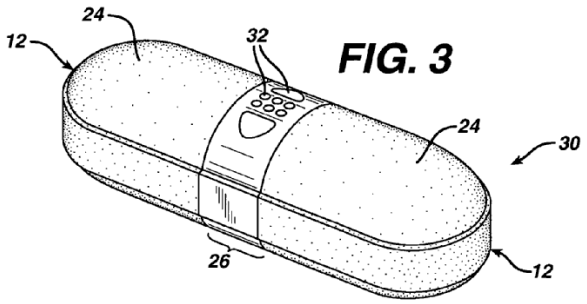


FIG. 3

Claim 1 of the main request relates however to a dosage form "wherein at least one opening is provided through at least the subcoating to expose the exterior surface of the core", which does not correspond to the dosage forms used in examples 6B and 5C. The possible configuration with one unique opening, or opening(s) of any undefined size or number cannot correspond to the very specific dosage forms described in example 6B and 5C.

Moreover, according to the appellant examples 6B and 5C have a specific gap width that the appellant calculated to be between 8.53-8.91%, which appears also to be very specific in view of the claimed 3-33% gap width.

Consequently, the improvement in speed of dissolution demonstrated in examples 6B and 5C cannot be extrapolated to the claimed subject-matter.

5.5.3 The experimental evidence submitted by the appellant cast further doubts as to the effects of the openings and of the gap width on the dissolution profile of the compositions of the main request.

In the dissolution tests reported in D25 (Annex I), it is shown that the presence of openings in the sub-coating provides no improvement in the dissolution rate. The results disclosed in this document appear to

indicate that the presence of openings does not reliably improve the dissolution.

5.5.4 D27 is an experimental study on the effect of varying gap width on the release profile of acetaminophen from gelcaps comprising a subcoating and a further gelatin coating, the gap width varying from no gap (0%) and 2.6% to 15.7% of the length of the uncoated core. The absence of a gap width (complete encapsulation with a gelatinous coating) leads to the slowest dissolution, while the absence of an outer shell of a comparative dosage form without any gelatinous coating has the fastest dissolution. As argued by the appellant, the results show a constant high dissolution profile corresponding to the claimed dissolution profile for all caplets with a gap but the evidence presented in D27 shows no significant difference in dissolution properties between a gap width below 3% (i.e. outside the range of claim 1) and a gap width above 5% (i.e. inside the range of claim 1) with either a 1.5% or 1.0% weight gain subcoating (see for instance Chart 1 on page 4).

5.5.5 Hence, in the Board's view, the alleged technical effect on providing a dosage form with improved dissolution while maintaining consumer preferences, i.e suitable swallowability, has not been credibly shown with regard to a gap through which the subcoating is exposed, the gap width being from 3% to 33% of the length of the elongated tablet, and the presence of one opening through at least the subcoating.

The problem is therefore as defined by the appellant, namely the provision of an alternative dosage form.

5.6 It remains to determine if the claimed solution is obvious.

The disclosure of columns 5 and 6 of D24 suggests the introduction of a subcoating in the caplets of Fig IB. In the Board's view, the mere adaptation of a known dosage form belongs to the field of the routine tasks for the person skilled in the art. In the present case, the choice of a gap width comprised between 3-33% without any demonstration that this causes an unexpected technical effect amounts to an arbitrary measure within the ordinary routine of a skilled practitioner and cannot contribute to an inventive step.

The use of openings for releasing active agents is also generally known, e.g. from document D8 which indicates that the presence of opening can be used to effect the desired release rate (see [0031]. Hence, the presence of at least one opening in the subcoating can neither contribute to an inventive step.

Consequently, the claimed solution, i.e a dosage form wherein the first and second gelatinous coatings form a gap through which the subcoating is exposed, the gap being from 3% to 33% of the length of the elongated tablet as measured along its longest axis (feature (iv)) and wherein at least one opening is provided through at least the subcoating to expose the exterior surface of the core (feature (v)) of claim 1 is obvious.

The main request does not meet the requirements of Article 56 EPC.

6. New auxiliary request 1 - Admittance into the appeal proceedings

6.1 This request has been filed during the oral proceedings before the Board. It corresponds to the claims of auxiliary request 4 previously on file but involves the deletion of claims 9-12 and 17. Claim 1 differs from claim 1 of the main request by the specification of the gap width, namely "the gap being from 3% to **21%** of the length of the elongated tablet" (emphasis in bold added).

6.2 Since the new auxiliary request 1 was filed during the oral proceedings before the Board, the provision of Article 13(2) RPBA 2020 are relevant and thus this request can only be taken into account if there are exceptional circumstances, which have been justified with cogent reasons by the party concerned. Furthermore, the criteria applicable under Article 13(1) RPBA 2020 may also be relied on: " The Board shall exercise its discretion in view of, inter alia, the suitability of the amendment to resolve the issues which were admissibly raised by another party in the appeal proceedings [...], whether the amendment is detrimental to procedural economy and, in case of an amendment to a patent application or patent, whether the party has demonstrated that any such amendment, prima facie, overcomes the issue raised by another party [...] and does not give rise to new objections".

6.3 In the present case, auxiliary request 4 on which the new auxiliary request 1 is based was filed with the reply to the statement of grounds of appeal. With respect to the independent claims of the main request, the independent claims of auxiliary request 4 have been amended to limit the range of gap size to 3-21%. In its

letter dated 20 April 2020, the appellant objected that there was no direct and unambiguous disclosure of the combination of the gap range of 3-21% with the feature of the subcoating weight gain of less than or equal to 3% as presented in at least claims 9 and 17 of Auxiliary Request 4 (cf. paragraphs [0068] and [0070] of the application as-filed).

The Board's preliminary opinion focused on the objection raised against the main request and did not specifically address this objection raised only against auxiliary request 4. During oral proceedings, this objection was discussed and the Board came to the conclusion that indeed claims 9 of auxiliary request 4 contravened the requirements of Article 123(2) EPC.

The Board notes that while this objection was susceptible to apply also to claim 9 of the main request, since the gap width originated from the same original passage of the original description, the appellant chose in opposition and in appeal proceedings to raise this objection only against claims 9 and 17 of auxiliary request 4. The absence of any objection under Article 123(2) EPC against claim 9 of the main request did not allow the opposition division to decide on this issue nor prompted the Board to issue a preliminary opinion specifically on it. This objection was then discussed for the first-time during the oral proceedings before the Board and the conclusion of the Board came as a surprise for the respondent. Having regard to this specific procedural context and considering that the deletion of some unvalid claims promotes procedural economy by clearly responding to existing objections without creating new ones, the Board decided to take this new request into account. This conclusion appears in line with the approach

followed in several decisions of the boards of appeals in similar circumstances (see e.g. T2080/18 5.1)

Consequently, the new auxiliary request 1 is admitted into the appeal proceedings (Article 13(2) RPBA 2020).

7. New Auxiliary request 1 - Sufficiency of disclosure

This request was objected by the appellant by reference to its written submission regarding sufficiency of disclosure of the previous auxiliary request 4, which was objected for the same reason as the main request, namely the subject-matter of dependent claim 7 (cf. point 3 of the present decision).

Hence, the conclusion reached for the main request applies *mutatis mutandis* for the new auxiliary request 1, which meets the requirements of Article 83 EPC.

8. New auxiliary request 1 - Inventive step

8.1 In comparison to claim 1 of the main request, claim 1 of the new auxiliary request 1 was amended with regard to the gap width feature, namely "the gap being from 3% to **21%** of the length of the elongated tablet as measured along its longest axis".

8.2 D24 remains the closest prior art; this document does not disclose explicitly the presence of features (b), (iv) and (v) of claim 1, namely the combination of the presence of a subcoating, a gap width of 3% to 21% of the length of the tablet, and the presence of at least one opening through the subcoating to expose the exterior surface of the core. Hence, the distinguishing features remain the same features as for the main request, with a further restriction in the width of the

gap, which is now 3 to 21% instead of 3 to 33% for the main request.

8.3 In the appellant's view, the problem is still the provision of an alternative dosage form.

The respondent's definition of the problem is to provide a dosage form with improved dissolution while maintaining consumer preferences.

8.4 The claimed solution is a gap width of 3% to 21% of the length of the tablet, and the presence of at least one opening through the subcoating to expose the exterior surface of the core.

8.5 The possible effects linked with the claimed solution had already been discussed for the main request under points 5.5.1-5.5.4 above.

Under points 5.5.2 to 5.5.4, t was concluded that there is no improvement of the dissolution profile linked with the distinguishing features. This conclusion applies *mutatis mutandis* to the invention claimed in claim 1 of the new auxiliary request 1.

In point 5.5.1 above, it was concluded that the effect of providing suitable swallowability or maintenance of the consumer preferences, i.e. the absence of a texture difference on the gelcaps, demonstrated in examples 8 and 9 could not be extrapolated to the subject-matter of claim 1 of the main request, since this effect was exclusively linked with a gap width of less than about 21% while claim 1 of the main request related to a gap width of 3-33%. The conclusion reached in point 5.5.1 does not apply to the subject-matter of claim 1 of the new auxiliary request 1, since its subject-matter is

now restricted to a gap width of 3-21%. Furthermore, in the Board's view there is no reason to consider that the effect on the texture would disappear by varying the amount of the coating.

Consequently, the effect of providing suitable swallowability and maintenance of the consumer preferences demonstrated in examples 8 and 9 can now be extrapolated to the subject-matter claimed in the new auxiliary request 1 and the technical problem can be formulated as the provision of a fast dissolution dosage form which maintains the consumer preference.

8.6 The question remaining is whether the skilled person, starting from Figure 1B of D24, would arrive at the subject-matter of claim 1 of the main request in an obvious manner in order to solve the problem posed.

D24 is totally silent about texture sensation and does not give any information about the gap width.

D8 was also mentioned by the appellant in its written submission in the context of obviousness. This document teaches that openings can be placed in a dosage form as illustrated by Figures 2-5, but does not contain any teaching in relation to a possible gap through the coating as required by claim 1 of auxiliary request 1.

Hence, neither D24 nor D8 teaches that the gap width may affect the consumer preference. Consequently, the skilled person facing the objective technical problem defined above would not have been motivated by any of the cited documents to provide a gap width in the range of about 3% to about 21 % of the overall length of the uncoated core.

Accordingly, the subject matter of claim 1 of the new auxiliary request 1 is inventive, and the new auxiliary request 1 meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition decision with the order to maintain the patent with the set of claims of the auxiliary request 1 filed during the oral proceedings and a description to be adapted thereto.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated