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Datasheet for the decision of 26 January 2021

Case Number: T 2029/18 - 3.3.07

Application Number: 09075209.8

Publication Number: 2098224

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:
Capsugel Belgium N.V.

Headword:
Rapidly disintegrating gelatinous coated tablets/Johnson & Johnson Consumer Inc.

Relevant legal provisions:
EPC Art. 123(2), 76(1), 100(b), 54, 56
RPBA 2020 Art. 13(1)

Keyword:
Main request - Amendments (Yes)
Main request - Sufficiency of disclosure (Yes)
Admission of new documents (No)
Request to hear an expert (No)
Request to provide samples (No)
Prior use (No)
Main request - Novelty (Yes)
Main request - Inventive step (Yes)

Decisions cited:
T 0748/91

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Case Number: T 2029/18 - 3.3.07

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

Appellant: (Opponent)	Capsugel Belgium N.V. Rijksweg 11 2880 Bornem (BE)
Representative:	HGF Benoordenhoutseweg 46 2596 BC Den Haag (NL)
Respondent: (Patent Proprietor)	Johnson & Johnson Consumer Inc. 199 Grandview Road Skillman, NJ 08558 (US)
Representative:	Kirsch, Susan Edith 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 1 June 2018 concerning maintenance of the European Patent No. 2098224 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. European patent No. 2 098 224 was granted on the basis of a set of 9 claims.

II. An opposition was filed under Article 100 (a), (b) and (c) EPC against the granted patent on the grounds that the subject-matter of the granted patent lacked novelty and inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed.

III. The appeal lies from the decision of the opposition division finding that the patent in amended form met the requirements of the EPC. The decision was based on the main request filed during the oral proceedings of 10 April 2018.

Independent claim 1 of the main request read as follows:

"1. A dosage form comprising:
a) a core having an exterior surface and first and second ends and comprising one or more active ingredients;
b) a first gelatinous coating over at least part of the core; and
c) a second gelatinous coating over at least part of the core;
wherein the first and second gelatinous coatings are provided on said first and second ends of the core;
wherein the total level of said first and second gelatinous coatings is from about 3 to about 10 weight percent based on the weight of the core;

wherein said first and second gelatinous coatings are form a gap through which the core is exposed;
wherein the width of the gap is from about 3% to about 21% of the overall length of the uncoated core; and
wherein the time for release of at least about 80% of one or more active ingredients contained in the core from the dosage form, using USP Apparatus II (paddle method) at 50 rpm with any dissolution media appropriate for the particular active ingredient and dosage form, is not more than 50 percent of the time specified in the applicable USP or NDA specifications for immediate release solid dosage forms containing such active ingredient."

IV. The documents cited during the opposition proceedings included *inter alia* the following:

A1: A screenshot of a website dated 12th February 2005
A2: Report by Maître Antoine Notte dated 25th February 2010
D1: US 5,234,099
D2: US 6,120,801
D3: USP II apparatus method
D4: Gap size measurements of Fig. 1B of D1
D5: Experimental report
D8: US 10/756,528
D9: Report from AC Nielsen Inc. NITRO database
D10: Report containing solubility tests performed on Tylenol Acetaminophen Rapid Release Gels made by Capsugel

V. According to the decision under appeal, claims 1-8 of the main request met the requirements of Articles 76(1) and 123(2) EPC.

The claimed invention was sufficiently disclosed. Claim 1 did not lack reproducibility in view of example 7 and paragraph [0058] of the patent, which provided sufficient information to the skilled person on how to achieve the technical effect mentioned, and the determination of USP parameters was known and standard for a skilled person. Finally, the opposed patent described the processes required to carry out the invention in clear technical terms such as to achieve the intended result.

The evidence submitted by the opponent failed to demonstrate that the dosage form of claim 1 of the main request was made available to the public before the patent's filling date. D9 did not provide any evidence to the occurrence of the public use and A2 failed to disclose any of the technical features of the dosage form of claim 1. Consequently, the claims of the main request were novel.

In view of the conclusions reached as to the relevance of the prior use, the opposition division did not consider necessary to assess the validity of the priority.

As regards inventive step, D1 was considered to be the closest prior art. Claim 1 differed in that it comprised feature (i), the total amount of said first and second gelatinous coatings, feature (ii), namely the width of the gap and feature (iii), namely the dissolution profile. The technical problem was seen as the provision of an improved capsule-like dosage form in terms of dissolution time and swallowability. Since neither D1, nor D2 provided the skilled person with the indication that the gap width was relevant for giving the user a suitable swallowability sensation, and since

D1 and D2 were silent regarding the gap width and the dissolution, the claimed solution was not obvious.

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

D11: Laboratory book extract of D10 test conditions
D12: Photograph of D10 products tested

VII. With a letter dated 21 February 2019, the patent proprietor (hereinafter the respondent) filed the main request as upheld by the opposition division and auxiliary requests 1 to 5.

VIII. With a letter dated 25 September 2019 the appellant submitted the following items of evidence:

D13: Summary of testing on Tylenol product (related to D9 to D12) received in Colmar, France on 7 February 2005
D14: Email confirmation Tylenol product delivery (related to D9 to D12)
D15: Email confirming Tylenol product testing (related to D9 to D12)
D16: Picture of Tylenol product received (related to D9 to D12)
D17: Tylenol product advert January 2005 (related to D9 and D12)
D18: Declaration of Delphine Nombret, testing of Tylenol product (related to D9 to D17)
D19: Declaration of William Chekan, purchaser of Tylenol product (related to D9 to D17)

IX. With a letter dated 30 December 2019, the respondent filed auxiliary requests 6 to 15. The respondent also requested that D13-D19 not be admitted into the proceedings.

X. A communication from the Board, dated 3 February 2020, was sent to the parties.

XI. With a letter dated 4 March 2020, the respondent filed auxiliary requests 16 to 23.

XII. Oral proceedings took place on 26 January 2021 by videoconference.

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

Main request - Amendments

Claim 1 of the main request was based on claims 18 and 21 of the parent application, which claim 21 recited the presence of a subcoating, a feature now absent from claim 1, and in which the term "subcoating" had been replaced by "core". This amendment could not be a correction of an obvious error as stated by the opposition division in its decision.

As regards claim 2, there was no basis in any dependent claim of the parent application or in the description for a release profile "after about 6 minutes", which had a different meaning that "within about 6 minutes" appearing in paragraph [035].

The subject-matter of claims 3, 4 and 5-8 did also not have any basis in the parent application.

Consequently, all claims of the main request contained subject-matter which extended beyond the scope of the parent application as filed and did not satisfy the requirements of Article 76(1) EPC or Article 123(2) EPC.

Main request - Sufficiency of disclosure

There was no concept fit for generalization in the description of the contested patent. The patent did not contain any teaching that would allow the effect specified in claim 2 of the main request to be obtained. All examples fell outside the scope of the claim. The failure of the disclosed embodiments to achieve the claimed technical effects meant that the patent lacked reproducibility across the whole scope of the claim.

Admission of documents D13-D19 into the proceedings

The documents had been filed at the earliest opportunity. The decision of the opposition division confirmed that there was a missing link between the documents relating to the prior use filed, with regard the amount of gelatinous coating and the dissolution profile. First D11-D12 were filed with the statement of grounds of appeal in response to the decision, and these documents were completed later by D13-D19.

None of D13-D19 were complex, they did not relate to new objections or new arguments. Moreover, the respondent had sufficient time to study them.

The documents were furthermore linked to the disclosure of D9 and D10.

Request to hear Ms Nombret on D9-D12

Ms Nombret was a witness from the purchase and the analysis of the product Tylenol in 2005 and should be heard for this reason.

Lack of novelty by public prior use

The product according to the main request had been made available to the public prior to 16 February 2005 by public sale.

Documents A1 and A2 evidenced that a TV commercial of the patentee showing the form and dissolution of Extra-Strength Tylenol Rapid Release Gels gel caps falling within the scope of the claims, was broadcast during Super Bowl on 6 February 2005.

This prior use was based on D9, D10, D11 and D12. D9 was a further evidence of public sale and prior use. All this evidence related to the product shown in D12. A single sale was sufficient to render the article sold available to the public. Furthermore, the possibility of a complete analysis of a prior sold product so as to enable an exact reproduction of such product was not necessary for destroying the novelty of a claimed product. It was evident therefore that Extra-Strength Tylenol Rapid Release Gels gelcaps falling within the scope of the claims were made available by the patentee to the public for sale before the filing date of 16 February 2005, and that all features of the claim could have been directly and unambiguously derived from a sample by simple visual and/or experimental analysis that would have been feasible to the skilled person.

Since this public prior use related to a use by the patentee, the standard of proof was far lower than "up to the hilt". Rather, the standard of balance of probabilities was applicable when both the patent proprietor and the opponent had access to the material of which public prior use is alleged.

It was clearly beyond any doubt that the main request lacked novelty over the public prior use, and therefore did not satisfy Article 54 EPC.

Main request - Inventive step

The main request differed from D1 by the gelatinous coating content, the time release profile and the gap width. No technical effect was demonstrated, any technical problem could only be formulated as finding an alternative, and such an alternative was obvious.

There was no effect shown for the gelatinous coating. The dissolution profile presented as the solution of the invention was also not effective across the scope of the claim. It provided no effect that distinguished the dosage form from other dosage forms. The dissolution performance of example 2G was better than that of example 6A which fell within the scope of the claim. The dissolution performance recited in the claim would not be surprising to the skilled person and the remaining features of the claim were mere arbitrary selections within the knowledge of the skilled person when implementing the prior art, in particular Fig IB of D1.

There was no evidence that the gap provided an effect. The example with no gap (Press-Fit®) shown in D5 had a dissolution performance that also fell within the

requirements of the claim. Hence, the width of the gap in the gelatinous coatings in the Press-Fit examples of D5 provided no notable effect or only minor improvements on dissolution.

The skilled person, using the method of D1 to produce a dosage form having the gap width implicitly disclosed or provided by the public disclosure would inevitably have considered the claimed level of gelatinous coating as one that is suitable for the required purposes, which is also well known for example from D2. The teaching of D1 showed that the width of the gap and the specific release profile would have been known and obvious to the skilled person as normal variants within this field.

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

Main request - Amendments

Claim 1 of the main request had basis in the parent application as filed at claims 18 and 21. The change of the term "subcoating" to the term "core" was the correction of an obvious error and was therefore allowable. Moreover, the change of the term "subcoating" could be considered an allowable amendment, since the skilled person was taught at page 13, lines 11 to 12 that the subcoating was not necessarily present.

Claim 2 of the main request had basis in the parent application as filed. The appellant attempted to create confusion by misconstruing the requirement of claim 2, which refers to a measurement of released acetaminophen where the measurement is taken after 6 minutes. The

formulation "after 6 minutes" was fundamentally the same as "within 6 minutes".

Claims 3 and 4 had a basis in the parent application as filed at claims 20 and 21. Claim 5-8 had a basis in the description of the parent application.

Main request - Sufficiency of disclosure

With regard to the issue concerning the 3% gap width, the appellant itself had successfully produced samples with a range of gap widths, including one with a gap width of 2.6%, when conducting the experiments reported in D5. This confirmed the sufficiency associated with this feature.

As regards the subject-matter of claim 2 , the patent provided information on the effect of the gap width on dissolution properties at paragraph [0058]. The patent also provided information in relation to the amount of subcoating applied at example 7, where it was demonstrated that a reduction in subcoating was associated with an increased dissolution rate.

Admission of D13-D19 into the proceedings

Only documents A1 and A2 were filed during the opposition proceedings to prove the prior use. Said documents were completed by the filing of D9 and D10 just before the oral proceedings before the opposition division. Later, documents D11 and D12 were filed with the statement of grounds of appeal.

It was possible to complete the evidence relating to the alleged prior use earlier, and the appellant had the opportunity to do it earlier. The new documents

filled more than a missing link, since D13 provided new technical information and e-mails were filed while they had been known for a long time, even before the opposition proceedings.

The filed documents added complexity to the case, and raised new questions about the prior use. They involved a full investigation at a late stage of the appeal proceedings. Consequently, they should not be admitted.

Request to hear Ms Nombret on D9-D12

This request was submitted very late, and it was not possible to know what would be said by Ms Nombret. Therefore, Ms Nombret should not be allowed to speak.

Lack of novelty by public prior use

The appellant had the burden of proof in relation to its allegation of prior use. The appellant needed to sufficiently demonstrate "(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". The appellant had not sufficiently demonstrated any of these criteria, since it merely pointed to separate pieces of evidence without sufficiently substantiating the link between them in a convincing way or demonstrating an evidence-based conclusion.

None of documents A1, A2, D9-D12 represented sufficient evidence in relation to any of the questions (when, what, where, how and by whom) that needed to be answered to substantiate an allegation of prior use.

The only novelty objection raised by the appellant related to the alleged prior use. Since the appellant had not sufficiently demonstrated this alleged prior use, it could not render the claims of the main request lacking novelty.

Main request - Inventive step

The closest prior art D1 was silent on the total level of the first and second gelatinous coatings, the presence and width of a gap that exposes a core, and the time for release of any active ingredient.

The effect associated with the claimed gap width was detailed in the patent at paragraph [0058]. In relation to the consumer preferences, the patent provided Examples 8 and 9 that demonstrated an effect. The experimental data submitted by the opponent as D5 supported also the presence of improved dissolution in the claimed range.

Hence, it had been demonstrated that the claimed gap width range had improved dissolution while maintaining consumer preferences, such as swallowability. Hence the objective technical problem facing the skilled person is to provide a dosage form with improved dissolution while maintaining consumer preferences.

The skilled person facing this objective technical problem 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 and the claimed subject-matter was inventive.

XV. Requests

The appellant (opponent) requested that the decision under appeal be set aside and the patent be revoked. The appellant also requested that Ms Nombret be able to provide oral testimony corroborating declaration D18 and the experimental report D13 and to show physical samples of the Patentee's Tylenol product.

The respondent requested that the appeal be dismissed (main request), alternatively that the decision under appeal be set aside and the patent be maintained according to the set of claims filed as auxiliary requests 1-5 with letter of 21 February 2019, or auxiliary requests 6-15 filed with letter of 30 December 2019, or auxiliary requests 16-23 filed with letter of 4 March 2020. The respondent also requested not to admit document D13 to D19.

Reasons for the Decision

1. Main request - Article 76(1) EPC

1.1 Claim 1

1.1.1 The feature of claim 1 "wherein the width of gap is from about 3% to about 21% of the overall length of the uncoated core" has been objected to by the appellant, in view of the absence of a subcoating in the claimed dosage form of claim 1, while dependent claim 21 of the parent application linked this feature with the presence of such subcoating, as follows:

"21. The dosage form of claim 18, wherein said first and second gelatinous coatings form a gap through which the **subcoating** is exposed; and **wherein the width of gap is from about 3% to about 21% of the overall length of the uncoated core**".

1.1.2 Paragraph [0057] of the parent application WO 2006/022805 discloses a dosage form having a gelatinous coating which forms a visually discernible gap, and wherein the presence of a subcoating is only presented as a preferred embodiment and therefore its presence is not obligatory. Said passage discloses further that "the width of the gap is from about 3% to about 21% of the length of the uncoated core". The claimed width gap is therefore disclosed directly and unambiguously in connection with a dosage form without any subcoating in said passage. For this reason, the subject-matter of claim 1 is derivable directly and unambiguously from the parent application.

1.1.3 Moreover, as argued by the respondent, claim 1 of the main request can also be seen as a combination of independent claim 18 and claim 21 of the parent application which discloses the feature relating to the width of the gap. In this context the Board agrees with the respondent for the reasons explained below, that the term "subcoating" used in claim 21 is clearly erroneous and that nothing else than the term "core" was meant.

The subject-matter of independent claim 18 of the parent application constitutes indeed the basis for claim 1 of the main request and relates unambiguously to a dosage form without subcoating. The subject-matter of dependent claim 21 of the parent application

presents an inconsistency since it claims at the same time the presence of a "subcoating" and of an "uncoated core", and it depends on claim 18, whose subject-matter excludes the presence of any subcoating, by referring explicitly to a core coated by a first and a second gelatinous coating, (cf. the feature "gelatinous coating over at least part of the core").

Accordingly, the Board agrees with the opposition division and with the respondent that the term "subcoating" in claim 21 of the original application is an obvious error. From the wording of the claim it is clear than nothing else other than the term "core" would have been intended.

Claim 1 of the main request finds therefore also a basis in claims 18 and 21 of the parent application.

1.2 Claims 2 and 3

The subject-matter of dependent claims 2 and 3 finds a basis in claims 19 and 20 of the parent application. Moreover, the Board agrees with the respondent that the wording "after 6 minutes" used in claim 2 is fundamentally the same as "within 6 minutes" used in paragraph [0035] of the parent application. Thus, also this paragraph provides a basis for the release profile defined in claim 2. The subject-matter of these claims is therefore disclosed directly and unambiguously in the parent application.

1.3 Claim 4

The subject-matter of claim 4 relates to a restriction of the gap width, namely "wherein the width of the gap

is from about 5% to about 21% of the overall length of the uncoated core".

Paragraph [0070] of the parent application relates to "a final dosage form 30 having a subcoating 22 at a level of not more than about 3.0%, e.g. not more than about 2.5%, or not more than about 2.1%, say about 2% relative to the weight of the uncoated core; **and/or** one or more gelatinous coatings 24 that form a gap 26, wherein the width of gap 26 is **at least about 5%** of the overall length of the uncoated core" (emphasis added by the Board).

In said passage, a gap width of "at least about 5%" is disclosed for a dosage form having a subcoating and/or one or more gelatinous coatings, i.e. two alternative embodiments, one of them being a dosage form without subcoating comprising only one or more gelatinous coatings. The passage of paragraph [0070] constitutes therefore a direct basis for a lower limit of the width of the gap range of "from about 5%", which can be combined with the gap width of "from about 3% to about 21%" of claim 18 of the parent application.

For this reason, the subject-matter of claim 4 is derivable directly and unambiguously from the parent application.

1.4 Claims 5-8

A direct and explicit basis for the subject-matter of these claims can be found, as it was given by the opposition division in its decision, in the following passages of the parent application:

- paragraph [0015] of the parent application discloses that "the core be a compressed dosage form", which is the subject-matter of dependent claim 5.
- paragraph [0014] of the parent application mentions that the compacted dosage form is "an elongated tablet", which is the subject-matter of claim 6.
- paragraph [0033] of the parent application discloses that "the dissolution characteristics of at least one active ingredient follow an immediate release profile", which is the subject-matter of dependent claim 7.
- paragraphs [0026]-[0027] of the parent application disclose the complete lists of active ingredient of dependent claim 8.

In the Board's view, these features are disclosed independently from the type of dosage form and therefore apply unambiguously to a dosage form as claimed by claim 1 of the main request, i.e. without subcoating. Consequently, the subject-matter of claims 5-8 is disclosed directly and unambiguously from the parent application.

1.5 Conclusion

The main request meets the requirements of Article 76(1) EPC.

2. Main request- Article 123(2) EPC

The patent application EP 09075209.8 has the same description as the the parent application WO 2006/022805 with the subject-matter of the claims of the parent application incorporated *expressis verbis* in pages 40 to 45 of the description as filed. The patent application contains furthermore a new set of 11 claims.

It follows that the conclusion as to Article 76(1) EPC apply *mutatis mutatis* and the main request meets the requirements of Article 123(2) EPC.

3. Main request - Sufficiency of disclosure

3.1 The description of the contested patent provides ample information and teaching as regards the claimed dosage form and its sub-parts, namely the core, the gelatinous coating, the gap, as well as the claimed dissolution profile and the process for preparing the claimed dosage form (see for instance *inter alia* paragraphs [0037], [0038] or [0052] of the specification).

The characteristics of the gap and its width is particularly discussed in paragraph [0052], which mentions the minimum attainable gap width dependent on the machine processing tolerance. The fact that a gap width comprised between 3% to 21% of the overall length of the uncoated core might not be compatible with any size of the uncoated core (for instance for uncoated cores of very small sizes the gap width may not be about 3%), as argued by the appellant, does not necessarily lead to an insufficiency of disclosure. It is indeed clear to the skilled person that said gap width range is in practice limited and must be adapted to the size of the uncoated core, so that the claimed values can only be as low or high as those which can be realistically achieved; as this information is given in the contested patent, a lack of sufficient disclosure on this point cannot be objected to. This was directly confirmed by the experiments D5 filed by the appellant, which show the preparation of dosage forms with a gap ranging from a width of 2.6% to 15.7% of the uncoated core.

As regards the claimed dissolution profile, there is a direct reference to a standard test of the US Pharmacopeia, for which complementary information is given in paragraph [0033] of the specification. The use of such test is known and common in the field of pharmacy and the skilled person would have no difficulty in implementing it.

Moreover, even if the patent does not comprise any example of dosage form without subcoating, the skilled person would not have any difficulty in preparing a dosage form as claimed in view of the teaching of the description and also of the teaching given in examples 2 to 6. Furthermore, example 7 shows that, even in the presence of a subcoating, the claimed dissolution profile is constantly reached after 15 minutes, which corresponds to the time of release of at least 80% of the active substance used in the examples, i.e. acetaminophen, in not more than 50 percent of the time specified in the applicable USP or NDA specifications for immediate release solid dosage forms containing such active ingredient. It is obvious that a dosage form without subcoating would reach an even faster dissolution profile than a dosage form with subcoating and the dissolution requirements of claim 1 will be met by a dosage form without subcoating.

Consequently, the description provides a sufficient disclosure for the claimed invention, and presents in particular a concept which is fit for generalization to the whole subject-matter of claim 1.

3.2 The Board could also not follow the appellant's objection as regards the subject-matter of claim 2.

Dependent claim 2 reads:

"2. The dosage form of claim 1, wherein the core comprises acetaminophen and from at least about 80% of the acetaminophen is released after 6 minutes in 37°C water using USP Apparatus II (paddle method) at 50 rpm.".

According to the appellant, the consequence of the effect that at least 80% is dissolved after 6 minutes is that no more than 20% can have dissolved by 6 minutes. As claim 2 falls within the scope of claim 1, and because the examples in the patent show that embodiments having the claimed composition features required by these claims fail to provide the technical effect specified in the claims, the patent clearly lacks reproducibility.

The interpretation and linked argumentation of the appellant result however from a fallacious reading of the terms of claim 2. The feature "at least about 80% of the acetaminophen is released after 6 minutes" must and can only be understood as it being released "within 6 minutes". This is the only possible reading and interpretation of the subject-matter of claim 2 in view of the teaching of the patent which relates to an immediate release dosage form and to the subject-matter of claim 1 (see par. [0033] of the specification).

Example 7 gives clearly examples fulfilling this requirement, as well as the experiments D5 provided by the appellant. Consequently, there cannot be a lack of sufficient disclosure with regard to the subject-matter of dependent claim 2.

3.3 Consequently, there are no reasons to deviate from the decision of the opposition division as regards sufficiency of disclosure, and the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

4. Admission of D13-D19 into the appeal proceedings

4.1 The documents D13-D19 have been filed by the appellant with its letter dated 25 September 2019, after it has filed its statement of grounds of appeal.

D13 is a presentation dated September 2019 of testing on Tylenol product received in Colmar, France, on 7 February 2005. It comprises testing on Tylenol on the gap width, the amount of gelatine coating and of the subcoating, and the dissolution profile.

D14 is an e-mail dated 7 February 2005, relating to the reception of Tylenol samples.

D15 is an e-mail dated 8 February 2005 relating to additional acetaminophen samples.

D16 is a dissolution test of Tylenol RR Gelcaps dated 3 March 2005.

D17 is a picture of Tylenol Rapid Release Gels from 21 January 2005.

D18 is a Declaration of Delphine Nombret relating to the testing of Tylenol product and D19 a declaration of William Chekan, purchaser of Tylenol product.

According to the appellant, these documents relate to evidence already on file, are filed directly in response to points raised by the patentee in their reply to the grounds of appeal, and correspond directly to points made in the decision of the opposition division. The contents of these documents are not complex or extensive, do not lengthen the proceedings in any way, and are prima facie highly relevant for the discussion of lack of novelty in light of public prior use.

4.2 The decision of the opposition division mentioned that the evidence submitted by the opponent failed to demonstrate that the dosage form of claim 1 of the main request was made available to the public before the patent's filing date. In particular, the opposition division observed that D9 did not provide any evidence to the occurrence of public use since it did not mention where, how or to whom the product was indeed sold, and it did not contain any evidence that linked the product codes disclosed within the sales report to the dosage form of A2 (cf. point 4.2.2 of the decision). Moreover, A2 fails to disclose any of the technical features of the dosage form of claim 1.

Hence, with the statement of grounds of appeal, the appellant filed D11 and D12. As argued by the appellant, these documents were filed directly in response to the decision of the opposition division, in particular to the part relating to lack of novelty; they directly related to documents D10 and A2 already on file.

4.3 According to Article 13(1) RPBA 2020, any amendment to a party's case after it has filed its grounds of appeal or reply is subject to the party's justification for

its amendment and may be admitted only at the discretion of the Board. Article 12, paragraphs 4 to 6 shall apply mutatis mutandis.

In view of these facts, the Board considers that documents D13-D19 should have been filed earlier, since relating directly to a point raised during the opposition proceedings and mentioned in the decision of the opposition, namely the absence of convincing evidence to the occurrence of public use and the absence of evidence that links the product codes disclosed within the sales report to the dosage form of A2. Moreover, the established jurisprudence regarding a public prior use is very clear about the requirements needed to prove such public prior use (i.e. when, what, where, how and by whom), and any evidence as to the prior use should be filed as early as possible

Said documents can in particular not be considered to constitute a response to the respondent's reply to the statement of grounds of appeal, since the respondent did not provide new arguments, and repeated only what it already argued during the opposition proceedings (cf. letter of 6 February 2018) and what was already presented in the decision of the opposition division, namely that the documents did not represent sufficient evidence of the alleged prior use.

Documents D13-D19 could also have been filed earlier during the opposition proceedings, since the content of documents D14-D17 was available already in 2005, while D18 and D19 were declarations relating at least partially to the prior use presented during the opposition proceedings. The experiments disclosed in D13 were performed on a product available in 2005, and could also have been performed and filed earlier; the

patentee furthermore already argued during the opposition proceedings that the evidence submitted by the opponent was insufficient to demonstrate that the prior use had occurred before the filing date (cf. letter of 6 February 2018).

Moreover, the documents D13-D19 add complexity to the case. First they are accompanied by a request to hear Ms Delphine Nombret to provide oral testimony corroborating declaration D18 and the experimental summary report D13. Furthermore, the relevance of D13 would need to be investigated, since claim 1 of the request does not relate to a dosage form with a subcoating, while the experiments D13 were performed on a dosage form with subcoatings. This would be clearly detrimental to the procedural economy.

Consequently, documents D13-D19 are not admitted in the appeal proceedings (Article 13(1) RPBA 2020).

5. Request to hear Ms Nombret

5.1 In view of the decision to not admit documents D13 to D19 into the appeal proceedings, the request to hear Ms Delphine Nombret on documents D13 and D18 must also be rejected.

5.2 During oral proceedings, the appellant requested for the first time that Ms Nombret be also heard as a witness on the alleged prior used disclosed in documents D9-D12.

The appellant did not provide any reason for submitting this request on this very late stage of the appeal proceedings.

It is also not clear at this very late stage of the appeal proceedings what will be the subject of this testimony, which is detrimental to the procedural economy.

Such request could indeed have been made sufficiently in advance of the oral proceedings so that all the parties would have been able to prepare themselves properly in relation to the proposed oral submissions. D9 and D10 were submitted during the opposition proceedings, and D11 and D12 were filed with the statement of grounds of appeal. The appellant had therefore several opportunities to request earlier that Ms Nombret be heard, even as early as during the opposition proceedings with regard to D9 and D10.

Consequently, the Board exerts its discretionary power and the request to hear Ms Nombret as a witness on the alleged public prior use in view of D9-D12 is rejected by the Board (Article 13(1) RPBA 2020).

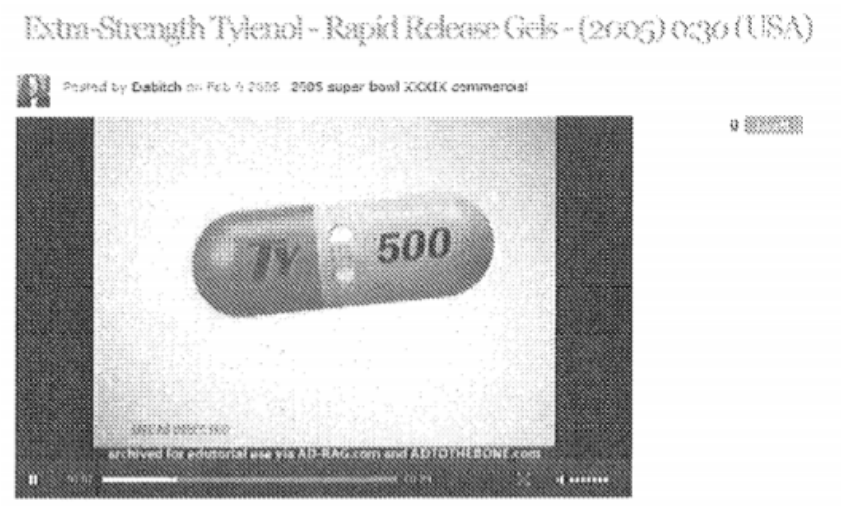
6. Main request - Lack of novelty in view of the alleged prior use

6.1 The appellant based its allegation on public prior use on documents A1, A2 and D9-D12.

6.1.1 A1 is a depiction of a website showing an advertisement for Tylenol, with pictures of boxes of several different Tylenol medicaments.

6.1.2 A2 comprises screen grabs of a commercial that has been broadcast on 6 February 2005 relating to "Extra Strength Tylenol Rapid Release Gels". Page 6 shows the same advertisement for Tylenol as in A1. A picture on

page 10 shows a dosage form in form of a caplet that has different colours and holes in the middle.



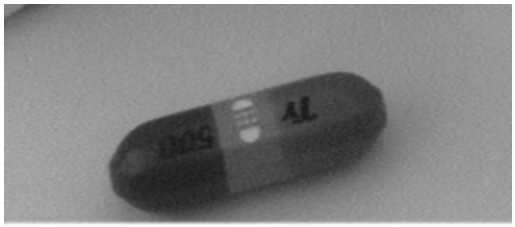
6.1.3 D9 is a table showing aside from a product code 030045048824 two different numbered results namely 158.975 for the week ending 29 January 2005 and 1.149.126 for the week ending 26 February 2005.

According to the appellant, these data constitute a sales report obtained from the ACNielsen Inc. NITRO database including a summary of sales of Tylenol product for the four week period ending 29 January 2005, and indicating total sales of over 200,000 units before the filing date of 16 February 2005. Hence, for the product code 030045048824 there were specifically 158.975 units sold for the week ending 29 January 2005.

6.1.4 D10 relates to experiments conducted on 24 February 2005, after the filing date of the contested patent. According to the appellant, the tested Tylenol Rapid Release Gels - RR gelcaps from batch JSA246 were received on 7th February 2005, i.e. before the filing date of the patent.

6.1.5 D11 represents 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 of the batch JSA246, received on 7 February 2005.

6.1.6 D12 is a photograph of the box and bottle of Tylenol Rapid Release Gels, which lists a product code number 3-0045-0488-24 and a batch number JSA246; it also shows a Tylenol gelcap aside the box. According to the appellant, this product was received on 7 February 2005 in Colmar, France.



6.2 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, 9th edition, English edition).

6.3 Document D9 merely discloses a table of undefined provenance. As observed by the respondent (point 5.7 of its reply), the appellant has offered no substantiation of exactly what the data of D9 demonstrate or any further explanation to corroborate the alleged sales.

In the Board's view, D9 does not 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 it does not mentions *inter alia* where, how or to or by whom the product was indeed sold.

The product code 3-0045-0488-24 mentioned in D9 is visible on the picture of document D12, which shows also the batch number JSA246 on the medicament box of Tylenol Rapid Release Gels. The medicament box of the batch number JSA246 has been reported in documents D10 and D11 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 D10 nor D11 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.

Consequently, the circumstances relating to the alleged prior use, in particular how the subject-matter of claim 1 was made public through that use, are not shown by document D9 and by any other documents D10-D12.

6.4 Consequently, the evidence submitted fails to support the appellant's allegation of public prior use. Said evidence fails to demonstrate how the dosage form of claim 1 of the main request was made available to the public before the patent's filing date.

The subject-matter of claim 1 of the main request is therefore novel over the alleged prior use.
In view of the above, the Board considers that a discussion or decision on the subject of priority in view of D8 is not necessary.

6.5 The Board does also not see reason to see physical samples of the patentee's Tylenol product, and this request from the appellant is also rejected.

7. Main request - Inventive step

7.1 The present invention relates to a dosage form comprising a tablet core having two ends. The tablet core is provided with a gelatinous coatings over both ends and has a faster disintegration and/or dissolution than other gelatinous coated products (see par. [0007] of specification).

7.2 D1 was considered as the closest prior art by the opposition division in its decision.

D1 discloses a caplet in Fig.1B that is coated with gelatin without any subcoating and wherein a seam area 13 is devoid of gelatin coating (see also column 5, lines 45-55).

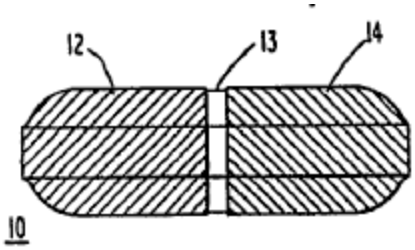


Fig. 1B

D1 also discloses gelcaps with a continuous coating overlapping at a seam region 13, as shown below.

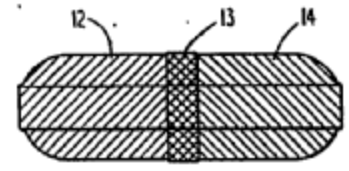


Fig. 1C

There is no disclosure of the amount of gelatinous coating to be used in any dosage form disclosed in document D1.

D1 does also not give any disclosure or teaching as to the gap width. It is furthermore not possible to determine the width of the gap on the basis of the figure, due to the absence of a scale or indication of the use of a true scale in the schematic view of Fig. 1B of D1; this figure is a schematic drawing and it is not possible to derive dimensions from such a depiction. 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 in particular different from the case T 748/91 mentioned by the appellant, 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.

The dissolution profile of a gelcap as shown in Figure 1B of D1 is also not explicitly given in D1, but it is implicit that it provides inevitably an immediate dissolution profile as claimed in claim 1 of the main request. This is demonstrated, as argued by the appellant, by the experiments of D5 and of example 7 of the contested patent. Both experiments show that a gelcap provided with a full covering gelatin coating without any gap exposing the core, has an acetaminophen dissolution profile falling under the scope of claim 1; the presence of a further gap within the gelatin coating would indeed irremediably accelerate the dissolution speed. It is therefore concluded that the gelcap of Figure 1B of D1 provides necessarily a dissolution profile as claimed in claim 1 of the main request, and that said dissolution profile cannot constitute a distinguishing feature.

7.3 The respondent sees the problem as the provision of a dosage form with improved dissolution, while maintaining consumer preference.

The appellant considers it to be the provision of an alternative dosage form.

7.4 The product defined in claim 1 is a gelcap characterized in that the total level of the gelatinous coating is from about 3 to about 10 weight percent based on the weight of the core and wherein the first and the second gelatinous coatings form a gap through which the core is exposed, the width of the gap being from about 3% to about 21% of the overall length of the uncoated core.

7.5 In support of the alleged technical effects, the respondent mentioned paragraph [0058] of the

specification, examples 8 and 9 of the contested patent, as well as document D5 filed by the appellant. The appellant also commented example 7 of the contested patent.

7.5.1 The experiments of document D5 and of example 7 of the contested patent have been performed with gelcaps comprising a subcoating, and there is no direct comparison made with a gelcap as claimed in the main request, i.e. without subcoating, or with a gelcap having an amount of gelatin coating or gap width different from the claimed subject-matter.

D5 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 0% and 2.6% to 15.7% of the length of the uncoated core; a further comparison is made with a gelcap without gap. The absence of a gap width (complete encapsulation with a gelatinous coating) leads to the slowest dissolution, while the absence of an outer shell (no gelatinous coating) has the fastest dissolution. The results show a constant high dissolution profile corresponding to the claimed dissolution profile for all caplets with a gap, namely more than 80% of release of acetaminophen in 15 minutes, which is the time corresponding to "50 percent of the time specified in the applicable USP or NDA specifications for immediate release solid dosage forms" containing said acetaminophen. Said results show that a caplet with a gap has a higher dissolution within the first minutes of the experiments than a caplet without any gap, i.e. 47.4% in 6 minutes for the caplet without gap (Presss-Fit®) and over 62.0 for the other caplets (X-Press-Fit®), as shown by the Table 5 of D2 below:

Time in min	Cores		Press-Fit®		XPress-Fit® 0.5 mm		XPress-Fit® 1.0 mm		XPress-Fit® 1.5 mm		XPress-Fit® 2.0 mm		XPress-Fit® 3.0 mm	
(n = 6)	Avg	*Std*	Avg	*Std*	Avg	*Std*	Avg	*Std*	Avg	*Std*	Avg	*Std*	Avg	*Std*
0	0.0	*0.0*	0.0	*0.0*	0.0	*0.0*	0.0	*0.0*	0.0	*0.0*	0.0	*0.0*	0.0	*0.0*
3	68.0	*3.9*	4.9	*1.2*	16.8	*13.3*	12.7	*6.4*	19.1	*8.7*	20.5	*5.3*	21.7	*6.5*
6	88.4	*2.1*	47.4	*7.3*	62.0	*11.4*	62.8	*9.8*	70.4	*7.7*	67.9	*4.5*	65.8	*5.9*
9	94.5	*1.0*	74.2	*6.2*	83.3	*5.4*	84.6	*5.1*	85.5	*4.0*	85.6	*3.0*	85.2	*3.1*
12	95.0	*0.7*	85.2	*5.3*	92.2	*3.5*	92.2	*2.7*	92.8	*2.4*	92.9	*2.2*	91.9	*1.1*
15	95.4	*0.7*	92.2	*2.9*	94.7	*1.8*	96.1	*1.1*	95.5	*0.8*	96.2	*1.0*	94.2	*1.3*

On the other hand, the experiments reported in example 7 of the patent show that gelcaps with a gap according to the claimed invention do not necessarily provide a faster dissolution of acetaminophen than gelcaps without any gap, since the dissolution profile of the gelcap of example 6A comprising a gap is slightly slower to the dissolution profile of the gelcap of example 2G without any gap. The dissolution profile of example 6A remains however as required by the subject-matter of claim 1 of the main request, as shown below.

Time (minutes):	3	6	9	12	15	30
Ex. 1 Caplet	82	97	99	100	100	100
Ex. 2A Uncoated Core	81	99	100	101	101	101
Ex, 2C Subcoated Core (4.5%)	4	84	99	101	101	102
Ex. 2G Gelcap	0	51	94	99	100	100
Ex. 3B Subcoated Core (4.5%)	17	90	98	99	99	100
Ex. 6A Short dipped from ex. 3B	0	47	91	95	97	98
Ex. 6B: 6A with laser openings	63	95	98	99	99	100
Ex. 4 Subcoated Core (2.0%)	77	96	98	99	99	99
Ex. 5B Short dipped from Ex. 4	40	89	96	97	98	99
Ex. 5C: 5B with laser openings	80	95	97	98	98	99

In view of the above, it is therefore not possible to conclude to the existence of an improved dissolution as argued by the respondent.

7.5.2 Example 8 of the contested patent provides a sensory evaluation of the gap width, and 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. [0090]).

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. [0095]). For all samples evaluated, 44-57% of the panelists could not detect a texture difference between the exposed subcoating gap in the middle of the gelcap and the geldipped ends.

Even if the tests performed in examples 8 and 9 of the patent related to gelcaps comprising a subcoating, said results are directly extrapolable to gelcaps without subcoating, since the presence of a further subcoating does not have any incidence on such sensory test, the possible perceptible texture transition being identical whether a subcoating is present or not.

7.5.3 An effect as to the maintenance of the consumer preference, i.e. the absence of a texture difference on the gelcaps, while providing a dosage form with a fast dissolution profile, is therefore proven.

Consequently, the problem appears to be the provision of a dosage form which maintains the consumer preference.

7.6 The question remaining is whether the skilled person, starting from Figure 1B of D1, would arrive at the subject-matter of claim 1 of the main request in an obvious manner in order to solve the problem posed.

D1 is totally silent about texture sensation and does not give any disclosure of information about the amount of gelatin coating or gap width.

D2 discloses a simulated capsule-like medicaments, more particularly a solid medicament caplet core subcoated with a mixture of a water-soluble, film-forming polymer and a hydrophobic plasticizer and over-coated with a smooth outer gelatin coating to provide the appearance of a capsule-like medicament, i.e. a gelcap. The gelcaps disclosed in D2 do furthermore not comprise any gap in the gelatin coating and do not envisage to incorporate any, the problem of D2 being different, namely the provision of an aesthetic coating (see col. 2, l. 20-25; see col. 5, l50-65, and the examples). Hence, neither D1 nor D2 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. The gap width consideration is indeed totally absent from the cited prior art.

Firstly, none of the cited documents considers the problem of providing a fast dissolution dosage form, while maintaining consumer preferences and so the

skilled person would not consider them to offer any guidance.

Further, none of the cited documents describes a gap width in the range of 3% to 21 %, even less the combination of the required gap width along with a total level of the first and second gelatinous coatings of about 3 to about 10 weight percent and the required release profile.

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

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated