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Datasheet for the decision of 29 January 2025

Case Number: T 0076/23 - 3.3.07

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Title of invention:
RESIDENCE STRUCTURES AND RELATED METHODS

Patent Proprietor:
Massachusetts Institute Of Technology
The Brigham and Women's Hospital, Inc.

Opponent:
D Young & Co LLP

Headword:
Residence structures/MIT

Relevant legal provisions:
EPC Art. 123(2), 56

Keyword:
Amendments - allowable (yes)
Inventive step - (yes)

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Case Number: T 0076/23 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 29 January 2025

Appellant: (Opponent)	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
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Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 25 November 2022 concerning maintenance of the European Patent No. 3155024 in amended form.**

Composition of the Board:

Chairman	A. Usuelli
Members:	M. Steendijk
	Y. Podbielski

Summary of Facts and Submissions

I. European patent 3 155 024 ("the patent") was granted on the basis of fourteen claims.

Independent claim 1 as granted defined a residence structure comprising a loadable polymeric component, a second polymeric component coupled thereto and at least one degradable linker comprising a portion of or coupled with tothe loadable and/or the second polymeric component.

II. The grant of the patent was opposed on the grounds that its subject-matter lacked novelty and inventive step, and that the patent comprised subject-matter extending beyond the content of the application as originally filed.

The opponent filed the appeal against the decision of the opposition division that the patent as amended in accordance with the patent proprietors' main request filed on 10 November 2021 met the requirements of the EPC.

Claim 1 of this main request defined:

(F1) "A residence structure, comprising:
(F2) a loadable polymeric component;
(F3) a second polymeric component coupled with the loadable polymeric component; and
(F4) at least one degradable linker comprising at least a portion of or coupled with the loadable polymeric component and/or the second polymeric component, wherein

(F4.1) i) the linker is configured to dissolve, degrade, mechanically weaken, and/or mechanically separate from at least one of the one or more polymeric components, or

(F4.2) ii) the degradable linker is configured to degrade such that the residence structure breaks apart, or

(F4.3) iii) the second polymeric component is different from the loadable polymeric component, or

(F4.4) iv) the degradable linker is a separate linker material, and wherein for each of i) to iv) either

(F5) a) the second polymeric component is coupled to the loadable polymeric component via the at least one degradable linker;

wherein at least one of the loadable polymeric component, the second polymeric component, and the degradable linker comprises an elastic polymeric component;

wherein the loadable polymeric component comprises at least about 60 wt% of the total structure weight;

wherein the residence structure has a folding force of at least about 0.2 N, wherein the folding force is determined by placing the structure in a funnel having a 20 cm upper diameter and a 2 cm lower diameter and measuring the forces required to move the structure through the 2 cm lower diameter by attaching a plunger to the tension cross-head of a tensile loading machine and the funnel to a clamp, and

pushing the structure through the funnel at a rate of 10 mm/min, while measuring the force and displacement, wherein the folding force is determined by measuring the force at which the structure folds and enters the 2 cm lower diameter tube; and

wherein the residence structure has an uncompressed cross-sectional dimension of at least about 2 cm, and wherein the residence structure is configured such that it is retained at a location internally of a subject; or

(F6) c) the loadable polymeric component comprises an active substance;
the residence structure is configured such that the active substance is released from the loadable polymeric material at a particular initial average rate as determined over the first 24 hours of release; and
wherein the active substance is released at an average rate of at least about 1% of the initial average rate over a 24 hour period after the first 24 hours of release.

The opposition division cited *inter alia* the following documents:

D1: US 5,002,772
D3: EP 0415671 A2
D10: Poster: "Ultra-long-acting oral therapies for Alzheimer's: Proof of principle
D16: Military Medicine (1969), 134(2), 98-103
D17: American Journal of Orthodontics (1970), 58(1), 21-40

D18: Journal of Animal Science (1968), 27(6), 1525-1526

The opposition division arrived at the following conclusions:

(a) The features of claim 1 of the main request defining

a residence structure (F1) comprising a loadable polymeric component (F2), a second polymeric component (F3) coupled thereto and at least a degradable linker (F4) comprising a portion of or coupled with tothe loadable and/or second polymeric component, wherein

- the linker couples the loadable and the second polymeric component; one of these components comprises an elastic polymeric component; the loadable component comprises 60 wt% of the total structure; the structure has a particular folding force and an uncompressed cross-sectional dimension of at least 2 cm; the structure is configured to be retained at an internal location of a subject (F5) or

- the loadable polymeric component comprises an active substance and is configured to provide for a particular average release over the first 24 hours and a release over the subsequent 24 hours of at least 1% of that initial release (F6)

were disclosed in the application as filed in claim 4 (the alternative characterized by feature F5) and claim 7 (the alternative characterized by feature F6).

The additional features of claim 1 of the main request defining the linker as configured to separate from at least one of the polymeric components (F4.1) or to degrade such that the structure breaks apart (F4.2), or the second polymeric component as different from the loadable component (F4.3), or the linker as a separate linker material (F4.4) were explicitly disclosed in the application as filed and evidently concerned aspects related to the linker of the residence structures as defined in original claims 4 and 7.

Claim 1 of the main request therefore complied with Article 123(2) EPC.

(b) For the assessment of inventive step, example 23 of document D3 and examples 7 and 8 of document D1 represented equally suitable starting points in the prior art.

The difference of the claimed subject-matter with example 23 of document D3 concerned not only the features F5 or F6 but also the feature F4, because in view of document D18 the epoxy resin used as linker in document D3 did not represent a degradable linker.

The difference of the claimed subject-matter with examples 7 and 8 of document D1 concerned in addition to features F5 or F6 also the feature F4, because the cyanoacrylate glue used as linker in document D1 did not represent a degradable linker. Moreover, a sleeve of polyvinylacetate phthalate (PVAP) which is attached to a tablet as described in the examples of document D1 did not correspond to the loadable polymeric component of feature F2.

No improved control over the retention and elimination of the claimed structure had been demonstrated with respect to the devices of the prior art. Moreover, the patent only reported drug release data for structures comprising the combination of features F5 and F6, which did not substantiate an effect for alternative structures comprising only one of the features F5 and F6. The objective technical problem therefore concerned the provision of an alternative residence structure.

The claimed subject-matter would not be obvious to skilled person, because the prior art did not provide the skilled person with any suggestion to use a degradable linker as defined under feature F4. Moreover, document D3 described the use of a shape memory component for folding the described structure and guided the skilled person away from using elastic materials for a structure with the folding force as defined under feature F5.

III. The following documents were filed during the appeal proceedings:

A19: Journal of Reinforced Plastics and Composites, 32(14) 1018–1029 (2013)
A20: Journal of Applied Polymer Science, Vol. 45, 2235-2238 (1992)

A21: NACE TECHNICAL COMMITTEE REPORTS, Vol. 12 pages 49–52
A22: Introduction to Organic and Biochemistry, Brooks/ Cole, 8th ed., 2013, page 553.

Documents A19 and A20 were introduced by the opponent with the statement of grounds of appeal.

Documents A21 and A22 were introduced by the patent proprietors with the reply to the appeal.

IV. The parties were invited to attend oral proceedings to be held on 30 January 2025.

In its communication under Article 15(1) RPBA the Board indicated that it intended to not admit any of documents A19-A22. The Board expressed its preliminary opinion that the main request complies with Article 123(2) EPC. The Board observed that the opponent acknowledged the novelty of the claimed subject-matter on the basis that the features F5 and F6 had not been disclosed in the prior art. The Board further indicated that the claimed solution to the objective technical problem of providing an improved residence structure or a residence structure allowing excellent control over its retention/elimination as well as over the release of the active compound would seem to involve an inventive step when starting from document D1 or document D3 as closest prior art.

V. With the letter of 19 December 2024 the opponent informed the Board that it would not be represented at the oral proceedings.

VI. With the communication of 15 January 2025 the Board cancelled the oral proceedings scheduled for 30 January 2025.

VII. The arguments of the opponent relevant to the present decision are summarized as follows:

(a) Admittance of new evidence

Documents A19 and A20 demonstrated that contrary to the finding in the decision under appeal epoxy resins as mentioned in document D3 are degradable in an acid environment.

(b) Basis for the amendments

The combination of the features F4.1-F4.4 with the specific alternatives characterized by features F5 and F6 was not directly and unambiguously derivable from the application as filed.

(c) Inventive step

(i) Starting from document D3

Document D3 described in example 23 (see page 21, lines 2-11) a residence structure comprising the features F1-F4 in the form of a gastric device composed of plates prepared from polynorborene comprising nicardipine hydrochloride which are adhered to an Y-shaped central part with an epoxy resin adhesive.

The epoxy resin for linking the drug-containing plates to the Y-shaped polynorbornene component as described for example 23 in document D3 qualified as a degradable linker (F4), which was confirmed by documents A19 and A20. Moreover, the initially joined components of the device are according to document D3 (see page 21, line 26) intended to

result in remnants which eventually exit the stomach when they are no longer joined. Regardless of the mention in document D3 of the erosion of another component the epoxy resin in document D3 would therefore anyway provide a link which degrades and thus represent a degradable linker as functionally defined under feature (F4). The epoxy resin as defined in document D3 also anticipated each of the features defined under F4.1-F4.4.

The difference of the claimed subject-matter with example 23 of document D3 therefore only involved the feature F5 or the feature F6.

No connection between the specific claim features and any particular identifiable technical effect had been demonstrated. Even if the feature of a degradable linker represented a further difference, the objective technical problem associated with each of the embodiments characterized by features F5 and F6 therefore merely concerned the provision of alternatives with respect to document D3.

The presence of an elastic polymer as defined under feature F5 did not constitute any difference, because the shape memory material of document D3 represented such an elastic polymer. The use of an elastic polymer would anyway be obvious as an alternative to provide for a structure that reverts to its initial shape after folding. Moreover the definition of a folding force of at least 0.2 N under feature F5 represented a trivial characteristic taking account of the forces in the stomach to be resisted and the bending strength of 690 g (6.8 N) mentioned in document D3 (see page 7,

Table 1) for a device that is effectively retained in the stomach.

The definition of a particular average release over the first 24 hours and the release over the subsequent 24 hours of at least 1% of that initial release (F6) represented a mere result to be achieved without specification of any concrete technical measure for its implementation. As such this feature represented the obvious result of the choice of suitable materials in view of their known properties. The defined release profile furthermore corresponded to the plasma levels reported in document D3 (see Figures 9 and 10) in the context of the equally relevant example 21.

Moreover, on the basis of the teaching in the patent the determination of the actual release from the residence structure would not be feasible. The release profile as defined under feature F6 was therefore to be understood by the skilled person as relating to the generated plasma levels. The defined plasma levels would, however, also depend on the elimination of the used active substance and would obviously be achieved by any substance with a $T_{1/2}$ of 4 hours or longer.

In as far as the definition of the degradable linker (F4) represented any difference with document D3, the use of such a degradable linker would represent an obvious alternative to achieve the separation of the linked components.

(ii) Starting from document D1

Document D1 described in examples 7 and 8 gastric residence structures comprising the features F1-F4 comprising receptacle in the form of a cylindrical PVAP sleeve which holds a radiopaque non-disintegrating $BaSO_4$ tablet or a controlled release glipizide tablet and to which nylon ribbons are attached with a cyanoacrylate glue.

The cyanoacrylate glue used in these examples to link the components of the disclosed residence structures clearly represented a degradable linker as defined under the features F4 and F4.1-F4.4. The relevant property of the cyanoacrylate glue was evident from the reported detachment of the nylon arms (see D1, column 14, lines 55-58) taking account of the general purpose of a gastric residence structure and the explanation in document D1 (see column 8, lines 3-10) that the described receptacle, the retention arms and/or the adhesive are constructed from degradable materials to permit safe timely exit from the stomach.

The PVAP sleeve to which the radioopaque or controlled release tablets are attached in examples 7 and 8 of document D1 represented a polymeric component which is loadable as defined under feature F2. Even if on the basis of paragraph [0137] of the patent the feature of the loadable polymeric component (F2) is understood to relate to a polymer into which agents can be loaded, such feature would still be inherent in the controlled release tablets described in document D1, because these tablets involve active agents loaded into polymers (see D1, column 3, lines 27-45) to which

the retention arms may also be directly attached (see D1, column 7, lines 39-46 and 56-61).

Regarding the effects of any distinguishing features the same considerations as mentioned in relation to document D3 applied. The objective technical problem associated with the embodiments characterized by features F5 and F6 therefore merely concerned the provision of alternatives with respect to document D1.

For similar reasons as explained in relation to document D3 the features F4, F5 and F6 would be obvious to the skilled person as a solution to the problem of providing an alternative residence structure.

Moreover, in as far as feature F2 could be considered to distinguish the claimed subject-matter, the replacement of a sleeve-covered tablet by a loadable polymeric component was obvious as an alternative in view of the matrix type tablets described in document D1 as well as the loadable polymeric component described for a related residence structure in document D3.

VIII. The arguments of the patent proprietors relevant to the present decision are summarized as follows:

(a) Admittance of new evidence

Documents A19 and A20 should have been filed during the first instance proceedings, because the argument that it had not been demonstrated that epoxy resins as mentioned in document D3 are degradable had already been raised in the patent

proprietors' response to the opposition. Moreover, it was not evident from documents A19 and A20 that the epoxy resin described in document D3 would indeed be degradable as defined for the linker in the patent.

Documents A21 and A22 demonstrated in this context that epoxy resins are not generally degradable under the relevant conditions.

(b) Basis for the amendments

The combination of the features F1-F4 with the alternatives of features F5 and F6 was adequately based on the original independent claims 4 and 7 and the specification of the determination of the folding force on page 56, lines 23-30 and the internal retention on page 16, lines 9-12 of the application as filed.

The application as filed also provided a basis for the features F4.1-F4.4 as further defining the linker and its relation to the polymeric components in a general manner. The skilled person therefore understood that these features F4.1-F4.4 are disclosed in the application as filed to complement the embodiments of the original claims 4 and 7 corresponding to the claimed alternatives characterized by features F5 and F6.

(c) Inventive step

(i) Starting from document D3

Document D3, in particular the residence structure described in example 23 comprising a drug

containing plate similar to the loadable polymeric component (F2), qualified exclusively as the most promising starting point in the prior art.

The claimed subject-matter differed from example 23 of document D3 not only by the features F5 or F6, but also by the feature F4.

The opponent had not demonstrated that the epoxy resin described in document D3 as a linker necessarily represented a degradable linker as defined under feature F4. Document D3 indicated the strong affinity of the epoxy resin as joining part (C) to the other components (A) and (C) (see D3, page 4, lines 4-6) and provided no indication that the epoxy resin represented an erodable material. Documents D17 and D18 as well as document A21 confirmed the stable nature of epoxy resins. Documents A19 and A20 did not support the opponent's assertion that the epoxy resin used in document D3 represented a degradable linker.

Moreover, the definition of a degradable linker (F4) required that the linker was itself degradable. The reference to "device remains" in document D3 (see page 21, line 26) did not imply that example 23 comprises a link which degrades, because the reference failed to identify the remains.

Example 23 of document D3 did not specify any particular feature for controlling the degradation of the disclosed structure. The general disclosure in document D3 (see page 5, lines 4-26) only suggested a degradable component in the form of an erodable limb comprising the active substance. As

indicated in the patent (see paragraph [0085]), the separation of the roles of the degradable linker (F4) and the loadable component F2 in the claimed structure provided the advantage of controlling the release of the active agent and the retention/ elimination of the structure separately and therefore more effectively. This advantage was illustrated by the experimental results reported in the patent concerning the variable retention depending on the nature of the linker (see Figures 19-21 relating to example 14) and the controlled release over several days (see Figures 24-26 relating to example 17) as well as by the results reported in the post-published document D10.

No reasons were evident why the mentioned effects and advantage would not be credibly achieved across the scope of the claims. The advantage relating to the controlled release was also inherent in the defined residence structure characterized by feature F5, in which the loadable component does not yet comprise the active agent, but nevertheless allows for the active agent to be loaded.

In view of the effect of the distinguishing feature of the degradable linker (F4) the objective technical problem therefore concerned the provision of an improved residence structure or at least the provision of a residence structure allowing excellent control over the retention/elimination as well as the release of the active compound.

The presence of an elastic component, the at least 60 wt% for the loadable component and the folding force of at least 0.2 N as defined under feature F5 as well as the particular release profile defined

under feature F6 represented further distinguishing features defining the claimed solution to the mentioned objective technical problem.

Document D3 did not demonstrate any retention beyond 24 hours and document D1 (see column 1, lines 42-45) confirmed that achieving retention of drugs in the proximal region of the gastrointestinal tract represented a difficult problem. Document D3 itself actually taught away from replacing the epoxy resin by a degradable linker (F4), because it describes that an erodible drug-release component is strongly joined to the shape memory material (see D3, page 3, line 58 to page 4, line 6). The opponent's argument that such replacement was obvious found no basis in the prior art and could only be based on hindsight.

The opponent's argument that example 21 of document D3 represents an equally viable starting position for assessing inventive step was not to be admitted. The opponent had not maintained this argument during the first instance proceedings and had failed to explain why example 21 represented an equally suitable starting point.

(ii) Starting from document D1

Document D1 represented a less promising starting point than document D3, because it described in examples 7 and 8 a retention structure which differed from the claimed residence structure not only by the features F4 and F5 or F6, but also by the feature F2.

The PVAP sleeve which merely holds a tablet as described in examples 7 and 8 of document D1 did not represent a loadable polymeric component as defined under feature F2. This followed from the definition under feature F6 that the loadable polymeric component comprises an active substance and that the active substance is released from this loadable polymeric component. An accordingly strict interpretation of the feature was confirmed by paragraph [0137] of the patent, which mentions the loading of the active agent into polymeric materials.

From the general reference to matrix-controlled release devices in document D1 (see column 3, lines 27-45) it could furthermore not be derived that a tablet as included in the specific devices of examples 7 or 8 represents a loadable polymeric component as defined under feature F2.

It had further not been demonstrated that the cyanoacrylate glue used to attach the nylon ribbons to the PVAP sleeve in examples 7 and 8 of document D1 represents a degradable linker as defined under feature F4.

Cyanoacrylate was not included in the list of degradable materials presented in document D1 (see columns 5-6, bridging paragraph). Moreover, the observed disintegration of the device of example 7 in the small intestine or colon (see D1, column 14, lines 55-58) did not allow for the conclusion that the cyanoacrylate was degradable. This was evident from a comparison of the device of example 7 with the device of example 6, which both apply the cyanoacrylate glue, but differ in the exchange of

the polyvinylchloride (PVC) sleeve in example 6 by the PVAP sleeve in example 7. In view of the explicit statement in document D1 that the device of example 7 differs from the device of example 6 by the incorporation of a mechanism for the disintegration (see D1, column 14, lines 2-4) the observed disintegration was likely the result of the use of a PVAP sleeve and not of any degradation of the cyanoacrylate glue.

Document D16 further confirmed that not all cyanoacrylates are degradable *in vivo* (see D16, pages 101 and 103).

The reference in document D1 (see page 8, lines 3-12) to the use of degradable materials for the receptacle of the tablet, the retention arms and/or the adhesive arms concerned alternative options which are only described in a general context. It could therefore not be concluded that the cyanoacrylate glue in the specific examples 7 and 8 is degradable.

Moreover, as explained in relation to document D3 the definition of a degradable linker (F4) required that the linker is itself degradable, which was not the case for the cyanoacrylate glue of document D1.

The retention times of 20 hours and 8 hours in examples 7 and 8 of document D1 indicated only a poor control of the retention in the stomach for the described devices (see D1, column 14, lines 52-55 and column 16, lines 1-3). By including a loadable polymeric component (F2) in the structure itself and by the separation of the roles of the linker (F4) and the loadable component (F2) the

claimed structure would, for the same reasons as explained in relation to document D3, provide the advantage of controlling the release of the active agent and the retention/elimination of the structure separately and therefore more effectively.

In view of the effect of the distinguishing features F2 and F4 the objective technical problem concerned the provision of an improved residence structure.

The presence of an elastic component, the at least 60 wt% for the loadable component and the folding force of at least 0.2 N as defined under feature F5 as well as the particular release profile defined under feature F6 represented further distinguishing features defining the claimed solution to the mentioned objective technical problem.

As explained in the context of document D3 the provision of gastric drug retention represented a difficult problem. Document D1 itself (see column 3, lines 31-33) taught away from the use of a loadable polymeric component (F2) by stating that the mechanism of the release was immaterial to the invention of document D1. Document D3 mentioned a similar structure as described in document D1 involving the fixation of a tablet to a device (see D3, page 4, lines 54-57) and failed to provide any suggestion towards the use of a degradable linker as a solution to the identified objective technical problem.

IX. The appellant-opponent requested that the decision under appeal be set aside and the patent be revoked in its entirety.

X. The respondents-patent proprietors requested that the appeal be dismissed and the patent be upheld based on the main request filed on 10 November 2021.

The patent proprietors further requested that documents A19 and A20 not be admitted into the appeal proceedings and that documents A21 and A22 are admitted in the event that documents A19 and A20 are nevertheless admitted.

The patent proprietors also requested that an objection of lack of inventive step starting from example 21 of document D3 not be admitted.

Reasons for the Decision

1. Admittance of new evidence

In its communication pursuant to Article 15(1) RPBA the Board indicated that it intended not to admit any of documents A19-A22. The Board explained that documents A19 and A20 should have been filed during the first instance proceedings and that no justification for the admittance of documents A21 and A22 was evident in the event that documents A19 and A20 were not admitted.

No substantive arguments were submitted by the parties in response to the preliminary opinion expressed by the Board in its communication.

The Board therefore confirms its assessment expressed in the communication pursuant to Article 15(1) RPBA and thus decides not to admit any of documents A19-A22 into the appeal proceedings.

2. Basis for the amendments - main request

In its communication pursuant to Article 15(1) RPBA the Board expressed its preliminary opinion that the main request complied with Article 123(2) EPC.

The Board explained that the combination of features F1-F4 with the alternatives of features F5 and F6 seemed adequately based on the originally filed independent claims 4 and 7 and the specification of the determination of the folding force on page 56, lines 23-30 and the internal retention on page 16, lines 9-12 of the application as filed. The Board pointed out that the application as filed also seemed to provide a basis for the features F4.1-F4.4 (see page 46, lines 2-4 for F4.1, page 16, lines 28-30 for F4.2, page 19, lines 5-7 for F4.3, page 20, lines 5-9 for F4.4). The Board further explained that, as argued by the patent proprietors, the identified passages in the application as filed relating to the features F4.1-F4.4 seemed to disclose these features in a general manner and that the skilled person would therefore understand that these features F4.1-F4.4 are disclosed to complement the embodiments of the original claims 4 and 7 corresponding to the claimed alternatives characterized by features F5 and F6.

No substantive arguments were submitted by the opponent in response to the preliminary opinion expressed by the Board in its communication.

The Board therefore confirms its assessment expressed in the communication pursuant to Article 15(1) RPBA and concludes that the main request complies with Article 123(2) EPC.

3. Inventive step - main request

3.1 Starting point in the prior art

3.1.1 It was not in dispute that example 23 of document D3 represents a suitable starting point in the prior art for the assessment of inventive step.

3.1.2 In agreement with the finding in the decision under appeal the Board considers that in addition to example 23 of document D3 the examples 7 and 8 of document D1 represent an alternative starting point that needs to be taken into account for the assessment of inventive step.

The patent proprietors' argument that example 23 of document D3 represents a more promising starting point than examples 7 and 8 of document D1 is not convincing in view of the patent proprietors' further argument that document D3 teaches away from the use of a degradable linker as defined under feature F4 of claim 1 of the main request. Notably, the patent proprietors have in this context not contested that document D1 mentions the possibility of using a degradable adhesive and would thus at least not teach away from a structure with a degradable linker (F4).

3.1.3 The Board does not admit the opponent's argument that example 21 of document D3 represents a further equally suitable starting point. From the minutes of the oral proceedings before the opposition division (see section

4.4.1.1) it is evident that the opponent had not maintained this argument during the first instance proceedings. Moreover, the opponent has not explained why example 21 would represent an equally suitable starting point. There are therefore no circumstances of the appeal case that could justify the admittance of this argument into the appeal proceedings (Article 12(6) RPBA).

3.2 Differences with example 23 of document D3

It was not in dispute that example 23 of document D3 describes a residence structure comprising the features F1-F3 of claim 1 of the main request.

In the Board's view the feature of a degradable linker as defined under feature F4 of claim 1 unambiguously requires a linker which degrades. The Board considers that the opponent has not demonstrated that the epoxy resin, which according to document D3 serves as a fusing agent with strong affinity to the other components (see D3, page 4, lines 5-6), necessarily represents a degradable linker as defined under feature F4. In this context it is not derivable from the mention in document D3 of erosion leaving remains of the device which exit the stomach (see D3, page 21, line 26) that the epoxy resin was degradable and not some other component of the device, because the remains are not further identified. In fact, document D3 actually suggests that a component of the device other than the fusing agent was erodible, namely tip portions of the Y-shaped device, which corresponds to the loadable polymeric component (F2) as defined in the claim 1 of the main request (see e.g. D3, page 3, line 58 to page 4, line 3).

The Board does not consider that the presence of an elastic polymer as defined under feature F5 of claim 1 could *per se* represent a distinguishing feature taking account of the reference in document D3 to the bending strength of the relevant material (see D3, page 7, Table 1).

It was further not in dispute that the amount of at least 60 wt% for the loadable component and the folding force of at least 0.2 N as defined under feature F5 as well as the particular release profile defined under feature F6 represent additional distinguishing features of claim 1 of the main request.

3.3 Differences with examples 7 and 8 of document D1

It was not in dispute that examples 7 and 8 of document D1 describe a residence structure comprising the features F1 and F3 of claim 1 of the main request.

The Board considers that a polyvinylacetate phthalate (PVAP) sleeve holding a tablet as described in examples 7 and 8 of document D1 may well represent a loadable polymeric component as defined under feature F2 of claim 1, because such a polymeric sleeve still comprises an active substance and thus releases the active substance from the tablet. In this context the Board observes that the reference in paragraph [0137] of the patent, which indicates that the active agent can be loaded into polymeric materials, is not indicative of a more restrictive interpretation of feature F2 that would exclude a polymeric sleeve holding a tablet as described in examples 7 and 8 of document D1.

On the other hand, the Board does not consider that the tablets of examples 7 and 8 themselves represent a loaded polymeric component as defined in feature F2 of claim 1, because it cannot be derived from document D1 that the tablets mentioned in examples 7 and 8 are tablets in which the active agents are loaded in a polymeric matrix.

As mentioned in section 3.2 above, the feature of a degradable linker as defined under feature F4 of claim 1 unambiguously requires in the Board's view a linker which degrades. The Board considers that the opponent has not demonstrated that the cyanoacrylate glue, which is in examples 7 and 8 of document D1 used to attach nylon ribbons to a PVAV sleeve holding a tablet, necessarily represents a degradable linker as defined under feature F4. The degradability of the used cyanoacrylate cannot be directly and unambiguously derived from the observed disintegration of the device of example 7 in the small intestine or colon (see D1, column 14, lines 55-58). Considering that document D1 indicates that the device of example 7 differs from the device of example 6 by the incorporation of a mechanism for disintegration (see D1, column 14, lines 2-4) and that both examples 6 and 7 describe the use of the cyanoacrylate glue, the observed disintegration is to be attributed to the use of PVAP sleeve in example 7 instead of the polyvinylchloride (PVC) sleeve in example 6, rather than to any degradation of the cyanoacrylate glue.

The Board is not convinced that the presence of an elastic polymer as defined under feature F5 of claim 1 could *per se* represent a distinguishing feature with respect to examples 7 and 8 of document D1, as these examples involve nylon ribbons as components. It could

hardly be maintained that a nylon ribbon should not exhibit some elasticity.

It was not in dispute that the loadable polymer component of at least 60 wt% and the folding force of at least 0.2 N as defined under feature F5 as well as the particular release profile defined under feature F6 represent additional distinguishing features of claim 1 of the main request.

3.4 The objective technical problem

The patent states in paragraph [0085] that the distinguishing feature of the degradable linker (F4) allows for a more independent control of the retention/ elimination of the structure from the release of the active agent. The experimental results in the patent illustrate this advantage with the reported variable retention depending on the nature of the linker (see Figures 19-21 relating to example 14) and the reported outstanding controlled release over several days (see Figures 24-26 relating to example 17). In this context the opponent has not substantiated why such advantage from the use of a degradable linker would not be realized within the whole scope of the claims. The Board further observes that the mentioned advantage is also embodied by a structure which does not yet comprise an active agent (alternative F5), because the presence of a loadable polymer provides for an active agent to be accommodated.

The Board therefore agrees with the patent proprietors that the objective technical problem concerns the provision of an improved residence structure or at least the provision of a residence structure allowing

excellent control over retention/elimination as well as release of the active compound.

3.5 Assessment of the solution

On the basis of the available prior art it would not have been obvious for the skilled person to employ a degradable linker (F4) in a residence structure as defined in claim 1 to solve the objective technical problem mentioned in section 3.4 above.

Document D3 does not provide any motivation to use a degradable adhesive for coupling the components of the described device, as it indicates the use of an erodable material for the drug containing component (see D3, page 3, line 58 to page 4, line 3). Document D1 indicates that in the preferred embodiments the receptacle for the drug and/or the retention arms and/or the adhesive are constructed from materials which soften, disintegrate, dissolve or degrade in the biological environment of use to permit the exit from the stomach (see D1, column 8, lines 3-11). However, document D1 does thereby not provide any suggestion that the use of specifically a degradable linker (F4) would provide for a solution to the qualified objective technical problem as identified in section 3.4 above.

3.6 Accordingly, the Board concludes that the main request complies with the requirement of inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar: The Chairman:

A. Vottner A. Usuelli

Decision electronically authenticated