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**Datasheet for the decision  
of 15 May 2024**

**Case Number:** T 1566/21 - 3.2.02

**Application Number:** 10840193.6

**Publication Number:** 2515992

**IPC:** A61M5/142, A61B5/00, A61B5/06,  
A61B5/07, A61J7/00, A61B5/145,  
A61M31/00, A61M37/00

**Language of the proceedings:** EN

**Title of invention:**  
SWALLOWABLE DRUG DELIVERY DEVICE

**Patent Proprietor:**  
Rani Therapeutics, LLC

**Opponent:**  
Novo Nordisk A/S

**Headword:**

**Relevant legal provisions:**  
EPC Art. 54(2), 56, 83, 123(2)  
RPBA 2020 Art. 12(6)

**Keyword:**

Amendments - added subject-matter (no)

Sufficiency of disclosure - (yes)

Novelty - (yes)

Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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**Case Number: T 1566/21 - 3.2.02**

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 15 May 2024**

**Appellant:** Rani Therapeutics, LLC  
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**Appellant:** Novo Nordisk A/S  
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**Representative:** Potter Clarkson  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
14 July 2021 concerning maintenance of the  
European Patent No. 2515992 in amended form.**

**Composition of the Board:**

**Chair** M. Alvazzi Delfrate  
**Members:** A. Martinez Möller  
Y. Podbielski

## **Summary of Facts and Submissions**

I. Appeals were filed by the patent proprietor and by the opponent against the interlocutory decision of the Opposition Division finding that then auxiliary request 2 filed during the oral proceedings before the Opposition Division met the requirements of the EPC.

II. Oral proceedings before the Board took place on 15 May 2024. At the end of the proceedings, the requests were as follows.

The appellant/proprietor ("proprietor") requested that the patent be maintained on the basis of auxiliary request 7 according to the numbering of letter of 30 January 2024. That request corresponds to the version of the patent maintained by the Opposition Division.

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

III. Claim 1 of auxiliary request 7 (corresponding to the version maintained by the opposition division) reads as follows:

"An ingestible device (10) suitable for swallowing into a lumen of a gastrointestinal tract of a patient, the lumen having a lumen wall, the device comprising: a capsule (20) having walls defining a perimeter of the capsule, the capsule comprising a generally cylindrical body portion with rounded ends, the capsule sized to pass through the intestinal tract;

a tissue penetrating member (40) having a needle or dart-like shape disposable in the capsule (20) and having a tissue penetrating end (45), the tissue penetrating member formed from a solid therapeutic agent preparation (100) comprising at least one therapeutic agent (101) which would chemically degrade or impose a deleterious effect on the patient if released within the lumen of the gastrointestinal tract, the tissue penetrating member (40) shaped and configured to be inserted into the lumen wall; and an actuator (60), the actuator coupled by a delivery member to the tissue penetrating member (40) and having a first configuration and a second configuration, the tissue penetrating member (40) having a needle or dart-like shape being retained within the capsule (20) and the tissue penetrating end being within the perimeter when the actuator (60) is in the first configuration, wherein the tissue penetrating member (40) is advanced from within the capsule (20), the tissue penetrating end emerging radially outwardly from the generally cylindrical body portion of the perimeter and entering into the lumen wall by movement of the actuator (60) from the first configuration to the second configuration, such that the tissue penetrating member (40) remains within the lumen wall to release therapeutic agent (101) and the deleterious effect or chemical degradation of the therapeutic agent (101) in the lumen is inhibited."

IV. The following documents are relevant to the present decision:

D1 US 2005/0267414 A1  
D2 US 2004/0253304 A1

- V. The opponent's arguments relevant to the present decision can be summarised as follows.

*Admittance of auxiliary request 7*

Auxiliary request 7 should not be admitted into the appeal proceedings. The Opposition Division was wrong to admit auxiliary request 7 (then auxiliary request 2) into the proceedings. The proprietor deliberately chose to delay the filing of the auxiliary requests until the oral proceedings despite the adverse preliminary opinion of the Opposition Division. No auxiliary request should have been admitted at the oral proceedings before the Opposition Division because any request could and should have been filed sooner. Moreover, auxiliary request 7 was *prima facie* unallowable.

*Added subject-matter*

Claim 1 of auxiliary request 7 comprised added subject-matter for three reasons.

Firstly, paragraphs [0006] and [0010] of the original application related to an aspect that could not be combined with original claim 1 because it did not mention that the therapeutic agent would chemically degrade or impose a deleterious effect if released within the lumen of the gastrointestinal (GI) tract.

Secondly, as argued in written proceedings in connection with auxiliary request 6, the original application did not provide basis to specify the shape of the capsule and the inclusion of a delivery member without also incorporating the other features showed in

Figures 2, 4 and 12 and described in combination at paragraph [0121].

Thirdly, the added feature "radially outwardly" was broader than the disclosure in the original application.

*Sufficiency of disclosure*

The feature that the deleterious effect or chemical degradation of the therapeutic agent was inhibited defined a result to be achieved. The contested patent did not provide any examples to understand to what extent any deleterious effect or chemical degradation should be reduced in order to satisfy the requirement for such effect to be inhibited.

Moreover, the specification did not teach the extent to which the tissue penetrating member should be inserted into the lumen wall and how long it should be inserted therein. Claim 1 covered delivery to the stomach and large intestine, but there was no way to ensure that the tissue penetrating member would enter the lumen wall in those cases.

*Novelty*

The subject-matter of claim 1 was not novel over D1.

Figure 2 of D1 was schematic. The person skilled in the art reading D1 would understand, in view of Figure 1 and paragraphs [0020] and [0023], that the end of the needles 4 was within the capsule's perimeter before actuation.

The feature "radially outwardly" should be construed as meaning that the tissue penetrating end emerged outward along a line extending from a centre of the generally cylindrical body. The needles of D1 emerged from a center point along the capsule's longitudinal axis, and thus emerged radially outwardly.

*Inventive step*

The subject-matter of claim 1 was not inventive when starting from D1. Even if the two above features were seen as distinguishing features, they had no synergistic effect. The feature of the tissue penetrating end being within the capsule's perimeter had no technical effect because claim 1 did not require the capsule to be sealed, hence the claimed arrangement did not prevent degradation.

The subject-matter of claim 1 was not inventive when starting from D2 either. The person skilled in the art looking for an alternative tissue penetrating member would use a tissue penetrating member formed from a solid therapeutic agent as taught by D1. They would recognise that a different fluid could be used to drive expulsion of the needle in D2.

VI. The proprietor's arguments relevant to the present decision can be summarised as follows.

*Admittance of auxiliary request 7*

Auxiliary request 7 had been filed in the opposition proceedings in response to the Opposition Division's change of opinion and had then been admitted. There was no legal basis for not considering it on appeal.

*Added subject-matter*

Claim 1 did not comprise added subject-matter.

Paragraphs [0006] and [0010] provided a basis for the amendments relating to the features of the shape of the tissue penetrating member and its retention within the lumen wall to release therapeutic agent. It was clear from the application as a whole that therapeutic agents which chemically degraded in the GI tract were envisaged.

The Figures provided a basis for the shape of the capsule and the inclusion of a delivery member.

The added-matter objection against the feature "radially outwardly" had been raised for the first time at the oral proceedings before the Board and should not be admitted.

*Sufficiency of disclosure*

The invention was sufficiently disclosed. Clarity was not a ground for opposition, so the alleged doubts related to the term "inhibited" had to be dismissed. It was clear from the wording of the claim that retention of the tissue penetrating member within the capsule and its later advancement inhibited the deleterious effect or chemical degradation. The new objections raised for the first time in the appeal proceedings should not be admitted.

*Novelty*

The subject-matter of claim 1 was novel over D1. D1 did not disclose that the tissue penetrating member was

within the capsule's perimeter. Figure 2 of D1 showed the needles protruding, and Figure 1 showed no needles because it did not refer only to the embodiment of Figure 2. D1 also did not disclose that the needles emerged radially outwardly from the cylindrical body portion of the capsule's perimeter.

*Inventive step*

The subject-matter of claim 1 was inventive.

If starting from D1, the distinguishing feature that the tissue penetrating end was within the capsule's perimeter had the effect of preventing degradation of at least the end of the tissue penetrating member. Moreover, it worked synergistically with the emergence of the tissue penetrating member to achieve an improved delivery of the therapeutic agent.

D1 and D2 used very different arrangements and modes of operation and could not be combined.

**Reasons for the Decision**

**1. The patent**

1.1 When a therapeutic agent preparation is swallowed, one or more of its therapeutic agents may chemically degrade if released within the lumen of the gastrointestinal (GI) tract. The invention relates to swallowable drug delivery devices that address this issue.

1.2 The ingestible device defined in independent claim 1 as granted comprises a capsule, a tissue penetrating

member and an actuator. The tissue penetrating member is formed from a solid therapeutic agent preparation comprising at least one therapeutic agent which would chemically degrade or impose a deleterious effect on the patient if released within the lumen of the GI tract. The tissue penetrating member is retained within the capsule and configured to be advanced from the capsule and into the lumen wall by movement of the actuator such that the tissue penetrating member remains within the lumen wall to release therapeutic agent.

**2. Admissibility of the opponent's appeal**

2.1 The admissibility of the opponent's appeal was challenged by the proprietor. This issue is however not decisive in view of the non-allowability of the appeal for the reasons set out below.

**3. Admittance of auxiliary request 7**

3.1 Auxiliary request 7 was admitted - as auxiliary request 2 - by the Opposition Division. The decision under appeal is based on auxiliary request 7. Hence auxiliary request 7 forms part of the appeal proceedings.

3.2 Even if the opponent's request not to admit auxiliary request 7 was construed as a request to exclude it, it is questionable whether there is a legal basis for excluding it on appeal.

3.3 In any event, in its discretionary decision to admit auxiliary request 7, the Opposition Division took into account that the request was a reaction to the development of the proceedings - following its change of view as compared with the preliminary opinion - and

that it corresponded to a request filed before the expiry of the time limit under Rule 116 EPC except for the omission of a feature deemed not to be necessary to comply with Article 123(2) EPC. As it is clear from the Opposition Division's findings, the Opposition Division was not of the view that the request was *prima facie* not allowable. The Board thus holds that the Opposition Division used its discretion according to the right principles and in a reasonable way.

- 3.4 The opponent's argument that no auxiliary request should have been admitted by the Opposition Division because any request could and should have been filed sooner is not convincing, because this would exclude any discretion by the Opposition Division to consider ongoing developments in the proceedings.
- 3.5 There is thus no reason to overturn the Opposition Division's discretionary decision to admit auxiliary request 7.

#### **4. Added subject-matter**

- 4.1 The opponent put forward three reasons why claim 1 of auxiliary request 7 comprised added subject-matter. Each of these reasons is addressed separately below.
- 4.2 No basis in paragraphs [0006] and [0010]
  - 4.2.1 The Opposition Division found that some of the amendments to claim 1 found basis in paragraphs [0006] and [0010] of the original application. This concerns in particular the addition of the features "needle or dart-like shape" and "the tissue penetrating member remains within the lumen wall to release therapeutic agent".

- 4.2.2 The opponent argued that paragraphs [0006] and [0010] related to an aspect that could not be combined with original claim 1 because the aspect described in paragraphs [0006] to [0018] did not mention that the therapeutic agent would chemically degrade or impose a deleterious effect if released within the lumen of the gastrointestinal (GI) tract.
- 4.2.3 Paragraph [0003] of the original application, in the background section, presents poor toleration and/or degradation within the GI tract as a limitation of oral delivery of drugs. Paragraphs [0004] and [0005] go on to indicate that "[e]mbodiments of the invention" are useful for the delivery of therapeutic agents which are poorly tolerated and/or chemically degraded within the GI tract. Paragraphs [0039] and [0172] disclose that therapeutic agents which would otherwise chemically degrade or cause deleterious effects in the GI tract can be delivered with embodiments of the invention. Hence, the original description presents this feature of the therapeutic agent as generally applying to the invention rather than as being specific to a particular aspect or embodiment, and thus as also applying to the aspect described in paragraphs [0006] to [0018].
- 4.2.4 The Board is thus not convinced by the added-matter objection in connection with the features added to claim 1 from paragraphs [0006] and [0010].
- 4.3 Shape of the capsule and delivery member
- 4.3.1 The opponent put forward that amending claim 1 to specify the shape of the capsule and the inclusion of a delivery member without also incorporating other

features from the drawings resulted in added subject-matter.

4.3.2 The claimed shape of the capsule and the delivery member are shown in several embodiments / figures of the application as filed. Even though each of the figures shows additional features, no inextricable link between these features and any other feature of the figures is apparent, nor was such a link to any specific feature identified by the opponent. Hence incorporating these features in isolation does not result in added subject-matter.

4.4 Feature "radially outwardly"

4.4.1 At the oral proceedings before the Board, the opponent raised for the first time an added-matter objection against the addition of the feature "radially outwardly". The opponent conceded that there were no exceptional circumstances within the meaning of Article 13(2) RPBA. Therefore, the Board decided not to admit this objection into the proceedings.

4.5 In summary, none of the objections of added subject-matter prejudices the maintenance of the patent on the basis of auxiliary request 7.

## **5. Sufficiency of disclosure**

5.1 The opponent put forward that inhibition of the deleterious effect or chemical degradation of the therapeutic agent was a result to be achieved and that the patent specification did not provide any examples to understand to what extent any deleterious effect or chemical degradation should be reduced in order to

satisfy the requirement for such effect to be inhibited.

5.2 The question of how much reduction is necessary to fall under the term "inhibited" is an issue of clarity. However, clarity is not a ground for opposition.

5.3 According to claim 1 of auxiliary request 7, inhibition of the adverse effect is achieved by retaining the tissue penetrating member within the capsule and advancing it into the lumen wall by movement of the actuator such that it remains within the lumen wall. The specification teaches in various embodiments how this retention within the capsule and subsequent advancement into the lumen wall can be carried out, thus disclosing the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

5.4 The opponent raised, for the first time with the opponent's statement of grounds of appeal, a further objection of insufficient disclosure related to the insertion of the tissue penetrating member into the lumen wall.

5.5 The opponent did not provide reasons for submitting this objection for the first time in the appeal proceedings. The objection could and should have been submitted in the first-instance proceedings. Hence, the Board did not admit it into the appeal proceedings (Articles 12(6), 2nd sentence, RPBA).

## **6. Main request - novelty over D1**

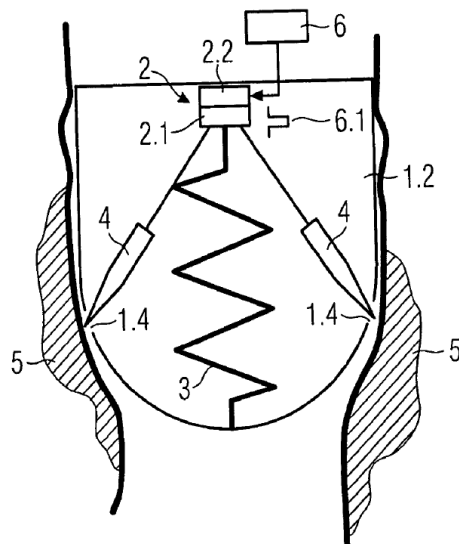
6.1 It was disputed whether or not D1 discloses the two following features of claim 1:

(a) "the tissue penetrating end being within the [capsule's] perimeter when the actuator is in the first configuration"; and

(b) "the tissue penetrating end emerging radially outwardly from the generally cylindrical body portion of the perimeter".

6.2 D1 discloses an endorobot that can be navigated using an external gradient field for bringing therapeutic agents into the interior of a patient's body. The objection of lack of novelty relies on the embodiment of Figures 2 and 3. Figure 2 reproduced hereinafter shows the endorobot's operating head 1.2 with a therapeutic agent that has the form of needles 4 (see paragraph [0023]), a tension spring 3, a stressing device 2 and a signal transmitter 6. Tissue surrounding the endorobot is shown with reference number 5.

FIG 2



6.3 As can be seen in Figure 2 of D1, the end of the needles 4 does not lie within the perimeter of the endorobot's capsule, but protrudes slightly. Even

taking into account that, according to paragraph [0010], the representation in the drawings is schematic, Figure 2 does not disclose above feature (a). The statement in paragraph [0023] that the therapeutic agent in Figure 2 has the form of needles 4 and is "stored directly in front of an outlet opening 1.4" does not allow a different conclusion, since "in front" does not necessarily require that the needles are within the perimeter of the capsule and the passage explicitly refers to what is shown in Figure 2.

6.4 The opponent pointed to the fact that Figure 1 shows the capsule with openings 1.4 and nothing protruding from them and refers to paragraph [0020] of the description that describes Figure 1 and discloses that from the openings 1.4 "a therapeutic agent 4 or 8 can emerge". However, it is clear from the reference to the therapeutic agent "4 or 8", i.e. needles 4 of the embodiment of Figures 2 and 3 or beads 8 of the embodiments of Figures 4 to 9, that the endorobot of Figure 1 can be used for various embodiments and is not specific to the embodiment with the needles 4. Therefore, no conclusion as to whether the needles 4 are within the capsule's perimeter can be drawn from paragraph [0020] and the fact that the needles are not depicted in Figure 1.

6.5 It follows that D1 does not disclose the above feature (a).

6.6 The opponent argued that the above feature (b) did not require that the tissue penetrating member emerged in a direction orthogonal to the capsule's longitudinal axis from the capsule, but only radially, i.e. that the tissue penetrating end emerged outward along a line

extending from a centre of the generally cylindrical body.

6.7 Even if this claim construction were to be followed, the tips of the needles 4 in D1 do not emerge along a line extending from the centre of the cylindrical body: as can be seen from Figure 1, the centre of the cylindrical body is located well above the capsule's bottom rounded end, i.e. well above the stressing device 2 visible in Figures 2 and 3. The opponent's further contention that any point along the longitudinal axis of the capsule would be a centre of the cylindrical body is incorrect in that it disregards that the centre of an object depends on the dimensions of that object.

6.8 In summary, D1 does not disclose any of the above features (a) and (b). The subject-matter of claim 1 is thus novel over D1.

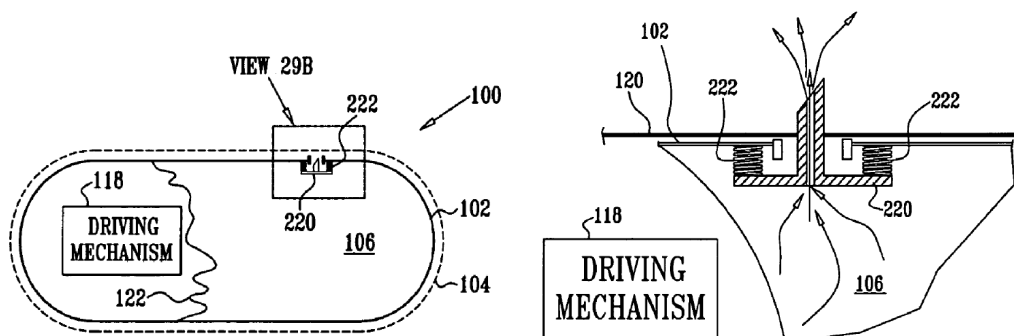
## **7. Main request - inventive step**

7.1 D1 can be regarded as a valid starting point for the invention of claim 1. The Board agrees with the opponent that there is no synergy between the above distinguishing features (a) and (b). Even if claim 1 does not require the capsule to be sealed, the arrangement of the end of the tissue penetrating member within the capsule prior to activation (i.e. feature (a)) reduces its exposure to the GI lumen and thus minimises degradation in the GI lumen of at least the end of the tissue penetrating member, thereby achieving a technical effect when compared to D1. The opponent did not point to any passage of D1 or of any other document that would address the problem of degradation of the end of the tissue penetrating member, let alone

solve it by means of feature (a). For this reason alone and irrespective of feature (b), the objection of lack of inventive step starting from D1 is not convincing.

7.2 In the written proceedings, the opponent also argued that the subject-matter of claim 1 lacked an inventive step over D2 in combination with D1.

7.3 D2 discloses an ingestible capsule with a hollow needle 220 which is initially contained within the body of the capsule 102. The capsule comprises a driving mechanism 108 that contains a gas generator 118 and a movable member 122 (e.g. a membrane of a piston). Upon activation of the driving mechanism 108 (e.g. by a sensor) gas is generated in gas generator 118. This gas applies pressure on the movable member 122 and thus on the drug 106. Pressure of the drug 106 results in a force applied at the needle 220 which surpasses the opposite force of the elastic elements 222. This thrusts the needle 220 out of the body of the capsule. The pressure of the drug 106 causes the drug to pass through the channel of the needle 220 and past the endothelial layer of the small intestine. When the pressure declines, the elastic elements 222 cause the hollow needle 220 to retract within the body of the capsule 102 (see [0073]-[0074], [0439], [0463]-[0465] as well as Figs. 29A-29B reproduced hereinafter).



7.4 It is common ground that D2 does not disclose at least the feature of a tissue penetrating member formed from a solid therapeutic agent preparation. D2 seeks to inject a liquid drug and to subsequently retract the needle. The releasing mechanism of D2 relies on the liquid drug applying force on the needle and on elastic elements 222 retracting the needle within a short period of time, hence not being compatible with a tissue penetration member made of drug. The opponent's assertion that the person skilled in the art would recognise that a different fluid should be used to apply force is speculative and not supported by any evidence.

7.5 It follows that none of the inventive-step objections against auxiliary request 7 is convincing. Since auxiliary request 7 corresponds to the version maintained by the Opposition Division, both appeals have to be dismissed.

## **Order**

### **For these reasons it is decided that:**

The appeals are dismissed.

The Registrar:

The Chair:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated