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**Datasheet for the decision of 19 January 2023**

**Case Number:** T 0042/19 - 3.2.01

**Application Number:** 13723906.7

**Publication Number:** 2846857

**IPC:** A61M5/20, A61M5/315

**Language of the proceedings:** EN

**Title of invention:**
INJECTION DEVICES USING A RESILIENTLY COMPRESSIBLE TORSION SPRING AS DRIVING FORCE

**Patent Proprietor:**
Owen Mumford Limited

**Opponent:**
Novo Nordisk A/S

**Headword:**

**Relevant legal provisions:**
EPC Art. 83, 52(1), 54, 56
RPBA Art. 12(4)
RPBA 2020 Art. 25

**Keyword:**

Public prior use (no) - insufficient evidence (yes)
Late-filed request to hear witness - admitted (no)
Sufficiency of disclosure - main request (yes)
Novelty - main request (yes)
Inventive step - main request (yes)
Late-filed facts - submitted with the statement of grounds of appeal - admitted (no)
Free evaluation of evidence

**Decisions cited:**

T 0855/96, T 1604/16, T 1418/17

**Catchword:**

1. A boards' power to review appealed decisions is not limited to points of law but extends to points of facts (in agreement with T 1604/16).

2. However, it is settled case law that a board is not obliged to take all the evidence anew and that parties do not have the right to have the taking of evidence repeated at their request before the board.

3. The principle of free evaluation of evidence, meaning that there are no firm rules on the probative value of the various types of evidence but that the deciding body is entrusted with weighing up all the evidence and basing its decision on what it is then satisfied has been established, implies a degree of freedom comparable to the one referred to by the Enlarged Board of Appeal in decision G 7/93, Reasons 2.6.

4. Thus, it is wise to similarly respect this freedom, especially when taking into account that a board, except when only reviewing documentary evidence, does not have the same first-hand impression of the probative value of a means of evidence as a department of first instance that has itself heard a witness or expert or inspected an object.

5. Although the Board is not limited in its decision, it normally seems useful to apply the test set out in decision T 1418/17, Reasons 1.3: Unless the law has been misapplied (e.g. application of the wrong standard of proof), a board of appeal should overrule a department of first instance's evaluation of evidence and replace it with its own only if it is apparent from that department's evaluation that it: (i) disregarded essential points, (ii) also considered irrelevant matters or (iii) violated the laws of thought, for instance in the form of logical errors and contradictions in its reasoning.

6. The evaluation of evidence only refers to establishing whether an alleged fact has been proven to the satisfaction of the deciding body. The discretion-like freedom is restricted to this question and does not extend to the further question of how the established facts are to be interpreted and what the legal consequences are

(see Reasons 3.2 to 3.6).

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**Case Number: T 0042/19 - 3.2.01**

# D E C I S I O N
# of Technical Board of Appeal 3.2.01
# of 19 January 2023

| | |
|---|---|
| **Appellant:** (Opponent) | Novo Nordisk A/S<br>Novo Allé<br>2880 Bagsvaerd (DK) |
| **Representative:** | Potter Clarkson<br>Chapel Quarter<br>Chapel Bar<br>Nottingham NG1 6HQ (GB) |
| **Respondent:** (Patent Proprietor) | Owen Mumford Limited<br>Brook Hill Woodstock<br>Oxford, Oxfordshire OX20 1TU (GB) |
| **Representative:** | Marks & Clerk LLP<br>15 Fetter Lane<br>London EC4A 1BW (GB) |
| **Decision under appeal:** | **Decision of the Opposition Division of the European Patent Office posted on 25 October 2018 rejecting the opposition filed against European patent No. 2846857 pursuant to Article 101(2) EPC.** |

**Composition of the Board:**

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|---|---|
| **Chairman** | G. Pricolo |
| **Members:** | V. Vinci |
| | P. Guntz |

## Summary of Facts and Submissions

I. The appeal filed by the appellant is directed against the decision of the opposition division to reject the opposition and maintain European patent No. 2 846 857 as granted.

II. In its decision, the opposition division held that the grounds for opposition pursuant to Article 100(a) in combination with Articles 54 and 56 EPC and to Article 100(b) in combination with Article 83 EPC were not prejudicial to the maintenance of the patent as granted. The opposition division came to the conclusion that the subject-matter of independent claims 1 and 11 as granted was novel within the meaning of Articles 52(1) and 54 EPC over documents:

D3: WO 2011 /045611 A2
D7: WO 2012/063061 A2
D9: WO 2011 /003979 A1
D11: WO 201 0/089418 A2
D13: WO 2009/007305 A1

and involved an inventive step within the meaning of Articles 52(1) and 56 EPC in view of documents D13 and D11 in combination.

A late-filed alleged public prior use of an insulin injection pen named *GensuPen* labelled as D18 and based on evidence D18.1 to D18.6 filed on 13 April 2018, D18.7 to D18.10 filed on 1 June 2018 and D18.11 to D18.14 filed on 3 August 2018 submitted in reaction to the preliminary opinion of the opposition division was admitted in the opposition proceedings as *prima facie*

relevant, but considered not sufficiently proven.

III. With a communication pursuant to Article 15(1) RPBA dated 6 May 2022, the Board informed the parties of its preliminary, non-binding assessment of the appeal.

Oral proceedings pursuant to Article 116 EPC were held before the Board on 19 January 2023 by videoconference.

IV. The appellant requested that the decision under appeal be set aside and that the European patent be revoked.

The respondent requested that the appeal be dismissed or, in the alternative, should the Board allow any aspect of the appeal, that the case be remitted to the opposition division for further prosecution on the basis of auxiliary requests 1 to 11 as submitted during the opposition proceedings.

V. Independent claim 1 as granted reads as follows (labelling of the features added by the Board):

*"An injection device including:*

*A1) a housing (12) for receiving a syringe (18) or cartridge for containing a medicament;*

*A2) a rotary drive shaft (24) mounted for rotation relative to said housing (12);*

*A3) an elongate coiled torsion spring (38) having respective formations (48,50) at opposite ends thereof with a first end formation (48) being anchored in a seat (56) on said rotary drive shaft (24) and a second end formation (50) being anchored in a seat (58) on a reaction component (14),*

*A4) whereby in use relative rotation of said rotary drive shaft (24) and said reaction component (14) in one angular direction strains said torsion spring (38), and release of said strained torsion spring causes expression of medicament from said syringe or cartridge;*

*A5) characterised wherein said torsion spring is longitudinally resiliently compressible between its end formations*

*A6) whereby during assembly of said injection device, the torsion spring may be longitudinally compressed and rotated, thereby causing the end formations (48, 50) of the torsion spring to be urged into engagement with said respective seats (58, 56)."*

Independent claim 11 as granted reads as follows (labelling of the features added by the Board):

*"A method of assembly of an injection device including:*

*B1) a housing (12, 16) for receiving a syringe or cartridge (18) for containing a medicament;*

*B2) a rotary drive shaft mounted for rotation (24);*

*B3) a reaction component (14), and*

*B4) an elongate coiled torsion spring (38) having respective formations (48,50) at opposite end regions thereof for engagement with respective seats (58,56) on said rotary driveshaft and said reaction component respectively, the method comprising:*

*B5) disposing said elongate coiled torsion spring (38)*

*between said driveshaft (24) and said reaction component (14); the method characterised by further comprising:*

*B6) effecting relative movement of said rotary driveshaft and said reaction component to cause said torsion spring to compress thereby urging said respective formations (48, 50) into engagement with the driveshaft and the reaction component respectively, and*

*B7) effecting relative rotation of said rotary driveshaft and said reaction component to cause said formations (48, 50) to be engaged and captured by said respective seats (58, 56).*"

## Reasons for the Decision

**MAIN REQUEST - PATENT AS GRANTED**

**Alleged lack of substantiation of the reply of the respondent**

1. Contrary to the allegation of the appellant, the reply of the respondent to the statement of grounds of appeal is sufficiently substantiated and meets the requirements of Article 12(2) RPBA 2020.

1.1 At the oral proceedings, the appellant relied on its arguments presented in writing and did not wish to make any further submission. Consequently, the Board has no reason to deviate from the assessment of this alleged issue presented in its preliminary opinion. This assessment is thus confirmed and is as follows:

1.2 The appellant essentially argued that the reply of the respondent did not sufficiently substantiate why the

decision under appeal should be upheld, as required by Article 12(2) RPBA version 2020 which, in view of the transitional provisions of Article 25 RPBA version 2020, applied to this appeal. The appellant alleged a lack of a reaction in substance to its appeal case, in particular regarding the contested interpretation of features A6 of claim 1; the disputed public prior use D18; and the objections of lack of disclosure, novelty and inventive step.

1.3 However, in the Board's view, the allegations of the appellant are not justified. With its reply, the respondent did legitimately take a position on all relevant issues at stake to the extent it considered appropriate and necessary. The mere allegation that not all the points raised by the appellant were dealt with, at least not sufficiently, in the reply cannot lead to the conclusion that the reply of the respondent does not meet the requirements of Article 12(2) RPBA 2020.

**Article 100(b) in combination with 83 EPC**

2. The ground for opposition raised by the appellant under Article 100(b) in combination with Article 83 EPC is not prejudicial to the maintenance of the patent as granted as correctly stated in the decision under appeal.

2.1 With its appeal, the appellant contested, among other points, the conclusion of the opposition division on compliance with Article 83 EPC.

2.2 At the oral proceedings, the appellant relied on its arguments presented in writing and did not wish to make any further submission. The Board has thus no reason to deviate from the assessment of this alleged issue

presented in its preliminary opinion, which it thus confirms and is as follows:

2.3 The appellant alleged that while independent claims 1 and 11 as granted potentially covered the possibility of delivering the medicament by a translation-free kinematic, the contested patent did not provide the person skilled in the art with any information on how the person skilled in the art could put in practice such an embodiment without undue burden, meaning that the requirements of Article 83 EPC were not met.

2.4 However, the Board concurs with the opposition division and the respondent that at least one way to carry out the claimed invention using a translation kinematic is clearly disclosed in the contested patent (see paragraphs [0018] to [0027]). This is not contested. As neither the dependent claims nor the whole patent disclosure indicate that the patent is meant to also cover an embodiment according to which the medicament is delivered by means of a translation-free kinematic, the person skilled in the art would implicitly exclude this merely theoretical possibility from the possible embodiments of the invention covered by the claims and would encounter no difficulties to carry out the claimed injection device by adopting the disclosed translation kinematic.

2.5 The Board thus confirms the positive assessment of compliance with Article 83 EPC of the first-instance department.

**Alleged public prior use of the *GensuPen***

3. The Board confirms the decision of the opposition division to dismiss the alleged public prior use D18 as

not sufficiently proven.

3.1 The conclusion of the opposition division that the public availability of an insulin injection device marked with the name *GensuPen* according to the sample D18.13 before the priority date of the contested patent was not sufficiently proven was contested by the opponent, which requested a reversal of this decision and that the alleged public prior use be considered state of the art under Article 54(2) EPC.

3.2 Regarding review by a board of the evaluation of evidence carried out by a deciding body of first instance, the Board notes that the principle of free evaluation of evidence applies to all departments of the EPO and thus also impacts the review in appeal proceedings. Unless the law has been misapplied (e.g. application of the wrong standard of proof), a board of appeal should therefore overrule a department of first instance's evaluation of evidence and replace it with its own only if it is apparent from that department's evaluation that it:

(i) disregarded essential points,
(ii) also considered irrelevant matters or
(iii) violated the laws of thought, for instance in the form of logical errors and contradictions in its reasoning (see T 1418/17, Reasons 1.3).

3.3 The Board agrees with decision T 1604/16 that the boards' power to review appealed decisions is not limited to points of law but extends to points of facts (see Reasons 3.1.7 referring to, *inter alia*, the explanatory remarks to new Article 12(2) RPBA 2020). Thus, a board has the power and a duty to overrule decisions not only on the grounds of an incorrect

application of the law but also on the grounds of deficiencies in the fact-finding process. However, it is settled case law that a board is not obliged to take all the evidence anew and that parties do not have the right to have the taking of evidence repeated at their request before the board. The boards usually just review the way in which the evidence was taken by the departments of first instance and, where they do not find any deficiencies, apply the law on the basis of the facts found in the decisions.

3.4 It is against this background that this Board, based on earlier decisions, undertook in T 1418/17 to formulate typical scenarios in which the evaluation of evidence by a body whose decision is to be reviewed should be overruled and where the evaluation of evidence by the deciding body should be respected, keeping in mind that the evaluation of evidence is a process that is first and foremost entrusted to the deciding body that has to weigh all the available and relevant evidence and, applying the correct standard of proof, has to decide whether, and give reasons why it is convinced that, a certain fact is to be considered proven or not. As the competent board in T 1604/16 stated, the evaluation of evidence is not, strictly speaking, a discretionary decision. However, the principle of free evaluation of evidence, meaning that there are no firm rules on the probative value of the various types of evidence but that the deciding body is entrusted with weighing up all the evidence and basing its decision on what it is then satisfied has been established, implies a degree of freedom comparable to the one referred to by the Enlarged Board of Appeal in decision G 7/93, Reasons 2.6. Thus, it is wise to similarly respect this freedom, especially when taking into account that a board, except when only reviewing documentary evidence,

does not have the same first-hand impression of the probative value of a means of evidence as a department of first instance that has itself heard a witness or expert or inspected an object.

3.5 The Board is well aware that a board, being a deciding body as well, is also entrusted with the weighing of evidence under the principle of free evaluation of evidence. As a consequence, it cannot be excluded that a board might come to a different conclusion than the body that issued the impugned decision. But being under the obligation to give reasons for its decision, the board must be able to convincingly demonstrate where the competent division erred. Where this is possible, one of the criteria set out in decision T 1418/17 will most probably be fulfilled. Where this does not seem possible, a board should think twice whether there really is a need to overrule the evaluation of evidence contained in the impugned decision. Thus, the Board can acknowledge much of the reasoning in decision T 1604/16 but is still convinced that the test set out in decision T 1418/17 gives valuable guidance for identifying cases where a board is prompted to set aside an impugned decision's evaluation and either apply its own evaluation of evidence or remit the case to the department of first instance. Respecting the department's evaluation of evidence in the remaining cases would both reflect and justify the standing practice, as outlined above, that the boards are not obliged to and regularly do not take evidence themselves but instead review the fact finding done by the department that issued the decision under appeal.

3.6 Finally, it should be kept in mind that the evaluation of evidence only refers to establishing whether an alleged fact has been proven to the satisfaction of the

deciding body. The discretion-like freedom referred to in point 3.5 above is restricted to this question and does not extend to the further question of how the established facts are to be interpreted and what the legal consequences are. Thus, the fear that a board's power to review decisions might be unduly limited is not shared.

3.7 The Board is convinced that in this case none of the aforementioned circumstances which would justify a review of the evaluation of evidence carried out by the opposition division can be identified in the reasoning which led to the conclusion that the alleged public prior use D18 was not sufficiently proven. The reasons are as follows.

3.8 Regarding the allegation of the appellant that the higher *up to the hilt* standard of proof was incorrectly applied by the opposition division to come to the conclusion that the alleged public prior use D18 was not sufficiently proven, the Board concurs with the respondent that the contested decision (see page 9, last paragraph) applied the lower standard of proof and came to the same conclusion based on the *balance of probabilities* standard which, incidentally, is the correct one in the current case taking into account that it cannot be asserted that all the relevant evidence, in particular the information on the effective date of availability of the *GensuPen* on the market, lay within the sphere of the appellant only. Furthermore, in view of the wording of the above-cited passage of the contested decision, the allegation of the appellant that the opposition division failed to define the applicable standard of proof is unjustified.

3.9 The Board also sees no reason for the criticism of the appellant that the opposition division only focused on the information of single pieces of evidence taken in isolation without duly evaluating any possible *indirect evidence* resulting from the information which could be gathered from all the available pieces of evidence when considered in combination. The Board finds that the opposition division correctly concluded that evidence D18.1 to D18.9 could not convincingly support the alleged public prior use of an insulin injection pen according to the sample D18.13 because they were not clearly linked to this product, meaning that the alleged public prior use was correctly assessed on the basis of the remaining evidence D18.10 to D18.14. No failure to consider all the information provided by the sets of evidence, either taken alone or in combination, can thus be found.

3.10 The Board also shares the doubts raised by the opposition division on the factual circumstances underlying the alleged public prior use which led to the decision to consider it not sufficiently proven. The Board notes that, as clearly stated in the EPO Guidelines G-IV, 7.2, (iii)), when a public prior use is alleged, all the circumstances relating to it must be indicated at the earliest stage, i.e. within the opposition period (see Case Law of the Boards of Appeal, 10th edn., IV. C. 2.2.8 i)) to allow the deciding department to determine whether and to what extent such a public prior use took place. This was not the case in the proceedings before the opposition division, as correctly stated in the decision under appeal, for the following reasons.

As regards the statement of Ms Simon (evidence 18.11 with its translation D18.12), the Board concurs with

the opposition division that no information is provided as to in what capacity she accessed the diabetic consultation room of the Polimed Medical Center in Katowice (Poland) and the precise circumstances under which Ms Simon obtained an insulin injection device named *GensuPen,* belonging to lot number 100804, a sample submitted as evidence D18.13. In fact, in addition to being silent on the complete personal details of the subscriber, i.e. address and date of birth, the declaration does not confirm that any member of the public could have accessed the consultation room of the Polimed Medical Center and obtained the insulin pen injector in question. The declaration of Ms Simon only states that on request a *GensuPen* of lot number 100804 was handed over to her for free. Whether she was a member of the public or whether this was possible for any member of the public and not only for a restricted number of patients undergoing, for example, an experimental treatment which, as such, would normally be subject to a confidentiality obligation, cannot be deduced from the declaration of Ms Simon. Furthermore, the related evidence and explanations submitted by the appellant during the opposition proceedings and later with the written submissions in appeal fail to explain why Ms Simon after having visited the consultation room of the Polimed Medical Center wrote on the same day a declaration which was used more than six years later in these opposition proceedings. The fact that this relevant information is completely missing indeed casts a shadow on the plausibility of the statement D18.11/ D18.12 of Ms Simon and, in the Board's view, justifies the conclusion of the opposition division that the public prior use, even under the lower standard of proof of the *balance of probabilities,* was not sufficiently proven because the circumstances were not fully and clearly specified. This same applies for the

same reasons to the declaration of Mr Lubawy presented as evidence D18.10.

3.11 During the oral proceedings before the Board, the appellant, in an attempt to fill the gap objected to by the opposition division, drew attention to evidence D18.4, namely an online article dated April 2012 reporting on infringement proceedings concerning an insulin injection pen marketed as *GensuPen* (no lot number is indicated) initiated by the appellant against the distributor of this product and alleged infringer *Bioton*. The appellant explained that on 27 February 2012, Mr Lubawy and Ms Simon visited the consultation room of the Polimed Medical Center on the instructions of the appellant as *test-buyers* as part of investigations started by the appellant for the ongoing infringement proceedings. The appellant expressed the view that the information provided by evidence D18.4 clearly implied the allegedly missing circumstances which triggered the visit to the consultation room of the Polimed Medical Center by Mr Lubawy and Ms Simon and also explained why the declarations were drafted on the same day as the visits. The appellant thus concluded that, contrary to the opposition division's view confirmed by the preliminary opinion of the Board, the circumstances of the alleged prior use were submitted at the time of filing the alleged prior use. Furthermore, it was argued that the burden of proof that the *GensuPen* was handed over under trial just to a restricted number of patients and that it could not be obtained on request and for free at the Polimed Medical Center in Katowice by any member of the public without any confidentiality obligation was born by the respondent, which did not provide any counter-submissions in this respect. Finally, the appellant concluded that if the opposition division had duly

considered all the evidence provided, it should have come, by correctly applying the lower standard of proof of the *balance of probabilities*, to the conclusion that, even in presence of some minor information gaps, i.e. some personal details of the subscribers, it was more probable that the public prior use indeed took place than not.

3.12 These arguments are not convincing for the following reasons:

3.13 The Board observes that contrary to the assertion of the appellant, it is not possible to derive a causal link between the infringement proceedings reported in the online article D18.4 and the circumstances of the alleged public prior use, i.e. the reason for the visits of Mr Lubawy and Ms Simon to the Polimed Medical Center, which are not provided in the declarations D18.10 and D18.11 on which the alleged public prior use is supposedly based. In fact, in the written submission of the appellant describing the significance of evidence D18.4, there is no indication that the infringement proceedings reported triggered the visits to the Polimed Medical Center of Mr Lubawy and Ms Simon as *test-buyers* on behalf of the appellant and the consequent acquisition of the *GensuPen* insulin injection device.

3.14 Thus, the impugned decision, see Reasons 3.1, is correct in stating that since no information has been submitted on the identity and background of the persons signing the declarations D18.10 and D18.11 and on the circumstances under which the devices were obtained by these persons, the factual basis is missing on which it could be decided that the *GensuPen* was available to the public. This situation has not substantially changed

with the new submissions in appeal proceedings. Without this fundamental information, it is irrelevant whether the burden of proof rests on the respondent that members of a certain group of persons (like hospital personal or patients in a study) were bound by a confidentiality agreement.

3.15 In conclusion, the Board does not see any reason to overrule the decision of the opposition division that the alleged public prior use of the *GensuPen* was not sufficiently proven and therefore that it did not represent a state of the art pursuant to Article 52(1) EPC. This conclusion renders it irrelevant to assess whether the *GensuPen* handed over to Mr Lubawy and Ms Simon was identical to the sample D18.13 and whether the sample is novelty-destroying for the subject-matter of independent claims 1 and 11 as granted.

3.16 Finally, the Board notes that the circumstances of the alleged prior use submitted by the appellant for the first time at the appeal oral proceedings are to be regarded, in the absence of any corroborating evidence, as mere allegations.

Request to summon Ms Marzena Nabrdalik as a witness

3.17 For the first time with the statement of grounds of appeal, the appellant offered the testimony of Ms Marzena Nabrdalik to fill the gaps objected to by the opposition division regarding the circumstances of the alleged public prior use. The respondent requested that this request be dismissed for being late filed.

3.18 The appellant explained that Ms Marzena Nabrdalik had been working for many years and was still working at the Polimed Medical Center in Katowice where the sample

of the *GensuPen* belonging to lot number 100804 was obtained by Mr Lubawy and Ms Simon. It was submitted that as she was the nurse responsible for this product over many years, she could confirm that the *GensuPen* was indeed freely distributed by the personnel of the medical centre to the patients on request and for many years. Regarding the question posed by the Board at the oral proceedings as to why the request to hear the witness was filed so late, i.e. not during the first-instance proceedings, the appellant argued that it had been confident that the evidence previously provided had been sufficient at least under the applicable lower standard of proof of the *balance of probabilities* to demonstrate that the alleged public prior use had taken place. Furthermore, it argued that filling the gaps identified by a department of the EPO for a public prior use allegation should be possible at any time and thus also during the appeal proceedings.

3.19 The reasons provided by the appellant in support of its request to hear Ms Nabrdalik as a witness are not convincing.

The Board firstly observes that the evidence presented at the first-instance department in support of the alleged public prior use D18 was not provided at once, as is generally required when a public prior use is claimed, but bit by bit at three different times, none of them within the period of opposition. Furthermore, doubts concerning the plausibility of the declaration of Ms Simon and objections against the precise circumstances underlying the alleged public prior use were raised by the respondent during the written opposition proceedings (see, for example, the paragraph titled "*Substantiation of circumstances*" on page 7 of its submission dated 7 August 2018). Therefore, with

its subsequent letter dated 4 September 2018 and, in any case, before the date of the oral proceedings, the appellant surely had the opportunity to attempt to fill the gaps objected to by the respondent and hence to submit the request to hear Ms Marzena Nabrdalik as a witness, being aware that if the late-filed alleged prior use was admitted, the opposition division also had to decide on whether the circumstances underlying the alleged public prior use were sufficiently detailed and proven. However, the appellant considered that the evidence already submitted was sufficient and legitimately, but deliberately, decided to rely only on it. In conclusion, in view of the circumstances of the first-instance proceedings summarised above, the Board is convinced that the request to hear Ms Marzena Nabrdalik as a witness could and should have been submitted in the first-instance proceedings. Thus, in exercise of the discretion provided by Article 12(4) RPBA in the 2007 version, the Board decides to disregard the request to hear the witness submitted by the appellant.

**Novelty: Articles 52(1) and 54 EPC**

4. The subject-matter of independent claims 1 and 11 as granted is novel over the prior art within the meaning of Articles 52(1) and 54 EPC as correctly stated by the opposition division in the decision under appeal.

4.1 With its appeal, the appellant contested the assessment of the opposition division that documents D3, D9 and D11/D11.1 are not prejudicial to novelty.

4.2 A disputed point is whether feature A6 of claim 1 imposes any clear technical limitation on the claimed

injection device.

4.3 The appellant alleged with its written submissions that, unlike the interpretation provided by the opposition division, feature A6 resulted in a mere *product-by-process* definition which did not impose any distinguishable technical limitation on the claimed injection device.

4.4 The Board does not agree and shares the interpretation provided by the opposition division supported by the respondent for the following reasons.

As convincingly stated by the opposition division and argued by the respondent, the wording of feature A6 results in a functional limitation on how the end formations of the torsion spring and the respective seats provided on the body of the injection device may potentially interact upon compression and rotation of the torsion spring when the injection device is assembled. This implies inherent technical limitations for the torsion spring itself, i.e. that it must be longitudinally resiliently compressible to a sufficient extent; for the design of its end portions; and for the cooperating shape and location of the seats on the reaction component and on the rotary drive shaft of the injection device, rather than this amounting to the addition of a mere process step attempting to define the injection device by its manufacturing/assembling method. Furthermore, the Board agrees with the respondent that the skilled person is perfectly able to determine whether a torsion spring, its end formations and the respective cooperating seats possibly provided in a similar prior-art injection device may potentially behave and cooperate in the manner defined by feature A6 of claim 1 as granted during assembly of the device

(or not). However, as correctly stressed by the opposition division and the appellant, any known injection device which in view of its inherent technical features is suitable for being assembled in the way indicated in feature A6 would also fall within the scope of claim 1 even if such a known device is disclosed to be assembled differently.

4.5 At the oral proceedings, the appellant accepted the interpretation provided by the opposition division and preliminarily confirmed by the Board but pointed out that the wording of feature A6 had to be interpretated broadly. It argued that the formulation of feature A6 does not require rotation of the spring to achieve engagement of the end formations of the torsion spring into the respective seats. Reference was made to paragraph [0022] of the contested patent.

4.6 The Board does not agree and like the respondent considers that the wording of feature A6 *"...the torsion spring may be longitudinally compressed and rotated, thereby causing the end formations ... to be urged in engagement with said respective seats"* (emphasis added) defines a clear cause-and-effect relationship between the compression and rotation of the spring and the engagement of its end portions into the respective seats.

Novelty over D3

4.7 The appellant referred to the second embodiment in Figures 7 and 8 of this prior-art document. It is undisputed that features A1 to A4 of claim 1 as granted are disclosed in D3 but that there is no explicit disclosure that the torsion spring (22) may potentially behave according to feature A6 when the injection

device is assembled. Therefore, the question at stake is whether the person skilled in the art would implicitly derive from the disclosure of D3 whether, after sliding the torsion spring (22) over driveshaft (24), engaging its ends into one of the slots (76) of the knob (70) and into the anchorage hole (32) of the driveshaft (24), respectively, may potentially be achieved in the way defined in feature A6 as asserted by the appellant, namely by compression and rotation of the torsion spring (22). The appellant drew attention to the passage on page 15, lines 14-17 stating that the torsion spring (22) may be formed *"with a wave or compression portion"*, thus allowing for the compression required by feature A5 used to achieve the functionality of feature A6.

4.8 The respondent replied that the assertions of the appellant were based on mere speculations not supported by the effective disclosure of D3. It firstly pointed out that the passage cited by the appellant did not refer to the relevant embodiment of Figures 7 and 8 in which the torsion spring is not shown. Furthermore, the respondent observed that in Figures 2, 3, 4 and 9, it was possible to see the torsion spring (22) but not the shape of its end portions.

4.9 After having considered the arguments provided by the parties, the Board concurs with the appellant that it is clear from the description of D3 that the slot (76) on the knob (70) and the anchoring hole (32) on the driveshaft (see Figures 7 and 8) serve to engage the front and rear ends of the torsion spring (22) respectively (see page 11, lines 15-17 and page 16, lines 11-14), the torsion spring also being part of this embodiment. Therefore, there is no doubt that the spring (22) is provided with *"end formations"* suitable

for being engaged with respective *"seats"* as meant in claim 1 (see features A3 and A6). The Board is further of the opinion that in view of the passage on page 15, line 21 to page 16, line 1 of D3 cited by the appellant, the person skilled in the art assumes that also the spring used in the second embodiment according to Figures 7 and 8 of D3 may be provided with "*a wave or compression portion*" as this was explicitly disclosed for the first embodiment in the cited passage on page 15, lines 14-17. However, the Board notes that the sentence immediately following this passage states that *"(t)his* [the provision of a compression portion on the torsion spring] *allows variations in length due to production variances to be accommodated"*. This renders it clear for the person skilled in the art that the compressibility which may be provided is of the same order of magnitude as the length of the manufacture tolerance that, for the nominal length which can be presumed for a torsion spring suitable for use in this kind of injection device, is < 1 mm. It follows that the axial compressibility which may potentially be associated to the torsion spring (22) of the device of D3 is certainly not sufficient for allowing the functionality required by feature A6, which cannot thus be considered potentially obtainable by the injection pen of this prior-art document. Feature A6 of claim 1 as granted is thus not directly and unambiguously disclosed in D3, as correctly stated by the opposition division.

Novelty over D9

5. Regarding this further novelty attack, the appellant referred during the oral proceedings to the same arguments provided in writing and did not wish to make

any further comment.

5.1 The arguments submitted in writing are similar to those provided to substantiate the novelty attack based on D3. The Board does not see any reason to deviate from its preliminary opinion supporting the view of the opposition division and the respondent that D9 is also not prejudicial to the novelty of claim 1 as granted. With reference to Figures 9, 11, 14 and 15, the appellant asserted, and it is not disputed,that seats are provided on the spring base (160) and on the driver (110) engaging and retaining the ends of the torsion spring (111) in a mounted state. However, the Board agrees with the respondent that the resulting conclusions of the appellant are based on mere speculation because it cannot be directly and unambiguously derived from the information contained in D9 that the compressibility of the spring in combination with the design of its end formations and with the shape and location of the seats on the spring base (160) and on the driver (110) are such to potentially allow, in combination, the functionality required by feature A6.

Novelty over D11/D11.1

5.2 The admissibility of document D11.1 and the excerpt of the *British Standard* Handbook labelled H2 submitted for the first time in the appeal proceedings was contested by the respondent. D11.1, which is the priority document of D11, contains identical drawings to the latter but with better image quality. The appellant justified the submission of D11.1 by arguing that the better image quality permitted appreciating that the torsion spring (15) of the injection device represented in Figures 1, 6 and 7 had spaced apart adjacent coils

which allowed for axial compression of the spring at least to some extent thus fulfilling, contrary to the view of the opposition division, feature A5 of claim 1 as granted. Furthermore, it was alleged that the person skilled in the art directly and unambiguously realised that a behaviour of the spring (15) during assembly according to feature A6 of claim 1 as granted was also potentially possible.

5.3 Irrespective of the admissibility issue raised by the respondent, the Board, in accordance with the opposition division, is not convinced that it can be directly and unambiguously derived only from the drawing of D11.1 that the torsion spring is compressible as meant in feature A5 of claim 1 and to the extent required by the functionality expressed in feature A6. The Board shares the view of the opposition division and the respondent that as neither the configuration of the end of the spring (15) nor the shape and location of the seats are shown or described in D11/D11.1, it cannot be considered to be directly and unambiguously disclosed that the above construction features of the known injection device are such to allow the functionality expressed by feature A6 of claim 1 as granted, with the same arguments presented for documents D3 and D9 applying.

5.4 The same arguments analogously apply to the corresponding feature B7 of independent method claim 11 as granted, which is thus also novel over the cited prior art as correctly decided by the opposition division.

**Inventive Step: Articles 52(1) and 56 EPC**

6. The subject-matter of independent claims 1 and 11 as granted involves an inventive step over the prior art within the meaning of Articles 52(1) and 56 EPC as decided by the opposition division.

6.1 This decision was contested by the appellant, which submitted for the first time with the statement of grounds of appeal several new lines of inventive-step attack based on D3, D7 and D11/D11.1 as the closest prior art. No submissions were made regarding the combination of D13 with D11, which was the basis for the only inventive-step attack presented during the opposition proceedings; consequently the only one dealt with in the contested decision.

6.2 The admissibility of these new inventive-step attacks was contested by the respondent under Article 12(4) RPBA 2007, which applies to the current case in view of the transitional provisions of Article 25(2) RPBA 2020. The respondent also objected that the submissions of the appellant on lack of inventive step were not directed to *"... arguments and evidence on which the decision under appeal was based .."* as required by Article 12(2) RPBA 2020, i.e. to the reasons given by the opposition division in support of its conclusion that the subject-matter of independent claims 1 and 11 was not obvious in view of D13 and D11 in combination.

6.3 The appellant argued that the submission of new lines of inventive-step attack was justified because it represented an appropriate and immediate reaction to developments in the previous proceedings. It made reference to decision T 855/96, alleging that only after having read the contested decision, the appellant

became aware of the distinguishing features identified by the opposition division and could thus prepare appropriate lines of inventive-step attack based on the reasoning of the decision.

6.4 The arguments of the appellant are not convincing for the following reasons.

The Board notes that no inventive-step attack was substantiated in writing during the opposition proceedings and that the sole submissions for this type of attack were presented on the spot at the oral proceedings upon positive assessment of novelty, i.e. an attack based on the combination of D13 with D11. The passage of the minutes (see points 1.6 and 1.6.1) referred to by the appellant in its written submission cannot imply the maintenance of any previous inventive-step attack submitted in writing because there was none. This circumstance is also confirmed by the preliminary opinion of the opposition division (see point 11) and by the following submissions of the appellant, which do not contain any reasoned inventive-step attack. The Board observes that as the decision is directed to the patent as granted, the appellant could and should have presented the inventive-step attacks now submitted with the appeal in the first-instance proceedings, also taking into account that it was clear throughout the whole opposition proceedings that feature A6 played a relevant role for the assessment of novelty and, thus, potentially, inventive step. Furthermore, it is clear from the minutes of the oral proceedings that after positively assessing novelty, the opposition division, at the request of the appellant, explained why independent claims 1 and 11 were considered novel over D3, D7, D11 and D13 "*in order to allow him* [the opponent] *to better prepare the*

*inventive step argumentations"* (see point 14.1 to 14.3 of the minutes). At this point, the oral proceedings were interrupted to give the appellant a last opportunity to submit its inventive-step attack/s (see point 14.4 of the minutes). The appellant legitimately but deliberately decided to submit a single inventive-step attack based on the combination of D13 with D11 and, after becoming aware that this attack was not successful, it declared that it did not wish to make any further submission (see point 19. of the minutes). In view of the circumstances and the developments of the opposition proceedings, there is thus no doubt that the new inventive-step attacks under discussion could and should have been filed in the first-instance proceedings, i.e. during oral proceedings at the latest. However, the appellant deliberately decided to rely on the combination of documents D13 and D11 only. Regarding decision T 855/96 cited by the appellant in support of the admissibility of the new inventive-step attacks, the Board notes that T 855/96 was handed down well before the entry in force of the RPBA 2007, which changed the case law of the boards to restrict the possibility of filing new submissions at the appeal proceedings.

6.5 For the above reasons, the Board considers it appropriate to exercise the discretion provided by Article 12(4) RPBA 2007 to hold inadmissible facts which could have been presented in the first-instance proceedings and decides not to admit the new inventive-step attacks in the appeal proceedings. Furthermore, as the appellant did not present any reason why the positive assessment of inventive step in view of D11 and D13 in combination in the contested decision was incorrect, the Board does not see any reason to deviate from the conclusion of the opposition division that the

subject-matter of independent claims 1 and 11 as granted is not rendered obvious by the cited prior art.

## Order

## For these reasons it is decided that:

The appeal is dismissed

The Registrar: The Chairman:

A. Vottner G. Pricolo

Decision electronically authenticated