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Datasheet for the decision of 9 October 2017

Case Number: T 0150/12 - 3.3.01

Application Number: 02744468.6

Publication Number: 1414956

IPC: C12N11/14, C12N11/10, C12N11/08, C12N9/98, C11D17/00, C11D3/386, C11D3/37

Language of the proceedings: EN

Title of invention:
HIGHLY IMPACT-RESISTANT GRANULES

Patent Proprietor:
Danisco US Inc.

Opponents:
Novozymes A/S
HENKEL AG & CO. KGAA

Headword:
Impact-resistant granules/DANISCO

Relevant legal provisions:
EPC Art. 56, 83, 84, 123(2)
RPBA Art. 13

Keyword:
Inventive step - (no)
Sufficiency of disclosure - (no)
Claims - product-by-process claims

Decisions cited:
T 0150/82, T 1993/07

Catchword:

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European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0150/12 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 9 October 2017

Appellant: (Patent Proprietor)	Danisco US Inc. 925 Page Mill Road Palo Alto, CA 94304-1013 (US)
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Appellant: (Opponent 1)	Novozymes A/S Krogshoejvej 36 2880 Bagsvaerd (DK)
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Party as of right: (Opponent 2)	HENKEL AG & CO. KGAA FJP D-40191 Düsseldorf (DE)
Representative:	Viering, Jentschura & Partner mbB Patent- und Rechtsanwälte Kennedydamm 55 / Roßstrasse 40476 Düsseldorf (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 11 January 2012 concerning maintenance of the European Patent No. 1414956 in amended form.**

Composition of the Board:

Chairwoman	D. Prietzel-Funk
Members:	T. Sommerfeld
	M. Pregetter

Summary of Facts and Submissions

I. European patent No. 1414956, which is based on European patent application No. 02744468.6 and was filed as an international patent application with the publication number WO 2003/000625, was granted with 28 claims.

II. Independent claims 1 and 25 as granted read as follows:

"1. A highly impact-resistant granule comprising a) an impact-sensitive particle including an active ingredient and b) a flexible film comprising a polymer surrounding said impact-sensitive particle, wherein said film has an elongation upon break of at least about 30% and said film comprises less than about 20% by weight of the highly impact-resistant granule, wherein said impact-sensitive particle has more than about 10% mass attrition and said highly impact-resistant granule has less than about 5% mass attrition mass attrition being determined by a Repeated/impact Test (RIT) at 216,000 collisions at 8.7 m/s and an amplitude of 1.5 cm."

"25. A method for making a highly-impact resistant enzyme-containing granule, said method comprising:
a) selecting a suitable core material;
b) coating the core of step a) with an enzyme layer comprising one or more enzymes selected from the group consisting of proteases, cellulase, amylases, and lipases; and
c) casting a water-soluble or water-dispersible film comprising a polyvinyl alcohol polymer and a glycerol plasticizer to the product of step b) wherein said film [h]as an elongation upon break of about 30% or more to produce a granule having an RIT dust value of 100,000 ng/g or less."

III. Two oppositions were filed against the granted patent, both opponents requesting revocation of the patent in its entirety; the grounds for opposition were Article 100(a) EPC in combination with Article 54 EPC (opponent 1) and in combination with Article 56 EPC (both opponents), Article 100(b) EPC (both opponents) and Article 100(c) EPC (opponent 1).

IV. By an interlocutory decision pronounced at oral proceedings, the opposition division decided that the patent be maintained in amended form on the basis of the first auxiliary request, version B, filed during oral proceedings (Articles 101(3)(a) and 106(2) EPC).

The opposition division considered that the claim set according to the main request (claims as granted) fulfilled the requirements of Article 123(2) EPC, 83 EPC and 54 EPC, but not those of Article 56 EPC. As regards the first auxiliary request, version A, the opposition division came to the conclusion that there were inconsistencies between the description and the claims, leading to doubts concerning the matter for which protection was sought, thereby rendering the claims unclear (Article 84 EPC).

V. The patent proprietor lodged an appeal against that decision. With the statement setting out the grounds of appeal, the appellant-patent proprietor requested that the decision under appeal be set aside and the patent be maintained as granted (main request) or, alternatively, according to auxiliary request 1 filed with the grounds of appeal. Auxiliary request 1 corresponded to the first auxiliary request, version A, considered by the opposition division. Opponent 1 also lodged an appeal against the decision. With the

statement setting out the grounds of appeal, appellant-opponent 1 requested that the decision under appeal be set aside and the patent be revoked in its entirety.

VI. Both appellants replied to each other's grounds of appeal. With its reply, the appellant-patent proprietor submitted auxiliary requests 2 to 9. Opponent 2 (party as of right) did not submit any reply to the grounds of appeal.

VII. The first oral proceedings before the board took place on 9 August 2016. During those proceedings, the discussion centered around the inventive step of claim 25 of the main request and claim 1 of auxiliary requests 7 and 8. In view of apparently new but *prima facie* relevant arguments raised by appellant-opponent 1 at the oral proceedings, the board decided to continue the appeal proceedings in writing in order to give the appellant-patent proprietor an opportunity to react properly.

VIII. A communication from the board ensued, summarising the issues discussed during the oral proceedings and inviting the parties to provide their comments. Both appellants replied, while opponent 2 did not make any submissions. With its reply, appellant-opponent 1 submitted new documents D31 and D32; with a further letter, the appellant-patent proprietor submitted document D33.

IX. During the second oral proceedings, the appellant-patent proprietor first submitted a new auxiliary request 1A to replace auxiliary request 1 on file, and then a new auxiliary request 1B to replace auxiliary request 1A.

The **main request** consists in the claims as granted.

Auxiliary request 1B comprises only 6 claims, claim 1 differing from granted claim 1 in that it contains the word "Device" inserted after "Repeated/impact Test".

Auxiliary requests 2 to 6 all comprise a claim which is identical to granted claim 25: claim 8 in **auxiliary request 2**, claim 3 in **auxiliary requests 3 and 4**, claim 21 in **auxiliary request 5** and claim 18 in **auxiliary request 6**.

In **auxiliary request 7**, claim 1 differs from claim 7 as granted by the following amendments:

"~~7~~1. A highly impact-resistant granule comprising, a core, an ~~active ingredient~~ enzyme, and a water-soluble or water-dispersible flexible film comprising a polymeric material surrounding said core and active ingredient, wherein said flexible film is less than about 20% by weight of the granule, and the elongation upon break is greater than about 30%, and wherein said flexible film is applied by a casting process."

In **auxiliary request 8**, claim 1 differs from claim 1 of auxiliary request 7 by replacement of "polymeric material" by "polyvinyl alcohol".

X. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

D6 GB 1483591
D8 Hsu et al. 2001, Pharmaceutical Development and Technology 6(2), 277-284
D22 US 6035716

D23 US 4675140
D26 Collins English Dictionary excerpt
D28 WO 98/26670
D30 PhD thesis Beekman (excerpt)
D31 Senuma et al. 2000, Biotechnol.Bioeng. 67(5), 616-622 (PubMed abstract)
D32 Online publication of the Southwest Research Institute
D33 Declaration of Mr Oxley

XI. The submissions of the appellant-patent proprietor, in so far as relevant to the present decision, may be summarised as follows:

Claim 25 of the main request: inventive step

The method of claim 25 differed from that of document D8 in that the polymer was applied by casting, the film had an elongation of at least 30%, the plasticiser was glycerol and the granules produced had a given RIT dust value. The patent made clear that the method by which the coating was applied made a significant difference: when done according to Example 3, it resulted in extremely low dust values (Example 5), while the dust values were much higher when the coating was done by spray-drying (Table 9 of Example 7). These conclusions were furthermore stated in paragraph [0087] of the patent. In D8 the coating was applied by fluid-bed coating, a method which was not encompassed in casting because it did not correspond to the definition of casting as given in paragraphs [0060] and [0062] of the patent, and as supported by paragraph [0040] and by the comparative examples. Even if following the opponent's arguments that fluid-bed coating could be performed under certain conditions so as to produce a continuous film, these were not the normal conditions which D8

would have used. Moreover, D8 did not disclose the coating of enzyme granules with a film having an elongation upon break of 30% or more because the test films were produced by spinning disc, while those used for coating were applied using the fluidised-bed coating method. This was contrary to the patent's teachings that it was important to prepare the test film using the same method that was applied for coating (paragraph [0040]), and in fact the patent showed that the elongation properties of films applied by spinning disc or by spray-coating were different (samples 1 to 4 on page 12, versus samples 12 to 15 on page 14). As to the RIT dust value, D8 used the Heubach test which related to completely different conditions, namely the use of shear forces rather than impact forces: the results obtained with the Heubach test could not be extrapolated to the RIT test, as was stated in paragraph [0021] of the patent and confirmed in Example 2, showing that commercially available granules (by definition, compliant with the Heubach test) did not perform well under the RIT test. There was no evidence on file that the granules of D8 would fulfil the RIT dust value required by the claim. The teaching of D8 that coating avoided dust was already well known in the art; D8 did not teach that a PVA coating would be capable of protecting from all stress settings. The plasticiser being glycerol was not disclosed in D8 either, but admittedly this difference did not play a role for inventive step. The relevant differences to D8 were thus the casting, the elongation upon break of above 30% and the RIT dust measurement. The casting and the elongation had the effect that there was lower dust formation caused by impact forces, as measured by RIT, and hence the technical problem could be formulated as "to find a method of making impact-resistant granules with low dusting under impact conditions". Starting

from D8, it would not have been obvious to arrive at the solution because D8 taught that elongation did not affect dust and there were no secondary documents teaching that there was a link between film elongation and dust generation in an impact-force setting. Hence the skilled person would not know how to modify D8 in order to arrive at a low dust level in an impact-stress environment. Contrary to the opponents' arguments, the RIT value was a limiting technical feature of the claim.

Auxiliary request 1B: Articles 123(2) and 83 EPC

As to Article 123(2) EPC, the passage on page 3 was not to be understood such that the device of D22 had to be necessarily employed.

In relation to Article 83 EPC, the disclosure of the RIT test device in the patent was sufficient to allow the skilled person to perform the test, and the opponent had not shown that this was not the case. Information on the sieve size was not required because the method did not necessarily involve the use of a sieve (patent paragraph [0021]; D22, column 6, line 42) and in fact, depending on the circumstances, other measuring methods could be more suitable. Moreover the skilled person would know how to choose a suitable sieve for the purpose. D22 also referred to the possibility of using a box made out of lightweight metal (column 4, line 22) and hence was not in contradiction with the teaching of the patent, which used aluminium (a soft metal according to Wikipedia); there was also no contradiction with D30. The onus was on the opponent to prove that the choice of materials mattered. There was also no evidence that the box size of the patent would not work. D22 explicitly stated

that the test was very well defined (column 9, line 43 ff.) and since the patent clearly pointed to D22, the skilled person was given this information even if D22 was not common general knowledge. This was not a newly formulated parameter since the RIT parameter had already been disclosed (D22).

Claim 1 of auxiliary requests 7 and 8: clarity

The coating of the particles was different and the difference could be seen at microscopic level: paragraph [0062] and Figure 1 of the patent.

XII. The appellant-opponent's arguments, in so far as relevant for the present decision, may be summarised as follows:

Claim 25 of the main request: inventive step

D8 was a document in the same field as the patent, was directed to the same problem of reducing dust of enzyme granules, and disclosed almost all features of claim 25. Although casting was not mentioned in D8, the definition of casting in the patent (paragraph [0060]) was so broad as to cover also the fluid-bed coating method of D8 because, depending on how it was run, it could also lead to the required result (D6, page 1, line 64 ff.). The term "casting" was normally used as referring to a method making use of a mould (D26, D28), and not to a method of coating, and there were no documents on file referring to casting in the context of coating. Therefore, the definition provided in the patent in paragraph [0060] became relevant. Moreover, paragraph [0062] of the patent, while inconsistent with the disclosure of paragraph [0060], did not limit the process to methods without atomisation, and in fact,

D31 to D33 confirmed that the spinning-disc method was an atomisation process. The coating film used in D8 had an elongation above 30% (Figure 1), as measured before coating, which was the same as in the patent (paragraph [0040]). Elongation being an absolute property of a polymeric film, it would be expected that the same value should always be obtained regardless of the method used for production of the film. As to the use of the Heubach test instead of the RIT test, these were just two different ways of measuring dust formation, RIT being rather an unusual test and not a commercially realistic one. RIT was only disclosed in D30 (PhD thesis), patented in D22 and used in the present patent. Without further definition of the test, the value given in the claim was arbitrary. Moreover, there was in fact no difference between D8 and the patent (figure 5) as regards the technical effect since dust in D8 was already minimal. Characterising dust in a different way did not involve an inventive step, given that both D8 and D6 disclosed low dust formation. The only feature missing in D8 was thus glycerol as plasticiser, and the objective technical problem could hence be formulated as the provision of an alternative plasticiser for polymer-coating around enzymes with the aim of reducing dust formation. Glycerol would be an obvious alternative since it was known that adding glycerol reduced dust generation (D6, page 7, left column, line 28 ff.). D8 (page 281, Figure 3) taught that increasing the plasticiser (PEG 600) led to enhanced toughness, which was the relevant characteristic for reducing dust formation.

Auxiliary request 1B: admissibility, Articles 123(2), 84 and 83 EPC

The request should not be admitted because it could have been filed earlier and it did not *prima facie* overcome the objections under inventive step since the same arguments would apply. Moreover there were objections of added subject-matter and lack of clarity.

There was added subject-matter because the passage on page 3 referred specifically to the device of D22 which was not part of the claim. Moreover the amendment rendered the claim unclear because it was not apparent what device should be used and the test conditions were not specified.

As regards Article 83 EPC, since the RIT was an unusual parameter, the skilled person would have to rely on the only available disclosure of the test, which was in D22 and D30, and would have no common general knowledge to supplement it: hence the patentee had the obligation to define this subject fully since it was not a standard test. There was however no indication on e.g. the material of the box, on the sieve size to be used, on the number and size of particles in the box. Moreover, although the patent's only information concerning the RIT test was the reference to D22, the conditions used in the patent were different, e.g. a box made of aluminium was used, while D22, though mentioning light metals (not aluminium) in column 4, line 22, used a plastic box in the working examples (column 6, lines 27 to 28). It was however apparent from D30 (page 58 under "Container Design") that the material used was extremely important, as was the number of particles (page 88) also in relation to their size (page 89, bottom).

Claim 1 of auxiliary requests 7 and 8: clarity

The granted product claim had been amended into a product-by-process claim, leading to clarity issues (T 150/82). It was not apparent how the process distinguished the granules from granules made by other processes. Moreover it was not clear what was covered by "casting".

XIII. The arguments of the other party (opponent 2), in so far as relevant to the present decision, may be summarised as follows:

Claim 25 of the main request: inventive step

Even if one considered that D8 did not disclose the use of films with elongation above 30%, there was no real correlation shown in the patent between elongation and dust formation (e.g. Table 9 on page 14 showing that films with elongations of 39% and 35% did not meet the dust requirements: samples 14 and 15); this was explicitly stated in the inventors' authored document D8. Hence there were in fact two partial technical problems. The first problem would be how to achieve films with elongation above 30%. The solution would be obvious, as it was taught in D6. The second partial problem would be to achieve granules with an RIT value as defined in the claim. However, this parameter was not a technical feature, just a result to be achieved, which should be achieved by simply following the method as claimed. If it was not necessarily achieved by that method, then the claim was either insufficiently disclosed or the technical problem was not solved over the whole scope of the claim.

XIV. The appellant-patent proprietor requests that the decision of the opposition division be set aside and that the patent be maintained as granted (main request)

or alternatively that the patent be maintained in amended form on the basis of the claims of auxiliary request 1B filed during oral proceedings, or of auxiliary requests 2 to 9 submitted with letter of 2 October 2012.

Appellant-opponent 1 requests that the decision under appeal be set aside and that the European patent be revoked.

There are no requests on file from opponent 2 (party as of right).

Reasons for the Decision

1. The appeals are admissible.

2. Amendment to a party's case (Article 13 RPBA)

2.1 Article 13(1) RPBA states that "Any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion. The discretion shall be exercised in view of inter alia the complexity of the new subject matter submitted, the current state of the proceedings and the need for procedural economy". Article 13(2) RPBA adds that "Other parties shall be entitled to submit their observations on any amendment not held inadmissible by the Board ex officio".

2.2 At the oral proceedings of 9 August 2016 (first oral proceedings), appellant-opponent 1 argued during the discussion of inventive step of claim 25 of the main request that the results of the patent only showed an improvement for coating by spinning disc and not for

casting (as claimed) in general, the latter being broader in meaning than coating by spinning disc. It was also a matter of discussion among the parties whether the spinning-disc process involved atomisation or not, and document D23 was cited in this context. The appellant-patent proprietor objected to these arguments, which were considered to represent an amendment of the case raised for the first time at the oral proceedings before the board. The appellant-patent proprietor noted that, based on the results shown in the examples, the patent categorically stated the advantages of casting (paragraph [0087]), and this had never been disputed by any of the parties during the whole opposition and appeal proceedings. Since according to established case law, advantages claimed by the patent were to be considered as given until they were contested, the appellant-patent proprietor had never been put in a position of having to prove these conclusions of the patent.

2.3 The board notes that, as argued by appellant-opponent 1, the feature "casting" had indeed already been extensively discussed before the opposition division: e.g. minutes of oral proceedings, section 6.1 and decision, section 6.4, wherein it is apparent that the opponents had argued that the term "casting" was defined so broadly in the patent as to also include atomisation processes such as the spray-coating of D6; a similar argumentation had been put forward by appellant-opponent 1 in its letter of 25 April 2016, page 5, third paragraph, wherein it is further stated that "[e]ven if the method claims were limited to a casting method such as the spinning disc method, they would still lack an inventive step". Further arguments relating to "casting" are found in section 8.3 of appellant-opponent 1's grounds of appeal, wherein the

argument was made that the claims were not limited to "casting" and that the term was unclear. The board however notes that the argument that the results of the patent only showed an improvement for coating by spinning disc, and not for casting in general, had in fact not been raised before. Nevertheless, in the board's view this argument does not necessarily add to the complexity of the case. It is based on a central issue of the discussion which already took place before the opposition division and, in order to enable the appellant-patent proprietor to address it properly, an adjournment of oral proceedings and the decision to continue the proceedings in writing, as requested by the appellant-patent proprietor, was considered justifiable.

2.4 The board hence exercised its discretion pursuant to Article 13(1) RPBA to admit the new argument.

3. Main request

Claim 25 - inventive step

3.1 The present patent relates to "highly impact-resistant granules comprising an active ingredient, preferably an enzyme, and a flexible film formed from a polymeric material surrounding the active ingredient as well as processes for producing the granules and flexible film" (paragraph [0002]). The aim of the patent is to provide granule formulations with better impact-resistance than the prior-art formulations, which, according to the patent, "do not always exhibit sufficient impact resistance during handling and as a result form dust when typical physical forces are encountered during handling" (paragraph [0004]).

3.2 Document D8, which studies the effect of coatings in the generation of dust by enzyme granules, is the closest prior art. D8 discloses methods for the production of enzyme-containing granules with "[t]ough polymeric coatings such as PVAL" that "keep the enzyme granules from generating dust when they are exposed to the handling of these granules" (page 278, left column, last paragraph); protease enzyme granules are used as models (page 279, right column, last paragraph); coating is made with a 20% PVAL stock solution prepared by dispersing PVAL in cold water (page 279, left column, second paragraph); granule preparation is done by fluidised-bed coating (page 279, right column, last paragraph), which can be considered a "casting" method according to the patent's definition in paragraph [0060] (see also below); and all films wherein Neodol or PEG 600 were used as plasticiser were shown to have an elongation above 30% (Figure 1). Hence, D8 discloses all features of the method claimed in claim 25, with the exception of the plasticiser being glycerol. Moreover, the method of D8 produces granules with extremely low dust formation: the Heubach test measurements shown in Figures 5 to 7 on page 282 are all between 0.3 and 0.5 mg, which, in relation to 13.5 g starting granule material (page 280, left column, second paragraph), represents a dust formation of below 0.000037% (0.5 mg / 13500 mg). Since there is no evidence on file that the choice of glycerol as plasticiser is associated with any technical effect over the use of other plasticisers, the technical problem can be formulated as the provision of an alternative method to produce impact-resistant granules, i.e. with reduced dust formation when subjected to impact forces. The solution is the method as claimed, and the board is satisfied that, in view of

the data shown in the patent, the problem has been plausibly solved.

3.3 However the board considers that the claimed solution does not involve an inventive step because glycerol had already been disclosed as a suitable plasticiser for enzyme-granule coating, in particular to reduce dust formation (D6, page 7, left column, lines 28 to 32). Hence, replacement of the plasticisers Neodol or PEG 600 by glycerol in the method of D8 would be an obvious alternative for the skilled person.

3.4 The appellant-patent proprietor essentially argued that document D8 further differed from the claimed subject-matter in that it did not disclose coating with films with an elongation above 30%, it did not apply the coating by a casting method, and the granules obtained did not have an RIT value of 100,000 ng/g or less. The board is however not convinced by these arguments, as explained below.

"elongation upon break of about 30% or more"

3.4.1 As stated above, D8 discloses that, apart from two films prepared with titanium dioxide (TiO_2), which is not a plasticiser, as apparent e.g. from D8's title, all other films had an elongation above 30% (Figure 1). It is a fact that film elongation was measured separately, i.e. before applying the film onto the granule (page 279, left column, paragraph bridging to right column), but so was it measured in the patent (paragraph [0040]), for understandable technical reasons. Moreover, although the claim does not impose any restriction as to the preparation method of the test film, the fact is that the tested films in D8 and in the patent are prepared by the same method, i.e. by

spinning disc. Hence, there can be no doubt that the films of D8 fulfil the elongation parameter according to the teachings of the patent, and it is irrelevant that different preparation methods of the test film may lead to different elongation values, as argued by the appellant-patent proprietor on the basis of a comparison of the elongation values between samples 1 to 5 on the patent's page 12 and samples 12 to 15 on page 14. A further requirement that the test film has to be prepared according to the same method as the granule is also not present in the claim. It is true that the patent states, in paragraph [0040], that "[t]he test film is produced in the same manner as the film of the granule", which includes "not only maintaining the film composition but also process conditions such as casting of the film as opposed to atomization", but there is no explicit teaching in the patent or elsewhere on file of whether this is mandatory and why. Clearly the authors of D8 did not consider that this made any difference, the whole study of D8 seemingly assuming that the films have the measured elongation values, independently of the fact that the test films were prepared by spinning disc and not by the fluid-bed coating method that was used for the granule preparation. Finally, the board considers that this feature is an intrinsic feature of the film that is to be used for granule coating: whether the same elongation is present in the film upon coating is unknown both in the patent and in D8 because no measurement was made, but this is also not part of claim 25 and thus not relevant.

"casting"

3.4.2 Casting is defined in the patent as "a process well known in the confectionary industry used to make

desserts such as gelatin or candies such as gumdrops" (paragraph [0059]). In the casting process, "a particle including a core and one or more active ingredients is enveloped within a continuous film of liquid or molten material (...) which is rapidly solidified, from about 1 second to about 2 minutes, by cooling, hardening, gelation, crosslinking or other such means of converting a liquid film into a solid film" (paragraph [0060]). The patent furthermore states that "[a] casting process is further distinguished from an atomization or layering process because a cast film is homogenous at a microscopic level and is not built up from deposition of discretely atomized droplets or patches, as shown in Fig. 1" (paragraph [0062]). Finally, the patent teaches that "[c]asting may be applied by a number of techniques referred to as dipping, spinning disk, and emulsion gelation" and that "[a]ccording to the present invention casting is preferably applied by spinning disk" (paragraph [0063]).

3.4.3 Among the methods disclosed in the patent as falling under the concept of "casting" (paragraph [0063]), at least spinning disc was known as a coating method for solid particles (D23). The term "casting" itself had not been used in the prior art in this context but rather in the context of the confectionary industry, as acknowledged in the patent (paragraph [0059] cited above). When turning to documents disclosing casting in the confectionary industry, it is apparent that the term refers to a process involving the use of moulds (see e.g. D28, abstract and cover figure); the use of a mould is also part of the dictionary definition of "casting" in D26. This is in contrast to the definition of "casting" in the patent (paragraph [0060]) which does not imply the use of a mould, nor do the

techniques listed in paragraph [0063] as examples of casting processes involve the use of moulds. Hence the term "casting" is used in the patent with a meaning that is not its usual meaning, and the skilled person has to rely on the patent's definition of the term when interpreting the claim. When taking the patent's definition of "casting" as it is found in paragraph [0060] cited above, the board comes to the conclusion that such definition does not allow to distinguish the patent's casting method from the fluidised-bed coating method disclosed in D8 because it is considered that this latter method also leads to "a core and one or more active ingredients" being "enveloped within a continuous film of liquid or molten material (...) which is rapidly solidified, from about 1 second to about 2 minutes, by cooling, hardening, gelation, crosslinking or other such means of converting a liquid film into a solid film".

3.4.4 The appellant-patent proprietor's arguments that the fluidised-bed coating method does not fall under the patent's definition of "casting" are not considered persuasive. While the fluidised-bed coating may be considered an atomisation process, which is stated to be distinct from a casting process in paragraph [0062] of the patent (supra), the fact is that also spinning disc, explicitly mentioned as the preferred casting method (paragraph [0063]), is recognised as an atomisation process, which is evident from documents D23, D31 and D32, and confirmed in the expert declaration submitted by the appellant-patent proprietor, D33 (paragraphs 5 and 6). Hence, there appears to be an inconsistency in the patent as to the definition of "casting". Since spinning disc, which is clearly seen as a casting method (indeed the preferred casting method according to the patent) includes

atomisation aspects, the board considers that the fact that a method involves atomisation does not per se exclude it from the casting definition of the patent. The decisive point is rather that the method should lead to enveloping by a continuous film (paragraph [0060]) which is homogeneous at a microscopic level and is not built up of discretely atomised droplets or patches (paragraph [0062]). The board is convinced that the conditions of a fluidised-bed coating method may be set so as to produce the desired result of having a homogeneous continuously enveloping film: the same is true for an atomisation process in general (D23). Contrary to the appellant-patent proprietor's arguments, such conditions would not be artificial or unusual, but instead would require e.g. choosing a droplet size within the normal range used for spray-coating (D6, page 1, line 64 ff.).

"to produce a granule having an RIT dust value of 100,000 ng/g or less"

3.4.5 The appellant-patent proprietor argued that this was a limiting feature distinguishing it from the method of D8. The board does not agree. Claim 25 is directed to a "method for making a highly-impact resistant enzyme-containing granule", the method being defined by a number of steps that are, as discussed above, also part of the method of D8 (with the exception of the use of a different plasticiser). Impact resistance is referred to in the patent in different passages, which all allow to conclude that the impact relates to the normal, typical forces to which the granules are exposed during handling: paragraph [0004] teaches that "prior art formulations, which produce particles or granules including an active ingredient, do not always exhibit sufficient impact resistance during handling and as a

result form dust when typical physical forces are encountered during handling" (emphasis added by the board); paragraph [0011] teaches that imparting impact resistance to the particle "results in a granule with reduced potential for dust formation because it is less subject to unwanted breakdown from impact forces during handling" (emphasis added by the board). The method of D8 also has the purpose of producing highly impact-resistant granules, as is apparent from page 278, left column, last paragraph, stating that "the coatings also keep the enzyme granules from generating dust when they are exposed to the handling of these granules" (emphasis added by the board). Hence, claim 25 is directed to a method with the same steps as D8 (except for the use of glycerol) for the same purpose as D8. The feature to be found at the end of claim 25, which attempts to further define the impact resistance of the granules, is either just another way of measuring the impact resistance sought (which is however not part of the method) or at most a result to be achieved. In any event, it is not a limiting feature of the claim, and hence not suitable for distinguishing the claimed method from the method of D8 or for contributing to inventive step.

3.4.6 If the appellant-patent proprietor's arguments that the feature is limiting were to be followed, then the following possible situations would arise: either the only difference to the method of D8, namely the use of glycerol as plasticiser, was responsible for this effect on dust formation (which was not shown in the patent), or else further conditions, which are not part of the claim, were required. Both situations would give rise to objections under Article 83 EPC.

3.4.7 The appellant-patent proprietor further argued that the RIT test was not comparable with the Heubach test used in D8 to measure dust formation because it measured dust caused by a type of force different to that used in the Heubach test, namely impact force rather than shear force. The patent itself had shown that commercial granules, which would implicitly have been compliant with the Heubach test, did not perform well under the RIT test conditions (Example 2). The board disagrees with this argumentation. First, while the two tests may be different and may measure different parameters, the fact is that they are not part of the claimed method. Second, there is no evidence in the patent or elsewhere on file that the granules of D8, which were shown to generate extremely little dust under the Heubach test (as discussed above), would not fulfil the RIT value requirement as well. In this context, the conclusions based on Example 2 of the patent start from the premise that the tested commercial granules necessarily complied with the Heubach test, but there is no evidence for this. Nor is it apparent that such compliance would be identical to that of the granules of D8.

3.5 Claim 25 of the main request thus lacks an inventive step. The main request is not allowable for lack of compliance with Article 56 EPC.

4. Auxiliary request 1B

Admissibility

4.1 Article 13(1) RPBA leaves it to the board's discretion to admit any amendment to a party's case after it has filed its grounds of appeal. This discretion shall be exercised in view of *inter alia* the complexity of the

new subject-matter submitted, the current state of the proceedings and the need for procedural economy. Moreover, amended claims submitted at such a late stage as oral proceedings should be admitted only if clearly allowable in the sense that it can be quickly ascertained that they overcome all outstanding issues without raising new ones (T 1993/07 of 13 October 2011, reasons 4.4.3).

4.2 Auxiliary request 1B was only filed at oral proceedings and hence its admissibility is at the discretion of the board, pursuant to Article 13 RPBA. This request was submitted as reaction to the conclusions of the board in relation to the main request and was based on granted claims 1 to 6, with an amendment to claim 1 (for the wording of the claim, see sections II and IX) to overcome an objection under Article 123(2) EPC.

4.3 Hence, the only difference to granted claims 1 to 6, which had always been in the appeal proceedings (as part of the main request, of previous auxiliary request 1 and of auxiliary request 2), was the addition of the word "device" in claim 1, which was a *bona fide* attempt by the appellant-patent proprietor to overcome an objection under Article 123(2) EPC. This amendment did not add to the complexity of the case nor did it impair procedural economy. Although the objection under Article 123(2) EPC had been raised already during the first-instance proceedings and had been reiterated during appeal, in view of the fact that the opposition division had decided in favour of the appellant-patent proprietor in this issue, it is acceptable that the appellant-patent proprietor did not find it necessary to present this amendment earlier.

4.4 The board thus decides, in the exercise of its discretion under Article 13(1) RPBA, to admit this request into the proceedings.

Article 123(2) EPC

4.5 The board is satisfied that the present claims comply with the requirements of Article 123(2) EPC. Claim 1 is based on originally filed claim 1, with the amendment finding basis on the passage at page 3, lines 26 to 30, of the application as filed (paragraph [0013] of the patent). Contrary to appellant-opponent 1's arguments, the board does not consider that this amendment, which does not include the reference to US patent 6035716 mentioned in the said passage at page 3, is an intermediate generalisation. Instead the board considers that the reference to said document, which is given between parenthesis, is just an example for informative purposes. Further claims 2 to 6 are identical, respectively, to claims 2 to 6 as originally filed.

Article 83 EPC

4.6 Article 83 EPC states that the European patent shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. For the assessment of sufficiency of disclosure, the teaching of the application as a whole is relevant, taking into account the common general knowledge of the skilled person. It is required that at least one way of enabling the person skilled in the art to carry out the invention is disclosed, but this is sufficient only if it allows the invention to be performed over the whole range claimed. If the

invention is defined by parameters, these must be sufficiently defined.

4.7 Present claim 1 is directed to a highly impact-resistant granule comprising an impact-sensitive particle including an active ingredient and a flexible film comprising a polymer surrounding said impact-sensitive particle. The film is further characterised by reference to its elongation upon break and weight percentage in relation to the granule, and the granule is further defined by its mass attrition percentage without the film. The highly impact-resistant granule itself is further characterised by the feature that it has "less than about 5% mass attrition mass attrition being determined by a Repeated/impact Test Device (RIT) at 216,000 collisions at 8.7 m/s and an amplitude of 1.5 cm". Apart from the weight percentage of film in relation to the whole granule, this is in fact the only functional parameter defining the claimed granule, since the other claim features are related either to the core (the impact-sensitive granule) or to the film (surrounding the core).

4.8 It is undisputed that the RIT test was not commonly used in the prior art. Hence, as regards this feature, the skilled person has to rely on the teaching of the patent together with the disclosure of documents mentioned in the patent in relation to this parameter. According to the patent, the RIT test was developed "[f]or purposes of modeling attrition of particles caused by impact forces, particularly the effects of large numbers of repeated impacts of defined magnitude" (paragraph [0021]). This paragraph further discloses how the test is performed: "a sample of granules is vibrated at a controlled frequency and amplitude within a chamber. The amount of damaged

particles or fragments (RIT mass attrition) is measured, or after removing all the granules and broken granule fragments the dust generated (RIT dust) is extracted from the box with a buffer and assayed for enzyme activity (See WO 98/03849 and USP 6,035,716)"; US 6035716 is document D22, while WO 98/03849 is the international patent application corresponding to US 6035716. Also paragraph [0013] of the patent makes reference to D22 and otherwise provides exactly the same disclosure of RIT as is in present claim 1. Further details of the test are given in the examples of the patent. In Example 1, in paragraph [0070], the test used to test impact-sensitive granules is disclosed as follows: "About 30 mg of granules were placed into an aluminum box of dimensions 2 cm x 3 cm x 1.5 cm and oscillated up and down at a frequency of 60 Hz causing the granules to impact the walls of the box at an impact velocity of 8.52 meters/second. The box was sealed to completely contain all of the dust generated during the test procedure. The test was run during 30 minutes resulting in 216,000 impacts or collisions with the box walls. At various time intervals (60 seconds, 120 seconds, see table 1 below), the box was opened and the content of the box was sieved through a 300 µm sieve to remove any fines or damaged particles. The percent mass attrition was determined and the undamaged fraction was put back into the box for further testing". In Example 5 (paragraph [0078]), in the context of testing impact-resistant granules, it is first disclosed that the "Repeated Impact Machine described in USP 6,035,716" (D22) was used, but then the test's further disclosure is identical to that given in paragraph [0070].

4.9 Hence, in the general part of the disclosure, the patent itself does not provide any more specific

indications concerning the RIT test used than the claim, apart from the reference to the device of D22. As argued by the opponents, it is however to be expected that the mass attrition value obtained for a given particle does not depend only on the number, speed and amplitude of the collisions used, but also that it is influenced by other factors such as the box dimensions and material (soft versus hard), the size and number of the granules, and the sieve size used, as discussed in D30, the PhD thesis originally disclosing the RIT test, and in D22. This information is given, at least in part, in the examples discussed above, but there is no teaching in the patent on how to extrapolate these conditions to other settings, e.g. to other granule sizes and amounts. Reference to D22 does not overcome this deficiency because it also does not teach how to choose the appropriate conditions for different settings.

4.10 The board is thus convinced that just by slightly varying parameters (within a technically reasonable range) such as box material or size, number of granules tested and size of the sieve, completely different results would be obtained even when using exactly the same amplitude, speed and number of collisions. Hence, the parameter is so insufficiently defined that the skilled person could not know without undue burden whether it was working within or outside the scope of the claims.

4.11 The appellant-patent proprietor essentially argued that the information given in the patent was sufficient to allow the skilled person to perform the test, and that further parameters were not part of the claim and hence had not to be defined. The board agrees only to the extent that the test as such could be reproduced but it

notes that, as reasoned above, depending on the conditions used, different results would be obtained. It is also true that the method did not necessarily involve the use of a sieve, other methods for mass determination being also possible (patent, paragraph [0021]; D22, column 6, line 42). However the claim is not limited to other methods but also includes the use of a sieve, which was explicitly taught in the patent; again, depending on the chosen size of the sieve in relation to the size and number of particles, different results would be obtained. D22 does provide information as to the sieve size, e.g. it uses a sieve size of 315 µm (column 4, line 66) and teaches that "[a] suitable method of damage assessment for larger samples is to sieve over half the original granule size e.g. 310 µm when granules of about 600 µm are used. It appears that smaller sieves can be used as well, as granule fragments are quickly reduced to a small size" (column 7, lines 23 to 28). However this information does not teach what sieve size should be used e.g. for smaller samples, nor is it clear what should be considered larger or smaller samples. The limited information available for the method of measurement allows thus for a great variability of the results obtained.

4.12 At least for the reasons given above, the board comes to the conclusion that the subject-matter of claim 1 of auxiliary request 1B is not sufficiently disclosed. Auxiliary request 1B is thus not allowable for lack of compliance with Article 83 EPC.

5. Auxiliary requests 2 to 6

Inventive step

5.1 Auxiliary requests 2 to 6 all contain a claim that is identical to claim 25 of the main request (section IX), with subject-matter that does not involve an inventive step. Hence, for the same reasons as for the main request, these requests are also not allowable for lack of inventive step (Article 56 EPC).

6. Auxiliary requests 7 and 8

Clarity (Article 84 EPC)

6.1 Claim 1 of these requests is based on claim 7 as granted, both having been amended to recite that the flexible film is applied by casting. Hence, the product of granted claim 7 (highly impact-resistance granule) is further defined in this claim by its process of production (for the exact wording of the claim, see section IX).

6.2 According to established case law, following T 150/82 (OJ 1984, 309, reasons 10.), product-by-process claims are admissible only if the product itself fulfils the requirements for patentability and it cannot be satisfactorily defined by reference to its composition, structure or some other testable parameters.

6.3 The appellant-patent proprietor argued that the granules produced by casting differ from granules produced by other methods, as shown in the patent in Figure 1 and also stated in paragraph [0062]: "a cast film is homogenous at a microscopic level and is not built up from deposition of discretely atomized droplets or patches, as shown in Fig. 1". As regards Figure 1, paragraph [0062] describes that "[t]he spin-coated film on the left forms a uniform coherent film

without layers" while "the spray-coated film on the right contains multi-layers (...)".

6.4 It follows from this argumentation that the granules made by the process indicated in the claim can be well distinguished at microscopic level from granules made by other processes. Accordingly, they can be - and could have been - satisfactorily defined by their microscopic structure, which is a testable parameter as shown in the patent (paragraph [0062] and Figure 1). Hence, at least this criterion for allowing product-by-process claims is not fulfilled by the present claim.

6.5 Claim 1 of auxiliary requests 7 and 8 thus lacks clarity. Auxiliary requests 7 and 8 are not allowable for lack of compliance with Article 84 EPC.

7. Auxiliary request 9

Inventive step

7.1 Claim 1 of this request is identical to claim 25 of the main request. Hence, for the same reasons as discussed above for the main request, auxiliary request 9 is also not allowable for lack of compliance with Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

M. Schalow D. Prietzel-Funk

Decision electronically authenticated