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Case Number: T 2159/14 - 3.2.07

Application Number: 09751667.8

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Title of invention:
PACKAGED IRON SUCROSE PRODUCTS

Applicant:
Hospira, Inc.

Headword:

Relevant legal provisions:
EPC Art. 56
RPBA Art. 13(1)

Keyword:
Inventive step - all requests (no)
Admissibility of fourth auxiliary request filed at the end of the oral proceedings (no)

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Case Number: T 2159/14 - 3.2.07

D E C I S I O N
of Technical Board of Appeal 3.2.07
of 24 November 2015

Appellant: (Applicant)	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 (US)
Representative:	Williams, Richard Andrew Norman HGF Limited 140 London Wall London EC2Y 5DN (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 2 June 2014 refusing European patent application No. 09751667.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	G. Patton
Members:	H. Hahn
	C. Brandt

Summary of Facts and Submissions

I. The applicant lodged an appeal against the decision of the examining division to refuse European patent application No. 09 751 667 8.

With its statement setting out the grounds of appeal the appellant requested that the decision be set aside and a patent granted or that the case be remitted to the examining division for further prosecution on the basis of claims 1-15 of the main request (corresponding to the main request underlying the impugned decision); alternatively it requested that the case be remitted on the basis of one of auxiliary requests 1 to 4, all requests as filed together with the statement of grounds of appeal. As a further auxiliary request oral proceedings were requested.

II. The following documents from the examination proceedings are mentioned in the present decision:

D1 = WO-A-03/007868;
D3 = Iacocca R. G. & Allgeier M. (2007), J. Mater. Sci. 42, pages 801-811;
D5 = Particle Counting in Injectable Solutions, 2007 updates, Particle Measuring Systems Inc. (2007); and
D6 = Remington: The Science and Practice of Pharmacy; 21st Edition (2005), "Containers and Closures", pages 809-811.

III. The examining division held that the subject-matter of claims 1 of the main, first and second auxiliary requests dated 28 March 2014 lacked inventive step in view of D1.

IV. With a communication annexed to a summons to oral proceedings scheduled for 24 November 2015 the board presented its preliminary and non-binding opinion with respect to the claims of the main request and auxiliary requests 1-4.

Auxiliary request 4 appeared not to be admissible into the proceedings in accordance with Article 12(4) RPBA.

The main request and auxiliary requests 1-3 appeared not to be formally allowable for not complying with Article 84 EPC.

Furthermore, it appeared that the subject-matter of independent claims 1, 12 and 15 of the main request lacked inventive step over the teachings of D1 (in which the glass container with a polydimethylsiloxane coating was considered to prevent glass delamination) and the common practice of the person skilled in the art, while the subject-matter of independent claims 8 and 13 of the main request appeared to lack inventive step over D6 and the common practice of the person skilled in the art.

The above conclusion concerning inventive step appeared to hold true for the independent claims of auxiliary requests 1 and 2.

V. With letter dated 21 October 2015 the appellant submitted a new main and first to third auxiliary requests together with arguments in order to deal with the board's objections raised in the summons.

VI. Oral proceedings before the board were held on 24 November 2015. At the start, the issue of inventive step of the subject-matter of product claim 1 of the

main request was discussed in view of the teaching of the closest prior art D1 in combination with the common general knowledge of the person skilled in the art, but also in the light of the disclosures of D3 and D5. This was followed by discussion of inventive step of the subject-matter of claims 1 of auxiliary requests 1 to 3. Thereafter the admissibility of the subsequently filed auxiliary request 4 into the proceedings was discussed.

The appellant finally requested that the decision under appeal be set aside and that a patent be granted on the basis of either the main request or alternatively one of the first to third auxiliary requests, all as filed with letter of 21 October 2015, or that the fourth auxiliary request filed during the oral proceedings on 24 November 2015 be admitted into the proceedings.

At the end of the oral proceedings the board announced its decision.

VII. Independent claim 1 of the main request reads as follows (amendments as compared to claim 1 of the application as originally filed [corresponding to the published WO2009/143439] are in bold, with deletions in strikethrough; emphasis added by the board):

"1. A packaged iron sucrose-product comprising:
(a) a **glass** container ~~constructed from a material comprising glass~~, the ~~container having an~~ inside surface **of which is provided by** ~~having formed thereon~~ a layer of ~~a material comprising~~ a silicone polymer; ~~and~~
(b) an aqueous iron sucrose **pharmaceutical** formulation **with a pH greater than 10.5** inside the container **and** in contact with the layer of ~~the material,~~ **silicone polymer and**

(c) a cap or stopper which seals the glass container; wherein upon storage of the product for a period of time from 3 to 12 months there is no delamination and the iron sucrose formulation is free of glass flakes as a result of glass delamination."

VIII. Claim 1 of the first auxiliary request differs from that of the main request in that the period of time from 3 to 12 months has been additionally specified to be **"at 25°C"**.

IX. Claims 1-5 of the second auxiliary request are identical to those of the first auxiliary requests (i.e. independent process claim 6 has been deleted).

X. Claims 1-5 of the third auxiliary request differ from claims 1-5 of the second auxiliary request in that the definition of the period of time of "from 3 to 12 months at 25°C" in claim 1 has been amended to now read "~~from~~ **of** 3, **6 or** ~~to~~ 12 months at 25°C".

XI. Claim 1 of the fourth auxiliary request reads as follows (amendments as compared to claim 1 of the third auxiliary request are in bold, with deletions in strikethrough; emphasis added by the board):

"1. A packaged iron sucrose product comprising:
(a) a glass container, the inside surface of which is provided by a layer of a silicone polymer;
(b) a~~n aqueous iron sucrose~~ pharmaceutical formulation **consisting essentially of iron sucrose and water for injection** with a pH ~~greater than 10.5~~ **of 11** inside the container and in contact with the layer of silicone polymer; and
(c) a cap or stopper which seals the glass container; wherein upon storage of the product for a period of

time of 3, 6 or 12 months at 25°C there is no delamination and the iron sucrose formulation is free of glass flakes as a result of glass delamination **as measured by scanning electron microscopy**."

XII. Insofar as is relevant for the present decision, the appellant essentially argued as follows:

The invention is based on the discovery that a pH of 10.5 of a pharmaceutical formulation comprising iron sucrose results in a glass delamination problem which can be prevented by a silicone polymer coating (see page 3 of the published application).

Feature (c) of claim 1 of the main request relating to the storage of the product does not define a result to be achieved but, since the former claim 1 did not include the time period with a particular time constraint, this amendment provides a more precise definition and enables the claim to be clarified. There was no other way without unduly restricting the scope of the claim.

An iron sucrose solution is very dark and a little opaque, so that it is difficult to see whether there are glass flakes present or not. The invention removes this risk since the inventive pharmaceutical formulations are free of glass flakes.

D1 is all about particulates in general but does not concern glass delamination, which is different to leaching. D1 only discloses particle measurement by counting with a Coulter Counter (electrical zone-sensing method) and does not refer to iron sucrose at a pH of greater than 10.5. According to D1 the pH (i.e. the negative decadic logarithm of the hydrogen ion [H^+-

ion] concentration in moles/l) generally **will** be in the range 4 to 10, i.e. it **has** to be within this range. The definition "alkaline solution" refers to a pH range of 7 to 10 which, if taken literally, points away from the invention. The pH range of 4-10 of dependent claim 8 of D1 is inconsistent with page 4 of the description.

In contrast to D1, the present application measures the number of glass flakes in pharmaceutical vials containing iron sucrose at a pH greater than 10.5, using scanning electron microscopy (SEM). According to example 2 no glass flakes were found after 12 months of storage under normal storage conditions (see page 20, table 3), and even under accelerated storage conditions no more than a few flakes per ml were found. D1 does not teach that it can avoid glass delamination at a pH of greater than 10.5, nor does it analyse the counted particles for glass.

There are two differences between the subject-matter of claim 1 and D1. Firstly, the pharmaceutical formulation comprises iron sucrose at a pH of greater than 10.5. Secondly, the packaged product after a storage period of 3 months or more does not contain glass flakes, which represents another product feature. Glass flakes are simply measured by filtering and subsequent analysis with SEM as described in paragraph [0037] of the published application.

The board's arguments are based on hindsight in view of D1, which is silent on the containers avoiding glass delamination. Paragraphs [0022] and [0026] of the present application cannot be used to interpret the meaning of D1. Too many assumptions have to be made to arrive at the invention. The invention eliminates glass flakes, whereas D1 only reduces particulate material

and not glass flakes. The silicone polymer teaching of D1 should not be interpreted as meaning a physical barrier since it only **reduces** the aluminium content and particle formation and concerns a different chemistry. D1 does not disclose that a polydimethylsiloxane (PDMS)-coated glass container avoids glass delamination, and the disclosure of paragraphs [0022] and [0026] of the present application cannot be used in hindsight to interpret the meaning of D1 to an average skilled reader. Starting with D1 and considering the distinguishing features, the objective problem is to avoid glass flakes forming due to glass delamination in an alkaline iron sucrose formulation having a pH of at least 10.5 when stored for up to a year in a siliconised glass container.

Taking account of the above understanding of the pH range of D1 a person of average skill in the art would not have considered that an iron sucrose solution of at least pH 10.5 would be free of glass flakes caused by glass delamination when stored in siliconised glass container for a period of 3 to 12 months. D1 would not have motivated a person of average skill to try storing said solution for more than 3 months in said glass container. The examples of D1 show that particulate can only be reduced and not eliminated, which teaches the person of average skill in the art away from attempting to use the container of D1 to prevent glass flakes as a result of glass delamination.

D5 is unspecific about glass flakes, and the form of the "glass" is not specified (see first page, sixth paragraph). D5 actually concerns debris from glass manufacturing at time zero, i.e. not after the storage of the formulation.

The passage of D3, page 802, left-hand column, in particular where the pH is of above 8, concerns unbuffered solutions, like the claimed iron sucrose solution. The described effect is in that case not unduly aggravated, since the pH will decrease.

No additional arguments are to be presented concerning inventive step of claims 1 of the first to third auxiliary requests.

It is requested that a new fourth auxiliary request be admitted (based on claims 1 and 5 of the third auxiliary request and restricted to a pH of 11) which takes account of the new issues discussed at the oral proceedings, namely the pH range, the possible buffering of the formulation and the measuring of the particles. Therefore this late-filed request should be admitted into the proceedings. D1 should not be construed to include solutions having a pH above 10 since said sentence on page 4, fourth paragraph, "will be in the range 4 to 10" should be interpreted as "has to be". Consequently, the skilled person is not taught to use the siliconised container according to D1 with a pharmaceutical formulation having a pH of 11.

Reasons for the Decision

1. *Admissibility of amendments made (Articles 84 and 123(2) EPC)*

Since the board considers that the subject-matter of claims 1 of the main request and the first to third auxiliary requests lacks inventive step (see point 2 below) there is no need in this decision to deal with

the question whether the amendments made therein comply with Articles 84 and 123(2) EPC.

2. *Inventive step (Article 56 EPC)*

First auxiliary request

The board came to the conclusion that the subject-matter of claim 1 of the more restricted first auxiliary request - which when compared to claim 1 of the main request (see point VII above) includes the additional feature defining the storage period to be "at 25°C" (see point VIII) - lacks inventive step over the teaching of D1 and the common general knowledge and practice of the person skilled in the art for the following reasons.

2.1 D1 - in the impugned decision the examining division regarded it as the closest prior art - represents the most promising springboard towards the invention (see Case Law, 7th edition 2013, section I.D.3.4).

2.1.1 D1 discloses the storage of liquid pharmaceutical compositions, particularly injectable parenteral compositions (particularly of blood plasma proteins such as albumin), in glass containers having a shelf-life in excess of 18 months, over which time the aluminium content is maintained below 200 µg/l, which is achieved by **silicone-coating the glass container**. Also the particles/ml post-autoclave and post-pasteurisation are kept to low levels (see abstract; and page 1, first paragraph). According to D1 it belongs to the prior art that glass containers tend to leach out aluminium into solutions in contact therewith over extended periods of time, particularly in the case of **alkaline solutions** (see page 1, second and third

paragraphs) and that particulates in injectable solutions may represent a further medical problem (see page 3, first paragraph).

2.1.2 D1 thus aims to mitigate the problems of aluminium leaching and/or particulate accumulation in such liquid compositions (see page 3, second paragraph). This problem is solved by storing the liquid pharmaceutical formulation in a glass container whose surface contacting the liquid composition is provided with a silicone polymer coating (see page 3, third paragraph, to page 4, first paragraph; amended claims 1 and 17) which silicone coating is preferably produced from **polydimethylsiloxane** (**PDMS**) which is then baked (see page 6, first paragraph, and amended claim 12). According to dependent method claim 8 the pH of the liquid composition is "in the range of 4 to 10" (see amended claim 8), while in the description it is stated that "Generally, the pH of the liquid composition will be in the range 4 to 10" and "Alkaline solutions generally exacerbate the problem of aluminium leaching and are preferably avoided" (see page 4, fourth paragraph).

2.1.3 The siliconisation treatment of D1 can be carried out in the known manner using any available silicone polymer or prepolymer and is, due to the cited prior art "Siliconisation of Parenteral Drug Packaging Components" (see page 6, first and second paragraphs), already known in the art. The silicone may be any of those known to be suitable and pharmaceutically acceptable.

2.1.4 According to D1 the problem of particulates in injectable solutions is also a known problem that can be increased by storage of these solutions in glass

containers (see page 3, first paragraph), but the siliconisation treatment of the container "also **reduces the number of particles shed from the container surface** - leading to reduced particulates in the liquid composition" and allows the previous British Pharmacopeia Standards limits of ≤1000 particles/ml to be achieved even post-autoclaving and post-pasteurisation (see page 6, third paragraph, to page 7, first paragraph; see also examples 3-5).

D1 further mentions testing the room-temperature storage stability of the packaged pharmaceutical formulations at 25°C as well as storage periods of 6 and 12 months at this temperature (see e.g. page 10, first paragraph; and figures 2 and 4).

2.1.5 The term "delamination" or "glass delamination" is nowhere used in D1, but the term "particulate" and "particulate matter" is used (see e.g. page 1, first paragraph, and page 8, second paragraph).

According to the US, EP and JP Pharmacopoeia standards for particle counting in injectable solutions discussed in D5 the term "**particulate matter**" refers to visible and smaller mobile solids unintentionally present in sterile parenteral products. This definition of D5 includes **solids made of glass** that are present as a contaminant in the parenteral product.

This definition does, however, **not** exclude any glass solids generated by a chemical reaction during the storing of the parenteral product, since "packaging components" are stated to be a potential source of this particulate contamination (see D5, page 1, penultimate and last paragraphs). The appellant's argument that D5 would have to be interpreted as only meaning glass

debris from the glass manufacturing step at the time zero, i.e. a quality control at the time of filling the glass container with the formulation, **cannot** be accepted, since when asked by the board it was not able to quote any basis in D5 that would support its limited interpretation. On the contrary, it is credible that the mentioned Pharmacopoeia standards of D5 likewise apply to stored injectable solutions which are ready to be used and may have been stored for several months (see for instance page 3, first to third paragraphs). Consequently, the board considers that the "particulate matter" of D1 includes glass flakes resulting from an optional glass delamination.

2.2 Thus, as also put forward by the appellant at the oral proceedings, the subject-matter of claim 1 of the first auxiliary request is distinguished from the PDMS-coated glass container containing an aqueous albumin formulation according to D1 in that the coated container contains "an iron sucrose formulation having a pH of greater than 10.5" and that "upon storage of the product for a period of time from 3 to 12 months at 25°C there is no delamination and the iron sucrose formulation is free of glass flakes as a result of glass delamination".

2.2.1 As already mentioned before, it is considered that a PDMS-coated glass container according to D1 having a uniform coating layer of this silicone polymer of a certain thickness - PDMS represents a preferred silicone polymer of the present application (compare paragraphs [0026] and [0027] as well as claim 16 as originally filed) - prevents glass delamination. This conclusion of an inherent property is based on the fact that identical materials when used and applied in the same manner result in the same layer structure

(according to the teaching of D1 as well as according to the present application, after application of the PDMS to the glass surface it is baked for a predetermined time and temperature to harden the coating and remove extractables), i.e. a coating layer of PDMS on at least the inside of an unspecified glass container should provide the same effect, namely should prevent the generation of glass flakes.

The appellant argued that D1 only reduces the number of particulates, but this argument cannot hold since **no** evidence was submitted which would prove that D1 does **not** prevent the generation of glass flakes. This deficiency was remarked on by the board in its communication annexed to the summons to oral proceedings, in which the appellant was additionally informed that it bore the burden of proof in this respect (see point 6.1.2 of the communication). However, the appellant did not discharge its burden.

2.2.2 Therefore the only technical effect of the distinguishing features is that the iron sucrose formulation can be stored for a certain period of time.

2.3 In view of the above, the objective technical problem for the person skilled in the art when starting from the silicone-polymer-coated glass container of D1 is therefore considered to only be the provision of an alternative application of the known container, i.e. for packaging another pharmaceutical formulation.

Consequently, the appellant's more ambitious technical problem, i.e. to avoid glass flakes forming due to glass delamination in an alkaline iron sucrose formulation having a pH of at least 10.5 when stored for up to a year in a siliconised glass container,

cannot be accepted, since glass delamination is already prevented by the inherent properties of the PDMS-coated glass container of D1. The fact that D1 does not measure at all whether the determined particles are glass particles is considered **not** to be particularly relevant in this context.

2.4 The board considers that the solution to this problem is obvious to the person skilled in the art, for the following reasons.

2.4.1 D1 teaches the person skilled in the art that the described invention is applicable to any other liquid pharmaceutical composition where there is a need to maintain low aluminium content on storage (see page 4, lines 8 to 12, and page 5, lines 9 to 11).

2.4.2 The disclosure of D1 at page 4, fourth paragraph, "**Generally**, the pH of the liquid composition **will be** in the range 4 to 10", i.e. in **general** the pH of the packages liquid composition **can be** within said range of **4 to 10**, teaches the skilled person that the range can be even greater, e.g. 3 or 11, since this wording further implies that there may be exceptions to this general range of 4 to 10 which may either have a lower or a higher pH. According to dependent claim 8 this range from 4 to 8 represents a preferred range which is **not** at odds with the statement that the pH is generally within said range. The appellant's arguments that claim 8 would be inconsistent with the statement on page 4 as well as that the compositions of D1 would have to have a pH within the range of 4 to 10 **cannot** hold.

2.4.3 The board remarks in this context that the skilled person would interpret this range of D1 by applying his common general knowledge and in particular the

applicable rounding rules to the next full digit within the applicable error margins of this range. Thus the skilled person would technically equate "in the range of 4 to 10" to "in the range of **3.5 to 10.4**".

2.4.4 Furthermore, the skilled person would also consider in this context his common general knowledge concerning silicone polymers and their general properties. Namely that silicone polymers are chemically inert, hydrophobic and stable within broad pH boundaries but are expected to degrade at the extreme pH values of about 0 and about 14. At the oral proceedings the appellant did **not** contest this common general knowledge of the person skilled in the art. Taking account of this knowledge he would arrive at the conclusion that a pH of the formulation in the aforementioned possible broader range of **3 to 11** might not be that critical for aluminium leaching from the siliconised glass container.

2.4.5 In view of these considerations the skilled person – also taking account of the fact that a pH of greater than 10.5, e.g. a pH of 10.51, is not that far from said upper pH value 10.4 – is therefore expected to carry out routine experiments with said iron sucrose solution at such a pH of 10.51 (which is well within said broader range of 3 to 11) and would therefore arrive at the subject-matter of claim 1 of the first auxiliary request without inventive skills (see Case Law, 7th edition 2013, section I.D.7.2) since he would establish with these routine experiments that the PDMS-coated glass container is perfectly suitable for the intended purpose.

In this context the board remarks that the person skilled in the art – when looking for a suitable

package for the known iron sucrose formulation - is principally considered to carry out routine experiments with **all** available commercial glass containers that appear to be suitable for the intended purpose, e.g. in view of the pH of the composition to be stored. It is unambiguously implicit that the used container and the coating materials have to be compatible with the pharmaceutical composition to be stored therein, i.e. they should be as inert as possible in order to avoid any reaction between components of said composition and the container materials and they also have to be approved for this purpose.

2.5 The appellant's further arguments to the contrary cannot hold for the following reasons.

2.5.1 The appellant’s interpretation of the sentence following the pH range on page 4 - "Alkaline solutions generally exacerbate the problem of aluminium leaching and are preferably avoided" - cannot hold since it has to be interpreted identically, namely that alkaline solutions - which means a pH range of greater than **7 to 14** (and not only greater than 7 to 10 as the appellant argues) - in **general** increase the problem of aluminium leaching. Consequently it is evident that in this context too there are exceptions since the common general knowledge concerning the general properties of silicone polymers has to be considered (see point 2.4.4 above). Therefore, these statements in D1 will be understood by the person skilled in the art such that alkaline pH values above said general range, i.e. above a pH of 10, should be avoided but in certain cases may nevertheless be used.

2.5.2 The argument that a difference of even 0.1 of a pH unit from e.g. 10.4 to 10.5 is significant and is in no way

"infinitesimal" in terms of proton concentration is considered not to be particularly relevant since the skilled person will read and understand the disclosure of D1 as encompassing pH values above 10 (see points 2.4.2 and 2.4.4 above).

2.5.3 The appellant's argument that the invention would be based on a **discovery**, i.e. that the inventors were the first to realise that a pH of 10.5 of a pharmaceutical formulation comprising iron sucrose results in a glass delamination problem, cannot hold.

This is because, in the prior art as evidenced by D3, glass delamination is a known phenomenon encountered in the pharmaceutical industry in the context of injectable (parenteral) solutions resulting in unacceptable visible foreign particulates therein (see D3, page 801, paragraph "Introduction"). This glass delamination is described in D3 as a very aggressive corrosion of glass resulting in glass degradation, which is influenced by the pH value of the aqueous solution (but also the chemical composition and processing history of the glass, temperature, duration of contact between glass and the aggressive environment). When dissolution is the dominant mechanism the governing reaction is the formation of silicic acid from silicon dioxide and water. Above a pH of 8, silicic acid formed by the reaction of silicon dioxide from the glass is ionised, which increases the solubility of said silicic acid in solution, whereby the silica dissolution action is driven forward (if unbuffered, the solution will decrease in pH due to said generation of silicic acid). Highly **basic solutions** (i.e. alkaline solutions) favour the congruent dissolution by simple dissociation and chemical reaction (see page 802, left-hand column), and

anions and cations can exacerbate this degradation process. Therefore it is already known from D3 that highly alkaline solutions are the cause of glass delamination.

The board's view is also supported by the prior art mentioned in the present application (see page 1, paragraph [0002]), where it is stated that glass delamination is accelerated by solutions containing various anions, especially under **alkaline conditions**.

Any specific effect of the iron sucrose component present in the pharmaceutical formulation on the glass delamination has, however, not been made credible by the appellant, who has not submitted any corresponding experimental evidence to discharge its burden of proof.

2.5.4 Taking account of point 2.2.1 above it is clear that the board's arguments are not based on hindsight in view of D1. Paragraphs [0022] and [0026] of the present application were quoted only to show that the glass container of D1 is provided with a uniform coating of the identical silicone polymer PDMS - which acts as a barrier coating with respect to the aqueous iron sucrose solution so that this solution cannot come into contact with the underlying glass container - like the present application, which therefore inherently provides the same technical effect (i.e. prevention of glass delamination).

The board further remarks in this respect that the person skilled in the art has actually only two options when aiming to provide a cheap reliable container for injectable pharmaceutical formulations: he can either try to modify the glass chemistry to minimise leaching and/or reduce generation of particles with alkaline

solutions (plastic containers are excluded due to the possibility of leaching plasticisers and unreacted monomers), or he can apply a barrier coating using a material which prevents contact of the alkaline solution with the underlying glass container as suggested by D1 (see e.g. page 1, second and third paragraphs). It is self-evident that such a barrier layer material has to be approved by the competent authority for use with medicaments, as is the case with the pharmaceutically acceptable silicone polymers disclosed in D1 (see page 6, first paragraph).

2.6 Taking account of the above the board therefore concludes that the subject-matter of product claim 1 of the first auxiliary request lacks inventive step (Article 56 EPC).

Main request

2.7 Since claim 1 of the first auxiliary request is narrower in scope than claim 1 of the main request, which latter does not require a storage temperature of "25°C" (compare points VII and VIII above), the above conclusion with respect to claim 1 of the first auxiliary request applies *a fortiori* to claim 1 of the main request.

Second auxiliary request

2.8 The same conclusion as in point above applies *a fortiori* to claim 1 of the second auxiliary request, which is identical to claim 1 of the first auxiliary request (see point IX above).

Third auxiliary request

2.9 The board considers that the same conclusion also applies to claim 1 of the third auxiliary request, comprising an amended definition of the storage period of the container for "**3**, 6 or **12** months at 25°C" (see point X above), since it is not apparent why this different definition, which – compared to the storage period range of "**3** to **12** months" specified in claim 1 of the first auxiliary request (see point VIII above) - identically includes the values of 3 and 12 months, should entail an inventive step. The appellant has not put forward a single argument in this respect.

The board therefore concludes that its subject-matter does not comply with the requirements of Article 56 EPC either. The main request and the first to third auxiliary requests are therefore not allowable under Article 56 EPC.

3. *Admissibility of the fourth auxiliary request into the proceedings (Article 13(1) RPBA)*

3.1 After the discussion on inventive step of the subject-matter of claims 1 of the main request and the first to third auxiliary requests the appellant submitted a fourth auxiliary request and argued that this totally new request was the result of the discussions concerning the pH range, the particles and the possible buffering of the alkaline solution.

3.2 The fourth auxiliary request was thus filed at a very late stage of the oral proceedings before the board. In exercising its discretion in accordance with Article 13(1) RPBA the board therefore examined whether this

late-filed request would be *prima facie* allowable with respect to inventive step.

3.2.1 The board considered that, taking account of the considerations in points 2.4.2 to 2.4.5 above, the skilled person would likewise have performed experiments with an iron sucrose solution having a pH of 11, particularly in view of the fact that a pH of 11 had been mentioned in the board's communication (see point 6.2.3). Therefore the appellant's arguments to the contrary cannot hold.

3.2.2 The board further considered that the added feature "as measured by scanning electron microscopy" - which relates to an analysing process step - does not allow the product *per se* of claim 1 of the fourth auxiliary request to be further characterised. Consequently, this feature need not be considered at all.

3.2.3 Concerning the added feature of a pharmaceutical formulation "**consisting essentially** of iron sucrose and water for injection" and the fact that the solution has a pH of 11, the board considers that this wording would not exclude any buffer from said solution, contrary to the appellant's view. In fact, "consisting essentially" does not fully define the pharmaceutical formulation.

Further, in order to maintain a constant pH, a buffer substance would have to be present in about the same amounts as the alkaline substance.

3.3 The board therefore decided not to admit the fourth auxiliary request into the proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

G. Nachtigall G. Patton

Decision electronically authenticated