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Datasheet for the decision of 16 June 2015

Case Number: T 0375/13 - 3.3.07

Application Number: 00914867.7

Publication Number: 1169062

IPC: A61K47/48, A61K49/00

Language of the proceedings: EN

Title of invention:
HEAT STABLE COATED COLLOIDAL IRON OXIDES

Patent Proprietor:
AMAG Pharmaceuticals, Inc.

Opponent:
Sandoz GmbH

Relevant legal provisions:
EPC Art. 84, 100(b), 111(1), 123(2), 123(3)
EPC R. 80
RPBA Art. 12(4), 13

Keyword:
Late-filed evidence - admitted (yes)
Amendment occasioned by ground for opposition - amendments allowable (yes)
Amendments - added subject-matter (no) - broadening of claim (no)
Claims - clarity in opposition appeal proceedings
Sufficiency of disclosure - (yes)
Remittal to the department of first instance - (yes)

Decisions cited:
T 0593/09

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Case Number: T 0375/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 16 June 2015

Appellant: (Patent Proprietor)	AMAG Pharmaceuticals, Inc. 100 Hayden Avenue Lexington MA 02421 (US)
Representative:	Hallybone, Huw George Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Opponent)	Sandoz GmbH Biochemiestrasse 10 6250 Kundl/Tirol (AT)
Representative:	Altmann, Andreas Herzog Fiesser & Partner Patentanwälte PartG mbB Isartorplatz 1 80331 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 4 January 2013 revoking European patent No. 1169062 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	J. Riolo
Members:	D. Semino
	P. Schmitz

Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies against the decision of the opposition division announced at the oral proceedings on 18 October 2012 to revoke European Patent 1 169 062. The patent was granted on the basis of 9 claims, claim 1 reading as follows:

"1. An autoclavable derivatized reduced polysaccharide iron oxide complex intended for administration to a mammalian subject, characterized in that it is obtainable by:
reacting a polysaccharide with a borohydride salt, or hydrogen in the presence of an hydrogenation catalyst, to produce a reduced polysaccharide;
derivatizing the reduced polysaccharide;
the derivatized reduced polysaccharide being produced at a temperature of less than 50°C; complexing the derivatized reduced polysaccharide with an iron salt to produce a derivatized reduced polysaccharide iron oxide complex; the complexing comprising adding a mixture of ferric and ferrous salts, cooling the resulting solution and adding ammonium hydroxide to neutralize the solution;
and
sterilizing the complex by autoclaving;
such complex being stable at a temperature of at least 100 °C."

Independent claim 7 related to a method of providing an autoclavable derivatized reduced polysaccharide iron oxide complex intended for administration to a mammalian subject, the method comprising the method steps listed in claim 1, such complex being stable at a temperature of at least 100 °C.

II. The decision was based on three sets of claims filed as main request during oral proceedings on 18 October 2012 and as auxiliary requests 1 and 2 with letter of 13 August 2012.

Claim 1 of the main request had the following wording:

"1. An autoclavable carboxymethylated reduced dextran iron oxide complex intended for administration by injection to a mammalian subject, characterized in that it is obtainable by:
reacting dextran with a borohydride salt, or hydrogen in the presence of an hydrogenation catalyst, to produce a reduced dextran;
carboxymethylating the reduced dextran;
the carboxymethylated reduced dextran being produced at a temperature of less than 50°C; complexing the carboxymethylated reduced dextran with an iron salt to produce a carboxymethylated reduced dextran iron oxide complex; the complexing comprising adding a mixture of ferric and ferrous salts in an acidic solution, cooling the resulting solution and adding ammonium hydroxide to neutralize the solution and recovering a superparamagnetic complex;
and
sterilizing the complex by autoclaving;
such complex being stable at a temperature of at least 121 °C for a period effective to sterilize the complex."

Claim 2 of the main request was a process claim corresponding to granted claim 7 and containing the same amendments as in claim 1 of the main request.

Claim 1 according to the auxiliary requests differed *inter alia* from claim 1 of the main request in that the mixture of ferric and ferrous salt was not defined as being "in an acidic solution" and the final step of the complexing step was not defined as a "recovering" step.

III. The decision under appeal can be summarised as follows:

a) The introduction of the term "by injection" with reference to the administration method was intended to limit the claim and met therefore the requirements of Rule 80 EPC. Moreover, it was clear to the skilled person how injectable solutions were prepared.

b) The use of the term "complex" instead of "colloid" in the recovery step met the requirements of Article 123(2) EPC, as the two terms were used in the patent with the same meaning.

c) With respect to sufficiency, the individual process steps, in spite of being broad, did not cause any problem of reproducibility. However, the feature "such complex being stable at a temperature of at least 121 °C for a period effective to sterilise the complex" resulted in a lack of sufficiency, as the skilled person did not find in the specification which parameter(s) he should measure, how to accomplish the measurement(s) and which standard(s) to apply in order to assess stability. Indeed, several parameters were mentioned in the patent, but it was not identified which one was to be measured to assess stability. In addition, no information was present on the variations allowed. Moreover, the available evidence did not prove that the required

stability measurements were well known in the field and corresponded to the standards required for approval of medicaments.

d) The same issue stood against auxiliary requests 1 and 2, which in addition infringed the requirements of Article 123(2) EPC in view of two missing features regarding the acidic solution and the recovering step.

IV. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal, the appellant filed four sets of claims as main request and auxiliary requests 1 to 3 and submitted the following pieces of evidence:

D23: The Unites States Pharmacopeia, USP 23 NF 18, January 1995, Sterilisation <1211>, pages 1976 to 1981
D24: Declaration of Eric B. Sheinin dated 12 May 2013 with annexes I and II
D25: US-A-6 048 515
D26: The Unites States Pharmacopeia, Fifth Supplement USP NF, 1996, Particulate Matter in Injections <788>, pages 3477 to 3482
D27: Extract from the British Library Catalogue confirming the publication date of D26
D28: Declaration of Jerry Lewis dated 10 May 2013 with annexes I and II
D29: European Medicines Agency, CHMP assessment report, "Rienso", 19 April 2012
D30: Extract from NDA, Section 3.2.P.8.1.2.9
D31: The Unites States Pharmacopeia, USP 23 NF 18, January 1995, Injections <1>, pages 1650 to 1652; Particulate Matter in Injections <788>, pages 1813 to 1819

V. With the reply to the statement of grounds, the respondent submitted the following pieces of evidence:

D32: Declaration by Ivan Plantan dated 7 September 2013 with CV
D33: Appendix A

VI. In reply to that letter of the respondent, the appellant submitted with letter of 17 March 2014 a declaration (D34: Declaration of Jerry Lewis dated 14 March 2014 with annexes I to IV) and seven sets of claims as main request and auxiliary requests 1 to 6, wherein the main requests and auxiliary requests 1, 3 and 5 corresponded to the requests filed with the statement of grounds.

The main request corresponded to the main request on which the decision was based.

VII. In a communication sent in preparation of oral proceedings the Board took position *inter alia* on the issue of sufficiency of disclosure expressing its preliminary opinion that lack of sufficiency of disclosure did not arise from the reasons in the appealed decision (points 4.1 and 4.2) and adding that only in case the evidence on file could convincingly show that the result present in claim 1 was not possible, a lack of sufficiency would arise (point 4.3). Reference was made to the tests of the respondent in D32 and to the critics thereto in the reply of the appellant.

VIII. With letter of 15 May 2015 the respondent requested that Mr. Plantan be allowed to intervene and to comment on specific technical questions during oral proceedings

and submitted the following additional pieces of evidence:

D35: Declaration of I. Plantan dated 4 May 2015
D36: Solvias Order Form dated 21 August 2013
D37: Declaration of A. Busch-Kauf dated 5 May 2015 including Annex-1, Annex-2 and Annex-3

IX. Oral proceedings were held on 16 June 2015.

X. The arguments of the appellant, as far as relevant to the present decision, can be summarised as follows:

Admittance of late filed evidence and apportionment of costs

a) The documents filed with the statement of grounds, in particular D26 and D31, were filed as a reaction to the decision, to fill in the gaps in the arguments not followed by the opposition division and should be admitted into the proceedings. On the other side, there was no justification for the filing of experimental evidence concerning sufficiency of disclosure only in appeal proceedings on the side of the respondent. On that basis, documents D32 and D33 should not be admitted into the proceedings. This applied even more to documents D35 to D37 with Annexes 1, 2 and 3 and the arguments related thereto which were filed shortly before the oral proceedings, because the previously filed evidence was deficient. If these pieces of evidence were not admitted, an apportionment of costs should be ordered in order to recompense the appellant for the resources expended in analysing the evidence.

Main request - Rule 80 EPC, Articles 123 and 84 EPC

b) The suitability of the claimed complex to administration "by injection" was a clear limitation of the claim, which implied limiting the complex to the ones meeting regulatory requirements and was meant to overcome the objection of lack of sufficiency; in view of that it was not against the requirements of Rule 80 EPC. As to the objections under Article 123(2) EPC, the original application disclosed products and processes for making such products, so as to give a clear basis for a product-by-process claim. Moreover, the open wording of a process step might result in a broad claim, but was not objectionable under Article 123(2) EPC. In addition the terms "complex" and "colloid" were used interchangeably in the application and the obtained complex was disclosed as being stable to autoclaving conditions and therefore "autoclavable". With regard to Article 123(3) EPC the broad stability condition in granted claim 1 was limited to a more stringent condition with no possible broadening of the scope of protection. An objection of lack of clarity for the stability condition could not be raised, as lack of clarity was not a ground of opposition; moreover, it was *prima facie* not relevant.

Main request - sufficiency

c) The decision of the opposition division appeared to be focused on the clarity of some terms in the claims, even though clarity was not a ground of opposition. The case law was clear in that a lack of sufficiency objection could not be upheld in

the absence of evidence (as was the case before the opposition division) and in that a distinction had to be drawn between an alleged lack of clarity at the boundaries of the claims and insufficiency, whereby insufficiency might arise only if a parameter was so ill-defined that the skilled person was not able to identify the technical measures necessary to solve the problem underlying the patent at issue. In the present case both the term "autoclaving" (normally consisting in a sterilisation at 121 °C) and the term "stable" were commonly used in the field with a meaning self-evident to the skilled person. Stability to autoclaving referred to the polymer coating not dissociating from the iron oxide core upon autoclaving. The patent itself mentioned several parameters, namely clumping, biodistribution changes, toxicity and pH, which could be measured in order to assess stability. In particular, it was necessary to look at the three parameters measured in Table 9 of the patent, namely pH, mean volume diameter (MVD) and the number of particulates. If any one of these parameters varied significantly or if the complex failed the USP test for particulates, which had clearly defined limits, then the complex was deemed to be unstable. Example 31 vs comparative example 30 showed a stable vs an unstable complex. The additional data in D28 showed that the complexes produced by the method set out in the claims were stable to multiple autoclave cycles. In summary, in order for the complex to be stable, it should be substantially unaffected by the autoclaving step and there should be no material effect on the biological purpose of the material, which should remain injectable after autoclaving.

Remittal

d) The objection of lack of sufficiency which led to the revocation decision was based on the lack of parameters, methods of measurements and standards for the determination of whether the claimed complex was stable. The lack of reproducibility based on experimental evidence was a completely different line followed by the respondent in appeal, which resulted in a fresh case on which the opposition division had not decided. Moreover, it was closely related to the issues of novelty and inventive step, which should be decided upon by the opposition division. In addition, part of the evidence had come very late, so that the appellant still needed time for a thorough analysis. For these reasons, only the objection of sufficiency decided upon in the appealed decision should be dealt with in appeal and then the case should be remitted for analysis of sufficiency of disclosure in view of the experimental evidence filed by the respondent together with examination of novelty and inventive step.

XI. The arguments of the respondent, as far as relevant to the present decision, can be summarised as follows:

Admittance of late filed evidence

a) Documents D26 and D31, filed by the appellant with the statement of grounds, should not be admitted into the proceedings as they could have been filed in first instance proceedings. As to the experimental evidence filed by the respondent, it was legitimate to file it in appeal, as the

decision on sufficiency was already in favour of the respondent, so that there was no need to file such experimental evidence at an earlier stage, and it was a reaction to issues raised for the first time in the statement of grounds. Documents D35 to D37 with Annexes 1, 2 and 3 were filed as a reaction to the criticisms of the appellant to the experimental evidence and the relevance of these criticisms given by the Board. The whole of the evidence filed by the respondent should therefore be admitted into the proceedings.

Main request - Rule 80 EPC, Articles 123 and 84 EPC

b) The introduction of the expression "by injection" with reference to the administration method in claim 1 was not caused by a ground of opposition and contravened therefore the requirements of Rule 80 EPC. Claim 1 of the main request did not meet the requirements of Article 123(2) EPC as there was no basis in the original application for a product-by-process claim, as the complexing step was worded in open manner ("the complexing comprising") while the whole process was worded in a closed manner, as it included a step of recovering a "complex" while the original application disclosed recovering of a "colloid" and as there was no basis for a complex as claimed which after autoclaving was still autoclavable as required by claim 1. The condition "stable at a temperature of at least 100 °C" in granted claim 1 imposed the requirement of stability at any condition, as e.g. for a very long time period, while the condition in claim 1 of the main request "stable at a temperature of at least 121 °C for a period effective to sterilise the complex" defined

a less stringent stability standard, therefore broadening the protection conferred contrary to the requirements of Article 123(3) EPC. The expression "being stable ... for a period effective to sterilize the complex" was unclear, since the period of time was not specifically defined.

Main request - sufficiency

c) The patent did not indicate which methods needed to be followed to assess whether a complex was stable within the meaning of the patent, which parameters should be measured and which tolerance in the variation of the measured parameters was allowed. The lack of a teaching which would enable the skilled person to determine whether a product was considered to be stable was so extreme as to result in lack of sufficiency. While the patent mentioned different parameters which were measured in the examples, such as MVD, pH or USP particulates, there was no disclosure of which of these parameters needed to be measured to assess stability. Other documents could not supplement what was missing in the patent itself. Not even in the arguments of the appellant it was clear which parameters were crucial, as in addition to MVD, pH and USP particulates the relevance of the possible dissociation of the coating, of clumping, of biodistribution changes and of toxicity was mentioned. As to the USP test for particulates different methods existed which gave significantly different results, which clearly resulted in a lack of disclosure. In addition, the lack of an indication of the allowed variations which applied to all parameters mentioned by the appellant also

led to the conclusion that the patent did not sufficiently disclose the subject-matter claimed. Even understanding the stability condition as meaning that the product was able to withstand a sterilisation step at at least 121 °C without losing its properties, namely without losing its suitability for the intended purpose, or while remaining substantially unaffected (which were two different conditions) did not help, as it was not known what were the allowed variations to maintain the diagnostic purpose and the required properties were different for different diagnostic purposes.

Remittal

d) As the appellant objected to the absence of verifiable facts to support lack of sufficiency in the statement of grounds, it was legitimate to corroborate the objection with further evidence. As this was done with the reply to the statement of grounds, there was sufficient time for the appellant to prepare and the whole debate on sufficiency of disclosure including the reproducibility of the invention in view of the experimental evidence should be dealt with in appeal proceedings. Remittal should be appropriate only if sufficiency were acknowledged after a complete examination of all sufficiency objections for an analysis of novelty and inventive step by the opposition division.

XII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division on the basis of the main request or, in the alternative, of one of auxiliary requests 1 to 6, all filed with letter of 17 March 2014. In

addition, the appellant requested that the evidence filed by the respondents in appeal, namely documents D32 and D33, as well as documents D35 to D37 and Annexes 1, 2 and 3 filed by letter of 15 May 2015 and the arguments related thereto not be admitted into the proceedings, and in case the documents of 15 May 2015 were not admitted into the proceedings, an apportionment of costs. Moreover, the appellant requested that the expert Mr Plantan not be allowed to address the Board during oral proceedings.

XIII. The respondent requested that the appeal be dismissed. In case the Board decided that any of the requests of the appellant met the requirements of Articles 100(b), 84 and 123 EPC and Rule 80 EPC, a remittal to the first instance was requested. In addition the respondent requested that documents D26 and D31 as well as auxiliary requests 2, 4 and 6 not be admitted into the proceedings.

Reasons for the Decision

Admittance of the late filed evidence and apportionment of costs

1. Documents D23 to D31 were filed by the appellant with the statement of grounds to counter the reasoning on sufficiency of disclosure in the appealed decision, in particular to support the position that the stability condition referred to autoclaving conditions and that the meaning of "stable" to autoclaving would be self-evident to the skilled person. Documents D32 and D33 were filed by the respondent as experimental evidence with the reply to the statement of grounds to counter the arguments of the appellant therein, in particular the view of the appellant that the respondent did not

provide verifiable facts which could raise any serious doubts. All these documents were therefore timely filed by the parties in appeal and can be seen as legitimate reactions to the decision or to the statement of grounds, so that the Board sees no reason under Article 12(4) RPBA not to admit them. On that basis documents D23 to D33 are admitted into the proceedings.

2. In reply to the filing of new experimental evidence, the appellant filed declaration D34 to express the doubts of an expert with regard to the experiments. With a late reply thereto the respondent filed documents D35 to D37 (with Annexes 1 to 3) to clarify the doubts expressed by the expert. These documents, in spite of having been filed after the statement of grounds and the reply thereto, can still be considered as a legitimate reaction to a new situation, namely the filing of new experimental evidence and the doubts expressed as to its correctness. While it is true that documents D35 to D37 were filed just a month before the oral proceedings, they do not add any experimental data, but provide only additional information on how and where the data in D32 and D33 were obtained. Moreover, their admittance into the proceedings does not cause any need of adjournment of the oral proceedings, as the Board decides anyway (see point 9, below) to remit the case to the opposition division for the analysis of sufficiency of disclosure in the light of the experimental evidence.

2.1 In view of that the Board finds it appropriate to exercise its discretion under Article 13 RPBA by admitting documents D34 to D37 and Annexes 1, 2 and 3 as well as the corresponding arguments into the proceedings.

3. As documents D35 to D37 and Annexes 1, 2 and 3 are admitted into the proceedings, the request of the appellant of apportionment of costs, which was conditional on these documents not being admitted into the proceedings, is not to be decided upon by the Board.

Main request - Rule 80 EPC, Articles 123 and 84 EPC

4. The amendment of claim 1 consisting in the introduction of the expression "by injection" gives a further specification to the intended use of the claimed complex which by means of that needs to be suitable for administration "by injection" and not simply suitable for any kind of administration. The fact that by means of this the appellant intended to limit the claim so as to possibly overcome *inter alia* the objection of lack of sufficiency is sufficient to meet the requirement of Rule 80 EPC.

5. The Board cannot follow the arguments of the respondent relating to a lack of a basis for the product-by-process of claim 1 with particular reference to what may be implied by the wording of the process steps, as it considers that a direct and unambiguous disclosure of the process (which is not denied by the respondent) directly implies the disclosure of the product obtained by the process. As to the use of the term "complex" instead of "colloid" in the recovering step, while the Board agrees with the respondent that a definition is given for the latter (page 16, lines 6 and 7) with the specification of a range for the particle size, the whole of the disclosure (see in particular the summary of the invention on pages 1 to 8 and the claims) addresses a method of providing a complex and the complex as such, so that the steps disclosed in the

original application to provide such a product (as e.g. the recovery step on page 15, lines 22-23) are understood by the skilled person as meant to obtain such a complex.

As to the complex being defined as "autoclavable" in claim 1 of the main request, such a term means that the complex may be subjected to autoclaving and it is therefore implied by the stability condition (a complex stable at a temperature of at least 121 °C for a period effective to sterilize the complex can be autoclaved, see in particular the understanding of the stability condition by a skilled person in point 8.4, below), which has not been objected to by the respondent and is based on original claim 20. In addition, both in the summary of the invention and in the claims all methods of providing an iron oxide complex include a sterilisation step (see page 1, line 25 - page 4, line 2 and claims 1 to 15) and all complexes are defined as being stable to sterilising conditions (see page 5, line 21 to page 6, line 4 and claims 18 to 29). As the skilled person understands that the methods of production disclosed are meant to produce the disclosed product, it is clear that by means of a process including a sterilisation step a product is obtained which is stable to sterilising conditions and therefore can be defined as autoclavable.

6. With regard to Article 123(3) EPC, the Board considers that the condition "stable at a temperature of at least 100 °C" cannot be understood by the skilled person as implying stability under any condition, as e.g. stability for any arbitrarily long period of time, all the more as such a condition would not make any technical sense (no medical product can be that stable). On the contrary, no limitation in time (or in

any other respect) is indicated in granted claim 1, so that a broad reading is to be given to the condition therein, which by virtue of the amendment in claim 1 of the main request ("stable at a temperature of at least 121 °C for a period effective to sterilize the complex") becomes more specific and more stringent, therefore not resulting in an extension of the protection conferred.

7. The feature objected to as lacking clarity ("being stable ... for a period effective to sterilize the complex") is the result of the amendment by means of which granted claim 2 is combined with granted claim 1. In line with decision G 3/14 of 24 March 2015 such a lack of clarity cannot be put into question in opposition proceedings.

Main request - revision of the decision on sufficiency

8. Lack of sufficiency on the basis of the feature "such complex being stable at a temperature of at least 121 °C for a period effective to sterilise the complex" was the main reason for revocation of the patent. In particular the opposition division came to the conclusion that the patent lacked sufficiency of disclosure, as the skilled person did not find in the specification which parameter(s) he should measure, how to accomplish the measurement(s) and which standard(s) to apply in order to assess stability. In the present decision only a revision of the appealed decision is accomplished with regard to sufficiency of disclosure, while the further objection based on additional evidence filed by the respondent in appeal will have to be analysed in subsequent opposition proceedings after remittal (see point 9, below).

8.1 The case in which undefined parameters or an undefined condition are used in the the claims and no details of the measuring methods are present in the patent is well known in the jurisprudence of the Boards of Appeal (Case Law of the Boards of Appeal of the EPO, 7th edition 2013, II.C.7.2), which jurisprudence should be taken into account in deciding on the issue. In this respect a central point according to the Board is that the question whether or not the skilled person knows if he is working within or outside of the scope of the claims is as such a matter of clarity of the claims and not of sufficiency of disclosure, particularly if an ambiguity exists at the edges of the claims. On the other side, the presence of an ill-defined parameter may under certain circumstances prevent the skilled person from being able to carry out the invention. Following T 0593/09 of 20 December 2011 (see point 4.1.4), the Board considers that what is decisive for establishing insufficiency is whether the parameter, in the specific case, is so ill-defined that the skilled person is not able, on the basis of the disclosure as a whole and using his common general knowledge, to identify (without undue burden) the technical measures necessary to put the claimed invention into practice.

8.2 In the present case the Board is of the view that the stability condition in claim 1 is not so ill-defined that a person skilled in the art is not in the position to carry out the claimed invention.

8.3 First of all, stability is in itself a fundamental condition of any pharmaceutical product, which, if suitable for the intended use at production, must remain suitable for that use up to the point in which it is employed. Even if in most cases a specific condition is not defined of what is meant by a stable

pharmaceutical product, the person skilled in the art would not consider the adjective "stable" as so uncommon and ill-defined as to lead to a lack of sufficiency.

8.4 In the opinion of the Board the specific stability condition in claim 1 of the main request is understood by the skilled person in this light as meaning that the product is able to withstand a sterilisation step at at least 121 °C (the autoclaving defined in the claim) without losing its properties, namely without losing its suitability for the intended purpose. In other words, as the product before sterilisation is suitable for administration by injection (apart from the potential presence of still to be eliminated micro-organisms), it must remain suitable for that use after sterilisation.

8.5 This reading of the claim is in agreement with the disclosure in the patent in suit.

8.5.1 In paragraph [0034] it is mentioned that, while terminal sterilisation (autoclaving) is a preferred method of sterilizing drugs for injection, upon exposure to the heat for the duration of the autoclaving process, the polymer coating can become dissociated from the iron oxide cores, which dissociation causes physical changes in the material, such as clumping, biodistribution changes (changes in plasma half life), and changes in toxicity profile (potential increases in adverse events).

8.5.2 In paragraph [0149] it is said that particles coated with carboxymethyl reduced dextran (i.e. according to claim 1 of the main request) showed even greater stability to the autoclaving process than particles

coated with carboxymethyl native dextran (not according to the claim). Reference was made to table 9 where it was shown that for the complex according to the invention (example 31) minimal variations were observed in the MVD, the pH and the number of particulates following autoclaving at 121 °C (the condition of claim 1, see paragraph [0147], first sentence) while the comparative complex showed a 10-50 fold increase in amount of particulate matter following autoclaving and had a larger change in pH.

8.6 In other words, it is indicated in the patent that a material which undergoes such physical changes as mentioned in paragraph [0034] clearly loses its suitability for the intended purpose and cannot be considered as stable and that, while several parameters may be associated to the concept of stability, greater stability is achieved when the material is not altered by the autoclaving step, so that if it is suitable for administration by injection before sterilisation, it remains suitable for that use after sterilisation.

8.7 As the condition of "suitability" for a specific use does not usually give rise to problems of sufficiency, even if normally a specific test with specific conditions is not defined, the same is valid for the present parameter. The limitation given by the condition may be broad and may not have sharply defined limits, but it does not appear to be so uncommon and ill-defined to prevent the skilled person from being able to carry out the invention. On the contrary, even if it is not stated in a conclusive way in the patent which parameters should be measured and which variations should be allowed, some indications are given (see paragraph [0149] and table 9, cited above) of relevant parameters and satisfactory variations,

which is more than what is normally present for a "suitability" condition.

8.8 With regard to how a product meeting the stability condition is obtained, the patent gives quite detailed information about the process for obtaining a complex according to the invention with the main process steps being included in claim 1 and it discloses at least one product (example 31) which is obtained according to the sequence of steps in claim 1 (see paragraph [0124] with reference to example 5 in paragraphs [0078] to [0080]), has properties which are unaffected by sterilisation at 121 °C (paragraphs [0147] to [0149] and table 9) and is disclosed as being stable.

8.9 Thus, based on the facts of the decision, it cannot be concluded that the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Remittal

9. Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given the opportunity of two readings of the important elements of a case. The essential function of an appeal is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance (Article 111(1) EPC).

9.1 While this typically applies when a first-instance department issues a decision against a party solely upon some issues which are decisive for the case and leaves other essential issues outstanding, remittal is equally to be considered in a case as the present one, in which the Board finds that the decision is not correct and a new issue even related to the same ground arises for the first time in appeal in view of new submissions and new evidence.

9.2 In the present case the objection of lack of sufficiency which led to the revocation decision was based on the lack of parameters, methods of measurements and standards for the determination of whether the claimed complex is stable. In this respect the Board finds that the decision of the opposition division does not hold good (see point 8, above). The lack of reproducibility based on experimental evidence is a completely different line followed by the respondent in appeal, which results in a fresh case on which the opposition division could not decide, as the experimental evidence and all the arguments related thereto were only filed in appeal.

9.3 In addition, the Board finds that this issue is closely related to the issues of novelty and inventive step, which both parties did not analyse in appeal proceedings, as they requested that the issues be decided upon by the opposition division. This is due to the fact that, if the line of arguments is followed that certain process steps necessarily lead to the desired result, this must equally apply to the patent (for the analysis of sufficiency) and to the prior art (for the analysis of novelty and inventive step). It is therefore reasonable that the related issues are decided together.

9.4 Taking all these facts into account, the Board considers a remittal to the first instance as appropriate.

9.5 None of the reasons invoked by the respondent is considered sufficient to justify a different conclusion. In particular, the fact that the evidence was filed with the reply to the statement of grounds, so that there was sufficient time for the appellant to react, does not change the facts that the issue was not decided upon by the first instance department, as the evidence and arguments were not brought before it, and that the outcome of this issue will have an impact on the examination of novelty and inventive step, which also have not yet been examined.

9.6 Thus, in view of the above considerations, the Board has reached the conclusion that, in the circumstances of the present case, it is appropriate to remit the case to the opposition division for the analysis of sufficiency of disclosure based on the experimental evidence provided by the respondent, as well as of the issues of novelty and inventive step on the basis of the main request.

Request that the expert of the respondent be allowed to speak during oral proceedings

10. As the experimental evidence filed by the respondent in appeal was not discussed during oral proceedings, there was no request during oral proceedings that the expert of the respondent be allowed to speak. The Board therefore did not need to decide whether he should be allowed to address the Board.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated