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Datasheet for the decision of 20 January 2010

Case Number: T 0560/09 - 3.3.10

Application Number: 05077887.7

Publication Number: 1674115

IPC: A61L 24/00

Language of the proceedings: EN

Title of invention:
Semi-synthetic platelet gel and method for the preparation thereof

Patentee:
Advance Holdings Limited

Opponent:
-

Headword:
Semi-synthetic platelet/ADVANCE HOLDINGS

Relevant legal provisions:
EPC Art. 84, 123(2)

Relevant legal provisions (EPC 1973):
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Keyword:
"Main an auxiliary requests 1 and 2: clarity of functional features (no) - no means of distinction"
"Auxiliary requests 3 to 5: amendments (not allowable)"

Decisions cited:
G 0002/88, T 0068/85, T 0337/95

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0560/09 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 20 January 2010

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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 13 October 2008 refusing European patent application No. 05077887.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: C. Komenda
Members: J.-C. Schmid
F. Blumer

Summary of Facts and Submissions

I. The appeal lodged on 12 December 2008 lies from the decision of the Examining Division dated 13 October 2008 refusing European patent application No. 05 077 887.7 with the European publication No. 1 674 115.

II. The decision of the Examining Division was based on the sets of claims according to the main and auxiliary requests 1 and 2.

Claim 1 of the main request read as follows:

"1. A semi-synthetic platelet gel, obtained from a platelet-rich plasma by adding a platelet activator and a synthetic polymer, comprising a platelet-rich plasma, at least one platelet activator that is able to activate the release of platelet growth factor, but is not capable of forming a clot in less than 15 minutes, and a biocompatible polymer selected from the group comprising carbomers, polyalkylene glycols, poloxamers, polyesters, polyethers, polyanhydrides, polyacrylates, polyvinyl acetates, polyvinyl pyrrolidones, polysaccharides, and derivatives thereof, wherein the said platelet-rich plasma and said at least one platelet activator have been added to the biocompatible polymer before the start of clot formation."

Claim 1 of auxiliary request 1 was identical to claim 1 of auxiliary request 2 and differed from claim 1 of the main request only in that "said at least one platelet activator is selected from the group comprising peptides capable of activating the thrombin receptor"

III. According to the Examining Division, claim 1 of these requests did not fulfil the requirement of clarity (Article 84 EPC), since there was no guidance in the claim how to achieve a platelet activator that is capable to activate the release of platelet growth factors, but is not capable of forming a clot in less of 15 minutes.

IV. On 26 October 2009, the Board issued a communication indicating *inter alia* that the application did not disclose a method permitting to determine without any ambiguity whether a platelet activator was "not capable of forming a clot in less than 15 minutes".

V. With letter dated 11 December 2009, the Appellant filed three further amended sets of claims as auxiliary requests 3, 4 and 5.

Claim 1 of auxiliary request 3, 4 and 5 differed from claim 1 of the main and auxiliary request 1 and 2 respectively only in that the wording "an amount of" was added before the wording "at least one platelet activator".

The Appellant submitted that the skilled person was able to determine the time of formation of a clot without the need of a detailed description in the application. The skilled person was moreover aware that the time for clot formation was depending from the amount and type of activator added and should be estimated empirically. He was perfectly able to choose from the known platelet activators the kind and the amount necessary to satisfy the requirement for an

activator of not being "capable of forming a clot in less of 15 minutes" without any ambiguity. The fact that the test must be estimated empirically was not a ground for sustaining that there was ambiguity in the method. The amount of the platelet activator used varied in the methods disclosed in the examples of the application because their activity also differed. A platelet activator for the purpose of the present application was to be understood as a certain amount of a certain kind of activator, which was able to activate the release of platelet growth factor, but was not capable of forming a clot in less than 15 minutes.

According the established case law (e.g. decision T 68/85, EPO OJ 1987, 228), it was permissible to draft claims including functional features. Moreover, the wording of the functional feature as such was perfectly comprehensible. The skilled man was easily able to determine the experimental conditions of a method of forming a clot and to ascertain without any ambiguity the time of its formation, the required time limit set for that formation, that is 15 minutes, being univocally determined in the claim. There was thus no lack of clarity at all in that feature. Even if some ambiguities existed in the method for determining the clot formation, this would not be prejudicial to the clarity of claim 1. There were ample methods disclosed in examples in the application indicating whether or not an activator satisfied that functional requirement or not. Example A gave clear instructions on how to obtain a platelet-rich plasma. Comparative examples 1 to 3 showed activators which were not suitable because they did not satisfy the functional requirement of not being capable of forming a clot in less than 15 minutes,

whereas examples 4 to 12 showed activators qualified for that function.

Furthermore, it was clear from the invention as a whole that the purpose of a threshold of 15 minutes for the clot formation was given to allow the skilled person sufficient time to safely add the biocompatible polymeric material before the formation of the clot. Hence, from that context, it was clear whether an activator was qualified for the invention or not. Further, it was also clear that calcium chloride in example 4 was an activator according to the invention while in comparative example 3 it was an activator outside the invention.

In the independent claims of auxiliary requests 3 to 5 "an amount of" was added before all occurrences of the expression "at least one platelet activator that is able to activate the release of platelet growth factor, but is not capable of forming a clot in less than 15 minutes". That meant that both the amount and the type of activator should be selected such that it activates the release of platelet growth factor without the formation of a clot in less than 15 minutes. The platelet activators disclosed in comparative examples 1 to 3 were not excluded for the purpose of the present application, provided that their amount in the gel was suitable to satisfy the requirement.

VI. The Appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the claims of the main request or, subsidiarily, on the basis of the claims of one of the auxiliary requests 1 to 5.

VII. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request and auxiliary requests 1 and 2: Article 84 EPC

2. Article 84 EPC in combination with Rule 43(1) EPC stipulates the requirements that the claims shall be clear and define the matter for which protection is sought in terms of the technical features of the invention. Those requirements serve the purpose of ensuring that the public is not left in any doubt as to which subject-matter is covered by a particular claim and which is not. From this principle of legal certainty, in the Board's judgement, it follows that a claim cannot be considered clear in the sense of Article 84 EPC if it does not unambiguously allow this distinction to be made (see decisions G 2/88, OJ EPO 1990, 93, point 2.5 of the reasons; T 337/95, OJ EPO 1996, 628, points 2.2 to 2.5 of the reasons). A claim comprising an unclear technical feature, hence, entails doubts as to the subject-matter covered by that claim. This applies all the more if the unclear feature is essential with respect to the invention in the sense that it is designed for delimiting the subject-matter claimed from the prior art, thereby giving rise to uncertainty as to whether or not the subject-matter claimed is anticipated. Thus, it is for the reason of

lack of legal certainty, that such a claim is not accepted to be clear in the sense of Article 84 EPC.

The technical features may also be expressed in general functional terms, if, from an objective point of view, such features cannot otherwise be defined more precisely without restricting the scope of the claim, and if these features provide instructions which are sufficiently clear for the skilled person to reduce them to practice without undue burden (see T 68/85, *loc. cit.* above). However, the function must be able to be verified by tests or procedures adequately specified in the description or known to the skilled person. That means not only that a feature in the claim must be comprehensible, but must also be non-ambiguous in the sense of it can be determined without any ambiguity whether the claimed functional requirement is satisfied of not. Hence, means of distinction are mandatory in order to allow a definition by a function instead of by a structure in a claim.

3. In the present case, claim 1 is directed to a semi-synthetic platelet gel composition comprising a platelet activator which is either not structurally characterized (main request) or is broadly defined as being a peptide (auxiliary requests 1 and 2). According to claim 1 the platelet activator is mainly characterized by the functional feature as being "not capable of forming a clot in less than 15 minutes". Therefore, the principle of legal certainty requires clear identification of the meaning of the technical feature "not capable of forming a clot in less than 15 minutes" in order to establish without any doubt the subject-matter covered by that claim, in particular,

since this technical feature defines one of the essential components of the claimed gel. Hence, there must be an unambiguous distinction between activators having the claimed function and activators not having this function.

4. The Appellant has neither alleged, nor provided any evidence of a generally applicable standardized method for the determination of the feature "not capable of forming a clot in less than 15 minutes" as such, nor is the Board aware of such method. On the contrary, the Appellant conceded that, in view of the biological matter involved, there can be no standardized method for the determination of the time of the formation of a clot.

Hence, due to the absence of any standardized method, the skilled person cannot verify whether this functional requirement is fulfilled without being confronted with the necessity to fix in an empirical way the experimental conditions of a method of forming a clot. Under these circumstances, it is entirely dependent on the skill, individual working method and laboratory practice of the skilled person to select an appropriate support material (e.g. platelet-rich plasma, gelled platelet-rich plasma, etc.) and experimental conditions for mixing the candidate activator into the support material to cause the formation of a clot (amounts, stirring, time of mixing, temperature, etc.). The resulting period of time for the clot formation will inevitably vary accordingly, thus rendering protean the characterisation of an activator by the function of being "not capable of forming a clot in less than 15 minutes".

The Board furthermore notes that this finding is supported by the application itself which teaches that the clot formation depends on the amount of the activator added (see page 3, line 5 to 7), with the consequence that the measured period of time for the clot formation strongly varies, so that a particular activator can fall either within the scope of the claim or outside, depending only on the quantity of the activator used in the method for forming the clot.

Hence, the definition of the (peptide) platelet activator by its ability of being "not capable of forming a clot in less than 15 minutes" lacks clarity, contrary to the requirement of Article 84 EPC.

5. The Appellant's argument that the claim did not no lack clarity because the wording of the functional feature *per se* was clear is not relevant in the present case, since the issue of lack of clarity is not caused by a lack of clarity of the wording of the claim *per se,* but because it is not possible to determine unambiguously whether or not an embodiment falls within the scope of the claim, which finding is not based on the clarity of the wording of the functional feature (see point 4 above). Accordingly, this argument must be rejected for lack of pertinence.

6. The Appellant's argument that with the methods disclosed in the examples of the application the skilled person would unequivocally recognise the qualified activators also does not convince the Board because these methods are not carried out with the same experimental protocol. Furthermore, it is worth noting

that comparative example 3 disqualifies calcium chloride for being a suitable platelet activator while this very same compound is qualified in example 4 as suitable.

7. The Appellant's argument based on the general context of preparation of the gel to provide guidance for the skilled man to recognise a suitable activator cannot convince the Board since anyway the activator is not defined in the claim by its intended function in the preparation of the gel in the Appellant's sense, i.e. to allow the skilled person sufficient time to safely add the polymeric material before the formation of the clot, so that this function is not a technical feature within the meaning of Rule 43(1) EPC characterizing the claimed gel or any ingredient thereof.

In claim 1 the activator is defined by the functional feature "not capable of forming a clot in less than 15 minutes", which is a technical characteristic which should allow the skilled person on an objective basis to establish unambiguously whether to qualify or to disqualify any activator as being "not capable of forming a clot in less than 15 minutes". This is not the case in the present application, since due to the lack of any standardized method, the same activator comprised in the claimed gel is open to be labelled "not capable of forming a clot in less than 15 minutes" or not depending on particular circumstances, thereby rendering the meaning of that feature protean.

8. Since the technical feature "not capable of forming a clot in less than 15 minutes" is unclear for the reasons given above, preventing the skilled person from

identifying the exact meaning thereof, the public is left in doubts as to the distinction of which activators are covered by claim 1 and which are not, which is at variance with the principle of legal certainty.

9. In these circumstances Appellant's main and auxiliary requests 1 and 2 must be rejected.

Auxiliary requests 3 to 5

10. *Amendments (Article 123(2) EPC)*

Claim 1 of auxiliary request 3 to 5 differs from claim 1 of the main and auxiliary request 1 and 2 respectively in that the gel comprises an amount of at least one platelet activator that is able to activate the release of platelet growth factor, but is not capable of forming a clot in less than 15 minutes.

It must first be examined by the Board whether or not the amendment complies with the requirement of (Article 123(2) EPC), i.e. whether it introduces subject-matter extending beyond the content of the application as filed.

In order to determine whether an amendment offends against Article 123(2) EPC it has to be examined whether or not a technical information has been introduced which a skilled person would not have objectively, i.e. directly and unambiguously, derived from the application as filed.

11. According to the Appellant this amendment is based on page 3, lines 5 to 7, on page 7 line 28 to page 8, line 3 and on the examples of the application as filed.

11.1 The passage on page 3 pertains to the section of the discussion of the state of the art and relates to drawbacks of known platelet gels disclosing that the time for clot formation depends on the amount and type of activators added and must be estimated empirically. Accordingly, this section does not form part of the disclosure of the invention and does not address the claimed semi synthetic gel. Accordingly, this section cannot constitute a proper basis for the amendment.

11.2 The section of page 7, line 28 to page 8, line 3 discloses the concentration of calcium salts or thrombin receptor activating peptides in the platelet-rich plasma. There is, however, no disclosure whatsoever in this section with respect to the required presence of platelet activators in the semi synthetic gel in an amount that is able to activate the release of platelet growth factor, but is not capable of forming a clot in less than 15 minutes.

11.3 The examples of the application as filed also do not provide a support for this amendment. Examples 1 to 3 are comparative examples and thus cannot support any amendment of the claimed gel and the other examples 4 and 5 do not report any clot formation at all. Accordingly, the examples of the application as filed do not provide a suitable support for the amendment requiring the presence of the platelet activators in an amount that is able to activate the release of platelet

growth factor, but is not capable of forming a clot in less than 15 minutes.

11.4 The Appellant further argued that the skilled person reading the application as filed would understand that both the activator and its amount should be selected to fulfil the requirement.

The finding of whether or not the subject-matter of a claim in a patent extends beyond the content of the application as filed is not a matter of what would be obvious for a skilled person, but rather a matter of which technical information a skilled person would directly and unambiguously derive from the content of the application as filed. In the present case, the fresh feature in claim 1 is not disclosed in the application as filed, so that the semi synthetic gel as now claimed comprising an amount of at least one platelet activator that is able to activate the release of platelet growth factor, but is not capable of forming a clot in less than 15 minutes, provides the skilled person with technical information which is not directly and unambiguously derivable from the content of the application as filed.

12. Consequently, claim 1 extends beyond the content of the application as filed, contrary to the requirement of Article 123(2) EPC, so that auxiliary requests 3 to 5 must be rejected.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

C. Rodríguez Rodríguez C. Komenda