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**Datasheet for the decision  
of 26 May 2015**

**Case Number:** T 1959/11 - 3.3.02

**Application Number:** 08170370.4

**Publication Number:** 2063272

**IPC:** G01N33/82, C07K14/47

**Language of the proceedings:** EN

**Title of invention:**

Porcine intrinsic factor

**Applicant:**

ABBOTT LABORATORIES

**Headword:**

Porcine intrinsic factor/ABBOTT

**Relevant legal provisions:**

RPBA Art. 12(4), 15(3)  
EPC Art. 56

**Keyword:**

Oral proceedings - held in absence of appellant  
Requests filed with grounds of appeal not admitted -  
requests not examined by the examining division  
Inventive step - (no)

**Decisions cited:**

G 0004/92

**Catchword:**



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Case Number: T 1959/11 - 3.3.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.02**  
**of 26 May 2015**

**Appellant:** ABBOTT LABORATORIES  
(Applicant) 100 Abbott Park Road  
Abbott Park, IL 60064-3500 (US)

**Representative:** Modiano, Micaela Nadia  
Modiano Josif Pisanty & Staub Ltd  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 15 March 2011  
refusing European patent application No.  
08170370.4 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** U. Oswald  
**Members:** T. Sommerfeld  
L. Bühler

## Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division, pronounced on 19 January 2011 and posted on 15 March 2011, in which European patent application 08170370.4, which was filed as a divisional application of the earlier European application 06734195.8, was refused under Article 97(2) EPC.
- II. The documents cited in the examination and appeal proceedings include the following:
- D1 Hewitt J et al., Genomics 1991(10), pp. 432-440  
D2 US 5227311
- III. The decision of the examining division was based on the set of claims of the then main and sole request, which was filed during oral proceedings on 19 January 2011. This request comprised 3 claims, of which independent claim 1 read as follows:
- "1. An isolated nucleic acid sequence comprising a nucleotide sequence having 100% identity to a nucleotide sequence selected from the group consisting of SEQ ID NO: 1 or of its complement, SEQ ID NO: 4 or of its complement, and SEQ ID NO: 7 or of its complement."
- IV. The examining division decided that the claims fulfilled the requirements of Articles 123(2), 76(1), 84 and 54 EPC but not those of Article 56 EPC.
- V. The applicant (hereinafter, the appellant) lodged an appeal against that decision, requesting that it be set aside and that a patent be granted according to the main request or, alternatively, according to the first,

second or third auxiliary requests, all filed with the statement of grounds of appeal.

The **main request** comprises 5 claims, claim 1 reading as follows:

"1. An isolated nucleic acid sequence comprising or complementary to a nucleotide sequence having 100% identity to a nucleotide sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 4, or an isolated nucleic acid sequence comprising or complementary to a nucleotide sequence having at least 85% identity to a nucleotide sequence consisting of SEQ ID NO: 7."

The **first and second auxiliary requests** comprise 3 claims each, claim 1 being identical to claim 1 of the main request.

The **third auxiliary request** also comprises 3 claims, claim 1 reading as follows:

"1. An isolated nucleic acid sequence comprising or complementary to a nucleotide sequence having 100% identity to a nucleotide sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 4, and SEQ ID NO: 7."

VI. As an annex to the summons to oral proceedings, the board issued a communication pursuant to Article 15(1) RPBA.

In said communication, the board summarised the situation and expressed a negative preliminary opinion concerning admissibility of the sets of claims filed

with the grounds of appeal. In addition, the board also made observations concerning inventive step.

VII. The appellant did not file any substantive reply to the board's communication but instead informed the board that it would not attend oral proceedings.

VIII. Oral proceedings took place on 26 May 2015 in the absence of the appellant.

IX. The appellant's arguments, in so far as relevant to the present decision, may be summarised as follows:

*Admissibility of requests*

No arguments were provided.

*Inventive step*

Document D1, considered as the closest prior art by the examining division, disclosed the cloning and isolation of human intrinsic factor. The technical effect derived from the difference to D1 was that a recombinant protein was provided for the first time which overcame the need to employ porcine intrinsic factor (IF) purified from natural sources. Although displaying an identity of 81%, there were important biochemical differences between human and porcine IF: in particular, they did not function in the same way when binding to vitamin B12, and thus it was not possible to simply replace the native porcine IF (which prior to the invention was the accepted "gold standard" in vitamin B12 testing) by recombinant human protein - even though it would in principle be more straightforward to employ the recombinant protein, since vitamin B12 assays were designed for the testing

of humans. At the priority date there was still a strong-felt need for recombinant porcine IF to replace native IF, as it could not have been expected that assays based on recombinant IF from other species would provide the required comparability to the established method. The fact that there was a lapse of more than 15 years between the publication of D1 and the completion of the applicant's invention was a pointer to the existence of an inventive step. The difficulties encountered with D1 were not eliminated by D2; on the contrary, although native porcine IF was known at the priority date (D2), the recombinant counterpart was still not available, which confirmed that the invention was not trivial.

- X. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, alternatively, on the basis of the first to third auxiliary request, all filed on 25 July 2011 with the statement of grounds of appeal.

### **Reasons for the Decision**

1. The appeal is admissible.
2. The oral proceedings before the board took place in the absence of the appellant who had been duly summoned but decided not to attend.

The present decision is based on facts and evidence put forward during the written proceedings and on which the appellant has had an opportunity to comment. Therefore

the conditions set forth in Enlarged Board of Appeal opinion G 4/92, OJ EPO 1994, 149, are met.

Moreover, as stipulated by Article 15(3) RPBA the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case.

3. Admissibility of requests

3.1 Appeal proceedings are intended to review the correctness of the decision of the first instance rather than to continue examination by other means. Thus, pursuant to Article 12(4) RPBA, it is at the discretion of the boards of appeal to admit requests which could have been presented in the proceedings before the department of first instance - or which were submitted but then withdrawn, as in the present case. When exercising their discretion, the boards take into account the circumstances of the particular case.

3.2 With the statement of the grounds of appeal, the appellant filed a main request and three auxiliary requests. None of these requests is identical to the sole request which was the subject of the contested decision. Instead, these requests correspond to the requests submitted with letter of 17 December 2010, as indicated by the appellant, but subsequently withdrawn and replaced by a sole "amended main request" (see the minutes of the oral proceedings, page 1, second and eighth paragraphs). By taking this course of action the appellant (then applicant), *de facto* prevented the examining division from reaching a decision on these requests.

- 3.3 In its communication accompanying the summons to oral proceedings, the board addressed the fact that the claims according to the requests at issue were identical to the ones withdrawn during the oral proceedings before the examining division and questioned the admissibility of said requests under Article 12(4) RPBA. The appellant has not, however, submitted any arguments in this respect.
- 3.4 The board notes that claim 1 of the main request encompasses sequences with at least 85% identity to SEQ ID No:7, while the claim 1 which was the subject of the appealed decision required 100% identity. Claim 1 of the present main request is thus broader than claim 1 decided upon by the examining division: such an amendment cannot therefore be considered a legitimate attempt to overcome the appealed decision. Moreover, the main request comprises claims 4 and 5 which were not part of the request decided upon by the examining division; as is apparent from the examination file, the examining division had raised objections under Articles 54 and 56 EPC against these claims (see the minutes of a telephone conversation sent 21 January 2011). Reinstating this request at appeal would thus compel the board to give a first ruling on critical issues, which is contrary to the purpose of appeal proceedings.
- 3.5 The board thus makes use of its discretion under Article 12(4) RPBA not to admit the main request into the proceedings. Since claim 1 of the first and second auxiliary requests is identical to claim 1 of the main request, these requests are also not admitted into the proceedings.



3.6 As regards the third auxiliary request, the board notes that the limitation of 100% identity to SEQ ID NO:7 is present in claim 1 (as well as in claims 2 and 3), that claims 4 and 5 of the main request have been deleted, and that the claims differ only to a minor degree from those considered by the examining division. The differences are not such as to hinder a review of the examining division's decision on inventive step. Therefore the board decides to admit the third auxiliary request into the proceedings.

4. Inventive step - third auxiliary request

4.1 The present claims are directed to nucleic acid sequences comprising or complementary to nucleotide sequences having 100% identity to a nucleotide sequence selected from the group consisting of SEQ ID NOs: 1, 4 and 7; these sequences encode the porcine intrinsic factor, corresponding to amino acid sequences SEQ ID NOs: 3, 6 and 9.

4.2 The board considers that document D2, which discloses the existence and isolation of porcine IF (see e.g. column 7, lines 53 and 54), is the closest prior art. The difference is that D2 does not disclose the nucleic acids encoding porcine IF, and the technical problem can be formulated as the cloning and provision of such nucleic acids. The solution consists of the nucleic acid sequences as claimed and, in view of the examples of the application, the problem can be considered as plausibly solved.

4.3 Since IF from other species and in particular human IF (D1) had already been cloned, it would be straightforward for the skilled person to construct probes enabling him to fish the correct porcine cDNA

without the need for inventive skill. Indeed, the availability of further homologue sequences (e.g. mouse and rat - page 2, last paragraph of the description as filed) would make it possible to determine regions of more conserved sequence, which assisted in the design of suitable primers for cloning. In view of the high sequence homology between the human and porcine proteins (identity of over 80%: see figures 5 and 7 of the application; see also page 27, lines 15 to 16 and 20 to 21, of the description as filed), the skilled person would have a reasonable expectation of success when embarking in the project of cloning porcine IF. This expectation of success would not be diminished by considerations concerning different binding properties towards vitamin B12, because said functional properties of the proteins are irrelevant for cloning, which is sequence-based and thus only requires availability of homologous nucleic acid sequences.

4.4 Contrary to the appellant's arguments, it is noted that the fact that the recombinant human protein could not be used to replace the native porcine protein in vitamin B12 testing would actually constitute a further incentive to attempt cloning of the porcine protein. According to the application (page 3, lines 3 to 10, and page 5, lines 19 to 24, of the description as filed), native porcine IF isolated using the procedures of the prior art lacked consistency in its purity and resulting performance in immunoassays, and therefore it was desirable to produce recombinant protein.

4.5 The skilled person had thus both the motivation and a reasonable expectation of success. Only routine PCR-based methods had to be used and, apart from the usual trial and error associated with cloning attempts based on homology to known genes, no technical difficulties

have been encountered which would justify an inventive step (see Example 1 of application, especially page 30, lines 18 to 27, of the description as filed).

4.6 In this context, appellant's argument that the lapse of 15 years between the publication of D1 (disclosing the cloning of human IF) and the priority date of the application should be taken as a pointer to inventive step cannot be accepted by the board. According to established case law, the "satisfaction of a long-felt need" alone is not to be regarded as indicative of inventive step: secondary indicia of this kind are only considered important for the assessment of inventive step in cases of doubt; they are not to be taken as justifying inventive step per se, when the overall picture of the state of the art leads to a different conclusion. In the present case, there are no doubts as to the absence of an inventive step upon an objective evaluation of the state of the art following the "problem-solution-approach".

4.7 The board thus comes to the conclusion that the claims of the third auxiliary request do not fulfil the requirements of Article 56 EPC.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



N. Maslin

U. Oswald

Decision electronically authenticated