BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

Datasheet for the decision of 30 January 2013

Case Number: J 0008/11 - 3.1.01

Application Number: 10001596.5

Publication Number: 2415877

IPC: C12Q 1/68, G01N 33/50

Language of the proceedings: EN

Title of invention:
Means and methods for diagnosing pancreatic cancer

Patentee:
Deutsches Krebsforschungszentrum

Opponent:
-

Headword:
Sequence listing/DKFZ

Relevant legal provisions:
EPC Art. 106(2)
EPC R. 30, 103(1)(a)
Decision of the President of the EPO dated 12 July 2007 concerning the filing of sequence listings

Relevant legal provisions (EPC 1973):
EPC R. 27a, 28

Keyword:
"Sequence listing for prior-art sequence (not required)"

Decisions cited:
J 0004/85, J 0033/89, J 0007/97, J 0007/11

Catchword:
See points 2 to 19 of the reasons.

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: J 0008/11 - 3.1.01

D E C I S I O N
of the Legal Board of Appeal 3.1.01
of 30 January 2013

Appellant: (Applicant)
Deutsches Krebsforschungszentrum
Im Neuenheimer Feld 280
D-69120 Heidelberg (DE)

Representative:
Dick, Alexander
Herzog Fiesser & Partner
Patentanwälte
Dudenstraße 46
D-68167 Mannheim (DE)

Decision under appeal:
Decision of the Receiving Section of the European Patent Office posted 22 December 2010 rejecting the applicant's requests that the Office withdraw the invitation under Rule 30(3) EPC and refund the late furnishing fee.

Composition of the Board:

Chairman: B. Günzel
Members: R. Moufang
R. Cramer

Summary of Facts and Submissions

I. The present appeal concerns a decision of the Receiving Section of the EPO, dispatched on 22 December 2010, refusing the applicant's requests that the invitation to remedy deficiencies pursuant to Rule 30(3) EPC be withdrawn and the late furnishing fee refunded.

II. European patent application 10001596.5 was filed on 17 February 2010 without a sequence listing. Its claim 1 was directed to a diagnostic method comprising, inter alia, the step of determining in a sample the amount of at least one biomarker selected from the biomarkers shown in Table 1 of the application. Table 1 listed 27 proteins with their names and database accession numbers. Page 3, lines 22 to 31 of the description contained the following passages:

> "The term 'biomarker' as used herein refers to a polypeptide as shown in Table 1 or a fragment or variant of such a polypeptide being associated to the presence or absence of pancreatic cancer to the same extent as the well known polypeptides recited in Table 1. The polypeptide biomarkers listed in Table 1, preferably, encompass the polypeptides referred to by public Uni Prot Accession numbers as well as variants of said polypeptides having essentially the same immunological and/or biological properties. Variants include polypeptides differ [sic] in their amino acid sequence due to the presence of conservative amino acid substitutions. Preferably, such variants have an amino acid sequence being at least 70%, at least 80%, at least 90%, at least

95%, at least 98% or at least 99% identical to the amino acid sequences of the aforementioned specific polypeptides."

III. On 1 July 2010 the Receiving Section sent out an invitation to remedy deficiencies pursuant to Rule 30(3) EPC. It was indicated that the application as filed contained a sequence listing which did not comply with the relevant rules since it did not include all the sequences disclosed in the application. In an annex to this invitation, it was pointed out, on the one hand, that where the application referred to sequences which belonged to the prior art and could be found in generally accessible databases, it was not necessary to include such sequences in the sequence listing, and, on the other hand, that where prior-art sequences were mentioned in claims or constituted essential features of the invention, they should be given in the sequence listing. The applicant was invited to remedy the deficiency indicated and to pay the late furnishing fee.

IV. In its response, the applicant submitted a sequence listing and paid the late furnishing fee. However it requested that the invitation according to Rule 30(3) EPC be withdrawn and the late furnishing fee be refunded, and submitted legal arguments in support of these requests.

V. Following a communication by the Receiving Section giving reasons why the applicant's requests could not be accepted, the applicant submitted further arguments and conditionally requested an appealable decision. The Receiving Section then dispatched the decision from which the present appeal lies.

VI. In its statement of grounds of appeal, the appellant requested that

- the decision of the Receiving Section be set aside,
- the invitation to remedy deficiencies be withdrawn,
- the late furnishing fee be refunded, and
- the appeal fee be reimbursed.

As an auxiliary measure, oral proceedings were requested.

VII. The arguments submitted by the appellant in its statements of grounds of appeal and before the Receiving Section can be summarised as follows:

- Pursuant to Rule 30(1) EPC, the filing of a sequence listing was required only if nucleotide or amino acid sequences were disclosed in the application. Accordingly, the Notice from the EPO dated 12 July 2007 concerning the filing of sequence listings (OJ EPO 2007, special edition No. 3, C.2, p. 84) stated that Rule 30(1) EPC governed "**disclosures** of nucleotide and/or amino acid sequences".

- The term "disclosed" had to be interpreted in the light of Rule 42(1) EPC which stated in sub-paragraph (c) that the description should disclose the invention, whereas in sub-paragraphs (b), (d), (e) and (f) - which dealt with the background art, the figures, the at least one way of carrying out the invention and the way in which the invention was industrially applicable - different terms, i.e. "indicate" and "describe", were used. Accordingly and in line with its dictionary definition, the

term "disclose" had to be understood as "to make known; reveal or uncover; allow to be seen; lay open to view". The term could therefore not be used in the context of something that was state of the art.

– The Notice from the EPO of 12 July 2007 also stated in point I.1.2 that "Where the description refers to sequences which belong to the prior art and can be found in publicly available sequence databases, it will not be necessary to include such sequences in the sequence listing". The further statement in the Notice that "Where the claim(s) refer(s) to prior art sequences or where sequences constitute essential features of the invention or are required for the prior art search, those sequences should be incorporated in the sequence listing" was not to be regarded as imposing an obligation in view of the use of the modal verb "should" (instead of "have to" or "must").

– In the present case the application did not literally disclose nucleic acid or amino acid sequences. The claimed diagnostic method did not refer to sequences but rather to biomarkers which were proteins. The biomarkers were listed in Table 1 of the application. These biomarkers as such were prior art, recited by their common names and publicly available under the respective database accession number. Furthermore, according to the description of the patent application, the term "biomarker" was not understood as being limited to the specific sequences publicly available, since

these sequences were merely one possibility among many others identifying the structure of the desired biomarker proteins. Due to the difference between the individuals, a protein might be represented by different amino acid sequences which were all allelic variants.

– There was no basis for assuming that the sequences were essential features of the invention. Such an assessment could be made only during substantive examination and was not a task of the Receiving Section. This was confirmed by the fact that the Receiving Section had apparently contacted a "competent" examiner.

– The sequence listing was not required for the prior-art search in the present case.

VIII. The board appointed oral proceedings to be held on 1 February 2013. The annex to the summons contained the board's preliminary opinion on the issues raised by the present appeal. The board expressed the view that the decision under appeal would have to be set aside, the invitation to remedy deficiencies under Rule 30(3) EPC withdrawn, and the late furnishing fee refunded, but that the appeal fee could not be reimbursed.

IX. In response to the summons, the appellant repeated the requests which it had already submitted in the grounds of appeal. It furthermore withdrew the auxiliary request for oral proceedings on the condition that the board decided on the remaining questions as indicated in the annex to the summons.

Reasons for the decision

Admissibility of the appeal

1. The appealed decision did not terminate the procedure up to grant concerning the present patent application. Pursuant to Article 106(2) EPC, it is therefore an admissibility requirement for the present appeal that the decision allowed a separate appeal. The board considers that the formulation "This decision is open to appeal" has to be interpreted as, at least implicitly, allowing a *separate* appeal. Thus the appeal is considered admissible.

Applicable legal provisions

2. The present appeal concerns a formal requirement which is laid down in Rule 30 EPC and which, if applicable, has to be complied with at the filing date. Accordingly, the appeal has to be assessed on the basis of the legal provisions which were in force at the filing date of the present application, i.e. on 17 February 2010 (for details see J 7/11 of 24 January 2012, point 2 of the Reasons). Thus, apart from Rule 30 EPC itself, the Decision of the President of the EPO dated 12 July 2007 concerning the filing of sequence listings (OJ EPO 2007, special edition No. 3, C.1, p. 26) is of relevance.

Interpretation of Rule 30(1) EPC

3. According to Rule 30(1) EPC, the filing of a sequence listing is required if nucleotide or amino acid sequences are disclosed in a European patent application. A corresponding requirement can be found in Rules 5.2(a) and 13ter.1(a) PCT which use the substantially identical wording "Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences".

4. The crucial issue in the present appeal is the interpretation of the term "disclosed" in Rule 30(1) EPC, namely the question whether a patent application which relates to the use of polypeptides well known in the prior art and which identifies these polypeptides by their common names and by database accession numbers concerning specific representative sequences has to be regarded as "disclosing" amino acid sequences.

5. In ascertaining the meaning of "disclosed" in Rule 30(1) EPC, it appears necessary to consider in more detail the legislative reasons for and the development of the requirement of filing sequence listings.

6. Already before the introduction of Rule 27a EPC 1973 (the predecessor provision of Rule 30 EPC) into the Implementing Regulations, the EPO published a Notice dated 15 November 1989 (Supplement to OJ EPO 12/1989) in which it strongly recommended that from 1 April 1990 patent applications containing nucleic acid and amino acid sequences should use a set of standard symbols and representation methods. In point 3 of the Notice, it was stated:

> "Paragraph 1.1 explains what inventions are affected by the rules. Patent applications containing disclosures of nucleotide or amino acid sequences **in which the applicant wishes to represent the sequence itself should include these representations** in conformity with the standards." (emphasis added)

At that time it was also well-established in the context of Rule 28 EPC 1973 (corresponding to Rule 31 EPC 2000) that a patent applicant who supplemented his written description by the deposit of micro-organisms or other biological material such as plasmids and viruses was not obliged to provide further written information concerning genetic sequences of this material. Such an obligation would have been irreconcilable with the very purpose of the deposit system, i.e. to make it possible to supplement the written description in cases where the biological material could not be described in such a manner as to enable the invention to be carried out by a skilled person. It was furthermore recognised that no deposit was necessary where the biological material was already publicly available, e.g. by means of a previous deposit (see Rule 28(1) EPC 1973).

7. By decision of the Administrative Council of the EPO of 5 June 1992 (OJ EPO 1992, 342) the Implementing Regulations of the EPC were amended inter alia by the insertion of a new Rule 27a which for the first time made sequence listings mandatory for European applications relating to nucleotide and amino acid sequences. New Rule 27a(1) EPC provided that the

description had to contain a sequence listing **if nucleotide or amino acid sequences were disclosed in the European patent application.**

8. The above decision was taken on the basis of Administrative Council document CA/7/92 dated 3 April 1992 which was drawn up by the President of the EPO. This document contained the following passages in points I.2 and 4 of its Part 1 (Explanatory Memorandum):

> "The President's decision will make it clear that the sequence listing must contain only those sequences which form part of the claimed invention and not those which are mentioned in the description as belonging to the state of the art."
> [...]
>
> **If, however, nucleotides or amino acids were originally included in the description only in the form of words, it would be inappropriate to request the applicant to file a sequence listing subsequently as this would inevitably result in new technical information being introduced** *[emphasis added]*. This may well be the case if the applicant has not yet sequenced the nucleotides or amino acids. Rule 27a EPC does not then apply, because the application does not contain any **sequences**, despite the fact that the invention refers to nucleotides or amino acids."

9. The details of the sequence listing requirement were then laid down in the Decision of the President of the EPO dated 11 December 1992 concerning the representation of nucleotide and amino acid sequences

in patent applications and the filing of sequence listings (Supplement No. 2 to OJ EPO 12/1992, p. 1). Its Article 1 stated:

> **"If the subject-matter of the invention disclosed in a European patent application is nucleotide or amino acid sequences** (in German: **"Hat die in einer europäischen Patentanmeldung offenbarte Erfindung Nucleotid- oder Aminosäuresequenzen zum Gegenstand"**) [emphasis added], the description shall contain a sequence listing complying with the WIPO Standard ST.23 reproduced in **Annex I**."

10. The EPO furthermore published a Notice dated 11 December 1992 (Supplement No. 2 to OJ EPO 12/1992, p. 3) which was intended to supplement the decisions of the Administrative Council and the President of the EPO and to clarify the new rules and the EPC and PCT procedures. In this Notice (see its Section I) the legislative goal of the new provisions was explained as follows:

> "The new provisions are intended to ensure that nucleotide and amino acid sequences are presented in a standardised form in European and international applications and to permit systematic EDP-based searches so that the quality of European and international search reports can continue to be guaranteed in the future. Finally, they will make it possible to set up, in co-operation with the United States Patent and Trademark Office (USPTO) and the Japanese Patent Office (JPO), an international patent sequence database which be accessible to the public."

11. The circumstances in which a sequence listing had to be filed were explained in point II.1.2 of the Notice as follows:

> "A sequence listing need only be filed for those sequences matching the definition given in WIPO Standard ST.23 paragraph 3(iii) and relating to the invention disclosed in the application.
>
> **A sequence listing is not required if the description refers to sequences which belong to the prior art. In this case, however, the sequence must be identified adequately - where applicable, by stating the database accession number - so that it can be found easily.**" [emphasis added]

12. It can be deduced from these explanations that at the time when new Rule 27a EPC was inserted into the Implementing Regulations and entered into force (on 1 January 1993) the EPO took the view that it was not the legislator's intention to make sequence listings mandatory in situations where the description merely referred to prior-art sequences, e.g. by indicating their common names and database accession numbers. The term "disclosed" in Rule 27a EPC was thus interpreted in a narrow manner in line with the explanatory memorandum in CA/7/92 (see point 8 above) and the established principles concerning the deposit of biological material, according to which no deposit is necessary where the biological material is already publicly available (e.g. by means of a previous deposit), and no genetic sequence information has to be provided when a deposit is made (see point 6 above).

13. In 1998 both the Decision of the President and the Notice from the EPO were replaced by amended versions (see Supplement No. 2 to OJ EPO 1998/11). However, the above-cited passages in Article 1 of the Decision and point II.1.2 of the Notice were not changed in substance.

14. After the revision of the EPC 2000 the Implementing Regulations were amended and Rule 27a EPC 1973 became new Rule 30 EPC 2000. Although amendments were made to the content of the rule, its paragraph (1) remained unchanged apart from the addition of a comma (see OJ EPO 2007, special edition No. 5, p. 45). The travaux préparatoires (see documents CA/PL PV 30 Nos. 88-93 and CA/PL PV 31 Nos. 21-23) do not contain any indication that the legislator intended this paragraph to be understood differently from before. The new Decision of the President dated 12 July 2007 concerning the filing of sequence listings (supra) uses in its Article 1(1) a wording ("If nucleotide or amino acid sequences are disclosed in a European patent application") that mirrors the wording of Rule 30(1) EPC.

15. However, in its updated Notice of 12 July 2007 concerning the filing of sequence listings (which replaced the 1998 version), the EPO interpreted Rule 30(1) EPC not exactly in the same way as it had done before. The relevant passage (see point I.1.2 of the Notice) now read:

> "Where the description refers to sequences which belong to the prior art and can be found in publicly accessible sequence databases, it will

> not be necessary to include such sequences in the sequence listing. [...] Where the claim(s) refer(s) to prior art sequences or where sequences constitute essential features of the invention or are required for the prior art search, those sequences should be incorporated in the sequence listing."

Thus, with respect to prior-art sequences referred to in the application, the 2007 version of the Notice makes a significant distinction. It considers that in certain circumstances a sequence listing is required, in others not.

16. However, the wording of Rule 30(1) EPC does not provide any basis for distinguishing different situations with respect to prior-art sequences referred to in patent applications. No such basis can be found in Article 1(1) of the Decision of the President dated 17 July 2007 either, which in any case could not change the meaning of Rule 30(1) EPC as the higher-ranking legal norm.

17. Furthermore, two of the criteria used as a basis for the distinction (i.e. "constitute essential features of the invention" and "required for the prior art search") seem to require a technical evaluation of the application. However, as rightly observed by the appellant, such a technical examination does not fall within the competence of the Receiving Section (see decisions J 4/85, OJ EPO 1986, 205, J 33/89, OJ EPO 1991, 288, and J 7/97 of 11 December 1997). Rather, the Receiving Section is restricted to a merely formal examination of the sequence listing requirements (see J 7/11 of 24 January 2012, points 9.2 and 15).

18. Hence, only a narrow interpretation of the term "disclosed", in line with the established practice and jurisprudence allowing references to publicly available deposits of biological material, reflects the intention of the legislator at the time when Rule 27a EPC 1973, the predecessor of Rule 30 EPC, was inserted into the Implementing Regulations (see points 6 to 14 above). This means that prior-art sequences do not require the filing of a sequence listing.

19. It follows from the above that the Receiving Section was wrong to apply Rule 30 EPC in the present case. Thus the decision under appeal has to be set aside, the invitation to remedy deficiencies under Rule 30(3) EPC withdrawn, and the late furnishing fee refunded.

Substantial procedural violation

20. The appellant did not submit any arguments in support of its request for reimbursement of the appeal fee. According to Rule 103(1)(a) EPC, such a reimbursement can be ordered only if is equitable by reason of a substantial procedural violation. In the present case the board fails to see any major procedural deficiency in the proceedings before the Receiving Section. In particular it appears that the right to be heard (Article 113(1) EPC) was respected and that the decision was fully reasoned (Rule 111(2) EPC).

21. The appellant argued before the Receiving Section that the invitation under Rule 30(3) EPC had incorrectly stated that a sequence listing had been submitted which did not comply with the relevant rules and that the

invitation had to be withdrawn for that reason alone. However, it seems that this erroneous statement did not mislead the appellant since the objection raised by the Receiving Section could be and was correctly understood in view of the further explanations contained in the annex to the invitation (see Sections III and IV above).

22. Therefore the appellant's request for reimbursement of the appeal fee cannot be allowed.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The invitation to remedy deficiencies under Rule 30(3) EPC is withdrawn.

3. The late furnishing fee is refunded.

4. The request for reimbursement of the appeal fee is refused.

The Registrar: The Chairman:

C. Eickhoff B. Günzel