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D E C I S I O N
of 23 October 2002

Case Number: T 0272/95 - 3.3.4

Application Number: 83307553.4

Publication Number: 0112149

IPC: C12N 15/16

Language of the proceedings: EN

Title of invention:
Molecular cloning and characterization of a further gene sequence coding for human relaxin

Patentee:
HOWARD FLOREY INSTITUTE OF EXPERIMENTAL PHYSIOLOGY AND MEDICINE

Opponent:
Aglietta, Amendola et al., Fraktion der Grünen im EP
Lannoye Paul- Fraktion der Grünen im EP

Headword:
Relaxin/HOWARD FLOREY INSTITUTE

Relevant legal provisions:
EPC Art. 99(1), 134, 52(2)(a), 53(a), 54, 56
EPC R. 55, 23(d), 23(e), 100(1)

Keyword:
"Admissibility of the opposition and appeal - yes"
"Contrary to ordre public or morality - no "
"Discovery - no"
"Novelty - yes"
"Inventive step - yes"

Decisions cited:

G 0003/99

Catchword:

-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0272/95 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 23 October 2002

Appellant: (Opponent 01)
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Representative:
-

Respondent: (Proprietor of the patent)
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Representative:
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 18 January 1995 rejecting the opposition filed against European patent No. 0 112 149 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairwoman: U. M. Kinkeldey
Members: F. L. Davison-Brunel

C. Holtz

Summary of facts and submissions

I. European patent No. 0 112 149 with the title "Molecular cloning and characterization of a further gene sequence coding for human relaxin" was maintained by the opposition division on the basis of the granted claims.

Granted claim 1 read as follows:

"1. A DNA fragment encoding human H2-preprorelaxin, said H2-preprorelaxin having the amino-acid sequence set out in Figure 2."

Granted claims 2 to 7 and 11 (partly) related to further DNA fragments encoding H2-relaxin. Claims 8 and 9 were directed to processes for the production of the fragments according to claims 1 to 7, claims 10, 11 (partly), 12 to 14 were directed to DNA transfer vectors comprising a DNA fragment encoding H2-relaxin. Claims 15 to 17 related to processes for making a DNA transfer vector comprising relaxin DNA, for making a fusion protein comprising relaxin, and for synthesizing H2-relaxin, respectively. Claims 18 to 24 were directed to H2-relaxin in various forms or to polypeptides having relaxin activity.

II. Two oppositions were filed by letter dated 9 January 1992. In this letter, the representatives were stated firstly to be acting for a group of 26 individuals representing the green fraction of the European parliament represented by the president of the fraction (Opponents (1)) and secondly, to be acting in a separate opposition for the president of the fraction

himself (Opponent (2)). One opposition fee was paid in the name of Opponents (1), and 18 of the 26 named persons subsequently filed an authorisation for the common representative.

III. The patent in suit was challenged under Article 100(a) EPC for lack of novelty and inventive step (Articles 54 and 56 EPC) as well as under Article 53(a) EPC as relating to subject-matter which was contrary to "ordre public" and morality and under Article 52 (2)(a) EPC for not being concerned with an invention but with a discovery.

IV. In its decision (OJ EPO, 1995, 388), the Opposition Division concluded under Article 53(a) EPC that an invention concerning a human gene was not an exception to patentability because it would not be universally regarded as outrageous: it did not amount to patenting life because DNA as such was not life but one of the many chemical entities participating in biological processes, no offence to human dignity had occurred as the woman who donated tissue was asked for her consent and her self-determination was not affected by the exploitation of the claimed molecules.
Under Article 52(2)(a) EPC, it was decided that in accordance with the long-standing EPO practice the claimed DNA fragments which were new in the sense of having no previously recognized existence were not to be considered as discoveries and, therefore, did not fall within the category of unpatentable inventions.

The existence of the claimed DNA fragments was not known or even hinted at before the priority date of the patent in suit. The requirements of novelty and inventive step were fulfilled.

V. Five persons from Opponents (1) filed a notice of appeal and paid the appeal fee through a non-professional representative on 28 March 1995. Opponent (2) did not file an appeal.

VI. In a communication dated 3 May 1995, the Board raised questions as to the admissibility of the appeal, inter alia because the notice of appeal was signed by a person not meeting the requirements of Article 134 EPC and because there was a change in the number of persons appealing in relation to the number of persons having filed the opposition.

VII. In response to the Board's communication, 17 persons filed authorisations for a professional representative on 13 July 1995. It was explained that one person had died since the decision under appeal had been taken. Opponent (2) filed a declaration that he intended to remain a party as of right under Article 107 EPC.

VIII. On 15 April 1999, the Board issued an interlocutory decision, referring to the Enlarged Board of Appeal (EBA) questions relating to the admissibility of an opposition and subsequent appeal jointly filed by a number of persons. The EBA answered these questions in decision G 3/99 (OJ EPO 2002, 347).

IX. Oral proceedings before the Technical Board of Appeal to hear the parties on all remaining issues were summoned to be held on 9 August 2002. The Board issued a communication pursuant to Article 11(2) of the Rules of Procedure of the Boards of Appeal indicating their provisional opinion that in view of decision G 3/99 (supra), the common opposition and appeal were both

admissible.

X. The Appellants/Opponents (1) withdrew their request for oral proceedings.

XI. The following documents are mentioned in the present decision:

(1): Hudson, P. et al., Nature, Vol. 291, pages 127 to 131, 1981,

(2): Haley,J. et al., DNA, Vol. 1, No. 2, pages 155 to 162, 24 August 1982.

XII. The Appellants' arguments on appeal may be summarized as follows:

Article 53 (a) EPC; exceptions to patentability

The same arguments were presented as had been presented to the opposition division (para IV, supra) to the avail that the claimed subject-matter constituted an exception to patentability under Article 53(a) EPC. The further opinion was expressed that it constituted a fundamental violation of a person's rights if an invention was derived from a his/her body and no consent had been obtained for the **specific** exploitation which was intended for the invention.

Article 52(2)(a) EPC; discoveries not being patentable matter

The essence of the invention was the elucidation of the genetic sequence of the H2-relaxin gene. In simple terms, the proprietor had obtained a code book from the

donors (the genetic material) and "cracked the code" (discovered the number and sequence of human relaxin genes). That was no more than a discovery of the characteristics of a substance which had existed in nature probably for many thousand years. So, in the meaning of the provision of Article 52(2)(a) EPC, the patent related to a discovery and, thus, was not patentable.

Articles 54 and 56 EPC; novelty, inventive step

As the gene encoding H2-relaxin was always present in the female body, it did not constitute novel subject-matter.

Even if it were considered novel, the fact remained that its isolation had only required well-known techniques and no difficulties were encountered in carrying out the experiment. Therefore, the claimed subject-matter was obvious especially in view of the prior art relating to the elucidation of the genetic sequence of the rat and porcine relaxin genes (documents (1) and (2)).

XIII. The Respondents (Patentees) essentially answered as follows:

The legal position with regard to the patenting of biotechnological inventions had changed significantly during the time the case had been pending and was now set out in Rules 23(b) to (e) of the European Patent Convention, which entered into force on 1 September 1999 (OJ EPO 1999, 437).

Article 53(a) EPC; exceptions to patentability

In Rule 23(d) EPC, four categories of biotechnological inventions were listed which were to be considered as exceptions to patentability under Article 53(a) EPC. The presently claimed invention did not fall under any of these categories and, therefore, was patentable.

Article 52(2)(a) EPC; discoveries not being patentable matter

Rule 23(e)(2) EPC made it clear that patent protection should extend to elements isolated from the human body or otherwise produced by means of a technical process even if the structure of that element was identical to that of a natural element. The claimed H2-relaxin DNA may, thus, be patented, in view of this provision.

Articles 54 and 56 EPC; novelty, inventive step

There was no disclosure in the prior art of the existence of H2-relaxin, let alone of a gene coding therefor. All claims were, therefore, novel.

No cogent reasons for there to be a lack of inventive step had been put forward. It was not even suspected before the priority date that H2-relaxin existed. All claims were inventive.

XIV. The Appellants requested that the decision under appeal be set aside and the patent be revoked.

The Respondents requested that the appeal be dismissed.

Reasons for the decision

Admissibility of the opposition and appeal by the Appellants

1. A notice of opposition was filed on behalf of 26 named persons (9 January 1992) and one opposition fee was paid (10 January 1992). Subsequently, a common representative was authorized by 18 of the 26 named individuals (3 May 1993). The Opposition Division decided that the opposition was admissible under Article 99(1) EPC and Rule 55 EPC and pursuant to Rule 100(1) EPC (decision of 18 January 1995). After the patent was maintained as granted, 5 out of the 18 individuals lodged an appeal in the name of the group through a non-entitled person. Subsequently, upon invitation by the Board of Appeal, 17 out of the 18 named individuals (the eighteenth being deceased) signed the notice of appeal and authorized a new common representative to act on their behalf (13 July 1995).

2. To the questions asked by the Board of Appeal in its interlocutory decision (section VIII, supra), in relation to the common opposition, the EBA (decision G 3/99, supra) answered that:

"1. An opposition filed in common by two or more persons which otherwise meets the requirements of Article 99 EPC and Rules 1 and 55 EPC, is admissible on payment of only one opposition fee.

"2. If the opposing party consists of a plurality of persons, an appeal must be filed by the common representative under Rule 100 EPC. Where the appeal is filed by a non-entitled person, the Board of Appeal shall consider it not to be duly signed and consequently invite the common representative to sign it within a given limit. The non-entitled person who

filed the appeal shall be informed of this invitation. If the previous common representative is no longer participating in the proceedings, a new common representative shall be determined pursuant to Rule 100 EPC.

"3. In order to safeguard the rights of the patent proprietor and in the interests of procedural efficiency, it has to be clear throughout the procedure who belongs to the group of common opponents or common appellants. If either a common opponent or appellant (including the common representative) intends to withdraw from the proceedings, the EPO shall be notified accordingly by the common representative or by the new common representative determined under Rule 100(1) EPC in order for the withdrawal to take effect."

3. Pursuant to Article 112(3) EPC, this decision is binding on the Board in assessing the admissibility of the opposition and appeal in the present case. A common representative was duly appointed (section VII, supra) and the further conditions set up by the EBA have also been met. For these reasons and taking into account that the further requirements of Article 99(1) and Rule 55 EPC for the filing of an opposition and, of Article 108 EPC and Rule 64 EPC for the filing of an appeal are fulfilled, the opposition and appeal are admissible.

Articles 53(a) and 52(2)(a) EPC, Rules 23(b) to (e) EPC

4. After the Directive 98/44/EC of 6 July 1998 was passed by the European Parliament, the Administrative Council of the EPO in its decision of 16 June 1999 amended the

Implementing Regulations of the European Patent Convention by adding to Part II of these Regulations a Chapter VI - Biotechnological inventions - comprising Rules 23(b) to 23(e), for the purpose of applying and interpreting the provisions of the Convention relevant to European patent applications and patents concerning biotechnological inventions. Article 2 of this decision states that it shall enter into force on 1 September 1999; the decision itself does not contain transitional provisions. The Board concludes from the absence of transitional provisions that the Administrative Council must have been of the opinion that Rules 23(b) to 23(e) EPC only gave a more detailed interpretation of the meaning of Article 53 EPC as intended from its inception, and hence were also applicable to cases already pending before 1 September 1999 such as the present case.

5. Having regard to Article 164(2) EPC, the Board has to examine whether or not the new rules insofar as they relate to Article 53(a) EPC are in conformity with this article. In decision G 1/98 (OJ EPO 2000, 11, point 5.3) dealing with the interpretation of Article 53(b) EPC, the EBA stated that Article 4(1)b and (3) of the EU biotechnology directive 98/44 (see supra) was intended to be interpreted in the same sense as the EBA interpreted the scope of Article 53(b) EPC (G 1/98, points 3.10, 5 and 6, see supra). This latter interpretation corresponds entirely to the new Rule 23(c) adopted by the Administrative Council, which in turn is based on the EU directive. The EBA, thus, found this Rule related to Article 53(b)EPC to be only interpretative. The present Board adopts this view, considers that the same holds true for the new rules as far as they relate to the interpretation of

Article 53(a) EPC and, thus, will apply Rules (e) and (d) to the present case.

Articles 53(a) and 52(2)(a) EPC; ordre public or morality; discoveries

6. The Appellants argued that the subject-matter of product claims 2 to 7, 10 to 14 and 18 to 21 fell within the category of exceptions to patentability or must be considered as a discovery of biological elements present in the human body which may not be patented.

7. To assess the validity of these arguments, Articles 53(a) and 52(2)(a) EPC are interpreted by the Board in accordance with the implementing Rules 23(d) and 23(e)(2)EPC. Rule 23(d) provides a list of processes and uses which are exceptions to patentability but does not mention any products. However, it is a non-exhaustive list, which implies that product claims relating to biological material may equally be found unallowable under Article 53 a) EPC. Rule 23(e)(2), however, defines which biological material originating from the human body may be patented. It states that:

"(2) An element isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequence of a gene may constitute a patentable invention, even if the structure of that element is identical to that of a natural element".

It follows from the text itself that the matter mentioned above is not to be considered as an exception

to patentability under Article 53(a) EPC. Claims 2 to 7, 10 to 14 and 18 to 21 are, thus, allowable under this article.

8. Claims 2 to 7, 10 to 14 and 18 to 21 directly or indirectly relate to DNAs encoding the human protein preprorelaxin or to the human preprorelaxin per se, which are described in the patent in suit on pages 9 to 15 as having been obtained by technical processes. They, thus, answer the definition of patentable elements of the human body given in Rule 23(e)(2) EPC. Accordingly, they do not fall within the category of inventions which may not be patented for being discoveries (Article 52(2)(a) EPC).

9. Thus, the Appellants' arguments under Articles 53(a) and 52(2)(a) EPC (see section IV and XII, supra) are answered by the new implementing Rules 23(d) and 23(e) EPC.

Article 54 EPC; novelty

10. There are no documents on file where the existence of the H2-relaxin gene is mentioned, let alone the sequences of this gene and of the corresponding H2-relaxin protein. Novelty is acknowledged.

Article 56 EPC; inventive step

11. The closest prior art is document (1) which describes the molecular cloning of the DNA encoding rat relaxin and also mentions that "The peptide hormone relaxin is produced...in many mammalian species, including pigs, rats and humans,....".

12. The problem to be solved can be defined as isolating and characterising a DNA encoding **a further** relaxin.

13. The solution provided to that problem is the human DNA fragment encoding the H2-relaxin having the specific sequence given in Figure 2.

14. Lack of inventive step was argued on the basis that a technique well-known at the priority date had been used to isolate this DNA fragment. The Board agrees that it may, then, have been common practice to isolate a DNA fragment from a given species by hybridisation of the cloned DNA to a probe consisting in the DNA encoding the same protein in another species, **when** there was some reason to expect that the sequences of both DNAs may be somewhat homologous **or at least when** no reasons existed to suspect an absence of homology. Here, there is evidence on file (document (2), page 155, right-hand column) relating to the cloning of the gene encoding porcine relaxin, that no significant hybridisation occurs between the rat and the porcine relaxin cDNAs. Thus, the skilled person would have had reasons to doubt that such an homology would exist between the human and rat or porcine relaxin DNAs ie. that the cloning technique using a probe derived from rat or porcine DNA would work. Furthermore, the skilled person may not have found it obvious to use the same cloning technique as that described in documents (1) and (2) based on the protein sequences of rat or porcine relaxin since the sequence of human relaxin was not known. Thus, there existed no reasonable expectation of success that the claimed human relaxin encoding DNA may be isolated. Inventive step is acknowledged.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

P. Cremona U. Kinkeldey