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Datasheet for the decision of 4 June 2013

Case Number: T 0923/09 - 3.3.08

Application Number: 97941508.0

Publication Number: 920534

IPC: C12Q 1/68

Language of the proceedings: EN

Title of invention:
Mutations in the diabetes susceptibility genes hepatocyte nuclear factor (HNF) HNF-1alpha, HNF-1beta and HNF-4alpha

Patent Proprietor:
Arch Development Corporation

Opponent:
Labor Lademannbogen

Headword:
Diabetes of the young/ARCH DEVELOPMENT CORPORATION

Relevant legal provisions:
EPC Art. 83, 113(1)

Keyword:
"Sufficiency of disclosure - no"

Decisions cited:
T 0182/89, T 0435/91, T 0609/02, T 1685/10

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0923/09 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 4 June 2013

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 9 February 2009 concerning maintenance of European patent No. 920534 in amended form.**

Composition of the Board:

Chairman: M. Wieser
Members: M. R. Vega Laso
J. Geschwind

Summary of Facts and Submissions

I. European patent No. 0 920 534 with the title "Mutations in the diabetes susceptibility genes hepatocyte nuclear factor (HNF) HNF-1alpha, HNF-1beta and HNF-4alpha" was granted on European patent application No. 97941508.0. The patent was granted with 64 claims.

II. An opposition to the grant of the patent was filed based on the grounds for opposition under Article 100(a) and (b) EPC, in particular that the claimed subject-matter lacked novelty (Article 54 EPC) and an inventive step (Article 56 EPC), and that the patent did not disclose the claimed invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

III. In an interlocutory decision under Articles 101(3)(a) and 106(2) EPC posted on 9 February 2009, the opposition division found that, as regarded the invention according to claim 29 of the main request (amended claims 1 to 64 filed at the oral proceedings), the requirements of Article 83 EPC were not fulfilled. However, claims 1 to 55 according to the auxiliary request (filed as "1st auxiliary request" at the oral proceedings) and the invention to which they related were considered to meet the requirements of the EPC.

IV. Independent claim 29 of the auxiliary request reads as follows:

"29. The use of HNF-1α polypeptides, HNF-1β polypeptides, or HNF-4α polypeptides for preparing a medicament for regulating diabetes in an animal."

V. The opponent (appellant) lodged an appeal against the interlocutory decision of the opposition division.

VI. Together with its statement of grounds of appeal, the appellant filed additional evidence and put forward arguments relating to sufficiency of disclosure and inventive step in respect of the claims regarded by the opposition division as allowable.

VII. The respondent (patent proprietor) replied to the statement of grounds of appeal.

VIII. As a subsidiary request, both parties requested oral proceedings.

IX. The parties were summoned to oral proceedings. In a communication under Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) attached to the summons, the board made observations with respect to the evidence submitted in appeal proceedings and expressed a provisional opinion on issues to be discussed during the oral proceedings, in particular issues in connection with Articles 123(2)(3), 84, 83 and 56 EPC.

X. By letter dated 6 May 2013 the respondent withdrew its request for oral proceedings and informed the board that it would not be represented at the oral proceedings.

XI. In reply to the board's communication, the appellant submitted observations and additional evidence in support of the objection of lack of inventive step.

XII. Oral proceedings were held on 4 June 2013, at which the appellant was not represented.

XIII. The submissions made by the appellant were essentially as follows:

The invention claimed in claims 29 to 44 was not sufficiently disclosed in the application as filed. Independent claims 29, 33, 38 and 43 had been amended in opposition proceedings by deleting the use of modulators of HNF-1α, HNF-1β or HNF-4α. In spite of the restriction to the use of the HNF polypeptides themselves, the requirements of Article 83 EPC were still not fulfilled because it was neither disclosed in the application as filed, nor was it known up to the present time, that the HNF polypeptides could in fact regulate diabetes in an animal. The contribution of the inventors was to identify some mutations in the HNF-1α, HNF-1β or HNF-4α genes associated with MODY (maturity-onset diabetes of the young). Even though this might allow the diagnosis of MODY, a possible use of the polypeptides for treating diabetes was completely speculative and not supported by either the examples in the application or evidence published later. Thus, in accordance with decision T 1685/10 of 6 June 2011, the requirements of Article 83 EPC were not fulfilled.

XIV. The submissions made by the respondent in writing, as far as they related to the decisive issues, may be summarized as follows:

The opposition division's finding that the requirements of Article 83 EPC were fulfilled, was correct. The

appellant had failed to present any verifiable facts to support its allegation that the HNF-1α, HNF-1β or HNF-4α polypeptides were not useful for the preparation of a medicament for regulating diabetes in an animal. The appellant's speculations with regard to allegedly non-working embodiments were entirely hypothetical and unfounded. The burden of proof to show insufficiency was clearly on the appellant (see decision T 182/89, OJ EPO 1991, 391). The inventors had identified HNF-1α, HNF-1β or HNF-4α as markers for diabetes and their experimental work had been rewarded with two "Nature" papers. In line with decision T 435/91 (OJ EPO 1995, 188), the allowed claims were in fair balance with this highly beneficial contribution to the field.

XV. The appellant (opponent) requested that the decision under appeal be set aside and the patent be revoked.

XVI. The respondent (patent proprietor) requested in writing that the appeal be dismissed.

Reasons for the Decision

Auxiliary request - Amended claim 29 - Article 83 EPC

1. Amended claim 29 of the auxiliary request underlying the decision under appeal relates to the use of HNF-1α, HNF-1β or HNF-4α polypeptides for preparing a medicament for regulating diabetes in an animal.

2. In the decision under appeal, the opposition division found that, with regard to claim 29 of the main request, the requirements of Article 83 EPC were not fulfilled.

However, the auxiliary request was considered to meet the requirements of the EPC, in particular those of Article 83 EPC. The opposition division stated that, in spite of the objections raised by the opponent (the present appellant), it did not have any further reasons to consider that the invention claimed according to the auxiliary request was not sufficiently disclosed in the application as filed (see section 4 of the decision under appeal).

3. This finding has been contested by the appellant arguing that the application does not include any information showing that suitability of the HNF-1α, HNF-1β or HNF-4α polypeptide to be manufactured and used for regulating diabetes.

4. According to the jurisprudence of the Boards of Appeal (see, *inter alia*, decision T 609/02 of 27 October 2004), where a therapeutic application is claimed in the form of the use of a substance for the manufacture of a medicament for a defined therapeutic application, attaining the claimed therapeutic effect is a functional technical feature of the claim. Consequently, in order to fulfil the requirements of Article 83 EPC the application as filed "*... must disclose the suitability of the product to be manufactured for the claimed therapeutic application*" (see decision T 609/02, point 9 of the Reasons).

5. In the present case, neither the general description nor the examples in the application as filed provide any technical information that could serve as guidance for a person skilled in the art seeking to carry out the invention claimed in claim 29. None of the examples

of the application relate to the use of the HNF-1α, HNF-1β or HNF-4α polypeptides for the manufacture of a medicament for the particular therapeutic application of regulating, i.e. treating or preventing diabetes in an animal. The examples in the application concern solely the identification of mutations in the HNF-1α, HNF-1β or HNF-4α genes associated with maturity-onset diabetes of the young (MODY), a relatively rare type of non-insulin-dependent diabetes mellitus characterized by an early age of onset (childhood or adolescence) and appearance in at least three consecutive generations. However, there is no technical information, for example in form of *in vitro* or *in vivo* experiments, to the avail that a polypeptide encoded by the HNF-1α, HNF-1β or HNF-4α gene has a direct effect on a metabolic mechanism specifically involved in MODY, let alone in any other type of diabetes.

6. Nor has the respondent submitted any experimental evidence showing that the HNF-1α, HNF-1β or HNF-4α polypeptides may in fact be suitable for treating or preventing diabetes, and in particular MODY.

7. Under these circumstances, the board cannot accept the respondent's argument that the burden of proof lies with the appellant. Although this might be generally true in the framework of establishing insufficiency of disclosure, it is certainly not the case when the application does not provide any technical information whatsoever, not even a single example that allows the skilled person to carry out the invention as claimed, i.e. in the present case to manufacture a medicament that has the effect of regulating diabetes, without an undue burden of experimentation.

8. In view of the above, the board concludes that the patent cannot be maintained on the basis of the claims according to the auxiliary request on file, because at least the invention according to claim 29 is not disclosed in the application as filed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Article 113(1) EPC

9. The reasons given by the board in the present decision refer to an objection which was apparent from the submissions of the appellant in appeal proceedings. The respondent was given the opportunity to file observations in writing and invited to oral proceedings under Article 116 EPC. Nevertheless, the respondent chose to withdraw its request for oral proceedings and not to be represented at the same. The provisions of Article 113(1) EPC are complied with (see also Article 15(3) RPBA).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

A. Wolinski M. Wieser