

08-10-07

STATEMENT OF GROUNDS

Re: European Patent No. 0411678 of Genctice Institute Inc.

Opposed by Amgen Inc.

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Without limiting the generality of the Grounds of Opposition as set out in the Notice of Opposition, there is set out hereinafter an indication of the facts, evidence and arguments in support of these grounds.

1. Claims 8 to 11 of the opposed Patent claim recombinant erythropoietin produced by CHO cells and characterized by having O-linked glycosylation. The problem to be solved was simply the production of recombinant erythropoietin which exhibited suitable activity *in vivo*. The problem to be solved by the opposed Patent, however, had already been solved in the same manner as recited in the opposed Patent because recombinant erythropoietin having suitable *in vivo* activity was produced using Chinese Hamster Ovary ("CHO") cells by Amgen Inc. as disclosed in EP-A-0148605. This recombinant erythropoietin also contains O-linked glycosylation as recited in Claims 8 to 11 of the opposed Patent. The particular type of glycosylation linkages was simply a result of the type of host cell used to produce the recombinant erythropoietin.

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2. The opposed Patent claims priority of three U.S. Applications, namely Serial Nos. 677813, 688622 and 693258. None of these Applications, however, contain any disclosure referring to the glycosylation pattern of the erythropoietin produced by the examples in the opposed Patent. The first mention of the glycosylation pattern, including O-linked glycosylation, was made in the filing of the International Application, WO 86/03520, which was filed on 3rd December 1985. Consequently, the claims at issue of the opposed Patent which recite O-linked glycosylation can only be accorded the priority date of 3rd December 1985. There was no disclosure in any of the prior Applications from which priority is claimed which would support the claims.
  
3. Claims 8 to 11 (and Claims 7 to 10 for Austria) of the opposed Patent lack novelty under Article 54(2) EPC in view of the teachings of EP-A-0148605 (Document 1) which discloses the production of recombinant erythropoietin as claimed using CHO cells. See Example 10 of Document 1. EP-A-0148605 is a novelty bar as of its earliest priority date, namely 13th December 1983. The presence of O-linked glycosylation in the product produced in accordance with Example 10 of EP-A-0148605 has been demonstrated. (See below).
  
4. EP-A-0148695 was published in July 1985 and product produced in accordance with Example 10 of EP-A-0148695 was

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on sale in the United States and Europe beginning in early 1985 by Amgen Biologicals, a Division of Amgen Inc. As demonstrated in the Declarations of Drs. Strickland and Browne of Amgen filed in connection with the Opposition by Cilag GmbH to the opposed Patent, samples of the same lot of product which was sold in the United States and Europe in August and September 1985 were analyzed according to methods available at that time and were shown to have O-linked glycosylation. This product was made according to the procedures of Example 10 in EP-A-0148605. The details of the sales of product and the analysis are reported in the Declarations.

5. Accordingly, a person skilled in the art could, in July 1985, have produced the recombinant product following Example 10, even in the absence of the availability of the product on the market, and analyze the product and detect the presence of O-linked glycosylation. Consequently, the novelty of Claims 8 to 11 (and Claims 7 to 10 for Austria) of the opposed Patent is destroyed by EP-A-0148605 and by the public use and sale of recombinant erythropoietin having O-linked glycosylation prior to the priority date of the claims of the opposed Patent. Reference is hereby made to the Technical Board of Appeal Decisions Nos: T99/85 and T114/86, which Decisions lay down the clear principle that a known product may not be patented again merely by being described in another way.

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6. Accordingly Claims 7 to 10 for Austria and Claims 8 to 11 for the remaining designated states of the opposed patent lack novelty.
  
7. If it is held that Claims 7 to 10 for Austria and Claims 8 to 11 for the remaining designated states are novel, then these Claims lack inventive step under Article 56 EPC. In view of the teachings of EP-A-0148605 of how to produce recombinant erythropoietin, it was a matter of routine in 1985 for a person skilled in the area of carbohydrate analysis to determine whether the recombinant erythropoietin produced in accordance with the teachings of EP-A-0148605 had O-linked glycosylation. It is not a patentable invention simply to analyze a known product and to report a particular structural feature determined through the analysis. There is a total lack of carbohydrate analysis reported in any of the United States Applications filed prior to the December 1985 PCT filing. Certainly, the continuing effort to analyze and determine the structure of erythropoietin does not provide a new invention each time a structural element is characterized because the simple elucidation of a structural feature of a known product does not qualify as a novel or inventive step in order to support patentability.
  
8. Accordingly Claims 7 to 10 for Austria and Claims 8 to 11 for the remaining designated states of the opposed Patent lack inventive step.

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9. It is respectfully requested that all claims be revoked or amended in some way that overcomes the objections raised herein. If the Opposition Division do not intend to revoke the Patents in toto, Oral Proceedings are requested.

Dated this 8th day of October 1992.

*J. D. Brown*  
*for*

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BROWN, John D.,  
Representative,  
Forrester & Boehmert,  
Franz-Joseph-Strasse 38,  
D-8000 MUNCHEN 40,  
Germany.

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