Amgen Inc. v. F. Hoffmann-LaRoche LTD et al Doc. 325 Att. 17
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PATENT APPLICATION

IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

Application of:	)	"PRODUCTION OF
	)	
FU-KUEN LIN	)	ERYTHROPOIETIN"
	)	
Serial No: 07/113,178	)	Group Art Unit 186
	)	
Filed: October 23, 1987	)	Examiner J. Kushan

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AMENDMENT

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

Responsive to the Official Action dated June 20, 1989, kindly amend the above-identified application as follows:

IN THE CLAIMS

Kindly amend the claims as follows:

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67. (Amended) A non-naturally occurring glycoprotein product of the expression of an exogenous DNA sequence in a non-human eucaryotic host cell, said product having a primary structural conformation and glycosylation sufficiently duplicative of that of a naturally occurring human erythropoietin to allow possession of the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells and having an average carbohydrate composition which differs from that of naturally occurring human erythropoietin.

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REMARKS

Applicant wishes to express appreciation to Examiners Kushan and Schain for their time and thoughtful consideration of the issues during the interview of June 22, 1989, with Mr. Steven Odre and the undersigned. It is earnestly believed that the interview materially advanced prosecution of the subject application (a copy of the Interview Summary is attached).

Reconsideration and allowance of the subject application are respectfully requested. The art cited in the subject Official Action has been carefully considered by the Applicant together with the Examiner's comments relative thereto and, in response, Claim 67 has been amended to read "a non-naturally occurring glycoprotein product of the expression of an exogenous DNA sequence in a non-human eucaryotic host cell". This amendment has been made without prejudice to Applicant's right to pursue the broader claim in a later application.

Claims 67-75 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the prior invention as set forth in claims 1-11 of U.S. Patent 4,667,016. Reconsideration is requested.

All of the claims of commonly owned Lai et al., U.S. Patent 4,667,016 relate to a process of purifying glycoproteins, including a process of purifying recombinant erythropoietin.

Chisum in Patents at §9.03[1] states:

> Double patenting is concerned with attempts to *claim* the same or related subject matter twice. Thus, the standard for comparison for the second patent is what was claimed in the first patent, not what was disclosed in the specification of the first patent. For example, an inventor may file one application disclosing A and B but claiming only A. Once the patent issues, the inventor may not claim A in a second patent because of the doctrine of double patenting. But he may be able to claim B if it is sufficiently distinct from A considering the prior art (other than the inventor's own disclosure of B).

Chisum at §9.03[3] in discussing obviousness-type double patenting notes:

> In the second type [of double patenting], the applicant seeks a second patent for a different invention which is, in the light of the prior art, an obvious modification of what is claimed in the first patent. This corresponds to the patentability standard for double patenting which most decisions follow. *The test for obvious modification is basically the same as the nonobviousness requirement of patentability with the difference that the disclosure of the first patent may not be used as prior art* (emphasis added).

See also In re Kaplan, 229 U.S.P.Q. 678 (CAFC, 1986).

There is nothing in the method of purification claims of the Lai et al. patent (the "first patent") which alone or in combination with other prior art references render obvious the recombinant glycoprotein product of subject claims. Clearly, the respective sets of claims are patentably distinct.

Claims 67-75 stand rejected under 35 U.S.C. §112, first and second paragraphs. Reconsideration is requested.

Regarding point 1 raised by the Examiner, the phrase "a primary structural conformation" particularly points out the subject matter which applicant regards as the invention, and is defined at page 19, line 2, of the subject specification as a "continuous sequence of amino acid residues". Further, page 90, lines 10-17 state "While the deduced sequences of amino acid residues of mammalian EPO provided by the illustrative examples essentially define the primary structural conformation of mature EPO, it will be understood that the specific sequence of 165 amino acid residues of monkey species EPO in Figure 5 and the 166 residues of human species EPO in Figure 6 do not limit the scope of useful polypeptides provided by the invention". Thus, it can be seen that the phrase "primary structural conformation" as used in the specification and claims, relates to amino acid sequence.

Regarding point 2, Claim 67 relates to a recombinant glycoprotein product having a "primary structural conformation and glycosylation sufficiently duplicative of that of naturally occurring human erythropoietin to allow possession of in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells". Applicant submits that the disclosure of the subject invention supports a claim of this breadth. Example 11, for example, relates to analogs of naturally occurring human erythropoietin, and the specification clearly enables one of skill in the art to prepare additional analogs having the properties claimed.

Regarding point 3 raised by the Examiner, Claim 67 relates to a glycoprotein product possessing the "in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells". As discussed with the Examiner during the interview, Claim 67 particularly points out and distinctly claims the subject matter of the subject invention.

Regarding point 4, the Examiner has stated that Applicant has not shown how to produce biologically active in vivo species of EPO produced by non-mammalian cell hosts. Examples 11 and 12 of the subject application relate to transfecting yeast cells and the expression of biologically active erythropoietin from such host cells. Although the yeast cell product may have a different level of activity from the mammalian cell product, it nonetheless has the claimed biological activity.

Claims 67-73 stand rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103 as obvious over Sugimoto et al. Reconsideration is requested in view of the above-noted claim revisions and further in view of the remarks which follow.

Claim 67 has been amended to state "a non-naturally occurring glycoprotein product of the expression of an exogenous DNA sequence in a non-human eucaryotic host cell...". Unlike the glycoprotein product of the subject claims, which results from the expression of an exogenous DNA sequence in a non-human eucaryotic host cell, Sugimoto et al. relates to erythropoietin assertedly produced by a human lymphoblastoid cell line. Applicant submits that there is no evidence or reason to believe that erythropoietin produced by a human lymphoblastoid cell line is identical to the glycoprotein product produced by a non-human transformed or transfected cell line. In the response filed December 5, 1988, the Strickland Declaration established the difference between human produced urinary erythropoietin and the recombinant glycoprotein. As discussed with the Examiner during the interview, urinary-derived erythropoietin is active in vivo. There is no teaching in Sugimoto et al. that the carbohydrate composition of the product produced is different from urinary-derived erythropoietin. Nor is there any teaching that the Sugimoto et al. product is the same as the recombinant glycoprotein claimed herein.

With regard to the alternative rejection under 35 U.S.C. §103, the Examiner is referred to pages 5-7 of the Response filed June 2, 1989 where evidence of Graham v. John Deere "secondary considerations" are discussed.

Claims 67-75 stand rejected under 35 U.S.C. §103 as being unpatentable over Sugimoto et al., in view of Papayannopoulo et al. Reconsideration is requested.

This rejection includes the same reference as the above-noted prior art rejection with the addition of the Papayannopoulo et al. reference which relates to increasing the hematocrit of animals. The subject matter of the claims is unobvious in view of these references for the reasons noted above in response to the first prior art rejection.

In view of the above, Applicant respectfully submits that all claims now pending herein fully and patentably define the present invention over the applied art of record. As such, entry of the Amendment and an early receipt of the Official Notice of Allowance is awaited.

* * *

Applicant wishes to draw the Examiner's attention to the fact that two interferences have been declared: (1) Interference 102,096 involves commonly owned U.S. Patent 4,703,008 (which resulted from U.S. Serial No. 675,298) which relates to the gene coding for erythropoietin, vectors containing the gene, and transfected host cells; and (2) Interference 102,097 involves commonly owned U.S. Serial No. 113,179 (a continuation of U.S. Serial No. 675,298) which relates to a process of producing recombinant erythropoietin. Both interferences involve Fritsch et al., U.S. Serial No. 693,258, assigned to Genetics Institute.

Applicant strongly believes that the subject application should not be involved as an application in an interference with Fritsch et al., and should be allowed to issue as a patent. The reasons for this position are set forth below.

The present application, filed October 23, 1987, is a continuation of U.S. Serial No. 675,298, filed November 30, 1984 (issued as U.S. Patent No. 4,703,008), which is in turn a continuation-in-part of U.S. Serial No. 655,841, filed September 28, 1984, which is in turn a continuation-in-part of U.S. Serial No. 582,185, filed February 21, 1984, which is in turn a continuation-in-part of U.S. Serial No. 561,024, filed December 13, 1983.

Fritsch et al., U.S. Serial no. 693,258, filed January 22, 1985, is a continuation-in-part of application Serial No. 688,622, filed January 3, 1985.

M.P.E.P. Section 2303 states:

> Interferences will not be declared between pending applications if there is a difference of more than 3 months in the effective filing dates of the oldest and the next oldest applications, in the case of inventions of a simple character, or a difference of more than 6 months in the effective filing dates of the applications in other cases, except in exceptional situations, as determined and approved by the group director.

The effective filing date of the subject application is December 13, 1983 while the effective filing date of Serial No. 693,258 is January 3, 1985. The difference in effective filing dates is almost 13 months, over twice the maximum period specified by the M.P.E.P. Additionally, a 608(b) showing is not in and of itself an "exceptional situation" under M.P.E.P. 2303.

It is manifest that a 608(b) showing with respect to a claim directed to a gene encoding erythropoietin is not necessarily sufficient with regard to claims to a biologically active glycoprotein.

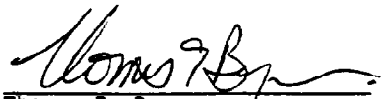
A declaration of interference prior to issuance of a patent on the subject matter claimed, would result in continued irreparable harm to Applicant and his Assignee by denying them access to an appropriate forum to seek redress for ongoing infringement activities. To declare an interference on applications filed more than six months apart would preclude the earlier application from enforcing claims in the appropriate forum for at least a two-year period while the interference is conducted, and more likely considerably longer than two years when pre-interference matters and the appeal process are considered. In the meantime, foreign competition would have risk-free access to the U.S. markets. Any potential infringing competition would not be prejudiced by issuance of the claims because all patent defenses would be available, and a party could copy claims of the issued patent.

Therefore, it is submitted that no interference should be declared between the present application and the Fritsch et al. application Ser. No. 693,258, and the subject application should be permitted to issue in accordance with M.P.E.P. 2303.

Should any small matters remain outstanding, the Examiner is encouraged to telephone Applicant's undersigned attorney collect at (805) 499-5725, so that same can be resolved without the necessity of an additional action and response thereto.

Respectfully submitted,

AMGEN INC.

By 

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July 11, 1989

The following cases have Fritsch as a named inventor and are related to the EPO cases in interference.

#	Serial #	Status	Location	Patent #	Claims
1	06/693,258	Interference	430	none	...
2	06/824,688	Suspended	18X (JPK)	none	8,13,17,28-31 (N,P)
3	07/136,478	no action	18B (GD)	none	?
4	07/386,280	no action	18X (JPK)	none	4 (broadly)

Case 1 is in interference now with respect to two counts, one for the gene and one for the process of making EPO. This case has pending non-elected claims drawn to mammalian cell produced recombinant EPO.

Case 2 has been suspended in view of the interference of case 1. This case also has pending non-elected claims to recombinant EPO produced in mammalian cell hosts. The restriction requirement was never made final during the prosecution of this application.

Case 3 has recently had a petition granted by the Group Director of 180, has had no actions taken on the case, and is not currently available for inspection to determine if it has a pending EPO claim.

Case 4 has not had an action taken in the case, and has one claim which is very broad which encompasses EPO as one species. The claim to the protein in that case is not specific for EPO, but the specification has examples drawn to recombinant EPO produced in mammalian cells.