

EXHIBIT M



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of

FU-KUEN LIN

Serial No.: Rule 60 Continuation of
07/113,179

Filed: November 6, 1990

For: PRODUCTION OF ERYTHROPOIETIN

November 6, 1990

PRELIMINARY AMENDMENT

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

Sir:

Please amend the above-identified continuation
application as follows:

IN THE SPECIFICATION

Please delete lines 3-6 and insert the following
text in place thereof:

--This is a continuation of my co-pending U.S.
Patent Application Serial No. 07/113,179, filed October 23,
1987, which is in turn a continuation of U.S. Patent
Application Serial No. 675,298, filed November 30, 1984
which issued as U.S. Letters Patent No. 4,703,008 on
October 27, 1987, which was a continuation-in-part of my co-

11a

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*2/b
3/13
encl.*

pending U.S. Patent Application Serial No. 561,024, filed December 13, 1983, now abandoned, and a continuation-in-part of Serial No. 582,185, filed February 21, 1984, now abandoned, and a continuation-in-part of Serial No. 655,841, filed September 28, 1984.--

Page 7, line 27, "32 member" should be

--32-member--.

Page 8, line 22, please delete the second occurrence of "the".

Page 11, line 3, "Expt.Hematol." should be

--Exp.Hematol.--.

Page 11, line 4, "(1980;" should be --(1980);--.

Page 11, line 5, please insert a space before "1832".

Page 13, line 13, please insert --- after "effects".

Page 13, lines 20-21, please insert --) after "propagation".

Page 22, line 4, "Tables V and VI" should be --Figures 5 and 6--.

Page 22, line 22, "Table VI" should be --Figure 6--.

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At page 25, following line 5 of the original text,
please insert the following: --Reference is made to FIGURES
1 through 21, wherein: FIGURE 1 is a graphic representation
of a radioimmunoassay analysis of products of the invention;
FIGURES 2 through 4 illustrate vector constructions
according to the invention, and, FIGURES 5 through 21 are
DNA and polypeptide sequences according to the invention.--

Page 27, line 24, "Example" should be

--Examples--.

Page 30, line 21, please delete "Asn" and insert

--Asn-- in place thereof.

Page 31, line 5, please delete "and RIA Analysis".

Page 32, line 35, please delete the comma (,) after "Springs".

Page 34, line 32, after "83", please insert

aa³
--deposited with the American Type Culture Collection, 12301
Parklawn Drive, Rockville, Md., under deposit Accession No.
A.T.C.C. 67545 on October 20, 1987--

At page 37, line 6, please delete "Table V" and
insert --FIGURE 5, comprising portions 5A, 5B and 5C.--.

At page 37, line 6, please delete "Table" and
insert --FIGURE--.

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Please delete the entire text of pages ~~38~~ through
40.

At page 41, line 1, please delete "Table V" and
insert in place thereof --FIGURE 5--.

Page 41, line 20, please delete "~~18~~", pp. 533-543
(1979) and insert --supra--.

Page 41, line 29, please delete "NEF-976" and
insert --NEF-972--.

Page 42, line 24, after "AhE1", please
insert--deposited with the American Type Culture Collection,
12301 Parklawn Drive, Rockville, Md., under deposit
Accession No. A.T.C.C. 40381 on October 20, 1987--

At page 42, line 25, please delete "Table VI" and
insert in place thereof --FIGURE 6, comprising portions 6A,
6B, 6C, 6D and 6E--.

Please delete the entire text of pages 43 through
47.

At page 48, line 1, please delete "Table VI" and
insert in place thereof --FIGURE 6--.

Page 48, line 15, please delete "glutamine" and
insert in place thereof --glutamic acid--.

Page 48, line 29, "Table VI" should be
--Figure 6--.

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At page 48, line 34, please delete "Table VI" and insert in place thereof --FIGURE 6--.

At page 49, line 1, please delete "Table" and insert in place thereof --FIGURE--.

At page 49, line 6, please delete "Table" and insert in place thereof --FIGURE--.

At page 49, line 8, please delete "Table 6" and insert in place thereof --FIGURE 6--.

At page 49, line 15, please delete "Table" and insert in place thereof --FIGURE--.

At page 49, line 16, please delete "Table VII, below," and insert in place thereof --FIGURE 9--.

At page 49, line 18, please delete "Table" and insert in place thereof --FIGURE--.

At page 49, line 27, please delete "Table 6" and insert in place thereof --FIGURE 6--.

Please delete the entire text of page 50.

Page 53, line 13, after "orientation" please insert --(vectors F, X and G)--.

Page 54, line 36, "EcoRI" should be --EcoRI--.

Page 55, line 13, "BamHI" should be --BamHI--.

Page 55, line 15, "BamHI" should be --BamHI--.

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Page 61, line 25, "hemogeneous" should be
--homogeneous--.

At page 63, line 35, please delete "Table 6" and
insert in place thereof --FIGURE 6--.

At page 65, line 34, please delete "Table 6" and
insert in place thereof -- FIGURE 6--.

At page 66, line 12, please delete "Tables VIII
through XIV below" and insert in place thereof --FIGURES 10
through 15 and 7--.

Please delete the entire text of pages 67
through 72.

At page 73, line 1, please delete "Table VIII" and
insert in place thereof --FIGURE 10--.

At page 73, lines 6 and 7, please delete
"Table IX" and insert in place thereof --FIGURE 11--.

At page 73, line 21, please delete "(Tables XI and
XIII)" and insert in place thereof --(FIGURES 13 and
15)--.

At page 73, line 23, please delete "Tables X and
XII" and insert in place thereof --FIGURES 12 and 14--.

At page 73, line 26, please delete "Table XI" and
insert in place thereof --FIGURE 13--.

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At page 73, line 32, please delete "Table XIV" and insert in place thereof --FIGURE 7--.

Page 74, line 9, after "1984", insert --(Published EPO Application No. 136,490)--.

At page 74, line 29, please delete "Table XIV" and insert in place thereof --FIGURE 7--.

At page 75, line 28, please delete "Tables XV through XXI" and insert in place thereof --FIGURES 16 through 21 and 8--.

At page 75, lines 30 and 31, please delete "Tables XV, XVII and XIX" and insert in place thereof --FIGURES 16, 18 and 20--.

At page 75, line 32, please delete "Tables XVI, XVIII and XX" and insert in place thereof --FIGURES 17, 19 and 21--.

Please delete the entire text of pages 97 through 82.

At page 83, line 21, please delete "Table XXI" and insert in place thereof --FIGURE 8--.

Page 86, line 2, please delete "33932, 33934 and 33933" and insert --39932, 39934 and 39933-- in place thereof.

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Page 88, line 36, "lablled" should be
--labelled--.

At page 89, line 16, please delete "Table VI" and
insert in place thereof --FIGURE 6--.

Page 89, line 21, please delete "118" and insert
--128-- in place thereof.

At page 90, line 15, please delete "Table V" and
insert in place thereof --FIGURE 5--.

At page 90, line 16, please delete "Table VI" and
insert in place thereof --FIGURE 6--.

At page 90, lines 29 and 30, please delete "Table
V and VI" and insert in place thereof --FIGURES 5 and 6--.

Page 91, line 29, please delete "a".

Page 92, line 10, "Table VI" should be
--Figure 6--.

At page 94, line 6, please delete "Tables V and
VI" and insert in place thereof --FIGURES 5 and 6--.

At page 94, line 14, please delete "Tables V and
VI" and insert in place thereof --FIGURES 5 and 6--.

At page 94, line 33, please delete "mammlain" and
insert in place thereof --mammalian--.

Page 95, line 10, "membrances" should be
--membranes--.

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IN THE DRAWINGS:

Please add the enclosed formal drawing Figures 5 through 21.

IN THE CLAIMS:

Add the following new claims:

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- 61. An erythropoietin-containing, ^{preparation} pharmaceutically-acceptable ~~composition~~ wherein human serum albumin is mixed with erythropoietin.
62. A ^{preparation} ~~composition~~ according to claim 61 containing a therapeutically effective amount of erythropoietin.
63. A composition according to claim 61 containing a therapeutically effective amount of recombinant erythropoietin. --
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REMARKS

In accordance with the provisions of 37 C.F.R. §1.607, the present continuation is being filed for the purpose of requesting an interference with all of the claims (claims 1-4) of U.S. Patent No. 4,879,272 issued to Naoto Shimoda et al on

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November 7, 1989, and assigned to Chugai Seiyaku Kabushiki Kaisha (hereinafter simply the "Chugai Patent"), copy attached.

It is requested that an interference be declared between each of the Chugai Patent claims 1-4 and claims 61-63 of the subject application presented above. It is suggested that the Applicant's claim 61 above be used as the count, i.e.:

PROPOSED COUNT

An erythropoietin-containing, pharmaceutically-acceptable composition wherein human serum albumin is mixed with erythropoietin.

Claim 61 is identical to the Chugai Patent claim 3 with the omission of the immaterial phrase which recites the mixing of the erythropoietin ("EPO") and human serum albumin "either during the preparation of said composition or just before administration thereof". This language is not in any sense patentably significant.

As will be evident, the count proposed above is broader than the broadest patent claim and thus constitutes a proper basis for interference.

Claims 1-4 of the Chugai Patent and Lin claims 61-63 should be designated as corresponding to the count.

Clearcut support is found in the Lin specification for the newly presented claims 61-63. In this regard, the Examiner's

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attention is directed to page 87, lines 17-22 and 29-31. Furthermore, such support is found in Lin's prior application Serial No. 655,841, filed September 28, 1984 (see page 77, line 33 through page 78, line 9). Thus, the Lin support antedates both the U.S. filing date of the Chugai Patent (October 4, 1985) as well as the priority date of the Chugai Patent (October 9, 1984), thereby clearly establishing priority in favor of Lin and warranting a declaration of interference between the present application and the Chugai Patent.

The amendments presented above to the specification correspond to those which are the subject of amendments and Certificates of Correction in Lin's "grandparent" U.S. Patent No. 4,703,008. In this regard, the Examiner will appreciate that the attached drawings are intended to replace the various tables referred to in the attached application pursuant to the amendments proposed herein as accepted in U.S. 4,703,008.

As noted in the attached request for filing of the application, the present Lin application is one of a chain of applications dating back to Serial No. 561,024, filed December 13, 1983 and now abandoned.

A prompt declaration of interference is respectfully solicited, the Applicant reserving his right to bring any motions

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and/or take any other action in the interference, once declared,
as may be deemed proper under the rules.

Respectfully submitted,

CUSHMAN, DARBY & CUSHMAN

By


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