

Exhibit 1

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GROUP 120

IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

Application of)	"PRODUCTION OF
FU-KUEN LIN)	ERYTHROPOIETIN"
Serial No. 675,298)	Group Art Unit 127
Filed November 30, 1984)	Examiner: J. Martinell

PRELIMINARY AMENDMENT ACCOMPANYING
PETITION TO MAKE SPECIAL BECAUSE OF ACTUAL
INFRINGEMENT (37 C.F.R. §1.102 & M.P.E.P. §708.02)

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

Sir:

Consistent with the requisites of M.P.E.P.
§708.02 VIII, this Preliminary Amendment is submitted with
Applicant's Petition to Make Special under 37 C.F.R. §1.102.
Please enter the following amendments.

IN THE SPECIFICATION

Page 30, line 21, please delete "Asn" and insert
--Asn-- in place thereof.

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

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

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

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

157

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

IN THE CLAIMS

Please cancel claims 37, 38 and 50 without prejudice. Please enter new claims 61 through 72.

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--61. A biologically functional circular plasmid or viral DNA vector including a DNA sequence according to claim 14.

62. A procaryotic or eucaryotic host cell stably transformed or transfected with a DNA vector according to claim 61.

63. A biologically functional circular plasmid or viral DNA vector including a DNA sequence according to claim 17.

64. A procaryotic or eucaryotic host cell stably transformed or transfected with a DNA vector according to claim 63.

65. A biologically functional circular plasmid or viral DNA vector including a DNA sequence according to claim 34.

66. A procaryotic or eucaryotic host cell stably transformed or transfected with a DNA vector according to claim 65.

- 2 -
158

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Cited*

67. A biologically functional circular plasmid or viral DNA vector including a DNA sequence according to claim 35.

68. A procaryotic or eucaryotic host cell stably transformed or transfected with a DNA vector according to claim 67.

69. A process for the production of a polypeptide having part or all of the primary structural conformation and one or more of the biological ^{activities} ~~properties~~ of naturally-occurring erythropoietin, said process comprising:

growing, under suitable nutrient conditions, procaryotic or eucaryotic host cells transformed or transfected with a DNA vector according to claim ⁶² ~~61~~, and isolating desired polypeptide products of the expression of DNA sequences in said vector.

70. A process for the production of a polypeptide having part or all of the primary structural conformation and one or more of the biological ^{activities} ~~properties~~ of naturally-occurring erythropoietin, said process comprising:

growing, under suitable nutrient conditions, procaryotic or eucaryotic host cells transformed or transfected with a DNA vector according to claim 63, and isolating desired polypeptide products of the expression of DNA sequences in said vector.

71. A process for the production of a polypeptide having part or all of the primary structural conformation and one or more of the biological ^{activities} ~~properties~~ of naturally-occurring erythropoietin, said process comprising:

1159

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deleted

growing, under suitable nutrient conditions, pro-
caryotic or eucaryotic host cells transformed or transfected
with a DNA vector according to claim 65, and isolating
desired polypeptide products of the expression of DNA
sequences in said vector.

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72. A process for the production of a polypeptide
having part or all of the primary structural conformation
and one or more of the biological ^{activities} ~~properties~~ of naturally-
occurring erythropoietin, said process comprising:

growing, under suitable nutrient conditions, pro-
caryotic or eucaryotic host cells transformed or transfected
with a DNA vector according to claim 67, and isolating
desired polypeptide products of the expression of DNA
sequences in said vector.--

REMARKS

Claims 1 through 36, 39 through 49, 51 through 60,
and new claims 61 through 72 are in the application. New
claims 61 through 72 comprehend precisely the same subject
matter previously claimed in original application claims 37,
38 and 50 whose cancellation is sought hereby. New claims
61 though 72 are believed to be in proper form and free of
any objection with respect to multiple dependency such as
was asserted by Examiner Martinell in the "International
Search Report" dated March 7, 1985 with respect to corres-
ponding Patent Cooperation Treaty Application US84/02021, a
copy of which is attached hereto as Exhibit No. 1.

- 4 -

160

Preliminary Election Of
Claims 14, 15, 17-36, 58 and 61-72

Consistent with the suggestion set forth in M.P.E.P. §708.02 VIII concerning the presentation of claims "directed to a single invention", and based on "Observations Where Unity Of Invention Is Lacking" set in the International Search Report (Exhibit No. 1) referred to above, Applicant herewith provisionally elects prosecution of claims 14, 15, 17-36, 58, and 61 through 72, all of which are directed to DNA sequences, vectors including such DNA sequences, host cells transformed or transfected with the claimed vectors, and processes for the production of polypeptides through use of claimed transformed or transfected hosts.

While applicant has made the above preliminary election "without traverse", it will be understood that the same is being made without prejudice to applicant's right to pursue claims to all patentable subject matter disclosed in his application and specifically to pursue the patenting of all presently non-elected claims.

Statement With Respect To "Pre-Examination Search"

Commencing prior to the filing of the first parent patent application leading up to the present application, and on an essentially continuous basis thereafter through to the present, Applicant, Applicant's assignee and Applicant's counsel have essentially continuously reviewed scientific publications, U.S. and foreign patents and foreign published patent applications in an attempt to identify prior art which may be deemed to be pertinent to the patentability of claims now pending in the present application. Also the subject of review by Applicant, his assignee and counsel

- 7 -

1161

have been those references which were cited, for example, in the International Search Report attached as Exhibit No. 1 hereto and in the examination of parent U.S. Application Serial No. 561,024. See, e.g., the copy of PTO-892 attached hereto as Exhibit 2. To the extent that any known references were determined to be potentially relevant to patentability of any in claims in the present application or any parent application at the time of filing, they were directly referred to in the text of the application.

In an attempt to respond to the suggestions contained in M.P.E.P. §708.02 IV(c)(d)(e), Applicant is concurrently submitting herewith an Information Disclosure Statement Under 37 C.F.R. §1.97 including Form PTO-1449. This Statement includes copies of all references cited in the present specification together with copies of all references which have come to the attention of Applicant's counsel since the filing date of the application.

Attached hereto as Exhibit No. 3 is a listing of a "sub-set" of the set of references supplied by the Information Disclosure Statement. This sub-set of references comprises those references which are presently believed by counsel to be "closely related to the subject matter encompassed by the claims" preliminarily elected herein (i.e., claims 14, 15, 17-36, 58, and 61-72 relating to DNA sequences, vectors, hosts and recombinant erythropoietin production processes). Comments concerning pertinence to patentability of these references are provided in a separate section (pages 2 to 5) within the Information Disclosure Statement.

- 6 -

1/16/02

Statement With Respect To Deposited Microorganisms

Applicant notes that microorganisms referred to by A.T.C.C. Deposit Number are either permanent A.T.C.C. stocks (e.g., COS-1 cells, CRL-1650) or were deposited on behalf of applicant under the provisions of the Budapest Treaty. Attached hereto as composite Exhibit No. 4 are copies of A.T.C.C. acknowledgements of Budapest Treaty status of the deposits made in connection with this application.

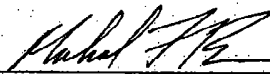
CONCLUSION

Applicant respectfully submits that claims 14, 15, 17-36, 58 and 61-72 are in condition for allowance and an early notice thereof is solicited.

Respectfully submitted,

MARSHALL, O'TOOLE, GERSTEIN,
MURRAY & BICKNELL

By


Michael F. Borun (Reg. No. 25,447)
A Member of the Firm
Attorneys for Applicants
Two First National Plaza
Chicago, Illinois 60603
(312) 346-5750

Chicago, Illinois

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- 1 -

1163