

EXHIBIT 19
Part 1 of 2



UNITED STATES DEPARTMENT OF COMMERCE
 Patent and Trademark Office
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 Washington, D.C. 20231

| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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EXAMINER

ART UNIT PAPER NUMBER

8/9

DATE MAILED:

This is a communication from the examiner in charge of your application.
 COMMISSIONER OF PATENTS AND TRADEMARKS

- This application has been examined Responsive to communication filed on 12/24/96 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
 Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. Claims 42-44, 46, and 61 are pending in the application.
 Of the above, claims _____ are withdrawn from consideration.
2. Claims 1-41, 45, 47-60, and 62-65 have been cancelled.
3. Claims _____ are allowed.
4. Claims 42-44, 46, and 61 are rejected.
5. Claims _____ are objected to.
6. Claims _____ are subject to restriction or election requirement.
7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. Formal drawings are required in response to this Office action.
9. The corrected or substitute drawings have been received on 12/24/96. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).
11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).
12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.
13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. Other

202

EXAMINER'S ACTION

Serial No. 08/468,369

Art Unit 1804

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on December 24, 1996 have been approved.

The amendment filed December 24, 1996 is in improper form because it deletes material from the previous version of claim 44 without indicating the deleted material in brackets. Applicant should cancel claim 44 and resubmit it as a newly filed claim in the next amendment.

Claim 61 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is incomplete because it is a process claim that fails to recite a positive process step.

Claims 42-44, 46, and 61 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Vertebrate cells that produce at least 100 U of erythropoietin per 10⁶ cells per 48 hours in culture are critical or essential to the practice of the invention, but is not enabled by the

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203

Serial No. 08/468,369

Art Unit 1804

disclosure. In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The instant application teaches and enables only cells that have been transformed with exogenous DNA that encodes erythropoietin (EPO) that have the high EPO production required by the claims. The instant application does not guide one of skill in the art in the discovery of non-transformed vertebrate cells that are capable of the high EPO production recited in the instant claims. That the discovery of non-transformed (i.e., not transformed with exogenous DNA) cells that produce the high levels of EPO recited in the claims is unlikely is evidenced by each of Choppin et al, Hagiwara et al, and Shiramizu et al, each of which discloses levels of EPO production by vertebrate cells in culture that are far below those levels required in the instant claims.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Art Unit 1804 at (703) 305-3014. The faxing of such papers

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204

Serial No. 08/468,369

Art Unit 1804

must conform with the rules published in the Official Gazette,
1156 OG 61 (November 16, 1993).

Any inquiry concerning this communication should be directed
to J. Martinell at telephone number (703) 308-0296.


JAMES MARTINELL, PH.D.
SENIOR LEVEL EXAMINER
GROUP 1800

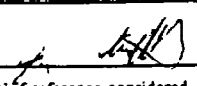
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| Form PTO-1449 INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) | U.S. Department of Commerce Patent and Trademark Office | App. Docket No. 11009/32022 | Serial No. 08/468,369 |
| | Applicant Fu-Kuen Lin | | |
| | Filing Date June 6, 1995 | Group 1804 | |

| U.S. PATENT DOCUMENTS | | | | | | | | |
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| *Examiner Initials | | Document # | Issue Date | Name | Class | Subclass | Source | Filing Date |
| <i>J</i> | A1 | 3,033,753 | 5/8/62 | White et al. | 322 167 | 74 74 | | |
| <i>L</i> | A2 | 3,865,801 | 2/11/75 | Chiba et al. | 278 260 | 112 112 | | |
| <i>L</i> | A3 | 4,237,224 | 12/2/80 | Cohen et al. | 435 | 68- ^{69.1} | | |
| <i>L</i> | A4 | 4,254,095 | 3/3/81 | Fisher et al. | 424 424 | + ⁵¹³ | | |
| <i>L</i> | A5 | 4,264,731 | 4/28/81 | Shine | 435 | 91.41 | | |
| <i>L</i> | A6 | 4,273,875 | 6/16/81 | Manis | 435 | 253- ^{61.4} | | |
| <i>L</i> | A7 | 4,293,652 | 10/6/81 | Cohen | 435 | 172.3 | | |
| <i>L</i> | A8 | 4,303,650 | 12/1/81 | Takezawa et al. | 424 424 | 177- ³¹⁷ | | |
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| <i>L</i> | A10 | 4,358,535 | 11/9/82 | Falkow et al. | 435 | 5 | | |
| <i>L</i> | A11 | 4,377,513 | 3/22/83 | Sugimoto et al. | 260 260 | 112- ³¹³ | | |
| <i>L</i> | A12 | 4,394,443 | 7/19/83 | Weissman et al. | 435 | 6 | | |
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| <i>L</i> | A14 | 4,399,216 | 8/16/83 | Axel et al. | 435 | 6 | | |
| <i>L</i> | A15 | 4,411,994 | 10/25/83 | Gilbert et al. | 435 | 71- ^{69.7} | | |
| <i>L</i> | A16 | 4,442,205 | 4/10/84 | Hamer et al. | 435 | 68- ^{69.3} | | |
| <i>L</i> | A17 | 4,465,624 | 8/14/84 | Chiba et al. | 260 260 | 112- ³¹³ | | |
| <i>L</i> | A18 | 4,468,464 | 8/28/84 | Cohen et al. | 435 | 317- ^{322.1} | | |
| <i>L</i> | A19 | 4,503,151 | 3/5/85 | Paddock | 435 | 68- ^{69.1} | | |
| <i>L</i> | A20 | 4,558,005 | 12/10/85 | Goldwasser et al. | 435 | 7.92 | | |
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| L | A27 | 4,710,473 | 12/1/87 | Morris | 435 | 320.1 | | |
| L | A28 | 4,757,006 | 7/12/88 | Toole et al. | 435 | 240.6 | | |
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| | A30 | 487,753 | | Bitter (not enclosed) | | | | |
| | A31 | 693,258 | 1/22/85 | Fritsch et al. (not enclosed) | | | | |

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|--------------------------|-----|------------|----------------------------|---------|--------|-----------------|-------------|----|
| *Examiner Initials | | Document # | Publication Date | Country | Source | Class/ Subclass | Translation | |
| | | | | | | | Yes | No |
| L | B1 | 0070685 | 1/26/83 | EPO | --- | --- | | |
| L | B2 | 0070687 | 1/26/83 | EPO | --- | --- | | |
| L | B3 | 0077670 | 4/27/83 | EPO | --- | --- | | |
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| L | B5 | 0116446 | 8/22/84 | EPO | --- | --- | | |
| L | B6 | 0117058 | 8/29/84 | EPO | --- | --- | | |
| L | B7 | 0117059 | 8/29/84 | EPO | --- | --- | | |
| L | B8 | 0117060 | 8/2/84 | EPO | --- | --- | | |
| L | B9 | 0123294 | 4/19/84 1/22/84 | EPO | --- | --- | | |
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| L | B14 | 85/03079 | 7/18/85 | PGF WO | --- | --- | | |

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| EXAMINER L <i>[Signature]</i> | DATE CONSIDERED 12/26/96 |
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| INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i> | | Applicant Fu-Kuen Lin | |
| | | Filing Date June 6, 1995 | Class 1804 |

| FOREIGN PATENT DOCUMENTS | | | | | | | |
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| ✓ | B15 | 85/04419 | 10/10/85 | PGT WJ | — | — | |
| ✓ | B16 | 86/03520 | 6/19/86 | PGT WJ | — | — | |
| ✓ | B17 | DE 33 16 297 A1 | 11/17/83 | Germany (Goeddel et al.) | — | — | |
| ✓ | B18 | DE 33 48 298 C2 | 11/17/83 | Germany (Goeddel et al.) | — | — | |

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| ✓ | C2 | Adamson, "The Polycythemias: Diagnosis and Treatment," <i>Hosp. Practice</i> , 18(12), 49-57 (December 1983) |
| ✓ | C3 | Aebi et al., "Sequence Requirements for Splicing of Higher Eukaryotic Nuclear Pre-mRNA," <i>Cell</i> , 47, 555-565 (Nov. 21, 1986) |
| ✓ | C4 | Agarwal et al., "A General Method for Detection and Characterization of an mRNA using an Oligonucleotide Probe," <i>J. Biol. Chem.</i> , 256, 1023-1028 (Jan. 25, 1981) |
| ✓ | C5 | Anderson et al., "Isolation of a genomic clone for bovine pancreatic trypsin inhibitor by using a unique-sequence synthetic DNA probe," <i>P.N.A.S. (USA)</i> , 80, 6838-6842 (November 1983) |
| ✓ | C6 | Antonsson et al., "Posttranslational Modifications of Fibromodulin," <i>J. Biol. Chem.</i> , 266(25), 16859-16861 (1991) |
| ✓ | C7 | Baciu et al., "Erythropoietin Interaction with the Mature Red Cell Membrane," <i>Ann. N.Y. Acad. Sci.</i> , 414, 66-72 (1983) |
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| ✓ | C10 | Benedum et al., "The primary structure of bovine chromogranin A: a representative of a class of acidic secretory proteins common to a variety of peptidergic cells," <i>EMBO J.</i> 5(7), 1495-1502 (1986) |

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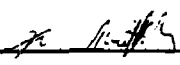
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| | | Applicant Fu-Kuen Lin | |
| | | Filing Date June 6, 1995 | Group 1804 |

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

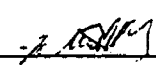
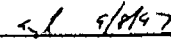
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) | | |
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| <input checked="" type="checkbox"/> | C11 | Bennetzen et al., "Codon Selection in Yeast," <i>J. Biol. Chem.</i> , 257(6), 3026-3031 (March 25, 1982) |
| <input checked="" type="checkbox"/> | C12 | Bentley et al., "Human immunoglobulin variable region genes-DNA sequences of two V _H genes and a pseudogene," <i>Nature</i> 288, 730-733 (December 1980) |
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| <input checked="" type="checkbox"/> | C20 | Bray et al., "Human cDNA clones for four species of G α -signal transduction protein," <i>P.N.A.S. (USA)</i> , 83, 8893-8897 (December 1986) |
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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) | | |
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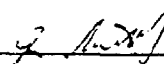
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| | Applicant Fu-Kuen Lin | | |
| | Filing Date June 6, 1995 | | Group 1804 |

| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) | | |
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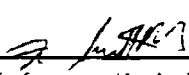
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| | <small>Applicant</small> Fu-Kuen Lin | | | |
| | <small>Filing Date</small> June 6, 1995 | | <small>Group</small> 1804 | |

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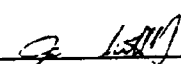
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215

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| | Applicant Fu-Kuen Lin | | |
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218

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| EXAMINER  | DATE CONSIDERED 12/24/96 |
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