

**EXHIBIT**  
**D**

8-9-89

U.S. Express Mail No. NB 134 248 235  
PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BOARD OF PATENT APPEALS AND INTERFERENCES**

Fritsch et al.

v.

Lin

}  
}  
}

Interference No. 102,096

and

Interference No. 102,097

Mark L. Caroff,  
Examiner-In-Chief

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

**Preliminary Motions  
of the  
Party Fritsch et al.**

**AM 17 005165**  
CONFIDENTIAL  
SUBJECT TO PROTECTIVE ORDER

AM-ITC 00332213

**Preliminary Motions in Interference No. 102,096**

**EXHIBIT A** MOTION FOR JUDGMENT UNDER 37 CFR §1.633(a) ON THE GROUND THAT THE CLAIM OF THE PARTY LIN CORRESPONDING TO THE COUNT IS UNPATENTABLE UNDER 35 U.S.C. §§ 102(e) AND/OR 103 IN VIEW OF TOOLE ET AL., U.S. PATENT NO. 4,757,006 (HEREINAFTER "TOOLE ET AL.").

**EXHIBIT B** MOTION FOR JUDGMENT UNDER 37 CFR §1.633(a) ON THE GROUND THAT THE CLAIM OF THE PARTY LIN CORRESPONDING TO THE COUNT IS NOT PATENTABLE TO THE PARTY LIN UNDER 35 U.S.C. § 112 (FIRST PARAGRAPH) BECAUSE THE SPECIFICATION UPON WHICH IT IS BASED FAILS TO DISCLOSE THE BEST MODE CONTEMPLATED BY THE INVENTOR OF CARRYING OUT HIS INVENTION. THE SPECIFICATION OF LIN IS FATALLY DEFECTIVE.

**EXHIBIT C** MOTION UNDER 37 CFR §1.633(d) TO SUBSTITUTE OR ADD NEWLY FILED APPLICATION SN 07/386,280, FILED JULY 28, 1989 (EXHIBIT 1).

**EXHIBIT D** MOTION UNDER 37 CFR §1.633(c) TO REDEFINE THE INTERFERING SUBJECT MATTER BY SUBSTITUTING AS THE SOLE COUNT OF INTERFERENCE CLAIM 1 OF APPLICATION S.N. 07/386,280, FILED JULY 28, 1989 (EXHIBIT 1) AND DESIGNATING CLAIM 2 AND OTHER OF THE CLAIMS OF THE PARTY LIN AS CORRESPONDING TO THE SUBSTITUTED COUNT.

U.S. Express Mail No. NB 134 248 235  
PATENT

EXHIBIT E MOTION UNDER 37 CFR §1.633(f) TO BE ACCORDED THE BENEFIT OF THE FILING DATE OF APPLICATION S.N. 136,478, FILED DECEMBER 23, 1987, THE FILING DATE OF S.N. 644,036, FILED AUGUST 24, 1984, OF WHICH IT IS A CONTINUATION, AND THE FILING DATE OF S.N. 546,650, FILED OCTOBER 28, 1983, NOW U.S. PATENT 4,757,006, OF WHICH IT IS A CONTINUATION-IN-PART.

EXHIBIT F MOTION UNDER 37 CFR § 1.633(g) ATTACKING THE BENEFIT ACCORDED THE PARTY LIN IN THE NOTICE DECLARING THE INTERFERENCE OF THE FILING DATE OF APPLICATIONS EARLIER FILED IN THE UNITED STATES ON THE GROUNDS THAT THOSE APPLICATIONS FAIL TO HAVE A DISCLOSURE WHICH SATISFIES 35 U.S.C. § 112 (FIRST PARAGRAPH).

EXHIBIT G MOTION TO COMBINE INTERFERENCE NO. 102,097 WITH THE INSTANT INTERFERENCE.

**Preliminary Motions in Interference No. 102,097**

**EXHIBIT H** MOTION FOR JUDGMENT UNDER 37 CFR § 1.633(a) ON THE GROUND THAT THE CLAIM OF LIN CORRESPONDING TO THE COUNT IS UNPATENTABLE UNDER 35 U.S.C §102(e) AND/OR 103 OVER TOOLE ET AL.

**EXHIBIT I** MOTION FOR JUDGMENT UNDER 37 CFR § 1.633(a) ON THE GROUND THAT CLAIM 65 CORRESPONDING TO THE COUNT IS UNPATENTABLE TO LIN UNDER 35 U.S.C. §112 (FIRST PARAGRAPH).

**EXHIBIT J** MOTION UNDER 37 CFR § 1.633(g) ATTACKING THE BENEFIT ACCORDED THE PARTY LIN IN THE NOTICE DECLARING THE INTERFERENCE OF THE FILING DATE OF APPLICATIONS EARLIER FILED IN THE UNITED STATES ON THE GROUNDS THAT THOSE APPLICATIONS FAIL TO HAVE A DISCLOSURE WHICH SATISFIES 35 U.S.C. § 112 (FIRST PARAGRAPH).

**EXHIBIT K** MOTION UNDER 37 CFR § 1.633(g) ATTACKING THE BENEFIT ACCORDED THE PARTY LIN IN THE NOTICE DECLARING THE INTERFERENCE OF THE FILING DATE OF APPLICATIONS EARLIER FILED IN THE UNITED STATES ON THE GROUNDS THAT THOSE APPLICATIONS FAIL TO HAVE A DISCLOSURE WHICH SATISFIES 35 U.S.C. § 112 (FIRST PARAGRAPH) IN RESPECT TO THE BEST MODE.

**EXHIBIT L** MOTION FOR JUDGMENT UNDER 37 CFR § 1.633(a) ON THE GROUND THAT THE CLAIM OF THE PARTY LIN

U.S. Express Mail No. NB 134 248 235  
PATENT

CORRESPONDING TO THE COUNT IS UNPATENTABLE TO  
LIN UNDER 35 U.S.C. § 102(b)

EXHIBIT M MOTION FOR JUDGMENT UNDER 37 CFR § 1.633(a) ON  
THE GROUND THAT THE CLAIM OF THE PARTY LIN  
CORRESPONDING TO THE COUNT IS UNPATENTABLE TO  
LIN UNDER 35 U.S.C. § 102(f)

EXHIBIT N MOTION UNDER 37 CFR §1.633(d) TO SUBSTITUTE OR  
ADD NEWLY FILED APPLICATION SN 07/386,280, FILED  
JULY 28, 1989 (EXHIBIT 1), FOR THE PARTY FRITSCH ET  
AL. APPLICATION S.N. 693,258.

EXHIBIT O MOTION UNDER 37 CFR §1.633(c) TO REDEFINE THE  
INTERFERENCE SUBJECT MATTER BY SUBSTITUTING  
THE SOLE COUNT OF INTERFERENCE WITH THE COUNT  
AS RECITED IN MOTION EXHIBIT E, CLAIM 1 OF NEWLY  
FILED APPLICATION S.N. 07/386,280, FILED JULY 28, 1989,  
(EXHIBIT 1) AND DESIGNATING CLAIM 2 AND OTHER OF  
THE CLAIMS OF THE PARTY LIN AS CORRESPONDING TO  
THE SUBSTITUTED COUNT.

EXHIBIT P MOTION UNDER 37 CFR §1.633(f) FOR FRITSCH ET AL. TO  
BE ACCORDED THE BENEFIT OF THE FILING DATE OF  
APPLICATION S.N. 136,478, FILED DECEMBER 23, 1987,  
THE FILING DATE OF S.N. 644,036, FILED AUGUST 24,  
1984, OF WHICH IT IS A CONTINUATION, AND THE FILING  
DATE OF S.N. 546,650, FILED OCTOBER 28, 1983, NOW U.S.  
PATENT 4,757,006, OF WHICH IT IS A CONTINUATION-IN-  
PART.

**U.S. Express Mail No. NB 134 248 235  
PATENT**

**EXHIBIT Q MOTION TO COMBINE INTERFERENCE NO. 102,096 WITH  
THE INSTANT INTERFERENCE.**

U.S. Express Mail No. NB 134 248 235  
PATENT

**EXHIBIT G MOTION TO COMBINE INTERFERENCE NO. 102,097 WITH  
THE INSTANT INTERFERENCE.**

**I. Statement of the Precise Relief Requested**

Motion to combine interference no. 102,097 with the instant interference and the dissolution thereof.

**II. Statement of the Material Facts in  
Support of the Motion**

1. According to the Memorandum Opinion and Order of the Commissioner, paper no. 14, the two interferences are to be handled "simultaneously" (page 11) and this is so because "efficient administration of justice dictates [the interferences] should be handled simultaneously" (page 14).
2. The interferences are to be kept to a "reasonably 'tight' schedule."
3. The count of this interference is directed to a composition of matter which functionally defines its capability ("DNA sequence encoding human erythropoietin"). The functional capabilities could be argued as defining what could be the conception and/or reduction to practice of the invention.
4. The count in the companion interference 102,097 relates to a process that is directed to the same goal of the count of this interference, i.e., the production of erythropoietin.

A process for the preparation of an in vivo biologically active glycosylated polypeptide comprising the steps of:



U.S. Express Mail No. NB 134 248 235  
PATENT

(a) growing a mammalian host cell which is capable of effecting post-translational glycosylation of polypeptides expressed therein and which is transformed or transfected with an isolated DNA sequence encoding a polypeptide having a primary structural conformation sufficiently duplicative of that of 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, or the progeny thereof, under nutrient conditions suitable to allow, in sequence,

(i) transcription within said host cell of said DNA to mRNA in the sequence of transcription reactions directed by the nucleotide sequence of said DNA;

(ii) translation within said host cell of said mRNA to a polypeptide in the sequence of translation reactions directed by the nucleotide sequence of said transcribed mRNA;

(iii) glycosylation within said host cell of said polypeptide in a pattern directed by the amino acid sequence of said translated polypeptide and sufficiently duplicative of the pattern of glycosylation of naturally occurring human erythropoietin to allow possession by the translated glycosylated polypeptide product of the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells; and

(b) isolating the glycosylated polypeptide so produced.

U.S. Express Mail No. NB 134 248 235  
PATENT

The isolated glycopeptide of this count is the human EPO which is to be generated by the gene of the count of interference no. 102,096.

**III. Statement of the Reasons Why the Relief Requested should be Granted**

For the purposes of further judicial economy and more efficiency of administration of justice, it is submitted that the two interferences be joined. For example,

- ◊ The inventors in both interferences are the same and joining of the interferences will avoid duplication of testimony.
- ◊ The evidence relative to conception, reduction to practice, best mode, enablement and the prior art, will come from common sources and oftentimes from the same documentation.
- ◊ Any discovery should relate to the issues of both interferences.
- ◊ The interferences in terms of subject matter are essentially the same and the interferences counts are different manifestations of the same "invention."
- ◊ The current two interferences necessitate duplicative motions concerning the same issues costing considerable extra time to be spent on the interferences.
- ◊ The interferences involve common questions of fact and law.
- ◊ Justice requires consolidation of the interferences.

**EXHIBIT Q MOTION TO COMBINE INTERFERENCE NO. 102,096 WITH THE  
INSTANT INTERFERENCE.**

**I. Statement of the Precise Relief Requested**

Motion to combine interference no. 102,096 with the instant interference and the dissolution thereof.

**II. Statement of the Material Facts in  
Support of the Motion**

1. According to the Memorandum Opinion and Order of the Commissioner, paper no. 14, the two interferences are to be handled "simultaneously" (page 11) and this is so because "efficient administration of justice dictates [the interferences] should be handled simultaneously" (page 14).
2. The interferences are to be kept to a "reasonably 'tight' schedule."
3. The count of this interference is directed to a process that is directed to the same goal of the count of this interference, i.e., the production of erythropoietin.
4. The count in the companion interference 102,096 relates to a composition of matter which functionally defines its capability ("DNA sequence encoding human erythropoietin"). The functional capabilities could be argued as defining what could be the conception and/or reduction to practice of the invention.

The isolated glycopeptide of the count this interference is the human EPO which is to be generated by the gene of the count of interference no. 102,096.

U.S. Express Mail No. NB 134 248 235  
PATENT

**III. Statement of the Reasons Why the Relief  
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The evidence relative to conception, reduction to practice, best mode, enablement and the prior art, will come from common sources and oftentimes from the same documentation.

Any discovery should relate to the issues of both interferences.

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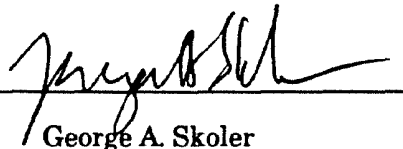
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The interferences involve common questions of fact and law.

Justice requires consolidation of the interferences.

U.S. Express Mail No. NB 134 248 235  
PATENT

Respectfully submitted,



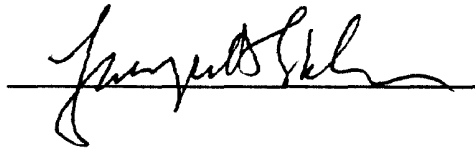
George A. Skoler

Reg. No. 19894

George A. Skoler P.C.  
3010 Westchester Avenue  
Purchase, NY 10577  
August 9, 1989

**CERTIFICATE OF MAILING (37 CFR §1.10)**

I hereby certify that this correspondence relating to the subject interference is being deposited with the United States Postal Service on August 9, 1989 in an envelope as "Express Mail Post Office to Addressee" mail label number NB 134 248 28X, in an envelope addressed to: Box Interference, Hon. Commissioner of Patents and Trademarks, Washington, D.C. 20231.

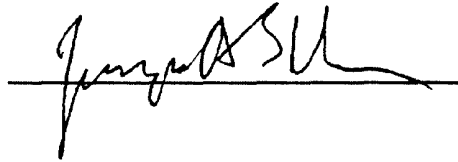


U.S. Express Mail No. NB 134 248 235  
PATENT

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on this 9th day of August, 1989, a true and correct copy of the MOTION UNDER 37 CFR §1.635 FOR EXTENSION OF TIME was served upon lead attorney Paul N. Kokulis, Esq. for the party Lin by U. S. Express Mail Label No. NM134 248 290 postage prepaid addressed to:

Paul N. Kokulis, Esq.  
Cushman, Darby & Cushman  
1615 L Street N.W.  
Washington, D.C. 20036

A handwritten signature in black ink, appearing to read "Paul N. Kokulis", is written over a horizontal line.