EXHIBIT

5

IN THE

UNITED STATES PATENT and TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

Interference No. 102,097

FRITSCH

v.

LIN

Examiner-in-Chief Marc L. Caroff

BRIEF FOR THE PARTY FRITSCH

KURT E. RICHTER
MORGAN & FINNEGAN
345 Park Avenue
New York, New York 10154
(212) 758-4800
Attorney for the Party Fritsch

Of Counsel:
EUGENE MOROZ
WILLIAM S. FEILER
MICHAEL P. DOUGHERTY
WILLIAM KROVATIN

GI's prior successful cloning of Factor VIII using separate pools of mixed oligonucleotide probes also demonstrates that in 1983, it was reasonable to expect success with the prior art methods: Factor VIII was a larger, more complex molecule than EPO, and represented a more difficult cloning challenge. Findings II-26, II-102, II-27. If the technique could be successfully used to clone the gene encoding a large fragment of Factor VIII, then it would have at least a reasonable likelihood of success in cloning EPO. Findings III-27, III-34.

The record therefore shows that one of ordinary skill in the art, aware of all the pertinent prior art, would have been taught to employ the cloning technique Lin used and would have had a reasonable expectation of successfully cloning the human EPO gene. This is all the law requires to render Lin's claims unpatentable under 35 U.S.C. § 103. Conclusions of Law III-18 - III-19.

V. LIN IS NOT THE TRUE INVENTOR OF THE PROCESS SET FORTH IN THE LIN CLAIMS CORRESPONDING TO THE COUNT OF THIS INTERFERENCE (MOTION M)

Deferred Fritsch Preliminary Motion M requests judgment that the Lin claims corresponding to the count of this interference are unpatentable to Lin under 35 U.S.C. §102(f). That statute provides:

A person shall be entitled to a patent unless . . . .

(f) he did not himself invent the subject matter sought to be patented[.]

The record here shows clearly that Dr. Lin "did not himself invent the subject matter" set forth in the Lin claims corresponding to the count in this interference. Accordingly, Fritsch's motion should be granted.

All of Lin's claims corresponding to the count recite the steps of (a) "growing a mammalian host cell ... which is transformed or transfected with an isolated DNA sequence encoding ... human erythropoietin ...." and (b) "isolating the glycosylated [EPO] polypeptide so produced." '179 Application claims 65-69. In other words, the claims cover the "expression" and "isolation" of recombinant human EPO.

Such expression of the EPO gene requires the completion of several complicated procedures after the gene itself has been isolated, e.g., design and construction of an expression vector with an appropriate origin of replication, viral promoter sequences, viral polyadenylation sequences and marker gene, insertion of the isolated gene into the vector, and selection of the transfected host cells with the most desirable growth characteristics and productivity. Finding V-2.

Dr. Lin took no part in any of these procedures. Indeed, Lin admits that he did not do any of the work at Amgen related to the expression of the EPO gene in mammalian host cells. Finding V-

4. Rather, all of the work at Amgen related to the development of mammalian expression systems was directed and supervised by Dr. Jeffrey Browne. Ralph Smalling assisted Dr. Browne. Finding V-3.

Dr. Lin's only efforts at EPO expression were directed to the expression of EPO in E. coli bacteria. Finding V-5. These are not mammalian cells and are not capable of expressing a polypeptide with the characteristics specified in the count. Lin cannot recall giving Dr. Browne any instructions or suggestions as to how mammalian expression should be carried out. Nor can Mr. Smalling recall ever receiving instructions from Dr. Lin. Finding V-4.

By the same token, Dr. Lin was not personally involved in the step of isolating the EPO glycoprotein, which refers to the step of purifying the erythropoietin. That effort was done by Dr. Strickland, and Dr. Lin gave him no instructions for accomplishing that task. Finding V-6. Dr. Lin had no participation in the suggested purification steps which are set forth in Example 10 for purifying the mammalian cell expression products from the cell culture medium. Finding V-6.

Dr. Lin's own testimony thus establishes that he did not himself invent either of the steps in a process comprising the steps of "growing a mammalian host cell" transfected with the human EPO gene and "isolating the glycosylated [EPO] polypeptide." This renders claims 65-69 of Lin's '179 application unpatentable under

35 U.S.C. § 102(f), and requires the entry of judgment against Lin as requested in Fritsch Motion M.

CONCLUSION

For the foregoing reasons, the Board should enter judgment:

1. That Dr. Edward Fritsch is the prior inventor of the subject matter defined by the count in this interference;

2. That Dr. Fritsch is the sole inventor of the subject matter claimed in the Fritsch application involved in this interference;

3. That Lin's claims corresponding to the count are unpatentable to Lin for failure to satisfy the best mode requirement of 35 U.S.C. § 112;

4. That Lin's claims corresponding to the count are unpatentable to Lin under 35 U.S.C. § 103; and

5. That Lin's claims corresponding to the count are unpatentable to Lin under 35 U.S.C. § 102(f).

Respectfully submitted,

MORGAN & FINNEGAN

Dated: July 8, 1991

By: Kurt E. Richter
Kurt E. Richter
Reg. No. 24,052
Attorney for the
Party Fritsch

Of Counsel:
Eugene Moroz
William S. Feiler
Michael P. Dougherty
William Krovatin

MORGAN & FINNEGAN
345 Park Avenue
New York, NY 10154
(212) 758-4800

CERTIFICATE OF SERVICE
AND FILING BY EXPRESS MAIL

It is hereby certified that on July 8, 1991 the original and three copies of the foregoing BRIEF FOR THE PARTY FRITSCH have been deposited with the United States Postal Service in an envelope as "Express Mail Post Office to Addressee" mail label number GB301075126US, in an envelope addressed to Box Interference, Hon. Commissioner of Patents and Trademarks, Washington, D.C. 20231, and that copies thereof have been served upon counsel for Lin by first class mail, postage-prepaid, and by overnight courier, addressed as follows:

Paul N. Kokulis, Esq.
CUSHMAN, DARBY & CUSHMAN
1615 L Street, N.W.
Washington, D.C. 20036-5601