

Exhibit 3

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Patent Appeals and Interferences**

FRITSCH et al.)	Interference No. 102,096
Junior Party)	and
)	Interference No. 102,097
v.)	
)	
LIN)	Examiner-in-Chief:
Senior Party)	Marc L. Caroff
)	

BOX INTERFERENCE

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

**REPLY BY SENIOR PARTY LIN TO THE OPPOSITION OF JUNIOR PARTY
FRITSCH ET AL TO MOTIONS OF SENIOR PARTY LIN
TO TERMINATE INTERFERENCES**

Sir:

The opposition of the junior party Fritsch et al has provided no evidence or legal rationale for continuing the subject interferences. As will be discussed more fully below, there is no legal or equitable basis to protract the present proceedings. The Examiner-in-Chief should promptly bring these matters to a final resolution.

Termination of the subject interferences is proper in view of the record now before the PTO, in particular the decision rendered by the United States District Court in Massachusetts in Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., and Genetics Institute,

AM 17 001294
CONFIDENTIAL
SUBJECT TO PROTECTIVE ORDER

LIN REPLY

Interference Nos. 102,096 and 102,097

Inc., Civil Action No. 87-2617-Y on December 11, 1989 (referred to herein as the "Federal Court Decision"). The Federal Court fully considered the Fritsch et al priority evidence, including anything of possible relevance in the Fritsch et al "Prima Facie Showing to 37 CFR 1.608(b)" which was the basis for instituting the subject interferences. In doing so, the Court rejected a Section 102(g) anticipation attack by Fritsch based on Fritsch's own work at Genetics Institute, and upheld claims of the Lin '008 patent including the following:

2. A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a human erythropoietin.

4. A procaryotic or eucaryotic host cell transformed or transfected with a DNA sequence according to claim 1, 2 or 3 in a manner allowing the host cell to express erythropoietin.

In determining that claim 2 (which is the same as the count in Interference 102,096) and claim 4 of the Lin '008 patent are valid, the Court recognized that Lin is the first inventor of a DNA sequence encoding human EPO, and of host cells to express rEPO. The discussion on pages 67-84 of the decision evaluates all of the priority evidence which was developed by the parties after extensive discovery and 38 days of trial (including the above-noted "Prima Facie Showing to 37 CFR 1.608(b)" by Fritsch et al). See also pages 27-44 of the decision where the Court summarizes the evidentiary record.

LIN REPLY

Interference Nos. 102,096 and 102,097

It is submitted that the Federal Court Decision is fully dispositive of the real issues in the subject interferences. The count of Interference 102,096 is the same as claim 2 of the Lin '008 patent which was upheld in the Court. Clearly Lin is entitled to priority on the record as to this matter. The same is true with regard to the count of Interference 102,097 since, if Lin was first to invent a host cell containing a DNA sequence in a manner allowing the host cell to express rEPO as determined by the Court, he is of necessity the first to invent the process of making rEPO using such the host cell (see the count of Interference 102,097).

Having chosen to raise the priority issue before the District Court, Fritsch et al should now be estopped from arguing that the Board should make the first priority determination. It was Fritsch et al who, chose to go forward in the District Court with a Section 102(g) defense based on the Fritsch et al work. This defense failed, after full consideration of the evidence, and they should now be estopped to retry priority and any other issues there decided, before the Board.

No substantive reasoning or authority is provided by Fritsch to support the contention that Lin's motions to terminate these Interferences fail to comply with the Rules of Practice. Indeed, the motions are clearly supported by the Rules of Practice and the rules were fully complied with as noted in Lin's motions.

A. The District Court has Jurisdiction to Determine Priority

Fritsch et al complain that there is no justification for granting the relief

LIN REPLY
Interference Nos. 102,096 and 102,097

sought by Lin on the premises that the Commissioner has sole and ultimate authority to determine priority of inventorship in the present case. It is unconscionable to think that a patentee having successfully defended a patent against a defense of prior inventorship (35 USC 102(g)) in a Federal District Court after extensive discovery and testimony, should be faced with another forum (the Patent Office) to argue the same issue based on the same evidence.

The arguments proffered by Fritsch et al (Opp-3)¹ represent a gross overstatement of the position. While the Patent Office is authorized to make the priority determination, this is not the only way priority can be determined in a binding way. Clearly, where a party to an Interference by his own choice raises the priority issue in a related proceeding where he has had a full opportunity to present his evidence and be heard, and that issue is decided against him before the Patent Office rules on priority, the earlier decision should be binding on him. As noted, it was Fritsch et al who raised the priority issue in the litigation and they have to live with the consequences.

Fritsch et al rely heavily on the holding in Sinko Tool & Mfg. Co. v. Automatic Devices Corp., 136 F.2d 186, 57 USPQ 356 (3d Cir. 1943)² to support their opposition. However, the factual situation in Sinko was substantively and fundamentally different from the present factual situation. In the present case, all of the priority evidence for both

¹ Reference to the Opposition of Party Fritsch et al to Motions of Party Lin to Terminate Interferences filed herein is made by the abbreviation "Opp-" followed by the relevant page number.

² A decision issued long prior to the establishment of 35 USC 135 in 1952.

LIN REPLY

Interference Nos. 102,096 and 102,097

parties was fully presented in the Court proceedings as to the subject matter directly at issue in the subject interferences. It is noted that the Opposition filed by Fritsch et al fails to even suggest the availability of any priority evidence for Fritsch et al additional to that which was presented to the Court for consideration and decision. That was not the case in Sinko. In Sinko, the priority evidence presented in the litigation, while the same as that relied on by Sinko in the interferences, was only used in the litigation in an attempt to invalidate patents not involved in the interferences and not to provide a basis for a Section 102(g) determination. In the present case, the Lin '008 was directly involved in the litigation and is in Interference No. 102,096. Additionally, Sinko did not involve a situation as here, where the party presenting the priority evidence in the litigation is now attempting to walk away from the resulting ruling.

B. Fritsch et al are Collaterally Estopped

The Fritsch et al contention that the doctrine of res judicata is inapplicable to the present case is a red herring. The real issue is one of estoppel. Indeed, the very authority relied upon by Fritsch et al to dismiss consideration of res judicata, clearly supports the position of Lin. The PTO has taken the position that where the real parties in interest in an interference were involved in prior litigation, as herein, the parties are bound under the doctrine of collateral estoppel. Thus, in English v. Herederg, 200 USPQ 597, (POBPI 1978) The Board held:

LIN REPLY

Interference Nos. 102,096 and 102,097

"We are of the opinion that the issue of actual reduction to practice by English in May, 1968 and January, 1969 was a matter actually presented and determined in the prior litigation and that this matter is not subject to further determination. Since the instant action is upon a different cause or demand than the prior action, our opinion is based on the principle of collateral estoppel. The real parties in interest are...the same parties involved in the prior litigation, and they are bound by the findings of actual reduction to practice...in this proceeding."

There can be no question but that the doctrine of collateral estoppel applies herein on the interference issues decided by the District Court.

C. The Decision of the District Court cannot be Disregarded

1. The Alleged Errors of the Court

The PTO cannot disregard the District Court ruling on priority as Fritsch et al suggest (Opp.-6) because of speculation by Fritsch et al as to possible error in the Court's ruling. The argument by Fritsch et al is tantamount to saying that a District Court is not bound by an Appeal Court decision because the District Court feels there might be some error in the appeal decision. The Court dealt thoroughly with the issue of priority invention. See again the decision beginning at page 67.

LIN REPLY
Interference Nos. 102,096 and 102,097

The Court took the position that this was a situation where the doctrine of simultaneous conception and reduction to practice could be applied. This position was adopted by the Court after fully consideration of the evidence. However, it is also clear from the decision that the Court considered Lin was the prior inventor whether or not the doctrine was applied. Thus, the Court stated at page 76:

"In any event, even assuming that the doctrine of simultaneous conception and reduction to practice does not apply here, and that the conception was sufficiently complete and operable in 1981, the Court would still reach the same conclusion that Dr. Lin has priority over Dr. Fritsch as the inventor of the 'purified and isolated' DNA sequence encoding erythropoietin...". (emphasis supplied)

2. The Standard of Proof is Irrelevant

Fritsch et al also argue that the District Court ruling should be disregarded because different standards of proof are somehow involved (Opp.-7). However, this argument has no merit at all. It is the Court's decision that counts. Furthermore, the standard of proof used by the Court, for all intents and purposes, is substantively equivalent to the burden of proof on Fritsch et al in the interference proceedings. The simple fact of the matter is that the Court found Lin to be the first inventor of the subject matter involved. It is hardly appropriate for Fritsch et al to now suggest that under some

LIN REPLY

Interference Nos. 102,096 and 102,097

kind of a "lesser" standard, they might have prevailed.

3. Fritsch's Prima Facie Rule 608(b) Showing was Considered

With respect to the Fritsch et al comments regarding their "Prima Facie Showing pursuant to 37 CFR 608(b)" (Opp.-9), it is noted that the Court considered all of the evidence relevant to priority as presented by the parties including all substantive sections of the Fritsch et al "Prima Facie Showing". See the Court's summary of the evidence at pages 27-44 of the decision and the Court's analysis of this evidence at pages 67-84. While the Magistrate may have indicated that she might not read all of the Prima Facie Rule 608(b) Showing notably the many pages of totally irrelevant documents, the decision (See again pages 27-44, 67-84) shows clearly that the Court fully evaluated all of the relevant Fritsch et al evidence in finding the Fritsch et al showing deficient.

It should be noted that in declaring Interference 102,097 between the Lin application and the Fritsch application, the Patent Office did not follow the MPEP 2303 six (6) month rule because it relied principally on the "Prima Facie Showing pursuant to 37 CFR 1.608(b)" by Fritsch et al. This showing was the only evidence at the PTO at the time the PTO was considering declaring the interference. The Court's decision repudiates the "Prima Facie Showing pursuant to 37 CFR 1.608(b)" by Fritsch et al which was the basis of declaring the subject interference. The Patent Office should not be a party to a situation which inflicts irreparable harm on the Senior Party by virtue of the Junior Party filing a 608(b) Prima Facie Showing which has been rejected by a Federal

LIN REPLY

Interference Nos. 102,096 and 102,097

Court.

4. The Court Fully Considered Best Mode

Contrary to what Fritsch et al argue, best mode was also fully dealt with by the Court. See pages 98-112 of the decision. This included the question as to whether or not host cells needed to be deposited, the Court concluding that those of ordinary skill in the art could produce mammalian host cell strains or lines with similar levels of production identified in Lin's Example 10 (decision, page 112).

D. The District Court Decision Should be Controlling in Interference No. 102,097

Fritsch errs in saying that the District Court case did not involve the count (process for making EPO) of Interference No. 102,097. The Court assessed the priority evidence regarding the DNA sequence used to make EPO and the reduction to practice of the sequence necessarily and inherently includes the use of that sequence to make EPO according to the count of Interference No. 102,097.

Fritsch et al allege that four issues of Interference 102,097 were not considered by the Court;

With regard to issues 1 and 2, the Court in upholding claim 2 and 4 of Lin's '008 patent, addressed disclosure, enablement, best mode and inventorship issues raised in Interference 102,097.

With regard to issue 3, the prior art cited in the Motions was considered by

LIN REPLY
Interference Nos. 102,096 and 102,097

the Court with regard to claims 2 and 4 of the '008 patent, and thus the Court addressed these issues insofar as Interference 102,097 is concerned.

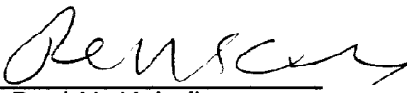
With regard to issue 4, as noted above, best mode was carefully considered relative to claim 4 of the '008 patent, and thus there is no best mode issue left in Interference 102,097.

In brief, the substantive priority issue was determined for both interferences by the District Court. There is no reason to continue the interference proceedings in the light of the Federal District Court's decision. However, in view of the Court's decision, Lin is submitting herewith a contingent motion proposing a new count for Interference No. 102,097 which is consistent with the language of claim 2 of the Lin '008 patent.

The subject interferences should be terminated.

Respectfully submitted,

CUSHMAN, DARBY & CUSHMAN

By: 
Paul N. Kokulis
Reg. No. 16,773
An attorney for the
party Lin

January 25, 1990

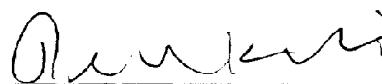
WTS:dmn
1615 L Street, N.W., 11th Floor
Washington, D.C. 20036
(202) 861-3000

LIN REPLY

Interference Nos. 102,096 and 102,097

CERTIFICATE OF SERVICE

It is hereby certified that a copy of the foregoing REPLY BY LIN TO THE OPPOSITION OF PARTY FRITSCH ET AL. TO MOTIONS OF PARTY LIN TO TERMINATE INTERFERENCES together with Exhibits has been sent this 25th day of January, 1990, by first-class mail, postage prepaid, to the attorney of record for the party Fritsch et al., George A. Skoler, Esq c/o Genetics Institute, Inc., 87 Cambridge Park Drive, Legal Affairs, Cambridge, Massachusetts 02140-2387.



Paul N. Kokulis