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Fritsch et al Rule 608(b) showing stands nullified and Fritsch et al have no valid basis for being in interference.

The decision of the Federal Circuit is manifestly binding on the PTO with respect to issues considered by the Court. In re Katz, *supra*. See also, for example, Henning v. Hunt, 106 USPQ 307, 313 (CCPA 1955) where the Court stated:

*The appeal, Civil Action 20,023, was taken for the purpose of reviewing the action of the Board of Appeals of the Patent Office, and the court reversed the board's decision, as noted in the above-cited conclusions of law. The court found that Hunt was entitled to the claim forming the count of the interference. The commissioner (and the Patent Office tribunals) cannot question the court's decisions; their failure or refusal to execute it by appropriate action would undoubtedly be corrected by judicial process; the decree of the court is the final adjudication on the question of right. Butterworth v. Hoe, 112 U.S. 50. If the Patent Office tribunals did not follow the court's decision, it would be tantamount to reversing the appellate court.*

As noted by the Commissioner in In re Pearne, 212 USPQ 467 (Comm'r Pat & TM 1981), "[in] appropriate circumstances, it may also be proper to consider the effect of any known litigation which the patent may have been involved." *Id.* at 468. The rationale of the Commissioner was clear:

*the federal courts and the PTO are jointly responsible for the overall administration of the patent system. ...[T]he maximum benefit to the system occurs when the PTO and the federal courts act in harmony. Accordingly, it scarcely seems appropriate for the PTO to relitigate in a reexamination proceeding an issue of patentability which has been resolved by a federal court on the merits after a thorough consideration of the prior art called to its attention in an adversary context. *Id.* at 4 68-469.*

Clearly, the effect of the Federal Circuit decision is that Lin has been determined to be prior to Fritsch et al under 35 USC 102(g) as to the process in issue

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(as well as to the subject matter of the related interferences). The Court's determination forecloses priority award and patentability of the subject matter at issue, to Fritsch. Paraphrasing Pearne, it scarcely seems appropriate for the PTO to relitigate in an interference proceeding issues which have been decided by a federal court on the merits after thorough consideration of matters called to its attention in an adversarial context by the same parties.

The Fritsch et al opposition to the Lin motion is without merit. The arguments by Fritsch et al are misplaced and the authorities they have cited relate to situations fundamentally different from the present case which is unique because of the involvement of the Federal Circuit in its determination of the priority, Section 103 patentability and best mode issues. There is clearly nothing analogous to the present situation in the authorities Fritsch et al rely on. Nor is it reasonable for Fritsch et al to suggest that this matter should be reconsidered on the basis that different standards of proof are involved. There can only be one standard of proof as to priority evidence, patentability and best mode, namely, the standard used by the Federal Circuit to decide these issues.

Furthermore, the decisions relied on by Fritsch et al were all decided before the formation of the Federal Circuit as the sole Appellate Court having jurisdiction over priority and patentability determinations by the Patent Office and the various district courts. Judge Learned Hand's notations in the 1943 Second Circuit Sinko decision<sup>11</sup>

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<sup>11</sup> Sinko Tool & Manufacturing Co. v. Automated Devices Corp., 136 F.2d 186, 189-90, 57 USPQ 356, 359-360 (2d Cir. 1963)

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concerning the authority of the Patent Office to determine priority of invention must be viewed in the context of the statutory charge to the Federal Circuit to review such decisions for errors in fact and law. Fritsch et al's reference to the unpublished opinion in Piher Sociedad Anomina v. CTS Corp., No. S. 78-174 (N.D.Ind. 1979) as "following" Sinko is without significance to the issues involved here. In that decision, the Indiana District Court, ruling in an action under 35 U.S.C. 146, remanded the case to the Patent Office for a decision on 102(g) issues which the Board had refused to determine on collateral estoppel grounds even though the parties had stipulated in an earlier district court action that 102(g) issues were to be determined in the first instance by the Patent Office.

Likewise, Fritsch et al's reference to Childers Foods, Inc. v. Rockingham Poultry Co-Op, Inc., 203 F.Supp. 794, 133 USPQ 648, 650 (W.D.Va. 1962) is both inapt and misleading. That case involved the denial of a stay of an infringement action pending interference proceedings. In quoting from the district court decision, Fritsch et al cropped the court's notation that it was the moving party's counsel who commented on the lack of influence of a district court determination on the conclusion to be reached in the interference. Moreover, in quoting the court's notation on the "particular expertise" of the Patent Office in determination of priority of invention, Fritsch et al failed to quote the very next sentence wherein the court denied any binding effect of such a determination, stating:

*[t]he conclusion reached on this question in the Interference Proceeding, while not binding on this court, would certainly be most helpful.*

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Fritsch et al's argument that, "[i]n this proceeding, however, Fritsch will prevail if he can prove prior conception by a preponderance of evidence" is legally unsound. It disregards the clearcut ruling of the Federal Circuit. The law of the case is that the invention of a purified and isolated DNA sequence encoding human EPO involved simultaneous conception and reduction to practice. Fritsch et al admit that this DNA sequence was reduced to practice in their hands long after Lin's reduction to practice. Thus, a "conception" of the DNA sequence by Fritsch et al prior to Lin's cannot be shown by any evidence, whether the standard of proof is by a preponderance of the evidence or on a clear and convincing basis.

Furthermore, Fritsch et al's arguments on the evidentiary showing which purportedly would allow them to prevail in this proceeding wholly ignores the District Court's evidentiary findings concerning priority of invention if it could have been possible to form a conception of the purified and isolated EPO gene without actually reducing it to practice, i.e. if proposing a possible cloning strategy amounted to conception of the gene. The District Court specifically found a corroborated conception of the same cloning strategy by Lin in October, 1981, i.e. two months before any date of conception alleged for Edward Fritsch (13 USPQ2d at page 1763). Thus, Fritsch et al cannot here establish prior conception by a preponderance of evidence when Edward Fritsch did not develop the idea of his cloning strategy until after Lin's corroborated conception of the same. Furthermore, the District Court specifically found that, even in the absence of proof of Lin's earlier conception of a cloning strategy, plaintiff (Lin's assignee) had proven lack of diligence by Edward Fritsch in reducing the strategy to practice (pages 1763-1764).

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Fritsch et al cannot, therefore, establish by a preponderance of evidence diligence towards reduction to practice before Lin when it has already been proven that Edward Fritsch was guilty of lapses in diligence virtually throughout the period between December 1981, through to contracting with Miyake for additional EPO protein in May of 1984, long after Lin had cloned the EPO gene (see again pages 1763-1764, 13 USPQ2d). While Fritsch et al have provided some additional evidence regarding the proposed diligence by Fritsch, they have failed to provide any evidence to rebut the lapses in diligence found by the District Court.

Fritsch et al cannot logically argue in opposition to Lin's motion that the present interference involves a different invention (expression process) from that involved in the litigation. They earlier said that the subject matter at issue in Interference No. 102,096 and the present case represent "different manifestations of the same invention". Additionally, the litigation addressed priority of invention of Lin's '008 claims to host cells transformed with the isolated EPO gene. Consideration of such claims is tantamount to consideration of the present process count, particularly in view of the District Court's findings on the in vivo biological activity of the products of those host cells.

In attempting to distinguish the District Court's determination, the Fritsch et al opposition tries to equate the "isolating" step of the count with "purifying". There is no valid basis for this. Isolating in the context of the count obviously means nothing more than separating the product from the cells (LR 229, 975). The culture media samples tested by Dr. Egrie were frequently referred to as isolates. It is also noted that Fritsch et al, when presenting their claims 72 and 73, which correspond to the count, referred

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to page 6, lines 18-20; page 27, line 23 through page 29, line 16 (i.e. Examples 6 and 7) and page 32, line 11 through page 34, line 23 (i.e. Examples 10-12) of their disclosure as support for these claims. See page 2, Paper No. 16 in the Fritsch et al application file. Nowhere in these portions of the Fritsch disclosure is there any indication that the expression product is purified. The examples refer (see Example 6, page 28, line 5) to harvesting and use of the supernatant media for assay (page 33, lines 1-3). This is exactly the process Lin discloses and the process shown in Lin's proofs. It involves isolation but not purification. Interestingly, page 6, lines 18-20 of the Fritsch et al specification, which Fritsch et al referred to for support, refers to "the production of EPO by in vitro expression of those genes". This is what the District Court found Lin was the first to do. The disclosure statement also goes completely contrary to the Fritsch et al arguments that expression without purification does not satisfy the count language.<sup>12</sup>

In presenting his motion for judgment with respect to patentability as well as priority issues, Lin is mindful of the holding in Perkins v. Kwon, 886 F.2d 325, 12 USPQ 1308 (Fed. Cir. 1989). However, the present situation is fundamentally different from that

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<sup>12</sup> See also the following cross-examination testimony by Lin which clearly and unequivocally distinguishes between isolation and purification (LR229):

BY MR. RICHTER:

- Q. What did Dr. Browne or Ralph Smalling do to isolate the glycosylated polypeptide?  
 A. In this case isolating does not mean purify. It means that glycosylate EPO is produced in the medium, is present in the medium, they isolate this medium and they use for the assay.  
 Q. Used for?  
 A. Used for the in vivo assay or in vitro assay, whatever we have to do with the products.  
 Q. And that's your understanding of the term "isolating"?  
 A. Yeah. That's right. Yes.

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in the Kwon case. A key difference is that Kwon involved the issue of whether or not priority should be determined at final hearing after the subject matter had been found unpatentable to a party. Disregarding priority in Kwon would have meant that the later inventor would obtain a patent because of an on-sale bar against the first inventor. In the present case, the Courts have already determined priority favorably to Lin. The present position is, therefore, the exact reverse of the Kwon situation. Moreover, the Courts have decided the same priority and best mode issues favorably to Lin based on the record before the Board. As reflected by the Fritsch et al briefs, the obviousness issue is not substantively different from that decided in the litigation. Issues dealt with and determined in the litigation should not be relitigated in the present proceedings. In re Katz, supra. See also Amoco Company v. Zarb, 402 F.Supp. 1001 (D.C. D.C., 1975); Nixon v. Richey, 513 F.2d 430, 438 (note 75) (D.C. Cir. 1975); IB Moore's Federal Practice, ¶ 0.416[3] at 523 (2nd Ed.).

The Lin motion for judgment should be granted for the reasons noted. No substantive issues remain for interference consideration.

**(b) Lin Is the Prior Inventor of the Subject Matter at Issue**

Since the Federal Circuit has found that Lin was the first to have a conception of the DNA sequence (upon reduction to practice), and it has not been questioned that Lin produced in vivo biologically active recombinant human EPO before Fritsch et al even conceived of the DNA sequence, it follows that Lin is entitled on the record to priority as to the present count. The argument presented by Fritsch et al in

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favor of priority based on his version of a probing method for possible use (FB 21-31) totally disregard the Courts' finding that conception of the purified and isolated EPO gene did not occur until the gene was reduced to practice. Fritsch had no concept of the constitution of the gene before the gene was isolated and identified. By that time, Lin had expressed recombinant human EPO and found it to have in vivo biological activity.

The Fritsch argument that he was diligent (FB 28-31) also bypasses the fundamental point that diligence is of no consequence until there is conception of an invention which Fritsch did not have until he actually reduced the EPO gene to practice. Lin does not believe Fritsch has established diligence over the time period he has alleged, particularly in view of the numerous time spaces of unexplained inactivity.

The Federal Circuit decision dealt squarely with the Fritsch et al arguments in affirming the District Court's finding that Lin was the first inventor of the EPO DNA gene on the basis of simultaneous conception and reduction to practice. Thus, the Court decision reads (18 USPQ2d at 1020):

*Defendants assert error in the district court's legal conclusion that in this case Lin's conception occurred simultaneously with reduction to practice. See, e.g. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1988), cert. denied, 480 U.S. 947 (1987). They claim that Fritsch was first to conceive a probing strategy of using two sets of fully-degenerate cDNA probes of two different regions of the EPO gene to screen a gDNA library, which was the strategy which the district court found eventually resulted in the successful identification and isolation of the EPO gene. Defendants further claim that Fritsch conceived this strategy in 1981, was diligent until he reduced the invention to practice in May of 1984, and thus should be held to be a 102(g) prior inventor over Lin, who reduced the invention to practice in September of 1983.*



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The Federal Circuit then went on to agree with the District Court's position regarding simultaneous conception and reduction to practice, stating (page 1021):

*The invention recited in claim 2 (the count) is a 'purified and isolated DNA sequence' encoding human EPO. The structure of this DNA sequence was unknown until 1983, when the gene was cloned by Lin; Fritsch was unaware of it until 1984. As Dr. Sadler, an expert for GI, testified in his deposition: 'You have to clone it first to get the sequence'... . Prior to 1983, the amino acid sequence for EPO was uncertain, and in some positions the sequence envisioned was incorrect. Thus, until Fritsch had a complete mental conception of a purified and isolated DNA sequence encoding EPO and a method for its preparation, in which the precise identity of the sequence is envisioned, or in terms of other characteristics sufficient to distinguish it from other genes, all he had was an objective to make an invention which he could not then adequately describe or define. (Matter in parenthesis and underscoring added.)*

It is to be noted that the argument considered by the Federal Circuit, and dismissed, is the exact approach that Fritsch et al attempt to again treat here as a de novo matter. However, Lin's priority case begins with the recognition by the Federal Circuit that Lin was the first to conceive and reduce to practice the purified and isolated DNA sequence encoding human EPO. Fritsch et al have not challenged this finding. It is also unchallenged by Fritsch that this sequence was used by Lin in transformed mammalian cells for expression to obtain in vivo biologically active recombinant human EPO and that all of this work was done by Lin before Fritsch et al even conceived the sequence, according to the Federal Circuit and District Court decisions. See pages 1020-1022 of the Federal Circuit decision and pages 1759-1764 of the District Court decision.

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The expression and isolation of the expression product as required to test for in vivo biological activity clearly meet the limitations of the present process count.<sup>13</sup> Hence, it is not necessary to go beyond the undisputed facts as found by the District Court and left unchanged by the Federal Circuit to determine that Lin's expression and determination of in vivo biological activity of the expressed product satisfies all of the limitations of the count of the present interference and represents reduction to practice by Lin well prior to the Fritsch et al conception date. However, the present Lin record also includes further confirmation that the expression and testing referred to by the District Court constituted reduction to practice of the process of the count. See, for example, the testimony of Drs. Browne and Egrie that the work which they did on Lin's behalf involved all of the features of the count (LR 30, 67, 68). Lin also confirmed this (LR 5).

It is important to recognize that the record in this interference contains no evidence on the issue of simultaneous conception and reduction to practice that was not before the District Court and the Federal Circuit. The testimony of Fritsch et al and his co-workers is, at best, duplicative of the Rule 608(b) testimony that was in evidence in the District Court and argued in the trial to establish prior conception of Edward Fritsch.<sup>14</sup>

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<sup>13</sup> As noted earlier, there is no basis whatsoever for Fritsch et al to argue that "isolating" in the claim means "purifying". The term "isolating" as used is obviously generic in nature and contemplates harvesting the expression media from the cells as done for test purposes. See again Lin's testimony (LR 229).

<sup>14</sup> If anything, Fritsch et al's 608(b) evidence was significantly weakened by cross-examination of these witnesses who were brought up to provide live testimony. Cross-examination established numerous instances of work previously credited to the GI EPO projects was actually for other GI projects and work on projects that had nothing to do with the two degenerate probe genomic library screening strategy allegedly conceived by Edward Fritsch in December, 1981. Likewise the Fritsch et al declaration testimony

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Fritsch et al have not presented any new evidence that Edward Fritsch's December, 1981, strategy amounted to an anything more than a goal of obtaining the purified and isolated EPO gene whatever its identity. No witness testified in this interference that Edward Fritsch or his designated co-inventors Hewick and Jacobs had any idea of precise identity of the EPO gene or of any characteristic of the gene sufficient to distinguish it from other genes. The record here reveals only what was revealed to the District Court, that until the EPO gene was cloned and sequenced at GI in 1984, all Fritsch et al had was "...an objective to make an invention which he [they] could not then adequately describe or define" (18 USPQ2d at page 1021).

Rather than address the factual foundations of the Federal Circuit's holding on simultaneous conception and reduction to practice, the Fritsch et al brief reverts to attempts (unsuccessfully presented in the District Court, the Federal Circuit and in preliminary motions<sup>15</sup> herein) to "transform" the claimed invention herein into a method of probing invention. Thus, despite Lin's assertions to the Examiner during prosecution of the '008 patent that

"the presently claimed subject matter involves novel DNA, not a novel method for obtaining it,"<sup>16</sup>

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of the Fritsch et al co-workers is riddled with objectionable presentations. (See Lin's Motion to Suppress Fritsch et al evidence and Opposition to Fritsch et al's Proposed Findings of Fact submitted herewith). The record herein only illuminates the colossal failure of that strategy until long after knowledge of Lin's success.

<sup>15</sup> See Fritsch et al Motion O, dismissed by the Examiner-in-Chief, attempting to substitute a process claim for the count.

<sup>16</sup> Page 17, 2d ¶, July 13, 1987 amendment.