

**EXHIBIT 1
(Part 3 of 4)**

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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 decision¹¹

¹¹ 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 Fritsch et al's reference to the unpublished opinion in Piher Sociedad Anomina v. CTS Corp., No. S. 78-174 (N.D.Ind. 1979) as "following" Sinko is without significance to the issues involved here.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 '006 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.¹²

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 USPO 1308 (Fed. Cir. 1989). However, the present situation is fundamentally different from that

¹² 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 novel 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.¹³ 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.¹⁴

¹³ 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).

¹⁴ 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 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 motions¹³ 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,"¹⁴

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.

¹³ See Fritsch et al Motion O. dismissed by the Examiner-in-Chief, attempting to substitute a process claim for the count.

¹⁴ Page 17, 2d ¶, July 13, 1987 amendment.

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Fritsch et al persist in characterizing the invention of the court as a strategy for isolating the EPO gene, which strategy was allegedly conceived by Edward Fritsch or by Fritsch et al at some time prior to Lin.¹⁷ The Federal Circuit's ruling completely disposes of this argument (18 USPQ2d at page 1021):

Fritsch had a goal of obtaining the isolated EPO gene, whatever its identity, and even had an idea of a possible method of obtaining it, but he did not conceive a purified and isolated DNA sequence encoding EPO and a viable method for obtaining it until after Lin. It is important to recognize that neither Fritsch nor Lin invented EPO or the EPO gene. The subject matter of claim 2 was the novel purified and isolated sequence which codes for EPO, and neither Fritsch nor Lin knew the structure or physical characteristics of it and had a viable method of obtaining that subject matter until it was actually obtained and characterized. Underscoring added.)

The Court disagreed completely with Fritsch's argument that Fritsch was the first inventor because of his probing strategy. Thus, the Court stated:

Defendants further argue that because the trial court found that the probing and screening method employed by Lin is what distinguished the invention of the '008 patent over the prior art, Fritsch's strategy in 1981 had priority over Lin's use of that strategy. We disagree. The trial court found that Fritsch's alleged conception in 1981 of an approach that might result in cloning the gene was mere speculation. Conception of a generalized approach for screening a DNA library that might be used to identify and clone the EPO gene or then unknown constitution is not conception of a "purified and isolated DNA sequence" encoding human EPO. It is not "a definite and permanent idea of the complete and operative invention". Fritsch's conception of a process had to be sufficiently specific that one skilled in the relevant art would succeed in cloning the EPO gene. See, Coleman, 754 F.2d at 359, 224 USPQ at 862. Clearly, he did not have that conception because he did not know the structure of EPO or the EPO gene.

¹⁷ The Fritsch et al brief (page 20) actually invites the Board to pick from among five dates for completeness of the Fritsch et al cloning strategy.

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Commenting further on the inadequacy of the Fritsch et al position, the Federal Circuit held that (pages 1021-1022):

The record indicates that several companies, as well as Amgen and Gl, were unsuccessful using Fritsch's approach. As the trial court correctly summarized:

'Given the utter lack of experience in probing genomic libraries with fully degenerate probes and the crudeness of the techniques available in 1981, it would have been mere speculation or at most a probable deduction from facts then known by Dr. Fritsch that his generalized approach would result in cloning the EPO gene.' 13 USPQ2d at 1760.

As expert testimony from both sides indicated, success in cloning the EPO gene was not assured until the gene was in fact isolated and its sequence known. Based on the uncertainties of the method and lack of information concerning the amino acid sequence of the EPO protein, the trial court was correct in concluding that neither party had an adequate conception of the DNA sequence until reduction to practice had been achieved; Lin was first to accomplish that goal.

Defendants also argue that the court failed to consider that 1983, just prior to Lin's conception, was the relevant time for determining the completeness of Fritsch's conception, not 1981. However, the record shows that the court did consider what occurred in 1983. Moreover, Fritsch had no more of a conception in 1983 than he did in 1981, because he did not then know the sequence of the gene encoding EPO. (Underscoring added.)

This means that all of the evidence from the District Court proceedings, which Fritsch et al have reintroduced into these proceedings, including his alleged strategy involving a possible method of probing suitable for cloning the DNA sequence, is of no consequence and can be dismissed as irrelevant to priority. According to the Federal Circuit decision, Fritsch et al could not have a conception of the DNA sequence until they had actually reduced to practice the DNA sequence. By that time, according

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to the undisputed facts. Lin had not only purified and isolated the DNA sequence but he or others at his request had used it to produce *in vivo* biologically active recombinant human EPO.

While the foregoing is believed to be dispositive of the priority issue as between Fritsch et al and Lin, it is useful to separately set out the District Court's undisputed findings as to the work done by Lin and Fritsch in reducing the invention to practice as this serves to underscore Lin's priority position. Thus, the District Court found, the Federal Circuit did not question, and Fritsch et al have not challenged, the following findings of facts as to Lin's work (at page 1748, 13 USPQ2d):

The successful cloning of the EPO gene took place in September or early October 1983. (Tr. 4, 64-66; 5, 123-124). This was the first time that Lin ever designed, ordered and used two sets of probes, both fully degenerate, from two different regions of the EPO gene to screen a genomic library. (Tr. 5, 91, 124). Amgen (someone other than Dr. Lin) sequenced the gene to confirm it was the EPO gene (Tr. 4,74).

In late October, 1983, Lin cloned the monkey cDNA EPO sequence. (Tr. 4, 72). On December 3, 1983, Lin also hybridized the human EPO gene to monkey EPO cDNA so that he could determine from an electron micrograph which area of the human DNA consisted of introns, and what the sizes of the exons and introns were. (Tr. 4, 68-72; PX 63-38).

By January 10, 1984, Amgen had expressed human EPO in human embryonic kidney cells called "293" cells and in COS cells, which are monkey kidney cells. (Tr. 4-75-77; PX 63-39; PX 63-41). Someone other than Dr. Lin did the work with the mammalian expression system. (Tr. 5, 51-52). Lin was personally involved in the E. Coli expression of EPO. (Tr. 5,52). On February 13 and 14, 1984, Amgen conducted experiments to show that the

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recombinant human EPO produced in the COS cell was biologically active. (Tr. 4, 80).

From March 1-9, 1984, Amgen conducted an in vivo bioassay and determined that the recombinant EPO was biologically active. (Tr. 4, 82-83).

On March 15, 1984, Lin obtained the human full length EPO cDNA gene. (Tr. 4, 83; 5, 28).

By May 2, 1984, human rEPO had been expressed in CHO cells. (Tr. 4, 86). Jeff Browne and Ralph Smalling worked together on the EPO project team, which Lin continued to head through 1984...

As for Fritsch et al, the District Court noted that Fritsch et al were unsuccessful in cloning the EPO gene prior to August, 1984 summarizing the Fritsch et al position as follows (page 1751):

On May 30, 1984, the genomic library for isolating the EPO gene was plated and hybridized using two sets of probes, both fully degenerate, from different regions of the amino acid sequence. (Tr. 26, 96-98). This process resulted in the identification of two clones in July, 1984, both of which were the full gene for EPO. (Tr. 26, 100-102). This was the first time that Gl used two sets of fully degenerate probes based on the correct amino acid sequence for EPO. (Tr. 31, 46). Also, Dr. Fritsch used a hybridization solution called TMAC, which had not been used by Dr. Lin when he cloned the EPO gene. (Tr. 7, 101; 26, 86).

The positive clones were then used to construct a single long probe to screen a cDNA library constructed from human fetal liver, and on August 6, 1984, cDNA clones were successfully isolated. (Tr. 26, 104-106). Gl transfected a CHO cell with a cDNA clone for EPO; this was the expression system with which Gl was most familiar. (Tr. 26, 107).

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The District Court's uncontested factual findings can thus be summarized in the following chronology:

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<u>ACTIVITY</u>	<u>DATE</u>
Lin clones human EPO gene	Sept.-Oct. 1983
Amgen (for Lin) confirms EPO gene by sequencing	Sept.-Oct. 1983
Lin clones monkey EPO gene	Late Oct. 1983
Amgen (for Lin) expresses human EPO gene in 293 and COS cells	Jan. 10, 1984
Amgen (for Lin) determines biological activity of recombinant human EPO gene expression product	Feb. 13-14, 1984
Amgen (for Lin) determines <u>in vivo</u> biological activity of recombinant human EPO gene expression product	March 1-9, 1984
Amgen (for Lin) expresses human EPO gene in CHO cells	May 2, 1984
Fritsch identifies two clones	July 1984
Fritsch expresses human EPO gene in CHO cells	after Aug. 1984

The above undisputed factual summary from the District Court decision thus clearly and unequivocally shows that Lin made the invention at issue, i.e., he expressed in vivo biologically active recombinant human EPO by a process involving culturing (or growing) a mammalian host cell transformed with the isolated EPO DNA

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sequence and isolating an in vivo biologically active expression product, before Fritsch et al even conceived of the essential DNA sequence".

It is appreciated that the Court decisions use shorthand language (e.g. "expressed") concerning the preparation process rather than reciting the specific language of the present count. However, there can be no distinction between Lin's expression of in vivo biologically active recombinant human EPO using 293, COS cells and CHO cells and the determination of its activity as found by the Courts and the specific language of the count. Glycosylation is necessary to provide in vivo biological activity. This is art-recognized and the Examiner-in-Chief has noted that Fritsch et al have not challenged this. See Paper No. 44, sentence bridging pages 2-3. Transforming or transfecting a mammalian host cell (e.g. 293, COS or CHO) with the DNA sequence of the Lin '008 patent and growing (or culturing) this transformed cell under nutrient condition necessarily and inherently involves transcription, translation and glycosylation as specified in steps (a)(i)(ii)(iii) of the Count to provide the in vivo biologically active recombinant EPO. Fritsch et al cannot challenge this as their claims corresponding to the Count simply recite culturing and isolating. Furthermore, they recognized the identity of the respectively claimed processes by not bringing a motion urging no interference in fact. This leave step (b) for consideration and Lin notes that determination of the in vivo biological activity obviously requires isolation (b) of the product from the host cells.

¹⁴While it is not necessary to do so in view of the Federal Circuit's simultaneous conception/reduction to practice position, it is noted that the District Court also found that Lin conceived the probing method in October, 1981, i.e. before Fritsch et al (13 USPQ2d at 1763). Hence, as noted earlier, Fritsch et al could not prevail even if, in theory, conception could occur prior to reduction to practice on the basis of the probing method.