ATTACHMENT B

2 of 3 DOCUMENTS

Fritsch et al v. Lin

Patent Interference No. 102,096

Application of Edward Fritsch, Rodney M. Hewick and Kenneth Jacobs filed January 22, 1985, Serial No. 06/693,258. Accorded benefit of U.S. Serial No. 06/688,622, filed January 3, 1985, abandoned.

Patent granted to Fu-Kuen Lin on October 27, 1987, Patent No. 4,703,008 filed November 30, 1984, Serial No. 06/675,298. Accorded benefit of U.S. Serial No. 06/561,024, filed December 13, 1983, abandoned; U.S. Serial No. 06/582,185, filed February 21, 1984, abandoned; U.S. Serial No. 06/655,841, filed September 28, 1984.

Board of Patent Appeals and Interferences

1991 Pat. App. LEXIS 29

December 3, 1991; Final Hearing August 29, 1991

[*1]

Serota, Chairman and R. Smith and Caroff, Examiners-in-Chief.

COUNSEL:

Kurt E. Richter, Bruce M. Eisen, David L. Berstein, Ellen J. Kapinos, Eugene Moroz, William S. Feiler and George A. Skoler for Fritsch et al. Oral argument by Kurt E. Richter.

Paul N. Kokulis, William E. Dominick, Albert W. Bicknell, William A. Marshall, Jerome B. Klose, Basil P. Mann, Alvin D. Shulman, Donald J. Brott, Owen J. Murray, Allen H. Gerstein, Nate F. Scarpelli, Edward M. O'Toole, Michael F. Borun, Carl E. Moore, Jr. and Watson T. Scott for Lin. Oral argument by Paul N. Kokulis and Michael F. Borun.

OPINIONBY: CAROFF

OPINION:

Caroff, Examiner-in-Chief.

This interference involves an application of the junior party, Fritsch et al (Fritsch), and a patent of the senior party, Lin. The Fritsch application is assigned to Genetics Institute, Inc. (GI) and the Lin patent is assigned to Amgen, Inc. (Amgen).

The subject matter in issue relates to a purified and isolated DNA sequence encoding for human erythropoietin (EPO), a protein consisting of 165 amino acids which is naturally produced in the body and which stimulates the production of red blood cells. Cf. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 18 USPQ* [*2] *2d 1016, 1018 (Fed. Cir. 1991)* (hereinafter referred to as the "Federal Circuit decision"). The sole count involved in this interference defines the subject matter at issue as follows:

Count 1

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

The claims of the parties which correspond to this count are:

Fritsch: Claims 1-8, 10, 13, 14, 16, 19, 22, 25, 26, 46, 48, 50, 52, 57, 58, 60, 62, 68-70 and 74

Lin: Claims 1, 2, 4-8, 11-29 and 31

Issues

The following issues are before us for adjudication:

1. Whether the Lin motion for judgment (Paper No. 123) which is based upon the aforementioned Federal Circuit decision should be granted. n1

n1 Consideration of the Lin motion for judgment and of the Fritsch opposition thereto (Paper No. 122) was deferred to final hearing in Paper No. 132.

2. Whether Fritsch has adduced sufficient evidence to establish prior inventorship with respect to the subject matter defined by the count.

3. Whether Fritsch has adduced sufficient evidence to establish that Lin has failed to satisfy the "best mode" requirement of *35 USC 112*. n2

n2 The "best mode" issue was originally raised by Fritsch in a preliminary motion (Motion B) and was deferred to final hearing in Paper No. 33.

[*3]

4. Whether Lin's involved claims are unpatentable to Lin under *35 USC 103*. n3

n3 The issue of "obviousness" under *35 USC 103* was originally raised by Fritsch in a preliminary motion (Motion A) and was deferred to final hearing in Paper No. 33.

5. Whether the Fritsch motion to correct inventorship (Paper No. 54), and companion motion for leave to file a corrected preliminary statement (Paper No. 52), should be granted. n4

n4 Consideration of the indicated motions, as well as associated oppositions and replies, was deferred to final hearing in Paper No. 56.

6. Whether the motion by Lin under 37 CFR 1.635 and 1.656(h) to suppress evidence (Paper No. 141) should be granted.

7. Whether the motion by Fritsch under 37 CFR 1.635 and 1.656(h) to suppress evidence (Paper No. 136/137) should be granted.

Both parties took testimony, submitted exhibits, and filed briefs. In addition, Lin submitted documents under § 1.682 (Paper No. 127) and Fritsch submitted proposed findings of fact and conclusions of law (Paper No. 135). n5

n5 The Fritsch testimony record, exhibits, brief, reply brief and proposed findings will hereinafter be respectively referred to as "FR", "FX", "FB", "FRB" and "PF" followed by an appropriate page or exhibit number. The Lin testimony, exhibits and brief will be similarly referred to as "LR", "LX" and "LB".

[*4]

No issue of interference-in-fact is before us.

1. The Lin Motion for Judgment

The fundamental question raised in the subject motion is whether the Federal Circuit decision is binding upon us as to issues 2 (priority), 3 (best mode) and 4 (obviousness) above. n6 For the reasons discussed below, the motion is granted to the extent that we shall follow and adopt the principles and findings set out in the Federal Circuit decision insofar as Fritsch has failed to present any new evidence, not before the court, which directly contradicts and outweights the evidence before the court. In other words, we are bound by the Federal Circuit decision to the extent of the evidence considered by the court, *viz.,* to the extent the record is the same, we are compelled to reach the same conclusions.

None of the case law cited by either party in this interference appears to be especially applicable to the situation at hand. Evidently, this is a case of first impression where we are asked in an interference proceeding to reconsider questions which have already been decided by a district court, and where the decision of the district court has been affirmed

on appeal to the Federal Circuit, [*5] our own appellate tribunal. In particular, none of the cases cited by Fritsch appear to involve a refusal by the Board in an interference proceeding to be bound by a final decision n7 of our reviewing court, albeit a decision affirming the holdings of a district court. In fact, decisions and legal principles enunciated by our reviewing court, now the Court of Appeals for the Federal Circuit, are binding and controlling on the Board. *Cf.,* Rivise and Caesar, Interference Law and Practice, Vol. IV. § 784, p. 2780 (Michie Co. 1948). Accordingly, in this case we must give due deference to the deliberations and conclusions of our appellate tribunal if the factual basis on which they rest has not been undermined by new evidence.

n7 We note that the Federal Circuit decision of interest here is now final (Paper Nos. 124, 126, 151).

2. Fritsch's Case for Priority

Fritsch conceded at final hearing that the invention at issue was successfully reduced to practice by Lin in October 1983 and thereafter by Fritsch. (PF II-343). In other words, Fritsch concedes that Lin actually reduced the subject invention to practice before Fritsch. Accordingly, in order to prevail on the [*6] issue of prior inventorship, Fritsch, as the last to reduce to practice, must establish that he was the first to conceive and proceeded with reasonable diligence to reduce the subject invention to practice from a time prior to conception by Lin. *35 USC 102*(g).

The evidence adduced by Fritsch establishes the following chronology of activities which inure to the benefit of Fritsch and GI. In December 1981, Fritsch envisioned a strategy for isolating the EPO gene which would involve using two sets of fully degenerate probes to screen a genomic DNA library. (PF II-8; FR 6546-47 (Maniatis)). This strategy was employed in 1982 and 1983 and resulted in a number of unsuccessful initial screenings (PF II-63 through II-86). By May 1983, Fritsch concluded that the initial screenings were unsuccessful because of a suspected error in the EPO amino acid sequence data which he had obtained from Dr. Hewick of GI and upon which he had relied to design complementary oligonucleotide probes. (PF II-86). It was later determined that the sequence data was indeed incorrect (FB-9; PF II-56, II-57). Accordingly, GI sought to obtain additional purified urinary EPO in order to derive more accurate EPO [*7] sequence information. These efforts were initially unsuccessful. Ultimately, in April 1984, GI purportedly obtained some purified EPO from a Dr. Miyake. The EPO was then used by Dr. Hewick to obtain new amino acid sequence data (PF II-105). Within about two months of obtaining the correct sequence information, Fritsch successfully obtained the EPO gene by employing his cloning strategy (PF II-105 through II-113).

Essentially the same set of facts was before the Federal Circuit. Based upon the record before it, the court agreed with the findings of the trial court n8 that, at the time in question, conception of a process for cloning the EPO gene was incomplete absent adequate knowledge of the structure of EPO or the EPO gene itself and, in view of the uncertainties of the envisioned cloning strategy and the lack of information concerning the amino acid sequence of EPO, neither party had an adequate conception of the DNA sequence until reduction to practice had been achieved.

n8 *Amgen, Inc. v. Chugai Pharmaceutical Co., 13 USPQ2d 1737 (D.Mass. 1990).* We note here that Chugai Pharmaceutical Co. (Chugai) is a licensee of GI, the assignee of junior party Fritsch.

We find [*8] no explicit reference by Fritsch in his opposition to Lin's motion for judgment, or in any of his briefs or at final hearing, to any new evidence, not before the court, which directly contradicts and outweights the evidence which led the court to conclude that knowledge of an appropriate EPO amino acid sequence is necessary for a complete conception of the subject invention and that the doctrine of simultaneous conception and reduction to practice is applicable in view of the state of technology involved. By way of example, we note that PF III-33, which is specifically relied on by Fritsch (FB-21), is based on the record before the trial court and not based on any new evidence. Therefore, we find no reason under any appropriate standard of proof to reach a conclusion different than that reached by the courts in which the issue of priority has already been litigated. Accordingly, we hold that Fritsch has failed to establish an adequate conception of the invention at issue prior to Lin's reduction to practice.

3. The Question of "Best Mode"

With respect to the issue of "best mode", Fritsch argues that Lin concealed the best mode of carrying out his invention by failing to deposit [*9] his preferred cell strain (CHO B11, 3.1) for expressing the EPO gene. Fritsch relies upon statements by the district court to the effect that the testimony is clear that no scientist could ever duplicate exactly the best mode host cells used by Amgen. However, as pointed out by Lin, both the district court and the Federal Circuit also determined in the Amgen v. Chugai litigation that the best mode of practicing the subject invention, including the preferred host cell strain, was described in sufficient detail in Example 10 of the involved Lin patent to apprise those of

ordinary skill in the art how to produce mammalian host cell strains or lines with levels of EPO production similar to those identified in Example 10. In other words, it has been determined that "the invention, as it relates to the best mode host cells, could be practiced by one skilled in the art following Example 10" and, therefore, a deposit is not required.

As explained more fully in the Federal Circuit decision *(18 USPQ2d at 1025):*

These materials are therefore not analogous to the biological cells obtained from unique soil samples. When a biological sample required for the practice of an invention is obtained [*10] from nature, the invention may be incapable of being practiced without access to that organism. Hence the deposit is required in that case. On the other hand, when, as is the case here, the organism is created by insertion of genetic material into a cell obtained from generally available sources, then all that is required is a description of the best mode and an adequate description of the means of carrying out the invention, not deposit of the cells. If the cells can be prepared without undue experimentation from known materials, based on the description in the patent specification, a deposit is not required. *See Feldman v. Auntstrup, 517 F.2d 1351, 1354, 186 USPQ 108, 111 (CCPA 1975),* ("No problem exists when the microorganisms used are known and readily available to the public."), *cert. denied, 424 U.S. 912 [188 USPQ 720]* (1976). Since the court found that that is the case here, we therefore hold that there is no failure to comply with the best mode requirement for lack of a deposit of the CHO cells when the *best mode* of preparing the cells has been disclosed and the best mode cells have been enabled, *i.e.,* they can be prepared by one skilled in the art from [*11] known materials using the description in the specification.

The court also indicated that the best mode requirement does not mandate a disclosure sufficient to enable exact duplication of the inventor's best mode. What is required, according to the Federal Circuit decision, is an adequate disclosure of the best mode and not a guarantee that every aspect of the specification be precisely and universally reproducible.

Based upon the foregoing findings, the "best mode" issue was decided in favor of Lin. We find no new evidence relied upon by Fritsch which directly contradicts and outweighs the evidence relied upon by the courts in reaching their findings concerning Lin's satisfaction of the "best mode" requirement. Therefore, we find no reason under any appropriate standard of proof to disturb those findings and, accordingly, hold that the Lin disclosure is sufficient to satisfy the "best mode" requirement of *35 USC 112.*

4. The Issue of "Obviousness"

According to the Federal Circuit and district court decisions, at the time of Lin's invention a person of ordinary skill in the field of gene cloning, armed with the knowledge available in the prior art, would have found it "obvious [*12] to try" to isolate the EPO gene using the probing technique employed by Lin but, in view of a difference of opinion among the experts, the evidence was found to be insufficient to establish that there was a "reasonable expectation of success" in cloning the EPO gene based on the probing strategy disclosed in the prior art.

To establish the obviousness of Lin's involved claims in this interference, Fritsch principally relies upon the Toole et al reference (U.S. Patent No. 4,757,006, FX-34) as prior art. However, according to Lin (Paper No. 123, page 7), the Toole et al reference was before the district court and thus, by implication, also before the Federal Circuit. This is not disputed by Fritsch. Thus, there appears to be no evidence before us which was not considered in the preceding litigation and, therefore, we find no basis for reaching a different conclusion on the question of "obviousness". Accordingly, we hold that the subject matter of Lin's involved claims would not have been obvious within the context of *35 USC 103.*

With respect to the Toole et al reference, it is instructive to repeat some of the remarks of the Examiner-in-Chief in his Decision on Motions (Paper No. [*13] 33) as to "Motion E" which we find to be pertinent with respect to the question of "obviousness" as well as the issues raised in Motion E. To wit, it was pointed out that the "earlier applications" of Fritsch's assignee, i.e., the Toole et al reference, do not specifically mention EPO and refer only to the production of a different protein, "Factor VIII:C". Further, the following averment by Fritsch was said to contradict any assertion that the cloning technique of Toole et al is generally applicable:

One cannot identify clearly all of the genes for which this cloning approach is applicable, however, it is quite clear that the numbers are quite small and constitute a readily identifiable class of materials.

It should be clear that the aforementioned statement, made under oath, suggests that the enabling scope of the Toole et al disclosure is limited with respect to the cloning of genes other than the factor VIII:C gene. In this regard, the Toole et al disclosure does not appear to provide any more guidance for cloning an EPO gene than the other prior art references which were considered in the preceding litigation.

5. The Fritsch Motion to Correct Inventorship

For the reasons [*14] discussed below, the subject motion shall be denied. While the motion may be considered moot in view of our determination of the issue of prior inventorship, we shall consider the motion on its merits for the sake of completeness. We note that the companion motion for leave to file a corrected preliminary statement involves the same questions raised in the motion at issue and, therefore, shall also be denied.

The party Fritsch argues that Hewick and Jacobs should be deleted as co-inventors since they were originally named as inventors under the mistaken belief that inventors are identified on the basis of the same standards by which coauthors of scientific papers are identified. (PF VII-11, 12).

According to the verified statements of the inventors and their attorney Skoler (FR 4196-4208), Hewick's scientific contribution included providing EPO amino acid sequence data and Jacobs' included procedures used in screening a genomic library and isolating the EPO gene. The statements indicate that the "error" in naming Hewick and Jacobs as inventors arose by reliance on their "scientific contributions" that did not meet the standard for "inventive contribution". However, the [*15] statements do not specifically indicate and explain the factual basis for the present belief that Hewick's and Jacobs' scientific contributions do not amount to inventive contributions.

Lin argues that the verified statements are essentially conclusory, at best, with no detailed explanation of how the alleged "error" occurred. Lin also asserts that the attempt to correct inventorship was not "diligently made" as required by 37 CFR 1.48(a) since there is no indication why the "error" was not discovered earlier when Fritsch was preparing its § 1.608(b) showing or its preliminary statement. In this regard, it is noted that the purported error is said by Fritsch to have been first discovered at a meeting held on September 10, 1990, yet Fritsch does not specifically deny the charge that Fritsch's trial counsel in the Boston infringement litigation argued as early as April 1989, over a year earlier, that Fritsch was the sole inventor of the subject matter defined by the count at issue here.

We entirely agree with Lin that the motion to correct inventorship should be denied for the reasons stated by Lin. For emphasis, we observe that Fritsch has established no factual basis to suport [*16] its conclusion that the scientific contributions of Hewick and Jacobs do not amount to inventive contributions. The fact that an overly broad standard was initially applied to identify the inventors at GI does not necessarily establish that an error was committed which actually resulted in an incorrect designation of inventors. In this regard, we note that the standards for determining joint inventorship are also fairly broad in scope - see *35 USC 116*.

We are aware that the statute governing inventorship conversion is remedial in nature and, therefore, is ordinarily liberally construed. However, in this case it has been determined in considering the question of prior inventorship that knowledge of correct EPO amino acid sequence information and precise procedures for isolating the EPO gene are critical aspects of conception with respect to the invention at issue. These are the very components of the invention to which Hewick and Jacobs are said to have contributed. Therefore, in our opinion, it was incumbent upon Fritsch to make a factual presentation and explain in detail why the contributions of Hewick and Jacobs should not be considered inventive. This Fritsch has failed to [*17] do.

6. The Lin Motion to Suppress

We do not reach the subject motion for decision. We find it unnecessary to consider the specific objections raised in the motion since we have found that Fritsch does not prevail on any substantive issue before us even after having considered all of Fritsch's evidence of record in its entirety. Therefore, there is no need to consider whether some of that evidence is admissible or not. In this regard, Lin himself recognizes in his motion (page 2) that it may not be necessary to consider the objections. Additionally, we observe that many of Lin's objections, and virtually all of those pertaining to Fritsch's proposed findings, go to the weight of the evidence rather than its admissibility.

7. The Fritsch Motion to Suppress

We find it unnecessary to consider the specific objections raised by Fritsch since, as should be apparent, none of our substantive determinations in this interference are based upon those portions of the record and exhibits to which Fritsch objects. Therefore, although we have considered all of the evidence introduced by the parties, in reaching our conclusions we gave no weight to the evidence which is objected to [*18] by Fritsch.

Judgment

For the foregoing reasons, judgment as to the subject matter of the count in issue is hereby awarded to Lin, the senior party.

Accordingly, Fu-Kuen Lin is entitled to his patent containing claims 1, 2, 4-6, 11-22, 28, 31 corresponding to the count. n9 Edward Fritsch, Rodney M. Hewick and Kenneth Jacobs, the junior party, are not entitled to a patent containing claims 1-8, 10, 13, 14, 16, 19, 22, 25, 26, 46, 48, 50, 52, 57, 58, 60, 62, 68-70, 74 corresponding to the count.

n9 We note that Lin's remaining claims corresponding to the count, i.e., claims 7, 8, 23-27, 29, were held to be invalid under *35 USC 112* in the Federal Circuit decision for lack of enablement.

Legal Topics:

For related research and practice materials, see the following legal topics:
Patent LawInequitable ConductGeneral OverviewPatent LawU.S. Patent & Trademark Office ProceedingsContinuation ApplicationsGeneral OverviewPatent LawU.S. Patent & Trademark Office ProceedingsInterferencesGeneral Overview