ATTACHMENT C

3 of 3 DOCUMENTS

Fritsch et al v. Lin

Patent Interference No. 102,097

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.

Application of Fu-Kuen Lin filed October 23, 1987, Serial No. 07/113,179. Accorded benefit of U.S. Serial No. 06/675,298, filed November 30, 1984, Patent No. 4,703,008, issued October 27, 1987; 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 30

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 an application of the senior party, Lin. The Fritsch application is assigned to Genetics Institute, Inc. (GI) and the Lin application is assigned to Amgen, Inc. (Amgen).

The subject matter in issue relates to a process for the preparation of an *in vivo* biologically active glycosylated polypeptide, namely the recombinant version of human erythropoietin (EPO). The process is more particularly defined by the sole count in this interference as follows:

Count 1

A process for the preparation [*2] of an *in vivo* biologically active glycosylated polypeptide comprising the steps of:

(a) growing a mammalian host cell which is capable of effecting post-translational glycosylation of polypeptides expressed therein and which is transformed or transfected with an isolated DNA sequence encoding a polypeptide having a primary structural conformation sufficiently duplicative of that of naturally occurring human erythropoietin to allow possession of the *in vivo* biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, or the progeny thereof, under nutrient conditions suitable to allow, in sequence,

(i) transcription within said host cell of said DNA to mRNA in the sequence of transcription reactions directed by the nucleotide sequence of said DNA;

(ii) translation within said host cell of said mRNA to a polypeptide in the sequence of translation reactions directed by the nucleotide sequence of said transcribed mRNA;

(iii) glycosylation within said host cell of said polypeptide in a pattern directed by the amino acid sequence of said translated polypeptide and sufficiently duplicative of the pattern of glycosylation of naturally [*3] occurring human erythropoietin to allow possession by the translated glycosylated polypeptide product of the *in vivo* biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells; and

(b) isolating the glycosylated polypeptide so produced.

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

Fritsch: Claims 72-73

Lin: Claims 65-69

Issues

The following issues are before us for adjudication:

1. Whether the Lin motion for judgment (Paper No. 131) should be granted. n1

n1 The subject motion is based upon the decision in *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991),* hereinafter referred to as the "Federal Circuit decision". Consideration of the subject motion and the opposition thereto (Paper No. 140) was deferred to final hearing in Paper No. 157.

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 I) and was deferred to final hearing in Paper No. 35.

[*4]

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 H) and was deferred to final hearing in Paper No. 35.

5. Whether the Fritsch motion to correct inventorship (Paper No. 61), and companion motion for leave to file a corrected preliminary statement (Paper No. 58), 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. 62.

6. Whether the motion by Lin under 37 CFR 1.635 and 1.656(h) to suppress evidence (Paper No. 168) should be granted.

7. Whether the motion by Fritsch under 37 CFR 1.635 and 1.656(h) to suppress evidence (Paper No. 163/164) should be granted.

8. Whether Lin's involved claims are unpatentable to Lin under *35 USC 102*(f). n5

n5 The issue under *35 USC 102*(f) was originally raised by Fritsch in a preliminary motion (Motion M) and was deferred to final hearing in Paper No. 35.

Both parties took testimony, submitted exhibits, and filed briefs. In addition, Lin submitted documents under § 1.682 (Paper No. 151) and Fritsch [*5] submitted proposed findings of fact and conclusions of law (Paper No. 162). n6

n6 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".

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

I. Issues 1-7

Of the issues enumerated above, all except issue No. 8 are essentially identical to the issues already considered in related Interference No. 102,096. With regard to the issue of prior inventorship in particular, we note that Fritsch conceded at final hearing that priority in each of the related interferences turns on isolation of the EPO gene, i.e., determination of priority in Interference No. 102,096 is dispositive on the issue of priority in the present interference (also see FB-24).

Accordingly, we refer to the concurrent final decision in the '096 interference for disposition of the issues which we have identified above as issues 1-7.

II. The Question of Lin's Inventorship under *35 USC 102*(f)

Fritsch asks us to find Lin's [*6] involved claims unpatentable under *35 USC 102*(f) since, according to Fritsch, Dr. Lin "did not himself invent the subject matter" set forth in the Lin claims corresponding to the count in this interference. In particular, Fritsch asserts that Dr. Lin took no part in developing the procedures at Amgen for expressing the EPO gene in mammalian host cells and isolating the resulting EPO product.

The record indicates that all the work at Amgen relating to expression of the EPO gene in mammalian host cells was directed and supervised by Dr. Browne, assisted by Ralph Smalling. Dr. Lin does not recall giving any instructions or suggestions as to how such expression should be carried out (PF V-3, 4). The effort to isolate the EPO glycoprotein expression product was carried out by Dr. Strickland, and Dr. Lin gave no specific instructions for accomplishing that task (PF V-6). However, the expression of the EPO gene in mammalian host cells using the DNA sequence isolated by Dr. Lin was carried out at Lin's request and on his behalf. (LR 3, 10, 41).

Lin argues that it is not essential for the inventor to be personally involved in carrying out process steps defined by the count where implementation [*7] of those steps does not require the exercise of inventive skill.

We agree with Lin. Initially, we note that statements in patent applications as to sole or joint invention are *prima facie* evidence of such fact; and a party, relying upon his application, does not have to prove such facts. Thus, a party who wishes to dispute sole inventorship as stated in an application, as Fritsch does in this case, has the burden of overcoming the *prima facie* effect of the application. Rivise and Caesar, Interference Law and Practice, Vol. III, § 407 (Michie Co. 1947). Fritsch has failed to satisfy the burden so imposed since Fritsch has adduced no evidence suggesting that the work done at Amgen relating to expression of the EPO gene in mammalian host cells and isolation of the resulting glycoprotein product involved anything other than the exercise of ordinary skill by practitioners in that field *Cf. Vanderkooi v. Hoeschele, 7 USPQ2d 1253 (BPAI 1987).* Indeed, Fritsch apparently acknowledges that expression of the EPO gene, once isolated, to obtain a recombinant EPO product would not have required more than ordinary skill (FB-24).

Judgment

For the foregoing reasons, judgment [*8] 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 a patent containing claims 65-69 corresponding to the count. Edward Fritsch, Rodney M. Hewick and Kenneth Jacobs, the junior party, are not entitled to a patent containing claims 72-73 corresponding to the count.

Legal Topics:

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