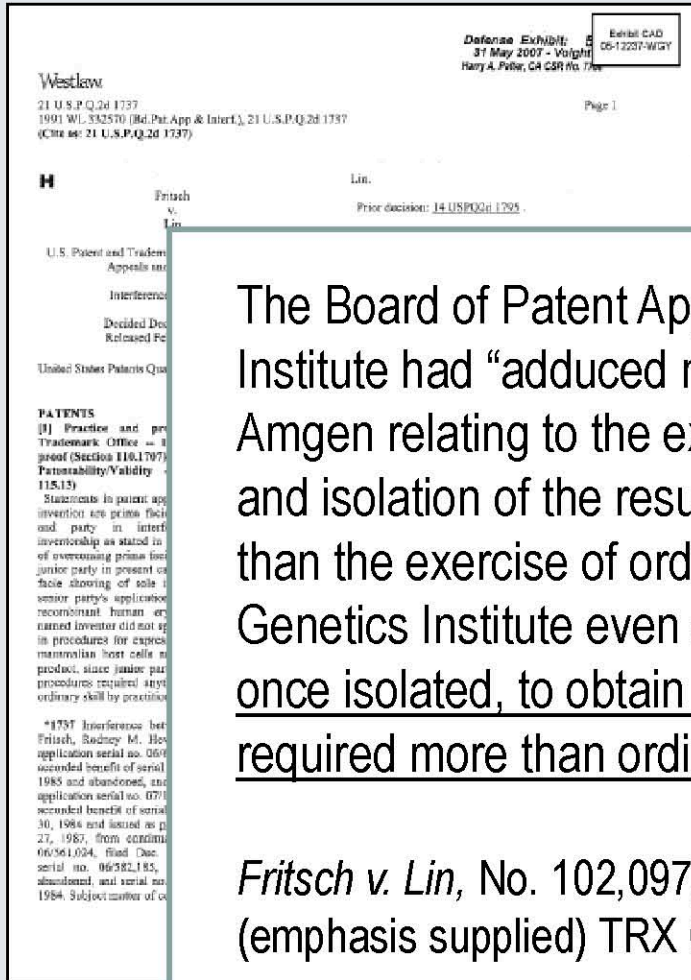


Attachment Part 4 of 4

The Board of Patent Appeals Decision



The Board of Patent Appeals and Interferences determined that Genetics Institute had “adduced no evidence suggesting that the work done at Amgen relating to the 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 the field” and that Genetics Institute even acknowledged “that expression of the EPO gene, once isolated, to obtain a recombinant EPO product would not have required more than ordinary skill.”

Fritsch v. Lin, No. 102,097, 21 U.S.P.Q. 2d at 1740 (Bd. Pat. App. & Interf. 1991) (emphasis supplied) TRX CAD



21 U.S.P.Q.2d 1731
 1991 WL 392569 (Bd. Pat. App. & Interf.), 21 U.S.P.Q.2d 1731
 (Cite as: 21 U.S.P.Q.2d 1731)

Fritsch
 v.
 Lin

U.S. Patent and Trademark Office Board of Patent
 Appeals and Interferences

Interference No. 102,096

Decided December 3, 1991
 Released February 3, 1992

United States Patents Quarterly Headnotes

PATENTS

[1] Practice and procedure in Patent and Trademark Office -- Board of Patent Appeals and Interferences -- In general (Section 110.1101)

JUDICIAL PRACTICE AND PROCEDURE

Procedure -- Prior adjudication -- Res judicata; collateral estoppel (Section 410.1503)

Board of Patent Appeals and Interferences must give due deference to deliberations and conclusions of the U.S. Court of Appeals for the Federal Circuit, and therefore board, in considering issues in interference which have already been considered by Federal Circuit on appeal of infringement suit involving same subject matter, must adopt findings of appellate tribunal on those issues if factual basis on which findings rest has not been undermined by new evidence.

PATENTS

[2] Patentability/Validity -- Date of invention -- Conception (Section 115.0403)
 Patentability/Validity -- Date of invention -- Reduction to practice (Section 115.0405)

JUDICIAL PRACTICE AND PROCEDURE

Procedure -- Prior adjudication -- Res judicata; collateral estoppel (Section 410.1503)

Junior party in interference has failed to establish conception of invention at issue prior to senior party's reduction to practice, since federal district court concluded in infringement suit that knowledge of appropriate erythropoietin amino acid sequence is

necessary for complete conception of invention, since court further concluded that simultaneous conception and reduction is applicable in view of state of technology since court's findings were affirmed on appeal since junior party has presented no evidence, not before district court, which contradicts or outweighs evidence support conclusions.

PATENTS

[3] Patentability/Validity -- Specificity mode (Section 115.1107)

JUDICIAL PRACTICE AND PROCEDURE

Procedure -- Prior adjudication -- Res judicata; collateral estoppel (Section 410.1503)

Junior party in interference has not shown party, by failing to deposit preferred cell expressing erythropoietin gene, concealed for producing invention relating to polynucleotide DNA sequences encoding human erythropoietin, that best mode disclosure is sufficient to satisfy best mode disclosure requirement without deposit of cells, since federal district court decision affirmed by U.S. Court of Appeals for the Federal Circuit, concluded that patent preferred host cell strain in sufficient detail one skilled in art to produce line of satisfactory levels of EPO production, junior party has presented no additional evidence which directly contradicts or outweighs evidence considered by courts in reaching that conclusion.

PATENTS

[4] Patentability/Validity -- Obviousness -- Relevant prior art -- Particular (Section 115.0903.03)

JUDICIAL PRACTICE AND PROCEDURE

Procedure -- Prior adjudication -- Res judicata; collateral estoppel (Section 410.1503)

Junior party in interference has not shown party's patent for DNA sequences encoding erythropoietin to be obvious in view of



1. The Lin Motion for Judgment

[1] 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. [FN6] 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 outweighs 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.

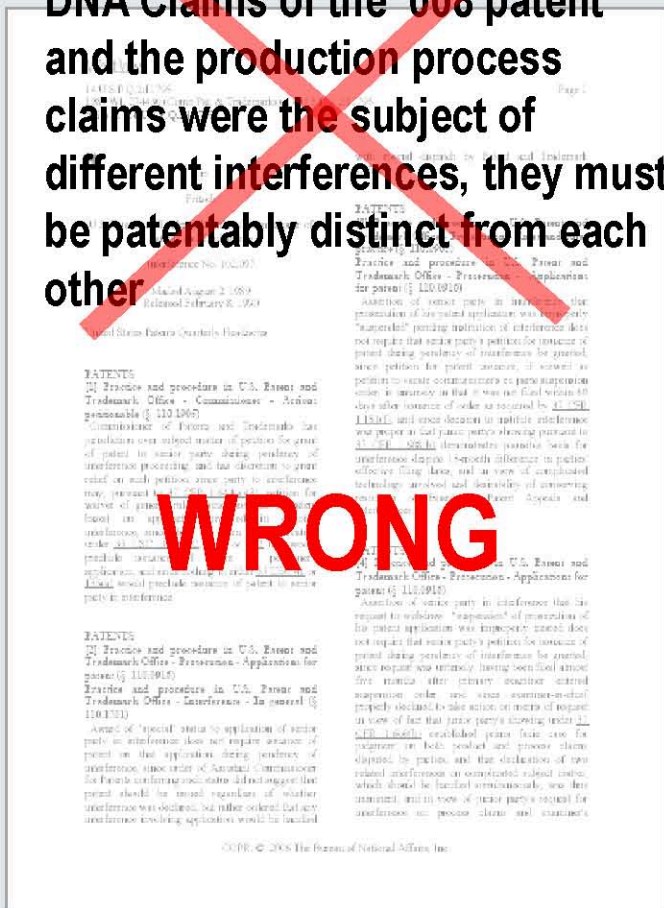
Amgen argued that because the DNA Claims of the '008 patent and the production process claims were the subject of different interferences, they must be patentably distinct from each other

WRONG

In Actuality...

Amgen failed to tell the PTO that during the interference proceedings, the Patent Judges, upon Amgen's urging ruled that the issues in both interference were the same:

"Of the issues enumerated above, all except issue No. 8 [Lin inventorship] 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 [Genetics Institute] 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." 21 U.S.P.Q. 2d at 1738-1739. (emphasis supplied)



PATENTS
Practice and procedure in U.S. Patent and Trademark Office - Prosecution - Applications for patent (§ 110.0910)

Amendment of claims in interference proceedings is not subject matter of invention. The purpose of the amendment is to clarify the claims and to avoid confusion. The amendment does not require invention. The amendment is subject to the provisions of 37 CFR 1.103 and 1.104.

PATENTS
Practice and procedure in U.S. Patent and Trademark Office - Prosecution - Applications for patent (§ 110.0910)

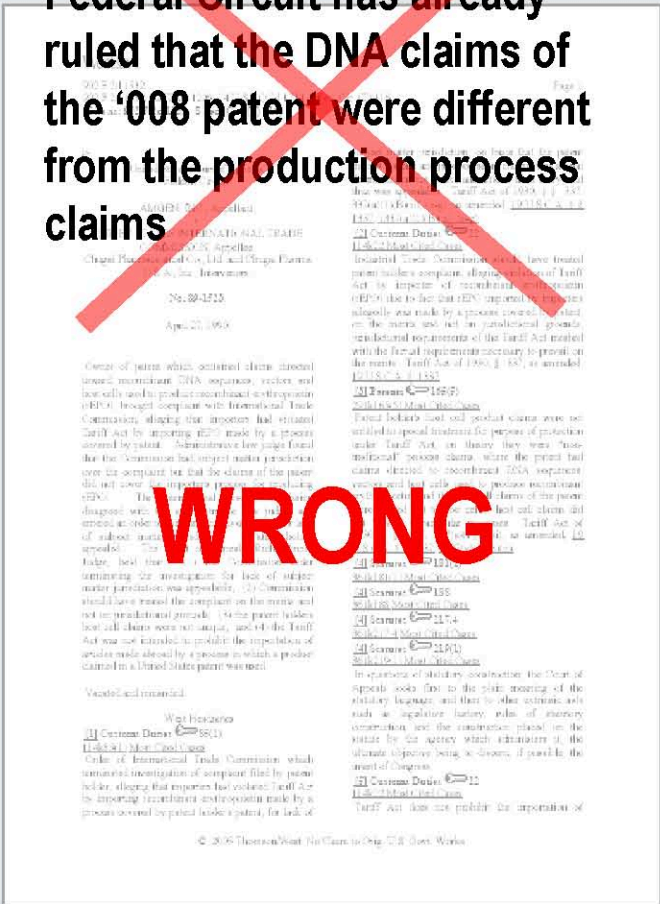
Amendment of claims in interference proceedings is not subject matter of invention. The purpose of the amendment is to clarify the claims and to avoid confusion. The amendment does not require invention. The amendment is subject to the provisions of 37 CFR 1.103 and 1.104.

Amgen argued that the ITC and Federal Circuit has already ruled that the DNA claims of the '008 patent were different from the production process claims

WRONG

In Actuality...

The Amgen v. ITC case had nothing to do with obviousness and merely stated that the '008 patent claims were to products, not processes. It did not stand for the idea that product claims cannot make obvious process claims. In fact, several Federal Circuit cases hold that they can. See *Geneva Pharmaceuticals*, 349 F.3d at 1385-86; *Research Corp.*, 10 Fed. Appx. at 856; *In re Lonardo*, 119 F.3d. at 968.



~~Amgen argued that because the production process claims were the first time anyone in the world made a biologically active glycosylated protein, they cannot be obvious~~

WRONG

In Actuality...

Even if this were true, Roche is not saying that the asserted claims are obvious because of other people's work. They are obvious from Amgen's own work on EPO. After all, the '008 patent claims:

"A procaryotic or eucaryotic host cell transformed or transfected with [a purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin] in a manner allowing the host cell to express erythropoeiten."



Amgen argued that one could not rely upon the prior art in assessing obviousness type double patenting

WRONG

In Actuality...

In re Longi (later claim reciting a catalyst reaction between a magnesium halide and a nitrogen titanium compound was rendered obvious over an earlier claim to a similar catalyst reaction due to the disclosures of four prior art references); *Barr Labs., Inc.*, 251 F.3d at 969-70 (considering prior art in determining whether claimed method was an inherent effect of earlier claimed method and thereby invalid for double patenting.); MPEP 804, ¶¶ 8.36-8.37 (“Claim [1] rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim [2] of U.S. Patent No. [3] in view of [4], [5].”) (emphasis added)

Judicial Estoppel

- The doctrine's primary utility is to safeguard the integrity of the courts by preventing parties from improperly manipulating the machinery of the judicial system.
- A party should not be allowed to play “fast and loose” with the judicial system.

See New Hampshire, 532 U.S. at 750, 121 S.Ct. 1808; *United States v. Levasseur*, 846 F.2d 786, 792 (1st Cir.1988).

Judicial Estoppel

- The requirements for judicial estoppel are as follows.
- First, the estopping position and the estopped position must be directly inconsistent. *See Faigin v. Kelly*, 184 F.3d 67, 82 (1st Cir.1999); *Levasseur*, 846 F.2d at 794.
- Second, the responsible party must have succeeded in persuading a court to accept its prior position. *Lydon v. Boston Sand & Gravel Co.*, 175 F.3d 6, 13 (1st Cir.1999); *Gens*, 112 F.3d at 572-73.