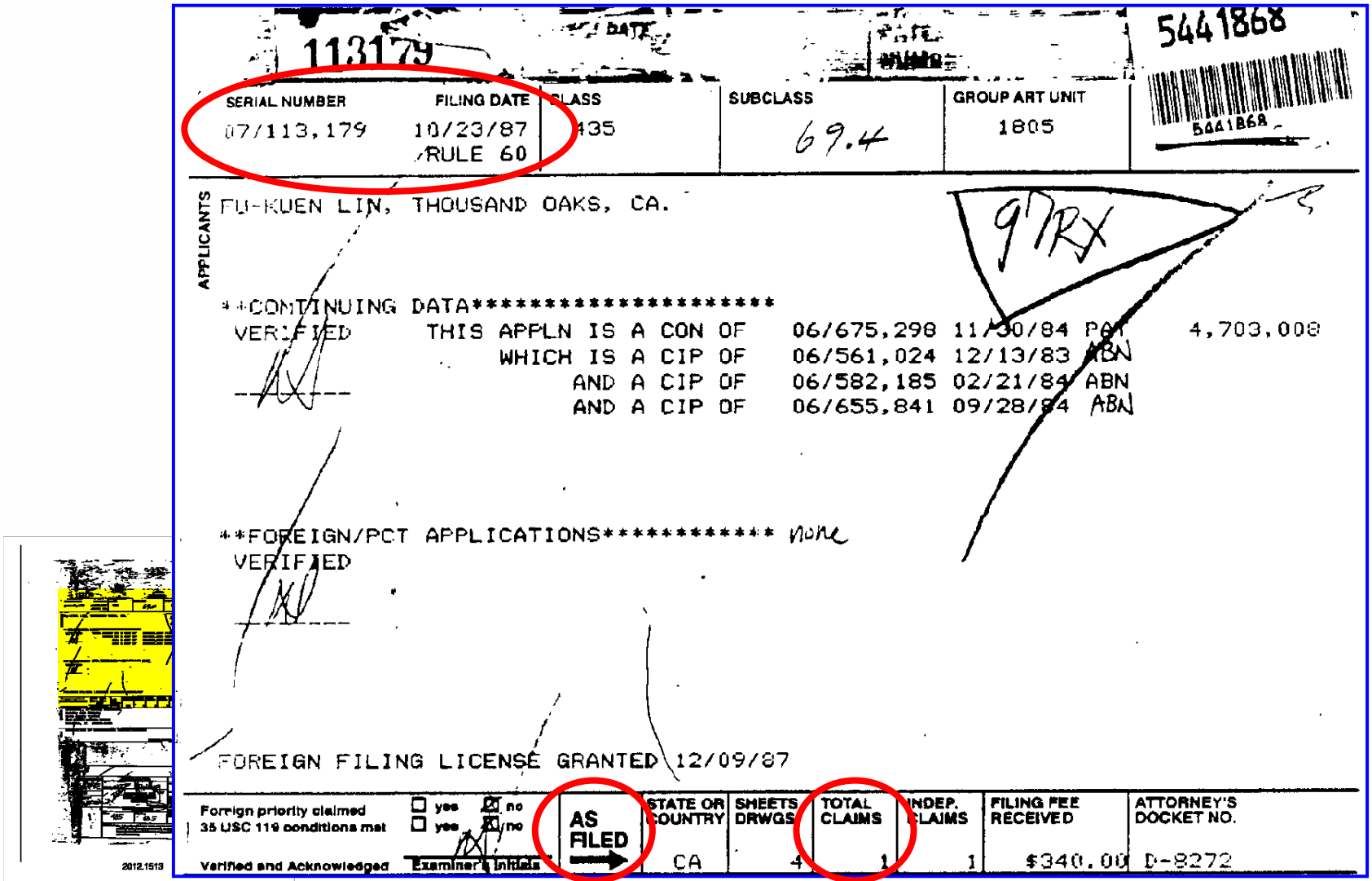
Obviousness-Type Double Patenting

Amgen's Supplemental Demonstratives

October 4, 2007

Amgen Inc. v. F. Hoffmann-La Roche, Ltd., No. 05-cv-12237-WGY

Total Claims In '179 Application "As Filed" = 1



113179

5441868

SERIAL NUMBER	FILING DATE	CLASS	SUBCLASS	GROUP ART UNIT
07/113,179	10/23/87 RULE 60	435	69.4	1805

APPLICANTS

FU-KUEN LIN, THOUSAND OAKS, CA.

9 RX

CONTINUING DATA********

VERIFIED

THIS APPLN IS A CON OF 06/675,298 11/30/84 PAT 4,703,008
WHICH IS A CIP OF 06/561,024 12/13/83 ABN
AND A CIP OF 06/582,185 02/21/84 ABN
AND A CIP OF 06/655,841 09/28/84 ABN

FOREIGN/PCT APPLICATIONS******** none

VERIFIED

FOREIGN FILING LICENSE GRANTED 12/09/87

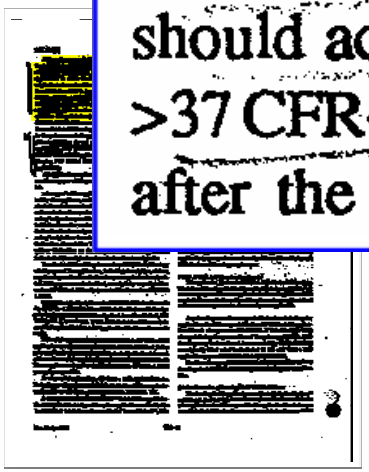
Foreign priority claimed 35 USC 119 conditions met	Verified and Acknowledged	Examiner's Initials	AS FILED	STATE OR COUNTRY	SHEETS DRWGS	TOTAL CLAIMS	INDEP. CLAIMS	FILING FEE RECEIVED	ATTORNEY'S DOCKET NO.
☐ yes ☒ no ☐ yes ☒ no				CA	4	1	1	$340.00	D-8272

2012.1513

TX 2012.1513 (PTO file wrapper for '179 application)

MPEP § 201.06(a): Preliminary Amendment Not Entered Until After Filing Date Has Been Granted

Although a copy of all original claims in the prior application must appear in the >37 CFR< 1.60 application, some of the claims may be canceled by request in the >37 CFR< 1.60 application in order to reduce the filing fee >,however, one original must remain at the time of granting the filing date< (see form 3.54, item >6<*). Any preliminary amendment presenting additional claims (claims not in the prior application as filed) should accompany the request for filing an application under >37 CFR< 1.60, but such an amendment will not be entered until after the filing date has been granted.



MPEP § 201.06(a) (5th Ed., Rev. 11, Apr. 1989); *see also* Docket Item 676, at 3-4.

Differences Between All ‘008 and ‘868 Asserted Claims

‘008 Claims	‘868 Claims
The ‘008 claims are to compositions of matter	The ‘868 claims **require** a **specific recited combination of steps**
The ‘008 claims require neither glycosylation nor a polypeptide	The ‘868 claims **require** production of a **glycosylated** polypeptide
The ‘008 claims do not require either *in vitro* or *in vivo* biological function	The ‘868 claims **require** that any EPO expressed have the stated ***in vivo* biological function**
The ‘008 claims do not require the production of any amount of EPO	The ‘868 claims **require** that the recited host cell be capable of producing **isolatable quantities** of EPO

See also Docket Item 1310, at 38-42.

Additional Differences Between Certain '008 and '868 Asserted Claims

'008 Claims	'868 Claims
'008 claim 7 covers an enormous number of DNAs coding for EPO analogs and '008 claims 25 and 27 cover host cells transformed or transfected with any of those numerous DNAs coding for EPO analogs	The '868 claims **exclude DNAs coding for EPO analogs**
'008 claims 7, 25 and 27 have been held invalid for lack of sufficient enablement	It is undisputed that the '868 claims are **sufficiently enabled**
'008 claims 2 and 7 do not require any host cell, and '008 claims 4 and 6 broadly cover any procaryotic and any eucaryotic host cell transformed or transfected with the recited DNA sequence	The '868 claims **require mammalian host cells**

See also Docket Item 1310, at 38-42.

Additional Differences Between All ‘008 and ‘698 Asserted Claims

‘008 Claims	‘698 Claims
The ‘008 claims do not require “amplified DNA”	The ‘698 claims **require** “**amplified DNA**”
The ‘008 claims do not require “amplified marker gene DNA”	‘698 claims 7 and 8 **require “amplified marker gene DNA”**

See also Docket Item 1310, at 43-44.

Judicial Estoppel

Two elements:

(1) the party's previously asserted position and presently asserted position must be "directly inconsistent, that is, mutually exclusive"

- *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 33 (1st Cir. 2004).
- *See also Simon v. Safelite Glass Corp.*, 128 F.3d 68, 72 (2d Cir. 1997) ("[T]here must be a true inconsistency between the statements in the two proceedings. If the statements can be reconciled there is no occasion to apply an estoppel.")

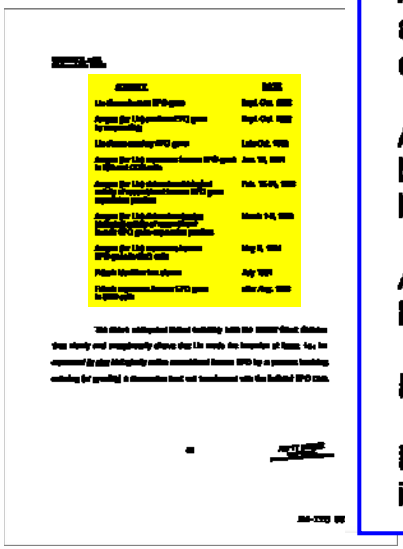
(2) "the first forum [must have] *accepted* the legal or factual assertion alleged to be at odds with the position advanced in the current forum . . ."

- *In re Gens*, 112 F.2d 569, 572 (1st Cir. 1997) (emphasis in original)
- *See also Merrill Lynch, Pierce, Fenner & Smith Inc. v. Georgiadis*, 903 F.2d 109, 114 (2d Cir. 1990) (Judicial estoppel "applies only if the party against whom the estoppel is claimed actually obtained a judgment as a result of the inconsistent position.")

The Board Referenced G.I.'s Position, Not Amgen's

G.I.'s '097 Priority Position	Amgen's '097 Priority Position	BPAI Ruling
"Accordingly, as in the '096 interference, priority turns upon the first conception of the purified and isolated EPO gene. The record establishes that Dr. Fritsch, not Dr. Lin, was the first to make such a conception of the isolated EPO gene and thereafter exercised reasonable diligence in reducing it to practice."	"The findings of the District Court, affirmed by the Federal Circuit, clearly show that Lin carried out the expression process using the DNA sequence to produce in vivo biologically active recombinant human EPO before Fritsch et al even conceived the DNA sequence."	"With regard to the issue of prior inventorship in particular, we note that ***Fritsch conceded*** at the 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***)."
Ex. GXH, at 24-25 ("FB-24") (emphasis added)	Ex. GUK, at 29 (emphasis in original)	TX 2012.1044-45 (emphasis added)

Amgen's Position: Lin Had *In Vivo* Activity Before Fritsch Even Had The Gene



ACTIVITY	DATE
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 in vivo 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

Ex. GUK, at 46