

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No.: 05-12237 WGY
)	
)	
F. HOFFMANN-LA ROCHE)	
LTD., a Swiss Company, ROCHE)	
DIAGNOSTICS GmbH, a German)	
Company and HOFFMANN-LA ROCHE)	
INC., a New Jersey Corporation,)	
)	
Defendants.)	
_____)	

**AMGEN INC.'S OPPOSITION TO ROCHE'S MOTION *IN LIMINE* TO PRECLUDE
AMGEN INC. FROM ASSERTING THAT THE GENERATION OF TRYPTIC
FRAGMENTS AND DETERMINATION OF THE AMINO ACID
SEQUENCE OF EPO WAS NOVEL AND NON-OBVIOUS**

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I. INTRODUCTION

Roche's motion *in limine* (Docket Item ("D.I.") 811) asks the Court to apply the doctrine of judicial estoppel to preclude Amgen from arguing that "prior to Dr. Lin's invention, the generation of tryptic fragments and determination of the amino acid sequence of EPO was novel and non-obvious to a person skilled in the art," because Roche interprets such arguments to be inconsistent with statements made by the Patent and Trademark Office ("PTO") during prosecution of the patents-in-suit. Roche's motion should be denied because Roche has not even come close to showing that the legal requirements of judicial estoppel are met. The only party attempting to play "fast and loose" with the Courts is Roche by filing this motion.

The prior "positions" that Roche points to as being inconsistent with Amgen's present position were those of the PTO. Contrary to Roche's misleading assertions, Amgen *never* stated during prosecution that the generation of tryptic fragments and determination of the amino acid sequence of EPO was not novel and non-obvious. The only Amgen position that Roche points to is that Amgen and Dr. Lin told the PTO that Amgen scientist Por Lai was not an inventor of the patents-in-suit. Roche argues that because Lai assisted with the sequencing on the tryptic fragments of urinary EPO that failing to name Lai as an inventor must mean that Lai's work was only routine effort within the skill in the art. But Roche's argument is a *non sequitur* because Dr. Lin's patents do not claim urinary EPO or the amino acid sequence of tryptic fragments of urinary EPO. The fact that Lai did some work that supported Lin's efforts to produce recombinant EPO does not make Lai an inventor of Lin's patents to a novel form of EPO and the processes for making it. As both the PTO and this Court have found, Lai never conceived any of Lin's inventions and was merely working under the direction of Dr. Lin. Thus, Amgen is not taking an inconsistent position with what it told the PTO, and there is simply no basis for the application of judicial estoppel.

This is not a situation where Amgen has secured a favorable decision based on one position, and then taken a contrary position in search of a legal advantage. Since neither of the two legal requirements for judicial estoppel is met, Roche's motion should be denied.

II. BACKGROUND

Dr. Lin is the sole inventor of each of the inventions claimed in the patents-in-suit. Dr. Lin is also the sole inventor of the separate inventions claimed in the now-expired U.S. Patent No. 4,703,008 ("the '008 patent"). During prosecution of the '008 patent, the examiner initially rejected certain claims under 35 U.S.C. §§ 102(a)/103 based on two publications coauthored by Dr. Lin and several other individuals, including Por Lai. In response, Dr. Lin filed two declarations (one addressing each publication) establishing his sole inventorship of the claimed subject matter. (D.I. 813, Exs. 4, 5.) Dr. Lin explained that Lai was not a co-inventor of the claimed subject matter as follows:

. . . Por H. Lai, also a coauthor of the publication referenced in Paragraph 11, was a research scientist who assisted in sequencing fragments of the erythropoietin protein, and while co-authoring said publication, is not a coinventor of the subject matter claimed in said patent application.

(D.I. 813, Ex. 4 at ¶ 14, Ex. 5 at ¶ 12.) Dr. Lin's declarations were both dated August 29, 1986.

(D.I. 813, Ex. 4 at 3, Ex. 5 at 3.) The '008 patent issued on October 27, 1987.

Lai did not file any protest with the PTO contending that he was a co-inventor of the subject matter claimed in the '008 patent. During litigation involving the '008 patent, this Court found that Dr. Lin's description of Lai's role was correct:

The record demonstrates that the statement that "Por H. Lai . . . was a research scientist who assisted in sequencing fragments of the erythropoietin protein" is correct.

. . . .

Regardless of who prepared the fragments, Dr. Lin was the one who selected the T-35 and T-38 fragments, designed the probes based on sequence information obtained by his assistant Por Lai, under his direction, and screened the library.

Amgen, Inc. v. Chugai Pharm. Co. Ltd., 13 U.S.P.Q.2d 1737, 1777 (D. Mass. 1989).

Several years later, on July 23, 1993, Lai filed two separate protests with the PTO contending that he should be named as a co-inventor on Application Nos. 07/113,178 (“the ‘178 application”) and 07/113,179 (“the ‘179 application”). (See D.I. 813, Exs. 1, 2.) Lai alleged that he had made the following contributions to the subject matter of the ‘178 and ‘179 applications:

- (a) design of key protein chemistry approaches to obtaining previously unknown EPO protein structure, e.g., fast tryptic digestion of urinary EPO which gave the desirable EPO peptide fragments;
- (b) development of novel protein microsequencing techniques necessary for working with minutely available proteins such as urinary EPO and its tryptic fragments;
- (c) precise selection, from the EPO tryptic peptides, of the EPO fragments, T-35 and T-38 based on their HPLC profiles as the first two fragments for structural studies;
- (d) successful determination of the amino acid sequences of EPO T-35 and T-38 fragments, and suggestion of use of these critical, essential EPO protein sequence information for the construction of DNA probes which were required for cloning of the EPO genes; and
- (e) elucidation of the previously unknown sequence of the EPO protein structure which was also used for confirming the complete EPO gene structure.

(D.I. 813, Ex. 1 at 1-2, Ex. 2 at 1-2.)

After considering Lai’s arguments and evidence, the examiners of the ‘178 and ‘179 applications both rejected Lai’s claim that he should be named as a co-inventor. (See D.I. 813, Exs. 6, 7.) The examiner of the ‘178 application determined that “the evidence presented in [Lai’s] Protest fails to set forth a *prima facie* case that Applicant Lin is not the sole inventor of the claimed invention.” (D.I. 813, Ex. 6 at 2.) The examiner further determined, among other things, that, while Lai “was an active participant in the sequencing of uEPO tryptic fragments,” it was not clear “whether such participation reflects inventive initiative or whether [Lai’s] actions were undertaken at [Lin’s] direction.” (*Id.* at 3.) Similarly, the examiner of the ‘179 application found “no clear and convincing evidence that [Lai] was not under the direction of Dr. Lin or that the amino acid sequencing was not done at [Lin’s] behest.” (D.I. 813, Ex. 7 at 3.) The ‘179

examiner concluded that “all of the submitted evidence remains consistent with the inventorship as originally presented by Dr. Lin.” (*Id.* at 5.) The ‘178 and ‘179 applications eventually led to the ‘933 and ‘868 patents-in-suit.

In the same office action rejecting Lai’s inventorship arguments, the examiner of the ‘178 application notified Amgen of its option to submit comments concerning Lai’s protest. (D.I. 813, Ex. 6 at 2.) The examiner of the ‘179 application did not make any such notification. (D.I. 813, Ex. 7.) Amgen elected not to make any statements to the PTO regarding Lai’s inventorship allegations. At no time during prosecution of the patents-in-suit did Amgen express any position or make any statements to the PTO regarding the novelty and non-obviousness of the generation of tryptic fragments and determination of the amino acid sequence of EPO.

III. ARGUMENT

The doctrine of judicial estoppel is designed “to safeguard the integrity of the courts.” *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 33 (1st Cir. 2004). “Courts are prone to invoke it when a litigant is playing fast and loose with the courts, and not otherwise.” *InterGen N.V. v. Grina*, 344 F.3d 134, 144 (1st Cir. 2003) (internal quotations omitted).

For judicial estoppel to apply, it is “widely agreed” that “at a minimum, two conditions must be satisfied.” *Alternative Sys.*, 374 F.3d at 33. First, the party’s previously asserted position and presently asserted position must be “directly inconsistent, that is, mutually exclusive.” *Id.*; 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.”). Second, “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 *Alternative Sys.*, 374 F.3d at 33 (The party to be estopped “must have succeeded in

persuading a court to accept its prior position.”); *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.”). Together, these two conditions give the impression that “either the first court has been misled or the second court will be misled, thus raising the specter of inconsistent determinations and endangering the integrity of the judicial process.” *Alternative Sys.*, 374 F.3d at 33.

Roche’s motion *in limine* fails to establish either essential element of a judicial estoppel claim. As to the first element, Amgen’s past and present positions are entirely consistent. The only prior positions attributable to Amgen that Roche identifies in its motion are Dr. Lin’s statements that he is the sole inventor of the inventions claimed in the patents-in-suit, and that Lai is not an inventor. (D.I. 812, at 2-3.) Amgen has always maintained that Dr. Lin is the sole inventor of the claims-in-suit, and its position in the present action is no different. Thus, Amgen’s past and present positions are anything but “directly inconsistent” or “mutually exclusive.”

Roche cannot identify any statement made by Amgen during prosecution of the patents-in-suit that the generation of tryptic fragments and determination of the amino acid sequence of EPO was *not* novel and non-obvious. Thus, there is no direct relationship between the evidence Roche is seeking to preclude and any prior statement or argument attributable to Amgen.

Roche appears to treat Dr. Lin’s 1986 statement that Lai was not a co-inventor as an admission that the work Lai performed at Lin’s behest was non-inventive and, therefore, routine and obvious. (*See, e.g.*, D.I. 811, at 1; D.I. 812, at 3.) This is an illogical leap. The reason Lai was not a co-inventor was because he did not contribute to the *conception* of the claimed inventions. Rather, he was working under the direction of Dr. Lin — as Lin’s “hands” — to

reduce to practice certain aspects of Lin's inventions. As this Court previously found, "Dr. Lin was the one who selected the T-35 and T-38 fragments, designed the probes based on sequence information obtained by his assistant Por Lai, under his direction, and screened the library." *Amgen, Inc. v. Chugai Pharm. Co. Ltd.*, 13 U.S.P.Q.2d 1737, 1777 (D. Mass. 1989). Similarly, the PTO determined that there was "no clear and convincing evidence that [Lai] was not under the direction of Dr. Lin or that the amino acid sequencing was not done at [Lin's] behest." (D.I. 813, Ex. 7 at 3.) The fact that Lai is not an inventor does not mean, as Roche assumes, that the tasks Lai was instructed to perform were obvious, and certainly does not mean that Dr. Lin's claimed inventions, as a whole, were obvious.

Roche's motion also fails to establish the second essential element of a judicial estoppel claim, because the PTO did not accept or rely on *any* statements by Amgen, much less any directly inconsistent statements (there were none), in rejecting Lai's co-inventorship arguments. At no time during prosecution of the patents-in-suit did Amgen express any position or make any statements to the PTO regarding the novelty and non-obviousness of the generation of tryptic fragments and determination of the amino acid sequence of EPO.

Roche attempts to mislead this Court in its brief by arguing that Amgen made statements to the PTO concerning Lai's inventorship protest, and that the PTO accepted and relied on these statements in rejecting Lai's arguments.¹ This is absolutely false. The PTO rejected Lai's protest based on the insufficiency of Lai's arguments and evidence, and not based on any arguments or evidence submitted by Amgen. (*See, e.g.*, D.I. 813, Ex. 6 at 2 ("It is the

¹ *See, e.g.*, D.I. 811, at 1 ("Amgen defeated Dr. Lai's protest by maintaining, as it had throughout prosecution, that Dr. Lai's contributions were non-inventive and, therefore, routine and obvious."); D.I. 812, at 4 ("The Patent Office adopted Amgen's position and prevented Dr. Lai from securing co-inventorship of the patents-in-suit . . ."); *id.* at 2 ("The Patent Office sided with Dr. Lin and Amgen . . ."); *id.* at 3 ("Dr. Lin and Amgen benefited from the Examiner adopting its position . . ."); *id.* (" . . . the aforementioned arguments used by Amgen to procure favorable judgments in prior proceedings.").

Examiner's opinion that the evidence presented in [Lai's] Protest fails to set forth a *prima facie* case that Applicant Lin is not the sole inventor of the claimed invention.”.) As mentioned above, Amgen elected not to make any statements to the PTO regarding the allegations in Lai's inventorship protest.² Because Lai was an employee of Amgen at the time the work was performed, even if the PTO had determined that Lai was a co-inventor of the Lin patents, Lai's rights were assignable to Amgen so the question of whether Lai was a co-inventor had no bearing on the prosecution of Lin's patents in the PTO or the validity of Lin's patents.

In a last-ditch effort to overcome the complete lack of support for its judicial estoppel arguments, Roche suggests, without citing any authority, that all of Lai's allegations, as well as the examiners' statements and reasons for rejecting those allegations, should be attributed to Amgen, because Amgen chose not to comment on these positions at the time. (*See* D.I. 812, at 3 (“If this was not truly Amgen's position, the duty of candor and good faith required Amgen to correct the Examiner at the time, not now.”).) This position is meritless. A failure to comment does not impose judicial estoppel, but rather, as discussed above, judicial estoppel only attaches where affirmative representations are made and relied upon by a court and later the party takes a directly inconsistent position. Moreover, the PTO's own rules recognize in similar contexts that the failure of an applicant to comment should not create an estoppel. The MPEP states that an applicant's decision to remain silent does not constitute an acquiescence to an examiner's reasons for allowance:

The examiner's statement of reasons for allowance is the personal opinion of the examiner as to why the claims are allowable. The examiner's statement should not create an *estoppel*. Only applicant's statements should create an *estoppel*. The failure of

² The only statements identified in Roche's brief that are attributable to Amgen are Dr. Lin's statements that he is the sole inventor of the claimed inventions and that Por Lai is not a co-inventor. Those statements were made more than five years before Lai filed his inventorship protest, and they do not address any of the specific arguments or evidence submitted by Lai.

applicant to comment on the examiner's statement of reasons for allowance should not be treated as acquiescence to the examiner's statement.

Manual of Patent Examining Procedure § 1302.14; *see also* 37 C.F.R. § 1.109 (1993) (“The applicant or patent owner may file a statement commenting on the reasons for allowance within such time as may be specified by the examiner. Failure to file such a statement shall not give rise to any implication that the applicant or patent owner agrees with or acquiesces in the reasoning of the examiner.”). Amgen agreed with the PTO's ultimate conclusion that Lai was not a co-inventor, and it also agreed with one of the bases for this conclusion, namely, that Lai did not contribute to the conception of the claimed inventions and was merely working under the direction of Dr. Lin. Under these circumstances, it was entirely reasonable for Amgen not to make any statements regarding the merits of Lai's arguments or the PTO's decision to reject Lai's arguments.

IV. CONCLUSION

Because neither of the legal requirements for application of judicial estoppel is present here, the Court should deny Roche's motion *in limine* (D.I. 811).

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

Of Counsel:

STUART L. WATT
WENDY A. WHITEFORD
MONIQUE L. CORDRAY
DARRELL G. DOTSON
KIMBERLIN L. MORLEY
ERICA S. OLSON
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

/s/ Michael R. Gottfried

D. DENNIS ALLEGRETTI (BBO#545511)
MICHAEL R. GOTTFRIED (BBO#542156)
PATRICIA R. RICH (BBO#640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4200
Facsimile: (857) 488-4201

LLOYD R. DAY, JR. (*pro hac vice*)
DAY CASEBEER
MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

WILLIAM GAEDE III (*pro hac vice*)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

KEVIN M. FLOWERS (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on the above date.

/s/ Michael R. Gottfried
Michael R. Gottfried