

EXHIBIT A

**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.)	
_____)	

**[PROPOSED] AMGEN INC.'S SURREPLY 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**

There is no legal basis for imputing inessential portions of the examiners' reasoning during prosecution of the patents-in-suit — taken out of context — to Amgen. Roche's motion is premised upon a fundamentally misleading characterization of the prosecution history. Roche misleadingly conflates Amgen's position that Por-Hsuing Lai was "not a co-inventor of the subject matter claimed in said patent application,"¹ with one of the two independent bases articulated by the examiners (not by Amgen) for the rejection of Lai's inventorship protest.

It is beyond dispute that Amgen never stated during prosecution that the generation of tryptic fragments and determination of the amino acid sequence of EPO were not novel and non-obvious. Amgen simply stated that Lai was not a co-inventor. This position was shared by the examiners of the '178 and '179 applications,² who each stated it as a separate basis for their ultimate conclusions that "the preponderance of evidence of record suggests that [*Dr. Lin*] is properly the sole inventor of the instant invention"³ and "[Lai] has failed to provide clear and convincing evidence that Dr. Lin did not himself invent the instantly claimed subject matter."⁴

Unable to identify any prior statement by Amgen that the generation of tryptic fragments and determination of the amino acid sequence of EPO were not novel and non-obvious, Roche attempts to attribute to Amgen the examiners' separate statements regarding inventiveness. Roche's argument is wholly without legal support.

Roche is wrong when it asserts that the duty of candor required Amgen to "correct" the examiner, even where Amgen agreed with the examiner's ultimate decision and with one of the

¹ Docket No. 813, Ex. 4 at ¶ 12; Ex. 5 at ¶ 12.

² Docket No. 813, Ex. 6 at 3 ("What is not clear, however, is whether such participation [by Lai] reflects inventive initiative or whether Protestor's actions were undertaken at Applicant's direction."); Ex. 7 at 3 ("While it may be that Dr. Lin was not a direct supervisor of Protestor, this mere fact is not evidence that the sequencing work performed by Protestor was not at the behest or suggestion of Dr. Lin.").

³ Docket No. 813, Ex. 6 at 3.

⁴ Docket No. 813, Ex. 7 at 5.

independent bases sufficient to justify that decision. As other courts have recognized, there is no such duty to correct all mistakes of a patent examiner.⁵

The *KangaRoos*⁶ case that Roche cites in its reply brief is not on point. In that case, the applicant was found by the trial court to have asserted before the examiner a priority date “so utterly devoid of merit it could have resulted only from an intent to mislead or at least gross negligence.”⁷ The examiner, though required to do so under the MPEP, failed to independently verify the applicant’s submission. The language Roche selectively quotes merely stands for the unremarkable proposition that where an applicant makes an affirmative misstatement, the failure of the examiner to catch that misstatement does not absolve the applicant of liability for inequitable conduct. Having so held, the Federal Circuit nevertheless reversed and remanded the district court’s summary judgment of inequitable conduct, since the trial court had failed to make the required separate finding of intent to deceive or mislead.⁸ The holding in *KangaRoos* has nothing to do with the facts underlying this motion. Here, it is beyond dispute that Amgen did not make *any* statements to the examiner regarding Lai’s inventorship protest or the novelty and non-obviousness of the generation of tryptic fragments and determination of the amino acid sequence of EPO — let alone any misstatements that could have triggered a duty of correction.⁹ Thus, *KangaRoos* is entirely inapposite.

These are not the only misleading arguments made by Roche in its reply brief. Roche’s

⁵ See, e.g., *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 98 F. Supp. 2d 362, 396 (S.D.N.Y. 2000) (declining to “impose . . . a higher burden of disclosure on patent applications and their attorneys” and rejecting as without authority defendant’s contention that patentee had committed inequitable conduct by failing to correct the PTO’s mistakes in evaluating obviousness in light of a disclosed reference).

⁶ *KangaRoos U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1576 (Fed. Cir. 1985).

⁷ *Id.* at 1573 (internal citation omitted).

⁸ *Id.* at 1575 (further noting that summary judgment is inappropriate as to questions of intent).

⁹ Dr. Lin’s statements that he is the sole inventor of the inventions claimed in the patents-in-suit were made years before Lai’s inventorship protest.

statement that inventorship must be correct or the applicant faces charges of inequitable conduct is irrelevant. It has always been Amgen's position that the inventorship of its patents is correct — and the PTO reached precisely this conclusion after evaluating Lai's evidence.

Finally, Roche attempts to dismiss the significance of the MPEP's admonition that the "examiner's statement should not create an *estoppel* . . . failure of applicant to comment on the examiner's statement of reasons for allowance should not be treated as acquiescence to the examiner's statement,"¹⁰ because it does not appear in the inventorship protest section of the MPEP. Amgen never suggested it did, but the rationale is equally applicable here. More importantly, however, there is no statement in the inventorship protest section of the MPEP that even suggests that silence constitutes adoption of all of an examiner's statements. Thus, Roche has failed to meet its burden of proving judicial estoppel and the Court should deny Roche's motion *in limine*.¹¹

¹⁰ MPEP § 1302.14 (emphasis in original); *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.").

¹¹ Docket No. 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

September 3, 2007

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