IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AMGEN, INC., IMMUNEX CORPORATION, AMGEN USA INC., AMGEN MANUFACTURING LIMITED, IMMUNEX RHODE ISLAND CORPORATION,	:	
Plaintiffs.	:	
v.	:	C. A. No. 06-259-MPT
ARIAD PHARMACEUTICALS, INC., et al.,	:	
Defendants.	:	

MEMORANDUM ORDER

The Amgen entities ("Amgen") move to amend and supplement their reply to the ARIAD entities ("ARIAD") counterclaims (D.I. 509) pursuant to Federal Rules of Civil Procedure ("FRCP") 15(a) and (d) to plead additional facts in support of their counterclaim for inequitable conduct on the basis that ARIAD failed to advise the PTO during the re-exam of the '516 patent of an expert deposition (Kadesch) and for concealing information on patent validity. ARIAD opposes the motion (D.I. 538) on the bases that the information was unknown and irrelevant, relying on MPEP § 2258 and 37 CFR 1.552. For the reasons contained herein, Amgen's motion to amend is granted.

1. Under FRCP 15(a), leave to amend "shall be freely given when justice so requires." Rule 15(d) authorizes the court to permit a party to supplement its pleading to set "forth transactions or occurrences of events which have happened since the date of the pleading sought to be supplemented." The decision to grant a motion to amend falls within the sound discretion of the court. *Foman v. Davis*, 371 U.S. 178, 182

(1962). Rule 15 clearly embodies a liberal approach to the allowance of amendments. It requires the court to grant leave to amend where there is no prejudice or delay. *Charpentier v. Godsil*, 937 F.3d 859, 864 (3d Cir. 1991). It promotes a policy of favoring decisions on the merits. *Micron Tech., Inc. v. Rambus, Inc.*, 409 F. Supp. 3d 552, 558 (D. Del. 2006). Leave to amend, however, may be denied where "(1) the moving party has demonstrated undue delay, bad faith or dilatory motives, (2) the amendment would be futile, or (3) the amendment would prejudice the other party." *Frazer v. Nationwide Mut. Ins. Co.*, 352 F.3d 107, 116-17 (3d Cir. 2003). ARIAD emphasizes that the proposed amended pleading would be futile because to establish inequitable conduct based on failure to disclose material information to the PTO, Amgen must show by clear and convincing evidence that the alleged nondisclosure occurred, that it was material and that ARIAD acted with the intent to deceive the PTO. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1048 (Fed. Cir. 1995).

2. In determining futility, the court applies the same standard for legal sufficiency as under Rule 12(b)(6), which requires the court to "accept all factual allegations in the complaint as true and give the pleader the benefit of all reasonable inferences that can be fairly drawn therefrom." *In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997); *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993). As a result, when drawing all reasonable inferences in favor of Amgen, amended pleadings are only insufficient if "no relief could be granted under any set of facts consistent with the allegations . . . ." *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 397 (3d Cir. 2000). Thus, the issue is not whether Amgen will succeed at trial on the proposed supplemental allegations, but whether Amgen has pled such allegations from which

support a claim. Further, Amgen's motion is to supplement its previous allegations of unenforceability. No prejudice or undue delay has been urged by ARIAD.

3. In its amendment, Amgen pleads affirmative acts of misconduct and evidence of intent, which accepted as true for the purpose of this decision, suggest a failure to disclose material information that was known or should have been known by ARIAD. Although this information, that is, Kadesch's deposition, was eventually submitted to the PTO, it was included with a number of other materials, with no attempt to advise the PTO of potential misrepresentations. *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1572-73 (Fed. Cir. 1983). Whether documents, depositions, declarations or other information are material and whether there has been a misrepresentation with the requisite intent are questions of fact to be determined by the court during the presentation of the evidence on inequitable conduct. Materiality is determined by the claims as construed. All are issues yet to be addressed by the court.

4. Amgen also points out that Kadesch's proffered opinion directly contradicts ARAID's written description and priority arguments in support of patentability on re-exam. Amgen claims that Kadesch's deposition recants his testimony in the *Eli Lilly* litigation, a prior related matter in another jurisdiction dealing with the '516 patent. Amgen raises issues as to when ARIAD knew or should have known of Kadesch's recanted testimony. It reiterates the obligation to disclose by counsel or an applicant under MPEP § 2001.06, who has notice that information exists which appears material and questionable. *See Brassler, U.S.A. I, L.P. v. Stryker Sales Corp.I*, 267 F.3d 1370, 1383 (Fed. Cir. 2001). Such evidence, as well as other evidence previously addressed herein, support affirmative acts to prevent disclosure of material information before the

PTO. Therefore,

IT IS ORDERED that the Amgen entities' motion for leave to amend (D.I. 509) is GRANTED. The Amgen entities' first amended reply as contained in exhibit A to D.I. 509 shall be filed as a separate document on or before February 8, 2008.

Dated: January 31, 2008

/s/ Mary Pat Thynge
UNITED STATES MAGISTRATE JUDGE