

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	CIVIL ACTION No.: 05-cv-12237WGY
)	
)	
F. HOFFMANN-LA ROCHE LTD,)	
ROCHE DIAGNOSTICS GmbH,)	
and HOFFMANN-LA ROCHE INC.)	
)	
Defendants.)	
)	
)	

**MEMORANDUM IN SUPPORT OF DEFENDANTS’ MOTION TO AMEND THEIR
SIXTH AFFIRMATIVE DEFENSE**

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively “Defendants”), seek leave of this Court pursuant to Fed. R. Civ. P. 15(a) to amend their double patenting affirmative defense (Sixth Affirmative Defense).

SUMMARY OF THE MOTION

Defendants’ double patenting affirmative defense currently asserts that the six patents-in-suit are invalid for double patenting over claims of Amgen’s earlier issued and now expired U.S. Patent No. 4,703,008 (“the ‘008 patent”). By this motion, Defendants specifically seek leave to amend their double patenting defense to add as separate grounds U.S. Patent No. 4,667,016, which is also owned by Amgen and was prosecuted by Amgen during the same time period as the six patents in suit, and U.S. Patent Nos. 5,441,868 (“the ‘868 patent”) and 5,618,698 (“the ‘698 patent”), which are two of the patents-in-suit. As amended, the defense would read as follows (new text underlined):

Sixth Defense - Double Patenting

37. The claims of the '868, '933, '698, '080, '349 and '422 patents are invalid for double patenting over claims of Amgen's earlier issued and now expired U.S. Patent No. 4,703,008 ("the '008 patent") and U.S. Patent No. 4,667,016; and the claims of the '349, '933, '080, and '422 patents are invalid for double patenting over the claims of the '868 and '698 patents.

Defendants request this amendment to their Sixth Affirmative Defense in good faith, as it is consistent with their position that the six patents-in-suit are invalid and unenforceable based on double patenting over claims in Amgen's prior patents. As previously detailed in Defendants' pleadings, during a prosecution spanning almost sixteen years, which included the refileing of ten continuation applications, Amgen unreasonably delayed in filing the claims of the patents-in-suit. Through this tactic, Amgen unjustly benefited from more than an additional decade of patent monopoly power, enjoying new protection for old technology. As set forth in Defendants' earlier pleadings, in each of the applications resulting in the various patents-in-suit, Amgen had claimed only minor obvious variations of a single invention first claimed in the '008 patent, which shares the same specification and single inventor, Fu-Kuen Lin, with the patents-in-suit.

Defendants have further discovered that in 1985, a patent application for the '016 patent was filed on behalf of Amgen, naming Amgen employee Por-Hsiung Lai as the inventor. The '016 patent issued in 1987 (before issuance of the '008 patent) for essentially the same invention that is the subject matter of the patents-in-suit. Thus, in addition to the fact that the claims in the patents-in-suit are invalid for double patenting over the claims in the '008 patent, the patents-in-suit are invalid because the claims are merely obvious variations on claims of the '016 patent. *See Eli Lilly and Company v. Barr Laboratories, Inc.*, 251 F.3d 955, 968-72 (Fed. Cir. 2001) (ruling that claims of patent were invalid due to double patenting over a later-filed but earlier-issued patent invented by a different employee of the same company). Further, the claims of the

'349, '933, '080, and '422 patents are invalid for double patenting over the claims of the '868 and '698 patents, which patents stem from the same application as the '349, '933, '080, and '422 patents, because they are merely obvious variations on the claims of these two earlier issued patents. *Id.*

ARGUMENT

A. Under Rule 15(a), the Court Should Freely Give Leave of a Party to Amend its Answer

Rule 15(a) of the Federal Rules of Civil Procedure provides that leave to amend “shall be freely given when justice so requires.” Fed.R.Civ.P. 15(a). The Supreme Court has emphasized the liberal nature of the rule, explaining that “[i]f the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, [the plaintiff] ought to be afforded an opportunity to test his claim on the merits.” *Foman v. Davis*, 371 U.S. 178, 182 (1962) (reversing denial of motion to amend complaint); *see Franks v. Ross*, 313 F.3d 184, 193 (4th Cir. 2002) (trial court’s denial of leave to amend complaint in light of intervening facts was abuse of discretion); *U.S. v. United States Trust Co.*, 106 F. R.D. 474, 476 (D. Mass. 1985) (“It is well established that amendments to pleadings should be freely allowed when the interests of justice so require.”).

The standard for granting leave to amend a pleading is well-established. “Absent futility, undue delay, undue prejudice and/or bad faith . . . Rule 15(a) generally requires allowance of amendments.” *Savoy v. White*, 139 F.R.D. 265, 267 (D. Mass. 1991); *see Edwards v. City of Goldsboro*, 178 F.3d 231, 242 (4th Cir. 1999) (“leave to amend a pleading should be denied *only when* the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would be futile.”) (citation omitted) (emphasis in original); *see also Cornwall v. U.S. Const. Mfg., Inc.*, 800 F.2d 250, 253 (Fed. Cir. 1986)

(“there must be some reason or some factor making it reasonably necessary’ to deny leave to amend”) (citation omitted).

Further, this same liberal standard for amending pleadings applies to amendments to an answer, in particular to amendments to add a defense to the answer. *See Smallwood v. United Air Lines, Inc.*, 661 F.2d 303, 306 (4th Cir. 1981) (allowing additional defense to defendant’s answer fifty days after filing original answer); *Bireline v. Seagondollar*, 567 F.2d 260, 262 (4th Cir. 1976) (finding no clear error in lower court’s granting leave to amend answer to add statute of limitations defense).

Nothing here invites any departure from Rule 15(a)’s general allowance of amendments. Because Defendants have brought this amendment in good faith and the amendment would not prejudice Amgen, the motion for leave to amend should be granted.

B. The Amendment Will Not Cause Amgen Undue Prejudice

In order for the Court to deny leave to amend the answer, the plaintiff must show that the proposed amendment will cause it undue prejudice. *See Edwards*, 178 F.3d at 242.

Leave to amend a pleading under Rule 15(a) has been granted at every stage of a litigation, even after the close of discovery or during trial. *See, e.g., Hanson v. Hunt Oil Co.*, 398 F.2d 578 (8th Cir. 1968) (amendment requested on first day of trial). Courts willingly give leave to amend, even where the amended complaint alleges new counterclaims or adds new parties. *See Farrell v. Hollingsworth*, 43 F.R.D. 362, 363 (D.S.C. 1968) (right to amend encompasses new case theories and new claims); *Leathers v. Serrell*, 376 F. Supp. 983, 984 n.1 (W.D. Va. 1974) (amending complaint to add new parties).

There is no reasonable claim that the nature of Defendants’ amendment will prejudice Amgen. No prejudice will arise from Defendants’ proposed amendment because the ‘016 patent

is closely related to the patent forming the basis of Defendants' original double patenting affirmative defense, and the '868 and '698 patents are patents-in-suit. Further, as owner of the '016 patent, Amgen can readily obtain all documents related to this patent from within its organization or from its law firm of Marshall, Gerstein & Borun LLP, which prosecuted the '016 patent on behalf of Amgen and is Amgen's counsel of record in this case. The additional burden of this defense is thus likely to be minimal, and Amgen cannot claim to be unduly prejudiced by this amendment.

Further, because Defendants' proposed amendment seeks only to expand an affirmative defense to Amgen's existing claims, rather than adding any new counterclaims or parties, it is highly unlikely that this amendment will cause delay in the case. Further, fact discovery is still underway, and expert reports have not yet been exchanged. Depositions of the inventors of the patents-in-suit have yet to be taken, and the pretrial conference and trial are not set to take place until July 2, 2007 and September 4, 2007, respectively. Accordingly, Amgen cannot claim that it would be unduly prejudiced by the proposed amendment to Defendants' affirmative defense.

C. The Proposed Amendment Would Not Be Futile

The proposed amendment is not futile. "Futility of a proposed amendment 'is gauged by reference to the liberal criteria of Federal Rule of Civil Procedure 12(b)(6).'" *Transwitch Corp. v. Galazar Networks, Inc.*, 377 F. Supp. 2d 284, 290 (D. Mass. 2004) (quoting *Hatch v. Dep't for Children, Youth & Their Families*, 274 F.3d 12, 19 (1st Cir. 2001)); see *One Beacon Ins. Co. v. Electrolux & Sears Roebuck & Co.*, 223 F.R.D. 21, 24 (D. Mass. 2004) ("amendment is not deemed futile as long as the proposed amended complaint sets forth a general scenario which, if proven, would entitle the plaintiff to relief against the defendant on some cognizable theory") (internal quotation omitted). Roche's proposed amendments on double patenting include all the

requisite factors for this defense. Accepting these allegations as true, Roche's defenses state a claim upon which relief may be granted under Rule 12(b)(6). Consequently, Amgen cannot establish futility under Rule 15.

CONCLUSION

Defendants' amendment to their Sixth Affirmative Defense is well grounded and brought in good faith, and Amgen will not be unduly prejudiced by this amendment. Because amendments to pleadings are freely given when justice requires, Defendants respectfully request that the Court grant them leave to amend their Sixth Affirmative Defense.

Dated: March 2, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

By their Attorneys,

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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 (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Julia Huston
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