

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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

**AMGEN INC.'S OPPOSITION AND MEMORANDUM TO
ORTHO BIOTECH PRODUCTS L.P.'S MOTION TO INTERVENE**

TABLE OF CONTENTS

	Page
I. INTRODUCTION.....	1
II. ORTHO’S MOTION TO INTERVENE SHOULD BE DENIED	3
A. Ortho is not entitled to intervene as a matter of right.	3
1. Ortho is not a “necessary party” under Rule 19.....	4
2. Ortho has failed to show that it has a cognizable legal interest relating to the property that is the subject of this action.....	8
a. Ortho, at most, asserts economic concerns unconnected to a direct, substantial, and legally protectable interest.....	9
b. Ortho cannot intervene since it has no standing.....	10
3. Even if there were a cognizable legal interest granted to it under the Product License Agreement, Ortho has not shown that its interests would be impaired.	12
4. Ortho has failed to show how Amgen will not adequately represent any interest Ortho may assert.....	13
B. This Court should not exercise its discretion under Rule 24(b) to allow Ortho to circumvent the 1985 Product License Agreement.....	15
1. Ortho Does Not Have A Claim For Which This Court Can Exercise Its Discretion Under 24(b).....	16
2. Ortho’s uninvited and unnecessary participation in this litigation prejudices Amgen by eviscerating its rights under the Product License Agreement.....	17
3. Amgen would be prejudiced by the introduction of issues not presently before the Court.	17
III. CONCLUSION.....	20

TABLE OF AUTHORITIES

	Page No.
Cases	
<i>Abbott Lab. v. Diamedix Corp.</i> , 47 F.3d 1128 (Fed. Cir. 1995)	12
<i>American Deposit Corp. v. Schacht</i> , 1995 U.S. Dist. LEXIS 2686 (N.D. Ill. 1995)	18
<i>Amgen, Inc. v. Elanex Pharmaceuticals, Inc.</i> , 1996 WL 84590 (W.D. Wash. 1996)	14
<i>Amgen, Inc. v. Hoechst Marion Roussel, Inc.</i> , 126 F. Supp. 2d 69 (D. Mass. 2001)	2, 14
<i>B. Fernandez & Hnos., Inc. v. Kellogg USA, Inc.</i> , Slip. Op., Docket Nos. 05-2187, 05-2188, 05-2189 at page 8 (1 st Cir. March 17, 2006).....	3
<i>Boeing Co. v. Comm’r of Patents and Trademarks</i> , 853 F.2d 878 (Fed. Cir. 1988)	14
<i>Chiles v. Thornburgh</i> , 865 F.2d 1197 (11 th Cir. 1989)	11
<i>Diamond v. Charles</i> , 476 U.S. 54 (1986).....	14
<i>EEOC v. Nat’l Children’s Ctr., Inc.</i> , 146 F.3d 1042 (D.C.Cir. 1998).....	10, 15
<i>FieldTurf, Inc. v. SouthWest Recreational Industries, Inc.</i> , 357 F.3d 1266 (Fed. Cir. 2004)	12
<i>Fisher v.The Gillette Co.</i> , 505 F. Supp. 184 (N.D. Ill. 1981)	8
<i>Greene v. United States</i> , 996 F.2d 973 (9 th Cir. 1993)	9
<i>In re Acushnet River</i> , 712 F. Supp. 1019 (D. Mass. 1989)	14
<i>Independent Petrochemical Corp. v. Aetna Casualty & Sur. Co.</i> , 105 F.R.D. 106 (D.D.C. 1985)	19

TABLE OF AUTHORITIES (Cont.)

	Page No.
<i>Innis, Speiden & Co. v. Food Machinery Corp.</i> , 2 F.R.D. 261 (D. Del. 1942)	8
<i>Int’l Business Machines Corp. v. Conner Peripherals, Inc.</i> , 30 U.S.P.Q.2d 1315 (N.D.Cal. 1994)	7
<i>Intellectual Property Dev., Inc. v. TCI Cablevision of Cal., Inc.</i> , 248 F.3d 1333 (Fed. Cir. 2001)	12
<i>IWork Software v. Corporate Express, Inc.</i> , 2003 U.S. Dist LEXIS 19686	17
<i>James v. Bellotti</i> , 733 F.2d 989 (1 st Cir. 1984)	11
<i>Lujan v. Defenders of Wildlife</i> , 504 U.S. 555 (1992).....	11
<i>Mangual v. Medina</i> , 317 F.3d 45 (1 st Cir. 2003)	11
<i>Matos v. Am. Airlines</i> , 2003 U.S.Dist. LEXIS 693 (S.D.N.Y. 2003)	19
<i>Mausolf v. Babbitt</i> , 85 F.3d 1295 (8 th Cir. 1996)	10, 11
<i>Mentor H/S, Inc. v. Medical Device Alliance, Inc.</i> , 240 F.3d 1016 (Fed. Cir. 2001)	12
<i>Nextel v. Town of Hanson</i> , 311 F. Supp. 2d 142 (D. Mass. 2004)	11
<i>Ortho Pharmaceutical Corp. v. Genetics Institute, Inc.</i> , 52 F.3d 1026 (Fed. Cir. 1995).	1, 7, 15
<i>Pfizer Inc. v. Elan Pharmaceutical Research Corp.</i> , 812 F. Supp. 1352 (D. Del. 1993).....	12
<i>Precision Shooting Equipment v. Allen</i> , 199 U.S.P.Q. 459 (E.D. Ill. 1978).....	8

TABLE OF AUTHORITIES (Cont.)

	Page No.
<i>Prima Tek II, L.L.C. v. A-Roo Co.</i> , 222 F.3d 1372 (Fed. Cir. 2000)	12
<i>Pub. Serv. Co. of N/H/ v. Patch</i> , 136 F.3d 197 (1 st Cir. 1998)	3
<i>Rawlings v. National Molasses Co.</i> , 394 F.2d 645 (9th Cir. 1968)	7
<i>Ruiz v. Estelle</i> , 161 F.3d 814 (5 th Cir. 1998)	11
<i>Sagebrush Rebellion, Inc. v. Watt</i> , 713 F.2d 525 (9 th Cir. 1983)	11
<i>Shea v. Angulo</i> , 19 F.3d 343 (7th Cir. 1994)	17, 19
<i>Sicom Systems Ltd. v. Agilent Technologies, Inc.</i> , 427 F.3d 971 (Fed. Cir. 2005)	12
<i>Southern Christian Leadership Conference v. Kelley</i> , 747 F.2d 777 (D.C. Cir. 1984)	8, 11
<i>U.S. v. American Bar Association</i> , 118 F.3d 776 (D.C. Cir. 1997)	16
<i>United States v. 39.36 Acres of Land</i> , 754 F.2d 855 (7 th Cir. 1985)	10, 11
<i>United States v. Peoples Benefit Life Ins. Co.</i> , 271 F.3d 411 (2d Cir. 2001)	8
<i>Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.</i> , 454 U.S. 464 (1982)	11
<i>Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.</i> , 944 F.2d 870 (Fed. Cir. 1991)	4, 5
<i>Washington Elec. Corp., Inc. v. Massachusetts Mun. Wholesale Elec. Co.</i> , 922 F.2d 92 (2d Cir. 1990)	8

TABLE OF AUTHORITIES (Cont.)

	Page No.
<i>Waterman v. Mackenzie</i> , 138 U.S. 252 (1890).....	4, 5
<i>Woburn Decreasing Co. v. Spencer Kellogg & Sons, Inc.</i> , 3 F.R.D. 7 (W.D.N.Y. 1943)	17
Statutes	
9 U.S.C. § 3	16
Rules	
Fed. R. Civ. P. 19(a)	4, 5, 7, 12
Fed. R. Civ. P. 24(a)	<i>passim</i>
Fed. R. Civ. P. 24(b)	3, 17, 19
Treatises	
7C Charles A. Wright, et al., <i>Federal Practice and Procedure</i> § 1913 (2d ed. 1986)	15
Wright, Miller, & Kane, <i>Federal Practice and Procedure</i> , Civ. 2d § 1614 (2 nd Ed. 1986)	5

I. INTRODUCTION

Amgen's complaint against Hoffmann-LaRoche, *et al.* ("Roche") seeks to enforce the exclusionary rights conferred to it by the Lin Patents. Asserting it is an "exclusive licensee," Ortho Biotech Products L.P. ("Ortho") seeks to intervene in this action. But Ortho overstates its legal interest in the Lin Patents. At most, Ortho has an exclusive right in a limited field to the use of a single licensed product. Simply put, Ortho has an exclusive *product* license for a limited field of use — not an exclusive *patent* license — and the terms of that license do not convey to Ortho the requisite legal interest in the Lin Patents to compel intervention. Indeed, Ortho's limited licensed rights were previously considered by this Court in an action by Ortho seeking damages against Genetics Institute and found to be insufficient to rise to the level of an exclusive licensee. The outcome should be the same here.

As this Court is aware, the patents-in-suit are owned by Amgen and are the result of Dr. Lin's pioneering work. Ortho sought and was granted a limited license from Amgen in 1985 through an agreement aptly entitled, "Product License Agreement." Through this agreement, Ortho obtained an "exclusive" right to sell *a single designated product* to a specified class of patients for specified uses. Amgen retained unto itself significant rights under the patents, including the following:

- the right to make or import the "Licensed Product" for all uses in the United States and the right to transfer such manufacturing right (as confirmed by binding arbitration in 1989 and 1992, and by this Court's decision in *Ortho v. Genetics Institute*¹),
- the right to use or sell the "Licensed Product" outside of Ortho's field of use (including *e.g.*, the right to sell EPO to dialysis patients and for all diagnostic purposes — a fact conceded by Ortho at pages 3, 8 of its Memorandum), and

¹ *Ortho Pharmaceutical Corp. v. Genetics Institute, Inc.*, 52 F.3d 1026, 1033 (Fed. Cir. 1995).

- the right to make or sell other products within Ortho’s field of use (as confirmed by binding arbitration in 1998).

Most importantly, the Product License Agreement exclusively reserves to Amgen the right to initiate suit against third-parties concerning the patents assigned to Amgen:

“Amgen shall have the right, but not the obligation, to bring, defend and maintain any appropriate suit or action.”²

With Amgen’s exercise of this right, as in this case and in *Amgen v. HMR/TKT*, Ortho has no right to join the suit unless Amgen expressly requests it to do so — something Amgen has not done.

Intervention as a matter of right requires that the party seeking to intervene establish that it has a “direct, substantial, and legally protectable interest” in the patents-in-suit.

Although Ortho professes to have various interests that might be affected by the present litigation, given the limitations of its license and the reservation of rights in Amgen, Ortho cannot show that it possesses the requisite legal interest in the patents-in-suit — as distinct from its licensed product — to permit intervention.

Moreover, Ortho can hardly contend that Amgen would inadequately represent whatever narrow interest Ortho may have in enforcing and upholding Amgen’s patents, since Amgen assuredly shares that interest in common with Ortho. After all, Ortho contentedly relied on Amgen’s exclusive efforts in the *Amgen v. HMR/TKT* litigation for almost 10 years. Insofar as Amgen’s patents are concerned, Ortho’s legitimate interests in enforcing and upholding Amgen’s patents are necessarily aligned with those of Amgen. Ortho’s limited

² Product License Agreement (hereinafter “PLA”), ¶ 8.02 (p. 35) (Exhibit 1 to the 3/8/06 Grossman Declaration).

interests can be adequately served by Amgen, whose broader interests in enforcing the patents not only encompass but exceed those of Ortho.

Ortho also argues that it has other interests that Amgen would not protect (e.g., the collection of damages, the prevention of an unfavorable settlement, or the ability to participate in any appeal), but these interests are contrary to the long-standing contractual agreement between Amgen and Ortho, which reserves the right to sue to Amgen.

Finally, Ortho's arguments under Federal Rule of Civil Procedure, Rule 24(b) are flawed. Ortho asserts irrelevant issues, ignores its obligation to arbitrate, and utterly rewrites the Product License Agreement. The facts simply do not support an exercise of discretion under Rule 24(b).

II. ORTHO'S MOTION TO INTERVENE SHOULD BE DENIED

A. ORTHO IS NOT ENTITLED TO INTERVENE AS A MATTER OF RIGHT.

Federal Rules of Civil Procedure, Rule 24(a) governs whether Ortho may intervene in an action as a matter of right and requires that Ortho show: (1) it timely moved to intervene³; (2) it has a cognizable legal interest relating to the property or transaction that is the subject of the action; (3) the disposition of the action threatens to create a practical impediment to its ability to protect its interest; and (4) no existing party adequately represents its interests.⁴

“The failure to satisfy [each and everyone one of these four conditions] dooms intervention.”⁵

³ Amgen does not challenge the timeliness of Ortho's motion.

⁴ *Pub. Serv. Co. of N/H/ v. Patch*, 136 F.3d 197, 204 (1st Cir. 1998); *B. Fernandez & Hnos., Inc. v. Kellogg USA, Inc.*, Slip. Op., Docket Nos. 05-2187, 05-2188, 05-2189 at page 8 (1st Cir. March 17, 2006), *see also*, Ortho Memorandum in Support of its Motion to Intervene (hereafter “Ortho Memo”), at 11.

⁵ *Id.*

1. Ortho is not a “necessary party” under Rule 19.

Side-stepping the requirements of Rule 24(a), Ortho first asserts that because the Product License Agreement identifies it to be an “exclusive licensee,” it is a “necessary party” under Rule 19 and, on that ground, entitled to intervene as a matter of right.⁶ But it is well settled that what the agreement in fact recites is dispositive — not the label the agreement attaches to the licensee.⁷

Under Rule 19(a)(2)(i),⁸ Ortho is a “necessary party” only if it can claim an “interest” relating to Amgen’s claims, and it is “so situated that disposition of the action in the person’s absence may as a practical matter impair or impede the person’s ability to protect that interest.” Ortho argues that it is a necessary party since it is an exclusive licensee within a field of use in which Roche’s acts will in part be occurring and that if it is not allowed to participate, as a “practical” matter, Ortho’s ability to prevent Roche’s market entry would be impaired, and it could not seek or collect damages. Ortho’s arguments, however, lack merit.

Ortho did not obtain a bundle of rights sufficient to make it a necessary party even for the field of use for which it obtained rights. To be considered an “exclusive licensee” having rights sufficient to permit participation as a matter of right in a litigation, the licensee must *in*

⁶ Ortho Memo, at 9-11.

⁷ “It is well settled that ‘whether a transfer of a particular right or interest under a patent is an assignment or a license does not depend upon the name by which it calls itself, but upon the legal effect of its provisions.’ *Waterman*, 138 U.S. at 256, 11th S.Ct. at 335. Therefore, the use of the term ‘exclusive license’ in the 1988 agreements is not dispositive; what the documents in fact recite is dispositive.” *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 875 (Fed. Cir. 1991)(applying *Waterman* to determine whether a party was necessary under Rule 19).

⁸ Ortho does not assert that it is a necessary party under Rule 19(a)(1) or 19(a)(2)(ii).

effect have obtained an assignment of rights.⁹ As articulated by the Supreme Court in *Waterman*, and reiterated by the Federal Circuit: “to determine whether a provision in an agreement constitutes an assignment or a license, one must ascertain the intention of the parties and examine the substance of what was granted.”¹⁰

Since the policy underlying Rule 19, as it pertains to patentees and licensees, is to prevent the possibility of two suits over the same patent against the same infringer,¹¹ whether an agreement grants to a licensee the most fundamental right granted by a patent — the right to exclude — will often be “dispositive.”¹² The limited right Ortho obtained falls far short of any right to exclude and can hardly be characterized as a *de facto* assignment.

Rather, Amgen — not Ortho — retained unto itself the fundamental right to sue third-party infringers and to retain damages in the event that it exercises this right:

8.02 INFRINGEMENT BY THIRD PARTIES

. . . AMGEN shall have the right, but not the obligation, to bring, defend and maintain any appropriate suit or action. If Amgen requests ORTHO to join AMGEN in such suit or action and ORTHO agrees to do so, ORTHO shall execute all papers and perform such acts as may be reasonably required and may, at its option, be represented by counsel of its choice. AMGEN shall pay ORTHO its reasonable expenses (including its attorney fees) in connection with any such suit or action In the event that AMGEN fails to take action with respect to such matters within a reasonable period . . . Ortho shall have the right, but not the obligation, to bring, defend and maintain any appropriate suit [sic] or action. . . . **Absent an agreement between the parties to jointly bring any action or suit hereunder and share the expenses**

⁹ *Waterman v. Mackenzie*, 138 U.S. 252, 255 (1890); *see also*, Wright, Miller, & Kane, *Federal Practice and Procedure*, Civ. 2d § 1614 (2nd Ed. 1986).

¹⁰ *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 874 (Fed. Cir. 1991)(considering a motion to dismiss for failure to name a necessary party under Rule 19).

¹¹ *See e.g.*, *Vaupel*, *supra*, 944 F.2d at 876.

¹² *Id.*

*thereof, any amount recovered in any such action or suit shall be retained by the party bearing its expenses thereof.*¹³

Since Amgen initiated suit against Roche and exercised its right not to invite Ortho to join the suit, Ortho has no protectable legal interest in Amgen's suit.

Moreover, although Ortho was granted the "exclusive" right to make and sell a single product (the "LICENSED PRODUCT") to a specified class of patients and the non-exclusive right to make the LICENSED PRODUCT using the LICENSED PATENTS under certain circumstances,¹⁴ Amgen's retained legal rights under the Product License Agreement are far more extensive in nature and scope. For instance, Amgen has retained rights to:

(1) make and sublicense the making of LICENSED PRODUCTS for all purposes (including to supply Ortho's U.S. requirements);¹⁵

(2) import LICENSED PRODUCTS into the United States;

(3) make, use, and sell all patented EPO products that fall outside the scope of the single molecule of human recombinant EPO that makes up the LICENSED PRODUCTS defined by the Product License Agreement;¹⁶ and

(4) use and sell EPO for dialysis and diagnostic purposes and for all non-human uses.¹⁷

¹³ PLA, ¶ 8.02 (Grossman Dec., Exh. 1).

¹⁴ See, PLA, ¶¶ 2.01(b), 5.01- 5.02 (Grossman Dec., Exh. 1).

¹⁵ *Id.*

¹⁶ Opinion of the American Arbitration Association, Dec. 18, 1998 at p. 1 (hereinafter "Opinion")(holding that Ortho's rights under the Product License Agreement were limited to a single molecule of human recombinant EPO, as described in Exhibit A of the Agreement), attached as Exhibit A (filed under seal) to the accompanying Declaration of Linda A. Sasaki-Baxley in Support of Amgen's Opposition to Ortho's Motion To Intervene ("Baxley Dec.").

¹⁷ PLA, ¶ 2.01(b) (Grossman Dec., Exh. 1).

Amgen’s retention of the right to make, use, and sell patented products that are not licensed to Ortho,¹⁸ and the right to maintain its patents without interference from Ortho¹⁹ plainly evidence that Amgen — not Ortho — holds the assignment to the patents-in-suit. By any measure, Ortho is not a necessary party under Rule 19.²⁰

Indeed, in *Ortho v. Genetics Institute*, both this Court and the Federal Circuit soundly rejected Ortho’s effort to appropriate Amgen’s right to exclude precisely on the ground that Ortho was nothing more than a “bare licensee” without standing to bring suit under a Lin Patent.²¹ In hopes of escaping this holding, Ortho asserts that the patent claims at issue in *Genetics Institute* were to “materials” for making EPO, whereas here claims to EPO products, among others, are at issue.²² But the difference in claims does not impact the force and effect of the holding that Ortho is not an exclusive licensee because Amgen retained the right to make EPO for all uses in the United States and the right to sublicense its manufacturing rights freely.

¹⁸ See e.g., *FieldTurf, Inc. v. SouthWest Recreational Industries, Inc.*, 357 F.3d 1266, 1269 (Fed. Cir. 2004)(“ . . . the licensor’s retention of a limited right to develop and market the patented invention indicates that the licensee failed to acquire all substantial rights . . .” (citations omitted)).

¹⁹ See e.g., *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 240 F.3d 1016 (Fed. Cir. 2001)(determining that licensee did not have standing to sue in its own name where patentee, *inter alia*, was obligated to pay maintenance fees on the patent).

²⁰ See, *Vaupel, supra*, 944 F.2d at 876 (affirming lower court decision that patentee was a necessary party where licensee did not have unfettered right to exclude others from the market); *Int’l Business Machines Corp. v. Conner Peripherals, Inc.*, 30 U.S.P.Q.2d 1315 (N.D.Cal. 1994)(denying motion to dismiss complaint for failure to name indispensable party (as defined by Rule 19) where co-owner of patent did not have any right to sue under the patent); *Rawlings v. National Molasses Co.*, 394 F.2d 645 (9th Cir. 1968). See also, in the context of a motion to dismiss for lack of standing to sue, the cases cited in footnote 38, *infra*.

²¹ See, *Ortho Pharmaceutical Corp., supra*, 52 F.3d at 1032.

²² Ortho Memo, at 7-8.

Since Ortho is not a true “exclusive licensee” of the claims-in-suit, Ortho’s reliance on *dicta* in *Aspex* is misplaced. Similarly, Ortho’s citations to *Fisher*,²³ *Precision Shooting Equipment*,²⁴ and *Innis*²⁵ are factually inapposite.

2. Ortho has failed to show that it has a cognizable legal interest relating to the property that is the subject of this action.

Turning to the requirements of Rule 24(a), Ortho has failed to show that it has a cognizable legal interest sufficient to support its motion to intervene and on that basis alone Ortho’s motion should be denied. The requirement that an intervenor demonstrate an interest in the property which is the subject of the action “refers not to *any* interest the applicant can put forward, but only to a legally protectable one.”²⁶ Thus, for an interest to be cognizable under Rule 24(a)(2), it must be “direct, substantial, and legally protectable.”²⁷

²³ In *Fisher v. The Gillette Co.*, 505 F. Supp. 184 (N.D. Ill. 1981), the Court granted an exclusive licensee’s motion to intervene as a matter of discretion, not as a matter of right based, in part, because the exclusive licensee was also contesting the validity of the licensed patents. Neither Ortho’s proposed Complaint, nor its position that it should be entitled to damages based on Roche’s infringement indicates that Ortho is contemplating making a similar argument.

²⁴ The party seeking to intervene in *Precision Shooting Equipment v. Allen*, 199 U.S.P.Q. 459 (E.D. Ill. 1978) similarly also sought to invalidate the patents it had exclusively licensed by its proposed complaint.

²⁵ In *Innis, Speiden & Co. v. Food Machinery Corp.*, 2 F.R.D. 261 (D. Del. 1942), the Court distinguished between a “bare license” and an “exclusive license,” stating that the three distinct rights of making a claimed article, using the claimed article, and selling the claimed article must be granted for there to be an exclusive license (2 FRD at 263), and granting the licensee’s motion to intervene only after finding that the licensee had been granted all three of these distinct rights (2 FRD at 264-265).

²⁶ *Southern Christian Leadership Conference v. Kelley*, 747 F.2d 777, 779 (D.C. Cir. 1984)(emphasis added).

²⁷ *United States v. Peoples Benefit Life Ins. Co.*, 271 F.3d 411, 415 (2d Cir. 2001), quoting *Washington Elec. Corp., Inc. v. Massachusetts Mun. Wholesale Elec. Co.*, 922 F.2d 92, 97 (2d Cir. 1990).

a. Ortho, at most, asserts economic concerns unconnected to a direct, substantial, and legally protectable interest.

But for the Product License Agreement between Amgen and Ortho, Ortho would have *no* rights or interests under the patents exclusively assigned to Amgen. Thus, whether there is any legal basis for Ortho to intervene in the present suit involving such patents must be determined from the allocation of rights as between Amgen and Ortho under the Product License Agreement.

As set forth above, the Product License Agreement grants to Ortho a license to operate — the right to a sell a specifically defined product free of liability for infringement under the Lin patents — it is not the blanket patent license Ortho represents in its motion.²⁸ Significantly, Ortho did not obtain any rights in or to the patents or the right to enforce the patents if Amgen took action to do so.²⁹ Ignoring these irrefutable facts, Ortho asserts that it has an economic interest in maintaining the “exclusivity” granted to it by Amgen.

But whether Ortho has a commercial interest in selling its EPO product is beside the point.³⁰ The salient question under the second prong of Rule 24(a) is whether it has a “direct, substantial, and legally protectable” interest in the patent claims-in-suit. The Product License Agreement shows that it does not. That interest remains exclusively in Amgen’s hands.³¹ Ortho therefore cannot satisfy Rule 24(a).

²⁸ See, fn 16.

²⁹ See, Section II.A.1.

³⁰ See, *Greene v. United States*, 996 F.2d 973, 976 (9th Cir. 1993)(“an economic stake in the outcome of the litigation, even if significant, is not enough” to qualify as a protectable interest under Rule 24(a)).

³¹ Note, on March 17, 1989, some 16 months after Amgen filed its original complaint against Chugai Pharmaceuticals and Genetics Institute for infringement of a Lin Patent in the *Amgen v. Chugai* litigation, Ortho moved to intervene to that suit. Amgen opposed Ortho’s motion, focusing on the untimeliness of the motion, as well as Ortho’s failure to show how Amgen

b. Ortho cannot intervene since it has no standing.

Ortho's motion to intervene under Rule 24(a) should also be denied because Ortho has no standing under Article III of the United States Constitution to participate in this suit.

The U.S. Constitution in Article III requires third parties to prove that they possess a cognizable legal right under which they can seek redress before they will be permitted to intervene in a litigation. The question arises whether the U.S. Congress in Rule 24(a) sought to permit such third parties to avoid this constitutional requirement. At present, there is a division amongst the circuits on this issue,³² with neither the First Circuit nor the District of Massachusetts squarely addressing the issue.³³

would not adequately represent it in that suit, as evidenced in part by Ortho's decision to sit back and wait for 16 months before filing its motion. This court properly denied Ortho's motion on both grounds.

At the time Amgen wrote its opposition, Amgen and Ortho were arbitrating their respective rights under the Product License Agreement and thus, regarding the second prong of Rule 24(a), Amgen essentially remained silent, relying on the then-pending arbitration to sort out the parties' contractual disputes. Consequently, then Magistrate Judge Saris, in her Report to this Court, stated that "Ortho has demonstrated-and there appears to be no dispute-that it has an interest relating to the property or transaction that is the subject of the action..." See, 5/26/89 Approval of 5/5/89 Report and Recommendation Re: Motion Of Ortho Pharmaceutical Corporation to Intervene In This Action Pursuant To Rules 24(a)(2) and 24(b)(2), Fed. R. Civ. P. (Docket No. 87-2617-Y) (hereinafter "Report") at 3, attached at Exhibit B to the Baxley Dec. Having succeeded in its efforts to prevent Ortho from intervening in that suit based on Ortho's failure to show timeliness or inadequate representation, Amgen did not appeal or otherwise challenge this finding.

After Ortho's motion was denied, the Arbitrator found, *inter alia*, that Amgen had retained the sole right to manufacture the product it had licensed to Ortho. Subsequent arbitrations have made plain that Amgen also retained the right to sell other products falling within the scope of the Lin Patents into Ortho's "exclusive" market. See, fn. 16. It is based in part on these findings that Amgen newly challenges Ortho's asserted showing of a legally protectable interest.

³² Compare, Circuits finding that intervenors must independently meet Article III standing requirements (*EEOC v. Nat'l Children's Ctr., Inc.*, 146 F.3d 1042, 1046 (D.C.Cir. 1998); *Mausolf v. Babbitt*, 85 F.3d 1295, 1300 (8th Cir. 1996); *United States v. 39.36 Acres of Land*, 754 F.2d 855, 859 (7th Cir. 1985)), with Circuits holding that intervenors need not show

For the reasons set forth by, among others, the D.C., 7th and 8th Circuits, Rule 24(a) should not be read to confer upon a third-party more rights as an intervenor than it would be entitled to otherwise.³⁴ The standing requirement is a constitutionally mandated prerequisite for federal jurisdiction, and “an essential and unchanging part of the case-or-controversy requirement of Article III.”³⁵ A lawsuit in federal court is not a forum for the airing of interested onlookers' concerns, nor an arena for public-policy debates.³⁶ Thus, “while Rule 24 promotes judicial economy by facilitating, where constitutionally permissible, the participation of interested parties in others’ lawsuits, the fact remains that a federal case is a limited affair, and not everyone with an opinion is invited to attend.”³⁷ This is especially the case here, where Ortho’s proposed complaint seeks a remedy — damages — that Amgen has not asked for.

standing so long as original parties remain in the case (*Sagebrush Rebellion, Inc. v. Watt*, 713 F.2d 525 (9th Cir. 1983); *Ruiz v. Estelle*, 161 F.3d 814, 830 (5th Cir. 1998); *Chiles v. Thornburgh*, 865 F.2d 1197, 1213 (11th Cir. 1989)).

³³ See e.g., *Mangual v. Medina*, 317 F.3d 45, 61-62 (1st Cir. 2003); *Nextel v. Town of Hanson*, 311 F. Supp. 2d 142, 150, n. 6 (D. Mass. 2004). But consider, *James v. Bellotti*, 733 F.2d 989, 994 (1st Cir. 1984)(suggesting that on remand that party seeking to intervene, like a necessary party, must establish standing).

³⁴ See, *Southern Christian Leadership Conference v. Kelley*, 747 F.2d 777, 779 (D.C. Cir. 1984); *Mausolf v. Babbitt*, 85 F.3d 1295, 1300 (8th Cir. 1996); *United States v. 39.36 Acres of Land*, 754 F.2d 855, 859 (7th Cir. 1985).

³⁵ *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992) (elements of standing doctrine are not “mere pleading requirements” but are “indispensable part” of case).

³⁶ See, e.g., *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 473 (1982) (Article III “forecloses the conversion of courts of the United States into judicial versions of college debating forums.”).

³⁷ *Mausolf v. Babbitt*, *supra*, 85 F.3d at 1301.

Because Ortho does not have the requisite bundle of rights, including the right to exclude others, to have standing to sue (as discussed above),³⁸ it is not entitled to intervene in Amgen's suit.

3. Even if there were a cognizable legal interest granted to it under the Product License Agreement, Ortho has not shown that its interests would be impaired.

Ortho argues that its interests in the Lin Patents would be impaired because if, on the one hand Amgen loses, it would be forced to confront a new competitor on the market, and, if on the other hand Amgen prevails, Ortho could not collect damages since Amgen could not collect damages and/or Amgen does not need to share the damages it would collect.

But this is part and parcel of the bargain that Ortho wrought. As discussed above, Ortho did not obtain the contractual right to bring suit if Amgen decides to do so without it. Likewise, Ortho has no contractual right to damages to a suit filed by Amgen, absent a

³⁸ *Sicom Systems Ltd. v. Agilent Technologies, Inc.*, 427 F.3d 971 (Fed. Cir. 2005)(determining that fewer than all substantial rights were granted where patentee, *inter alia*, retained right to permit infringement in certain instances); *FieldTurf, Inc. v. SouthWest Recreational Industries, Inc.*, *supra*, 357 F.3d at 1269 (“without granting [the licensee] the right to enforce the patent, either explicitly or impliedly, the document conveys no more than a bare license . . . the licensor’s retention of a limited right to develop and market the patented invention [also] indicates that the licensee failed to acquire all substantial rights . . .” (citations omitted)); *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 240 F.3d 1016 (Fed. Cir. 2001)(determining that licensee did not have standing to sue in its own name where patentee retained first right to sue infringers and was obligated to pay maintenance fees on the patent); *Intellectual Property Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1344-1345 (Fed. Cir. 2001)(determining that “exclusive licensee” was not a necessary party under Rule 19 where licensee had been granted fewer than all substantial rights necessary to make license an “assignment” because patentee had not transferred sole right to sue infringers); *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1380 (Fed. Cir. 2000)(determining that “exclusive worldwide right to make use and sell” was insufficient where right to exclude others was not effectively granted); *Abbott Lab. v. Diamedix Corp.*, 47 F.3d 1128, 1133 (Fed. Cir. 1995)(determining that less than all substantial rights were granted where patentee retained right to sue infringers if licensee did not bring suit); *Pfizer Inc. v. Elan Pharmaceutical Research Corp.*, 812 F. Supp. 1352, 1373 (D. Del. 1993).

separate agreement by the parties. Indeed, regardless of whether Roche is ultimately found to infringe, Ortho does not lose the limited right granted to it under the Product License Agreement — the ability to sell for a specified use a specified EPO product developed using Amgen’s technology and know-how, as well the inventions described in the Lin Patents.

To contrive a basis for asserting its legal interests will be impaired, Ortho’s present motion effectively urges the Court to disregard Amgen’s retained rights and rewrite the Product Agreement License. Short of this, there are no legitimate interests that will be impaired if Ortho’s motion is denied.

4. Ortho has failed to show how Amgen will not adequately represent any interest Ortho may assert

Ortho argues that Amgen cannot adequately represent Ortho’s interests because: (a) Amgen may not be allowed to maintain its suit against Roche, (b) Amgen could not recover certain damages, (c) there are alleged commercial interests that could incent Amgen to settle the dispute to Ortho’s disadvantage, and (d) Ortho would not be allowed to participate in an appeal unless it was allowed to intervene.³⁹

As set forth above, Ortho has no cognizable legal interest in this litigation that Amgen could fail to adequately represent, and thus, this Court need not even reach this issue. Assuming, however, that Ortho’s rights are cognizable, each of Ortho’s assertions is incorrect.

Ortho’s first assertion, that Amgen could not maintain suit against Roche unless Ortho were to intervene, is not borne out by the facts, as set forth above. Ortho’s final three assertions are contradicted by both Amgen’s and Ortho’s actions, most tellingly each party’s

³⁹ Ortho Memo at 15-16.

course of conduct in a related matter that was previously before this Court and is now on appeal: *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*⁴⁰

In the almost 10 years of the *HMR/TKT* litigation, no one — and especially not Ortho — ever contended that Ortho was a necessary party. At no point during the course of that litigation, did Ortho ever complain that Amgen lacked standing to sue HMR/TKT or that it would be denied damages if it were not allowed to participate. In that litigation, Ortho was content to rely upon Amgen’s representation of Ortho’s “interests.” And, Ortho was indeed well represented as HMR/TKT have never impacted Ortho’s economic interests in EPO.⁴¹

Amgen’s actions in the *Genetics Institute* litigation also speak more loudly than Ortho’s words. In that litigation, even though Ortho expressed grave concern that it would not be adequately represented by Amgen and that Amgen could settle that case to its advantage and Ortho’s disadvantage, in fact, Amgen successfully asserted the first Lin Patent against Genetics Institute and Chugai Pharmaceuticals, now a wholly-owned Roche subsidiary, without compromising Ortho’s rights under the Product License Agreement.⁴²

Finally, as this Court found, Amgen’s representation of Ortho’s rights to sell its EPO product to non-dialysis patients has been (and will continue to be) more than adequate. This Court previously determined that Ortho’s interests under the Product License Agreement are

⁴⁰ 126 F. Supp. 2d 69 (D. Mass. 2001).

⁴¹ Indeed, the HMR/TKT matter is not the only case in which Ortho has been content to rely upon Amgen’s representation of any interests Ortho may have. See, *Amgen, Inc. v. Elanex Pharmaceuticals, Inc.*, 1996 WL 84590 (W.D. Wash. 1996).

⁴² Additionally, as to Ortho’s last point, its reliance on *In re Acushnet River* is misplaced. As both the Supreme Court and Federal Circuit have made clear, Ortho cannot rely alone on its intervenor status to bring an appeal unless it has standing on its own to bring suit. *Diamond v. Charles*, 476 U.S. 54, 68 (1986); *Boeing Co. v. Comm’r of Patents and Trademarks*, 853 F.2d 878, 880 (Fed. Cir. 1988).

adequately represented by Amgen in a litigation involving a Lin Patent.⁴³ Fundamental to this determination, *inter alia*, were this Court's findings that, notwithstanding Ortho's assertions about the animosity between Amgen and Ortho and that Amgen had an incentive to settle its suit against Genetics Institute to Ortho's disadvantage, Amgen had evidenced strong incentive to protect its patents, Ortho's assertions regarding settlement were speculative (even on the eve of trial), and in any event, Ortho's rights are protected under the license and it could resort to arbitration under the license if it is unsatisfied with a settlement.⁴⁴ Ortho's baseless assertions to the contrary cannot serve to support its motion to intervene.

B. THIS COURT SHOULD NOT EXERCISE ITS DISCRETION UNDER RULE 24(b) TO ALLOW ORTHO TO CIRCUMVENT THE 1985 PRODUCT LICENSE AGREEMENT.

“[P]ermissive intervention is an inherently discretionary enterprise,” with courts enjoying considerable discretion “to deny a motion for permissive intervention even if the movant established an independent jurisdictional basis, submitted a timely motion, and advanced a claim or defense that shares a common question with the main action.”⁴⁵ Where Ortho has no contractual right to bring a claim against Roche, where any Ortho complaint about Amgen's enforcement of the Lin Patents or its purported rights to enforce the Lin Patents are subject to arbitration, where Ortho's participation in this suit would essentially

⁴³ See, Report (Baxley Dec. Exh. B); *see also*, *Ortho Pharmaceutical Corp. v. GI*, 52 F.3d at 1029.

⁴⁴ See Report at 13-16 (Baxley Dec., Exh. B).

⁴⁵ *EEOC v. Nat'l Children's Ctr., Inc.*, 146 F.3d 1042, 1046-48 (D.C. Cir. 1998); *see also* 7C Charles A. Wright, et al., *Federal Practice and Procedure* § 1913, at 376-77 (2d ed. 1986) (“If there is no right to intervene under Rule 24(a), it is wholly discretionary with the court whether to allow intervention under Rule 24(b) and even though there is a common question

remake the Product License Agreement's key provisions, and where Amgen would be prejudiced by Ortho's participation in this suit, Rule 24(b) should not be applied.

1. Ortho Does Not Have A Claim For Which This Court Can Exercise Its Discretion Under 24(b)

The policies favoring intervention under Rule 24(b) are "litigative economy, reduced risks of inconsistency, and increased information (which might reduce the risk of error)."⁴⁶ None of these policies are served by Ortho's participation in this suit.

Without Amgen requesting or causing Ortho to join this lawsuit in accordance with paragraph 8.02 of the Product License Agreement, Ortho does not have an assertable "claim" against Roche.⁴⁷ Thus, there can be no claim or question that is common to both Ortho and Amgen by Amgen's complaint for declaratory judgment of infringement against Roche.

Rather, Ortho's only "claim," if it is dissatisfied with either Amgen's enforcement of the Lin Patents or if it disputes Amgen's sole right to "bring, defend and maintain" the action against Roche, is for breach of the Product License Agreement, or for an adjudication of its rights under it. But, as the Product License Agreement plainly states, any dispute arising from the Agreement must be arbitrated.⁴⁸ Under these circumstances, no litigative economy or other policy favoring intervention under Rule 24(b) can be served and discretion advises against Ortho's motion to intervene.

of law or fact, or the requirements of Rule 24(b) are otherwise satisfied, the court may refuse to allow intervention."(footnotes omitted)).

⁴⁶ *U.S. v. American Bar Association*, 118 F.3d 776, 782 (D.C. Cir. 1997).

⁴⁷ PLA, ¶ 8.02 (Grossman Dec, Exh. 1); *see infra*, Section II.A.1-2.

⁴⁸ PLA, ¶10.07 (Grossman Dec., Exh. 1); *see also*, 9 U.S.C. § 3.

2. Ortho's uninvited and unnecessary participation in this litigation prejudices Amgen by eviscerating its rights under the Product License Agreement.

In 1985, Amgen and Ortho reached agreement that transferred to Ortho certain know-how and technology, as well as the right to sell a specified EPO product for specified uses. Amgen received a set consideration for these transferred rights. Today, Ortho asserts that it would be equitable for this Court to exercise the limited discretion granted to it under Rule 24(b) and give Ortho rights for which it never paid consideration and for which Amgen would have never granted to Ortho even if Ortho had been willing to pay for them. The discretion granted to this Court under Rule 24(b) should not extend so far.

3. Amgen would be prejudiced by the introduction of issues not presently before the Court.

To satisfy the requirements of Rule 24(b), Ortho asserts that neither Amgen nor Roche will be prejudiced by Ortho's participation since Ortho brings its motion in the "nascent" stage of this litigation. Ortho's assertion collapses the separate "timeliness" and "prejudice" requirements explicitly set forth in Rule 24(b) in an attempt to unduly narrow the issue to only whether Ortho's motion is timely. Under Rule 24(b), however, a party is prejudiced if the presence of an intervenor might shift the focus of the litigation from the pending issues to those introduced by the intervenor.⁴⁹

⁴⁹ *Shea v. Angulo*, 19 F.3d 343, 346 n.2 (7th Cir. 1994); *IWork Software v. Corporate Express, Inc.*, 2003 U.S. Dist LEXIS 19686, *16 (N.D. Ill. 2003) ("webMethods' proposed intervention would result in additional, lengthy discovery and an extended trial, due to the proposed expanded scope of the suit. This will cause not only postponement of an already lengthy process, but will also prejudice defendants."); *Woburn Decreasing Co. v. Spencer Kellogg & Sons, Inc.*, 3 F.R.D. 7, 10 (W.D.N.Y. 1943)(denying motion to intervene under Rule 24(b) where additional conspiracy claim related to patents at issue would unduly delay and prejudice suit for patent infringement).

Amgen's complaint against Roche sounds in equity and seeks declaratory judgment of patent infringement only. It does not seek damages. Ortho's proposed Complaint does — almost the entirety of Ortho's motion to intervene relies on its claim for damages. Ortho's injection of damages into a case where no damages have been previously requested, and where history tells us with the diligent efforts of the parties and the Court's calendar no damages will accrue before the matter is resolved,⁵⁰ prejudices Amgen by enlarging the scope of the litigation, expanding the relief sought, and delaying final resolution of the parties' dispute.⁵¹ Delay in final resolution is especially prejudicial here where Amgen seeks to exercise its exclusionary rights prior to Roche's market entry.

More to the point, in order to calculate the damages Ortho asserts it would be owed, Ortho would need to first establish that it is entitled to monetary relief under the Product License Agreement notwithstanding the Agreement's language and Amgen's (and presumably Roche's) position to the contrary. Resolution of this issue could require inquiry into Amgen and Ortho's more than 20-year course of dealing, including six arbitrations, each of which addresses the parties' respective rights under the Product License Agreement. Resolution of this issue is also specifically reserved for arbitration.⁵²

⁵⁰ *Consider*, Amgen sued HMR/TKT in 1997. After an administrative hold, the matter was taken up in 1999 and this Court reached its decision in the matter before HMR/TKT ever entered into the market.

⁵¹ *American Deposit Corp. v. Schacht*, 1995 U.S. Dist. LEXIS 2686 (N.D. Ill. 1995)(denying Rule 24(b) motion for prejudice to the existing plaintiff, where request would enlarge scope of litigation and expand relief sought).

⁵² PLA, ¶ 10.07 (Grossman Dec., Exh. 1).

Courts consistently have refused to exercise discretion granted under Rule 24(b) in such a circumstance.⁵³ In *Shea v. Angulo*, at issue was a contractual dispute between a stock broker (Shea) and a financial investor adviser house (First Capital Advisers) over commissions owed to Shea. A third-party sought to intervene in the action by asserting that it had an agreement with Shea entitling it to share in any commission paid by First Capital Advisers to Shea as a result of the litigation. The Seventh Circuit, affirming the lower court's denial of a motion to intervene, stated that there could be no abuse of district court's denial of the motion to intervene under Rule 24(b) where intervention would introduce "a complex factual question completely unrelated to the quarrel between the original parties to the suit." Similarly, in *Matos v. American Airlines*, the District Court for the Southern District of New York denied a motion to intervene under Rule 24(b) where the right to participate in an airplane crash tort suit depended on first establishing paternity between intervenor and a party killed in the crash.

Ortho's participation, and specifically, its claim for damages would likewise shift the focus of Amgen's request for declaratory relief for patent infringement, the sole cause of action in Amgen's complaint, to complex factual questions arising out of the Product License Agreement, and thus would unduly prejudice Amgen. Under this circumstance, the Court should exercise the discretion afforded it under Rule 24(b) and deny Ortho's motion.

⁵³ See e.g., *Shea, supra*, 19 F.3d at 346, n.2; *Matos v. Am. Airlines*, 2003 U.S. Dist. LEXIS 693 (S.D.N.Y. 2003)); see also, *Independent Petrochemical Corp. v. Aetna Casualty & Sur. Co.*, 105 F.R.D. 106 (D.D.C. 1985), *aff'd*, 784 F.2d 1131 (D.C. Cir. 1986)(holding that "a mere provable claim" does not amount to a sufficient interest for purposes of Rule 24(a)).

III. CONCLUSION

Amgen respectfully requests that this Court deny Ortho's motion to intervene under Rules 24(a) and (b).

Respectfully Submitted,
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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 April 11, 2006.

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