UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LAROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN LAROCHE INC., a New Jersey Corporation, Defendants.	05-CV-12237-WGY Hon. William G. Young

MEMORANDUM IN SUPPORT OF ORTHO'S MOTION TO INTERVENE

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Pursuant to Rule 24, Fed. R. Civ. P., Ortho Biotech Products, L.P. ("Ortho") respectfully submits this memorandum of law in support of its motion to intervene as a plaintiff in this action. A copy of Ortho's proposed Complaint is attached hereto as Exhibit A.

STATEMENT OF FACTS

This case is the latest in a series of actions in this Court involving patents on erythropoietin ("EPO"), a naturally-occurring protein that helps correct anemia by stimulating the bone marrow to produce red blood cells. Plaintiff Amgen Inc. ("Amgen") filed its complaint on November 8, 2005. The defendants are F. Hoffmann-LaRoche Ltd., a Swiss Company; Roche Diagnostics GmbH, a German Company; and Hoffmann LaRoche Inc., a New Jersey Corporation (collectively "Roche"). Roche has not yet responded to the complaint.

In this action, Amgen alleges that Roche is, or will soon be, infringing six U.S. patents relating to EPO. The patents fall into two broad groups:

1. The first group includes patents that cover pharmaceutical compositions comprising various forms of EPO. The patents in this category are U.S. Patent Nos. 5,955,422 (the "'422 patent"), 5,547,933 (the "'933 patent"), and 5,621,080 (the "'080 patent"). The '422 patent claims pharmaceutical compositions comprising human EPO purified from mammalian cells grown in culture; and the '933 patent claims non-naturally occurring human EPO glycoproteins; the '080 claims non-naturally occurring EPO glycoproteins and pharmaceutical compositions containing such EPO glycoproteins. *See* D.I. 1-1 at ¶14(b), (d) and (f).

2. The second group consists of patents directed to processes and cells for the manufacture of EPO. The patents in this category are U.S. Patent Nos. 5,441,868 (the "'868 patent"), 5,618,698 (the "'698 patent"), 5,765,349 (the "'349 patent"). See D.I. 1-1 at ¶14(a), (c) and (e).

Ortho seeks to intervene **only** with respect to claims of infringement of patents in the first group, *i.e.*, the '422, '933 and '080 patents, which are directed to pharmaceutical

compositions comprising various forms of EPO (the "EPO Product Patents"). Ortho does not seek to intervene with respect to claims of infringement of patents in the second group, which concern processes and cells for the manufacture of EPO.

According to Amgen's complaint, Roche is currently making an EPO product, referred to as "PEG-EPO," that "contains EPO as claimed in [the EPO Product Patents]." *See* D.I. 1-1 ¶ 19. "But for the glycosylated human EPO contained in PEG-EPO, PEG-EPO would not stimulate the production of red blood cells when administered to patients." *Id.* ¶ 24. Roche is "currently importing" its infringing PEG-EPO product into the United States, *id.* ¶ 18, and is "making meaningful preparations to market and sell PEG-EPO in the United States." *Id.* ¶ 28.

A. Ortho's Exclusive License

By virtue of a license agreement between Ortho and Amgen, Ortho is an exclusive licensee under Amgen's EPO Product Patents. The agreement gives Ortho an exclusive license to sell EPO products in a broad field of use: all human uses other than dialysis and diagnostics. Ortho currently markets EPO in the United States, under the brand name Procrit®, for a variety of non-dialysis, non-diagnostic purposes.

Ortho's exclusive license is set forth in a Product License Agreement ("PLA") between Ortho and Amgen dated September 30, 1985. *See* Exhibit 1 to the accompanying Declaration of Harman Avery Grossman, Esq. ("Grossman Dec."). The PLA grants to Ortho, *inter alia*, an "exclusive license . . . to sell LICENSED PRODUCTS in the LICENSED TERRITORY." *Id.* ¶ 2.01(a). The PLA defines "LICENSED PRODUCTS" to include "any PRODUCTS for use in the LICENSED FIELD . . . which are within the scope of a VALID LICENSED CLAIM of a LICENSED PATENT . . . ." *Id.* ¶ 1.13. "PRODUCTS" include "EPO for all human uses in the LICENSED FIELD." *Id.* at ¶ 1.21. "EPO," in turn, is defined by reference to an attachment (Exhibit A to the PLA) that shows the amino acid sequence and glycosylation pattern for recombinant human erythropoietin. *Id.* ¶ 1.05 and Exh. A thereto.

The "LICENSED FIELD" with respect to EPO is "all indications for human use except dialysis and diagnostics." *Id.* ¶ 1.10(a). (Amgen reserved for itself the right to sell EPO for dialysis and diagnostics.) The "LICENSED TERRITORY" for EPO is "the United States, its territories and possessions . . . ." *Id.* ¶ 1.14.

The "LICENSED PATENTS" are defined in ¶ 1.12 to include all patents listed in Exhibit D to the PLA, as well as all patents issuing from divisions, continuations and continuations-in-part of those patents. All of the patents that Amgen is asserting in this case, including the EPO Product Patents, are continuations or continuations-in-part of patents listed in Exhibit D, and accordingly come within the PLA's definition of "LICENSED PATENTS."

The PLA thus gives Ortho an exclusive license, under Amgen's EPO Product Patents, to sell glycosylated recombinant human EPO in the United States for all human uses except dialysis and diagnostics. Ortho is the *only* party permitted to sell such products for non-dialysis and non-diagnostic purposes. Because Roche's PEG-EPO falls within Ortho's exclusive license, Ortho has a direct financial and legal interest in the outcome of this action, including the enforcement of Amgen's EPO Product Patents against Roche.

B. Roche's Infringing Activities Fall Within Ortho's Exclusive Field of Use

Roche's ongoing "preparations to market and sell PEG-EPO in the United States," D.I. 1-1 at ¶ 28, include preparations to sell PEG-EPO in Ortho's exclusive non-dialysis field of use. Public statements disseminated by Roche make this clear. For example, a Roche press release dated November 12, 2005 reported on a clinical study finding that Roche's PEG-EPO product "was able to control anemia in patients with chronic kidney disease (CKD) not on dialysis within a narrow target range . . . ." *See* Exh. A ¶ 24; Grossman Dec. Exh. 3. The specified indication – non-dialysis CKD – is within Ortho's exclusive field of use. Similarly, an "Investor Update" dated February 1, 2006 and currently available on Roche's website states that Roche is conducting a clinical trial program for PEG-EPO that "includes six trials involving 2,400 patients with chronic kidney disease (both on dialysis and not on dialysis)" and that

"Roche plans to file marketing applications worldwide for [PEG-EPO] in renal anemia in 2006." *See* Exh. A ¶ 23; Grossman Dec. Exh. 4.

C. The Relationship Between Ortho and Amgen

In addition to their contractual relationship under the PLA, Amgen and Ortho are direct competitors in the market for anti-anemia products, and have frequently found themselves on opposite sides of adversarial proceedings. For a variety of reasons, Ortho reasonably believes that it cannot rely upon Amgen fully to protect its interests in this action.

Ortho must participate as a party to this action in order to recover damages for Roche's infringing acts in Ortho's exclusive field of use. Unless Roche is enjoined from selling PEG-EPO prior to its commercial introduction, Ortho will be entitled to an award of damages based on sales of the product for any non-dialysis, non-diagnostic uses. As a matter of law (*see* Section I.B.3., *infra*), Amgen cannot seek to recover these damages; only Ortho can.

Even if Amgen had the legal right to collect damages on Ortho's behalf, Ortho's participation would be necessary to protect Ortho's economic interests. The PLA expressly provides that, unless Ortho is made a party, Amgen may keep for itself any damages recovered on account of Roche's infringement. *See* Grossman Dec. Exh. 1 ¶ 8.02 ("Absent an agreement between the parties to jointly bring any action or suit hereunder and share the expenses thereof, any amount recovered in any such action or suit shall be retained by the party bearing its expenses thereof"). To date, Amgen and Ortho have not reached any agreement jointly to pursue this action. Indeed, although it was contractually obligated to do so[1], Amgen failed to contact Ortho in any manner prior to initiating this proceeding, or to share any of its evidence with Ortho. Amgen has since rebuffed Ortho's request that it be added as a co-plaintiff. *See* Grossman Dec. ¶ 13.

[1] Paragraph 8.02 of the PLA provides that "[e]ither party shall promptly notify the other party of any infringement of any LICENSED PATENTS . . . and shall provide the other party with all available evidence relating thereto. AMGEN and ORTHO shall then consult with each other as to the best manner in which to proceed. . . ." Grossman Dec. Exh. 1 ¶ 8.02.

Amgen's unwillingness to cooperate with Ortho in the prosecution of this action should come as no surprise, as the companies are fierce competitors and otherwise have had a troubled and litigious commercial relationship. Indeed, Ortho is currently prosecuting an antitrust action against Amgen in federal court, based on Amgen's employment of unlawful and anticompetitive contracting practices. *See Ortho Biotech Products, L.P. v. Amgen Inc.*, No. 3:05-cv-4850-SRC-JJH (D.N.J.) (Grossman Dec. ¶ 4 and Exh. 2). Aside from that ongoing court litigation, the companies have a lengthy history as adversaries in a series of hotly-contested arbitrations, including:

- A 1989 arbitration in which Amgen was found to have impeded Ortho's entry into the U.S. EPO market, and in which Ortho was awarded damages of $164 million;
- A 1996 arbitration in which Amgen was found to have made extensive "spillover" sales of EPO in Ortho's exclusive field of use, resulting in an award to Ortho of $159 million; and
- A 2002 arbitration that resulted in the denial of Amgen's application to terminate Ortho's exclusive license.

See Grossman Dec. ¶¶ 3-5. In addition, in 2002, Ortho intervened on the side of the Government in response to an unsuccessful attempt by Amgen to overturn a reimbursement ruling that prevented Amgen from gaining an unfair competitive advantage over Ortho. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 107 (D.C. Cir. 2004). This longstanding track record of continuous disputes heightens Ortho's concern that it cannot fully rely upon Amgen to protect its interests in this matter.

Moreover, while Ortho and Amgen have a shared interest in enforcing the EPO Product Patents against would-be competitors such as Roche, their interests are not necessarily in full alignment. As noted above, although it has granted Ortho an exclusive license under its EPO Product Patents to sell EPO within Ortho's broad field of use, Amgen also markets another anti-anemia product, called Aranesp®, that competes directly with Ortho's Procrit brand of EPO. Amgen sells Aranesp not only for dialysis patients but also for anemic patients with CKD who are not on dialysis, and for anemic oncology patients – markets in which Ortho also competes.

Amgen thus has a commercial incentive to pursue a settlement with Roche that benefits Amgen, and protects Amgen's markets, but prejudices Ortho.

In short, Ortho has ample reason for concern that its interests in this proceeding are not being fully protected by Amgen.

D. This Court's Prior Decisions Support Intervention Here

Over a decade ago, this Court: (a) denied a motion by Ortho to intervene in the *Amgen Inc. v. Chugai Pharmaceutical Co.* case just prior to the start of the liability trial, and (b) subsequently held that Ortho lacked standing to sue for damages based on sales in Europe of products manufactured in the United States using materials covered by one of Amgen's EPO patents. The current motion presents issues that are quite distinct, and require a different result.

1. Ortho's Motion To Intervene in *Amgen v. Chugai*

In 1987, Amgen sued Chugai Pharmaceutical Co. and Genetics Institute, Inc. for infringement of U.S. Patent No. 4,703,008 ("the '008 patent"), which claimed DNA sequences and host cells used for the manufacture of EPO. That action was bifurcated into separate phases for liability and damages. In 1989, just prior to the trial on liability, Ortho moved to intervene under Fed. R. Civ. P. 24.

This Court denied Ortho's motion on two grounds: (1) it was untimely; and (2) Amgen could adequately represent Ortho's interests. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 1989 WL 87484 (D. Mass. May 5, 1989) (Saris, M.J.). As to *both* factors, the Court relied upon Ortho's "substantial" delay in moving to intervene. *Id.* at *5. Though the action was filed in October 1987, Ortho did not move to intervene until March 1989 – roughly 15 months later. *Id.* at *1, *2. Indeed, Ortho admitted that "it knew about the [] action at least thirteen months before it filed its motion to intervene." *Id.* at *5. By the time Ortho brought its motion, the liability trial was less than five months away, *id.* at *2, and allowing Ortho to intervene at that late stage would have resulted in an unacceptable postponement of the trial date, *id.* at *6. For these reasons, the Court refused to "excuse [Ortho's] delay." *Id.* at *5. As the Court put it,

"[p]arties having knowledge of the pendency of litigation which may affect their interests sit idle at their peril." *Id.*

The Court similarly found that Ortho's protracted delay in moving to intervene provided powerful evidence that Amgen could adequately protect Ortho's interests in that proceeding. "If Ortho believed that its interests would not be adequately represented by Amgen, it is hard to see why those interests were no less implicated by the original filing of the suit, the motion for preliminary injunction and various motions for summary judgment, than the actual trial." *Id.* The Court concluded that it was "hard-pressed to credit Ortho's arguments that it is not contented with Amgen's representation with respect to the '008 patent since it relied on Amgen for over thirteen months in this action . . . ." *Id.* at *6.

The facts at hand are entirely different. Unlike Ortho's earlier effort, there is nothing untimely about Ortho's motion to intervene in this action. Rather, Ortho's motion is being made at the very outset of the case, even before the defendants have answered. Accordingly, the Court's rationale for denying Ortho intervention in *Amgen v. Chugai* has no application to the present facts.

2. Ortho's Separate Suit for Damages

The *Amgen v. Chugai* case proceeded to trial on liability, and this Court found that Amgen's '008 patent was valid, enforceable and infringed by Chugai and Genetics Institute. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 706 F. Supp. 94 (D. Mass. 1989), *aff'd in part, rev'd in part*, 927 F.2d 1200 (Fed. Cir. 1991).

In 1991, after decisions by both this Court and the Federal Circuit on liability, Ortho brought its own action against Genetics Institute seeking damages for lost sales in Europe of EPO products made by Genetics Institute using host cells covered by the '008 patent. This Court dismissed Ortho's complaint for lack of standing. *Amgen, Inc. v. Chugai Pharm. Co. Ltd.*, 808 F. Supp. 894 (D. Mass. 1992), *aff'd sub nom. Ortho Pharmaceuticals Corp. v. Genetics Institute, Inc.*, 52 F.3d 1026 (Fed. Cir. 1995). In doing so, the Court emphasized that "the '008

patent . . . covers certain products – machines or starting materials – used to manufacture EPO, but does not cover the product EPO itself." *Id.* at 901; *see also id.* at 897 (the '008 patent does *not* cover the product EPO itself") (emphasis in original). Ortho's exclusive license, however, was limited to the sale of EPO, and did not extend to the use of cells or "machines" for EPO manufacture. Accordingly, Ortho was not an exclusive licensee with respect to the patent claims asserted and infringing activities alleged, and lacked standing to sue Genetics Institute for damages. *Id.* at 903-04.

The situation here is markedly different. Unlike the '008 patent at issue in the prior litigation, the EPO Product Patents asserted by Amgen in this action claim various forms of the product EPO itself. *See* D.I. 1-1 at ¶ 14. Ortho has an exclusive license under Amgen's EPO Product Patents to sell EPO in the United States for all human uses except dialysis and diagnostics. This exclusive license is sufficient to confer standing upon Ortho to bring and maintain an action (together with Amgen, its licensor) for infringing acts in Ortho's exclusive field of use (*see* Point I.C., *infra*). Not only does this exclusive patent license provide standing; it gives Ortho a strong interest in the outcome of this action that makes intervention appropriate.

ARGUMENT

Ortho is entitled to intervene in this action "as of right" under Rule 24(a), Fed. R. Civ. P. An exclusive licensee such as Ortho is a "necessary party" in an action for infringement within its exclusive field of use, and a necessary party is automatically entitled to intervene. Even if Ortho were not deemed a necessary party, it meets the test for intervention as of right under Rule 24(a). (Point I)

If, for some reason, the Court were to determine that Ortho cannot satisfy the standards of Rule 24(a), it nonetheless should grant Ortho's motion for "permissive intervention" under the more lenient standards of Rule 24(b), Fed. R. Civ. P. (Point II)

I. ORTHO IS ENTITLED TO INTERVENE AS OF RIGHT

Rule 24 of the Federal Rules of Civil Procedure is entitled "Intervention." Rule 24(a) sets forth the requirements for "Intervention of Right"; Rule 24(b) addresses "Permissive Intervention." Rule 24(a) states:

> Upon timely application anyone shall be permitted to intervene in an action: . . . (2) when the applicant claims an interest relating to the property or transaction which is the subject of the action and the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing parties.

A. Ortho Is a Necessary Party and Is Thus Entitled To Intervene

It is well established in this Circuit that, if a movant is a necessary party under Rule 19(a)(2)(i), then he is "entitled to intervene as a matter of right under Fed. R. Civ. P. 24(a)." *Ferrofluidics Corp. v. Advanced Vacuum Components, Inc.*, 968 F.2d 1463, 1472 (1st Cir. 1992); *see also Metropolitan Life Insurance Co. v. Ditmore*, 729 F.2d 1, 9, (1st Cir. 1984)); *Pujol v. Shearson American Express, Inc.*, 877 F.2d 132, 135 (1st Cir. 1989) (noting that Rule 24(a)(2) is a "counterpart" to Rule 19(a)(2)(i)). Here, Ortho is a "necessary party" under Rule 19(a)(2)(i), so it is entitled to intervene as of right.

Rule 19(a) is labeled "Persons to be Joined if Feasible." It states, in relevant part, that

> A person who is subject to service of process and whose joinder will not deprive the court of jurisdiction over the subject matter of the action shall be joined as a party in the action if . . . (2) the person claims an interest relating to the subject of the action and is so situated that disposition of the action in the person's absence may (i) as a practical matter impair or impede the person's ability to protect that interest . . . .

Rule 19(a), Fed. R. Civ. P.

Ortho meets these requirements because it is an exclusive licensee under Amgen's EPO Product Patents within a field of use in which allegedly infringing acts are occurring, or

will imminently occur.[2] Ortho claims a clear interest in the subject matter of this action – the enforcement of the patent monopoly to which Ortho is exclusively licensed. And adjudication of Amgen's claims in Ortho's absence would, as a practical matter, impair or impede Ortho's ability to protect its interest – both in terms of blocking Roche's entry into Ortho's exclusive field of use, and in terms of collecting any damages owed to Ortho on account of infringing acts of Roche. Ortho is therefore a necessary party under Rule 19(a)(2)(i).

The U.S. Court of Appeals for the Federal Circuit has recently addressed the issue of whether an exclusive licensee such as Ortho is a necessary party in an infringement suit brought by the patent holder, and has answered it in the affirmative. In *Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336 (Fed. Cir. 2006), a patent was issued to Chao as inventor and Contour as assignee. Contour then entered into an exclusive license agreement with Chic. Roughly two weeks later, Chic executed a sublicense agreement by which it transferred all of its rights under the patent to another party, Aspex, which effectively replaced Chic as the exclusive licensee. An infringement action was initiated by Contour (the assignee) and Aspex (the exclusive licensee). But the complaint was filed a few days prior to formal execution of the sublicense agreement between Chic and Aspex.

On appeal, the Federal Circuit remanded to the district court for further fact finding on the issue of whether the legal transfer of rights from Chic to Aspex occurred prior or subsequent to the filing of the complaint. The Court of Appeals explained that whichever entity (Chic or Aspex) was the exclusive licensee as of the commencement of the action was a "necessary party" to the infringement suit. "For the same policy reasons that a patentee must be joined in any lawsuit involving his or her patent, *there must be joinder of any exclusive licensee.*" *Aspex Eyewear*, 434 F.3d at 1344 (citing *Independent Wireless Tel. Co. v. Radio Corp of Amer.*, 269 U.S. 459, 466 (1926) (emphasis added)). "If the license between Chic and Aspex was not

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[2] The reason why the infringement must occur within the exclusive licensee's defined field of use is that the licensee's standing extends only to acts of infringement within this field. *See* Point I.C., *infra*.

effective at the time of the original complaint, then Chic was a necessary party" that was required to have been joined. *Id.*

Ortho is an exclusive licensee under Amgen's EPO Product Patents, and an exclusive licensee is a "necessary party" to any infringement action – at least where, as here, the alleged infringement occurs within the licensee's exclusive field of use. Ortho is therefore a necessary party under Rule 19(a)(2)(i) and is entitled to intervene as of right in this matter. *See, e.g., Fisher v. The Gillette Co.*, 505 F. Supp. 184, 186 (N.D. Ill. 1981) (exclusive licensee entitled to intervention as of right); *Precision Shooting Equipment, Inc. v. Allen*, 199 U.S.P.Q. 459, 461 (E.D. Ill. 1978) (same); *Innis, Speiden & Co. v. Food Machinery Corp.*, 2 F.R.D. 261, 264 (D. Del. 1942) (same).

B. Ortho Satisfies the Standards of Rule 24(a)

Even if Ortho were not a necessary party under Rule 19, it would nonetheless be entitled to intervene as of right under Rule 24(a). Intervention of right requires a four-part showing: (1) timeliness; (2) a cognizable interest relating to the property or transaction that is the subject of the action; (3) potential impairment of that interest; and (4) inadequate representation by existing parties. *Travelers Indem. Co. v. Dingwell*, 884 F.2d 629, 637 (1st Cir. 1989). Ortho meets all of these requirements. In addition, Ortho has standing to participate in an action for infringement in its exclusive field of use.

1. This Motion Is Timely

Ortho has *moved* to intervene at the very outset of this case. Amgen filed its complaint on November 8, 2005. As of the date of this motion, Roche has not responded to the complaint. There has been no initial scheduling conference, and no discovery has been taken. In these circumstances, there is no question but that Ortho's motion is timely. *See North America Specialty Ins. Co. v. Seacoast Crane Co., Inc.*, 226 F.R.D. 27, 29 (D. Me. 2005) (motion to intervene filed prior to an answer, approximately two months after the filing of the complaint, deemed timely); *Cabot LNG Corp. v. Puerto Rico Electric Power Auth.*, 162 F.R.D. 427, 430 (D.

P.R. 1995) (motion made three months after filing of complaint deemed timely); *Tutein v. Daley*, 43 F. Supp. 2d 113, 126-27 (D. Mass. 1999) (same); *One Beacon Ins. Co. v. Electrolux*, 223 F.R.D. 21, 24 (D. Mass. 2004) (motion deemed timely where intervention "would not cause further delay" and action was "in a nascent stage").

2. Ortho Has a Cognizable Interest in this Action

The requirement that the intervenor have a "cognizable interest" in the action is satisfied where, as here, the intervenor's claims bear a "sufficiently close relationship to the dispute" and its interest is "direct, not contingent." *Conservation Law Foundation, Inc. v. Mosbacher*, 966 F.2d 39, 42 (1st Cir. 1992) (quoting *Travelers Indem.*, 884 F.2d at 638).

Ortho's claims are directly related to this dispute. According to Amgen's complaint, Roche is making meaningful preparations to infringe Amgen's EPO Product Patents by marketing and selling PEG-EPO in the United States. Ortho has an exclusive license under these patents, and Roche's sale of PEG-EPO within Ortho's exclusive field (all human uses other than dialysis and diagnostics) would directly harm Ortho. Courts routinely find that such economic or legal interests in the subject matter of the action are sufficient to warrant intervention as of right. *See Conservation Law Foundation*, 966 F.2d at 42-43 (intervention proper where outcome of action would substantially affect intervenors' business); *Public Service Co. of New Hampshire v. Patch*, 136 F.3d 197, 205 (1st Cir. 1998) (potential economic harm is a factor in determining an intervenor's interest); *Cabot LNG Corp.*, 162 F.R.D. at 430 (intervenors had substantial interest where their economic interests could be adversely affected by the outcome); *Lennox Industries, Inc. v. Caicedo Yusti*, 172 F.R.D. 617, 621 (D. P.R. 1997) (finding a substantial interest where the intervenor claimed an interest in real property subject to foreclosure action).[3]

[3] Ortho's interest is "direct, not contingent," *Conservation Law Foundation*, 966 F.2d at 42, because it flows directly from the issues before this Court and does not depend upon the outcome of any other case or contingency. *Compare Amgen v. Chugai*, 808 F. Supp. at 905 n.15 (recovery of damages depended on "the contingency of Ortho's success in some other suit").

3. Ortho's Interest May Be Impaired Absent Intervention

In determining whether a movant's interest may be impaired in its absence, courts look to the practical consequences to the movant of denying intervention. *Cabot LNG*, 162 F.R.D. at 430. Impairment exists where the outcome of the case may have an adverse effect on the movant's interest and foreclose the possibility of protecting that interest in a subsequent proceeding. *Conservation Law Foundation*, 966 F.2d at 42-43. The intervenor need not show that it would be legally bound by the judgment in the original action under the principles of *res judicata*. *Cabot LNG Corp.*, 162 F.R.D. at 430.

Ortho's interests could be seriously impaired by the outcome of this case. If Roche were to prevail on the issues of validity, enforceability or infringement, Roche would be able to sell PEG-EPO in Ortho's exclusively licensed field of use. And Ortho would be hard-pressed to complain about that infringement later in a separate suit. "A licensee cannot stand by until a patentee's suit is concluded and then seek to vindicate its rights in a second suit." *Ortho v. Genetics Institute*, 52 F.3d at 1035.

Even if Amgen were to prevail on the merits, Ortho would not be made whole for injuries caused by Roche's sales in its exclusive field of use unless it is permitted to intervene. That is true for legal, contractual and practical reasons. First, as a legal matter, Amgen would not have the right to recover damages for injuries suffered by Ortho due to infringement in its exclusive field of use; only Ortho is entitled to recover such damages. *See Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004) ("While Poly-America may have the right to sue under its patents . . . it can recover only its own lost profits, not Poly-Flex's"); *Cold Metal Process Co. v. E.W. Bliss Co.*, 285 F.2d 231, 241 (6th Cir. 1960); *Bakelite Corp. v. Lubri-Zol Dev. Corp.*, 34 F. Supp. 142, 144 (D. Del. 1940) ("measure of damages . . . would be one measure for the patent owner and a different measure for the exclusive licensee. The rules of equity do not allow the patent owner to recover the damages sustained by his exclusive licensee.").

Second, even if Amgen could seek damages based on injury to Ortho, it would not be contractually obligated to share any portion of the damage award with Ortho unless Ortho were made a party. *See* Grossman Dec. Exh. 1 at ¶ 8.02 ("Absent an agreement between the parties to jointly bring any action or suit hereunder and share the expenses thereof, any amount recovered in any such action or suit shall be retained by the party bearing its expenses thereof.").

Third, if Ortho is ever going to recover damages for Roche's sales in its exclusive field of use, it must be made a party to this action now. Ortho cannot sit on the sidelines while this action proceeds, and then later seek to recover damages from Roche if it is found to infringe. *See Ortho v. Genetics Institute*, 52 F.3d at 1035 ("A licensee cannot stand by until a patentee's suit is concluded and then seek to vindicate its rights in a second suit").

For all of these reasons, denying Ortho's motion could result in serious impairment of Ortho's economic interests. Intervention is therefore proper.

4. Amgen Does Not Adequately Represent Ortho's Interests

The Supreme Court has stated that the burden of showing "inadequate representation" for purposes of Rule 24(a) "should be treated as minimal." *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972); *see also Dimond v. District of Columbia*, 792 F.2d 179, 192 (D.C. Cir. 1986) (burden is "not onerous"). To meet the "inadequate representation" requirement, "[a]n intervenor need only show that representation [of its interests] **may be** inadequate, not that it is inadequate." *Conservation Law Foundation*, 966 F.2d at 44 (emphasis added); *see also Trbovich*, 404 U.S. at 538 n.10. As one commentator has noted,

> given [the *Trbovich*] standard, the applicant should be treated as the best judge of whether the existing parties adequately represent his or her interests, and [] any doubt regarding adequacy of representation should be resolved in favor of the proposed intervenor.

6 *Moore's Federal Practice* § 24.03[4][a], at 24-42 (3d ed. 2005).

The First Circuit has adopted a three-part test to assess whether the representation offered by an existing party may be inadequate:

(1) Are the interests of the party present in the suit sufficiently similar to that

> of the absentee, such that the legal arguments of the latter will undoubtedly be made by the former;
>
> (2) is that present party capable and willing to make such arguments; and
>
> (3) if permitted to intervene, would the intervenor add some necessary element to the proceedings that would not be covered by the parties in the suit?

United Nuclear Corp. v. Cannon, 696 F.2d 141, 144 (1st Cir. 1982) (*see Blake v. Pallan*, 554 F.2d 947, 954-55 (9th Cir. 1977)).

Where the intervenor and the existing party have the "same ultimate goal," there is a presumption of adequate representation. *United Nuclear*, 696 F.2d at 144. However, the presumption does not arise where, as here, there is no assurance that the objectives of the existing party are identical to those of the intervenor. Even where the presumption does arise, the burden of overcoming it is, as noted, only "minimal." *Trbovich*, 404 U.S. at 538 n.10.

There are several reasons why the representation accorded by Amgen may be inadequate to protect Ortho's interests. First, as discussed above, Ortho is a necessary party under Rule 19(a) and the Federal Circuit's recent decision in *Aspex*. Without Ortho's participation, it is questionable whether Amgen can obtain *any* relief, let alone all the relief to which Ortho may be entitled.

Second, as noted, Ortho cannot rely upon Amgen to recover damages for injuries caused by Roche's infringement in Ortho's exclusive field of use. Amgen has no right to seek money damages suffered by its licensee, and even if it did, Amgen would have no contractual obligation to surrender any such recovery to Ortho. Although a damages award is not imminent at this time, to protect its ability to recover damages in the future, Ortho must join in this action now. *See Amgen v. Chugai*, 1989 WL 87484 at *5 (denying leave to intervene shortly before trial).

Third, apart from the issue of damages, the PLA's division of the U.S. EPO market between Amgen's reserved field (dialysis and diagnostics) and Ortho's exclusive licensed field (all other human uses) creates commercial interests and incentives for Amgen that differ

from those of Ortho. The problem is exacerbated by the fact that Amgen sells another anti-anemia product, Aranesp, that competes with EPO for both dialysis and non-dialysis sales. As a result, Amgen may find it desirable to settle this case on terms that advance Amgen's commercial interests at Ortho's expense. Intervention is necessary to protect against that outcome. *See Amgen v. Chugai*, 808 F. Supp. at 905 n.15 ("Ortho would appear to have no difficulty meeting the inadequacy of representation requirement by virtue of the fact that Genetics and Amgen appear close to settlement"); *Nextel Communications of Mid-Atlantic, Inc. v. Town of Hanson*, 311 F. Supp.2d 142, 153 (D. Mass. 2004) (finding a "genuine potential for divergence of interests" where the existing party "might change or soften [its] position based on its broader geographic and institutional interests").

Finally, intervention is appropriate in order to preserve Ortho's ability to participate in this case on appeal. *See, e.g., In re Acushnet River*, 712 F. Supp. 1019, 1024 n.6 (D. Mass. 1989) (putative intervenor would be prejudiced because denial of intervention would leave it unable to participate on appeal). In short, Ortho's "minimal" burden of showing that Amgen's representation "may" be inadequate is readily met. *Trbovich*, 404 U.S. at 538 n.10; *Conservation Law Foundation*, 966 F.2d at 44.

C. Ortho Has Standing as an Exclusive Licensee To Bring and Maintain an Action for Infringement in its Exclusive Field of Use

As an exclusive licensee in a defined field of use, Ortho has standing together with the patent owner (Amgen) to sue for infringing acts within its exclusively licensed field. *See Abbott Labs v. Diamedix Corp.*, 47 F.3d 1128, 1131 (Fed. Cir. 1995) ("an exclusive licensee may join an infringement suit as co-plaintiff with [the] patentee") (citing *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1579 & n.7 (Fed. Cir. 1991)); *Weinar v. Rollform, Inc.*, 744 F.2d 797, 806-07 (Fed. Cir. 1984) (licensee with exclusive right to sell licensed products may sue for and obtain relief for infringement in conjunction with patent owner); *Amgen v. Chugai*, 808 F. Supp. at 899 ("An exclusive licensee generally has standing to sue for infringement against anyone operating without the stated authority in the stated area of exclusivity").

Moreover, "the standing of an exclusive licensee can be predicated on the grant of an exclusive right to make, use, or sell a patented invention within a limited field." *Amgen v. Chugai*, 808 F. Supp. at 903. An exclusive license can be created, among other things, by granting a right to sell a patented invention without granting the right to make or use it, *Weinar*, 744 F.2d 797, or by virtue of a field of use limitation. *See, e.g., Pratt & Whitney Co. v. United States*, 153 F. Supp. 409, 411 (Ct. Cl. 1957) ("a licensee under an exclusive license for a limited use has the right to maintain an action in the name of the licensor for an unlawful use of the patent within this limited field"); *Amgen v. Chugai*, 808 F. Supp. at 900 (an "exclusive license can be created by a grant of exclusivity based solely on geographic, time, or field of use limitations"). Of course, the alleged "infringement [must] occur[] within [the licensee's] stated area of exclusivity." *Id.* at 901.

Ortho readily meets these requirements. As discussed above, the PLA grants Ortho the exclusive right under the EPO Product Patents to sell EPO in the United States for all human uses except dialysis and diagnostics. Ortho seeks to intervene in this action only with respect to Roche's alleged infringement of those patents to which Ortho is exclusively licensed, and only as to such infringing acts as may occur within Ortho's exclusive field of use. These limitations are spelled out in Ortho's proposed complaint (Exhibit A hereto), and fully satisfy the requirements of standing for exclusive licensees. *See Amgen v. Chugai*, 808 F. Supp. at 900-01.

II. IN ANY EVENT, ORTHO SHOULD BE GRANTED PERMISSION TO INTERVENE UNDER RULE 24(B)

Even if Ortho did not satisfy the requirements for intervention as of right under Rule 24(a), it would nonetheless be entitled to the relief it seeks. This Court has broad discretion under Rule 24(b) to allow intervention on a permissive basis. *See Travelers Indemnity*, 884 F.2d at 641 ("the district court enjoys broad discretion in making determinations regarding permissive intervention under Rule 24(b)(2)"); *see also Int'l Paper Co. v. Inhabitants of Town of Jay, Maine*, 887 F.2d 338, 344 (1st Cir. 1989). There is no reason to deny such permission to Ortho here.

> Rule 24(b) provides in pertinent part that
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> Upon timely application anyone may be permitted to intervene in an action: . . . (2) when an applicant's claim or defense and the main action have a question of law or fact in common. . . . In exercising its discretion the court shall consider whether the intervention will unduly delay or prejudice the adjudication of the rights of the original parties.

In addition, a court may consider many of the factors that are applicable for intervention as of right. *Langone v. Flint Ink North America Corp.*, 231 F.R.D. 114, 121 (D. Mass. 2005). The standards for permissive intervention are readily satisfied here.

A. There Are Common Question of Fact and Law

Ortho's claims against Roche present numerous factual and legal issues that are identical to those presented by Amgen's complaint. These issues include (a) the proper construction of the claims of Amgen's EPO Product Patents; (b) whether Roche's PEG-EPO infringes these claims; (c) whether the EPO Product Patents are valid; and (d) whether such patents are enforceable.

B. Intervention Would Neither Delay This Case Nor Result In any Prejudice to the Original Parties

As discussed above, this case is in a "nascent stage." *One Beacon*, 223 F.R.D. at 24. Roche has not yet responded to the complaint, and no discovery has been conducted. Permitting Ortho to intervene at this early stage would not delay the resolution of this action or otherwise prejudice the rights of any party.

C. This Court Has Independent Grounds for Subject Matter Jurisdiction

"[P]ermissive intervention ordinarily must be supported by independent jurisdictional grounds." *International Paper*, 887 F.2d at 346. This requirement is readily satisfied. The Court has subject matter jurisdiction over Ortho's claims for infringement of the EPO Product Patents pursuant to 28 U.S.C. § 1338(a), which gives the district courts original jurisdiction of any civil action arising under any Act of Congress relating to patents.

CONCLUSION

For the reasons stated above, Ortho's motion to intervene should be granted.

Dated: March 9, 2006