UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, vs. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, AND HOFFMANN-LA ROCHE INC., Defendants	CIVIL ACTION No.: 05-CV-12237WGY

DEFENDANTS' MEMORANDUM IN OPPOSITION TO ORTHO'S MOTION TO INTERVENE

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I. PRELIMINARY STATEMENT

F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively, "Roche") respectfully submit this memorandum of law in opposition to the motion of Ortho Biotech Products, L.P. ("Ortho") to intervene as plaintiff in this lawsuit with Amgen Inc. ("Amgen"). Alternatively, Roche seeks limited and expedited discovery of the facts necessary to determine the merits of the intervention issue.

From the onset, Ortho's motion to intervene should be denied because its underlying cause of action is futile. As with Amgen's pleading, Ortho's proposed complaint seeks a declaratory judgment of infringement. And like Amgen, all of Ortho's infringement allegations are limited to Roche's current attempts to seek approval from the U.S. Food and Drug Administration ("FDA") of its drug product CERA. As a result, and as explained at length in Roche's Memorandum in Support of its Motion to Dismiss For Lack of Subject Matter Jurisdiction and Failure to State a Claim, (filed concurrently herein), Roche has a complete defense to every allegation of infringement that Ortho seeks at this time based, *inter alia*, upon 35 U.S.C. §271(e)(1).

Moreover, this Court and the Federal Circuit have already ruled that Ortho is merely a nonexclusive licensee under the very same Product License Agreement ("PLA") at issue here. *See Amgen, Inc. v. Chugai Pharm. Co.,* 808 F. Supp. 894, 902 (D. Mass. 1992) (Young, C.J.), *aff'd sub nom. Ortho Pharm. Corp. v. Genetics Inst., Inc.*, 52 F.3d 1026 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 907 (1995). As a nonexclusive licensee under this agreement, Ortho has no standing to join suit with Amgen, and cannot intervene as of right or by permission.

As discussed in those decisions, the PLA discloses numerous limitations that Amgen placed on Ortho's right to make, use, sell, and alienate its product. Under the PLA these

limitations apply equally to all of the "Licensed Patents" which are the subject of the PLA and include all of the patents-in-suit. The multiple limitations within the PLA restrain the entire bundle of rights that come with Amgen's patents and demonstrate that the agreement grants only a nonexclusive license to Ortho.

Finally, should the Court decide not to dismiss Ortho's motion outright, the Court should allow Roche to conduct limited and expedited discovery of Ortho's license under the Amgen patents. Ortho has not even provided a complete copy of its PLA with Amgen, which is central to whether Ortho can intervene in this lawsuit. Moreover, Ortho's motion identifies no fewer than three separate arbitration proceedings where the terms of the PLA were construed and certain rights originating from that agreement were adjudicated. Obviously, Amgen and Ortho are in possession of this information through their decades long disputes over this agreement. But Roche, who potentially stands to lose the most from this motion should the Court allow another plaintiff to try to distract Roche from seeking FDA approval of CERA, presently does not have access.

Among the more critical and fundamental questions requiring immediate answers from Ortho and Amgen include:

- Why did Ortho not produce the complete PLA, along with any amendments?
- Are there any other agreements between Amgen and Ortho that define their respective rights with respect to the patents-in-suit and covered products, such as other Product License Agreements or Technology License Agreements ("TLAs")?
- What did the numerous arbitration proceedings decide with respect to the rights of Amgen and Ortho under the agreements?

- Why is Ortho only seeking to intervene for purposes of the product patents, when the plain terms of the PLA seem to provide Ortho with equal rights under the process patents?

- Are there any other proceedings pending or terminated between Amgen and Ortho that affect the parties' performance under the PLA and their respective rights thereunder?

Before permitting Ortho to intervene, this Court should require Ortho and Amgen to respond to these questions and more, because they go to the fundamental basis of Ortho's proposed intervention, namely, whether Ortho is an exclusive licensee under the PLA.

II. ARGUMENT

ORTHO FAILED TO MEET ITS BURDEN OF INTERVENTION

A. Ortho's Intervention At This Early Stage Would Be Futile

Ortho's motion to intervene should be denied because its underlying cause of action is futile. Just as with Amgen's pleading, Ortho's proposed Complaint In Intervention[1] identifies the following activities as alleged acts of infringement: (1) an anticipated filing of an application with the FDA to sell the accused product; (2) news of clinical trials for purposes of submitting data to the FDA; (3) hiring management, sales, and support personnel, as well as outside consultants; (4) contacting potential customers; and (5) completing construction of overseas manufacturing facilities. Ex. A at ¶¶ 21-26.

However, as demonstrated in Roche's Motion to Dismiss For Lack of Subject Matter Jurisdiction and Failure to State a Claim, and supporting Memorandum and Exhibits, which are being concurrently filed and incorporated by reference herein, Roche has complete defenses to every one of these allegations by virtue of (1) the safe harbor provision of 35 U.S.C.§ 271(e)(1);

[1] Ortho's proposed complaint is attached as Exhibit A to Ortho's memorandum in support of its motion to intervene ("Ortho's memo"), and referred to herein as "Ex. A."

(2) Ortho's failure to state a cause of action of infringement pursuant to Fed. R. Civ. P. 12(b)(6); and (3) Ortho's failure to plead any imminent acts to justify a case or controversy under the Declaratory Judgment Act, 28 U.S.C. § 2201.

Therefore, to conserve judicial resources, the Court should first decide Roche's pending Motion To Dismiss For Lack Of Subject Matter Jurisdiction And Failure To State A Claim, because resolution of that motion in Roche's favor will render Ortho's motion to intervene moot. *See United States v. One Sixth Share of James J. Bulger*, No. 95-11513DPW, 2002 WL 550405, at *3 (D. Mass. Mar. 28, 2002) (Woodlock, J.) (upon deciding grounds for vacating judgment at outset, "I find any right to participate at this time by these Claimants . . . to be futile . . . . I will deny the efforts of the three claimants to intervene."); *E.E.O.C. v. Victoria's Secret Stores, Inc.*, No. 02-6715, 2003 WL 21282193, at *1 (E.D. Pa. Jan. 13, 2003) ("A motion to intervene will thus be denied where the proposed complaint-in-intervention fails on its face to state a cognizable claim."); *Ceribelli v. Elghanayan*, No. 91 Civ. 3337 (CSH), 1994 WL 529853, at *2 (S.D.N.Y. Sept. 28, 1994) (legal futility is a basis to reject intervention under Rule 24); *State Farm Mut. Auto. Ins. Co. v. United States*, No. 02-1799, 2003 WL 1873089, at *3 n.1 (E.D. La. Apr. 10, 2003) (on motion to intervene, "[b]ecause the Court finds that intervention is futile, the Court does not reach defendant's arguments as to timeliness.").

B. This Court And The Federal Circuit Previously Held That Ortho Was Not An Exclusive Licensee

In *Chugai*, this Court ruled that Ortho was merely a nonexclusive licensee under the very same PLA[2] at issue *here* in denying Ortho standing to sue as a co-plaintiff with Amgen against

[2] The PLA is attached as Exhibit 1 to Ortho's memo and referred to herein as "Ex. 1."

Genetics Institute. 808 F. Supp. at 902. In facts remarkably similar[3] to those here, this Court presented the issue as follows:

> First, Ortho contends that the license agreements give it the exclusive right to use the patented inventions in the United States to make EPO. Ortho admits that in these agreements Amgen reserves the right to use the patented inventions in the U.S. to make EPO for sale in the U.S. for diagnostic and dialysis purposes. Ortho correctly argues, however, that the exclusivity of its license to use the inventions claimed under the '008 patent in the U.S. to make EPO depends not on whether Amgen reserved the same right for itself, but rather on whether Amgen expressly or impliedly promised not to grant this right to other third parties.

Id. at 901. In examining the PLA, this Court determined that because Amgen retained the right to grant additional licenses to the use the patented invention in the U.S. for dialysis and diagnostic purposes, this indicated that Ortho was not an exclusive licensee under the agreement. *Id.* at 902 ("It is true that § 2.01 refers to Ortho's license as an 'exclusive license.' The Court interprets this reference to an 'exclusive license' to mean only that Amgen cannot license to a third party Ortho's exclusive right to manufacture EPO in the U.S. for sale abroad and not that Amgen can not sub-license its own right to manufacture EPO in the U.S. for sale in the U.S. for diagnostics or dialysis.") (emphasis added). As a result, this Court determined that Ortho lacked standing as an exclusive licensee to sue Genetics Institute. *Id*. at 904.[4]

The Federal Circuit affirmed. *See Ortho*, 52 F.3d 1026. In describing this Court's decision, the Federal Circuit noted that:

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[3] Considering that this decision involved Ortho, Amgen, and the very PLA at issue here, it is disconcerting that Ortho downplays the significance of this decision to a brief section in the middle of its brief, with no discussion at all of the Federal Circuit's affirmance.

[4] Ortho provided another argument in support of its claim as an exclusive licensee that involved the sale of EPO abroad. This Court also rejected that argument. *Id.*

> In ruling on the motion, the [trial] court first rejected Ortho's argument that it could premise standing based upon paragraph 2.01(a) of the license agreement. The court reasoned that because Amgen did not promise not to sublicense its own right to use its '008 invention to manufacture EPO in the United States, Ortho held a nonexclusive license under this provision.

Id. at 1030. The Federal Circuit proceeded to affirm, stating:

> Despite this implied license, the trial court found Ortho had no proprietary interest in the '008 patent based on its rights under either paragraph (a) or (b). It was a nonexclusive licensee. With respect to patent rights, Ortho had an implied license to use the '008 invention in one location in the United States. It is undisputed that that right was nonexclusive inasmuch as Amgen had the right to license others to do the same.

Id. at 1033. The Court then concluded that "Ortho is a bare, that is, nonexclusive, licensee and has no standing to bring or join a suit for infringement against Genetics." *Id.* at 1034 (emphasis added).

While these decisions by this Court and the Federal Circuit involved the '008 patent, which now is the expired parent patent of the patents-in-suit in this litigation, this fact does not diminish the fundamental basis for determining that Ortho is merely a nonexclusive licensee under the bundle of rights in the PLA. Namely, under the PLA, Amgen has the right to license others in the United States to make and sell and EPO whether under the expired '008 patent or subsequently issued Amgen product patents. *Id.* at 1030 ("The court reasoned that because Amgen did not promise not to sublicense its own right to use its '008 invention to manufacture EPO in the United States, Ortho held a nonexclusive license under this provision."). The Federal Circuit's decision applies to all of the "Licensed Patents" including all of the patents-in-suit. PLA, Ex. 1, ¶¶ 1.12, 2.01(a). The limitations on Ortho's rights under ¶ 2.01(a), which led the Federal Circuit to conclude that Ortho only had a nonexclusive license, apply equally to all of the Licensed Patents, including the '008 patent there at issue and the patents-in-suit.

Therefore, this Court and the Federal Circuit has already held the same PLA to mean that Ortho is nothing more than a nonexclusive licensee. Indeed, this should be issue preclusion against Ortho. After all, there is an identity of issues between those prior decisions and Ortho's current attempt to intervene because they all center around whether Ortho is an nonexclusive licensee under the PLA. Moreover, the prior decisions are adverse to Ortho and decided by courts of competent jurisdiction. *See Kyricopoulos v. Town of Orleans*, 967 F.2d 14, 16 (1st Cir. 1992) ("Under Massachusetts law, issue preclusion (or collateral estoppel) is appropriate where there is 'an identity of issues, a finding adverse to the party against whom it is being asserted, and a judgment by a court or tribunal of competent jurisdiction.'") (citation omitted).

C. Because Ortho Is Not An Exclusive Licensee Under The Product License Agreement, It Has No Standing To Intervene As Of Right Or By Permission

Standing in a suit for patent infringement is based on the Patent Act, which states in pertinent part: "A patentee shall have remedy by civil action for infringement of his patent." 35 U.S.C. § 281 (2005). The term "patentee" addresses not only the party to whom the patent was issued, but also "the successors in title to the patentee." 35 U.S.C. § 100(d).

The Federal Circuit specifically held that Ortho was a "nonexclusive licensee" under the PLA and thus had no standing to sue. *Ortho*, 52 F.3d at 1034. This is consistent with other Federal Circuit decisions. "[A] nonexclusive license or 'bare' license . . . confers no constitutional standing on the licensee under the Patent Act to bring suit or even to join a suit with the patentee because a nonexclusive . . . licensee suffers no legal injury from infringement." *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1345 (Fed. Cir. 2001) (citations omitted). Moreover, because nonexclusive licensees lack standing in patent infringement suits, they cannot meet the necessary party requirements of Fed. R. Civ. P. 19(a) or

the intervention as of right standards of Fed. R. Civ. P. 24(a). As the Federal Circuit stated in *Abbott Labs. v. Diamedix Corp.*, 47 F.3d 1128, 1130 (Fed. Cir. 1995),

> The parties to this appeal have focused principally on whether intervention should have been granted under Fed. R. Civ. P. 24 and, in particular, whether the district court properly denied intervention on the ground that [the licensee] adequately represents [the patentee's] interests [who was denied by the district court intervention] in the infringement action. We believe, however, that this case can best be resolved by addressing a related but logically antecedent question: whether a licensee . . . has the statutory right to bring an action for infringement without joining the patent owner . . . ."

See also Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1553-54 (Fed. Cir. 1995) (independent sales operators moved to intervene as exclusive licensees, but such intervention was inappropriate because the licensees were limited, lacked standing, and thus could not intervene).

1. Ortho Failed To Demonstrate That It Is Nothing More Than A Bare (Non-Exclusive) Licensee

While Ortho maintains that it is an "exclusive" licensee of Amgen's product patents in the fields of non-dialysis and non-diagnostics, Amgen limited every substantial right under the PLA to such a degree that the Court must again find that Ortho is merely a bare licensee.

The test of whether a licensee is exclusive or non-exclusive ("bare") turns on "the intent of the parties to the license as manifested by the terms of the their agreement and examining the substance of the grant." *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (citing *Ortho*, 52 F.3d at 1033-34). Merely because an agreement contains the word "exclusive" does not control the issue; rather it "is the substance of the arrangement" which controls. *Id*; *Chugai*, 808 F. Supp. at 901-02 (reiterating that the mere word "exclusive" within a license agreement is not controlling). When a party receives neither an express nor implied promise of exclusivity under

the patent, then the licensee receives a "bare license" and "has received only the patentee's promise that that party will not be sued for infringement." *Rite-Hite*, 56 F.3d at 1552. The burden of proving exclusivity is upon the licensee seeking to asserting it. *See, e.g., Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1250 (Fed. Cir. 2000).

Ortho's lack of exclusivity in any field of use militates for the conclusion that Ortho is a "bare licensee" and does not have standing to join Amgen's action. *See also Pfizer v. Elan Pharm. Research Corp.*, 812 F. Supp. 1352, 1373 (D. Del. 1993) (holding the licensee lacked standing because the licensor retained a nonexclusive sublicense); *Raber v. Pittway Corp.*, 23 U.S.P.Q.2d 1313, 1314-15 (N.D. Cal. 1992) (transferee lacked standing where transferor retained non-cancelable, royalty-free license under the patent, the right to grant sublicenses to its subsidiaries, and veto power of assignment); *Calgon Corp. v. Nalco Chem. Co.*, 726 F. Supp. 983, 986-87 (D. Del. 1989) (transferee lacked standing where the transferor retained the right to make and market products and retained a veto power over assignment and right of first refusal to sue for infringement).

The terms of the PLA only grant Ortho a limited field of use over the patent. Courts have held that licensing a field of use less then the full breadth of the patent will result in the license not being deemed exclusive. *See Etherington v. Hardee*, 290 F.2d 28 (5th Cir. 1961)); *Channel Master Corp. v. JFD Elec. Corp.*, 260 F. Supp. 568, 571-72 (E.D.N.Y. 1966).

2. Amgen Reserved The Right To Sue, And Did Not Confer Such Rights On Ortho

Under the PLA, Amgen retained for itself the right to sue under the patent and reserved the right to make decisions on litigation strategy. The right to sue has consistently been a key issue in determining the nature of a license agreement, militating for nonexclusivity where the

patentee retains such right. *See Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336, 1342 (Fed. Cir. 2006) (stating "[a] key factor has often been where the right to sue for infringement lies" and finding that the patentee did not retain the right to make decisions on litigation strategy as key in holding the license exclusive, and citing *Prima Tek II, LLC v. A-Roo Co.*, 222 F.3d 1372, 1380 (Fed. Cir. 2000), for the proposition that retention of the right to sue as crucial in determining the exclusivity of a license).

Here, Amgen expressly reserved the right to sue for infringement. The PLA states that "AMGEN shall have the right, but not the obligation, to bring...any appropriate suit or action." (Ex. 1 at ¶ 8.02). The PLA states Ortho's independent right to bring suit accrues only if Amgen fails to take action after six months upon receiving evidence of infringement. *Id.* Six months is a long and significant time to retain absolute control of such an important right. The reservation of rights by Amgen demonstrates its intent to not grant Ortho an exclusive license. That Amgen and Ortho signed an agreement wherein Ortho's right to sue was subject first to Amgen's absolute refusal, demonstrates neither party intended that Ortho have the rights of an exclusive licensee. *See Pfizer*, 812 F. Supp. at 1373 (holding that "[the licensee] cannot be said to stand on 'equal footing' with [the patent licensor] . . . when [the licensee's] right to sue is conditioned upon [the patent licensor's] right of first refusal"); *Ortho*, 52 F.3d at 1034 (stating "being only a nonexclusive licensee, Ortho has no inherent or implied right to sue which the [PLA] clause regulates as between the parties").

3. Amgen Limited Ortho's Ability To Make, Use, Sell And Sublicense

Where, as here, the patentee has limited virtually all of the licensee's bundle of rights, courts find that the license can not be exclusive. In *Pfizer v. Elan*, Pfizer, a licensee of Bayer, attempted to bring suit against Elan for infringement. 812 F. Supp. at 1355. In Bayer's license

to Pfizer, Bayer maintained several rights under the patent, including (1) retention of manufacturing rights for itself and/or an affiliate; (2) retention of a right to acquire a non-exclusive, royalty-free sublicense for itself or an affiliate to make, have made, use and sell the licensed patent; (3) Pfizer not able to assign its rights under the license agreement without the express written consent of Bayer; and (4) Pfizer's right to use, make and sell was limited to the territory of the United States. *Id.* at 1372. The court held that Pfizer's interests "are not exclusive, and the transfer of rights under the Agreement does not meet *Waterman's* definition of exclusivity." *Id.* at 1373 (citing *Waterman v. Mackenzie,* 138 U.S. 252, 255 (1891)).

The PLA contains more limiting provisions over Ortho, than the Bayer license with Pfizer. The PLA (1) limits Ortho's right to manufacture the drug[5]; (2) limits Ortho's right to sublicense[6]; (3) limits the field of use for which Ortho may sell its product[7]; and (4) limits the territory in which Ortho may sell its product[8]. Amgen and Ortho, by agreeing that virtually all aspects of Ortho's rights under the PLA should be limited, have made clear their intention that the PLA is merely a bare license.

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[5] *See* PLA, Ex. 1, at ¶ 2.01(a) "AMGEN hereby grants Ortho . . . an exclusive right to make in one location . . ."

[6] The license agreement requires Ortho give "prior written notice to Amgen" prior to sublicensing, and Ortho may not license the right to manufacture the patented products to any non-affiliate third party: "Ortho may . . . sublicense . . . to any affiliate, or any third party, to use and sell [the ability to sublicense the right to make is not included] . . . (ii) [Ortho may sublicense] to any one controlled affiliate to make in one location, use and sell Licensed Products . . ." *Id.*

[7] *Id.* at ¶ 1.10 (stating Ortho has the right to have made and use the licensed products in the licensed field which is "with respect to EPO: all indications for human use except dialysis and diagnostics . . .").

[8] *Id.* at ¶ 1.14 (the "licensed territory" granted to Ortho "shall mean to include: (a) with respect to EPO: the United States, its territories and possessions, including the Commonwealth of Puerto Rico . . .").

4. Amgen Reserved The Right To Sublicense Under The Agreement

A license awarded by a patentee that does not explicitly promise to refrain from granting subsequent licenses should not be held exclusive, unless the intention of the parties compels otherwise. *See Chugai*, 808 F. Supp. at 901-902 (refusing to interpret an implied promise not to sub-license where no clause existed within the agreement) (citing 6 Lipscomb, *Walker on Patents* § 20:58 at 203 (1987) (stating the Court should "not read limitations into the [license] agreement which could have been readily inserted by the parties")); *Textile*, 134 F.3d at 1485 (holding a license was not exclusive because it was silent regarding the right of the patentee to license to third parties and the court was obliged to "assume that [the patentee] retained such rights"). Nothing in this license manifests such an intent. In fact, the limitations on the right to make, use, sell, alienate, the reservation of the right to sue by Amgen, and its incursion into Ortho's allegedly exclusive field of use all demonstrate the parties merely intended this license to be a limited or "bare" one.

5. Permissive Joinder Of Ortho Is Inappropriate Because Ortho Lacks Subject Matter Jurisdiction

As Ortho concedes in its brief, "permissive intervention ordinarily must be supported by independent jurisdictional grounds." *Int'l Paper Co. v. Inhabitants of Town of Jay*, 887 F.2d 338, 346 (1st Cir. 1989). Ortho, as a bare licensee, has no standing and consequently, its appearance in this case cannot be supported by independent jurisdictional grounds. Accordingly, this Court should therefore deny Ortho's motion for permissive intervention. *See, e.g., Intellectual Prop. Dev.*, 248 F.3d at 1345 (stating "a nonexclusive license or 'bare' license . . . confers no constitutional standing on the licensee under the Patent Act to bring suit or even to join a suit with the patentee because a nonexclusive . . . licensee suffers no legal injury from infringement").

D. Ortho Failed To Demonstrate That Amgen Cannot Adequately Represent Ortho's Interest

As a limited licensee, Ortho has no cognizable interest in Amgen's suit. Even assuming Ortho was not a limited licensee (it is), this Court should deny intervention because any interest assertable by Ortho is completely protected by Amgen, making Ortho's presence superfluous, and potentially confusing. Of the two rights asserted by Ortho as the foundation for its intervention — the protection of its field of use and collecting damages from Roche — the former is completely protected by Amgen's alleged demands in this suit, and the latter is premature and baseless. Amgen seeks a permanent injunction on all of Roche's activity *including* any alleged field of exclusivity claimed by Ortho, thus Ortho's presence at trial is unnecessary. Further, neither Amgen nor Ortho may seek damages against Roche at this time because there has been no infringing acts, only allegations of prospective infringement.

Moreover, Ortho's plea that it cannot rely upon Amgen to recover damages rings hollow in view of the express terms of the PLA. After all, Ortho specifically contracted under ¶ 8.02 of the PLA that Amgen not only had the exclusive right to bring a lawsuit as the sole plaintiff, but that Amgen would then recover all damages from its bringing of such a suit. (PLA, Ex. 1 at ¶ 8.02 ("any amount recovered in any such action or suit shall be retained by the party bearing its expenses thereof.")).

If Ortho's Motion Is Not Summarily Denied, Roche Requires Discovery Of Ortho's Relationship With Amgen

If this Court decides not to summarily deny Ortho's motion (which Roche believes is mandated by the Federal Circuit's prior decision) this Court should allow Roche expedited and limited discovery on the issue of Ortho's standing prior to determining whether to permit Ortho to intervene. The limited discovery would be warranted because only Ortho and Amgen possess

the evidence regarding Ortho's rights in the patents-in-suit, including the PLA which Ortho failed to disclose in its entirety as an exhibit to its motion.

E. Should This Court Not Deny Ortho's Motion Outright, Roche Should Be Allowed Expedited Discovery Because Only Ortho and Amgen Know Their Rights With Respect To The Patents-In-Suit And Any Covered Products

As stated by Ortho in its motion, its relationship with Amgen with respect to their rights under the patents-in-suit has been "troubled and litigious," as well as "hotly contested." (Ortho memo at 5). Moreover, in describing its relationship with Amgen, Ortho identifies at least three separate arbitration proceedings with Amgen between the years 1989 - 2002 that apparently interpreted various terms of the PLA, which resulted in substantial damages payments to each other. *Id.*

While these events play a fundamental role in deciding whether Ortho should be allowed to intervene in this action, Roche has been completely shut out from these salient facts. Ortho has not even produced a complete copy of the PLA, and Roche has no way in determining whether there were any subsequent amendments to this agreement. From this Court's *Chugai* decision, it is apparent that there was more than one PLA, as well as numerous Technology License Agreements ("TLAs") that carved out the parties' respective rights. *See Chugai*, 808 F. Supp. at 897 ("On September 30, 1985, Ortho entered into Technology License Agreements ("TLAs") and Product License Agreements ("PLAs") with Kirin-Amgen and Amgen separately.") (emphasis added). Yet, Ortho has attached only an excerpt from one of those agreements as part of its motion to intervene. (Ex. 1).

Roche requires discovery on all PLAs and TLAs between Ortho and Amgen, as well as the prior arbitrations involving these agreements. To determine a licensee's right to intervene in a patentee's infringement action, the touchstone issue is what type of license exists between the

licensee and patentee: an assignment, exclusive license or merely a bare license. Ortho's bald assertion that it is an exclusive licensee while attaching only a limited portion of the PLA is grossly insufficient to allow Roche and this Court to evaluate this relationship.

Classifying a license agreement as bare or exclusive requires a review of all the words of the pertinent agreements, and any information elucidating the intentions the parties bestowed on those words. *See Waste Stream Envtl., Inc. v. Lynn Water & Sewer Comm'n*, 15 Mass. L. Rptr. 723, 2003 WL 917086, at *4 (Mass. Super. Ct. 2003) (citing Restatement (Second) of Contracts § 202(4), at 86 (1981)); *Ortho*, 52 F.3d at 1033-34. A wealth of history of the parties' intentions toward these agreements exists in the numerous disputes between Ortho and Amgen, and Roche should be entitled to expedited discovery of at least the following:

- Complete copies of any agreement, including PLAs and TLAs, between Ortho and Amgen involving the patents-in-suit, including amendments, draft agreements and documents evidencing their negotiation;

- Complete copies of any agreement between Amgen and a third party involving the patents-in-suit, including amendments, draft agreements and documents evidencing their negotiation;

- Rulings, dispositive motions, expert reports, and transcripts of any arbitration proceeding or any other proceedings between Amgen and Ortho involving the PLAs, TLAs, and/or the patents-in-suit.

While Amgen is likely to be in possession of these materials, Roche cannot rely upon Amgen to protect Roche's interests to oppose yet another party's attempts to interfere with Roche's statutorily protected right to seek FDA approval of its drug. After all, should Ortho be allowed to join Amgen in this lawsuit as co-plaintiff, Ortho's interests would be aligned with Amgen to preserve the validity of the patents-in-suit and seek declaratory relief of infringement.

Discovery of these materials will no doubt provide more information that counters Ortho's unwarranted assertion that it is an exclusive licensee of the patents-in-suit. Moreover, they will hopefully resolve a number of anomalies concerning Ortho's alleged exclusive rights to the patents-in-suit that at present cannot be adequately explained.

For example, Ortho has maintained that it seeks intervention only with respect to Amgen's product patents, and suggests that it is an exclusive licensee under only these product patents (Ortho memo at 2). However, under the plain reading of the PLA, Ortho apparently has equal rights to Amgen's process patents, which are identified as U.S. Patent Nos. 5,441,868 (the "'868 patent"), 5,618,698 (the "'698 patent"), and 5,765,349 (the "'349 patent").

Under ¶ 1.13 of the PLA, Licensed Products are defined as products for use in the licensed field "(iii) which are manufactured or packaged within the scope of a VALID LICENSED CLAIM of a LICENSED PATENT." (Ex. 1).

Under ¶ 1.12, "LICENSED PATENTS" are defined to include "any patent application listed in Exhibit D, and any division, continuation, or continuation-in-part of any such application, and any patent which shall issue based on such application, division, continuation or continuation-in-part." *Id.* Exhibit D identifies U.S. patent application 561,024. *Id.* Importantly, all of the patents-in-suit, including both the EPO product patents and the EPO process patents issued from continuation applications from the '024 application, and as a result constitute "Licensed Patents" under the PLA. *Id.* Thus to the extent that Ortho is alleging exclusive rights to its licensed field of non-dialysis and non-diagnostics with respect to the product patents, it should also have equal rights under the process patents. Yet inexplicably, Ortho has decided to forego its rights under those patents.

F. Roche's Request For Expedited Discovery Should Be Granted

The Federal Rules of Civil Procedure make clear that federal courts have broad authority to expedite discovery in response to pre-trial motions and prior to hearings on such motions. *See, e.g., New York v. U.S. Metals Ref. Co.*, 771 F.2d 796, 805 (3d Cir. 1985) (stating Rule 26 "provides very broad discovery and gives the trial court wide discretion to manage the process"); *Dimension Data N. Am., Inc. v. NetStar-1, Inc.*, 226 F.R.D. 528, 531 (E.D.N.C. 2005) (stating "Rule 26(b) provides the court with broad discretion in structuring discovery, stating 'for good cause, the court may order discovery of any matter relevant to the subject matter involved in the action.'") (quoting Fed. R. Civ. P. 26(b)(1)).

The prevailing test in district courts for adjudging whether expedited discovery is warranted is the "reasonableness test." *See, e.g., Sheehan v. Netversant-New England, Inc.*, 345 F. Supp. 2d 130, 132 (D. Mass. 2004) (Gorton, J.) (granting "expedited discovery" only so far as needed to "reasonably suit Plaintiff's immediate needs" because "any broader expedited discovery would be unduly burdensome"); *In re Websecure, Inc. Sec. Litig.*, No. 97-10662-GAO, 1997 WL 770414, at *4 (D. Mass. Nov. 26, 1997) (O'Toole, J.) (stating "plaintiffs' request to take expedited discovery is a reasonable one . . . the request . . . is both 'particularized' and 'necessary . . . to prevent undue prejudice' to the plaintiffs, and it is therefore permissible . . .").

Reasonableness can be determined by (1) whether the scope of the expedited discovery request is tailored to the claimed purpose for which it will be used; (2) assessing the harm caused to the moving party if expedited discovery is denied; (3) assessing the burden of discovery on the opposing party; (4) whether the timing of the request is reasonable; and (5) whether expedited discovery would facilitate the management of the case. *See, e.g. Entm't Tech. Corp. v. Walt Disney Imagineering*, No. 03-3546, 2003 WL 22519440, at *4-*6 (E.D. Pa.

Oct. 02, 2003); *Semitool, Inc. v. Tokyo Electron Am., Inc.*, 208 F.R.D. 273, 275-77 (N.D. Cal. 2002).

The following demonstrates that Roche's request for discovery over the Ortho-Amgen arbitrations and the complete agreements is reasonable and should be granted.

1. Discovery Of The Amgen-Ortho Arbitrations And License Agreement Would Be Narrowly Tailored

Roche's discovery request should be granted because it is narrowly tailored and seeks discovery only on core documents, directly relevant to Ortho's motion to intervene. *See, e.g. Sica v. Connecticut*, 331 F. Supp. 2d 82, 88 (D. Conn. 2004) (awarding limited expedited discovery to address pre-trial issues); *Walt Disney Imagineering*, 2003 WL 22519440, at *5.

In *RDS Group Ltd. v. Davison*, the defendant served "wide-ranging" requests for documents regarding ownership and control of various corporations that the Plaintiff claimed to own. No. 02-CV-8168, 2003 U.S. Dist. LEXIS 1337, at *5 (E.D. Pa. Jan. 17, 2003). Despite the over-broad request by the defendant, the court held "at least some of the discovery Defendant seeks is proper at this time." *Id.* at *6. Because the plaintiff raised various issues regarding ownership and license agreements during the lead up to filing the complaint the court held that "discovery of these issues is appropriate for pre-hearing purposes." *Id.* at *7.

Here, Roche is making narrow requests regarding discrete topics, namely, the PLAs, TLAs, any settlements between Ortho and Amgen, and the arbitration and other proceedings between the parties relating to the patents-in-suit, including the rulings and the parties' underlying papers on dispositive issues. These materials may be essential to the issue of whether the license is limited or exclusive, and thus whether Ortho has a basis to intervene. In *Maguire Indus., Inc. v. Harrington & Richardson Arms Co.*, 79 F. Supp. 81 (D. Mass. 1948) (Healey, J.),

the court held that an exclusive licensee's settlement agreement with the patentee licensor stripped the licensee of standing to sue competitors for infringement. Similar to *Maguire*, Amgen and Ortho have apparently entered into a number of binding agreements as a result of arbitration, and any one of them may have directly impacted Ortho's standing in the present case.

Even more basic, this discovery directly relates to the parties' intentions behind the license - a fundamental factor in assessing the nature of the PLA. Ortho cannot dispute the relevancy of these documents, as it brought them into issue and relied on them several times throughout its brief as its basis to intervene.[9] *RDS Group*, 2003 U.S. Dist. LEXIS 1337, at *7, *10 (discovery granted on documents related to ownership and licensing by the plaintiff because the plaintiff raised such issues in pre-trial communications). As of now, these key pieces of information remain privy solely to Amgen and Ortho, while neither this Court nor Roche can properly investigate their relevance. The request of this evidence is narrowly tailored and must be discoverable on an expedited basis to allow time for Roche to properly respond and this Court to properly adjudicate Ortho's motion to intervene.

2. The Burden On Ortho And Amgen In Producing Evidence Is Minimal, While The Consequences On Roche If It Did Not Acquire The Evidence Would Be Substantial

The burden on Ortho is minimal because Roche is only requesting very specific discovery pertaining to discrete topics of the PLAs, TLAs, and arbitration proceedings. Since Ortho has brought this motion on intervention, it should be willing to provide the full agreements, as well as the transcripts, expert reports, and dispositive motions, as these should have been kept in the ordinary course of its business. These documents, beyond being relevant

[9] *See, e.g.* Ortho Memo at 5, citing arbitrations as basis for "Ortho's concern that it cannot fully rely upon Amgen to protect its interests in this matter").

to the discreet issue of intervention, also pertain to issues of infringement, namely, the scope and coverage of the patents-in-suit. As such, Ortho can hardly complain of the burden of production, since, if Ortho is allowed to intervene, it will likely have to produce the discovery anyway. Hence, Ortho will not be prejudiced by having to produce these documents in advance of intervention. *See Semitool,* 208 F.R.D. at 277 (holding no "real prejudice" in requiring expedited discovery where opposing party was represented by "sophisticated counsel," "engaged in pre-litigation discussion for over a year" and should have known such information would need to be discovered at some point).

3. Roche's Request For Discovery Is Reasonably Timed And Benefits Efficient Case Management And Administrative Justice

Roche's request for expedited discovery should be granted because it is a pressing issue currently before the Court rather than a speculative one. *See KBG Holding Corp. v. Union Bank & Trust Co.*, Nos. 02-1183, -1204, 56 Fed. Appx. 111, 114 (4th Cir. Jan. 08, 2003). The need for this information is now, while Ortho seeks to intervene. If Roche is denied its request for expedited discovery, Ortho may be erroneously allowed to intervene. Then, later in the case as discovery proceeds and Roche acquires documents relating to the arbitration agreements, the Court may have to readdress the appropriateness of Ortho's presence. *See, e.g., Prima Tek II,* 222 F.3d 1372 (holding that lack of standing can never be waived, and on appeal overturning an award by the district court for attorney's fees and costs to a licensee because the licensee lacked standing). If this Court denies expedited discovery and rules on Ortho's motion to intervene on, at best, a shrouded factual backdrop, the Court runs the risk of the case becoming bogged down when the arbitration documents are later disclosed for the underlying issues of infringement. At that point, the standing issue may again resurface and result in duplicate adjudication. *See*

Semitool, 208 F.R.D. at 276-77 (holding when expedited discovery conserves party resources and expedites the litigation this militates for allowing the discovery).

III. CONCLUSION

For all the foregoing reasons, Roche respectfully requests that Ortho's Motion to Intervene be denied outright with prejudice. In the alternative, Roche respectfully requests that the Court grant limited and expedited discovery into the complete Product License Agreements and Technology License Agreements between Ortho and Amgen regarding the patents-in-suit, and the arbitration proceedings between those two entities based upon those agreements.

DATED: Boston, Massachusetts
April 11, 2006

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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