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

REPLY MEMORANDUM IN FURTHER SUPPORT OF ORTHO'S MOTION TO INTERVENE

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Ortho Biotech Products, L.P. ("Ortho") respectfully submits this reply memorandum of law in further support of its motion to intervene as a plaintiff in this action.

Preliminary Statement

Amgen and Roche both vehemently oppose Ortho's motion to intervene, but neither can set forth a valid basis to deny Ortho's request. Contrary to the position taken by both parties, the facts and applicable law demonstrate that Ortho has a legally cognizable interest in the asserted patents, and thus has standing to participate in this action as a co-plaintiff.

Amgen argues that Ortho lacks the "bundle of rights" necessary bring an infringement action, and that only a licensee that "in effect [has] obtained an **assignment** of rights" under the patent may sue. That is the rule only insofar as a licensee seeks to sue **alone**. A party such as Ortho that seeks to join an action as a co-plaintiff with the patent owner need only show that it is an exclusive licensee within a field of use in which the alleged infringement occurs. As even Amgen grudgingly admits, that is the situation here: Ortho has the exclusive right under Amgen's EPO Product Patents to sell recombinant human EPO for all human uses except dialysis and diagnostics, and Roche's infringement will occur in Ortho's exclusive field of use. Ortho thus has the requisite legal interest to take part in this action.

Unlike Amgen, Roche acknowledges the governing legal standard (*i.e.*, an exclusive licensee may join in an infringement action brought by the patent owner), but inexplicably disputes that Ortho is an exclusive licensee. Pointing to a variety of rights that Amgen reserved to itself under the PLA – such as the right to manufacture EPO, the right to sublicense manufacturing, and the right to sell EPO outside Ortho's exclusive field – Roche contends that Ortho's license is simply too narrow to be deemed "exclusive." But whatever rights were reserved to Amgen **outside** Ortho's exclusive field, that fact remains that Ortho has **sole** right to sell recombinant human EPO for all non-dialysis, non-diagnostic purposes – without

any opportunity on Amgen's part to compete within this field or to license others to do so. That is all that is needed to make Ortho's license "exclusive" and allow it to join as a plaintiff in this action.

Roche argues in the alternative that it should be permitted the opportunity to rummage through the annals of the various private arbitrations between Ortho and Amgen, in the hopes of uncovering some support for its claim that Ortho's exclusive license is actually not exclusive. If these materials including anything helpful on this point – such as a favorable decision by an arbitrator or (as Roche postulates) a secret amendment to the PLA – then Amgen surely would have submitted it as part of its opposition to Ortho's motion. Ortho's documented assertion and Amgen's admission that the PLA permits only Ortho to sell recombinant human EPO under Amgen's EPO Product Patents for use by non-dialysis patients is a more than ample basis upon which to grant Ortho's motion to intervene.

There is no need for a fishing expedition or for protracted argument on Ortho's motion. Ortho's request for intervention should be granted.

I. ORTHO IS AS EXCLUSIVE LICENSEE UNDER THE EPO PRODUCT PATENTS AND THEREFORE HAS STANDING TO INTERVENE IN THIS ACTION

A. Ortho Is an Exclusive Licensee Under the EPO Product Patents

The relevant "test for exclusivity is . . .whether the licensor has promised explicitly or implicitly not to grant any additional licenses to third parties." *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 808 F. Supp. 894, 900 (D. Mass. 1992), *aff'd sub nom Ortho Pharm. Corp. v. Genetics Institute, Inc.*, 52 F.3d 1026 (Fed. Cir. 1995); *see also Textile Prods., Inc., v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998). Neither Amgen nor Roche can seriously contend that Amgen may grant additional licenses under the EPO Product Patents to sell recombinant human EPO within Ortho's field of use.

On this point, the language of the PLA itself is clear. Paragraph 2.01(a) grants to Ortho an "exclusive license . . . to sell LICENSED PRODUCTS . . .." "LICENSED PRODUCTS" is defined as "PRODUCTS" including "EPO" (recombinant human erythropoietin) for use in the "LICENSED FIELD" (here, all human uses except dialysis and diagnostics). Grossman Dec. Exh. 1 ¶¶ 1.05, 1.10, 1.13, 1.21. Nothing in the PLA remotely suggests that, notwithstanding this exclusive grant, Amgen may (i) sell EPO itself for non-dialysis or non-diagnostic uses, or (ii) license another party to do so.[1]

And in fact, as even Amgen reluctantly admits, there is no such right on Amgen's part. One need look no further than page one of Amgen's brief to find an acknowledgement that, under the PLA, "Ortho obtained an 'exclusive' right to sell a single designated product [*i.e.*, recombinant human EPO] . . . for specified uses [*i.e.*, all uses aside from dialysis and diagnostics]." Amgen could hardly deny this, for it has made the same admission publicly many times in the past. For example, in its 1986 Annual Report, issued shortly after the PLA was executed on September 30, 1985, Amgen stated that Ortho had been "granted an exclusive license to sell any [EPO] products" under Amgen's proprietary, recombinant human EPO patents and know-how. Zalesin Supp. Decl. Exh. A. Even a United States Court of Appeals has recognized that "[u]nder the [PLA], Amgen granted Ortho an exclusive royalty-bearing license to market and sell EPO in the United States for all therapeutic indications except dialysis . . . ." *Ortho Pharm. Corp. v. Amgen, Inc.*, 882 F.2d 806, 808 (3d Cir. 1989).

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[1] Roche complains that Ortho did not submit the full text of the PLA along with its motion, thereby suggesting that Ortho may have concealed from Roche (and from the Court) relevant and contradictory portions of PLA. In fact, as set forth in the Grossman Declaration, Ortho has already made part of the record on this motion *all* relevant provisions of the PLA. Nevertheless, to allay Roche's suspicions, Ortho is submitting herewith a complete copy of the PLA with only one term redacted – the royalty rate that Ortho pays Amgen for sales of EPO within its exclusive field of use. *See* Zalesin Supplemental Decl. Exh. B. Roche cannot contend that the amount of this percentage has any bearing on the issues raised by Ortho's motion to intervene.

Neither Amgen nor Roche makes any showing to the contrary. Amgen attempts to obscure the fact that Ortho has an exclusive license within its field of use by positing a meaningless distinction between a "product license" on the one hand (which Amgen acknowledges Ortho has), and a "patent license" on the other hand (which Amgen argues Ortho lacks). (*See* Amgen Br. at 1, 6). Such labels are irrelevant. A "product" license alone can confer standing to sue, even though the patent under which the license is granted may extend to products or processes beyond the licensed product. So long as the licensee possesses the *exclusive* right to sell the patented product, it may join in an action to block the sale of the patented product by another party. *See 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 from infringement in conjunction with patent owner).

Roche's arguments fare no better. For example, Roche notes that "[t]he terms of the PLA only grant Ortho a limited field of use over the patent" (Roche Br. at 9). That may be true, but it is irrelevant. As this Court has held, "an exclusive license can be created by a grant of exclusivity based solely on . . . field-of-use limitations." *Chugai Pharm.*, 808 F. Supp. at 902. Ignoring this pertinent language, Roche focuses instead upon this Court's finding in *Chugai* that, insofar as the right to **manufacture** EPO in the United States is concerned, Ortho's right under the PLA is non-exclusive. Again, that is true but has no bearing on Ortho's motion. Ortho seeks to intervene only with respect to Amgen's claims for infringement of the EPO Product Patents, which preclude anyone other than Ortho from **selling** recombinant human EPO for non-dialysis, non-diagnostic use. Nothing in the *Chugai* decision speaks to Ortho's exclusivity in connection with such product sales.[2]

[2] Roche professes to be dumbfounded why Ortho would seek to intervene only for purposes of asserting Amgen's EPO Product Patents and not its manufacturing patents. To the extent the

The PLA makes Ortho the only party that can lawfully sell recombinant human EPO in the United States for human uses other than dialysis and diagnostics. Amgen has no right to sell such products itself or to license third parties to do so. Accordingly, Ortho's license is "exclusive" – not only because the PLA uses such terminology, but because, in fact, the right granted to Ortho is exclusive.

B. As an Exclusive Licensee, Ortho Has Standing To Intervene as Amgen's Co-Plaintiff in this Action

As set forth in our opening brief, it is well-established that exclusive licensees such as Ortho that have "received . . . the right to practice the invention within a given [field], [and] the patentee's express or implied promise that others shall be excluded from practicing the invention within that [field] as well," possess standing to sue as a co-plaintiff with the patentee. *Rite-Hite Corp. v. Kelley Co., Inc.,* 56 F.3d 1538, 1552 (Fed. Cir. 1995).

Thus, as this Court has observed, "[a]n exclusive licensee generally has standing to sue for infringement against anyone operating without the stated authority in the stated area of exclusivity . . .[and] has the power to join the patent holder in a suit for infringement either as a willing or unwilling plaintiff or defendant, in order to enforce the right granted in the license." *Chugai*, 808 F. Supp. at 899-900 (internal quotes omitted). Thus, "if the terms of the Ortho-Amgen . . . Product License Agreement preclude Amgen from granting further licenses under the patent within the stated area given to Ortho" (which they do), "then Ortho is an 'exclusive licensee' with the legal capacity to sue for patent infringement within this stated area . . . [provided] that the infringement have occurred within Ortho's 'stated area of exclusivity.'" (which it has). *Id.* It is as simple as that.

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reason is not already obvious, we restate it: Ortho's license to sell recombinant human EPO under the EPO Product Patents is exclusive, while its license to manufacture EPO under the EPO Process Patents is not.

Unable to muster any argument under relevant law, Amgen relies upon line of cases that have no application to the facts at hand. Specifically, Amgen claims that "[t]o be considered an 'exclusive licensee' having rights sufficient to permit participation . . . in a litigation, the licensee must in effect have obtained an assignment of rights." (Amgen Br. at 4-5 (emphasis omitted). Amgen then proceeds to list the various rights it reserved under the PLA in order to demonstrate that Ortho did not receive a *de facto* assignment.

The problem with this argument is that it overlooks the critical distinction between an exclusive licensee that seeks to join in an action as a co-plaintiff with the patent holder (the situation here) with an exclusive licensee that seeks to sue on its own. Only in the latter situation must the license be a "*de facto*" or "virtual" assignment.[3] *See, e.g., Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 240 F.3d 1016, 1017 (Fed. Cir. 2001) ("we have permitted an exclusive licensee to bring suit in its own name if the exclusive licensee holds "all substantial rights" in the patent[;] '[a]n exclusive licensee that does not have all substantial rights has standing to sue third parties only as a co-plaintiff with the patentee") (citations omitted); *Weinar v. Rollform Inc.*, 744 F.2d 797, 806-07 (Fed. Cir. 1984) (a licensee with exclusive rights to sell licensed products may sue for and obtain relief from infringement in conjunction with patent owner); *Abbott Labs. v. Diamedix Corp.*, 47 F.3d 1128, 1131 (Fed. Cir. 1995) (a "licensee may obtain sufficient rights in the patent to be entitled to seek relief from infringement, but to do so, it ordinarily must join the patent owner"). Amgen's "*de facto* assignment" argument simply has no application to the facts of this case.

[3] Amgen implicitly recognizes this distinction when it notes that the purpose for this rule is to prevent duplicative suits under the same patent – one by the patent holder and one by the licensee – against the same infringer. (*See* Amgen Br. at 5). Yet Amgen fails to note that there is no risk of that here, because Ortho has moved to join Amgen's lawsuit rather than instituting an action of its own.

Effectively repeating Amgen's error, Roche goes to great lengths to parse the rights granted and reserved under the PLA. (*See* Roche Br. at 9-12). But the only relevant "test for exclusivity is . . .whether the licensor has promised explicitly or implicitly not to grant any additional licenses to third parties." *Chugai*, 808 F. Supp. at 900; *see also Textile Prods.*, 134 F.3d at 1484. As demonstrated above, Amgen has no right under the PLA to grant any license to permit anyone other than Ortho to sell recombinant human EPO for non-dialysis, non-diagnostic uses. The fact that Amgen may have retained "substantial rights" under the EPO Product Patents has no bearing on whether Ortho may join in Amgen's infringement action.

Finally, both Amgen and Roche note that, under the PLA, "Ortho did not obtain the contractual right to bring suit if Amgen decides to do so without it" (Amgen Br. at 12). This argument ignores the fact that "[s]tanding to sue for infringement depends entirely on the putative plaintiff's proprietary interest in the patent, not on any contractual arrangements among the parties regarding who may sue and who will be bound by judgments." *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1381 (Fed. Cir. 2000). In other words, it is Ortho's status as an exclusive licensee – not the PLA's delegation of responsibility for litigation – that governs Ortho's standing to sue. *See also Ortho Pharm.*, 52 F.3d at 1034 ("a contract cannot change the statutory requirement for suit to be brought by the 'patentee'").

Because it is an exclusive licensee within a field of use in which Roche's infringement is occurring, Ortho has standing to sue Roche for infringement – so long as it joins Amgen, the patent holder, in its action. Ortho has satisfied all these requirements. Its motion to intervene should be granted.

II. ORTHO IS ENTITLED TO INTERVENE BECAUSE IT IS A NECESSARY PARTY

Other than to contest Ortho's status as an exclusive licensee, neither Amgen nor Roche confronts Ortho's argument that, under the Federal Circuit's recent decision in *Aspex Eyeware, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336 (Fed. Cir. 2006), Ortho is a necessary party under Rule 19, and is therefore entitled to intervene as of right under Rule 24, Fed. R. Civ. P.[4] As discussed in our opening brief, *Aspex* squarely holds that "[f]or 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)).

As an exclusive licensee of Amgen's EPO Product Patents with respect to the accused recombinant human EPO product being developed by Roche, Ortho is a necessary party to this action. In this Circuit, necessary parties under Rule 19 are entitled to intervene as of right. *Ferrofluidics Corp. v. Advanced Vacuum Components, Inc.*, 968 F.2d 1463, 1472 (1st Cir. 1992) (necessary parties under Rule 19 may intervene as a matter of right); *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). Ortho's motion should therefore be granted.

III. AMGEN DOES NOT ADEQUATELY REPRESENT ORTHO'S INTERESTS

In our opening brief, we pointed out that the representation offered by Amgen is inadequate for several reasons, including: (1) Ortho cannot rely upon Amgen to recover damages for Roche's infringement in Ortho's exclusive field of use; and (2) Amgen has competitive incentives to settle this action on terms that benefit Amgen and prejudice Ortho.

[4] Indeed, Amgen does not mention *Aspex* at all and Roche merely cites it for a proposition unrelated to its core holding (*see* Roche Br. at 10).

Amgen gives this argument the back of the hand (as does Roche), asserting that "Amgen's representation of Ortho's rights . . . has been (and will continue to be) more than adequate." (Amgen Br. at 14; *see also* Roche Br. at 13). Such platitudes do nothing to address Ortho's specific concerns – particularly in light of this Circuit's rule allowing intervention so long as the intervenor can show that the existing party's representation ***may*** be inadequate, not that it ***is*** inadequate.

Amgen notes that Ortho was content to allow Amgen to prosecute on its own the infringement action in this Court against HMR and TKT. But that case was filed in 1997, years before Amgen began to compete with Ortho with another anti-anemia product, Aranesp. (*See* Amgen Br. at 18 n.50).[5] The fact that Ortho chose to rely upon Amgen's representation when their interests were aligned does not "contradict" Ortho's reasonable belief today that it cannot count on its direct competitor to fully protect its interests in this matter.

IV. ORTHO'S MOTION TO INTERVENE SHOULD BE GRANTED EVEN IF THIS COURT DECIDES TO GRANT ROCHE'S MOTION TO DISMISS

Roche argues that, if this Court grants Roche's separate motion to dismiss, then Ortho's motion to intervene will necessarily be rendered moot. (*See* Roche Br. at 3-4). This is incorrect. To the contrary, refusal to grant Ortho's motion prior to any dismissal of Amgen's complaint would deprive Ortho of its right to appeal any such order. Accordingly, Ortho respectfully requests that, irrespective of its decision on Roche's motion, the Court grant Ortho's motion to intervene in this action.

[5] Aranesp was not approved for sale until 2001 – the same year that this Court rendered its decision in the HMR/TKT case. *See* "About Amgen, Company History, Milestones," available at www.amgen.com/about/milestones.html; *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 f. Supp. 2d 69 (D. Mass. 2001).

Conclusion

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

Dated: May 11, 2006

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