UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN, INC, Plaintiff, v. F. HOFFMAN-LAROCHE LTD, ROCHE DIAGNOSTICS GMBH, & HOFFMAN LAROCHE INC, Defendants.	)	CIVIL ACTION NO. 05-12237-WGY

MEMORANDUM AND ORDER

YOUNG, D.J. October 20, 2006

I. INTRODUCTION

Amgen, Inc. ("Amgen") commenced this action against F. Hoffman-LaRoche Ltd., Roche Diagnostics GmbH, & Hoffman-LaRoche, Inc. (collectively "Roche/Hoffman") seeking a declaratory judgment that Roche/Hoffman currently infringes or will infringe Amgen's patents for erythropoietin ("EPO"). Am. Compl. ¶ 26 [Doc. No. 52]. The patents at issue are U.S. Patent Nos.

5,441,868 (the "'868 patent"), 5,547,933 (the "'933 patent"), 5,618,698 (the "'698 patent"), 5,621,080 (the "'080 patent), 5,756,349 (the "'349 patent"), and 5,955,422 (the "'422 patent). Id. ¶¶ 14, 26.

II. PROCEDURAL HISTORY

Amgen filed a complaint in this action on November 8, 2005 [Doc. No. 1]. On March 9, 2006, Ortho Biotech Products, L.P.'s ("Ortho") filed a motion to intervene in this action on the side of Amgen. See Mot. to Intervene [Doc. No. 16]. On April 11, 2005, Roche/Hoffman filed a motion to dismiss for failure to state a claim and for lack of subject matter jurisdiction. See Mot. to Dismiss [Doc. No. 44]. Roche Diagnostics GmbH and F. Hoffman LaRoche Ltd. also filed motions to dismiss for lack of personal jurisdictional, see Roche Diagnostics Mot. to Dismiss [Doc. No. 38]; F. Hoffman-La Roche's Mot. to Dismiss [Doc. Nos. 41], but later withdrew those motions, see F. Hoffman-LaRoche Notice of Withdrawal [Doc. No. 83; Roche Diagnostics GmbH Notice of Withdrawal [Doc. No. 84].

III. MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM

Roche/Hoffman's motion to dismiss for failure to state a claim attacks Amgen's allegation of current infringement arguing it has not been sufficiently pled in light of the "safe harbor" provision of 35 U.S.C. § 271(e)(1). Def. Mem. at 1. The United States Code states that except as otherwise provided in title 35,

whoever without authority "makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent . . . infringes the patent." 35 U.S.C. § 271(a).

Section 271(e)(1)creates a limited exception to this provision.

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1).

A. Alleged Facts

For purposes of this motion, all facts alleged in the complaint are taken as true. Arturet Velez v. R.J. Reynolds Tobacco Co., 429 F.3d 10, 13 (1st Cir. 2005).

"On information and belief, [Roche/Hoffman is] currently importing into the United States a pharmaceutical composition containing a recombinant human EPO product that Roche[/Hoffman] calls 'Ro50-3821'" [referred to by Amgen as "PEG-EPO" and by Roche/Hoffman as "CERA"]. Am. Compl. ¶ 18. PEG-EPO/CERA contains glycosylated human EPO, to which Roche has attached a polyethylene glycol ("PEG") polymer. Id. ¶ 20. PEG-EPO/CERA, on information and belief, contains EPO as claimed in the '933, '080, '422 patents and produces glycoslyated human EPO "by means

of one or more of the processes claimed in the '868, '698 and '349 patents." Id. ¶¶ 19, 21. The addition of PEG to glycosylated human EPO does not materially change the glycosylated human EPO contained in PEG-EPO/CERA. Id. ¶ 23.

On April 19, 2006, Roche submitted its Biologic License Application ("BLA") with the United States Food and Drug Administration to sell pharmaceutical compositions containing PEG-EPO for the treatment of anemia associated with chronic kidney disease.[1] Id. at 27. "Upon information and belief, Roche has completed all Phase III clinical trials it believes necessary to support its application for approval in the United States." Id. Roche announced that it expects to obtain regulatory approval to market and sell PEG-EPO in the United States within the next 12-14 months. Id. ¶ 28.

In addition to filing the BLA, upon information and belief, Roche/Hoffman has been making preparations to market and sell PEG-EPO in the United States, including:

> a. Hiring key management, support, and sales personnel, including actively recruiting Amgen marketing and medical personnel involved in the sale and use of recombinant human EPO, to market and sell PEG-EPO upon receipt of regulatory approval to market and sell PEG-

[1] The primary difference between the original complaint and the amended complaint is that the original complaint does not contain this assertion that Roche/Hoffman filed this application. See Compl. ¶ 27 (discussing the anticipated filing of Roche/Hoffman's BLA application). The complaint was amended so that this information could be included in Amgen's claim. Pl. Opp'n at 2 n.2.

> EPO in the United States;
> b. Retaining outside consultants and vendors to assist in its marketing and sale of PEG-EPO in the United States;
> c. Contacting potential customers, including large dialysis organizations ("LDOs"), to solicit interest in purchasing PEG-EPO from Roche upon regulatory approval in the United States; and
> d. Completing construction and commencing operations of a new facility in Penzberg, Germany to manufacture the recombinant human EPO in PEG-EPO for export to the United States, at a reported cost of 182 million Euros.

Id. ¶ 29.

B. Standard of Review

As this Court has noted, a motion to dismiss under Rule 12(b)(6) tests the sufficiency of the plaintiff's pleadings, and, as a result, must be considered in light of the liberal notice pleading requirements of the Federal Rules. See Andrews-Clarke v. Lucent Technologies, 157 F.Supp.2d 93, 96 (D. Mass. 2001)(Dein, M.J.). Accordingly, "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claims which would entitle him to relief." Roeder v. Alpha Indus., Inc., 814 F.2d 22, 25 (1st Cir. 1987)(quoting Conley v. Gibson, 355 U.S. 41, 45-46 (1957))(emphasis added); see also Rogan v. Menino, 175 F.3d 75, 78 (1st Cir. 1999)(noting that the plaintiff must "set forth factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery."). Moreover, "[t]he Court must accept as true

all of the allegations made in the complaint and draw all reasonable inferences in the Plaintiff's favor." Baker v. Coxe, 940 F.Supp. 409, 414 (D. Mass. 1996)(Saris, J.), aff'd, 230 F.3d 470 (1st Cir. 2000) (citing Coyne v. City of Somerville, 972 F.2d 440, 442-43 (1st Cir. 1992)); see also Conley, 335 U.S. at 45-46. The standard for dismissal, however, is not without any bite. In taking the plaintiff's allegations as true, the Court is not obliged to credit bald assertions or unsubstantiated conclusions. See Campagna v. Massachusetts Dep't of Envtl. Prot., 334 F.3d 150, 155 (1st Cir. 2003).

C. Amgen's Complaint Properly Alleges Current Infringement

Roche/Hoffman argues that because all of their allegedly infringing acts are protected from infringement by the safe harbor exemption, Amgen does not state a claim for current infringement.[2] Def. Mem. at 11. Further, Roche/Hoffman contends

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[2] It was initially unclear from Amgen's opposition whether it was pressing its allegation of current infringement. In directly addressing Roche/Hoffman's Rule 12(b)(6) motion to dismiss, Amgen sent mixed messages:

> Roche's argument that Amgen's Complaint fails to state a claim for which relief can be granted is meritless. The Complaint (and First Amended Complaint) sounds in declaratory relief for future infringement. Thus, Roche's complaints about Amgen's failure to allege actual infringement and that Roche's activities all fall within protection of the § 271(e)(1) safe harbor are irrelevant. Moreover, contrary to Roche's assertion, Amgen has never conceded that Roche's meaningful preparations to infringe fall within the safe harbor.

Pl. Opp'n at 19 (emphasis added).

that Amgen makes no specific allegation of an act that would constitute infringement that falls outside the Section 271(e)(1) safe harbor and instead relies on an unsupported assertion that Roche is currently importing an infringing drug. Id.

This Court has previously noted that it is unclear "whether the [Section 271(e)(1)] exemption is an affirmative defense, rather than a part of the statutory definition of infringement that [the plaintiff] must establish." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 3 F. Supp. 2d 104, 109 (D. Mass. 1998).[3] If regarded as an affirmative defense, the applicability of this exemption must be raised by Roche/Hoffman in their responsive pleading and not by Amgen. See Fed. R. Civ. P. 12(b) ("Every defense, in law or fact to a claim for relief in any pleading . . . shall be asserted in the responsive pleading thereto if one is required . . . ."). Roche/Hoffman's Rule 12(b)(6) motion would, therefore, necessarily fail, since Amgen's allegations comply

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Amgen also states that the declaratory relief it seeks is not directed at activities falling within the Section 271(e)(1) exemption. Id. at 16.

Roche/Hoffman interpreted Amgen's statements in its opposition as a concession that there is no claim for current infringement and asked that its motion to dismiss as to existing acts of infringement be granted pursuant to Rule 12(b)(6). Def. Rep. at 8-9. Subsequent filings make clear that Amgen's claim for current infringement is live.

[3] The Court did not resolve this question in Hoechst but presumed the exemption to be an affirmative defense in ruling that the defendants' alleged acts of infringement fell within the safe harbor exemption and that the defendants were entitled to summary judgment. 3 F.Supp.2d at 109-111.

with Section 271(a) in alleging the importing of a patented drug. The Court rules that 271(e)(1) safe harbor provision is an affirmative defense that must be asserted by the defendant. The Court's interpretation is supported by several other courts, including the Federal Circuit, which have referred to the 271(e)(1) exemption as an affirmative defense or a defense.[4] See Intermedics v. Ventritex Co., No. 92-1076, 1993 U.S. App. LEXIS 3620, *2-3 (Fed. Cir. February 22, 1993) (referring to Ventritex's right to assert the Section 271(e)(1) defense); Eli Lilly & Co. v. Medtronic,Inc., 872 F.2d 402, 404 (Fed. Cir. 1989) (describing as a matter of first impression the issue of whether the noninfringement defense of Rule 271(e)(1) applies to medical devices), aff'd, 496 U.S. 661 (1990); Nextell Therapeutics v. Amcell Corp., 199 F.Supp.2d 197, 203-06 (D. Del. 2002) (referring to the Rule 272(e)(1) defense throughout the opinion). Embrex, Inc. v. Service Engineering Corp., No. 5:96-CV-824-BR, 1998 U.S. Dist. LEXIS 15143, *28-29 (E.D. N.C. June 23, 1998) (granting the plaintiff's motion for summary judgement disallowing the Rule 271(e)(1) "affirmative defense" where defendant failed to produce any evidence to indicate that this defense was applicable), aff'd

[4] Indeed, the International Trade Commission opinion submitted by Roche/Hoffman also refers to Section 271(e)(1) as providing an "affirmative defense." International Trade Commission's Initial Determination Granting Respondents' Summary Determination Motion No. 568-1 That There Is No Violation of Section 337 ("Initial Determination") at 4.

in part, vacated in part on other grounds, 216 F.3d 1343 (Fed. Cir. 2000); see also Eli Lilly, 496 U.S. at 625 (Kennedy, J. dissenting) (describing the majority opinion as allowing Section 271(e)(1) to be used as a defense to a claim of infringement of a medical device). Since the Section 271(e)(1) provision is properly considered a defense rather than an element of a claim of infringement, Amgen's complaint is properly pleaded.

Notwithstanding this analysis, even were it necessary to plead acts on the part of Roche/Hoffman that fall outside the Section 271(e)(1) provision, the Court would conclude that Amgen's complaint supported a claim of current infringement -- defined as infringing acts under Section 271(a) that are not subject to the safe harbor 271(e)(1) exemption. Amgen's allegations regarding the execution of clinical trials are, of course, protected by the safe harbor exemption and cannot, as matter of law, constitute current infringement. Moreover, other preparatory acts -- building a plant, soliciting interest in the product, hiring sales and managerial staff -- are not acts of infringement under Section 271(a); Roche/Hoffman is not making, using, selling or offering to sell the patented invention. See 35 U.S.C. 271(a). Amgen, however, does alleges that Roche/Hoffman is importing a drug into the United States which is materially indistinguishable from Amgen's patented invention -- an act which would constitute infringement under Section 271(a).

This Court cannot conclude, as matter of law, that because Roche/Hoffman is in the process of submitting information to the FDA, that this importation of the alleged infringing drug must be solely for uses that reasonably relate to the submission of that information. See Amylin Pharma. v. Regents of the Univ. of Minnesota, No. 96cv2061, 1998 U.S. Dist. LEXIS 5695, *8-10 (S.D. Cal. January 15, 1998) (denying a motion to dismiss based on the safe harbor provision because a factual dispute existed as to the applicability of the provision that should not be resolved on a motion to dismiss). This allegation, therefore, sufficiently states a claim for which relief can be granted regardless of whether the Section 271(e)(1) exemption is considered an affirmative defense or an element of Amgen's infringement action.

Amgen's claim of current infringement is properly pleaded and the motion to dismiss pursuant to rule 12(b)(6) [Doc. No. 44] is DENIED.

IV. MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

Roche/Hoffman also argues that any claims of future infringement must be dismissed due to the failure of Amgen to present an "actual controversy" as required under the Declaratory Judgment Act. Def. Mem. at 12.

A. Standard of Review

Once a defendant challenges the jurisdictional basis of a claim under Rule 12(b)(1), the plaintiff bears the burden of

proving jurisdiction. Aversa v. United States, 99 F.3d 1200, 1209 (1st Cir. 1996). "Jurisdiction must be apparent from the face of the pleadings." PSC 2000 LP v. Romulus Telecomms, Inc., 148 F.3d 32, 35 (1st Cir. 1998). In ruling on a motion to dismiss for lack of jurisdiction that challenges the sufficiency of the plaintiff's allegations, the Court accepts the plaintiff's version of jurisdictionally-significant facts as true and "assesses whether the plaintiff has propounded an adequate basis for subject matter jurisdiction". Valentin v. Hospital Bella Vista, 254 F.3d 358, 363 (1st Cir. 2001). The Court credits "the plaintiff's well-pleaded factual allegations (taken from the complaint, . . . augmented by an explanatory affidavit or other repository of uncontested facts), draw[s] all reasonable inferences from them in [the plaintiff's] favor, and dispose of the challenge accordingly." Id.

A party may also challenge the accuracy of the jurisdictional facts asserted by the plaintiff and "proffer materials of evidentiary quality in support of that position." Id. at 363. In this instance, the court makes differential fact-finding, lending no presumptive weight to the plaintiff's jurisdictional averments. Id. The court enjoys broad discretion to order discovery, consider extrinsic evidence and hold evidentiary hearings to determine its jurisdiction. Skwira v. United States, 344 F.3d 64, 72 (1st Cir. 2003). "In certain

situations, the predicate facts may be so inextricably linked to the merits of the controversy that the district court should defer resolution of the jurisdictional issue until the time of trial." Id. at 72, n.3.

B. Actual Controversy Requirement

For a court to have jurisdiction under the Declaratory Judgment Act, 28 U.S.C. § 2201, there must be a "true, actual controversy" -- the conflict must be real and immediate. Lang v. Pacific Marine & Supply Co., 895 F.2d 761, 764 (Fed. Cir. 1990). To meet the controversy requirement in a suit by a patentee against an alleged future infringer, two elements must be present:

> (1) the defendant must be engaged in an activity directed toward making, selling or using subject to an infringement charge under 35 U.S.C. § 271(a) . . . or be making meaningful preparation for such activity; and (2) acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming.

Id.

Even when an actual controversy exists, the court has substantial discretion to decline jurisdiction, as the "statute provides that a court 'may declare the rights and other legal relations of an interested party.'" Wilton v. Seven Falls Co., 515 U.S. 277, 286 (1995) (quoting 28 U.S.C. § 2201(a)).

1. Evidence of An Actual Controversy

Based on Roche/Hoffman's own admissions, the companies are

engaged or are engaging in the following activities regarding the drug at issue:

> Ongoing clinical trials for the treatment of anemia in cancer therapy patients, Def. Mem. at 14;
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> The completion of Phase 3 clinical trials for the treatment of anemia of chronic kidney disease patients and analysis of data from those trials; at least one of the trials will continue to provide additional safety data, Decl. of Iris Kingma-Johnson ¶ 9 [Doc. No. 46];
>
> The filing of a Biologics License Application for the drug in issue - CERA/PEG-EPO for the treatment of anemia associated with chronic kidney disease on April 19, 2006., Decl. of Howard Suh ¶ 3 [Doc. No. 51][5];
>
> The announcement of this filing by a press release entitled "Roche Submits Application with FDA to Market C.E.R.A. for the Treatment of Renal Anemia", Id., Ex. A - News Release.

In addition, Amgen has submitted evidence that Roche/Hoffman is hiring "key management, support, and sales personnel," Am. Compl. ¶ 7. See Decl. of Michael R. Gottfried ("Gottfried Decl."), Exs. 10-12 (Roche job postings for management and marketing positions for CERA/PEG-EPO). Roche/Hoffman does not

[5] Roche/Hoffman does not expect to file a BLA for CERA for the treatment of anemia in cancer patients until 2009. Def. Mem. at 14.

contest that they are hiring such personnel to manage pre-clinical and clinical trials and "to develop marketing and sales strategies for use if and when Roche gains approval to market and sell CERA." Def. Mem. at 15. Amgen has also submitted evidence that Roche/Hoffman will be hosting a conference in Hamburg, Germany in May 2006 for a Anemia Global Expert Meeting where 800 nephrologists will be in attendance and the program will include "a development update on the novel compound C.E.R.A." Gottfried Decl., Ex. 11 (Invitation to Anemia Global Expert Meeting).

Roche/Hoffman admits in its brief that the companies are constructing a facility to manufacture the drug, indicating that this is a necessary part of the FDA approval process "because the sponsor must present detailed information about the facility in which the drug will be manufactured"; and that the company has been contacting large dialysis organizations to attract patients for clinical trials. Def. Mem. at 15-16.

In determining whether the first prong of the "actual controversy" test is satisfied, courts consider the nature of the acts and whether they suggest that infringement is sufficiently immediate. Lang, 895 F.2d at 764. Roche/Hoffman argues that all of the acts identified by Amgen are related to the FDA approval process and, as part of the approval process, 1) these acts are not, as a matter of law, sufficiently immediate, id. at 12-13,

and 2) they are covered by the safe harbor exemption[6] and, as such, cannot be used to establish "meaningful preparation" to infringe, id. at 14-15. Roche/Hoffman relies on Telectronics Pacing System v. Ventritex, Inc., 982 F.2d 1520 (Fed. Cir. 1992) for both propositions. In Telectronics, however, the Federal Circuit ruled that there could be no declaratory judgment action where the alleged infringer had just began conducting clinical trials only three months prior to the filing of the complaint and had publicized the results of the clinical trials to investors, journalists, and physicians, among others. Id. at 1521. The Federal Circuit ruled that, at the commencement of the suit, the

[6] In support of this position, Roche/Hoffman submitted to the Court an initial determination by a hearing officer for the International Trade Commission ("Trade Commission") that, upon a record equivalent to that for summary judgment, Roche/Hoffman's acts with regard to CERA/PEG-EPO are within the Section 271(e)(1) safe harbor. See Initial Determination at 1, 23. This Court may not consider this in its determination of Roche/Hoffman's Rule 12(b)(6) motion. Such a determination most be based solely on the allegations in the complaint. With respect to the Rule 12(b)(1) motion, though this Court has reviewed the hearing officer's well-reasoned opinion, this Court accords no weight to the fact-finding made by the hearing officer. The hearing officer based his ruling on documents and deposition testimony which are not before this Court. See, e.g., Initial Determination at 15-18 (citing deposition transcripts). This Court will proceed with what evidence is before it at this time. The ruling of the Trade Commission is permissive only, Texas Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1569 (Fed. Cir. 1996) (ruling that decisions of the Trade Commission involving patent issues have no preclusive effect), though this Court is bound by Federal Circuit rulings on appeal from Trade Commission decisions, id.. Finally, as discussed infra, even if the Court credited the hearing officer's determination that Roche/Hoffman is acting within the safe harbor, it would not change the Court's analysis with regard to the Rule 12(b)(1) motion.

device had only recently began clinical trials and was "years away from potential FDA approval." Id. at 1527. This case cannot stand for either proposition put forth by Roche/Hoffman.

In Glaxo v. Novopharm, Ltd, the Federal Circuit held, in direct contradiction to the theory that exempted acts cannot be considered, that a defendant's systematic attempts to meet the applicable regulatory requirements -- the filing of an Abbreviated New Drug Application ("ANDA application") (an act protected by Rule 271(e)(1))[7] -- and preparation to import its product were properly considered in establishing jurisdiction for a declaratory judgment action. 110 F.3d 1562, 1571 (Fed. Cir. 1997). The Federal Circuit specifically ruled that:

> Some of Novapharm's acts that form the basis of the declaratory judgment action are of course protected from liability for infringement under § 271(e)(1) . . . . Nevertheless, the protected status of Novapharm's activities leading to its submissions to the FDA does not by itself prevent the district court from considering Glaxo's request for declaratory relief because such relief is directed to the time after the ANDA is approved, when § 271(e)(1) no longer provides shelter against infringement liability . . . . [Allegations sufficient to establish a case or controversy] may include, . . . imminent FDA approval and actual threats of future infringement. Therefore, the district court properly exercised its discretion to

[7] The infringement statute allows an action for infringement where an ANDA application is filed, but this applies only to claims directed to drugs or methods for using drugs. See 35 U.S.C. § 271(e)(2). Since section 271(e)(2) could not provide jurisdiction over claims directed to methods for making drugs, Glaxo's claim of infringement could not be based on section 271(e)(2) had to be based on the Declaratory Judgment Act. Glaxo, 110 F.3d at 1570.

> hear Glaxo's declaratory judgment action, even though the action was premised in part on actions protected under § 271(e)(1)."

Id. (emphasis added).

Further, the acts of constructing a manufacturing facility and hiring key personnel are not acts covered by the Section 271(e)(1) exemption because, as stated before, they are not acts of "making, selling, or offering to sell" the infringing product under section 271(a). As in Glaxo, where preparing to import the product was considered in determining jurisdiction, preparing to make or sell the product may also be properly consider as meaningful preparation; and these acts, in no way implicate the section 271(e)(1) exemption.

Roche/Hoffman's completion of several clinical trials and, more importantly, the filing of their Biologics License Application for CERA/PEG-EPO, although protected by section 271(e)(1), are significant indicia of an "actual controversy." These acts, coupled with the construction of a manufacturing facility and the hiring of key personnel, whose purpose is, in part, to develop marketing and sales strategies together establish the existence of the immediacy required by Lang.

Roche/Hoffman also argues that Amgen cannot rely on Glaxo for the proposition that the filing of an application establishes the immediacy necessary for jurisdiction because Glaxo involved the filing of an ANDA application -- an application for approval

of a generic drug -- and the process for approval is shorter for those applications. Def. Rep. at 10-11. Roche/Hoffman has submitted evidence that approval of an ANDA application could take between 22 and 24 months. See Suh Decl. Exh. 4 (Median Total Approval Time for Priority and Standard NME's and New BLA's for 2004 - 24.7). But see Suh Decl. Exh. 5 (Median Total Approval Time for BLA Applications in 2004 19.77 months). Amgen argues that approval of the application will likely be between 10-13 months because of the FDA's performance goal to review and act on 90% of all new "Standard" drug applications in 10 months, see Suh Decl. Ex. 6 - PDUFA Reauthorization Performance Goals and Procedures at 1, and that the FDA has been meeting this goal, with median approvals for new Standard Applications in 2003 being 13.8 months, see Goldman Dec., Ex. 2 - FY2004 Performance Report to the President and Congress at 3.

An approval date that is 20 to 24 months away can be considered sufficiently imminent by this Court. Two years is not the "years away" described in Telelectronics where clinical trials had only begun three months prior to the filing of the complaint. The systematic attempts of Roche/Hoffman to meet the regulatory requirement coupled with the acts of hiring key sales and managerial personnel and constructing a manufacturing facility are sufficient to satisfy the first prong -- "meaningful preparation" to engage in the alleged infringing activity.

The "reasonable apprehension" test is also satisfied in this case. As early as August 1993, William Burns, Global Pharmaceuticals Head for Roche, stated that Roche is prepared to face patent litigation from Amgen and is quoted as saying "Knowing Amgen from having worked with them over the years and having observed them over the years, I think that we should expect that they will take us to court. Growth by litigation has been almost a byline of the company." Gottfried Decl., Ex. 20; Roche Will Challenge Amgen in U.S. EPO Market; Oncology Business Growing, "The Pink Sheet", FDC Reports, Vol. 65, No. 031, at 23 (August 4, 2003). In the same article Burns indicated the company's expectation to enter the U.S. EPO market with the allegedly infringing drug. Id. Amgen has on several occasions publically stated that it is quite certain that CERA infringes its patents and that Amgen intends to defend those patents. Id.; Gottfried Decl., Ex. 14; Q3 2003 Amgen Earnings Conference Call, October 21, 2003 at 6, 12. Business analysts have also been predicting litigation, labeling the probable action a "battle royal" that will be the "mother of all biotech patent cases." Gottfried Decl., Ex. 18; Amgen - Peer Perform: Shifting the Focus From Medicare To Emerging EPO Competition – CERA Battle Will Like Be Intense, Bear Stearns Equity Reseach at 1, April 20, 2005 (predicting litigation in 2007); see Roche & Amgen: Taking CERA Seriously, Berstein Research Call at 10, October 15, 2002

(predicting that litigation could start at any time). The evidence suggests a refusal of Roche to change course in spite of threats of litigation from Amgen and predictions of litigation from outside parties.

Given that the test for the existence of an actual controversy is satisfied, the Court is warranted in exercising jurisdiction over this declaratory judgment action. As stated previously, however, the Court, in its discretion, need not exercise jurisdiction. This Court stated in Hoechst:

> Even assuming that the Court has jurisdiction, however, numerous considerations militate against exercising that jurisdiction. Not only is FDA approval uncertain, but the process or the product itself may be altered during the interval in ways that are material to an infringement analysis. Any declaration issued by this Court now may be rendered moot by such alterations.
>
> More important, subjecting the Defendants to an infringement litigation at present may run afoul of the Congressional policy underlying the section 271(e)(1) exemption.
> ....
> Although, it is true that Amgen seeks only a declaration of its rights, which would not preclude continuing exempt activities, the use of the declaratory action could easily become a tool of harassment and intimidation for use in discouraging early efforts at competition. Because the Defendants in this case will violate the law only if they step outside the protective safe harbor that Congress has created, this Court is hesitant to invade that harbor under the auspice of declaratory relief.

3 F.Supp.2d at 113.

The Court then ruled that the Hoechst case be

administratively closed, to be reopened upon motion of either party for good cause shown. Id. at 113. The Court further noted that "the issuance by the FDA of a product license presumptively would show good cause, since the section 271(e)(1) exemption would cease to apply." Id. The Court also indicated that other events prior to FDA approval may also constitute good cause. Id.

Although the Court was concerned about its ruling being rendered moot by FDA revisions, the Court in Hoechst was more concerned with invading the protective safe harbor. In Hoechst, this Court made its ruling on a motion for summary judgment, holding, consistent with what discovery revealed, that all the defendant's current acts were protected by the safe harbor provision. Id. at 109-113. The Court has made no such ruling in this action and, faced with a motion to dismiss, must presume -- based on Amgen's allegations -- that Roche is operating outside the safe harbor exemption. Accordingly, the Court will not decline jurisdiction over this case at this time. The motion to dismiss pursuant to Rule 12(b)(1) [Doc No. 44] is, therefore, DENIED.

V. MOTION TO INTERVENE

As noted above, Ortho Biotech Products, L.P. ("Ortho") has moved to intervene in this action on the side of Amgen. See Mot. to Intervene [Doc. No. 16].

A. Facts

On September 30, 1985, Ortho signed a license agreement with Amgen that encompasses the art claimed in the product patents at issue. The agreement grants Ortho an "exclusive license to make in one location, have made and use LICENSED KNOW-HOW, LICENSED PATENTS, and LICENSED PRODUCTS in the LICENSED TERRITORY in the LICENSED FIELD and to sell LICENSED PRODUCTS in the LICENCED TERRITORY." Decl. of Harman Avery Grossman [Doc. No. 18] ("Grossman Decl."), Ex. 1 ("Product License Agreement") at 11 (Art. 2.01(a)). The "LICENSED FIELD" includes broad rights in EPO for human use except for dialysis and diagnostic purposes. Id. at 5 (Art. 1.10(a)). The "LICENSED TERRITORY" includes the United States. Id. at 7 (Art. 1.14(a)). Amgen does not seriously dispute that the patents and products at issue in the underlying suit are within the scope of Ortho's license. See Amgen's Opp'n to Ortho's Mot. [Doc. No. 34] ("Amgen's Opp'n") at 8-9. In addition, the agreement contains an arbitration clause providing that "any dispute [that] should arise between the parties hereto as to the . . . enforceability . . . of this AGREEMENT . . . be settled by arbitration. See Product License Agreement at 44 (Art. 10.07).

Finally, the agreement provides a protocol in the event of infringement by third parties:

> Either 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. AMGEN shall have the right, but not the obligation, to bring, defend and maintain any appropriate suit or action. If AMGEN requests ORTHO to join AMGEN in such suit or action and ORTHO agrees to so do, ORTHO shall execute all papers and perform such other acts as may be reasonably required and may, at its option be represented by counsel of its choice. AMGEN shall pay ORTHO its reasonable expenses (including its attorney's fees) in connection with any such suit or action. . . . In the event AMGEN fails to take action with respect to such matters within a reasonable period, not more than six (6) months, following receipt of such notice and evidence, ORTHO shall have the right, but not the obligation, to bring, defend and maintain any appropriate . . . suit or action. . . . 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.

Product License Agreement at 38-39 (Art. 8.02) (emphasis added).

Here, Amgen opposes Ortho's intervention in this action.

B. Discussion

Ortho argues that it should be allowed to intervene as of right under substantive patent law and the Federal Rules of Civil Procedure.

Rule 24(a) provides for intervention as of right:

> 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.

Rules 24(a)(2) and 19(a)(2)(i), which provides for involuntary joinder of necessary parties, were intended to be counterparts. Pujol v. Shearson Am. Express, Inc., 877 F.2d 132, 135 (1st Cir. 1989). This makes sense: Rule 19 covers necessary plaintiffs who are not a part of the litigation and provides a way involuntarily to bring them into the case, whereas Rule 24(a) provides necessary plaintiffs a right to intervene should they so choose. Thus, if a party would be necessary to the litigation under Rule 19, then it should be allowed to intervene as of right under Rule 24(a). Ortho argues it is such a party.

Under substantive patent law, only a patentee may bring an action for patent infringement. 35 U.S.C. § 281. A successor in interest to the patent -- an assignee -- is treated as equivalent to the patentee for those purposes, id. § 100(d), as are exclusive licensees with "all substantial rights", Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 875 (Fed. Cir. 1991). Those successors who are not assignees (or exclusive licensees with all substantial rights) who are "seeking enforcement of the patent can sue, if at all, only with the patentee or in the name of the patentee." Ortho Pharm. Corp. v. Genetics Inst., Inc., 52 F.3d 1026, 1030 (Fed. Cir. 1995). "Bare licensees" -- as opposed to exclusive licensees (those licensees with at least one "of the proprietary sticks from the bundle of patent rights," id. at 1031-32) -- have no standing to sue at

all, either alone or jointly. Id. at 1031.

To be an exclusive licensee with all substantial rights, one must possess at least the right to make, use, and vend patented products, to sue for infringement, and to sublicense at will. Aspex Eyewear, Inc. v. Miracle Optics, Inc., 434 F.3d 1336, 1342 (Fed. Cir. 2006). In this case, Ortho properly does not contend that it is an exclusive licensee with all substantial rights; it has no unimpeded right to sue for infringement. See Product License Agreement at 38-39 (Art. 8.02). Contrary to Amgen's contentions, however, see Amgen's Opp'n at 4-8, Ortho is an exclusive licensee. The Product License Agreement makes that fact quite plain. Id. at 11 (Art. 2.01(a)). As such, Ortho does have standing to join Amgen's infringement suit against Roche/Hoffmann. Ortho Pharm. Corp., 52 F.3d at 1031-32.

Though it is true that the Court must look to the substance of an agreement in order to determine its effect on a party's standing, see Vaupel, 944 F.2d at 875, the Court reads a grant of an "exclusive license to make in one location, have made and use LICENSED KNOW-HOW, LICENSED PATENTS and LICENSED PRODUCTS in the LICENSED TERRITORY in the LICENSED FIELD and to sell LICENSED PRODUCTS in LICENSED TERRITORY" to be exactly what it says it is: an exclusive license. This is quite sufficient for joint standing purposes.

Amgen's citation to such cases as Vaupel and Field Turf,

Inc. v. SouthWest Recreational Indus., Inc., 357 F.3d 1266 (Fed. Cir. 2004), is particularly inapt, as those cases dealt with distinguishing between a plain exclusive licensee and an exclusive licensee with all substantial rights. Amgen's opposition memorandum, either in a fundamental misunderstanding of patent law or a deliberate attempt at obfuscation, conflates bare licensees with exclusive licensees for standing purposes. As stated above, no one -- not even Ortho -- claims to have all substantial rights such that it has standing to sue alone; Ortho seeks merely to join Amgen's infringement suit against Roche/Hoffmann.

The decision that Ortho has standing to sue, however, does not answer the question of the hour: Is Ortho a necessary party to Amgen's suit? More generally, is an exclusive licensee a necessary party to an infringement action brought by the patent owner?

In the seminal case of Independent Wireless Tel. Co. v. Radio Corp., 269 U.S. 459 (1926), the Supreme Court held that "both the owner and the exclusive licensee are generally necessary parties in the action . . . ." Id. at 466. The case, however, "involved a suit originally brought by an exclusive licensee", not one brought by the patent owner. Dr. Fred Harfield's Sportstrength Training Equip. Co. v. Balik, 174 F.R.D. 496, 500 (M.D. Fla. 1997). Decades of case law recognized

this distinction as significant: "It does not follow . . . that when there is a patent infringement lawsuit between a patent owner and a competitor, an exclusive licensee is a necessary party to the litigation." Boler Co. v. Raydan Mfg., Inc., 415 F. Supp. 2d 896, 905 (N.D. Ill. 2006) (emphasis omitted); see also Dr. Fred Harfield's, 174 F.R.D. at 500 (citing Comptograph Co. v. Universal Accountant Machine Co., 142 F. 539, 545 (C.C.N.D. Ill. 1906) ("I know of no authority that requires that the owner of a patent must join his licensee as a party complainant.")); Corixa Corp. v. IDEC Pharms. Corp., No. CIV.A.01-615-GMS, 2002 WL 265094, *2 (D. Del. Feb. 25, 2002) ("[W]hile likely a proper party . . . , [the exclusive licensee] is not a necessary party.").

The sensible judgment behind these statements is that the motivation behind the Independent Wireless decision usually is not implicated in a case where a patent owner brings suit without the exclusive licensee. The reason a patent owner should be joined in a suit brought by an exclusive licensee is judicial economy and justice: to prevent the potentially pernicious effects of two or more (possibly inconsistent) lawsuits involving the same patent. See Independent Wireless, 269 U.S. at 468; Ortho Pharm. Corp., 52 F.3d at 1030-31, 1034-35. Given that an exclusive licensee without all substantial rights cannot sue alone, there usually is no similar risk of multiple suits if such

licensee is not joined in an action by the patent owner.

Ortho argues that the recent case of Aspex Eyewear, Inc. v. Miracle Optics, Inc., 434 F.3d 1336 (Fed. Cir. 2006), compels the opposite conclusion. In Aspex, the patentee, Contour, licensed its patent to Chic. For the most part, the license was exclusive, granting many substantial rights, but left Contour with a reversionary interest in the right to sue for infringement. Id. at 1338. On April 5, 2001, Chic assigned all of its rights under the license to Aspex. Id. A week earlier, however, on March 28, Aspex and Contour had brought an infringement suit against an alleged infringer. Id. The district court dismissed the entire suit, holding first that Contour had no standing because it had assigned ownership in the patent to Chic (i.e., had granted Chic all substantial rights in the patent), and second that Aspex had no standing because Chic's assignment of patent rights was not in writing[8] before the suit was initiated. Therefore, the district court ruled that Chic, as the effective owner, should have been joined in the action which now included only Aspex (who was an exclusive licensee at most[9]). Id. at 1338-39.

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[8] Assignment of a patent must be in writing. 35 U.S.C. § 261.

[9] Unlike a patent assignment, a patent license need not be in writing. Waymark Corp. v. Porta Sys. Corp., 334 F.3d 1358, 1364 (Fed. Cir. 2003).

The Federal Circuit reversed both rulings. First, that court held that Contour did not assign all substantial patent rights to Chic. Id. at 1340-44. The holding explained that keeping a reversion in the right to sue was sufficient to deprive Chic of an effective assignment. Id. at 1342-43. Based upon this judgment, the conclusion naturally followed according to established patent law: As the patent owner, not only was Contour a proper party, it was a necessary party. Id. at 1343.

The court then went on to analyze Aspex's standing to sue. Id. at 1344. It started by citing Independent Wireless: "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." Id. (citing Independent Wireless, 269 U.S. at 466). Though it was clear that Aspex had become the exclusive licensee by April 5 (the date of the agreement between it and Chic), it was unclear if Aspex was an exclusive licensee on April 28 (the day the suit was filed). "If the license between Chic and Aspex was not effective at the time of the original complaint, then Chic was a necessary party and it has not been joined. If Aspex was an exclusive licensee at the proper time, then Chic was not a necessary party and Aspex was in fact a proper plaintiff." Id. As additional findings were possibly required, the Federal Circuit remanded the case to the district court for a determination in the first instance. Id.

Ortho claims that Aspex requires Ortho's joinder in the present suit. Regardless whether it was Chic or Aspex which was the exclusive licensee, one of them was, and as such, it was a necessary party to the action. Despite decades of implicit (and sometimes explicit, see supra) court interpretations that exclusive licensees are not necessary parties in suits brought by patent owners, based on the Federal Circuit's recent ruling in Aspex, Ortho's argument is well taken. At least one commentator has recognized Aspex's holding just so:

> A party who holds an exclusive license to at least one of the exclusionary rights in the patent will have standing to join with the patentee as a co-plaintiff. Indeed, not only does the exclusive licensee have the right to join a suit brought by the patentee, the Federal Circuit has held that the exclusive licensee must be joined.

Robert A. Matthews, Jr., 1 Annotated Patent Digest § 9:47 (2006) (emphasis added). Such a rule ostensibly furthers the goal of preventing multiple concurrent or seriatim lawsuits that was articulated by the Supreme Court in Independent Wireless in support of its adoption of the reverse rule. Even though an exclusive licensee may not sue alone, it arguably could force a patentee to join its suit involuntarily. See Independent Wireless, 269 U.S. at 468-75; Waterman v. Mackenzie, 138 U.S. 252, 255-56 (1891). Pursuant to Aspex, the Court rules that an exclusive licensee must be joined in an infringement suit brought by the patent owner.

The Court reaches this conclusion with some hesitation.[10] The Federal Circuit in Aspex did not give any indication that it was making such a significant statement regarding the law of patent standing. Patent owners can divide their bundle of rights not only into separate exclusive licenses to make, sell, and use the patented item, but also divide each of those licenses into exclusive licenses of infinite geographical or temporal scope. Requiring all exclusive licensees to join patent infringement actions could complicate litigation exponentially. Throwing so many property "sticks" into the fire of litigation risks creating an unmanageable conflagration.

Recognizing this, one commentator has noted that "[i]t is possible that circumstances, such as an agreement whereby the exclusive licensee waives its right to join a suit brought by the patentee and agrees to be bound by any determination rendered in that suit, would negate the requirement that an exclusive licensee be joined in the suit, since the policy goal of precluding the possibility of multiple lawsuits would be

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[10] Hesitation is especially warranted in the present case, which involves the very patent, the very parties, and the very Product License Agreement which has been twice before the Federal Circuit without a word regarding Ortho's status as a necessary party. See Ortho Pharm. Corp. v. Genetics Inst., Inc., 52 F.3d 1026 (Fed. Cir. 1995); Amgen, Inc. v. Chugai Pharm Co., 927 F.2d 1200 (Fed. Cir. 1991). This Court assumes this silence stems from the fact that the alleged infringement in that litigation was not relevant to Ortho's status as an exclusive licensee, but only as a bare licensee.

achieved." Matthews, supra, § 9:47. This Court agrees. Not only is a contract exception to the rule of Aspex logical, it is likely necessary to the efficient administration of patent infringement suits. A patentee simply must be able to draft license agreements so as to preclude their exclusive licensees from being deemed necessary parties to any patent infringement actions it may bring.

In this case, Amgen and Ortho have entered into a license agreement which purports to put Amgen in the driver's seat in actions relating to infringement of the licenced patents, giving it the right to exclude Ortho from such suits. See Product License Agreement at 38 (Art. 8.02). Ortho, however, contends that the required consultation prior to the filing of any such suit did not take place here; thus, Ortho should nevertheless be allowed to intervene. See Motion Hearing (May 10, 2006) [Doc. No. 82], Tr. at 8-9. The dispute over Ortho's right to intervene, therefore, is, at root, a contract dispute -- the type of dispute which must be arbitrated. See Product License Agreement at 44 (Art. 10.07).

Normally, this Court is fully competent to entertain and decide issues of contract interpretation. Federal policy, however, overwhelmingly favors arbitration, see Moses H. Cone Mem'l Hosp. v. Mercury Constr. Co., 460 U.S. 1, 24-25 (1983) -- even in the context of patent licensing disputes, see In re

Powertex, Inc., 14 F.3d 612 (Fed. Cir. 1993) (unpublished table decision). The Court rules, therefore, that if Ortho wishes to intervene in the present action, it must first seek from an arbitral panel an interpretation of its license agreement with Amgen regarding whatever right it may presently have under the Product License Agreement to do so. Moreover, should an arbitral panel decide that the Product License Agreement precludes Ortho from intervening, for Amgen to take advantage of the exception to Aspex that the Court here recognizes, Amgen must be able to show -- also through an interpretation by an arbitral panel -- that Ortho agreed in the Product License Agreement to be bound by the results of the present litigation. Of course, the parties are free to agree on Ortho's intervention (or nonintervention) pursuant to conditions of their own choosing.[11]

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[11] This same result would be obtained, minus Amgen's required showing, were the Court were to analyze Ortho's motion to intervene under normal Rule 24 analyses. "[T]he exclusive licensee may in most cases intervene to protect [its] rights . . ." Holliday v. Long Mfg. Co., 18 F.R.D. 45, 49 (E.D.N.C. 1955).

Ortho meets the requirements for intervention as of right under Rule 24(a): an interest in the litigation which could be impaired or impeded by its absence and which (allegedly) is not adequately represented. Possessing an exclusive license in a patent provides the licensee a "sufficiently close relationship to the dispute between the litigants" and an interest which is "direct, not contingent." Conservation Law Found., Inc. v. Mosbacher, 966 F.2d 39, 42 (1st Cir. 1992) (internal quotation marks omitted). Also, any adjudication involving the validity of the EPO patents or the nature of Roche/Hoffmann's activity would have preclusive effect on any later adjudication involving Ortho's license. This is sufficient impairment under Rule 24(a). See Cabot LNG Corp. v. Puerto Rico Elec. Power Auth., 162 F.R.D.

C. Conclusion

For the reasons set forth above, Ortho's Motion to Intervene [Doc. No. 16] is DENIED without prejudice, subject to the determination of the issue of contract interpretation by an arbitral panel.

SO ORDERED.

/s/ William G. Young

WILLIAM G. YOUNG
DISTRICT JUDGE

427, 430 (D.P.R. 1995). Finally, the history of antagonism between Amgen and Ortho over this exclusive license is sufficient for the Court to conclude that Ortho has met its "minimal" burden of showing that Amgen's "representation of [its] interest 'may be' inadequate", Trbovich v. United Mine Workers, 404 U.S. 528, 538 n.10 (1972) -- even if there were a presumption of adequacy because of Amgen's and Ortho's similar (or identical) ultimate goals, see Moosehead Sanitary Dist. v. S.G. Phillips Corp., 610 F.2d 49, 54 (1st Cir. 1979).

Rights may be waived, though, and the Product License Agreement granting Amgen control over patent infringement litigation appears to do just that. See Product License Agreement at 38 (Art. 8.02). As detailed above, however, there is some dispute regarding how that clause is to operate. This dispute must be arbitrated.

Likewise, given the Court's conclusions with respect to Ortho's right to intervene, it follows *a fortiori* that Ortho would be permitted to intervene under Rule 24(b) -- absent the existence of Article 8.02 in the Product License Agreement.