EXHIBIT B

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

AMGEN, INC.,
Plaintiff,

v.

CIVIL ACTION NO. 87-2617-Y

CHUGAI PHARMACEUTICAL CO., LTD., et al.,
Defendants.

DOCKETED

REPORT AND RECOMMENDATION RE: MOTION OF ORTHO PHARMACEUTICAL CORPORATION TO INTERVENE IN THIS ACTION PURSUANT TO RULES 24(a)(2) AND 24(b)(2), FED. R. CIV. P. (LOCKET ...)

MAY 5, 1989

SARIS, U.S.M.

On March 17, 1989 Ortho Pharmaceutical Corporation ("Ortho") moved to intervene in this action pursuant to Fed. R. Civ. P. 24(a)(2) and 24(b)(2). Plaintiff Amgen, Inc., ("Amgen") vigorously opposes the motion. The court recommends that the motion be denied on the ground it is untimely.

Background

The instant action was filed on October 27, 1987. Amgen alleges that defendants Chugai Pharmaceutical Co. ("Chugai") and Genetics Institute, Inc. ("GI") have infringed its patent No. 4,703,008 ("'008 patent") which includes claims for DNA sequences encoding erythropoietin as well as host cells

May 26, 1989
This report and recommendation is approved and the motion of Ortho Pharmaceutical Corporation to intervene is denied.

William G. Young
District Judge

DOCKETED

153

A 75964

transformed or transfected with a DNA sequence. Erythropoietin is a protein which stimulates the body's production of red blood cells and is used primarily for the clinical treatment of anemia, particularly anemia caused by renal disease. Chugai and GI have filed a counterclaim charging Amgen with, among other things, infringing their patent No. 4,677,195("'195 patent"), a patent for compositions comprised of highly purified erythropoietin. GI is the owner of the patent and Chugai is the exclusive licensee.

The day after Amgen brought this suit in Boston, GI and Chugai filed suit against Amgen and Kirin-Amgen, Inc., a joint venture company of Amgen and the Japanese company, Kirin Brewery, in the Southern District of California. Defendants counterclaimed for infringement of the '008 patent. This Los Angeles suit is the mirror image of the Boston suit so far as the patent issues are concerned.

In February, 1988, in the California action, GI and Chugai moved to join Ortho as an additional party defendant pursuant to Fed. R. Civ. P. 15 and 20 on the ground that Ortho had entered into product and technology licensing agreements with both Amgen and Kirin-Amgen; that the licensing agreements provided for the sharing of technology and resources for the commercialization of the allegedly infringing erythropoietin; that their right to relief arose out of the same transactions or occurrences as

against Amgen; and that there were common factual and legal issues in the case, in particular the issue of infringement of the patent, and inducement of infringement. See Docket 117, Appendix, Ex. C. Ortho moved to dismiss for lack of venue pursuant to 28 U.S.C. § 1400(b). Venue was reserved as a trial issue by decision of February 6, 1989, and Ortho's Answer was filed on February 27, 1989. The Answer asserts infringement of the '008 patent and invalidity of the '195 patent.

Meanwhile, the Massachusetts action was not dormant. Chugai and GI filed a motion for partial summary judgment on the claim that Amgen infringed the claims of the '195 patent. On February 24, 1988, the court heard oral argument and then granted the motion. Chugai filed a motion for summary judgment on May 12, 1988 seeking a determination that the '008 patent is unenforceable due to Amgen's alleged acts of patent misuse or, in the alternative, that the '008 patent contains no process claims, and thus does not cover Chugai's process of manufacturing recombinant erythropoietin. The court granted Chugai's motion for partial summary judgment only to the extent of ruling that the '008 patent does not contain a process claim. See Memorandum and Order, dated January 31, 1989.

On January 24, 1989 the Court issued a temporary restraining order enjoining defendants from, among other things, exporting, shipping or delivering to others certain recombinant

erythropoietin. On February 2, 1989, the court heard oral argument on plaintiff's motion for a preliminary injunction. At the outset the the trial judge noted that the case "cries out for a trial,", that he was trying a criminal case which would last a year, and suggested consent to trial before a magistrate in "view of the necessity, really, the litigation necessity, to try this case and move it forward." Transcript of hearing, dated February 2, 1989.

On February 7, 1989, the court issued an order finding that Amgen had shown a reasonable likelihood of success on the merits of the validity of the patent; that it would suffer irreparable injury due to the needs of an incipient market and attendant burdens on a new company; that the balance of equities was best struck by mandating an injunction that required the defendant GI to place with the Court all profits of the sale of erythropoietin ("EPO"); and that as to the public interest, "recombinant EPO is an extraordinarily valuable medicine that promises marked relief from renal failure." Because of this public interest, the court would not enter an order to delay or prevent production or shipping of erythropoietin.

The case was referred to a magistrate on February 7, 1989. Discovery has been expedited, and trial is scheduled to begin on August 7, 1989. According to counsel, depositions have been taking place as many as six days a week, often with more than

one deposition occurring in a day. The parties have agreed that the case should be bifurcated into the liability and damage issues.

On March 17, 1989 Ortho moved to intervene. Oral argument on the motion to intervene took place on April 27, 1989. At the hearing counsel for Amgen, Chugai and GI all concurred that the trial should go forward as scheduled, and opposed any continuances.[1]

ARGUMENT

The threshold question is whether a magistrate has the authority under 28 U.S.C. § 636(c) to rule on a motion to intervene pursuant to Fed. R. Civ. P. 24. Section 636 (c)(1) states:

> Upon the consent of the parties, a full-time United States magistrate...may conduct any or all proceedings in a jury or nonjury civil matter and order the entry of judgment in the case, when specially designated to exercise such jurisdiction by the district court or courts he serves.

(Emphasis added). See Fed. R. Civ. P. 73 (no district judge or magistrate shall be informed of a party's response to the clerk's notification concerning the opportunity to consent to

---

[1]Originally, in their joint response to the motion to intervene, defendants conditionally consented to the motion for intervention as long as they got an extension of at least one month to review the documents in Ortho's possession. Docket 129. At the hearing, defendants changed their position, and urged that the trial go forward as scheduled.

the exercise by a magistrate of civil jurisdiction "unless all parties have consented to the referral of the matter to a magistrate").

The requirement of consent is of constitutional dimension. The First Circuit has held that the delegation of power to magistrates to conduct consensual trials and enter judgments without de novo review by a district judge does not violate the litigants' Article III rights where the parties have voluntarily consented to have the action handled through to judgment by a magistrate. See Goldstein v. Kelleher, 728 F. 2d 32, 36 (1st Cir. 1984) cert. denied, 469 U.S. 852 (1984)(litigants' Article III interests are safeguarded by the consensual nature of the reference).

Neither the statute nor the Federal Rules of Civil Procedure address the authority of a magistrate to rule on a motion to intervene pursuant to Fed. R. Civ. P. 24(a) and (b) after the original parties have consented to trial before the magistrate. As Wright and Miller commented:

> It seems possible that in some cases, after the original parties have consented that a magistrate should exercise the district court's jurisdiction, an additional party or parties may enter the case and insist on a trial before an Article III judge. The Act and Rule 73(a) make no provision for subsequently added parties, but the legislative history indicates that the voluntary consent of all the parties is required to invoke the jurisdictional provisions of Section 636(c).

Wright and Miller, 12 Federal Practice and Procedure §3077.2

(1988 Supp. p. 61).

Under Rule 24(a), upon timely application, one has an absolute right to intervene when the applicant claims an interest in the property or transaction involved which is not adequately protected by the existing parties, and which might be adversely affected by the outcome of the action. 3B Moore's Federal Practice ¶24.05 (1987 at p. 24-26).

Here, none of the parties has challenged the authority of the magistrate to rule on the motion to intervene, and indeed at a status conference, counsel for Ortho indicated that Ortho would probably consent to trial before the magistrate. Nonetheless, as a matter of constitutional law, statutory construction, and interpretation of Fed. R. Civ. P. 73, this court concludes that it does not have the authority pursuant to 28 U.S.C. § 636(c) to rule on the motion to intervene. See Guess v. Chenault, 108 F.R.D. 446, 449 (N.D. Ind. 1985)(when plaintiff filed an amended complaint adding another defendant as a "real party in interest" after all the parties had consented to trial before a magistrate, the magistrate did not have jurisdiction over this new defendant which did not consent to trial before him, but he did have authority to retain jurisdiction over the original parties, and to sever the claim against the non-consenting defendant pursuant to Fed. R. Civ. P. 42(b)). Accordingly, this court will issue a report and

recommendation to the trial court with respect to the motion to intervene.

2. Intervention.

Ortho argues that as a licensee of the patent it should be permitted to intervene as of right pursuant to Fed. R. Civ. P. 24(a)(2) and (b)(2). In support of the motion, it submits the affidavit of Dennis N. Longstreet, the President of the Biotech Division. See Appendix, Ex. A. The affidavit contains the following relevant information. Ortho, a wholly owned subsidiary of Johnson & Johnson, is involved in the research, development and marketing of pharmaceutical and biological productions. It has been interested in the potential for erythropoietin since at least the early 1980's when it participated in an experiment purifying small quantifies of erythropoietin under zero gravity conditions on a Space Shuttle mission.

In the mid-1980's Amgen had done significant bio-engineering work on erythropoietin, but had financial and staffing concerns. In September 1985 Amgen and Ortho entered into a series of contracts pursuant to which Ortho provided Amgen with millions of dollars of financial support and with technical expertise to complete the erythropoietin project. In exchange, Amgen granted Ortho certain of its patent rights. Specifically, Otho received the exclusive license to offer erythropoietin in the United States except for dialysis and diagnostic

applications which were reserved to Amgen. Ortho was granted foreign exclusivity for erythropoietin sales including dialysis.

Ortho contends that Amgen failed to live up to its obligations under the Exclusive Product License to represent its interests before the Food and Drug Administration. This alleged breach of duty has resulted in litigation and an arbitration prodeeding. Both Amgen and Ortho, at the hearing, agreed that relations between the two companies are acrimonious.

The proposed complaint of intervenor Ortho charges GI and Chugai with violating the '008 patent, and seeks a declaratory judgment that defendants' patent '195 is valid.

Fed. R. Civ. P. 24(a) provides:

> Upon timely application anyone shall be permitted to intervene in an action...when the applicant claims an interest relating to the property or transactions 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.

Rule 24(b)(2) provides that on timely application, anyone may be permitted to intervene in an action when an applicant's claim or defense and the main action have a question of law or fact in common.

Ortho has demonstrated -- and there appears to be no dispute -- that it has an interest relating to the property or

transaction which is the subject of the action, and that it is so situated that the disposition of the action would as a practical matter impair or impede its ability to protect that interest. Certainly Ortho's claims and defenses and the main action present questions of law and fact in common. Indeed, courts have granted motions to intervene brought by exclusive licensees of a patent in litigation involving the validity or infringement of the patent. See Fisher v. The Gillette Co., 505 F. Supp. 184, 186 (N.D. Ill. 1981)(it is highly desirable that in a litigation between the patentee and a major alleged infringer, the exclusive licensee with a substantial economic stake in the outcome should be able to have its own rights adjudicated vis-a-vis both parties); Innis, Speiden & Co. v. Food Machinery Corp., 2 F.R.D. 261, 264 (D.Del. 1942)(Pursuant to Rule 24(a) and (b), court allowed motion of exclusive licensee to intervene as plaintiff in suit by patentee charging defendant with patent infringement); cf. Precision Shooting Equipment, Inc. v. Allen, 199 U.S.P.Q. 459, 461 (E.D. Ill. 1978)(Pursuant to Fed. R. Civ. P. 24(b), licensee allowed to intervene as plaintiff challenging validity of patent.)

Amgen argues, however, that the motion is not timely since Ortho has been fully aware of the pendancy of this action since "well prior to February, 1988"; a preliminary injunction has been issued; and the parties agreed to consent to jurisdiction

before a magistrate, at the urging of the trial court, because of the need for a decision before the end of 1989. Amgen also points out that no discovery has been taken of Ortho.

Fed. R. Civ. P. 24 dicates that any motion to intervene must be timely. United States v. Metropolitan District Comm., 865 F.2d 2, 5 (1st Cir. 1989), citing NAACP v. New York, 413 U.S. 345, 365 (1973). The First Circuit has established four factors for evaluating the timeliness issue: (i) the length of time the prospective intervenors knew or reasonably should have known of their interest before they petitioned to intervene; (ii) the prejudice to existing parties due to the intervenor's failure to petition for intervention promptly; (iii) the prejudice the prospective intervenors would suffer if not allowed to intervene; and (iv) the existence of unusual circumstances militating for or against intervention. Id. The court will examine each of these factors separately as follows:

(i) The delay in filing the motion to intervene is substantial. Ortho does not dispute that it knew about the Massachusetts action at least thirteen months before it filed its motion to intervene. Nonetheless, it justifies this delay in two ways. First, it argues that it was forced into the present controversy by the grant of GI's motion to join it in the California action and by the denial of Ortho's motion to dismiss the action on February 6, 1989. Docket 137 p. 2. Second, counsel

argues that because of the case backlog in Massachusetts, he could reasonably have expected that the action in California would be tried before the action in Massachusetts and Ortho could not have anticipated that the parties would consent to an expedited trial before a magistrate. However, these justifications do not excuse the delay. Parties having knowledge of the pendency of litigation which may affect their interests sit idle at their peril. Narragansett Indian Tribe v. Ribo, Inc., 868 F.2d 5, 7 (1st Cir. 1989)(belated intervention was not allowed where intervenors, believing the lawsuit was frivolous, expected it would be dismissed). If Ortho believed that its interests would not be adequately represented by Amgen, it is hard to see why those interests were no less implicated by the original filing of the suit, the motion for preliminary injunction and the various motions for summary judgment, than the actual trial. The fact that Ortho did not expect the parties to consent to a trial before a magistrate does not justify the delay. See also United Nuclear Corp. v. Cannon, 696 F.2d 141, 143 (1st Cir. 1982)("United Nuclear Corp.")(the fact that ongoing settlement discussions eventually collapsed did not justify waiting seven and one half months to move to intervene since the intervenor "was surely aware that settlement negotiations often collapse").

ii. Amgen and defendants oppose intervention because of

their concern that the need for Ortho to engage in discovery,and to take discovery of Ortho, would postpone the trial date of August 7, 1989 by at least a couple of months. Defendants point out that Ortho has just produced a half a million documents in the California action, which would have to be reviewed. Even Ortho expressed doubt that it could be ready for trial by August 7, 1989. Ordinarily, a delay of a few months would not be prejudicial, particularly in a case of this importance and complexity. However, a preliminary injunction has issued requiring defendant GI to put profits from the sale of erythropoietin into an escrow account, and as the trial court has stated, the outcome of this case is not only of great significance to the parties involved, but involves a matter of great public interest because erythropoietin is "an extraordinarily valuable medicine that promises marked relief from renal failure." Docket 88. Therefore, a delay of even a few months would prejudice the parties, and the public.

iii. Ortho has not demonstrated it would be substantially prejudiced by a denial of the motion to intervene. It argues that Amgen does not adequately represent its interests because of the animosity between the two companies, and points to Amgen's purported failure to adequately represent Ortho before the Food and Drug Administration ("FDA"). Ortho also argues that as a result of Amgen's failure to meet these obligations

before the FDA, Amgen will become a competitor in the sale of erythropoietin once regulatory approvals are obtained, and will have every reason to exclude Ortho from that market. Docket 137, p. 7.

A prospective intervenor faces a presumption of adequacy when it has the same ultimate goal as a party. United Nuclear Corp., 696 F. 2d at 144. To overcome that presumption, petitioner ordinarily must demonstrate adversity of interest, collusion, or nonfeasance. The First Circuit has looked at three factors on adequacy of representation:

> (1) Are the interests of a present party in the suit sufficiently similar to that of the absentee such that the legal arguments of the latter will undoubtedly be made by the former; (2) is that present party capable and willing to make such arguments; and (3) if permitted to intervene, would the intervenor add some necessary element to the proceedings which would not be covered by the parties in the suit?

Id., citing Blake v. Pallan, 554 F. 2d 947, 954-955 (9th Cir. 1977).

Here, Amgen's ultimate goal in defending the '008 patent, and in challenging the '195 patent appears to be identical to Ortho's. The fact that there are disputes under the license agreements does not diminish Amgen's strong incentive to protect the patent. Amgen has talented trial counsel from both Boston and Chicago aggressively seeking through temporary restraining

orders, preliminary injunctions and an expedited trial schedule, to prosecute its patent rights. It has also vigorously pressed its claims in related proceedings before the International Claims Commission. Further, the court is hard-pressed to credit Ortho's arguments that it is not contented with Amgen's representation with respect to the '008 patent since it relied on Amgen for over thirteen months in this action, and fought to be dismissed from the California action.

Ortho was unable to articulate any specific way in which it would be prejudiced by denial of its application. First, it points out that it manufactures some of its own erythopoietin which has different characteristics than the erythropoietin manufactured by Amgen and therefore it will be prejudiced if it is not permitted to defend itself against defendants' claim of infringement. Further, it argues that because of the difference in the characteristics of its erythropoieten, it should be able to litigate the meaning of the claims in the '195 patent with respect to homogeneity. However, to the extent Ortho can show it was not adequately represented by Amgen concerning erythropoietin produced by Ortho, it will not be barred from raising this issue either in the California action or elsewhere. Second, Ortho expresses concern that since there is such animosity between Amgen and it, if there is a settlement, Amgen will not protect Ortho's license rights. However, settlement at

this point seems speculative[2] and to the extent Amgen violates the exclusive license agreements, Ortho can resort to litigation, as it has in the past.

iv. Because of the importance of erythropoietin, and the pending preliminary injunction, there are unusual circumstances militating against intervention and for a speedy trial.

CONCLUSION

The Court recommends that the motion to intervene be denied.[3]

PATTI B. SARIS
United States Magistrate

---

[2]At the hearing, counsel for Amgen stated that it had invited Ortho to settlement discussions, but declined to promise that Ortho would be invited to all settlement discussions.

[3]Any objections to this Report and Recommendation must be filed with the Clerk of Court within ten days of receipt of the Report and Recommendation and must identify the portion of the Report and Recommendation to which objection is made and the basis for such objection. Any party may respond to another party's objections within ten days after service of the objections. Failure to file objections within the specified time waives the right to appeal the district court's order. United States v. Escoboza Vega, 678 F.2d 376, 378-379 (1st Cir. 1982); United States v. Valencia-Copete, 792 F.2d 4, 6 (1st Cir. 1986).

D