UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN, INC., Plaintiff, v. F.HOFFMANN-LA ROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN LA ROCHE INC., a New Jersey Corporation Defendants.	)	CIVIL ACTION NO. 05-12237-WGY

MEMORANDUM AND ORDER

YOUNG, D.J. March 30, 2007

I. INTRODUCTION

Amgen, Inc. ("Amgen") initiated this action against F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche/Hoffmann") seeking a declaratory judgment that Roche/Hoffmann currently infringes or will infringe Amgen's patents for erythropoietin ("EPO"). 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). Am. Compl. [Doc. No. 52] ¶¶ 14, 26. Roche/Hoffmann filed counterclaims, a number of which Amgen moved to dismiss. Amgen Mot. to Dismiss [Doc. No. 150].

A. Procedural Posture

Amgen initiated this action on November 8, 2005. [Doc. No. 1]. On March 9, 2006, Ortho Biotech Products, L.P. ("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/Hoffmann 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/Hoffmann argued in essence that there was no sufficient allegation in Amgen's complaint that it was infringing, about to infringe, or inducing infringement, and that, in any event, its activities fell within the "safe harbor" provision of 35 U.S.C. § 271(e)(1).[1] On October 20, 2006, this Court denied both Ortho's motion to intervene and Roche/Hoffmann's motion to dismiss.

Subsequently, Amgen moved to dismiss Roche/Hoffmann's counterclaim counts I-IX. Following oral argument, the Court denied the motion to dismiss Counterclaim Counts I (Walker Process claim) and VI (tortious interference with business relationships). The Court allowed without prejudice the dismissal of Counterclaim Count II (sham litigation). The Court took under advisement the motion to dismiss the remaining

[1] Roche Diagnostics GmbH and F. Hoffmann La Roche Ltd. also filed motions to dismiss for lack of personal jurisdictional [Doc. Nos. 38 & 41], but later withdrew those motions [Doc. Nos. 83 & 84].

Counterclaim Counts III (monopolization), IV (attempted monopolization), and V (unreasonable restraints of trade), and VII-IX (state law claims). The Court also dismissed without prejudice Roche/Hoffmann's Affirmative Defense XII (equitable estoppel). Subsequently, Roche/Hoffmann moved to amend its answer and counterclaims with respect to Counterclaim II and Affirmative Defense XII [Doc. No. 252].

B. Alleged Facts

Although Amgen seeks to dismiss a number of Roche/Hoffmann's counterclaims, its own allegations (set out in this section) are pertinent.

Amgen alleges that Roche/Hoffmann is "currently importing into the United States a pharmaceutical composition containing a recombinant human EPO product" that contains EPO as claimed in the '933, '080, and '422 patents. Am. Compl. ¶¶ 18, 19. Amgen further alleges that Roche/Hoffmann is producing glycoslyated human EPO "by means of one or more of the processes claimed in the '868, '698 and '349 patents." Id. ¶ 21.

Amgen refers to the allegedly infringing product as "PEG-EPO" and Roche/Hoffmann refers to it as "CERA." PEG-EPO/CERA contains glycosylated human EPO, to which Roche/Hoffmann has attached a polyethylene glycol ("PEG") polymer. Id. ¶ 20. Allegedly, 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/Hoffmann submitted its Biologic License Application ("BLA") to the United States Food and Drug Administration in order to sell pharmaceutical compositions containing PEG-EPO/CERA for the treatment of anemia associated with chronic kidney disease. Id. ¶ 27. Amgen states that upon information and belief, Roche/Hoffmann has "completed all Phase III clinical trials it believes necessary to support its application for approval in the United States." Id. Amgen claims that Roche/Hoffmann has announced that it expects to obtain regulatory approval to market and sell PEG-EPO/CERA in the United States within the next 12-14 months. Id. ¶ 28.

Amgen further alleges that Roche/Hoffmann is preparing to market and sell PEG-EPO/CERA 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/CERA upon receipt of regulatory approval to market and sell PEG-EPO/CERA in the United States;

b. Retaining outside consultants and vendors to assist in its marketing and sale of PEG-EPO/CERA in the United States;

c. Contacting potential customers, including large dialysis organizations, to solicit interest in purchasing PEG-EPO/CERA from Roche/Hoffmann 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/CERA for export to the United States, at a reported cost of 182 million Euros.

Id. ¶ 29.

C. Federal Jurisdiction

The Court has exclusive jurisdiction over this action for patent infringement pursuant to 28 U.S.C. § 1338(a).

II. DISCUSSION

A. Standard of review

On a motion to dismiss, a court must accept as true "the well-pleaded facts as they appear in the complaint, extending [the non-moving party] every reasonable inference in his favor." Coyne v. City of Somerville, 972 F.2d 440, 442-43 (1st Cir. 1992) (citation omitted). The complaint may not be dismissed unless

"it appears beyond doubt that the [non-moving party] can prove no set of facts in support of his claim 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)). This standard is no less applicable to antitrust claims (or counterclaims) where "dismissals prior to giving the [non-moving party] ample opportunity for discovery should be granted very sparingly." Hospital Bldg. Co. v. Trustees of Rex Hosp., 425 U.S. 738, 746 (1976); see also Hewlett-Packard Co. v. Boston Scientific Corp., 77 F. Supp. 2d 189, 195 (D. Mass. 1999) (Saris, J). Thus, "[t]he issue is whether the complaint states a claim under the Sherman Act, assuming the factual allegations to be true and indulging to a reasonable degree [the non-moving party] who has not yet had an opportunity to conduct discovery." Morales-Villalobos v. Garcia-Llorens, 316 F.3d 51, 53 (1st Cir. 2003) (citation omitted).

B. Standing

Amgen's central argument for dismissing counterclaims III, IV and V is that Roche/Hoffmann lacks standing because it has not properly alleged antitrust injury. Amgen Mem. [Doc. No. 151] at 2-3. In order to recover antitrust damages under section 4 of the Clayton Act, a claimant must aver injuries "of the type the antitrust laws were intended to prevent." Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977). The antitrust

standing inquiry is not a black-letter rule, but rather a "balancing test comprised of many constant and variable factors." City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 264-65 (3rd Cir. 1998) (quotation marks omitted). The Federal Circuit has approved the following criteria for determining whether a claimant possesses antitrust standing:

> (1) whether there is a causal connection between an antitrust violation and harm to the plaintiff and the defendants intended to cause that harm;
>
> (2) whether the nature of the plaintiff's alleged injury was of the type the antitrust laws were intended to forestall;
>
> (3) the directness or indirectness of the asserted injury;
>
> (4) whether the claim rests on some abstract or speculative measure of harm; and
>
> (5) the strong interest in keeping the scope of complex antitrust trials within judicially manageable limits, avoiding both duplicative recoveries and the complex apportionment of damages.

Indium Corp. of America v. Semi-Alloys, Inc., 781 F.2d 879, 882 (Fed. Cir. 1985) (citing Associated General Contractors of California, Inc. v. California State Council of Carpenters, 459 U.S. 519, 537-45 (1983)).

This Court rules that Roche/Hoffmann has sufficiently pled an antitrust injury as to survive Amgen's motion to dismiss. Here is why:

This Court has previously held that a potential competitor does not lack antitrust standing merely because it is not yet in the market. Amtrol, Inc. v. Vent-Rite Valve Corp., 646 F. Supp. 1168, 1176-78 (D. Mass. 1986); see also, e.g., Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 806-07 (D.C. Cir. 2001) (stating that a potential competitor must demonstrate intent and preparedness to enter a market); Bristol-Myers Squibb Co. v. Ben Venue Labs., 90 F. Supp. 2d 540, 545-46 (D.N.J. 2000) (holding that a pharmaceutical competitor yet to receive FDA approval nonetheless had antitrust standing).

Amgen attempts to distinguish these cases by arguing that, in regulated markets, such as the one at issue here, the absence of regulatory approval breaks the causative link required to create antitrust standing. See Amgen Mem. at 4 & n.10 (citing City of Pittsburgh v. West Penn Power Comp., 147 F.3d 256 (3d. Cir. 1998); Bristol-Myers Squibb Co. v. Copley Pharm., Inc., 144 F. Supp. 2d 21 (D. Mass. 2000) (Tauro, J.); Andrx Pharms., Inc. v. Friedman, 83 F. Supp. 2d 179 (D.D.C. 2000), rev'd in part sub nom., Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799 (2001)).

In City of Pittsburgh, the city sued two electrical utilities for antitrust violations in connection with their proposed merger. The Third Circuit held that the city lacked standing to assert an antitrust claim. The court reasoned that the proposed merger did not lessen competition but rather maintained the status quo because one of the two companies never had a license to compete. Any injury was speculative at best because the company without a license might have never obtained one. 147 F.3d at 266-68. City of Pittsburgh is distinguishable because Amgen has alleged that FDA approval of PEG-EPO/CERA is imminent and that Roche/Hoffmann is making meaningful preparations to market PEG-EPO/CERA. Am. Compl. ¶ 28. Moreover, this Court, on October 20, 2006, ruled that FDA approval to sell PEG-EPO/CERA was sufficiently imminent to create an actual controversy to sustain, against Roche/Hoffmann's motion to dismiss, Amgen's patent claims for declaratory relief. Oct. 20, 2006 Order [Doc. No. 121] at 17-18. Amgen cannot have it both ways. Roche/Hoffmann has, unlike the electric company in City of Pittsburgh, demonstrated "a substantial likelihood of undertaking the claimed enterprise." Amtrol, 646 F. Supp. at 1178.

Amgen also cites Bristol-Myers, a case somewhat more similar to the case at bar. In that case, Judge Tauro dismissed the antitrust counterclaim of Copley Pharmaceutical for lack of standing. He based his holding on the following grounds: "Copley

has not received the tentative regulatory approval required for market entry. Copley also is not the first filer, and cannot enter the market until Par's 180 market-exclusivity period expires. Thus the statutory scheme, not Bristol's lawsuit, prevents Copley from entering the market." 144 F. Supp. 2d at 24-25. In noting that Copley did not have FDA approval, Judge Tauro -- as does Amgen in this case -- relied on Andrx, 83 F. Supp. 2d 179, a district court case that was subsequently reversed in part by the D.C. Circuit. In Andrx, the district court appeared to state a broad rule that FDA approval is a necessary requisite to antitrust standing. 83 F. Supp. 2d at 184. On appeal, the D.C. Circuit clarified that the anticipation of FDA approval may suffice since all that is necessary is demonstration of intent and preparedness to enter a market. Andrx, 256 F.3d at 806-08. Here, Roche/Hoffmann has fulfilled the intent and preparedness test.

In any event, Bristol-Myers is distinguishable because Judge Tauro cited, as a second ground, the fact that Copley would have been barred from entering the market even if the patentee had welcomed its entrance because Copley was not the first filer under the statutory scheme. 144 F. Supp. 2d at 24-25. By contrast, in the present case, no competitor other than Amgen stands in the way of Roche/Hoffmann's entering the market.

Bristol-Myers is further distinguishable because in that case, the party alleging antitrust claims did not allege harms relating to litigation expenses. 144 F. Supp. 2d at 25. In the instant case, Roche/Hoffmann has alleged that litigation expenses relating to the Walker Process[2] counterclaim (Counterclaim Count I) constitute present antitrust injury. See CVD, Inc. v. Raytheon Co. 769 F.2d 842, 858 (1st Cir. 1985); Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986, 997 (9th Cir. 1979); Novo Nordisk of N. Am., Inc. v. Genentech, Inc., 885 F. Supp. 522, 525 (S.D.N.Y. 1995). Amgen attempts to distinguish the present case from those just cited by asserting that in those cases the threat of litigation was so overwhelming that the threat alone would have impaired competition. Transcript of Oral Argument [Doc. No. 205] at 13:14-14:6. According to this argument, since Roche/Hoffmann is a multibillion-dollar Swiss corporation which is not going to be stopped by the threat of the present litigation, defending a allegedly fraudulent patent infringement suit is not enough to cause antitrust injury. Id. at 14:7-12. The Court disagrees. In Handgards and Novo Nordisk, the courts held that the enforcement of a patent obtained by fraud may

[2] See Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172 (1965) (holding that the enforcement of a patent procured by fraud on the patent office may violate the Sherman Act, provided the other elements necessary to an antitrust claim are present).

constitute a violation of the Sherman Act, provided the other elements of a claim are established. Handgards, 601 F.2d at 993; Novo Nordisk, 885 F. Supp. at 526; cf. CVD, 769 F.2d at 851 (holding that bad faith prosecution of a trade secrets claim can constitute antitrust injury). This Court reads these cases as conferring antitrust standing upon those who sufficiently plead an antitrust injury based upon the prosecution of a fraudulently obtained patent. Since this Court must here take the facts alleged in the counterclaims in the light most favorable to Roche/Hoffmann and draw all inferences in its favor, Coyne, 972 F.2d at 442-43, this Court, without expressing any opinion as to the merits of the Walker Process claim, holds that Roche/Hoffmann has sufficiently pled a bad faith prosecution of an allegedly invalid patent, and thus has antitrust standing.

III. Miscellaneous Matters

A. Roche/Hoffmann's Sham Litigation Claim and Equitable Estoppel Defense.

On December 20, 2006, this court dismissed without prejudice Roche/Hoffmann's Counterclaim Count II (sham litigation) and Affirmative Defense XII (equitable estoppel). Subsequently, Roche/Hoffmann sought to file an amended answer and counterclaim again asserting these claims. Defs.' Mot. for Leave to Amend Their Answer and Counterclaims [Doc. No. 252]. After carefully

reviewing these submissions, the Court denies Roche/Hoffmann's motion to so amend.

With respect to the sham litigation claim, this Court is not persuaded that Amgen's decision to initiate the International Trade Commission ("ITC") action was objectively baseless. Roche/Hoffmann pled that Amgen's ITC action was intended to harm Roche/Hoffmann through the process rather than through the outcome of ITC's action, allegations that satisfy the two prerequisites for sham litigation under the established law. Nevertheless, Amgen contends that a party that petitions the government in good faith for redress is generally immune from antitrust liability under the Noerr-Pennington doctrine, which protects the right to petition to governmental bodies. See United Mine Workers of Am. v. Pennington, 381 U.S. 657, 669-72 (1965); Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 137-44 (1961).

Courts have established a two-part pleading requirement for overcoming Noerr-Pennington immunity: (1) facts sufficient to show that the challenged petitioning activity is "objectively baseless" in the sense that "no reasonable litigant could realistically expect success on the merits"; and (2) facts showing that the petitioner was subjectively motivated by an intent to use the act of petitioning -- as opposed to the legislative or adjudicated outcome of the petitioning process --

to interfere directly with the business relationships of a competitor. Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60-61 (1993); In re Relafen Antitrust Litigation, 346 F. Supp. 2d 349, 359-60 (D. Mass. 2004).

Roche/Hoffmann has failed to satisfy the first prong. Amgen has sufficiently argued that when it filed its petition with the ITC, it reasonably believed that Roche/Hoffmann had already transgressed, or would imminently transgress, whatever exemption its infringing imports previously enjoyed from liability for violation of 19 U.S.C. § 1337. Amgen's Opp'n to Roche's Mot. to Amend Answer and Counterclaim [Doc. No. 270], at 3-4. As it was, Amgen's petition led to an independent investigation by the ITC. Renee Dubord Brown Decl. [Doc. No. 152], Ex. 1. The fact that the ITC later reached a decision adverse to Amgen's position does not by itself render the claim without foundation. See Professional Real Estate Investors, 508 U.S. at 61 n.5; Bio-Tech. Gen. Corp. v. Genentech, Inc., 886 F.Supp. 377, 381 (S.D.N.Y. 1995) ("[T]he mere fact of losing the underlying lawsuit does not lead to the conclusion that it was a 'sham'"). The "harm" that Roche/Hoffmann alleges may have flowed from the ITC's independent

decision to investigate and allow discovery, not Amgen's conduct.[3]

With respect to the equitable estoppel defense, this Court has previously expressed its skepticism about this affirmative defense because it seems completely inconsistent with the rest of Roche/Hoffmann's argument. See Tr. at 4:18-5:2. Nevertheless, this Court decided to dismiss the defense without prejudice in order to let Roche/Hoffmann plead the facts with more particularity. Id. 19:25-20:2. Although Roche/Hoffmann has moved to amend, this Court remains unpersuaded that this defense should stand.

In order to assert an equitable estoppel defense, Roche/Hoffmann would have to show: (1) affirmative conduct by Amgen inducing the belief that it abandoned its claims against Roche/Hoffmann and (2) detrimental reliance on Roche/Hoffmann's part. See A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020, 1042-43 (Fed. Cir. 1992). Roche/Hoffmann does not allege that Amgen communicated anything misleading directly to it, or that Amgen engaged in misleading conduct during any relationship with Roche/Hoffmann. Rather, Roche/Hoffmann alleges that its own monitoring of Amgen's activities over the course of ten years led it to assume that Amgen would not enforce its

[3] The Court also rejects Roche/Hoffmann's argument that Amgen's patent infringement claims are a sham.

patents. See Proposed Amended Answer ¶ 98; Tr. at 5:3-6:2. This is insufficient to establish an equitable estoppel defense.

B. The State Law Counterclaims

The Court presently denies Amgen's motion to dismiss the state law counterclaims without further analysis. In light of the foregoing, the antitrust counterclaims remain in the case with all their attendant consequences for discovery and trial. There will be time enough at the summary judgement or other pre-trial stages to consider the state law issues upon a developed record.

C. The American jury

There is more to this motion practice than meets the eye. Amgen has largely prevailed in an earlier jury-waived action before this session of this Court. See Amgen, Inc., v. Hoechst Marion Roussel, Inc., 457 F.3d 1293, 1295-97 (recounting procedural history). That exhaustive litigation involved the same patents that are here at issue. It is not surprising therefore, given the permissive venue requirements for patent cases, 28 U.S.C. 1400(b), that Amgen brought the instant declaratory judgement action in the District of Massachusetts and denominated it a "related" case pursuant to Local Rule 40.1(G)(1)-(3) so that it would be assigned to this session of

the Court. Amgen filed a declaratory action seeking only equitable relief, for which there is no right to a trial by jury.

Roche/Hoffmann has a different agenda. For all the reasons Amgen seeks this judge in this Court, Roche/Hoffmann naturally prefers a fresh fact-finder, to wit, an American jury. What is more, in a case with both equitable (non-jury) and legal (jury) issues, the jury determination may govern the equitable decree. Dairy Queen, Inc. v. Wood, 369 U.S. 469, 479 (1962).

These principles markedly change the potential complexion of this case. No matter how shallow the antitrust claims -- and, while they survive this motion to dismiss, they appear somewhat wanting -- they insure (as long as they remain in the case) that the patent issues (e.g., anticipation, infringement) will be tried to a jury. This Court will assiduously insure that the jury has presented to it all those issues which it must resolve. See, e.g., MacNeill Engineering Co., Inc. v. Trisport, Ltd., 126 F. Supp. 2d 51 (D. Mass. 2001) (case tried to a jury); MediaCom Corp. v. Rates Technology, Inc. 34 F. Supp. 2d 76 (D. Mass. 1998) (case for the jury).

Since it appears that judge and jury will be working together to resolve this case, a host of issues necessarily arises. One occurs to me now, and I use this relatively brief memorandum to raise it with the parties:

I will have to explain to the jury the construction of any disputed terms in the patents. Roche/Hoffmann was not a party to the earlier litigation and it is not bound by any of the determinations -- legal or factual -- made therein. See Markman v. Westview Instruments, Inc., 517 U.S. 370, 391 (1996). What then is the status of claim constructions made by this Court and affirmed by the Federal Circuit in the earlier case? Since these constructions are matters of law, id. at 372, do they have precedential force, binding Roche/Hoffmann as well as Amgen in this subsequent case? I express no opinion on this issue but, at an appropriate time, it must be faced.

IV. Conclusion

In accordance with the discussion above, this Court rules that Roche/Hoffmann has standing to bring Counterclaims III, IV, and V, and that prudence counsels denying the dismissal of the state law counterclaims as well. Amgen's motion to dismiss these counterclaims is therefore DENIED. Further, Counterclaim II and Affirmative Defense XII are hereby DISMISSED.

SO ORDERED.

/s/ William G. Young

WILLIAM G. YOUNG
DISTRICT JUDGE