UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No.: 05-12237 WGY
F. HOFFMANN-LAROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN LAROCHE INC., a New Jersey Corporation,	)	
Defendants.	)	

AMGEN INC.'S OPPOSITION TO ROCHE'S MOTION FOR LEAVE TO AMEND ITS COUNTERCLAIMS AND AFFIRMATIVE DEFENSES

Roche's Proposed Amended Answer and Counterclaim ("Amended Counterclaim") fails to cure the deficiencies that previously led this Court to dismiss Roche's sham litigation claim and equitable estoppel defense. Roche's original sham litigation counterclaim failed to allege facts sufficient to show that Amgen lacked an objective basis to file its ITC petition or its complaint in this action, and the Amended Counterclaim fails to rectify this deficiency. Nothing alleged by Roche changes the fact that Amgen had probable cause to petition the ITC for relief, or that the ITC independently decided to proceed with the investigation and independently decided to permit discovery, even though it ultimately disagreed with Amgen's legal argument that Roche's undisputed activities constituted an incipient or imminent violation of Section 337.

Similarly, Roche's effort to replead a sham litigation claim based on this District Court action also fails. Its newly added assertion that Amgen lacks an objective basis to claim

infringement of two of its six patents is not only demonstrably wrong, but insufficient as a matter of law to support a sham litigation claim.[1]

Finally, Roche's amended equitable estoppel defense fails to overcome the fact that, as this Court stated, it is "utterly inconsistent with everything of record that I know of about [Amgen's] conduct."[2] Nothing in the Amended Counterclaim demonstrates any relationship, conduct, statement or communication between Amgen and Roche that could have "lulled" Roche into a sense of security that Amgen would not enforce its patents against Roche. Indeed, to the contrary, Roche, in its own statements, conceded that it fully anticipated a lawsuit by Amgen based on its own observations of Amgen's statements and public actions. Accordingly, Roche's proposed Amended Counterclaim is futile and its request for leave to amend should be denied.[3]

I. ROCHE'S AMENDED COUNTERCLAIM FAILS TO CURE THE DEFICIENCIES NOTED BY THE COURT WITH REGARD TO ITS COUNTERCLAIM THAT THE ITC ACTION WAS SHAM LITIGATION.[4]

Roche sets forth its amended allegations regarding the ITC action in ¶¶46-60 of the Amended Counterclaim.[5] A review of these allegations reveals that all Roche has done is add arguments from its prior briefings to its allegations and reiterated details about the ITC proceeding

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[1] *C.R. Bard, Inc. v. M3 Systems*, 157 F.3d 1340, 1369 (Fed. Cir. 1998) (reversing the district court's finding of sham litigation when the totality of the evidence of sham litigation concerned only one of the two patents in suit).

[2] Hearing Transcript from Motion to Dismiss Hearing, December 20, 2006 ("Hearing Tr.") at 4-5 [Docket No. 196].

[3] *See Foman v. Davis*, 371 U.S. 178, 182 (1962) ("repeated failure to cure deficiencies by amendments previously allowed" and "futility of amendment" are proper grounds for a denial of a motion for leave to amend); *Judge v. City of Lowell*, 160 F.3d 67, 79 (1st Cir. 1998) (denying motion to amend a complaint as futile because the amendment proffered by plaintiff failed to cure the deficiency identified by the court in its prior examination of the third amended complaint); *Glassman v. Computervision Corp.*, 90 F.3d 617, 623 (1st Cir. 1996).

[4] Roche's arguments regarding the standing issue is nothing more than an improper attempt to respond to Amgen's Opposition to Roche's request for leave to file a sur-reply to Amgen's Motion to Dismiss, which included as one basis Roche's lack of standing. In any event, for the reasons set forth in our prior briefing on the point, Roche's arguments on this point fail. If the Court would like Amgen to further brief the issue, Amgen is happy to file a supplemental brief.

[5] Even with this additional attempt to amend, Roche still fails to quantify the costs it allegedly incurred or specifically to identify any other alleged harm it suffered.

that were already before this Court when it ruled that Roche's claim should be dismissed.[6] None of these "new" allegations provide a basis for the Court to reconsider its conclusion that Amgen's filing of the ITC action was protected by *Noerr-Pennington* immunity. Therefore, Roche's sham litigation counterclaim fails.[7]

A. Because Amgen's Decision To Initiate The ITC Action Was Based On ITC Precedents, It Was Objectively Reasonable.

The Supreme Court has held that a "litigation cannot be deprived of immunity as a sham unless the litigation is objectively baseless."[8] Nothing Roche adds in its Amended Counterclaim renders Amgen's action in filing the ITC action objectively baseless. Rather, the ITC's independent action in finding that Amgen's complaint merited further investigation, and the totality of the facts surrounding the ITC action, confirm that there was probable cause for Amgen to press its case, and therefore, do not support a sham litigation claim.

When Amgen filed its petition with the ITC, Amgen reasonably believed that Roche had already transgressed, or would imminently transgress, whatever exemption its infringing imports previously enjoyed from liability for violation of 19 U.S.C. § 1337.[9] A solution to this problem rested with the ITC, [10] because it is the ITC that has the broad power under Section 337 to "prevent

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[6] As noted in *Bio-Tech Gen. Corp. v. Genentech, Inc.* 267 F.3d 1325, 1332 (Fed. Cir. 2001), the entire record of an ITC proceeding may properly be considered by a district court in reviewing a motion to dismiss or claims of "sham litigation."

[7] *Prof. Real Estate Investors, Inc., et al. v. Columbia Pictures Indus., Inc. et al.,("PRE")*, 508 U.S. 49, 60 (1993) (finding that where the "suit is immunized under *Noerr*, [] an antitrust claim premised on the sham exception must fail").

[8] *Id.* at 51.

[9] *See, e.g., In re Certain Variable Speed Wind Turbines & Components Thereof*, Inv. No. 337-TA-376, Initial Determination, 1996 ITC LEXIS 251, at *31-32 (May 30, 1996) ("[P]resumably, there could be an imminent importation without a sale, for example, in the case of a single respondent that already owns a stock of infringing goods overseas and is threatening to bring goods into the United States in short order.").

[10] The public policy behind providing protection to a patentee also demonstrates that Amgen's attempt to avail itself of such protection was objectively reasonable. To allow it to be any other way would mean that a patentee would be effectively deprived of the ability to seek recourse from the ITC for an alleged infringer's actions until after that infringer has received FDA approval and

every type and form of unfair practice," including "unfair acts in their incipiency."[11] Amgen's assertion that the ITC possessed such power was the natural extension of the ITC's prior decisions in *Wind Turbines* and *Copper Rod*, which held that the 1998 amendments to Section 337 "were intended to strengthen the statute's effectiveness in addressing the problems caused by importation of goods that infringe U.S. intellectual property rights" and " . . . did not intend to restrict or limit the Commission's authority to reach unfair acts in their incipiency, which was present in the prior law."[12] Therefore, Amgen's petition was objectively reasonable as it was "warranted by existing law," or at the very least was based on an objectively "good faith argument for the extension, modification or reversal of existing law."[13] Indeed, the ITC found that Amgen's complaint merited further investigation, and independently decided to institute an investigation.[14]

Roche's contention that the ITC's decision against Amgen means that Amgen did not have an objective basis to seek redress in the ITC fails. As the Supreme Court held in *PRE*, "a court must 'resist the understandable temptation to engage in *post hoc* reasoning by concluding' that an ultimately unsuccessful 'action must have been unreasonable or without foundation.'"[15] This is especially true when the adverse decision, like the ITC decision here, is based on an unsettled question of law.[16]

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entered the market, and as a result the patentee's exclusionary rights would be impermissibly compromised. This cannot be what was intended.

[11] *Certain Apparatus for the Continuous Production of Copper Rod*, Inv. No. 337-TA-89, 214 U.S.P.Q. (BNA) 892, 895 (1980).

[12] *Id.*; *see also In re Certain Variable Speed Wind Turbines & Components Thereof*, Inv. No. 337-TA-376, Initial Determination, 1996 ITC LEXIS 251, at *31, 32 (May 30, 1996).

[13] *PRE*, 508 U.S. at 65.

[14] *See In re Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin*, Inv. No. 337-TA-568 ("*In re EPO*"), Notice of Investigation (May 9, 2006) [Decl. of Renee Dubord Brown filed on Nov. 27, 2006, Ex. 1] [Docket No. 152].

[15] *PRE*, 508 U.S. at 61, n.5; *see also Bio-Tech Gen. Corp. v. Genetech, Inc.*, 886 F. Supp. 377, 381 (S.D.N.Y. 1995) ("the mere fact of losing the underlying lawsuit does not lead to the conclusion that it was a 'sham'").

[16] *Id.* at 64-65; *see also C.R. Bard*, 157 F.3d at 1369 ("sham litigation requires more than a failed

At the December 20th hearing on the Motion to Dismiss, the Court noted that it had dealt extensively with the issue of sham litigation in a prior case.[17] That case was *In re Relafen Antitrust Litigation*, 360 F. Supp. 2d. 166 (D. Mass. 2005). Quoting the Supreme Court's holding in *PRE*, this Court noted in *Relafen* that

> [the] 'objective prong' of sham litigation incorporates 'the notion of probable cause, as understood and applied in the common law tort of wrongful civil proceedings.' In that context, 'probable cause to institute civil proceedings requires no more than a reasonable belief that there is a chance that a claim may be held valid upon adjudication.' Just as the existence of probable cause establishes an 'absolute defense' to the tort of wrongful civil proceedings, so too does it 'irrefutably demonstrate[]' that an antitrust defendant is 'entitled to *Noerr* immunity.'[18]

In *Relafen*, because the facts tending to show the existence of probable cause were in dispute, the Court denied the defendant's motion to dismiss the sham litigation claim. Here, however, as this Court implicitly noted when it stated that it had decided as a matter of law that this case could proceed forward, the facts alleged by Roche establish that Amgen had a reasonable belief there was a chance its petition would be sustained.[19] That is, if Amgen's view of the unsettled ITC law was correct, then the facts it alleged, and which Roche does not contest, would support a claim.

Moreover, the ITC's decision to summarily dismiss the investigation was based on its decision of two previously unresolved issues of law, not a determination that Amgen's factual allegations were incorrect, let alone objectively baseless. Accepting as true Amgen's allegations that Roche had filed an application for FDA approval to import and sell peg-EPO in the United States, and was preparing to commence commercial sales in the United States, the Commission nonetheless held that such conduct did not constitute an incipient or imminent violation of Section

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legal theory"); Even today, Amgen has confidence in the legal position it took before the ITC as demonstrated by its recent appeal to the Federal Circuit on this very issue.

[17] Hearing Tr. at 8 [Docket No. 196].

[18] *In re Relafen Antitrust Litigation*, 360 F. Supp. 2d at 179 (D. Mass. 2005).

[19] Hearing Tr. at 8 [Docket No. 196].

337. In addition, the ITC also ruled that the defense created under §271(e)(1) applies to the importation of products made abroad by means of a process claimed in a United States patent, notwithstanding the plain statutory language of 19 U.S.C. §1337(a)(1)(B)(ii) to the contrary. Neither issue has previously been addressed by the Federal Circuit and both issues are now pending before that court as part of Amgen's pending appeal from the ITC decision. Based on these legal arguments, as well as the other arguments advanced by Amgen in its pending appeal of the ITC decision, it was objectively reasonable for Amgen to petition to the ITC for the relief Amgen sought.[20]

B. Roche's Proposed Amended § 271(e)(1) Allegations Still Fail To Establish That The ITC Litigation Was Objectively Baseless.

As noted above, the allegations that Roche asserts in its proposed amended sham litigation counterclaim regarding the ITC litigation were already before this Court when Roche's original sham litigation counterclaim was dismissed. Such an amendment does not cure the deficiencies previously noted by this Court.

Contrary to Roche's assertion, the totality of facts alleged by Roche demonstrates that Amgen's actions were, indeed, objectively reasonable. Roche's Biologics License Application ("BLA") filing, which occurred on April 18, 2006 (before the ITC action was initiated), indicated that Roche believed its product was ready for approval and commercial sale in the United States, and was taking the steps necessary to import peg-EPO for imminent non-exempt sale and use.[21] As Amgen has alleged, these steps included: hiring staff and personnel, including sales representatives and marketing personnel, sufficient to sell peg-EPO immediately upon receipt of market approval;

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[20] *PRE*, 508 U.S. at 64-65*; see also C.R. Bard, Inc. v. M3 Systems*, 157 F.3d at 1369 ("sham litigation requires more than a failed legal theory").

[21] Upon filing a BLA, an alleged infringer is representing to the FDA that its product is safe and efficacious for use by and commercial sale to the public, that the manufacturing process by which the product is made is final, and that it intends to market and sell the product upon receiving FDA approval to do so. *See* 21 C.F.R. §601.2.

retaining consultants necessary to obtain governmental and private reimbursement for customers of peg-EPO in the US; commencing operation of a new facility to manufacture the recombinant human EPO in peg-EPO for export to the United States; and contacting the largest distributors of EPO products in the United States, presumably to generate interest in its pegylated EPO products.

When Roche moved to dismiss the investigation asserting § 271(e)(1) as a defense, the ITC staff found Roche's supporting papers and declarations to be "conclusory" in nature and recommended discovery. The ALJ agreed and ordered discovery to proceed on an expedited and limited basis.[22] Clearly, the ITC staff believed there was a reasonable basis for finding that Amgen's Amended Complaint merited further discovery, and the ALJ agreed.[23] This independent consideration by the ITC, its staff and the ALJ demonstrates that the ITC action was not "objectively baseless."

Furthermore, Roche's own statements and documents have confirmed that Amgen's actions were reasonable. As Roche recently represented to this Court in response to Amgen's Motion to Dismiss Defendants' antitrust claims, and as Amgen alleged in its ITC action, Roche is poised to enter the U.S. market and compete with Amgen's ESA products.[24]

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[22] *See In re EPO*, Order No. 3 Granting Complainant's Motion No. 568-2 for Extension, Setting Procedural Schedule for the Section 271 (e)(1) Defense and Rescheduling Preliminary Conference to July 18 (May 26, 2006), *previously filed with the Court in* Roche's Supplemental Mem., Ex. B [Docket No. 99].

[23] It is important to note that while the ITC ordered discovery, the discovery was not completed. At the time of the Initial Determination, Amgen's motion to compel was pending along with four motions to quash filed by third-parties. Accordingly, the ITC's decision was based on Roche's self-serving declarations, which Amgen was unable to effectively challenge because it was prevented from obtaining the most relevant information through discovery. Such action by the ITC was improper because summary determination is "improper where 'the record contains facts which, if explored and developed, might lead the Commission to accept the position of the nonmoving party.'" *Certain Set-Top Boxes and Components Thereof*, Inv. No. 337-TA-454, 2001 ITC LEXIS 391, Order No. 8 at 7-8 (May 2002) *citing Certain Recombinant Erthropoietin*, Inv. No. 337-TA-281, Initial Determination (Jan. 1989).

[24] *See* Roche's Mem. in Opp. to Amgen's Motion to Dismiss p. 8 [Docket No. 162].

C. Amgen's Action In Initiating The ITC Action Was Not Objectively Baseless And The Court Need Not Consider Amgen's Subjective Motivation.

Because Roche's amended allegations fail to allege facts sufficient to show that Amgen's petition was objectively baseless, the Court does not need to address whether Amgen was motivated by some purpose other than legal redress of its asserted rights.[25] But even if the Court were to reach this issue, the fact remains that Amgen's petition was subjectively reasonable and not pressed for an improper purpose. Amgen initiated the ITC action to protect its rights with respect to patents that had previously been tested, upheld, and enforced. The same facts that demonstrate that Amgen's action was objectively reasonable clearly demonstrate that Amgen also had a subjectively reasonable basis to act as it did. In fact, even in the face of an allegation of sham litigation, Amgen holds firm to its belief that it was entitled to relief from the ITC, and it has appealed the ITC's decision to the Federal Circuit to pursue that relief.

D. Roche's Proposed Amended Counterclaim Still Fails To Plead A Cognizable Harm.

The sham litigation exception does not apply unless it is the process itself, not the requested governmental action, that is used to achieve an anticompetitive effect causing harm.[26] Here the "harm" Roche alleges flows directly from the ITC's independent decisions to institute the investigation and allow limited discovery.[27] Roche's alleged "harm" stems from the ITC's decision , not Amgen's use of the ITC process.

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[25] *PRE*, 508 U.S. at 60 (only after a showing that the suit is objectively baseless, must the court consider the subjective motive); *see also Relafen*, 360 F. Supp.2d at 179 ("The second, subjective prong of the sham definition thus becomes relevant only if a challenged litigation is objectively mertiless.").

[26] "The 'sham' exception to *Noerr* encompasses situations in which persons uses the governmental *process* – as opposed to the *outcome* of that process – as an anticompetitive weapon . . .[T]he purpose of delaying a competitor's entry into the market does not render lobbying activity a 'sham,' unless (as no evidence suggested was true here) the delay is sought to be achieved only by the lobbying process itself, and not by the governmental action that the lobbying seeks." *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 380-81 (1991).

[27] Roche's proposed amendment alleges that Amgen filed its ITC complaint solely to increase Roche's cost, distract key Roche employees, intimidate clinical investigators through discovery

Having failed to plead a "sham litigation," the right to petition the ITC for an investigation of Roche's importation of peg-EPO falls squarely within the immunity provided by *Noerr-Pennington*, which protects those who petition the government for redress, urging government action.[28] The limited *Noerr* exception for government actions that are merely "ministerial" does not apply because the decision to institute an investigation and grant discovery were discretionary acts of the ITC performed after an independent review of Amgen's Amended Complaint and additional briefing. [29] In particular, the ITC's decision to grant discovery was discretionary and therefore not purely ministerial.

For all of these reasons, Roche's request for leave to amend its counterclaim to include a claim for sham litigation should be denied.

II. ROCHE'S FAILURE TO ALLEGE THAT THE ENTIRE DISTRICT COURT COMPLAINT IS BASELESS IS FATAL TO ITS SHAM LITIGATION CLAIM.

In dismissing Roche's original sham litigation counterclaim, the Court warned Roche that it was "very troubled" by Roche's claim with respect to this action, and admonished Roche that:

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subpoenas, and delay CERA's entry. *See* Amended Counterclaim at ¶¶57-60. These allegations are the same allegations, with slightly more detail, that Roche raised in its original counterclaim and therefore, as set forth in Amgen's motion to dismiss they are insufficient because, as in *Sessions Tank*, the harm complained of flows directly from the governmental action, and thus Amgen is not liable. *See Sessions Tank Liners, Inc. v. Joor Mfg., Inc.*, 17 F.3d 295, 299 (9th Cir. 1994) (noting that "Sessions has never proved that it sustained injuries from anything other than the actions of municipal authorities.").

[28] "'Where a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action,' those urging the governmental action enjoy absolute immunity from antitrust liability for the anticompetitive restraint." *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988) *quoting Noerr*, 365 U.S. at 136. *See also Sessions Tank Liners*, 17 F.3d at 299; *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 818 (D.C. Cir. 2001) ("if anticompetitive harm is caused by the decision of a court, even though granted at the request of a private party, no private restraint of trade occurs because the intervening government action breaks the casual chain.").

[29] *See In re: Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 369 (S.D.N.Y. 2002) (stating "in deciding whether a particular type of conduct is petitioning activity for Noerr-Pennington purposes, it is critical to distinguish between activities in which the government acts or renders a decision only after an independent review of the merits of a petition and activities in which the government acts in a merely ministerial or non-discretionary capacity in direct reliance on the representations made by private parties.").

> [y]ou have an awful lot to prove there. And the denial of the motion to dismiss, even if their case now collapses, would seem to make it **improbable, virtually to the point of extinction, that you could recover for the sham litigation defense**."[30]
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> Because when I denied the motion to dismiss, it seems to me on a legal standard I have ruled because I don't make factual findings, that there is a viable claim. Of course I can be reviewed on it. But isn't that inconsistent as matter of law with there being a sham litigation liability on Amgen's part.[31]

Undeterred by the Court's admonition, Roche now seeks to reassert its same baseless sham litigation claim on the shoulders of alleged defects in two of the six patents asserted by Amgen.

A. Amgen's Probable Cause To Institute The District Court Action Precludes Roche's Sham Litigation Claim As A Matter Of Law.

In analyzing Roche's purported sham litigation claim, the Court must assess whether Amgen had probable cause to *institute* the District Court proceeding at the time the action was commenced.[32] Probable cause to *commence* an action is an absolute defense to a claim of sham litigation.[33] "When a court has found that an antitrust defendant claiming *Noerr* immunity has probable cause to sue ...[it] irrefutably demonstrates that an antitrust plaintiff has not proved the objective prong of the sham [litigation claim]."[34] Furthermore, where the facts that formed the basis for bringing the underlying action are not in dispute, "a court may decide probable cause as a matter of law."[35] Here, Roche cannot establish any facts to support a sham litigation claim in connection

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[30] Hearing Tr. at p. 7 (emphasis added) [Docket No. 196].

[31] Id. at p. 8 [Docket No. 196].

[32] "The existence of probable cause to *institute* legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation." *See PRE*, 508 U.S. at 62. Roche agrees that the appropriate inquiry is at the time the proceeding is commenced where it alleges that "Amgen's ITC allegations ***lacked a basis when made."*** *See* Roche's Mem. in Support of Motion to Amend at 8.

[33] *See PRE*, 508 U.S. at 63.

[34] *Id*.

[35] *Id*.

with the District Court action because Amgen had probable cause to institute the litigation and the Court has already denied Roche's Motion to Dismiss on §271(e)(i) grounds.

Amgen's complaint before this Court concerns Roche's conduct with respect to six patents. Roche's sham litigation claim, however, is not asserted with respect to Amgen's pleaded assertion that Roche has directly infringed or will directly infringe claims 1-2 of the '868 patent, claims 4-9 of the '698 patent, claim 7 of the '349 patent and claim 1 of the '422 patent. Accordingly, even if Roche's assertions with respect to the '080 and '933 patents were true, there can be no basis for asserting that Amgen is engaging in sham litigation where Roche has not disputed that Amgen had probable cause to commence this litigation in connection with the four other patents asserted by Amgen and the Court has already rejected Roche's 271(e)(i) defenses.[36] Accordingly, Roche's continuing efforts to assert such a claim are futile.

1. Roche's Arguments Relating to the '080 Patent do not Support its Faulty Sham Litigation Claim.

At the time Amgen filed its amended Complaint in April 2006, the Federal Circuit had not ruled on the applicability of the doctrine of equivalents with respect to claims 2, 3 and 4 of the '080 patent.[37] Indeed, the prior decision of this Court had held that Amgen had successfully rebutted any presumption of estoppel resulting from its amendment of the claims during prosecution, and that Amgen was therefore free to assert infringement of the '080 claims under the Doctrine of Equivalents.[38] Thus, even if Amgen had asserted only the '080 patent, Roche cannot state a claim for sham litigation because there is no dispute that Amgen had probable cause to initiate the District

[36] *See C.R. Bard, Inc. v. M3 Systems*, 157 F.3d at 1369 (reversing the district court's finding of sham litigation when the totality of the evidence of sham litigation concerned only one of the two patents in suit); *VAE Nortrak N. Am., Inc. v. Progress Rail Servs. Corp.*, 459 F. Supp. 2d 1142, 1166 (N.D. Ala. 2006) ("This court's understanding of Noerr-Pennington is that the entire lawsuit - not just certain alleged claims - must be objectively baseless and brought with the requisite level of subjective mal-motive in order for the doctrine not to apply."); *Boston Sci. Corp. v. Schneider (Eur.) AG*, 983 F. Supp. 245, 272-3 (D. Mass. 1997) ("I doubt that the sham litigation exception to the Noerr-Pennington doctrine applies to independent claims as opposed to an entire suit.").

[37] The time for appeal of the Federal Circuit's August 2006 decision has not expired.

Court action. Because Roche's motion to amend its sham litigation claim does not allege and cannot allege any facts to establish that Amgen's claim of infringement was objectively baseless as of April 2006, it should be denied. If, as Roche claims, it has a defense to infringement of the '080 claims, it is free to raise that defense in an appropriate motion on the merits – not in a sham litigation claim.

2. Roche's Argument with Respect to the '933 Patent is Contrary to the Patent Statute.

Roche's assertion in its Amended Counterclaim that claim 9 of the '933 patent, which is dependent on a number of other claims of the '933 patent, was held invalid for lack of definiteness by both this Court and the Federal Circuit is wrong.[39] In addition to Claims 1 and 2 (which contain the disputed language), Claim 9 also claims dependency on Claims 3, 4, 5, or 6, none of which contain the limitations of Claims 1 or 2. Pursuant to 35 U.S.C. § 282:

> A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim.[40]

Accordingly, despite Roche's assertions to the contrary, Claim 9 remains a valid and enforceable claim as it depends from Claims 3, 4, 5, or 6.[41]

In *Amgen Inc. v. Hoechst Marion Roussel, Inc.* ("Amgen I"), this Court found that because the limitation in claim 1 of the '933 patent (which requires the claimed erythropoietin glycoprotein

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[38] *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 287 F. Supp. 2d 126, 159-60 (D. Mass. 2003).

[39] *See* Amended Counterclaim ¶65 [Exhibit A to Docket 251].

[40] *See also Dystar Textilfarben GMBH & Co. Deutschland KG, v. C.H. Patrick Co.*, 464 F.3d 1356, 1372 (Fed. Cir. 2006) ("[D]ependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim."), *quoting Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1370 (Fed. Cir. 2003).

[41] Roche's argument that the assertion of the '933 patent is a "sham" also fails because Roche has chosen to ignore the fact that Amgen has asserted a number of claims (7-8, 11-12, and 14) of the '933 patent that are not dependant on claims 1 and 2, and thus are wholly unaffected by Roche's argument about claim 9. *See* Ex. C to Roche's Motion for Leave to Amend their Answer and Counterclaims (Plaintiff's Response to First Set of Interrogatories (nos. 1-12), Response No. 1).

to have glycosylation which "differs from that of human urinary erythropoietin") was indefinite, the claims of the '933 patent asserted in that litigation were not literally infringed.[42] This Court went on to find that "[b]ecause, ***in this litigation***, Claim 9 is dependent upon either Claim 1 or Claim 2 and the Court has found that GA-EPO literally infringes neither, so too with respect to Claim 9."[43] In making this statement, however, this Court inherently recognized that in a ***different*** litigation, Claim 9 may be asserted as depending on a different independent claim, which is the case herein, such that infringement in this case may still be found.

Based on the plain language of 35 U.S.C. § 282, a multiply-dependant claim, such as claim 9 of the '933 patent, is independently presumed valid and can be independently infringed, despite its dependence on an independent claim that has been held invalid. Indeed, this Court's holding in Amgen I expressly acknowledged the requirements of this statute by noting that "[b]ut for its dependency upon non-infringed claims [in this litigation], judgment of infringement on Claim 9 would be appropriate in light of the evidence regarding the other limitations in Claim 9."[44]

Although on appeal the Federal Circuit affirmed the finding that certain claims of the '933 patent are invalid for indefiniteness under §112, it ***did not*** hold dependent claim 9 to be invalid. Rather, the Federal Circuit held "we agree with the district court that the claims requiring 'glycosylation which differs' are invalid for indefiniteness."[45] As such, only those claims which

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[42] *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 126 F. Supp. 2d 69, 91 (D. Mass. 2001) ("The phrase "glycosylation which differs" is recited only in Claim 1 of the '933 patent and relates to Claims 2 and 9 of the same patent by dependency.").

[43] *See Id.* at 174 (emphasis added) ("Claim 9 recites a "pharmaceutical composition comprising an effective amount [of] a glycoprotein product effective for erythropoietin therapy according to Claim 1, 2, 3, 4, 5, or 6 and a pharmaceutically acceptable diluent, adjuvant or carrier.").

[44] *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 126 F. Supp. 2d at 130.

[45] *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 314 F.3d 1313, 1342 (Fed. Cir. 2003).

require the claimed erythropoietin glycoprotein to have glycosylation which "differs from that of human urinary erythropoietin" were found invalid.[46]

III. ROCHE AGAIN FAILS TO PLEAD AND ESTABLISH THE NECESSARY ELEMENTS OF ITS EQUITABLE ESTOPPEL DEFENSE.

At the December 20th hearing on the Motion to Dismiss, this Court pinpointed the obvious deficiencies in Roche's affirmative defense of equitable estoppel stating that it was:

> utterly inconsistent with everything of record that I know of about their conduct. And because Rule 11 works here, I'm wondering whether you're serious about that defense because it's, because it's so inconsistent.[47]

The response of Roche's counsel was merely to repeat the same inadequate facts and arguments that Roche again asserts in its Amended Counterclaim. After hearing Roche's recitation of facts and argument at the Motion to Dismiss Hearing, the Court found such contentions meritless, and dismissed the equitable estoppel defense, stating: "I see nothing here, I don't see how you can plead [equitable estoppel]."[48] Nothing has changed with the Amended Counterclaim. Roche's "new" allegations are merely a reiteration of the same flawed arguments already rejected by the Court, and, therefore, they are not sufficient to plead the elements of equitable estoppel.

Roche still does not allege any relationship, conduct, statement or communications between Amgen and Roche that could have "lulled" Roche into a sense of security that Amgen would not enforce its patents against Roche.[49] Indeed, to the contrary, Roche, in it own statements conceded that it fully anticipated a lawsuit by Amgen based on Amgen's conduct and public statements. Therefore, Roche cannot plead equitable estoppel as a matter of law because it has not shown, and

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[46] The Federal Circuit's recent decision in Amgen IV noted in a footnote that "in Amgen II, we affirmed the ruling of the district court in Amgen I that claims 1, 2, and 9 of the '933 patent are invalid." *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 457 F. Supp.2d 1293, n.5 (Fed. Cir. 2006).

[47] Hearing Tr. at pp. 4-5 [Docket No. 196].

[48] Hearing Tr. at pp. 19-20 [Docket No. 196].

[49] *A.C. Aukerman Co. v. R.L. Chaides Construction Co.*, 960 F.2d 1020, 1028 (Fed. Cir. 1992).

cannot show, any set of facts that would establish this defense.[50] Therefore, the same result should follow and Roche's Amended Counterclaim should be denied as futile.

A. Roche Cannot Show The Requisite Misleading Relationship, Conduct, Statements Or Communication By Amgen.

Despite what is now Roche's third attempt to adequately plead this affirmative defense, it has not asserted-- because it cannot assert -- any facts that show a relationship, conduct, statement or communication by Amgen directed to Roche that could plausibly be interpreted to support an argument that Amgen "did not intend to press an infringement claim against [Roche]."[51] As the Federal Circuit held in *A.C. Aukerman*, the case upon which Roche relies, equitable estoppel requires some statement or conduct by Amgen directed to Roche in a misleading manner that Roche "will not be disturbed" by Amgen in its activities.[52]

Roche does not allege that Amgen communicated anything misleading directly to it, or that Amgen engaged in misleading conduct during any relationship with Roche, but rather that Roche's own monitoring of Amgen's activities over the course of 10 years led it "to assume" that Amgen would not enforce its patents.[53] This is simply insufficient to establish an equitable estoppel

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[50] Amgen expressly incorporates herein all arguments asserted in connection with Amgen Inc.'s Motion to Strike Roche's Affirmative Defenses Nos. 2, 7, 8, 10 and 12. [Docket No. 153].

[51] *A.C. Aukerman Co*, 960 F.2d at 1042.

[52] *Id.*; *See also R2 Med. Sys. v. Katecho*, Inc., 931 F. Supp. 1397, 1416 (N.D. Ill. 1996) (internal citations omitted) ("[c]ourts have required communication between the parties either somehow encouraging the challenged activity, or indicating an intent to enforce the patent rights followed by inaction.").

[53] In its restated allegations, Roche merely points to a potpourri of unrelated events since 1991, that, even given their broadest interpretation, do not demonstrate any act or communication by Amgen directed to Roche that gave Roche any indication that Amgen would not enforce its patents against it. For instance, one of Roche's restated allegations is that as early as 1991, Amgen knew its patents could not claim generic products covering all EPO analogs *i.e.* derivatives. (Amended Counterclaim ¶ 98, Twelfth Defense). Roche in no way alleges any misleading conduct, statement or communication by Amgen to Roche, but merely recites what it believed Amgen knew and did not know in 1991. Similarly, another of Roche's restated allegations is that by 1998 Amgen was telling the world during its arbitration with Johnson & Johnson that Amgen's Aranesp was not EPO, and not part of the product license of the patents-in-suit. (Amended Counterclaim ¶98, Twelfth Defense). Again, this is not an allegation of a misleading statement, conduct or communication by Amgen to Roche, or any matter in which Roche was even involved. Thus, Roche fails to plead the necessary first element of equitable estoppel.

defense because "[t]he alleged infringer may not rely upon its unilateral expectations or even reasonable hopes in concluding that no possible patent challenge exists."[54]

Moreover, Roche's assumption is inconsistent with the fact that Amgen has consistently told Roche, and has repeatedly stated publicly, that it would vigorously enforce its patents, including but not limited to as early as 2003, when Amgen's CEO openly stated: "we're confident in our patents. We'll defend them vigorously....As we wrap up TKT, we'll get ready for [Roche] if that's what it takes...."[55] Roche has not disputed these facts, but has merely referred to Amgen's public warning statements to Roche as "self-serving" and "irrelevant."[56] However, Amgen's statements are particularly relevant here to demonstrate that Amgen has never wavered in its position to vigorously enforce its patent rights against Roche and has never indicated that it would abandon any claim against Roche for infringement.

B. Roche's Own Statements Refute Any Claim Of Reliance, And Merit The Dismissal Of An Equitable Estoppel Defense.

Reliance "is essential to equitable estoppel."[57] Roche cannot show that it "substantially relied" on any conduct by Amgen in continuing its activities since Roche's own statements directly contradict its claim of reliance. Specifically, Roche's CEO of Global Pharmaceuticals announced to the world, again as early as 2003, that:

[54] *See R2 Med. Sys. v. Katecho, Inc.*, 931 F. Supp. at 1417 (internal citations omitted).

[55] *See* 4/25/06 Decl. of Michael R. Gottfried ("Gottfried Decl.") In Support of Amgen Inc's Opp'n to Defs. Mot. To Dismiss for Lack of Subject Matter Jurisdiction and Failure to State a Claim For Which Relief May Be Granted ("Opp. To Mot. To Dismiss"), Ex. 14 at 6. [Docket No. 54] Additional public warnings by Amgen to Roche that it would vigorously enforce its patent rights against Roche have been previously set forth out in Amgen's Motion to Strike and in the Opp. To Mot. To Dismiss [Docket Nos. 153 and 54, respectively].

[56] *See* Roche's Reply Mem. In Further Support of its Mot. To Dismiss For Lack of Subject Matter Jurisdiction and Failure to State a Claim. [Docket No. 62].

[57] *A.C. Aukerman*, 960 F.2d at 1042.

> [k]nowing 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.**[58]

Roche's statements leave no doubt that Roche expected to be sued by Amgen for its infringing activities and that it believed Amgen would file suit. Such a belief was formed precisely because Amgen's conduct "over the years" demonstrated its consistent and vigorous enforcement of its patents. Roche's own statements not only belie any claim of prejudicial reliance, but also demonstrate that rather than "lulling" Roche into a false sense of security, it was in fact Amgen's unwavering conduct of enforcing its patent rights that led Roche to anticipate it would be sued by Amgen for its infringing activities.[59] Accordingly, Roche's contention now that it actually drew a contrary conclusion from "having observed Amgen over the years" prior to 2003 is nothing short of bad faith.[60]

In addition, as previously detailed by Amgen in its Memorandum in Support of its Motion to Strike, Roche's claims of reliance are in direct conflict with Roche's antitrust claims, which assert that Amgen has vigorously enforced its patents resulting in high barriers to entry into the market.[61]

Roche can present no set of facts to demonstrate that Amgen "lulled" it into a sense of security that Amgen would not assert its patent rights against Roche, particularly where Roche's public statements telegraphed to the world that, having watched Amgen "over the years," Roche fully expected to be sued. As these statements demonstrate, Roche's equitable estoppel defense is baseless. If Roche is allowed to proceed with this defense, Amgen will be prejudiced by an

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[58] *See* Gottfried Decl., Ex. 19 (emphasis added) [Docket No. 54].

[59] Roche cannot plausibly claim reliance on any conduct by Amgen after Roche affirmed that it expected to be sued. Thus, its attempt to argue reliance on Amgen's statement in December 2005, after this action was filed, further demonstrates Roche's bad faith. *See* Amended Counterclaim ¶98, Twelfth Defense.

[60] Even after Roche's 2003 statement and acknowledgement, Roche did not discontinue development of peg-EPO and proceeded with Phase III Clinical Trials in 2004.

[61] *See* Amgen's Memorandum in Support of its Motion to Strike at 16-17 [Docket No. 154].

unjustified expansion of the scope of discovery and unnecessary expenditure of time and litigation resources.

III. CONCLUSION

Based on the foregoing, having failed to overcome the deficiencies previously noted by this Court, Roche's Motion for Leave to file an Amended Answer and Counterclaim should be denied.

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Respectfully Submitted,
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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of electronic filing and paper copies will be sent to those indicated as non-registered participants on February 2, 2007.

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