



Caution

As of: Feb 17, 2012

**NYCOMED US INC., Plaintiff, -against- GLENMARK GENERICS LTD., et al.,
Defendants.**

08-CV-5023 (CBA)(RLM)

**UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW
YORK**

2010 U.S. Dist. LEXIS 29267

March 26, 2010, Decided

March 26, 2010, Filed

SUBSEQUENT HISTORY: Later proceeding at *Nycomed US, Inc. v. Glenmark Generics, Inc.*, 2010 U.S. Dist. LEXIS 33090 (E.D.N.Y., Apr. 5, 2010)

Related proceeding at *Glenmark Pharmaceuticals, S.A. v. Nycomed U.S., Inc.*, 2010 N.Y. Misc. LEXIS 2046 (N.Y. Sup. Ct., Apr. 23, 2010)

PRIOR HISTORY: *Nycomed US, Inc. v. Glenmark Generics, Inc.*, 2010 U.S. Dist. LEXIS 20788 (E.D.N.Y., Mar. 8, 2010)

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff pharmaceutical company sued defendant pharmaceutical companies alleging patent infringement. Plaintiff moved to amend to assert claims for bad faith, unclean hands, and exceptional case. Defendants opposed the motion and moved to file an amended answer alleging inequitable conduct before the Patent and Trademark Office (PTO). The motions were referred to a magistrate for a ruling and for issuance of a report and recommendation.

OVERVIEW: Plaintiff alleged that defendants infringed its patent by seeking approval to market a generic lotion. Defendants denied liability and asserted affirmative defenses and counterclaims. Finding that an exceptional case was not an independent claim, but merely the basis for attorneys' fees in a patent suit, the magistrate granted plaintiff *Fed. R. Civ. P. 15(a)* leave to amend to seek attorneys' fees. However, the magistrate otherwise recommended denying plaintiff leave to amend, finding that its claim for willful infringement based on incorporating by reference a prior pleading did not contain any specific factual allegations, and in any event, such an amendment would be futile since defendants had not engaged in any asserted unlawful activities with respect to the patent. Plaintiffs' unclean hands and bad faith claims were more properly presented on a motion for fees if plaintiff prevailed. However, the court granted defendants' *Rule 15(a)* motion to amend to allege inequitable conduct before the PTO, finding that the motion was timely, defendants were diligent, and plaintiff failed to establish prejudice from granting the motion or that such an amendment would be futile.

OUTCOME: The magistrate granted plaintiff's motion to amend only to permit it to add a request for attorneys' fees; the magistrate otherwise recommended denying plaintiff's motion to amend. The court granted defendants' motion to amend their answer and reopened discovery for the limited purpose of allowing plaintiff take discovery regarding defendants' newly added inequitable conduct allegation.

LexisNexis(R) Headnotes

Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > Leave of Court

Civil Procedure > Judicial Officers > Judges > Discretion

[HN1] Pursuant to *Fed. R. Civ. P. 15*, where a responsive pleading has already been filed, a party may amend its pleading only with the opposing party's written consent or the court's leave, which should be freely granted when justice so requires *Fed. R. Civ. P. 15(a)(2)*. Amendments are favored because they tend to facilitate a proper decision on the merits. Mere technicalities should not prevent cases from being decided on the merits. Consistent with *Rule 15*'s mandate, leave to amend should be granted absent evidence of undue delay, bad faith or dilatory motive on the part of the movant, undue prejudice to the opposing party, or futility. Whether to grant leave to amend is a decision committed to the discretion of the district court.

Civil Procedure > Pleading & Practice > Defenses, Demurrers & Objections > Failures to State Claims
Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > Leave of Court

[HN2] Futility is one of the grounds on which leave to amend a pleading should be denied. An amendment is futile where it fails to state a claim under the principles employed by the court when deciding on a *Fed. R. Civ. P. 12(b)(6)* motion to dismiss. Leave to file an amended pleading must be denied where the proposed pleading fails to state a claim.

Patent Law > Remedies > Collateral Assessments > Attorney Fees

[HN3] Allegations regarding exceptional case do not give rise to a separate cause of action; rather, a party pleading

"exceptional case" is simply noting its intention to move for attorney fees at the conclusion of the case, pursuant to 35 U.S.C.S. § 285.

Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > Leave of Court

[HN4] That amendments would not serve any purpose is a valid ground to deny a motion for leave to amend.

Civil Procedure > Pleading & Practice > Pleadings > Complaints > General Overview

Civil Procedure > Pleading & Practice > Pleadings > Rule Application & Interpretation

[HN5] Although there is no prescribed procedure for referring to incorporated matter, references to prior allegations must be direct and explicit, in order to enable a responding party to ascertain the nature and extent of the incorporation. A *Rule Fed. R. Civ. P. 10(c)* adoption clause that does little more than make wholesale reference to the contents of a prior pleading exemplifies the kind of incorporation that fails to give the requisite guidance to the responding party.

Patent Law > Infringement Actions > Infringing Acts > General Overview

Patent Law > Remedies > Collateral Assessments > Increased Damages

[HN6] The tort of willful infringement arises upon deliberate disregard for the property rights of the patentee and, if proven, may be accompanied by enhanced damages under 35 U.S.C.S. § 284.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

Patent Law > Remedies > Damages > General Overview

[HN7] The Hatch-Waxman Act--which amends the Federal Food, Drug and Cosmetics Act and patent laws--expressly precludes damages or other monetary relief for an act of infringement based on an abbreviated new drug application filing or certification unless there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug. 35 U.S.C.S. § 271(e)(4)(C).

Civil Procedure > Sanctions > Misconduct & Unethical Behavior > General Overview

Patent Law > Infringement Actions > Infringing Acts > General Overview

Patent Law > Remedies > Collateral Assessments > Attorney Fees

[HN8] Litigation misconduct is entirely distinct from willful infringement. Willful infringement is but one of a number of bases on which a court may make an "exceptional case" finding and award fees under 35 U.S.C.S. § 285.

Civil Procedure > Sanctions > Misconduct & Unethical Behavior > General Overview

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[HN9] The U.S. Court of Appeals for the Federal Circuit has expressly declined to equate willful infringement with filing an infringing, and even a baseless, abbreviated new drug application, even when followed by litigation misconduct.

Administrative Law > Judicial Review > Reviewability > Preclusion

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[HN10] Private parties cannot bring actions for misconduct before the U.S. Food and Drug Administration (FDA) under the guise of the Hatch-Waxman Act. The provision of the Hatch-Waxman Act governing certifications by abbreviated new drug application filers cannot be enforced by a private party in a patent infringement action, but must be enforced, if at all, only in the context of an action under the Administrative Procedure Act.

Patent Law > Infringement Actions > Infringing Acts > General Overview

Patent Law > Remedies > Equitable Relief > Injunctions

Patent Law > Statutory Bars > Experimental Use > General Overview

[HN11] 35 U.S.C.S. § 271(e)(4)(B) provides that injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug. 35 U.S.C.S. § 271(e)(4)(B).

Administrative Law > Judicial Review > Reviewability > Preclusion

Governments > Legislation > Statutory Remedies & Rights

[HN12] Private rights of action to enforce federal law must be created by Congress, and a court's search for congressional intent begins and often ends with the text and structure of the statute at issue. Where the statute empowers an agency to enforce its regulations, a court will not assume that Congress intended to authorize by implication additional judicial remedies for private citizens suing to enforce those regulations.

Civil Procedure > Pleading & Practice > Defenses, Demurrers & Objections > Motions to Dismiss

Civil Procedure > Pleading & Practice > Defenses, Demurrers & Objections > Motions to Strike > Immaterial Matters

Civil Procedure > Pleading & Practice > Defenses, Demurrers & Objections > Motions to Strike > Redundant Matters

Civil Procedure > Pleading & Practice > Pleadings > Complaints > Requirements

[HN13] *Fed. R. Civ. P.* 8 requires that a complaint contain a short and plain statement of the claim showing that the pleader is entitled to relief. *Fed. R. Civ. P.* 8(a)(2). The statement should be short because unnecessary prolixity in a pleading places an unjustified burden on the court and the party who must respond to it because they are forced to select the relevant material from a mass of verbiage. To ameliorate this problem, a district court has the power, on its own initiative or in response to a motion by the defendant, to strike any portions of a pleading that are redundant or immaterial, *Fed. R. Civ. P.* 12(f), or to dismiss the complaint.

Civil Procedure > Pretrial Matters > Conferences > Scheduling Conferences

[HN14] *Fed. R. Civ. P.* 16(b) provides that scheduling orders--including provisions limiting the time for amending the pleadings--may be modified only for good cause and with the judge's consent. *Fed. R. Civ. P.* 16(b).

Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > Leave of Court

Civil Procedure > Pretrial Matters > Conferences > Scheduling Conferences

[HN15] Despite the lenient standard of *Fed. R. Civ. P.*

15(a), a district court does not abuse its discretion in denying leave to amend the pleadings after the deadline set in the scheduling order where the moving party has failed to establish good cause.

Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > Leave of Court

Civil Procedure > Pretrial Matters > Conferences > Scheduling Conferences

[HN16] The U.S. Court of Appeals for the Second Circuit in *Parker* did not mandate that the "good cause" standard automatically apply in every case, but rather, upheld a trial court's discretion to deny a late application for failing to meet the "good cause" requirement under *Fed. R. Civ. P. 16(b)*. A moving party's diligence is not the only consideration, and a district court, in exercising its discretion under *Rule 16(b)*, also may consider other relevant factors including, in particular, whether allowing an amendment of the pleading at this stage of the litigation will prejudice the opposing party.

Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > Leave of Court

Evidence > Procedural Considerations > Burdens of Proof > Allocation

[HN17] A party opposing the motion for leave to amend has the burden of establishing that an amendment would be prejudicial.

Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > Leave of Court

[HN18] The type of prejudice that warrants denial of leave to amend is usually such that it puts the opposing party at an unfair disadvantage, such as the addition of a new claim on the eve of trial. In this regard, the need to conduct additional discovery is not, in itself, sufficient to constitute prejudice. The fact that one party has spent time and money preparing for trial will usually not be deemed prejudice sufficient to warrant a deviation from the rule broadly allowing amendment to pleadings. This principle applies with particular force where trial has not yet commenced and is not likely to do so for some time. The fact that discovery has ended does not alter this conclusion. The prejudice that would flow from any additional required discovery can generally be mitigated by adjustments to the discovery schedule.

Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > Leave of Court
Evidence > Procedural Considerations > Burdens of Proof > Allocation

[HN19] A party opposing an amendment has the burden of establishing that leave to amend would be prejudicial or futile.

Civil Procedure > Pleading & Practice > Pleadings > Heightened Pleading Requirements > Fraud Claims

Patent Law > Inequitable Conduct > General Overview
Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview

[HN20] *Fed. R. Civ. P. 9(b)* requires identification of the specific who, what, when, where and how of the material misrepresentation or omission committed before the Patent and Trademark Office (PTO). Although knowledge and intent may be averred generally, a pleading of inequitable conduct under *Rule 9(b)* must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO. A pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy *Rule 9(b)*.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > Elements

[HN21] Information is considered material where either (a) there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent, 37 *C.F.R. § 1.56(a) (1991)*; or (b) it falls within the standards set forth in Patent and Trademark Office Rule 56, which provides that information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (2) it refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the Patent and Trademark Office, or (ii) asserting an argument of patentability.

Evidence > Inferences & Presumptions > Inferences
Evidence > Procedural Considerations > Circumstantial & Direct Evidence

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview

[HN22] In a patent case, intent rarely can be, and need not be, proven by direct evidence. Instead, an intent to deceive is usually inferred from the facts and circumstances surrounding the conduct at issue. Furthermore, the more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa.

Evidence > Inferences & Presumptions > Inferences Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview

[HN23] Intent may be inferred where a patent applicant knew that withheld information would be material to the Patent and Trademark Office's consideration of the patent application, especially where the examiner repeatedly raises an issue to which the information relates.

Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > Leave of Court

[HN24] In making a determination on a motion for leave to amend, a court should not consider the merits of a claim or defense unless the amendment is clearly frivolous or legally insufficient on its face. If the movant has at least colorable grounds for relief, justice requires that the court grant leave to amend.

Civil Procedure > Pleading & Practice > Pleadings > Heightened Pleading Requirements > Fraud Claims

Patent Law > Inequitable Conduct > General Overview

[HN25] The heightened pleading requirements of *Fed. R. Civ. P. 9(b)* do not require that an alleged infringer prove the merits of its claim. What is determinative is that the patentee is given fair notice of the basis for the alleged infringer's inequitable conduct defense.

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JUDGES: ROANNE L. MANN, UNITED STATES MAGISTRATE JUDGE.

OPINION BY: ROANNE L. MANN

OPINION

MEMORANDUM AND ORDER/REPORT AND RECOMMENDATION

ROANNE L. MANN, UNITED STATES MAGISTRATE JUDGE:

Plaintiff Nycomed U.S. Inc. ("Nycomed" or "plaintiff") commenced this civil action on December 12, 2008, alleging that defendants Glenmark Generics Ltd. and Glenmark Generics Inc., USA (collectively, "Glenmark" or "defendant") infringed Nycomed's patent for its Cutivate(R) Fluticasone Lotion 0.05%, *U.S. Patent No. 7,300,669* ("*'669 Patent*"), by seeking approval to market a generic fluticasone lotion. See generally Complaint ("Compl."), ECF Docket Entry ("D.E.") # 1. On January 12, 2009, Glenmark filed its answer to the complaint, denying liability and asserting four affirmative defenses. See generally Answer ("Ans."), D.E. # 10. Glenmark also counterclaimed for declarations that (1) Glenmark's fluticasone lotion product does not infringe any of the claims of the '*'669 Patent*'; (2) the '*'669 Patent* is

invalid; (3) the '669 Patent is unenforceable on account of Nycomed's inequitable conduct before the United States Patent and Trademark Office ("PTO"); and (4) this is an exceptional case, entitling Glenmark to attorney fees [*3] under 35 U.S.C. § 285. See *id.* (Counterclaims) PP 144-52. In a reply filed on February 17, 2009, Nycomed denied the allegations made in Glenmark's counterclaims. See generally Nycomed's Reply to Defendants' Counterclaims, D.E. # 32. With Nycomed's consent, Glenmark amended its answer on July 24, 2009, to drop its affirmative defense of laches; Glenmark's counterclaims remained unchanged. See generally Amended Answer ("Am. Ans."), D.E. # 108; Stipulation Regarding Motion and Defense, D.E. # 104. Nycomed filed its reply to Glenmark's amended pleading on August 10, 2009. See Reply to Defendants' Amended Counterclaims ("8/10/09 Pl. Reply"), D.E. # 123.

By letter dated September 18, 2009, plaintiff sought a pre-motion conference and leave to amend the complaint, in order to assert claims for bad faith, unclean hands, and exceptional case, based on Glenmark's submission of allegedly "false and misleading information" to the Food and Drug Administration ("FDA") and the "withholding of critical information from the Court and Nycomed." See Plaintiff's Motion to Amend/Correct/Supplement Complaint ("9/18/09 Pl. Mot.") at 1, D.E. # 143; *id.* Ex. A ([Proposed] Amended Complaint ("Am. Compl.)) PP [*4] 69, 78-149. Nycomed supplemented its letter-motion by letter dated November 20, 2009. See Reply to Response to Motion ("11/20/09 Pl. Supp."), D.E. # 195. Defendant opposes Nycomed's motion to amend as futile, arguing that Nycomed has failed to plead any cognizable causes of action with regard to any of the prospective additional claims. See Defendant's Response in Opposition to Plaintiff's Motion to Amend ("9/29/09 Def. Opp."), D.E. # 169.

Not to be outdone, Glenmark wrote to the Court on November 13, 2009, seeking leave to file a Second Amended Answer, alleging a new theory of inequitable conduct before the PTO; specifically, Nycomed is alleged to have falsely told the PTO that Nycomed's Cutivate(R) lotion possessed unexpected and superior potency as compared with the prior art Cutivate(R) cream, despite the fact that the FDA had been told that there was no difference in potency between the cream and lotion. See Letter Motion for Leave to File Defendants' Second Amended Answer, Affirmative Defenses and

Counterclaims ("11/13/09 Def. Mot.") at 1, D.E. # 190; *id.* Ex. A (Defendants' [Proposed Second] Amended Answer ("Second Am. Ans.")). Predictably, Nycomed opposes the motion, arguing [*5] that it is "unduly belated" and that the new inequitable conduct claim "fails to meet the standards for pleading" such a claim "with particularity" Response in Opposition to Letter Motion for Leave to File Defendants' Second Amended Answer ("11/18/09 Pl. Opp."), D.E. # 194.

For the reasons that follow, Nycomed's motion to amend its complaint is granted in limited part, to allow Nycomed to include in its *ad damnum* clause an allegation of exceptional case and request for attorney fees; the Court recommends that Nycomed's motion to amend otherwise be denied. Glenmark's motion to amend its pleading is granted.¹

¹ The Second Circuit has characterized a motion to amend as "nondispositive." See *Fielding v. Tollaksen*, 510 F.3d 175, 178 (2d Cir. 2007). Nevertheless, out of an abundance of caution, and because this Court concludes that Nycomed's proposed claims should be foreclosed, this opinion has been designated as a Report and Recommendation that Nycomed's motion to amend to add those claims be denied, and as a Memorandum and Order granting Glenmark's motion to amend and granting Nycomed leave to add a request for attorney fees in its prayer for relief. See generally *Schiller v. City of New York*, No. 04 Civ. 7922(RJS)(JCF), 2009 U.S. Dist. LEXIS 15551, 2009 WL 497580, at *2 (S.D.N.Y. Feb. 27, 2009); [*6] *Wilson v. City of New York*, No. 06 Civ. 219 (ARR)(VVP), 2008 U.S. Dist. LEXIS 35461, 2008 WL 1909212, at *3-4 (E.D.N.Y. Apr. 30, 2008) (collecting cases).

DISCUSSION

[HN1] Pursuant to *Rule 15 of the Federal Rules of Civil Procedure*, where, as here, a responsive pleading has already been filed, a party may amend its pleading "only with the opposing party's written consent or the court's leave[,]" which should be "freely" granted "when justice so requires." *Fed. R. Civ. P. 15(a)(2)*. Amendments are favored because they "tend to facilitate a proper decision on the merits." *Sokolski v. Trans Union Corp.*, 178 F.R.D. 393, 396 (E.D.N.Y. 1998) (internal quotation marks and citations omitted); see also *Monahan v. New York City Dep't of Corr.*, 214 F.3d 275, 283 (2d

Cir. 2000) ("[M]ere technicalities should not prevent cases from being decided on the merits[.]") (citations omitted). Therefore, consistent with Rule 15's mandate, leave to amend should be granted "absent evidence of undue delay, bad faith or dilatory motive on the part of the movant, undue prejudice to the opposing party, or futility . . ." *Id.* at 283 (citing *Foman v. Davis*, 371 U.S. 178, 182, 83 S. Ct. 227, 9 L. Ed. 2d 222 (1962)). [*7] Whether to grant leave to amend is a decision committed to the discretion of the district court. See *Ruffolo v. Oppenheimer & Co.*, 987 F.2d 129, 131 (2d Cir. 1993) (per curiam) (quoting 3 James Wm. Moore et al., *Moore's Federal Practice* P 15.08[4], at 15-64 (2d ed. 1992)).

I. Nycomed's Motion to Amend

In addition to its original claims for direct infringement and inducement of infringement, Nycomed's proposed new pleading contains two new counts: one entitled "Bad Faith and Unclean Hands" (Count Three) and another entitled "Exceptional Case" (Count Four). See Am. Compl. at pp. 17, 31. Although not expressly included in its amended pleading or initial application to amend, Nycomed also purports to add allegations of willful infringement. Compare Transcript of Oral Argument on December 4, 2009 ("12/4/09 Tr.") at 4, and 11/20/09 Pl. Supp. at 5-7, with 9/18/09 Pl. Mot. & Ex. A thereto.

Glenmark opposes Nycomed's amendments, on the ground that each of the proposed claims is futile. See 9/29/09 Def. Opp. at 1, 3. [HN2] Futility is one of the grounds on which leave to amend a pleading should be denied. See *Monahan*, 214 F.3d at 283 (citing *Foman*, 371 U.S. at 182). An amendment is futile where it "fails [*8] to state a claim under the principles employed by the Court when deciding on a *Rule 12(b)(6)* motion to dismiss." *Magee v. Paul Revere Life Ins. Co.*, 172 F.R.D. 647, 650 (E.D.N.Y. 1997) (citations omitted); see also *Champion Titanium Horseshoe, Inc. v. Wyman-Gordon Inv. Castings, Inc.*, 925 F.Supp. 188, 189 (S.D.N.Y. 1996) ("[L]eave to file an amended pleading . . . must be denied where the proposed pleading fails to state a claim.") (citing *Azurite Corp. v. Amster & Co.*, 52 F.3d 15, 19 (2d Cir. 1995)).

As discussed below, this Court concludes that Nycomed has not stated valid claims under any of the three articulated theories.

A. Exceptional Case

Nycomed has conceded, as it must, that [HN3] allegations regarding exceptional case do not give rise to a separate cause of action; rather, a party pleading "exceptional case" is simply noting its intention to move for attorney fees at the conclusion of the case, pursuant to 35 U.S.C. § 285.² See *Eli Lilly & Co. v. Wockhardt Ltd., Cause No. 1:08-cv-1547-WTL-TAB*, 2009 U.S. Dist. LEXIS 85934, 2009 WL 3032349, at *2 (S.D. Ind. Sept. 18, 2009) ("While the parties refer to Lilly's exceptional case allegations as a 'claim,' the Court believes it is more appropriate to view it as an [*9] expression of Lilly's intention to file a § 285 motion following trial in the event it is the prevailing party."); 11/20/09 Pl. Supp. at 3 (citing *Wockhardt*, Nycomed concedes that its "exceptional case allegations are more appropriately viewed as an expression of Nycomed's intention to file a § 285 motion following trial in the event that it is the prevailing party"); 12/4/09 Tr. at 6 (Nycomed acknowledged, at oral argument, that it would be sufficient to include in the *ad damnum* clause a demand for fees under *section 285*).

2 *Section 285* provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party" in patent cases. 35 U.S.C. § 285.

Nycomed should be permitted to amend its complaint to include in its prayer for relief a demand for attorney fees under *section 285*, as Glenmark has done in each of its pleadings. See Ans. at p. 35; Am. Ans. at p. 35; Second Am. Ans. at p. 40. Nycomed's expression of intent to move for fees requires no further verbiage in the pleading. The Court is aware of no precedent that has defined an assertion of "exceptional case" as a separate cause of action.³ Therefore, Nycomed should not be permitted to include a separate [*10] count based on exceptional case, or the allegations underlying that nonexistent cause of action.⁴ As the Second Circuit has opined: [HN4] "That the amendments would not serve any purpose is a valid ground to deny a motion for leave to amend." *Kaster v. Modification Sys., Inc.*, 731 F.2d 1014, 1018 (2d Cir. 1984). If and when Nycomed prevails, it will have an opportunity to make the requisite showing to support its motion for fees.⁵

3 Plaintiff cites the case of *Novartis Pharmaceuticals Corp. v. Teva Pharmaceuticals USA, Inc., No. Civ.A.05-CV-1887 (DM)*, 2005 U.S. Dist. LEXIS 39341, 2005 WL 3664014 (D.N.J.

Dec. 30, 2005), in which a judge of the District of New Jersey declined to strike allegations of "willful infringement/ litigation misconduct," on the ground that those allegations "support [plaintiff's] request for exceptional case status" 2005 U.S. Dist. LEXIS 39341, [WL] at *2. That decision rests on what this Court concludes is a flawed view of "willful infringement" and "exceptional case," see *infra* pp. 10-11, and its reasoning has been rejected by other jurists, including within the same district. See, e.g., *Celgene Corp. v. Teva Pharms. USA, Inc.*, 412 F.Supp.2d 439, 444 (D.N.J. 2006).

4 For the same reason, Glenmark should, in amending [*11] its pleading, drop its fourth counter-claim, entitled "Declaration of Exceptional Case." See Second Am. Ans. (Counterclaims) PP 153-54; see also 12/4/09 Tr. at 40 (Glenmark agrees at oral argument that exceptional case is "not something that needs to be pled").

5 The Court declines the parties' invitation to address the merits of Nycomed's allegations of misconduct, see 9/29/09 Def. Opp. at 2; 11/20/09 Pl. Supp. at 4 -- an issue better left for a later day.

B. Willful Infringement

1. Incorporation By Reference

Although Nycomed's proposed amended complaint and letter-motion of September 18th are silent on the issue of willful infringement, Nycomed alleges in its November 20th supplemental letter, and confirmed at oral argument, that it purports to assert a claim of willful infringement. See 11/20/09 Pl. Supp. at 5-7; 12/4/09 Tr. at 3. Unable to fathom the precise contours of Nycomed's willful infringement claim, the Court infers that it is based at least in part on what Nycomed characterizes as Glenmark's litigation misconduct. See 11/20/09 Pl. Supp. at 5 (citing *Novartis Pharms. v. Teva Pharms.*, 2005 U.S. Dist. LEXIS 39341, 2005 WL 3664014 (discussing plaintiff's "claim of willful infringement/litigation misconduct")). [*12] In order to read a willful infringement claim into its amended complaint, Nycomed relies on *Rule 10(c) of the Federal Rules of Civil Procedure*,⁶ and a single sentence in the proposed pleading, wherein Nycomed "incorporates the subject matter of its August 10, 2009 pleading entitled, 'Nycomed's Reply to Defendants' Amended

Counterclaims,' as if fully set forth herein." Am. Compl. P 69. See 11/20/09 Pl. Supp. at 5-6; 12/4/09 Tr. at 3-4.

6 *Rule 10(c)* provides, in pertinent part, that "statement[s] in a pleading may be adopted by reference elsewhere in the same pleading or in any other pleading or motion." *Fed. R. Civ. P. 10(c)*.

Nycomed's incorporation-by-reference argument is unavailing. [HN5] "Although there is no prescribed procedure for referring to incorporated matter, the references to prior allegations must be direct and explicit, in order to enable the responding party to ascertain the nature and extent of the incorporation." *United States v. Int'l Longshoremen's Ass'n*, 518 F.Supp.2d 422, 461 (E.D.N.Y. 2007) (quoting 5A WRIGHT & MILLER, FEDERAL PRACTICE & PROCEDURE: CIVIL 3d § 1326 (citing, *inter alia*, *Arce v. Walker*, 139 F.3d 329, 336 n.7 (2d Cir. 1998))). A *Rule 10(c)* adoption clause [*13] that does little more than make wholesale reference to the contents of a prior pleading exemplifies the kind of incorporation that fails to give the requisite "guidance to the responding party." *Wolfe v. Charter Forest Behavioral Health Sys., Inc.*, 185 F.R.D. 225, 229 (W.D. La. 1999); accord *Hinton v. Trans Union, LLC*, 654 F.Supp.2d 440, 447-48 (E.D. Va. 2009); see *Levitch v. Columbia Broadcasting System, Inc.*, 94 F.R.D. 292, 295 (S.D.N.Y. 1982).

Here, Nycomed purports to incorporate "the subject matter" of its August 10, 2009 Reply, by an adoption clause arbitrarily inserted at the end of its fact discussion, immediately preceding the declaration of its first claim for direct infringement. See Am. Compl. P 69. Most of the averments in the incorporated pleading make no specific factual allegations, but instead include denials of allegations in defendant's counterclaims. See generally 8/10/09 Pl. Reply, D.E. # 123. To be sure, some of these denials include language alluding to "evidence of Glenmark's willful infringement" in submitting its Abbreviated New Drug Application ("ANDA") to the FDA. See 8/10/09 Pl. Reply PP 49, 50, 55-70, 72, 76-78, 82-93, 98-99, 101-02, 146, 148-50. Nevertheless, [*14] none of Nycomed's pleadings articulates a separate claim for willful infringement, and surely not one based on litigation misconduct. The wholesale incorporation of Nycomed's 8/10/09 Reply thus makes it impossible to ascertain precisely which previously asserted facts are being realleged and for what purpose.⁷ Such an

obfuscating "backdoor" approach to pleading should not be countenanced, notwithstanding *Rule 10(c)*'s broader objective "to encourage pleadings that are short and free of unneeded repetition." *Wolfe*, 185 F.R.D. at 230. Nycomed's proposed amended complaint does not contain a claim for willful infringement, and Nycomed should not be permitted to concoct one by incorporating its entire prior pleading.

7 Moreover, as the Court observed at oral argument, Nycomed's 8/10/09 Reply will be superseded once Nycomed and Glenmark file amended pleadings. See *Levitch*, 94 F.R.D. at 294 ("After the filing of an amended pleading prior pleadings are deemed withdrawn unless specifically referred to."); 12/4/09 Tr. at 8.

2. Willful Infringement vs. Exceptional Case

In any event, even if Nycomed had expressly pled a cause of action for willful infringement, this Court would recommend that it be [*15] disallowed. Nycomed concedes that such a claim would be "surplusage" in this case. See 12/4/09 Tr. at 6, 18. Moreover, it appears that Nycomed misapprehends the gist of a claim for willful infringement.

As the Federal Circuit has explained, [HN6] "[t]he tort of willful infringement arises upon deliberate disregard for the property rights of the patentee" and, if proven, "may be accompanied by enhanced damages" under 35 U.S.C. § 284. *Vulcan Eng'g Co. v. Fata Aluminium, Inc.*, 278 F.3d 1366, 1378 (Fed. Cir. 2002); see also *Yarway Corp. v. Eur-Control USA, Inc.*, 775 F.2d 268, 277 (Fed. Cir. 1985). Here, however, [HN7] the Hatch-Waxman Act -- which amends the Federal Food, Drug and Cosmetics Act ("FFDCA") and patent laws, and under which this patent infringement action was brought -- expressly precludes "damages or other monetary relief" for an act of infringement based on an ANDA filing or certification unless "there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . ." 35 U.S.C. § 271(e)(4)(C).⁸ As it is undisputed that Glenmark has not engaged in any of the aforementioned activities, Nycomed will not [*16] recover damages if it prevails, and there thus can be no damages to enhance under *section 284* based on a finding of willfulness. See 12/4/09 Tr. at 5. Therefore, Nycomed's "claim" of willfulness is of no discernible legal import.

8 Even absent such activities, however, "a court may award attorney fees under *section 285*" in exceptional cases. 35 U.S.C. § 271(e)(4).

Furthermore, relying on *Novartis Pharmaceuticals v. Teva Pharmaceuticals*, 2005 U.S. Dist. LEXIS 39341, 2005 WL 3664014,⁹ Nycomed mistakenly equates "willful infringement" with "exceptional case" and assumes that litigation misconduct may support a finding of willful infringement. See 11/20/09 Pl. Supp. at 5. In fact, the Federal Circuit has made clear that those concepts are not interchangeable, and that [HN8] litigation misconduct is entirely distinct from willful infringement. See *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350 (Fed. Cir. 2004) ("This court has recognized many types of misconduct that may create an exceptional case for purposes of awarding fees, including inequitable conduct before the PTO, *litigation misconduct* such as vexatious or unjustified litigation or frivolous filings, *and willful infringement*." (emphasis added); accord *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1346-47 (Fed. Cir. 2000). [*17] In other words, willful infringement is but one of a number of bases on which a court may make an "exceptional case" finding and award fees under 35 U.S.C. § 285. See *Yamanouchi*, 231 F.3d at 1347 ("In assessing whether a case qualifies as exceptional, the district court must look at the totality of the circumstances.").

9 See *supra* note 3.

Contrary to the premise of Nycomed's theory of willful infringement, [HN9] the Federal Circuit has expressly declined to equate willful infringement with filing an infringing (and even a baseless) ANDA, even when followed by litigation misconduct. In *Glaxo Group*, the Federal Circuit clarified its earlier opinion in *Yamanouchi*:

In *Yamanouchi*, the district court had found that the generic company's ANDA filing constituted willful infringement, but we did not adopt that rationale on appeal. Instead we cautioned that the trial court "need not have elevated the ANDA certification into a finding of willful infringement" and held that Danbury's entire conduct justified the award of attorney's fees Therefore, in

Yamanouchi, we did not agree that the generic company had engaged in willful infringement, but rather determined that an award of attorney's fees [*18] was permitted because the generic had filed numerous baseless filings supporting its fruitless and meritless arguments, both in its case at trial and in its ANDA certification. Such unjustified litigation and misconduct has always justified a finding of an exceptional case.

Glaxo Group, 376 F.3d at 1350 (citations omitted).

As previously noted, and consistent with the rationale of *Glaxo Group*, Nycomed is entitled to amend its complaint to express its intent to pursue an award of attorney fees under 35 U.S.C. § 285; if it prevails, Nycomed may argue to the Court that the case is exceptional, and may proffer Glenmark's alleged misconduct in connection with its ANDA filing and certification, as well as in this litigation.¹⁰ Nycomed may not, however, use its quest for attorney fees as a hook on which to hang an unarticulated and legally defective claim for willful infringement.

10 As previously noted, see *supra* note 5, the Court expresses no view on the merits of Nycomed's allegations of misconduct.

C. Bad Faith and Unclean Hands

Finally, Nycomed seeks to amend the complaint to add allegations of bad faith and unclean hands, based on "Glenmark's submission of false and misleading information [*19] to the FDA . . . and the withholding of critical information from the Court and Nycomed." 9/18/09 Pl. Mot. at 1; see *id.* Ex. A PP 78-147. The Court has already addressed Nycomed's allegations of litigation misconduct, and has concluded that they do not give rise to a separate cause of action for willful infringement.¹¹ Nycomed cannot alter this conclusion simply by affixing a different label to its count. Significantly, Nycomed cites no authority to support its assertion of a claim for "Bad Faith and Unclean Hands." On the contrary, Nycomed seeks to justify its inclusion of allegations of litigation misconduct by characterizing them as "evidence of exceptional case" 9/18/09 Pl. Mot. at 2. Consistent with the rationale of *Glaxo Group*, Nycomed's assertions of litigation misconduct may be presented on a motion for fees should Nycomed prevail. See *Glaxo Group*, 376

F.3d at 1350. Those allegations do not, however, give rise to a separate cause of action, by whatever name.

11 See *supra* pp. 9-11.

Nycomed's allegations of misconduct before the FDA likewise fail to state a legally cognizable claim. According to Nycomed, "Glenmark made material and false and misleading omissions and misrepresentations [*20] to the FDA concerning the bioequivalence clinical study that forms the basis of its ANDA." 9/18/09 Pl. Mot. at 2. Specifically, Nycomed charges that that study was performed "in an invalid fashion that is not permitted by the FDA or by any acceptable standards of clinical study practice and Glenmark significantly deviated from its study protocol." *Id.* This Court agrees with Glenmark that "this is nothing more than a transparent attempt to enforce FFDCa provisions and underlying FDA regulations through a private cause of action." 9/29/09 Def. Opp. at 1.

Nycomed's attempt to plead a claim for misconduct before the FDA contravenes clear and controlling authority that [HN10] private parties cannot bring such actions under the guise of the Hatch-Waxman Act. See *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 777 (Fed. Cir. 2002) (holding that the provision of the Hatch-Waxman Act governing certifications by ANDA filers "cannot be enforced by a private party in a patent infringement action, but must be enforced, if at all, only in the context of an action under the Administrative Procedure Act ('APA')"); *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1376 (Fed. Cir. 2002) (a claim [*21] of improper conduct in an FDA proceeding could not be raised under the FFDCa but would have to be raised initially before the FDA and thereafter in a judicial review proceeding brought under the APA); *Mylan Pharms. v. Thompson*, 268 F.3d 1323, 1332 (Fed. Cir. 2001) (holding that generic drug applicant could not assert a private cause of action challenging the FDA's listing of a particular name-brand drug); see also *AstraZeneca AB v. Mut. Pharm. Co.*, 221 F. Supp. 2d 528, 534 (E.D. Pa. March 12, 2002) (rejecting patentees' argument that "inadequate notice [under the Hatch-Waxman Act by an ANDA filer] constitutes an actionable violation under the Hatch-Waxman Act"; patentees failed to provide any authority for their claim "that poor notice, in and of itself, allows the court to order the withdrawal of an ANDA application or to notify the FDA that it has not fulfilled the notice requirement").

As the Federal Circuit declared in *Mylan Pharmaceuticals*: "We see nothing in the Hatch-Waxman Amendments to alter the statement in section 337(a) of the FDCA that 'all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" [*22] *21 U.S.C. § 337(a) (1994)*.¹² *Mylan Pharms.*, 268 F.3d at 1332.

Nycomed makes no attempt to distinguish the foregoing Federal Circuit precedent, nor does it provide any caselaw sustaining similar private causes of action. Complaining that Glenmark "mischaracterize[s] Nycomed's bad faith and unclean hands allegations as a claim seeking to enforce FDA regulations," 11/20/09 Pl. Supp. at 1, Nycomed cites a series of statutory provisions dealing with *criminal* violations -- and thereby underscores the correctness of Glenmark's objections. See 9/18/09 Pl. Letter at 2 (citing *21 U.S.C. § 335*, and *18 U.S.C. §§ 371, 1001, and 1501*).¹² Nycomed's argument overlooks the firmly established principle that criminal statutes generally cannot be enforced by civil actions. See, e.g., *United States v. Claflin*, 97 U.S. 546, 547, 24 L. Ed. 1082 (1878) (statute that provided a penalty for fraudulently or knowingly importing goods contrary to law "contemplated a criminal proceeding, and not a civil action of debt"); *Official Publ'ns, Inc. v. Kable News Co.*, 884 F.2d 664, 667 (2d Cir. 1989) (mail and wire fraud statutes "do not provide a private right of action").

¹² *Section 335 of Title 21, United States Code*, entitled "Hearing [*23] before report of criminal violation," provides that before referring a violation of the FDCA to a United States Attorney's Office for criminal prosecution, the Secretary of Health and Human Services must give the target notice and an opportunity to be heard. See *21 U.S.C. § 335*. The three provisions of the federal criminal code cited by Nycomed likewise in no way purport to create private causes of action. See *18 U.S.C. § 371* (making it a crime to conspire to commit a federal offense or to defraud the United States or any agency thereof); *18 U.S.C. § 1001* (making it a crime to make a materially false representation, or conceal a material fact, in a matter within the jurisdiction of a branch of the federal government); *18 U.S.C. § 1501* (making it crime to assault or resist a person attempting to serve a legal writ or process of a federal court). With respect to the latter, the

Court assumes that Nycomed intended to cite *18 U.S.C. § 1505*, which makes it a crime to obstruct proceedings before federal departments and agencies.

In its supplemental submission, Nycomed devises two new arguments. First, Nycomed cites a series of cases addressing "the inherent power of the court to impose sanctions [*24] for bad-faith conduct." 11/20/09 Pl. Supp. at 3. However, that inherent power extends to abusive litigation practices, and not to alleged misconduct before an administrative agency. Moreover, a court's power to levy sanctions for litigation abuses does not create a corresponding cause of action, and none of the cited cases holds otherwise. Nycomed had the right to move for sanctions based on Glenmark's alleged withholding of documents in this case; it did so, the Court ruled, and Nycomed continues to litigate this issue *ad nauseum*. The Court's "inherent powers" do not entitle Nycomed to pursue a "claim" for discovery misconduct.

As its latest alternative legal theory, Nycomed relies on the language of [HN11] *35 U.S.C. § 271(e)(4)(B)*, which provides that "injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug" *35 U.S.C. § 271(e)(4)(B)*; see 11/20/09 Pl. Supp. at 2; see also 12/4/09 Tr. at 25-27. Nycomed ignores the plain language of that provision, which provides that "[f]or an act of infringement," including the filing of an ANDA for an [*25] infringing drug, the court may grant such injunctive relief "against an *infringer*" *35 U.S.C. § 271(e)(4)(B)* (emphasis added). In other words, an injunction may be granted to prevent the commercial manufacture, use, sale or importation of a drug *that has been found to be infringing*. In contrast, Nycomed's demand for equitable relief, such as "[a]n Order directing the Parties to inform the FDA of the materially false and misleading omissions and misrepresentations in Glenmark's ANDA," and "[a]n Order requiring Glenmark to withdraw its ANDA,"¹³ is independent of Nycomed's infringement claims; Nycomed would have the Court grant such relief on the basis of Glenmark's alleged violations of FDA regulations and criminal statutes, regardless of whether or not Glenmark is guilty of patent infringement. *Section 271(e)(4)(B)* does not authorize such relief or such a cause of action.

13 See Am. Compl. at p. 33.

It is hornbook law that [HN12] "private rights of action to enforce federal law must be created by Congress," and that a court's search for congressional intent begins and often ends with the text and structure of the statute at issue. *Alexander v. Sandoval*, 532 U.S. 275, 286, 289, 121 S. Ct. 1511, 149 L. Ed. 2d 517 (2001). [*26] Where, as here, the statute empowers an agency to enforce its regulations, the Court will not assume that Congress intended to authorize by implication additional judicial remedies for private citizens suing to enforce those regulations. See *id.* at 289; *Middlesex County Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 14-15, 101 S. Ct. 2615, 69 L. Ed. 2d 435 (1981). Accordingly, Nycomed does not state a legally cognizable claim for "bad faith and unclean hands" based on Glenmark's alleged misconduct before the FDA.

Finally, it bears noting that the inclusion of Nycomed's allegations of misconduct before the FDA are merely a pretext for putting this information before that agency. During oral argument, Nycomed's counsel stated:

We're not asking for a private cause of action, we're not asking for relief against the FDA. . . . [W]e have these documents that show [Glenmark] did the fraud. The FDA should be informed about that.

12/4/09 Tr. at 12. The Court then asked if the instant dispute is really about "whether or not the protective order should be modified or designations should be modified so that you're authorized as opposed to directed to inform the FDA?" *Id.* Plaintiff's counsel agreed: "That's what we mean, that's [*27] better said." *Id.*¹⁴

14 This Court has since dealt directly with the problem of overdesignation of allegedly confidential information. See Memorandum and Order (March 8, 2010), D.E. # 250.

Stated differently, Nycomed has improperly used its motion to amend as a vehicle by which it seeks to air its various grievances against Glenmark, despite their lack of connection to any valid cause of action. Simply put, Nycomed's proposed pleading is "littered with unnecessary . . . language in the nature of trash-talking." *Roberto's Fruit Mkt. v. Schaffer*, 13 F.Supp.2d 390, 396 (E.D.N.Y. 1998).

[HN13] *Rule 8 of the Federal Rules of Civil Procedure* requires that a complaint "contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." *Fed. R. Civ. P. 8(a)(2)*. The Second Circuit has declared that "[t]he statement should be short because '[u]nnecessary prolixity in a pleading places an unjustified burden on the court and the party who must respond to it because they are forced to select the relevant material from a mass of verbiage.'" *Salahuddin v. Cuomo*, 861 F.2d 40, 42 (2d Cir. 1988) (quoting 5 Wright & Miller, *Federal Practice & Procedure* § 1281, at 365 (1969)); [*28] accord *Jones v. Nat'l Commc'ns & Surveillance Networks*, 266 F.App'x 31, 32 (2d Cir. Feb. 21, 2008); *Infanti v. Scharpf*, No. 06 CV 6552 (ILG), 2008 U.S. Dist. LEXIS 45501, 2008 WL 2397607, at *1 (E.D.N.Y. June 10, 2008). To ameliorate this problem, the district court "has the power, on its own initiative or in response to a motion by the defendant, to strike any portions [of a pleading] that are redundant or immaterial, see *Fed.R.Civ.P. 12(f)*, or to dismiss the complaint." *Salahuddin*, 861 F.2d at 42; see *In re Merrill Lynch & Co. Research Reports Sec. Litig.*, 218 F.R.D. 76, 78 (S.D.N.Y. 2003).

As in the case of *Pappas v. Bank of America Corp.*, 309 F.App'x 536, 539 (2d Cir. Feb. 17, 2009), the problems with each of the three proposed new claims should have been apparent to Nycomed before moving to add them to the complaint. Because the three claims could not survive a motion to dismiss, and the supporting factual allegations would be stricken as immaterial under *Rule 12(f)*, Nycomed's motion to amend the complaint should be denied as futile, except that Nycomed may add to the section entitled "Relief Sought" a demand for attorney fees under 35 U.S.C. § 285.

II. Glenmark's Motion to Amend

Glenmark seeks to amend its [*29] already amended answer in order to substitute a new counterclaim and affirmative defense alleging that Nycomed engaged in inequitable conduct before the PTO. Specifically, the proposed pleading asserts that Nycomed falsely represented to the PTO that results of testing unexpectedly established that Nycomed's fluticasone propionate (Cutivate(R)) lotion exhibited greater vasoconstriction (potency) than the prior art fluticasone propionate cream. Glenmark further alleges in its proposed pleading that the information furnished to the PTO was intentionally false, and was contrary to

information previously provided to the FDA, in connection with the New Drug Application ("NDA") filing for Cutivate(R) lotion; the FDA had been advised of the results of a 1998 study (FPLA 1001) that showed no statistical difference in the efficacy of the fluticasone creams and lotions. According to Glenmark, the false information provided to the PTO misled the Patent Examiner into withdrawing rejections of the patent based on obviousness. See Second Am. Ans. (Counterclaims) PP 55-72. Based on the aforesaid allegations, Glenmark proposes to assert an affirmative defense that "[p]laintiff's claims are unenforceable [*30] due to inequitable conduct," *id.* (Affirmative Defenses) P 79, and a corresponding counterclaim. See *id.* (Counterclaims) PP 149-52.

Nycomed opposes Glenmark's motion to amend on several grounds: that the request is untimely, highly prejudicial to Nycomed, and fails to meet the pleading standards mandated by *Rule 9(b) of the Federal Rules of Civil Procedure*, as construed by the Federal Circuit in *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009). See 11/18/09 Pl. Opp. at 1-3, D.E. # 194. For the reasons discussed below, this Court disagrees.

A. Timeliness

Noting that fact discovery closed on August 17, 2009, Nycomed complains that Glenmark's application is "extremely belated," coming "more than three months after it completed all of the discovery that it claimed it needed." 11/18/09 Pl. Opp. at 1, 2 (emphasis in original); see 12/4/09 Tr. at 84 (stating that Glenmark's delay is "way too long"). In an argument raised for the first time at oral argument, Nycomed asserts that the absence of prejudice "isn't important in the Second Circuit" in determining whether to grant leave to amend. See 12/4/09 Tr. at 81 (citing *Parker v. Columbia Pictures Indus.*, 204 F.3d 326 (2d Cir. 2000); [*31] *Oppenheimer v. Metal Mgt., Inc.*, No. 08 Civ. 3697 (LTS)(FM), 2009 U.S. Dist. LEXIS 71608, 2009 WL 2432729 (S.D.N.Y. July 31, 2009)). Nycomed's argument rests on a distorted reading of the law in this circuit.

In *Parker*, the Second Circuit considered the interplay between *Rule 15(a)*, which provides that leave to amend shall be "freely give[n]," *Fed. R. Civ. P. 15(a)*, and [HN14] *Rule 16(b)*, which now provides that scheduling orders -- including provisions limiting the time for amending the pleadings -- "may be modified

only for good cause and with the judge's consent." *Fed. R. Civ. P. 16(b)*. The Second Circuit held in *Parker* that [HN15] "despite the lenient standard of *Rule 15(a)*, a district court does not abuse its discretion in denying leave to amend the pleadings after the deadline set in the scheduling order where the moving party has failed to establish good cause." *Parker*, 204 F.3d at 340.

Although he was on notice of the information supporting the proposed amendment at the time he commenced the lawsuit, the plaintiff in *Parker* did not seek leave to amend until after the defendant moved for summary judgment. The district court therefore found that the plaintiff had not demonstrated cause for failing to comply with the court's [*32] deadline, and it refused to allow him to amend. See *id.* at 340-41. On appeal, the Second Circuit concluded that the district court "did not abuse its discretion in denying the request on the basis of untimeliness." *Id.* at 339.

Relying on *Parker* and Magistrate Judge Maas' opinion in *Oppenheimer*, 2009 U.S. Dist. LEXIS 71608, 2009 WL 2432729, at *2, Nycomed argues that "the mere absence of prejudice is not sufficient to satisfy the good cause requirement of *Rule 16(b)*." 12/4/09 Tr. at 81. Nycomed overlooks the fact that in deciding whether to grant leave to amend, a court is not required to consider *Rule 16(b)* in isolation. As the court observed in *Calabro v. Stone*, No. CV 2003-4522 CBA MDG, 2005 U.S. Dist. LEXIS 5527, 2005 WL 327547 (E.D.N.Y. Jan. 27, 2005): [HN16] "[T]he Second Circuit in *Parker* did not mandate that the 'good cause' standard automatically apply in every case, but rather, upheld a trial court's *discretion* to deny a late application for failing to meet the 'good cause' requirement under *Rule 16(b)*." *Id.* at *1 (emphasis in original); accord *Bridgeport Music, Inc. v. Universal Music Group, Inc.*, 248 F.R.D. 408, 412 (S.D.N.Y. 2008). In fact, in an opinion that post-dates *Parker*, the Second Circuit expressly noted that the moving party's [*33] diligence "is not . . . the only consideration," and that the district court, in exercising its "discretion under *Rule 16(b)*, also may consider other relevant factors including, in particular, whether allowing the amendment of the pleading at this stage of the litigation will prejudice" the opposing party. *Kassner v. 2nd Ave. Delicatessan Inc.*, 496 F.3d 229, 244 (2d Cir. 2007); accord *Jackson v. Roslyn Bd. of Educ.*, 596 F.Supp.2d 581, 585 (E.D.N.Y. 2009); see also *Holmes v. Grubman*, 568 F.3d 329, 334-35 (2d Cir. 2009) (stating that "the lenient standard under *Rule 15(a)* . . . must be balanced against" the

requirements of *Rule 16(b)*). Thus, "the Court [of Appeals] left open the possibility that amendments could be permitted even where a plaintiff had not been diligent in seeking an amendment," inasmuch as "both Rules should be considered simultaneously" and the factors balanced. *Castro v. City of New York*, No. 06-CV-2253 (RER), 2010 U.S. Dist. LEXIS 19935, 2010 WL 889865, at *2 (E.D.N.Y. March 6, 2010).

In this case, after balancing the *Rule 16(b)* and *Rule 15(a)* considerations, the Court rejects Nycomed's timeliness challenge.

1. Glenmark's Diligence

The deadline for amending the pleadings in this case was June 2, [*34] 2009. See Schedule (Feb. 17, 2009), D.E. # 30-1. Glenmark argues that it did not become aware of the inconsistent representations to the FDA and PTO until depositions that were held at the end of July 2009, see 12/4/09 Tr. at 65, and that it waited for this Court to rule on its motion to compel related answers to interrogatories before seeking permission to amend. See id. at 65-66; 11/13/09 Def. Mot. at 3.¹⁵ Nycomed counters that this purported justification "makes no sense": While "Glenmark is essentially arguing that it waited all this time because it did not have sufficient discovery to support the counterclaim," it nevertheless is now seeking to add those allegations despite the fact that the Court denied its request for the awaited discovery. See 11/18/09 Pl. Opp. at 2.

15 The motion was denied on October 20, 2009. See Memorandum and Order (Oct. 20, 2009), at 4, D.E. # 185.

Glenmark cannot be faulted for failing to comply with the June 2nd deadline for amending the pleadings; like Nycomed, it did not acquire the information underlying the proposed amendment until after the expiration of that deadline.¹⁶ Nycomed does not dispute, and the Court finds, that Glenmark had good cause [*35] for failing to move before the June 2nd deadline. In essence, what Nycomed complains of is not Glenmark's failure to comply with the deadline, but rather its failure to move sooner *after* the deadline.

16 Nycomed's motion to amend -- which was still pending when Glenmark filed its cross-motion -- was likewise filed after the June 2nd deadline for amending the pleadings, as well

as after the August 17th deadline for fact discovery. See 9/18/09 Pl. Mot. Moreover, Glenmark's motion preceded (by one week) Nycomed's letter-brief supplementing its own motion to amend the complaint. See 11/13/09 Def. Mem.; 11/20/09 Pl. Supp.

Although the justification proffered by Glenmark cannot be characterized as compelling, it is not, as Nycomed suggests, irrational. That Glenmark preferred to have additional discovery before drafting its amended pleading is entirely understandable, and a three-month delay does not qualify as "extremely belated," 11/18/09 Pl. Opp. at 1, especially when contrasted with far longer delays that have been tolerated by courts in granting motions to amend. See *Margel v. E.G.L. Gem Lab Ltd.*, No. 04 Civ. 1514(PAC)(HBP), 2010 U.S. Dist. LEXIS 10622, 2010 WL 445192, at *10 (S.D.N.Y. Feb. 8, 2010) (granting motion [*36] to amend despite delay of at least six months; collecting Second Circuit cases allowing amendments after delays ranging from two to five years); *Pall Corp. v. Cuno Inc.*, 681 F. Supp. 2d 258, 2010 U.S. Dist. LEXIS 4175, 2010 WL 301954, at *5 (E.D.N.Y. 2010) (although the two related cases had been pending for twelve and six years, no trial date had yet been set); see also *Johnson & Johnson v. Guidant Corp.*, No. 06 Civ. 7685(RJS), 2010 U.S. Dist. LEXIS 13936, 2010 WL 571814, at *6 n.7 (S.D.N.Y. Feb. 16, 2010) (although *Rule 16(b)* deadline for amending the pleadings had expired nearly one year earlier, court would reach the merits of plaintiff's motion to amend); *Zomba Recording Corp. v. MP3.com, Inc.*, No. 00 Civ. 6831(JSR), 2001 U.S. Dist. LEXIS 9647, 2001 WL 770926, at *1 (S.D.N.Y. July 10, 2001) (despite "extended delay," court exercises its discretion to allow amendment in the absence of prejudice). Notwithstanding Parker, the Second Circuit has not abrogated the principle that delay alone, in the absence of bad faith or prejudice, is usually not sufficient reason for denying a motion to amend. See *Parker*, 204 F.3d at 339; *Ruotolo v. City of New York*, 514 F.3d 184, 191 (2d Cir. 2008). The Court therefore turns to Nycomed's claim of prejudice.

2. Prejudice

[HN17] "The [*37] party opposing the motion for leave to amend has the burden of establishing that an amendment would be prejudicial." *Kirkland v. City of New York*, No. 06 CV 0331(NG)(CLP), 2007 U.S. Dist. LEXIS 38374, 2007 WL 1541367, at *3 (E.D.N.Y. May

25, 2007) (internal quotation and citation omitted). Nycomed argues that it will be "highly prejudiced" if the amendment is allowed, because the facts necessary to Nycomed's defense to such inequitable conduct allegations reside with third parties, such as the original applicants/owners of the '669 Patent, the original inventors of the '669 Patent, the attorneys who drafted the application, and the FPLA 1001 investigators.¹⁷ 11/18/09 Pl. Opp. at 2. When the Court inquired at oral argument whether the prejudice would be mitigated if the Court reopened discovery, Nycomed's counsel avoided a direct response, and instead asserted -- incorrectly -- that "[p]rejudice isn't important . . ." 12/4/09 Tr. at 81; but see *supra* pp. 20-21.

17 Nycomed also includes the Patent Examiner on its list. See 11/18/09 Pl. Opp. at 2. However, discovery of the Patent Examiner is not permitted. See *W. Elec. Co., Inc. v. Piezo Tech.*, 860 F.2d 428, 432 (Fed. Cir. 1988) (patent examiners are quasi-judicial [*38] officials who cannot be compelled to testify regarding their mental processes in reaching a decision on a patent application).

[HN18] "The type of prejudice that warrants denial of leave to amend is usually such that it puts [the opposing party] at an unfair disadvantage," such as the addition of a new claim on the eve of trial. See *In re Osage Exploration Co.*, 104 F.R.D. 45, 49 (S.D.N.Y. 1984); see *Monahan v. New York City Dep't of Corr.*, 214 F.3d 275, 284 (2d Cir. 2000) ("[W]e will be most hesitant to allow amendment where doing so unfairly surprises the non-movant and impedes the fair prosecution of the claim."); *Margel*, 2010 U.S. Dist. LEXIS 10622, 2010 WL 445192, at *11 (court allows plaintiffs to amend to assert new theory, because "it will not result in an undue burden") (collecting cases). In this regard, "the need to conduct additional discovery is not, in itself, sufficient to constitute prejudice." *Margel*, 2010 U.S. Dist. LEXIS 10622, 2010 WL 445192, at *12 (citing, *inter alia*, *S.S. Silberblatt, Inc. v. East Harlem Pilot Block*, 608 F.2d 28, 43 (2d Cir. 1979)); accord *Lawrence v. Starbucks Corp.*, No. 08 Civ. 3734(LTS)(JCF), 2009 U.S. Dist. LEXIS 114909, 2009 WL 4794247, at *4 (S.D.N.Y. Dec. 10, 2009); *Hampton Bays Connections, Inc. v. Duffly*, 212 F.R.D. 119, 123 (E.D.N.Y. 2003); [*39] see also *Monahan*, 214 F.3d at 284 ("the fact that one party has spent time and money preparing for trial will usually not be deemed prejudice sufficient to warrant a deviation

from the rule broadly allowing amendment to pleadings"). This principle applies with particular force where, as here, "trial has not yet commenced and is not likely to do so for some time." *S.S. Silberblatt*, 608 F.2d at 42. The fact that discovery has ended does not alter this conclusion. See *Hampton Bays Connections*, 212 F.R.D. at 123. "The prejudice that would flow from any additional required discovery can generally be mitigated by adjustments to the discovery schedule." *Margel*, 2010 U.S. Dist. LEXIS 10622, 2010 WL 445192, at *12; accord *Calabro*, 2005 U.S. Dist. LEXIS 5527, 2005 WL 327547, at *2 (finding "no prejudice since defendant will be given an opportunity to conduct discovery" regarding the new claim).

Judged by these standards, Nycomed's claim of prejudice is unavailing. In the circumstances presented, where the Court is prepared to reopen discovery to allow Nycomed to obtain the information needed to meet the new allegations, Nycomed has identified no legally cognizable prejudice. Although discovery has closed, no trial date has been set and none is likely [*40] to be set in the near future, while Nycomed relentlessly presses for discovery sanctions and/or additional discovery regarding Glenmark's electronically stored information, and while the parties litigate the propriety of the Court's order striking the *Markman* submissions, as well as the appointment of a special master.¹⁸ In short, this case is hardly at an advanced stage of litigation and Nycomed has exhibited no eagerness to accelerate the pace of these proceedings. To reopen discovery on the inequitable conduct allegations would not unduly delay the case or unfairly disadvantage Nycomed. The Court therefore rejects Nycomed's timeliness challenge and reaches the merits of its argument that the proposed amendment would be futile. See generally *Jackson*, 596 F.Supp.2d at 586 (despite five-month delay, which the court characterizes as "some evidence of a lack of diligence," the court reaches the merits of plaintiff's proposed new claim: "Although the plaintiff was slow to file the instant motion, the claimed prejudice is not the type of prejudice that the Court regards as a bar to amendment.").

18 See, e.g., Plaintiff's Letter In Response to Factual Matters Regarding Glenmark's ESI Search [*41] (Feb. 17, 2010), D.E. # 235; Defendant's Motion for Reconsideration Regarding Order on Motion for Reconsideration (Jan. 4, 2010), D.E. # 214; Plaintiff's Response in Opposition to Letter Motion to Appoint Special Master (March 3,

2010), D.E. # 247.

B. Futility

Nycomed next contends that Glenmark's inequitable conduct allegations fail to meet the pleading standards enunciated by the Federal Circuit in *Exergen*, 575 F.3d 1312. See 11/18/09 Pl. Opp. at 2-3. Nycomed thus opposes Glenmark's motion to amend on the ground of futility. As courts in this circuit have repeatedly held, [HN19] "[t]he party opposing an amendment has the burden of establishing that leave to amend would be prejudicial or futile." ¹⁹ *Staskowski v. County of Nassau*, 05 Civ. 5984(SJF)(WDW), 2007 U.S. Dist. LEXIS 86319, 2007 WL 4198341, at *4 (E.D.N.Y. Nov. 21, 2007); accord *Margel*, 2010 U.S. Dist. LEXIS 10622, 2010 WL 445192, at *3; *Penn Mut. Life Ins. Co. v. Madow*, No. CV 07-3188(AKT), 2009 U.S. Dist. LEXIS 25416, 2009 WL 804719, at *3 (E.D.N.Y. March 26, 2009); *Lugosch v. Congel*, 00-CV-784, 2002 U.S. Dist. LEXIS 8455, 2002 WL 1001003, at *1 (N.D.N.Y. May 14, 2002); *Blaskiewicz v. County of Suffolk*, 29 F.Supp.2d 134, 137-38 (E.D.N.Y. 1998); *Harrison v. NBD Inc.*, 990 F.Supp. 179, 185 (E.D.N.Y. 1998). Nycomed has not met its burden.

19 Regional [*42] law governs procedural matters not unique to patent law. See, e.g. *Pressure Prods. Med. Supplies v. Greatbatch Ltd.*, 599 F.3d 1308, 2010 U.S. App. LEXIS 6132, 2010 WL 1051154, at *3 (Fed. Cir. March 24, 2010); *Exergen*, 575 F.3d at 1318.

In *Exergen*, the Federal Circuit clarified the heightened standard for pleading inequitable conduct, a concept related to fraud. Specifically, *Exergen* held that [HN20] "*Rule 9(b)* requires identification of the specific who, what, when, where and how of the material misrepresentation or omission committed before the PTO." 575 F.3d at 1327; see *id.* at 1328. The court further declared that

although 'knowledge' and 'intent' may be averred generally, a pleading of inequitable conduct under *Rule 9(b)* must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this

information with a specific intent to deceive the PTO.

Id. at 1328-29. Accordingly, "[a] pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, [*43] does not satisfy *Rule 9(b)*." *Id.* at 1326-27.

Glenmark's proposed amended pleading asserts the following inequitable conduct before the PTO: Nycomed's allegedly false representation to the PTO that Nycomed's fluticasone propionate lotion was unexpectedly found to exhibit greater vasoconstriction than the prior art fluticasone propionate cream, and Nycomed's allegedly deceitful withholding of the contrary test results furnished to the FDA in connection with the NDA filing for the same lotion. See Second Am. Ans. (Counterclaims) PP 51-72. Glenmark identifies a particular individual (Robert Anderson) alleged to have been responsible for the omission and false statement to the PTO: the person who conducted the due diligence process relating to the NDA and supervised the prosecution of the '669 Patent. *Id.* PP 51-63; see 11/13/09 Def. Mot. at 2.

Nycomed challenges the sufficiency of Glenmark's allegations in several respects. First, Nycomed complains that the proposed pleading fails to allege that Mr. Anderson knew of the relevance of the FPLA 1001 test results to either the '669 Patent or to arguments before the PTO; and fails to allege that he intended to deceive or mislead the PTO. See 11/18/09 [*44] Pl. Opp. at 3. Additionally, Nycomed argues that Glenmark "never acquired any proof that a material misrepresentation or omission occurred." *Id.*

a. Materiality

Nycomed's materiality challenge can be swiftly rejected. [HN21] Information is considered material where either (a) "there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent," *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1364 (Fed. Cir. 2007) (citing 37 C.F.R. § 1.56(a) (1991)); or (b) it falls within the standards set forth in PTO *Rule 56*, which provides in pertinent part that "[i]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and . . . (2) [i]t refutes,

or is inconsistent with, a position the applicant takes in: (i) [o]pposing an argument of unpatentability relied on by the [PTO], or (ii) [a]sserting an argument of patentability." *Cargill*, 476 F.3d at 1364 (quoting 37 C.F.R. § 1.56(b) (2006)). See generally *Pall Corp.*, *F.Supp.2d* , 2010 U.S. Dist. LEXIS 4175, 2010 WL 301954, at *2-3. Clearly, when measured against either of these standards, Nycomed's alleged [*45] misrepresentation and omission were not only material but *highly* material.

According to Glenmark's proposed pleading, the statements Nycomed made to the PTO concerning the relative potencies of the fluticasone propionate lotion and prior art cream directly contradicted the data from and conclusions of study FPLA 1001, which were communicated to the FDA in connection with the same lotion product but were intentionally withheld from the PTO. See Second Am. Ans. (Counterclaims) PP 60-66; see also 11/13/09 Def. Mot. at 2. Glenmark further avers that on July 26, 2007, after the PTO Examiner had on several occasions rejected the claims as obvious, Nycomed, in order to overcome those rejections, amended its patent application to include for each pending claim a limitation based on the supposed unexpected increased vasoconstriction. See Second Am. Ans. (Counterclaims) PP 43-44, 52-54, 67-72; 11/13/09 Def. Mot. at 2. In fact, in issuing a Notice of Allowance and withdrawing the PTO's rejection for obviousness, the Patent Examiner expressly cited Nycomed's arguments concerning the lotion's unexpected greater potency as compared with the prior art cream. See Second Am. Ans. (Counterclaims) PP [*46] 75-76; 11/13/09 Def. Mot. at 2. Glenmark's particularized allegations of materiality thus bear no resemblance to those found wanting in *Exergen*. There the court concluded that the alleged infringer's generalized pleading that "the withheld references are 'material' and 'not cumulative'" was defective, in that those allegations failed to explain "'why' the withheld information [was] material and not cumulative, and 'how' an examiner would have used this information in assessing the patentability of the claims." *Exergen*, 575 F.3d at 1329-30. In contrast, in the instant case, Glenmark's pleading explains "why" the alleged omission and misrepresentation are material and the latter not cumulative; "where" the misrepresentation and omission can be found; and "how" the examiner would -- and in fact did -- rely on the false information (and the absence of the contrary test results) in withdrawing the prior rejection of the claims and stating the PTO's reasons

for allowing the patent. Any challenge to the materiality of the allegedly false or withheld information is plainly frivolous.

b. Intent to Deceive

Nycomed additionally objects that the proposed pleading fails to allege sufficient knowledge [*47] and intent on the part of Mr. Anderson, the person identified in Glenmark's inequitable conduct allegations. This Court disagrees.

Glenmark asserts that in connection with Nycomed's predecessor's acquisition of the Cutivate(R) line of products, Mr. Anderson -- who later supervised the prosecution of the '669 Patent -- was responsible for conducting the due diligence inquiry concerning the corresponding NDA. See Second Am. Ans. (Counterclaims) PP 58-59; 11/13/09 Def. Mot. at 2. According to Glenmark, Mr. Anderson thus became aware of the results of study FPLA 1001, as reported to the FDA, and was aware of the contrary statements submitted to the PTO in July 2007, under his supervision, with intent to deceive. See Second Am. Ans. (Counterclaims) PP 60, 63, 68-69; 11/13/09 Def. Mot. at 2. Accordingly, Glenmark's pleading particularizes the "who, what, when, where and how" of the material misrepresentation and omission committed before the PTO.

Again citing *Exergen*, and Mr. Anderson's exculpatory deposition testimony, Nycomed argues that the facts alleged in Glenmark's proposed pleading do not support an inference of an intent to deceive. See 11/18/09 Pl. Opp. at 3. However, the Federal [*48] Circuit has long recognized that [HN22] "[i]ntent rarely can be, and need not be, proven by direct evidence. Instead, an intent to deceive is usually inferred from the facts and circumstances surrounding the conduct at issue." *Cargill*, 476 F.3d at 1364 (citations omitted). Furthermore, "[t]he more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa." *Id.* (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997)); accord *Pall Corp.*, *F.Supp.2d* , 2010 U.S. Dist. LEXIS 4175, 2010 WL 301954, at *2.

In *Exergen*, the pleading was so devoid of specific facts that the court could not ascertain the materiality of the withheld references or the identity of any specific individual alleged to have knowledge of the withheld

material information. See *Exergen*, 575 F.3d at 1329-30. In those circumstances, the court concluded that no facts were alleged from which one could reasonably infer the requisite intent to deceive. See *id.* at 1330-31. Here, however, Glenmark has adequately pled sufficient facts to support an inference of scienter. Significantly, the proposed pleading asserts that the allegedly [*49] false information was provided in response to the Patent Examiner's rejections of the patent based on obviousness, and the FPLA 1001 study results were withheld for the same reason. As the Federal Circuit has acknowledged, [HN23] "intent may be inferred where a patent applicant knew . . . that withheld information would be material to the PTO's consideration of the patent application," especially where, as here, "the examiner repeatedly raises an issue to which the information relates." *Cargill*, 476 F.3d at 1366 (citing *Critikon*, 120 F.3d at 1256); accord *Pall Corp.*, F.Supp.2d , 2010 U.S. Dist. LEXIS 4175, 2010 WL 301954, at *3.

Faced with a similar challenge to a motion to amend, another court in this circuit distinguished *Exergen* and permitted the defendant to add allegations of inequitable conduct:

Unlike the situation in *Exergen*, where the pleading stated generally that the corporation was aware of two patents but provided no factual basis to infer that any specific individual knew of specific information in the patents that was material to the claims of the patent-in-suit, [the defendant] has specifically alleged the individuals involved, the information withheld and why it was material. Evidence that [the [*50] two named inventors of the patent-in-suit] submitted a drawing to the PTO that omitted the features that allegedly rendered the pending claims unpatentable could give rise to an inference that they did so knowingly and with deceptive intent.

Synventive Molding Solutions, Inc. v. Husky Injection Molding Sys., No. 2:08-CV-136, 2009 U.S. Dist. LEXIS 102031, 2009 WL 3172740, at *3 (D. Vt. Oct. 1, 2009) (citation omitted). So too here, Glenmark's allegations that Nycomed, under Mr. Anderson's supervision, omitted testing results consistent with the PTO's rejections of the claims as obvious, and made material

false statements about the results of testing, could give rise to an inference of culpable knowledge and intent.

A recent decision from this district reached the same result as *Synventive*, concluding that the defendant's factual allegations concerning the patentee's inequitable conduct before the PTO "amply set forth the who, what, when, where and how of each material misrepresentation or omission" *Pall Corp.*, F.Supp.2d , 2010 U.S. Dist. LEXIS 4175, 2010 WL 301954, at *5. In doing so, the court further found that "when viewed as a whole, the facts alleged in the proposed Amended Answer support an inference that [the patentee] [*51] intended to deceive the PTO" *Id.*

Rather than view Glenmark's factual allegations as a whole, Nycomed challenges the sufficiency of Glenmark's *evidence*, and proffers explanations as to why Mr. Anderson would not have been aware of the FPLA 1001 study or of the source of the data submitted to the PTO. See 11/18/09 Pl. Opp. at 3. Nycomed misconstrues the nature of the Court's inquiry in ruling on a motion to amend:

[HN24] In making this determination, the Court should not consider the merits of a claim or defense unless the amendment is "clearly frivolous or legally insufficient on its face If the [movant] has at least colorable grounds for relief, justice . . . require[s] that the court grant leave to amend"

Pall Corp., F.Supp.2d , 2010 U.S. Dist. LEXIS 4175, 2010 WL 301954, at *4 (quoting *Blaskiewicz v. County of Suffolk*, 29 F.Supp.2d 134, 138 (E.D.N.Y. 1998)). Glenmark's proposed amendments satisfy these standards. Nycomed's challenge to the sufficiency of Glenmark's proof of scienter "attack[s] the merits of [Glenmark's] inequitable conduct claim, not whether the claim has been adequately pled." *Synventive*, 2009 U.S. Dist. LEXIS 102031, 2009 WL 3172740, at *3. However, "[w]hether or not [Glenmark's] counterclaim [and [*52] affirmative defense] for unenforceability due to inequitable conduct can survive summary judgment awaits the appropriate motion." *Id.* at *3; see *HTC Corp. v. IPCOM GmbH & Co., KG*, 671 F.Supp.2d 146, 151 (D.D.C. 2009) (patentee's arguments "that the prior art references are lengthy and [the alleged infringer] has not proven that the named inventors read the [relevant] pages

. . . confuse the burdens of proof at trial with the pleading requirements of *Rule 9(b)*").

This Court's rejection of Nycomed's arguments is consistent with the recent rulings of various district courts in interpreting and applying *Exergen*. In fact, in a decision issued about a month ago by the Eastern District of Michigan, the court reviewed a number of those cases and observed that "[a]ll of these district court holdings found that inequitable conduct affirmative defenses were sufficiently pled -- on far fewer facts than those advanced by" the defendant in that case. *Somanetics Corp. v. CAS Med. Sys., Inc.*, *F.Supp.2d* , 2010 U.S. Dist. LEXIS 17006, 2010 WL 729021, at *4 (E.D. Mich. Feb. 25, 2010) (emphasis in original); see *id.* at *4-5 (discussing *WesternGeco v. Ion Geophysical Corp.*, *Civil Action No. 09-CV-1827*, 2009 U.S. Dist. LEXIS 100277, 2009 WL 3497123, at *7 (S.D. Tex. Oct. 28, 2009) [*53] ([HN25] "The heightened pleading requirements of *Rule 9(b)* do not require that [the allege infringer] prove the merits of its claim. What is determinative here is that [the patentee] was given fair notice of the basis for [the alleged infringer's] inequitable conduct defense."); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, *Civ. No. 08-309-JFF-LPS*, 2009 U.S. Dist. LEXIS 118383, 2009 WL 4928024, at *8 (D. Del. Dec. 18, 2009); *HTC Corp.*, 671 *F.Supp.2d* at 150-52; *Konami Digital Entm't v. Harmonix Music Sys., Inc.*, *Civil Action No. 6:08CV286-JDL*, 2009 U.S. Dist. LEXIS 117468, 2009 WL 5061812, at *2 (E.D. Tex. Dec. 14, 2009) ("The Federal Circuit teaches that these [factual] allegations need not be a 'smoking gun,' but rather sufficient grounds to infer the requisite knowledge and intent.")). Many more post-*Exergen* cases can now be added to the list of those that have repudiated arguments similar to those advanced by Nycomed. See, e.g., *CIVIX-DDI, LLC v. Hotels.com, LP*, *No. 05 C 6869*, 2010 U.S. Dist. LEXIS 8073, 2010 WL 431467, at *13 (N.D. Ill. Feb. 1, 2010) (granting motion to amend; whether named individual's representations were inconsistent "goes to whether Defendants' factual allegations are true, not whether Defendants have pleaded their inequitable conduct [*54] claims and defenses with particularity under *Rule 9(b)*, which they have done"); *The Braun Corp. v. Vantage Mobility Int'l, LLC*, *Cause No. 2:06-CF-50-JVB-PRC*, 2010 U.S. Dist. LEXIS 6839, 2010 WL 403749, at *8 (N.D. Ind. Jan. 27, 2010) (finding that accused infringer's inequitable conduct allegations satisfied the *Exergen* pleading standard, and rejecting the patentee's argument that at the pleading stage - as opposed to the proof stage

-- the inference of intent to deceive had to be "the single most reasonable inference able to be drawn from the evidence"); *WebXchange Inc. v. FedEx Corp.*, *C.A. No. 08-133-JFF*, 2010 U.S. Dist. LEXIS 4529, 2010 WL 299243, at *3 (D. Del. Jan. 20, 2010) (granting motion to amend and ruling that factual determinations about the named individual's knowledge and intent to deceive are not appropriate on such a motion); *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, *No. 09-CV-01-bbc*, 2010 U.S. Dist. LEXIS 556, 2010 WL 55847, at *12-13 (W.D. Wis. Jan. 5, 2010) (denying motion to dismiss inequitable conduct counterclaims); *ICU Med., Inc. v. RyMed Techs., Inc.*, 674 *F. Supp. 2d* 574, 2009 U.S. Dist. LEXIS 117353, 2009 WL 4884023, at *4 (D. Del. 2009) (granting accused infringer leave to amend to add inequitable conduct defense); *Lincoln Nat'l Life v. Transamerica Fin. Life Ins. Co.*, *Cause No. 1:08-CV-135*, 2009 U.S. Dist. LEXIS 110599, 2009 WL 4547131, at *2-4 (N.D. Ind. Nov. 25, 2009) [*55] (granting leave to amend, and holding that alleged infringers' allegation that at least two individuals knew of the withheld references during the prosecution of the patent-in-suit, and that the references were highly material yet were not disclosed to the examiner, were sufficient to create a reasonable inference of intent to deceive).

In sum, "[t]he issue before the Court is not whether [Glenmark] will ultimately prevail, but whether it is entitled to offer evidence" to support its allegations of inequitable conduct. *Pall Corp.*, *F.Supp.2d* , 2010 U.S. Dist. LEXIS 4175, 2010 WL 301954, at *4. For the foregoing reasons, this Court concludes that it is so entitled. By the same token, Nycomed is entitled to the opportunity to discover evidence to defend itself against those allegations. Accordingly, discovery will be reopened for a short period for that limited purpose.

CONCLUSION

For the reasons detailed above, the Court recommends that Nycomed's motion to amend its complaint be denied, except that Nycomed may add a demand for attorney fees in its prayer for relief; and Glenmark's motion to amend is granted. The amended [*56] pleadings shall be filed by March 30, 2010. Discovery is reopened until June 1, 2010, for the limited purpose of allowing Nycomed to take discovery regarding Glenmark's newly added inequitable conduct allegations.

Any objections to the rulings and/or

recommendations in this opinion must be filed with the Honorable Carol B. Amon on or before **April 9, 2010**. Failure to file objections in a timely manner may waive a right to appeal the District Court order.

SO ORDERED.

Dated: Brooklyn, New York

March 26, 2010

ROANNE L. MANN

UNITED STATES MAGISTRATE JUDGE