IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

In re RIGEL PHARMACEUTICALS, INC. SECURITIES LITIGATION

No. C 09-00546 JSW

This Document Relates To:

ALL ACTIONS.

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

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Now before the Court is the motion of defendants Rigel Pharmaceuticals, Inc. ("Rigel"), James M. Grower ("Grower"), Ryan D. Maynard ("Maynard"), Donald G. Payan ("Payan"), Raul R. Rodriguez ("Rodriguez"), Elliot B. Grossbard ("Grossbard"), Jean Deleage ("Deleage"), Bradford S. Goodwin ("Goodwin"), Gary A. Lyons ("Lyons"), Walter H. Moos ("Moos"), Hollings C. Renton ("Renton"), Peter S. Ringrose ("Ringrose") and Stephen A. Sherwin ("Sherwin") (collectively, "Defendants"). Having carefully reviewed the parties papers and considered their arguments and the relevant legal authority, and good cause appearing, the Court hereby grants Defendants' motion.[1]

BACKGROUND

Lead Plaintiff Inter-Local Pension Fund GCC/IBT ("Plaintiff") brings this action individually and on behalf of all other persons who purchased or otherwise acquired the

[1] The Court GRANTS the motion of Defendants Credit Suisse Securities (USA) LLC, Thomas Weisel Partners LLC, Oppenheimer & Co. Inc., and Jefferies & Company, Inc. to join in the motion to dismiss. The Court DENIES the parties' requests for judicial notice because the Court did not need to consider the requests in order to resolve the motion to dismiss.

common stock of Rigel between December 13, 2007 and February 3, 2009 (the "Class Period"),[2] pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. 240.10b-5. Plaintiff further bring claims on behalf of itself and persons who purchased Rigel stock traceable to the registration statement and prospectus issued in connection with Rigel's February 2008 offering, pursuant to Sections 11, 12, and 15 of the Securities Exchange Act of 1934, 15 U.S.C. §§ 77k, 77l, and 77o.

Plaintiff alleges that Defendants made material misrepresentations when they disclosed the results of a clinical trial for R788. Rheumatoid arthritis is an autoimmune disease characterized by chronic inflamation that affects the joints and other tissues. (Consolidated Complaint ("Compl."), ¶ 3.) Rigel was developing a new drug, R788, for the treatment of rheumatoid arthritis. Rigel conducted a Phase IIa clinical trial to evaluate the safety and preliminary clinical efficacy of R788 in patients with active rheumatoid arthritis despite therapy with methotrexate. (*Id.*) The clinical trial was a multi-center, randomized, double-blind, placebo-controlled, ascending dose study involving 189 patients in the United States and Mexico. (*Id.*) The patients were placed into cohorts receiving either 50, 100, or 150 mg of R788 orally twice daily over a twelve week period. Within each cohort, patients were assigned on a three to one basis to receive R788 or a placebo. (*Id.*, ¶ 46.) Rigel measured efficacy for each participant based on the American College of Rheumatology criteria ("ACR"), which denote at least a twenty percent improvement (ACR 20), at least a fifty percent improvement (ACR 50), or at least a seventy percent improvement (ACR 70). (*Id.*)

On December 13, 2007, Rigel issued a press release entitled: "Rigel's R788 Demonstrates Significant Improvement in Rheumatoid Arthritis in Phase IIa Clinical Study; Achieves Statistically Significant ACR20, ACR50 & ACR70 Results." (*Id.*, ¶ 48.) The press release stated, in part:

> Rigel Pharmaceuticals, Inc. . . . today announced that its oral syk kinase inhibitor, **R788** (tamatinib fosdium), **has demonstrated statistically significant**

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[2] The Court has not yet certified a class and refers to the time period involved as the "Class Period" for ease of reference.

results in treating Rheumatoid Arthritis (RA) patients in a recently completed Phase 2 clinical trial. Groups treated with R788 at 100mg and 150mg po bid (orally, twice daily), showed higher ACR20, ACR50, ACR70 and DAS28 response rates than the placebo group. The efficacy results for the 100mg and the 150mg dose groups were fairly comparable. Dramatically, the onset of the effect in these dose groups occurred as early as one week after initiation of therapy. We believe that the significant ACR scores and good tolerability observed in this clinical trial, and the further benefit of oral delivery may make R788 a favorable alternative to the currently marketed biological agents.

* * *

"This clinical study has shown that R788 treatment can achieve impressive ACR response rates," said Elliott Grossbard, M.D., senior vice president of medical development at Rigel. "In this clinical trial both the 100mg and 150mg doses improved arthritis symptoms and did so quickly. We plan to initiate the next clinical trial with R788 in RA in 2008," he added.

Efficacy Results*

Treatment Assigned	Number	ACR 20	ACR 50	ACR 70	DAS28-CRP 2.6,
po bid	(N)	% (N)	% (N)	% (N)	% (N)
Placebo	47	38% (18)	19%(9)	4% (2)	17% (8)
50 mg	46	32% (15)	17% (8)	2% (1)	20% (9)
100 mg	49	65% (32) (p=.008)	49% (24) (p=.002)	33% (16) (p<.001)	35% (17) (p=.005)
150 mg	47	72% (34) (p<.001)	57% (27) (p<.001)	40% (19) (p<.001)	47% (22) (p<.001)

* * *

James M. Gower, chairman and chief executive officer of Rigel said, **"These very important clinical trial results are a major milestone for Rigel as we establish the potential of R788 in RA and its value as an alternative to current therapies.** In addition, given these results and the recent results in ITP, **we believe that R788 may be a useful drug in the treatment of autoimmune diseases."**

Safety Results

The most common clinically meaningful adverse events noted in the clinical trial were dose-related neutropenia, mild elevations of liver function tests, and gastrointestinal (GI) side effects. Dose reduction (to one half the assigned dose, by taking the drug once per day) was pre-specified in the protocol, contingent on neutrophil counts and/or liver function tests. Notably, a vast majority of the patients (19 out of 21) who had their dose reduced, successfully completed the clinical trial with minimal safety issues.

The key safety results are shown in the table below:

	Placebo po BID N=47	50mg po BID N=46	100mg po BID N=49	150mg po BID N=47
Completed Study at Reduced Dose (N)	1	0	5	13
Dropouts (N):	11	6	6	8
Withdrew Consent	6	3	2	1
Adverse Event	2	1	3	6
Other	3	2	1	1
Neutropenia (N) Requiring dose reduction	0	0	5	10
ALT > 3XULN (N)	2	0	0	3
Diarrhea (N) (severity moderate or greater)	0	3	2	10
Upper GI side effects (N) (gastritis, nausea, dyspepsia) (severity moderate or greater)	2	1	2	12
Hypertension (N) (severity moderate or greater)	0	0	2	0

(*Id.*) (emphasis in original.)

On the same day, Rigel also held a press conference. (*Id.*, ¶ 49.) During the call Grower and Grossbard made the following statements regarding the results of the Phase IIa clinical trial:

> [Gower:] We were very pleased to be able to announce **highly statistically significant results of a Phase 2 trial of 788 in patients with rheumatoid arthritis.** And I would like to introduce Dr. Elliot Grossbard to take us through the study results. Elliot?
>
> * * *
>
> [Grossbard:] The efficacy results are shown in the graph on the handout that many of you may have downloaded. **As you can see, the highly significant effect for both the ACR 20, 50, 70 and DAS28 score.** The p values are uniformly less than .008, usually less than .001. Of note, although not included in this graph, is that the onset of the effect was within one week, and you could see significant differences between the patients at one week after the initiation of treatment.

We have concluded that the 100 milligram and 150 milligram dose groups have impressive and statistically significant improvements over placebo, and that the onset occurs very, very early. The efficacy results for the two effective doses were fairly comparable, and the 100 milligrams bid dose kind of caught up by the end so that they were really equivalent. The 50 milligram dose [does] not appear to be much better than placebo, and so overall there was a good dose response.

With regard to safety, which is going to be a close focus of the future program, because I think this study fairly establishes with certainty that this drug is effective in rheumatoid arthritis.

We had a number of dose reductions in the study, either due to ALP elevations, or much more commonly, neutrophil counts below 1500. Typically I would ask the sites to hold the drug until the ALP came back towards normal, or the neutrophil count went above 1500, and then they would restart at half the dose.

Of the patients who had their doses reduced, and overall there were about 20 or close to 20 in the study, 18 of those 20 finished the study at the reduced dose. And the ACR 20 response rate in that group was greater than 80%, and the ACR 50 response rate was greater than 50%. So it would appear that at least in patients who are responding you can reduce the dose significantly, ameliorate some of the concerns and still maintain a very significant clinical effect.

In terms of dropouts, there were more dropouts in the placebo group than in any R788 group. Most of those in the placebo were under the category withdrew consent, which often, if not always, means the patients were unsatisfied with the way their treatment was going. At the 150 milligram dose we had a number of dropouts for adverse events.

The incidence of neutropenia, as I mentioned, was modest. In the 100 milligram dose I think there were five patients out of the 49, but it was a much higher percentage of the dose 150 milligrams twice a day.

In terms of ALP elevations greater than three times the upper limit of normal, which is the marker that FDA recently recommended in their guidelines for development of new (technical difficulty) there were two patients in the placebo group who had ALP elevations, and three in the high dose group, and none in the two intermediate groups. The most prevalent side effect beyond neutropenia in the high dose group was a combination of gastrointestinal side effects, diarrhea and nausea, dyspepsia and so on.

The incidence of reported moderate hypertension was quite low, although the way case report forms are filled out an occasional patients [sic] had a notation for his systolic blood pressure increase, and an occasional one had diastolic blood pressure increase. And it is hard to know exactly what that means, so I'm reporting to you here those where the case report forms noted, hypertension of moderate severity. So in conclusion we think the 100 milligram dose was well tolerated. The 150 milligram dose somewhat less so. But with dose reductions almost all the patients were able to finish the study.

The most common side effects were neutropenia and gastrointestinal side effects and they are most prevalent in the 150 milligram bid dose.

> I think – my personal opinion is that **this study establishes with very little uncertainty that this drug at 100 milligrams a day – 100 milligrams twice a day or more is highly effective in the treatment of rheumatoid arthritis in terms of clinical signs and symptoms.** We have not investigated the question of bone erosions and joint damage – we will in a future study.
>
> The benefits are seen quickly, as early as one week after treatment. And the fact that we're talking here about pills and not injections make this a very interesting compound going forward into our next set of studies.

(*Id.*) (emphasis in original.)

Grossbard further stated in the conference call that he was going to be working closely with Dr. Michael Weinblatt to write a paper and that the publication of the paper would be the next significant statement about the results of the study. (Declaration of Shannon M. Eagan, Ex. C (transcript of December 13, 2007 conference call) at 6.)

According to Plaintiffs, the statements made on December 13, 2009 were false because Defendants:

> failed to disclose that: (1) patients in Mexico had higher response rates in both the placebo and treated arms than the U.S. patients, which may have contributed disproportionately to the overall reported benefit observed at the higher doses, as nearly all patients in the 150mg cohort and no patients in the 50mg cohort were from Mexico; (2) there was a dose-dependent increase in average blood pressure of 20-30mmHg in five patients (not two, as reported on December 13, 2007), which was important because it could signal an increase in cardiovascular risk, the mechanism that caused the increase was not well understood and the increase in blood pressure could be a stumbling block for some pharmaceutical companies that were considering licensing the drug; (3) nine patients (not three, as reported on December 13, 2007) experienced increased liver enzymes compared to patients taking the placebo; (4) 20 patients (not 15, as reported on December 13, 2007) experienced neutropenia; (5) 34 patients (not 15, as reported on December 13, 2007) experienced diarrhea; and (6) 35 patients (not 15, as reported on December 13, 2007) experienced upper gastrointestinal side effects.

(Compl., ¶ 54.)

Defendants did not publicly disclose the adverse information until October 27, 2008. (*Id.*) On October 27, 2008, Rigel disclosed the following ACR response data by country:

	Placebo	**50MG**	**100MG**	**150MG**
# of U.S. patients	**25**	**46**	**21**	**5**
ACR20	6 (24%)	15 (33%)	11 (52%)	2 (40%)
ACR50	1 (4%)	8 (17%)	6 (29%)	2 (40%)
ACR70	0 (0%)	1 (2%)	3 (14%)	2 (40%)

	Placebo	50MG	100MG	150MG
# of Mexican patients	**22**	**0**	**28**	**42**
ACR20	12 (55%)	0 (0%)	21 (75%)	32 (76%)
ACR50	8 (36%)	0 (0%)	18 (64%)	25 (60%)
ACR70	2 (9%)	0 (0%)	13 (46%)	17 (40%)

(*Id*., ¶ 56.)

On October 27, 2008, Grossbard acknowledged that he knew about the differing response rates on December 13, 2007. He stated:

> The issue of Mexico/US interaction before the study – I think we actually mentioned this at our original discussion on the Web after the study was over. I was concerned that there might be such an interaction.
>
> And so, I requested before the study was unblinded that we do a country interaction and it turned out there was one. And the issue of the interaction was that ***the placebo rate was much higher in Mexico than in the US. And the response rate was much higher in Mexico than in the US.***

(*Id*., ¶ 57) (emphasis in original.)

ANALYSIS

A. Applicable Pleading Standards.

1. Motion to Dismiss for Failure to State a Claim.

A motion to dismiss is proper under Federal Rule of Civil Procedure 12(b)(6) where the pleadings fail to state a claim upon which relief can be granted. The complaint is construed in the light most favorable to the non-moving party and all material allegations in the complaint are taken to be true. *Sanders v. Kennedy*, 794 F.2d 478, 481 (9th Cir. 1986). Rule 8(a) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." Accordingly, motions to dismiss for failure to state a claim pursuant to Rule 12(b)(6) are typically disfavored; complaints are construed liberally to set forth some basis for relief, as long as they provide basic notice to the defendants of the charges against them. *In re McKesson HBOC, Inc. Sec. Litig.*, 126 F. Supp. 1248, 1257 (N.D. Cal. 2000). Where a plaintiff alleges

fraud, however, Rule 9(b) requires the plaintiff to state with particularity the circumstances constituting fraud. *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d 1541, 1547-49 (9th Cir. 1994).

Even under the liberal pleading standard of Rule 8(a), "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). Pursuant to *Twombly*, a plaintiff must not merely allege conduct that is conceivable but must instead allege "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. __, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. at 556). "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully. ... When a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (quoting *Twombly*, 550 U.S. at 556-57) (internal quotation marks omitted). The Court may consider the facts alleged in the complaint, documents attached to the complaint, documents relied upon but not attached to the complaint when the authenticity of those documents is not questioned, and other matters for which the Court can take judicial notice. *Zucco Partners LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009).

In the securities context, the pleading requirements are even more stringent.

2. Private Securities Litigation Reform Act.

To plead a claim under section 10(b) and Rule 10b-5 based on misstatements, a plaintiff must allege (1) a misrepresentation or omission, (2) of material fact, (3) made with scienter, (4) on which the plaintiff justifiably relied, (5) that proximately caused the alleged loss. *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1177 (9th Cir. 2009); *Zucco Partners LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009). To plead a claim based on market manipulation, a plaintiff must allege, *inter alia*, that the defendant engaged in manipulative acts,

that plaintiff suffered damage, which was caused by his or her reliance on an assumption that the market was free of manipulation, and that the defendant acted with scienter. *See, e.g., ATSI Communications, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 102 (2d Cir. 2007).

"At the pleading stage, a complaint stating claims under section 10(b) and Rule 10b-5 must satisfy the dual pleading requirements of ... Rule 9(b) and the PSLRA." *Zucco Partners*, 552 F.3d at 990. Thus, the PSLRA requires that "a complaint 'plead with particularity both falsity and scienter.'" *Id.* (quoting *Gompper v. VISX*, 298 F.3d 893, 895 (9th Cir. 2002), in turn quoting *Ronconi v. Larkin*, 253 F.3d 423, 429 (9th Cir. 2001)). Where a plaintiff asserts a Section 20(a) claim based on an underlying violation of section 10(b), the pleading requirements for both violations are the same. *See In re Ramp Networks, Inc. Sec. Lit.*, 201 F. Supp. 2d 1051, 1063 (N.D. Cal. 2002).

Under the PSLRA, actions based on allegations of material misstatements or omissions must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. §78u-4(b)(1). In order to adequately plead scienter, the PSLRA requires that the plaintiff "'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Id.* at 991 (quoting 15 U.S.C. § 78u-4(b)(2)).

"To adequately demonstrate that the 'defendant acted with the required state of mind,' a complaint must 'allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness.'" *Zucco Partners*, 552 F.3d at 991 (quoting *In re Daou Sys., Inc.*, 411 F.3d 1006, 1014-15 (9th Cir. 2005)). The Ninth Circuit recently clarified that a court should "conduct a dual inquiry," when it evaluates the scienter element. *Id.* at 991-92. First, a court should determine "whether any of the plaintiff's allegations, standing alone are sufficient to create a strong inference of scienter." *Id.* at 992. Second, "if no individual allegations are sufficient," a court should "conduct a 'holistic' review of the same allegations to determine whether the individual allegations combine to create a strong inference of intentional conduct or deliberate recklessness." *Id.*; *accord Sicracusano*, 2009 WL 3448282 at *12.

"'[I]n determining whether the pleaded facts give rise to a strong inference of scienter, the court must take into account plausible opposing inferences.'" *Siracusano*, 585 F.3d 1167, 1180 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 310 (2007)). As the Supreme Court stated in *Tellabs*, a plaintiff sufficiently alleges scienter "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. The inquiry "is inherently comparative." *Id.* "A court must compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." *Zucco Partners*, 552 F.3d 991 (citing *Tellabs*, 551 U.S. at 324). If the allegations are insufficient to state a claim, a court should grant leave to amend, "unless it is clear that the complaint could not be saved by any amendment." *Id.* at 989 (quoting *Livid Holdings, Ltd. v. Solomon Smith Barney, Inc.*, 416 F.3d 940, 946 (9th Cir. 2005).

B. Plaintiff's Consolidated Complaint.

The PSLRA requires that plaintiffs allege with the requisite particularity each statement alleged to be false or misleading, the reason or reasons why the statement was false or misleading, and if those allegations are made on information and belief, all facts on which that belief is formed. *See* 15 U.S.C. § 78u-4(b)(1)(B); *see also Employers Teamsters Local Nos. 175 and 505 Pension Trust Fund v. Clorox Co.*, 353 F.3d 1125, 1134 (9th Cir. 2004).

Plaintiff sets forth the statements which it contends are materially false and misleading in paragraphs 48 and 49 of its Complaint. These paragraphs contain extensive block quotes with multiple statements. These paragraphs, on their face, appear to contain true facts or statements which Plaintiff does not seem to contest. For example, Plaintiff alleges that on December 13, 2007, [Rigel] issued a press release. Plaintiff then quotes large portions of the press release. (Compl., ¶ 48.) It is unlikely that Plaintiff contends that the *entire* quoted portion of the press release is false and misleading.

In paragraphs 54, 55, 61, 68, 71, 73 and 74, Plaintiff alleges that Defendants failed to disclose material safety data. To be actionable under Section 10(b) and Rule 10b-5, an alleged

omission must render some affirmative public statement misleading. In order for an omission to be misleading, "it must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *See Brody v. Transitional Hospitals Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002) (citing *McCormick v. The Fund American Cos.*, 26 F.3d 869, 880 (9th Cir. 1994)). Plaintiff fails to specifically identify what affirmative public statement or statements the alleged omissions rendered misleading.

At the hearing, Plaintiff's counsel attempted to clarify which statements it alleges are false and misleading statements and what affirmative statements were rendered misleading by omissions. Plaintiff submitted a complaint with highlighted statements and stated that the highlighted statements were the statement that it contends are false and misleading. However, again, Plaintiff highlighted statements which, on their face, appear to contain true facts or statements which Plaintiff does not seem to contest. For example, Plaintiff highlighted the following statement in paragraph 12: "On January 24, 2008, Rigel filed with the SEC an S-3ASR Registration Statement and Form 424B3 Preliminary Prospectus for the Offering, which incorporated by reference the materially false and misleading December 13, 2007 Form 8-K." Additionally, Plaintiff highlighted substantial portions of the block quotes alleged in other paragraphs. Moreover, Plaintiff failed to distinguish between the statements it alleges were affirmative material false and misleading statements and those affirmative public statements it contends were rendered misleading by omissions.[3]

In the absence of clearly identified misrepresentations and/or omissions, the Court cannot evaluate whether such misrepresentations and/or omissions are sufficiently alleged, let alone whether such statements or omissions were material or made with the requisite scienter. As the party bringing this action, Plaintiff is responsible for identifying with particularity what statements are false and misleading. 15 U.S.C. § 78u-4(b)(1). Plaintiff has not fulfilled its

[3] At the hearing, Plaintiff's counsel argued that the Court should not just consider the actual statements made, but the impression that the statements provided when considered in context and in conjunction with the purpose of the study. To the extent Plaintiff intends to argue that statements which are not actually false or misleading, but contribute to a general false impression when considered with other statements, are actionable, Plaintiff should be prepared to provide authority in support of this proposition.

responsibility in this regard, and the Court is "unwilling ... to search through" the Complaint in an effort to link the allegedly false statements to the reasons those statements purportedly are false. *In re Autodesk Sec. Lit.*, 132 F. Supp. 2d 833, 841-842 (N.D. Cal. 2000). Therefore, the Court grants Defendants motion to dismiss, but will provide Plaintiff leave to amend.

CONCLUSION

For the foregoing reasons, the Court grants Defendants' motion to dismiss. If Plaintiff chooses to file an amended complaint, Plaintiff should *clearly identify* which *specific* statements within the documents or block quotes it contends are false or misleading and which *specific* affirmative public statement or statements it alleges were rendered misleading by any alleged omissions. Plaintiff shall file any amended complaint within thirty days of the date of this Order. If an amended complaint is filed, Defendants shall either file an answer or move to dismiss within twenty days of service of the amended complaint. If Plaintiff does not file an amended complaint within thirty days, the Court will dismiss this action without prejudice.

IT IS SO ORDERED.

Dated: December 21, 2009

JEFFREY S. WHITE
UNITED STATES DISTRICT JUDGE