UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
LEXINGTON

PHILIP C. WEISS, et al.,	)	
	)	
Plaintiffs,	)	
	)	Civil Action No. 5:05-527-JMH
v.	)	
	)	
ASTELLAS PHARMA U.S., INC., et al.,	)	**ORDER**
	)	
	)	
Defendants.	)	

** ** ** ** **

On May 10, 2006, the Court dismissed Plaintiffs' intentional misrepresentation claims against Astellas Pharma U.S., Inc. ("APUS") and Novartis Pharmaceutical Corp. ("Novartis"), finding that Plaintiffs had failed to plead fraud with the particularity required by Federal Rule of Civil Procedure ("Rule") 9(b). The Court allowed Plaintiffs to file a second amended complaint restating their claims. APUS and Novartis have filed motions to dismiss the new claims, arguing that the second amended complaint still does not meet the requirements of Rule 9(b). All responses and replies having been filed, these matters are now ripe for review.

I. Standard of Review

Rule 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity," and the Sixth Circuit requires that "a plaintiff, *at a minimum* . . . allege the time, place, and content of the alleged misrepresentation on which he or she relied; the

fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *Coffey v. Foamex L.P.*, 2 F.3d 157, 161-162 (6th Cir. 1993)(emphasis added). Or, to put it another way, "Rule 9(b) requires that the plaintiff specify the who, what, when, where, and how of the alleged fraud." *Sanderson v. HCA*, 447 F.3d 873, 877 (6th Cir. 2006)(internal quotation marks omitted). In evaluating whether a complaint meets these requirements, the Court must keep in mind the generally relaxed standards of notice pleading. *See id.* at 876.

II. The Prior Order

The Court found that Plaintiffs' first amended complaint failed to allege the time, the place, or with a few exceptions, the content of the fraud with any particularity whatsoever. The Court noted that "[t]he misrepresentations claimed by Plaintiffs apparently include all affirmative statements of safety and all times when Defendants failed to disclose the unspecified risks that they had learned of from the unspecified research." Order of May 10, at 5.

The Court also noted that the claims against APUS and Novartis were "near-verbatim copies" of each other, with only the names of the companies and the names of the drugs changed. Counsel for the Plaintiffs seems to have taken offense at what he perceives as the implication that he practices, as he calls it, "cookie-cutter law," but in noting the identical allegations, the Court was only trying

to make one point, and it is a point Plaintiffs have neither addressed nor remedied: In order to make identical fraud allegations against two different drug companies,[1] who manufactured and sold two different drugs through separate marketing campaigns, with different brochures, different product inserts, and different drug representatives, the claims *have* to be stated at a level of generality that pushes the limits, to say the least, of the particularity requirement.[2]

III. The Second Amended Complaint

Surprisingly little has been added in the second amended complaint. As far as the Court can tell, the changes largely consist of certain allegations that were already in the complaint once against each company now being asserted multiple times against each company.[3] There are, however, a few new items. First,

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[1] The number of companies would be five if one counted the allegations against the foreign drug companies, which were also identical to the claims against APUS and Novartis. All allegations were (and still are in the second amended complaint) phrased as, for example, "APUS and API intentionally misrepresented . . ." or "NPC, Swiss Novartis and Novartis Germany had specific knowledge . . . ." There is no differentiation in the allegations against each company.

[2] The Court was not suggesting that there is anything wrong with cutting and pasting *per se*, and the Court was certainly not implying anything about Plaintiffs' counsel. The identical allegations would not have been noteworthy but for the requirement that fraud claims be alleged with particularity.

[3] Things that were already alleged, and are now alleged with greater frequency, do not remedy the problems identified in the prior order. These would include Plaintiffs' general allegations that the companies represented the drugs to be "safe,"

Plaintiffs state that misrepresentations occurred in August and November of 2003, when he was first prescribed Elidel and Protopic, respectively.[4] Second, Plaintiffs state more explicitly that they relied on the representations. The latter does not change the result; the Court's prior order made no mention of a lack of reliance allegations. As to the former, it plugs one hole, but it is not enough. The statement that "APUS and API represented" something in November of 2003 is not particular, when one is still left wondering whether these representations were made in television or magazine ads, or in brochures, or through statements by drug representatives, or in product inserts, or by representations on each company's website.[5]

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or to "not pose any unreasonable or inherent health risks." The Court also can ignore new allegations that are general in the same fashion as the allegations in the first complaint, such as that each set of companies "made material representations that [their drug] had been clinically and laboratory tested and medically proven safe."

[4] These dates of first prescription were mentioned in the earlier complaints as well, but not in the context of identifying the times of the misrepresentations.

[5] The Court also notes that Plaintiffs continue to attempt to allege fraud with statements like "Defendants NPC, Swiss Novartis and Novartis Germany intentionally misrepresented the safety of Elidel through its product brochures, product inserts, information, and by oral presentations made by its employees to Weiss' healthcare provider, Dr. Joseph Bark." Aside from the failure to differentiate between the representations of three companies, listing "product brochures, product inserts, information, and . . . oral presentations made by its employees" all together in one prefatory sentence does not add specificity; to the contrary, it prevents the subsequent allegations from giving fair notice of which statements are alleged to have been made

Having had their fraud claims dismissed once already for a lack of particularity, Plaintiffs might have been expected to add allegations in the form of, for example, "The product insert in each container of Elidel said *x*, *y*, and *z*, and *x*, *y*, and *z* are not true," where *x*, *y*, and *z* are specific assertions by Novartis. Or else Plaintiffs might have linked one of their legitimately content-specific allegations to a particular "who, . . . when, where, [or] how," as required under *Sanderson*, 447 F.3d at 877. For example, Plaintiffs might have alleged that "APUS ran adds in a magazine in 2003 that Plaintiffs read in which APUS claimed that Protopic is 'steroid-free' and 'safe to use as a first-line therapy.'" There are, however, no statements in the second amended complaint that are remotely comparable to these examples. Instead, the fraud allegations are of the same non-particular nature as those already rejected in the first amended complaint.

The Court cannot find that any of Plaintiffs' fraud allegations meet what the Sixth Circuit has described as the *minimum* standard, namely that Plaintiffs must "allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *Coffey*, 2 F.3d at 161-162. While one or two elements of the "who, what, when, where, and how" required under *Sanderson*, 447 F.3d at 877,

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through which medium.

are occasionally stated, the whole package of "who, what, when, where, and how" is never put together for any of the alleged misrepresentations. Therefore, the fraud claims must be dismissed.

IV. Conclusion

Accordingly, and for the foregoing reasons, **IT IS ORDERED:**

(1) That the motions to dismiss [Record Nos. 72 & 74] be, and the same hereby are, **GRANTED.**

(2) That Plaintiffs' intentional misrepresentation claims against Astellas Pharma U.S., LLC, and Novartis Pharmaceutical Corp. be, and the same hereby are, **DISMISSED WITH PREJUDICE.**

This the 14th day of July, 2006.

Signed By:
Joseph M. Hood
United States District Judge