UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FORT PIERCE DIVISION

CASE NO. 2:17-CV-14302-ROSENBERG/MAYNARD

Dennis McWilliams et al.,

Plaintiffs,

vs.

Novartis AG et al.,

Defendants.
_____/

PLAINTIFFS' MOTION TO FOR PARTIAL RECONSIDERATION OF ORDER ON SUMMARY JUDGMENT

COMES NOW, Plaintiffs Dennis and Lori McWilliams, and respectfully move the Court to partially reconsider its Order Granting in Part and Denying in Part Novartis Pharmaceuticals Corporation's Motion for Summary Judgment dated July 9, 2018 (Doc. 92) ("Order"). In support of this motion, Plaintiffs state as follow:

Plaintiffs respectfully request that the Court partially reconsider its Order as it pertains to granting summary judgment on Plaintiffs' claim for punitive damages. Applying New Jersey law, the Court entered summary judgment on Plaintiffs' punitive damages claim under the mistaken impression that Plaintiffs did not argue that the exception to New Jersey's prohibition on punitive damages applied. *See* Order, Doc. No. 92, at p. 15 n.3. Therefore, the Court did not analyze the exception or whether it is preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001). *Id.*

Plaintiffs, however, *did* argue that the exception to New Jersey's prohibition on punitive damages applies and that such damages are not preempted. Specifically, in the concluding footnote of Plaintiffs' opposition to Novartis's motion, Plaintiffs argued:

> For reasons already briefed (Doc. No. 28), even if New Jersey law applies, Plaintiffs have still created a triable issue of fact on punitive damages. Under New Jersey law, punitive damages are available "where the product manufacturer knowingly withheld or misrepresented [material and relevant] information required to be submitted under the agency's regulation." N.J.S.A. § 2A:58C-5c. Here, Plaintiffs have shown that Novartis both withheld material information related to atherosclerosis-related conditions associated with Tasigna, and further made material misrepresentations to the FDA about such information, intentionally misrepresenting to the FDA, among other things, the state of the medical literature on the association and Novartis's own internal analyses regarding the association. This is sufficient to create a triable issue of fact. Further, punitive damages under New Jersey law are not preempted. *Forman v. Novartis Pharms. Corp.*, 793 F. Supp. 2d 598, 607 (E.D.N.Y. 2011); *Chiles v. Novartis Pharms. Corp.*, No. 3:06-cv-96-J-25 JBT (M.D. Fla. Feb. 25, 2013) (Order, Doc. No. 214).

Plaintiffs' Opp. Br., Doc. No. 63, at p. 18, n.4.

Reconsideration is appropriate here because the Court declined to analyze whether the New Jersey exception applies on a mistaken assumption that the issue was not argued. Courts have distilled three major grounds justifying reconsideration: (1) an intervening change in controlling law; (2) the availability of new evidence; and (3) the need to correct clear error or manifest injustice. *Mesa v. Penn. Higher Ed. Assistance*, No. 16-Civ-24577, 2018 WL 624492, at *1 (S.D. Fla. Jan. 30, 2018). While motions for reconsideration are not vehicles to resubmit arguments already considered and rejected by the Court, they are "appropriate where, for example, the Court has patently misunderstood a party…, or has made an error not of reasoning but of apprehension." *Id.* Motions for reconsideration are subject to the Court's "substantial discretion." *Id.*

Here, the Court entered summary judgment on Plaintiffs' punitive damages claim under New Jersey law on the mistaken belief that "Plaintiffs do not argue that [New Jersey's] exception applies." Order, Doc. No. 92, at p. 15 n.3. Plaintiffs, however, did argue that New Jersey's exception applies, and thus Plaintiffs respectfully request that the Court consider Plaintiffs' arguments.

As argued in Plaintiffs' opposition brief, Plaintiffs have demonstrated a triable issue of fact on punitive damages under New Jersey law. Doc. No. 63, at p.18, n. 4. Under New Jersey law, punitive damages are available "where the product manufacturer knowingly withheld or misrepresented [material and relevant] information required to be submitted under the agency's regulation." N.J.S.A. § 2A:58C-5c. Plaintiffs have shown that Novartis not only withheld from the FDA material information related to atherosclerosis-related conditions associated with Tasigna, but that it knowingly made material misrepresentations to the FDA, including:

(1) that a thorough literature review revealed only one abstract reporting two cases of Tasigna patients developing peripheral vascular disease, when in fact there were multiple peer-reviewed articles that described the occurrence of rapidly developing peripheral and other vascular disease in multiple patients, and recommended that doctors monitor patients for developing disease and/or rethink any decision to switch patients from Gleevec to Tasigna; and

(2) that an internal advisory board concluded that there was no data supporting a causal association between Tasigna and atherosclerosis, when in reality a substantial number of the board members told Novartis that they believed there was a causal relationship.

These misrepresentations and omissions are detailed in Plaintiffs' opposition and supporting exhibits. *See* Plaintiffs' Opp. Br., Doc. No. 63, at pp. 14-15, 16, 18 (describing material misrepresentations and omissions from Novartis to the FDA about the risk of atherosclerosis-related vascular disease); Plaintiffs' Statement of Material Facts, Doc. No. 64, at ¶¶ 44, 49 (describing in more detail the evidence cited in Plaintiffs' opposition brief showing Novartis's misrepresentations to the FDA). Thus Plaintiffs have demonstrated a triable issue of fact as to whether the exception to New Jersey's punitive damages prohibition applies.

Further, while Plaintiffs recognize that some non-binding authority holds that New Jersey's punitive damages exception is preempted under *Buchman*, multiple courts, including a sister

Florida district court, have held that section 2A:58C-5c is *not* preempted under *Buchman*, where, as here, a plaintiff's claims are based on misrepresentations to parties other than the FDA, such as patients and the medical community. *See Forman v. Novartis Pharms. Corp.*, 793 F. Supp. 2d 598, 607 (E.D.N.Y. 2013); *Novartis Pharms. Corp.*, No. 3:06-cv-96-J-25 JBT (M.D. Fla. Feb. 25, 2013) (Order, Doc. No. 214). Plaintiffs expressly argued these points in its opposition to Novartis's motion for summary judgment, and in its opposition to Novartis's motion to dismiss, which Plaintiffs incorporated by reference into their summary judgment opposition. *See* Doc. No. 63, at p. 18, n.4; Doc No. 28, at pp. 9-10. Plaintiffs submit that this is the better-reasoned view, and respectfully request that the Court, on reconsideration, hold that Plaintiffs' punitive damages claim is not preempted under *Buchman.*

CONCLUSION

For these reasons, Plaintiffs request that the Court partially reconsider its Order, deny summary judgment on Plaintiffs' claim for punitive damages, and for any other relief the Court deems just and proper.

Dated: July 13, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 13, 2018 the foregoing document was served upon counsel of record via electronic mail.

/s/ Bryan F. Aylstock
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